Zuranolon (Zurzuvae™)

Biogen GmbH

Anhang 4-I zu Modul 4 A
Ergebnisse der Studie SKYLARK

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-301 - ITT population

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Variable Statistic or Category	Placebo (N=101)	Zuranolone (N=99)	Total (N=200)
Age at informed consent date (years)			
n	101	99	200
Mean (SD)	30.9 (5.93)	29.9 (5.88)	30.4 (5.91)
Median	31.0	30.0	31.0
Q1, Q3	26.0, 36.0	25.0, 34.0	26.0, 35.0
Min, Max	19, 43	19, 44	19, 44
Age at informed consent date (years) - Category, n (%)			
n [1]	101	99	200
18-24 years	13 (12.9)	19 (19.2)	32 (16.0)
25-45 years	88 (87.1)	80 (80.8)	168 (84.0)
Ethnicity, n (%)			
n [1]	101	99	200
Not Hispanic or Latino	58 (57.4)	64 (64.6)	122 (61.0)
Hispanic or Latino	43 (42.6)	33 (33.3)	76 (38.0)
Not Reported	0	2 (2.0)	2 (1.0)

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-301-itta.rtf **Run Date:** 11JUL2025

Summary of Demographics and Baseline Characteristics: 217-PPD-301 - ITT population

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Variable Statistic or Category	Placebo (N=101)	Zuranolone (N=99)	Total (N=200)
Race, n (%)			
n [1]	101	99	200
White	70 (69.3)	68 (68.7)	138 (69.0)
Black or African American	20 (19.8)	26 (26.3)	46 (23.0)
More than One Race	2 (2.0)	3 (3.0)	5 (2.5)
Other	4 (4.0)	0	4 (2.0)
American Indian or Alaska Native	3 (3.0)	0	3 (1.5)
Asian	1 (1.0)	1 (1.0)	2 (1.0)
Native Hawaiian or Other Pacific Islander	0	0	0
Not Reported	1 (1.0)	1 (1.0)	2 (1.0)
Race - Category, n (%)			
n [1]	101	99	200
Black or African American	20 (19.8)	26 (26.3)	46 (23.0)
White	70 (69.3)	68 (68.7)	138 (69.0)
Other	11 (10.9)	5 (5.1)	16 (8.0)
Education level, n (%) [2]			
n [1]	99	96	195
Less than or equal to 12th grade, no diploma	4 (4.0)	4 (4.2)	8 (4.1)
12th grade diploma or GED	33 (33.3)	31 (32.3)	64 (32.8)
Some college but no degree	25 (25.3)	22 (22.9)	47 (24.1)
Occupational associate degree	3 (3.0)	2 (2.1)	5 (2.6)
Academic associate degree	6 (6.1)	6 (6.3)	12 (6.2)
Bachelor's degree	18 (18.2)	24 (25.0)	42 (21.5)
Master's degree	9 (9.1)	5 (5.2)	14 (7.2)
Professional degree	1 (1.0)	2 (2.1)	3 (1.5)
Doctoral degree	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-301-itta.rtf **Run Date:** 11JUL2025

Summary of Demographics and Baseline Characteristics: 217-PPD-301 - ITT population

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Variable Statistic or Category	Placebo (N=101)	Zuranolone (N=99)	Total (N=200)
Civil/Marital status, n (%) [2]			
n [1]	99	96	195
Married	51 (51.5)	37 (38.5)	88 (45.1)
Never Married	39 (39.4)	40 (41.7)	79 (40.5)
Divorced	3 (3.0)	7 (7.3)	10 (5.1)
Domestic Partner	6 (6.1)	11 (11.5)	17 (8.7)
Single	0	1 (1.0)	1 (0.5)
Employment status, n (%) [2]			
n [1]	99	96	195
Full-time (>= 35 hours per week)	25 (25.3)	33 (34.4)	58 (29.7)
Part-time (< 35 hours per week)	12 (12.1)	7 (7.3)	19 (9.7)
Retired	0	1 (1.0)	1 (0.5)
Unemployed	54 (54.5)	44 (45.8)	98 (50.3)
Other	8 (8.1)	11 (11.5)	19 (9.7)
Country, n (%)			
n [1]	101	99	200
US	99 (98.0)	96 (97.0)	195 (97.5)
Rest of World	2 (2.0)	3 (3.0)	5 (2.5)

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-301-itta.rtf **Run Date:** 11JUL2025

Summary of Demographics and Baseline Characteristics: 217-PPD-301 - ITT population

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Variable Statistic or Category	Placebo (N=101)	Zuranolone (N=99)	Total (N=200)
Height (cm)			
n	98	97	195
Mean (SD)	162.87 (6.482)	163.19 (7.679)	163.03 (7.086)
Median	162.85	163.30	163.00
Q1, Q3	158.00, 167.50	157.50, 167.60	157.50, 167.60
Min, Max	149.9, 181.6	144.8, 182.9	144.8, 182.9
Weight (kg)			
n	98	98	196
Mean (SD)	78.97 (19.493)	82.29 (18.701)	80.63 (19.125)
Median	74.45	80.05	78.70
Q1, Q3	64.90, 91.70	68.10, 96.20	66.75, 94.10
Min, Max	48.6, 137.0	47.7, 142.9	47.7, 142.9
BMI (kg/m^2)			
n	98	97	195
Mean (SD)	29.61 (6.261)	30.86 (6.331)	30.23 (6.311)
Median	28.76	31.07	29.69
Q1, Q3	25.38, 33.46	26.49, 34.81	25.49, 34.58
Min, Max	18.7, 44.8	19.0, 44.8	18.7, 44.8

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-301-itta.rtf **Run Date:** 11JUL2025

Summary of Demographics and Baseline Characteristics: 217-PPD-301 - ITT population

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Variable Statistic or Category	Placebo (N=101)	Zuranolone (N=99)	Total (N=200)
BMI (kg/m^2) - Category, n (%)			
n [1]	98	97	195
<=18.4	0	0	0
18.5-24.9	22 (22.4)	20 (20.6)	42 (21.5)
25-29.9	34 (34.7)	24 (24.7)	58 (29.7)
>=30	42 (42.9)	53 (54.6)	95 (48.7)
BMI (kg/m^2) - Category 2, n (%)			
n [1]	98	97	195
<=24.9	22 (22.4)	20 (20.6)	42 (21.5)
25-29.9	34 (34.7)	24 (24.7)	58 (29.7)
>=30	42 (42.9)	53 (54.6)	95 (48.7)
Baseline antidepressant use, n (%)			
n [1]	101	99	200
Yes	15 (14.9)	15 (15.2)	30 (15.0)
No	86 (85.1)	84 (84.8)	170 (85.0)

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-301-itta.rtf **Run Date:** 11JUL2025

Summary of Demographics and Baseline Characteristics: 217-PPD-301 - ITT population

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Variable Statistic or Category	Placebo (N=101)	Zuranolone (N=99)	Total (N=200)
Baseline HAMD-17 Total Score - Category, n (%)			
n [1]	98	98	196
<28 (median of baseline HAMD-17 total score)	32 (32.7)	33 (33.7)	65 (33.2)
>=28 (median of baseline HAMD-17 total score)	66 (67.3)	65 (66.3)	131 (66.8)
Onset of PPD, n (%)			
n [1]	101	99	200
3rd Trimester	32 (31.7)	35 (35.4)	67 (33.5)
Postpartum	69 (68.3)	64 (64.6)	133 (66.5)
History of PPD, n (%)			
n [1]	101	99	200
1st Episode	90 (89.1)	82 (82.8)	172 (86.0)
Recurrent Episode	11 (10.9)	17 (17.2)	28 (14.0)

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-301-itta.rtf **Run Date:** 11JUL2025

Summary of Demographics and Baseline Characteristics: 217-PPD-301 - ITT population

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Variable Statistic or Category	Placebo (N=101)	Zuranolone (N=99)	Total (N=200)
Family History of PPD, n (%)			
n [1]	101	99	200
Yes	16 (15.8)	21 (21.2)	37 (18.5)
No/Unknown	85 (84.2)	78 (78.8)	163 (81.5)
COVID-19 History, n (%) [2]			
n [1]	101	99	200
COVID-19	0	1 (1.0)	1 (0.5)
Suspected COVID-19	0	0	0
Patient Isolation	0	0	0
SARS-CoV-2 Test Positive	6 (5.9)	3 (3.0)	9 (4.5)
Hospitalization	0	0	0
Not Impacted	95 (94.1)	95 (96.0)	190 (95.0)
Depression with Elevated Anxiety, by Baseline HAMD-17 Anxiety Subscale, n (%)			
n [1]	98	98	196
>=7 (Normalized Score >=39)	96 (98.0)	94 (95.9)	190 (96.9)
<7 (Normalized Score <39)	2 (2.0)	4 (4.1)	6 (3.1)

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-301-itta.rtf **Run Date:** 11JUL2025

Summary of Demographics and Baseline Characteristics: 217-PPD-301 - ITT population

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Variable Statistic or Category	Placebo (N=101)	Zuranolone (N=99)	Total (N=200)
Depression with Elevated Anxiety, by Baseline HAMA Total Score, n (%)			
n [1]	98	98	196
>=20	77 (78.6)	74 (75.5)	151 (77.0)
<20	21 (21.4)	24 (24.5)	45 (23.0)
Any antidepressant medication ever taken, n (%)			
n [1]	101	99	200
Yes	33 (32.7)	36 (36.4)	69 (34.5)
No	68 (67.3)	63 (63.6)	131 (65.5)
Concomitant Procedures - Psychotherapy, n (%) [2]			
n [1]	101	99	200
Yes	1 (1.0)	2 (2.0)	3 (1.5)
No	100 (99.0)	97 (98.0)	197 (98.5)

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-301-itta.rtf **Run Date:** 11JUL2025

1.2 Dargestellt nach der Safety-Population

Summary of Demographics and Baseline Characteristics: 217-PPD-301 - Safety population

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Variable Statistic or Category	Placebo (N=98)	Zuranolone (N=98)	Total (N=196)
Age at informed consent date (years)			
n	98	98	196
Mean (SD)	31.0 (5.95)	30.0 (5.90)	30.5 (5.93)
Median	31.0	30.0	31.0
Q1, Q3	26.0, 36.0	25.0, 34.0	26.0, 35.0
Min, Max	19, 43	19, 44	19, 44
Age at informed consent date (years) - Category, n (%)			
n [1]	98	98	196
18-24 years	12 (12.2)	19 (19.4)	31 (15.8)
25-45 years	86 (87.8)	79 (80.6)	165 (84.2)
Ethnicity, n (%)			
n [1]	98	98	196
Not Hispanic or Latino	56 (57.1)	64 (65.3)	120 (61.2)
Hispanic or Latino	42 (42.9)	33 (33.7)	75 (38.3)
Not Reported	0	1 (1.0)	1 (0.5)

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-301-safc.rtf **Run Date:** 11JUL2025

Summary of Demographics and Baseline Characteristics: 217-PPD-301 - Safety population

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Variable Statistic or Category	Placebo (N=98)	Zuranolone (N=98)	Total (N=196)
Race, n (%)			
n [1]	98	98	196
White	69 (70.4)	68 (69.4)	137 (69.9)
Black or African American	18 (18.4)	25 (25.5)	43 (21.9)
More than One Race	2 (2.0)	3 (3.1)	5 (2.6)
Other	4 (4.1)	0	4 (2.0)
American Indian or Alaska Native	3 (3.1)	0	3 (1.5)
Asian	1 (1.0)	1 (1.0)	2 (1.0)
Native Hawaiian or Other Pacific Islander	0	0	0
Not Reported	1 (1.0)	1 (1.0)	2 (1.0)
Race - Category, n (%)			
n [1]	98	98	196
Black or African American	18 (18.4)	25 (25.5)	43 (21.9)
White	69 (70.4)	68 (69.4)	137 (69.9)
Other	11 (11.2)	5 (5.1)	16 (8.2)
Education level, n (%) [2]			
n [1]	96	95	191
Less than or equal to 12th grade, no diploma	3 (3.1)	4 (4.2)	7 (3.7)
12th grade diploma or GED	32 (33.3)	30 (31.6)	62 (32.5)
Some college but no degree	25 (26.0)	22 (23.2)	47 (24.6)
Occupational associate degree	3 (3.1)	2 (2.1)	5 (2.6)
Academic associate degree	6 (6.3)	6 (6.3)	12 (6.3)
Bachelor's degree	17 (17.7)	24 (25.3)	41 (21.5)
Master's degree	9 (9.4)	5 (5.3)	14 (7.3)
Professional degree	1 (1.0)	2 (2.1)	3 (1.6)
Doctoral degree	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-301-safc.rtf **Run Date:** 11JUL2025

Summary of Demographics and Baseline Characteristics: 217-PPD-301 - Safety population

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Variable Statistic or Category	Placebo (N=98)	Zuranolone (N=98)	Total (N=196)
Civil/Marital status, n (%) [2]			
n [1]	96	95	191
Married	50 (52.1)	37 (38.9)	87 (45.5)
Never Married	37 (38.5)	39 (41.1)	76 (39.8)
Divorced	3 (3.1)	7 (7.4)	10 (5.2)
Domestic Partner	6 (6.3)	11 (11.6)	17 (8.9)
Single	0	1 (1.1)	1 (0.5)
Employment status, n (%) [2]			
n [1]	96	95	191
Full-time (>= 35 hours per week)	24 (25.0)	32 (33.7)	56 (29.3)
Part-time (< 35 hours per week)	10 (10.4)	7 (7.4)	17 (8.9)
Retired	0	1 (1.1)	1 (0.5)
Unemployed	54 (56.3)	44 (46.3)	98 (51.3)
Other	8 (8.3)	11 (11.6)	19 (9.9)
Country, n (%)			
n [1]	98	98	196
US	96 (98.0)	95 (96.9)	191 (97.4)
Rest of World	2 (2.0)	3 (3.1)	5 (2.6)

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-301-safc.rtf **Run Date:** 11JUL2025

Summary of Demographics and Baseline Characteristics: 217-PPD-301 - Safety population

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Variable Statistic or Category	Placebo (N=98)	Zuranolone (N=98)	Total (N=196)
Height (cm)			
n	98	97	195
Mean (SD)	162.87 (6.482)	163.19 (7.679)	163.03 (7.086)
Median	162.85	163.30	163.00
Q1, Q3	158.00, 167.50	157.50, 167.60	157.50, 167.60
Min, Max	149.9, 181.6	144.8, 182.9	144.8, 182.9
Weight (kg)			
n	98	98	196
Mean (SD)	78.97 (19.493)	82.29 (18.701)	80.63 (19.125)
Median	74.45	80.05	78.70
Q1, Q3	64.90, 91.70	68.10, 96.20	66.75, 94.10
Min, Max	48.6, 137.0	47.7, 142.9	47.7, 142.9
BMI (kg/m^2)			
n	98	97	195
Mean (SD)	29.61 (6.261)	30.86 (6.331)	30.23 (6.311)
Median	28.76	31.07	29.69
Q1, Q3	25.38, 33.46	26.49, 34.81	25.49, 34.58
Min, Max	18.7, 44.8	19.0, 44.8	18.7, 44.8

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-301-safc.rtf **Run Date:** 11JUL2025

Summary of Demographics and Baseline Characteristics: 217-PPD-301 - Safety population

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Variable Statistic or Category	Placebo (N=98)	Zuranolone (N=98)	Total (N=196)
BMI (kg/m^2) - Category, n (%)			
n [1]	98	97	195
<=18.4	0	0	0
18.5-24.9	22 (22.4)	20 (20.6)	42 (21.5)
25-29.9	34 (34.7)	24 (24.7)	58 (29.7)
>=30	42 (42.9)	53 (54.6)	95 (48.7)
BMI (kg/m^2) - Category 2, n (%)			
n [1]	98	97	195
<=24.9	22 (22.4)	20 (20.6)	42 (21.5)
25-29.9	34 (34.7)	24 (24.7)	58 (29.7)
>=30	42 (42.9)	53 (54.6)	95 (48.7)
Baseline antidepressant use, n (%)			
n [1]	98	98	196
Yes	15 (15.3)	15 (15.3)	30 (15.3)
No	83 (84.7)	83 (84.7)	166 (84.7)

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-301-safc.rtf **Run Date:** 11JUL2025

Summary of Demographics and Baseline Characteristics: 217-PPD-301 - Safety population

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Variable Statistic or Category	Placebo (N=98)	Zuranolone (N=98)	Total (N=196)
Baseline HAMD-17 Total Score - Category, n (%)			
n [1]	98	98	196
<28 (median of baseline HAMD-17 total score)	32 (32.7)	33 (33.7)	65 (33.2)
>=28 (median of baseline HAMD-17 total score)	66 (67.3)	65 (66.3)	131 (66.8)
Onset of PPD, n (%)			
n [1]	98	98	196
3rd Trimester	31 (31.6)	34 (34.7)	65 (33.2)
Postpartum	67 (68.4)	64 (65.3)	131 (66.8)
History of PPD, n (%)			
n [1]	98	98	196
1st Episode	87 (88.8)	81 (82.7)	168 (85.7)
Recurrent Episode	11 (11.2)	17 (17.3)	28 (14.3)

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-301-safc.rtf **Run Date:** 11JUL2025

Summary of Demographics and Baseline Characteristics: 217-PPD-301 - Safety population

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Variable Statistic or Category	Placebo (N=98)	Zuranolone (N=98)	Total (N=196)
Family History of PPD, n (%)			
n [1]	98	98	196
Yes	16 (16.3)	21 (21.4)	37 (18.9)
No/Unknown	82 (83.7)	77 (78.6)	159 (81.1)
COVID-19 History, n (%) [2]			
n [1]	98	98	196
COVID-19	0	1 (1.0)	1 (0.5)
Suspected COVID-19	0	0	0
Patient Isolation	0	0	0
SARS-CoV-2 Test Positive	6 (6.1)	3 (3.1)	9 (4.6)
Hospitalization	0	0	0
Not Impacted	92 (93.9)	94 (95.9)	186 (94.9)
Depression with Elevated Anxiety, by Baseline HAMD-17 Anxiety Subscale, n (%)			
n [1]	98	98	196
>=7 (Normalized Score >=39)	96 (98.0)	94 (95.9)	190 (96.9)
<7 (Normalized Score <39)	2 (2.0)	4 (4.1)	6 (3.1)

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-301-safc.rtf **Run Date:** 11JUL2025

Summary of Demographics and Baseline Characteristics: 217-PPD-301 - Safety population

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Variable Statistic or Category	Placebo (N=98)	Zuranolone (N=98)	Total (N=196)
Depression with Elevated Anxiety, by Baseline HAMA Total Score, n (%)			
n [1]	98	98	196
>=20	77 (78.6)	74 (75.5)	151 (77.0)
<20	21 (21.4)	24 (24.5)	45 (23.0)
Any antidepressant medication ever taken, n (%)			
n [1]	98	98	196
Yes	33 (33.7)	36 (36.7)	69 (35.2)
No	65 (66.3)	62 (63.3)	127 (64.8)
Concomitant Procedures - Psychotherapy, n (%) [2]			
n [1]	98	98	196
Yes	1 (1.0)	2 (2.0)	3 (1.5)
No	97 (99.0)	96 (98.0)	193 (98.5)

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-301-safc.rtf **Run Date:** 11JUL2025

1.3 PPD-Schweregrad

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Cumulative Frequency of Baseline MADRS Total Score: 217-PPD-301 - ITT population (Moderate Baseline MADRS Severity Subgroup)

Page: 1 of 1

	Placebo (N=45)	Zuranolone (N =45)	Total (N =90)
Baseline MARDS Total Score, n (%)			
22	1 (2.2)	0	1 (1.1)
<= 23	2 (4.4)	0	2 (2.2)
<= 24	2 (4.4)	2 (4.4)	4 (4.4)
<= 25	3 (6.7)	4 (8.9)	7 (7.8)
<= 26	4 (8.9)	6 (13.3)	10 (11.1)
<= 27	4 (8.9)	8 (17.8)	12 (13.3)
<= 28	7 (15.6)	9 (20.0)	16 (17.8)
<= 29	12 (26.7)	13 (28.9)	25 (27.8)
<= 30	15 (33.3)	19 (42.2)	34 (37.8)
<= 31	21 (46.7)	22 (48.9)	43 (47.8)
<= 32	29 (64.4)	29 (64.4)	58 (64.4)
<= 33	37 (82.2)	33 (73.3)	70 (77.8)
<= 34	45 (100)	45 (100)	90 (100)

Source: biib125/v_a/germany_amnog/t-bl-madrs-mod.sas:t-bl-madrs-mod-301-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-301 - ITT population

Page: 1 of 3

	Placebo (N = 101)	Zuranolone (N = 99)	Overall (N = 200)
Baseline MADRS Total Score			
n	97	98	195
Mean	35.0	35.5	35.2
SD	4.78	5.37	5.08
Median	35.0	36.0	35.0
Min, Max	22, 46	24, 49	22, 49
Baseline MADRS Total Score Group, n (%)			
n	97	98	195
20 - 34 (Moderate)	45 (46.4)	45 (45.9)	90 (46.2)
>= 35 (Severe)	52 (53.6)	53 (54.1)	105 (53.8)
Baseline EPDS Total Score			
n	98	98	196
Mean	20.1	21.1	20.6
SD	4.14	3.68	3.94
Median	21.0	21.0	21.0
Min, Max	6, 27	13, 30	6, 30

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 1 participant (zuranolone) with a CGI-S score of 3 (Mildly Ill).

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

Source: biib125/v_a/germany_amnog/t-summ-dis-sev.sas:t-summ-dis-sev-301-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-301 - ITT population

Page: 2 of 3

	Placebo (N = 101)	Zuranolone (N = 99)	Overall (N = 200)
Baseline EPDS Total Score Group, n (%)			
n	98	98	196
< 20	35 (35.7)	34 (34.7)	69 (35.2)
>= 20	63 (64.3)	64 (65.3)	127 (64.8)
Baseline CGI-S Score			
n	98	98	196
Mean	4.9	5.0	4.9
SD	0.58	0.66	0.62
Median	5.0	5.0	5.0
Min, Max	4, 6	3, 6	3, 6
Baseline CGI-S Score Group, n (%)			
n	98	98	196
4 (Moderately Ill) [1]	20 (20.4)	21 (21.4)	41 (20.9)
5 (Markedly Ill)	65 (66.3)	59 (60.2)	124 (63.3)
6 (Severely Ill)	13 (13.3)	18 (18.4)	31 (15.8)

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 1 participant (zuranolone) with a CGI-S score of 3 (Mildly Ill).
[2] Includes 3 zuranolone and 2 placebo participants with a PHQ-9 total score that indicates mild depression, and 1 placebo participant with a PHQ-9 total score that indicates minimal depression.
Source: biib125/v_a/germany_amnog/t-summ-dis-sev.sas:t-summ-dis-sev-301-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-301 - ITT population

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	Placebo (N = 101)	Zuranolone (N = 99)	Overall (N = 200)
Baseline PHQ-9 Total Score			
n	98	98	196
Mean	19.0	19.1	19.0
SD	4.55	4.39	4.46
Median	20.0	20.0	20.0
Min, Max	4, 27	7, 27	4, 27
Baseline PHQ-9 Total Score Group, n (%)			
n	98	98	196
<= 14 (Mild to Moderate Depression) [2]	18 (18.4)	18 (18.4)	36 (18.4)
15-19 (Moderately Severe Depression)	28 (28.6)	27 (27.6)	55 (28.1)
>=20 (Severe Depression)	52 (53.1)	53 (54.1)	105 (53.6)

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.

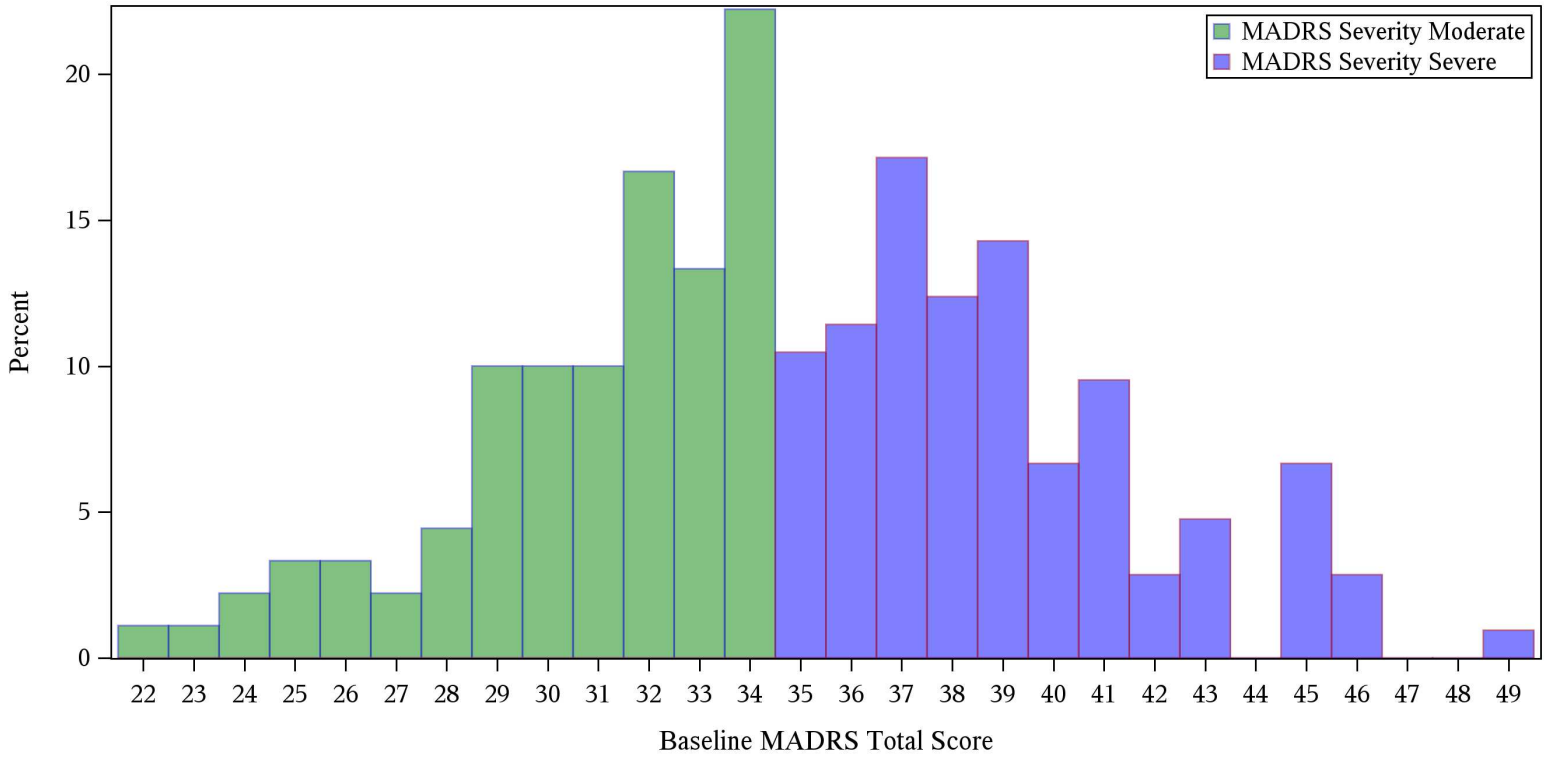
NOTE 1: Treatment group percentages are based on n, the number of participants with non-missing data.

[1] Includes 1 participant (zuranolone) with a CGI-S score of 3 (Mildly Ill).

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

Source: biib125/v_a/germany_amnog/t-summ-dis-sev.sas:t-summ-dis-sev-301-itta.rtf **Run Date:** 22OCT2025

Histogram of Baseline MADRS Total Score by Baseline MADRS Severity: 217-PPD-301 - ITT population
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Source: biib125/v_a/germany_amnog/f-hist-madrs.sas:f-hist-madrs-301-itta.rtf **Run Date:** 02OCT2025

2 Morbidität

2.1 HAMD-17

2.1.1 MMRM

Model-based Results on Change from Baseline in Hamilton Rating Scale for Depression (HAMD-17) Total Score: 217-PPD-301 - ITT population

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	Placebo (N=101)	Zuranolone (N=99)
Day 3		
n	96	98
LS Mean (SE)	-6.14 (0.710)	-9.53 (0.704)
95% CI for the LS Mean	-7.54, -4.74	-10.92, -8.14
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.39 (0.999)
95% CI for the LS Mean		-5.36, -1.42
p-value		0.0008
Hedges' g (Zuranolone vs. Placebo)		-0.486
95% CI for Hedges' g		-0.7714, -0.2003
Day 8		
n	95	93
LS Mean (SE)	-9.47 (0.763)	-13.17 (0.764)
95% CI for the LS Mean	-10.98, -7.96	-14.68, -11.66
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.70 (1.080)
95% CI for the LS Mean		-5.83, -1.57
p-value		0.0007
Hedges' g (Zuranolone vs. Placebo)		-0.498
95% CI for Hedges' g		-0.7882, -0.2076

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-301-ovr.sas:t-hamd-mmrm-301-ovr-itta.rtf **Run Date:** 18JUL2025

Model-based Results on Change from Baseline in Hamilton Rating Scale for Depression (HAMD-17) Total Score: 217-PPD-301 - ITT population

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	Placebo (N=101)	Zuranolone (N=99)
Day 15		
n	90	93
LS Mean (SE)	-11.60 (0.823)	-15.61 (0.817)
95% CI for the LS Mean	-13.22, -9.98	-17.22, -14.00
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-4.01 (1.159)
95% CI for the LS Mean		-6.30, -1.72
p-value		0.0007
Hedges' g (Zuranolone vs. Placebo)		-0.509
95% CI for Hedges' g		-0.8039, -0.2149
Day 21		
n	83	84
LS Mean (SE)	-13.27 (0.867)	-15.75 (0.866)
95% CI for the LS Mean	-14.98, -11.56	-17.46, -14.04
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.48 (1.226)
95% CI for the LS Mean		-4.90, -0.06
p-value		0.0445
Hedges' g (Zuranolone vs. Placebo)		-0.312
95% CI for Hedges' g		-0.6168, -0.0065

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-301-ovr.sas:t-hamd-mmrm-301-ovr-itta.rtf **Run Date:** 18JUL2025

Model-based Results on Change from Baseline in Hamilton Rating Scale for Depression (HAMD-17) Total Score: 217-PPD-301 - ITT population

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	Placebo (N=101)	Zuranolone (N=99)
Day 28		
n	85	77
LS Mean (SE)	-13.40 (0.875)	-16.31 (0.884)
95% CI for the LS Mean	-15.12, -11.67	-18.05, -14.57
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.91 (1.244)
95% CI for the LS Mean		-5.37, -0.46
p-value		0.0203
Hedges' g (Zuranolone vs. Placebo)		-0.367
95% CI for Hedges' g		-0.6776, -0.0557
Day 45		
n	85	84
LS Mean (SE)	-14.45 (0.902)	-17.95 (0.903)
95% CI for the LS Mean	-16.23, -12.67	-19.73, -16.17
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.50 (1.277)
95% CI for the LS Mean		-6.02, -0.98
p-value		0.0067
Hedges' g (Zuranolone vs. Placebo)		-0.420
95% CI for Hedges' g		-0.7250, -0.1153

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-301-ovr.sas:t-hamd-mmrm-301-ovr-itta.rtf **Run Date:** 18JUL2025

2.1.2 Ansprechen

2.1.2.1 Responder-Analysen

2.1.2.1 .1 ITT-Population

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score): 217-PPD-301 - ITT population

Page: 1 of 6

Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Number of evaluable subjects [1]	98	98
Day 3		
Number of subjects with a response, n (%) [2]	12 (12.2)	26 (26.5)
Number of subjects with missing evaluation, n (%)	2 (2.0)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.173
95% CI for the RR		(1.166, 4.051)
p-value for RR		0.0145
OR - Odds Ratio (Zuranolone vs. Placebo)		2.609
95% CI for the OR		(1.233, 5.523)
p-value for OR		0.0122
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.140
95% CI for the ARR		(0.034, 0.247)
p-value for ARR		0.0100

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-resp50-301-ovr.sas:t-hamd-resp50-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score): 217-PPD-301 - ITT population

Page: 2 of 6

Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 8		
Number of subjects with a response, n (%) [2]	24 (24.5)	47 (48.0)
Number of subjects with missing evaluation, n (%)	3 (3.1)	5 (5.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.957
95% CI for the RR		(1.307, 2.931)
p-value for RR		0.0011
OR - Odds Ratio (Zuranolone vs. Placebo)		2.870
95% CI for the OR		(1.561, 5.279)
p-value for OR		0.0007
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.236
95% CI for the ARR		(0.105, 0.366)
p-value for ARR		0.0004

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-resp50-301-ovr.sas:t-hamd-resp50-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score): 217-PPD-301 - ITT population

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Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 15		
Number of subjects with a response, n (%) [2]	35 (35.7)	53 (54.1)
Number of subjects with missing evaluation, n (%)	8 (8.2)	5 (5.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.512
95% CI for the RR		(1.095, 2.087)
p-value for RR		0.0120
OR - Odds Ratio (Zuranolone vs. Placebo)		2.138
95% CI for the OR		(1.201, 3.808)
p-value for OR		0.0099
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.183
95% CI for the ARR		(0.046, 0.320)
p-value for ARR		0.0089

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-resp50-301-ovr.sas:t-hamd-resp50-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score): 217-PPD-301 - ITT population

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Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 21		
Number of subjects with a response, n (%) [2]	35 (35.7)	50 (51.0)
Number of subjects with missing evaluation, n (%)	15 (15.3)	14 (14.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.418
95% CI for the RR		(1.020, 1.973)
p-value for RR		0.0379
OR - Odds Ratio (Zuranolone vs. Placebo)		1.891
95% CI for the OR		(1.062, 3.367)
p-value for OR		0.0304
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.153
95% CI for the ARR		(0.015, 0.290)
p-value for ARR		0.0296

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-resp50-301-ovr.sas:t-hamd-resp50-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score): 217-PPD-301 - ITT population

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Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 28		
Number of subjects with a response, n (%) [2]	35 (35.7)	48 (49.0)
Number of subjects with missing evaluation, n (%)	13 (13.3)	21 (21.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.364
95% CI for the RR		(0.977, 1.904)
p-value for RR		0.0685
OR - Odds Ratio (Zuranolone vs. Placebo)		1.745
95% CI for the OR		(0.983, 3.098)
p-value for OR		0.0574
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.134
95% CI for the ARR		(-0.003, 0.271)
p-value for ARR		0.0561

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-resp50-301-ovr.sas:t-hamd-resp50-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score): 217-PPD-301 - ITT population

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Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 45		
Number of subjects with a response, n (%) [2]	46 (46.9)	52 (53.1)
Number of subjects with missing evaluation, n (%)	13 (13.3)	14 (14.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.121
95% CI for the RR		(0.847, 1.485)
p-value for RR		0.4241
OR - Odds Ratio (Zuranolone vs. Placebo)		1.287
95% CI for the OR		(0.734, 2.255)
p-value for OR		0.3785
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.062
95% CI for the ARR		(-0.078, 0.202)
p-value for ARR		0.3860

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-resp50-301-ovr.sas:t-hamd-resp50-301-ovr-itta.rtf **Run Date:** 18JUL2025

2.1.2.1 .2 Subgruppen

2.1.2.1 .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-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	98	98	
Number of subjects with response at Day 15, n (%)	35 (35.7)	53 (54.1)	
Number of subjects with response at Day 45, n (%)	46 (46.9)	52 (53.1)	
Age Group (years)			0.8759
Day 15			
18 - 24, n / N (%)	6/12 (50.0)	13/19 (68.4)	
25 - 45, n / N (%)	29/86 (33.7)	40/79 (50.6)	
Day 45			
18 - 24, n / N (%)	6/12 (50.0)	12/19 (63.2)	
25 - 45, n / N (%)	40/86 (46.5)	40/79 (50.6)	

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 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-resp50-301-int.sas:t-hamd-resp50-301-int-itta.rtf **Run Date:** 18JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score): Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			0.7318
Day 15			
<28, n / N (%)	13/32 (40.6)	17/33 (51.5)	
>=28, n / N (%)	22/66 (33.3)	36/65 (55.4)	
Day 45			
<28, n / N (%)	12/32 (37.5)	18/33 (54.5)	
>=28, n / N (%)	34/66 (51.5)	34/65 (52.3)	
Race Group (Black or African American, White)			0.1895
Day 15			
Black or African American, n / N (%)	6/18 (33.3)	14/25 (56.0)	
White, n / N (%)	26/69 (37.7)	38/68 (55.9)	
Day 45			
Black or African American, n / N (%)	6/18 (33.3)	16/25 (64.0)	
White, n / N (%)	37/69 (53.6)	35/68 (51.5)	

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 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-resp50-301-int.sas:t-hamd-resp50-301-int-itta.rtf **Run Date:** 18JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score): Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			0.2261
Day 15			
Yes, n / N (%)	9/15 (60.0)	7/15 (46.7)	
No, n / N (%)	26/83 (31.3)	46/83 (55.4)	
Day 45			
Yes, n / N (%)	9/15 (60.0)	7/15 (46.7)	
No, n / N (%)	37/83 (44.6)	45/83 (54.2)	

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.
Source: biib125/v_a/germany_amnog/t-hamd-resp50-301-int.sas:t-hamd-resp50-301-int-itta.rtf **Run Date:** 18JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score): Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			0.6682(a) 0.9995(b) 0.5731(c)
Day 15			
<=24.9, n / N (%)	6/22 (27.3)	9/20 (45.0)	
25-29.9, n / N (%)	13/34 (38.2)	12/24 (50.0)	
>=30, n / N (%)	16/42 (38.1)	32/53 (60.4)	
Day 45			
<=24.9, n / N (%)	12/22 (54.5)	8/20 (40.0)	
25-29.9, n / N (%)	17/34 (50.0)	14/24 (58.3)	
>=30, n / N (%)	17/42 (40.5)	29/53 (54.7)	

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-resp50-301-int.sas:t-hamd-resp50-301-int-itta.rtf **Run Date:** 18JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score): Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Onset of PPD			0.8217
Day 15			
3rd Trimester, n / N (%)	14/31 (45.2)	16/34 (47.1)	
Postpartum, n / N (%)	21/67 (31.3)	37/64 (57.8)	
Day 45			
3rd Trimester, n / N (%)	14/31 (45.2)	19/34 (55.9)	
Postpartum, n / N (%)	32/67 (47.8)	33/64 (51.6)	
Family History of PPD			0.3263
Day 15			
Yes, n / N (%)	9/16 (56.3)	11/21 (52.4)	
No/Unknown, n / N (%)	26/82 (31.7)	42/77 (54.5)	
Day 45			
Yes, n / N (%)	9/16 (56.3)	12/21 (57.1)	
No/Unknown, n / N (%)	37/82 (45.1)	40/77 (51.9)	

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-resp50-301-int.sas:t-hamd-resp50-301-int-itta.rtf **Run Date:** 18JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score): Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
History of PPD			0.7850
Day 15			
1st Episode, n / N (%)	30/87 (34.5)	42/81 (51.9)	
Recurrent Episode, n / N (%)	5/11 (45.5)	11/17 (64.7)	
Day 45			
1st Episode, n / N (%)	41/87 (47.1)	42/81 (51.9)	
Recurrent Episode, n / N (%)	5/11 (45.5)	10/17 (58.8)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			0.2835
Day 15			
<20, n / N (%)	8/21 (38.1)	14/24 (58.3)	
>=20, n / N (%)	27/77 (35.1)	39/74 (52.7)	
Day 45			
<20, n / N (%)	13/21 (61.9)	15/24 (62.5)	
>=20, n / N (%)	33/77 (42.9)	37/74 (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 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-resp50-301-int.sas:t-hamd-resp50-301-int-itta.rtf **Run Date:** 18JUL2025

2.1.2.1 .2 .2 Subgruppenanalysen

2.1.2.1 .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-301 - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =19)
Number of evaluable subjects [1]	12	19
Day 3		
Number of subjects with a response, n (%) [2]	3 (25.0)	6 (31.6)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.542
95% CI for the RR		(0.507, 4.687)
p-value for RR		0.4454
Day 8		
Number of subjects with a response, n (%) [2]	6 (50.0)	14 (73.7)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.799
95% CI for the RR		(0.801, 4.038)
p-value for RR		0.1548

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-resp50-301-by.sas:t-hamd-resp50-301-by-age-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =19)
Day 15		
Number of subjects with a response, n (%) [2]	6 (50.0)	13 (68.4)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.670
95% CI for the RR		(0.744, 3.748)
p-value for RR		0.2135
Day 21		
Number of subjects with a response, n (%) [2]	4 (33.3)	15 (78.9)
Number of subjects with missing evaluation, n (%)	2 (16.7)	1 (5.3)
RR - Relative Risk (Zuranolone vs. Placebo)		2.891
95% CI for the RR		(1.196, 6.987)
p-value for RR		0.0184

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-resp50-301-by.sas:t-hamd-resp50-301-by-age-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =19)
Day 28		
Number of subjects with a response, n (%) [2]	7 (58.3)	12 (63.2)
Number of subjects with missing evaluation, n (%)	0	2 (10.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.321
95% CI for the RR		(0.629, 2.777)
p-value for RR		0.4618
Day 45		
Number of subjects with a response, n (%) [2]	6 (50.0)	12 (63.2)
Number of subjects with missing evaluation, n (%)	1 (8.3)	1 (5.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.542
95% CI for the RR		(0.758, 3.135)
p-value for RR		0.2319

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-resp50-301-by.sas:t-hamd-resp50-301-by-age-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=88)	Zuranolone (N =80)
Number of evaluable subjects [1]	86	79
Day 3		
Number of subjects with a response, n (%) [2]	9 (10.5)	20 (25.3)
Number of subjects with missing evaluation, n (%)	2 (2.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.412
95% CI for the RR		(1.170, 4.975)
p-value for RR		0.0171
Day 8		
Number of subjects with a response, n (%) [2]	18 (20.9)	33 (41.8)
Number of subjects with missing evaluation, n (%)	3 (3.5)	5 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.990
95% CI for the RR		(1.223, 3.238)
p-value for RR		0.0056

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-resp50-301-by.sas:t-hamd-resp50-301-by-age-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=88)	Zuranolone (N =80)
Day 15		
Number of subjects with a response, n (%) [2]	29 (33.7)	40 (50.6)
Number of subjects with missing evaluation, n (%)	8 (9.3)	5 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.497
95% CI for the RR		(1.037, 2.162)
p-value for RR		0.0312
Day 21		
Number of subjects with a response, n (%) [2]	31 (36.0)	35 (44.3)
Number of subjects with missing evaluation, n (%)	13 (15.1)	13 (16.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.226
95% CI for the RR		(0.842, 1.785)
p-value for RR		0.2887

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-resp50-301-by.sas:t-hamd-resp50-301-by-age-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=88)	Zuranolone (N =80)
Day 28		
Number of subjects with a response, n (%) [2]	28 (32.6)	36 (45.6)
Number of subjects with missing evaluation, n (%)	13 (15.1)	19 (24.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.396
95% CI for the RR		(0.946, 2.059)
p-value for RR		0.0926
Day 45		
Number of subjects with a response, n (%) [2]	40 (46.5)	40 (50.6)
Number of subjects with missing evaluation, n (%)	12 (14.0)	13 (16.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.086
95% CI for the RR		(0.793, 1.486)
p-value for RR		0.6081

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-resp50-301-by.sas:t-hamd-resp50-301-by-age-itta.rtf **Run Date:** 25JUL2025

2.1.2.1 .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-301 - 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=32)	Zuranolone (N =33)
Number of evaluable subjects [1]	32	33
Day 3		
Number of subjects with a response, n (%) [2]	4 (12.5)	7 (21.2)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.609
95% CI for the RR		(0.535, 4.837)
p-value for RR		0.3972
Day 8		
Number of subjects with a response, n (%) [2]	9 (28.1)	14 (42.4)
Number of subjects with missing evaluation, n (%)	0	1 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.371
95% CI for the RR		(0.699, 2.688)
p-value for RR		0.3583

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 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-resp50-301-by.sas:t-hamd-resp50-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

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-301 - 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=32)	Zuranolone (N =33)
Day 15		
Number of subjects with a response, n (%) [2]	13 (40.6)	17 (51.5)
Number of subjects with missing evaluation, n (%)	2 (6.3)	1 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.171
95% CI for the RR		(0.733, 1.870)
p-value for RR		0.5092
Day 21		
Number of subjects with a response, n (%) [2]	13 (40.6)	18 (54.5)
Number of subjects with missing evaluation, n (%)	5 (15.6)	2 (6.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.266
95% CI for the RR		(0.812, 1.976)
p-value for RR		0.2977

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 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-resp50-301-by.sas:t-hamd-resp50-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

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-301 - 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=32)	Zuranolone (N =33)
Day 28		
Number of subjects with a response, n (%) [2]	9 (28.1)	14 (42.4)
Number of subjects with missing evaluation, n (%)	6 (18.8)	5 (15.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.457
95% CI for the RR		(0.786, 2.701)
p-value for RR		0.2319
Day 45		
Number of subjects with a response, n (%) [2]	12 (37.5)	18 (54.5)
Number of subjects with missing evaluation, n (%)	5 (15.6)	3 (9.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.391
95% CI for the RR		(0.866, 2.236)
p-value for RR		0.1724

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 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-resp50-301-by.sas:t-hamd-resp50-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

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-301 - 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=66)	Zuranolone (N =65)
Number of evaluable subjects [1]	66	65
Day 3		
Number of subjects with a response, n (%) [2]	8 (12.1)	19 (29.2)
Number of subjects with missing evaluation, n (%)	2 (3.0)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.385
95% CI for the RR		(1.115, 5.102)
p-value for RR		0.0250
Day 8		
Number of subjects with a response, n (%) [2]	15 (22.7)	33 (50.8)
Number of subjects with missing evaluation, n (%)	3 (4.5)	4 (6.2)
RR - Relative Risk (Zuranolone vs. Placebo)		2.242
95% CI for the RR		(1.354, 3.713)
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 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 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-resp50-301-by.sas:t-hamd-resp50-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

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-301 - 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=66)	Zuranolone (N =65)
Day 15		
Number of subjects with a response, n (%) [2]	22 (33.3)	36 (55.4)
Number of subjects with missing evaluation, n (%)	6 (9.1)	4 (6.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.658
95% CI for the RR		(1.107, 2.482)
p-value for RR		0.0142
Day 21		
Number of subjects with a response, n (%) [2]	22 (33.3)	32 (49.2)
Number of subjects with missing evaluation, n (%)	10 (15.2)	12 (18.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.503
95% CI for the RR		(0.989, 2.284)
p-value for RR		0.0564

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 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-resp50-301-by.sas:t-hamd-resp50-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

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-301 - 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=66)	Zuranolone (N =65)
Day 28		
Number of subjects with a response, n (%) [2]	26 (39.4)	34 (52.3)
Number of subjects with missing evaluation, n (%)	7 (10.6)	16 (24.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.362
95% CI for the RR		(0.940, 1.975)
p-value for RR		0.1025
Day 45		
Number of subjects with a response, n (%) [2]	34 (51.5)	34 (52.3)
Number of subjects with missing evaluation, n (%)	8 (12.1)	11 (16.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.030
95% CI for the RR		(0.740, 1.433)
p-value for RR		0.8607

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 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-resp50-301-by.sas:t-hamd-resp50-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

2.1.2.1 .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-301 - ITT population

Page: 1 of 6

Race Group = Black or African American

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =26)
Number of evaluable subjects [1]	18	25
Day 3		
Number of subjects with a response, n (%) [2]	1 (5.6)	7 (28.0)
Number of subjects with missing evaluation, n (%)	1 (5.6)	0
RR - Relative Risk (Zuranolone vs. Placebo)		6.090
95% CI for the RR		(0.765, 48.493)
p-value for RR		0.0879
Day 8		
Number of subjects with a response, n (%) [2]	3 (16.7)	10 (40.0)
Number of subjects with missing evaluation, n (%)	2 (11.1)	2 (8.0)
RR - Relative Risk (Zuranolone vs. Placebo)		2.900
95% CI for the RR		(0.858, 9.801)
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 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-resp50-301-by.sas:t-hamd-resp50-301-by-race-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Race Group: 217-PPD-301 - ITT population

Page: 2 of 6

Race Group = Black or African American

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =26)
Day 15		
Number of subjects with a response, n (%) [2]	6 (33.3)	14 (56.0)
Number of subjects with missing evaluation, n (%)	4 (22.2)	3 (12.0)
RR - Relative Risk (Zuranolone vs. Placebo)		2.030
95% CI for the RR		(1.060, 3.888)
p-value for RR		0.0327
Day 21		
Number of subjects with a response, n (%) [2]	4 (22.2)	12 (48.0)
Number of subjects with missing evaluation, n (%)	7 (38.9)	7 (28.0)
RR - Relative Risk (Zuranolone vs. Placebo)		2.610
95% CI for the RR		(1.108, 6.148)
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 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-resp50-301-by.sas:t-hamd-resp50-301-by-race-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Race Group: 217-PPD-301 - ITT population

Page: 3 of 6

Race Group = Black or African American

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =26)
Day 28		
Number of subjects with a response, n (%) [2]	4 (22.2)	14 (56.0)
Number of subjects with missing evaluation, n (%)	7 (38.9)	6 (24.0)
RR - Relative Risk (Zuranolone vs. Placebo)		3.045
95% CI for the RR		(1.215, 7.632)
p-value for RR		0.0175
Day 45		
Number of subjects with a response, n (%) [2]	6 (33.3)	16 (64.0)
Number of subjects with missing evaluation, n (%)	5 (27.8)	3 (12.0)
RR - Relative Risk (Zuranolone vs. Placebo)		2.320
95% CI for the RR		(1.172, 4.593)
p-value for RR		0.0157

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-resp50-301-by.sas:t-hamd-resp50-301-by-race-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Race Group: 217-PPD-301 - ITT population

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Race Group = White

Study Visit Statistics	Placebo (N=70)	Zuranolone (N =68)
Number of evaluable subjects [1]	69	68
Day 3		
Number of subjects with a response, n (%) [2]	9 (13.0)	18 (26.5)
Number of subjects with missing evaluation, n (%)	1 (1.4)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.035
95% CI for the RR		(0.986, 4.201)
p-value for RR		0.0547
Day 8		
Number of subjects with a response, n (%) [2]	19 (27.5)	36 (52.9)
Number of subjects with missing evaluation, n (%)	0	3 (4.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.928
95% CI for the RR		(1.239, 3.001)
p-value for RR		0.0036

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-resp50-301-by.sas:t-hamd-resp50-301-by-race-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Race Group: 217-PPD-301 - ITT population

Page: 5 of 6

Race Group = White

Study Visit Statistics	Placebo (N=70)	Zuranolone (N =68)
Day 15		
Number of subjects with a response, n (%) [2]	26 (37.7)	38 (55.9)
Number of subjects with missing evaluation, n (%)	3 (4.3)	2 (2.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.487
95% CI for the RR		(1.027, 2.154)
p-value for RR		0.0358
Day 21		
Number of subjects with a response, n (%) [2]	28 (40.6)	37 (54.4)
Number of subjects with missing evaluation, n (%)	7 (10.1)	7 (10.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.345
95% CI for the RR		(0.939, 1.925)
p-value for RR		0.1058

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-resp50-301-by.sas:t-hamd-resp50-301-by-race-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Race Group: 217-PPD-301 - ITT population

Page: 6 of 6

Race Group = White

Study Visit Statistics	Placebo (N=70)	Zuranolone (N =68)
Day 28		
Number of subjects with a response, n (%) [2]	27 (39.1)	32 (47.1)
Number of subjects with missing evaluation, n (%)	5 (7.2)	15 (22.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.206
95% CI for the RR		(0.818, 1.777)
p-value for RR		0.3440
Day 45		
Number of subjects with a response, n (%) [2]	37 (53.6)	35 (51.5)
Number of subjects with missing evaluation, n (%)	7 (10.1)	10 (14.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.963
95% CI for the RR		(0.700, 1.323)
p-value for RR		0.8141

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-resp50-301-by.sas:t-hamd-resp50-301-by-race-itta.rtf **Run Date:** 25JUL2025

2.1.2.1 .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-301 - ITT population

Page: 1 of 6

Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=15)	Zuranolone (N =15)
Number of evaluable subjects [1]	15	15
Day 3		
Number of subjects with a response, n (%) [2]	2 (13.3)	2 (13.3)
Number of subjects with missing evaluation, n (%)	1 (6.7)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.220
95% CI for the RR		(0.180, 8.275)
p-value for RR		0.8386
Day 8		
Number of subjects with a response, n (%) [2]	3 (20.0)	8 (53.3)
Number of subjects with missing evaluation, n (%)	0	1 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		3.254
95% CI for the RR		(1.130, 9.372)
p-value for RR		0.0288

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-resp50-301-by.sas:t-hamd-resp50-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Baseline Antidepressant Use: 217-PPD-301 - ITT population

Page: 2 of 6

Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=15)	Zuranolone (N =15)
Day 15		
Number of subjects with a response, n (%) [2]	9 (60.0)	7 (46.7)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.949
95% CI for the RR		(0.379, 2.375)
p-value for RR		0.9109
Day 21		
Number of subjects with a response, n (%) [2]	8 (53.3)	5 (33.3)
Number of subjects with missing evaluation, n (%)	1 (6.7)	1 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.763
95% CI for the RR		(0.252, 2.310)
p-value for RR		0.6317

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-resp50-301-by.sas:t-hamd-resp50-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Baseline Antidepressant Use: 217-PPD-301 - ITT population

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Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=15)	Zuranolone (N =15)
Day 28		
Number of subjects with a response, n (%) [2]	7 (46.7)	8 (53.3)
Number of subjects with missing evaluation, n (%)	2 (13.3)	1 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.394
95% CI for the RR		(0.547, 3.554)
p-value for RR		0.4861
Day 45		
Number of subjects with a response, n (%) [2]	9 (60.0)	7 (46.7)
Number of subjects with missing evaluation, n (%)	1 (6.7)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.949
95% CI for the RR		(0.378, 2.382)
p-value for RR		0.9112

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-resp50-301-by.sas:t-hamd-resp50-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Baseline Antidepressant Use: 217-PPD-301 - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=86)	Zuranolone (N =84)
Number of evaluable subjects [1]	83	83
Day 3		
Number of subjects with a response, n (%) [2]	10 (12.0)	24 (28.9)
Number of subjects with missing evaluation, n (%)	1 (1.2)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.400
95% CI for the RR		(1.226, 4.699)
p-value for RR		0.0106
Day 8		
Number of subjects with a response, n (%) [2]	21 (25.3)	39 (47.0)
Number of subjects with missing evaluation, n (%)	3 (3.6)	4 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.857
95% CI for the RR		(1.203, 2.868)
p-value for RR		0.0052

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-resp50-301-by.sas:t-hamd-resp50-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Baseline Antidepressant Use: 217-PPD-301 - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=86)	Zuranolone (N =84)
Day 15		
Number of subjects with a response, n (%) [2]	26 (31.3)	46 (55.4)
Number of subjects with missing evaluation, n (%)	8 (9.6)	5 (6.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.769
95% CI for the RR		(1.219, 2.568)
p-value for RR		0.0027
Day 21		
Number of subjects with a response, n (%) [2]	27 (32.5)	45 (54.2)
Number of subjects with missing evaluation, n (%)	14 (16.9)	13 (15.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.667
95% CI for the RR		(1.154, 2.408)
p-value for RR		0.0065

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-resp50-301-by.sas:t-hamd-resp50-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Baseline Antidepressant Use: 217-PPD-301 - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=86)	Zuranolone (N =84)
Day 28		
Number of subjects with a response, n (%) [2]	28 (33.7)	40 (48.2)
Number of subjects with missing evaluation, n (%)	11 (13.3)	20 (24.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.429
95% CI for the RR		(0.982, 2.079)
p-value for RR		0.0624
Day 45		
Number of subjects with a response, n (%) [2]	37 (44.6)	45 (54.2)
Number of subjects with missing evaluation, n (%)	12 (14.5)	14 (16.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.216
95% CI for the RR		(0.891, 1.660)
p-value for RR		0.2168

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-resp50-301-by.sas:t-hamd-resp50-301-by-adt-itta.rtf **Run Date:** 25JUL2025

2.1.2.1 .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-301 - ITT population

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

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =20)
Number of evaluable subjects [1]	22	20
Day 3		
Number of subjects with a response, n (%) [2]	2 (9.1)	4 (20.0)
Number of subjects with missing evaluation, n (%)	1 (4.5)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.277
95% CI for the RR		(0.458, 11.315)
p-value for RR		0.3145
Day 8		
Number of subjects with a response, n (%) [2]	5 (22.7)	7 (35.0)
Number of subjects with missing evaluation, n (%)	0	2 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.594
95% CI for the RR		(0.596, 4.259)
p-value for RR		0.3526

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-resp50-301-by.sas:t-hamd-resp50-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =20)
Day 15		
Number of subjects with a response, n (%) [2]	6 (27.3)	9 (45.0)
Number of subjects with missing evaluation, n (%)	1 (4.5)	2 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.708
95% CI for the RR		(0.730, 3.994)
p-value for RR		0.2170
Day 21		
Number of subjects with a response, n (%) [2]	5 (22.7)	10 (50.0)
Number of subjects with missing evaluation, n (%)	4 (18.2)	4 (20.0)
RR - Relative Risk (Zuranolone vs. Placebo)		2.277
95% CI for the RR		(0.964, 5.378)
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 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-resp50-301-by.sas:t-hamd-resp50-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =20)
Day 28		
Number of subjects with a response, n (%) [2]	7 (31.8)	8 (40.0)
Number of subjects with missing evaluation, n (%)	1 (4.5)	8 (40.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.301
95% CI for the RR		(0.580, 2.918)
p-value for RR		0.5230
Day 45		
Number of subjects with a response, n (%) [2]	12 (54.5)	8 (40.0)
Number of subjects with missing evaluation, n (%)	0	5 (25.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.759
95% CI for the RR		(0.405, 1.422)
p-value for RR		0.3891

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-resp50-301-by.sas:t-hamd-resp50-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =24)
Number of evaluable subjects [1]	34	24
Day 3		
Number of subjects with a response, n (%) [2]	2 (5.9)	7 (29.2)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		4.943
95% CI for the RR		(1.021, 23.921)
p-value for RR		0.0470
Day 8		
Number of subjects with a response, n (%) [2]	7 (20.6)	13 (54.2)
Number of subjects with missing evaluation, n (%)	2 (5.9)	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		2.623
95% CI for the RR		(1.213, 5.673)
p-value for RR		0.0143

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-resp50-301-by.sas:t-hamd-resp50-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =24)
Day 15		
Number of subjects with a response, n (%) [2]	13 (38.2)	12 (50.0)
Number of subjects with missing evaluation, n (%)	4 (11.8)	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.304
95% CI for the RR		(0.726, 2.342)
p-value for RR		0.3750
Day 21		
Number of subjects with a response, n (%) [2]	16 (47.1)	13 (54.2)
Number of subjects with missing evaluation, n (%)	6 (17.6)	3 (12.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.147
95% CI for the RR		(0.690, 1.909)
p-value for RR		0.5965

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-resp50-301-by.sas:t-hamd-resp50-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =24)
Day 28		
Number of subjects with a response, n (%) [2]	15 (44.1)	14 (58.3)
Number of subjects with missing evaluation, n (%)	5 (14.7)	4 (16.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.318
95% CI for the RR		(0.805, 2.158)
p-value for RR		0.2724
Day 45		
Number of subjects with a response, n (%) [2]	17 (50.0)	14 (58.3)
Number of subjects with missing evaluation, n (%)	6 (17.6)	4 (16.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.163
95% CI for the RR		(0.736, 1.838)
p-value for RR		0.5178

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-resp50-301-by.sas:t-hamd-resp50-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

Study Visit Statistics	Placebo (N=42)	Zuranolone (N =53)
Number of evaluable subjects [1]	42	53
Day 3		
Number of subjects with a response, n (%) [2]	8 (19.0)	15 (28.3)
Number of subjects with missing evaluation, n (%)	1 (2.4)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.467
95% CI for the RR		(0.686, 3.136)
p-value for RR		0.3225
Day 8		
Number of subjects with a response, n (%) [2]	12 (28.6)	26 (49.1)
Number of subjects with missing evaluation, n (%)	1 (2.4)	2 (3.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.695
95% CI for the RR		(0.974, 2.950)
p-value for RR		0.0617

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-resp50-301-by.sas:t-hamd-resp50-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

Study Visit Statistics	Placebo (N=42)	Zuranolone (N =53)
Day 15		
Number of subjects with a response, n (%) [2]	16 (38.1)	32 (60.4)
Number of subjects with missing evaluation, n (%)	3 (7.1)	2 (3.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.565
95% CI for the RR		(1.003, 2.441)
p-value for RR		0.0483
Day 21		
Number of subjects with a response, n (%) [2]	14 (33.3)	26 (49.1)
Number of subjects with missing evaluation, n (%)	5 (11.9)	7 (13.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.453
95% CI for the RR		(0.873, 2.420)
p-value for RR		0.1509

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-resp50-301-by.sas:t-hamd-resp50-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

Study Visit Statistics	Placebo (N=42)	Zuranolone (N =53)
Day 28		
Number of subjects with a response, n (%) [2]	13 (31.0)	25 (47.2)
Number of subjects with missing evaluation, n (%)	7 (16.7)	9 (17.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.505
95% CI for the RR		(0.881, 2.572)
p-value for RR		0.1349
Day 45		
Number of subjects with a response, n (%) [2]	17 (40.5)	29 (54.7)
Number of subjects with missing evaluation, n (%)	7 (16.7)	5 (9.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.335
95% CI for the RR		(0.859, 2.075)
p-value for RR		0.1993

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-resp50-301-by.sas:t-hamd-resp50-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

2.1.2.1 .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-301 - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =35)
Number of evaluable subjects [1]	31	34
Day 3		
Number of subjects with a response, n (%) [2]	5 (16.1)	13 (38.2)
Number of subjects with missing evaluation, n (%)	1 (3.2)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.459
95% CI for the RR		(0.993, 6.092)
p-value for RR		0.0518
Day 8		
Number of subjects with a response, n (%) [2]	7 (22.6)	19 (55.9)
Number of subjects with missing evaluation, n (%)	3 (9.7)	2 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		2.577
95% CI for the RR		(1.259, 5.277)
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 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 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-resp50-301-by.sas:t-hamd-resp50-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =35)
Day 15		
Number of subjects with a response, n (%) [2]	14 (45.2)	16 (47.1)
Number of subjects with missing evaluation, n (%)	4 (12.9)	3 (8.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.146
95% CI for the RR		(0.675, 1.945)
p-value for RR		0.6128
Day 21		
Number of subjects with a response, n (%) [2]	12 (38.7)	16 (47.1)
Number of subjects with missing evaluation, n (%)	6 (19.4)	5 (14.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.318
95% CI for the RR		(0.749, 2.321)
p-value for RR		0.3385

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 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-resp50-301-by.sas:t-hamd-resp50-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =35)
Day 28		
Number of subjects with a response, n (%) [2]	11 (35.5)	15 (44.1)
Number of subjects with missing evaluation, n (%)	6 (19.4)	8 (23.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.268
95% CI for the RR		(0.684, 2.352)
p-value for RR		0.4507
Day 45		
Number of subjects with a response, n (%) [2]	14 (45.2)	19 (55.9)
Number of subjects with missing evaluation, n (%)	6 (19.4)	7 (20.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.316
95% CI for the RR		(0.802, 2.160)
p-value for RR		0.2768

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 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-resp50-301-by.sas:t-hamd-resp50-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=69)	Zuranolone (N =64)
Number of evaluable subjects [1]	67	64
Day 3		
Number of subjects with a response, n (%) [2]	7 (10.4)	13 (20.3)
Number of subjects with missing evaluation, n (%)	1 (1.5)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.957
95% CI for the RR		(0.837, 4.574)
p-value for RR		0.1212
Day 8		
Number of subjects with a response, n (%) [2]	17 (25.4)	28 (43.8)
Number of subjects with missing evaluation, n (%)	0	3 (4.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.758
95% CI for the RR		(1.074, 2.877)
p-value for RR		0.0247

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 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-resp50-301-by.sas:t-hamd-resp50-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=69)	Zuranolone (N =64)
Day 15		
Number of subjects with a response, n (%) [2]	21 (31.3)	37 (57.8)
Number of subjects with missing evaluation, n (%)	4 (6.0)	2 (3.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.835
95% CI for the RR		(1.221, 2.758)
p-value for RR		0.0035
Day 21		
Number of subjects with a response, n (%) [2]	23 (34.3)	34 (53.1)
Number of subjects with missing evaluation, n (%)	9 (13.4)	9 (14.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.522
95% CI for the RR		(1.016, 2.280)
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 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 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-resp50-301-by.sas:t-hamd-resp50-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=69)	Zuranolone (N =64)
Day 28		
Number of subjects with a response, n (%) [2]	24 (35.8)	33 (51.6)
Number of subjects with missing evaluation, n (%)	7 (10.4)	13 (20.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.432
95% CI for the RR		(0.960, 2.134)
p-value for RR		0.0781
Day 45		
Number of subjects with a response, n (%) [2]	32 (47.8)	33 (51.6)
Number of subjects with missing evaluation, n (%)	7 (10.4)	7 (10.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.076
95% CI for the RR		(0.764, 1.517)
p-value for RR		0.6735

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 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-resp50-301-by.sas:t-hamd-resp50-301-by-onset-itta.rtf **Run Date:** 25JUL2025

2.1.2.1 .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-301 - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =21)
Number of evaluable subjects [1]	16	21
Day 3		
Number of subjects with a response, n (%) [2]	2 (12.5)	6 (28.6)
Number of subjects with missing evaluation, n (%)	1 (6.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.261
95% CI for the RR		(0.514, 9.939)
p-value for RR		0.2802
Day 8		
Number of subjects with a response, n (%) [2]	6 (37.5)	10 (47.6)
Number of subjects with missing evaluation, n (%)	1 (6.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.256
95% CI for the RR		(0.568, 2.775)
p-value for RR		0.5730

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-resp50-301-by.sas:t-hamd-resp50-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Family History of PPD: 217-PPD-301 - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =21)
Day 15		
Number of subjects with a response, n (%) [2]	9 (56.3)	11 (52.4)
Number of subjects with missing evaluation, n (%)	3 (18.8)	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		0.921
95% CI for the RR		(0.503, 1.685)
p-value for RR		0.7898
Day 21		
Number of subjects with a response, n (%) [2]	10 (62.5)	12 (57.1)
Number of subjects with missing evaluation, n (%)	3 (18.8)	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		0.904
95% CI for the RR		(0.527, 1.552)
p-value for RR		0.7153

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-resp50-301-by.sas:t-hamd-resp50-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Family History of PPD: 217-PPD-301 - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =21)
Day 28		
Number of subjects with a response, n (%) [2]	8 (50.0)	13 (61.9)
Number of subjects with missing evaluation, n (%)	4 (25.0)	3 (14.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.225
95% CI for the RR		(0.669, 2.243)
p-value for RR		0.5117
Day 45		
Number of subjects with a response, n (%) [2]	9 (56.3)	12 (57.1)
Number of subjects with missing evaluation, n (%)	3 (18.8)	2 (9.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.005
95% CI for the RR		(0.567, 1.780)
p-value for RR		0.9867

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-resp50-301-by.sas:t-hamd-resp50-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Family History of PPD: 217-PPD-301 - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=85)	Zuranolone (N =78)
Number of evaluable subjects [1]	82	77
Day 3		
Number of subjects with a response, n (%) [2]	10 (12.2)	20 (26.0)
Number of subjects with missing evaluation, n (%)	1 (1.2)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.130
95% CI for the RR		(1.067, 4.253)
p-value for RR		0.0321
Day 8		
Number of subjects with a response, n (%) [2]	18 (22.0)	37 (48.1)
Number of subjects with missing evaluation, n (%)	2 (2.4)	5 (6.5)
RR - Relative Risk (Zuranolone vs. Placebo)		2.189
95% CI for the RR		(1.369, 3.500)
p-value for RR		0.0011

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-resp50-301-by.sas:t-hamd-resp50-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Family History of PPD: 217-PPD-301 - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=85)	Zuranolone (N =78)
Day 15		
Number of subjects with a response, n (%) [2]	26 (31.7)	42 (54.5)
Number of subjects with missing evaluation, n (%)	5 (6.1)	4 (5.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.720
95% CI for the RR		(1.180, 2.508)
p-value for RR		0.0048
Day 21		
Number of subjects with a response, n (%) [2]	25 (30.5)	38 (49.4)
Number of subjects with missing evaluation, n (%)	12 (14.6)	13 (16.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.619
95% CI for the RR		(1.087, 2.410)
p-value for RR		0.0176

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-resp50-301-by.sas:t-hamd-resp50-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Family History of PPD: 217-PPD-301 - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=85)	Zuranolone (N =78)
Day 28		
Number of subjects with a response, n (%) [2]	27 (32.9)	35 (45.5)
Number of subjects with missing evaluation, n (%)	9 (11.0)	18 (23.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.381
95% CI for the RR		(0.932, 2.046)
p-value for RR		0.1081
Day 45		
Number of subjects with a response, n (%) [2]	37 (45.1)	40 (51.9)
Number of subjects with missing evaluation, n (%)	10 (12.2)	12 (15.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.151
95% CI for the RR		(0.836, 1.587)
p-value for RR		0.3889

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-resp50-301-by.sas:t-hamd-resp50-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

2.1.2.1 .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-301 - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=90)	Zuranolone (N =82)
Number of evaluable subjects [1]	87	81
Day 3		
Number of subjects with a response, n (%) [2]	9 (10.3)	21 (25.9)
Number of subjects with missing evaluation, n (%)	2 (2.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.526
95% CI for the RR		(1.228, 5.197)
p-value for RR		0.0118
Day 8		
Number of subjects with a response, n (%) [2]	20 (23.0)	36 (44.4)
Number of subjects with missing evaluation, n (%)	3 (3.4)	5 (6.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.949
95% CI for the RR		(1.232, 3.082)
p-value for RR		0.0043

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-resp50-301-by.sas:t-hamd-resp50-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by History of PPD: 217-PPD-301 - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=90)	Zuranolone (N =82)
Day 15		
Number of subjects with a response, n (%) [2]	30 (34.5)	42 (51.9)
Number of subjects with missing evaluation, n (%)	8 (9.2)	5 (6.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.516
95% CI for the RR		(1.059, 2.170)
p-value for RR		0.0231
Day 21		
Number of subjects with a response, n (%) [2]	30 (34.5)	41 (50.6)
Number of subjects with missing evaluation, n (%)	14 (16.1)	13 (16.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.479
95% CI for the RR		(1.031, 2.123)
p-value for RR		0.0335

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-resp50-301-by.sas:t-hamd-resp50-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by History of PPD: 217-PPD-301 - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=90)	Zuranolone (N =82)
Day 28		
Number of subjects with a response, n (%) [2]	31 (35.6)	36 (44.4)
Number of subjects with missing evaluation, n (%)	13 (14.9)	21 (25.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.257
95% CI for the RR		(0.866, 1.825)
p-value for RR		0.2286
Day 45		
Number of subjects with a response, n (%) [2]	41 (47.1)	42 (51.9)
Number of subjects with missing evaluation, n (%)	12 (13.8)	13 (16.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.109
95% CI for the RR		(0.815, 1.509)
p-value for RR		0.5102

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-resp50-301-by.sas:t-hamd-resp50-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by History of PPD: 217-PPD-301 - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=11)	Zuranolone (N =17)
Number of evaluable subjects [1]	11	17
Day 3		
Number of subjects with a response, n (%) [2]	3 (27.3)	5 (29.4)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.113
95% CI for the RR		(0.325, 3.807)
p-value for RR		0.8645
Day 8		
Number of subjects with a response, n (%) [2]	4 (36.4)	11 (64.7)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.836
95% CI for the RR		(0.781, 4.321)
p-value for RR		0.1638

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-resp50-301-by.sas:t-hamd-resp50-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by History of PPD: 217-PPD-301 - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=11)	Zuranolone (N =17)
Day 15		
Number of subjects with a response, n (%) [2]	5 (45.5)	11 (64.7)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.469
95% CI for the RR		(0.708, 3.048)
p-value for RR		0.3016
Day 21		
Number of subjects with a response, n (%) [2]	5 (45.5)	9 (52.9)
Number of subjects with missing evaluation, n (%)	1 (9.1)	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.202
95% CI for the RR		(0.548, 2.636)
p-value for RR		0.6460

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-resp50-301-by.sas:t-hamd-resp50-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by History of PPD: 217-PPD-301 - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=11)	Zuranolone (N =17)
Day 28		
Number of subjects with a response, n (%) [2]	4 (36.4)	12 (70.6)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.003
95% CI for the RR		(0.867, 4.628)
p-value for RR		0.1039
Day 45		
Number of subjects with a response, n (%) [2]	5 (45.5)	10 (58.8)
Number of subjects with missing evaluation, n (%)	1 (9.1)	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.336
95% CI for the RR		(0.625, 2.856)
p-value for RR		0.4555

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-resp50-301-by.sas:t-hamd-resp50-301-by-hist-itta.rtf **Run Date:** 25JUL2025

2.1.2.1 .2 .2 .9 Depression mit Angst

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =24)
Number of evaluable subjects [1]	21	24
Day 3		
Number of subjects with a response, n (%) [2]	1 (4.8)	3 (12.5)
Number of subjects with missing evaluation, n (%)	1 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.075
95% CI for the RR		(0.265, 16.230)
p-value for RR		0.4867
Day 8		
Number of subjects with a response, n (%) [2]	1 (4.8)	11 (45.8)
Number of subjects with missing evaluation, n (%)	1 (4.8)	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		8.122
95% CI for the RR		(1.439, 45.850)
p-value for RR		0.0177

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 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-resp50-301-by.sas:t-hamd-resp50-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =24)
Day 15		
Number of subjects with a response, n (%) [2]	8 (38.1)	14 (58.3)
Number of subjects with missing evaluation, n (%)	1 (4.8)	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.361
95% CI for the RR		(0.743, 2.494)
p-value for RR		0.3189
Day 21		
Number of subjects with a response, n (%) [2]	7 (33.3)	17 (70.8)
Number of subjects with missing evaluation, n (%)	3 (14.3)	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.769
95% CI for the RR		(0.941, 3.327)
p-value for RR		0.0764

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 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-resp50-301-by.sas:t-hamd-resp50-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =24)
Day 28		
Number of subjects with a response, n (%) [2]	7 (33.3)	12 (50.0)
Number of subjects with missing evaluation, n (%)	2 (9.5)	5 (20.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.386
95% CI for the RR		(0.689, 2.785)
p-value for RR		0.3598
Day 45		
Number of subjects with a response, n (%) [2]	13 (61.9)	15 (62.5)
Number of subjects with missing evaluation, n (%)	1 (4.8)	3 (12.5)
RR - Relative Risk (Zuranolone vs. Placebo)		0.857
95% CI for the RR		(0.548, 1.340)
p-value for RR		0.4978

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 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-resp50-301-by.sas:t-hamd-resp50-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

Study Visit Statistics	Placebo (N=77)	Zuranolone (N =74)
Number of evaluable subjects [1]	77	74
Day 3		
Number of subjects with a response, n (%) [2]	11 (14.3)	23 (31.1)
Number of subjects with missing evaluation, n (%)	1 (1.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.170
95% CI for the RR		(1.140, 4.131)
p-value for RR		0.0183
Day 8		
Number of subjects with a response, n (%) [2]	23 (29.9)	36 (48.6)
Number of subjects with missing evaluation, n (%)	2 (2.6)	4 (5.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.630
95% CI for the RR		(1.075, 2.471)
p-value for RR		0.0213

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 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-resp50-301-by.sas:t-hamd-resp50-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

Study Visit Statistics	Placebo (N=77)	Zuranolone (N =74)
Day 15		
Number of subjects with a response, n (%) [2]	27 (35.1)	39 (52.7)
Number of subjects with missing evaluation, n (%)	7 (9.1)	4 (5.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.497
95% CI for the RR		(1.031, 2.172)
p-value for RR		0.0338
Day 21		
Number of subjects with a response, n (%) [2]	28 (36.4)	33 (44.6)
Number of subjects with missing evaluation, n (%)	12 (15.6)	13 (17.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.220
95% CI for the RR		(0.826, 1.802)
p-value for RR		0.3184

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 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-resp50-301-by.sas:t-hamd-resp50-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

Study Visit Statistics	Placebo (N=77)	Zuranolone (N =74)
Day 28		
Number of subjects with a response, n (%) [2]	28 (36.4)	36 (48.6)
Number of subjects with missing evaluation, n (%)	11 (14.3)	16 (21.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.333
95% CI for the RR		(0.915, 1.942)
p-value for RR		0.1348
Day 45		
Number of subjects with a response, n (%) [2]	33 (42.9)	37 (50.0)
Number of subjects with missing evaluation, n (%)	12 (15.6)	11 (14.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.161
95% CI for the RR		(0.824, 1.637)
p-value for RR		0.3938

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 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.

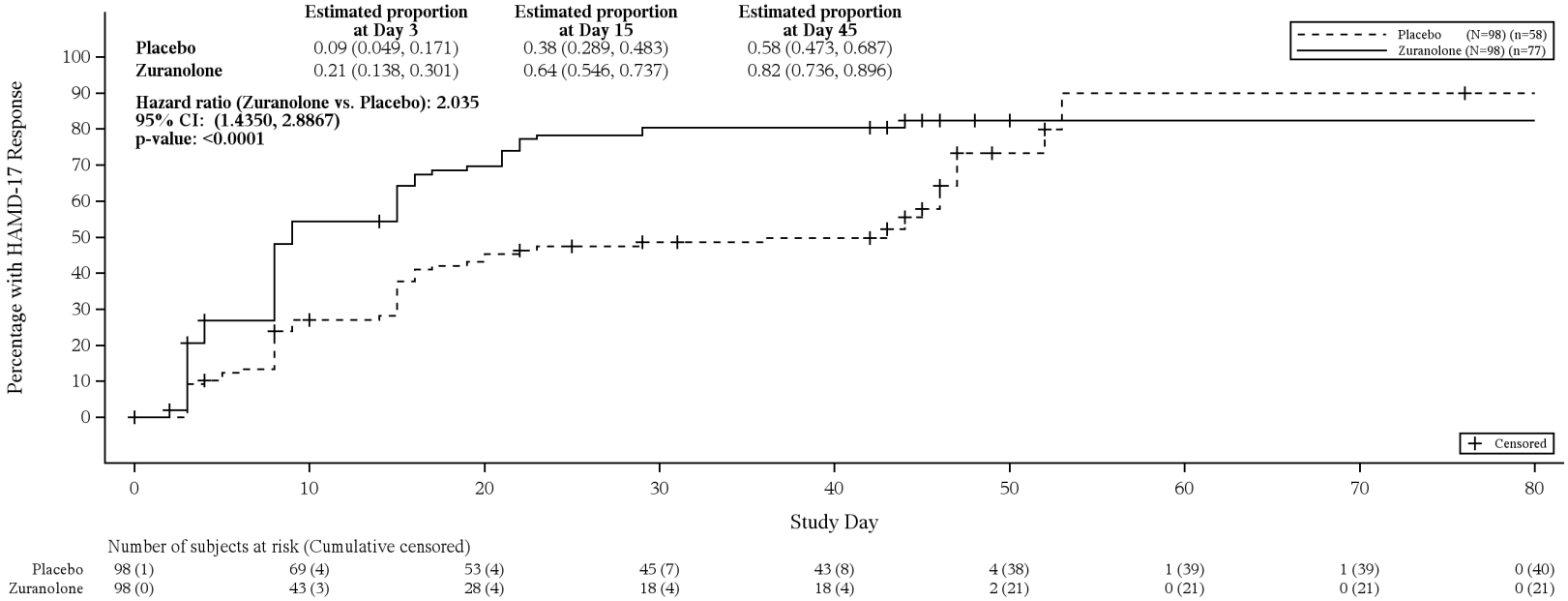
Source: biib125/v_a/germany_amnog/t-hamd-resp50-301-by.sas:t-hamd-resp50-301-by-hama-itta.rtf **Run Date:** 25JUL2025

2.1.2.2 TTE-Analysen

2.1.2.2 .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-301 - 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-301-ovr.sas:f-hamd-resp50-tte-301-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-301 - ITT population

Page: 1 of 1

	Placebo (N=101)	Zuranolone (N=99)
Number of evaluable subjects [1]	98	98
Number of subjects with response, n (%) [2]	58 (59.2)	77 (78.6)
Time to first HAMD-17 response (days) [3]		
25th percentile - Q1 (95% CI)	9.0 (8.0 , 15.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	43.0 (16.0 , 46.0)	9.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	52.0 (46.0, NE)	22.0 (16.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.035
95% CI for the HR		(1.4350 , 2.8867)
p-value for the HR		<0.0001

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-301-ovr.sas:t-hamd-resp50-tte-301-ovr-itta.rtf **Run Date:** 18JUL2025

2.1.2.2 .2 Subgruppen

2.1.2.2 .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-301 - ITT population

Page: 1 of 2

Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	98	98	
Number of subjects with response, n (%)	58 (59.2)	77 (78.6)	
Age Group (years)			
18 - 24, n / N (%)	10/12 (83.3)	18/19 (94.7)	0.9555
25 - 45, n / N (%)	48/86 (55.8)	59/79 (74.7)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	16/32 (50.0)	26/33 (78.8)	0.6294
>=28, n / N (%)	42/66 (63.6)	51/65 (78.5)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	8/18 (44.4)	18/25 (72.0)	0.9920
White, n / N (%)	44/69 (63.8)	57/68 (83.8)	
Antidepressant Use at Baseline			
Yes, n / N (%)	11/15 (73.3)	10/15 (66.7)	0.1041
No, n / N (%)	47/83 (56.6)	67/83 (80.7)	

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 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-301-int.sas:t-hamd-resp50-tte-301-int-itta.rtf **Run Date:** 18JUL2025

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-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9, n / N (%)	13/22 (59.1)	16/20 (80.0)	0.3835(a)
25-29.9, n / N (%)	23/34 (67.6)	17/24 (70.8)	0.9046(b)
>=30, n / N (%)	22/42 (52.4)	43/53 (81.1)	0.3763(c)
Onset of PPD			
3rd Trimester, n / N (%)	20/31 (64.5)	30/34 (88.2)	0.7732
Postpartum, n / N (%)	38/67 (56.7)	47/64 (73.4)	
Family History of PPD			
Yes, n / N (%)	12/16 (75.0)	17/21 (81.0)	0.0701
No/Unknown, n / N (%)	46/82 (56.1)	60/77 (77.9)	
History of PPD			
1st Episode, n / N (%)	52/87 (59.8)	63/81 (77.8)	0.9577
Recurrent Episode, n / N (%)	6/11 (54.5)	14/17 (82.4)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	13/21 (61.9)	20/24 (83.3)	0.6536
>=20, n / N (%)	45/77 (58.4)	57/74 (77.0)	

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-301-int.sas:t-hamd-resp50-tte-301-int-itta.rtf **Run Date:** 18JUL2025

2.1.2.2 .2 .2 Subgruppenanalysen

2.1.2.2 .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-301 - ITT population

Page: 1 of 2

Age Group (years) = 18-24

	Placebo (N=13)	**Zuranolone (N=19)**
Number of evaluable subjects [1]	12	19
Number of subjects with response, n (%) [2]	10 (83.3)	18 (94.7)
Time to first HAMD-17 response (days) [3]		
25th percentile - Q1 (95% CI)	5.5 (3.0 , 9.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	12.5 (3.0 , 44.0)	8.0 (4.0 , 9.0)
75th percentile - Q3 (95% CI)	36.5 (9.0, NE)	9.0 (8.0 , 23.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.560
95% CI for the HR		(0.9189 , 7.1341)
p-value for the HR		0.0721

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-301-by.sas:t-hamd-resp50-tte-301-by-age-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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Age Group (years) = 25-45

	Placebo (N=88)	Zuranolone (N=80)
Number of evaluable subjects [1]	86	79
Number of subjects with response, n (%) [2]	48 (55.8)	59 (74.7)
Time to first HAMD-17 response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (8.0 , 15.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	44.0 (17.0 , 47.0)	15.0 (8.0 , 16.0)
75th percentile - Q3 (95% CI)	52.0 (47.0, NE)	29.0 (17.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.995
95% CI for the HR		(1.3494 , 2.9491)
p-value for the HR		0.0005

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-301-by.sas:t-hamd-resp50-tte-301-by-age-itta.rtf **Run Date:** 25JUL2025

2.1.2.2 .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-301 - ITT population

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

	Placebo (N=32)	Zuranolone (N=33)
Number of evaluable subjects [1]	32	33
Number of subjects with response, n (%) [2]	16 (50.0)	26 (78.8)
Time to first HAMD-17 response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (4.0 , 16.0)	8.0 (3.0 , 8.0)
50th percentile - median (95% CI)	53.0 (8.0, NE)	9.0 (8.0 , 22.0)
75th percentile - Q3 (95% CI)	NE (53.0, NE)	23.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.036
95% CI for the HR		(1.0746 , 3.8591)
p-value for the HR		0.0292

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-301-by.sas:t-hamd-resp50-tte-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

	Placebo (N=66)	Zuranolone (N=65)
Number of evaluable subjects [1]	66	65
Number of subjects with response, n (%) [2]	42 (63.6)	51 (78.5)
Time to first HAMD-17 response (days) [3]		
25th percentile - Q1 (95% CI)	14.0 (6.0 , 15.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	29.0 (15.0 , 46.0)	8.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	47.0 (46.0, NE)	21.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.969
95% CI for the HR		(1.2928 , 2.9977)
p-value for the HR		0.0016

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-301-by.sas:t-hamd-resp50-tte-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

2.1.2.2 .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-301 - ITT population

Page: 1 of 2

Race Group = Black or African American

	Placebo (N=20)	Zuranolone (N=26)
Number of evaluable subjects [1]	18	25
Number of subjects with response, n (%) [2]	8 (44.4)	18 (72.0)
Time to first HAMD-17 response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (3.0 , 16.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	43.0 (15.0, NE)	15.0 (4.0 , 21.0)
75th percentile - Q3 (95% CI)	NE (43.0, NE)	21.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.585
95% CI for the HR		(1.0021 , 6.6655)
p-value for the HR		0.0495

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-301-by.sas:t-hamd-resp50-tte-301-by-race-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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Race Group = White

	Placebo (N=70)	Zuranolone (N=68)
Number of evaluable subjects [1]	69	68
Number of subjects with response, n (%) [2]	44 (63.8)	57 (83.8)
Time to first HAMD-17 response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (8.0 , 15.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	43.0 (16.0 , 46.0)	8.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	47.0 (46.0, NE)	21.0 (15.0 , 44.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.340
95% CI for the HR		(1.5495 , 3.5339)
p-value for the HR		<0.0001

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-301-by.sas:t-hamd-resp50-tte-301-by-race-itta.rtf **Run Date:** 25JUL2025

2.1.2.2 .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-301 - ITT population

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Antidepressant Use at Baseline = Yes

	Placebo (N=15)	Zuranolone (N=15)
Number of evaluable subjects [1]	15	15
Number of subjects with response, n (%) [2]	11 (73.3)	10 (66.7)
Time to first HAMD-17 response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (3.0 , 15.0)	8.0 (3.0 , 8.0)
50th percentile - median (95% CI)	16.0 (8.0, NE)	9.0 (8.0, NE)
75th percentile - Q3 (95% CI)	53.0 (16.0, NE)	NE (9.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.346
95% CI for the HR		(0.5325 , 3.4040)
p-value for the HR		0.5297

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-301-by.sas:t-hamd-resp50-tte-301-by-adt-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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Antidepressant Use at Baseline = No

	Placebo (N=86)	Zuranolone (N=84)
Number of evaluable subjects [1]	83	83
Number of subjects with response, n (%) [2]	47 (56.6)	67 (80.7)
Time to first HAMD-17 response (days) [3]		
25th percentile - Q1 (95% CI)	9.0 (8.0 , 15.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	44.0 (16.0 , 47.0)	9.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	52.0 (46.0, NE)	21.0 (15.0 , 44.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.316
95% CI for the HR		(1.5772 , 3.4010)
p-value for the HR		<0.0001

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-301-by.sas:t-hamd-resp50-tte-301-by-adt-itta.rtf **Run Date:** 25JUL2025

2.1.2.2 .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-301 - ITT population

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

	Placebo (N=22)	Zuranolone (N=20)
Number of evaluable subjects [1]	22	20
Number of subjects with response, n (%) [2]	13 (59.1)	16 (80.0)
Time to first HAMD-17 response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (3.0 , 43.0)	8.0 (3.0 , 15.0)
50th percentile - median (95% CI)	43.0 (15.0, NE)	15.0 (8.0 , 21.0)
75th percentile - Q3 (95% CI)	47.0 (44.0, NE)	22.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		3.809
95% CI for the HR		(1.6252 , 8.9288)
p-value for the HR		0.0021

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-301-by.sas:t-hamd-resp50-tte-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

	Placebo (N=34)	Zuranolone (N=24)
Number of evaluable subjects [1]	34	24
Number of subjects with response, n (%) [2]	23 (67.6)	17 (70.8)
Time to first HAMD-17 response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (8.0 , 15.0)	3.0 (3.0 , 8.0)
50th percentile - median (95% CI)	20.0 (15.0 , 46.0)	8.0 (3.0 , 29.0)
75th percentile - Q3 (95% CI)	46.0 (29.0, NE)	44.0 (9.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.866
95% CI for the HR		(0.9453 , 3.6840)
p-value for the HR		0.0722

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-301-by.sas:t-hamd-resp50-tte-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

	Placebo (N=42)	Zuranolone (N=53)
Number of evaluable subjects [1]	42	53
Number of subjects with response, n (%) [2]	22 (52.4)	43 (81.1)
Time to first HAMD-17 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)	45.0 (14.0, NE)	9.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	53.0 (52.0, NE)	21.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.132
95% CI for the HR		(1.2453 , 3.6491)
p-value for the HR		0.0058

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-301-by.sas:t-hamd-resp50-tte-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

2.1.2.2 .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-301 - ITT population

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Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=35)
Number of evaluable subjects [1]	31	34
Number of subjects with response, n (%) [2]	20 (64.5)	30 (88.2)
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)	16.0 (9.0 , 44.0)	8.0 (3.0 , 9.0)
75th percentile - Q3 (95% CI)	47.0 (29.0, NE)	15.0 (8.0 , 29.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.395
95% CI for the HR		(1.3094 , 4.3801)
p-value for the HR		0.0046

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-301-by.sas:t-hamd-resp50-tte-301-by-onset-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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Onset of PPD = Postpartum

	Placebo (N=69)	Zuranolone (N=64)
Number of evaluable subjects [1]	67	64
Number of subjects with response, n (%) [2]	38 (56.7)	47 (73.4)
Time to first HAMD-17 response (days) [3]		
25th percentile - Q1 (95% CI)	9.0 (8.0 , 16.0)	8.0 (4.0 , 8.0)
50th percentile - median (95% CI)	45.0 (17.0 , 47.0)	15.0 (8.0 , 16.0)
75th percentile - Q3 (95% CI)	52.0 (46.0, NE)	44.0 (16.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.937
95% CI for the HR		(1.2491 , 3.0032)
p-value for the HR		0.0031

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-301-by.sas:t-hamd-resp50-tte-301-by-onset-itta.rtf **Run Date:** 25JUL2025

2.1.2.2 .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-301 - ITT population

Page: 1 of 2

Family History of PPD = Yes

	Placebo (N=16)	Zuranolone (N=21)
Number of evaluable subjects [1]	16	21
Number of subjects with response, n (%) [2]	12 (75.0)	17 (81.0)
Time to first HAMD-17 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 (6.0 , 16.0)	8.0 (4.0 , 21.0)
75th percentile - Q3 (95% CI)	16.0 (15.0, NE)	22.0 (9.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.020
95% CI for the HR		(0.4808 , 2.1661)
p-value for the HR		0.9579

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-301-by.sas:t-hamd-resp50-tte-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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Family History of PPD = No/Unknown

	Placebo (N=85)	Zuranolone (N=78)
Number of evaluable subjects [1]	82	77
Number of subjects with response, n (%) [2]	46 (56.1)	60 (77.9)
Time to first HAMD-17 response (days) [3]		
25th percentile - Q1 (95% CI)	14.0 (8.0 , 16.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	44.0 (20.0 , 47.0)	9.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	52.0 (47.0, NE)	22.0 (16.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.305
95% CI for the HR		(1.5490 , 3.4290)
p-value for the HR		<0.0001

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-301-by.sas:t-hamd-resp50-tte-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

2.1.2.2 .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-301 - ITT population

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History of PPD = 1st Episode

	Placebo (N=90)	Zuranolone (N=82)
Number of evaluable subjects [1]	87	81
Number of subjects with response, n (%) [2]	52 (59.8)	63 (77.8)
Time to first HAMD-17 response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (8.0 , 15.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	43.0 (16.0 , 46.0)	9.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	52.0 (46.0, NE)	22.0 (17.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.076
95% CI for the HR		(1.4248 , 3.0250)
p-value for the HR		0.0001

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-301-by.sas:t-hamd-resp50-tte-301-by-hist-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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History of PPD = Recurrent Episode

	Placebo (N=11)	Zuranolone (N=17)
Number of evaluable subjects [1]	11	17
Number of subjects with response, n (%) [2]	6 (54.5)	14 (82.4)
Time to first HAMD-17 response (days) [3]		
25th percentile - Q1 (95% CI)	5.0 (3.0 , 14.0)	3.0 (2.0 , 8.0)
50th percentile - median (95% CI)	14.0 (4.0, NE)	8.0 (3.0 , 15.0)
75th percentile - Q3 (95% CI)	NE (8.0, NE)	15.0 (8.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.091
95% CI for the HR		(0.7667 , 5.7051)
p-value for the HR		0.1496

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-301-by.sas:t-hamd-resp50-tte-301-by-hist-itta.rtf **Run Date:** 25JUL2025

2.1.2.2 .2 .2 .9 Depression mit Angst

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

	Placebo (N=21)	Zuranolone (N=24)
Number of evaluable subjects [1]	21	24
Number of subjects with response, n (%) [2]	13 (61.9)	20 (83.3)
Time to first HAMD-17 response (days) [3]		
25th percentile - Q1 (95% CI)	16.0 (5.0 , 36.0)	8.0 (3.0 , 9.0)
50th percentile - median (95% CI)	46.0 (16.0 , 47.0)	9.0 (8.0 , 21.0)
75th percentile - Q3 (95% CI)	47.0 (46.0, NE)	22.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		3.011
95% CI for the HR		(1.3394 , 6.7668)
p-value for the HR		0.0077

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-301-by.sas:t-hamd-resp50-tte-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Response (>=50% reduction from baseline in total score) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

	Placebo (N=77)	Zuranolone (N=74)
Number of evaluable subjects [1]	77	74
Number of subjects with response, n (%) [2]	45 (58.4)	57 (77.0)
Time to first HAMD-17 response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (6.0 , 15.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	29.0 (15.0 , 47.0)	8.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	53.0 (47.0, NE)	22.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.853
95% CI for the HR		(1.2461 , 2.7548)
p-value for the HR		0.0023

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.

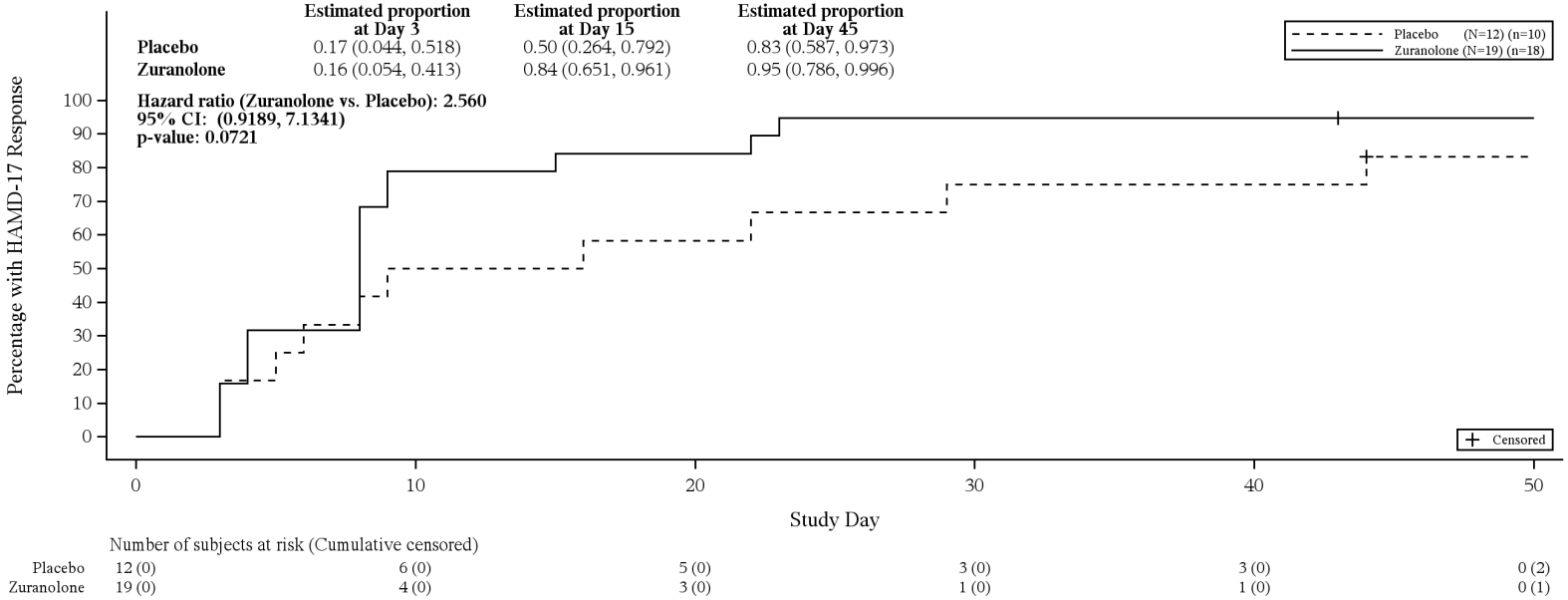
Source: biib125/v_a/germany_amnog/t-hamd-resp50-tte-301-by.sas:t-hamd-resp50-tte-301-by-hama-itta.rtf **Run Date:** 25JUL2025

2.1.2.2 .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-301 - 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 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.

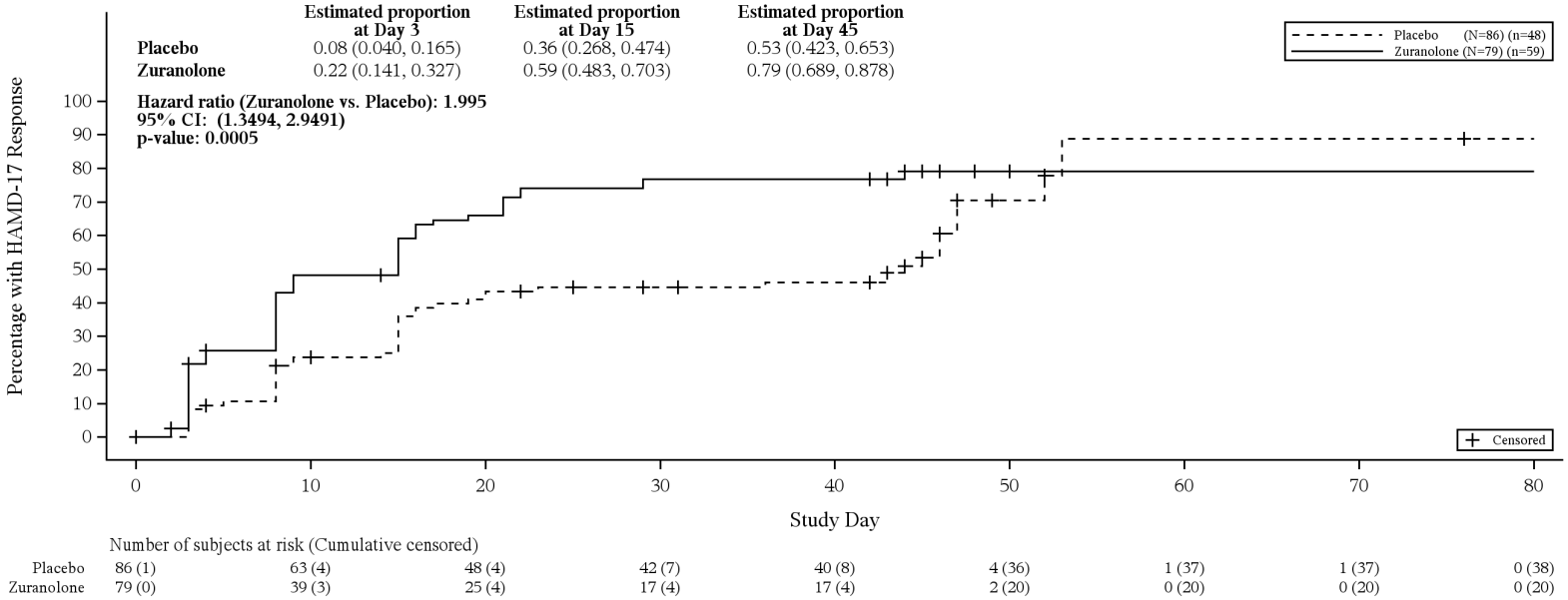
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-resp50-tte-301-by.sas:f-hamd-resp50-tte-301-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-301 - ITT population

Page: 2 of 19

Age Group (years) = 25-45



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.

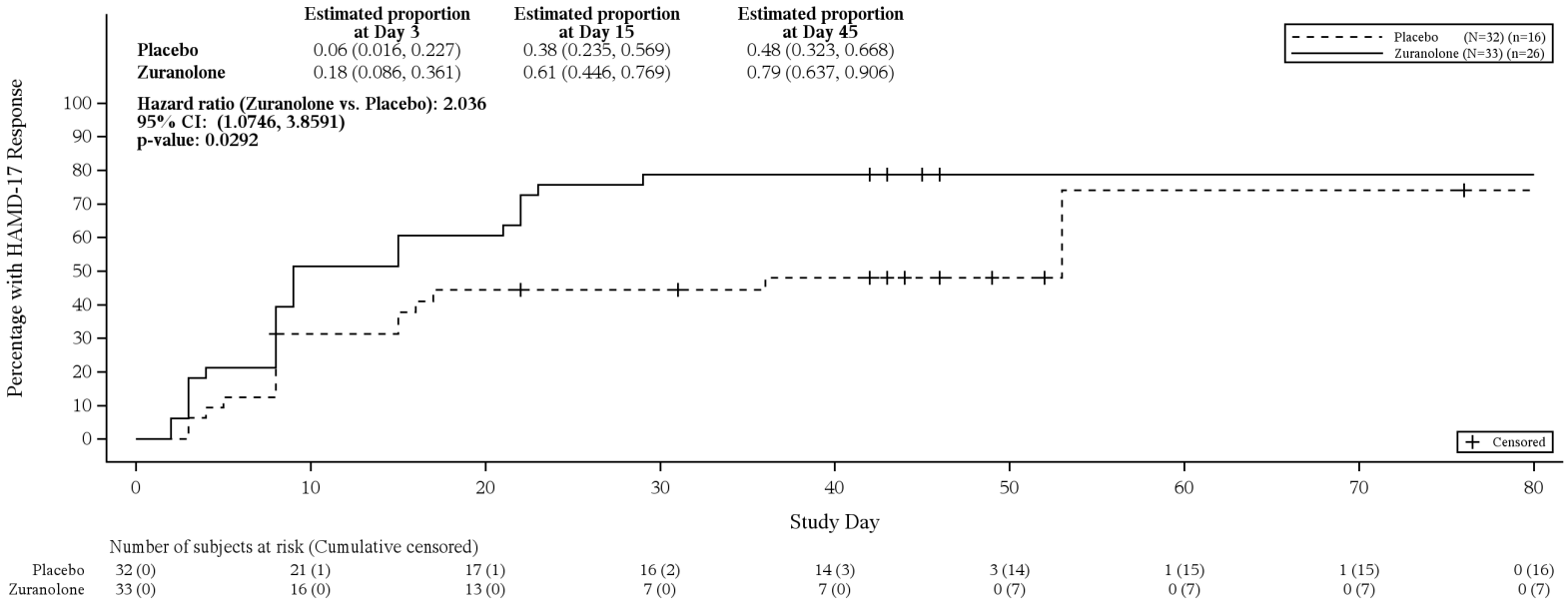
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-resp50-tte-301-by.sas:f-hamd-resp50-tte-301-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-301 - 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.

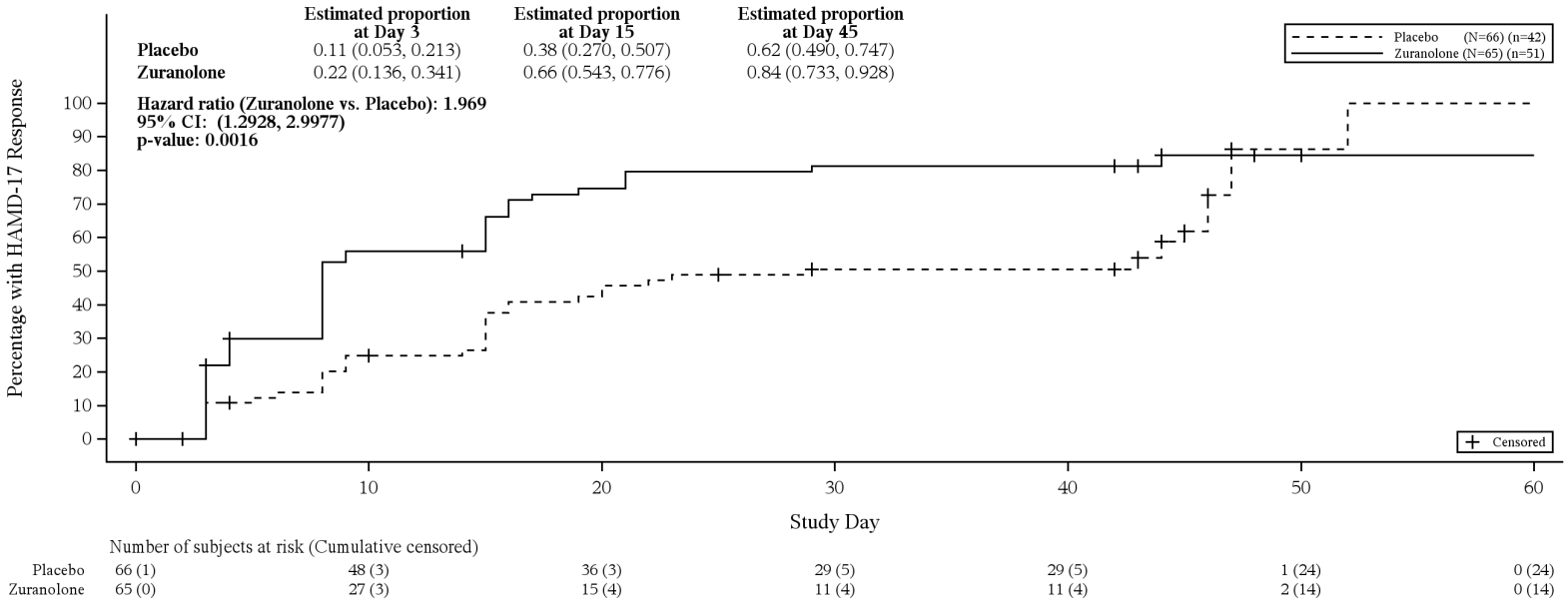
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-resp50-tte-301-by.sas:f-hamd-resp50-tte-301-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-301 - 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.

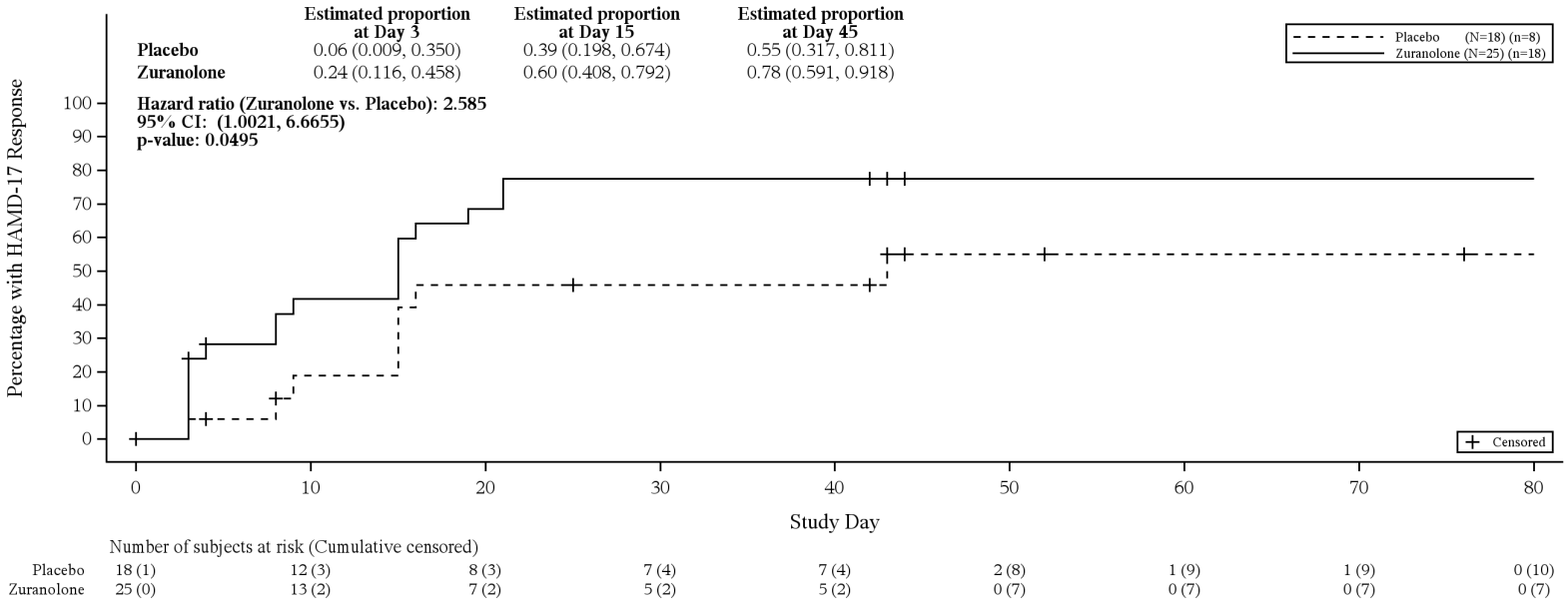
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-resp50-tte-301-by.sas:f-hamd-resp50-tte-301-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-301 - ITT population

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Race Group = Black or African American



Number of subjects at risk (Cumulative censored)

Placebo	18 (1)	12 (3)	8 (3)	7 (4)	7 (4)	2 (8)	1 (9)	1 (9)	0 (10)
Zuranolone	25 (0)	13 (2)	7 (2)	5 (2)	5 (2)	0 (7)	0 (7)	0 (7)	0 (7)

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.

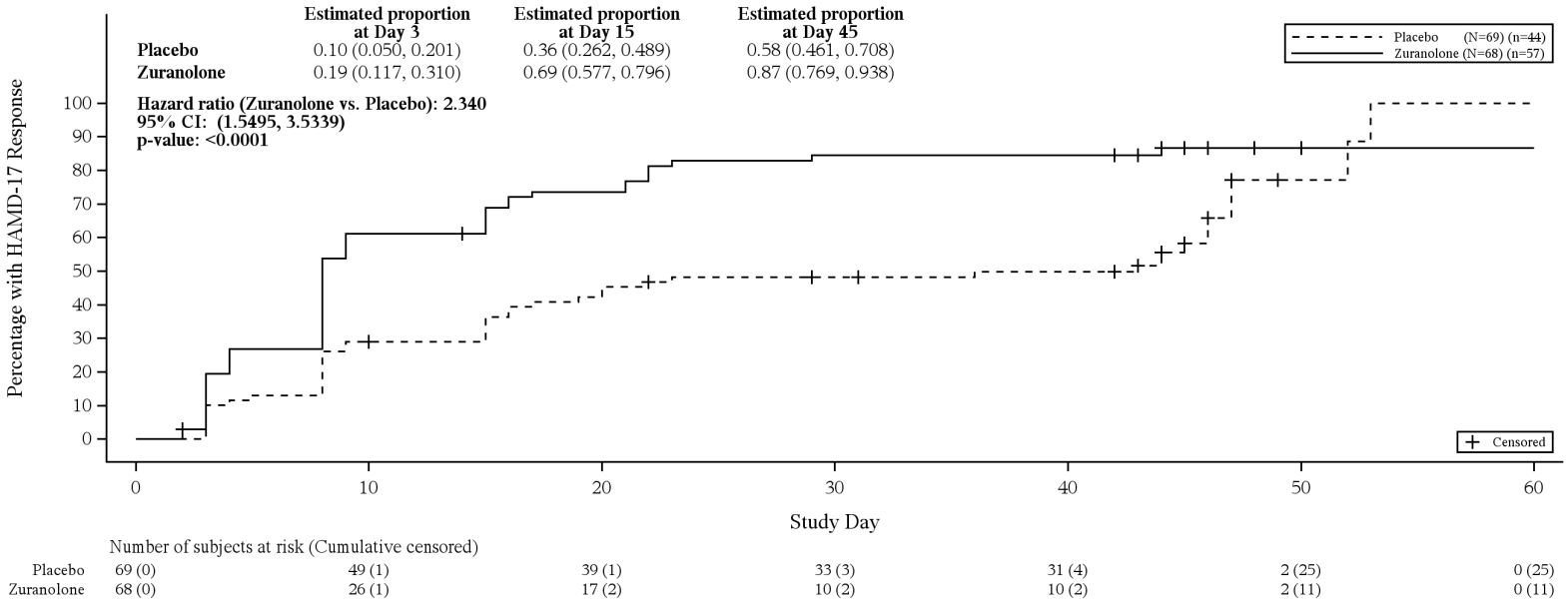
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-resp50-tte-301-by.sas:f-hamd-resp50-tte-301-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-301 - 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.

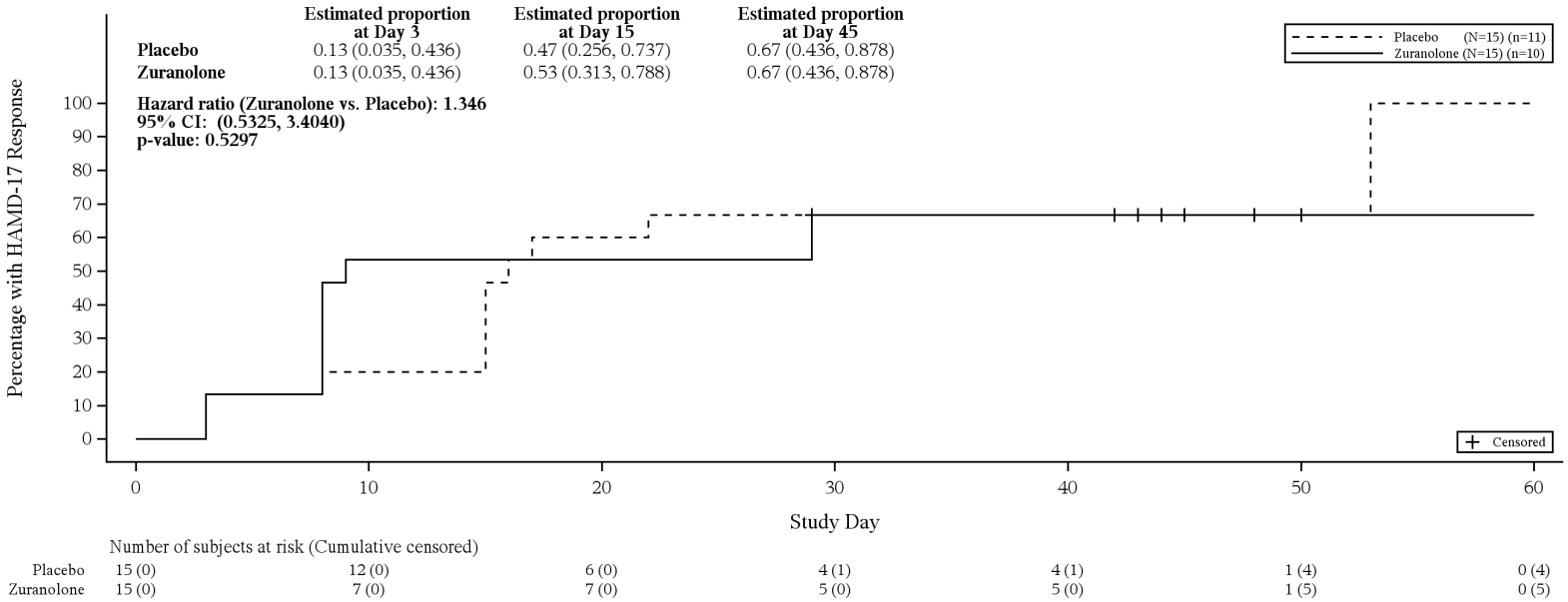
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-resp50-tte-301-by.sas:f-hamd-resp50-tte-301-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-301 - ITT population

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Antidepressant Use at Baseline = Yes



Number of subjects at risk (Cumulative censored)

Placebo	15 (0)	12 (0)	6 (0)	4 (1)	4 (1)	1 (4)	0 (4)
Zuranolone	15 (0)	7 (0)	7 (0)	5 (0)	5 (0)	1 (5)	0 (5)

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.

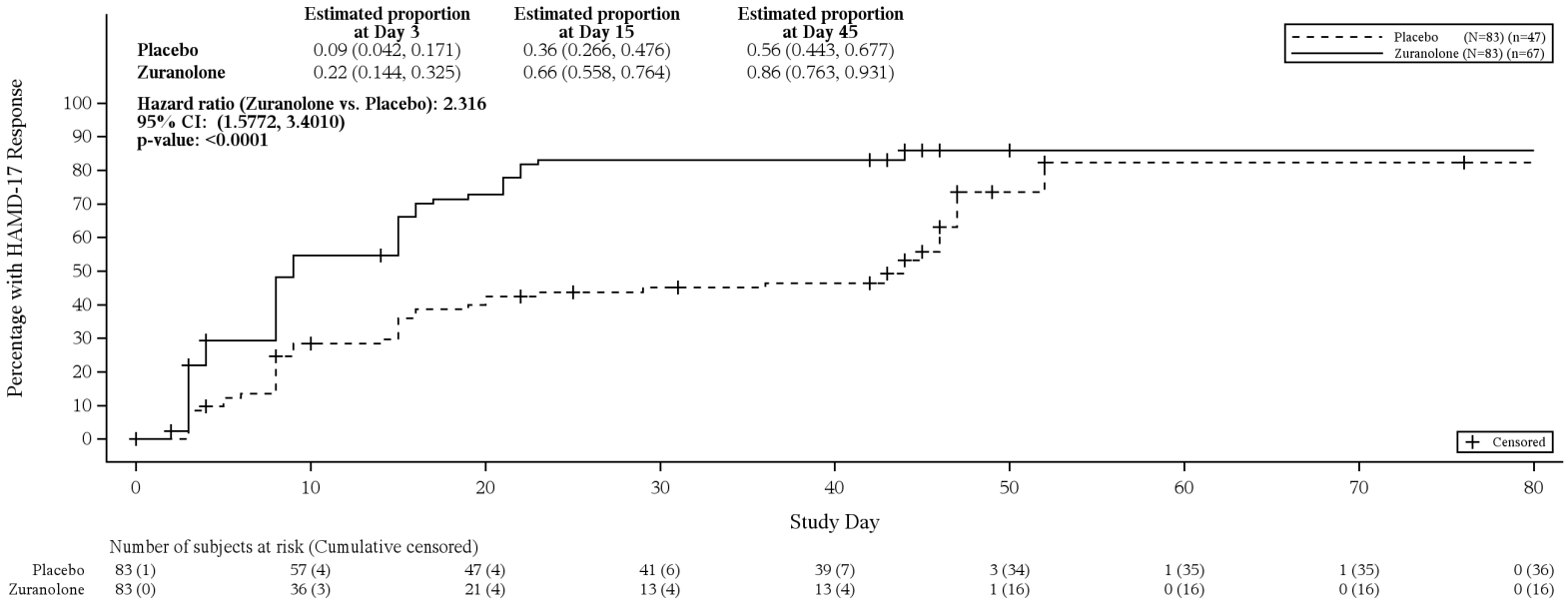
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-resp50-tte-301-by.sas:f-hamd-resp50-tte-301-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-301 - ITT population

Page: 8 of 19

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.

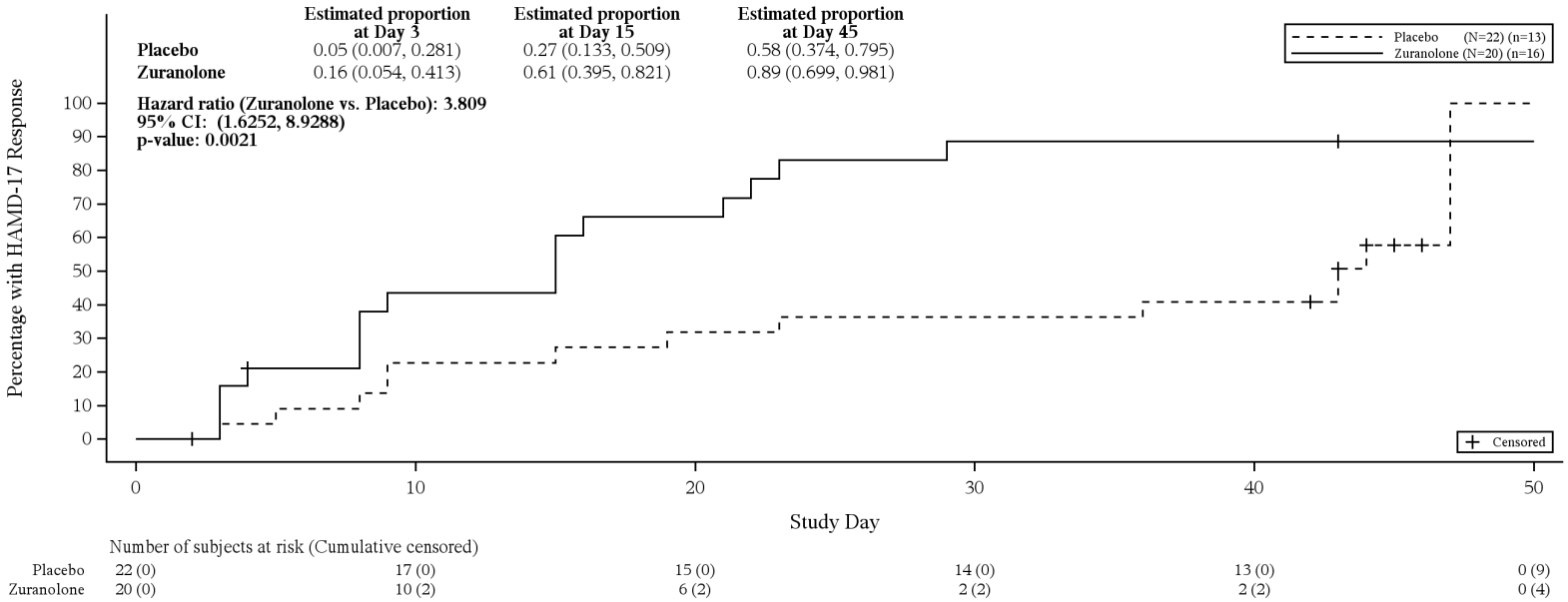
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-resp50-tte-301-by.sas:f-hamd-resp50-tte-301-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-301 - 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.

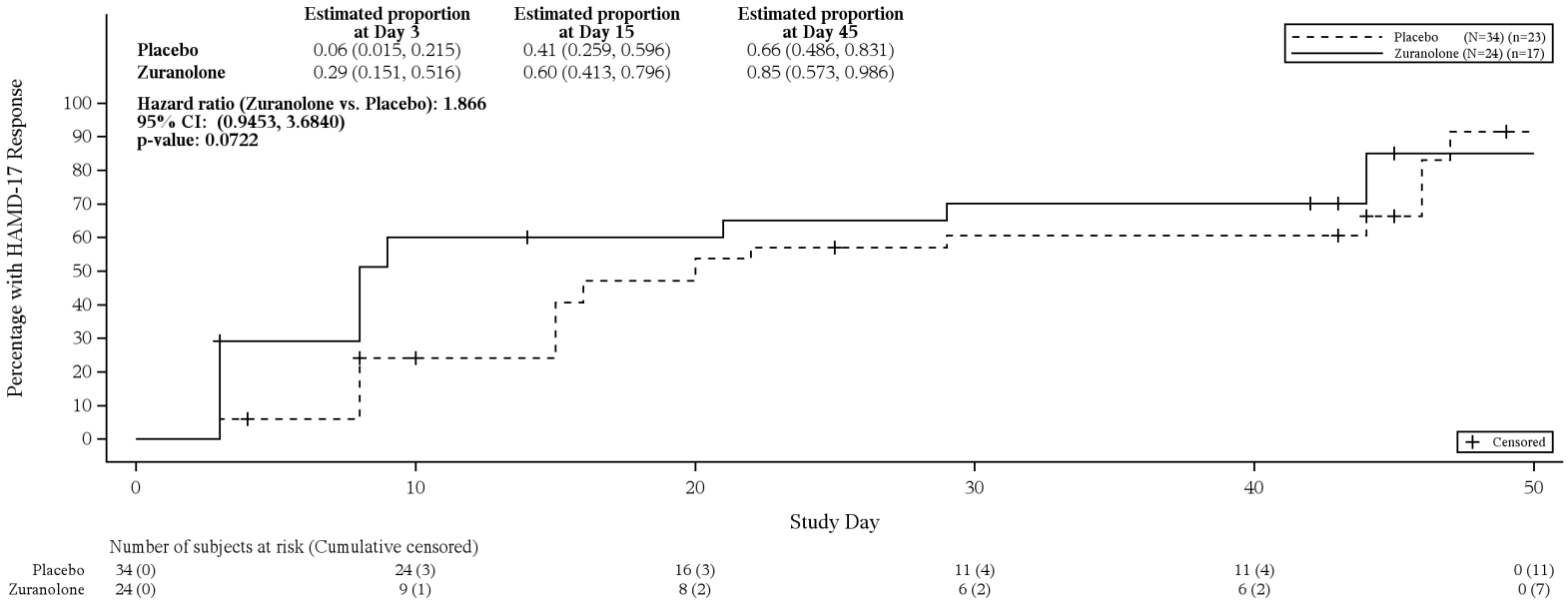
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-resp50-tte-301-by.sas:f-hamd-resp50-tte-301-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-301 - 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.

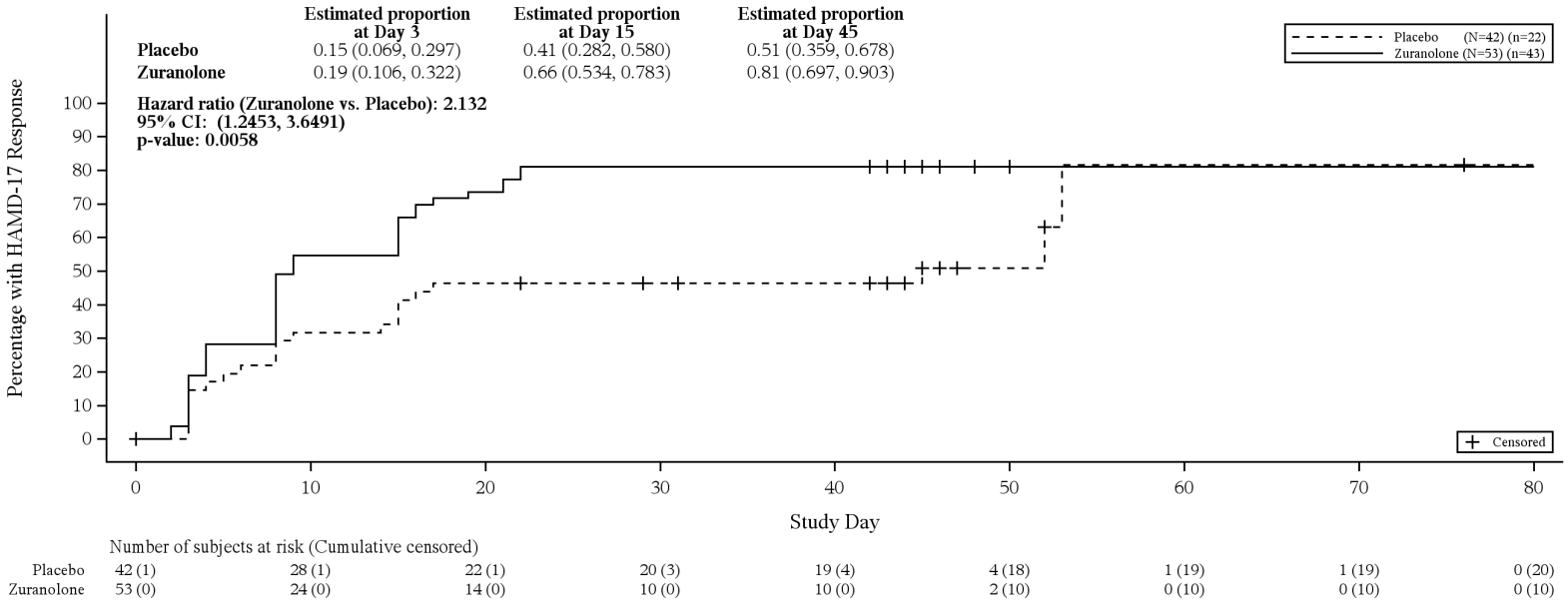
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-resp50-tte-301-by.sas:f-hamd-resp50-tte-301-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-301 - ITT population

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



Number of subjects at risk (Cumulative censored)

Placebo	42 (1)	28 (1)	22 (1)	20 (3)	19 (4)	4 (18)	1 (19)	1 (19)	0 (20)
Zuranolone	53 (0)	24 (0)	14 (0)	10 (0)	10 (0)	2 (10)	0 (10)	0 (10)	0 (10)

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.

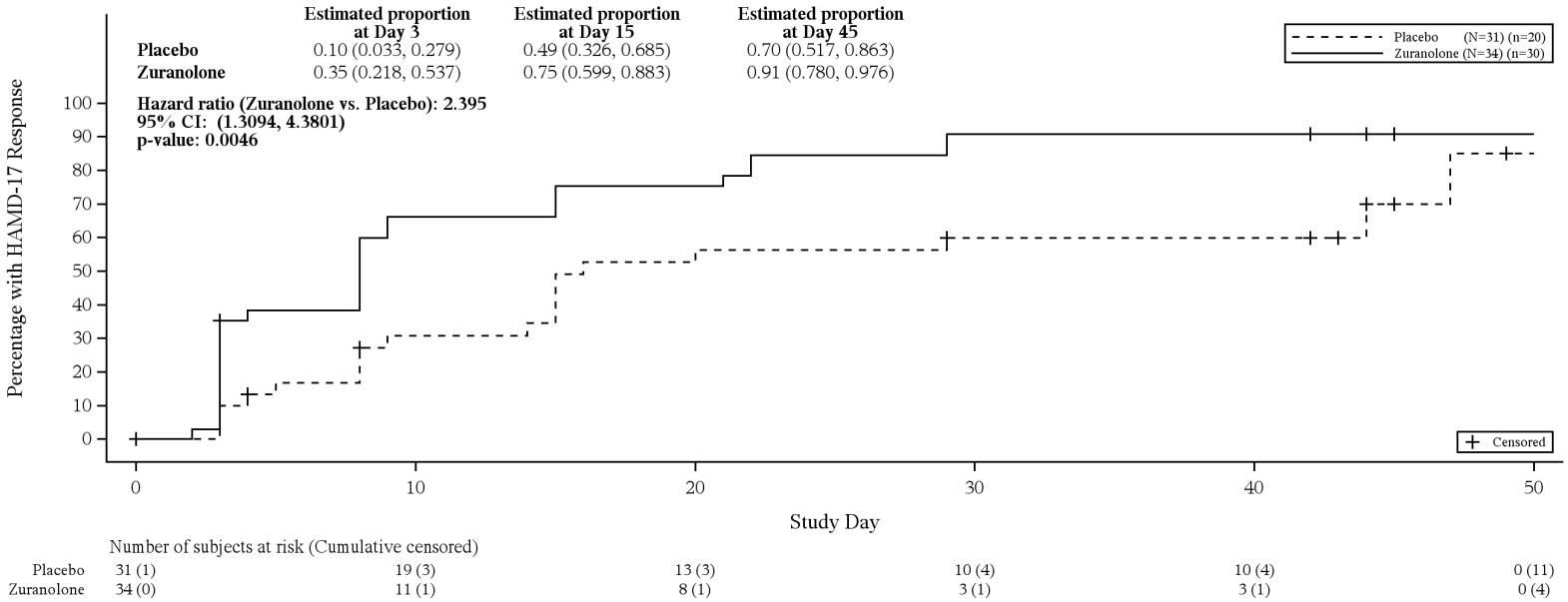
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-resp50-tte-301-by.sas:f-hamd-resp50-tte-301-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-301 - 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 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.

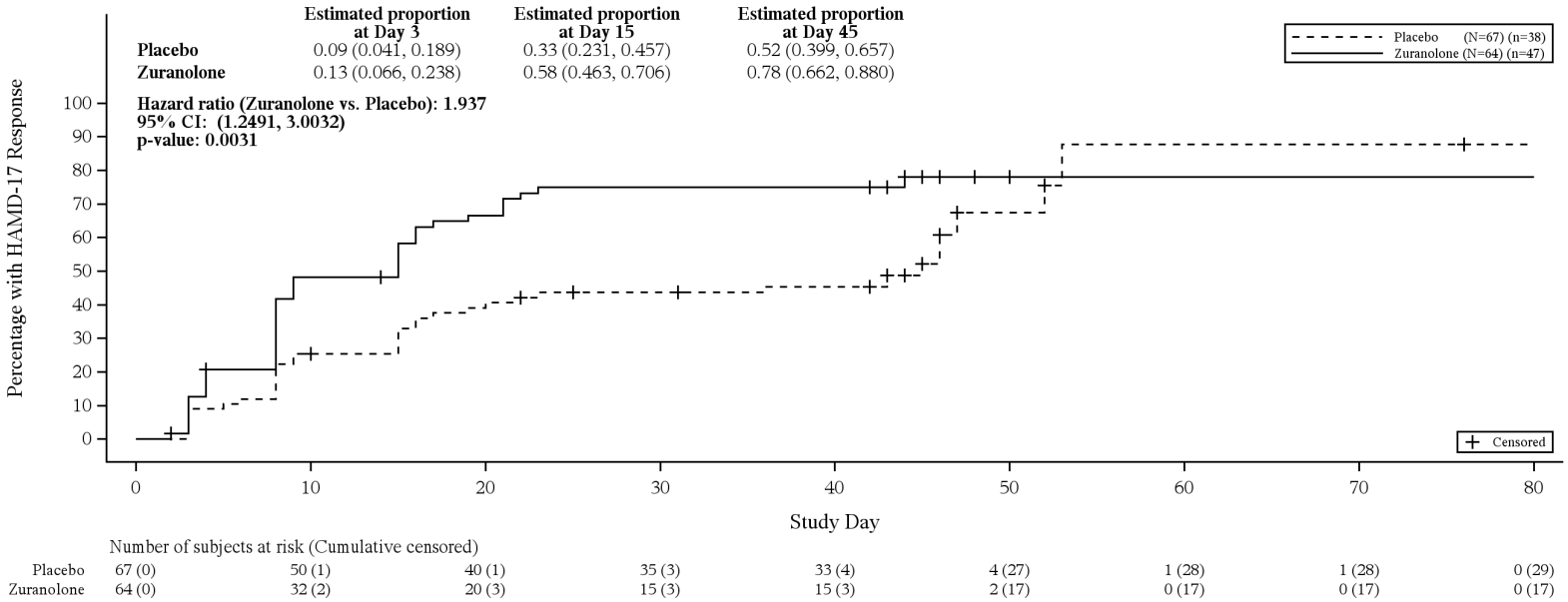
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-resp50-tte-301-by.sas:f-hamd-resp50-tte-301-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-301 - 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 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.

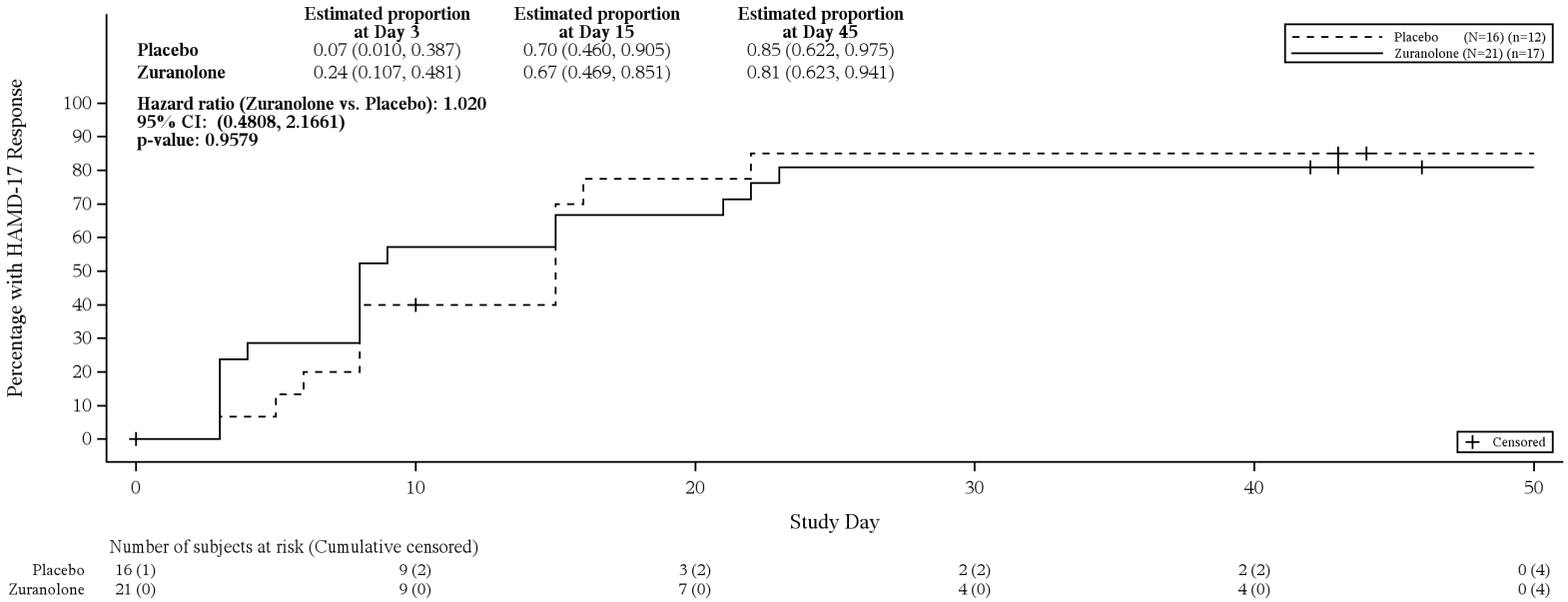
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-resp50-tte-301-by.sas:f-hamd-resp50-tte-301-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-301 - 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.

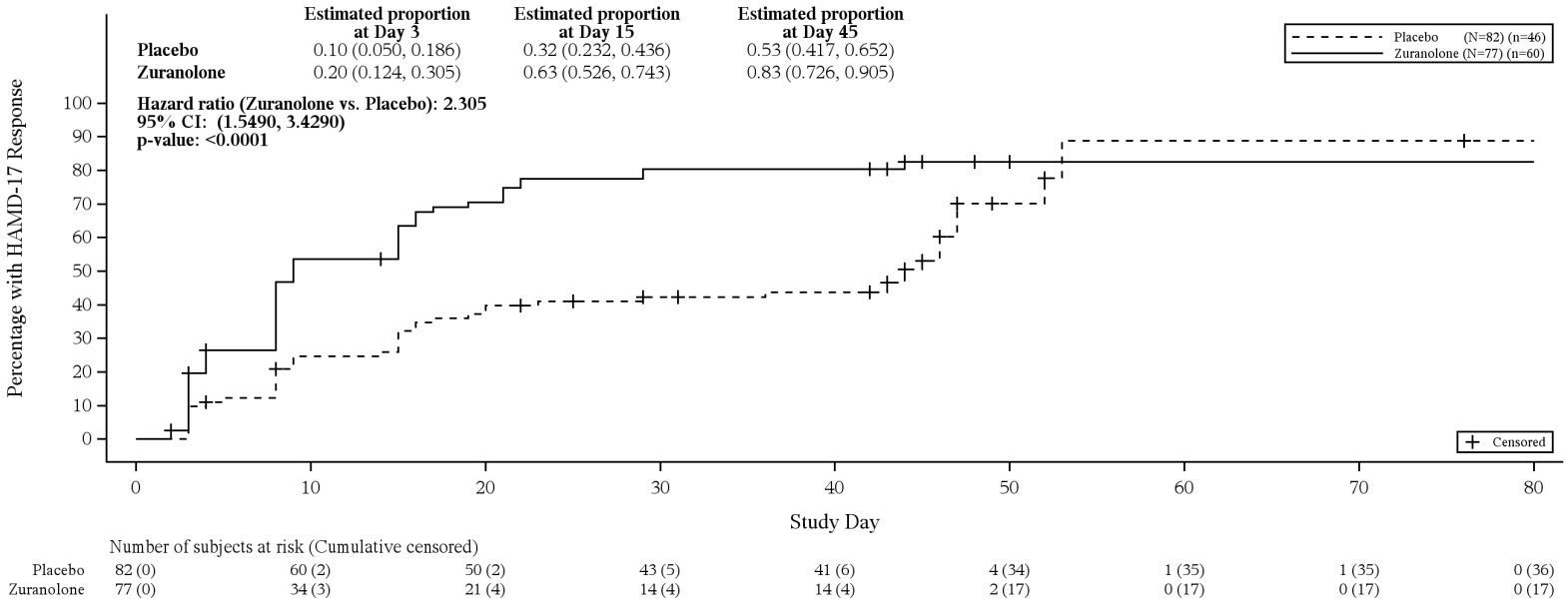
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-resp50-tte-301-by.sas:f-hamd-resp50-tte-301-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-301 - ITT population

Page: 15 of 19

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.

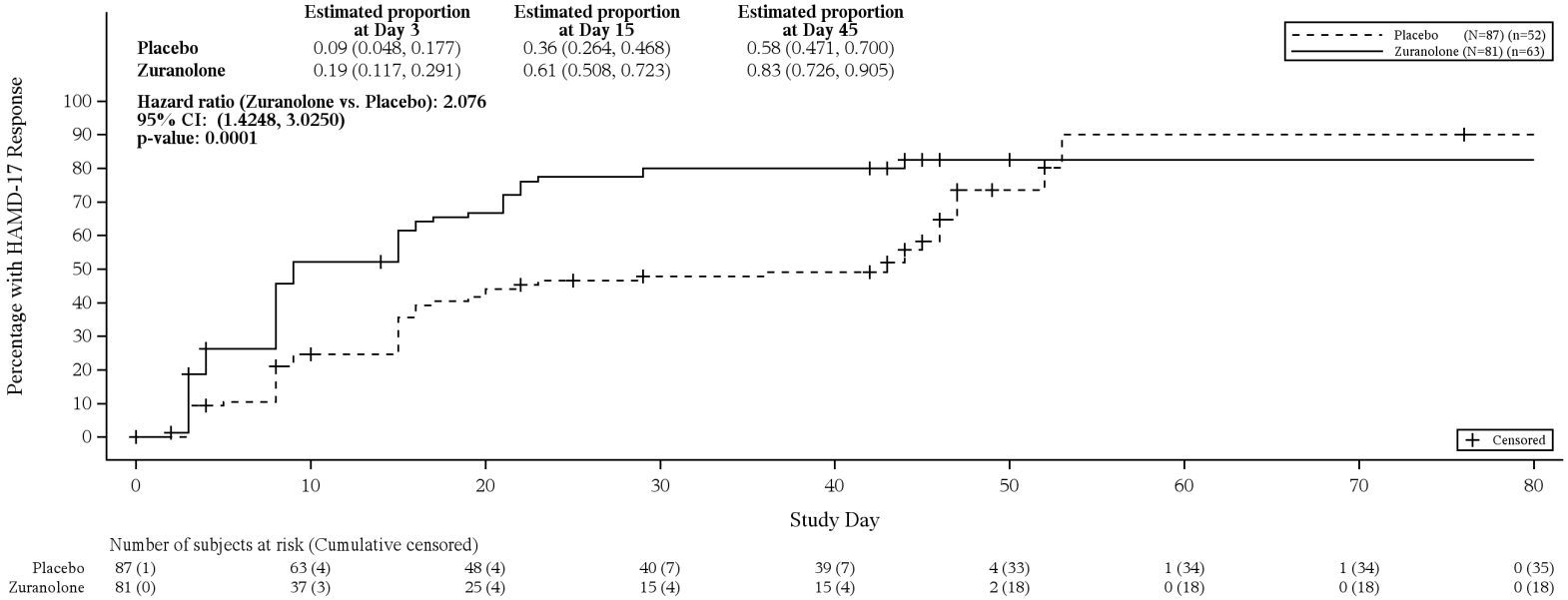
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-resp50-tte-301-by.sas:f-hamd-resp50-tte-301-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-301 - 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.

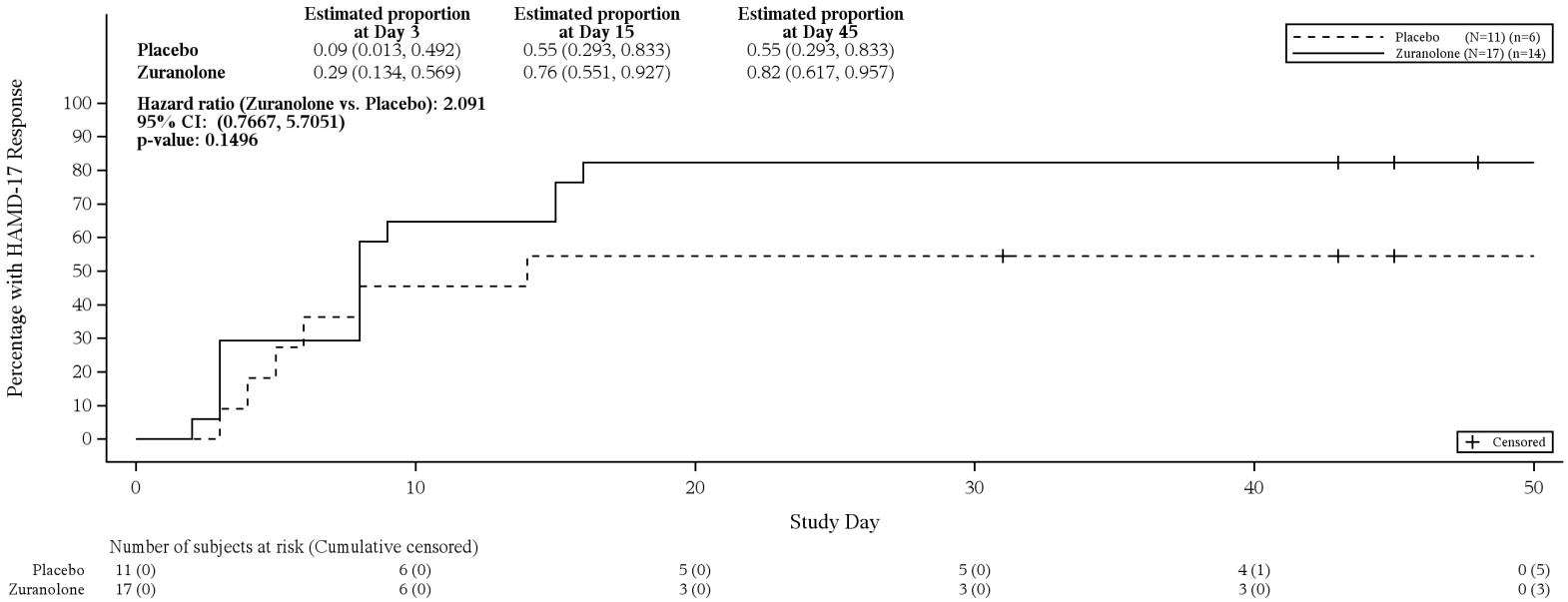
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-resp50-tte-301-by.sas:f-hamd-resp50-tte-301-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-301 - 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.

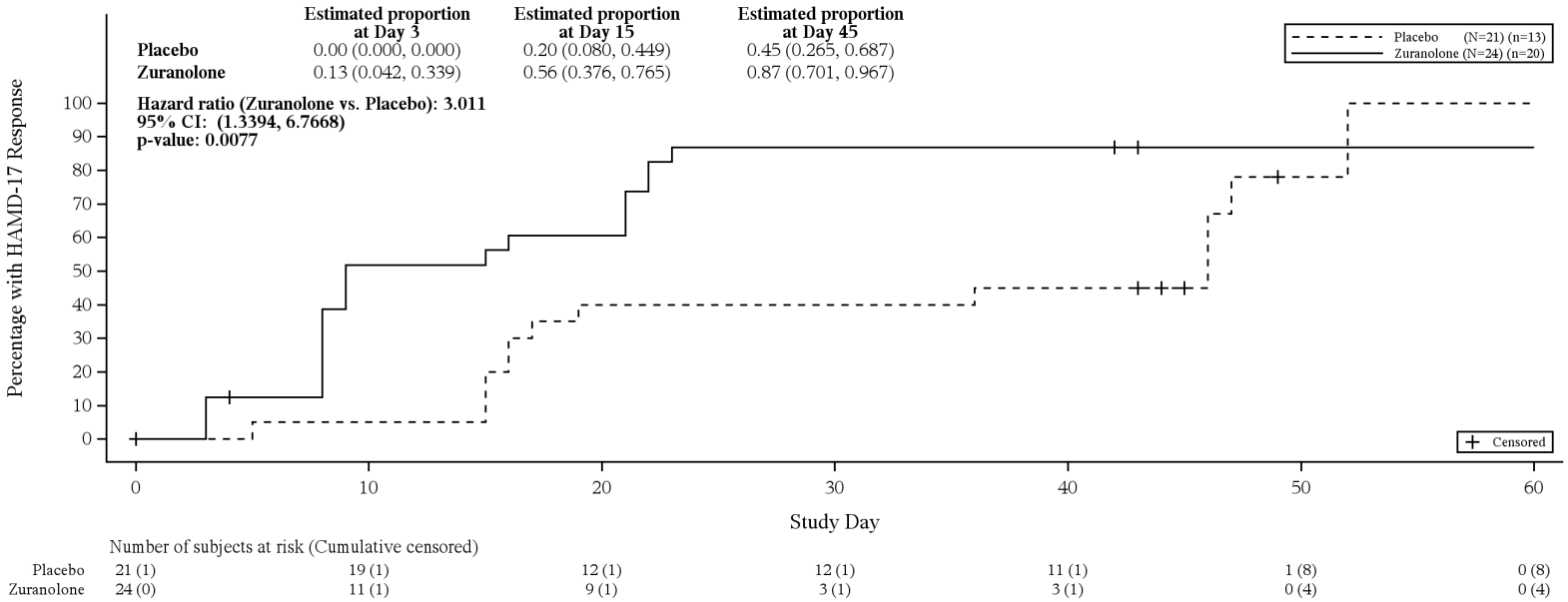
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-resp50-tte-301-by.sas:f-hamd-resp50-tte-301-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-301 - 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 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.

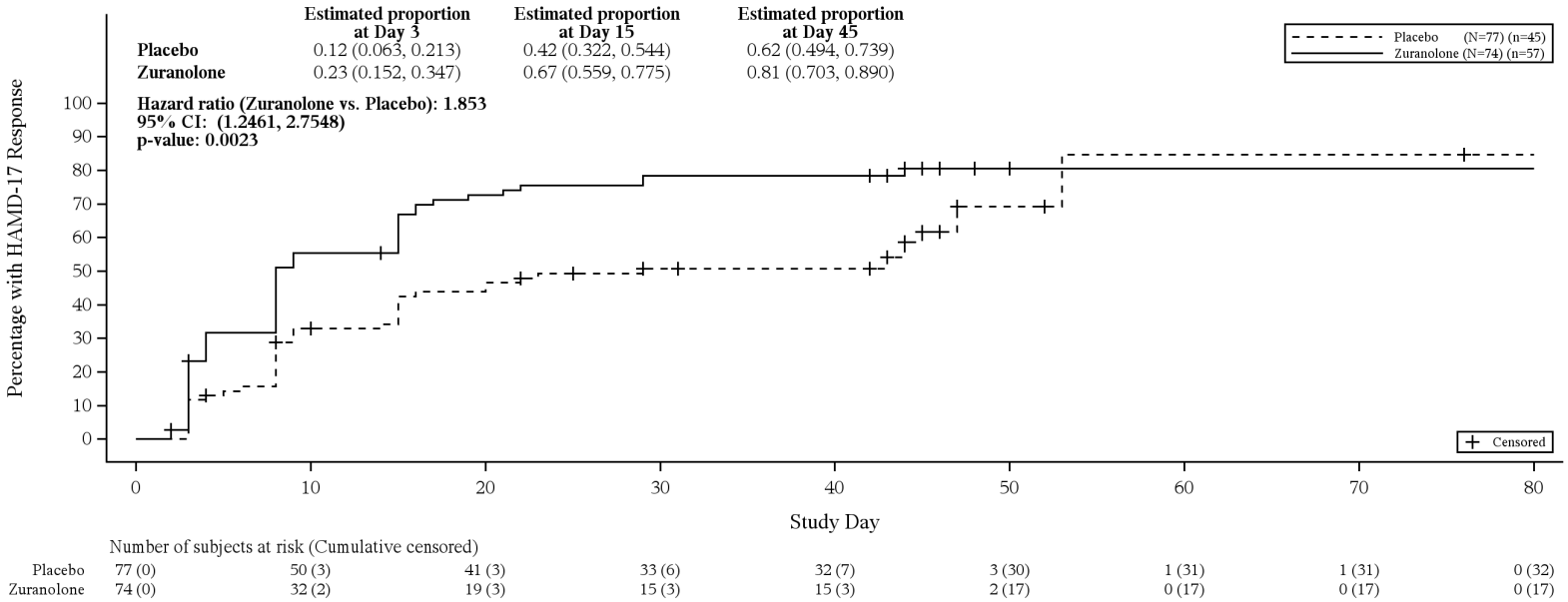
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-resp50-tte-301-by.sas:f-hamd-resp50-tte-301-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-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20



Number of subjects at risk (Cumulative censored)

Placebo	77 (0)	50 (3)	41 (3)	33 (6)	32 (7)	3 (30)	1 (31)	1 (31)	0 (32)
Zuranolone	74 (0)	32 (2)	19 (3)	15 (3)	15 (3)	2 (17)	0 (17)	0 (17)	0 (17)

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-301-by.sas:f-hamd-resp50-tte-301-by-itta.rtf **Run Date:** 08JAN2026

2.1.3 Remission

2.1.3.1 Responder-Analysen

2.1.3.1 .1 ITT-Population

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission: 217-PPD-301 - ITT population

Page: 1 of 6

Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Number of evaluable subjects [1]	98	98
Day 3		
Number of subjects with a remission, n (%) [2]	5 (5.1)	8 (8.2)
Number of subjects with missing evaluation, n (%)	2 (2.0)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.593
95% CI for the RR		(0.538, 4.715)
p-value for RR		0.4002
OR - Odds Ratio (Zuranolone vs. Placebo)		1.642
95% CI for the OR		(0.515, 5.235)
p-value for OR		0.4017
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-301-ovr.sas:t-hamd-remi-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission: 217-PPD-301 - ITT population

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Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 8		
Number of subjects with a remission, n (%) [2]	11 (11.2)	17 (17.3)
Number of subjects with missing evaluation, n (%)	3 (3.1)	5 (5.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.536
95% CI for the RR		(0.757, 3.118)
p-value for RR		0.2345
OR - Odds Ratio (Zuranolone vs. Placebo)		1.657
95% CI for the OR		(0.729, 3.767)
p-value for OR		0.2278
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-301-ovr.sas:t-hamd-remi-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission: 217-PPD-301 - ITT population

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Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 15		
Number of subjects with a remission, n (%) [2]	15 (15.3)	25 (25.5)
Number of subjects with missing evaluation, n (%)	8 (8.2)	5 (5.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.650
95% CI for the RR		(0.925, 2.944)
p-value for RR		0.0897
OR - Odds Ratio (Zuranolone vs. Placebo)		1.891
95% CI for the OR		(0.924, 3.871)
p-value for OR		0.0813
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-301-ovr.sas:t-hamd-remi-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission: 217-PPD-301 - ITT population

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Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 21		
Number of subjects with a remission, n (%) [2]	17 (17.3)	25 (25.5)
Number of subjects with missing evaluation, n (%)	15 (15.3)	14 (14.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.470
95% CI for the RR		(0.850, 2.542)
p-value for RR		0.1677
OR - Odds Ratio (Zuranolone vs. Placebo)		1.624
95% CI for the OR		(0.812, 3.247)
p-value for OR		0.1700
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-301-ovr.sas:t-hamd-remi-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission: 217-PPD-301 - ITT population

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Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 28		
Number of subjects with a remission, n (%) [2]	20 (20.4)	26 (26.5)
Number of subjects with missing evaluation, n (%)	13 (13.3)	21 (21.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.302
95% CI for the RR		(0.782, 2.168)
p-value for RR		0.3100
OR - Odds Ratio (Zuranolone vs. Placebo)		1.403
95% CI for the OR		(0.721, 2.728)
p-value for OR		0.3186
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-301-ovr.sas:t-hamd-remi-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission: 217-PPD-301 - ITT population

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Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 45		
Number of subjects with a remission, n (%) [2]	25 (25.5)	37 (37.8)
Number of subjects with missing evaluation, n (%)	13 (13.3)	14 (14.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.481
95% CI for the RR		(0.971, 2.258)
p-value for RR		0.0685
OR - Odds Ratio (Zuranolone vs. Placebo)		1.765
95% CI for the OR		(0.957, 3.254)
p-value for OR		0.0688
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-301-ovr.sas:t-hamd-remi-301-ovr-itta.rtf **Run Date:** 18JUL2025

2.1.3.1 .2 Subgruppen

2.1.3.1 .2 .1 Interaktionstest

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission: Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	98	98	
Number of subjects with response at Day 15, n (%)	15 (15.3)	25 (25.5)	
Number of subjects with response at Day 45, n (%)	25 (25.5)	37 (37.8)	
Age Group (years)			0.7451
Day 15			
18 - 24, n / N (%)	5/12 (41.7)	7/19 (36.8)	
25 - 45, n / N (%)	10/86 (11.6)	18/79 (22.8)	
Day 45			
18 - 24, n / N (%)	3/12 (25.0)	10/19 (52.6)	
25 - 45, n / N (%)	22/86 (25.6)	27/79 (34.2)	

NOTE 1: p-value is derived using Method 4, 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-301-int.sas:t-hamd-remi-301-int-itta.rtf **Run Date:** 18JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission: Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			0.3518
Day 15			
<28, n / N (%)	4/32 (12.5)	8/33 (24.2)	
>=28, n / N (%)	11/66 (16.7)	17/65 (26.2)	
Day 45			
<28, n / N (%)	7/32 (21.9)	13/33 (39.4)	
>=28, n / N (%)	18/66 (27.3)	24/65 (36.9)	
Race Group (Black or African American, White)			0.0247
Day 15			
Black or African American, n / N (%)	2/18 (11.1)	7/25 (28.0)	
White, n / N (%)	12/69 (17.4)	17/68 (25.0)	
Day 45			
Black or African American, n / N (%)	1/18 (5.6)	12/25 (48.0)	
White, n / N (%)	22/69 (31.9)	25/68 (36.8)	

NOTE 1: p-value is derived using Method 4, 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-301-int.sas:t-hamd-remi-301-int-itta.rtf **Run Date:** 18JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission: Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			0.5561
Day 15			
Yes, n / N (%)	4/15 (26.7)	2/15 (13.3)	
No, n / N (%)	11/83 (13.3)	23/83 (27.7)	
Day 45			
Yes, n / N (%)	4/15 (26.7)	6/15 (40.0)	
No, n / N (%)	21/83 (25.3)	31/83 (37.3)	

NOTE 1: p-value is derived using Method 4, 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-301-int.sas:t-hamd-remi-301-int-itta.rtf **Run Date:** 18JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission: Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			0.1436(a) 0.2456(b) 0.6192(c)
Day 15			
<=24.9, n / N (%)	3/22 (13.6)	4/20 (20.0)	
25-29.9, n / N (%)	3/34 (8.8)	7/24 (29.2)	
>=30, n / N (%)	9/42 (21.4)	14/53 (26.4)	
Day 45			
<=24.9, n / N (%)	8/22 (36.4)	5/20 (25.0)	
25-29.9, n / N (%)	9/34 (26.5)	10/24 (41.7)	
>=30, n / N (%)	8/42 (19.0)	21/53 (39.6)	

NOTE 1: p-value is derived using Method 4, 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-301-int.sas:t-hamd-remi-301-int-itta.rtf **Run Date:** 18JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission: Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Onset of PPD			0.9657
Day 15			
3rd Trimester, n / N (%)	5/31 (16.1)	8/34 (23.5)	
Postpartum, n / N (%)	10/67 (14.9)	17/64 (26.6)	
Day 45			
3rd Trimester, n / N (%)	8/31 (25.8)	12/34 (35.3)	
Postpartum, n / N (%)	17/67 (25.4)	25/64 (39.1)	
Family History of PPD			0.8503
Day 15			
Yes, n / N (%)	3/16 (18.8)	6/21 (28.6)	
No/Unknown, n / N (%)	12/82 (14.6)	19/77 (24.7)	
Day 45			
Yes, n / N (%)	5/16 (31.3)	9/21 (42.9)	
No/Unknown, n / N (%)	20/82 (24.4)	28/77 (36.4)	

NOTE 1: p-value is derived using Method 4, 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-301-int.sas:t-hamd-remi-301-int-itta.rtf **Run Date:** 18JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission: Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
History of PPD			0.5815
Day 15			
1st Episode, n / N (%)	12/87 (13.8)	21/81 (25.9)	
Recurrent Episode, n / N (%)	3/11 (27.3)	4/17 (23.5)	
Day 45			
1st Episode, n / N (%)	21/87 (24.1)	29/81 (35.8)	
Recurrent Episode, n / N (%)	4/11 (36.4)	8/17 (47.1)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			0.9090
Day 15			
<20, n / N (%)	4/21 (19.0)	8/24 (33.3)	
>=20, n / N (%)	11/77 (14.3)	17/74 (23.0)	
Day 45			
<20, n / N (%)	8/21 (38.1)	11/24 (45.8)	
>=20, n / N (%)	17/77 (22.1)	26/74 (35.1)	

NOTE 1: p-value is derived using Method 4, 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-301-int.sas:t-hamd-remi-301-int-itta.rtf **Run Date:** 18JUL2025

2.1.3.1 .2 .2 Subgruppenanalysen

2.1.3.1 .2 .2 .1 Alter

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =19)
Number of evaluable subjects [1]	12	19
Day 3		
Number of subjects with a response, n (%) [2]	1 (8.3)	2 (10.5)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.993
95% CI for the RR		(0.102, 9.674)
p-value for RR		0.9954
Day 8		
Number of subjects with a response, n (%) [2]	4 (33.3)	5 (26.3)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.621
95% CI for the RR		(0.233, 1.652)
p-value for RR		0.3398

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 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-301-by.sas:t-hamd-remi-301-by-age-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =19)
Day 15		
Number of subjects with a response, n (%) [2]	5 (41.7)	7 (36.8)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.695
95% CI for the RR		(0.276, 1.752)
p-value for RR		0.4408
Day 21		
Number of subjects with a response, n (%) [2]	2 (16.7)	6 (31.6)
Number of subjects with missing evaluation, n (%)	2 (16.7)	1 (5.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.490
95% CI for the RR		(0.353, 6.284)
p-value for RR		0.5871

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 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-301-by.sas:t-hamd-remi-301-by-age-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Age Group: 217-PPD-301 - ITT population

Page: 3 of 6

Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =19)
Day 28		
Number of subjects with a response, n (%) [2]	4 (33.3)	7 (36.8)
Number of subjects with missing evaluation, n (%)	0	2 (10.5)
RR - Relative Risk (Zuranolone vs. Placebo)		0.869
95% CI for the RR		(0.318, 2.372)
p-value for RR		0.7842
Day 45		
Number of subjects with a response, n (%) [2]	3 (25.0)	10 (52.6)
Number of subjects with missing evaluation, n (%)	1 (8.3)	1 (5.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.655
95% CI for the RR		(0.538, 5.094)
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 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 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-301-by.sas:t-hamd-remi-301-by-age-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=88)	Zuranolone (N =80)
Number of evaluable subjects [1]	86	79
Day 3		
Number of subjects with a response, n (%) [2]	4 (4.7)	6 (7.6)
Number of subjects with missing evaluation, n (%)	2 (2.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.636
95% CI for the RR		(0.477, 5.603)
p-value for RR		0.4335
Day 8		
Number of subjects with a response, n (%) [2]	7 (8.1)	12 (15.2)
Number of subjects with missing evaluation, n (%)	3 (3.5)	5 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.869
95% CI for the RR		(0.774, 4.516)
p-value for RR		0.1646

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 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-301-by.sas:t-hamd-remi-301-by-age-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=88)	Zuranolone (N =80)
Day 15		
Number of subjects with a response, n (%) [2]	10 (11.6)	18 (22.8)
Number of subjects with missing evaluation, n (%)	8 (9.3)	5 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.963
95% CI for the RR		(0.965, 3.990)
p-value for RR		0.0625
Day 21		
Number of subjects with a response, n (%) [2]	15 (17.4)	19 (24.1)
Number of subjects with missing evaluation, n (%)	13 (15.1)	13 (16.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.381
95% CI for the RR		(0.755, 2.526)
p-value for RR		0.2944

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 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-301-by.sas:t-hamd-remi-301-by-age-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Age Group: 217-PPD-301 - ITT population

Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=88)	Zuranolone (N =80)
Day 28		
Number of subjects with a response, n (%) [2]	16 (18.6)	19 (24.1)
Number of subjects with missing evaluation, n (%)	13 (15.1)	19 (24.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.295
95% CI for the RR		(0.718, 2.334)
p-value for RR		0.3900
Day 45		
Number of subjects with a response, n (%) [2]	22 (25.6)	27 (34.2)
Number of subjects with missing evaluation, n (%)	12 (14.0)	13 (16.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.338
95% CI for the RR		(0.834, 2.148)
p-value for RR		0.2273

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 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-301-by.sas:t-hamd-remi-301-by-age-itta.rtf **Run Date:** 25JUL2025

2.1.3.1 .2 .2 .2 Schwere der Erkrankung

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline HAMD-17 Total Score: 217-PPD-301 - 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=32)	Zuranolone (N =33)
Number of evaluable subjects [1]	32	33
Day 3		
Number of subjects with a response, n (%) [2]	2 (6.3)	1 (3.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.479
95% CI for the RR		(0.045, 5.056)
p-value for RR		0.5405
Day 8		
Number of subjects with a response, n (%) [2]	3 (9.4)	4 (12.1)
Number of subjects with missing evaluation, n (%)	0	1 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.278
95% CI for the RR		(0.304, 5.368)
p-value for RR		0.7380

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 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-301-by.sas:t-hamd-remi-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline HAMD-17 Total Score: 217-PPD-301 - 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=32)	Zuranolone (N =33)
Day 15		
Number of subjects with a response, n (%) [2]	4 (12.5)	8 (24.2)
Number of subjects with missing evaluation, n (%)	2 (6.3)	1 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.916
95% CI for the RR		(0.640, 5.740)
p-value for RR		0.2452
Day 21		
Number of subjects with a response, n (%) [2]	6 (18.8)	8 (24.2)
Number of subjects with missing evaluation, n (%)	5 (15.6)	2 (6.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.278
95% CI for the RR		(0.502, 3.253)
p-value for RR		0.6074

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 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-301-by.sas:t-hamd-remi-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline HAMD-17 Total Score: 217-PPD-301 - 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=32)	Zuranolone (N =33)
Day 28		
Number of subjects with a response, n (%) [2]	6 (18.8)	10 (30.3)
Number of subjects with missing evaluation, n (%)	6 (18.8)	5 (15.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.597
95% CI for the RR		(0.666, 3.830)
p-value for RR		0.2942
Day 45		
Number of subjects with a response, n (%) [2]	7 (21.9)	13 (39.4)
Number of subjects with missing evaluation, n (%)	5 (15.6)	3 (9.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.780
95% CI for the RR		(0.820, 3.863)
p-value for RR		0.1450

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 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-301-by.sas:t-hamd-remi-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline HAMD-17 Total Score: 217-PPD-301 - 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=66)	Zuranolone (N =65)
Number of evaluable subjects [1]	66	65
Day 3		
Number of subjects with a response, n (%) [2]	3 (4.5)	7 (10.8)
Number of subjects with missing evaluation, n (%)	2 (3.0)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.337
95% CI for the RR		(0.630, 8.670)
p-value for RR		0.2044
Day 8		
Number of subjects with a response, n (%) [2]	8 (12.1)	13 (20.0)
Number of subjects with missing evaluation, n (%)	3 (4.5)	4 (6.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.628
95% CI for the RR		(0.725, 3.654)
p-value for RR		0.2378

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 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-301-by.sas:t-hamd-remi-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline HAMD-17 Total Score: 217-PPD-301 - 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=66)	Zuranolone (N =65)
Day 15		
Number of subjects with a response, n (%) [2]	11 (16.7)	17 (26.2)
Number of subjects with missing evaluation, n (%)	6 (9.1)	4 (6.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.548
95% CI for the RR		(0.785, 3.053)
p-value for RR		0.2074
Day 21		
Number of subjects with a response, n (%) [2]	11 (16.7)	17 (26.2)
Number of subjects with missing evaluation, n (%)	10 (15.2)	12 (18.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.548
95% CI for the RR		(0.790, 3.034)
p-value for RR		0.2033

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 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-301-by.sas:t-hamd-remi-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline HAMD-17 Total Score: 217-PPD-301 - 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=66)	Zuranolone (N =65)
Day 28		
Number of subjects with a response, n (%) [2]	14 (21.2)	16 (24.6)
Number of subjects with missing evaluation, n (%)	7 (10.6)	16 (24.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.145
95% CI for the RR		(0.612, 2.140)
p-value for RR		0.6723
Day 45		
Number of subjects with a response, n (%) [2]	18 (27.3)	24 (36.9)
Number of subjects with missing evaluation, n (%)	8 (12.1)	11 (16.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.335
95% CI for the RR		(0.809, 2.203)
p-value for RR		0.2575

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 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-301-by.sas:t-hamd-remi-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

2.1.3.1 .2 .2 .3 Abstammung

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Race Group: 217-PPD-301 - ITT population

Page: 1 of 6

Race Group = Black or African American

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =26)
Number of evaluable subjects [1]	18	25
Day 3		
Number of subjects with a response, n (%) [2]	0	2 (8.0)
Number of subjects with missing evaluation, n (%)	1 (5.6)	0
RR - Relative Risk (Zuranolone vs. Placebo)		3.65
95% CI for the RR		(0.186, 71.806)
p-value for RR		0.3938
Day 8		
Number of subjects with a response, n (%) [2]	1 (5.6)	6 (24.0)
Number of subjects with missing evaluation, n (%)	2 (11.1)	2 (8.0)
RR - Relative Risk (Zuranolone vs. Placebo)		4.32
95% CI for the RR		(0.568, 32.842)
p-value for RR		0.1574

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-301-by.sas:t-hamd-remi-301-by-race-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Race Group: 217-PPD-301 - ITT population

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Race Group = Black or African American

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =26)
Day 15		
Number of subjects with a response, n (%) [2]	2 (11.1)	7 (28.0)
Number of subjects with missing evaluation, n (%)	4 (22.2)	3 (12.0)
RR - Relative Risk (Zuranolone vs. Placebo)		2.52
95% CI for the RR		(0.591, 10.743)
p-value for RR		0.2115
Day 21		
Number of subjects with a response, n (%) [2]	2 (11.1)	8 (32.0)
Number of subjects with missing evaluation, n (%)	7 (38.9)	7 (28.0)
RR - Relative Risk (Zuranolone vs. Placebo)		2.88
95% CI for the RR		(0.692, 11.988)
p-value for RR		0.1460

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-301-by.sas:t-hamd-remi-301-by-race-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Race Group: 217-PPD-301 - ITT population

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Race Group = Black or African American

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =26)
Day 28		
Number of subjects with a response, n (%) [2]	2 (11.1)	8 (32.0)
Number of subjects with missing evaluation, n (%)	7 (38.9)	6 (24.0)
RR - Relative Risk (Zuranolone vs. Placebo)		2.88
95% CI for the RR		(0.692, 11.988)
p-value for RR		0.1460
Day 45		
Number of subjects with a response, n (%) [2]	1 (5.6)	12 (48.0)
Number of subjects with missing evaluation, n (%)	5 (27.8)	3 (12.0)
RR - Relative Risk (Zuranolone vs. Placebo)		8.64
95% CI for the RR		(1.232, 60.603)
p-value for RR		0.0300

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-301-by.sas:t-hamd-remi-301-by-race-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Race Group: 217-PPD-301 - ITT population

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Race Group = White

Study Visit Statistics	Placebo (N=70)	Zuranolone (N =68)
Number of evaluable subjects [1]	69	68
Day 3		
Number of subjects with a response, n (%) [2]	4 (5.8)	5 (7.4)
Number of subjects with missing evaluation, n (%)	1 (1.4)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.27
95% CI for the RR		(0.356, 4.523)
p-value for RR		0.7140
Day 8		
Number of subjects with a response, n (%) [2]	9 (13.0)	10 (14.7)
Number of subjects with missing evaluation, n (%)	0	3 (4.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.13
95% CI for the RR		(0.489, 2.601)
p-value for RR		0.7785

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-301-by.sas:t-hamd-remi-301-by-race-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Race Group: 217-PPD-301 - ITT population

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Race Group = White

Study Visit Statistics	Placebo (N=70)	Zuranolone (N =68)
Day 15		
Number of subjects with a response, n (%) [2]	12 (17.4)	17 (25.0)
Number of subjects with missing evaluation, n (%)	3 (4.3)	2 (2.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.44
95% CI for the RR		(0.744, 2.778)
p-value for RR		0.2802
Day 21		
Number of subjects with a response, n (%) [2]	14 (20.3)	16 (23.5)
Number of subjects with missing evaluation, n (%)	7 (10.1)	7 (10.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.16
95% CI for the RR		(0.615, 2.187)
p-value for RR		0.6471

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-301-by.sas:t-hamd-remi-301-by-race-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Race Group: 217-PPD-301 - ITT population

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Race Group = White

Study Visit Statistics	Placebo (N=70)	Zuranolone (N =68)
Day 28		
Number of subjects with a response, n (%) [2]	17 (24.6)	17 (25.0)
Number of subjects with missing evaluation, n (%)	5 (7.2)	15 (22.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.01
95% CI for the RR		(0.566, 1.818)
p-value for RR		0.9608
Day 45		
Number of subjects with a response, n (%) [2]	22 (31.9)	25 (36.8)
Number of subjects with missing evaluation, n (%)	7 (10.1)	10 (14.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.15
95% CI for the RR		(0.724, 1.835)
p-value for RR		0.5482

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-301-by.sas:t-hamd-remi-301-by-race-itta.rtf **Run Date:** 25JUL2025

2.1.3.1 .2 .2 .4 Antidepressiva-Nutzung

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline Antidepressant Use: 217-PPD-301 - ITT population

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Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=15)	Zuranolone (N =15)
Number of evaluable subjects [1]	15	15
Day 3		
Number of subjects with a response, n (%) [2]	0	1 (6.7)
Number of subjects with missing evaluation, n (%)	1 (6.7)	0
RR - Relative Risk (Zuranolone vs. Placebo)		3.00
95% CI for the RR		(0.132, 68.259)
p-value for RR		0.4908
Day 8		
Number of subjects with a response, n (%) [2]	2 (13.3)	4 (26.7)
Number of subjects with missing evaluation, n (%)	0	1 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		2.00
95% CI for the RR		(0.429, 9.321)
p-value for RR		0.3774

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-301-by.sas:t-hamd-remi-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline Antidepressant Use: 217-PPD-301 - ITT population

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Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=15)	Zuranolone (N =15)
Day 15		
Number of subjects with a response, n (%) [2]	4 (26.7)	2 (13.3)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.50
95% CI for the RR		(0.107, 2.330)
p-value for RR		0.3774
Day 21		
Number of subjects with a response, n (%) [2]	3 (20.0)	5 (33.3)
Number of subjects with missing evaluation, n (%)	1 (6.7)	1 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.67
95% CI for the RR		(0.483, 5.757)
p-value for RR		0.4193

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-301-by.sas:t-hamd-remi-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline Antidepressant Use: 217-PPD-301 - ITT population

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Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=15)	Zuranolone (N =15)
Day 28		
Number of subjects with a response, n (%) [2]	4 (26.7)	5 (33.3)
Number of subjects with missing evaluation, n (%)	2 (13.3)	1 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.25
95% CI for the RR		(0.415, 3.766)
p-value for RR		0.6917
Day 45		
Number of subjects with a response, n (%) [2]	4 (26.7)	6 (40.0)
Number of subjects with missing evaluation, n (%)	1 (6.7)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.50
95% CI for the RR		(0.528, 4.258)
p-value for RR		0.4462

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-301-by.sas:t-hamd-remi-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline Antidepressant Use: 217-PPD-301 - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=86)	Zuranolone (N =84)
Number of evaluable subjects [1]	83	83
Day 3		
Number of subjects with a response, n (%) [2]	5 (6.0)	7 (8.4)
Number of subjects with missing evaluation, n (%)	1 (1.2)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.40
95% CI for the RR		(0.463, 4.234)
p-value for RR		0.5512
Day 8		
Number of subjects with a response, n (%) [2]	9 (10.8)	13 (15.7)
Number of subjects with missing evaluation, n (%)	3 (3.6)	4 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.44
95% CI for the RR		(0.653, 3.194)
p-value for RR		0.3638

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-301-by.sas:t-hamd-remi-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline Antidepressant Use: 217-PPD-301 - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=86)	Zuranolone (N =84)
Day 15		
Number of subjects with a response, n (%) [2]	11 (13.3)	23 (27.7)
Number of subjects with missing evaluation, n (%)	8 (9.6)	5 (6.0)
RR - Relative Risk (Zuranolone vs. Placebo)		2.09
95% CI for the RR		(1.091, 4.009)
p-value for RR		0.0264
Day 21		
Number of subjects with a response, n (%) [2]	14 (16.9)	20 (24.1)
Number of subjects with missing evaluation, n (%)	14 (16.9)	13 (15.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.43
95% CI for the RR		(0.775, 2.633)
p-value for RR		0.2529

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-301-by.sas:t-hamd-remi-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline Antidepressant Use: 217-PPD-301 - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=86)	Zuranolone (N =84)
Day 28		
Number of subjects with a response, n (%) [2]	16 (19.3)	21 (25.3)
Number of subjects with missing evaluation, n (%)	11 (13.3)	20 (24.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.31
95% CI for the RR		(0.739, 2.332)
p-value for RR		0.3538
Day 45		
Number of subjects with a response, n (%) [2]	21 (25.3)	31 (37.3)
Number of subjects with missing evaluation, n (%)	12 (14.5)	14 (16.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.48
95% CI for the RR		(0.929, 2.345)
p-value for RR		0.0991

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-301-by.sas:t-hamd-remi-301-by-adt-itta.rtf **Run Date:** 25JUL2025

2.1.3.1 .2 .2 .5 BMI

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline BMI (kg/m^2) Group: 217-PPD-301 - ITT population

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

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =20)
Number of evaluable subjects [1]	22	20
Day 3		
Number of subjects with a response, n (%) [2]	2 (9.1)	1 (5.0)
Number of subjects with missing evaluation, n (%)	1 (4.5)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.586
95% CI for the RR		(0.057, 5.969)
p-value for RR		0.6514
Day 8		
Number of subjects with a response, n (%) [2]	3 (13.6)	2 (10.0)
Number of subjects with missing evaluation, n (%)	0	2 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.781
95% CI for the RR		(0.138, 4.415)
p-value for RR		0.7795

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 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-301-by.sas:t-hamd-remi-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline BMI (kg/m^2) Group: 217-PPD-301 - ITT population

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

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =20)
Day 15		
Number of subjects with a response, n (%) [2]	3 (13.6)	4 (20.0)
Number of subjects with missing evaluation, n (%)	1 (4.5)	2 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.561
95% CI for the RR		(0.408, 5.982)
p-value for RR		0.5155
Day 21		
Number of subjects with a response, n (%) [2]	4 (18.2)	2 (10.0)
Number of subjects with missing evaluation, n (%)	4 (18.2)	4 (20.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.586
95% CI for the RR		(0.126, 2.726)
p-value for RR		0.4952

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 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-301-by.sas:t-hamd-remi-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline BMI (kg/m^2) Group: 217-PPD-301 - ITT population

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

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =20)
Day 28		
Number of subjects with a response, n (%) [2]	6 (27.3)	4 (20.0)
Number of subjects with missing evaluation, n (%)	1 (4.5)	8 (40.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.781
95% CI for the RR		(0.261, 2.332)
p-value for RR		0.6575
Day 45		
Number of subjects with a response, n (%) [2]	8 (36.4)	5 (25.0)
Number of subjects with missing evaluation, n (%)	0	5 (25.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.732
95% CI for the RR		(0.303, 1.766)
p-value for RR		0.4873

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 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-301-by.sas:t-hamd-remi-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline BMI (kg/m^2) Group: 217-PPD-301 - ITT population

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

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =24)
Number of evaluable subjects [1]	34	24
Day 3		
Number of subjects with a response, n (%) [2]	1 (2.9)	2 (8.3)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.862
95% CI for the RR		(0.264, 31.075)
p-value for RR		0.3875
Day 8		
Number of subjects with a response, n (%) [2]	1 (2.9)	5 (20.8)
Number of subjects with missing evaluation, n (%)	2 (5.9)	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		7.154
95% CI for the RR		(0.855, 59.847)
p-value for RR		0.0694

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 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-301-by.sas:t-hamd-remi-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline BMI (kg/m^2) Group: 217-PPD-301 - ITT population

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

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =24)
Day 15		
Number of subjects with a response, n (%) [2]	3 (8.8)	7 (29.2)
Number of subjects with missing evaluation, n (%)	4 (11.8)	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		3.339
95% CI for the RR		(0.912, 12.218)
p-value for RR		0.0685
Day 21		
Number of subjects with a response, n (%) [2]	6 (17.6)	10 (41.7)
Number of subjects with missing evaluation, n (%)	6 (17.6)	3 (12.5)
RR - Relative Risk (Zuranolone vs. Placebo)		2.385
95% CI for the RR		(1.033, 5.505)
p-value for RR		0.0417

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 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-301-by.sas:t-hamd-remi-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline BMI (kg/m^2) Group: 217-PPD-301 - ITT population

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

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =24)
Day 28		
Number of subjects with a response, n (%) [2]	6 (17.6)	9 (37.5)
Number of subjects with missing evaluation, n (%)	5 (14.7)	4 (16.7)
RR - Relative Risk (Zuranolone vs. Placebo)		2.146
95% CI for the RR		(0.955, 4.823)
p-value for RR		0.0645
Day 45		
Number of subjects with a response, n (%) [2]	9 (26.5)	10 (41.7)
Number of subjects with missing evaluation, n (%)	6 (17.6)	4 (16.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.590
95% CI for the RR		(0.805, 3.140)
p-value for RR		0.1818

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 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-301-by.sas:t-hamd-remi-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline BMI (kg/m^2) Group: 217-PPD-301 - ITT population

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

Study Visit Statistics	Placebo (N=42)	Zuranolone (N =53)
Number of evaluable subjects [1]	42	53
Day 3		
Number of subjects with a response, n (%) [2]	2 (4.8)	5 (9.4)
Number of subjects with missing evaluation, n (%)	1 (2.4)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.969
95% CI for the RR		(0.400, 9.693)
p-value for RR		0.4049
Day 8		
Number of subjects with a response, n (%) [2]	7 (16.7)	10 (18.9)
Number of subjects with missing evaluation, n (%)	1 (2.4)	2 (3.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.125
95% CI for the RR		(0.473, 2.677)
p-value for RR		0.7901

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 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-301-by.sas:t-hamd-remi-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline BMI (kg/m^2) Group: 217-PPD-301 - ITT population

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

Study Visit Statistics	Placebo (N=42)	Zuranolone (N =53)
Day 15		
Number of subjects with a response, n (%) [2]	9 (21.4)	14 (26.4)
Number of subjects with missing evaluation, n (%)	3 (7.1)	2 (3.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.225
95% CI for the RR		(0.595, 2.524)
p-value for RR		0.5822
Day 21		
Number of subjects with a response, n (%) [2]	7 (16.7)	12 (22.6)
Number of subjects with missing evaluation, n (%)	5 (11.9)	7 (13.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.350
95% CI for the RR		(0.588, 3.101)
p-value for RR		0.4796

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 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-301-by.sas:t-hamd-remi-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline BMI (kg/m^2) Group: 217-PPD-301 - ITT population

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

Study Visit Statistics	Placebo (N=42)	Zuranolone (N =53)
Day 28		
Number of subjects with a response, n (%) [2]	8 (19.0)	13 (24.5)
Number of subjects with missing evaluation, n (%)	7 (16.7)	9 (17.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.280
95% CI for the RR		(0.586, 2.793)
p-value for RR		0.5359
Day 45		
Number of subjects with a response, n (%) [2]	8 (19.0)	21 (39.6)
Number of subjects with missing evaluation, n (%)	7 (16.7)	5 (9.4)
RR - Relative Risk (Zuranolone vs. Placebo)		2.067
95% CI for the RR		(1.013, 4.216)
p-value for RR		0.0459

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 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-301-by.sas:t-hamd-remi-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

2.1.3.1 .2 .2 .6 Beginn der PPD

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =35)
Number of evaluable subjects [1]	31	34
Day 3		
Number of subjects with a response, n (%) [2]	2 (6.5)	4 (11.8)
Number of subjects with missing evaluation, n (%)	1 (3.2)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.806
95% CI for the RR		(0.356, 9.154)
p-value for RR		0.4752
Day 8		
Number of subjects with a response, n (%) [2]	4 (12.9)	6 (17.6)
Number of subjects with missing evaluation, n (%)	3 (9.7)	2 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.361
95% CI for the RR		(0.429, 4.315)
p-value for RR		0.6008

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-301-by.sas:t-hamd-remi-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =35)
Day 15		
Number of subjects with a response, n (%) [2]	5 (16.1)	8 (23.5)
Number of subjects with missing evaluation, n (%)	4 (12.9)	3 (8.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.461
95% CI for the RR		(0.543, 3.930)
p-value for RR		0.4530
Day 21		
Number of subjects with a response, n (%) [2]	5 (16.1)	10 (29.4)
Number of subjects with missing evaluation, n (%)	6 (19.4)	5 (14.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.805
95% CI for the RR		(0.697, 4.674)
p-value for RR		0.2239

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-301-by.sas:t-hamd-remi-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =35)
Day 28		
Number of subjects with a response, n (%) [2]	6 (19.4)	9 (26.5)
Number of subjects with missing evaluation, n (%)	6 (19.4)	8 (23.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.339
95% CI for the RR		(0.538, 3.332)
p-value for RR		0.5297
Day 45		
Number of subjects with a response, n (%) [2]	8 (25.8)	12 (35.3)
Number of subjects with missing evaluation, n (%)	6 (19.4)	7 (20.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.351
95% CI for the RR		(0.632, 2.891)
p-value for RR		0.4379

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-301-by.sas:t-hamd-remi-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=69)	Zuranolone (N =64)
Number of evaluable subjects [1]	67	64
Day 3		
Number of subjects with a response, n (%) [2]	3 (4.5)	4 (6.3)
Number of subjects with missing evaluation, n (%)	1 (1.5)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.399
95% CI for the RR		(0.321, 6.104)
p-value for RR		0.6550
Day 8		
Number of subjects with a response, n (%) [2]	7 (10.4)	11 (17.2)
Number of subjects with missing evaluation, n (%)	0	3 (4.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.634
95% CI for the RR		(0.669, 3.992)
p-value for RR		0.2816

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-301-by.sas:t-hamd-remi-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=69)	Zuranolone (N =64)
Day 15		
Number of subjects with a response, n (%) [2]	10 (14.9)	17 (26.6)
Number of subjects with missing evaluation, n (%)	4 (6.0)	2 (3.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.747
95% CI for the RR		(0.860, 3.548)
p-value for RR		0.1227
Day 21		
Number of subjects with a response, n (%) [2]	12 (17.9)	15 (23.4)
Number of subjects with missing evaluation, n (%)	9 (13.4)	9 (14.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.331
95% CI for the RR		(0.681, 2.599)
p-value for RR		0.4032

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-301-by.sas:t-hamd-remi-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=69)	Zuranolone (N =64)
Day 28		
Number of subjects with a response, n (%) [2]	14 (20.9)	17 (26.6)
Number of subjects with missing evaluation, n (%)	7 (10.4)	13 (20.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.272
95% CI for the RR		(0.691, 2.341)
p-value for RR		0.4394
Day 45		
Number of subjects with a response, n (%) [2]	17 (25.4)	25 (39.1)
Number of subjects with missing evaluation, n (%)	7 (10.4)	7 (10.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.555
95% CI for the RR		(0.935, 2.584)
p-value for RR		0.0886

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-301-by.sas:t-hamd-remi-301-by-onset-itta.rtf **Run Date:** 25JUL2025

2.1.3.1 .2 .2 .7 PPD in der Familie

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Family History of PPD: 217-PPD-301 - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =21)
Number of evaluable subjects [1]	16	21
Day 3		
Number of subjects with a response, n (%) [2]	2 (12.5)	1 (4.8)
Number of subjects with missing evaluation, n (%)	1 (6.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.369
95% CI for the RR		(0.036, 3.841)
p-value for RR		0.4046
Day 8		
Number of subjects with a response, n (%) [2]	3 (18.8)	4 (19.0)
Number of subjects with missing evaluation, n (%)	1 (6.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.985
95% CI for the RR		(0.229, 4.247)
p-value for RR		0.9840

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 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-301-by.sas:t-hamd-remi-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Family History of PPD: 217-PPD-301 - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =21)
Day 15		
Number of subjects with a response, n (%) [2]	3 (18.8)	6 (28.6)
Number of subjects with missing evaluation, n (%)	3 (18.8)	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.478
95% CI for the RR		(0.408, 5.356)
p-value for RR		0.5523
Day 21		
Number of subjects with a response, n (%) [2]	4 (25.0)	5 (23.8)
Number of subjects with missing evaluation, n (%)	3 (18.8)	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		0.924
95% CI for the RR		(0.285, 2.990)
p-value for RR		0.8945

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 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-301-by.sas:t-hamd-remi-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Family History of PPD: 217-PPD-301 - ITT population

Page: 3 of 6

Family History of PPD = Yes

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =21)
Day 28		
Number of subjects with a response, n (%) [2]	4 (25.0)	8 (38.1)
Number of subjects with missing evaluation, n (%)	4 (25.0)	3 (14.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.478
95% CI for the RR		(0.520, 4.201)
p-value for RR		0.4638
Day 45		
Number of subjects with a response, n (%) [2]	5 (31.3)	9 (42.9)
Number of subjects with missing evaluation, n (%)	3 (18.8)	2 (9.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.330
95% CI for the RR		(0.525, 3.366)
p-value for RR		0.5473

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 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-301-by.sas:t-hamd-remi-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Family History of PPD: 217-PPD-301 - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=85)	Zuranolone (N =78)
Number of evaluable subjects [1]	82	77
Day 3		
Number of subjects with a response, n (%) [2]	3 (3.7)	7 (9.1)
Number of subjects with missing evaluation, n (%)	1 (1.2)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.486
95% CI for the RR		(0.666, 9.277)
p-value for RR		0.1752
Day 8		
Number of subjects with a response, n (%) [2]	8 (9.8)	13 (16.9)
Number of subjects with missing evaluation, n (%)	2 (2.4)	5 (6.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.731
95% CI for the RR		(0.759, 3.949)
p-value for RR		0.1920

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 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-301-by.sas:t-hamd-remi-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Family History of PPD: 217-PPD-301 - ITT population

Page: 5 of 6

Family History of PPD = No

Study Visit Statistics	Placebo (N=85)	Zuranolone (N =78)
Day 15		
Number of subjects with a response, n (%) [2]	12 (14.6)	19 (24.7)
Number of subjects with missing evaluation, n (%)	5 (6.1)	4 (5.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.687
95% CI for the RR		(0.878, 3.241)
p-value for RR		0.1164
Day 21		
Number of subjects with a response, n (%) [2]	13 (15.9)	20 (26.0)
Number of subjects with missing evaluation, n (%)	12 (14.6)	13 (16.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.639
95% CI for the RR		(0.877, 3.063)
p-value for RR		0.1214

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 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-301-by.sas:t-hamd-remi-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Family History of PPD: 217-PPD-301 - ITT population

Page: 6 of 6

Family History of PPD = No

Study Visit Statistics	Placebo (N=85)	Zuranolone (N =78)
Day 28		
Number of subjects with a response, n (%) [2]	16 (19.5)	18 (23.4)
Number of subjects with missing evaluation, n (%)	9 (11.0)	18 (23.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.199
95% CI for the RR		(0.660, 2.178)
p-value for RR		0.5521
Day 45		
Number of subjects with a response, n (%) [2]	20 (24.4)	28 (36.4)
Number of subjects with missing evaluation, n (%)	10 (12.2)	12 (15.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.492
95% CI for the RR		(0.921, 2.415)
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 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 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-301-by.sas:t-hamd-remi-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

2.1.3.1 .2 .2 .8 PPD in der Anamnese

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by History of PPD: 217-PPD-301 - ITT population

Page: 1 of 6

History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=90)	Zuranolone (N =82)
Number of evaluable subjects [1]	87	81
Day 3		
Number of subjects with a response, n (%) [2]	3 (3.4)	6 (7.4)
Number of subjects with missing evaluation, n (%)	2 (2.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.159
95% CI for the RR		(0.555, 8.397)
p-value for RR		0.2669
Day 8		
Number of subjects with a response, n (%) [2]	8 (9.2)	13 (16.0)
Number of subjects with missing evaluation, n (%)	3 (3.4)	5 (6.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.754
95% CI for the RR		(0.761, 4.041)
p-value for RR		0.1871

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 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-301-by.sas:t-hamd-remi-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by History of PPD: 217-PPD-301 - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=90)	Zuranolone (N =82)
Day 15		
Number of subjects with a response, n (%) [2]	12 (13.8)	21 (25.9)
Number of subjects with missing evaluation, n (%)	8 (9.2)	5 (6.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.889
95% CI for the RR		(0.991, 3.598)
p-value for RR		0.0531
Day 21		
Number of subjects with a response, n (%) [2]	13 (14.9)	21 (25.9)
Number of subjects with missing evaluation, n (%)	14 (16.1)	13 (16.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.744
95% CI for the RR		(0.935, 3.253)
p-value for RR		0.0806

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 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-301-by.sas:t-hamd-remi-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by History of PPD: 217-PPD-301 - ITT population

Page: 3 of 6

History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=90)	Zuranolone (N =82)
Day 28		
Number of subjects with a response, n (%) [2]	17 (19.5)	19 (23.5)
Number of subjects with missing evaluation, n (%)	13 (14.9)	21 (25.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.206
95% CI for the RR		(0.674, 2.158)
p-value for RR		0.5274
Day 45		
Number of subjects with a response, n (%) [2]	21 (24.1)	29 (35.8)
Number of subjects with missing evaluation, n (%)	12 (13.8)	13 (16.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.490
95% CI for the RR		(0.928, 2.395)
p-value for RR		0.0990

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 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-301-by.sas:t-hamd-remi-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by History of PPD: 217-PPD-301 - ITT population

Page: 4 of 6

History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=11)	Zuranolone (N =17)
Number of evaluable subjects [1]	11	17
Day 3		
Number of subjects with a response, n (%) [2]	2 (18.2)	2 (11.8)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.554
95% CI for the RR		(0.087, 3.524)
p-value for RR		0.5315
Day 8		
Number of subjects with a response, n (%) [2]	3 (27.3)	4 (23.5)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.739
95% CI for the RR		(0.204, 2.672)
p-value for RR		0.6442

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 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-301-by.sas:t-hamd-remi-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by History of PPD: 217-PPD-301 - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=11)	Zuranolone (N =17)
Day 15		
Number of subjects with a response, n (%) [2]	3 (27.3)	4 (23.5)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.739
95% CI for the RR		(0.189, 2.882)
p-value for RR		0.6626
Day 21		
Number of subjects with a response, n (%) [2]	4 (36.4)	4 (23.5)
Number of subjects with missing evaluation, n (%)	1 (9.1)	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		0.554
95% CI for the RR		(0.165, 1.864)
p-value for RR		0.3399

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 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-301-by.sas:t-hamd-remi-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by History of PPD: 217-PPD-301 - ITT population

Page: 6 of 6

History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=11)	Zuranolone (N =17)
Day 28		
Number of subjects with a response, n (%) [2]	3 (27.3)	7 (41.2)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.292
95% CI for the RR		(0.397, 4.212)
p-value for RR		0.6704
Day 45		
Number of subjects with a response, n (%) [2]	4 (36.4)	8 (47.1)
Number of subjects with missing evaluation, n (%)	1 (9.1)	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.108
95% CI for the RR		(0.401, 3.064)
p-value for RR		0.8436

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 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-301-by.sas:t-hamd-remi-301-by-hist-itta.rtf **Run Date:** 25JUL2025

2.1.3.1 .2 .2 .9 Depression mit Angst

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

Page: 1 of 6

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =24)
Number of evaluable subjects [1]	21	24
Day 3		
Number of subjects with a response, n (%) [2]	1 (4.8)	2 (8.3)
Number of subjects with missing evaluation, n (%)	1 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.677
95% CI for the RR		(0.160, 17.530)
p-value for RR		0.6661
Day 8		
Number of subjects with a response, n (%) [2]	1 (4.8)	5 (20.8)
Number of subjects with missing evaluation, n (%)	1 (4.8)	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		4.191
95% CI for the RR		(0.523, 33.611)
p-value for RR		0.1773

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 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-301-by.sas:t-hamd-remi-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

Page: 2 of 6

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =24)
Day 15		
Number of subjects with a response, n (%) [2]	4 (19.0)	8 (33.3)
Number of subjects with missing evaluation, n (%)	1 (4.8)	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.677
95% CI for the RR		(0.616, 4.560)
p-value for RR		0.3114
Day 21		
Number of subjects with a response, n (%) [2]	6 (28.6)	10 (41.7)
Number of subjects with missing evaluation, n (%)	3 (14.3)	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.397
95% CI for the RR		(0.681, 2.866)
p-value for RR		0.3617

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 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-301-by.sas:t-hamd-remi-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

Page: 3 of 6

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =24)
Day 28		
Number of subjects with a response, n (%) [2]	5 (23.8)	10 (41.7)
Number of subjects with missing evaluation, n (%)	2 (9.5)	5 (20.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.677
95% CI for the RR		(0.723, 3.886)
p-value for RR		0.2284
Day 45		
Number of subjects with a response, n (%) [2]	8 (38.1)	11 (45.8)
Number of subjects with missing evaluation, n (%)	1 (4.8)	3 (12.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.153
95% CI for the RR		(0.604, 2.198)
p-value for RR		0.6662

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 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-301-by.sas:t-hamd-remi-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

Study Visit Statistics	Placebo (N=77)	Zuranolone (N =74)
Number of evaluable subjects [1]	77	74
Day 3		
Number of subjects with a response, n (%) [2]	4 (5.2)	6 (8.1)
Number of subjects with missing evaluation, n (%)	1 (1.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.562
95% CI for the RR		(0.459, 5.318)
p-value for RR		0.4756
Day 8		
Number of subjects with a response, n (%) [2]	10 (13.0)	12 (16.2)
Number of subjects with missing evaluation, n (%)	2 (2.6)	4 (5.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.250
95% CI for the RR		(0.574, 2.719)
p-value for RR		0.5744

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 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-301-by.sas:t-hamd-remi-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

Study Visit Statistics	Placebo (N=77)	Zuranolone (N =74)
Day 15		
Number of subjects with a response, n (%) [2]	11 (14.3)	17 (23.0)
Number of subjects with missing evaluation, n (%)	7 (9.1)	4 (5.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.609
95% CI for the RR		(0.808, 3.205)
p-value for RR		0.1760
Day 21		
Number of subjects with a response, n (%) [2]	11 (14.3)	15 (20.3)
Number of subjects with missing evaluation, n (%)	12 (15.6)	13 (17.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.420
95% CI for the RR		(0.697, 2.891)
p-value for RR		0.3337

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 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-301-by.sas:t-hamd-remi-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Depression (HAMD-17) Remission by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

Page: 6 of 6

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

Study Visit Statistics	Placebo (N=77)	Zuranolone (N =74)
Day 28		
Number of subjects with a response, n (%) [2]	15 (19.5)	16 (21.6)
Number of subjects with missing evaluation, n (%)	11 (14.3)	16 (21.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.111
95% CI for the RR		(0.592, 2.083)
p-value for RR		0.7434
Day 45		
Number of subjects with a response, n (%) [2]	17 (22.1)	26 (35.1)
Number of subjects with missing evaluation, n (%)	12 (15.6)	11 (14.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.593
95% CI for the RR		(0.945, 2.685)
p-value for RR		0.0808

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 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.

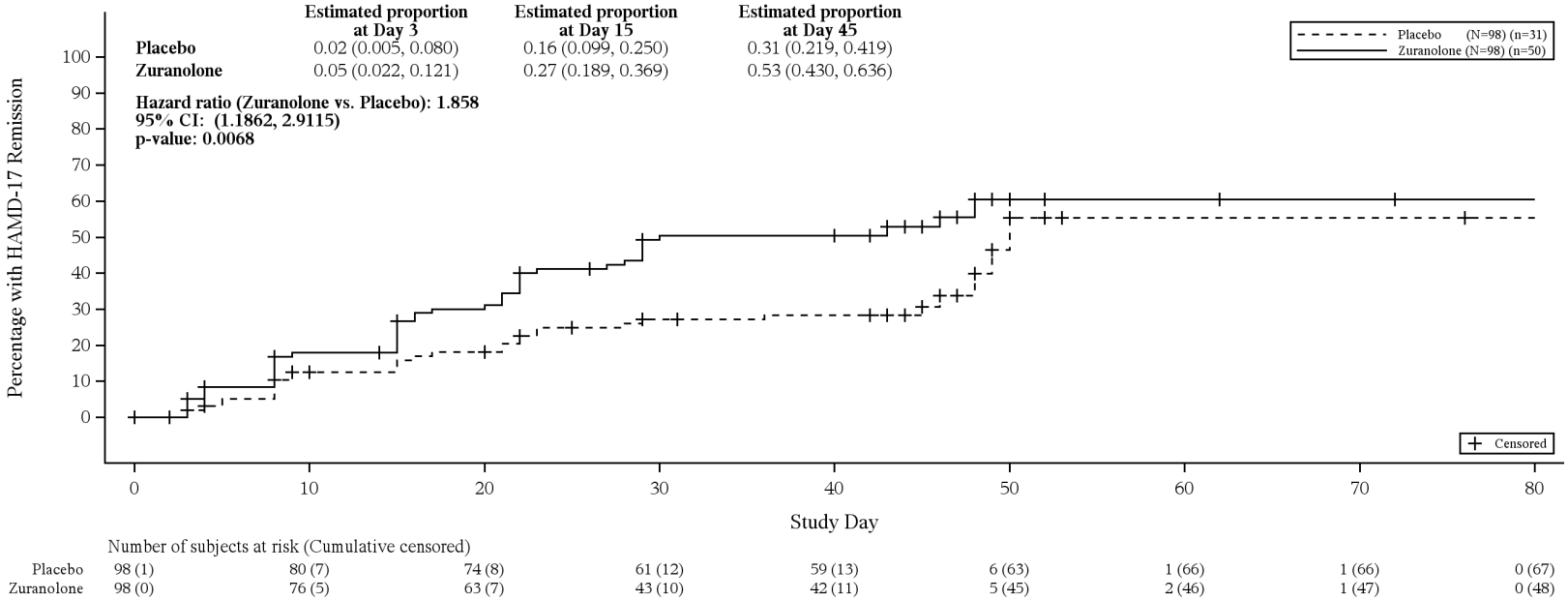
Source: biib125/v_a/germany_amnog/t-hamd-remi-301-by.sas:t-hamd-remi-301-by-hama-itta.rtf **Run Date:** 25JUL2025

2.1.3.2 TTE-Analysen

2.1.3.2 .1 ITT-Population

Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission: 217-PPD-301 - ITT population

Page: 1 of 1



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-301-ovr.sas:f-hamd-remi-tte-301-ovr-itta.rtf **Run Date:** 16DEC2025

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission: 217-PPD-301 - ITT population

Page: 1 of 1

	Placebo (N=101)	Zuranolone (N=99)
Number of evaluable subjects [1]	98	98
Number of subjects with response, n (%) [2]	31 (31.6)	50 (51.0)
Time to first HAMD-17 remission (days) [3]		
25th percentile - Q1 (95% CI)	28.0 (15.0 , 48.0)	15.0 (8.0 , 21.0)
50th percentile - median (95% CI)	50.0 (48.0, NE)	30.0 (22.0, NE)
75th percentile - Q3 (95% CI)	NE (50.0, NE)	NE (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.858
95% CI for the HR		(1.1862 , 2.9115)
p-value for the HR		0.0068

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-301-ovr.sas:t-hamd-remi-tte-301-ovr-itta.rtf **Run Date:** 18JUL2025

2.1.3.2 .2 Subgruppen

2.1.3.2 .2 .1 Interaktionstest

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission: Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

Page: 1 of 2

Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	98	98	
Number of subjects with response, n (%)	31 (31.6)	50 (51.0)	
Age Group (years)			
18 - 24, n / N (%)	5/12 (41.7)	13/19 (68.4)	0.9870
25 - 45, n / N (%)	26/86 (30.2)	37/79 (46.8)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	8/32 (25.0)	16/33 (48.5)	0.6450
>=28, n / N (%)	23/66 (34.8)	34/65 (52.3)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	3/18 (16.7)	13/25 (52.0)	0.2210
White, n / N (%)	26/69 (37.7)	36/68 (52.9)	
Antidepressant Use at Baseline			
Yes, n / N (%)	7/15 (46.7)	7/15 (46.7)	0.2797
No, n / N (%)	24/83 (28.9)	43/83 (51.8)	

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-301-int.sas:t-hamd-remi-tte-301-int-itta.rtf **Run Date:** 18JUL2025

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission: Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9, n / N (%)	8/22 (36.4)	8/20 (40.0)	0.2649(a)
25-29.9, n / N (%)	11/34 (32.4)	14/24 (58.3)	0.4575(b)
>=30, n / N (%)	12/42 (28.6)	27/53 (50.9)	0.6204(c)
Onset of PPD			
3rd Trimester, n / N (%)	9/31 (29.0)	17/34 (50.0)	0.8219
Postpartum, n / N (%)	22/67 (32.8)	33/64 (51.6)	
Family History of PPD			
Yes, n / N (%)	6/16 (37.5)	10/21 (47.6)	0.3455
No/Unknown, n / N (%)	25/82 (30.5)	40/77 (51.9)	
History of PPD			
1st Episode, n / N (%)	26/87 (29.9)	41/81 (50.6)	0.3863
Recurrent Episode, n / N (%)	5/11 (45.5)	9/17 (52.9)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	8/21 (38.1)	14/24 (58.3)	0.9721
>=20, n / N (%)	23/77 (29.9)	36/74 (48.6)	

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-301-int.sas:t-hamd-remi-tte-301-int-itta.rtf **Run Date:** 18JUL2025

2.1.3.2 .2 .2 Subgruppenanalysen

2.1.3.2 .2 .2 .1 Alter

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission by Age Group: 217-PPD-301 - ITT population

Page: 1 of 2

Age Group (years) = 18-24

	Placebo (N=13)	Zuranolone (N=19)
Number of evaluable subjects [1]	12	19
Number of subjects with response, n (%) [2]	5 (41.7)	13 (68.4)
Time to first HAMD-17 remission (days) [3]		
25th percentile - Q1 (95% CI)	9.0 (5.0, NE)	8.0 (3.0 , 16.0)
50th percentile - median (95% CI)	NE (8.0, NE)	16.0 (8.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (16.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.105
95% CI for the HR		(0.6434 , 6.8857)
p-value for the HR		0.2184

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-301-by.sas:t-hamd-remi-tte-301-by-age-itta.rtf **Run Date:** 25JUL2025

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission by Age Group: 217-PPD-301 - ITT population

Page: 2 of 2

Age Group (years) = 25-45

	Placebo (N=88)	Zuranolone (N=80)
Number of evaluable subjects [1]	86	79
Number of subjects with response, n (%) [2]	26 (30.2)	37 (46.8)
Time to first HAMD-17 remission (days) [3]		
25th percentile - Q1 (95% CI)	29.0 (21.0 , 49.0)	20.0 (9.0 , 22.0)
50th percentile - median (95% CI)	50.0 (48.0, NE)	46.0 (27.0, NE)
75th percentile - Q3 (95% CI)	NE (50.0, NE)	NE (48.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.824
95% CI for the HR		(1.1020 , 3.0189)
p-value for the HR		0.0194

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-301-by.sas:t-hamd-remi-tte-301-by-age-itta.rtf **Run Date:** 25JUL2025

2.1.3.2 .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-301 - ITT population

Page: 1 of 2

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

	Placebo (N=32)	Zuranolone (N=33)
Number of evaluable subjects [1]	32	33
Number of subjects with response, n (%) [2]	8 (25.0)	16 (48.5)
Time to first HAMD-17 remission (days) [3]		
25th percentile - Q1 (95% CI)	36.0 (8.0, NE)	18.0 (8.0 , 27.0)
50th percentile - median (95% CI)	NE (NE, NE)	30.0 (22.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.174
95% CI for the HR		(0.9274 , 5.0963)
p-value for the HR		0.0740

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-301-by.sas:t-hamd-remi-tte-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline HAMD-17 Total Score: 217-PPD-301 - ITT population

Page: 2 of 2

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

	Placebo (N=66)	Zuranolone (N=65)
Number of evaluable subjects [1]	66	65
Number of subjects with response, n (%) [2]	23 (34.8)	34 (52.3)
Time to first HAMD-17 remission (days) [3]		
25th percentile - Q1 (95% CI)	22.0 (9.0 , 48.0)	15.0 (8.0 , 21.0)
50th percentile - median (95% CI)	49.0 (46.0, NE)	29.0 (21.0, NE)
75th percentile - Q3 (95% CI)	50.0 (48.0, NE)	NE (48.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.696
95% CI for the HR		(0.9967 , 2.8846)
p-value for the HR		0.0514

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-301-by.sas:t-hamd-remi-tte-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

2.1.3.2 .2 .2 .3 Abstammung

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission by Race Group: 217-PPD-301 - ITT population

Page: 1 of 2

Race Group = Black or African American

	Placebo (N=20)	Zuranolone (N=26)
Number of evaluable subjects [1]	18	25
Number of subjects with response, n (%) [2]	3 (16.7)	13 (52.0)
Time to first HAMD-17 remission (days) [3]		
25th percentile - Q1 (95% CI)	NE (8.0, NE)	9.0 (3.0 , 29.0)
50th percentile - median (95% CI)	NE (23.0, NE)	43.0 (15.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (43.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		5.115
95% CI for the HR		(1.3515 , 19.3561)
p-value for the HR		0.0162

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-301-by.sas:t-hamd-remi-tte-301-by-race-itta.rtf **Run Date:** 25JUL2025

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission by Race Group: 217-PPD-301 - ITT population

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Race Group = White

	Placebo (N=70)	Zuranolone (N=68)
Number of evaluable subjects [1]	69	68
Number of subjects with response, n (%) [2]	26 (37.7)	36 (52.9)
Time to first HAMD-17 remission (days) [3]		
25th percentile - Q1 (95% CI)	22.0 (9.0 , 45.0)	15.0 (8.0 , 22.0)
50th percentile - median (95% CI)	49.0 (46.0, NE)	29.0 (22.0, NE)
75th percentile - Q3 (95% CI)	NE (49.0, NE)	NE (48.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.594
95% CI for the HR		(0.9600 , 2.6462)
p-value for the HR		0.0715

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-301-by.sas:t-hamd-remi-tte-301-by-race-itta.rtf **Run Date:** 25JUL2025

2.1.3.2 .2 .2 .4 Antidepressiva-Nutzung

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline Antidepressant Use: 217-PPD-301 - ITT population

Page: 1 of 2

Antidepressant Use at Baseline = Yes

	Placebo (N=15)	Zuranolone (N=15)
Number of evaluable subjects [1]	15	15
Number of subjects with response, n (%) [2]	7 (46.7)	7 (46.7)
Time to first HAMD-17 remission (days) [3]		
25th percentile - Q1 (95% CI)	17.0 (8.0 , 29.0)	8.0 (3.0 , 22.0)
50th percentile - median (95% CI)	NE (15.0, NE)	NE (8.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.414
95% CI for the HR		(0.4560 , 4.3823)
p-value for the HR		0.5488

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-301-by.sas:t-hamd-remi-tte-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline Antidepressant Use: 217-PPD-301 - ITT population

Page: 2 of 2

Antidepressant Use at Baseline = No

	Placebo (N=86)	Zuranolone (N=84)
Number of evaluable subjects [1]	83	83
Number of subjects with response, n (%) [2]	24 (28.9)	43 (51.8)
Time to first HAMD-17 remission (days) [3]		
25th percentile - Q1 (95% CI)	45.0 (15.0 , 49.0)	15.0 (9.0 , 22.0)
50th percentile - median (95% CI)	50.0 (48.0, NE)	30.0 (22.0, NE)
75th percentile - Q3 (95% CI)	NE (50.0, NE)	NE (48.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.098
95% CI for the HR		(1.2718 , 3.4613)
p-value for the HR		0.0037

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-301-by.sas:t-hamd-remi-tte-301-by-adt-itta.rtf **Run Date:** 25JUL2025

2.1.3.2 .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-301 - ITT population

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

	Placebo (N=22)	Zuranolone (N=20)
Number of evaluable subjects [1]	22	20
Number of subjects with response, n (%) [2]	8 (36.4)	8 (40.0)
Time to first HAMD-17 remission (days) [3]		
25th percentile - Q1 (95% CI)	22.0 (3.0, NE)	15.0 (3.0 , 30.0)
50th percentile - median (95% CI)	NE (22.0, NE)	NE (15.0, NE)
75th percentile - Q3 (95% CI)	NE (45.0, NE)	NE (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.261
95% CI for the HR		(0.4692 , 3.3902)
p-value for the HR		0.6455

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-301-by.sas:t-hamd-remi-tte-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline BMI (kg/m^2) Group: 217-PPD-301 - ITT population

Page: 2 of 3

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

	Placebo (N=34)	Zuranolone (N=24)
Number of evaluable subjects [1]	34	24
Number of subjects with response, n (%) [2]	11 (32.4)	14 (58.3)
Time to first HAMD-17 remission (days) [3]		
25th percentile - Q1 (95% CI)	29.0 (15.0 , 49.0)	16.0 (3.0 , 22.0)
50th percentile - median (95% CI)	49.0 (46.0, NE)	22.0 (16.0, NE)
75th percentile - Q3 (95% CI)	NE (48.0, NE)	NE (28.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		3.207
95% CI for the HR		(1.3140 , 7.8292)
p-value for the HR		0.0105

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-301-by.sas:t-hamd-remi-tte-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission by Baseline BMI (kg/m^2) Group: 217-PPD-301 - ITT population

Page: 3 of 3

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

	Placebo (N=42)	Zuranolone (N=53)
Number of evaluable subjects [1]	42	53
Number of subjects with response, n (%) [2]	12 (28.6)	27 (50.9)
Time to first HAMD-17 remission (days) [3]		
25th percentile - Q1 (95% CI)	23.0 (8.0, NE)	15.0 (8.0 , 22.0)
50th percentile - median (95% CI)	NE (50.0, NE)	46.0 (22.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (48.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.867
95% CI for the HR		(0.9425 , 3.6988)
p-value for the HR		0.0734

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-301-by.sas:t-hamd-remi-tte-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

2.1.3.2 .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-301 - ITT population

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Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=35)
Number of evaluable subjects [1]	31	34
Number of subjects with response, n (%) [2]	9 (29.0)	17 (50.0)
Time to first HAMD-17 remission (days) [3]		
25th percentile - Q1 (95% CI)	21.0 (5.0, NE)	15.0 (3.0 , 23.0)
50th percentile - median (95% CI)	50.0 (29.0, NE)	29.0 (21.0, NE)
75th percentile - Q3 (95% CI)	NE (50.0, NE)	NE (46.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.985
95% CI for the HR		(0.8786 , 4.4845)
p-value for the HR		0.0992

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-301-by.sas:t-hamd-remi-tte-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission by Onset of PPD: 217-PPD-301 - ITT population

Page: 2 of 2

Onset of PPD = Postpartum

	Placebo (N=69)	Zuranolone (N=64)
Number of evaluable subjects [1]	67	64
Number of subjects with response, n (%) [2]	22 (32.8)	33 (51.6)
Time to first HAMD-17 remission (days) [3]		
25th percentile - Q1 (95% CI)	28.0 (15.0 , 48.0)	15.0 (8.0 , 21.0)
50th percentile - median (95% CI)	49.0 (46.0, NE)	43.0 (22.0, NE)
75th percentile - Q3 (95% CI)	NE (49.0, NE)	NE (48.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.790
95% CI for the HR		(1.0422 , 3.0761)
p-value for the HR		0.0349

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-301-by.sas:t-hamd-remi-tte-301-by-onset-itta.rtf **Run Date:** 25JUL2025

2.1.3.2 .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-301 - ITT population

Page: 1 of 2

Family History of PPD = Yes

	Placebo (N=16)	Zuranolone (N=21)
Number of evaluable subjects [1]	16	21
Number of subjects with response, n (%) [2]	6 (37.5)	10 (47.6)
Time to first HAMD-17 remission (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (3.0, NE)	15.0 (3.0 , 29.0)
50th percentile - median (95% CI)	49.0 (8.0, NE)	30.0 (15.0, NE)
75th percentile - Q3 (95% CI)	49.0 (NE, NE)	NE (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.114
95% CI for the HR		(0.3940 , 3.1516)
p-value for the HR		0.8383

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-301-by.sas:t-hamd-remi-tte-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission by Family History of PPD: 217-PPD-301 - ITT population

Page: 2 of 2

Family History of PPD = No/Unknown

	Placebo (N=85)	Zuranolone (N=78)
Number of evaluable subjects [1]	82	77
Number of subjects with response, n (%) [2]	25 (30.5)	40 (51.9)
Time to first HAMD-17 remission (days) [3]		
25th percentile - Q1 (95% CI)	29.0 (16.0 , 48.0)	15.0 (8.0 , 22.0)
50th percentile - median (95% CI)	NE (48.0, NE)	29.0 (22.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (48.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.035
95% CI for the HR		(1.2339 , 3.3573)
p-value for the HR		0.0054

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-301-by.sas:t-hamd-remi-tte-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

2.1.3.2 .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-301 - ITT population

Page: 1 of 2

History of PPD = 1st Episode

	Placebo (N=90)	Zuranolone (N=82)
Number of evaluable subjects [1]	87	81
Number of subjects with response, n (%) [2]	26 (29.9)	41 (50.6)
Time to first HAMD-17 remission (days) [3]		
25th percentile - Q1 (95% CI)	29.0 (16.0 , 48.0)	15.0 (8.0 , 21.0)
50th percentile - median (95% CI)	NE (48.0, NE)	30.0 (22.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (48.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.013
95% CI for the HR		(1.2290 , 3.2978)
p-value for the HR		0.0055

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-301-by.sas:t-hamd-remi-tte-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission by History of PPD: 217-PPD-301 - ITT population

Page: 2 of 2

History of PPD = Recurrent Episode

	Placebo (N=11)	Zuranolone (N=17)
Number of evaluable subjects [1]	11	17
Number of subjects with response, n (%) [2]	5 (45.5)	9 (52.9)
Time to first HAMD-17 remission (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (4.0, NE)	16.0 (3.0 , 29.0)
50th percentile - median (95% CI)	50.0 (5.0, NE)	43.0 (8.0, NE)
75th percentile - Q3 (95% CI)	50.0 (NE, NE)	NE (43.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.266
95% CI for the HR		(0.3540 , 4.5244)
p-value for the HR		0.7171

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-301-by.sas:t-hamd-remi-tte-301-by-hist-itta.rtf **Run Date:** 25JUL2025

2.1.3.2 .2 .2 .9 Depression mit Angst

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

Page: 1 of 2

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

	Placebo (N=21)	Zuranolone (N=24)
Number of evaluable subjects [1]	21	24
Number of subjects with response, n (%) [2]	8 (38.1)	14 (58.3)
Time to first HAMD-17 remission (days) [3]		
25th percentile - Q1 (95% CI)	21.5 (5.0, NE)	15.0 (3.0 , 21.0)
50th percentile - median (95% CI)	NE (21.0, NE)	29.0 (15.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (29.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.009
95% CI for the HR		(0.7874 , 5.1245)
p-value for the HR		0.1443

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-301-by.sas:t-hamd-remi-tte-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

Page: 2 of 2

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

	Placebo (N=77)	Zuranolone (N=74)
Number of evaluable subjects [1]	77	74
Number of subjects with response, n (%) [2]	23 (29.9)	36 (48.6)
Time to first HAMD-17 remission (days) [3]		
25th percentile - Q1 (95% CI)	29.0 (15.0 , 49.0)	16.0 (8.0 , 22.0)
50th percentile - median (95% CI)	50.0 (48.0, NE)	43.0 (22.0, NE)
75th percentile - Q3 (95% CI)	NE (50.0, NE)	NE (48.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.844
95% CI for the HR		(1.0917 , 3.1156)
p-value for the HR		0.0221

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.

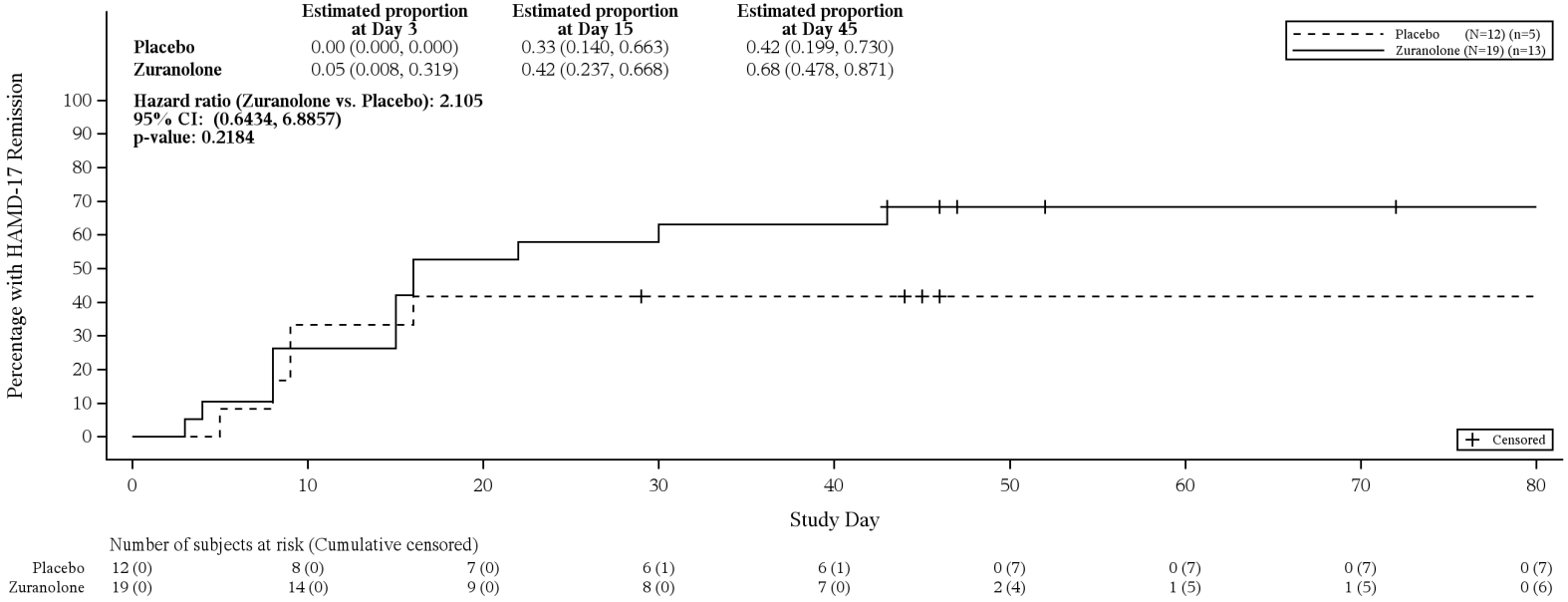
Source: biib125/v_a/germany_amnog/t-hamd-remi-tte-301-by.sas:t-hamd-remi-tte-301-by-hama-itta.rtf **Run Date:** 25JUL2025

2.1.3.2 .2 .3 Kaplan-Meier-Plots

Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Depression (HAMD-17) Remission by Subgroup: 217-PPD-301 - ITT population

Page: 1 of 19

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.

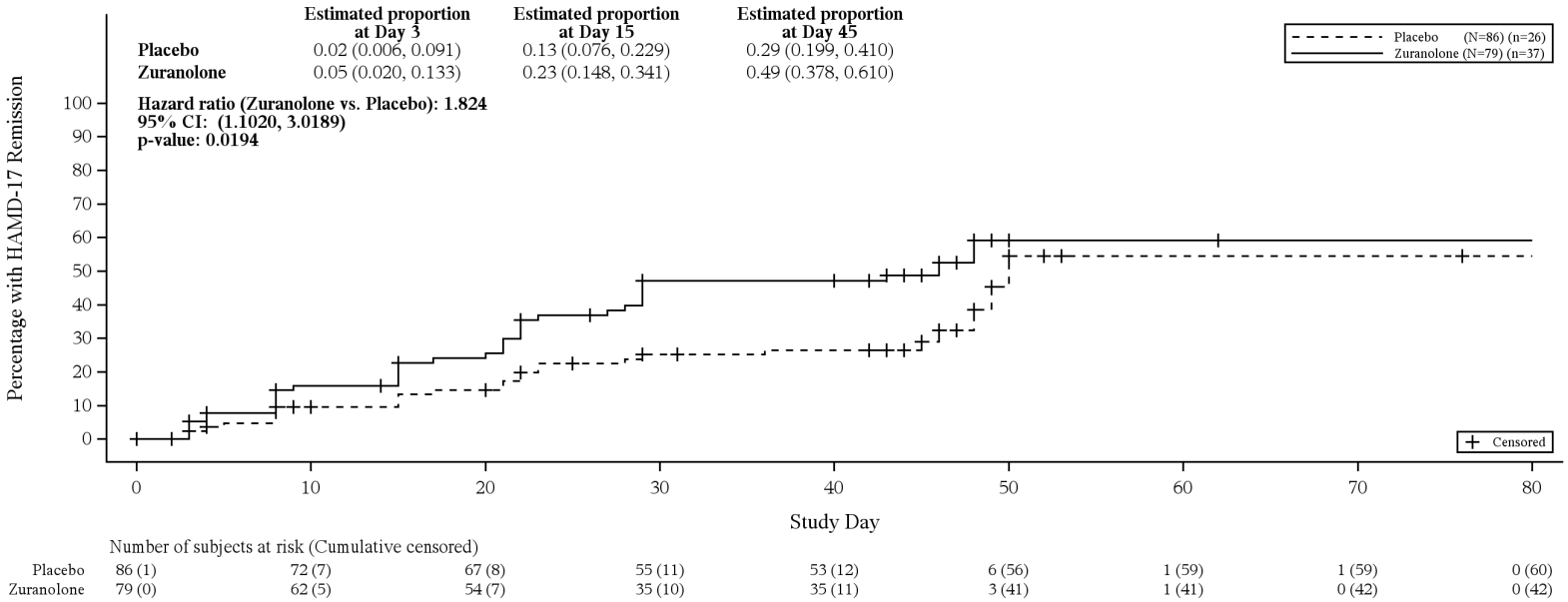
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-remi-tte-301-by.sas:f-hamd-remi-tte-301-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-301 - ITT population

Page: 2 of 19

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.

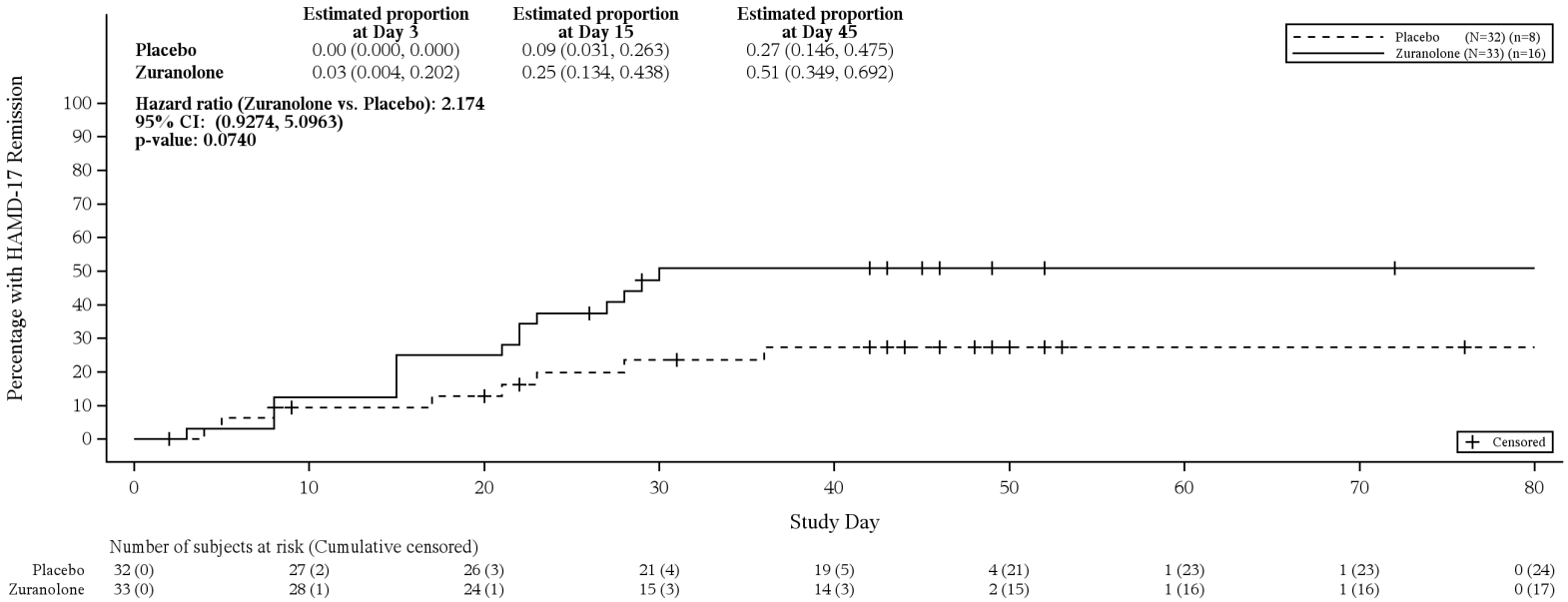
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-remi-tte-301-by.sas:f-hamd-remi-tte-301-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-301 - 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	32 (0)	27 (2)	26 (3)	21 (4)	19 (5)	4 (21)	1 (23)	1 (23)	0 (24)
Zuranolone	33 (0)	28 (1)	24 (1)	15 (3)	14 (3)	2 (15)	1 (16)	1 (16)	0 (17)

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.

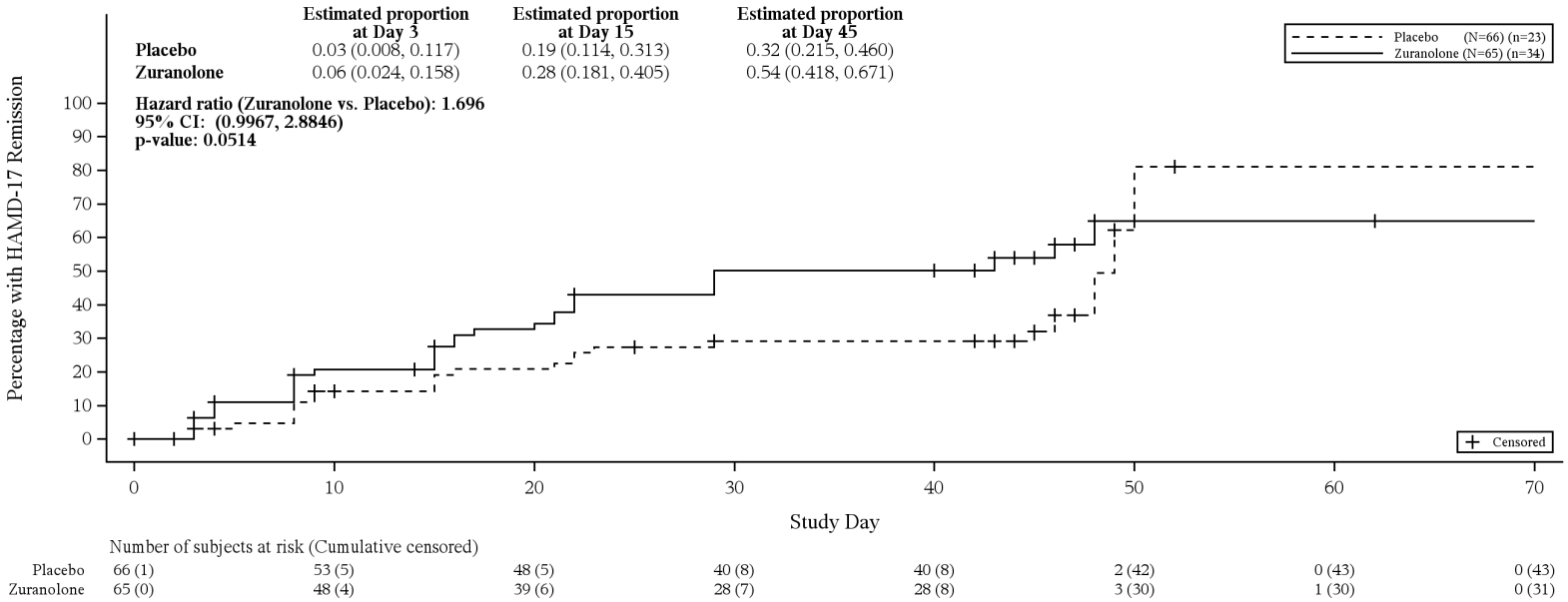
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-remi-tte-301-by.sas:f-hamd-remi-tte-301-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-301 - 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 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.

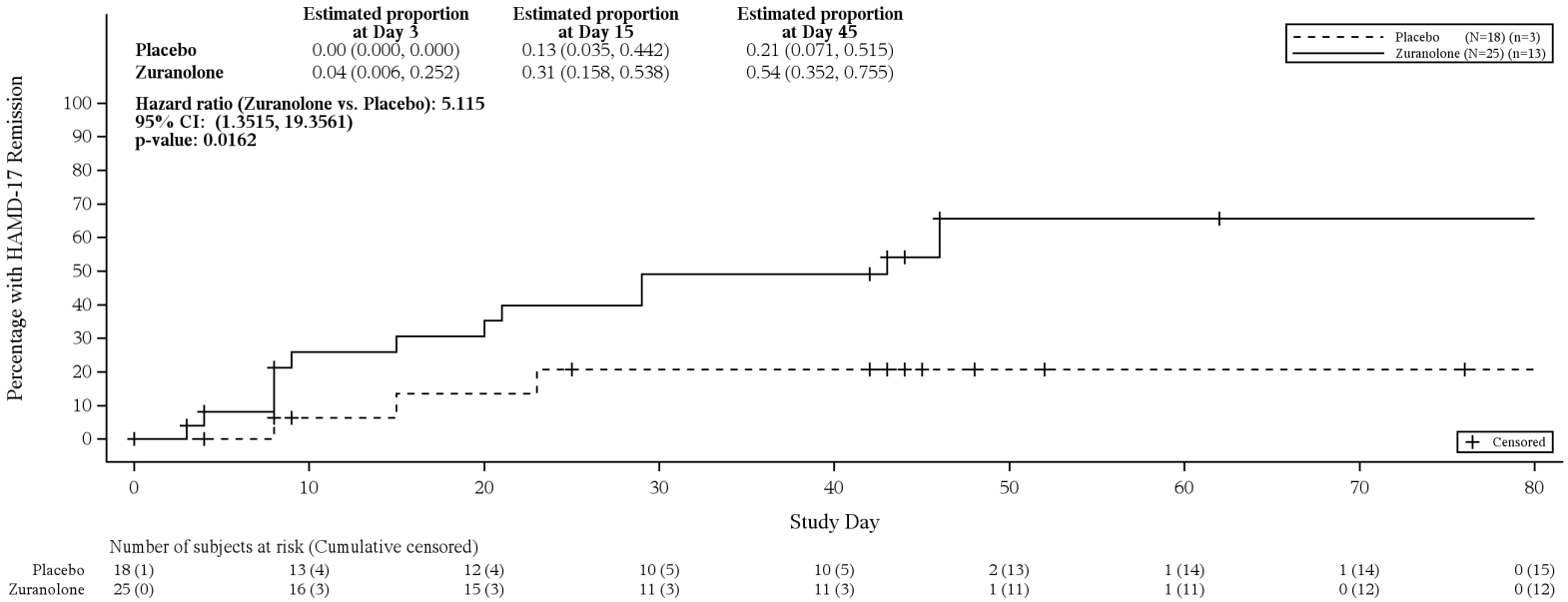
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-remi-tte-301-by.sas:f-hamd-remi-tte-301-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-301 - ITT population

Page: 5 of 19

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.

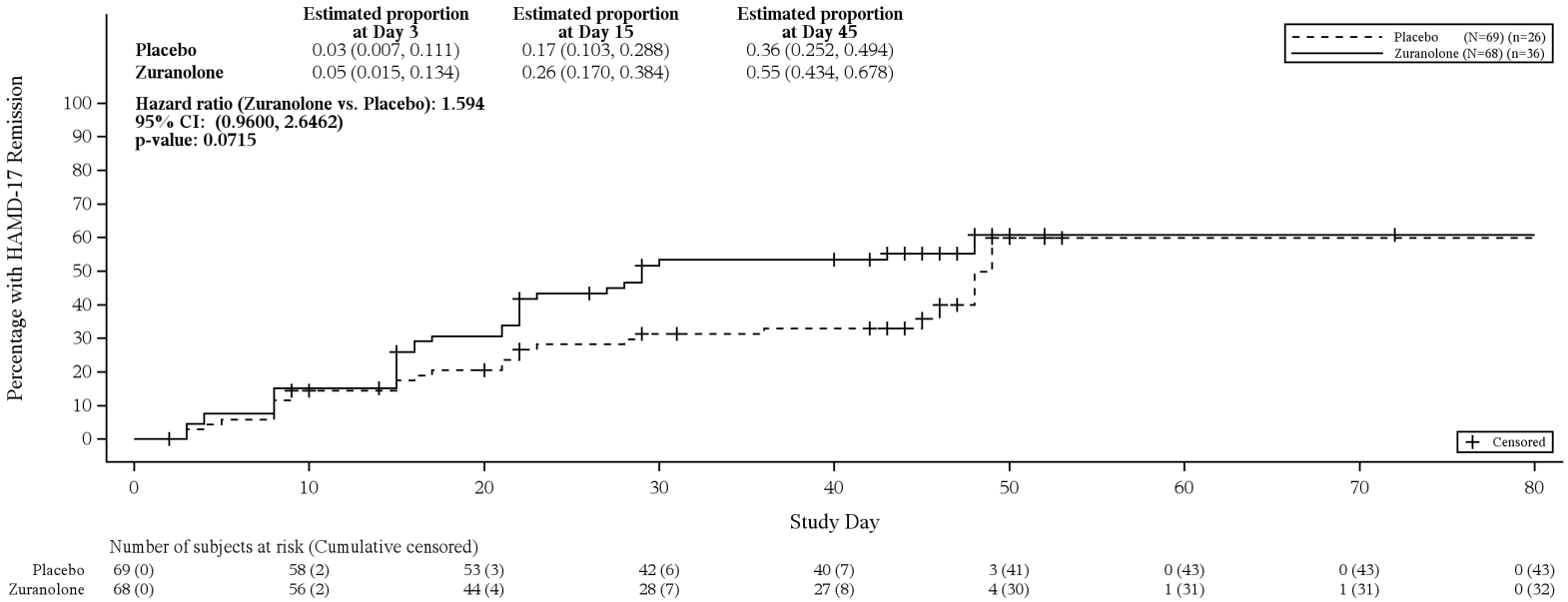
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-remi-tte-301-by.sas:f-hamd-remi-tte-301-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-301 - ITT population

Page: 6 of 19

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.

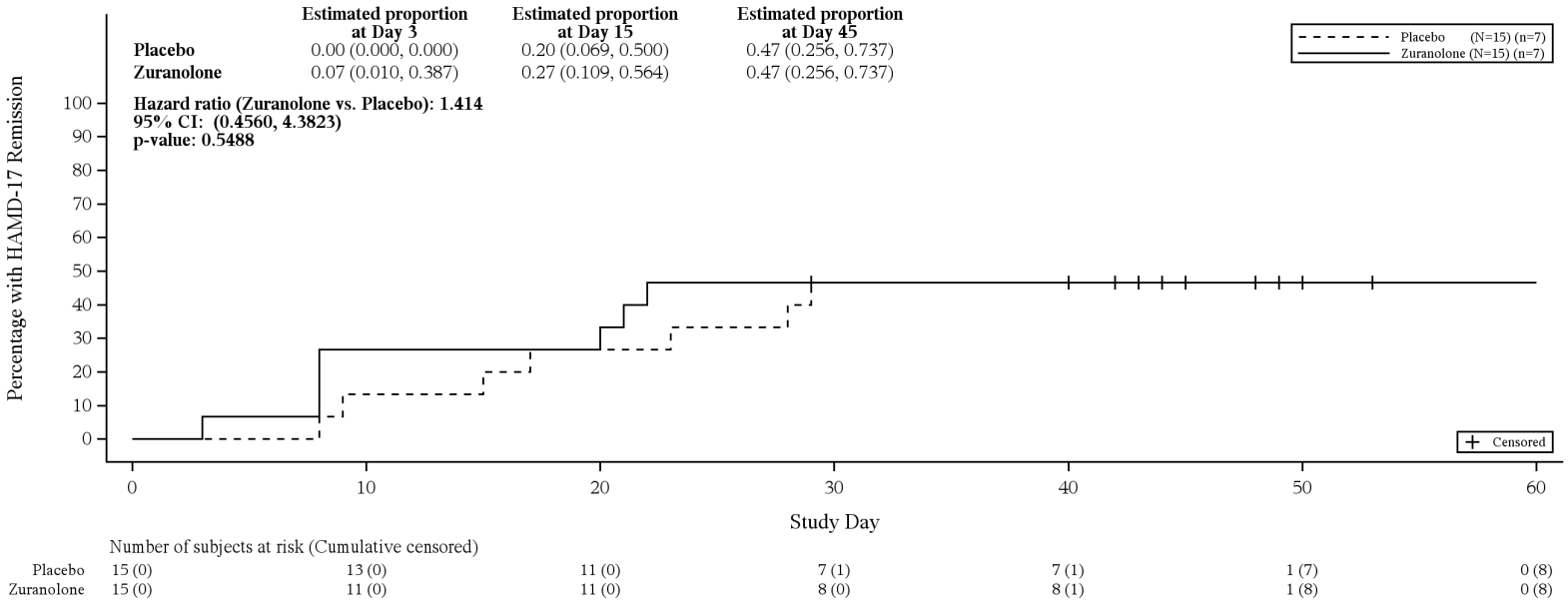
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-remi-tte-301-by.sas:f-hamd-remi-tte-301-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-301 - ITT population

Page: 7 of 19

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.

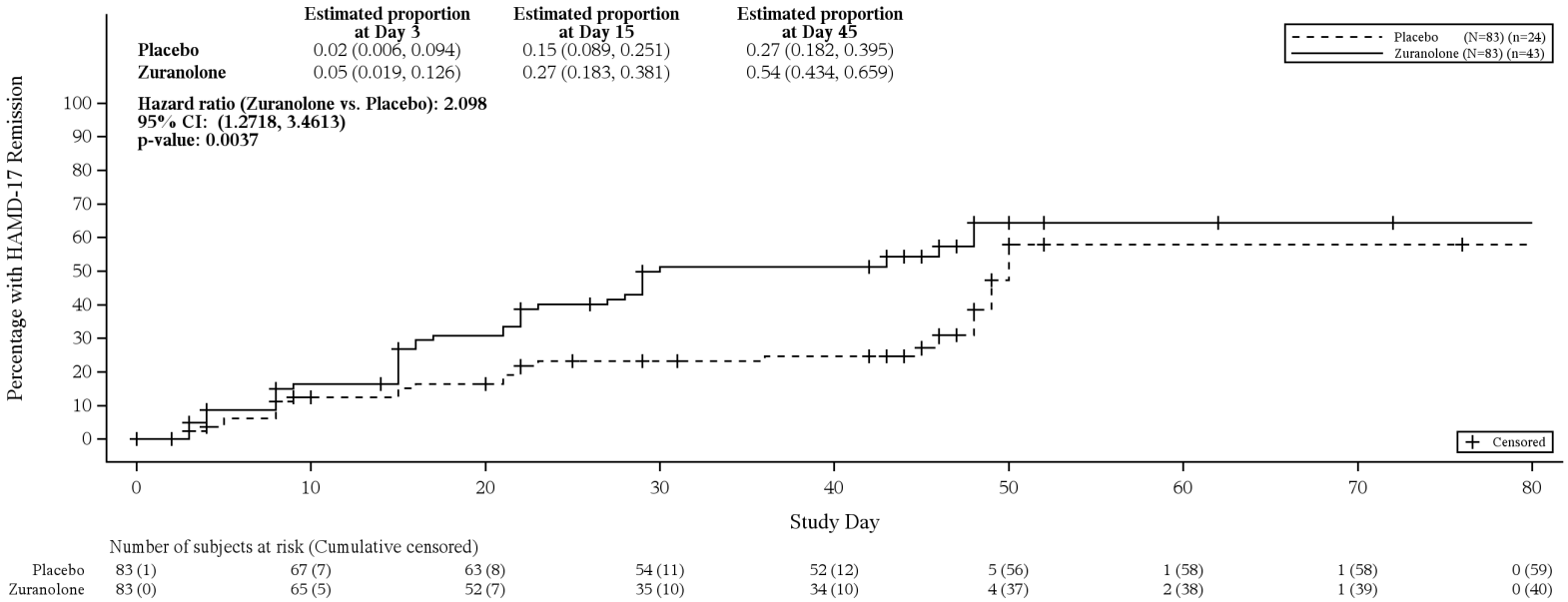
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-remi-tte-301-by.sas:f-hamd-remi-tte-301-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-301 - ITT population

Page: 8 of 19

Antidepressant Use at Baseline = No



Number of subjects at risk (Cumulative censored)

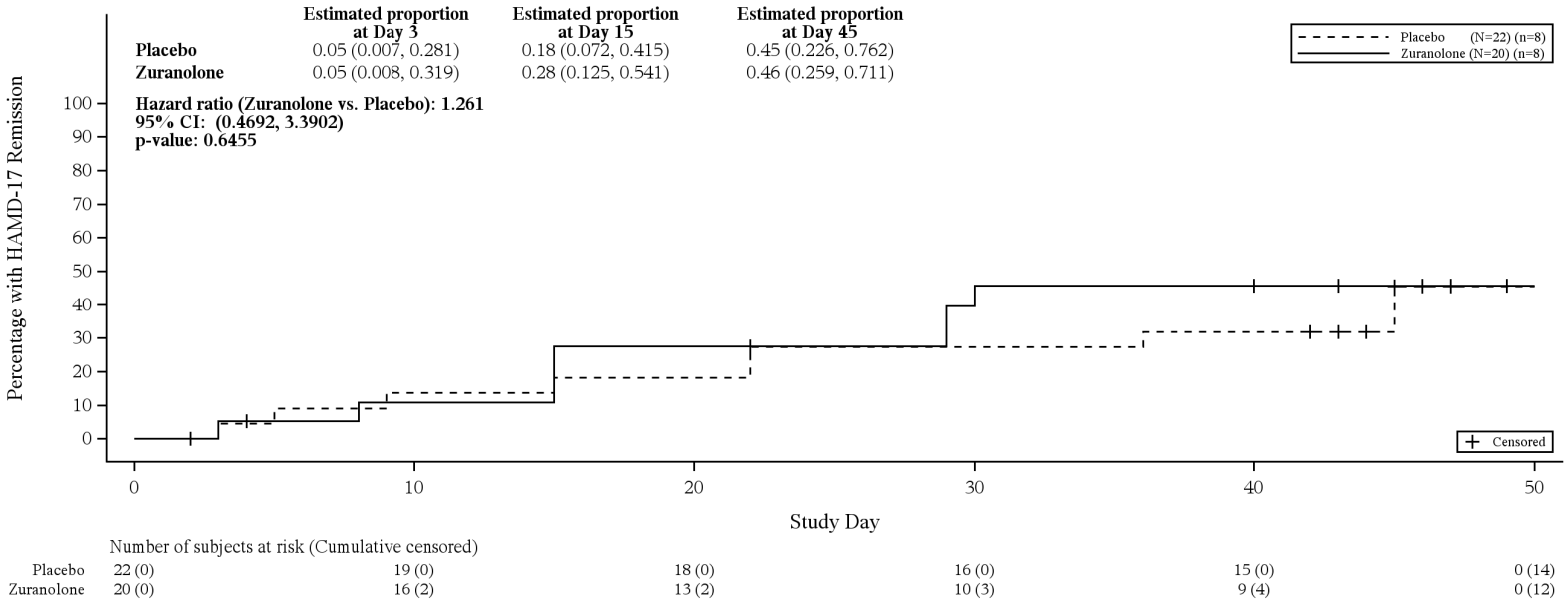
Placebo	83 (1)	67 (7)	63 (8)	54 (11)	52 (12)	5 (56)	1 (58)	1 (58)	0 (59)
Zuranolone	83 (0)	65 (5)	52 (7)	35 (10)	34 (10)	4 (37)	2 (38)	1 (39)	0 (40)

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-301-by.sas:f-hamd-remi-tte-301-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-301 - 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 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.

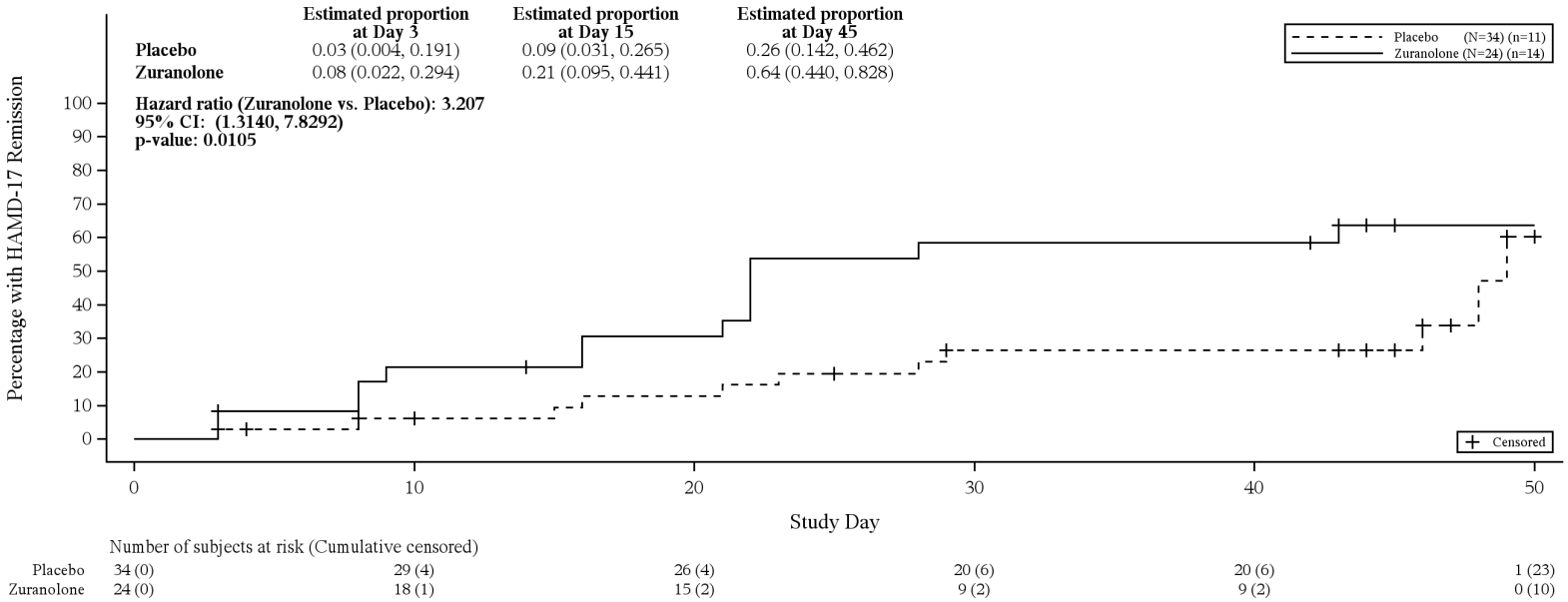
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-remi-tte-301-by.sas:f-hamd-remi-tte-301-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-301 - ITT population

Page: 10 of 19

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.

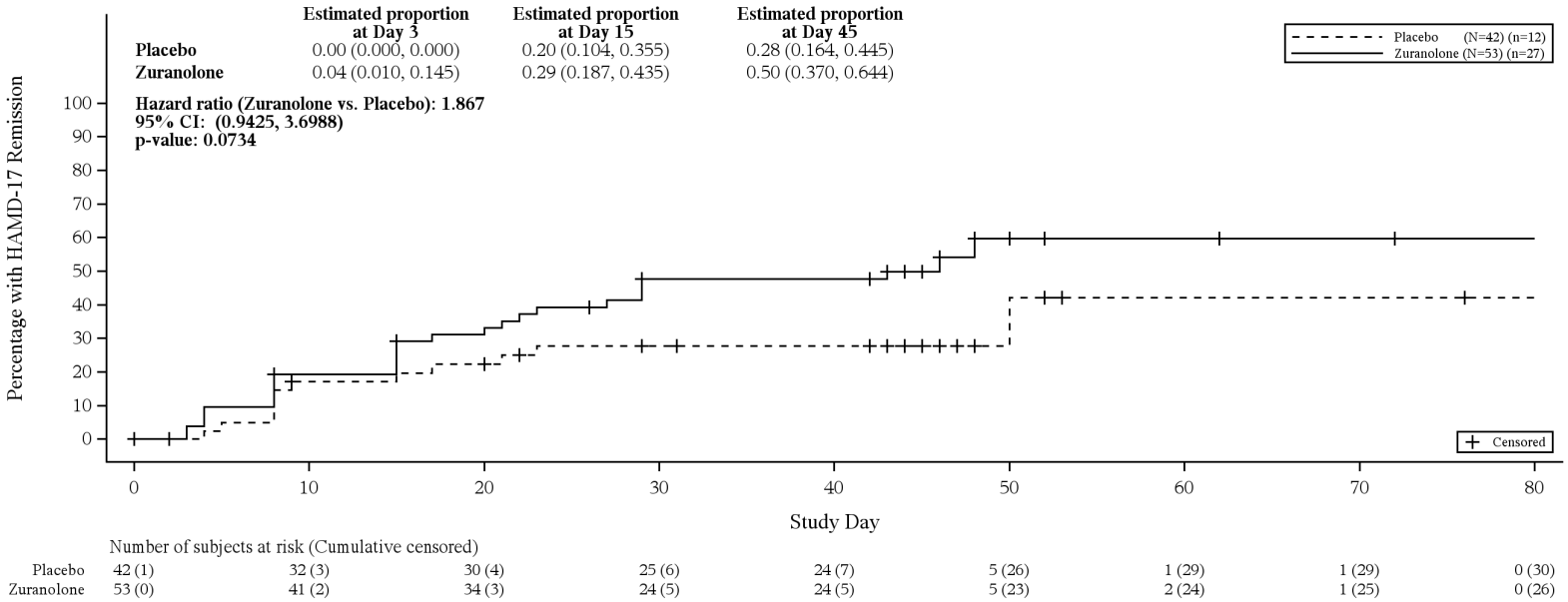
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-remi-tte-301-by.sas:f-hamd-remi-tte-301-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-301 - ITT population

Page: 11 of 19

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.

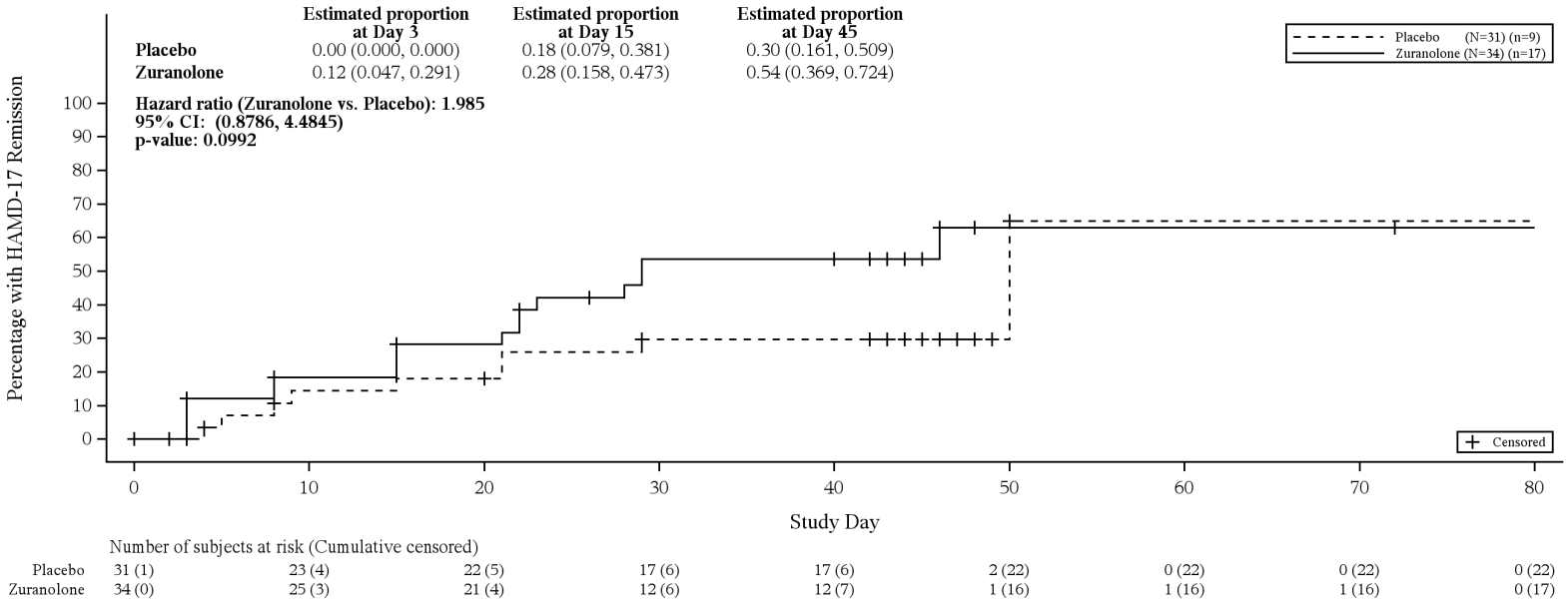
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-remi-tte-301-by.sas:f-hamd-remi-tte-301-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-301 - 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.

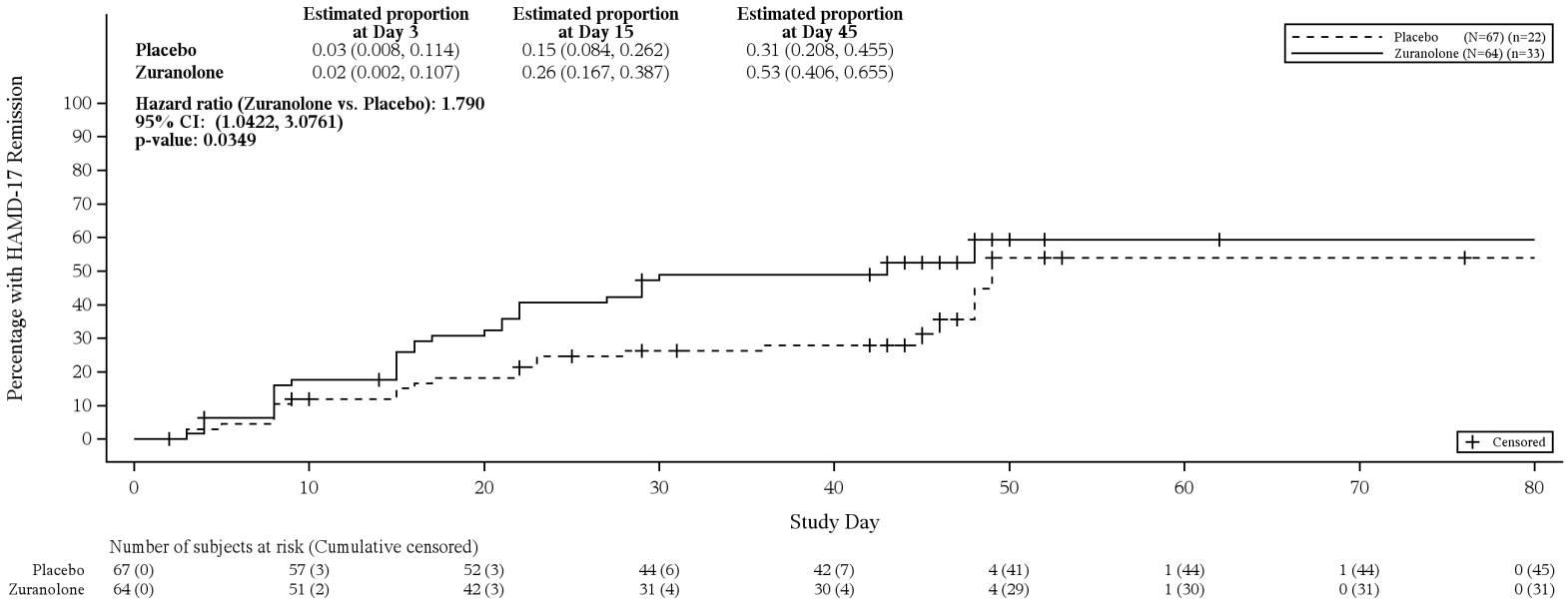
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-remi-tte-301-by.sas:f-hamd-remi-tte-301-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-301 - 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.

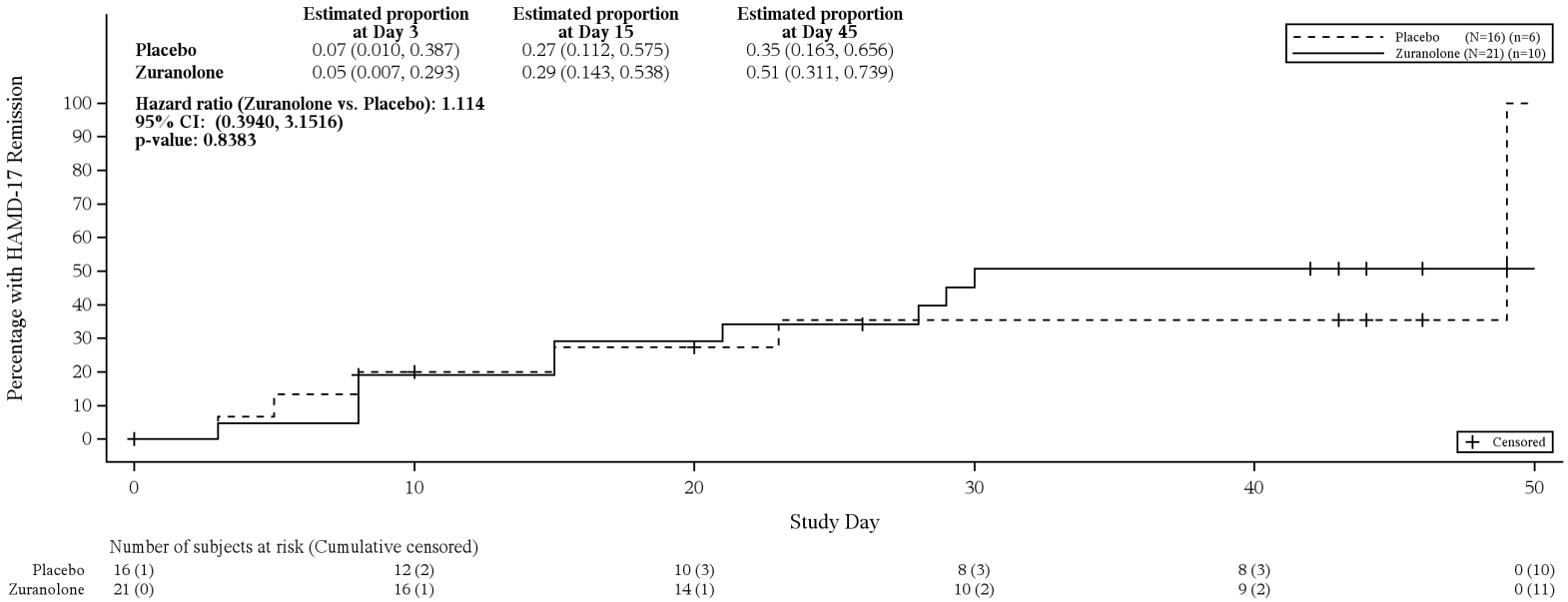
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-remi-tte-301-by.sas:f-hamd-remi-tte-301-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-301 - ITT population

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Family History of PPD = Yes



Number of subjects at risk (Cumulative censored)

Placebo	16 (1)	12 (2)	10 (3)	8 (3)	8 (3)	0 (10)
Zuranolone	21 (0)	16 (1)	14 (1)	10 (2)	9 (2)	0 (11)

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.

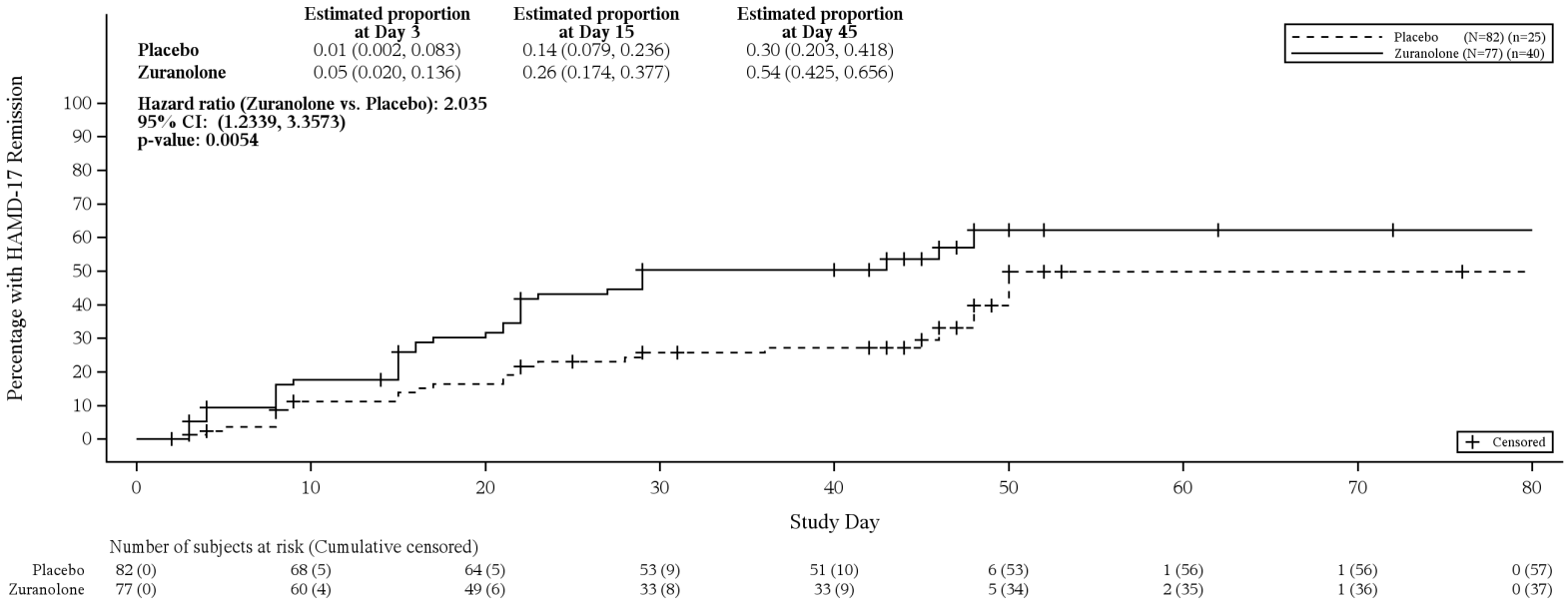
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-remi-tte-301-by.sas:f-hamd-remi-tte-301-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-301 - ITT population

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Family History of PPD = No/Unknown



Number of subjects at risk (Cumulative censored)

Placebo	82 (0)	68 (5)	64 (5)	53 (9)	51 (10)	6 (53)	1 (56)	1 (56)	0 (57)
Zuranolone	77 (0)	60 (4)	49 (6)	33 (8)	33 (9)	5 (34)	2 (35)	1 (36)	0 (37)

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.

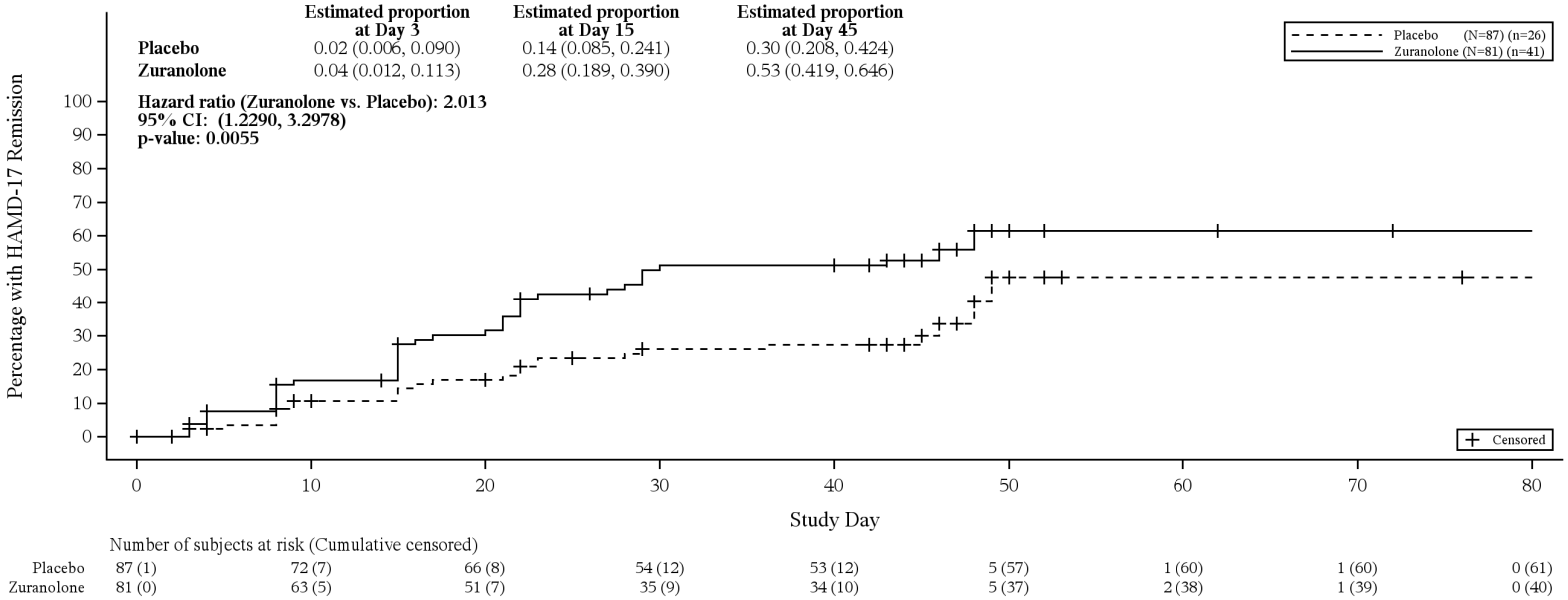
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-remi-tte-301-by.sas:f-hamd-remi-tte-301-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-301 - 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.

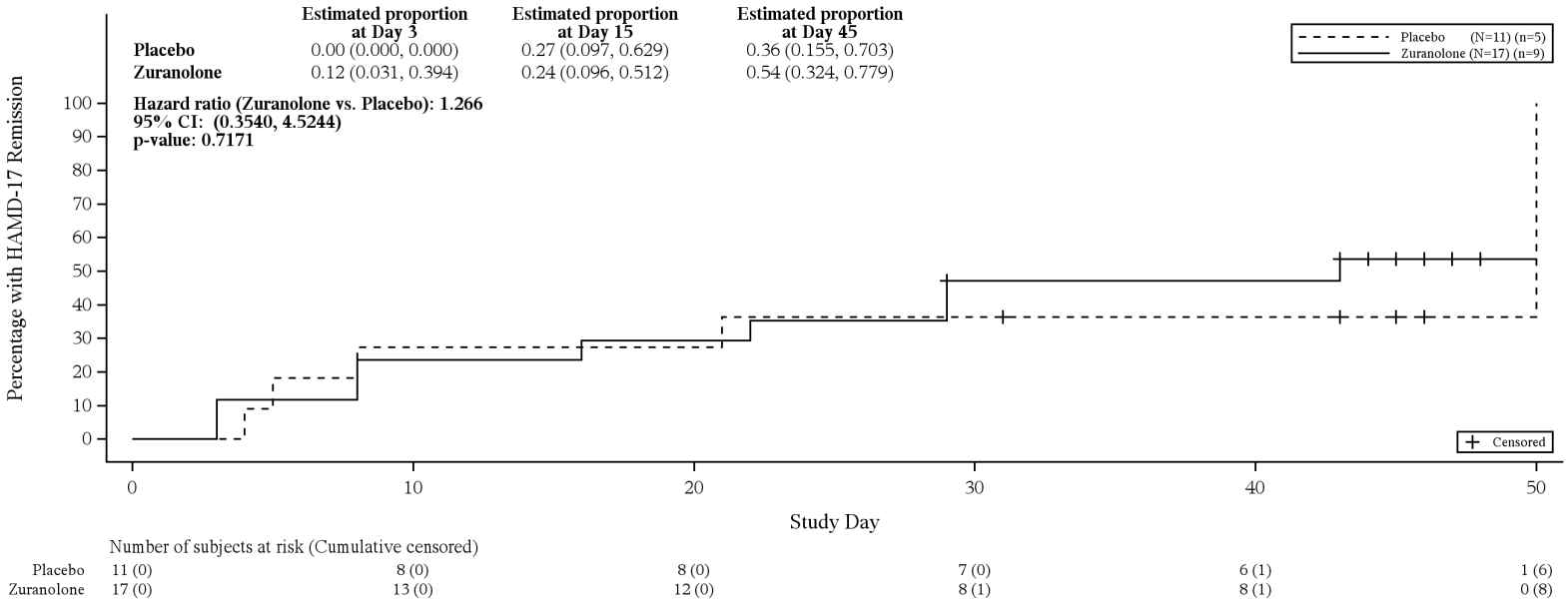
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-remi-tte-301-by.sas:f-hamd-remi-tte-301-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-301 - ITT population

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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.

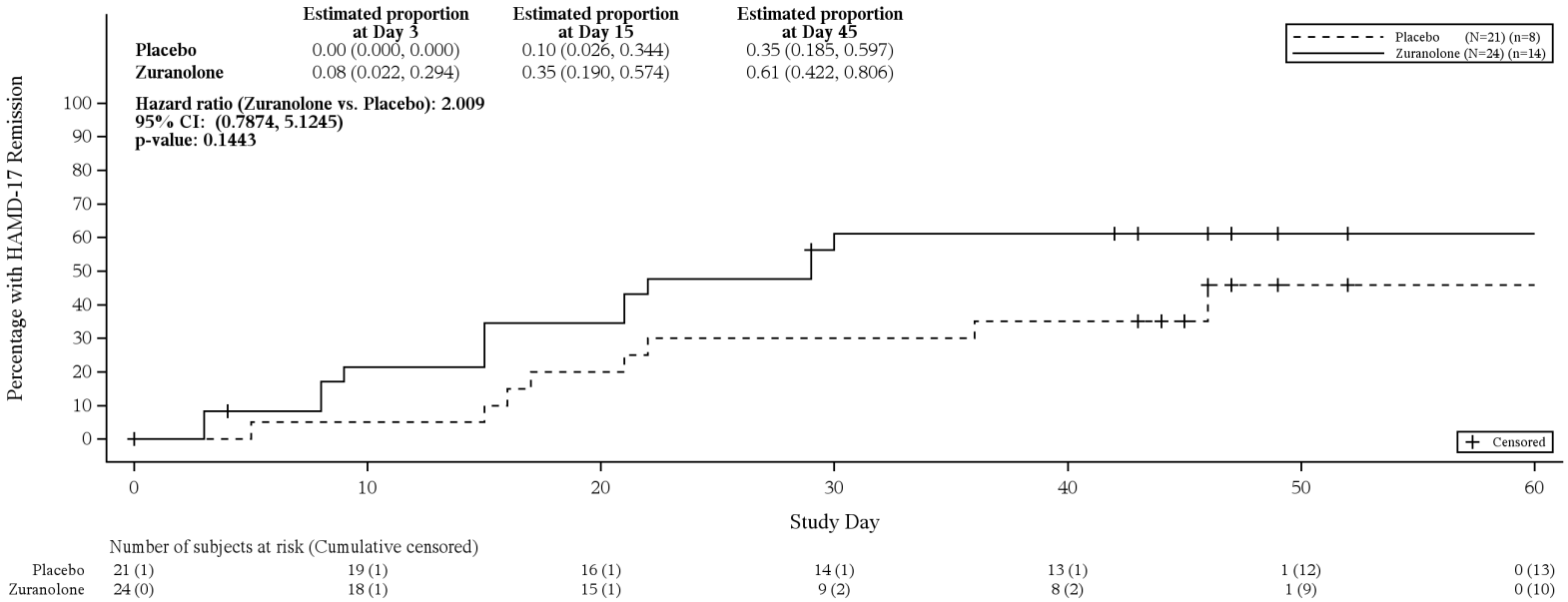
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-remi-tte-301-by.sas:f-hamd-remi-tte-301-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-301 - 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 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.

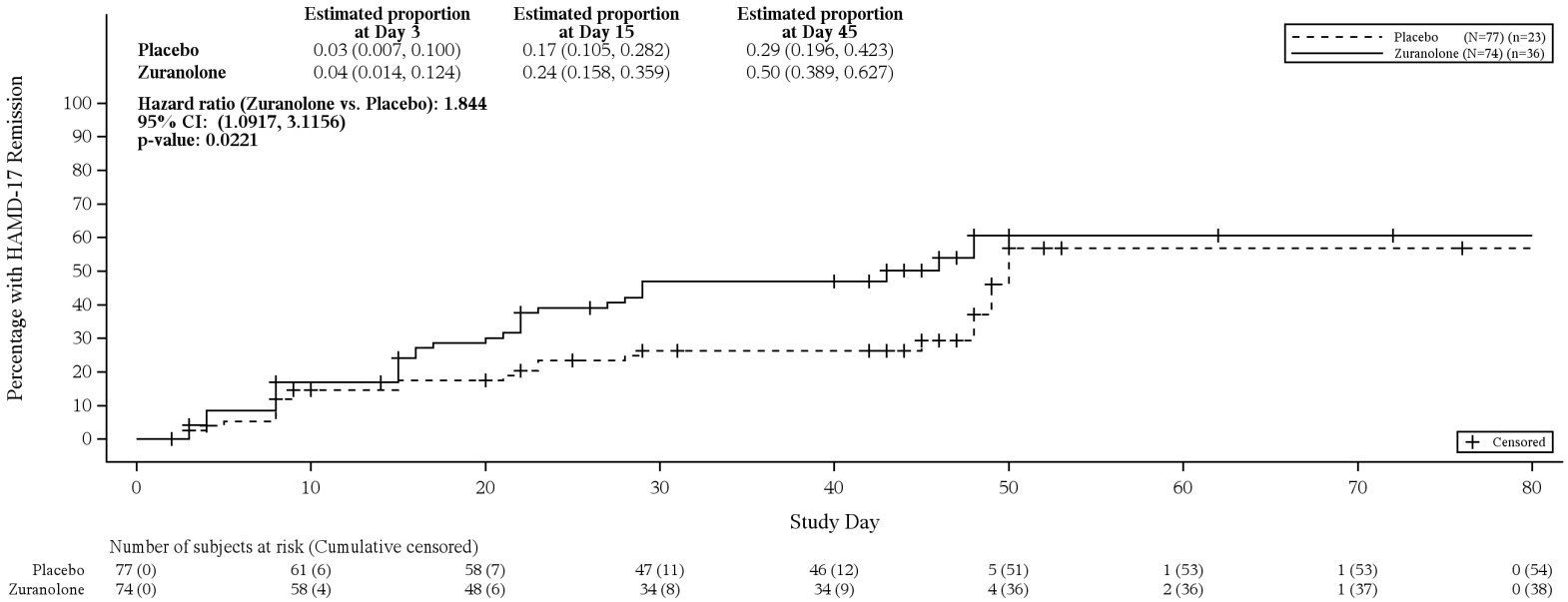
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAMD-17 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-hamd-remi-tte-301-by.sas:f-hamd-remi-tte-301-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-301 - ITT population

Page: 19 of 19

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20



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-301-by.sas:f-hamd-remi-tte-301-by-itta.rtf **Run Date:** 08JAN2026

2.2 MADRS

2.2.1 MMRM

Model-based Results on Change from Baseline in Montgomery-Asberg Depression Rating Scale (MADRS) Total Score: 217-PPD-301 - ITT population

Page: 1 of 2

	Placebo (N=101)	Zuranolone (N=99)
Day 8		
n	94	93
LS Mean (SE)	-11.80 (1.104)	-16.38 (1.109)
95% CI for the LS Mean	-13.97, -9.62	-18.57, -14.20
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-4.59 (1.565)
95% CI for the LS Mean		-7.68, -1.50
p-value		0.0038
Hedges' g (Zuranolone vs. Placebo)		-0.427
95% CI for Hedges' g		-0.7169, -0.1370
Day 15		
n	89	92
LS Mean (SE)	-14.64 (1.209)	-19.70 (1.202)
95% CI for the LS Mean	-17.03, -12.26	-22.08, -17.33
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-5.06 (1.706)
95% CI for the LS Mean		-8.43, -1.69
p-value		0.0034
Hedges' g (Zuranolone vs. Placebo)		-0.439
95% CI for Hedges' g		-0.7341, -0.1443

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-301-ovr.sas:t-madrs-mmrm-301-ovr-itta.rtf **Run Date:** 18JUL2025

Model-based Results on Change from Baseline in Montgomery-Asberg Depression Rating Scale (MADRS) Total Score: 217-PPD-301 - ITT population

Page: 2 of 2

	Placebo (N=101)	Zuranolone (N=99)
Day 28		
n	81	76
LS Mean (SE)	-16.85 (1.218)	-20.25 (1.228)
95% CI for the LS Mean	-19.25, -14.44	-22.67, -17.83
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.40 (1.730)
95% CI for the LS Mean		-6.82, 0.01
p-value		0.0508
Hedges' g (Zuranolone vs. Placebo)		-0.313
95% CI for Hedges' g		-0.6274, 0.0024
Day 45		
n	84	84
LS Mean (SE)	-17.75 (1.275)	-22.46 (1.274)
95% CI for the LS Mean	-20.27, -15.24	-24.97, -19.94
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-4.71 (1.803)
95% CI for the LS Mean		-8.26, -1.15
p-value		0.0098
Hedges' g (Zuranolone vs. Placebo)		-0.401
95% CI for Hedges' g		-0.7064, -0.0955

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-301-ovr.sas:t-madrs-mmrm-301-ovr-itta.rtf **Run Date:** 18JUL2025

2.2.2 Ansprechen

2.2.2.1 Responder-Analysen

2.2.2.1 .1 ITT-Population

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score): 217-PPD-301 - ITT population

Page: 1 of 4

Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Number of evaluable subjects [1]	97	98
Day 8		
Number of subjects with a response, n (%) [2]	25 (25.8)	44 (44.9)
Number of subjects with missing evaluation, n (%)	3 (3.1)	5 (5.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.742
95% CI for the RR		(1.165, 2.607)
p-value for RR		0.0069
OR - Odds Ratio (Zuranolone vs. Placebo)		2.347
95% CI for the OR		(1.280, 4.303)
p-value for OR		0.0058
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.191
95% CI for the ARR		(0.059, 0.323)
p-value for ARR		0.0045

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-resp50-301-ovr.sas:t-madrs-resp50-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score): 217-PPD-301 - ITT population

Page: 2 of 4

Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 15		
Number of subjects with a response, n (%) [2]	33 (34.0)	52 (53.1)
Number of subjects with missing evaluation, n (%)	8 (8.2)	6 (6.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.559
95% CI for the RR		(1.117, 2.178)
p-value for RR		0.0091
OR - Odds Ratio (Zuranolone vs. Placebo)		2.191
95% CI for the OR		(1.229, 3.904)
p-value for OR		0.0078
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.191
95% CI for the ARR		(0.055, 0.327)
p-value for ARR		0.0060

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-resp50-301-ovr.sas:t-madrs-resp50-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score): 217-PPD-301 - ITT population

Page: 3 of 4

Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 28		
Number of subjects with a response, n (%) [2]	35 (36.1)	45 (45.9)
Number of subjects with missing evaluation, n (%)	16 (16.5)	22 (22.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.271
95% CI for the RR		(0.903, 1.789)
p-value for RR		0.1684
OR - Odds Ratio (Zuranolone vs. Placebo)		1.503
95% CI for the OR		(0.846, 2.669)
p-value for OR		0.1643
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.098
95% CI for the ARR		(-0.039, 0.236)
p-value for ARR		0.1612

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-resp50-301-ovr.sas:t-madrs-resp50-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score): 217-PPD-301 - ITT population

Page: 4 of 4

Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 45		
Number of subjects with a response, n (%) [2]	43 (44.3)	55 (56.1)
Number of subjects with missing evaluation, n (%)	13 (13.4)	14 (14.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.265
95% CI for the RR		(0.952, 1.680)
p-value for RR		0.1052
OR - Odds Ratio (Zuranolone vs. Placebo)		1.603
95% CI for the OR		(0.910, 2.825)
p-value for OR		0.1024
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.117
95% CI for the ARR		(-0.022, 0.257)
p-value for ARR		0.0989

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-resp50-301-ovr.sas:t-madrs-resp50-301-ovr-itta.rtf **Run Date:** 18JUL2025

2.2.2.1 .2 Subgruppen

2.2.2.1 .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-301 - ITT population

Page: 1 of 6

Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	97	98	
Number of subjects with response at Day 15, n (%)	33 (34.0)	52 (53.1)	
Number of subjects with response at Day 45, n (%)	43 (44.3)	55 (56.1)	
Age Group (years)			0.6352
Day 15			
18 - 24, n / N (%)	5/11 (45.5)	14/19 (73.7)	
25 - 45, n / N (%)	28/86 (32.6)	38/79 (48.1)	
Day 45			
18 - 24, n / N (%)	4/11 (36.4)	13/19 (68.4)	
25 - 45, n / N (%)	39/86 (45.3)	42/79 (53.2)	

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.
Source: biib125/v_a/germany_amnog/t-madrs-resp50-301-int.sas:t-madrs-resp50-301-int-itta.rtf **Run Date:** 18JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score): Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			0.7974
Day 15			
<28, n / N (%)	11/32 (34.4)	16/33 (48.5)	
>=28, n / N (%)	22/65 (33.8)	36/65 (55.4)	
Day 45			
<28, n / N (%)	11/32 (34.4)	19/33 (57.6)	
>=28, n / N (%)	32/65 (49.2)	36/65 (55.4)	
Race Group (Black or African American, White)			0.0162
Day 15			
Black or African American, n / N (%)	4/17 (23.5)	13/25 (52.0)	
White, n / N (%)	24/69 (34.8)	38/68 (55.9)	
Day 45			
Black or African American, n / N (%)	3/17 (17.6)	16/25 (64.0)	
White, n / N (%)	37/69 (53.6)	37/68 (54.4)	

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 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-resp50-301-int.sas:t-madrs-resp50-301-int-itta.rtf **Run Date:** 18JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score): Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			0.0425
Day 15			
Yes, n / N (%)	9/15 (60.0)	6/15 (40.0)	
No, n / N (%)	24/82 (29.3)	46/83 (55.4)	
Day 45			
Yes, n / N (%)	9/15 (60.0)	7/15 (46.7)	
No, n / N (%)	34/82 (41.5)	48/83 (57.8)	

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 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-resp50-301-int.sas:t-madrs-resp50-301-int-itta.rtf **Run Date:** 18JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score): Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			0.2770(a) 0.2739(b) 0.9714(c)
Day 15			
<=24.9, n / N (%)	8/22 (36.4)	9/20 (45.0)	
25-29.9, n / N (%)	10/34 (29.4)	13/24 (54.2)	
>=30, n / N (%)	15/41 (36.6)	30/53 (56.6)	
Day 45			
<=24.9, n / N (%)	11/22 (50.0)	10/20 (50.0)	
25-29.9, n / N (%)	16/34 (47.1)	14/24 (58.3)	
>=30, n / N (%)	16/41 (39.0)	30/53 (56.6)	

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-resp50-301-int.sas:t-madrs-resp50-301-int-itta.rtf **Run Date:** 18JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score): Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Onset of PPD			0.7741
Day 15			
3rd Trimester, n / N (%)	10/30 (33.3)	15/34 (44.1)	
Postpartum, n / N (%)	23/67 (34.3)	37/64 (57.8)	
Day 45			
3rd Trimester, n / N (%)	10/30 (33.3)	19/34 (55.9)	
Postpartum, n / N (%)	33/67 (49.3)	36/64 (56.3)	
Family History of PPD			0.1483
Day 15			
Yes, n / N (%)	10/16 (62.5)	11/21 (52.4)	
No/Unknown, n / N (%)	23/81 (28.4)	41/77 (53.2)	
Day 45			
Yes, n / N (%)	8/16 (50.0)	12/21 (57.1)	
No/Unknown, n / N (%)	35/81 (43.2)	43/77 (55.8)	

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 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-resp50-301-int.sas:t-madrs-resp50-301-int-itta.rtf **Run Date:** 18JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score): Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
History of PPD			0.9263
Day 15			
1st Episode, n / N (%)	27/86 (31.4)	40/81 (49.4)	
Recurrent Episode, n / N (%)	6/11 (54.5)	12/17 (70.6)	
Day 45			
1st Episode, n / N (%)	38/86 (44.2)	44/81 (54.3)	
Recurrent Episode, n / N (%)	5/11 (45.5)	11/17 (64.7)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			0.4724
Day 15			
<20, n / N (%)	6/21 (28.6)	13/24 (54.2)	
>=20, n / N (%)	27/76 (35.5)	39/74 (52.7)	
Day 45			
<20, n / N (%)	14/21 (66.7)	15/24 (62.5)	
>=20, n / N (%)	29/76 (38.2)	40/74 (54.1)	

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 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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2.2.2.1 .2 .2 Subgruppenanalysen

2.2.2.1 .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-301 - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =19)
Number of evaluable subjects [1]	11	19
Day 8		
Number of subjects with a response, n (%) [2]	4 (36.4)	13 (68.4)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.977
95% CI for the RR		(0.863, 4.529)
p-value for RR		0.1069
Day 15		
Number of subjects with a response, n (%) [2]	5 (45.5)	14 (73.7)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.704
95% CI for the RR		(0.860, 3.376)
p-value for RR		0.1268

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-resp50-301-by.sas:t-madrs-resp50-301-by-age-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =19)
Day 28		
Number of subjects with a response, n (%) [2]	6 (54.5)	11 (57.9)
Number of subjects with missing evaluation, n (%)	0	3 (15.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.115
95% CI for the RR		(0.550, 2.263)
p-value for RR		0.7621
Day 45		
Number of subjects with a response, n (%) [2]	4 (36.4)	13 (68.4)
Number of subjects with missing evaluation, n (%)	1 (9.1)	1 (5.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.977
95% CI for the RR		(0.824, 4.743)
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 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-resp50-301-by.sas:t-madrs-resp50-301-by-age-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=88)	Zuranolone (N =80)
Number of evaluable subjects [1]	86	79
Day 8		
Number of subjects with a response, n (%) [2]	21 (24.4)	31 (39.2)
Number of subjects with missing evaluation, n (%)	3 (3.5)	5 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.615
95% CI for the RR		(1.016, 2.566)
p-value for RR		0.0427
Day 15		
Number of subjects with a response, n (%) [2]	28 (32.6)	38 (48.1)
Number of subjects with missing evaluation, n (%)	8 (9.3)	6 (7.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.484
95% CI for the RR		(1.014, 2.173)
p-value for RR		0.0421

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-resp50-301-by.sas:t-madrs-resp50-301-by-age-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=88)	Zuranolone (N =80)
Day 28		
Number of subjects with a response, n (%) [2]	29 (33.7)	34 (43.0)
Number of subjects with missing evaluation, n (%)	16 (18.6)	19 (24.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.282
95% CI for the RR		(0.869, 1.893)
p-value for RR		0.2109
Day 45		
Number of subjects with a response, n (%) [2]	39 (45.3)	42 (53.2)
Number of subjects with missing evaluation, n (%)	12 (14.0)	13 (16.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.178
95% CI for the RR		(0.864, 1.607)
p-value for RR		0.3011

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.

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2.2.2.1 .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-301 - 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=32)	Zuranolone (N =33)
Number of evaluable subjects [1]	32	33
Day 8		
Number of subjects with a response, n (%) [2]	8 (25.0)	12 (36.4)
Number of subjects with missing evaluation, n (%)	0	1 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.503
95% CI for the RR		(0.712, 3.173)
p-value for RR		0.2847
Day 15		
Number of subjects with a response, n (%) [2]	11 (34.4)	16 (48.5)
Number of subjects with missing evaluation, n (%)	2 (6.3)	1 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.470
95% CI for the RR		(0.818, 2.641)
p-value for RR		0.1975

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 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-resp50-301-by.sas:t-madrs-resp50-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Baseline HAMD-17 Total Score: 217-PPD-301 - 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=32)	Zuranolone (N =33)
Day 28		
Number of subjects with a response, n (%) [2]	9 (28.1)	15 (45.5)
Number of subjects with missing evaluation, n (%)	7 (21.9)	5 (15.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.689
95% CI for the RR		(0.864, 3.302)
p-value for RR		0.1254
Day 45		
Number of subjects with a response, n (%) [2]	11 (34.4)	19 (57.6)
Number of subjects with missing evaluation, n (%)	5 (15.6)	3 (9.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.737
95% CI for the RR		(0.996, 3.030)
p-value for RR		0.0518

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 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-resp50-301-by.sas:t-madrs-resp50-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Baseline HAMD-17 Total Score: 217-PPD-301 - 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=66)	Zuranolone (N =65)
Number of evaluable subjects [1]	65	65
Day 8		
Number of subjects with a response, n (%) [2]	17 (26.2)	32 (49.2)
Number of subjects with missing evaluation, n (%)	3 (4.6)	4 (6.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.882
95% CI for the RR		(1.166, 3.039)
p-value for RR		0.0097
Day 15		
Number of subjects with a response, n (%) [2]	22 (33.8)	36 (55.4)
Number of subjects with missing evaluation, n (%)	6 (9.2)	5 (7.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.635
95% CI for the RR		(1.092, 2.447)
p-value for RR		0.0169

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 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-resp50-301-by.sas:t-madrs-resp50-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Baseline HAMD-17 Total Score: 217-PPD-301 - ITT population

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

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =65)
Day 28		
Number of subjects with a response, n (%) [2]	26 (40.0)	30 (46.2)
Number of subjects with missing evaluation, n (%)	9 (13.8)	17 (26.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.165
95% CI for the RR		(0.788, 1.722)
p-value for RR		0.4447
Day 45		
Number of subjects with a response, n (%) [2]	32 (49.2)	36 (55.4)
Number of subjects with missing evaluation, n (%)	8 (12.3)	11 (16.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.131
95% CI for the RR		(0.819, 1.564)
p-value for RR		0.4549

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 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-resp50-301-by.sas:t-madrs-resp50-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

2.2.2.1 .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-301 - ITT population

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Race Group = Black or African American

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =26)
Number of evaluable subjects [1]	17	25
Day 8		
Number of subjects with a response, n (%) [2]	2 (11.8)	11 (44.0)
Number of subjects with missing evaluation, n (%)	2 (11.8)	2 (8.0)
RR - Relative Risk (Zuranolone vs. Placebo)		4.286
95% CI for the RR		(1.137, 16.150)
p-value for RR		0.0316
Day 15		
Number of subjects with a response, n (%) [2]	4 (23.5)	13 (52.0)
Number of subjects with missing evaluation, n (%)	4 (23.5)	3 (12.0)
RR - Relative Risk (Zuranolone vs. Placebo)		2.532
95% CI for the RR		(1.169, 5.486)
p-value for RR		0.0185

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-resp50-301-by.sas:t-madrs-resp50-301-by-race-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Race Group: 217-PPD-301 - ITT population

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Race Group = Black or African American

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =26)
Day 28		
Number of subjects with a response, n (%) [2]	2 (11.8)	13 (52.0)
Number of subjects with missing evaluation, n (%)	8 (47.1)	7 (28.0)
RR - Relative Risk (Zuranolone vs. Placebo)		5.065
95% CI for the RR		(1.302, 19.699)
p-value for RR		0.0192
Day 45		
Number of subjects with a response, n (%) [2]	3 (17.6)	16 (64.0)
Number of subjects with missing evaluation, n (%)	5 (29.4)	3 (12.0)
RR - Relative Risk (Zuranolone vs. Placebo)		4.156
95% CI for the RR		(1.428, 12.094)
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 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-resp50-301-by.sas:t-madrs-resp50-301-by-race-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Race Group: 217-PPD-301 - ITT population

Page: 3 of 4

Race Group = White

Study Visit Statistics	Placebo (N=70)	Zuranolone (N =68)
Number of evaluable subjects [1]	69	68
Day 8		
Number of subjects with a response, n (%) [2]	19 (27.5)	32 (47.1)
Number of subjects with missing evaluation, n (%)	0	3 (4.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.713
95% CI for the RR		(1.085, 2.707)
p-value for RR		0.0210
Day 15		
Number of subjects with a response, n (%) [2]	24 (34.8)	38 (55.9)
Number of subjects with missing evaluation, n (%)	3 (4.3)	3 (4.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.611
95% CI for the RR		(1.094, 2.371)
p-value for RR		0.0157

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-resp50-301-by.sas:t-madrs-resp50-301-by-race-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Race Group: 217-PPD-301 - ITT population

Page: 4 of 4

Race Group = White

Study Visit Statistics	Placebo (N=70)	Zuranolone (N =68)
Day 28		
Number of subjects with a response, n (%) [2]	29 (42.0)	30 (44.1)
Number of subjects with missing evaluation, n (%)	7 (10.1)	15 (22.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.052
95% CI for the RR		(0.715, 1.549)
p-value for RR		0.7955
Day 45		
Number of subjects with a response, n (%) [2]	37 (53.6)	37 (54.4)
Number of subjects with missing evaluation, n (%)	7 (10.1)	10 (14.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.017
95% CI for the RR		(0.747, 1.386)
p-value for RR		0.9130

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-resp50-301-by.sas:t-madrs-resp50-301-by-race-itta.rtf **Run Date:** 25JUL2025

2.2.2.1 .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-301 - ITT population

Page: 1 of 4

Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=15)	Zuranolone (N =15)
Number of evaluable subjects [1]	15	15
Day 8		
Number of subjects with a response, n (%) [2]	5 (33.3)	4 (26.7)
Number of subjects with missing evaluation, n (%)	0	1 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.758
95% CI for the RR		(0.242, 2.373)
p-value for RR		0.6342
Day 15		
Number of subjects with a response, n (%) [2]	9 (60.0)	6 (40.0)
Number of subjects with missing evaluation, n (%)	0	1 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.690
95% CI for the RR		(0.328, 1.454)
p-value for RR		0.3295

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-resp50-301-by.sas:t-madrs-resp50-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Baseline Antidepressant Use: 217-PPD-301 - ITT population

Page: 2 of 4

Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=15)	Zuranolone (N =15)
Day 28		
Number of subjects with a response, n (%) [2]	8 (53.3)	7 (46.7)
Number of subjects with missing evaluation, n (%)	2 (13.3)	1 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.891
95% CI for the RR		(0.437, 1.817)
p-value for RR		0.7512
Day 45		
Number of subjects with a response, n (%) [2]	9 (60.0)	7 (46.7)
Number of subjects with missing evaluation, n (%)	1 (6.7)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.759
95% CI for the RR		(0.399, 1.443)
p-value for RR		0.4005

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-resp50-301-by.sas:t-madrs-resp50-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Baseline Antidepressant Use: 217-PPD-301 - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=86)	Zuranolone (N =84)
Number of evaluable subjects [1]	82	83
Day 8		
Number of subjects with a response, n (%) [2]	20 (24.4)	40 (48.2)
Number of subjects with missing evaluation, n (%)	3 (3.7)	4 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.972
95% CI for the RR		(1.265, 3.072)
p-value for RR		0.0027
Day 15		
Number of subjects with a response, n (%) [2]	24 (29.3)	46 (55.4)
Number of subjects with missing evaluation, n (%)	8 (9.8)	5 (6.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.893
95% CI for the RR		(1.284, 2.790)
p-value for RR		0.0013

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-resp50-301-by.sas:t-madrs-resp50-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Baseline Antidepressant Use: 217-PPD-301 - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=86)	Zuranolone (N =84)
Day 28		
Number of subjects with a response, n (%) [2]	27 (32.9)	38 (45.8)
Number of subjects with missing evaluation, n (%)	14 (17.1)	21 (25.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.387
95% CI for the RR		(0.940, 2.045)
p-value for RR		0.0992
Day 45		
Number of subjects with a response, n (%) [2]	34 (41.5)	48 (57.8)
Number of subjects with missing evaluation, n (%)	12 (14.6)	14 (16.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.389
95% CI for the RR		(1.012, 1.907)
p-value for RR		0.0421

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-resp50-301-by.sas:t-madrs-resp50-301-by-adt-itta.rtf **Run Date:** 25JUL2025

2.2.2.1 .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-301 - ITT population

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

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =20)
Number of evaluable subjects [1]	22	20
Day 8		
Number of subjects with a response, n (%) [2]	5 (22.7)	6 (30.0)
Number of subjects with missing evaluation, n (%)	0	2 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.380
95% CI for the RR		(0.502, 3.793)
p-value for RR		0.5323
Day 15		
Number of subjects with a response, n (%) [2]	8 (36.4)	9 (45.0)
Number of subjects with missing evaluation, n (%)	1 (4.5)	2 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.294
95% CI for the RR		(0.625, 2.678)
p-value for RR		0.4875

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-resp50-301-by.sas:t-madrs-resp50-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

Page: 2 of 6

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

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =20)
Day 28		
Number of subjects with a response, n (%) [2]	8 (36.4)	5 (25.0)
Number of subjects with missing evaluation, n (%)	2 (9.1)	8 (40.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.719
95% CI for the RR		(0.290, 1.783)
p-value for RR		0.4764
Day 45		
Number of subjects with a response, n (%) [2]	11 (50.0)	10 (50.0)
Number of subjects with missing evaluation, n (%)	0	5 (25.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.046
95% CI for the RR		(0.592, 1.847)
p-value for RR		0.8781

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-resp50-301-by.sas:t-madrs-resp50-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =24)
Number of evaluable subjects [1]	34	24
Day 8		
Number of subjects with a response, n (%) [2]	8 (23.5)	12 (50.0)
Number of subjects with missing evaluation, n (%)	2 (5.9)	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		2.084
95% CI for the RR		(1.002, 4.334)
p-value for RR		0.0493
Day 15		
Number of subjects with a response, n (%) [2]	10 (29.4)	13 (54.2)
Number of subjects with missing evaluation, n (%)	4 (11.8)	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.806
95% CI for the RR		(0.971, 3.361)
p-value for RR		0.0620

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-resp50-301-by.sas:t-madrs-resp50-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =24)
Day 28		
Number of subjects with a response, n (%) [2]	15 (44.1)	14 (58.3)
Number of subjects with missing evaluation, n (%)	7 (20.6)	5 (20.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.297
95% CI for the RR		(0.795, 2.115)
p-value for RR		0.2975
Day 45		
Number of subjects with a response, n (%) [2]	16 (47.1)	14 (58.3)
Number of subjects with missing evaluation, n (%)	6 (17.6)	4 (16.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.216
95% CI for the RR		(0.769, 1.923)
p-value for RR		0.4036

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-resp50-301-by.sas:t-madrs-resp50-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

Study Visit Statistics	Placebo (N=42)	Zuranolone (N =53)
Number of evaluable subjects [1]	41	53
Day 8		
Number of subjects with a response, n (%) [2]	12 (29.3)	26 (49.1)
Number of subjects with missing evaluation, n (%)	1 (2.4)	2 (3.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.635
95% CI for the RR		(0.940, 2.847)
p-value for RR		0.0820
Day 15		
Number of subjects with a response, n (%) [2]	15 (36.6)	30 (56.6)
Number of subjects with missing evaluation, n (%)	3 (7.3)	3 (5.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.510
95% CI for the RR		(0.939, 2.428)
p-value for RR		0.0894

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-resp50-301-by.sas:t-madrs-resp50-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

Page: 6 of 6

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

Study Visit Statistics	Placebo (N=42)	Zuranolone (N =53)
Day 28		
Number of subjects with a response, n (%) [2]	12 (29.3)	25 (47.2)
Number of subjects with missing evaluation, n (%)	7 (17.1)	9 (17.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.572
95% CI for the RR		(0.894, 2.767)
p-value for RR		0.1165
Day 45		
Number of subjects with a response, n (%) [2]	16 (39.0)	30 (56.6)
Number of subjects with missing evaluation, n (%)	7 (17.1)	5 (9.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.415
95% CI for the RR		(0.897, 2.232)
p-value for RR		0.1351

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-resp50-301-by.sas:t-madrs-resp50-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

2.2.2.1 .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-301 - ITT population

Page: 1 of 4

Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =35)
Number of evaluable subjects [1]	30	34
Day 8		
Number of subjects with a response, n (%) [2]	8 (26.7)	16 (47.1)
Number of subjects with missing evaluation, n (%)	3 (10.0)	2 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.808
95% CI for the RR		(0.910, 3.589)
p-value for RR		0.0908
Day 15		
Number of subjects with a response, n (%) [2]	10 (33.3)	15 (44.1)
Number of subjects with missing evaluation, n (%)	4 (13.3)	3 (8.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.400
95% CI for the RR		(0.737, 2.661)
p-value for RR		0.3039

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 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-resp50-301-by.sas:t-madrs-resp50-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Onset of PPD: 217-PPD-301 - ITT population

Page: 2 of 4

Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =35)
Day 28		
Number of subjects with a response, n (%) [2]	9 (30.0)	15 (44.1)
Number of subjects with missing evaluation, n (%)	6 (20.0)	8 (23.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.503
95% CI for the RR		(0.780, 2.899)
p-value for RR		0.2236
Day 45		
Number of subjects with a response, n (%) [2]	10 (33.3)	19 (55.9)
Number of subjects with missing evaluation, n (%)	6 (20.0)	7 (20.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.737
95% CI for the RR		(0.952, 3.171)
p-value for RR		0.0720

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 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-resp50-301-by.sas:t-madrs-resp50-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Onset of PPD: 217-PPD-301 - ITT population

Page: 3 of 4

Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=69)	Zuranolone (N =64)
Number of evaluable subjects [1]	67	64
Day 8		
Number of subjects with a response, n (%) [2]	17 (25.4)	28 (43.8)
Number of subjects with missing evaluation, n (%)	0	3 (4.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.715
95% CI for the RR		(1.046, 2.813)
p-value for RR		0.0326
Day 15		
Number of subjects with a response, n (%) [2]	23 (34.3)	37 (57.8)
Number of subjects with missing evaluation, n (%)	4 (6.0)	3 (4.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.680
95% CI for the RR		(1.140, 2.475)
p-value for RR		0.0087

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 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-resp50-301-by.sas:t-madrs-resp50-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=69)	Zuranolone (N =64)
Day 28		
Number of subjects with a response, n (%) [2]	26 (38.8)	30 (46.9)
Number of subjects with missing evaluation, n (%)	10 (14.9)	14 (21.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.204
95% CI for the RR		(0.810, 1.788)
p-value for RR		0.3585
Day 45		
Number of subjects with a response, n (%) [2]	33 (49.3)	36 (56.3)
Number of subjects with missing evaluation, n (%)	7 (10.4)	7 (10.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.135
95% CI for the RR		(0.818, 1.574)
p-value for RR		0.4484

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 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-resp50-301-by.sas:t-madrs-resp50-301-by-onset-itta.rtf **Run Date:** 25JUL2025

2.2.2.1 .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-301 - ITT population

Page: 1 of 4

Family History of PPD = Yes

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =21)
Number of evaluable subjects [1]	16	21
Day 8		
Number of subjects with a response, n (%) [2]	7 (43.8)	10 (47.6)
Number of subjects with missing evaluation, n (%)	1 (6.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.096
95% CI for the RR		(0.542, 2.214)
p-value for RR		0.7991
Day 15		
Number of subjects with a response, n (%) [2]	10 (62.5)	11 (52.4)
Number of subjects with missing evaluation, n (%)	3 (18.8)	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		0.842
95% CI for the RR		(0.482, 1.472)
p-value for RR		0.5471

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 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-resp50-301-by.sas:t-madrs-resp50-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Family History of PPD: 217-PPD-301 - ITT population

Page: 2 of 4

Family History of PPD = Yes

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =21)
Day 28		
Number of subjects with a response, n (%) [2]	8 (50.0)	12 (57.1)
Number of subjects with missing evaluation, n (%)	4 (25.0)	3 (14.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.149
95% CI for the RR		(0.619, 2.135)
p-value for RR		0.6594
Day 45		
Number of subjects with a response, n (%) [2]	8 (50.0)	12 (57.1)
Number of subjects with missing evaluation, n (%)	3 (18.8)	2 (9.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.147
95% CI for the RR		(0.617, 2.132)
p-value for RR		0.6655

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 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-resp50-301-by.sas:t-madrs-resp50-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Family History of PPD: 217-PPD-301 - ITT population

Page: 3 of 4

Family History of PPD = No

Study Visit Statistics	Placebo (N=85)	Zuranolone (N =78)
Number of evaluable subjects [1]	81	77
Day 8		
Number of subjects with a response, n (%) [2]	18 (22.2)	34 (44.2)
Number of subjects with missing evaluation, n (%)	2 (2.5)	5 (6.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.989
95% CI for the RR		(1.233, 3.210)
p-value for RR		0.0049
Day 15		
Number of subjects with a response, n (%) [2]	23 (28.4)	41 (53.2)
Number of subjects with missing evaluation, n (%)	5 (6.2)	5 (6.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.879
95% CI for the RR		(1.253, 2.815)
p-value for RR		0.0023

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 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-resp50-301-by.sas:t-madrs-resp50-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Family History of PPD: 217-PPD-301 - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=85)	Zuranolone (N =78)
Day 28		
Number of subjects with a response, n (%) [2]	27 (33.3)	33 (42.9)
Number of subjects with missing evaluation, n (%)	12 (14.8)	19 (24.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.287
95% CI for the RR		(0.862, 1.921)
p-value for RR		0.2179
Day 45		
Number of subjects with a response, n (%) [2]	35 (43.2)	43 (55.8)
Number of subjects with missing evaluation, n (%)	10 (12.3)	12 (15.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.294
95% CI for the RR		(0.941, 1.780)
p-value for RR		0.1134

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 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-resp50-301-by.sas:t-madrs-resp50-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

2.2.2.1 .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-301 - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=90)	Zuranolone (N =82)
Number of evaluable subjects [1]	86	81
Day 8		
Number of subjects with a response, n (%) [2]	19 (22.1)	34 (42.0)
Number of subjects with missing evaluation, n (%)	3 (3.5)	5 (6.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.920
95% CI for the RR		(1.197, 3.077)
p-value for RR		0.0068
Day 15		
Number of subjects with a response, n (%) [2]	27 (31.4)	40 (49.4)
Number of subjects with missing evaluation, n (%)	8 (9.3)	6 (7.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.589
95% CI for the RR		(1.085, 2.328)
p-value for RR		0.0174

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-resp50-301-by.sas:t-madrs-resp50-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by History of PPD: 217-PPD-301 - ITT population

Page: 2 of 4

History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=90)	Zuranolone (N =82)
Day 28		
Number of subjects with a response, n (%) [2]	31 (36.0)	33 (40.7)
Number of subjects with missing evaluation, n (%)	15 (17.4)	22 (27.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.142
95% CI for the RR		(0.777, 1.679)
p-value for RR		0.5001
Day 45		
Number of subjects with a response, n (%) [2]	38 (44.2)	44 (54.3)
Number of subjects with missing evaluation, n (%)	12 (14.0)	13 (16.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.242
95% CI for the RR		(0.909, 1.697)
p-value for RR		0.1736

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-resp50-301-by.sas:t-madrs-resp50-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by History of PPD: 217-PPD-301 - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=11)	Zuranolone (N =17)
Number of evaluable subjects [1]	11	17
Day 8		
Number of subjects with a response, n (%) [2]	6 (54.5)	10 (58.8)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.163
95% CI for the RR		(0.579, 2.336)
p-value for RR		0.6714
Day 15		
Number of subjects with a response, n (%) [2]	6 (54.5)	12 (70.6)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.396
95% CI for the RR		(0.748, 2.602)
p-value for RR		0.2945

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-resp50-301-by.sas:t-madrs-resp50-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by History of PPD: 217-PPD-301 - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=11)	Zuranolone (N =17)
Day 28		
Number of subjects with a response, n (%) [2]	4 (36.4)	12 (70.6)
Number of subjects with missing evaluation, n (%)	1 (9.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.093
95% CI for the RR		(0.907, 4.832)
p-value for RR		0.0835
Day 45		
Number of subjects with a response, n (%) [2]	5 (45.5)	11 (64.7)
Number of subjects with missing evaluation, n (%)	1 (9.1)	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.535
95% CI for the RR		(0.731, 3.224)
p-value for RR		0.2577

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-resp50-301-by.sas:t-madrs-resp50-301-by-hist-itta.rtf **Run Date:** 25JUL2025

2.2.2.1 .2 .2 .9 Depression mit Angst

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

Page: 1 of 4

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =24)
Number of evaluable subjects [1]	21	24
Day 8		
Number of subjects with a response, n (%) [2]	2 (9.5)	11 (45.8)
Number of subjects with missing evaluation, n (%)	1 (4.8)	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		4.779
95% CI for the RR		(1.168, 19.556)
p-value for RR		0.0296
Day 15		
Number of subjects with a response, n (%) [2]	6 (28.6)	13 (54.2)
Number of subjects with missing evaluation, n (%)	1 (4.8)	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.882
95% CI for the RR		(0.857, 4.133)
p-value for RR		0.1151

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 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-resp50-301-by.sas:t-madrs-resp50-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =24)
Day 28		
Number of subjects with a response, n (%) [2]	8 (38.1)	11 (45.8)
Number of subjects with missing evaluation, n (%)	4 (19.0)	5 (20.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.192
95% CI for the RR		(0.591, 2.404)
p-value for RR		0.6228
Day 45		
Number of subjects with a response, n (%) [2]	14 (66.7)	15 (62.5)
Number of subjects with missing evaluation, n (%)	1 (4.8)	3 (12.5)
RR - Relative Risk (Zuranolone vs. Placebo)		0.937
95% CI for the RR		(0.599, 1.465)
p-value for RR		0.7754

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 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-resp50-301-by.sas:t-madrs-resp50-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

Study Visit Statistics	Placebo (N=77)	Zuranolone (N =74)
Number of evaluable subjects [1]	76	74
Day 8		
Number of subjects with a response, n (%) [2]	23 (30.3)	33 (44.6)
Number of subjects with missing evaluation, n (%)	2 (2.6)	4 (5.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.470
95% CI for the RR		(0.959, 2.253)
p-value for RR		0.0771
Day 15		
Number of subjects with a response, n (%) [2]	27 (35.5)	39 (52.7)
Number of subjects with missing evaluation, n (%)	7 (9.2)	5 (6.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.480
95% CI for the RR		(1.019, 2.151)
p-value for RR		0.0397

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 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-resp50-301-by.sas:t-madrs-resp50-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

Study Visit Statistics	Placebo (N=77)	Zuranolone (N =74)
Day 28		
Number of subjects with a response, n (%) [2]	27 (35.5)	34 (45.9)
Number of subjects with missing evaluation, n (%)	12 (15.8)	17 (23.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.284
95% CI for the RR		(0.865, 1.907)
p-value for RR		0.2146
Day 45		
Number of subjects with a response, n (%) [2]	29 (38.2)	40 (54.1)
Number of subjects with missing evaluation, n (%)	12 (15.8)	11 (14.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.406
95% CI for the RR		(0.984, 2.009)
p-value for RR		0.0614

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 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.

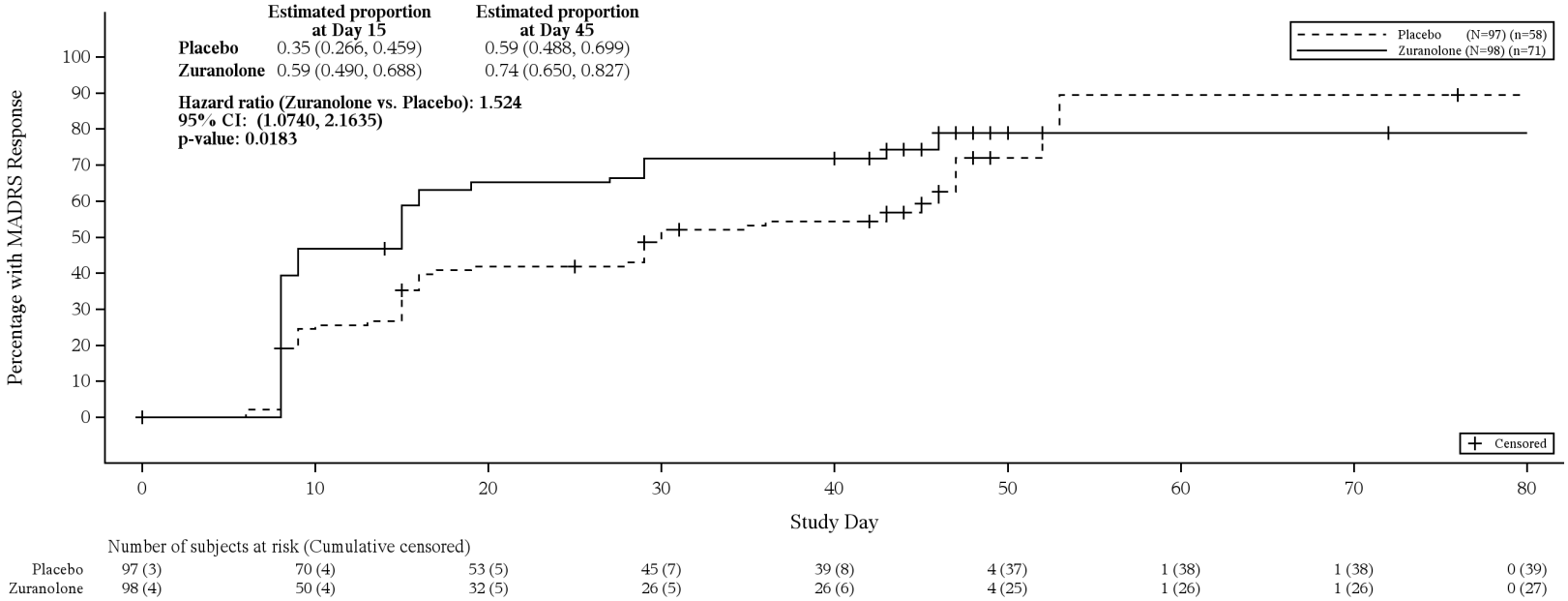
Source: biib125/v_a/germany_amnog/t-madrs-resp50-301-by.sas:t-madrs-resp50-301-by-hama-itta.rtf **Run Date:** 25JUL2025

2.2.2.2 TTE-Analysen

2.2.2.2 .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-301 - 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-301-ovr.sas:f-madrs-resp50-tte-301-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-301 - ITT population

Page: 1 of 1

	Placebo (N=101)	Zuranolone (N=99)
Number of evaluable subjects [1]	97	98
Number of subjects with response, n (%) [2]	58 (59.8)	71 (72.4)
Time to first MADRS response (days) [3]		
25th percentile - Q1 (95% CI)	10.0 (8.0 , 15.0)	8.0 (NE, NE)
50th percentile - median (95% CI)	30.0 (16.0 , 46.0)	15.0 (9.0 , 16.0)
75th percentile - Q3 (95% CI)	52.0 (47.0, NE)	46.0 (27.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.524
95% CI for the HR		(1.0740 , 2.1635)
p-value for the HR		0.0183

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-301-ovr.sas:t-madrs-resp50-tte-301-ovr-itta.rtf **Run Date:** 18JUL2025

2.2.2.2 .2 Subgruppen

2.2.2.2 .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-301 - ITT population

Page: 1 of 2

Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	97	98	
Number of subjects with response, n (%)	58 (59.8)	71 (72.4)	
Age Group (years)			
18 - 24, n / N (%)	8/11 (72.7)	16/19 (84.2)	0.9817
25 - 45, n / N (%)	50/86 (58.1)	55/79 (69.6)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	16/32 (50.0)	22/33 (66.7)	0.9781
>=28, n / N (%)	42/65 (64.6)	49/65 (75.4)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	6/17 (35.3)	18/25 (72.0)	0.2065
White, n / N (%)	46/69 (66.7)	50/68 (73.5)	
Antidepressant Use at Baseline			
Yes, n / N (%)	12/15 (80.0)	8/15 (53.3)	0.0233
No, n / N (%)	46/82 (56.1)	63/83 (75.9)	

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-301-int.sas:t-madrs-resp50-tte-301-int-itta.rtf **Run Date:** 18JUL2025

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-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9, n / N (%)	14/22 (63.6)	14/20 (70.0)	0.9004(a)
25-29.9, n / N (%)	22/34 (64.7)	17/24 (70.8)	0.5504(b)
>=30, n / N (%)	22/41 (53.7)	39/53 (73.6)	0.6077(c)
Onset of PPD			
3rd Trimester, n / N (%)	15/30 (50.0)	25/34 (73.5)	0.6272
Postpartum, n / N (%)	43/67 (64.2)	46/64 (71.9)	
Family History of PPD			
Yes, n / N (%)	13/16 (81.3)	15/21 (71.4)	0.0238
No/Unknown, n / N (%)	45/81 (55.6)	56/77 (72.7)	
History of PPD			
1st Episode, n / N (%)	52/86 (60.5)	57/81 (70.4)	0.6253
Recurrent Episode, n / N (%)	6/11 (54.5)	14/17 (82.4)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	14/21 (66.7)	17/24 (70.8)	0.9197
>=20, n / N (%)	44/76 (57.9)	54/74 (73.0)	

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 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-301-int.sas:t-madrs-resp50-tte-301-int-itta.rtf **Run Date:** 18JUL2025

2.2.2.2 .2 .2 Subgruppenanalysen

2.2.2.2 .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-301 - ITT population

Page: 1 of 2

Age Group (years) = 18-24

	Placebo (N=13)	**Zuranolone (N=19)**
Number of evaluable subjects [1]	11	19
Number of subjects with response, n (%) [2]	8 (72.7)	16 (84.2)
Time to first MADRS response (days) [3]		
25th percentile - Q1 (95% CI)	9.0 (6.0 , 29.0)	8.0 (NE, NE)
50th percentile - median (95% CI)	29.0 (8.0, NE)	8.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	NE (16.0, NE)	16.0 (8.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.392
95% CI for the HR		(0.9179 , 6.2339)
p-value for the HR		0.0743

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-301-by.sas:t-madrs-resp50-tte-301-by-age-itta.rtf **Run Date:** 25JUL2025

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Age Group: 217-PPD-301 - ITT population

Page: 2 of 2

Age Group (years) = 25-45

	Placebo (N=88)	Zuranolone (N=80)
Number of evaluable subjects [1]	86	79
Number of subjects with response, n (%) [2]	50 (58.1)	55 (69.6)
Time to first MADRS response (days) [3]		
25th percentile - Q1 (95% CI)	13.0 (8.0 , 15.0)	8.0 (NE, NE)
50th percentile - median (95% CI)	35.0 (16.0 , 47.0)	15.0 (9.0 , 27.0)
75th percentile - Q3 (95% CI)	52.0 (47.0, NE)	46.0 (29.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.558
95% CI for the HR		(1.0526 , 2.3070)
p-value for the HR		0.0267

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-301-by.sas:t-madrs-resp50-tte-301-by-age-itta.rtf **Run Date:** 25JUL2025

2.2.2.2 .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-301 - ITT population

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

	Placebo (N=32)	Zuranolone (N=33)
Number of evaluable subjects [1]	32	33
Number of subjects with response, n (%) [2]	16 (50.0)	22 (66.7)
Time to first MADRS response (days) [3]		
25th percentile - Q1 (95% CI)	13.0 (8.0 , 17.0)	8.5 (8.0 , 15.0)
50th percentile - median (95% CI)	53.0 (15.0, NE)	15.0 (9.0 , 46.0)
75th percentile - Q3 (95% CI)	NE (53.0, NE)	NE (29.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.572
95% CI for the HR		(0.8193 , 3.0153)
p-value for the HR		0.1737

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-301-by.sas:t-madrs-resp50-tte-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

	Placebo (N=66)	Zuranolone (N=65)
Number of evaluable subjects [1]	65	65
Number of subjects with response, n (%) [2]	42 (64.6)	49 (75.4)
Time to first MADRS response (days) [3]		
25th percentile - Q1 (95% CI)	9.0 (8.0 , 16.0)	8.0 (NE, NE)
50th percentile - median (95% CI)	29.0 (16.0 , 45.0)	9.0 (8.0 , 16.0)
75th percentile - Q3 (95% CI)	47.0 (45.0, NE)	29.0 (16.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.600
95% CI for the HR		(1.0455 , 2.4501)
p-value for the HR		0.0304

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-301-by.sas:t-madrs-resp50-tte-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

2.2.2.2 .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-301 - ITT population

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Race Group = Black or African American

	Placebo (N=20)	Zuranolone (N=26)
Number of evaluable subjects [1]	17	25
Number of subjects with response, n (%) [2]	6 (35.3)	18 (72.0)
Time to first MADRS response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (8.0, NE)	8.0 (NE, NE)
50th percentile - median (95% CI)	NE (15.0, NE)	15.0 (8.0 , 29.0)
75th percentile - Q3 (95% CI)	NE (NE, NE)	46.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.868
95% CI for the HR		(1.0715 , 7.6745)
p-value for the HR		0.0360

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-301-by.sas:t-madrs-resp50-tte-301-by-race-itta.rtf **Run Date:** 25JUL2025

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Race Group: 217-PPD-301 - ITT population

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Race Group = White

	Placebo (N=70)	Zuranolone (N=68)
Number of evaluable subjects [1]	69	68
Number of subjects with response, n (%) [2]	46 (66.7)	50 (73.5)
Time to first MADRS response (days) [3]		
25th percentile - Q1 (95% CI)	10.0 (8.0 , 15.0)	8.0 (NE, NE)
50th percentile - median (95% CI)	30.0 (16.0 , 46.0)	15.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	47.0 (46.0, NE)	43.0 (16.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.481
95% CI for the HR		(0.9855 , 2.2248)
p-value for the HR		0.0588

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-301-by.sas:t-madrs-resp50-tte-301-by-race-itta.rtf **Run Date:** 25JUL2025

2.2.2.2 .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-301 - ITT population

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Antidepressant Use at Baseline = Yes

	Placebo (N=15)	Zuranolone (N=15)
Number of evaluable subjects [1]	15	15
Number of subjects with response, n (%) [2]	12 (80.0)	8 (53.3)
Time to first MADRS response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (8.0 , 15.0)	9.0 (8.0 , 15.0)
50th percentile - median (95% CI)	16.0 (8.0 , 29.0)	29.0 (8.0, NE)
75th percentile - Q3 (95% CI)	53.0 (16.0, NE)	NE (29.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.642
95% CI for the HR		(0.2562 , 1.6095)
p-value for the HR		0.3448

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-301-by.sas:t-madrs-resp50-tte-301-by-adt-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

Page: 2 of 2

Antidepressant Use at Baseline = No

	Placebo (N=86)	Zuranolone (N=84)
Number of evaluable subjects [1]	82	83
Number of subjects with response, n (%) [2]	46 (56.1)	63 (75.9)
Time to first MADRS response (days) [3]		
25th percentile - Q1 (95% CI)	13.0 (8.0 , 16.0)	8.0 (NE, NE)
50th percentile - median (95% CI)	36.0 (19.0 , 47.0)	9.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	52.0 (47.0, NE)	29.0 (16.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.816
95% CI for the HR		(1.2363 , 2.6661)
p-value for the HR		0.0024

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-301-by.sas:t-madrs-resp50-tte-301-by-adt-itta.rtf **Run Date:** 25JUL2025

2.2.2.2 .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-301 - ITT population

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

	Placebo (N=22)	Zuranolone (N=20)
Number of evaluable subjects [1]	22	20
Number of subjects with response, n (%) [2]	14 (63.6)	14 (70.0)
Time to first MADRS response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (8.0 , 29.0)	8.0 (8.0 , 15.0)
50th percentile - median (95% CI)	33.0 (15.0, NE)	17.5 (8.0 , 46.0)
75th percentile - Q3 (95% CI)	NE (36.0, NE)	46.0 (19.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.471
95% CI for the HR		(0.6812 , 3.1781)
p-value for the HR		0.3257

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-301-by.sas:t-madrs-resp50-tte-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

	Placebo (N=34)	Zuranolone (N=24)
Number of evaluable subjects [1]	34	24
Number of subjects with response, n (%) [2]	22 (64.7)	17 (70.8)
Time to first MADRS response (days) [3]		
25th percentile - Q1 (95% CI)	10.0 (8.0 , 16.0)	8.0 (8.0 , 9.0)
50th percentile - median (95% CI)	29.0 (15.0 , 46.0)	9.0 (8.0 , 29.0)
75th percentile - Q3 (95% CI)	46.0 (30.0, NE)	29.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.460
95% CI for the HR		(0.7544 , 2.8252)
p-value for the HR		0.2613

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-301-by.sas:t-madrs-resp50-tte-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

	Placebo (N=42)	Zuranolone (N=53)
Number of evaluable subjects [1]	41	53
Number of subjects with response, n (%) [2]	22 (53.7)	39 (73.6)
Time to first MADRS response (days) [3]		
25th percentile - Q1 (95% CI)	9.0 (8.0 , 16.0)	8.0 (NE, NE)
50th percentile - median (95% CI)	47.0 (15.0 , 53.0)	12.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	53.0 (47.0, NE)	43.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.675
95% CI for the HR		(0.9861 , 2.8444)
p-value for the HR		0.0564

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-301-by.sas:t-madrs-resp50-tte-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

2.2.2.2 .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-301 - ITT population

Page: 1 of 2

Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=35)
Number of evaluable subjects [1]	30	34
Number of subjects with response, n (%) [2]	15 (50.0)	25 (73.5)
Time to first MADRS response (days) [3]		
25th percentile - Q1 (95% CI)	9.0 (8.0 , 15.0)	8.0 (NE, NE)
50th percentile - median (95% CI)	30.0 (13.0, NE)	12.0 (8.0 , 27.0)
75th percentile - Q3 (95% CI)	NE (47.0, NE)	37.5 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.814
95% CI for the HR		(0.9445 , 3.4826)
p-value for the HR		0.0737

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-301-by.sas:t-madrs-resp50-tte-301-by-onset-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

Page: 2 of 2

Onset of PPD = Postpartum

	Placebo (N=69)	Zuranolone (N=64)
Number of evaluable subjects [1]	67	64
Number of subjects with response, n (%) [2]	43 (64.2)	46 (71.9)
Time to first MADRS response (days) [3]		
25th percentile - Q1 (95% CI)	10.0 (8.0 , 16.0)	8.0 (NE, NE)
50th percentile - median (95% CI)	30.0 (16.0 , 46.0)	15.0 (8.0 , 19.0)
75th percentile - Q3 (95% CI)	52.0 (46.0, NE)	46.0 (19.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.470
95% CI for the HR		(0.9635 , 2.2411)
p-value for the HR		0.0739

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-301-by.sas:t-madrs-resp50-tte-301-by-onset-itta.rtf **Run Date:** 25JUL2025

2.2.2.2 .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-301 - ITT population

Page: 1 of 2

Family History of PPD = Yes

	Placebo (N=16)	Zuranolone (N=21)
Number of evaluable subjects [1]	16	21
Number of subjects with response, n (%) [2]	13 (81.3)	15 (71.4)
Time to first MADRS response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (6.0 , 10.0)	8.0 (8.0 , 9.0)
50th percentile - median (95% CI)	15.0 (8.0 , 15.0)	15.0 (8.0 , 46.0)
75th percentile - Q3 (95% CI)	16.0 (15.0, NE)	46.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.711
95% CI for the HR		(0.3325 , 1.5184)
p-value for the HR		0.3778

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-301-by.sas:t-madrs-resp50-tte-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

Page: 2 of 2

Family History of PPD = No/Unknown

	Placebo (N=85)	Zuranolone (N=78)
Number of evaluable subjects [1]	81	77
Number of subjects with response, n (%) [2]	45 (55.6)	56 (72.7)
Time to first MADRS response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (8.0 , 19.0)	8.0 (NE, NE)
50th percentile - median (95% CI)	43.0 (29.0 , 47.0)	15.0 (8.0 , 16.0)
75th percentile - Q3 (95% CI)	52.0 (47.0, NE)	43.0 (19.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.804
95% CI for the HR		(1.2121 , 2.6847)
p-value for the HR		0.0036

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-301-by.sas:t-madrs-resp50-tte-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

2.2.2.2 .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-301 - ITT population

Page: 1 of 2

History of PPD = 1st Episode

	Placebo (N=90)	Zuranolone (N=82)
Number of evaluable subjects [1]	86	81
Number of subjects with response, n (%) [2]	52 (60.5)	57 (70.4)
Time to first MADRS response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (9.0 , 16.0)	8.0 (NE, NE)
50th percentile - median (95% CI)	30.0 (17.0 , 46.0)	15.0 (8.0 , 19.0)
75th percentile - Q3 (95% CI)	52.0 (46.0, NE)	46.0 (29.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.467
95% CI for the HR		(1.0049 , 2.1404)
p-value for the HR		0.0471

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-301-by.sas:t-madrs-resp50-tte-301-by-hist-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

Page: 2 of 2

History of PPD = Recurrent Episode

	Placebo (N=11)	Zuranolone (N=17)
Number of evaluable subjects [1]	11	17
Number of subjects with response, n (%) [2]	6 (54.5)	14 (82.4)
Time to first MADRS response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (6.0 , 8.0)	8.0 (8.0 , 9.0)
50th percentile - median (95% CI)	8.0 (8.0, NE)	9.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	NE (8.0, NE)	15.0 (9.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.600
95% CI for the HR		(0.5733 , 4.4678)
p-value for the HR		0.3693

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-301-by.sas:t-madrs-resp50-tte-301-by-hist-itta.rtf **Run Date:** 25JUL2025

2.2.2.2 .2 .2 .9 Depression mit Angst

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

Page: 1 of 2

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

	Placebo (N=21)	Zuranolone (N=24)
Number of evaluable subjects [1]	21	24
Number of subjects with response, n (%) [2]	14 (66.7)	17 (70.8)
Time to first MADRS response (days) [3]		
25th percentile - Q1 (95% CI)	18.0 (8.0 , 30.0)	8.0 (8.0 , 9.0)
50th percentile - median (95% CI)	35.5 (17.0, NE)	15.0 (8.0 , 29.0)
75th percentile - Q3 (95% CI)	52.0 (36.0, NE)	46.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.518
95% CI for the HR		(0.7143 , 3.2239)
p-value for the HR		0.2780

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-301-by.sas:t-madrs-resp50-tte-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Response (>=50% reduction from baseline in total score) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

Page: 2 of 2

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

	Placebo (N=77)	Zuranolone (N=74)
Number of evaluable subjects [1]	76	74
Number of subjects with response, n (%) [2]	44 (57.9)	54 (73.0)
Time to first MADRS response (days) [3]		
25th percentile - Q1 (95% CI)	9.0 (8.0 , 15.0)	8.0 (NE, NE)
50th percentile - median (95% CI)	29.0 (15.0 , 47.0)	15.0 (8.0 , 16.0)
75th percentile - Q3 (95% CI)	53.0 (47.0, NE)	43.0 (16.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.509
95% CI for the HR		(1.0095 , 2.2568)
p-value for the HR		0.0449

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.

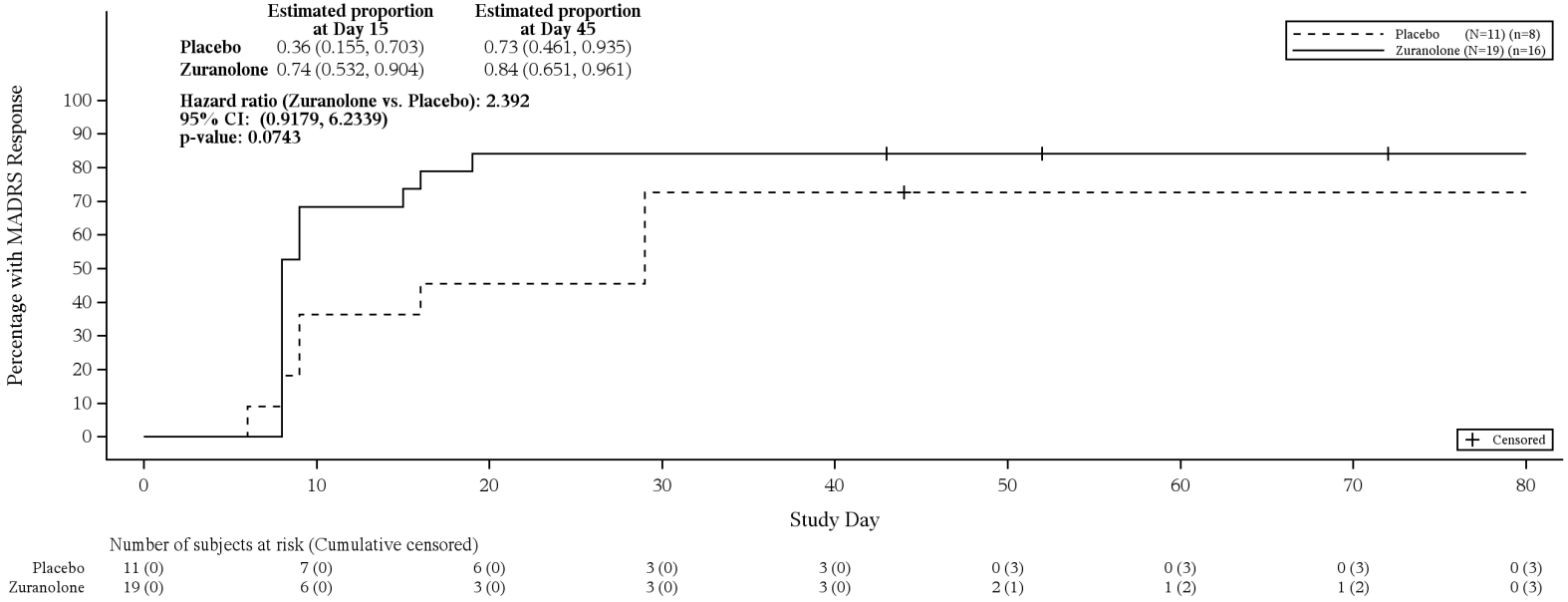
Source: biib125/v_a/germany_amnog/t-madrs-resp50-tte-301-by.sas:t-madrs-resp50-tte-301-by-hama-itta.rtf **Run Date:** 25JUL2025

2.2.2.2 .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-301 - 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 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.

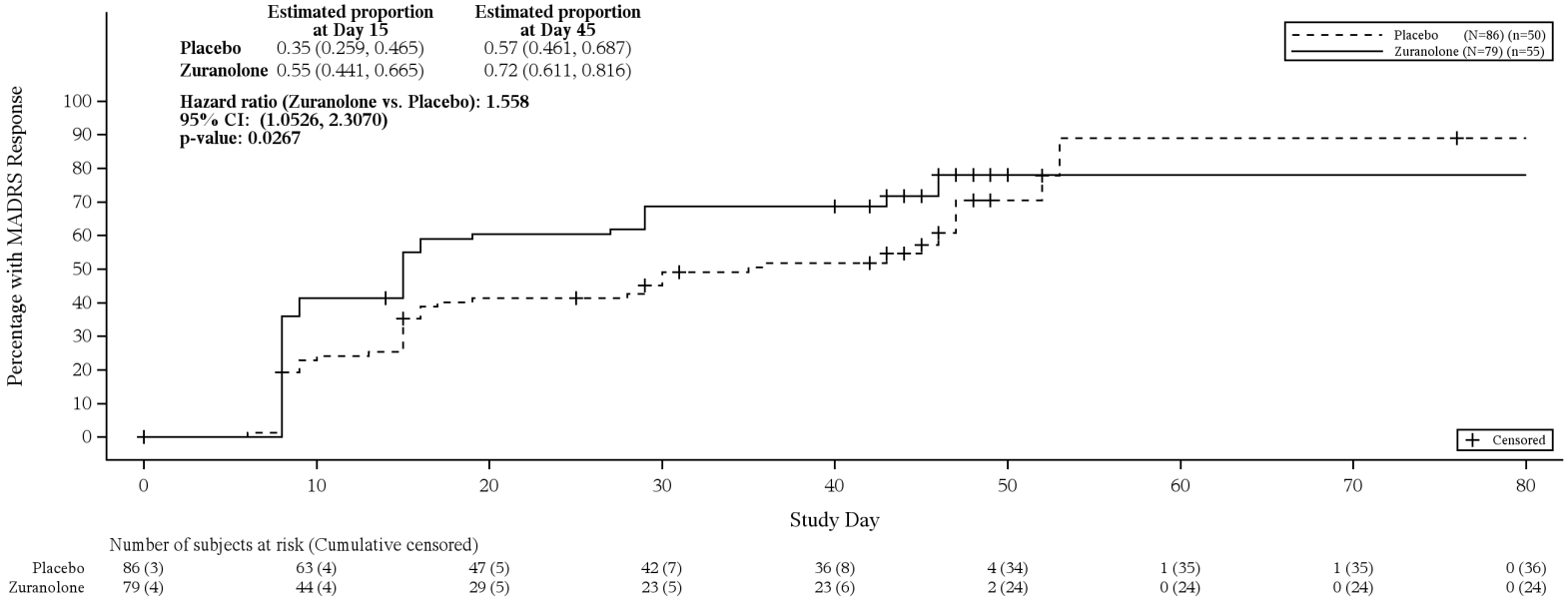
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate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

Source: biib125/v_a/amnog_kmplots/f-madrs-resp50-tte-301-by.sas:f-madrs-resp50-tte-301-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-301 - ITT population

Page: 2 of 19

Age Group (years) = 25-45



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.

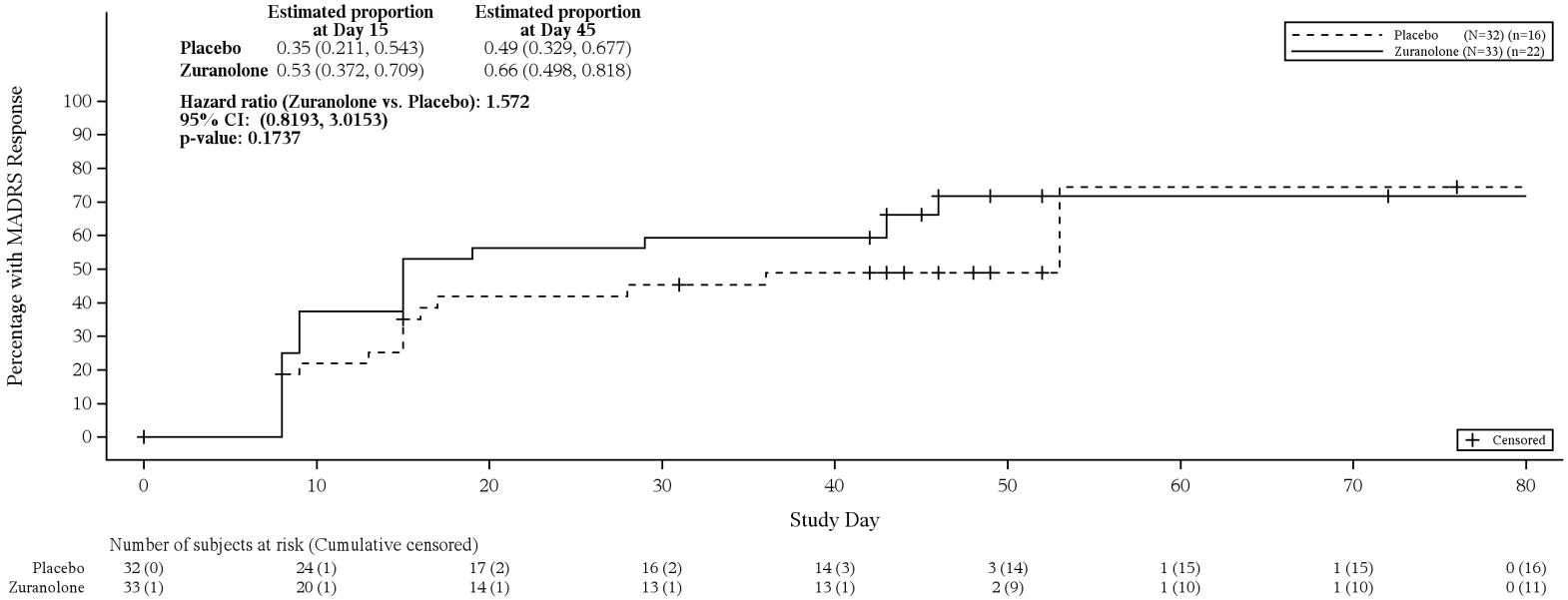
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate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

Source: biib125/v_a/amnog_kmplots/f-madrs-resp50-tte-301-by.sas:f-madrs-resp50-tte-301-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-301 - ITT population

Page: 3 of 19

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 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.

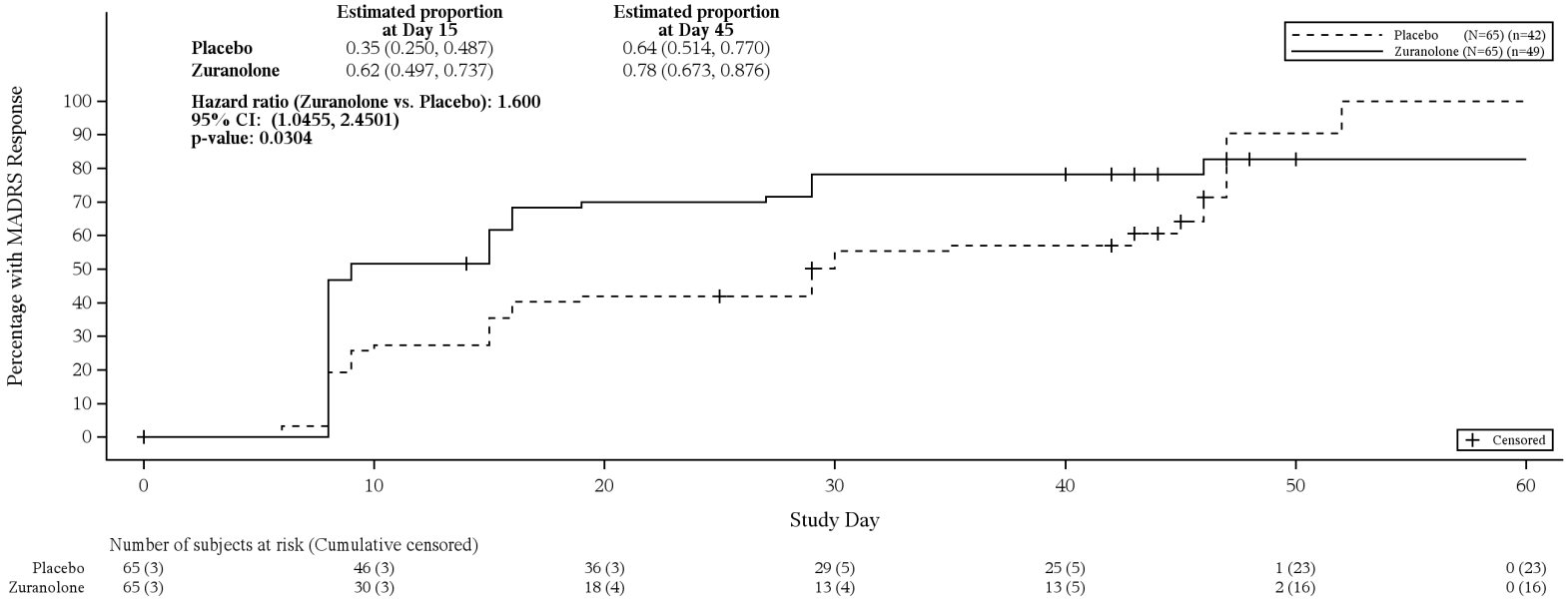
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate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

Source: biib125/v_a/amnog_kmplots/f-madrs-resp50-tte-301-by.sas:f-madrs-resp50-tte-301-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-301 - 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 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.

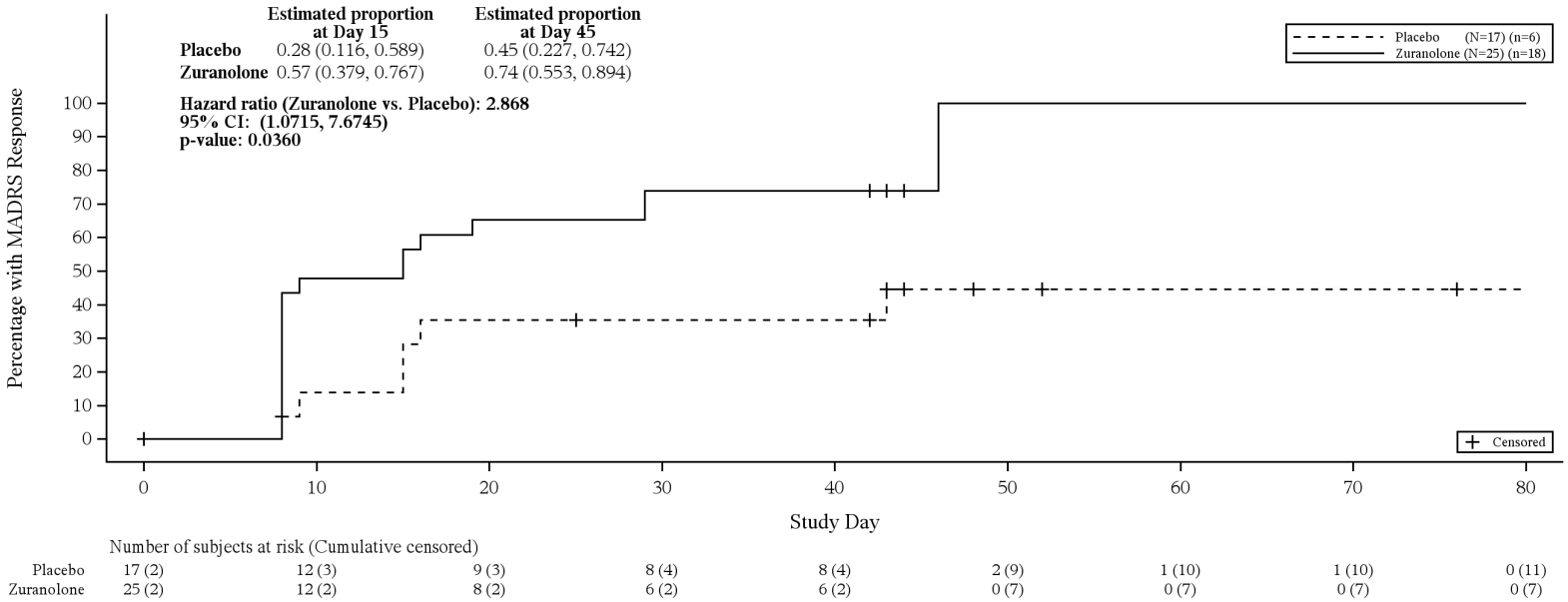
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate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

Source: biib125/v_a/amnog_kmplots/f-madrs-resp50-tte-301-by.sas:f-madrs-resp50-tte-301-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-301 - ITT population

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Race Group = Black or African American



Number of subjects at risk (Cumulative censored)

Placebo	17 (2)	12 (3)	9 (3)	8 (4)	8 (4)	2 (9)	1 (10)	1 (10)	0 (11)
Zuranolone	25 (2)	12 (2)	8 (2)	6 (2)	6 (2)	0 (7)	0 (7)	0 (7)	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.

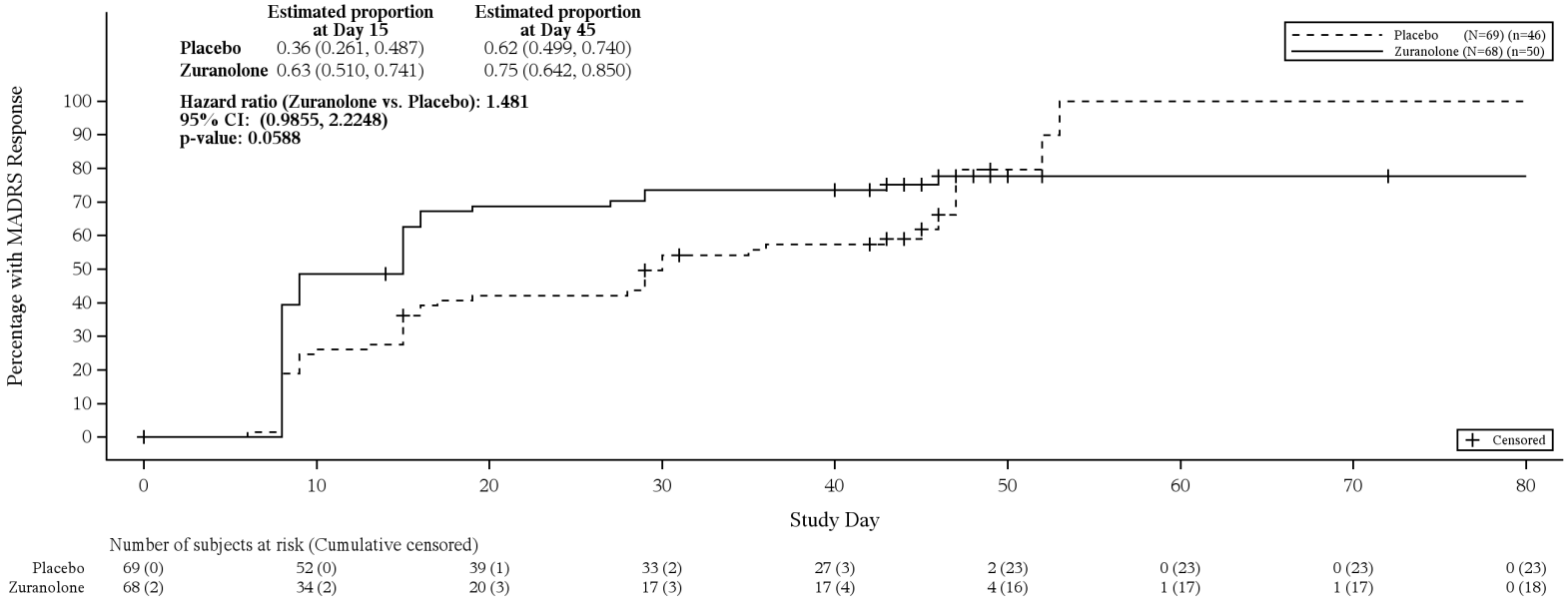
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate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

Source: biib125/v_a/amnog_kmplots/f-madrs-resp50-tte-301-by.sas:f-madrs-resp50-tte-301-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-301 - ITT population

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Race Group = White



Number of subjects at risk (Cumulative censored)

Placebo	69 (0)	52 (0)	39 (1)	33 (2)	27 (3)	2 (23)	0 (23)	0 (23)	0 (23)
Zuranolone	68 (2)	34 (2)	20 (3)	17 (3)	17 (4)	4 (16)	1 (17)	1 (17)	0 (18)

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.

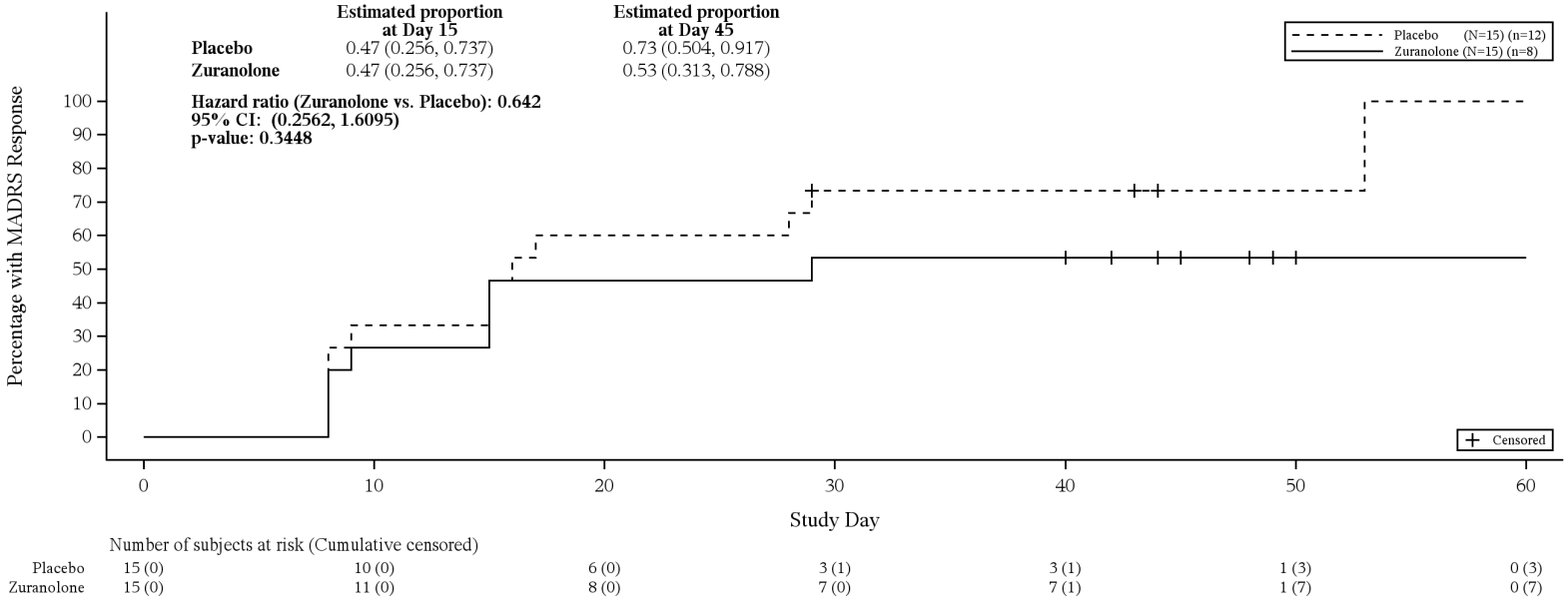
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate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

Source: biib125/v_a/amnog_kmplots/f-madrs-resp50-tte-301-by.sas:f-madrs-resp50-tte-301-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-301 - ITT population

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Antidepressant Use at Baseline = Yes



Number of subjects at risk (Cumulative censored)

Placebo	15 (0)	10 (0)	6 (0)	3 (1)	3 (1)	1 (3)	0 (3)
Zuranolone	15 (0)	11 (0)	8 (0)	7 (0)	7 (1)	1 (7)	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.

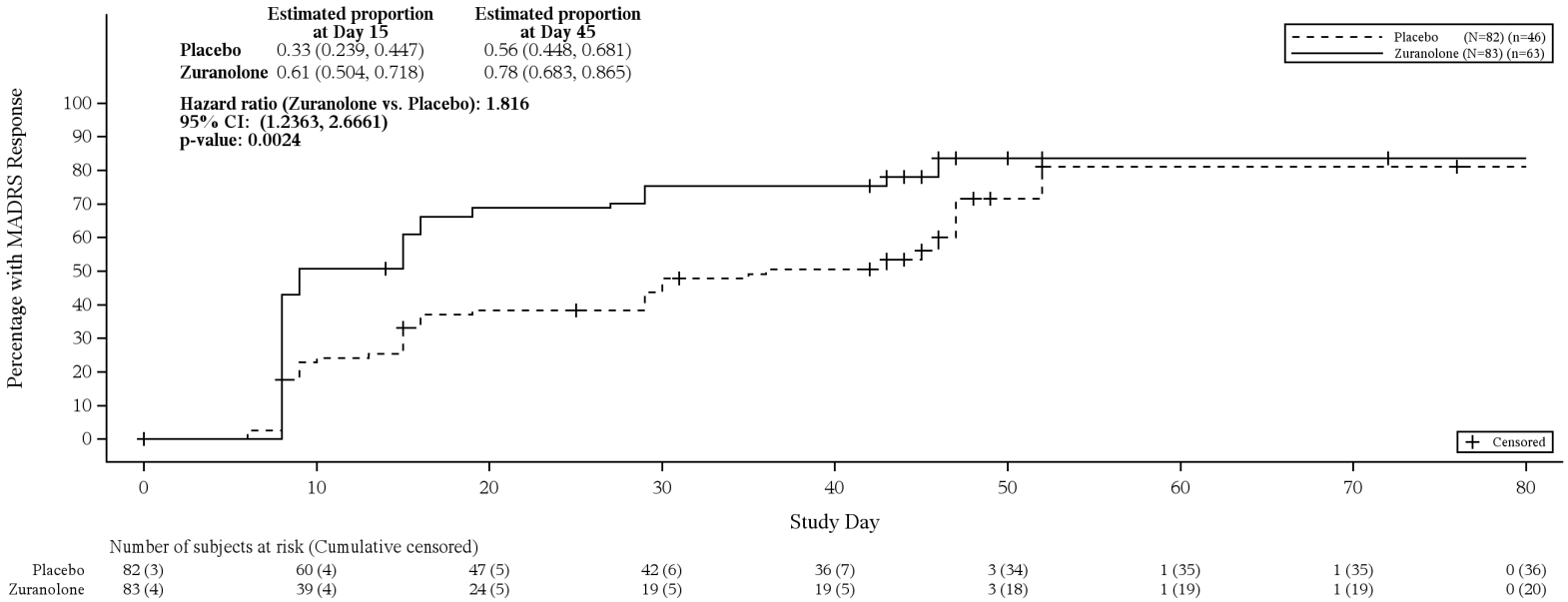
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate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

Source: biib125/v_a/amnog_kmplots/f-madrs-resp50-tte-301-by.sas:f-madrs-resp50-tte-301-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-301 - 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 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.

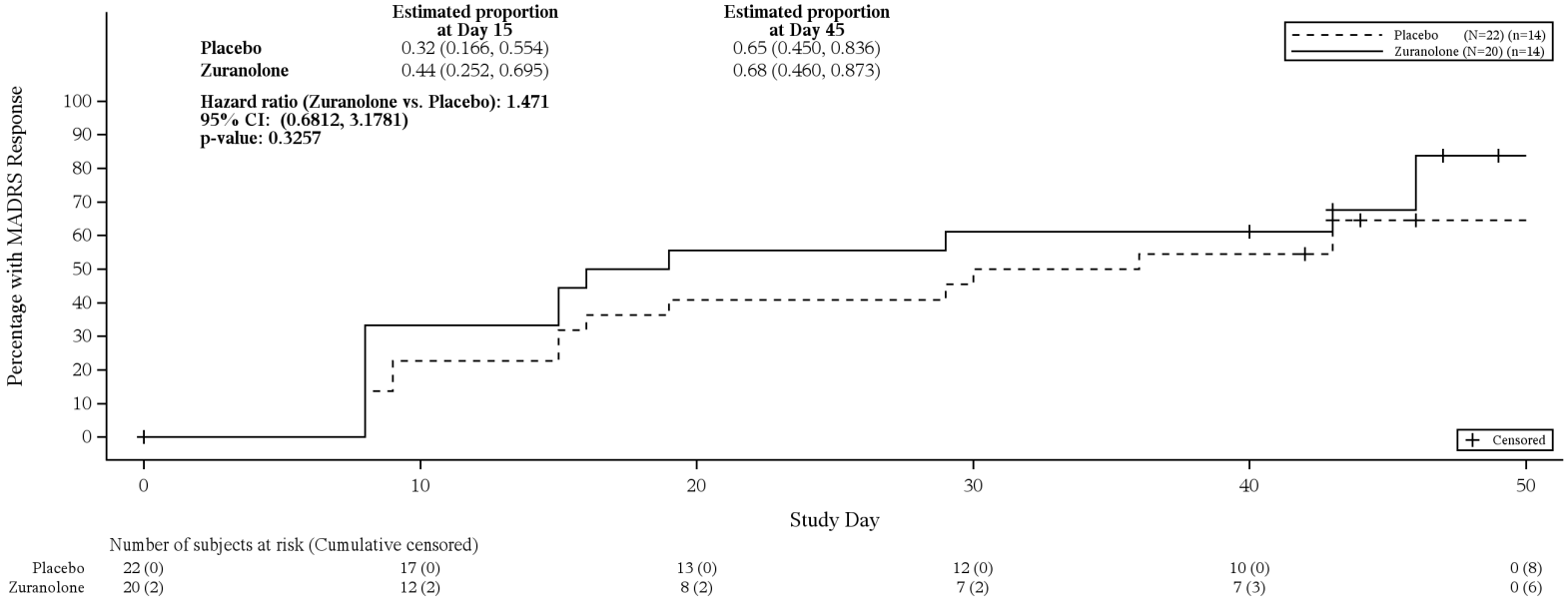
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate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

Source: biib125/v_a/amnog_kmplots/f-madrs-resp50-tte-301-by.sas:f-madrs-resp50-tte-301-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-301 - 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 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.

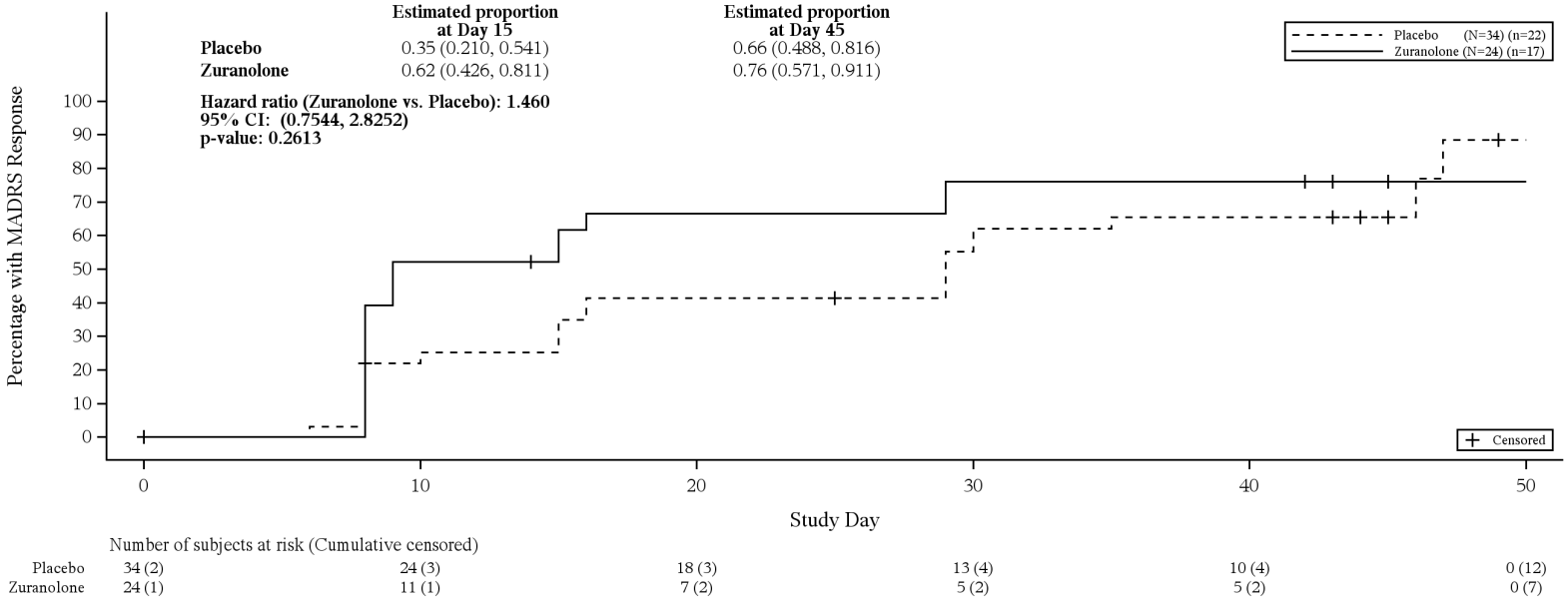
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate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

Source: biib125/v_a/amnog_kmplots/f-madrs-resp50-tte-301-by.sas:f-madrs-resp50-tte-301-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-301 - 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 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.

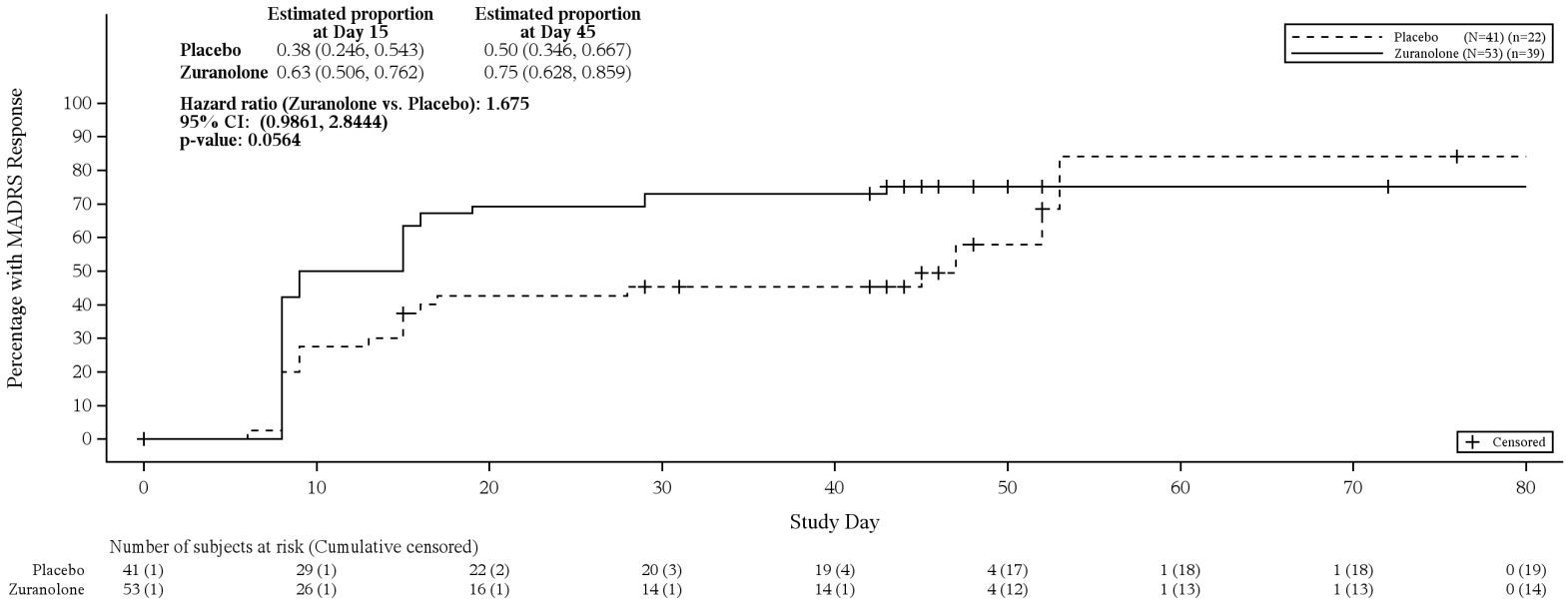
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate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

Source: biib125/v_a/amnog_kmplots/f-madrs-resp50-tte-301-by.sas:f-madrs-resp50-tte-301-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-301 - 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 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.

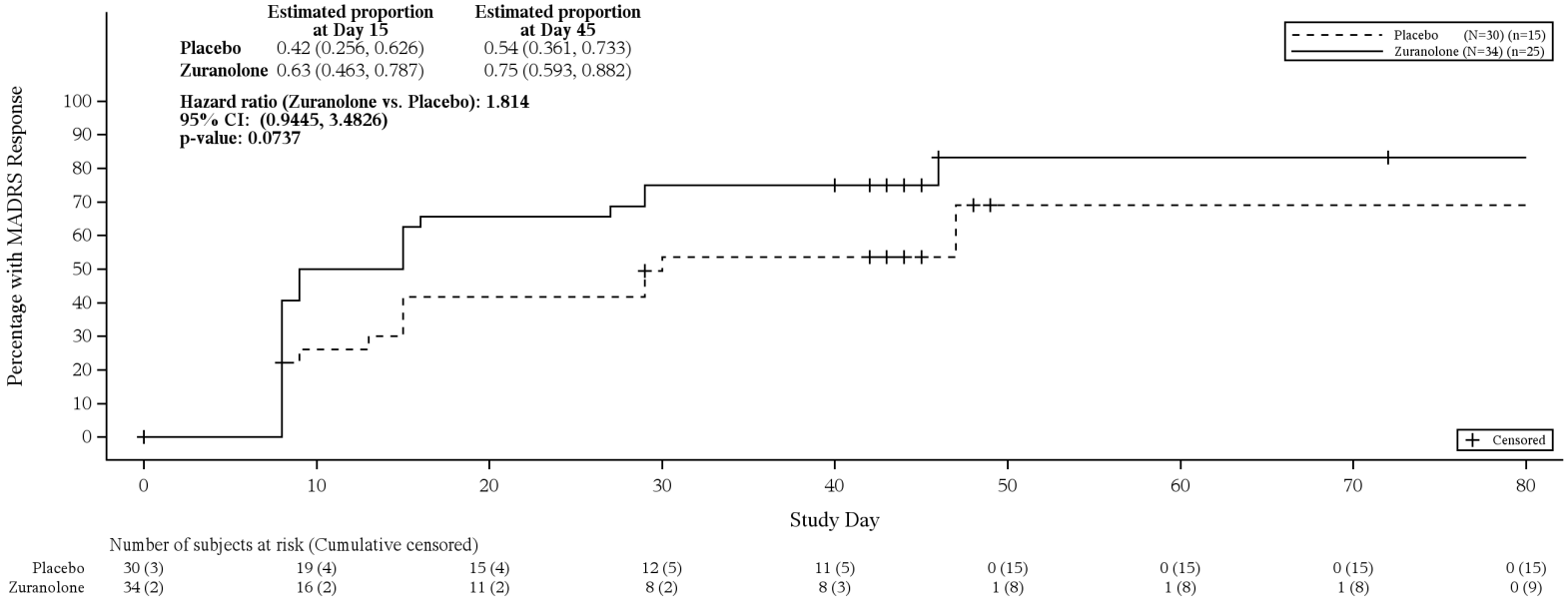
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate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

Source: biib125/v_a/amnog_kmplots/f-madrs-resp50-tte-301-by.sas:f-madrs-resp50-tte-301-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-301 - 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.

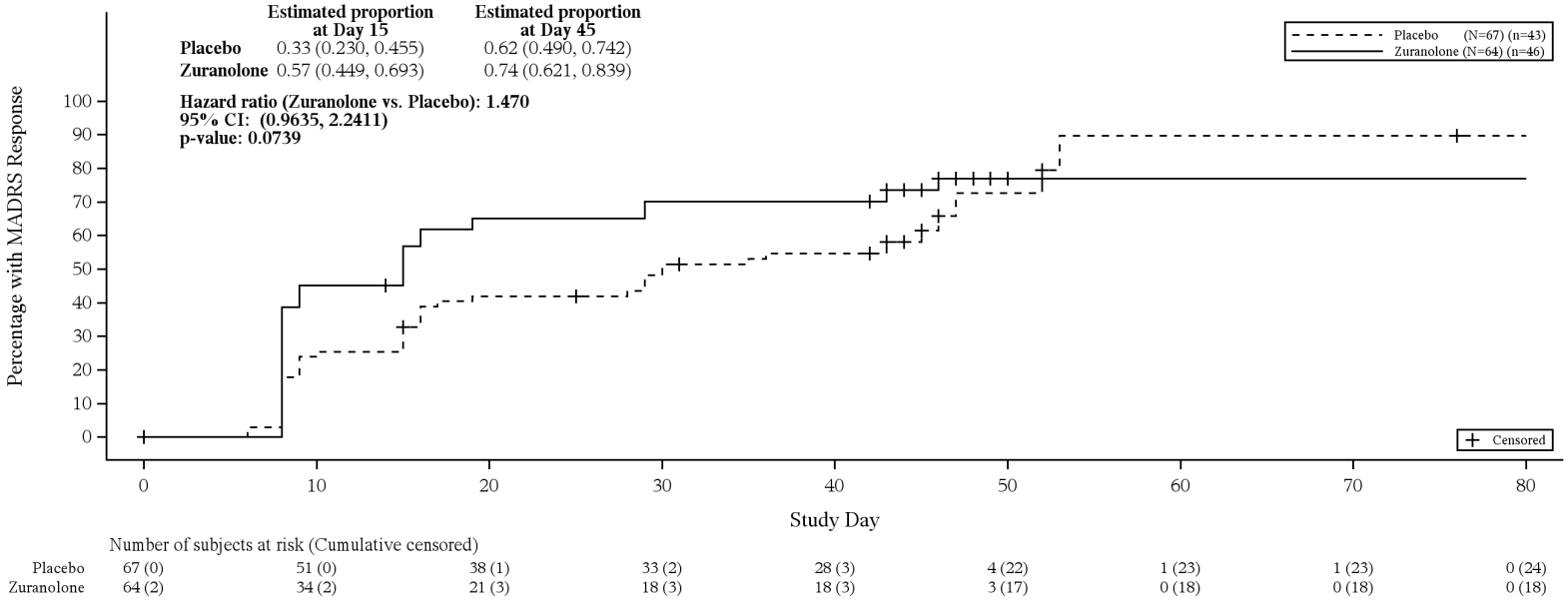
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate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

Source: biib125/v_a/amnog_kmplots/f-madrs-resp50-tte-301-by.sas:f-madrs-resp50-tte-301-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-301 - 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 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.

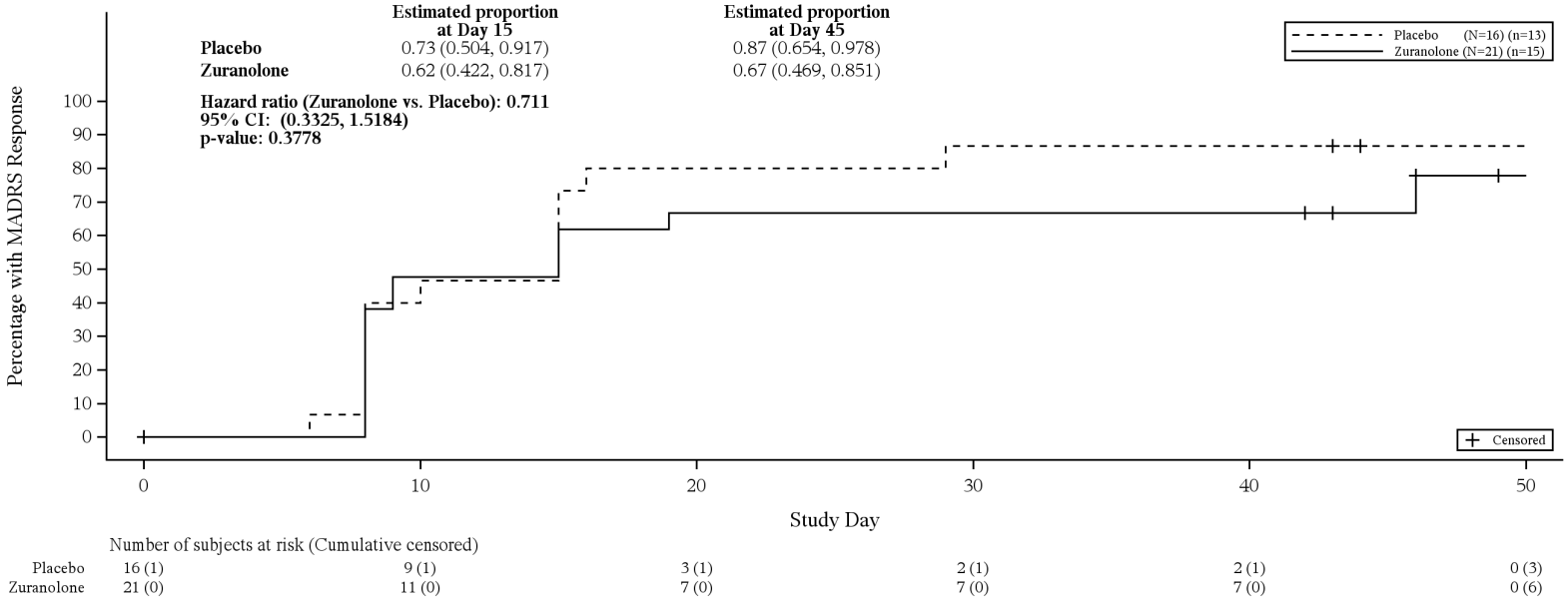
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate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

Source: biib125/v_a/amnog_kmplots/f-madrs-resp50-tte-301-by.sas:f-madrs-resp50-tte-301-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-301 - 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.

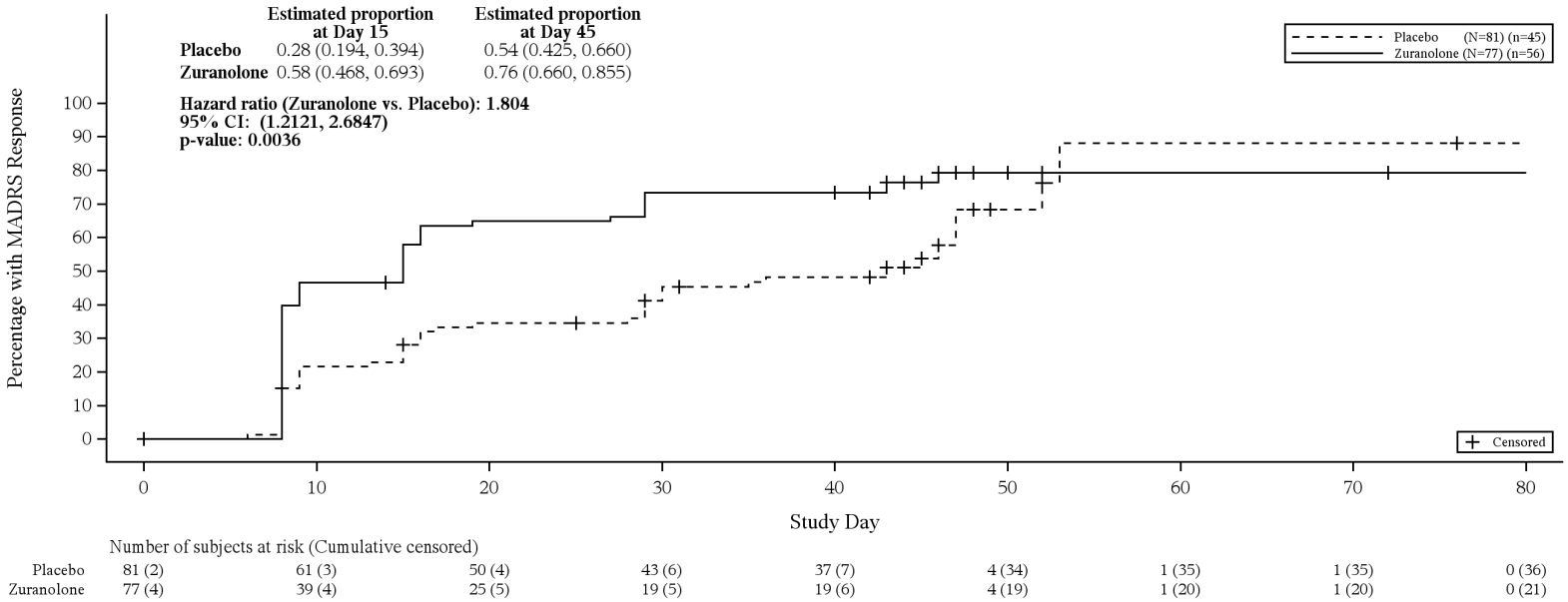
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate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

Source: biib125/v_a/amnog_kmplots/f-madrs-resp50-tte-301-by.sas:f-madrs-resp50-tte-301-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-301 - ITT population

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Family History of PPD = No/Unknown



Number of subjects at risk (Cumulative censored)

Placebo	81 (2)	61 (3)	50 (4)	43 (6)	37 (7)	4 (34)	1 (35)	1 (35)	0 (36)
Zuranolone	77 (4)	39 (4)	25 (5)	19 (5)	19 (6)	4 (19)	1 (20)	1 (20)	0 (21)

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.

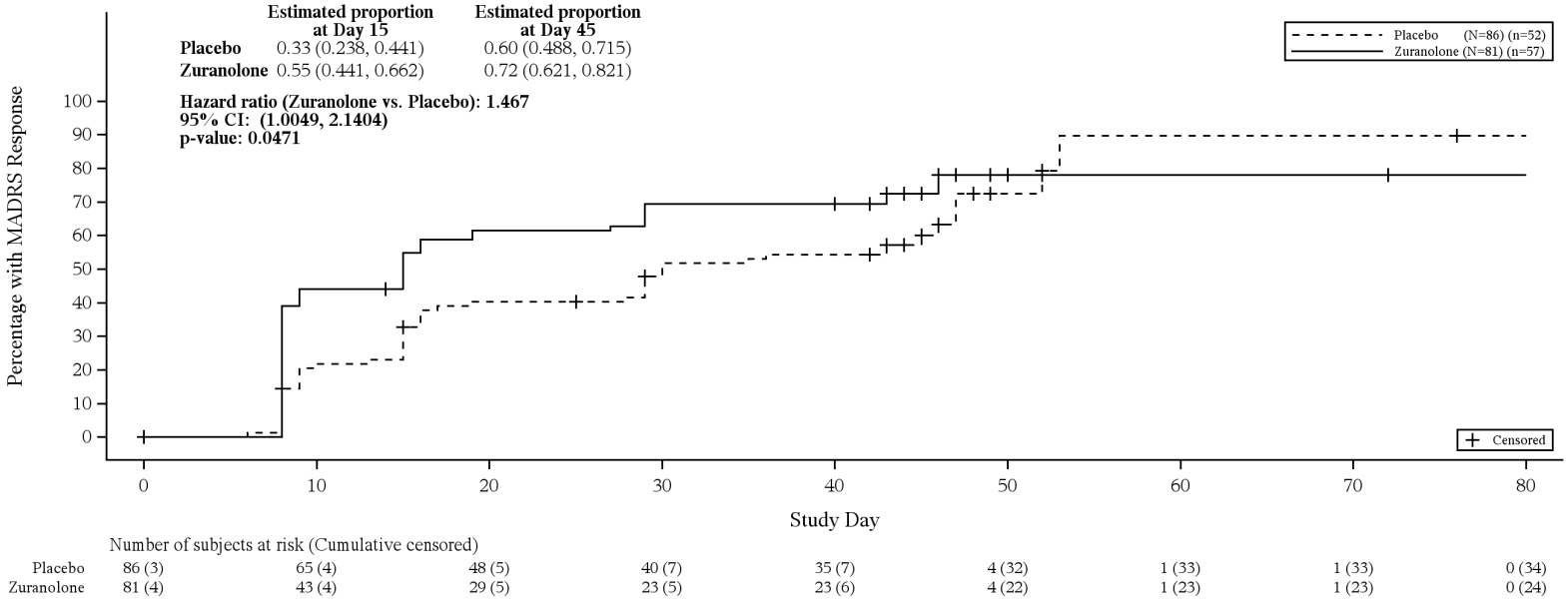
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate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

Source: biib125/v_a/amnog_kmplots/f-madrs-resp50-tte-301-by.sas:f-madrs-resp50-tte-301-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-301 - ITT population

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History of PPD = 1st Episode



Number of subjects at risk (Cumulative censored)

Placebo	86 (3)	65 (4)	48 (5)	40 (7)	35 (7)	4 (32)	1 (33)	1 (33)	0 (34)
Zuranolone	81 (4)	43 (4)	29 (5)	23 (5)	23 (6)	4 (22)	1 (23)	1 (23)	0 (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.

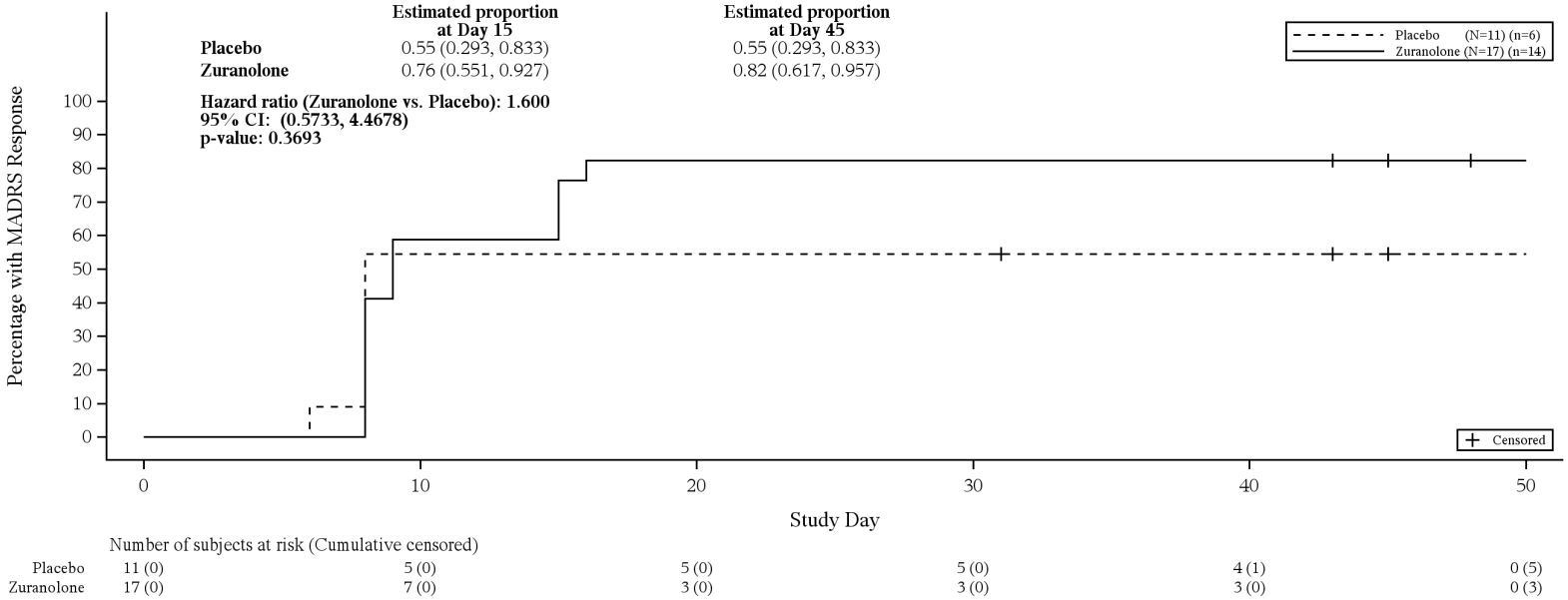
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate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

Source: biib125/v_a/amnog_kmplots/f-madrs-resp50-tte-301-by.sas:f-madrs-resp50-tte-301-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-301 - 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 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.

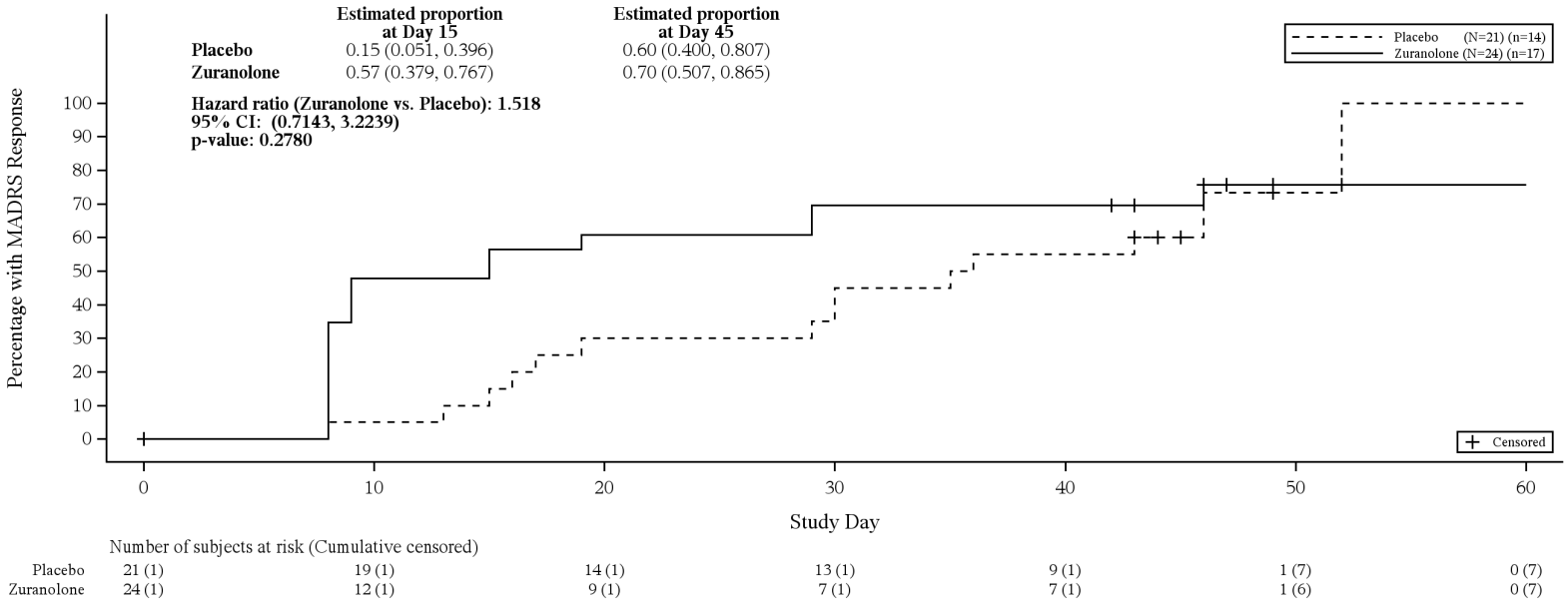
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate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

Source: biib125/v_a/amnog_kmplots/f-madrs-resp50-tte-301-by.sas:f-madrs-resp50-tte-301-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-301 - 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 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.

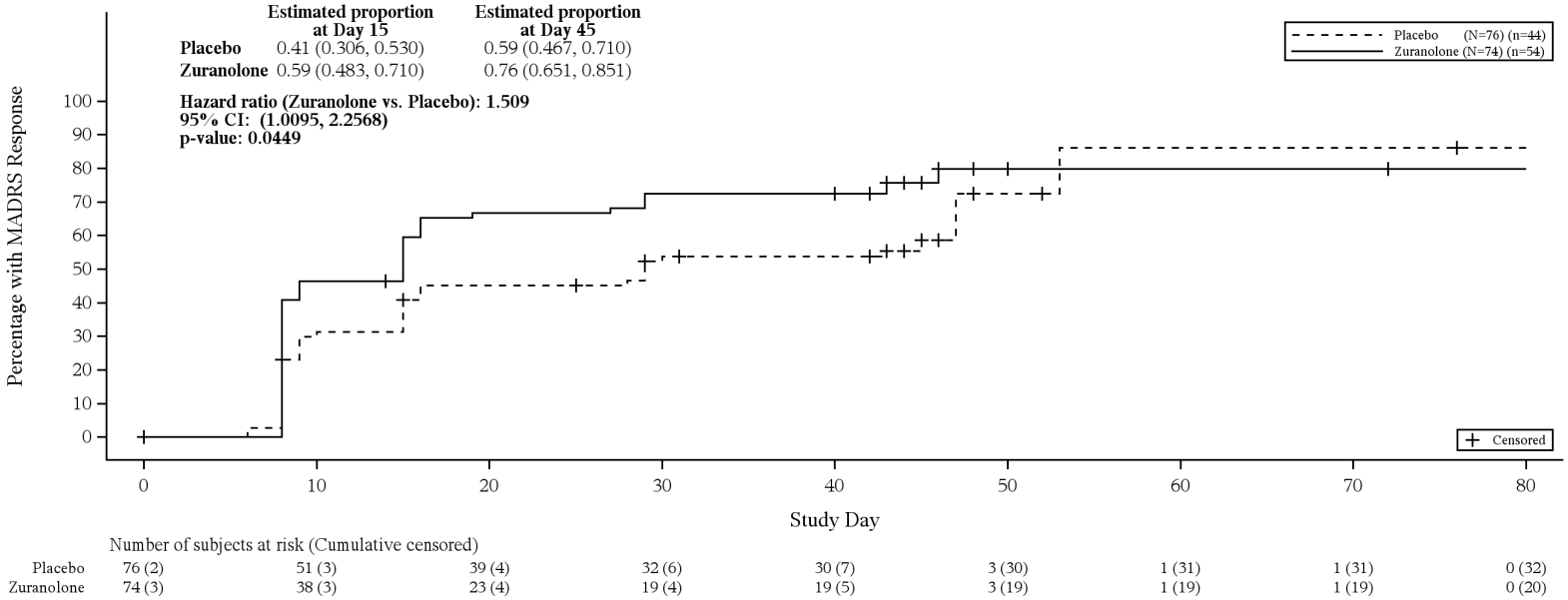
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate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

Source: biib125/v_a/amnog_kmplots/f-madrs-resp50-tte-301-by.sas:f-madrs-resp50-tte-301-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-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20



Number of subjects at risk (Cumulative censored)

Placebo	76 (2)	51 (3)	39 (4)	32 (6)	30 (7)	3 (30)	1 (31)	1 (31)	0 (32)
Zuranolone	74 (3)	38 (3)	23 (4)	19 (4)	19 (5)	3 (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 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-301-by.sas:f-madrs-resp50-tte-301-by-itta.rtf **Run Date:** 08JAN2026

2.2.3 Remission

2.2.3.1 Responder-Analysen

2.2.3.1 .1 ITT-Population

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission: 217-PPD-301 - ITT population

Page: 1 of 4

Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Number of evaluable subjects [1]	97	98
Day 8		
Number of subjects with a remission, n (%) [2]	17 (17.5)	22 (22.4)
Number of subjects with missing evaluation, n (%)	3 (3.1)	5 (5.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.279
95% CI for the RR		(0.725, 2.256)
p-value for RR		0.3952
OR - Odds Ratio (Zuranolone vs. Placebo)		1.386
95% CI for the OR		(0.681, 2.821)
p-value for OR		0.3673
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.049
95% CI for the ARR		(-0.064, 0.162)
p-value for ARR		0.3931

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-301-ovr.sas:t-madrs-remi-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission: 217-PPD-301 - ITT population

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Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 15		
Number of subjects with a remission, n (%) [2]	23 (23.7)	38 (38.8)
Number of subjects with missing evaluation, n (%)	8 (8.2)	6 (6.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.612
95% CI for the RR		(1.046, 2.483)
p-value for RR		0.0304
OR - Odds Ratio (Zuranolone vs. Placebo)		2.069
95% CI for the OR		(1.114, 3.845)
p-value for OR		0.0214
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.156
95% CI for the ARR		(0.029, 0.283)
p-value for ARR		0.0161

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-301-ovr.sas:t-madrs-remi-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission: 217-PPD-301 - ITT population

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Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 28		
Number of subjects with a remission, n (%) [2]	26 (26.8)	33 (33.7)
Number of subjects with missing evaluation, n (%)	16 (16.5)	22 (22.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.254
95% CI for the RR		(0.818, 1.921)
p-value for RR		0.2988
OR - Odds Ratio (Zuranolone vs. Placebo)		1.406
95% CI for the OR		(0.762, 2.593)
p-value for OR		0.2751
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.072
95% CI for the ARR		(-0.056, 0.199)
p-value for ARR		0.2696

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-301-ovr.sas:t-madrs-remi-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission: 217-PPD-301 - ITT population

Page: 4 of 4

Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 45		
Number of subjects with a remission, n (%) [2]	32 (33.0)	40 (40.8)
Number of subjects with missing evaluation, n (%)	13 (13.4)	14 (14.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.227
95% CI for the RR		(0.850, 1.770)
p-value for RR		0.2753
OR - Odds Ratio (Zuranolone vs. Placebo)		1.416
95% CI for the OR		(0.790, 2.539)
p-value for OR		0.2424
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.081
95% CI for the ARR		(-0.053, 0.215)
p-value for ARR		0.2339

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-301-ovr.sas:t-madrs-remi-301-ovr-itta.rtf **Run Date:** 18JUL2025

2.2.3.1 .2 Subgruppen

2.2.3.1 .2 .1 Interaktionstest

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission: Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	97	98	
Number of subjects with response at Day 15, n (%)	23 (23.7)	38 (38.8)	
Number of subjects with response at Day 45, n (%)	32 (33.0)	40 (40.8)	
Age Group (years)			0.3611
Day 15			
18 - 24, n / N (%)	3/11 (27.3)	12/19 (63.2)	
25 - 45, n / N (%)	20/86 (23.3)	26/79 (32.9)	
Day 45			
18 - 24, n / N (%)	3/11 (27.3)	11/19 (57.9)	
25 - 45, n / N (%)	29/86 (33.7)	29/79 (36.7)	

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 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.
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Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission: Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			0.9714
Day 15			
<28, n / N (%)	9/32 (28.1)	12/33 (36.4)	
>=28, n / N (%)	14/65 (21.5)	26/65 (40.0)	
Day 45			
<28, n / N (%)	8/32 (25.0)	14/33 (42.4)	
>=28, n / N (%)	24/65 (36.9)	26/65 (40.0)	
Race Group (Black or African American, White)			0.0304
Day 15			
Black or African American, n / N (%)	3/17 (17.6)	10/25 (40.0)	
White, n / N (%)	17/69 (24.6)	27/68 (39.7)	
Day 45			
Black or African American, n / N (%)	3/17 (17.6)	12/25 (48.0)	
White, n / N (%)	27/69 (39.1)	28/68 (41.2)	

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 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-301-int.sas:t-madrs-remi-301-int-itta.rtf **Run Date:** 18JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission: Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			0.2074
Day 15			
Yes, n / N (%)	7/15 (46.7)	5/15 (33.3)	
No, n / N (%)	16/82 (19.5)	33/83 (39.8)	
Day 45			
Yes, n / N (%)	7/15 (46.7)	6/15 (40.0)	
No, n / N (%)	25/82 (30.5)	34/83 (41.0)	

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 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-301-int.sas:t-madrs-remi-301-int-itta.rtf **Run Date:** 18JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission: Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			0.1071(a) 0.1904(b) 0.6189(c)
Day 15			
<=24.9, n / N (%)	6/22 (27.3)	6/20 (30.0)	
25-29.9, n / N (%)	6/34 (17.6)	10/24 (41.7)	
>=30, n / N (%)	11/41 (26.8)	22/53 (41.5)	
Day 45			
<=24.9, n / N (%)	8/22 (36.4)	6/20 (30.0)	
25-29.9, n / N (%)	13/34 (38.2)	12/24 (50.0)	
>=30, n / N (%)	11/41 (26.8)	21/53 (39.6)	

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 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-301-int.sas:t-madrs-remi-301-int-itta.rtf **Run Date:** 18JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission: Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Onset of PPD			0.9069
Day 15			
3rd Trimester, n / N (%)	8/30 (26.7)	11/34 (32.4)	
Postpartum, n / N (%)	15/67 (22.4)	27/64 (42.2)	
Day 45			
3rd Trimester, n / N (%)	9/30 (30.0)	15/34 (44.1)	
Postpartum, n / N (%)	23/67 (34.3)	25/64 (39.1)	
Family History of PPD			0.5202
Day 15			
Yes, n / N (%)	6/16 (37.5)	8/21 (38.1)	
No/Unknown, n / N (%)	17/81 (21.0)	30/77 (39.0)	
Day 45			
Yes, n / N (%)	6/16 (37.5)	10/21 (47.6)	
No/Unknown, n / N (%)	26/81 (32.1)	30/77 (39.0)	

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 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-301-int.sas:t-madrs-remi-301-int-itta.rtf **Run Date:** 18JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission: Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
History of PPD			0.9270
Day 15			
1st Episode, n / N (%)	18/86 (20.9)	29/81 (35.8)	
Recurrent Episode, n / N (%)	5/11 (45.5)	9/17 (52.9)	
Day 45			
1st Episode, n / N (%)	29/86 (33.7)	31/81 (38.3)	
Recurrent Episode, n / N (%)	3/11 (27.3)	9/17 (52.9)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			0.5371
Day 15			
<20, n / N (%)	5/21 (23.8)	10/24 (41.7)	
>=20, n / N (%)	18/76 (23.7)	28/74 (37.8)	
Day 45			
<20, n / N (%)	11/21 (52.4)	11/24 (45.8)	
>=20, n / N (%)	21/76 (27.6)	29/74 (39.2)	

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 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.
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2.2.3.1 .2 .2 Subgruppenanalysen

2.2.3.1 .2 .2 .1 Alter

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =19)
Number of evaluable subjects [1]	11	19
Day 8		
Number of subjects with a response, n (%) [2]	4 (36.4)	8 (42.1)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.214
95% CI for the RR		(0.456, 3.235)
p-value for RR		0.6975
Day 15		
Number of subjects with a response, n (%) [2]	3 (27.3)	12 (63.2)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.429
95% CI for the RR		(0.844, 6.987)
p-value for RR		0.0997

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-301-by.sas:t-madrs-remi-301-by-age-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =19)
Day 28		
Number of subjects with a response, n (%) [2]	3 (27.3)	9 (47.4)
Number of subjects with missing evaluation, n (%)	0	3 (15.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.822
95% CI for the RR		(0.597, 5.560)
p-value for RR		0.2922
Day 45		
Number of subjects with a response, n (%) [2]	3 (27.3)	11 (57.9)
Number of subjects with missing evaluation, n (%)	1 (9.1)	1 (5.3)
RR - Relative Risk (Zuranolone vs. Placebo)		2.226
95% CI for the RR		(0.756, 6.559)
p-value for RR		0.1465

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-301-by.sas:t-madrs-remi-301-by-age-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=88)	Zuranolone (N =80)
Number of evaluable subjects [1]	86	79
Day 8		
Number of subjects with a response, n (%) [2]	13 (15.1)	14 (17.7)
Number of subjects with missing evaluation, n (%)	3 (3.5)	5 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.198
95% CI for the RR		(0.598, 2.399)
p-value for RR		0.6099
Day 15		
Number of subjects with a response, n (%) [2]	20 (23.3)	26 (32.9)
Number of subjects with missing evaluation, n (%)	8 (9.3)	6 (7.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.446
95% CI for the RR		(0.886, 2.361)
p-value for RR		0.1401

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-301-by.sas:t-madrs-remi-301-by-age-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Age Group: 217-PPD-301 - ITT population

Page: 4 of 4

Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=88)	Zuranolone (N =80)
Day 28		
Number of subjects with a response, n (%) [2]	23 (26.7)	24 (30.4)
Number of subjects with missing evaluation, n (%)	16 (18.6)	19 (24.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.161
95% CI for the RR		(0.719, 1.875)
p-value for RR		0.5419
Day 45		
Number of subjects with a response, n (%) [2]	29 (33.7)	29 (36.7)
Number of subjects with missing evaluation, n (%)	12 (14.0)	13 (16.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.113
95% CI for the RR		(0.738, 1.677)
p-value for RR		0.6108

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-301-by.sas:t-madrs-remi-301-by-age-itta.rtf **Run Date:** 25JUL2025

2.2.3.1 .2 .2 .2 Schwere der Erkrankung

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Baseline HAMD-17 Total Score: 217-PPD-301 - 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=32)	Zuranolone (N =33)
Number of evaluable subjects [1]	32	33
Day 8		
Number of subjects with a response, n (%) [2]	4 (12.5)	5 (15.2)
Number of subjects with missing evaluation, n (%)	0	1 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.242
95% CI for the RR		(0.366, 4.214)
p-value for RR		0.7278
Day 15		
Number of subjects with a response, n (%) [2]	9 (28.1)	12 (36.4)
Number of subjects with missing evaluation, n (%)	2 (6.3)	1 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.325
95% CI for the RR		(0.655, 2.679)
p-value for RR		0.4334

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-301-by.sas:t-madrs-remi-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Baseline HAMD-17 Total Score: 217-PPD-301 - 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=32)	Zuranolone (N =33)
Day 28		
Number of subjects with a response, n (%) [2]	7 (21.9)	11 (33.3)
Number of subjects with missing evaluation, n (%)	7 (21.9)	5 (15.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.562
95% CI for the RR		(0.694, 3.515)
p-value for RR		0.2815
Day 45		
Number of subjects with a response, n (%) [2]	8 (25.0)	14 (42.4)
Number of subjects with missing evaluation, n (%)	5 (15.6)	3 (9.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.739
95% CI for the RR		(0.859, 3.521)
p-value for RR		0.1241

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-301-by.sas:t-madrs-remi-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Baseline HAMD-17 Total Score: 217-PPD-301 - 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=66)	Zuranolone (N =65)
Number of evaluable subjects [1]	65	65
Day 8		
Number of subjects with a response, n (%) [2]	13 (20.0)	17 (26.2)
Number of subjects with missing evaluation, n (%)	3 (4.6)	4 (6.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.345
95% CI for the RR		(0.717, 2.525)
p-value for RR		0.3559
Day 15		
Number of subjects with a response, n (%) [2]	14 (21.5)	26 (40.0)
Number of subjects with missing evaluation, n (%)	6 (9.2)	5 (7.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.911
95% CI for the RR		(1.115, 3.273)
p-value for RR		0.0184

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-301-by.sas:t-madrs-remi-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Baseline HAMD-17 Total Score: 217-PPD-301 - 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=66)	Zuranolone (N =65)
Day 28		
Number of subjects with a response, n (%) [2]	19 (29.2)	22 (33.8)
Number of subjects with missing evaluation, n (%)	9 (13.8)	17 (26.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.191
95% CI for the RR		(0.725, 1.957)
p-value for RR		0.4896
Day 45		
Number of subjects with a response, n (%) [2]	24 (36.9)	26 (40.0)
Number of subjects with missing evaluation, n (%)	8 (12.3)	11 (16.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.114
95% CI for the RR		(0.733, 1.694)
p-value for RR		0.6119

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-301-by.sas:t-madrs-remi-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

2.2.3.1 .2 .2 .3 Abstammung

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Race Group: 217-PPD-301 - ITT population

Page: 1 of 4

Race Group = Black or African American

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =26)
Number of evaluable subjects [1]	17	25
Day 8		
Number of subjects with a response, n (%) [2]	1 (5.9)	7 (28.0)
Number of subjects with missing evaluation, n (%)	2 (11.8)	2 (8.0)
RR - Relative Risk (Zuranolone vs. Placebo)		5.789
95% CI for the RR		(0.732, 45.795)
p-value for RR		0.0961
Day 15		
Number of subjects with a response, n (%) [2]	3 (17.6)	10 (40.0)
Number of subjects with missing evaluation, n (%)	4 (23.5)	3 (12.0)
RR - Relative Risk (Zuranolone vs. Placebo)		2.756
95% CI for the RR		(1.237, 6.141)
p-value for RR		0.0131

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-301-by.sas:t-madrs-remi-301-by-race-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Race Group: 217-PPD-301 - ITT population

Page: 2 of 4

Race Group = Black or African American

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =26)
Day 28		
Number of subjects with a response, n (%) [2]	2 (11.8)	10 (40.0)
Number of subjects with missing evaluation, n (%)	8 (47.1)	7 (28.0)
RR - Relative Risk (Zuranolone vs. Placebo)		4.135
95% CI for the RR		(1.065, 16.050)
p-value for RR		0.0402
Day 45		
Number of subjects with a response, n (%) [2]	3 (17.6)	12 (48.0)
Number of subjects with missing evaluation, n (%)	5 (29.4)	3 (12.0)
RR - Relative Risk (Zuranolone vs. Placebo)		3.308
95% CI for the RR		(1.063, 10.290)
p-value for RR		0.0388

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-301-by.sas:t-madrs-remi-301-by-race-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Race Group: 217-PPD-301 - ITT population

Page: 3 of 4

Race Group = White

Study Visit Statistics	Placebo (N=70)	Zuranolone (N =68)
Number of evaluable subjects [1]	69	68
Day 8		
Number of subjects with a response, n (%) [2]	13 (18.8)	14 (20.6)
Number of subjects with missing evaluation, n (%)	0	3 (4.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.103
95% CI for the RR		(0.561, 2.166)
p-value for RR		0.7770
Day 15		
Number of subjects with a response, n (%) [2]	17 (24.6)	27 (39.7)
Number of subjects with missing evaluation, n (%)	3 (4.3)	3 (4.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.626
95% CI for the RR		(0.981, 2.696)
p-value for RR		0.0596

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-301-by.sas:t-madrs-remi-301-by-race-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Race Group: 217-PPD-301 - ITT population

Page: 4 of 4

Race Group = White

Study Visit Statistics	Placebo (N=70)	Zuranolone (N =68)
Day 28		
Number of subjects with a response, n (%) [2]	22 (31.9)	22 (32.4)
Number of subjects with missing evaluation, n (%)	7 (10.1)	15 (22.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.024
95% CI for the RR		(0.628, 1.669)
p-value for RR		0.9250
Day 45		
Number of subjects with a response, n (%) [2]	27 (39.1)	28 (41.2)
Number of subjects with missing evaluation, n (%)	7 (10.1)	10 (14.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.062
95% CI for the RR		(0.707, 1.595)
p-value for RR		0.7732

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-301-by.sas:t-madrs-remi-301-by-race-itta.rtf **Run Date:** 25JUL2025

2.2.3.1 .2 .2 .4 Antidepressiva-Nutzung

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Baseline Antidepressant Use: 217-PPD-301 - ITT population

Page: 1 of 4

Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=15)	Zuranolone (N =15)
Number of evaluable subjects [1]	15	15
Day 8		
Number of subjects with a response, n (%) [2]	3 (20.0)	3 (20.0)
Number of subjects with missing evaluation, n (%)	0	1 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.975
95% CI for the RR		(0.216, 4.395)
p-value for RR		0.9735
Day 15		
Number of subjects with a response, n (%) [2]	7 (46.7)	5 (33.3)
Number of subjects with missing evaluation, n (%)	0	1 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.697
95% CI for the RR		(0.280, 1.738)
p-value for RR		0.4394

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-301-by.sas:t-madrs-remi-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Baseline Antidepressant Use: 217-PPD-301 - ITT population

Page: 2 of 4

Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=15)	Zuranolone (N =15)
Day 28		
Number of subjects with a response, n (%) [2]	7 (46.7)	6 (40.0)
Number of subjects with missing evaluation, n (%)	2 (13.3)	1 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.870
95% CI for the RR		(0.380, 1.992)
p-value for RR		0.7418
Day 45		
Number of subjects with a response, n (%) [2]	7 (46.7)	6 (40.0)
Number of subjects with missing evaluation, n (%)	1 (6.7)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.879
95% CI for the RR		(0.382, 2.023)
p-value for RR		0.7624

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-301-by.sas:t-madrs-remi-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Baseline Antidepressant Use: 217-PPD-301 - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=86)	Zuranolone (N =84)
Number of evaluable subjects [1]	82	83
Day 8		
Number of subjects with a response, n (%) [2]	14 (17.1)	19 (22.9)
Number of subjects with missing evaluation, n (%)	3 (3.7)	4 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.350
95% CI for the RR		(0.727, 2.506)
p-value for RR		0.3415
Day 15		
Number of subjects with a response, n (%) [2]	16 (19.5)	33 (39.8)
Number of subjects with missing evaluation, n (%)	8 (9.8)	5 (6.0)
RR - Relative Risk (Zuranolone vs. Placebo)		2.044
95% CI for the RR		(1.223, 3.414)
p-value for RR		0.0063

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-301-by.sas:t-madrs-remi-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Baseline Antidepressant Use: 217-PPD-301 - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=86)	Zuranolone (N =84)
Day 28		
Number of subjects with a response, n (%) [2]	19 (23.2)	27 (32.5)
Number of subjects with missing evaluation, n (%)	14 (17.1)	21 (25.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.411
95% CI for the RR		(0.855, 2.330)
p-value for RR		0.1778
Day 45		
Number of subjects with a response, n (%) [2]	25 (30.5)	34 (41.0)
Number of subjects with missing evaluation, n (%)	12 (14.6)	14 (16.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.341
95% CI for the RR		(0.886, 2.029)
p-value for RR		0.1657

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-301-by.sas:t-madrs-remi-301-by-adt-itta.rtf **Run Date:** 25JUL2025

2.2.3.1 .2 .2 .5 BMI

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Baseline BMI (kg/m^2) Group: 217-PPD-301 - ITT population

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

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =20)
Number of evaluable subjects [1]	22	20
Day 8		
Number of subjects with a response, n (%) [2]	5 (22.7)	2 (10.0)
Number of subjects with missing evaluation, n (%)	0	2 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.456
95% CI for the RR		(0.105, 1.973)
p-value for RR		0.2932
Day 15		
Number of subjects with a response, n (%) [2]	6 (27.3)	6 (30.0)
Number of subjects with missing evaluation, n (%)	1 (4.5)	2 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.139
95% CI for the RR		(0.438, 2.962)
p-value for RR		0.7895

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-301-by.sas:t-madrs-remi-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Baseline BMI (kg/m^2) Group: 217-PPD-301 - ITT population

Page: 2 of 6

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

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =20)
Day 28		
Number of subjects with a response, n (%) [2]	5 (22.7)	3 (15.0)
Number of subjects with missing evaluation, n (%)	2 (9.1)	8 (40.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.683
95% CI for the RR		(0.189, 2.470)
p-value for RR		0.5615
Day 45		
Number of subjects with a response, n (%) [2]	8 (36.4)	6 (30.0)
Number of subjects with missing evaluation, n (%)	0	5 (25.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.854
95% CI for the RR		(0.353, 2.064)
p-value for RR		0.7264

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-301-by.sas:t-madrs-remi-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Baseline BMI (kg/m^2) Group: 217-PPD-301 - ITT population

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

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =24)
Number of evaluable subjects [1]	34	24
Day 8		
Number of subjects with a response, n (%) [2]	4 (11.8)	8 (33.3)
Number of subjects with missing evaluation, n (%)	2 (5.9)	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		2.735
95% CI for the RR		(0.926, 8.076)
p-value for RR		0.0686
Day 15		
Number of subjects with a response, n (%) [2]	6 (17.6)	10 (41.7)
Number of subjects with missing evaluation, n (%)	4 (11.8)	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		2.279
95% CI for the RR		(0.968, 5.365)
p-value for RR		0.0593

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-301-by.sas:t-madrs-remi-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Baseline BMI (kg/m^2) Group: 217-PPD-301 - ITT population

Page: 4 of 6

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

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =24)
Day 28		
Number of subjects with a response, n (%) [2]	11 (32.4)	10 (41.7)
Number of subjects with missing evaluation, n (%)	7 (20.6)	5 (20.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.243
95% CI for the RR		(0.645, 2.394)
p-value for RR		0.5153
Day 45		
Number of subjects with a response, n (%) [2]	13 (38.2)	12 (50.0)
Number of subjects with missing evaluation, n (%)	6 (17.6)	4 (16.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.262
95% CI for the RR		(0.717, 2.222)
p-value for RR		0.4195

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-301-by.sas:t-madrs-remi-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Baseline BMI (kg/m^2) Group: 217-PPD-301 - ITT population

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

Study Visit Statistics	Placebo (N=42)	Zuranolone (N =53)
Number of evaluable subjects [1]	41	53
Day 8		
Number of subjects with a response, n (%) [2]	8 (19.5)	12 (22.6)
Number of subjects with missing evaluation, n (%)	1 (2.4)	2 (3.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.165
95% CI for the RR		(0.527, 2.575)
p-value for RR		0.7054
Day 15		
Number of subjects with a response, n (%) [2]	11 (26.8)	22 (41.5)
Number of subjects with missing evaluation, n (%)	3 (7.3)	3 (5.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.554
95% CI for the RR		(0.854, 2.826)
p-value for RR		0.1488

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-301-by.sas:t-madrs-remi-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Baseline BMI (kg/m^2) Group: 217-PPD-301 - ITT population

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

Study Visit Statistics	Placebo (N=42)	Zuranolone (N =53)
Day 28		
Number of subjects with a response, n (%) [2]	10 (24.4)	20 (37.7)
Number of subjects with missing evaluation, n (%)	7 (17.1)	9 (17.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.554
95% CI for the RR		(0.819, 2.947)
p-value for RR		0.1774
Day 45		
Number of subjects with a response, n (%) [2]	11 (26.8)	21 (39.6)
Number of subjects with missing evaluation, n (%)	7 (17.1)	5 (9.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.483
95% CI for the RR		(0.806, 2.730)
p-value for RR		0.2056

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-301-by.sas:t-madrs-remi-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

2.2.3.1 .2 .2 .6 Beginn der PPD

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =35)
Number of evaluable subjects [1]	30	34
Day 8		
Number of subjects with a response, n (%) [2]	4 (13.3)	7 (20.6)
Number of subjects with missing evaluation, n (%)	3 (10.0)	2 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.613
95% CI for the RR		(0.533, 4.886)
p-value for RR		0.3975
Day 15		
Number of subjects with a response, n (%) [2]	8 (26.7)	11 (32.4)
Number of subjects with missing evaluation, n (%)	4 (13.3)	3 (8.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.270
95% CI for the RR		(0.583, 2.768)
p-value for RR		0.5479

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-301-by.sas:t-madrs-remi-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =35)
Day 28		
Number of subjects with a response, n (%) [2]	7 (23.3)	9 (26.5)
Number of subjects with missing evaluation, n (%)	6 (20.0)	8 (23.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.179
95% CI for the RR		(0.500, 2.783)
p-value for RR		0.7065
Day 45		
Number of subjects with a response, n (%) [2]	9 (30.0)	15 (44.1)
Number of subjects with missing evaluation, n (%)	6 (20.0)	7 (20.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.574
95% CI for the RR		(0.808, 3.065)
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 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-301-by.sas:t-madrs-remi-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=69)	Zuranolone (N =64)
Number of evaluable subjects [1]	67	64
Day 8		
Number of subjects with a response, n (%) [2]	13 (19.4)	15 (23.4)
Number of subjects with missing evaluation, n (%)	0	3 (4.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.213
95% CI for the RR		(0.629, 2.342)
p-value for RR		0.5647
Day 15		
Number of subjects with a response, n (%) [2]	15 (22.4)	27 (42.2)
Number of subjects with missing evaluation, n (%)	4 (6.0)	3 (4.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.843
95% CI for the RR		(1.092, 3.111)
p-value for RR		0.0221

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-301-by.sas:t-madrs-remi-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=69)	Zuranolone (N =64)
Day 28		
Number of subjects with a response, n (%) [2]	19 (28.4)	24 (37.5)
Number of subjects with missing evaluation, n (%)	10 (14.9)	14 (21.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.320
95% CI for the RR		(0.814, 2.140)
p-value for RR		0.2604
Day 45		
Number of subjects with a response, n (%) [2]	23 (34.3)	25 (39.1)
Number of subjects with missing evaluation, n (%)	7 (10.4)	7 (10.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.155
95% CI for the RR		(0.740, 1.803)
p-value for RR		0.5253

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-301-by.sas:t-madrs-remi-301-by-onset-itta.rtf **Run Date:** 25JUL2025

2.2.3.1 .2 .2 .7 PPD in der Familie

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Family History of PPD: 217-PPD-301 - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =21)
Number of evaluable subjects [1]	16	21
Day 8		
Number of subjects with a response, n (%) [2]	4 (25.0)	5 (23.8)
Number of subjects with missing evaluation, n (%)	1 (6.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.920
95% CI for the RR		(0.288, 2.938)
p-value for RR		0.8876
Day 15		
Number of subjects with a response, n (%) [2]	6 (37.5)	8 (38.1)
Number of subjects with missing evaluation, n (%)	3 (18.8)	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		0.925
95% CI for the RR		(0.403, 2.123)
p-value for RR		0.8534

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-301-by.sas:t-madrs-remi-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Family History of PPD: 217-PPD-301 - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =21)
Day 28		
Number of subjects with a response, n (%) [2]	6 (37.5)	10 (47.6)
Number of subjects with missing evaluation, n (%)	4 (25.0)	3 (14.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.166
95% CI for the RR		(0.555, 2.452)
p-value for RR		0.6848
Day 45		
Number of subjects with a response, n (%) [2]	6 (37.5)	10 (47.6)
Number of subjects with missing evaluation, n (%)	3 (18.8)	2 (9.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.165
95% CI for the RR		(0.563, 2.410)
p-value for RR		0.6808

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-301-by.sas:t-madrs-remi-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Family History of PPD: 217-PPD-301 - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=85)	Zuranolone (N =78)
Number of evaluable subjects [1]	81	77
Day 8		
Number of subjects with a response, n (%) [2]	13 (16.0)	17 (22.1)
Number of subjects with missing evaluation, n (%)	2 (2.5)	5 (6.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.379
95% CI for the RR		(0.721, 2.635)
p-value for RR		0.3313
Day 15		
Number of subjects with a response, n (%) [2]	17 (21.0)	30 (39.0)
Number of subjects with missing evaluation, n (%)	5 (6.2)	5 (6.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.860
95% CI for the RR		(1.125, 3.076)
p-value for RR		0.0156

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-301-by.sas:t-madrs-remi-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Family History of PPD: 217-PPD-301 - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=85)	Zuranolone (N =78)
Day 28		
Number of subjects with a response, n (%) [2]	20 (24.7)	23 (29.9)
Number of subjects with missing evaluation, n (%)	12 (14.8)	19 (24.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.216
95% CI for the RR		(0.732, 2.022)
p-value for RR		0.4501
Day 45		
Number of subjects with a response, n (%) [2]	26 (32.1)	30 (39.0)
Number of subjects with missing evaluation, n (%)	10 (12.3)	12 (15.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.207
95% CI for the RR		(0.795, 1.833)
p-value for RR		0.3769

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-301-by.sas:t-madrs-remi-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

2.2.3.1 .2 .2 .8 PPD in der Anamnese

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by History of PPD: 217-PPD-301 - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=90)	Zuranolone (N =82)
Number of evaluable subjects [1]	86	81
Day 8		
Number of subjects with a response, n (%) [2]	13 (15.1)	17 (21.0)
Number of subjects with missing evaluation, n (%)	3 (3.5)	5 (6.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.420
95% CI for the RR		(0.737, 2.733)
p-value for RR		0.2945
Day 15		
Number of subjects with a response, n (%) [2]	18 (20.9)	29 (35.8)
Number of subjects with missing evaluation, n (%)	8 (9.3)	6 (7.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.749
95% CI for the RR		(1.063, 2.876)
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 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-301-by.sas:t-madrs-remi-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by History of PPD: 217-PPD-301 - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=90)	Zuranolone (N =82)
Day 28		
Number of subjects with a response, n (%) [2]	23 (26.7)	24 (29.6)
Number of subjects with missing evaluation, n (%)	15 (17.4)	22 (27.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.133
95% CI for the RR		(0.699, 1.836)
p-value for RR		0.6133
Day 45		
Number of subjects with a response, n (%) [2]	29 (33.7)	31 (38.3)
Number of subjects with missing evaluation, n (%)	12 (14.0)	13 (16.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.160
95% CI for the RR		(0.775, 1.738)
p-value for RR		0.4704

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-301-by.sas:t-madrs-remi-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by History of PPD: 217-PPD-301 - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=11)	Zuranolone (N =17)
Number of evaluable subjects [1]	11	17
Day 8		
Number of subjects with a response, n (%) [2]	4 (36.4)	5 (29.4)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.715
95% CI for the RR		(0.237, 2.157)
p-value for RR		0.5509
Day 15		
Number of subjects with a response, n (%) [2]	5 (45.5)	9 (52.9)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.029
95% CI for the RR		(0.450, 2.352)
p-value for RR		0.9461

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-301-by.sas:t-madrs-remi-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by History of PPD: 217-PPD-301 - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=11)	Zuranolone (N =17)
Day 28		
Number of subjects with a response, n (%) [2]	3 (27.3)	9 (52.9)
Number of subjects with missing evaluation, n (%)	1 (9.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.715
95% CI for the RR		(0.565, 5.206)
p-value for RR		0.3411
Day 45		
Number of subjects with a response, n (%) [2]	3 (27.3)	9 (52.9)
Number of subjects with missing evaluation, n (%)	1 (9.1)	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.715
95% CI for the RR		(0.560, 5.253)
p-value for RR		0.3450

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-301-by.sas:t-madrs-remi-301-by-hist-itta.rtf **Run Date:** 25JUL2025

2.2.3.1 .2 .2 .9 Depression mit Angst

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =24)
Number of evaluable subjects [1]	21	24
Day 8		
Number of subjects with a response, n (%) [2]	1 (4.8)	6 (25.0)
Number of subjects with missing evaluation, n (%)	1 (4.8)	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		4.659
95% CI for the RR		(0.646, 33.589)
p-value for RR		0.1268
Day 15		
Number of subjects with a response, n (%) [2]	5 (23.8)	10 (41.7)
Number of subjects with missing evaluation, n (%)	1 (4.8)	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.476
95% CI for the RR		(0.601, 3.626)
p-value for RR		0.3956

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-301-by.sas:t-madrs-remi-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =24)
Day 28		
Number of subjects with a response, n (%) [2]	5 (23.8)	10 (41.7)
Number of subjects with missing evaluation, n (%)	4 (19.0)	5 (20.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.583
95% CI for the RR		(0.670, 3.740)
p-value for RR		0.2951
Day 45		
Number of subjects with a response, n (%) [2]	11 (52.4)	11 (45.8)
Number of subjects with missing evaluation, n (%)	1 (4.8)	3 (12.5)
RR - Relative Risk (Zuranolone vs. Placebo)		0.766
95% CI for the RR		(0.424, 1.384)
p-value for RR		0.3774

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-301-by.sas:t-madrs-remi-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

Study Visit Statistics	Placebo (N=77)	Zuranolone (N =74)
Number of evaluable subjects [1]	76	74
Day 8		
Number of subjects with a response, n (%) [2]	16 (21.1)	16 (21.6)
Number of subjects with missing evaluation, n (%)	2 (2.6)	4 (5.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.047
95% CI for the RR		(0.568, 1.932)
p-value for RR		0.8825
Day 15		
Number of subjects with a response, n (%) [2]	18 (23.7)	28 (37.8)
Number of subjects with missing evaluation, n (%)	7 (9.2)	5 (6.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.618
95% CI for the RR		(0.991, 2.640)
p-value for RR		0.0543

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-301-by.sas:t-madrs-remi-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

Study Visit Statistics	Placebo (N=77)	Zuranolone (N =74)
Day 28		
Number of subjects with a response, n (%) [2]	21 (27.6)	23 (31.1)
Number of subjects with missing evaluation, n (%)	12 (15.8)	17 (23.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.140
95% CI for the RR		(0.695, 1.871)
p-value for RR		0.6030
Day 45		
Number of subjects with a response, n (%) [2]	21 (27.6)	29 (39.2)
Number of subjects with missing evaluation, n (%)	12 (15.8)	11 (14.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.439
95% CI for the RR		(0.912, 2.271)
p-value for RR		0.1178

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.

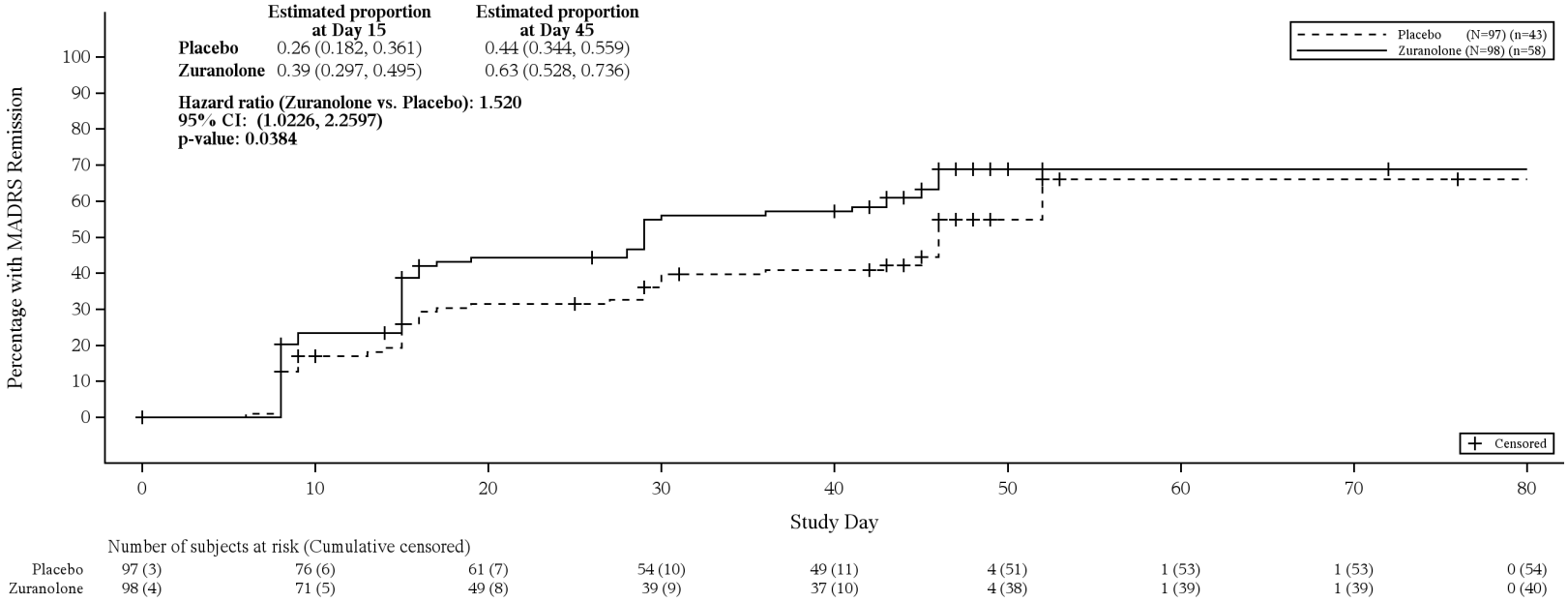
Source: biib125/v_a/germany_amnog/t-madrs-remi-301-by.sas:t-madrs-remi-301-by-hama-itta.rtf **Run Date:** 25JUL2025

2.2.3.2 TTE-Analysen

2.2.3.2 .1 ITT-Population

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission: 217-PPD-301 - ITT population

Page: 1 of 1



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-301-ovr.sas:f-madrs-remi-tte-301-ovr-itta.rtf **Run Date:** 12DEC2025

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission: 217-PPD-301 - ITT population

Page: 1 of 1

	Placebo (N=101)	Zuranolone (N=99)
Number of evaluable subjects [1]	97	98
Number of subjects with response, n (%) [2]	43 (44.3)	58 (59.2)
Time to first MADRS remission (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (9.0 , 29.0)	15.0 (8.0 , 15.0)
50th percentile - median (95% CI)	46.0 (30.0, NE)	29.0 (16.0 , 43.0)
75th percentile - Q3 (95% CI)	NE (52.0, NE)	NE (46.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.520
95% CI for the HR		(1.0226 , 2.2597)
p-value for the HR		0.0384

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-301-ovr.sas:t-madrs-remi-tte-301-ovr-itta.rtf **Run Date:** 18JUL2025

2.2.3.2 .2 Subgruppen

2.2.3.2 .2 .1 Interaktionstest

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission: Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

Page: 1 of 2

Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	97	98	
Number of subjects with response, n (%)	43 (44.3)	58 (59.2)	
Age Group (years)			
18 - 24, n / N (%)	6/11 (54.5)	15/19 (78.9)	0.7774
25 - 45, n / N (%)	37/86 (43.0)	43/79 (54.4)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	12/32 (37.5)	17/33 (51.5)	0.8389
>=28, n / N (%)	31/65 (47.7)	41/65 (63.1)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	6/17 (35.3)	15/25 (60.0)	0.5426
White, n / N (%)	33/69 (47.8)	42/68 (61.8)	
Antidepressant Use at Baseline			
Yes, n / N (%)	10/15 (66.7)	6/15 (40.0)	0.0217
No, n / N (%)	33/82 (40.2)	52/83 (62.7)	

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 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-301-int.sas:t-madrs-remi-tte-301-int-itta.rtf **Run Date:** 18JUL2025

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission: Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

Page: 2 of 2

Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9, n / N (%)	10/22 (45.5)	9/20 (45.0)	0.4872(a)
25-29.9, n / N (%)	17/34 (50.0)	14/24 (58.3)	0.3067(b)
>=30, n / N (%)	16/41 (39.0)	34/53 (64.2)	0.7391(c)
Onset of PPD			
3rd Trimester, n / N (%)	12/30 (40.0)	19/34 (55.9)	0.8185
Postpartum, n / N (%)	31/67 (46.3)	39/64 (60.9)	
Family History of PPD			
Yes, n / N (%)	11/16 (68.8)	12/21 (57.1)	0.0272
No/Unknown, n / N (%)	32/81 (39.5)	46/77 (59.7)	
History of PPD			
1st Episode, n / N (%)	37/86 (43.0)	45/81 (55.6)	0.7135
Recurrent Episode, n / N (%)	6/11 (54.5)	13/17 (76.5)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	11/21 (52.4)	16/24 (66.7)	0.7375
>=20, n / N (%)	32/76 (42.1)	42/74 (56.8)	

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-301-int.sas:t-madrs-remi-tte-301-int-itta.rtf **Run Date:** 18JUL2025

2.2.3.2 .2 .2 Subgruppenanalysen

2.2.3.2 .2 .2 .1 Alter

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Age Group: 217-PPD-301 - ITT population

Page: 1 of 2

Age Group (years) = 18-24

	Placebo (N=13)	Zuranolone (N=19)
Number of evaluable subjects [1]	11	19
Number of subjects with response, n (%) [2]	6 (54.5)	15 (78.9)
Time to first MADRS remission (days) [3]		
25th percentile - Q1 (95% CI)	9.0 (6.0 , 29.0)	8.0 (8.0 , 15.0)
50th percentile - median (95% CI)	29.0 (8.0, NE)	15.0 (8.0 , 16.0)
75th percentile - Q3 (95% CI)	NE (16.0, NE)	30.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.859
95% CI for the HR		(0.7080 , 4.8808)
p-value for the HR		0.2081

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-301-by.sas:t-madrs-remi-tte-301-by-age-itta.rtf **Run Date:** 25JUL2025

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Age Group: 217-PPD-301 - ITT population

Page: 2 of 2

Age Group (years) = 25-45

	Placebo (N=88)	Zuranolone (N=80)
Number of evaluable subjects [1]	86	79
Number of subjects with response, n (%) [2]	37 (43.0)	43 (54.4)
Time to first MADRS remission (days) [3]		
25th percentile - Q1 (95% CI)	16.0 (13.0 , 30.0)	15.0 (8.0 , 17.0)
50th percentile - median (95% CI)	46.0 (36.0, NE)	36.0 (28.0 , 46.0)
75th percentile - Q3 (95% CI)	NE (52.0, NE)	NE (46.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.477
95% CI for the HR		(0.9441 , 2.3115)
p-value for the HR		0.0876

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-301-by.sas:t-madrs-remi-tte-301-by-age-itta.rtf **Run Date:** 25JUL2025

2.2.3.2 .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-301 - ITT population

Page: 1 of 2

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

	Placebo (N=32)	Zuranolone (N=33)
Number of evaluable subjects [1]	32	33
Number of subjects with response, n (%) [2]	12 (37.5)	17 (51.5)
Time to first MADRS remission (days) [3]		
25th percentile - Q1 (95% CI)	16.0 (8.0 , 36.0)	15.0 (8.0 , 28.0)
50th percentile - median (95% CI)	NE (17.0, NE)	29.0 (15.0, NE)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.485
95% CI for the HR		(0.7050 , 3.1278)
p-value for the HR		0.2982

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-301-by.sas:t-madrs-remi-tte-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Baseline HAMD-17 Total Score: 217-PPD-301 - ITT population

Page: 2 of 2

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

	Placebo (N=66)	Zuranolone (N=65)
Number of evaluable subjects [1]	65	65
Number of subjects with response, n (%) [2]	31 (47.7)	41 (63.1)
Time to first MADRS remission (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (8.0 , 29.0)	9.0 (8.0 , 15.0)
50th percentile - median (95% CI)	46.0 (30.0, NE)	29.0 (15.0 , 43.0)
75th percentile - Q3 (95% CI)	52.0 (46.0, NE)	46.0 (43.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.659
95% CI for the HR		(1.0244 , 2.6872)
p-value for the HR		0.0396

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-301-by.sas:t-madrs-remi-tte-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

2.2.3.2 .2 .2 .3 Abstammung

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Race Group: 217-PPD-301 - ITT population

Page: 1 of 2

Race Group = Black or African American

	Placebo (N=20)	Zuranolone (N=26)
Number of evaluable subjects [1]	17	25
Number of subjects with response, n (%) [2]	6 (35.3)	15 (60.0)
Time to first MADRS remission (days) [3]		
25th percentile - Q1 (95% CI)	16.0 (9.0, NE)	8.0 (8.0 , 15.0)
50th percentile - median (95% CI)	NE (15.0, NE)	29.0 (9.0 , 46.0)
75th percentile - Q3 (95% CI)	NE (43.0, NE)	46.0 (29.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.395
95% CI for the HR		(0.8609 , 6.6602)
p-value for the HR		0.0943

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-301-by.sas:t-madrs-remi-tte-301-by-race-itta.rtf **Run Date:** 25JUL2025

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Race Group: 217-PPD-301 - ITT population

Page: 2 of 2

Race Group = White

	Placebo (N=70)	Zuranolone (N=68)
Number of evaluable subjects [1]	69	68
Number of subjects with response, n (%) [2]	33 (47.8)	42 (61.8)
Time to first MADRS remission (days) [3]		
25th percentile - Q1 (95% CI)	16.0 (9.0 , 29.0)	15.0 (8.0 , 15.0)
50th percentile - median (95% CI)	46.0 (30.0, NE)	29.0 (15.0 , 43.0)
75th percentile - Q3 (95% CI)	52.0 (52.0, NE)	NE (43.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.552
95% CI for the HR		(0.9801 , 2.4561)
p-value for the HR		0.0609

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-301-by.sas:t-madrs-remi-tte-301-by-race-itta.rtf **Run Date:** 25JUL2025

2.2.3.2 .2 .2 .4 Antidepressiva-Nutzung

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Baseline Antidepressant Use: 217-PPD-301 - ITT population

Page: 1 of 2

Antidepressant Use at Baseline = Yes

	Placebo (N=15)	Zuranolone (N=15)
Number of evaluable subjects [1]	15	15
Number of subjects with response, n (%) [2]	10 (66.7)	6 (40.0)
Time to first MADRS remission (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (8.0 , 16.0)	15.0 (8.0, NE)
50th percentile - median (95% CI)	17.0 (9.0, NE)	NE (9.0, NE)
75th percentile - Q3 (95% CI)	NE (17.0, NE)	NE (NE, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.544
95% CI for the HR		(0.1962 , 1.5064)
p-value for the HR		0.2412

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-301-by.sas:t-madrs-remi-tte-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Baseline Antidepressant Use: 217-PPD-301 - ITT population

Page: 2 of 2

Antidepressant Use at Baseline = No

	Placebo (N=86)	Zuranolone (N=84)
Number of evaluable subjects [1]	82	83
Number of subjects with response, n (%) [2]	33 (40.2)	52 (62.7)
Time to first MADRS remission (days) [3]		
25th percentile - Q1 (95% CI)	16.0 (9.0 , 36.0)	15.0 (8.0 , 15.0)
50th percentile - median (95% CI)	46.0 (45.0, NE)	29.0 (15.0 , 41.0)
75th percentile - Q3 (95% CI)	NE (52.0, NE)	NE (43.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.883
95% CI for the HR		(1.2140 , 2.9213)
p-value for the HR		0.0047

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-301-by.sas:t-madrs-remi-tte-301-by-adt-itta.rtf **Run Date:** 25JUL2025

2.2.3.2 .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-301 - ITT population

Page: 1 of 3

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

	Placebo (N=22)	Zuranolone (N=20)
Number of evaluable subjects [1]	22	20
Number of subjects with response, n (%) [2]	10 (45.5)	9 (45.0)
Time to first MADRS remission (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (8.0 , 45.0)	15.0 (8.0 , 45.0)
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 (45.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.078
95% CI for the HR		(0.4306 , 2.6977)
p-value for the HR		0.8728

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-301-by.sas:t-madrs-remi-tte-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Baseline BMI (kg/m^2)
Group: 217-PPD-301 - ITT population
Page: 2 of 3
BMI (kg/m^2) Group 2 = 25-29.9

	Placebo (N=34)	Zuranolone (N=24)
Number of evaluable subjects [1]	34	24
Number of subjects with response, n (%) [2]	17 (50.0)	14 (58.3)
Time to first MADRS remission (days) [3]		
25th percentile - Q1 (95% CI)	16.0 (8.0 , 30.0)	8.0 (8.0 , 15.0)
50th percentile - median (95% CI)	46.0 (29.0 , 46.0)	16.0 (9.0, NE)
75th percentile - Q3 (95% CI)	NE (46.0, NE)	NE (16.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.697
95% CI for the HR		(0.8006 , 3.5987)
p-value for the HR		0.1676

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-301-by.sas:t-madrs-remi-tte-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Baseline BMI (kg/m^2)
Group: 217-PPD-301 - ITT population

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

	Placebo (N=42)	Zuranolone (N=53)
Number of evaluable subjects [1]	41	53
Number of subjects with response, n (%) [2]	16 (39.0)	34 (64.2)
Time to first MADRS remission (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (8.0 , 29.0)	15.0 (8.0 , 15.0)
50th percentile - median (95% CI)	52.0 (16.0, NE)	29.0 (15.0 , 36.0)
75th percentile - Q3 (95% CI)	NE (52.0, NE)	NE (36.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.755
95% CI for the HR		(0.9643 , 3.1949)
p-value for the HR		0.0656

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-301-by.sas:t-madrs-remi-tte-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

2.2.3.2 .2 .2 .6 Beginn der PPD

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Onset of PPD: 217-PPD-301 - ITT population

Page: 1 of 2

Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=35)
Number of evaluable subjects [1]	30	34
Number of subjects with response, n (%) [2]	12 (40.0)	19 (55.9)
Time to first MADRS remission (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (8.0 , 29.0)	15.0 (8.0 , 29.0)
50th percentile - median (95% CI)	NE (15.0, NE)	41.0 (15.0 , 46.0)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (43.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.495
95% CI for the HR		(0.7198 , 3.1034)
p-value for the HR		0.2811

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-301-by.sas:t-madrs-remi-tte-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Onset of PPD: 217-PPD-301 - ITT population

Page: 2 of 2

Onset of PPD = Postpartum

	Placebo (N=69)	Zuranolone (N=64)
Number of evaluable subjects [1]	67	64
Number of subjects with response, n (%) [2]	31 (46.3)	39 (60.9)
Time to first MADRS remission (days) [3]		
25th percentile - Q1 (95% CI)	16.0 (8.0 , 30.0)	15.0 (8.0 , 15.0)
50th percentile - median (95% CI)	46.0 (36.0, NE)	28.0 (15.0 , 43.0)
75th percentile - Q3 (95% CI)	NE (52.0, NE)	NE (45.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.574
95% CI for the HR		(0.9793 , 2.5288)
p-value for the HR		0.0610

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-301-by.sas:t-madrs-remi-tte-301-by-onset-itta.rtf **Run Date:** 25JUL2025

2.2.3.2 .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-301 - ITT population

Page: 1 of 2

Family History of PPD = Yes

	Placebo (N=16)	Zuranolone (N=21)
Number of evaluable subjects [1]	16	21
Number of subjects with response, n (%) [2]	11 (68.8)	12 (57.1)
Time to first MADRS remission (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (6.0 , 15.0)	15.0 (8.0 , 28.0)
50th percentile - median (95% CI)	16.0 (8.0 , 30.0)	29.0 (15.0, NE)
75th percentile - Q3 (95% CI)	30.0 (15.0, NE)	NE (29.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.702
95% CI for the HR		(0.3085 , 1.5976)
p-value for the HR		0.3990

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-301-by.sas:t-madrs-remi-tte-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Family History of PPD: 217-PPD-301 - ITT population

Page: 2 of 2

Family History of PPD = No/Unknown

	Placebo (N=85)	Zuranolone (N=78)
Number of evaluable subjects [1]	81	77
Number of subjects with response, n (%) [2]	32 (39.5)	46 (59.7)
Time to first MADRS remission (days) [3]		
25th percentile - Q1 (95% CI)	17.0 (9.0 , 43.0)	15.0 (8.0 , 15.0)
50th percentile - median (95% CI)	52.0 (45.0, NE)	29.0 (15.0 , 45.0)
75th percentile - Q3 (95% CI)	NE (52.0, NE)	NE (45.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.854
95% CI for the HR		(1.1768 , 2.9224)
p-value for the HR		0.0078

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-301-by.sas:t-madrs-remi-tte-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

2.2.3.2 .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-301 - ITT population

Page: 1 of 2

History of PPD = 1st Episode

	Placebo (N=90)	Zuranolone (N=82)
Number of evaluable subjects [1]	86	81
Number of subjects with response, n (%) [2]	37 (43.0)	45 (55.6)
Time to first MADRS remission (days) [3]		
25th percentile - Q1 (95% CI)	16.0 (13.0 , 30.0)	15.0 (8.0 , 15.0)
50th percentile - median (95% CI)	46.0 (36.0, NE)	29.0 (16.0 , 46.0)
75th percentile - Q3 (95% CI)	NE (52.0, NE)	NE (46.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.514
95% CI for the HR		(0.9781 , 2.3442)
p-value for the HR		0.0628

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-301-by.sas:t-madrs-remi-tte-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by History of PPD: 217-PPD-301 - ITT population

Page: 2 of 2

History of PPD = Recurrent Episode

	Placebo (N=11)	Zuranolone (N=17)
Number of evaluable subjects [1]	11	17
Number of subjects with response, n (%) [2]	6 (54.5)	13 (76.5)
Time to first MADRS remission (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (6.0 , 16.0)	9.0 (8.0 , 15.0)
50th percentile - median (95% CI)	16.0 (8.0, NE)	16.0 (9.0 , 46.0)
75th percentile - Q3 (95% CI)	NE (14.0, NE)	46.0 (16.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.100
95% CI for the HR		(0.3779 , 3.2009)
p-value for the HR		0.8614

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-301-by.sas:t-madrs-remi-tte-301-by-hist-itta.rtf **Run Date:** 25JUL2025

2.2.3.2 .2 .2 .9 Depression mit Angst

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

Page: 1 of 2

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

	Placebo (N=21)	Zuranolone (N=24)
Number of evaluable subjects [1]	21	24
Number of subjects with response, n (%) [2]	11 (52.4)	16 (66.7)
Time to first MADRS remission (days) [3]		
25th percentile - Q1 (95% CI)	24.5 (13.0 , 46.0)	9.0 (8.0 , 15.0)
50th percentile - median (95% CI)	46.0 (19.0, NE)	28.0 (15.0 , 45.0)
75th percentile - Q3 (95% CI)	52.0 (46.0, NE)	NE (29.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.716
95% CI for the HR		(0.7689 , 3.8279)
p-value for the HR		0.1875

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-301-by.sas:t-madrs-remi-tte-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

Page: 2 of 2

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

	Placebo (N=77)	Zuranolone (N=74)
Number of evaluable subjects [1]	76	74
Number of subjects with response, n (%) [2]	32 (42.1)	42 (56.8)
Time to first MADRS remission (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (8.0 , 29.0)	15.0 (8.0 , 15.0)
50th percentile - median (95% CI)	NE (29.0, NE)	29.0 (16.0 , 46.0)
75th percentile - Q3 (95% CI)	NE (NE, NE)	NE (46.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.436
95% CI for the HR		(0.9024 , 2.2850)
p-value for the HR		0.1268

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.

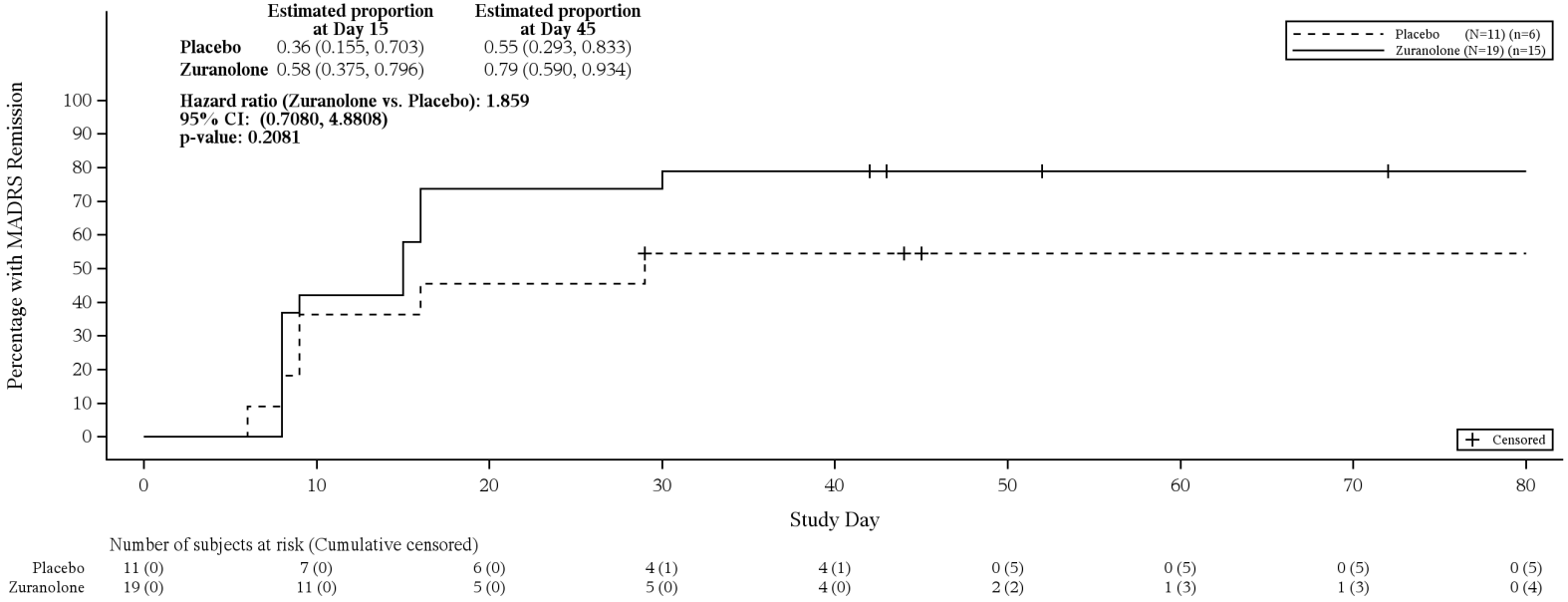
Source: biib125/v_a/germany_amnog/t-madrs-remi-tte-301-by.sas:t-madrs-remi-tte-301-by-hama-itta.rtf **Run Date:** 25JUL2025

2.2.3.2 .2 .3 Kaplan-Meier-Plots

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Subgroup: 217-PPD-301 - ITT population

Page: 1 of 19

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.

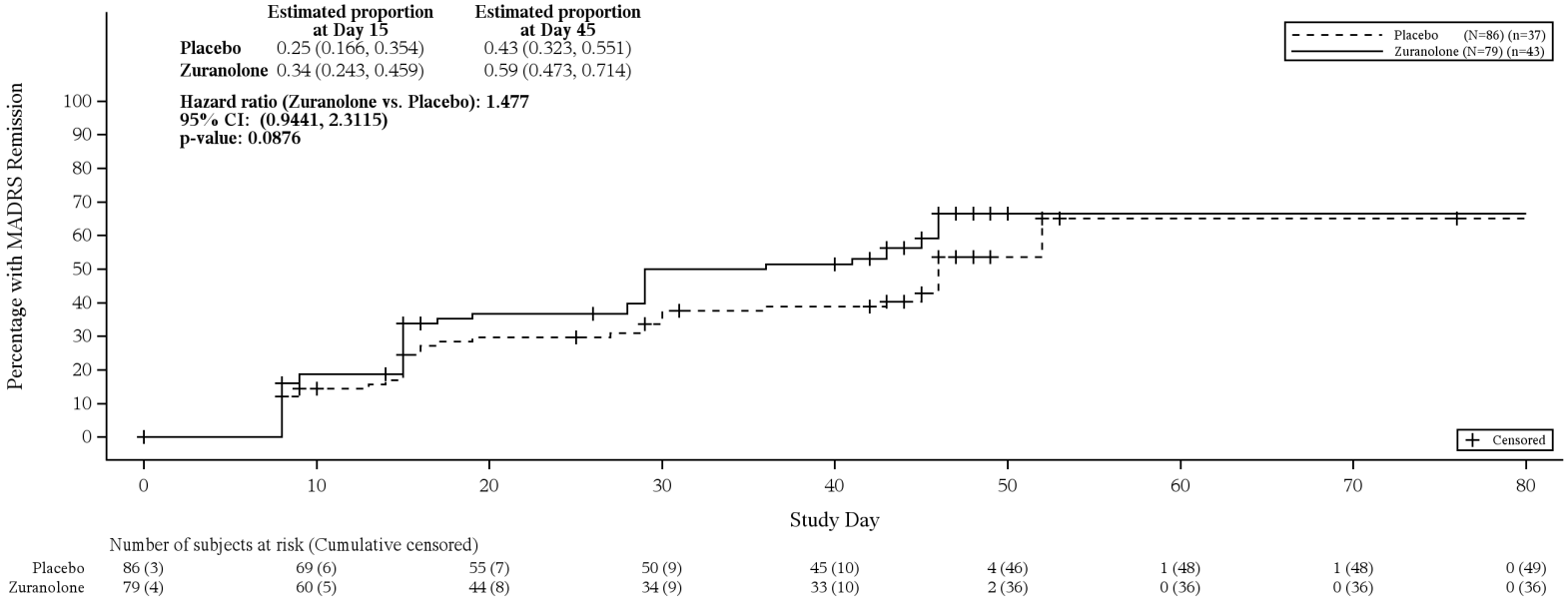
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate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

Source: biib125/v_a/amnog_kmplots/f-madrs-remi-tte-301-by.sas:f-madrs-remi-tte-301-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Subgroup: 217-PPD-301 - ITT population

Page: 2 of 19

Age Group (years) = 25-45



Number of subjects at risk (Cumulative censored)

Placebo	86 (3)	69 (6)	55 (7)	50 (9)	45 (10)	4 (46)	1 (48)	1 (48)	0 (49)
Zuranolone	79 (4)	60 (5)	44 (8)	34 (9)	33 (10)	2 (36)	0 (36)	0 (36)	0 (36)

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.

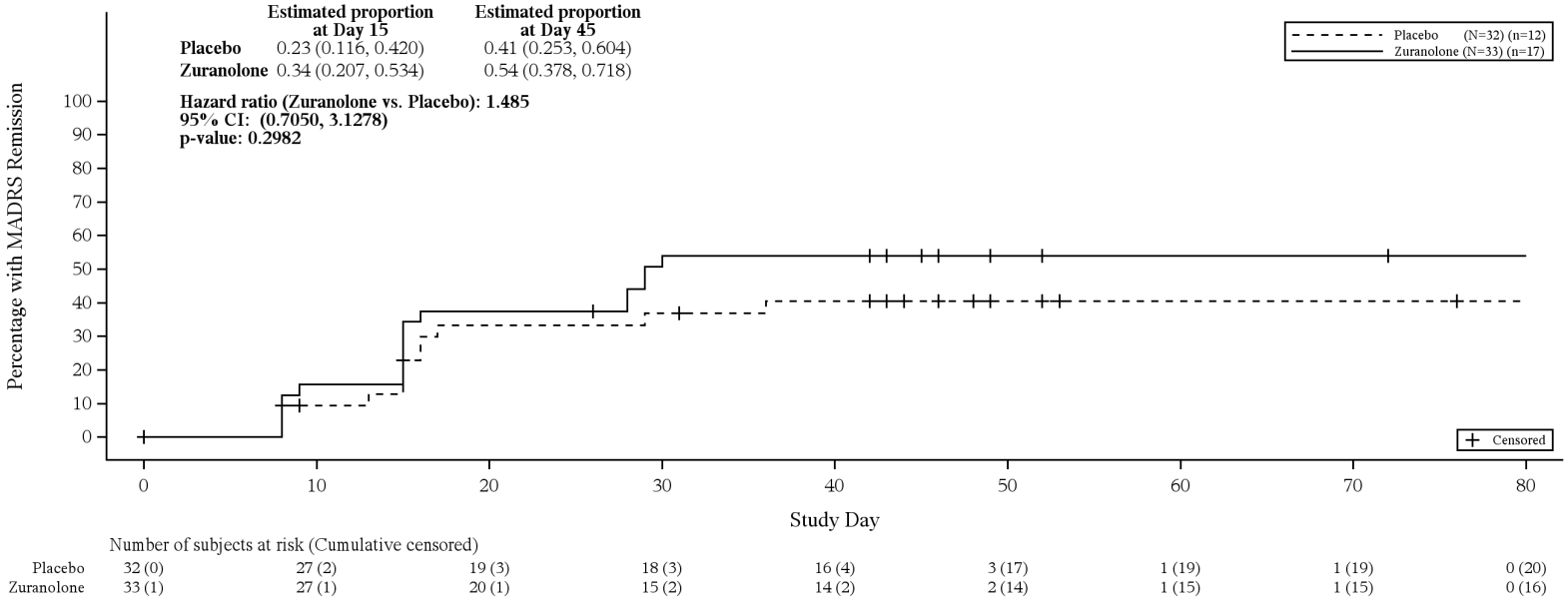
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate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

Source: biib125/v_a/amnog_kmplots/f-madrs-remi-tte-301-by.sas:f-madrs-remi-tte-301-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Subgroup: 217-PPD-301 - 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	32 (0)	27 (2)	19 (3)	18 (3)	16 (4)	3 (17)	1 (19)	1 (19)	0 (20)
Zuranolone	33 (1)	27 (1)	20 (1)	15 (2)	14 (2)	2 (14)	1 (15)	1 (15)	0 (16)

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.

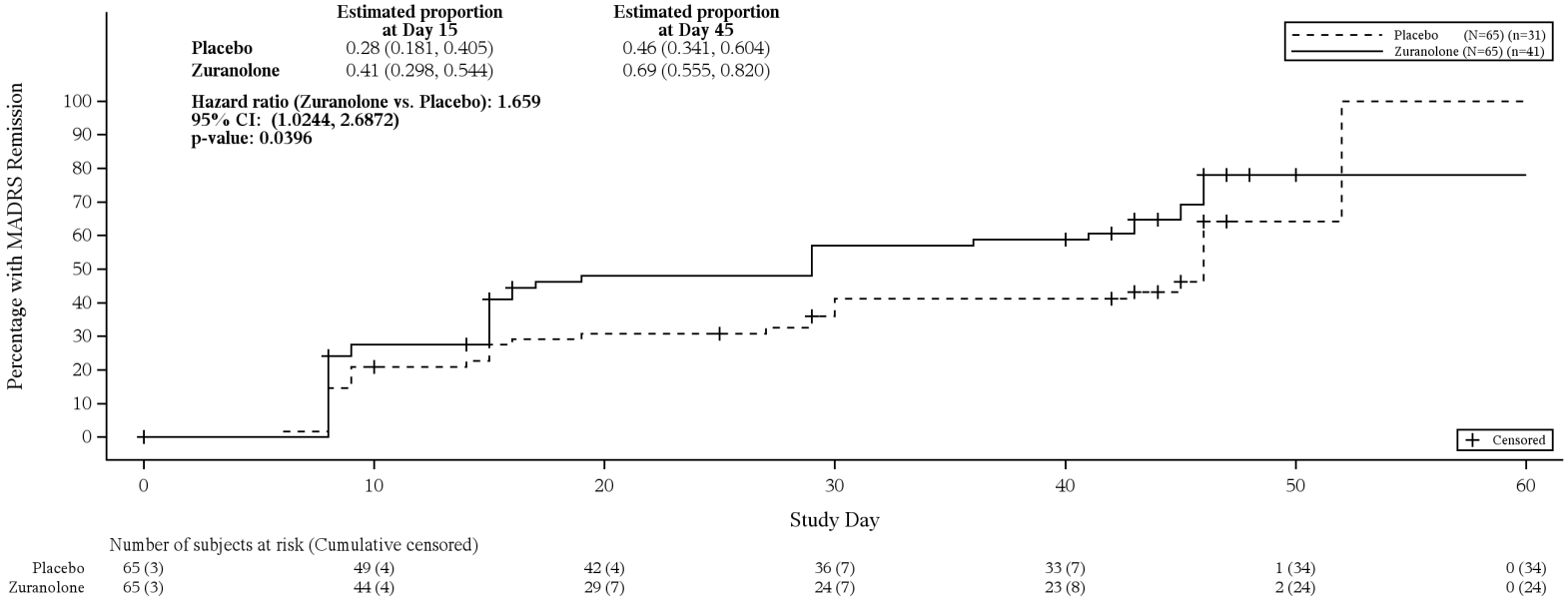
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate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

Source: biib125/v_a/amnog_kmplots/f-madrs-remi-tte-301-by.sas:f-madrs-remi-tte-301-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Subgroup: 217-PPD-301 - 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.

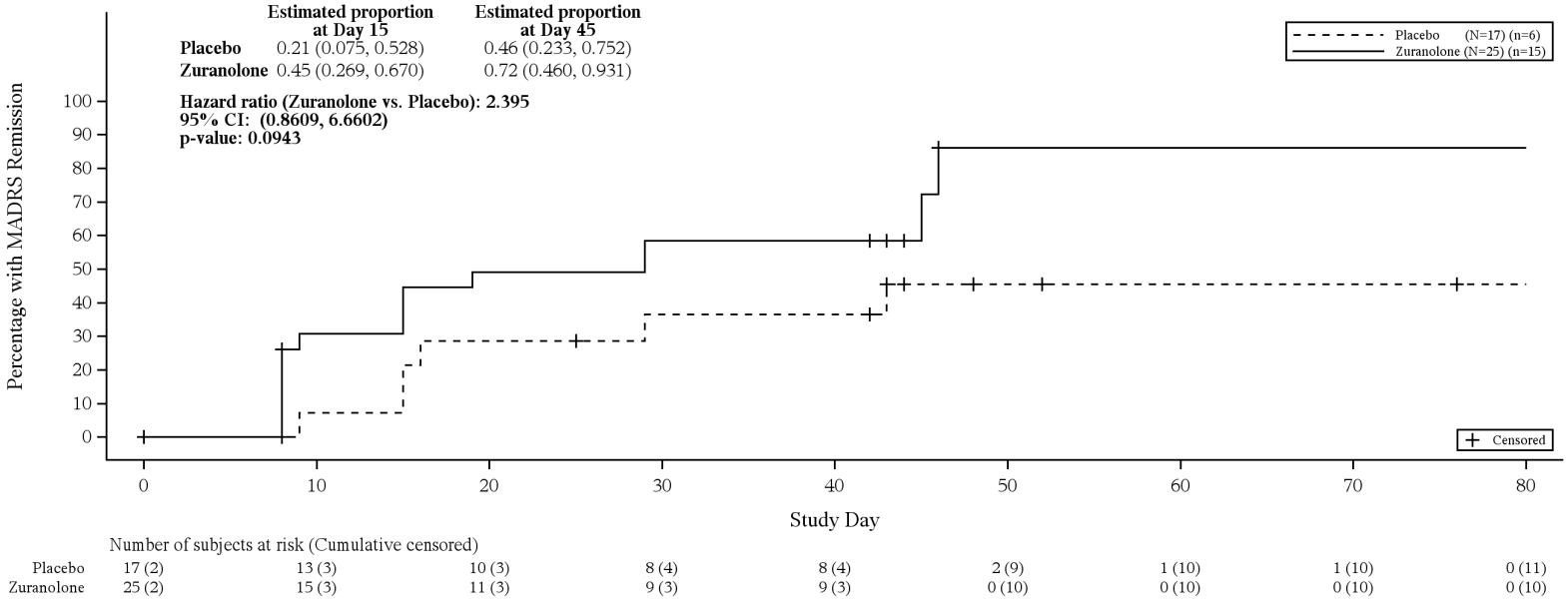
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate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

Source: biib125/v_a/amnog_kmplots/f-madrs-remi-tte-301-by.sas:f-madrs-remi-tte-301-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Subgroup: 217-PPD-301 - ITT population

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Race Group = Black or African American



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.

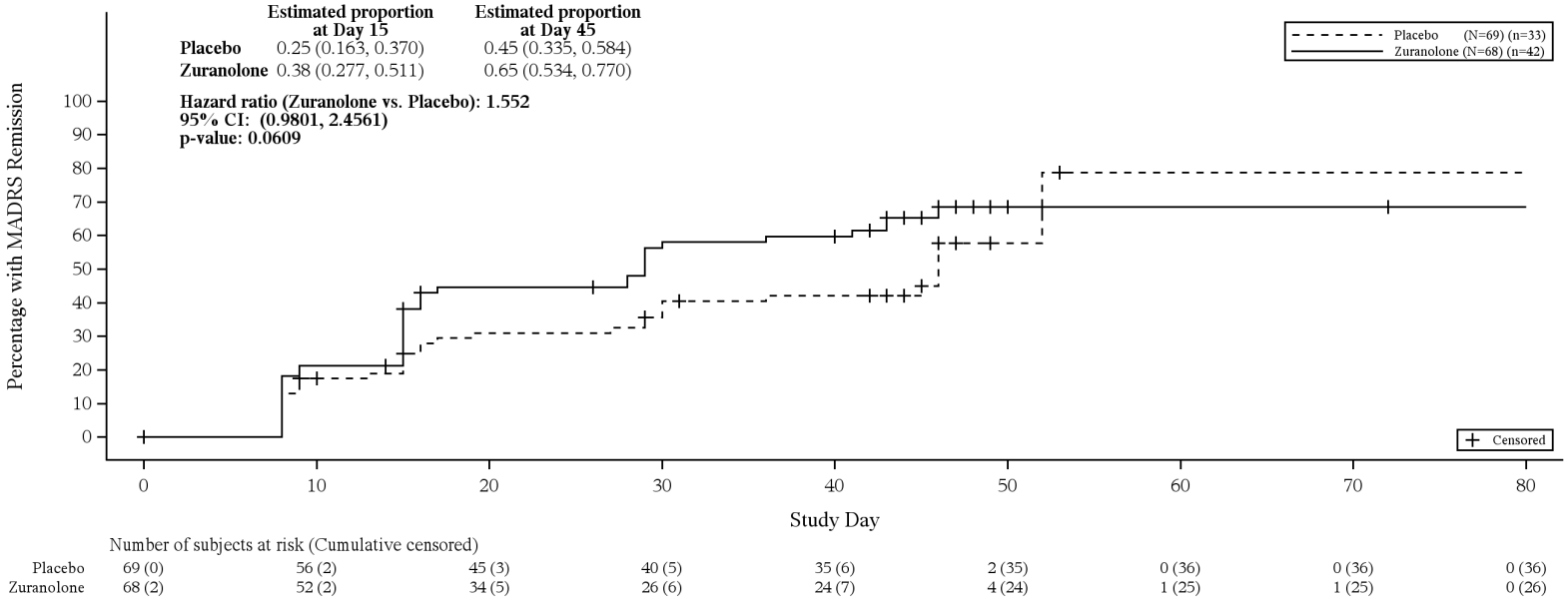
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate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

Source: biib125/v_a/amnog_kmplots/f-madrs-remi-tte-301-by.sas:f-madrs-remi-tte-301-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Subgroup: 217-PPD-301 - ITT population

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Race Group = White



Number of subjects at risk (Cumulative censored)

Placebo	69 (0)	56 (2)	45 (3)	40 (5)	35 (6)	2 (35)	0 (36)	0 (36)	0 (36)
Zuranolone	68 (2)	52 (2)	34 (5)	26 (6)	24 (7)	4 (24)	1 (25)	1 (25)	0 (26)

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.

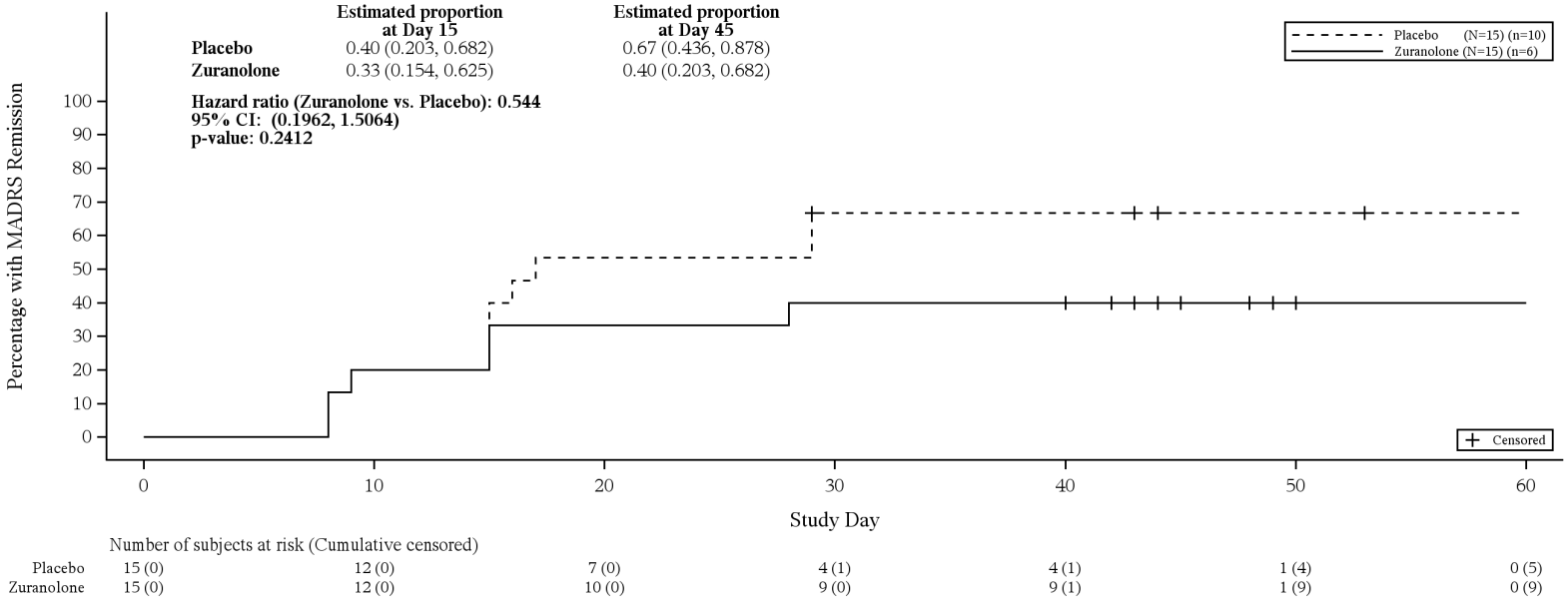
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate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

Source: biib125/v_a/amnog_kmplots/f-madrs-remi-tte-301-by.sas:f-madrs-remi-tte-301-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Subgroup: 217-PPD-301 - ITT population

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Antidepressant Use at Baseline = Yes



Number of subjects at risk (Cumulative censored)

Placebo	15 (0)	12 (0)	7 (0)	4 (1)	4 (1)	1 (4)	0 (5)
Zuranolone	15 (0)	12 (0)	10 (0)	9 (0)	9 (1)	1 (9)	0 (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.

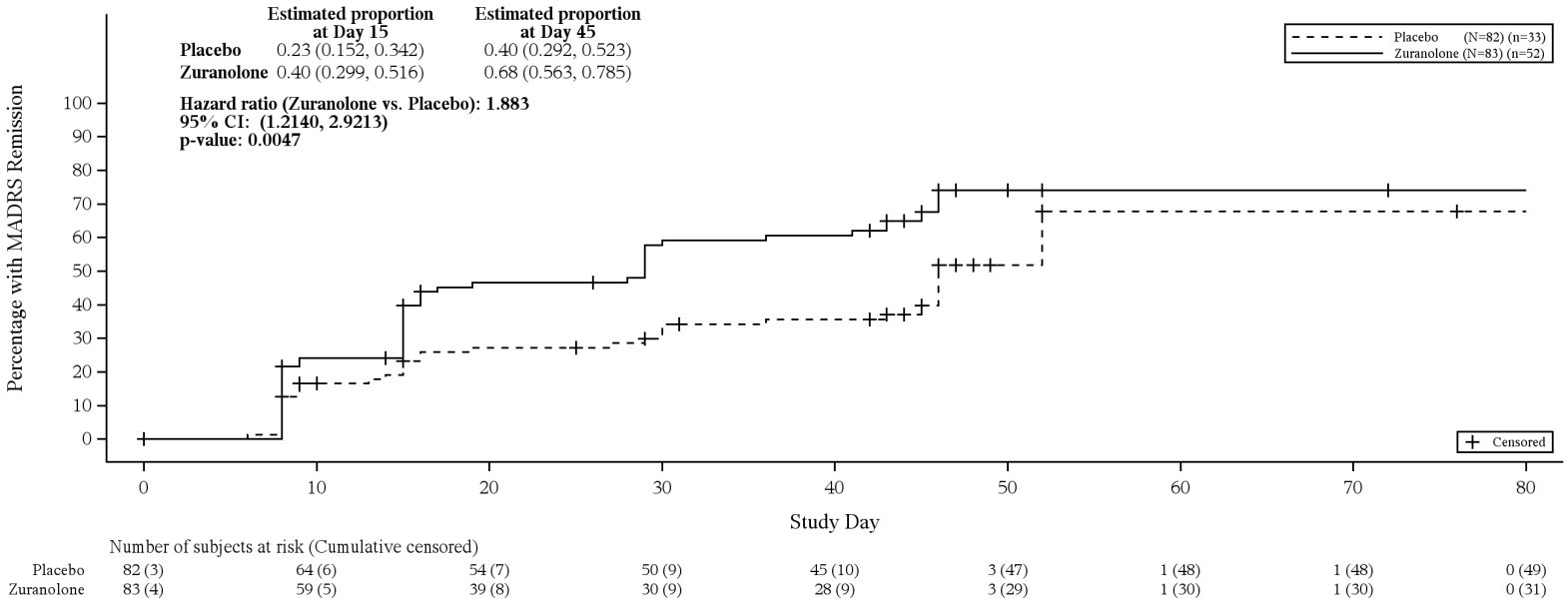
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate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

Source: biib125/v_a/amnog_kmplots/f-madrs-remi-tte-301-by.sas:f-madrs-remi-tte-301-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Subgroup: 217-PPD-301 - ITT population

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Antidepressant Use at Baseline = No



Number of subjects at risk (Cumulative censored)

Placebo	82 (3)	64 (6)	54 (7)	50 (9)	45 (10)	3 (47)	1 (48)	1 (48)	0 (49)
Zuranolone	83 (4)	59 (5)	39 (8)	30 (9)	28 (9)	3 (29)	1 (30)	1 (30)	0 (31)

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.

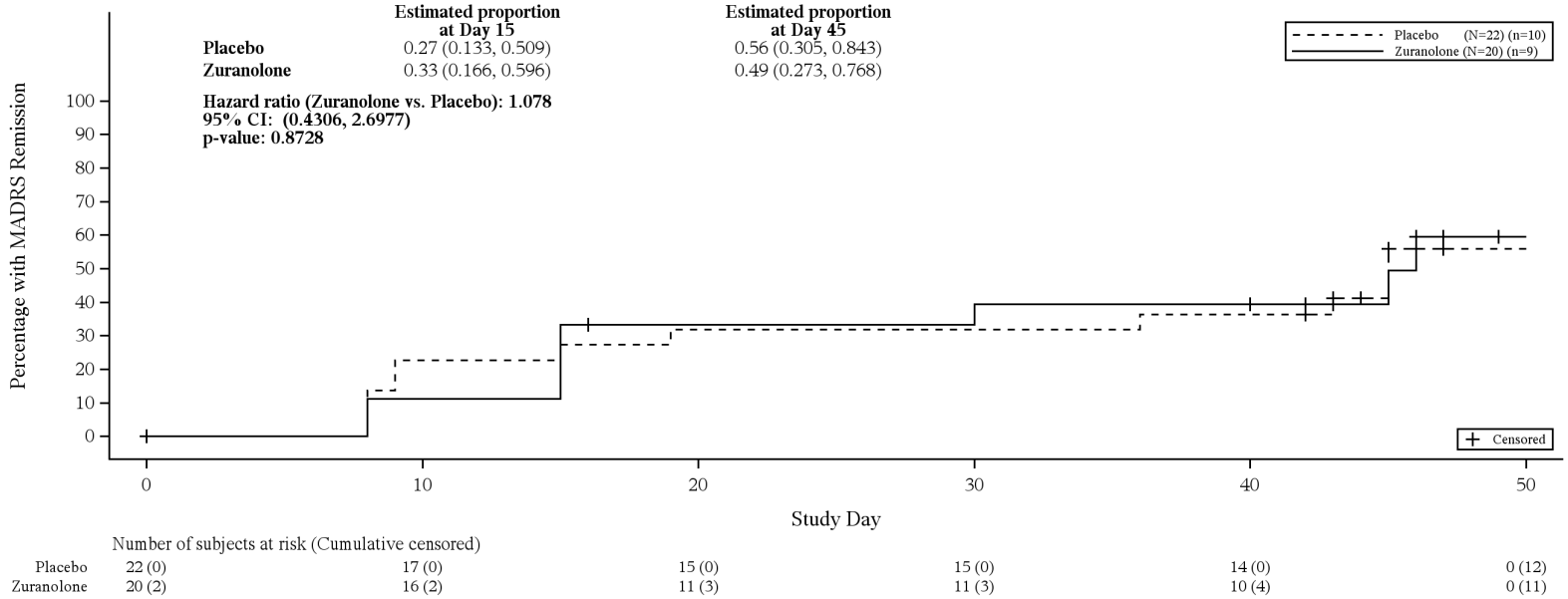
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate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

Source: biib125/v_a/amnog_kmplots/f-madrs-remi-tte-301-by.sas:f-madrs-remi-tte-301-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Subgroup: 217-PPD-301 - 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.

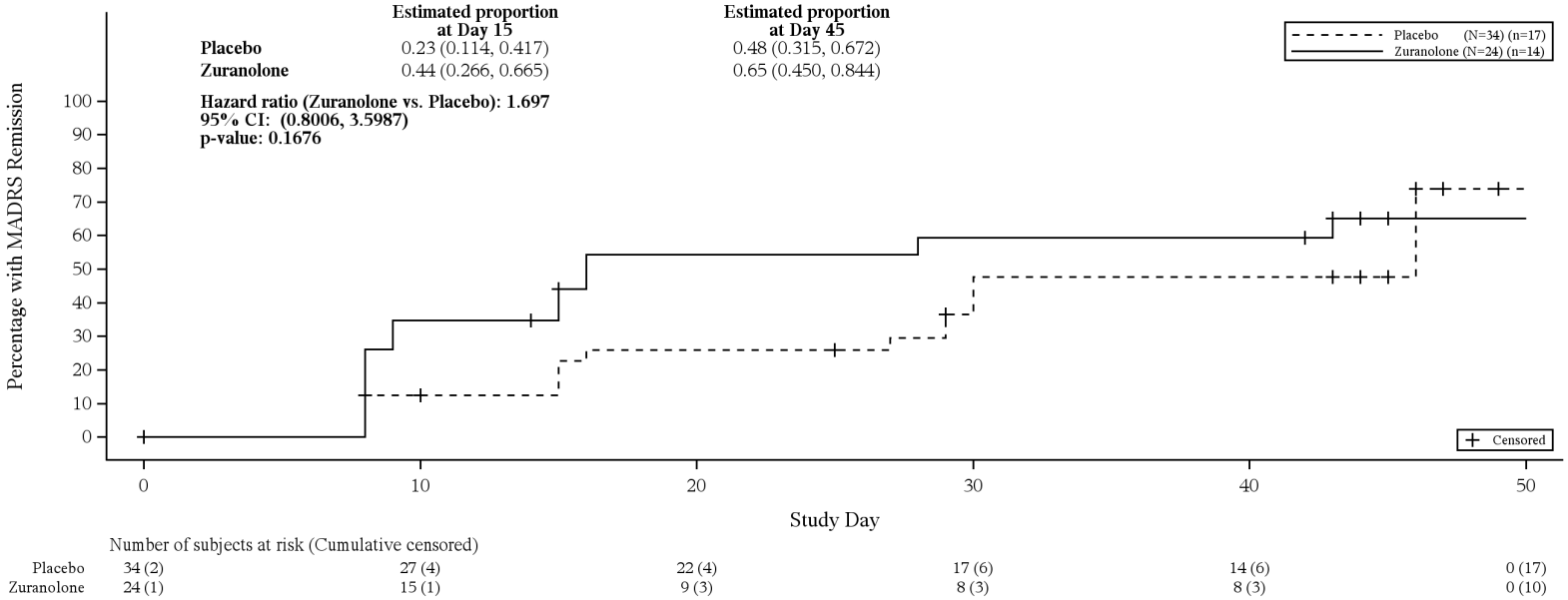
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate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

Source: biib125/v_a/amnog_kmplots/f-madrs-remi-tte-301-by.sas:f-madrs-remi-tte-301-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Subgroup: 217-PPD-301 - 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.

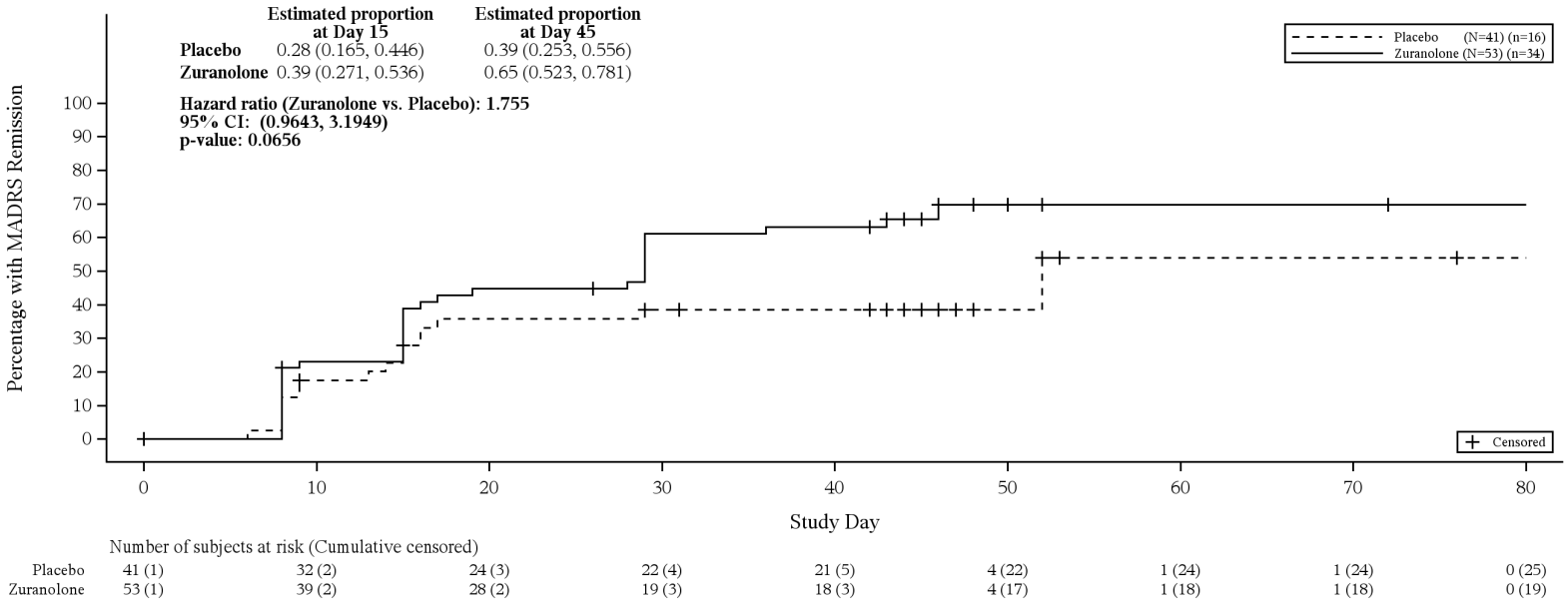
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate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

Source: biib125/v_a/amnog_kmplots/f-madrs-remi-tte-301-by.sas:f-madrs-remi-tte-301-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Subgroup: 217-PPD-301 - ITT population

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



Number of subjects at risk (Cumulative censored)

Placebo	41 (1)	32 (2)	24 (3)	22 (4)	21 (5)	4 (22)	1 (24)	1 (24)	0 (25)
Zuranolone	53 (1)	39 (2)	28 (2)	19 (3)	18 (3)	4 (17)	1 (18)	1 (18)	0 (19)

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.

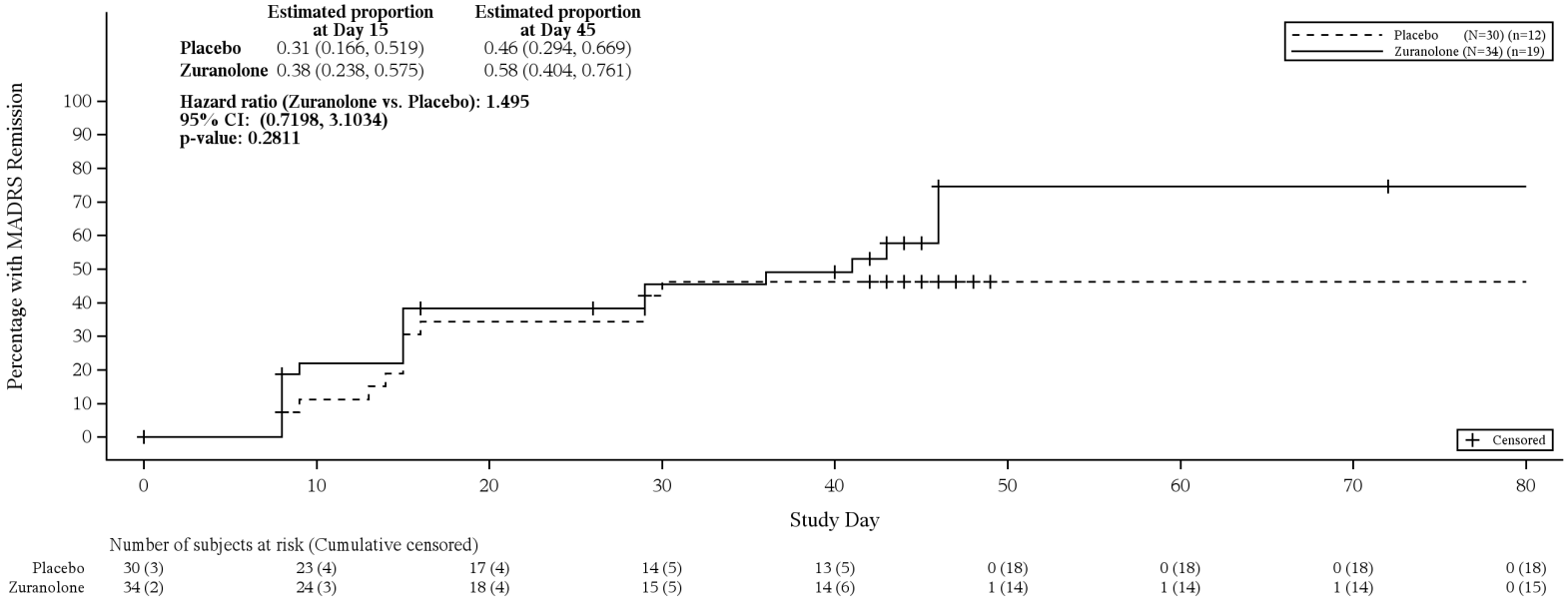
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate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

Source: biib125/v_a/amnog_kmplots/f-madrs-remi-tte-301-by.sas:f-madrs-remi-tte-301-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Subgroup: 217-PPD-301 - ITT population

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Onset of PPD = 3rd trimester



Number of subjects at risk (Cumulative censored)

Placebo	30 (3)	23 (4)	17 (4)	14 (5)	13 (5)	0 (18)	0 (18)	0 (18)	0 (18)
Zuranolone	34 (2)	24 (3)	18 (4)	15 (5)	14 (6)	1 (14)	1 (14)	1 (14)	0 (15)

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.

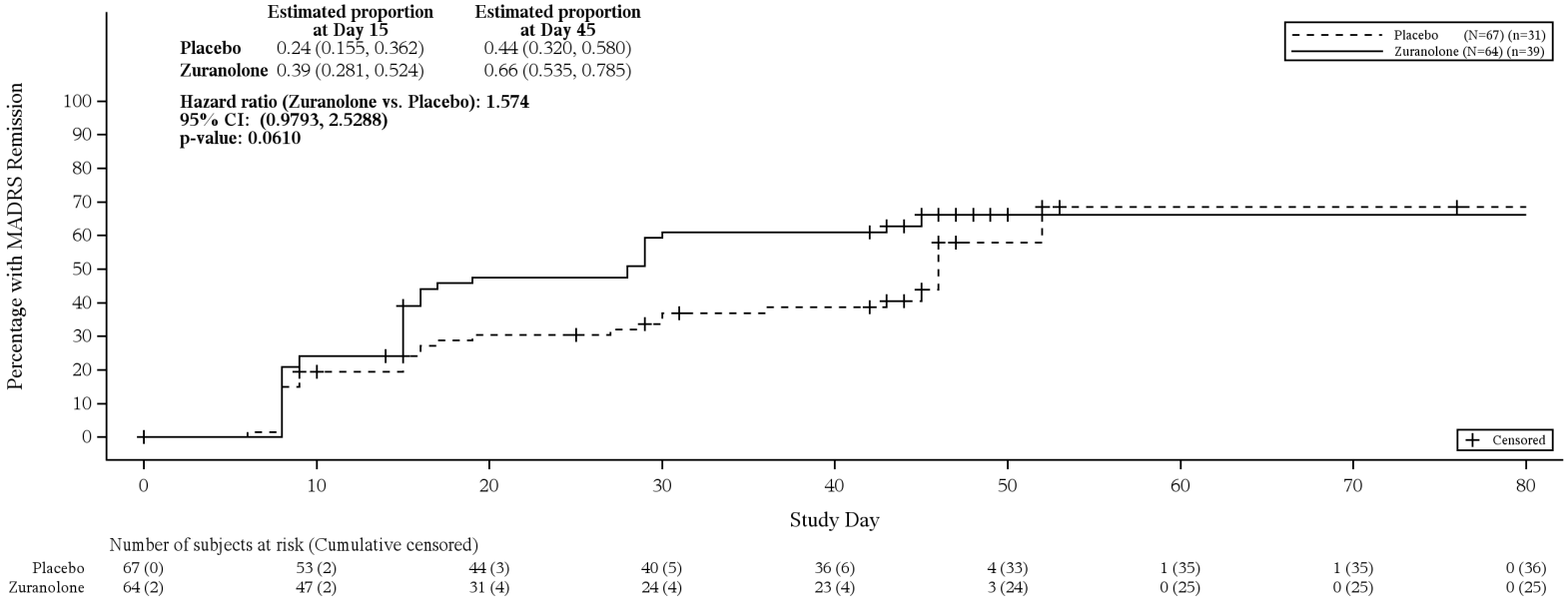
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate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

Source: biib125/v_a/amnog_kmplots/f-madrs-remi-tte-301-by.sas:f-madrs-remi-tte-301-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Subgroup: 217-PPD-301 - ITT population

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Onset of PPD = Postpartum



Number of subjects at risk (Cumulative censored)

Placebo	67 (0)	53 (2)	44 (3)	40 (5)	36 (6)	4 (33)	1 (35)	1 (35)	0 (36)
Zuranolone	64 (2)	47 (2)	31 (4)	24 (4)	23 (4)	3 (24)	0 (25)	0 (25)	0 (25)

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.

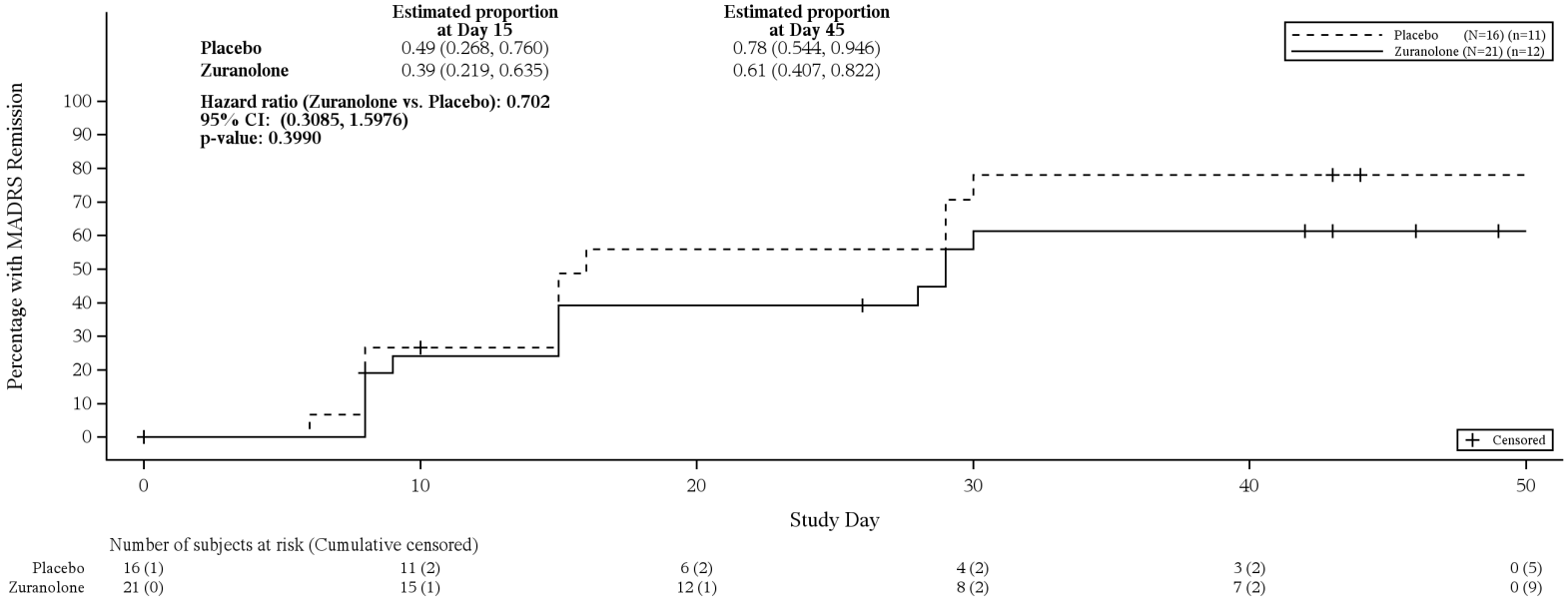
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate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

Source: biib125/v_a/amnog_kmplots/f-madrs-remi-tte-301-by.sas:f-madrs-remi-tte-301-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Subgroup: 217-PPD-301 - 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.

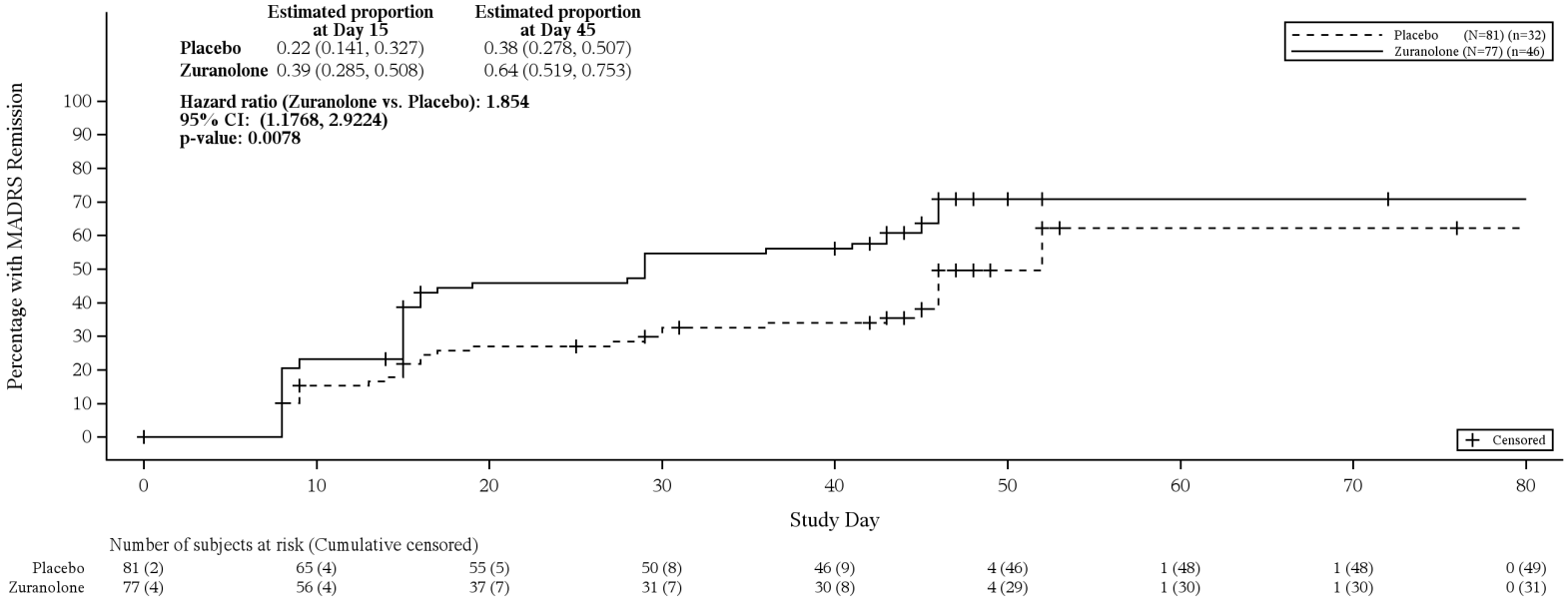
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate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

Source: biib125/v_a/amnog_kmplots/f-madrs-remi-tte-301-by.sas:f-madrs-remi-tte-301-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Subgroup: 217-PPD-301 - ITT population

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Family History of PPD = No/Unknown



Number of subjects at risk (Cumulative censored)

Placebo	81 (2)	65 (4)	55 (5)	50 (8)	46 (9)	4 (46)	1 (48)	1 (48)	0 (49)
Zuranolone	77 (4)	56 (4)	37 (7)	31 (7)	30 (8)	4 (29)	1 (30)	1 (30)	0 (31)

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.

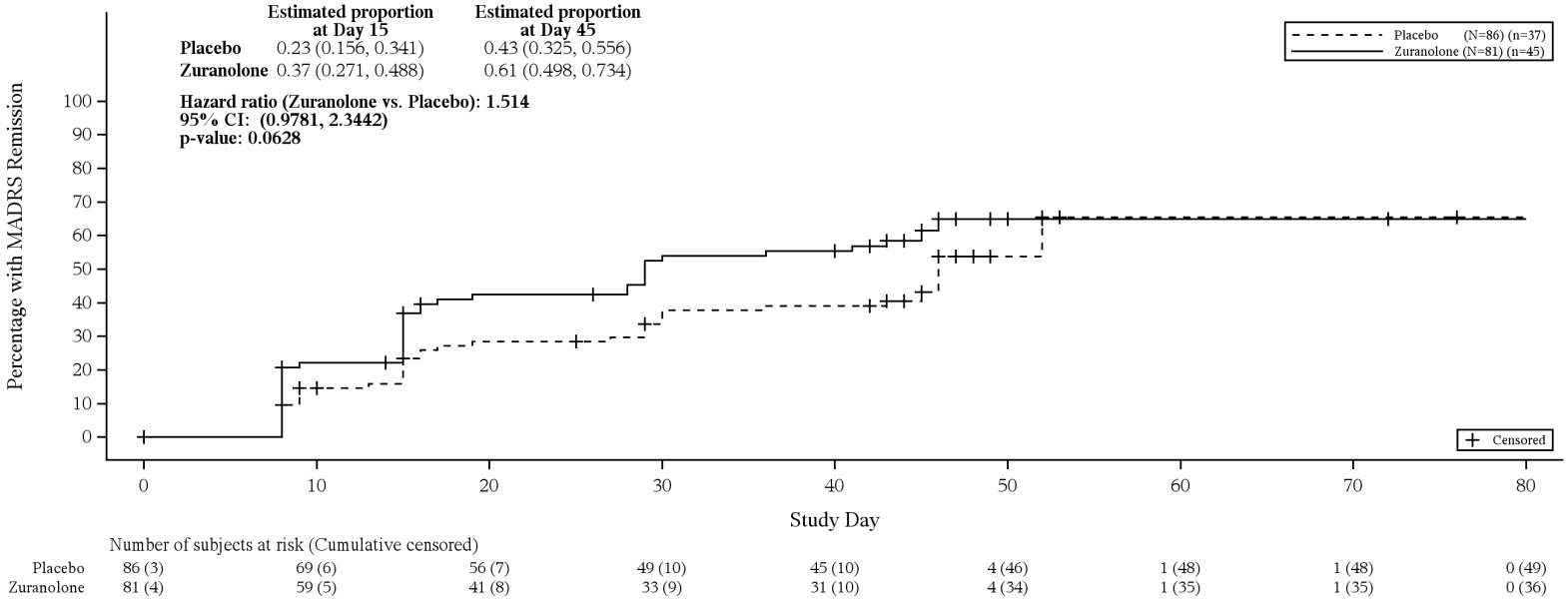
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate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

Source: biib125/v_a/amnog_kmplots/f-madrs-remi-tte-301-by.sas:f-madrs-remi-tte-301-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Subgroup: 217-PPD-301 - ITT population

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History of PPD = 1st Episode



Number of subjects at risk (Cumulative censored)

Placebo	86 (3)	69 (6)	56 (7)	49 (10)	45 (10)	4 (46)	1 (48)	1 (48)	0 (49)
Zuranolone	81 (4)	59 (5)	41 (8)	33 (9)	31 (10)	4 (34)	1 (35)	1 (35)	0 (36)

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.

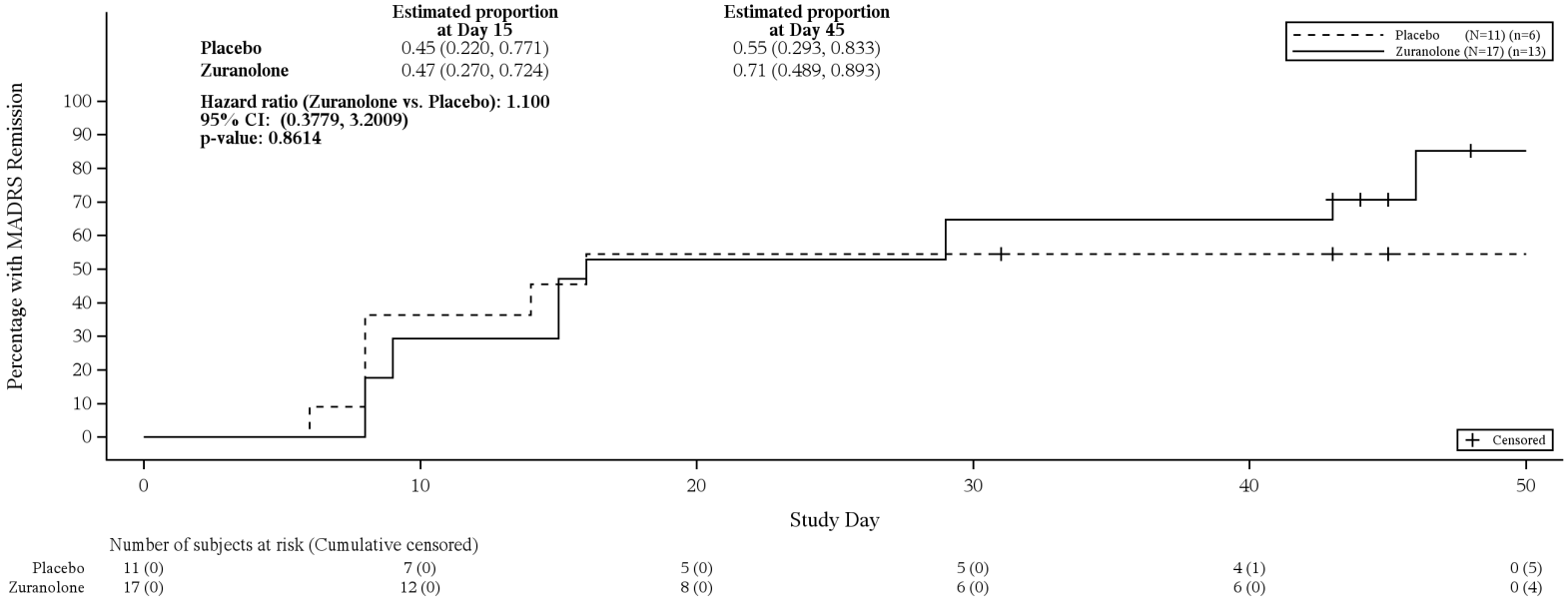
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate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

Source: biib125/v_a/amnog_kmplots/f-madrs-remi-tte-301-by.sas:f-madrs-remi-tte-301-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Subgroup: 217-PPD-301 - ITT population

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History of PPD = Recurrent 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.

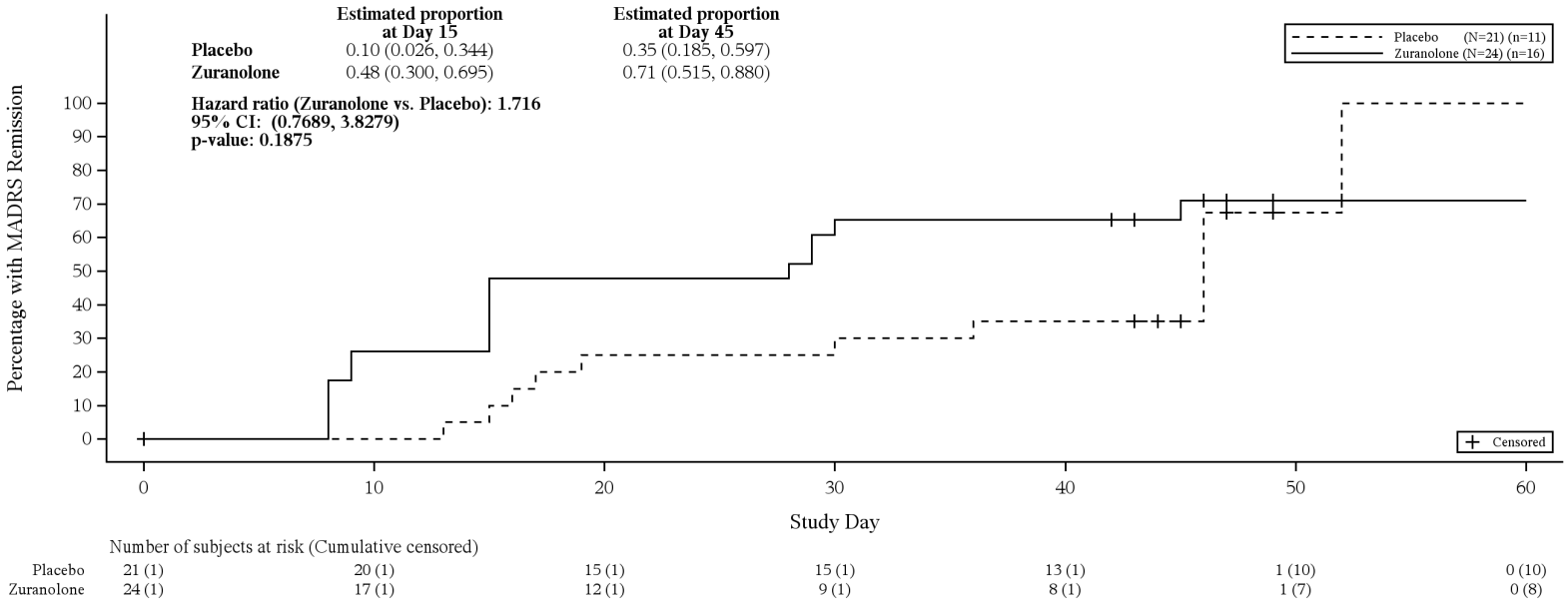
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate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

Source: biib125/v_a/amnog_kmplots/f-madrs-remi-tte-301-by.sas:f-madrs-remi-tte-301-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Subgroup: 217-PPD-301 - 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 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.

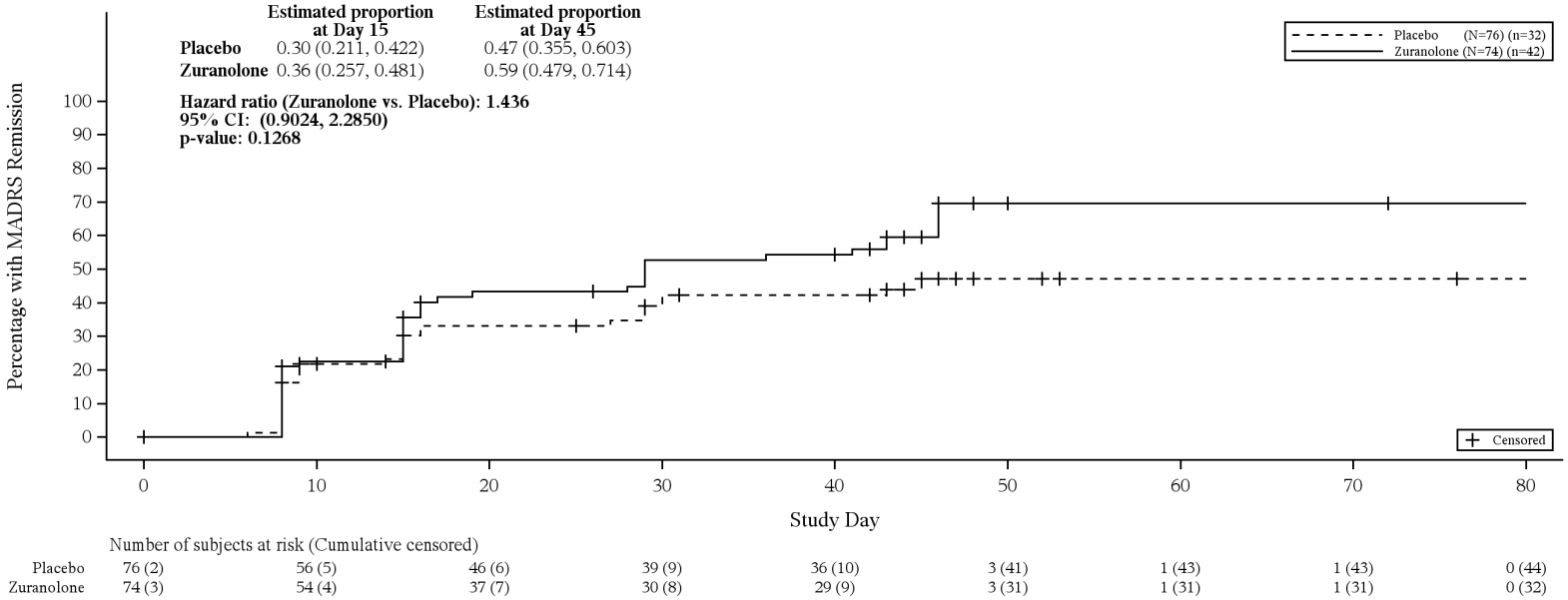
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline MADRS total score, and treatment. Model covariate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

Source: biib125/v_a/amnog_kmplots/f-madrs-remi-tte-301-by.sas:f-madrs-remi-tte-301-by-itta.rtf **Run Date:** 08JAN2026

Kaplan-Meier Plot for Time to First Montgomery-Asberg Depression Rating Scale (MADRS) Remission by Subgroup: 217-PPD-301 - 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 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-301-by.sas:f-madrs-remi-tte-301-by-itta.rtf **Run Date:** 08JAN2026

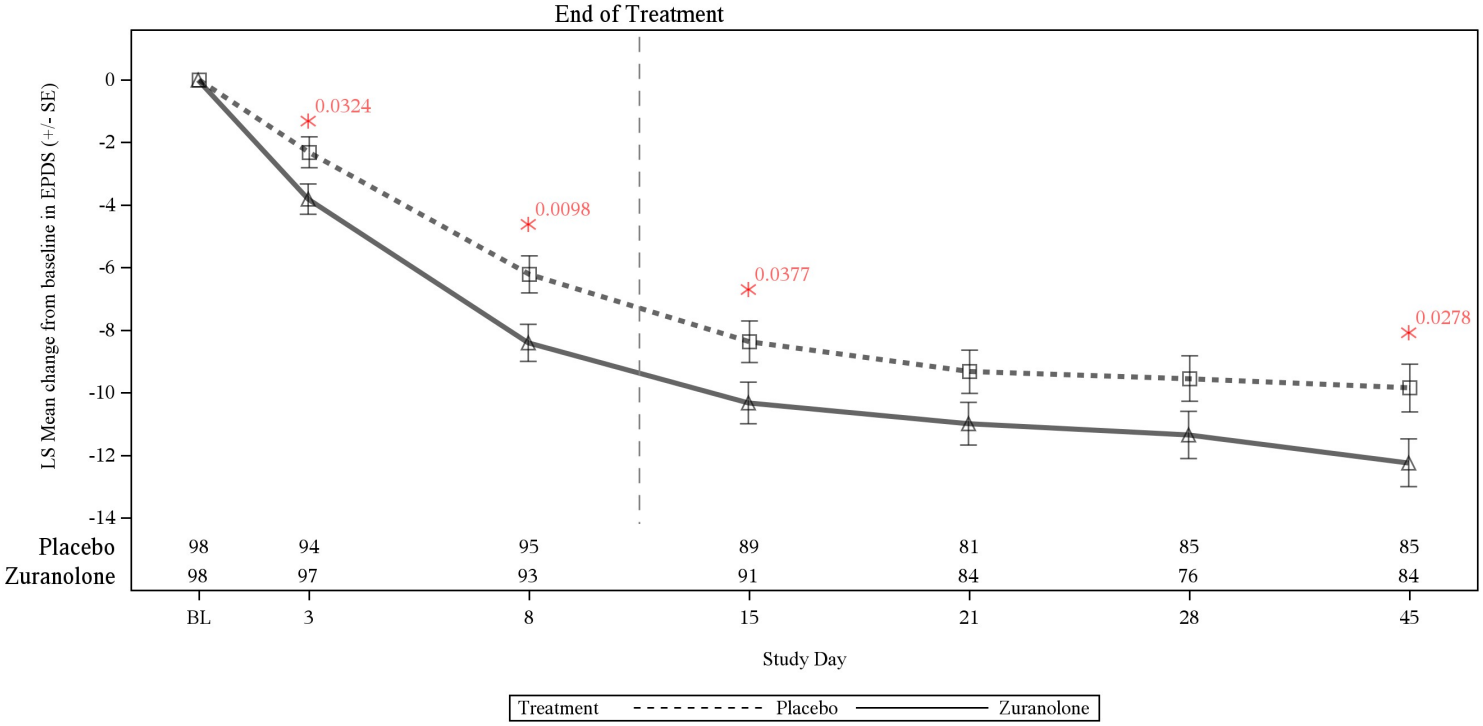
2.3 EPDS

2.3.1 MMRM

2.3.1.1 ITT-Population

Line Plot of LS Mean Change (+/- SE) from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score over Time: 217-PPD-301 - 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 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-301-ovr.sas:f-epds-mmrm-301-ovr-itta.rtf **Run Date:** 18JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score: 217-PPD-301 - ITT population

Page: 1 of 3

	Placebo (N=101)	Zuranolone (N=99)
Day 3		
n	94	97
LS Mean (SE)	-2.31 (0.491)	-3.80 (0.486)
95% CI for the LS Mean	-3.28, -1.34	-4.76, -2.84
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.50 (0.694)
95% CI for the LS Mean		-2.86, -0.13
p-value		0.0324
Hedges' g (Zuranolone vs. Placebo)		-0.311
95% CI for Hedges' g		-0.5961, -0.0254
Day 8		
n	95	93
LS Mean (SE)	-6.21 (0.590)	-8.40 (0.595)
95% CI for the LS Mean	-7.37, -5.05	-9.58, -7.23
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.19 (0.840)
95% CI for the LS Mean		-3.85, -0.54
p-value		0.0098
Hedges' g (Zuranolone vs. Placebo)		-0.379
95% CI for Hedges' g		-0.6678, -0.0909

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-301-ovr.sas:t-epds-mmrm-301-ovr-itta.rtf **Run Date:** 18JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score: 217-PPD-301 - ITT population

Page: 2 of 3

	Placebo (N=101)	Zuranolone (N=99)
Day 15		
n	89	91
LS Mean (SE)	-8.36 (0.662)	-10.32 (0.660)
95% CI for the LS Mean	-9.67, -7.06	-11.63, -9.02
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.96 (0.937)
95% CI for the LS Mean		-3.81, -0.11
p-value		0.0377
Hedges' g (Zuranolone vs. Placebo)		-0.311
95% CI for Hedges' g		-0.6048, -0.0169
Day 21		
n	81	84
LS Mean (SE)	-9.32 (0.688)	-10.98 (0.685)
95% CI for the LS Mean	-10.68, -7.97	-12.33, -9.63
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.65 (0.973)
95% CI for the LS Mean		-3.57, 0.27
p-value		0.0911
Hedges' g (Zuranolone vs. Placebo)		-0.263
95% CI for Hedges' g		-0.5699, 0.0432

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-301-ovr.sas:t-epds-mmrm-301-ovr-itta.rtf **Run Date:** 18JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score: 217-PPD-301 - ITT population

Page: 3 of 3

	Placebo (N=101)	Zuranolone (N=99)
Day 28		
n	85	76
LS Mean (SE)	-9.54 (0.731)	-11.34 (0.745)
95% CI for the LS Mean	-10.98, -8.10	-12.81, -9.87
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.80 (1.046)
95% CI for the LS Mean		-3.86, 0.27
p-value		0.0875
Hedges' g (Zuranolone vs. Placebo)		-0.270
95% CI for Hedges' g		-0.5808, 0.0408
Day 45		
n	85	84
LS Mean (SE)	-9.84 (0.758)	-12.23 (0.761)
95% CI for the LS Mean	-11.34, -8.35	-13.73, -10.73
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.39 (1.076)
95% CI for the LS Mean		-4.51, -0.26
p-value		0.0278
Hedges' g (Zuranolone vs. Placebo)		-0.340
95% CI for Hedges' g		-0.6434, -0.0360

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-301-ovr.sas:t-epds-mmrm-301-ovr-itta.rtf **Run Date:** 18JUL2025

2.3.1.2 Subgruppen

2.3.1.2 .1 Interaktionstest

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score: Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Age Group (years)			
18 - 24	12	19	0.4777
25 - 45	86	79	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28	32	33	0.7159
>=28	66	65	
Race Group (Black or African American, White)			
Black or African American	18	25	0.1913
White	69	68	
Antidepressant Use at Baseline			
Yes	15	15	0.1374
No	83	83	

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-301-int.sas:t-epds-mmrm-301-int-itta.rtf **Run Date:** 18JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score: Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9	22	20	0.3079(a)
25-29.9	34	24	0.4555(b)
>=30	42	53	0.6875(c)
Onset of PPD			
3rd Trimester	31	34	0.9781
Postpartum	67	64	
Family History of PPD			
Yes	16	21	0.1923
No/Unknown	82	77	
History of PPD			
1st Episode	87	81	0.4387
Recurrent Episode	11	17	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20	21	24	0.9552
>=20	77	74	

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-301-int.sas:t-epds-mmrm-301-int-itta.rtf **Run Date:** 18JUL2025

2.3.1.2 .2 Subgruppenanalysen

2.3.1.2 .2 .1 Alter

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 18-24

	Placebo (N=13)	**Zuranolone (N=19)**
Day 3		
n	12	19
LS Mean (SE)	-5.58 (1.483)	-5.87 (1.177)
95% CI for the LS Mean	-8.61, -2.54	-8.28, -3.46
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.29 (1.909)
95% CI for the LS Mean		-4.20, 3.62
p-value		0.8791
Hedges' g (Zuranolone vs. Placebo)		-0.055
95% CI for Hedges' g		-0.7780, 0.6677
Day 8		
n	12	19
LS Mean (SE)	-8.66 (1.638)	-11.92 (1.300)
95% CI for the LS Mean	-12.02, -5.29	-14.59, -9.25
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.26 (2.106)
95% CI for the LS Mean		-7.59, 1.06
p-value		0.1331
Hedges' g (Zuranolone vs. Placebo)		-0.556
95% CI for Hedges' g		-1.2923, 0.1794

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-301-by.sas:t-epds-mmrm-301-by-age-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 18-24

	Placebo (N=13)	Zuranolone (N=19)
Day 15		
n	12	19
LS Mean (SE)	-10.83 (1.575)	-12.66 (1.250)
95% CI for the LS Mean	-14.06, -7.59	-15.23, -10.09
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.83 (2.026)
95% CI for the LS Mean		-6.00, 2.33
p-value		0.3740
Hedges' g (Zuranolone vs. Placebo)		-0.325
95% CI for Hedges' g		-1.0520, 0.4024
Day 21		
n	9	18
LS Mean (SE)	-11.41 (1.717)	-14.59 (1.301)
95% CI for the LS Mean	-14.93, -7.89	-17.27, -11.91
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.18 (2.168)
95% CI for the LS Mean		-7.63, 1.27
p-value		0.1538
Hedges' g (Zuranolone vs. Placebo)		-0.581
95% CI for Hedges' g		-1.3958, 0.2342

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-301-by.sas:t-epds-mmrm-301-by-age-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 18-24

	Placebo (N=13)	Zuranolone (N=19)
Day 28		
n	12	16
LS Mean (SE)	-9.99 (1.842)	-14.02 (1.524)
95% CI for the LS Mean	-13.77, -6.22	-17.13, -10.90
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-4.02 (2.402)
95% CI for the LS Mean		-8.94, 0.89
p-value		0.1046
Hedges' g (Zuranolone vs. Placebo)		-0.621
95% CI for Hedges' g		-1.3871, 0.1448
Day 45		
n	11	18
LS Mean (SE)	-10.69 (2.046)	-14.52 (1.616)
95% CI for the LS Mean	-14.88, -6.51	-17.83, -11.21
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.82 (2.617)
95% CI for the LS Mean		-9.18, 1.53
p-value		0.1550
Hedges' g (Zuranolone vs. Placebo)		-0.543
95% CI for Hedges' g		-1.3062, 0.2198

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-301-by.sas:t-epds-mmrm-301-by-age-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 25-45

	Placebo (N=88)	Zuranolone (N=80)
Day 3		
n	82	78
LS Mean (SE)	-1.79 (0.506)	-3.34 (0.523)
95% CI for the LS Mean	-2.79, -0.79	-4.37, -2.31
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.55 (0.730)
95% CI for the LS Mean		-2.99, -0.11
p-value		0.0355
Hedges' g (Zuranolone vs. Placebo)		-0.334
95% CI for Hedges' g		-0.6460, -0.0217
Day 8		
n	83	74
LS Mean (SE)	-5.83 (0.618)	-7.57 (0.653)
95% CI for the LS Mean	-7.05, -4.61	-8.86, -6.28
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.74 (0.901)
95% CI for the LS Mean		-3.52, 0.04
p-value		0.0551
Hedges' g (Zuranolone vs. Placebo)		-0.308
95% CI for Hedges' g		-0.6228, 0.0076

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-301-by.sas:t-epds-mmrm-301-by-age-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 25-45

	Placebo (N=88)	Zuranolone (N=80)
Day 15		
n	77	72
LS Mean (SE)	-7.96 (0.733)	-9.80 (0.765)
95% CI for the LS Mean	-9.41, -6.51	-11.32, -8.29
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.84 (1.061)
95% CI for the LS Mean		-3.94, 0.26
p-value		0.0849
Hedges' g (Zuranolone vs. Placebo)		-0.283
95% CI for Hedges' g		-0.6058, 0.0400
Day 21		
n	72	66
LS Mean (SE)	-9.00 (0.746)	-10.09 (0.781)
95% CI for the LS Mean	-10.47, -7.52	-11.63, -8.54
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.09 (1.082)
95% CI for the LS Mean		-3.23, 1.05
p-value		0.3158
Hedges' g (Zuranolone vs. Placebo)		-0.171
95% CI for Hedges' g		-0.5052, 0.1640

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-301-by.sas:t-epds-mmrm-301-by-age-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 25-45

	Placebo (N=88)	Zuranolone (N=80)
Day 28		
n	73	60
LS Mean (SE)	-9.43 (0.799)	-10.62 (0.849)
95% CI for the LS Mean	-11.01, -7.85	-12.30, -8.94
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.19 (1.167)
95% CI for the LS Mean		-3.50, 1.12
p-value		0.3099
Hedges' g (Zuranolone vs. Placebo)		-0.177
95% CI for Hedges' g		-0.5188, 0.1656
Day 45		
n	74	66
LS Mean (SE)	-9.67 (0.823)	-11.73 (0.866)
95% CI for the LS Mean	-11.30, -8.05	-13.44, -10.01
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.05 (1.196)
95% CI for the LS Mean		-4.42, 0.31
p-value		0.0882
Hedges' g (Zuranolone vs. Placebo)		-0.289
95% CI for Hedges' g		-0.6227, 0.0445

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-301-by.sas:t-epds-mmrm-301-by-age-itta.rtf **Run Date:** 25JUL2025

2.3.1.2 .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-301 - ITT population

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

	Placebo (N=32)	Zuranolone (N=33)
Day 3		
n	32	32
LS Mean (SE)	-1.23 (0.705)	-3.37 (0.707)
95% CI for the LS Mean	-2.64, 0.18	-4.78, -1.95
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.14 (1.011)
95% CI for the LS Mean		-4.16, -0.12
p-value		0.0385
Hedges' g (Zuranolone vs. Placebo)		-0.523
95% CI for Hedges' g		-1.0208, -0.0243
Day 8		
n	32	32
LS Mean (SE)	-4.79 (0.985)	-6.64 (0.986)
95% CI for the LS Mean	-6.76, -2.82	-8.61, -4.67
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.85 (1.403)
95% CI for the LS Mean		-4.65, 0.96
p-value		0.1931
Hedges' g (Zuranolone vs. Placebo)		-0.325
95% CI for Hedges' g		-0.8182, 0.1683

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-301-by.sas:t-epds-mmrm-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Baseline HAMD-17 Total Score: 217-PPD-301 - ITT population

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

	Placebo (N=32)	Zuranolone (N=33)
Day 15		
n	30	32
LS Mean (SE)	-7.06 (1.076)	-9.17 (1.056)
95% CI for the LS Mean	-9.21, -4.91	-11.28, -7.05
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.10 (1.516)
95% CI for the LS Mean		-5.13, 0.93
p-value		0.1703
Hedges' g (Zuranolone vs. Placebo)		-0.348
95% CI for Hedges' g		-0.8500, 0.1537
Day 21		
n	27	31
LS Mean (SE)	-6.78 (1.190)	-10.51 (1.153)
95% CI for the LS Mean	-9.16, -4.41	-12.81, -8.20
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.72 (1.665)
95% CI for the LS Mean		-7.05, -0.40
p-value		0.0288
Hedges' g (Zuranolone vs. Placebo)		-0.581
95% CI for Hedges' g		-1.1077, -0.0543

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-301-by.sas:t-epds-mmrm-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Baseline HAMD-17 Total Score: 217-PPD-301 - ITT population

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

	Placebo (N=32)	Zuranolone (N=33)
Day 28		
n	26	27
LS Mean (SE)	-7.56 (1.409)	-9.79 (1.378)
95% CI for the LS Mean	-10.38, -4.74	-12.55, -7.03
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.23 (1.977)
95% CI for the LS Mean		-6.18, 1.73
p-value		0.2645
Hedges' g (Zuranolone vs. Placebo)		-0.305
95% CI for Hedges' g		-0.8466, 0.2367
Day 45		
n	27	30
LS Mean (SE)	-7.81 (1.321)	-11.31 (1.275)
95% CI for the LS Mean	-10.45, -5.17	-13.86, -8.76
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.51 (1.843)
95% CI for the LS Mean		-7.19, 0.18
p-value		0.0618
Hedges' g (Zuranolone vs. Placebo)		-0.498
95% CI for Hedges' g		-1.0257, 0.0301

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-301-by.sas:t-epds-mmrm-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Baseline HAMD-17 Total Score: 217-PPD-301 - ITT population

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

	Placebo (N=66)	Zuranolone (N=65)
Day 3		
n	62	65
LS Mean (SE)	-2.81 (0.647)	-4.07 (0.638)
95% CI for the LS Mean	-4.09, -1.53	-5.33, -2.81
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.26 (0.910)
95% CI for the LS Mean		-3.06, 0.54
p-value		0.1689
Hedges' g (Zuranolone vs. Placebo)		-0.244
95% CI for Hedges' g		-0.5934, 0.1051
Day 8		
n	63	61
LS Mean (SE)	-6.88 (0.734)	-9.37 (0.743)
95% CI for the LS Mean	-8.33, -5.43	-10.84, -7.90
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.48 (1.046)
95% CI for the LS Mean		-4.55, -0.41
p-value		0.0191
Hedges' g (Zuranolone vs. Placebo)		-0.424
95% CI for Hedges' g		-0.7801, -0.0681

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-301-by.sas:t-epds-mmrm-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Baseline HAMD-17 Total Score: 217-PPD-301 - ITT population

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

	Placebo (N=66)	Zuranolone (N=65)
Day 15		
n	59	59
LS Mean (SE)	-8.97 (0.847)	-10.95 (0.852)
95% CI for the LS Mean	-10.65, -7.29	-12.64, -9.26
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.98 (1.203)
95% CI for the LS Mean		-4.36, 0.40
p-value		0.1024
Hedges' g (Zuranolone vs. Placebo)		-0.301
95% CI for Hedges' g		-0.6641, 0.0617
Day 21		
n	54	53
LS Mean (SE)	-10.56 (0.844)	-11.21 (0.854)
95% CI for the LS Mean	-12.23, -8.88	-12.90, -9.52
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.65 (1.202)
95% CI for the LS Mean		-3.03, 1.73
p-value		0.5876
Hedges' g (Zuranolone vs. Placebo)		-0.104
95% CI for Hedges' g		-0.4836, 0.2748

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-301-by.sas:t-epds-mmrm-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Baseline HAMD-17 Total Score: 217-PPD-301 - ITT population

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

	Placebo (N=66)	Zuranolone (N=65)
Day 28		
n	59	49
LS Mean (SE)	-10.44 (0.854)	-12.21 (0.890)
95% CI for the LS Mean	-12.13, -8.74	-13.98, -10.45
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.78 (1.235)
95% CI for the LS Mean		-4.22, 0.67
p-value		0.1527
Hedges' g (Zuranolone vs. Placebo)		-0.276
95% CI for Hedges' g		-0.6569, 0.1044
Day 45		
n	58	54
LS Mean (SE)	-10.76 (0.926)	-12.77 (0.952)
95% CI for the LS Mean	-12.60, -8.93	-14.66, -10.89
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.01 (1.329)
95% CI for the LS Mean		-4.64, 0.62
p-value		0.1334
Hedges' g (Zuranolone vs. Placebo)		-0.284
95% CI for Hedges' g		-0.6564, 0.0886

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-301-by.sas:t-epds-mmrm-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

2.3.1.2 .2 .3 Abstammung

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Race Group: 217-PPD-301 - ITT population

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Race Group = Black or African American

	Placebo (N=20)	Zuranolone (N=26)
Day 3		
n	17	25
LS Mean (SE)	-2.16 (1.391)	-4.10 (1.160)
95% CI for the LS Mean	-4.98, 0.66	-6.45, -1.75
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.94 (1.820)
95% CI for the LS Mean		-5.62, 1.74
p-value		0.2933
Hedges' g (Zuranolone vs. Placebo)		-0.329
95% CI for Hedges' g		-0.9487, 0.2915
Day 8		
n	16	23
LS Mean (SE)	-5.65 (1.847)	-9.33 (1.542)
95% CI for the LS Mean	-9.41, -1.88	-12.47, -6.18
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.68 (2.414)
95% CI for the LS Mean		-8.60, 1.24
p-value		0.1374
Hedges' g (Zuranolone vs. Placebo)		-0.486
95% CI for Hedges' g		-1.1331, 0.1611

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-301-by.sas:t-epds-mmrm-301-by-race-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Race Group: 217-PPD-301 - ITT population

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Race Group = Black or African American

	Placebo (N=20)	Zuranolone (N=26)
Day 15		
n	14	21
LS Mean (SE)	-8.99 (2.048)	-12.06 (1.696)
95% CI for the LS Mean	-13.17, -4.80	-15.53, -8.59
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.07 (2.668)
95% CI for the LS Mean		-8.52, 2.38
p-value		0.2589
Hedges' g (Zuranolone vs. Placebo)		-0.388
95% CI for Hedges' g		-1.0703, 0.2943
Day 21		
n	11	18
LS Mean (SE)	-9.27 (1.767)	-13.01 (1.455)
95% CI for the LS Mean	-12.88, -5.67	-15.98, -10.04
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.74 (2.300)
95% CI for the LS Mean		-8.43, 0.95
p-value		0.1142
Hedges' g (Zuranolone vs. Placebo)		-0.605
95% CI for Hedges' g		-1.3706, 0.1615

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-301-by.sas:t-epds-mmrm-301-by-race-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Race Group: 217-PPD-301 - ITT population

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Race Group = Black or African American

	Placebo (N=20)	Zuranolone (N=26)
Day 28		
n	11	19
LS Mean (SE)	-8.96 (1.867)	-13.40 (1.502)
95% CI for the LS Mean	-12.75, -5.18	-16.45, -10.34
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-4.43 (2.407)
95% CI for the LS Mean		-9.32, 0.45
p-value		0.0739
Hedges' g (Zuranolone vs. Placebo)		-0.679
95% CI for Hedges' g		-1.4414, 0.0830
Day 45		
n	13	22
LS Mean (SE)	-7.21 (2.088)	-14.24 (1.678)
95% CI for the LS Mean	-11.45, -2.97	-17.66, -10.82
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-7.03 (2.688)
95% CI for the LS Mean		-12.50, -1.57
p-value		0.0132
Hedges' g (Zuranolone vs. Placebo)		-0.895
95% CI for Hedges' g		-1.6115, -0.1776

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-301-by.sas:t-epds-mmrm-301-by-race-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Race Group: 217-PPD-301 - ITT population

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Race Group = White

	Placebo (N=70)	Zuranolone (N=68)
Day 3		
n	67	68
LS Mean (SE)	-1.96 (0.522)	-3.61 (0.521)
95% CI for the LS Mean	-2.99, -0.92	-4.64, -2.57
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.65 (0.746)
95% CI for the LS Mean		-3.12, -0.17
p-value		0.0289
Hedges' g (Zuranolone vs. Placebo)		-0.378
95% CI for Hedges' g		-0.7186, -0.0379
Day 8		
n	69	65
LS Mean (SE)	-6.41 (0.660)	-8.22 (0.678)
95% CI for the LS Mean	-7.71, -5.10	-9.57, -6.88
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.82 (0.953)
95% CI for the LS Mean		-3.70, 0.07
p-value		0.0588
Hedges' g (Zuranolone vs. Placebo)		-0.328
95% CI for Hedges' g		-0.6686, 0.0135

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-301-by.sas:t-epds-mmrm-301-by-race-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Race Group: 217-PPD-301 - ITT population

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Race Group = White

	Placebo (N=70)	Zuranolone (N=68)
Day 15		
n	65	65
LS Mean (SE)	-8.24 (0.733)	-9.80 (0.742)
95% CI for the LS Mean	-9.69, -6.79	-11.27, -8.33
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.56 (1.049)
95% CI for the LS Mean		-3.63, 0.52
p-value		0.1405
Hedges' g (Zuranolone vs. Placebo)		-0.259
95% CI for Hedges' g		-0.6038, 0.0867
Day 21		
n	60	61
LS Mean (SE)	-9.45 (0.809)	-10.56 (0.817)
95% CI for the LS Mean	-11.05, -7.85	-12.17, -8.94
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.11 (1.155)
95% CI for the LS Mean		-3.40, 1.17
p-value		0.3382
Hedges' g (Zuranolone vs. Placebo)		-0.174
95% CI for Hedges' g		-0.5307, 0.1834

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-301-by.sas:t-epds-mmrm-301-by-race-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Race Group: 217-PPD-301 - ITT population

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Race Group = White

	Placebo (N=70)	Zuranolone (N=68)
Day 28		
n	64	52
LS Mean (SE)	-9.88 (0.868)	-10.73 (0.910)
95% CI for the LS Mean	-11.60, -8.16	-12.53, -8.93
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.85 (1.263)
95% CI for the LS Mean		-3.35, 1.65
p-value		0.5020
Hedges' g (Zuranolone vs. Placebo)		-0.125
95% CI for Hedges' g		-0.4911, 0.2414
Day 45		
n	62	58
LS Mean (SE)	-10.23 (0.887)	-11.70 (0.912)
95% CI for the LS Mean	-11.99, -8.48	-13.50, -9.89
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.47 (1.277)
95% CI for the LS Mean		-3.99, 1.06
p-value		0.2528
Hedges' g (Zuranolone vs. Placebo)		-0.209
95% CI for Hedges' g		-0.5675, 0.1505

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-301-by.sas:t-epds-mmrm-301-by-race-itta.rtf **Run Date:** 25JUL2025

2.3.1.2 .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-301 - ITT population

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Antidepressant Use at Baseline = Yes

	Placebo (N=15)	Zuranolone (N=15)
Day 3		
n	13	15
LS Mean (SE)	-2.71 (1.407)	-2.71 (1.351)
95% CI for the LS Mean	-5.60, 0.17	-5.49, 0.06
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.00 (1.951)
95% CI for the LS Mean		-4.00, 4.00
p-value		0.9998
Hedges' g (Zuranolone vs. Placebo)		0.000
95% CI for Hedges' g		-0.7426, 0.7428
Day 8		
n	15	14
LS Mean (SE)	-6.37 (1.655)	-6.09 (1.680)
95% CI for the LS Mean	-9.76, -2.97	-9.53, -2.65
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.28 (2.362)
95% CI for the LS Mean		-4.56, 5.12
p-value		0.9058
Hedges' g (Zuranolone vs. Placebo)		0.043
95% CI for Hedges' g		-0.6853, 0.7715

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-301-by.sas:t-epds-mmrm-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Baseline Antidepressant Use: 217-PPD-301 - ITT population

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Antidepressant Use at Baseline = Yes

	Placebo (N=15)	Zuranolone (N=15)
Day 15		
n	15	14
LS Mean (SE)	-9.97 (1.691)	-7.44 (1.704)
95% CI for the LS Mean	-13.44, -6.50	-10.93, -3.95
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.53 (2.404)
95% CI for the LS Mean		-2.40, 7.46
p-value		0.3016
Hedges' g (Zuranolone vs. Placebo)		0.380
95% CI for Hedges' g		-0.3547, 1.1151
Day 21		
n	14	14
LS Mean (SE)	-9.55 (1.943)	-8.86 (1.943)
95% CI for the LS Mean	-13.53, -5.56	-12.85, -4.87
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.69 (2.751)
95% CI for the LS Mean		-4.96, 6.33
p-value		0.8043
Hedges' g (Zuranolone vs. Placebo)		0.092
95% CI for Hedges' g		-0.6494, 0.8330

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-301-by.sas:t-epds-mmrm-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Baseline Antidepressant Use: 217-PPD-301 - ITT population

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Antidepressant Use at Baseline = Yes

	Placebo (N=15)	Zuranolone (N=15)
Day 28		
n	13	14
LS Mean (SE)	-10.16 (2.068)	-10.02 (2.057)
95% CI for the LS Mean	-14.40, -5.92	-14.24, -5.80
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.14 (2.920)
95% CI for the LS Mean		-5.84, 6.12
p-value		0.9622
Hedges' g (Zuranolone vs. Placebo)		0.018
95% CI for Hedges' g		-0.7371, 0.7728
Day 45		
n	14	15
LS Mean (SE)	-7.21 (2.240)	-8.78 (2.220)
95% CI for the LS Mean	-11.80, -2.62	-13.33, -4.23
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.57 (3.156)
95% CI for the LS Mean		-8.04, 4.89
p-value		0.6225
Hedges' g (Zuranolone vs. Placebo)		-0.180
95% CI for Hedges' g		-0.9096, 0.5500

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-301-by.sas:t-epds-mmrm-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Baseline Antidepressant Use: 217-PPD-301 - ITT population

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Antidepressant Use at Baseline = No

	Placebo (N=86)	Zuranolone (N=84)
Day 3		
n	81	82
LS Mean (SE)	-2.19 (0.516)	-4.07 (0.517)
95% CI for the LS Mean	-3.21, -1.17	-5.09, -3.05
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.88 (0.735)
95% CI for the LS Mean		-3.33, -0.43
p-value		0.0116
Hedges' g (Zuranolone vs. Placebo)		-0.398
95% CI for Hedges' g		-0.7084, -0.0883
Day 8		
n	80	79
LS Mean (SE)	-6.13 (0.631)	-8.90 (0.635)
95% CI for the LS Mean	-7.38, -4.88	-10.16, -7.65
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.77 (0.899)
95% CI for the LS Mean		-4.55, -0.99
p-value		0.0024
Hedges' g (Zuranolone vs. Placebo)		-0.486
95% CI for Hedges' g		-0.8018, -0.1710

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-301-by.sas:t-epds-mmrm-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Baseline Antidepressant Use: 217-PPD-301 - ITT population

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Antidepressant Use at Baseline = No

	Placebo (N=86)	Zuranolone (N=84)
Day 15		
n	74	77
LS Mean (SE)	-7.96 (0.716)	-10.94 (0.713)
95% CI for the LS Mean	-9.38, -6.55	-12.35, -9.53
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.98 (1.015)
95% CI for the LS Mean		-4.98, -0.97
p-value		0.0039
Hedges' g (Zuranolone vs. Placebo)		-0.475
95% CI for Hedges' g		-0.7984, -0.1513
Day 21		
n	67	70
LS Mean (SE)	-9.15 (0.736)	-11.49 (0.731)
95% CI for the LS Mean	-10.60, -7.69	-12.93, -10.04
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.34 (1.041)
95% CI for the LS Mean		-4.40, -0.28
p-value		0.0262
Hedges' g (Zuranolone vs. Placebo)		-0.382
95% CI for Hedges' g		-0.7196, -0.0436

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-301-by.sas:t-epds-mmrm-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Baseline Antidepressant Use: 217-PPD-301 - ITT population

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Antidepressant Use at Baseline = No

	Placebo (N=86)	Zuranolone (N=84)
Day 28		
n	72	62
LS Mean (SE)	-9.33 (0.780)	-11.61 (0.799)
95% CI for the LS Mean	-10.87, -7.79	-13.19, -10.03
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.28 (1.120)
95% CI for the LS Mean		-4.49, -0.07
p-value		0.0434
Hedges' g (Zuranolone vs. Placebo)		-0.351
95% CI for Hedges' g		-0.6932, -0.0088
Day 45		
n	71	69
LS Mean (SE)	-10.22 (0.797)	-13.02 (0.803)
95% CI for the LS Mean	-11.79, -8.64	-14.61, -11.43
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.81 (1.135)
95% CI for the LS Mean		-5.05, -0.56
p-value		0.0146
Hedges' g (Zuranolone vs. Placebo)		-0.415
95% CI for Hedges' g		-0.7504, -0.0806

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-301-by.sas:t-epds-mmrm-301-by-adt-itta.rtf **Run Date:** 25JUL2025

2.3.1.2 .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-301 - ITT population

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

	Placebo (N=22)	Zuranolone (N=20)
Day 3		
n	21	20
LS Mean (SE)	-2.88 (0.972)	-3.54 (0.997)
95% CI for the LS Mean	-4.86, -0.89	-5.58, -1.50
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.66 (1.396)
95% CI for the LS Mean		-3.51, 2.19
p-value		0.6384
Hedges' g (Zuranolone vs. Placebo)		-0.145
95% CI for Hedges' g		-0.7586, 0.4677
Day 8		
n	22	18
LS Mean (SE)	-6.78 (1.210)	-6.03 (1.324)
95% CI for the LS Mean	-9.25, -4.31	-8.73, -3.34
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.75 (1.795)
95% CI for the LS Mean		-2.91, 4.41
p-value		0.6794
Hedges' g (Zuranolone vs. Placebo)		0.130
95% CI for Hedges' g		-0.4936, 0.7535

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-301-by.sas:t-epds-mmrm-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Baseline BMI (kg/m^2) Group: 217-PPD-301 - ITT population

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

	Placebo (N=22)	Zuranolone (N=20)
Day 15		
n	21	18
LS Mean (SE)	-8.95 (1.454)	-8.31 (1.588)
95% CI for the LS Mean	-11.91, -5.98	-11.55, -5.07
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.64 (2.155)
95% CI for the LS Mean		-3.75, 5.03
p-value		0.7692
Hedges' g (Zuranolone vs. Placebo)		0.093
95% CI for Hedges' g		-0.5368, 0.7230
Day 21		
n	17	16
LS Mean (SE)	-9.74 (1.360)	-9.91 (1.476)
95% CI for the LS Mean	-12.53, -6.95	-12.93, -6.88
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.17 (2.009)
95% CI for the LS Mean		-4.29, 3.95
p-value		0.9338
Hedges' g (Zuranolone vs. Placebo)		-0.028
95% CI for Hedges' g		-0.7112, 0.6543

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-301-by.sas:t-epds-mmrm-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Baseline BMI (kg/m^2) Group: 217-PPD-301 - ITT population

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

	Placebo (N=22)	Zuranolone (N=20)
Day 28		
n	21	12
LS Mean (SE)	-8.99 (1.649)	-11.27 (1.974)
95% CI for the LS Mean	-12.39, -5.60	-15.30, -7.24
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.28 (2.577)
95% CI for the LS Mean		-7.56, 3.00
p-value		0.3838
Hedges' g (Zuranolone vs. Placebo)		-0.312
95% CI for Hedges' g		-1.0256, 0.4009
Day 45		
n	22	15
LS Mean (SE)	-10.10 (1.566)	-11.63 (1.808)
95% CI for the LS Mean	-13.32, -6.88	-15.33, -7.93
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.53 (2.397)
95% CI for the LS Mean		-6.44, 3.38
p-value		0.5280
Hedges' g (Zuranolone vs. Placebo)		-0.209
95% CI for Hedges' g		-0.8673, 0.4487

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-301 - ITT population

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

	Placebo (N=34)	Zuranolone (N=24)
Day 3		
n	33	23
LS Mean (SE)	-1.36 (0.770)	-3.66 (0.917)
95% CI for the LS Mean	-2.91, 0.18	-5.50, -1.81
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.29 (1.197)
95% CI for the LS Mean		-4.69, 0.11
p-value		0.0612
Hedges' g (Zuranolone vs. Placebo)		-0.513
95% CI for Hedges' g		-1.0534, 0.0282
Day 8		
n	32	23
LS Mean (SE)	-6.24 (0.918)	-9.45 (1.082)
95% CI for the LS Mean	-8.08, -4.39	-11.62, -7.27
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.21 (1.422)
95% CI for the LS Mean		-6.06, -0.35
p-value		0.0284
Hedges' g (Zuranolone vs. Placebo)		-0.608
95% CI for Hedges' g		-1.1556, -0.0602

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-301 - ITT population

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

	Placebo (N=34)	Zuranolone (N=24)
Day 15		
n	30	23
LS Mean (SE)	-8.01 (1.150)	-11.05 (1.328)
95% CI for the LS Mean	-10.32, -5.70	-13.72, -8.38
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.04 (1.759)
95% CI for the LS Mean		-6.58, 0.49
p-value		0.0901
Hedges' g (Zuranolone vs. Placebo)		-0.472
95% CI for Hedges' g		-1.0229, 0.0783
Day 21		
n	27	21
LS Mean (SE)	-10.21 (1.172)	-13.57 (1.350)
95% CI for the LS Mean	-12.57, -7.85	-16.29, -10.85
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.36 (1.791)
95% CI for the LS Mean		-6.96, 0.24
p-value		0.0667
Hedges' g (Zuranolone vs. Placebo)		-0.537
95% CI for Hedges' g		-1.1173, 0.0433

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-301 - ITT population

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

	Placebo (N=34)	Zuranolone (N=24)
Day 28		
n	29	20
LS Mean (SE)	-10.71 (1.235)	-12.68 (1.448)
95% CI for the LS Mean	-13.20, -8.22	-15.60, -9.77
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.98 (1.906)
95% CI for the LS Mean		-5.81, 1.86
p-value		0.3053
Hedges' g (Zuranolone vs. Placebo)		-0.297
95% CI for Hedges' g		-0.8693, 0.2761
Day 45		
n	28	20
LS Mean (SE)	-11.42 (1.233)	-13.54 (1.439)
95% CI for the LS Mean	-13.90, -8.94	-16.44, -10.65
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.12 (1.898)
95% CI for the LS Mean		-5.94, 1.70
p-value		0.2697
Hedges' g (Zuranolone vs. Placebo)		-0.322
95% CI for Hedges' g		-0.8990, 0.2559

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-301 - ITT population

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

	Placebo (N=42)	Zuranolone (N=53)
Day 3		
n	40	53
LS Mean (SE)	-3.12 (0.813)	-3.85 (0.705)
95% CI for the LS Mean	-4.74, -1.51	-5.25, -2.44
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.72 (1.104)
95% CI for the LS Mean		-2.92, 1.47
p-value		0.5136
Hedges' g (Zuranolone vs. Placebo)		-0.136
95% CI for Hedges' g		-0.5472, 0.2748
Day 8		
n	41	51
LS Mean (SE)	-6.25 (0.978)	-8.68 (0.867)
95% CI for the LS Mean	-8.20, -4.31	-10.40, -6.95
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.42 (1.330)
95% CI for the LS Mean		-5.06, 0.22
p-value		0.0717
Hedges' g (Zuranolone vs. Placebo)		-0.379
95% CI for Hedges' g		-0.7935, 0.0360

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-301 - ITT population

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

	Placebo (N=42)	Zuranolone (N=53)
Day 15		
n	38	49
LS Mean (SE)	-8.70 (1.012)	-10.51 (0.891)
95% CI for the LS Mean	-10.71, -6.69	-12.28, -8.74
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.81 (1.372)
95% CI for the LS Mean		-4.53, 0.92
p-value		0.1908
Hedges' g (Zuranolone vs. Placebo)		-0.282
95% CI for Hedges' g		-0.7081, 0.1434
Day 21		
n	37	46
LS Mean (SE)	-8.71 (1.094)	-9.96 (0.968)
95% CI for the LS Mean	-10.88, -6.53	-11.89, -8.04
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.25 (1.482)
95% CI for the LS Mean		-4.20, 1.69
p-value		0.4002
Hedges' g (Zuranolone vs. Placebo)		-0.185
95% CI for Hedges' g		-0.6187, 0.2488

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-301 - ITT population

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

	Placebo (N=42)	Zuranolone (N=53)
Day 28		
n	35	43
LS Mean (SE)	-9.21 (1.175)	-10.73 (1.039)
95% CI for the LS Mean	-11.55, -6.87	-12.80, -8.67
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.52 (1.588)
95% CI for the LS Mean		-4.68, 1.63
p-value		0.3401
Hedges' g (Zuranolone vs. Placebo)		-0.216
95% CI for Hedges' g		-0.6637, 0.2313
Day 45		
n	35	48
LS Mean (SE)	-8.65 (1.243)	-11.71 (1.073)
95% CI for the LS Mean	-11.12, -6.18	-13.85, -9.58
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.06 (1.660)
95% CI for the LS Mean		-6.36, 0.24
p-value		0.0685
Hedges' g (Zuranolone vs. Placebo)		-0.406
95% CI for Hedges' g		-0.8462, 0.0338

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 Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=35)
Day 3		
n	29	34
LS Mean (SE)	-2.67 (1.035)	-4.84 (0.966)
95% CI for the LS Mean	-4.74, -0.60	-6.78, -2.91
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.17 (1.419)
95% CI for the LS Mean		-5.01, 0.67
p-value		0.1311
Hedges' g (Zuranolone vs. Placebo)		-0.382
95% CI for Hedges' g		-0.8822, 0.1176
Day 8		
n	28	32
LS Mean (SE)	-6.04 (1.106)	-8.45 (1.040)
95% CI for the LS Mean	-8.25, -3.83	-10.53, -6.37
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.41 (1.524)
95% CI for the LS Mean		-5.46, 0.64
p-value		0.1193
Hedges' g (Zuranolone vs. Placebo)		-0.404
95% CI for Hedges' g		-0.9160, 0.1086

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-301-by.sas:t-epds-mmrm-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=35)
Day 15		
n	27	31
LS Mean (SE)	-8.94 (1.304)	-10.15 (1.224)
95% CI for the LS Mean	-11.55, -6.32	-12.61, -7.70
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.22 (1.793)
95% CI for the LS Mean		-4.81, 2.38
p-value		0.5003
Hedges' g (Zuranolone vs. Placebo)		-0.176
95% CI for Hedges' g		-0.6932, 0.3407
Day 21		
n	25	29
LS Mean (SE)	-9.52 (1.262)	-11.68 (1.184)
95% CI for the LS Mean	-12.05, -6.98	-14.06, -9.31
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.17 (1.736)
95% CI for the LS Mean		-5.65, 1.31
p-value		0.2173
Hedges' g (Zuranolone vs. Placebo)		-0.336
95% CI for Hedges' g		-0.8744, 0.2028

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.

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Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=35)
Day 28		
n	25	26
LS Mean (SE)	-10.29 (1.274)	-11.91 (1.215)
95% CI for the LS Mean	-12.85, -7.73	-14.35, -9.47
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.62 (1.766)
95% CI for the LS Mean		-5.16, 1.92
p-value		0.3630
Hedges' g (Zuranolone vs. Placebo)		-0.253
95% CI for Hedges' g		-0.8043, 0.2981
Day 45		
n	25	27
LS Mean (SE)	-10.70 (1.356)	-13.22 (1.289)
95% CI for the LS Mean	-13.42, -7.98	-15.81, -10.64
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.52 (1.876)
95% CI for the LS Mean		-6.28, 1.24
p-value		0.1850
Hedges' g (Zuranolone vs. Placebo)		-0.367
95% CI for Hedges' g		-0.9157, 0.1815

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 Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = Postpartum

	Placebo (N=69)	Zuranolone (N=64)
Day 3		
n	65	63
LS Mean (SE)	-2.15 (0.538)	-3.25 (0.549)
95% CI for the LS Mean	-3.22, -1.09	-4.34, -2.17
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.10 (0.773)
95% CI for the LS Mean		-2.63, 0.43
p-value		0.1564
Hedges' g (Zuranolone vs. Placebo)		-0.251
95% CI for Hedges' g		-0.5985, 0.0973
Day 8		
n	67	61
LS Mean (SE)	-6.27 (0.702)	-8.37 (0.731)
95% CI for the LS Mean	-7.66, -4.88	-9.82, -6.93
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.10 (1.017)
95% CI for the LS Mean		-4.11, -0.09
p-value		0.0411
Hedges' g (Zuranolone vs. Placebo)		-0.363
95% CI for Hedges' g		-0.7129, -0.0135

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 Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = Postpartum

	Placebo (N=69)	Zuranolone (N=64)
Day 15		
n	62	60
LS Mean (SE)	-8.09 (0.771)	-10.41 (0.794)
95% CI for the LS Mean	-9.62, -6.57	-11.98, -8.84
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.32 (1.109)
95% CI for the LS Mean		-4.52, -0.12
p-value		0.0386
Hedges' g (Zuranolone vs. Placebo)		-0.376
95% CI for Hedges' g		-0.7343, -0.0182
Day 21		
n	56	55
LS Mean (SE)	-9.23 (0.828)	-10.62 (0.849)
95% CI for the LS Mean	-10.87, -7.59	-12.30, -8.94
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.39 (1.188)
95% CI for the LS Mean		-3.74, 0.96
p-value		0.2452
Hedges' g (Zuranolone vs. Placebo)		-0.220
95% CI for Hedges' g		-0.5933, 0.1531

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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 Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = Postpartum

	Placebo (N=69)	Zuranolone (N=64)
Day 28		
n	60	50
LS Mean (SE)	-9.22 (0.911)	-11.10 (0.956)
95% CI for the LS Mean	-11.02, -7.41	-13.00, -9.21
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.89 (1.322)
95% CI for the LS Mean		-4.51, 0.73
p-value		0.1559
Hedges' g (Zuranolone vs. Placebo)		-0.272
95% CI for Hedges' g		-0.6486, 0.1055
Day 45		
n	60	57
LS Mean (SE)	-9.48 (0.919)	-11.74 (0.947)
95% CI for the LS Mean	-11.30, -7.66	-13.62, -9.87
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.27 (1.322)
95% CI for the LS Mean		-4.88, 0.35
p-value		0.0889
Hedges' g (Zuranolone vs. Placebo)		-0.315
95% CI for Hedges' g		-0.6800, 0.0496

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-301-by.sas:t-epds-mmrm-301-by-onset-itta.rtf **Run Date:** 25JUL2025

2.3.1.2 .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-301 - ITT population

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Family History of PPD = Yes

	Placebo (N=16)	Zuranolone (N=21)
Day 3		
n	15	21
LS Mean (SE)	-1.76 (1.468)	-3.88 (1.239)
95% CI for the LS Mean	-4.75, 1.23	-6.40, -1.36
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.11 (1.937)
95% CI for the LS Mean		-6.05, 1.82
p-value		0.2828
Hedges' g (Zuranolone vs. Placebo)		-0.361
95% CI for Hedges' g		-1.0287, 0.3069
Day 8		
n	15	21
LS Mean (SE)	-8.23 (1.508)	-7.31 (1.273)
95% CI for the LS Mean	-11.30, -5.16	-9.89, -4.72
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.92 (1.987)
95% CI for the LS Mean		-3.12, 4.97
p-value		0.6452
Hedges' g (Zuranolone vs. Placebo)		0.154
95% CI for Hedges' g		-0.5099, 0.8171

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-301-by.sas:t-epds-mmrm-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Family History of PPD: 217-PPD-301 - ITT population

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Family History of PPD = Yes

	Placebo (N=16)	Zuranolone (N=21)
Day 15		
n	13	20
LS Mean (SE)	-10.65 (1.827)	-9.83 (1.511)
95% CI for the LS Mean	-14.38, -6.91	-12.92, -6.73
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.82 (2.383)
95% CI for the LS Mean		-4.06, 5.69
p-value		0.7342
Hedges' g (Zuranolone vs. Placebo)		0.119
95% CI for Hedges' g		-0.5797, 0.8180
Day 21		
n	13	20
LS Mean (SE)	-11.38 (1.787)	-11.32 (1.490)
95% CI for the LS Mean	-15.03, -7.72	-14.37, -8.26
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.06 (2.339)
95% CI for the LS Mean		-4.73, 4.85
p-value		0.9803
Hedges' g (Zuranolone vs. Placebo)		0.009
95% CI for Hedges' g		-0.6896, 0.7069

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-301-by.sas:t-epds-mmrm-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Family History of PPD: 217-PPD-301 - ITT population

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Family History of PPD = Yes

	Placebo (N=16)	Zuranolone (N=21)
Day 28		
n	12	17
LS Mean (SE)	-11.55 (2.008)	-11.39 (1.688)
95% CI for the LS Mean	-15.68, -7.42	-14.86, -7.92
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.16 (2.634)
95% CI for the LS Mean		-5.26, 5.57
p-value		0.9530
Hedges' g (Zuranolone vs. Placebo)		0.022
95% CI for Hedges' g		-0.7172, 0.7608
Day 45		
n	13	19
LS Mean (SE)	-11.67 (1.887)	-11.50 (1.577)
95% CI for the LS Mean	-15.53, -7.82	-14.72, -8.28
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.17 (2.470)
95% CI for the LS Mean		-4.87, 5.22
p-value		0.9440
Hedges' g (Zuranolone vs. Placebo)		0.025
95% CI for Hedges' g		-0.6806, 0.7303

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-301-by.sas:t-epds-mmrm-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Family History of PPD: 217-PPD-301 - ITT population

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Family History of PPD = No/Unknown

	Placebo (N=85)	Zuranolone (N=78)
Day 3		
n	79	76
LS Mean (SE)	-2.46 (0.511)	-3.76 (0.525)
95% CI for the LS Mean	-3.47, -1.45	-4.80, -2.72
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.30 (0.736)
95% CI for the LS Mean		-2.76, 0.15
p-value		0.0787
Hedges' g (Zuranolone vs. Placebo)		-0.283
95% CI for Hedges' g		-0.5995, 0.0335
Day 8		
n	80	72
LS Mean (SE)	-5.85 (0.643)	-8.69 (0.675)
95% CI for the LS Mean	-7.12, -4.58	-10.03, -7.36
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.84 (0.935)
95% CI for the LS Mean		-4.69, -1.00
p-value		0.0028
Hedges' g (Zuranolone vs. Placebo)		-0.492
95% CI for Hedges' g		-0.8148, -0.1685

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-301-by.sas:t-epds-mmrm-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Family History of PPD: 217-PPD-301 - ITT population

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Family History of PPD = No/Unknown

	Placebo (N=85)	Zuranolone (N=78)
Day 15		
n	76	71
LS Mean (SE)	-7.97 (0.716)	-10.51 (0.745)
95% CI for the LS Mean	-9.39, -6.56	-11.98, -9.03
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.54 (1.036)
95% CI for the LS Mean		-4.58, -0.49
p-value		0.0156
Hedges' g (Zuranolone vs. Placebo)		-0.402
95% CI for Hedges' g		-0.7286, -0.0751
Day 21		
n	68	64
LS Mean (SE)	-8.95 (0.758)	-10.90 (0.788)
95% CI for the LS Mean	-10.45, -7.46	-12.45, -9.34
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.94 (1.095)
95% CI for the LS Mean		-4.11, 0.22
p-value		0.0785
Hedges' g (Zuranolone vs. Placebo)		-0.307
95% CI for Hedges' g		-0.6502, 0.0365

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-301-by.sas:t-epds-mmrm-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Family History of PPD: 217-PPD-301 - ITT population

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Family History of PPD = No/Unknown

	Placebo (N=85)	Zuranolone (N=78)
Day 28		
n	73	59
LS Mean (SE)	-9.20 (0.798)	-11.42 (0.848)
95% CI for the LS Mean	-10.78, -7.62	-13.09, -9.74
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.22 (1.167)
95% CI for the LS Mean		-4.53, 0.09
p-value		0.0594
Hedges' g (Zuranolone vs. Placebo)		-0.331
95% CI for Hedges' g		-0.6761, 0.0147
Day 45		
n	72	65
LS Mean (SE)	-9.53 (0.841)	-12.50 (0.882)
95% CI for the LS Mean	-11.19, -7.86	-14.24, -10.75
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.97 (1.221)
95% CI for the LS Mean		-5.39, -0.56
p-value		0.0162
Hedges' g (Zuranolone vs. Placebo)		-0.414
95% CI for Hedges' g		-0.7531, -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-301-by.sas:t-epds-mmrm-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

2.3.1.2 .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-301 - ITT population

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History of PPD = 1st Episode

	Placebo (N=90)	Zuranolone (N=82)
Day 3		
n	84	80
LS Mean (SE)	-1.67 (0.491)	-3.70 (0.508)
95% CI for the LS Mean	-2.64, -0.70	-4.70, -2.70
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.03 (0.711)
95% CI for the LS Mean		-3.43, -0.62
p-value		0.0049
Hedges' g (Zuranolone vs. Placebo)		-0.443
95% CI for Hedges' g		-0.7533, -0.1335
Day 8		
n	84	76
LS Mean (SE)	-6.06 (0.619)	-8.36 (0.648)
95% CI for the LS Mean	-7.28, -4.84	-9.64, -7.08
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.30 (0.899)
95% CI for the LS Mean		-4.08, -0.52
p-value		0.0115
Hedges' g (Zuranolone vs. Placebo)		-0.403
95% CI for Hedges' g		-0.7162, -0.0894

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-301-by.sas:t-epds-mmrm-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by History of PPD: 217-PPD-301 - ITT population

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History of PPD = 1st Episode

	Placebo (N=90)	Zuranolone (N=82)
Day 15		
n	78	74
LS Mean (SE)	-8.04 (0.703)	-10.04 (0.729)
95% CI for the LS Mean	-9.43, -6.65	-11.48, -8.60
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.00 (1.015)
95% CI for the LS Mean		-4.01, 0.00
p-value		0.0502
Hedges' g (Zuranolone vs. Placebo)		-0.319
95% CI for Hedges' g		-0.6388, 0.0014
Day 21		
n	71	68
LS Mean (SE)	-9.02 (0.710)	-11.27 (0.736)
95% CI for the LS Mean	-10.43, -7.62	-12.73, -9.82
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.25 (1.026)
95% CI for the LS Mean		-4.27, -0.22
p-value		0.0300
Hedges' g (Zuranolone vs. Placebo)		-0.370
95% CI for Hedges' g		-0.7050, -0.0342

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-301-by.sas:t-epds-mmrm-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by History of PPD: 217-PPD-301 - ITT population

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History of PPD = 1st Episode

	Placebo (N=90)	Zuranolone (N=82)
Day 28		
n	74	59
LS Mean (SE)	-9.57 (0.772)	-11.25 (0.821)
95% CI for the LS Mean	-11.10, -8.05	-12.87, -9.63
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.67 (1.130)
95% CI for the LS Mean		-3.91, 0.56
p-value		0.1406
Hedges' g (Zuranolone vs. Placebo)		-0.257
95% CI for Hedges' g		-0.6005, 0.0864
Day 45		
n	75	68
LS Mean (SE)	-9.98 (0.769)	-12.29 (0.803)
95% CI for the LS Mean	-11.50, -8.46	-13.88, -10.70
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.31 (1.115)
95% CI for the LS Mean		-4.51, -0.10
p-value		0.0403
Hedges' g (Zuranolone vs. Placebo)		-0.345
95% CI for Hedges' g		-0.6752, -0.0140

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-301-by.sas:t-epds-mmrm-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by History of PPD: 217-PPD-301 - ITT population

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History of PPD = Recurrent Episode

	Placebo (N=11)	Zuranolone (N=17)
Day 3		
n	10	17
LS Mean (SE)	-6.79 (1.740)	-4.73 (1.325)
95% CI for the LS Mean	-10.40, -3.19	-7.49, -1.98
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.06 (2.249)
95% CI for the LS Mean		-2.60, 6.71
p-value		0.3697
Hedges' g (Zuranolone vs. Placebo)		0.354
95% CI for Hedges' g		-0.4331, 1.1404
Day 8		
n	11	17
LS Mean (SE)	-6.68 (2.021)	-8.97 (1.611)
95% CI for the LS Mean	-10.83, -2.53	-12.28, -5.66
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.29 (2.637)
95% CI for the LS Mean		-7.70, 3.12
p-value		0.3929
Hedges' g (Zuranolone vs. Placebo)		-0.326
95% CI for Hedges' g		-1.0894, 0.4371

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-301-by.sas:t-epds-mmrm-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by History of PPD: 217-PPD-301 - ITT population

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History of PPD = Recurrent Episode

	Placebo (N=11)	Zuranolone (N=17)
Day 15		
n	11	17
LS Mean (SE)	-10.22 (2.041)	-11.91 (1.626)
95% CI for the LS Mean	-14.42, -6.03	-15.26, -8.56
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.69 (2.662)
95% CI for the LS Mean		-7.16, 3.79
p-value		0.5321
Hedges' g (Zuranolone vs. Placebo)		-0.238
95% CI for Hedges' g		-0.9988, 0.5231
Day 21		
n	10	16
LS Mean (SE)	-10.99 (2.362)	-10.20 (1.876)
95% CI for the LS Mean	-15.86, -6.11	-14.08, -6.33
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.78 (3.063)
95% CI for the LS Mean		-5.53, 7.10
p-value		0.8008
Hedges' g (Zuranolone vs. Placebo)		0.100
95% CI for Hedges' g		-0.6910, 0.8901

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-301-by.sas:t-epds-mmrm-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by History of PPD: 217-PPD-301 - ITT population

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History of PPD = Recurrent Episode

	Placebo (N=11)	Zuranolone (N=17)
Day 28		
n	11	17
LS Mean (SE)	-8.59 (2.392)	-12.03 (1.911)
95% CI for the LS Mean	-13.50, -3.67	-15.96, -8.10
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.44 (3.107)
95% CI for the LS Mean		-9.82, 2.94
p-value		0.2781
Hedges' g (Zuranolone vs. Placebo)		-0.416
95% CI for Hedges' g		-1.1821, 0.3503
Day 45		
n	10	16
LS Mean (SE)	-8.26 (2.837)	-12.10 (2.257)
95% CI for the LS Mean	-14.09, -2.43	-16.75, -7.46
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.84 (3.661)
95% CI for the LS Mean		-11.36, 3.67
p-value		0.3031
Hedges' g (Zuranolone vs. Placebo)		-0.410
95% CI for Hedges' g		-1.2079, 0.3880

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-301-by.sas:t-epds-mmrm-301-by-hist-itta.rtf **Run Date:** 25JUL2025

2.3.1.2 .2 .9 Depression mit Angst

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

	Placebo (N=21)	Zuranolone (N=24)
Day 3		
n	20	24
LS Mean (SE)	-1.77 (0.914)	-4.47 (0.835)
95% CI for the LS Mean	-3.62, 0.08	-6.15, -2.78
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.70 (1.241)
95% CI for the LS Mean		-5.20, -0.19
p-value		0.0358
Hedges' g (Zuranolone vs. Placebo)		-0.646
95% CI for Hedges' g		-1.2542, -0.0371
Day 8		
n	20	23
LS Mean (SE)	-4.42 (1.094)	-6.44 (1.016)
95% CI for the LS Mean	-6.64, -2.21	-8.49, -4.38
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.02 (1.495)
95% CI for the LS Mean		-5.04, 1.01
p-value		0.1853
Hedges' g (Zuranolone vs. Placebo)		-0.405
95% CI for Hedges' g		-1.0102, 0.2005

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-301-by.sas:t-epds-mmrm-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

	Placebo (N=21)	Zuranolone (N=24)
Day 15		
n	20	23
LS Mean (SE)	-7.87 (1.384)	-9.88 (1.288)
95% CI for the LS Mean	-10.68, -5.07	-12.49, -7.27
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.01 (1.893)
95% CI for the LS Mean		-5.85, 1.83
p-value		0.2951
Hedges' g (Zuranolone vs. Placebo)		-0.319
95% CI for Hedges' g		-0.9217, 0.2843
Day 21		
n	17	23
LS Mean (SE)	-9.01 (1.386)	-12.00 (1.264)
95% CI for the LS Mean	-11.82, -6.21	-14.56, -9.44
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.98 (1.878)
95% CI for the LS Mean		-6.78, 0.82
p-value		0.1207
Hedges' g (Zuranolone vs. Placebo)		-0.498
95% CI for Hedges' g		-1.1340, 0.1386

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-301-by.sas:t-epds-mmrm-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

Page: 3 of 6

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

	Placebo (N=21)	Zuranolone (N=24)
Day 28		
n	19	19
LS Mean (SE)	-10.30 (1.667)	-10.71 (1.603)
95% CI for the LS Mean	-13.68, -6.93	-13.95, -7.47
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.41 (2.314)
95% CI for the LS Mean		-5.09, 4.28
p-value		0.8611
Hedges' g (Zuranolone vs. Placebo)		-0.056
95% CI for Hedges' g		-0.6920, 0.5800
Day 45		
n	20	21
LS Mean (SE)	-11.37 (1.478)	-12.76 (1.399)
95% CI for the LS Mean	-14.36, -8.38	-15.59, -9.93
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.39 (2.037)
95% CI for the LS Mean		-5.51, 2.73
p-value		0.4999
Hedges' g (Zuranolone vs. Placebo)		-0.209
95% CI for Hedges' g		-0.8227, 0.4054

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-301-by.sas:t-epds-mmrm-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

Page: 4 of 6

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

	Placebo (N=77)	Zuranolone (N=74)
Day 3		
n	74	73
LS Mean (SE)	-2.50 (0.573)	-3.54 (0.582)
95% CI for the LS Mean	-3.63, -1.36	-4.69, -2.39
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.04 (0.823)
95% CI for the LS Mean		-2.67, 0.58
p-value		0.2065
Hedges' g (Zuranolone vs. Placebo)		-0.208
95% CI for Hedges' g		-0.5324, 0.1160
Day 8		
n	75	70
LS Mean (SE)	-6.74 (0.686)	-9.00 (0.708)
95% CI for the LS Mean	-8.09, -5.38	-10.40, -7.60
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.27 (0.991)
95% CI for the LS Mean		-4.23, -0.31
p-value		0.0235
Hedges' g (Zuranolone vs. Placebo)		-0.378
95% CI for Hedges' g		-0.7070, -0.0498

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-301-by.sas:t-epds-mmrm-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

Page: 5 of 6

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

	Placebo (N=77)	Zuranolone (N=74)
Day 15		
n	69	68
LS Mean (SE)	-8.55 (0.762)	-10.44 (0.778)
95% CI for the LS Mean	-10.06, -7.04	-11.98, -8.90
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.89 (1.094)
95% CI for the LS Mean		-4.06, 0.27
p-value		0.0856
Hedges' g (Zuranolone vs. Placebo)		-0.294
95% CI for Hedges' g		-0.6309, 0.0425
Day 21		
n	64	61
LS Mean (SE)	-9.49 (0.795)	-10.54 (0.815)
95% CI for the LS Mean	-11.06, -7.92	-12.15, -8.92
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.05 (1.143)
95% CI for the LS Mean		-3.31, 1.21
p-value		0.3613
Hedges' g (Zuranolone vs. Placebo)		-0.163
95% CI for Hedges' g		-0.5142, 0.1884

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-301-by.sas:t-epds-mmrm-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

Page: 6 of 6

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

	Placebo (N=77)	Zuranolone (N=74)
Day 28		
n	66	57
LS Mean (SE)	-9.36 (0.819)	-11.46 (0.851)
95% CI for the LS Mean	-10.98, -7.74	-13.14, -9.78
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.10 (1.186)
95% CI for the LS Mean		-4.45, 0.24
p-value		0.0783
Hedges' g (Zuranolone vs. Placebo)		-0.319
95% CI for Hedges' g		-0.6754, 0.0379
Day 45		
n	65	63
LS Mean (SE)	-9.44 (0.876)	-12.02 (0.896)
95% CI for the LS Mean	-11.18, -7.71	-13.79, -10.24
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.57 (1.257)
95% CI for the LS Mean		-5.06, -0.09
p-value		0.0425
Hedges' g (Zuranolone vs. Placebo)		-0.360
95% CI for Hedges' g		-0.7093, -0.0106

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.

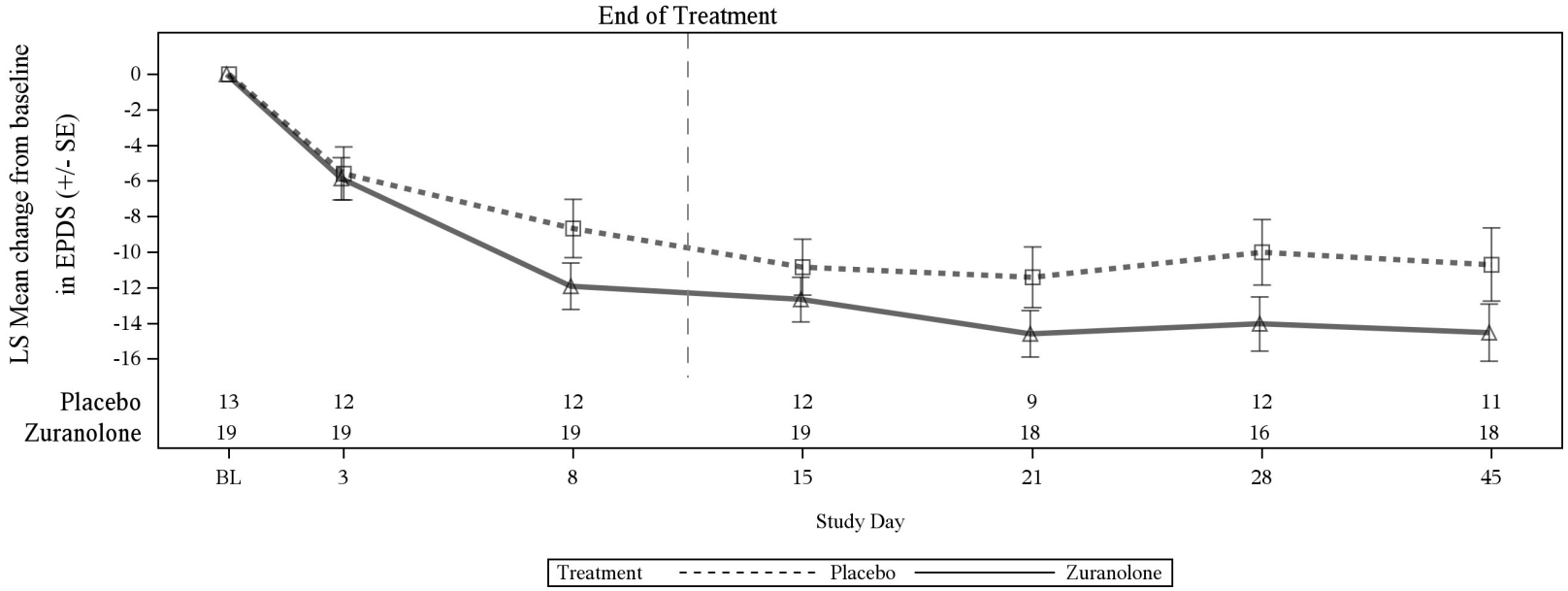
Source: biib125/v_a/germany_amnog/t-epds-mmrm-301-by.sas:t-epds-mmrm-301-by-hama-itta.rtf **Run Date:** 25JUL2025

2.3.1.2 .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-301 - ITT population

Page: 1 of 19

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.

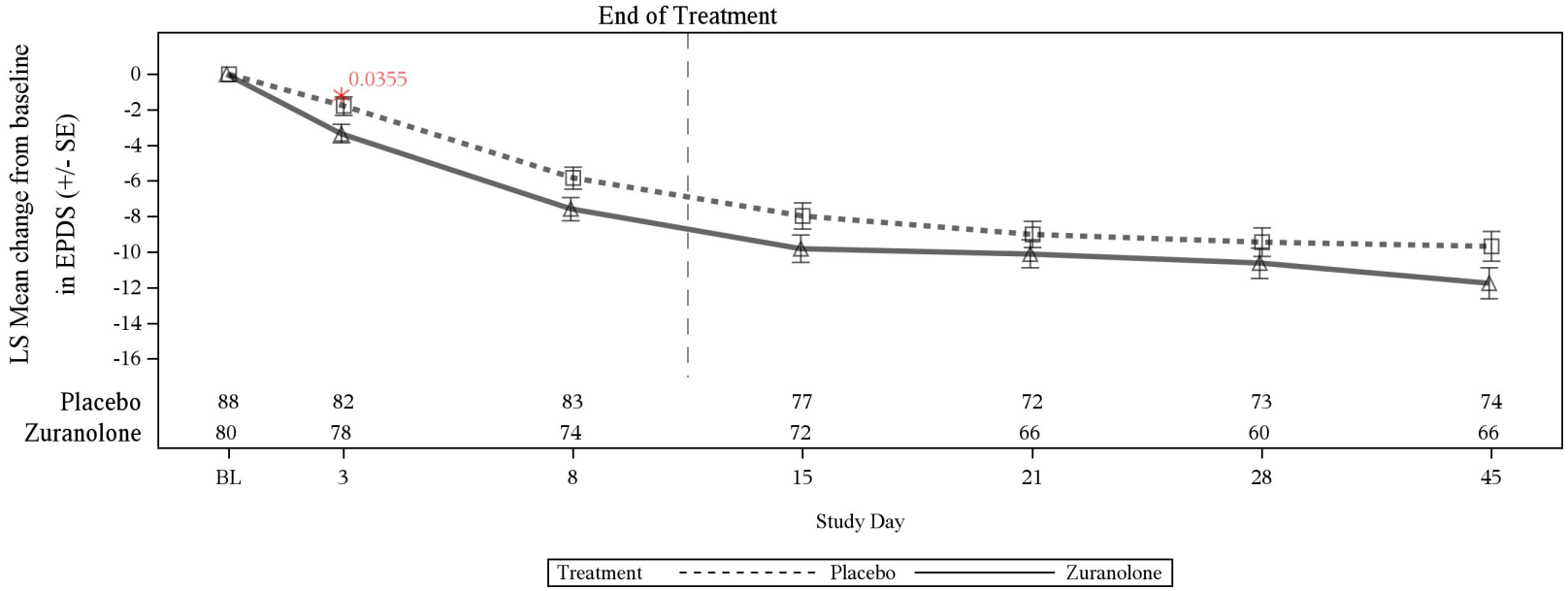
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/f-epds-mmrm-301-by.sas:f-epds-mmrm-301-by-itta.rtf **Run Date:** 18JUL2025

Line Plot of LS Mean Change (+/- SE) from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score over Time by Subgroup: 217-PPD-301 - ITT population

Page: 2 of 19

Age Group (years) = 25-45



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

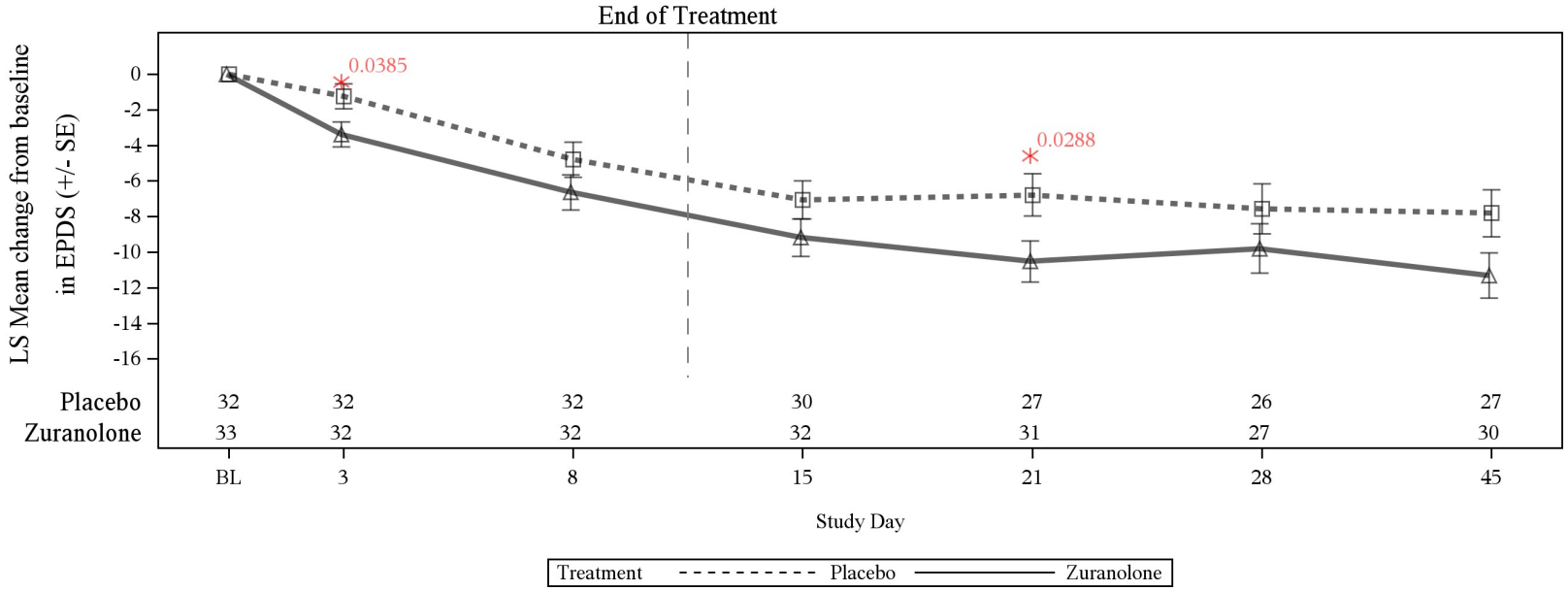
NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline 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-301-by.sas:f-epds-mmrm-301-by-itta.rtf **Run Date:** 18JUL2025

Line Plot of LS Mean Change (+/- SE) from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score over Time by Subgroup: 217-PPD-301 - ITT population

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.

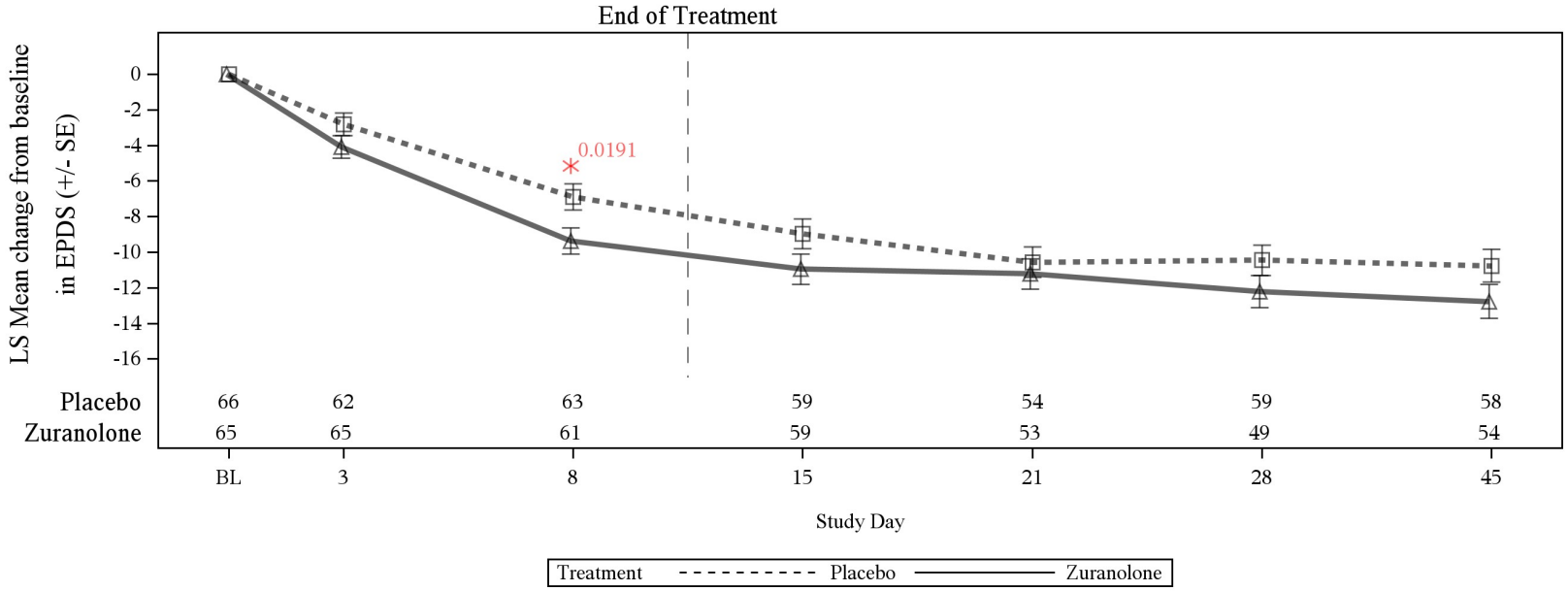
NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline 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-301-by.sas:f-epds-mmrm-301-by-itta.rtf **Run Date:** 18JUL2025

Line Plot of LS Mean Change (+/- SE) from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score over Time by Subgroup: 217-PPD-301 - ITT population

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.

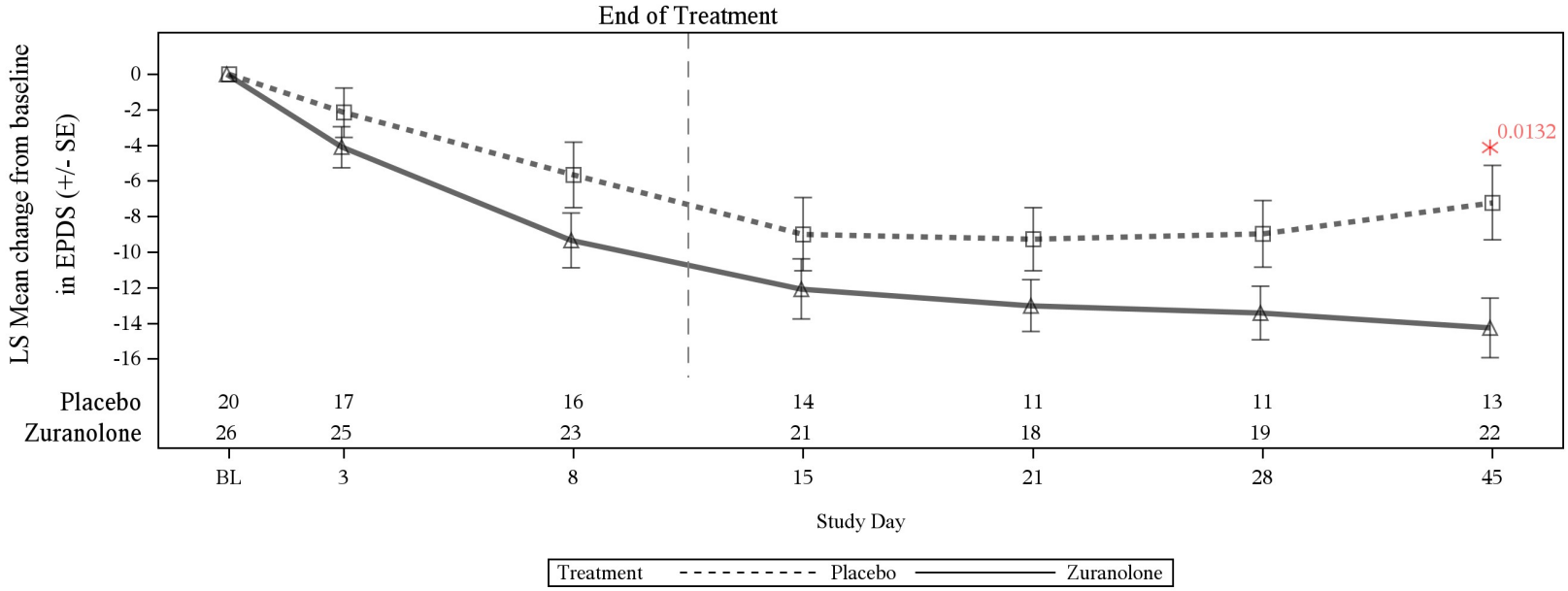
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/f-epds-mmrm-301-by.sas:f-epds-mmrm-301-by-itta.rtf **Run Date:** 18JUL2025

Line Plot of LS Mean Change (+/- SE) from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score over Time by Subgroup: 217-PPD-301 - 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.

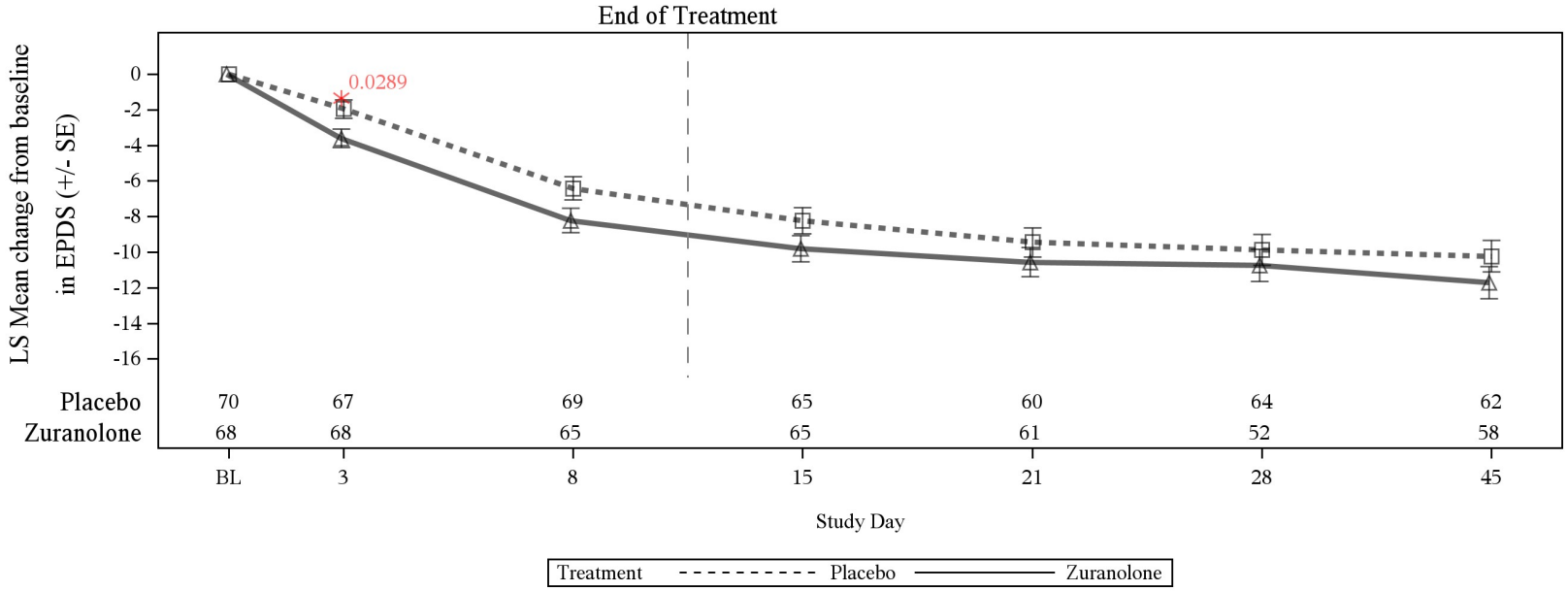
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/f-epds-mmrm-301-by.sas:f-epds-mmrm-301-by-itta.rtf **Run Date:** 18JUL2025

Line Plot of LS Mean Change (+/- SE) from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score over Time by Subgroup: 217-PPD-301 - ITT population

Page: 6 of 19

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.

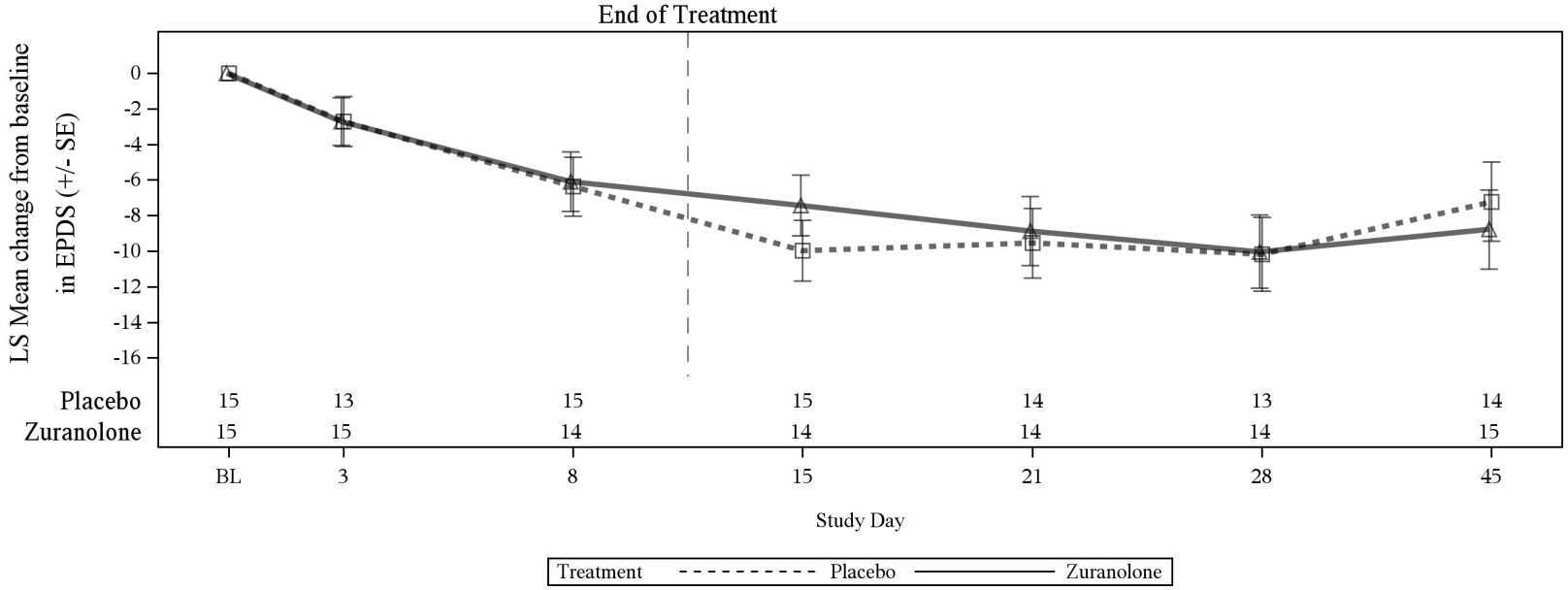
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/f-epds-mmrm-301-by.sas:f-epds-mmrm-301-by-itta.rtf **Run Date:** 18JUL2025

Line Plot of LS Mean Change (+/- SE) from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score over Time by Subgroup: 217-PPD-301 - 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 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.

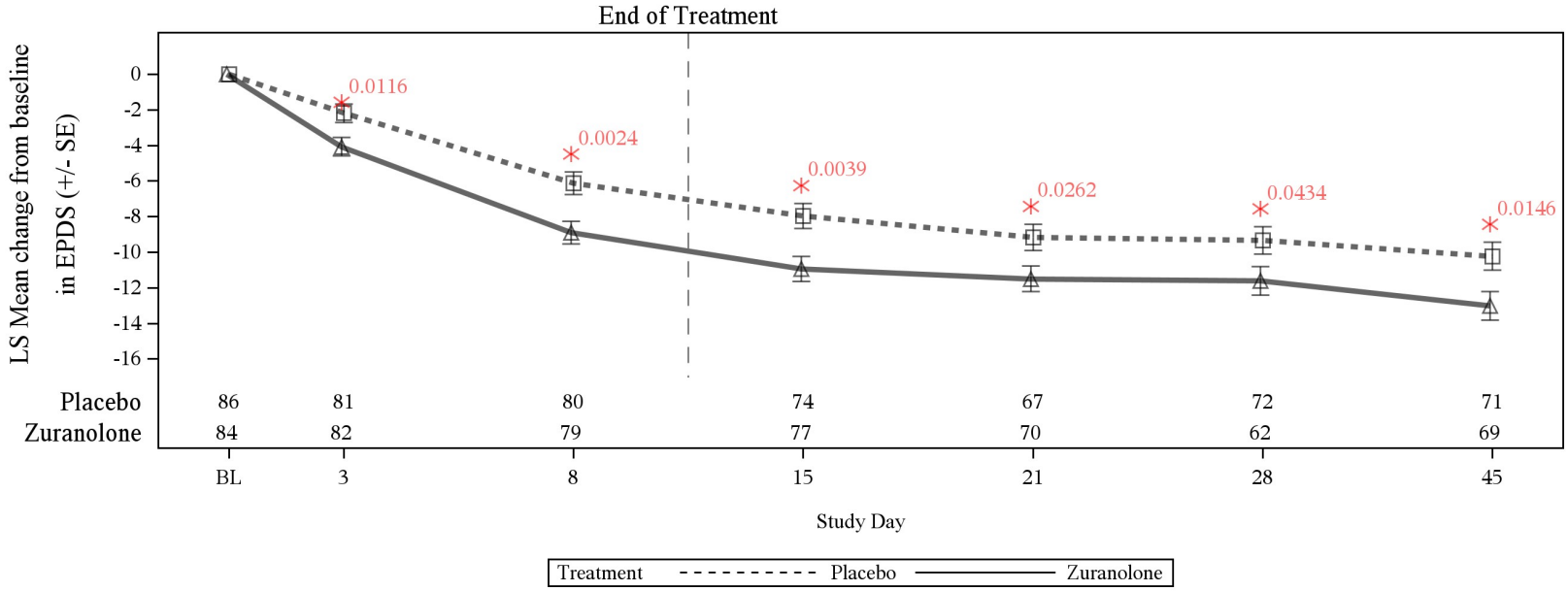
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/f-epds-mmrm-301-by.sas:f-epds-mmrm-301-by-itta.rtf **Run Date:** 18JUL2025

Line Plot of LS Mean Change (+/- SE) from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score over Time by Subgroup: 217-PPD-301 - ITT population

Page: 8 of 19

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.

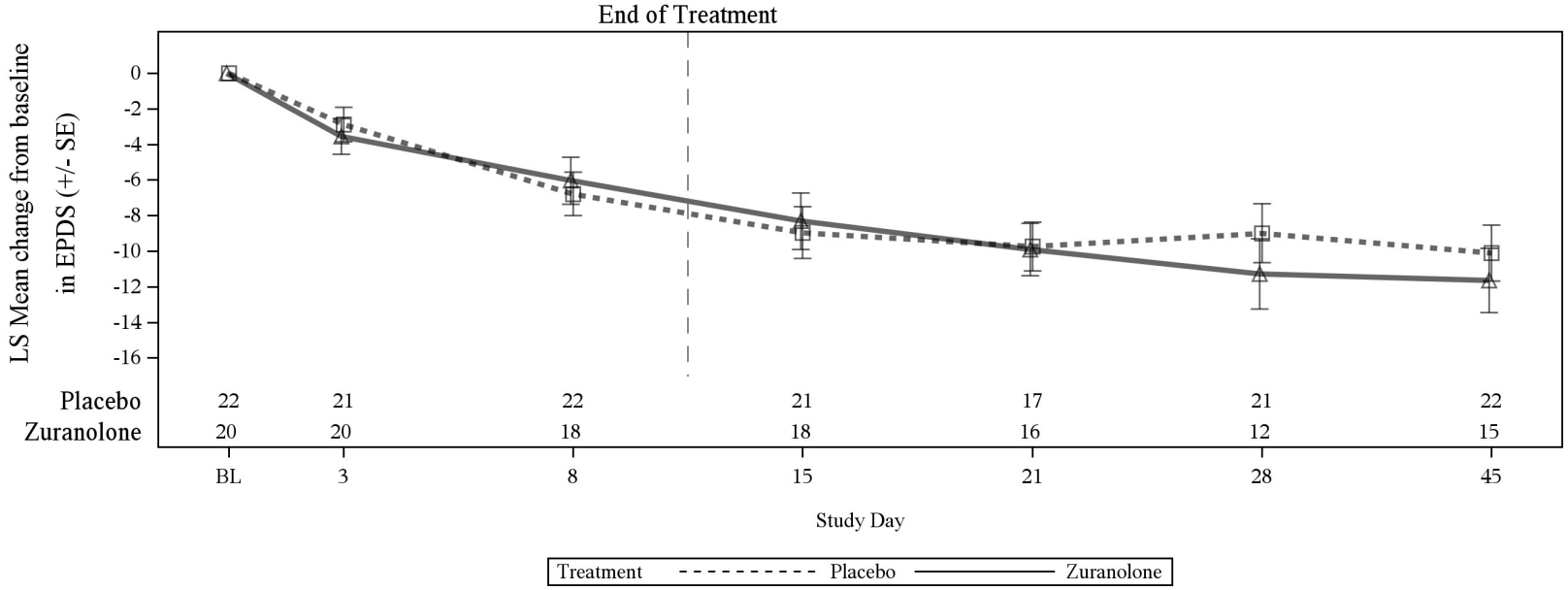
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/f-epds-mmrm-301-by.sas:f-epds-mmrm-301-by-itta.rtf **Run Date:** 18JUL2025

Line Plot of LS Mean Change (+/- SE) from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score over Time by Subgroup: 217-PPD-301 - 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.

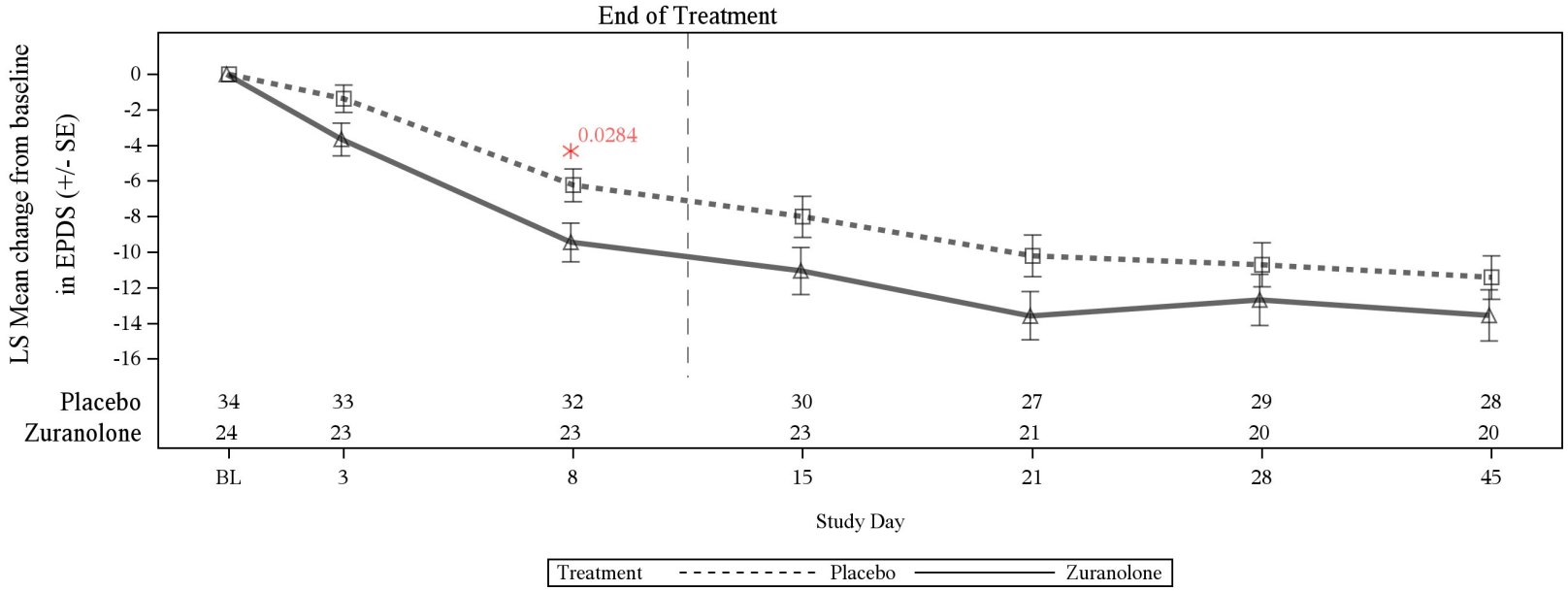
NOTE 1: Model used is the Mixed Model for Repeated Measures (MMRM) with antidepressant use at baseline, baseline EPDS total score, treatment, assessment time point, and time point-by-treatment interaction as fixed effects with unstructured covariance structure. Model covariate antidepressant use at baseline 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-301-by.sas:f-epds-mmrm-301-by-itta.rtf **Run Date:** 18JUL2025

Line Plot of LS Mean Change (+/- SE) from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score over Time by Subgroup: 217-PPD-301 - ITT population

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.

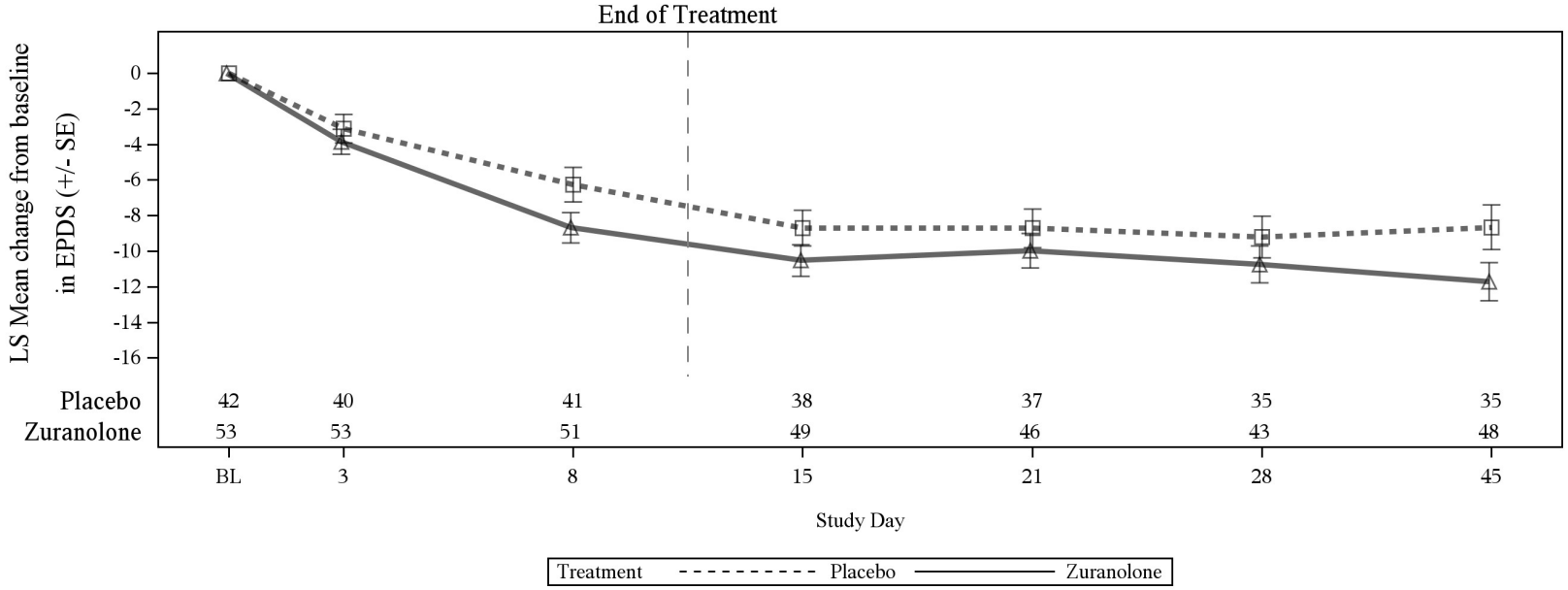
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/f-epds-mmrm-301-by.sas:f-epds-mmrm-301-by-itta.rtf **Run Date:** 18JUL2025

Line Plot of LS Mean Change (+/- SE) from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score over Time by Subgroup: 217-PPD-301 - 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.

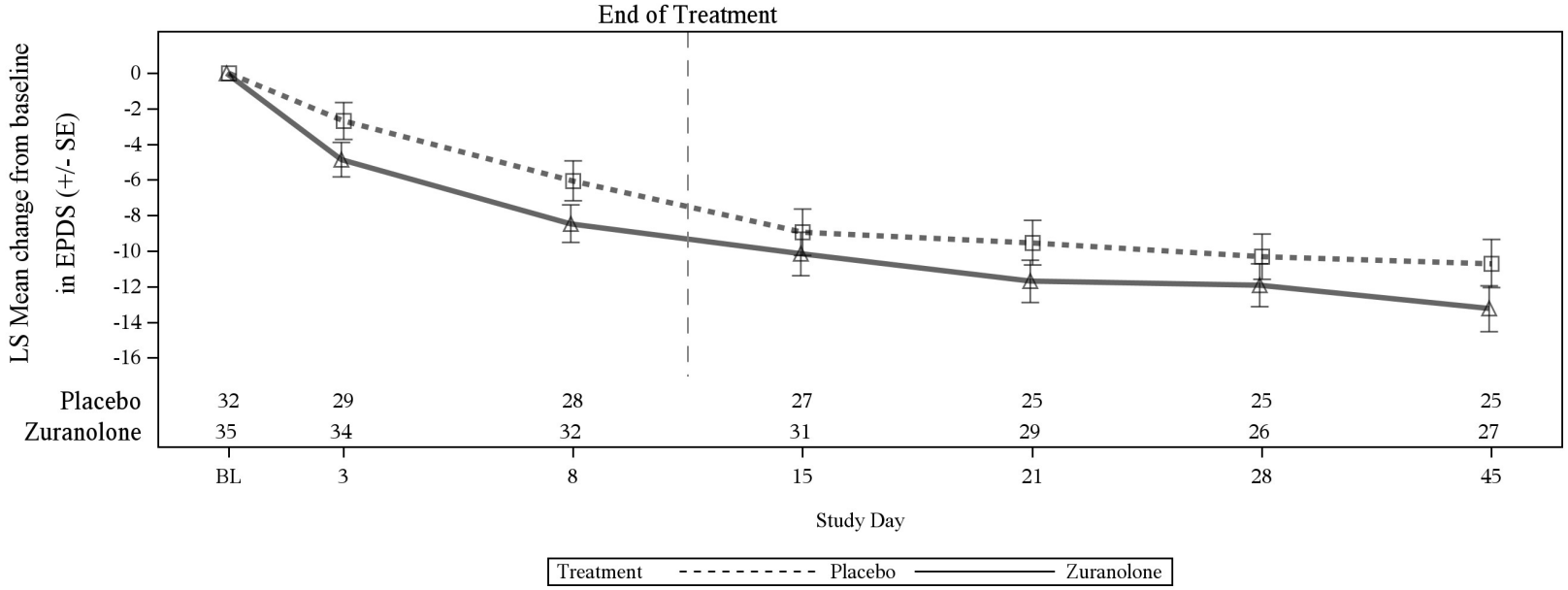
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/f-epds-mmrm-301-by.sas:f-epds-mmrm-301-by-itta.rtf **Run Date:** 18JUL2025

Line Plot of LS Mean Change (+/- SE) from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score over Time by Subgroup: 217-PPD-301 - ITT population

Page: 12 of 19

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.

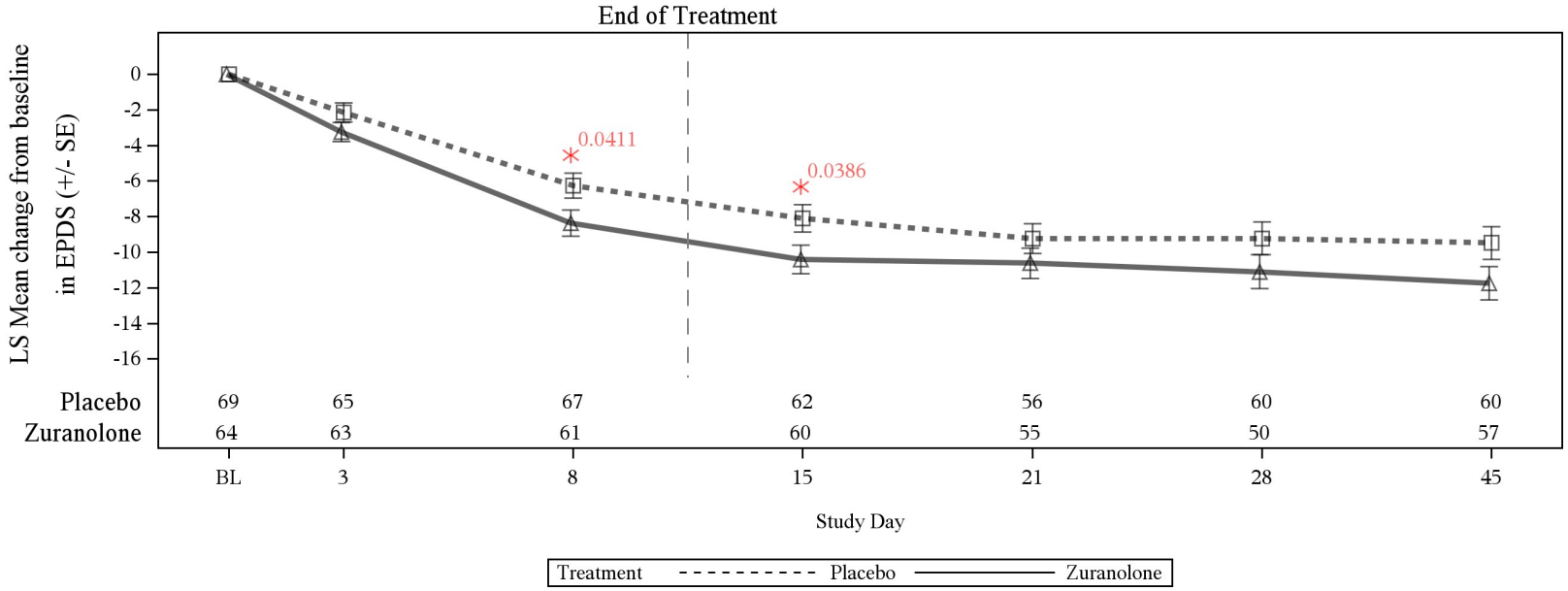
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/f-epds-mmrm-301-by.sas:f-epds-mmrm-301-by-itta.rtf **Run Date:** 18JUL2025

Line Plot of LS Mean Change (+/- SE) from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score over Time by Subgroup: 217-PPD-301 - ITT population

Page: 13 of 19

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.

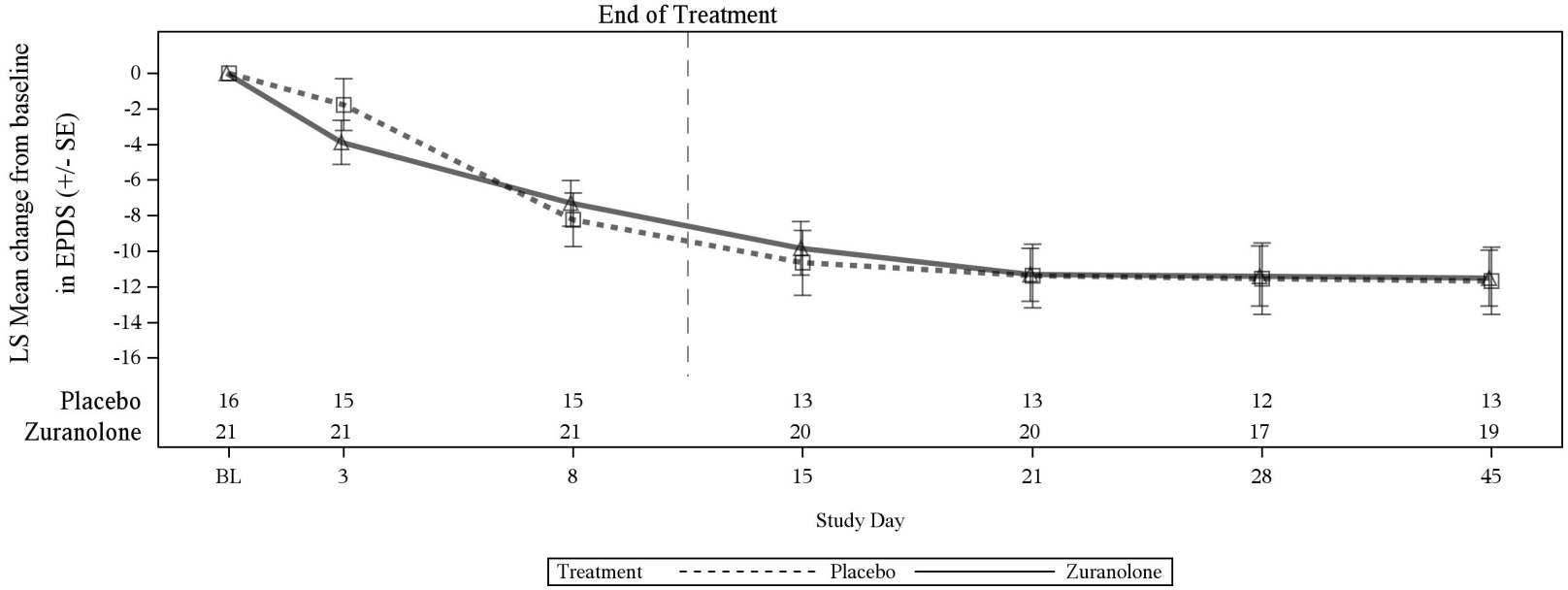
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/f-epds-mmrm-301-by.sas:f-epds-mmrm-301-by-itta.rtf **Run Date:** 18JUL2025

Line Plot of LS Mean Change (+/- SE) from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score over Time by Subgroup: 217-PPD-301 - 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.

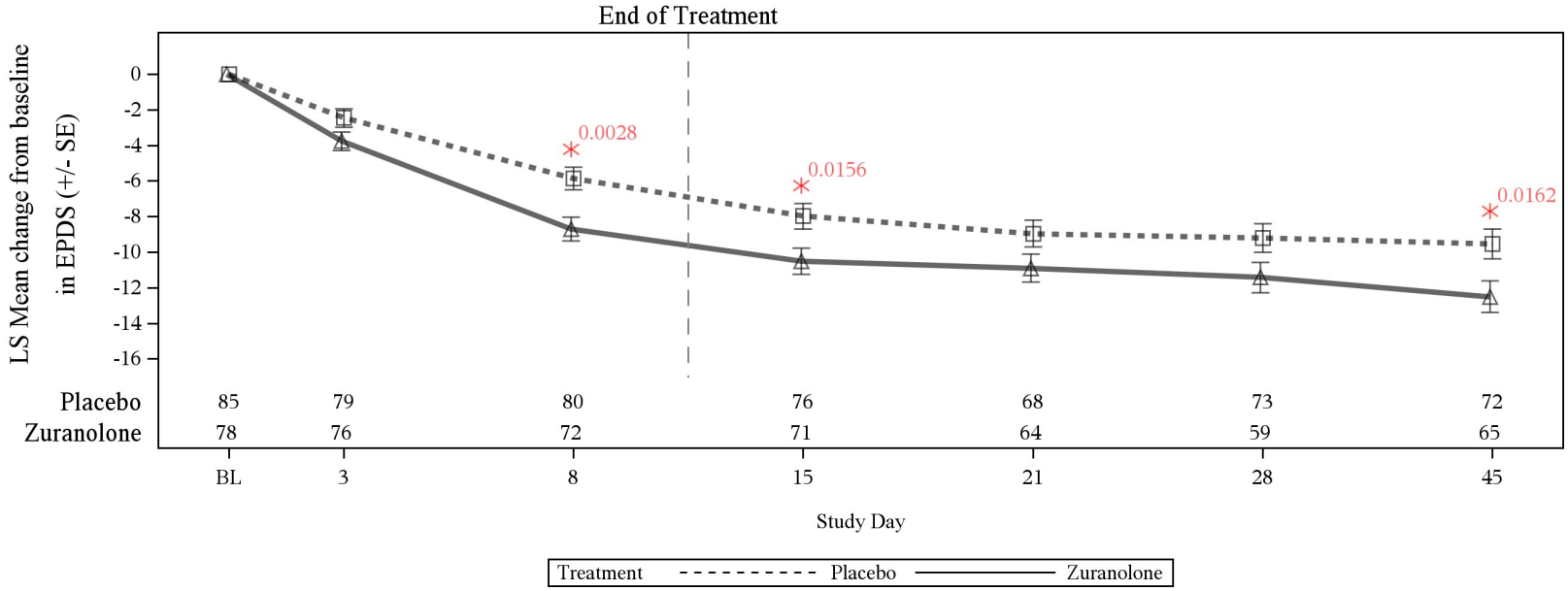
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/f-epds-mmrm-301-by.sas:f-epds-mmrm-301-by-itta.rtf **Run Date:** 18JUL2025

Line Plot of LS Mean Change (+/- SE) from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score over Time by Subgroup: 217-PPD-301 - 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.

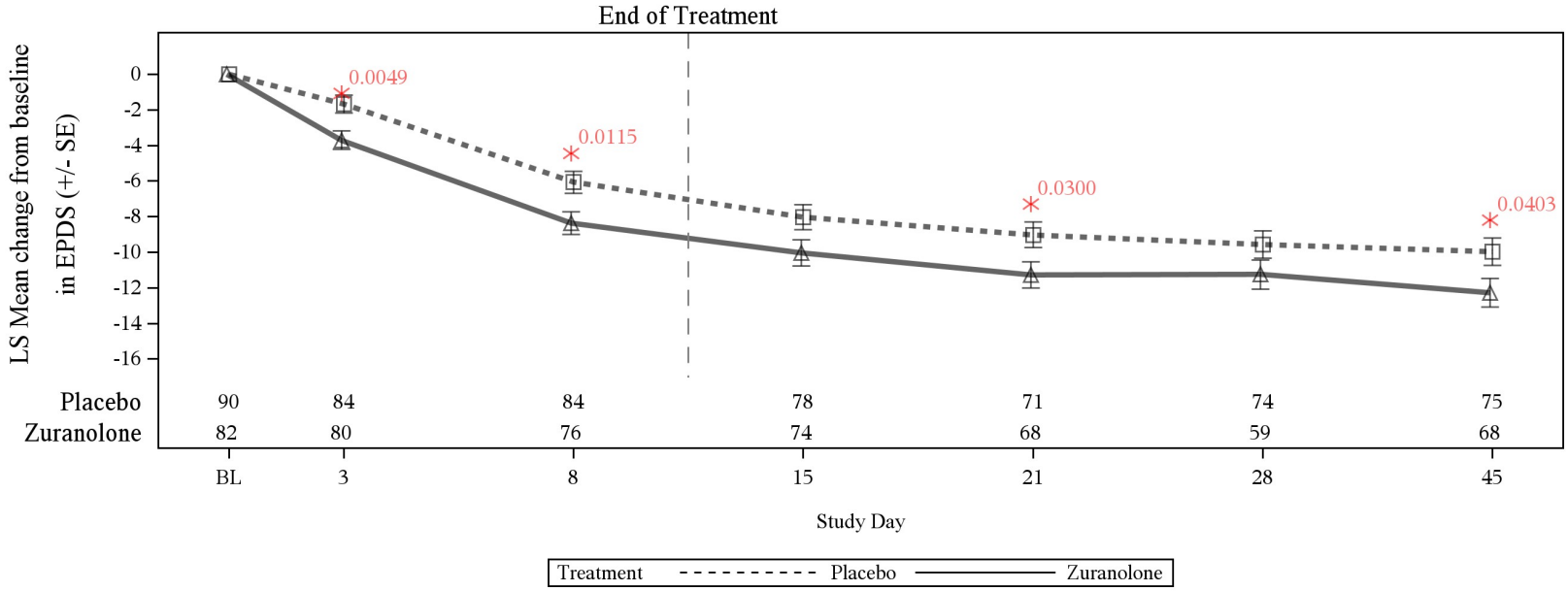
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/f-epds-mmrm-301-by.sas:f-epds-mmrm-301-by-itta.rtf **Run Date:** 18JUL2025

Line Plot of LS Mean Change (+/- SE) from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score over Time by Subgroup: 217-PPD-301 - 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.

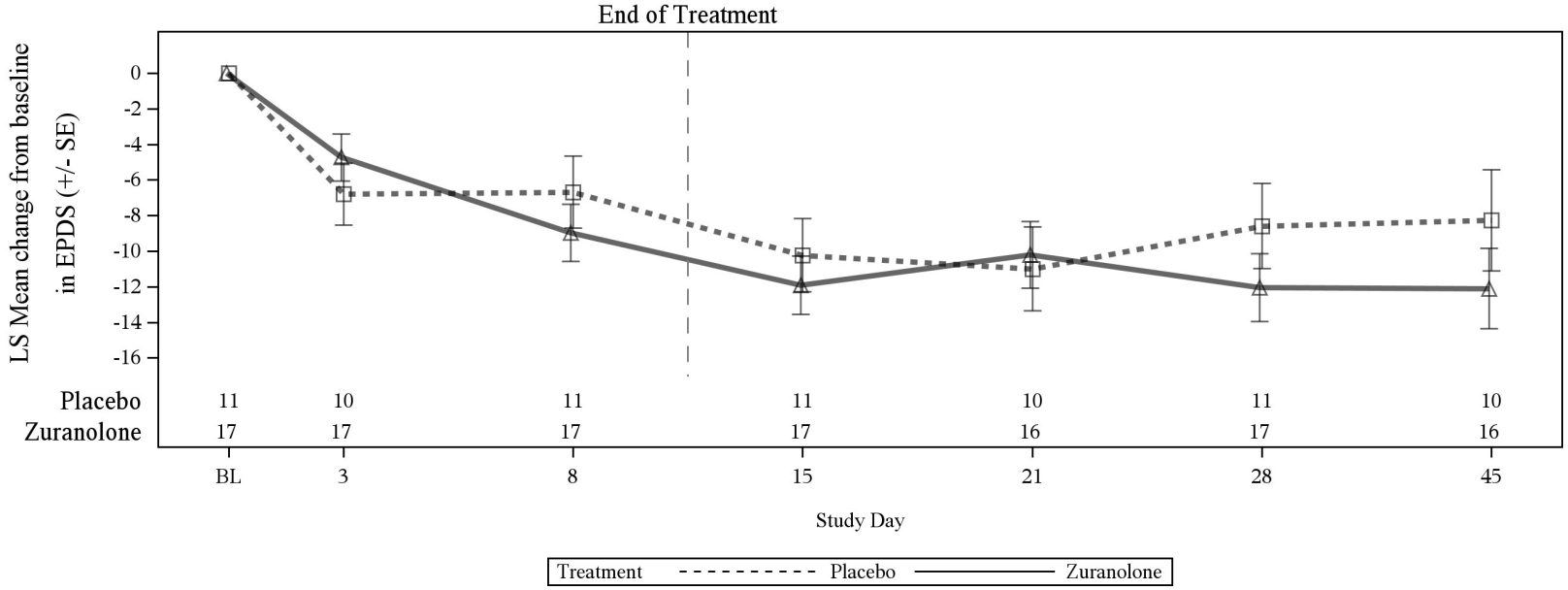
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/f-epds-mmrm-301-by.sas:f-epds-mmrm-301-by-itta.rtf **Run Date:** 18JUL2025

Line Plot of LS Mean Change (+/- SE) from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score over Time by Subgroup: 217-PPD-301 - 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.

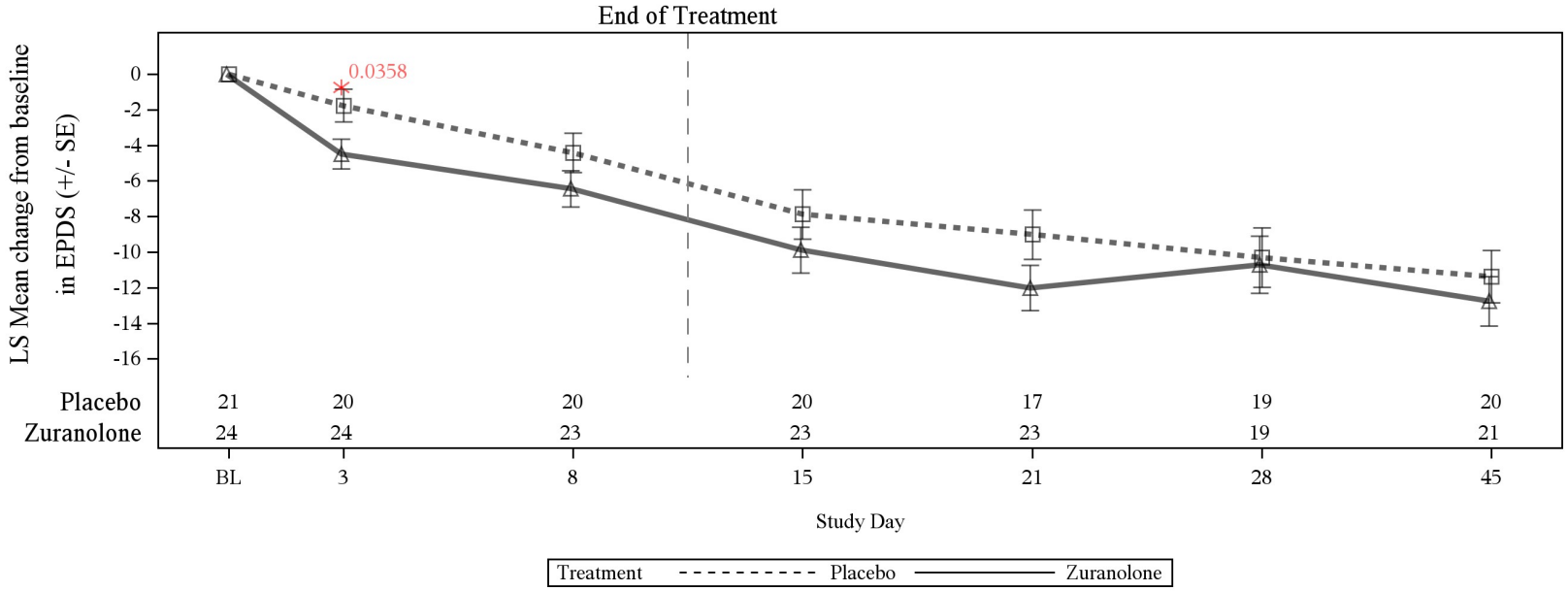
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/f-epds-mmrm-301-by.sas:f-epds-mmrm-301-by-itta.rtf **Run Date:** 18JUL2025

Line Plot of LS Mean Change (+/- SE) from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score over Time by Subgroup: 217-PPD-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20



Abbreviations: LS = Least-squares; SE = Standard 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.

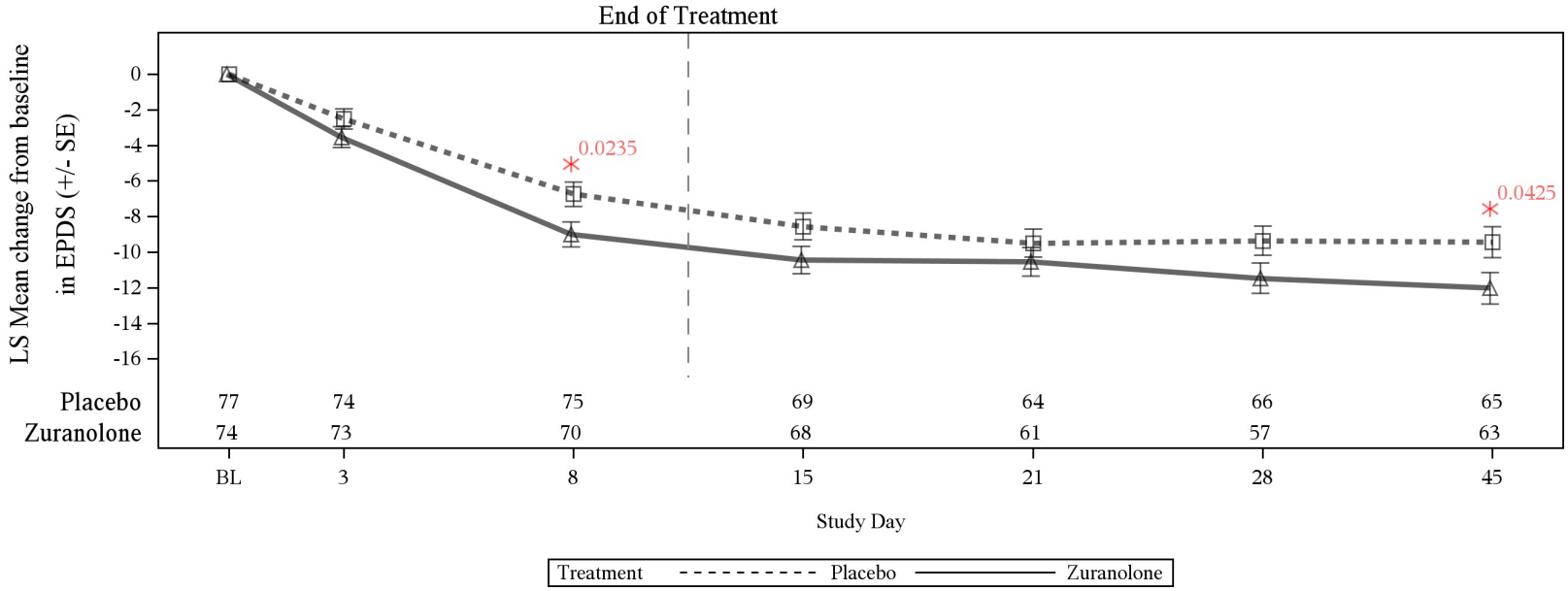
NOTE 2: The EPDS total score was calculated as the sum of the 10 individual item scores, where higher scores indicate more severe symptoms. A negative change indicates improvement.

Source: biib125/v_a/germany_amnog/f-epds-mmrm-301-by.sas:f-epds-mmrm-301-by-itta.rtf **Run Date:** 18JUL2025

Line Plot of LS Mean Change (+/- SE) from Baseline in Edinburgh Postpartum Depression Scale (EPDS) Total Score over Time by Subgroup: 217-PPD-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20



Abbreviations: LS = Least-squares; SE = Standard 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-301-by.sas:f-epds-mmrm-301-by-itta.rtf **Run Date:** 18JUL2025

2.3.2 Ansprechen

2.3.2.1 Responder-Analysen

2.3.2.1 .1 ITT-Population

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline): 217-PPD-301 - ITT population

Page: 1 of 6

Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Number of evaluable subjects [1]	98	98
Day 3		
Number of subjects with a response, n (%) [2]	20 (20.4)	38 (38.8)
Number of subjects with missing evaluation, n (%)	4 (4.1)	1 (1.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.892
95% CI for the RR		(1.199, 2.986)
p-value for RR		0.0061
OR - Odds Ratio (Zuranolone vs. Placebo)		2.310
95% CI for the OR		(1.220, 4.374)
p-value for OR		0.0101
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-resp15-301-ovr.sas:t-epds-resp15-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline): 217-PPD-301 - ITT population

Page: 2 of 6

Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 8		
Number of subjects with a response, n (%) [2]	56 (57.1)	66 (67.3)
Number of subjects with missing evaluation, n (%)	3 (3.1)	5 (5.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.169
95% CI for the RR		(0.947, 1.445)
p-value for RR		0.1468
OR - Odds Ratio (Zuranolone vs. Placebo)		1.459
95% CI for the OR		(0.814, 2.613)
p-value for OR		0.2042
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-resp15-301-ovr.sas:t-epds-resp15-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline): 217-PPD-301 - ITT population

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Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 15		
Number of subjects with a response, n (%) [2]	61 (62.2)	71 (72.4)
Number of subjects with missing evaluation, n (%)	9 (9.2)	7 (7.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.145
95% CI for the RR		(0.948, 1.383)
p-value for RR		0.1589
OR - Odds Ratio (Zuranolone vs. Placebo)		1.499
95% CI for the OR		(0.821, 2.737)
p-value for OR		0.1870
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-resp15-301-ovr.sas:t-epds-resp15-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline): 217-PPD-301 - ITT population

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Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 21		
Number of subjects with a response, n (%) [2]	57 (58.2)	72 (73.5)
Number of subjects with missing evaluation, n (%)	17 (17.3)	14 (14.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.180
95% CI for the RR		(0.949, 1.466)
p-value for RR		0.1363
OR - Odds Ratio (Zuranolone vs. Placebo)		1.867
95% CI for the OR		(1.004, 3.471)
p-value for OR		0.0484
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-resp15-301-ovr.sas:t-epds-resp15-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline): 217-PPD-301 - ITT population

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Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 28		
Number of subjects with a response, n (%) [2]	66 (67.3)	63 (64.3)
Number of subjects with missing evaluation, n (%)	13 (13.3)	22 (22.4)
RR - Relative Risk (Zuranolone vs. Placebo)		0.923
95% CI for the RR		(0.750, 1.134)
p-value for RR		0.4445
OR - Odds Ratio (Zuranolone vs. Placebo)		0.803
95% CI for the OR		(0.437, 1.474)
p-value for OR		0.4782
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-resp15-301-ovr.sas:t-epds-resp15-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline): 217-PPD-301 - ITT population

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Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 45		
Number of subjects with a response, n (%) [2]	61 (62.2)	69 (70.4)
Number of subjects with missing evaluation, n (%)	13 (13.3)	14 (14.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.108
95% CI for the RR		(0.905, 1.356)
p-value for RR		0.3214
OR - Odds Ratio (Zuranolone vs. Placebo)		1.336
95% CI for the OR		(0.728, 2.450)
p-value for OR		0.3494
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-resp15-301-ovr.sas:t-epds-resp15-301-ovr-itta.rtf **Run Date:** 18JUL2025

2.3.2.1 .2 Subgruppen

2.3.2.1 .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-301 - ITT population

Page: 1 of 6

Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	98	98	
Number of subjects with response at Day 15, n (%)	61 (62.2)	71 (72.4)	
Number of subjects with response at Day 45, n (%)	61 (62.2)	69 (70.4)	
Age Group (years)			0.4123
Day 15			
18 - 24, n / N (%)	10/12 (83.3)	18/19 (94.7)	
25 - 45, n / N (%)	51/86 (59.3)	53/79 (67.1)	
Day 45			
18 - 24, n / N (%)	8/12 (66.7)	18/19 (94.7)	
25 - 45, n / N (%)	53/86 (61.6)	51/79 (64.6)	

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 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-resp15-301-int.sas:t-epds-resp15-301-int-itta.rtf **Run Date:** 18JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

Page: 2 of 6

Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			0.1386
Day 15			
<28, n / N (%)	17/32 (53.1)	22/33 (66.7)	
>=28, n / N (%)	44/66 (66.7)	49/65 (75.4)	
Day 45			
<28, n / N (%)	16/32 (50.0)	27/33 (81.8)	
>=28, n / N (%)	45/66 (68.2)	42/65 (64.6)	
Race Group (Black or African American, White)			0.4074
Day 15			
Black or African American, n / N (%)	10/18 (55.6)	16/25 (64.0)	
White, n / N (%)	42/69 (60.9)	52/68 (76.5)	
Day 45			
Black or African American, n / N (%)	6/18 (33.3)	18/25 (72.0)	
White, n / N (%)	45/69 (65.2)	48/68 (70.6)	

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 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-resp15-301-int.sas:t-epds-resp15-301-int-itta.rtf **Run Date:** 18JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			0.1405
Day 15			
Yes, n / N (%)	10/15 (66.7)	10/15 (66.7)	
No, n / N (%)	51/83 (61.4)	61/83 (73.5)	
Day 45			
Yes, n / N (%)	8/15 (53.3)	9/15 (60.0)	
No, n / N (%)	53/83 (63.9)	60/83 (72.3)	

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-resp15-301-int.sas:t-epds-resp15-301-int-itta.rtf **Run Date:** 18JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			0.3735(a) 0.1567(b) 0.4813(c)
Day 15			
<=24.9, n / N (%)	14/22 (63.6)	11/20 (55.0)	
25-29.9, n / N (%)	25/34 (73.5)	17/24 (70.8)	
>=30, n / N (%)	22/42 (52.4)	42/53 (79.2)	
Day 45			
<=24.9, n / N (%)	16/22 (72.7)	12/20 (60.0)	
25-29.9, n / N (%)	25/34 (73.5)	17/24 (70.8)	
>=30, n / N (%)	20/42 (47.6)	39/53 (73.6)	

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 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-resp15-301-int.sas:t-epds-resp15-301-int-itta.rtf **Run Date:** 18JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Onset of PPD			0.7549
Day 15			
3rd Trimester, n / N (%)	20/31 (64.5)	22/34 (64.7)	
Postpartum, n / N (%)	41/67 (61.2)	49/64 (76.6)	
Day 45			
3rd Trimester, n / N (%)	19/31 (61.3)	24/34 (70.6)	
Postpartum, n / N (%)	42/67 (62.7)	45/64 (70.3)	
Family History of PPD			0.6024
Day 15			
Yes, n / N (%)	10/16 (62.5)	13/21 (61.9)	
No/Unknown, n / N (%)	51/82 (62.2)	58/77 (75.3)	
Day 45			
Yes, n / N (%)	11/16 (68.8)	15/21 (71.4)	
No/Unknown, n / N (%)	50/82 (61.0)	54/77 (70.1)	

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.
Source: biib125/v_a/germany_amnog/t-epds-resp15-301-int.sas:t-epds-resp15-301-int-itta.rtf **Run Date:** 18JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
History of PPD			0.3379
Day 15			
1st Episode, n / N (%)	53/87 (60.9)	58/81 (71.6)	
Recurrent Episode, n / N (%)	8/11 (72.7)	13/17 (76.5)	
Day 45			
1st Episode, n / N (%)	55/87 (63.2)	56/81 (69.1)	
Recurrent Episode, n / N (%)	6/11 (54.5)	13/17 (76.5)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			0.3927
Day 15			
<20, n / N (%)	13/21 (61.9)	18/24 (75.0)	
>=20, n / N (%)	48/77 (62.3)	53/74 (71.6)	
Day 45			
<20, n / N (%)	15/21 (71.4)	20/24 (83.3)	
>=20, n / N (%)	46/77 (59.7)	49/74 (66.2)	

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 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-resp15-301-int.sas:t-epds-resp15-301-int-itta.rtf **Run Date:** 18JUL2025

2.3.2.1 .2 .2 Subgruppenanalysen

2.3.2.1 .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-301 - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =19)
Number of evaluable subjects [1]	12	19
Day 3		
Number of subjects with a response, n (%) [2]	4 (33.3)	12 (63.2)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.792
95% CI for the RR		(0.718, 4.471)
p-value for RR		0.2111
Day 8		
Number of subjects with a response, n (%) [2]	9 (75.0)	17 (89.5)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.128
95% CI for the RR		(0.731, 1.741)
p-value for RR		0.5852

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-resp15-301-by.sas:t-epds-resp15-301-by-age-itta.rtf **Run Date:** 25JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =19)
Day 15		
Number of subjects with a response, n (%) [2]	10 (83.3)	18 (94.7)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.075
95% CI for the RR		(0.755, 1.532)
p-value for RR		0.6881
Day 21		
Number of subjects with a response, n (%) [2]	7 (58.3)	18 (94.7)
Number of subjects with missing evaluation, n (%)	3 (25.0)	1 (5.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.536
95% CI for the RR		(0.882, 2.674)
p-value for RR		0.1293

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-resp15-301-by.sas:t-epds-resp15-301-by-age-itta.rtf **Run Date:** 25JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-301 - ITT population

Page: 3 of 6

Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =19)
Day 28		
Number of subjects with a response, n (%) [2]	9 (75.0)	15 (78.9)
Number of subjects with missing evaluation, n (%)	0	3 (15.8)
RR - Relative Risk (Zuranolone vs. Placebo)		0.996
95% CI for the RR		(0.640, 1.548)
p-value for RR		0.9842
Day 45		
Number of subjects with a response, n (%) [2]	8 (66.7)	18 (94.7)
Number of subjects with missing evaluation, n (%)	1 (8.3)	1 (5.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.344
95% CI for the RR		(0.866, 2.087)
p-value for RR		0.1879

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-resp15-301-by.sas:t-epds-resp15-301-by-age-itta.rtf **Run Date:** 25JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=88)	Zuranolone (N =80)
Number of evaluable subjects [1]	86	79
Day 3		
Number of subjects with a response, n (%) [2]	16 (18.6)	26 (32.9)
Number of subjects with missing evaluation, n (%)	4 (4.7)	1 (1.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.723
95% CI for the RR		(1.008, 2.946)
p-value for RR		0.0467
Day 8		
Number of subjects with a response, n (%) [2]	47 (54.7)	49 (62.0)
Number of subjects with missing evaluation, n (%)	3 (3.5)	5 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.106
95% CI for the RR		(0.858, 1.425)
p-value for RR		0.4377

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-resp15-301-by.sas:t-epds-resp15-301-by-age-itta.rtf **Run Date:** 25JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=88)	Zuranolone (N =80)
Day 15		
Number of subjects with a response, n (%) [2]	51 (59.3)	53 (67.1)
Number of subjects with missing evaluation, n (%)	9 (10.5)	7 (8.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.102
95% CI for the RR		(0.876, 1.386)
p-value for RR		0.4057
Day 21		
Number of subjects with a response, n (%) [2]	50 (58.1)	54 (68.4)
Number of subjects with missing evaluation, n (%)	14 (16.3)	13 (16.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.145
95% CI for the RR		(0.904, 1.452)
p-value for RR		0.2620

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-resp15-301-by.sas:t-epds-resp15-301-by-age-itta.rtf **Run Date:** 25JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=88)	Zuranolone (N =80)
Day 28		
Number of subjects with a response, n (%) [2]	57 (66.3)	48 (60.8)
Number of subjects with missing evaluation, n (%)	13 (15.1)	19 (24.1)
RR - Relative Risk (Zuranolone vs. Placebo)		0.893
95% CI for the RR		(0.706, 1.129)
p-value for RR		0.3450
Day 45		
Number of subjects with a response, n (%) [2]	53 (61.6)	51 (64.6)
Number of subjects with missing evaluation, n (%)	12 (14.0)	13 (16.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.021
95% CI for the RR		(0.809, 1.287)
p-value for RR		0.8639

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-resp15-301-by.sas:t-epds-resp15-301-by-age-itta.rtf **Run Date:** 25JUL2025

2.3.2.1 .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-301 - 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=32)	Zuranolone (N =33)
Number of evaluable subjects [1]	32	33
Day 3		
Number of subjects with a response, n (%) [2]	5 (15.6)	14 (42.4)
Number of subjects with missing evaluation, n (%)	0	1 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		2.565
95% CI for the RR		(1.053, 6.249)
p-value for RR		0.0382
Day 8		
Number of subjects with a response, n (%) [2]	16 (50.0)	20 (60.6)
Number of subjects with missing evaluation, n (%)	0	1 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.145
95% CI for the RR		(0.744, 1.762)
p-value for RR		0.5383

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-resp15-301-by.sas:t-epds-resp15-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Baseline HAMD-17 Total Score: 217-PPD-301 - 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=32)	Zuranolone (N =33)
Day 15		
Number of subjects with a response, n (%) [2]	17 (53.1)	22 (66.7)
Number of subjects with missing evaluation, n (%)	2 (6.3)	1 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.185
95% CI for the RR		(0.796, 1.765)
p-value for RR		0.4025
Day 21		
Number of subjects with a response, n (%) [2]	16 (50.0)	28 (84.8)
Number of subjects with missing evaluation, n (%)	5 (15.6)	2 (6.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.603
95% CI for the RR		(1.101, 2.333)
p-value for RR		0.0138

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-resp15-301-by.sas:t-epds-resp15-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Baseline HAMD-17 Total Score: 217-PPD-301 - 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=32)	Zuranolone (N =33)
Day 28		
Number of subjects with a response, n (%) [2]	18 (56.3)	20 (60.6)
Number of subjects with missing evaluation, n (%)	6 (18.8)	6 (18.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.018
95% CI for the RR		(0.678, 1.527)
p-value for RR		0.9324
Day 45		
Number of subjects with a response, n (%) [2]	16 (50.0)	27 (81.8)
Number of subjects with missing evaluation, n (%)	5 (15.6)	3 (9.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.546
95% CI for the RR		(1.056, 2.263)
p-value for RR		0.0251

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-resp15-301-by.sas:t-epds-resp15-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Baseline HAMD-17 Total Score: 217-PPD-301 - 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=66)	Zuranolone (N =65)
Number of evaluable subjects [1]	66	65
Day 3		
Number of subjects with a response, n (%) [2]	15 (22.7)	24 (36.9)
Number of subjects with missing evaluation, n (%)	4 (6.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.597
95% CI for the RR		(0.928, 2.748)
p-value for RR		0.0911
Day 8		
Number of subjects with a response, n (%) [2]	40 (60.6)	46 (70.8)
Number of subjects with missing evaluation, n (%)	3 (4.5)	4 (6.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.148
95% CI for the RR		(0.896, 1.469)
p-value for RR		0.2747

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-resp15-301-by.sas:t-epds-resp15-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Baseline HAMD-17 Total Score: 217-PPD-301 - 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=66)	Zuranolone (N =65)
Day 15		
Number of subjects with a response, n (%) [2]	44 (66.7)	49 (75.4)
Number of subjects with missing evaluation, n (%)	7 (10.6)	6 (9.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.111
95% CI for the RR		(0.895, 1.381)
p-value for RR		0.3401
Day 21		
Number of subjects with a response, n (%) [2]	41 (62.1)	44 (67.7)
Number of subjects with missing evaluation, n (%)	12 (18.2)	12 (18.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.071
95% CI for the RR		(0.830, 1.382)
p-value for RR		0.5978

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-resp15-301-by.sas:t-epds-resp15-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Baseline HAMD-17 Total Score: 217-PPD-301 - 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=66)	Zuranolone (N =65)
Day 28		
Number of subjects with a response, n (%) [2]	48 (72.7)	43 (66.2)
Number of subjects with missing evaluation, n (%)	7 (10.6)	16 (24.6)
RR - Relative Risk (Zuranolone vs. Placebo)		0.894
95% CI for the RR		(0.709, 1.127)
p-value for RR		0.3433
Day 45		
Number of subjects with a response, n (%) [2]	45 (68.2)	42 (64.6)
Number of subjects with missing evaluation, n (%)	8 (12.1)	11 (16.9)
RR - Relative Risk (Zuranolone vs. Placebo)		0.931
95% CI for the RR		(0.729, 1.190)
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 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-resp15-301-by.sas:t-epds-resp15-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

2.3.2.1 .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-301 - ITT population

Page: 1 of 6

Race Group = Black or African American

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =26)
Number of evaluable subjects [1]	18	25
Day 3		
Number of subjects with a response, n (%) [2]	4 (22.2)	9 (36.0)
Number of subjects with missing evaluation, n (%)	1 (5.6)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.653
95% CI for the RR		(0.610, 4.481)
p-value for RR		0.3233
Day 8		
Number of subjects with a response, n (%) [2]	9 (50.0)	15 (60.0)
Number of subjects with missing evaluation, n (%)	2 (11.1)	2 (8.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.224
95% CI for the RR		(0.696, 2.153)
p-value for RR		0.4819

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-resp15-301-by.sas:t-epds-resp15-301-by-race-itta.rtf **Run Date:** 25JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-301 - ITT population

Page: 2 of 6

Race Group = Black or African American

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =26)
Day 15		
Number of subjects with a response, n (%) [2]	10 (55.6)	16 (64.0)
Number of subjects with missing evaluation, n (%)	4 (22.2)	4 (16.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.175
95% CI for the RR		(0.709, 1.949)
p-value for RR		0.5308
Day 21		
Number of subjects with a response, n (%) [2]	9 (50.0)	17 (68.0)
Number of subjects with missing evaluation, n (%)	7 (38.9)	7 (28.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.388
95% CI for the RR		(0.809, 2.379)
p-value for RR		0.2336

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-resp15-301-by.sas:t-epds-resp15-301-by-race-itta.rtf **Run Date:** 25JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-301 - ITT population

Page: 3 of 6

Race Group = Black or African American

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =26)
Day 28		
Number of subjects with a response, n (%) [2]	7 (38.9)	18 (72.0)
Number of subjects with missing evaluation, n (%)	7 (38.9)	6 (24.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.889
95% CI for the RR		(0.991, 3.602)
p-value for RR		0.0534
Day 45		
Number of subjects with a response, n (%) [2]	6 (33.3)	18 (72.0)
Number of subjects with missing evaluation, n (%)	5 (27.8)	3 (12.0)
RR - Relative Risk (Zuranolone vs. Placebo)		2.204
95% CI for the RR		(1.095, 4.435)
p-value for RR		0.0268

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-resp15-301-by.sas:t-epds-resp15-301-by-race-itta.rtf **Run Date:** 25JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-301 - ITT population

Page: 4 of 6

Race Group = White

Study Visit Statistics	Placebo (N=70)	Zuranolone (N =68)
Number of evaluable subjects [1]	69	68
Day 3		
Number of subjects with a response, n (%) [2]	12 (17.4)	27 (39.7)
Number of subjects with missing evaluation, n (%)	2 (2.9)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.157
95% CI for the RR		(1.204, 3.866)
p-value for RR		0.0098
Day 8		
Number of subjects with a response, n (%) [2]	41 (59.4)	48 (70.6)
Number of subjects with missing evaluation, n (%)	0	3 (4.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.122
95% CI for the RR		(0.883, 1.427)
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 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-resp15-301-by.sas:t-epds-resp15-301-by-race-itta.rtf **Run Date:** 25JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-301 - ITT population

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Race Group = White

Study Visit Statistics	Placebo (N=70)	Zuranolone (N =68)
Day 15		
Number of subjects with a response, n (%) [2]	42 (60.9)	52 (76.5)
Number of subjects with missing evaluation, n (%)	4 (5.8)	3 (4.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.187
95% CI for the RR		(0.947, 1.487)
p-value for RR		0.1360
Day 21		
Number of subjects with a response, n (%) [2]	39 (56.5)	52 (76.5)
Number of subjects with missing evaluation, n (%)	9 (13.0)	7 (10.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.278
95% CI for the RR		(1.002, 1.631)
p-value for RR		0.0484

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-resp15-301-by.sas:t-epds-resp15-301-by-race-itta.rtf **Run Date:** 25JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-301 - ITT population

Page: 6 of 6

Race Group = White

Study Visit Statistics	Placebo (N=70)	Zuranolone (N =68)
Day 28		
Number of subjects with a response, n (%) [2]	50 (72.5)	42 (61.8)
Number of subjects with missing evaluation, n (%)	5 (7.2)	16 (23.5)
RR - Relative Risk (Zuranolone vs. Placebo)		0.805
95% CI for the RR		(0.637, 1.018)
p-value for RR		0.0702
Day 45		
Number of subjects with a response, n (%) [2]	45 (65.2)	48 (70.6)
Number of subjects with missing evaluation, n (%)	7 (10.1)	10 (14.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.023
95% CI for the RR		(0.815, 1.283)
p-value for RR		0.8470

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-resp15-301-by.sas:t-epds-resp15-301-by-race-itta.rtf **Run Date:** 25JUL2025

2.3.2.1 .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-301 - ITT population

Page: 1 of 6

Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=15)	Zuranolone (N =15)
Number of evaluable subjects [1]	15	15
Day 3		
Number of subjects with a response, n (%) [2]	5 (33.3)	3 (20.0)
Number of subjects with missing evaluation, n (%)	2 (13.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.693
95% CI for the RR		(0.202, 2.382)
p-value for RR		0.5609
Day 8		
Number of subjects with a response, n (%) [2]	10 (66.7)	8 (53.3)
Number of subjects with missing evaluation, n (%)	0	1 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.924
95% CI for the RR		(0.481, 1.778)
p-value for RR		0.8139

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-resp15-301-by.sas:t-epds-resp15-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-301 - ITT population

Page: 2 of 6

Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=15)	Zuranolone (N =15)
Day 15		
Number of subjects with a response, n (%) [2]	10 (66.7)	10 (66.7)
Number of subjects with missing evaluation, n (%)	0	1 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.156
95% CI for the RR		(0.695, 1.922)
p-value for RR		0.5773
Day 21		
Number of subjects with a response, n (%) [2]	11 (73.3)	9 (60.0)
Number of subjects with missing evaluation, n (%)	1 (6.7)	1 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.945
95% CI for the RR		(0.513, 1.743)
p-value for RR		0.8575

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-resp15-301-by.sas:t-epds-resp15-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-301 - ITT population

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Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=15)	Zuranolone (N =15)
Day 28		
Number of subjects with a response, n (%) [2]	10 (66.7)	10 (66.7)
Number of subjects with missing evaluation, n (%)	2 (13.3)	1 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.156
95% CI for the RR		(0.668, 1.998)
p-value for RR		0.6048
Day 45		
Number of subjects with a response, n (%) [2]	8 (53.3)	9 (60.0)
Number of subjects with missing evaluation, n (%)	1 (6.7)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.300
95% CI for the RR		(0.722, 2.340)
p-value for RR		0.3817

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-resp15-301-by.sas:t-epds-resp15-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-301 - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=86)	Zuranolone (N =84)
Number of evaluable subjects [1]	83	83
Day 3		
Number of subjects with a response, n (%) [2]	15 (18.1)	35 (42.2)
Number of subjects with missing evaluation, n (%)	2 (2.4)	1 (1.2)
RR - Relative Risk (Zuranolone vs. Placebo)		2.266
95% CI for the RR		(1.351, 3.803)
p-value for RR		0.0019
Day 8		
Number of subjects with a response, n (%) [2]	46 (55.4)	58 (69.9)
Number of subjects with missing evaluation, n (%)	3 (3.6)	4 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.225
95% CI for the RR		(0.968, 1.550)
p-value for RR		0.0919

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-resp15-301-by.sas:t-epds-resp15-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-301 - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=86)	Zuranolone (N =84)
Day 15		
Number of subjects with a response, n (%) [2]	51 (61.4)	61 (73.5)
Number of subjects with missing evaluation, n (%)	9 (10.8)	6 (7.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.162
95% CI for the RR		(0.942, 1.433)
p-value for RR		0.1614
Day 21		
Number of subjects with a response, n (%) [2]	46 (55.4)	63 (75.9)
Number of subjects with missing evaluation, n (%)	16 (19.3)	13 (15.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.330
95% CI for the RR		(1.059, 1.671)
p-value for RR		0.0143

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-resp15-301-by.sas:t-epds-resp15-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-301 - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=86)	Zuranolone (N =84)
Day 28		
Number of subjects with a response, n (%) [2]	56 (67.5)	53 (63.9)
Number of subjects with missing evaluation, n (%)	11 (13.3)	21 (25.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.919
95% CI for the RR		(0.737, 1.146)
p-value for RR		0.4546
Day 45		
Number of subjects with a response, n (%) [2]	53 (63.9)	60 (72.3)
Number of subjects with missing evaluation, n (%)	12 (14.5)	14 (16.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.100
95% CI for the RR		(0.892, 1.355)
p-value for RR		0.3732

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-resp15-301-by.sas:t-epds-resp15-301-by-adt-itta.rtf **Run Date:** 25JUL2025

2.3.2.1 .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-301 - ITT population

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

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =20)
Number of evaluable subjects [1]	22	20
Day 3		
Number of subjects with a response, n (%) [2]	5 (22.7)	6 (30.0)
Number of subjects with missing evaluation, n (%)	1 (4.5)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.317
95% CI for the RR		(0.477, 3.633)
p-value for RR		0.5949
Day 8		
Number of subjects with a response, n (%) [2]	13 (59.1)	10 (50.0)
Number of subjects with missing evaluation, n (%)	0	2 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.844
95% CI for the RR		(0.507, 1.405)
p-value for RR		0.5146

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-resp15-301-by.sas:t-epds-resp15-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =20)
Day 15		
Number of subjects with a response, n (%) [2]	14 (63.6)	11 (55.0)
Number of subjects with missing evaluation, n (%)	1 (4.5)	2 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.862
95% CI for the RR		(0.547, 1.358)
p-value for RR		0.5225
Day 21		
Number of subjects with a response, n (%) [2]	11 (50.0)	14 (70.0)
Number of subjects with missing evaluation, n (%)	5 (22.7)	4 (20.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.397
95% CI for the RR		(0.846, 2.306)
p-value for RR		0.1914

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-resp15-301-by.sas:t-epds-resp15-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

Page: 3 of 9

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

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =20)
Day 28		
Number of subjects with a response, n (%) [2]	15 (68.2)	10 (50.0)
Number of subjects with missing evaluation, n (%)	1 (4.5)	8 (40.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.732
95% CI for the RR		(0.429, 1.248)
p-value for RR		0.2518
Day 45		
Number of subjects with a response, n (%) [2]	16 (72.7)	12 (60.0)
Number of subjects with missing evaluation, n (%)	0	5 (25.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.823
95% CI for the RR		(0.526, 1.288)
p-value for RR		0.3942

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-resp15-301-by.sas:t-epds-resp15-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =24)
Number of evaluable subjects [1]	34	24
Day 3		
Number of subjects with a response, n (%) [2]	6 (17.6)	9 (37.5)
Number of subjects with missing evaluation, n (%)	1 (2.9)	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		2.088
95% CI for the RR		(0.838, 5.204)
p-value for RR		0.1142
Day 8		
Number of subjects with a response, n (%) [2]	23 (67.6)	17 (70.8)
Number of subjects with missing evaluation, n (%)	2 (5.9)	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.029
95% CI for the RR		(0.725, 1.461)
p-value for RR		0.8739

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-resp15-301-by.sas:t-epds-resp15-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =24)
Day 15		
Number of subjects with a response, n (%) [2]	25 (73.5)	17 (70.8)
Number of subjects with missing evaluation, n (%)	4 (11.8)	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		0.946
95% CI for the RR		(0.686, 1.306)
p-value for RR		0.7375
Day 21		
Number of subjects with a response, n (%) [2]	22 (64.7)	20 (83.3)
Number of subjects with missing evaluation, n (%)	7 (20.6)	3 (12.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.265
95% CI for the RR		(0.942, 1.699)
p-value for RR		0.1176

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-resp15-301-by.sas:t-epds-resp15-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =24)
Day 28		
Number of subjects with a response, n (%) [2]	26 (76.5)	18 (75.0)
Number of subjects with missing evaluation, n (%)	5 (14.7)	4 (16.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.964
95% CI for the RR		(0.718, 1.294)
p-value for RR		0.8053
Day 45		
Number of subjects with a response, n (%) [2]	25 (73.5)	17 (70.8)
Number of subjects with missing evaluation, n (%)	6 (17.6)	4 (16.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.946
95% CI for the RR		(0.691, 1.297)
p-value for RR		0.7323

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-resp15-301-by.sas:t-epds-resp15-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

Study Visit Statistics	Placebo (N=42)	Zuranolone (N =53)
Number of evaluable subjects [1]	42	53
Day 3		
Number of subjects with a response, n (%) [2]	9 (21.4)	23 (43.4)
Number of subjects with missing evaluation, n (%)	2 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.834
95% CI for the RR		(0.953, 3.528)
p-value for RR		0.0694
Day 8		
Number of subjects with a response, n (%) [2]	20 (47.6)	38 (71.7)
Number of subjects with missing evaluation, n (%)	1 (2.4)	2 (3.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.363
95% CI for the RR		(0.952, 1.952)
p-value for RR		0.0906

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-resp15-301-by.sas:t-epds-resp15-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

Study Visit Statistics	Placebo (N=42)	Zuranolone (N =53)
Day 15		
Number of subjects with a response, n (%) [2]	22 (52.4)	42 (79.2)
Number of subjects with missing evaluation, n (%)	4 (9.5)	4 (7.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.370
95% CI for the RR		(0.992, 1.891)
p-value for RR		0.0560
Day 21		
Number of subjects with a response, n (%) [2]	24 (57.1)	37 (69.8)
Number of subjects with missing evaluation, n (%)	5 (11.9)	7 (13.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.106
95% CI for the RR		(0.804, 1.522)
p-value for RR		0.5359

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-resp15-301-by.sas:t-epds-resp15-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

Study Visit Statistics	Placebo (N=42)	Zuranolone (N =53)
Day 28		
Number of subjects with a response, n (%) [2]	25 (59.5)	34 (64.2)
Number of subjects with missing evaluation, n (%)	7 (16.7)	10 (18.9)
RR - Relative Risk (Zuranolone vs. Placebo)		0.976
95% CI for the RR		(0.704, 1.353)
p-value for RR		0.8831
Day 45		
Number of subjects with a response, n (%) [2]	20 (47.6)	39 (73.6)
Number of subjects with missing evaluation, n (%)	7 (16.7)	5 (9.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.399
95% CI for the RR		(0.982, 1.994)
p-value for RR		0.0633

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-resp15-301-by.sas:t-epds-resp15-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

2.3.2.1 .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-301 - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =35)
Number of evaluable subjects [1]	31	34
Day 3		
Number of subjects with a response, n (%) [2]	8 (25.8)	14 (41.2)
Number of subjects with missing evaluation, n (%)	2 (6.5)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.595
95% CI for the RR		(0.775, 3.285)
p-value for RR		0.2051
Day 8		
Number of subjects with a response, n (%) [2]	17 (54.8)	22 (64.7)
Number of subjects with missing evaluation, n (%)	3 (9.7)	2 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.176
95% CI for the RR		(0.781, 1.772)
p-value for RR		0.4381

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-resp15-301-by.sas:t-epds-resp15-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =35)
Day 15		
Number of subjects with a response, n (%) [2]	20 (64.5)	22 (64.7)
Number of subjects with missing evaluation, n (%)	4 (12.9)	3 (8.8)
RR - Relative Risk (Zuranolone vs. Placebo)		0.990
95% CI for the RR		(0.686, 1.429)
p-value for RR		0.9561
Day 21		
Number of subjects with a response, n (%) [2]	18 (58.1)	25 (73.5)
Number of subjects with missing evaluation, n (%)	6 (19.4)	5 (14.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.293
95% CI for the RR		(0.903, 1.851)
p-value for RR		0.1609

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-resp15-301-by.sas:t-epds-resp15-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =35)
Day 28		
Number of subjects with a response, n (%) [2]	20 (64.5)	22 (64.7)
Number of subjects with missing evaluation, n (%)	6 (19.4)	8 (23.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.012
95% CI for the RR		(0.707, 1.449)
p-value for RR		0.9477
Day 45		
Number of subjects with a response, n (%) [2]	19 (61.3)	24 (70.6)
Number of subjects with missing evaluation, n (%)	6 (19.4)	7 (20.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.170
95% CI for the RR		(0.821, 1.666)
p-value for RR		0.3851

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-resp15-301-by.sas:t-epds-resp15-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=69)	Zuranolone (N =64)
Number of evaluable subjects [1]	67	64
Day 3		
Number of subjects with a response, n (%) [2]	12 (17.9)	24 (37.5)
Number of subjects with missing evaluation, n (%)	2 (3.0)	1 (1.6)
RR - Relative Risk (Zuranolone vs. Placebo)		2.015
95% CI for the RR		(1.123, 3.615)
p-value for RR		0.0188
Day 8		
Number of subjects with a response, n (%) [2]	39 (58.2)	44 (68.8)
Number of subjects with missing evaluation, n (%)	0	3 (4.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.134
95% CI for the RR		(0.896, 1.435)
p-value for RR		0.2951

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-resp15-301-by.sas:t-epds-resp15-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=69)	Zuranolone (N =64)
Day 15		
Number of subjects with a response, n (%) [2]	41 (61.2)	49 (76.6)
Number of subjects with missing evaluation, n (%)	5 (7.5)	4 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.163
95% CI for the RR		(0.941, 1.437)
p-value for RR		0.1622
Day 21		
Number of subjects with a response, n (%) [2]	39 (58.2)	47 (73.4)
Number of subjects with missing evaluation, n (%)	11 (16.4)	9 (14.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.147
95% CI for the RR		(0.883, 1.489)
p-value for RR		0.3034

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-resp15-301-by.sas:t-epds-resp15-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=69)	Zuranolone (N =64)
Day 28		
Number of subjects with a response, n (%) [2]	46 (68.7)	41 (64.1)
Number of subjects with missing evaluation, n (%)	7 (10.4)	14 (21.9)
RR - Relative Risk (Zuranolone vs. Placebo)		0.892
95% CI for the RR		(0.694, 1.145)
p-value for RR		0.3689
Day 45		
Number of subjects with a response, n (%) [2]	42 (62.7)	45 (70.3)
Number of subjects with missing evaluation, n (%)	7 (10.4)	7 (10.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.096
95% CI for the RR		(0.855, 1.405)
p-value for RR		0.4686

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-resp15-301-by.sas:t-epds-resp15-301-by-onset-itta.rtf **Run Date:** 25JUL2025

2.3.2.1 .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-301 - ITT population

Page: 1 of 6

Family History of PPD = Yes

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =21)
Number of evaluable subjects [1]	16	21
Day 3		
Number of subjects with a response, n (%) [2]	4 (25.0)	7 (33.3)
Number of subjects with missing evaluation, n (%)	1 (6.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.349
95% CI for the RR		(0.476, 3.824)
p-value for RR		0.5730
Day 8		
Number of subjects with a response, n (%) [2]	11 (68.8)	14 (66.7)
Number of subjects with missing evaluation, n (%)	1 (6.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.981
95% CI for the RR		(0.610, 1.578)
p-value for RR		0.9381

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-resp15-301-by.sas:t-epds-resp15-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Family History of PPD: 217-PPD-301 - ITT population

Page: 2 of 6

Family History of PPD = Yes

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =21)
Day 15		
Number of subjects with a response, n (%) [2]	10 (62.5)	13 (61.9)
Number of subjects with missing evaluation, n (%)	3 (18.8)	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.002
95% CI for the RR		(0.596, 1.686)
p-value for RR		0.9929
Day 21		
Number of subjects with a response, n (%) [2]	11 (68.8)	19 (90.5)
Number of subjects with missing evaluation, n (%)	3 (18.8)	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.332
95% CI for the RR		(0.917, 1.935)
p-value for RR		0.1326

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-resp15-301-by.sas:t-epds-resp15-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Family History of PPD: 217-PPD-301 - ITT population

Page: 3 of 6

Family History of PPD = Yes

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =21)
Day 28		
Number of subjects with a response, n (%) [2]	10 (62.5)	15 (71.4)
Number of subjects with missing evaluation, n (%)	4 (25.0)	4 (19.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.157
95% CI for the RR		(0.706, 1.896)
p-value for RR		0.5639
Day 45		
Number of subjects with a response, n (%) [2]	11 (68.8)	15 (71.4)
Number of subjects with missing evaluation, n (%)	3 (18.8)	2 (9.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.051
95% CI for the RR		(0.685, 1.615)
p-value for RR		0.8187

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-resp15-301-by.sas:t-epds-resp15-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Family History of PPD: 217-PPD-301 - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=85)	Zuranolone (N =78)
Number of evaluable subjects [1]	82	77
Day 3		
Number of subjects with a response, n (%) [2]	16 (19.5)	31 (40.3)
Number of subjects with missing evaluation, n (%)	3 (3.7)	1 (1.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.972
95% CI for the RR		(1.185, 3.282)
p-value for RR		0.0090
Day 8		
Number of subjects with a response, n (%) [2]	45 (54.9)	52 (67.5)
Number of subjects with missing evaluation, n (%)	2 (2.4)	5 (6.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.176
95% CI for the RR		(0.922, 1.500)
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 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-resp15-301-by.sas:t-epds-resp15-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Family History of PPD: 217-PPD-301 - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=85)	Zuranolone (N =78)
Day 15		
Number of subjects with a response, n (%) [2]	51 (62.2)	58 (75.3)
Number of subjects with missing evaluation, n (%)	6 (7.3)	6 (7.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.157
95% CI for the RR		(0.942, 1.422)
p-value for RR		0.1635
Day 21		
Number of subjects with a response, n (%) [2]	46 (56.1)	53 (68.8)
Number of subjects with missing evaluation, n (%)	14 (17.1)	13 (16.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.173
95% CI for the RR		(0.919, 1.496)
p-value for RR		0.2007

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-resp15-301-by.sas:t-epds-resp15-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Family History of PPD: 217-PPD-301 - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=85)	Zuranolone (N =78)
Day 28		
Number of subjects with a response, n (%) [2]	56 (68.3)	48 (62.3)
Number of subjects with missing evaluation, n (%)	9 (11.0)	18 (23.4)
RR - Relative Risk (Zuranolone vs. Placebo)		0.872
95% CI for the RR		(0.693, 1.098)
p-value for RR		0.2450
Day 45		
Number of subjects with a response, n (%) [2]	50 (61.0)	54 (70.1)
Number of subjects with missing evaluation, n (%)	10 (12.2)	12 (15.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.099
95% CI for the RR		(0.877, 1.378)
p-value for RR		0.4126

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-resp15-301-by.sas:t-epds-resp15-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

2.3.2.1 .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-301 - ITT population

Page: 1 of 6

History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=90)	Zuranolone (N =82)
Number of evaluable subjects [1]	87	81
Day 3		
Number of subjects with a response, n (%) [2]	14 (16.1)	31 (38.3)
Number of subjects with missing evaluation, n (%)	3 (3.4)	1 (1.2)
RR - Relative Risk (Zuranolone vs. Placebo)		2.304
95% CI for the RR		(1.331, 3.988)
p-value for RR		0.0029
Day 8		
Number of subjects with a response, n (%) [2]	48 (55.2)	55 (67.9)
Number of subjects with missing evaluation, n (%)	3 (3.4)	5 (6.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.192
95% CI for the RR		(0.938, 1.516)
p-value for RR		0.1512

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-resp15-301-by.sas:t-epds-resp15-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-301 - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=90)	Zuranolone (N =82)
Day 15		
Number of subjects with a response, n (%) [2]	53 (60.9)	58 (71.6)
Number of subjects with missing evaluation, n (%)	9 (10.3)	7 (8.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.139
95% CI for the RR		(0.918, 1.413)
p-value for RR		0.2381
Day 21		
Number of subjects with a response, n (%) [2]	48 (55.2)	61 (75.3)
Number of subjects with missing evaluation, n (%)	16 (18.4)	13 (16.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.322
95% CI for the RR		(1.051, 1.663)
p-value for RR		0.0170

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-resp15-301-by.sas:t-epds-resp15-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-301 - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=90)	Zuranolone (N =82)
Day 28		
Number of subjects with a response, n (%) [2]	58 (66.7)	49 (60.5)
Number of subjects with missing evaluation, n (%)	13 (14.9)	22 (27.2)
RR - Relative Risk (Zuranolone vs. Placebo)		0.879
95% CI for the RR		(0.696, 1.110)
p-value for RR		0.2788
Day 45		
Number of subjects with a response, n (%) [2]	55 (63.2)	56 (69.1)
Number of subjects with missing evaluation, n (%)	12 (13.8)	13 (16.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.059
95% CI for the RR		(0.853, 1.316)
p-value for RR		0.6014

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-resp15-301-by.sas:t-epds-resp15-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-301 - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=11)	Zuranolone (N =17)
Number of evaluable subjects [1]	11	17
Day 3		
Number of subjects with a response, n (%) [2]	6 (54.5)	7 (41.2)
Number of subjects with missing evaluation, n (%)	1 (9.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.856
95% CI for the RR		(0.400, 1.831)
p-value for RR		0.6889
Day 8		
Number of subjects with a response, n (%) [2]	8 (72.7)	11 (64.7)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.009
95% CI for the RR		(0.637, 1.599)
p-value for RR		0.9693

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-resp15-301-by.sas:t-epds-resp15-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-301 - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=11)	Zuranolone (N =17)
Day 15		
Number of subjects with a response, n (%) [2]	8 (72.7)	13 (76.5)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.193
95% CI for the RR		(0.796, 1.786)
p-value for RR		0.3926
Day 21		
Number of subjects with a response, n (%) [2]	9 (81.8)	11 (64.7)
Number of subjects with missing evaluation, n (%)	1 (9.1)	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		0.897
95% CI for the RR		(0.575, 1.399)
p-value for RR		0.6316

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-resp15-301-by.sas:t-epds-resp15-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-301 - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=11)	Zuranolone (N =17)
Day 28		
Number of subjects with a response, n (%) [2]	8 (72.7)	14 (82.4)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.284
95% CI for the RR		(0.863, 1.911)
p-value for RR		0.2171
Day 45		
Number of subjects with a response, n (%) [2]	6 (54.5)	13 (76.5)
Number of subjects with missing evaluation, n (%)	1 (9.1)	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.590
95% CI for the RR		(0.860, 2.939)
p-value for RR		0.1390

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-resp15-301-by.sas:t-epds-resp15-301-by-hist-itta.rtf **Run Date:** 25JUL2025

2.3.2.1 .2 .2 .9 Depression mit Angst

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =24)
Number of evaluable subjects [1]	21	24
Day 3		
Number of subjects with a response, n (%) [2]	5 (23.8)	10 (41.7)
Number of subjects with missing evaluation, n (%)	1 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.732
95% CI for the RR		(0.704, 4.265)
p-value for RR		0.2319
Day 8		
Number of subjects with a response, n (%) [2]	9 (42.9)	15 (62.5)
Number of subjects with missing evaluation, n (%)	1 (4.8)	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.444
95% CI for the RR		(0.808, 2.579)
p-value for RR		0.2147

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-resp15-301-by.sas:t-epds-resp15-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =24)
Day 15		
Number of subjects with a response, n (%) [2]	13 (61.9)	18 (75.0)
Number of subjects with missing evaluation, n (%)	1 (4.8)	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.199
95% CI for the RR		(0.807, 1.783)
p-value for RR		0.3692
Day 21		
Number of subjects with a response, n (%) [2]	11 (52.4)	23 (95.8)
Number of subjects with missing evaluation, n (%)	4 (19.0)	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.811
95% CI for the RR		(1.201, 2.732)
p-value for RR		0.0046

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-resp15-301-by.sas:t-epds-resp15-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =24)
Day 28		
Number of subjects with a response, n (%) [2]	14 (66.7)	15 (62.5)
Number of subjects with missing evaluation, n (%)	2 (9.5)	5 (20.8)
RR - Relative Risk (Zuranolone vs. Placebo)		0.928
95% CI for the RR		(0.605, 1.424)
p-value for RR		0.7327
Day 45		
Number of subjects with a response, n (%) [2]	15 (71.4)	20 (83.3)
Number of subjects with missing evaluation, n (%)	1 (4.8)	3 (12.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.155
95% CI for the RR		(0.839, 1.590)
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 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-resp15-301-by.sas:t-epds-resp15-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

Study Visit Statistics	Placebo (N=77)	Zuranolone (N =74)
Number of evaluable subjects [1]	77	74
Day 3		
Number of subjects with a response, n (%) [2]	15 (19.5)	28 (37.8)
Number of subjects with missing evaluation, n (%)	3 (3.9)	1 (1.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.858
95% CI for the RR		(1.090, 3.166)
p-value for RR		0.0227
Day 8		
Number of subjects with a response, n (%) [2]	47 (61.0)	51 (68.9)
Number of subjects with missing evaluation, n (%)	2 (2.6)	4 (5.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.080
95% CI for the RR		(0.856, 1.362)
p-value for RR		0.5155

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-resp15-301-by.sas:t-epds-resp15-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

Study Visit Statistics	Placebo (N=77)	Zuranolone (N =74)
Day 15		
Number of subjects with a response, n (%) [2]	48 (62.3)	53 (71.6)
Number of subjects with missing evaluation, n (%)	8 (10.4)	6 (8.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.099
95% CI for the RR		(0.880, 1.373)
p-value for RR		0.4061
Day 21		
Number of subjects with a response, n (%) [2]	46 (59.7)	49 (66.2)
Number of subjects with missing evaluation, n (%)	13 (16.9)	13 (17.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.060
95% CI for the RR		(0.826, 1.361)
p-value for RR		0.6458

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-resp15-301-by.sas:t-epds-resp15-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

Study Visit Statistics	Placebo (N=77)	Zuranolone (N =74)
Day 28		
Number of subjects with a response, n (%) [2]	52 (67.5)	48 (64.9)
Number of subjects with missing evaluation, n (%)	11 (14.3)	17 (23.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.919
95% CI for the RR		(0.727, 1.161)
p-value for RR		0.4781
Day 45		
Number of subjects with a response, n (%) [2]	46 (59.7)	49 (66.2)
Number of subjects with missing evaluation, n (%)	12 (15.6)	11 (14.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.060
95% CI for the RR		(0.829, 1.356)
p-value for RR		0.6411

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.

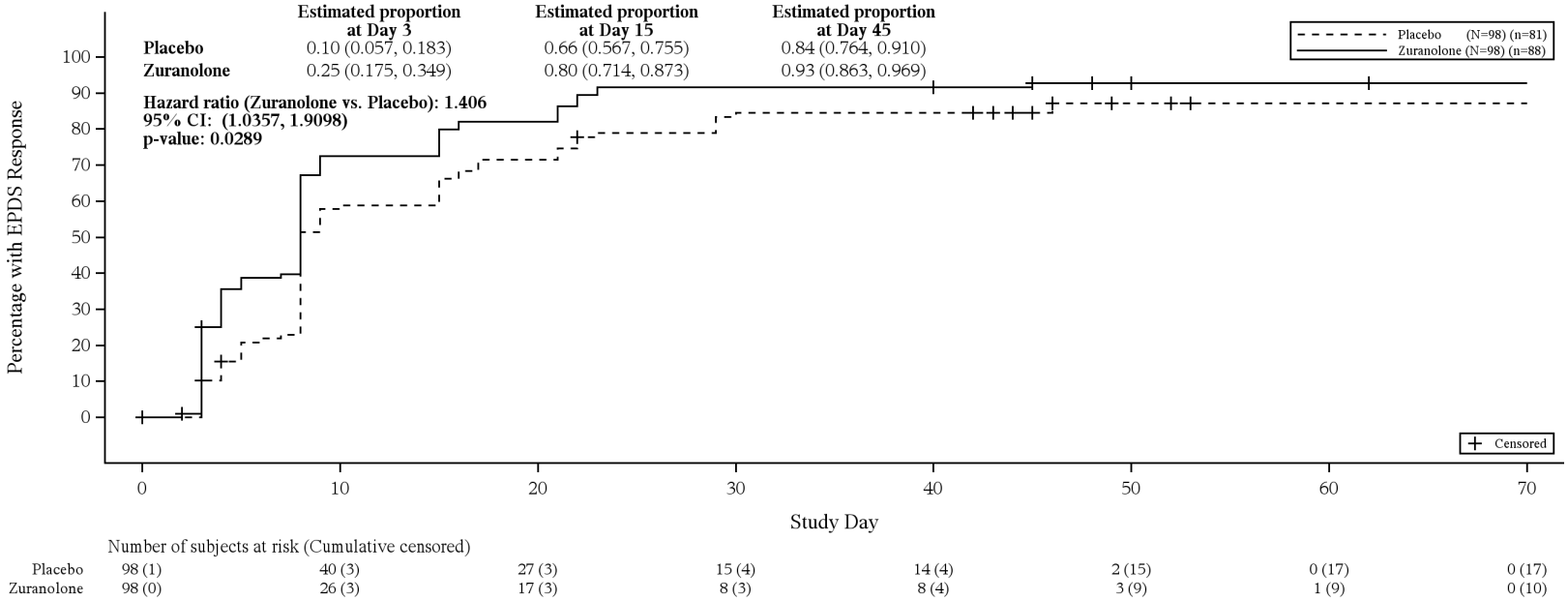
Source: biib125/v_a/germany_amnog/t-epds-resp15-301-by.sas:t-epds-resp15-301-by-hama-itta.rtf **Run Date:** 25JUL2025

2.3.2.2 TTE-Analysen

2.3.2.2 .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-301 - ITT population

Page: 1 of 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.
Source: biib125/v_a/amnog_kmplots/f-epds-resp15-tte-301-ovr.sas:f-epds-resp15-tte-301-ovr-itta.rtf **Run Date:** 12DEC2025

Summary of Time to First Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline): 217-PPD-301 - ITT population

Page: 1 of 1

	Placebo (N=101)	Zuranolone (N=99)
Number of evaluable subjects [1]	98	98
Number of subjects with response, n (%) [2]	81 (82.7)	88 (89.8)
Time to first EPDS response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (5.0 , 8.0)	4.0 (3.0 , 4.0)
50th percentile - median (95% CI)	8.0 (8.0 , 15.0)	8.0 (7.0 , 8.0)
75th percentile - Q3 (95% CI)	22.0 (15.0 , 29.0)	15.0 (8.0 , 21.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.406
95% CI for the HR		(1.0357 , 1.9098)
p-value for the HR		0.0289

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-301-ovr.sas:t-epds-resp15-tte-301-ovr-itta.rtf **Run Date:** 18JUL2025

2.3.2.2 .2 Subgruppen

2.3.2.2 .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-301 - ITT population

Page: 1 of 2

Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	98	98	
Number of subjects with response, n (%)	81 (82.7)	88 (89.8)	
Age Group (years)			
18 - 24, n / N (%)	10/12 (83.3)	19/19 (100.0)	0.4229
25 - 45, n / N (%)	71/86 (82.6)	69/79 (87.3)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	25/32 (78.1)	30/33 (90.9)	0.3733
>=28, n / N (%)	56/66 (84.8)	58/65 (89.2)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	13/18 (72.2)	23/25 (92.0)	0.7595
White, n / N (%)	58/69 (84.1)	61/68 (89.7)	
Antidepressant Use at Baseline			
Yes, n / N (%)	13/15 (86.7)	11/15 (73.3)	0.0405
No, n / N (%)	68/83 (81.9)	77/83 (92.8)	

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-301-int.sas:t-epds-resp15-tte-301-int-itta.rtf **Run Date:** 18JUL2025

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-301 - ITT population

Page: 2 of 2

Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9, n / N (%)	18/22 (81.8)	18/20 (90.0)	0.9425(a)
25-29.9, n / N (%)	31/34 (91.2)	22/24 (91.7)	0.8763(b)
>=30, n / N (%)	32/42 (76.2)	47/53 (88.7)	0.7947(c)
Onset of PPD			
3rd Trimester, n / N (%)	26/31 (83.9)	31/34 (91.2)	0.8266
Postpartum, n / N (%)	55/67 (82.1)	57/64 (89.1)	
Family History of PPD			
Yes, n / N (%)	14/16 (87.5)	21/21 (100.0)	0.3988
No/Unknown, n / N (%)	67/82 (81.7)	67/77 (87.0)	
History of PPD			
1st Episode, n / N (%)	71/87 (81.6)	73/81 (90.1)	0.4414
Recurrent Episode, n / N (%)	10/11 (90.9)	15/17 (88.2)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	16/21 (76.2)	24/24 (100.0)	0.1443
>=20, n / N (%)	65/77 (84.4)	64/74 (86.5)	

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-301-int.sas:t-epds-resp15-tte-301-int-itta.rtf **Run Date:** 18JUL2025

2.3.2.2 .2 .2 Subgruppenanalysen

2.3.2.2 .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-301 - ITT population

Page: 1 of 2

Age Group (years) = 18-24

	Placebo (N=13)	**Zuranolone (N=19)**
Number of evaluable subjects [1]	12	19
Number of subjects with response, n (%) [2]	10 (83.3)	19 (100.0)
Time to first EPDS response (days) [3]		
25th percentile - Q1 (95% CI)	4.5 (3.0 , 8.0)	3.0 (3.0 , 4.0)
50th percentile - median (95% CI)	8.0 (3.0 , 15.0)	4.0 (3.0 , 8.0)
75th percentile - Q3 (95% CI)	12.0 (8.0, NE)	8.0 (4.0 , 15.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.696
95% CI for the HR		(0.7769 , 3.7032)
p-value for the HR		0.1848

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-301-by.sas:t-epds-resp15-tte-301-by-age-itta.rtf **Run Date:** 25JUL2025

Summary of Time to First Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 25-45

	Placebo (N=88)	Zuranolone (N=80)
Number of evaluable subjects [1]	86	79
Number of subjects with response, n (%) [2]	71 (82.6)	69 (87.3)
Time to first EPDS response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (5.0 , 8.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	9.0 (8.0 , 15.0)	8.0 (NE, NE)
75th percentile - Q3 (95% CI)	22.0 (16.0 , 30.0)	15.0 (9.0 , 21.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.334
95% CI for the HR		(0.9533 , 1.8659)
p-value for the HR		0.0928

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-301-by.sas:t-epds-resp15-tte-301-by-age-itta.rtf **Run Date:** 25JUL2025

2.3.2.2 .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-301 - ITT population

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

	Placebo (N=32)	Zuranolone (N=33)
Number of evaluable subjects [1]	32	33
Number of subjects with response, n (%) [2]	25 (78.1)	30 (90.9)
Time to first EPDS response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (4.0 , 8.0)	4.0 (3.0 , 5.0)
50th percentile - median (95% CI)	12.0 (8.0 , 23.0)	8.0 (4.0 , 9.0)
75th percentile - Q3 (95% CI)	30.0 (16.0, NE)	21.0 (8.0 , 23.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.736
95% CI for the HR		(1.0089 , 2.9870)
p-value for the HR		0.0464

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-301-by.sas:t-epds-resp15-tte-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

Page: 2 of 2

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

	Placebo (N=66)	Zuranolone (N=65)
Number of evaluable subjects [1]	66	65
Number of subjects with response, n (%) [2]	56 (84.8)	58 (89.2)
Time to first EPDS response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (4.0 , 8.0)	3.5 (3.0 , 5.0)
50th percentile - median (95% CI)	8.0 (8.0 , 10.0)	8.0 (5.0 , 8.0)
75th percentile - Q3 (95% CI)	17.0 (15.0 , 29.0)	15.0 (8.0 , 16.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.306
95% CI for the HR		(0.8991 , 1.8980)
p-value for the HR		0.1609

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-301-by.sas:t-epds-resp15-tte-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

2.3.2.2 .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-301 - ITT population

Page: 1 of 2

Race Group = Black or African American

	Placebo (N=20)	Zuranolone (N=26)
Number of evaluable subjects [1]	18	25
Number of subjects with response, n (%) [2]	13 (72.2)	23 (92.0)
Time to first EPDS response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 8.0)	3.0 (3.0 , 8.0)
50th percentile - median (95% CI)	9.0 (5.0 , 16.0)	8.0 (4.0 , 15.0)
75th percentile - Q3 (95% CI)	23.0 (8.0, NE)	15.0 (8.0 , 22.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.365
95% CI for the HR		(0.6806 , 2.7358)
p-value for the HR		0.3812

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-301-by.sas:t-epds-resp15-tte-301-by-race-itta.rtf **Run Date:** 25JUL2025

Summary of Time to First Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-301 - ITT population

Page: 2 of 2

Race Group = White

	Placebo (N=70)	Zuranolone (N=68)
Number of evaluable subjects [1]	69	68
Number of subjects with response, n (%) [2]	58 (84.1)	61 (89.7)
Time to first EPDS response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (4.0 , 8.0)	4.0 (3.0 , 5.0)
50th percentile - median (95% CI)	8.0 (8.0 , 15.0)	8.0 (5.0 , 8.0)
75th percentile - Q3 (95% CI)	22.0 (15.0 , 46.0)	9.0 (8.0 , 16.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.524
95% CI for the HR		(1.0504 , 2.2105)
p-value for the HR		0.0265

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-301-by.sas:t-epds-resp15-tte-301-by-race-itta.rtf **Run Date:** 25JUL2025

2.3.2.2 .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-301 - ITT population

Page: 1 of 2

Antidepressant Use at Baseline = Yes

	Placebo (N=15)	Zuranolone (N=15)
Number of evaluable subjects [1]	15	15
Number of subjects with response, n (%) [2]	13 (86.7)	11 (73.3)
Time to first EPDS response (days) [3]		
25th percentile - Q1 (95% CI)	3.0 (3.0 , 8.0)	8.0 (3.0 , 8.0)
50th percentile - median (95% CI)	8.0 (3.0 , 15.0)	9.0 (7.0 , 21.0)
75th percentile - Q3 (95% CI)	17.0 (8.0, NE)	NE (9.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.699
95% CI for the HR		(0.3107 , 1.5706)
p-value for the HR		0.3855

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-301-by.sas:t-epds-resp15-tte-301-by-adt-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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Antidepressant Use at Baseline = No

	Placebo (N=86)	Zuranolone (N=84)
Number of evaluable subjects [1]	83	83
Number of subjects with response, n (%) [2]	68 (81.9)	77 (92.8)
Time to first EPDS response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (5.0 , 8.0)	3.0 (3.0 , 4.0)
50th percentile - median (95% CI)	9.0 (8.0 , 15.0)	8.0 (4.0 , 8.0)
75th percentile - Q3 (95% CI)	22.0 (15.0 , 30.0)	9.0 (8.0 , 16.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.628
95% CI for the HR		(1.1694 , 2.2658)
p-value for the HR		0.0039

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-301-by.sas:t-epds-resp15-tte-301-by-adt-itta.rtf **Run Date:** 25JUL2025

2.3.2.2 .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-301 - ITT population

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

	Placebo (N=22)	Zuranolone (N=20)
Number of evaluable subjects [1]	22	20
Number of subjects with response, n (%) [2]	18 (81.8)	18 (90.0)
Time to first EPDS response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 8.0)	5.0 (3.0 , 8.0)
50th percentile - median (95% CI)	8.0 (8.0 , 22.0)	8.0 (5.0 , 21.0)
75th percentile - Q3 (95% CI)	29.0 (8.0, NE)	22.0 (8.0 , 23.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.627
95% CI for the HR		(0.8293 , 3.1931)
p-value for the HR		0.1569

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-301-by.sas:t-epds-resp15-tte-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

	Placebo (N=34)	Zuranolone (N=24)
Number of evaluable subjects [1]	34	24
Number of subjects with response, n (%) [2]	31 (91.2)	22 (91.7)
Time to first EPDS response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (4.0 , 8.0)	3.0 (3.0 , 8.0)
50th percentile - median (95% CI)	8.0 (8.0 , 9.0)	8.0 (3.0 , 9.0)
75th percentile - Q3 (95% CI)	15.0 (8.0 , 21.0)	9.0 (8.0 , 21.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.256
95% CI for the HR		(0.7206 , 2.1875)
p-value for the HR		0.4218

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-301-by.sas:t-epds-resp15-tte-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

	Placebo (N=42)	Zuranolone (N=53)
Number of evaluable subjects [1]	42	53
Number of subjects with response, n (%) [2]	32 (76.2)	47 (88.7)
Time to first EPDS 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 , 21.0)	8.0 (4.0 , 8.0)
75th percentile - Q3 (95% CI)	29.0 (17.0, NE)	15.0 (8.0 , 16.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.516
95% CI for the HR		(0.9432 , 2.4379)
p-value for the HR		0.0857

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-301-by.sas:t-epds-resp15-tte-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

2.3.2.2 .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-301 - ITT population

Page: 1 of 2

Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=35)
Number of evaluable subjects [1]	31	34
Number of subjects with response, n (%) [2]	26 (83.9)	31 (91.2)
Time to first EPDS response (days) [3]		
25th percentile - Q1 (95% CI)	5.0 (3.0 , 8.0)	3.0 (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)	17.0 (8.0 , 30.0)	15.0 (8.0 , 21.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.456
95% CI for the HR		(0.8468 , 2.5048)
p-value for the HR		0.1741

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-301-by.sas:t-epds-resp15-tte-301-by-onset-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

Page: 2 of 2

Onset of PPD = Postpartum

	Placebo (N=69)	Zuranolone (N=64)
Number of evaluable subjects [1]	67	64
Number of subjects with response, n (%) [2]	55 (82.1)	57 (89.1)
Time to first EPDS response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (4.0 , 8.0)	4.0 (3.0 , 5.0)
50th percentile - median (95% CI)	9.0 (8.0 , 15.0)	8.0 (7.0 , 8.0)
75th percentile - Q3 (95% CI)	23.0 (15.0, NE)	15.0 (8.0 , 22.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.360
95% CI for the HR		(0.9360 , 1.9756)
p-value for the HR		0.1068

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-301-by.sas:t-epds-resp15-tte-301-by-onset-itta.rtf **Run Date:** 25JUL2025

2.3.2.2 .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-301 - ITT population

Page: 1 of 2

Family History of PPD = Yes

	Placebo (N=16)	Zuranolone (N=21)
Number of evaluable subjects [1]	16	21
Number of subjects with response, n (%) [2]	14 (87.5)	21 (100.0)
Time to first EPDS response (days) [3]		
25th percentile - Q1 (95% CI)	5.0 (3.0 , 8.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	8.0 (5.0 , 10.0)	8.0 (4.0 , 9.0)
75th percentile - Q3 (95% CI)	15.0 (8.0, NE)	15.0 (8.0 , 22.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.308
95% CI for the HR		(0.6363 , 2.6884)
p-value for the HR		0.4653

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-301-by.sas:t-epds-resp15-tte-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

Page: 2 of 2

Family History of PPD = No/Unknown

	Placebo (N=85)	Zuranolone (N=78)
Number of evaluable subjects [1]	82	77
Number of subjects with response, n (%) [2]	67 (81.7)	67 (87.0)
Time to first EPDS response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (4.0 , 8.0)	3.0 (3.0 , 4.0)
50th percentile - median (95% CI)	9.0 (8.0 , 15.0)	8.0 (5.0 , 8.0)
75th percentile - Q3 (95% CI)	22.0 (16.0 , 46.0)	15.0 (8.0 , 21.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.475
95% CI for the HR		(1.0449 , 2.0823)
p-value for the HR		0.0271

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-301-by.sas:t-epds-resp15-tte-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

2.3.2.2 .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-301 - ITT population

Page: 1 of 2

History of PPD = 1st Episode

	Placebo (N=90)	Zuranolone (N=82)
Number of evaluable subjects [1]	87	81
Number of subjects with response, n (%) [2]	71 (81.6)	73 (90.1)
Time to first EPDS response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (5.0 , 8.0)	4.0 (3.0 , 4.0)
50th percentile - median (95% CI)	9.0 (8.0 , 15.0)	8.0 (7.0 , 8.0)
75th percentile - Q3 (95% CI)	22.0 (15.0 , 46.0)	15.0 (8.0 , 21.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.473
95% CI for the HR		(1.0592 , 2.0486)
p-value for the HR		0.0213

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-301-by.sas:t-epds-resp15-tte-301-by-hist-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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History of PPD = Recurrent Episode

	Placebo (N=11)	Zuranolone (N=17)
Number of evaluable subjects [1]	11	17
Number of subjects with response, n (%) [2]	10 (90.9)	15 (88.2)
Time to first EPDS response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 5.0)	3.0 (2.0 , 8.0)
50th percentile - median (95% CI)	5.0 (4.0 , 21.0)	8.0 (3.0 , 15.0)
75th percentile - Q3 (95% CI)	21.0 (5.0, NE)	15.0 (8.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.411
95% CI for the HR		(0.5932 , 3.3577)
p-value for the HR		0.4359

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-301-by.sas:t-epds-resp15-tte-301-by-hist-itta.rtf **Run Date:** 25JUL2025

2.3.2.2 .2 .2 .9 Depression mit Angst

Summary of Time to First Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

Page: 1 of 2

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

	Placebo (N=21)	Zuranolone (N=24)
Number of evaluable subjects [1]	21	24
Number of subjects with response, n (%) [2]	16 (76.2)	24 (100.0)
Time to first EPDS response (days) [3]		
25th percentile - Q1 (95% CI)	6.5 (3.0 , 8.0)	4.0 (3.0 , 7.0)
50th percentile - median (95% CI)	15.0 (5.0 , 22.0)	8.0 (4.0 , 8.0)
75th percentile - Q3 (95% CI)	25.5 (15.0, NE)	12.5 (8.0 , 22.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.033
95% CI for the HR		(1.0365 , 3.9871)
p-value for the HR		0.0390

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-301-by.sas:t-epds-resp15-tte-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Time to First Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

Page: 2 of 2

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

	Placebo (N=77)	Zuranolone (N=74)
Number of evaluable subjects [1]	77	74
Number of subjects with response, n (%) [2]	65 (84.4)	64 (86.5)
Time to first EPDS response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (5.0 , 8.0)	3.0 (3.0 , 4.0)
50th percentile - median (95% CI)	8.0 (8.0 , 9.0)	8.0 (5.0 , 8.0)
75th percentile - Q3 (95% CI)	21.0 (15.0 , 29.0)	15.0 (8.0 , 21.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.226
95% CI for the HR		(0.8633 , 1.7414)
p-value for the HR		0.2547

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.

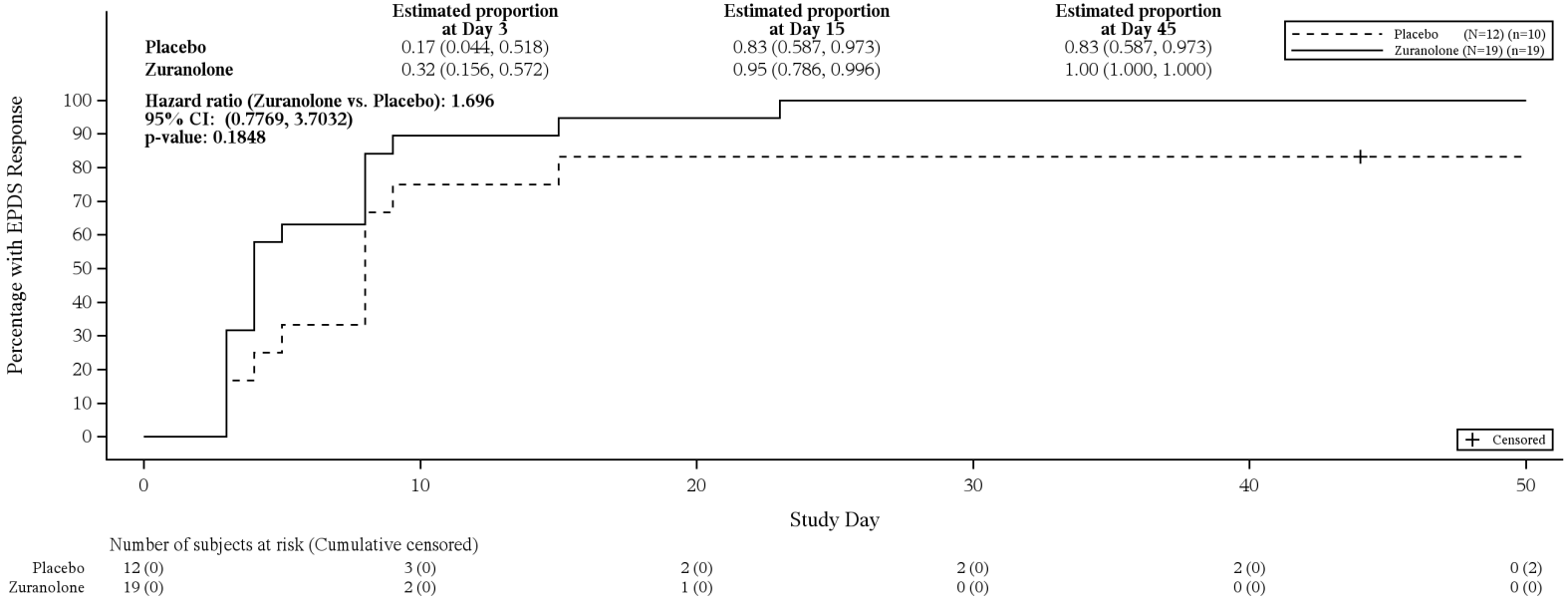
Source: biib125/v_a/germany_amnog/t-epds-resp15-tte-301-by.sas:t-epds-resp15-tte-301-by-hama-itta.rtf **Run Date:** 25JUL2025

2.3.2.2 .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-301 - 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.

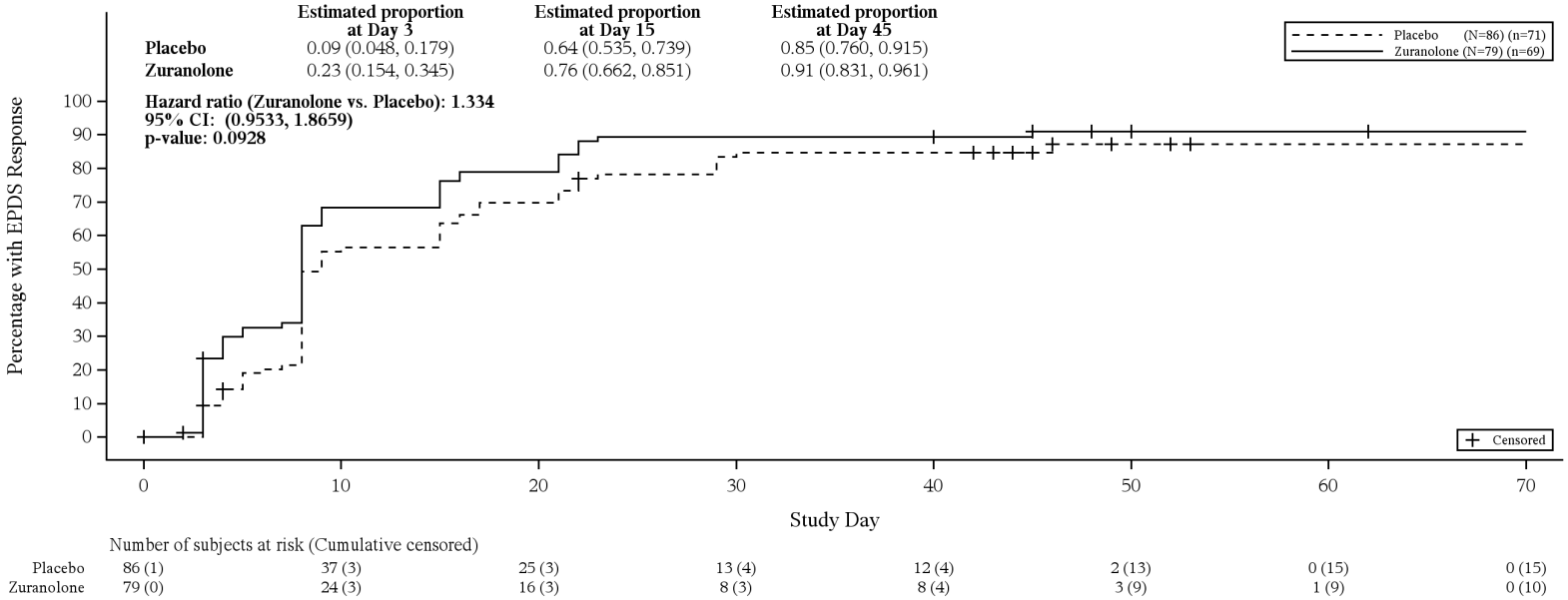
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline EPDS total score, and treatment. Model covariate antidepressant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

Source: biib125/v_a/amnog_kmplots/f-epds-resp15-tte-301-by.sas:f-epds-resp15-tte-301-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-301 - ITT population

Page: 2 of 19

Age Group (years) = 25-45



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.

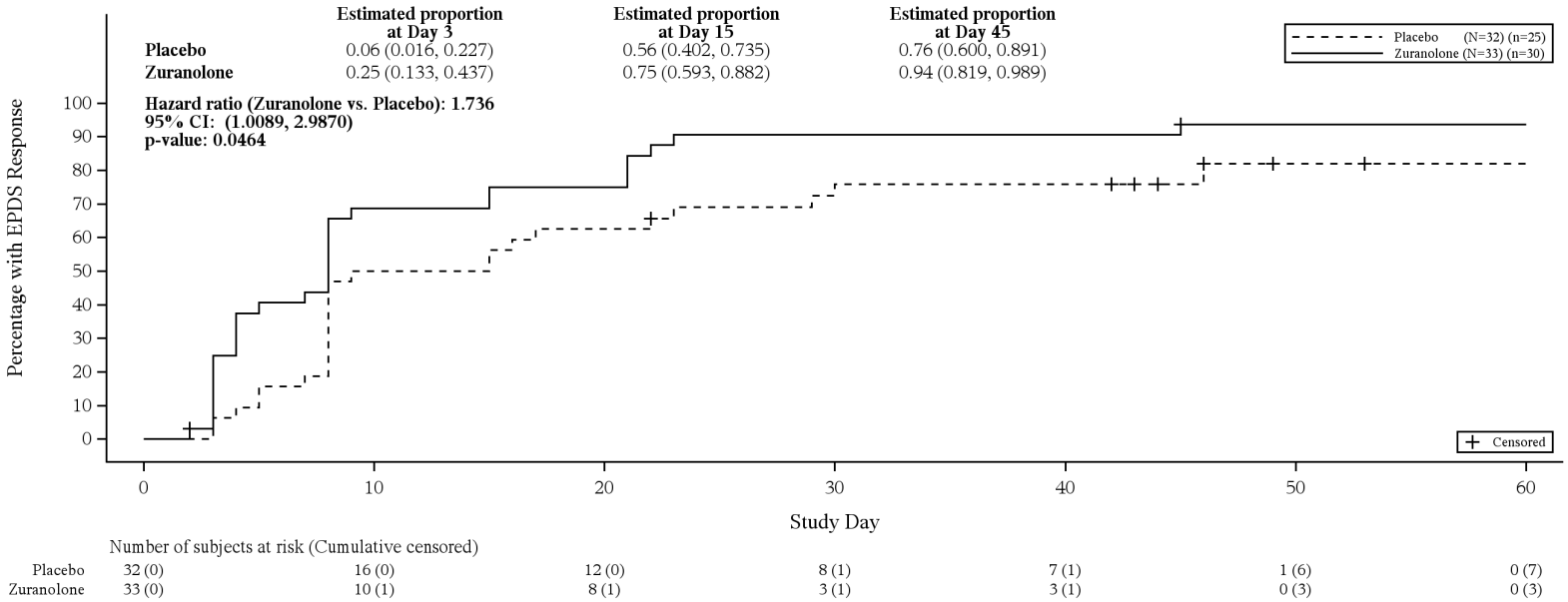
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline EPDS total score, and treatment. Model covariate antidepressant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

Source: biib125/v_a/amnog_kmplots/f-epds-resp15-tte-301-by.sas:f-epds-resp15-tte-301-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-301 - 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	32 (0)	16 (0)	12 (0)	8 (1)	7 (1)	1 (6)	0 (7)
Zuranolone	33 (0)	10 (1)	8 (1)	3 (1)	3 (1)	0 (3)	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.

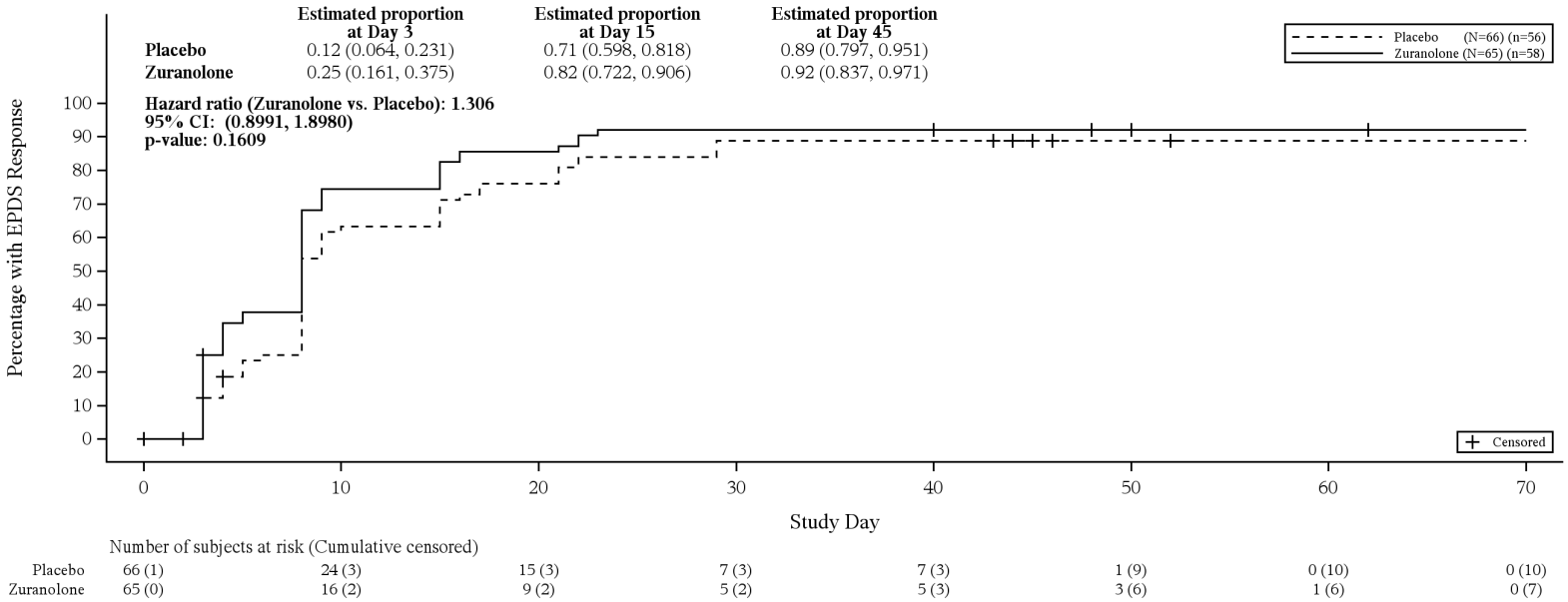
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline EPDS total score, and treatment. Model covariate antidepressant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

Source: biib125/v_a/amnog_kmplots/f-epds-resp15-tte-301-by.sas:f-epds-resp15-tte-301-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-301 - 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 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.

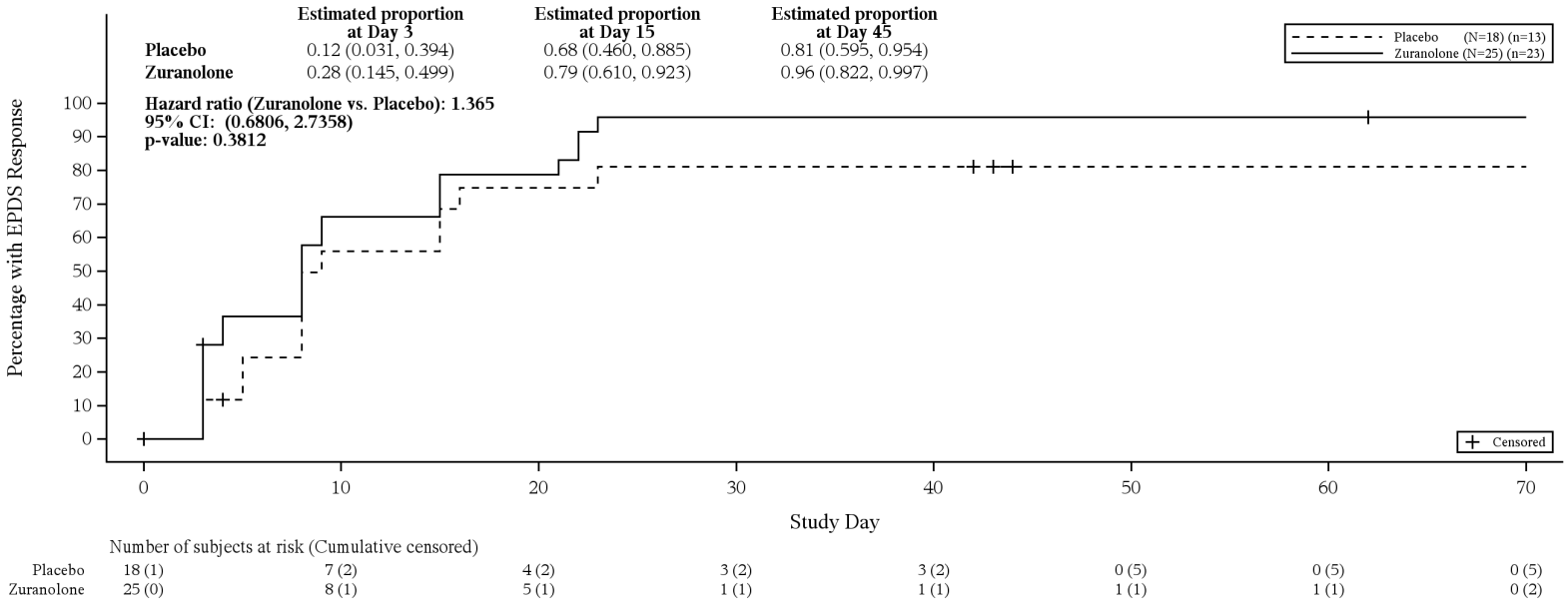
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline EPDS total score, and treatment. Model covariate antidepressant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

Source: biib125/v_a/amnog_kmplots/f-epds-resp15-tte-301-by.sas:f-epds-resp15-tte-301-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-301 - ITT population

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Race Group = Black or African American



Number of subjects at risk (Cumulative censored)

Placebo	18 (1)	7 (2)	4 (2)	3 (2)	3 (2)	0 (5)	0 (5)	0 (5)
Zuranolone	25 (0)	8 (1)	5 (1)	1 (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 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.

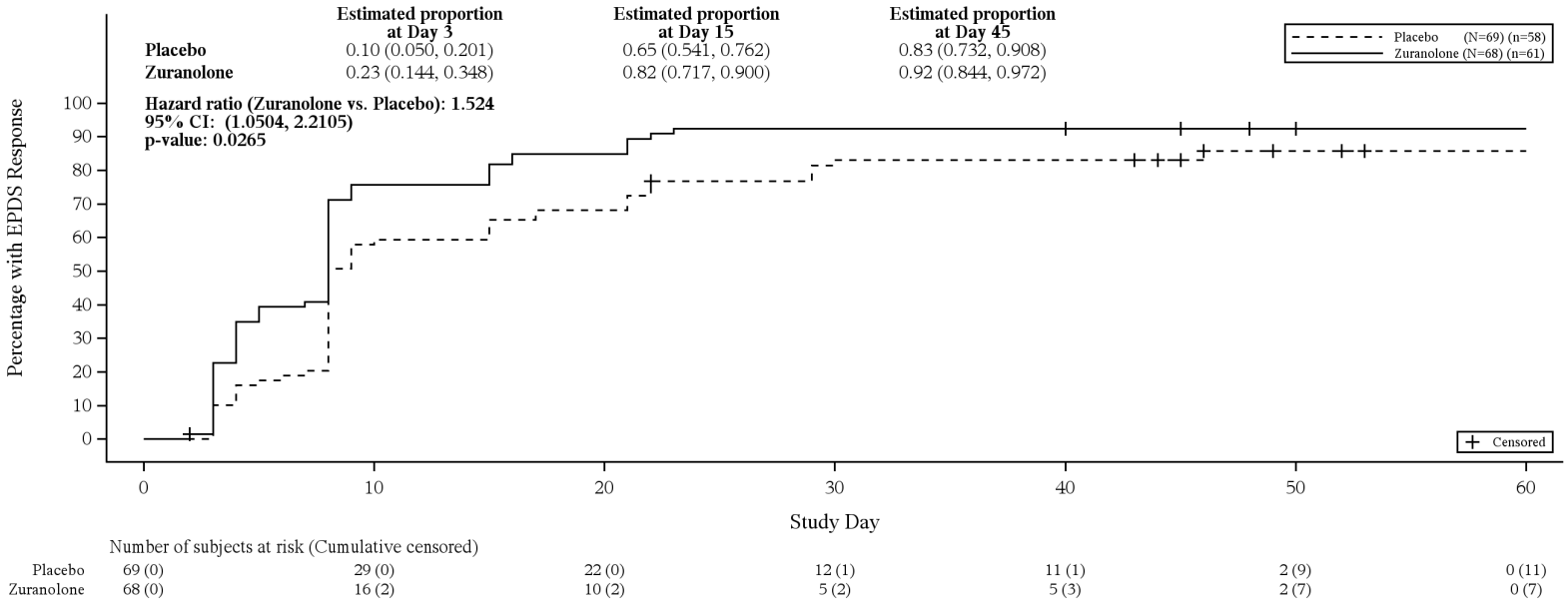
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline EPDS total score, and treatment. Model covariate antidepressant 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-301 - 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.

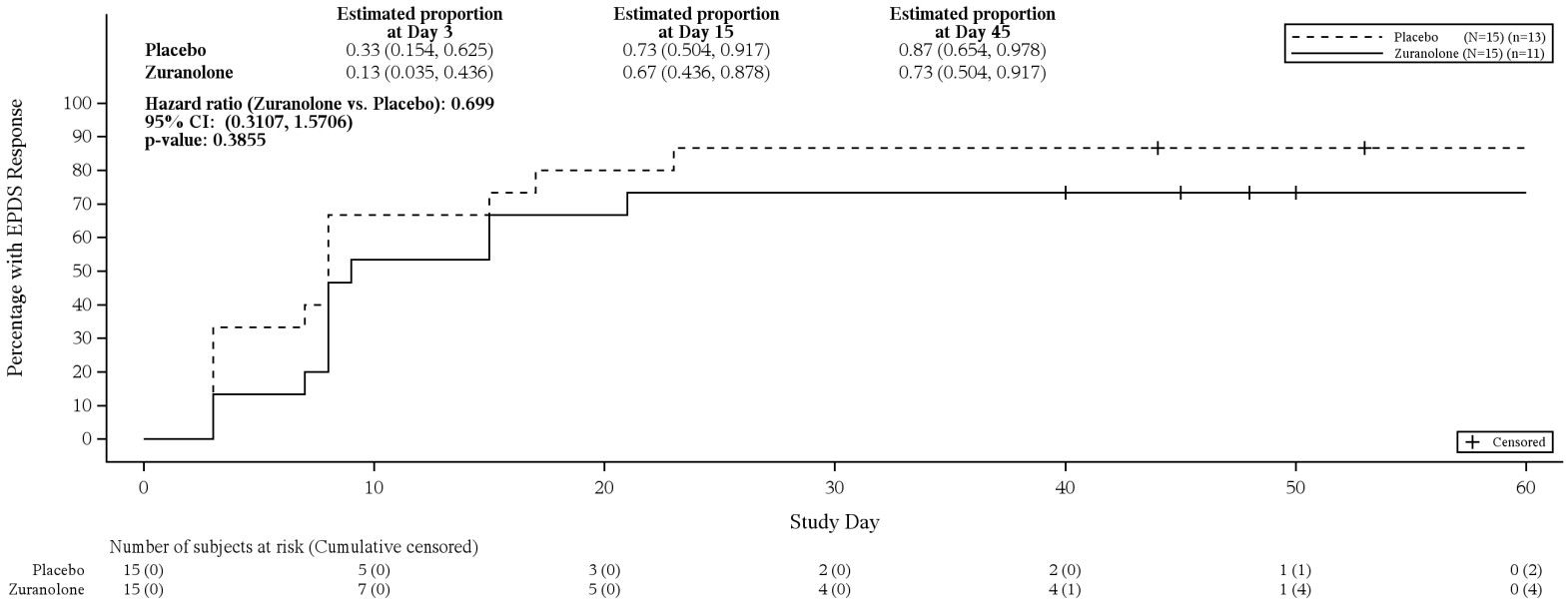
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline EPDS total score, and treatment. Model covariate antidepressant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

Source: biib125/v_a/amnog_kmplots/f-epds-resp15-tte-301-by.sas:f-epds-resp15-tte-301-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-301 - 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 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.

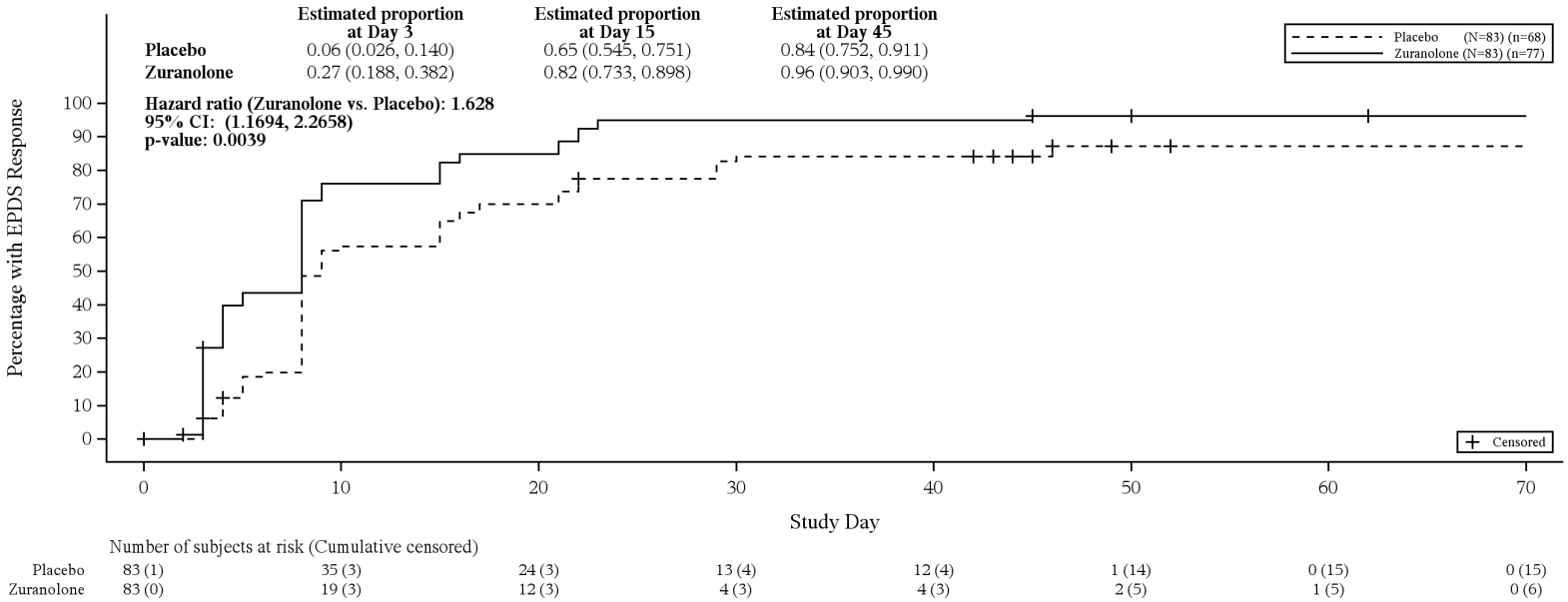
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline EPDS total score, and treatment. Model covariate antidepressant 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-301 - ITT population

Page: 8 of 19

Antidepressant Use at Baseline = No



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.

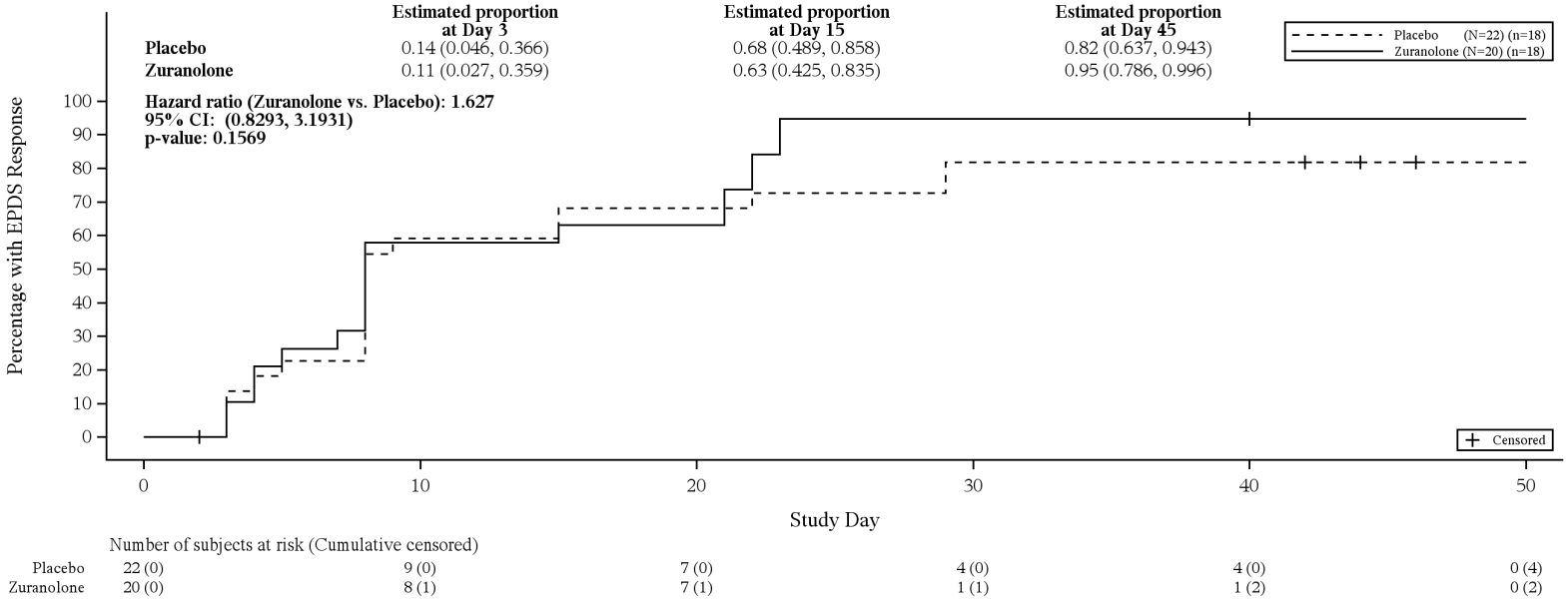
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline EPDS total score, and treatment. Model covariate antidepressant 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-301 - ITT population

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



Number of subjects at risk (Cumulative censored)

Placebo	22 (0)	9 (0)	7 (0)	4 (0)	4 (0)	0 (4)
Zuranolone	20 (0)	8 (1)	7 (1)	1 (1)	1 (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.

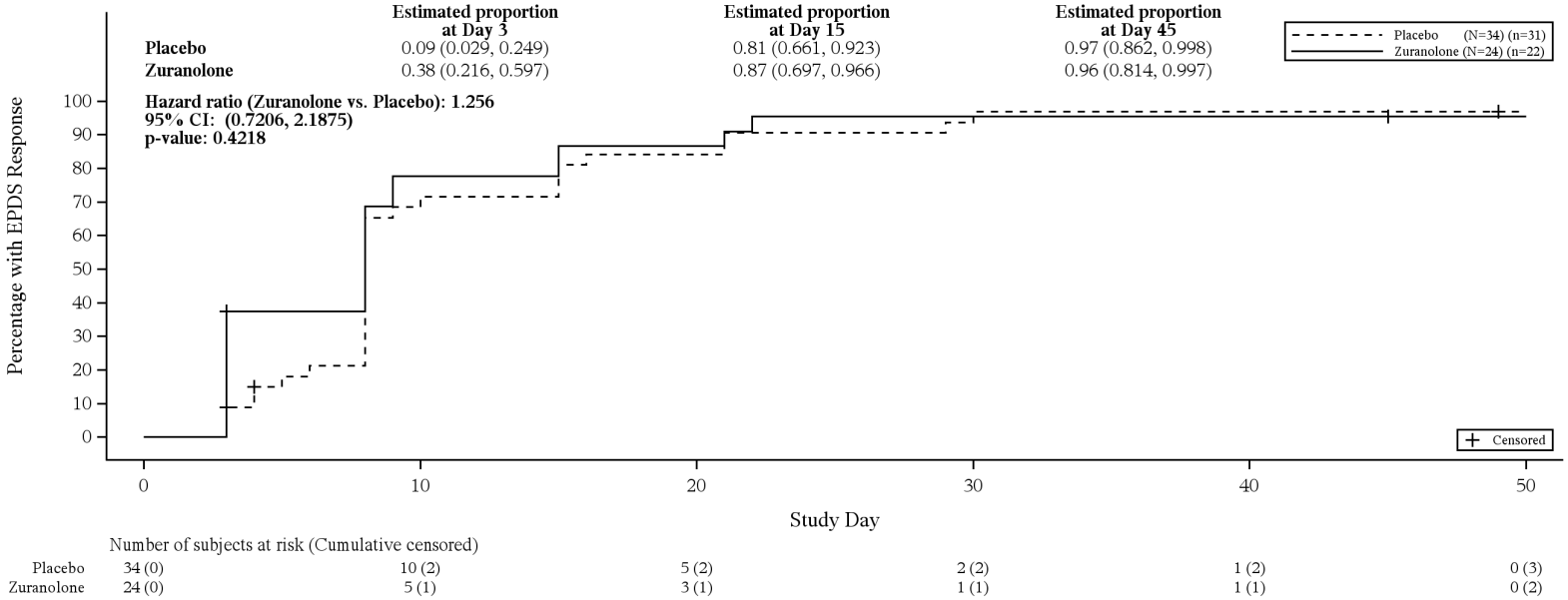
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline EPDS total score, and treatment. Model covariate antidepressant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

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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-301 - ITT population

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



Number of subjects at risk (Cumulative censored)

Placebo	34 (0)	10 (2)	5 (2)	2 (2)	1 (2)	0 (3)
Zuranolone	24 (0)	5 (1)	3 (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 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.

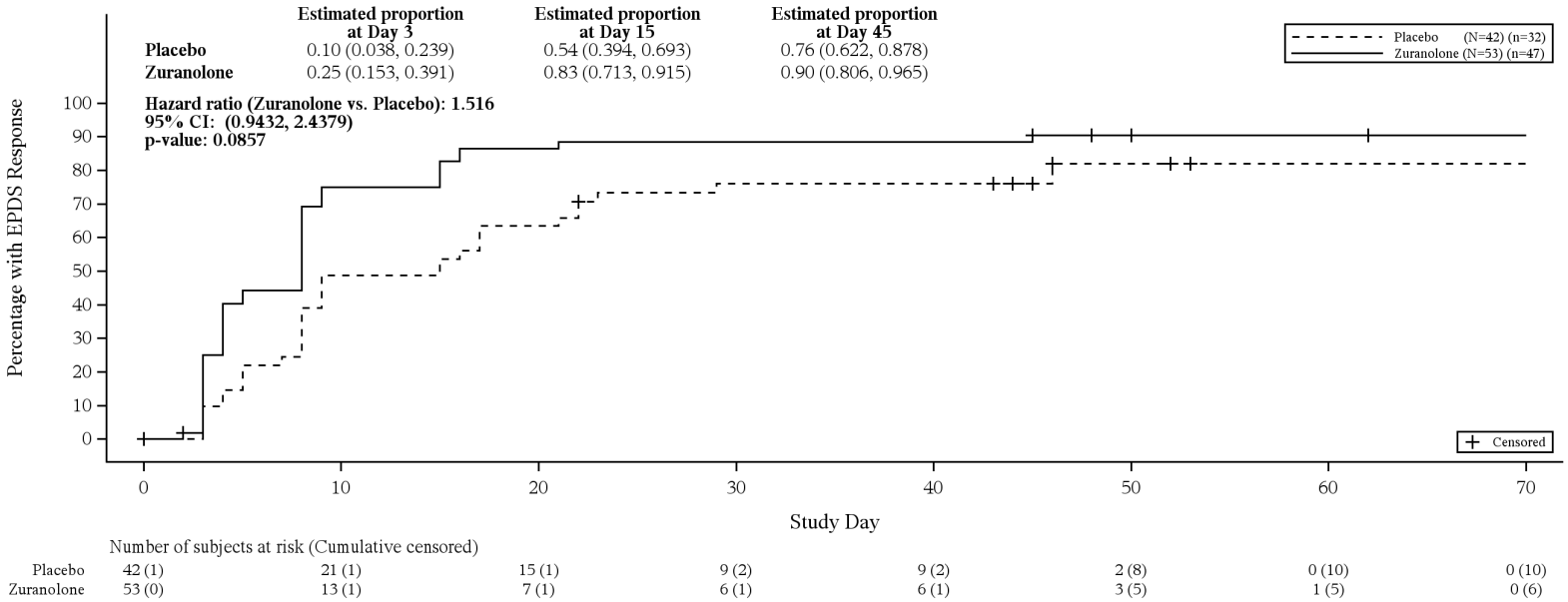
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline EPDS total score, and treatment. Model covariate antidepressant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

Source: biib125/v_a/amnog_kmplots/f-epds-resp15-tte-301-by.sas:f-epds-resp15-tte-301-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-301 - ITT population

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



Number of subjects at risk (Cumulative censored)

Placebo	42 (1)	21 (1)	15 (1)	9 (2)	9 (2)	2 (8)	0 (10)	0 (10)
Zuranolone	53 (0)	13 (1)	7 (1)	6 (1)	6 (1)	3 (5)	1 (5)	0 (6)

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.

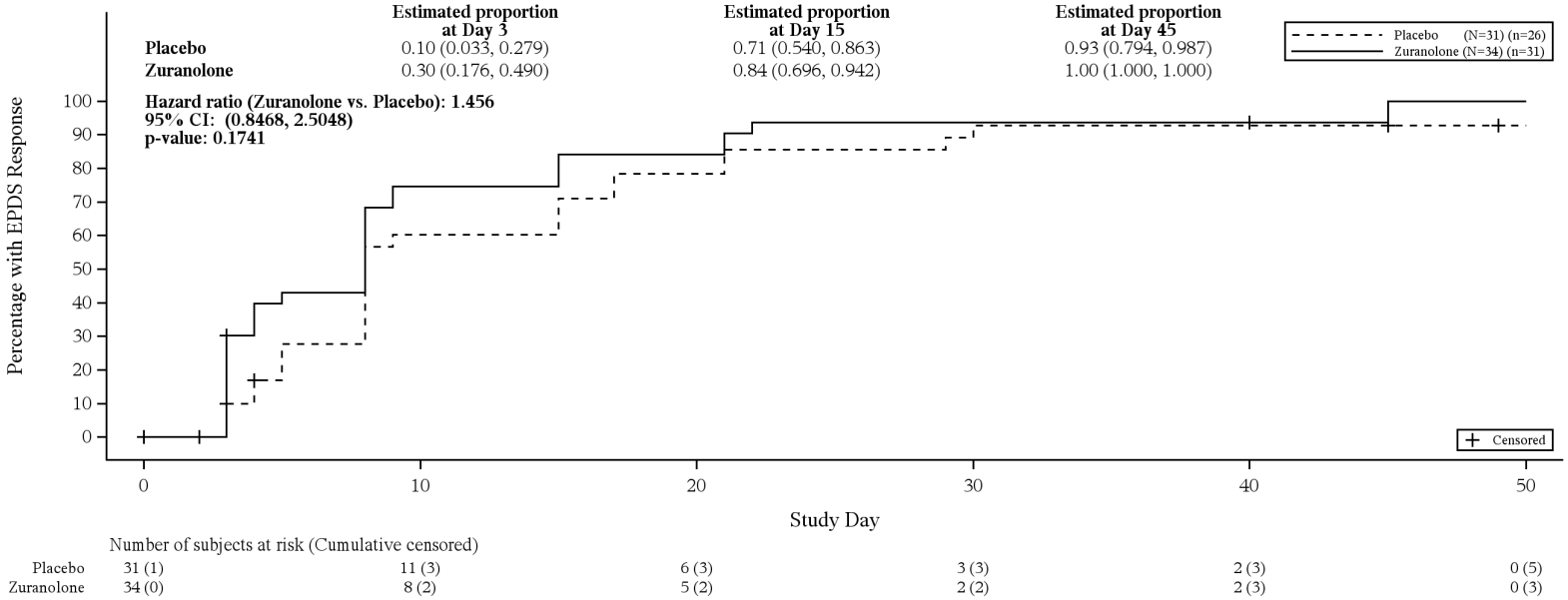
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline EPDS total score, and treatment. Model covariate antidepressant 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-301 - 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 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.

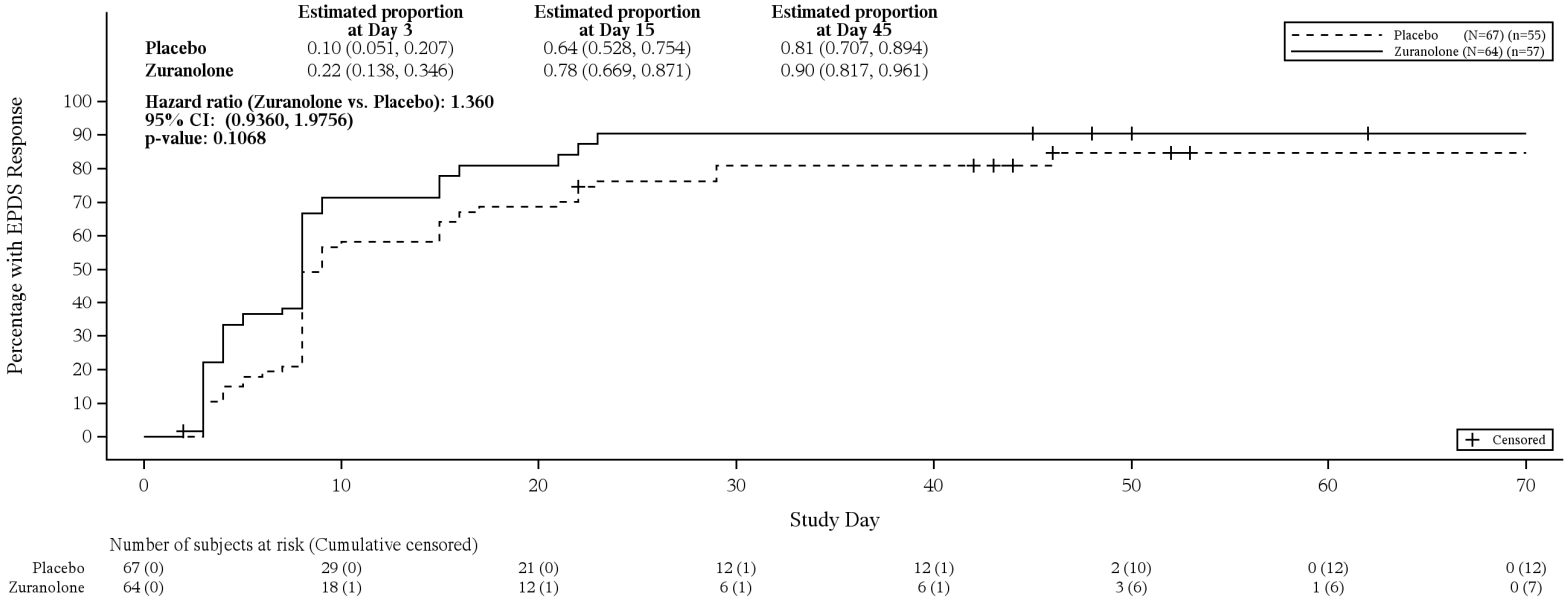
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline EPDS total score, and treatment. Model covariate antidepressant 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-301 - 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.

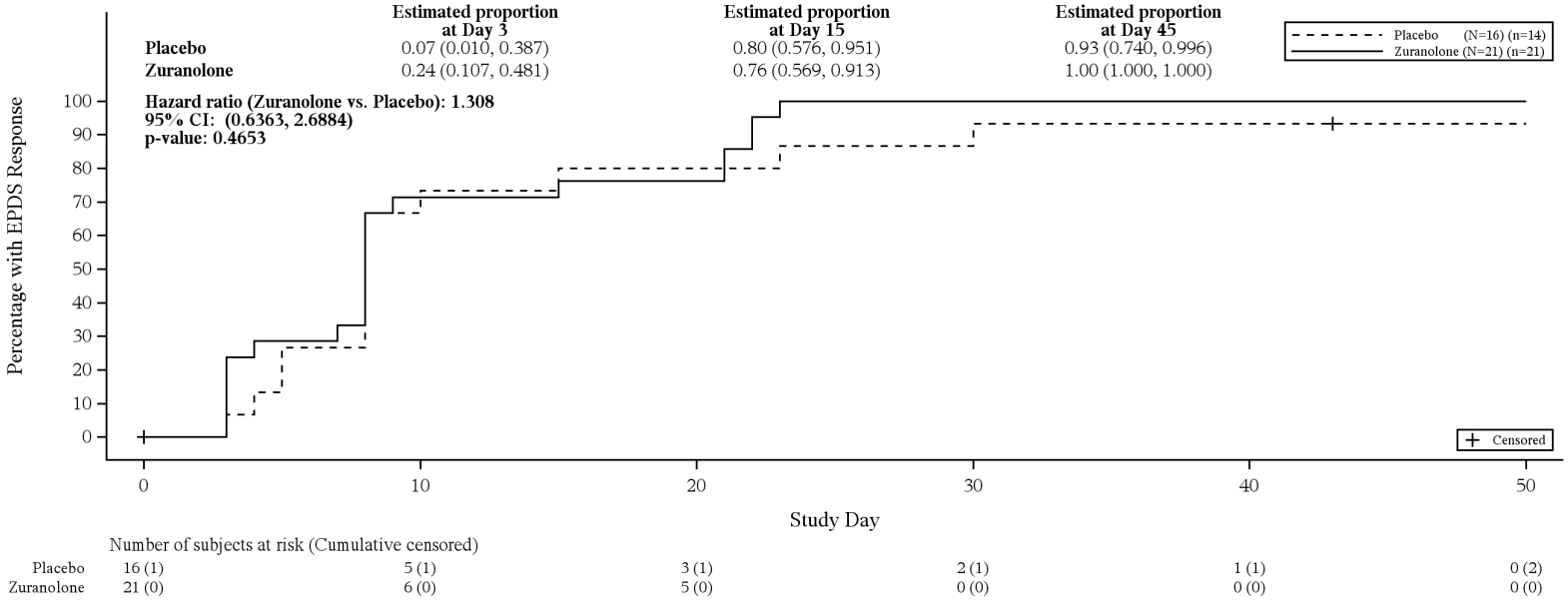
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline EPDS total score, and treatment. Model covariate antidepressant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

Source: biib125/v_a/amnog_kmplots/f-epds-resp15-tte-301-by.sas:f-epds-resp15-tte-301-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-301 - ITT population

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Family History of PPD = Yes



Number of subjects at risk (Cumulative censored)

Placebo	16 (1)	5 (1)	3 (1)	2 (1)	1 (1)	0 (2)
Zuranolone	21 (0)	6 (0)	5 (0)	0 (0)	0 (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.

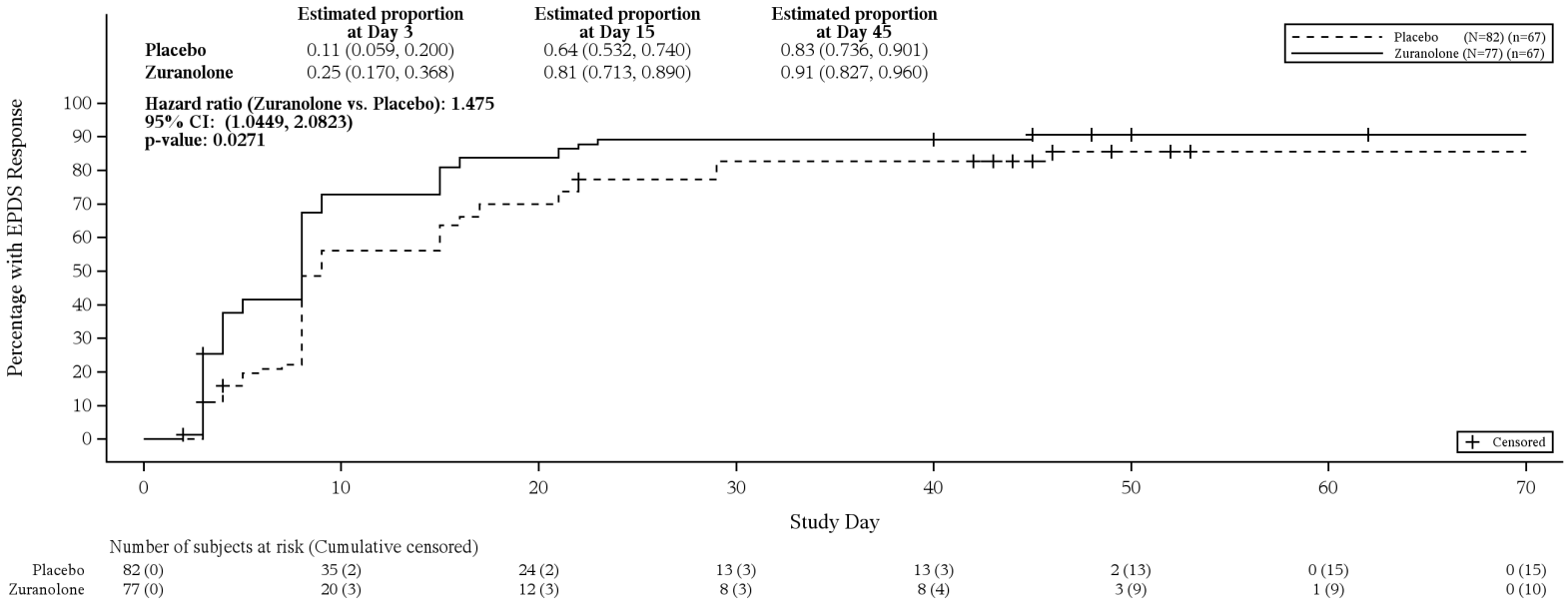
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline EPDS total score, and treatment. Model covariate antidepressant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

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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-301 - ITT population

Page: 15 of 19

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.

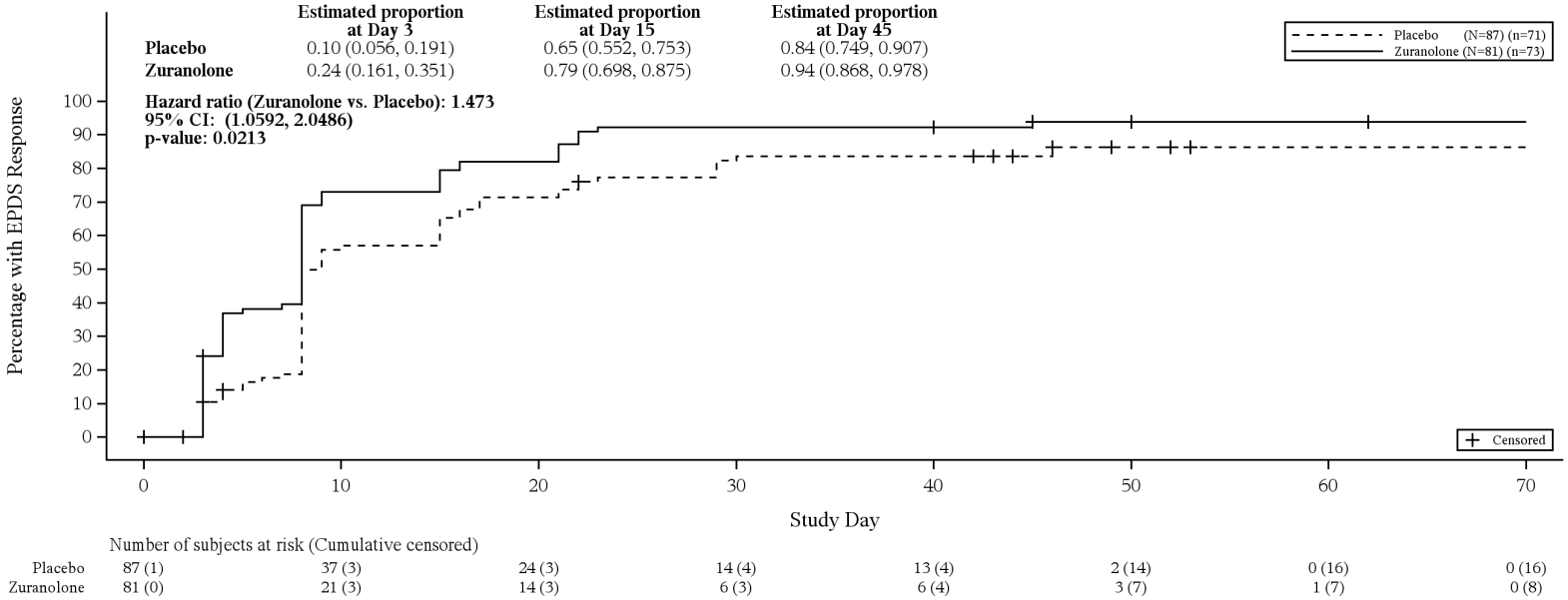
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline EPDS total score, and treatment. Model covariate antidepressant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

Source: biib125/v_a/amnog_kmplots/f-epds-resp15-tte-301-by.sas:f-epds-resp15-tte-301-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-301 - 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.

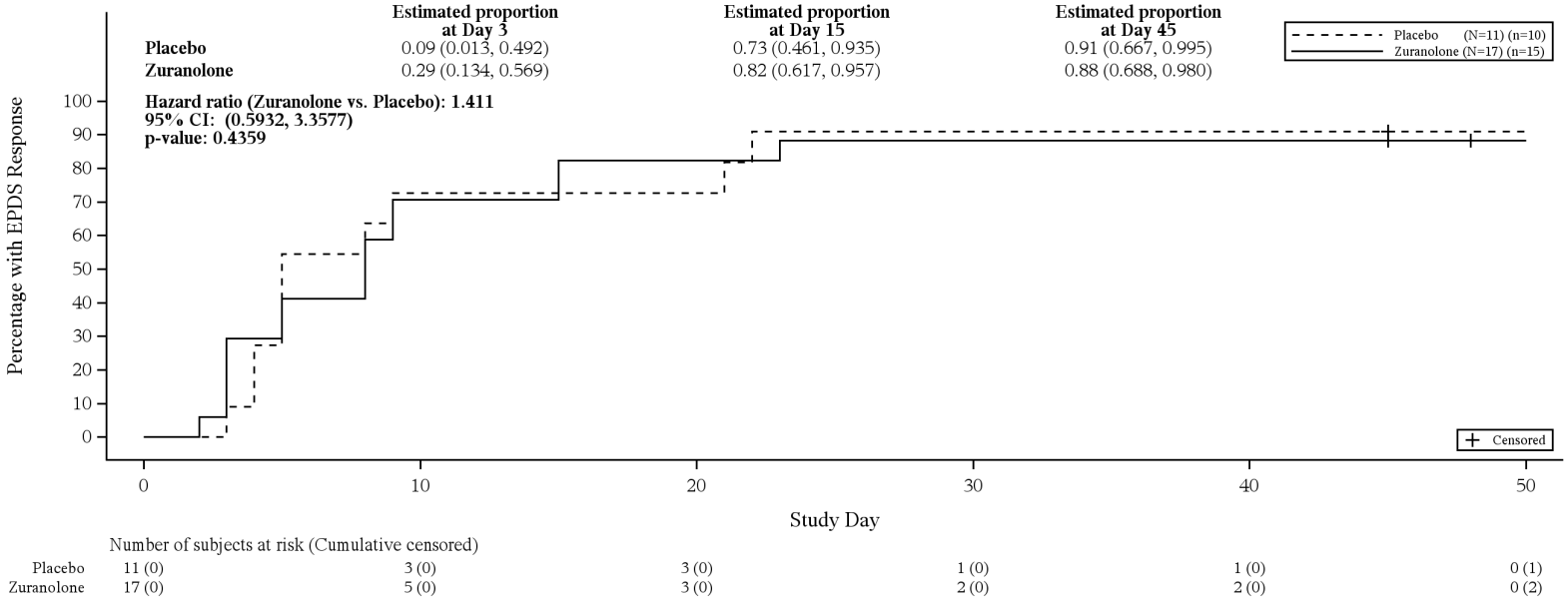
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline EPDS total score, and treatment. Model covariate antidepressant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

Source: biib125/v_a/amnog_kmplots/f-epds-resp15-tte-301-by.sas:f-epds-resp15-tte-301-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-301 - ITT population

Page: 17 of 19

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.

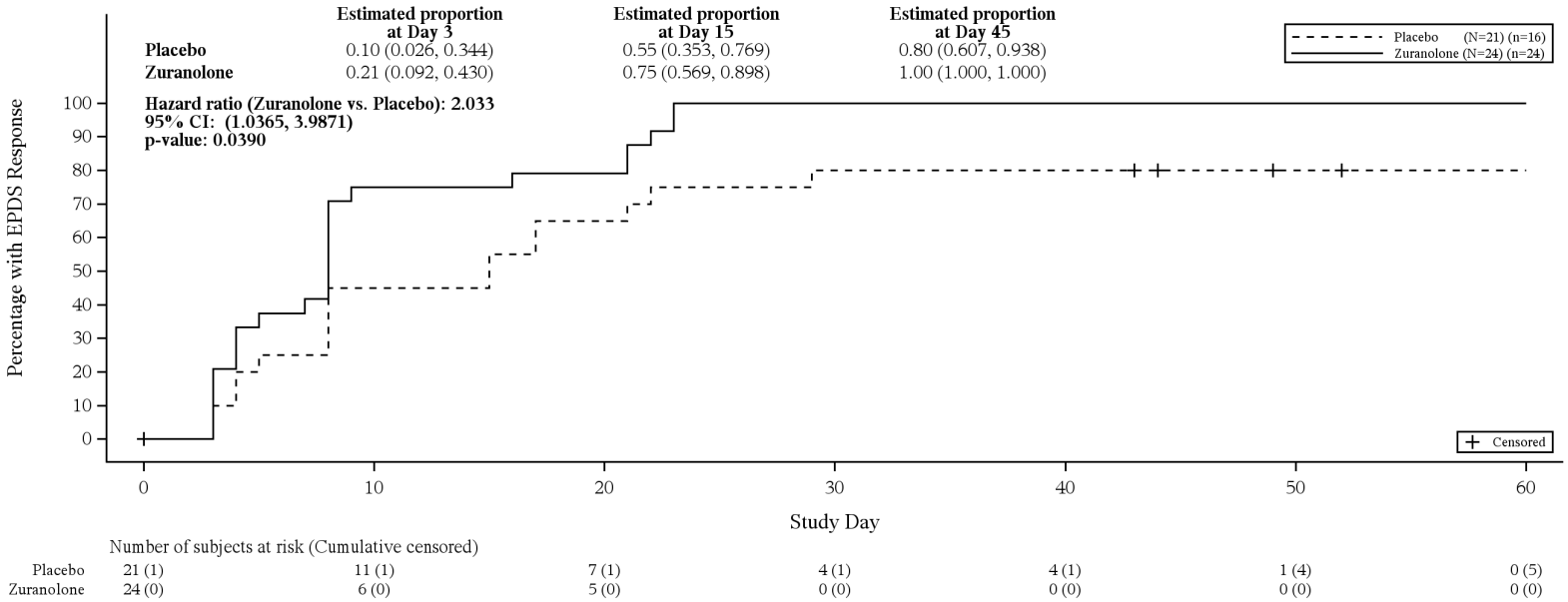
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline EPDS total score, and treatment. Model covariate antidepressant 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-301 - 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.

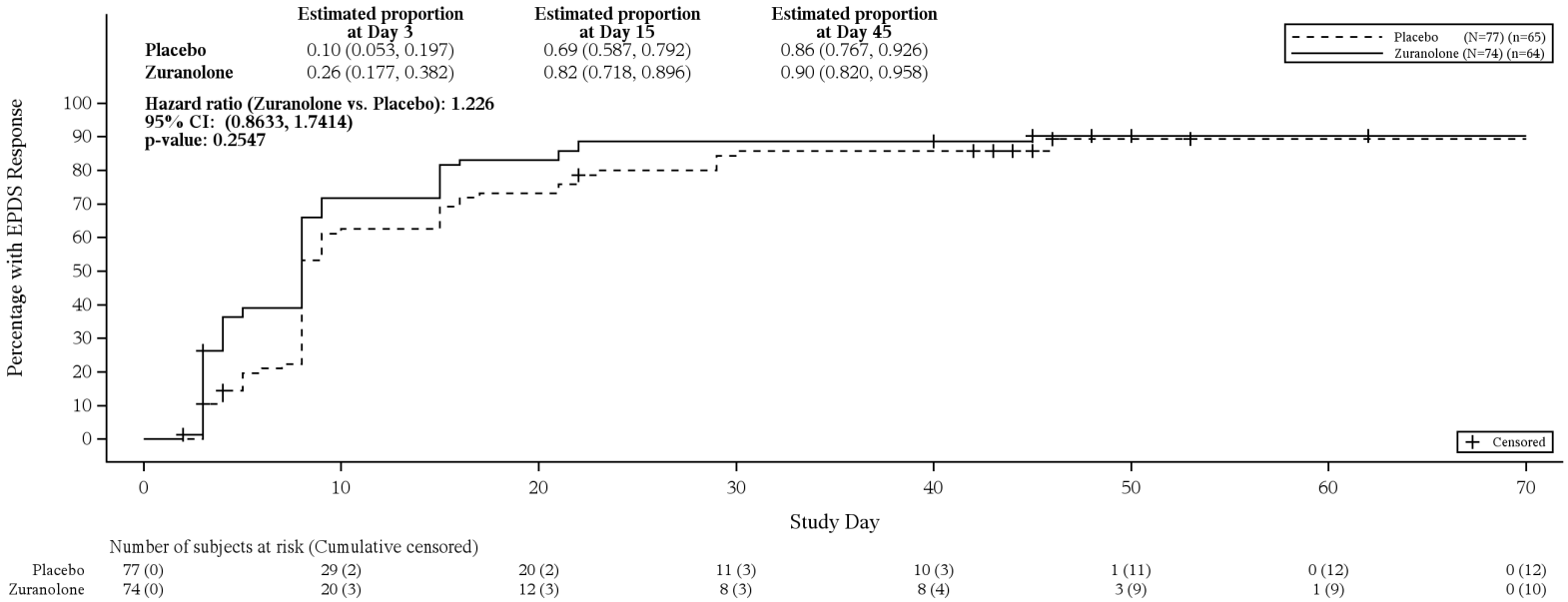
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Kaplan-Meier Plot for Time to First Edinburgh Postpartum Depression Scale (EPDS) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-301 - ITT population

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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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2.3.3 Verschlechterung

2.3.3.1 Responder-Analysen

2.3.3.1 .1 ITT-Population

Summary of Edinburgh Postpartum Depression Scale (EPDS) Worsening (>=15% of total scale range increase from baseline): 217-PPD-301 - ITT population

Page: 1 of 6

Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Number of evaluable subjects [1]	98	98
Day 3		
Number of subjects with worsening, n (%) [2]	4 (4.1)	0
Number of subjects with missing evaluation, n (%)	4 (4.1)	1 (1.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.11
95% CI for the RR		(0.006, 2.036)
p-value for RR		0.1387
OR - Odds Ratio (Zuranolone vs. Placebo)		0.11
95% CI for the OR		(0.006, 2.007)
p-value for OR		0.1350
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.04
95% CI for the ARR		(-0.084, 0.003)
p-value for ARR		0.0677

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-wors15-301-ovr.sas:t-epds-wors15-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Worsening (>=15% of total scale range increase from baseline): 217-PPD-301 - ITT population

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Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 8		
Number of subjects with worsening, n (%) [2]	1 (1.0)	1 (1.0)
Number of subjects with missing evaluation, n (%)	3 (3.1)	5 (5.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.00
95% CI for the RR		(0.063, 15.762)
p-value for RR		1.0000
OR - Odds Ratio (Zuranolone vs. Placebo)		1.00
95% CI for the OR		(0.062, 16.217)
p-value for OR		1.0000
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.00
95% CI for the ARR		(-0.028, 0.028)
p-value for ARR		1.0000

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-wors15-301-ovr.sas:t-epds-wors15-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Worsening (>=15% of total scale range increase from baseline): 217-PPD-301 - ITT population

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Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 15		
Number of subjects with worsening, n (%) [2]	1 (1.0)	0
Number of subjects with missing evaluation, n (%)	9 (9.2)	7 (7.1)
RR - Relative Risk (Zuranolone vs. Placebo)		0.33
95% CI for the RR		(0.014, 8.084)
p-value for RR		0.4995
OR - Odds Ratio (Zuranolone vs. Placebo)		0.33
95% CI for the OR		(0.013, 8.199)
p-value for OR		0.4988
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.01
95% CI for the ARR		(-0.038, 0.018)
p-value for ARR		0.4767

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-wors15-301-ovr.sas:t-epds-wors15-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Worsening (>=15% of total scale range increase from baseline): 217-PPD-301 - ITT population

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Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 21		
Number of subjects with worsening, n (%) [2]	0	0
Number of subjects with missing evaluation, n (%)	17 (17.3)	14 (14.3)

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-wors15-301-ovr.sas:t-epds-wors15-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Worsening (>=15% of total scale range increase from baseline): 217-PPD-301 - ITT population

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Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 28		
Number of subjects with worsening, n (%) [2]	1 (1.0)	1 (1.0)
Number of subjects with missing evaluation, n (%)	13 (13.3)	22 (22.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.00
95% CI for the RR		(0.063, 15.762)
p-value for RR		1.0000
OR - Odds Ratio (Zuranolone vs. Placebo)		1.00
95% CI for the OR		(0.062, 16.217)
p-value for OR		1.0000
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.00
95% CI for the ARR		(-0.028, 0.028)
p-value for ARR		1.0000

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-wors15-301-ovr.sas:t-epds-wors15-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Worsening (>=15% of total scale range increase from baseline): 217-PPD-301 - ITT population

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Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 45		
Number of subjects with worsening, n (%) [2]	2 (2.0)	1 (1.0)
Number of subjects with missing evaluation, n (%)	13 (13.3)	14 (14.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.50
95% CI for the RR		(0.046, 5.424)
p-value for RR		0.5688
OR - Odds Ratio (Zuranolone vs. Placebo)		0.49
95% CI for the OR		(0.044, 5.548)
p-value for OR		0.5683
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.01
95% CI for the ARR		(-0.045, 0.024)
p-value for ARR		0.5603

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-wors15-301-ovr.sas:t-epds-wors15-301-ovr-itta.rtf **Run Date:** 18JUL2025

2.3.3.1 .2 Subgruppen

2.3.3.1 .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-301 - ITT population

Page: 1 of 6

Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	98	98	
Number of subjects with response at Day 15, n (%)	1 (1.0)	0	
Number of subjects with response at Day 45, n (%)	2 (2.0)	1 (1.0)	
Age Group (years)			NA
Day 15			
18 - 24, n / N (%)	0/12	0/19	
25 - 45, n / N (%)	1/86 (1.2)	0/79	
Day 45			
18 - 24, n / N (%)	1/12 (8.3)	0/19	
25 - 45, n / N (%)	1/86 (1.2)	1/79 (1.3)	

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-wors15-301-int.sas:t-epds-wors15-301-int-itta.rtf **Run Date:** 24JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Worsening (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	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 (%)	1/32 (3.1)	0/33	
>=28, n / N (%)	0/66	0/65	
Day 45			
<28, n / N (%)	0/32	1/33 (3.0)	
>=28, n / N (%)	2/66 (3.0)	0/65	
Race Group (Black or African American, White)			NA
Day 15			
Black or African American, n / N (%)	1/18 (5.6)	0/25	
White, n / N (%)	0/69	0/68	
Day 45			
Black or African American, n / N (%)	0/18	0/25	
White, n / N (%)	2/69 (2.9)	1/68 (1.5)	

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-wors15-301-int.sas:t-epds-wors15-301-int-itta.rtf **Run Date:** 24JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Worsening (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			NA
Day 15			
Yes, n / N (%)	0/15	0/15	
No, n / N (%)	1/83 (1.2)	0/83	
Day 45			
Yes, n / N (%)	1/15 (6.7)	1/15 (6.7)	
No, n / N (%)	1/83 (1.2)	0/83	

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-wors15-301-int.sas:t-epds-wors15-301-int-itta.rtf **Run Date:** 24JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Worsening (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	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 (%)	0/22	0/20	
25-29.9, n / N (%)	0/34	0/24	
>=30, n / N (%)	1/42 (2.4)	0/53	
Day 45			
<=24.9, n / N (%)	0/22	0/20	
25-29.9, n / N (%)	0/34	0/24	
>=30, n / N (%)	2/42 (4.8)	1/53 (1.9)	

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-wors15-301-int.sas:t-epds-wors15-301-int-itta.rtf **Run Date:** 24JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Worsening (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Onset of PPD			NA
Day 15			
3rd Trimester, n / N (%)	0/31	0/34	
Postpartum, n / N (%)	1/67 (1.5)	0/64	
Day 45			
3rd Trimester, n / N (%)	1/31 (3.2)	0/34	
Postpartum, n / N (%)	1/67 (1.5)	1/64 (1.6)	
Family History of PPD			NA
Day 15			
Yes, n / N (%)	0/16	0/21	
No/Unknown, n / N (%)	1/82 (1.2)	0/77	
Day 45			
Yes, n / N (%)	0/16	0/21	
No/Unknown, n / N (%)	2/82 (2.4)	1/77 (1.3)	

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-wors15-301-int.sas:t-epds-wors15-301-int-itta.rtf **Run Date:** 24JUL2025

Summary of Edinburgh Postpartum Depression Scale (EPDS) Worsening (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
History of PPD			NA
Day 15			
1st Episode, n / N (%)	1/87 (1.1)	0/81	
Recurrent Episode, n / N (%)	0/11	0/17	
Day 45			
1st Episode, n / N (%)	1/87 (1.1)	0/81	
Recurrent Episode, n / N (%)	1/11 (9.1)	1/17 (5.9)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			NA
Day 15			
<20, n / N (%)	0/21	0/24	
>=20, n / N (%)	1/77 (1.3)	0/74	
Day 45			
<20, n / N (%)	0/21	0/24	
>=20, n / N (%)	2/77 (2.6)	1/74 (1.4)	

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-wors15-301-int.sas:t-epds-wors15-301-int-itta.rtf **Run Date:** 24JUL2025

2.3.3.1 .2 .2 Subgruppenanalysen

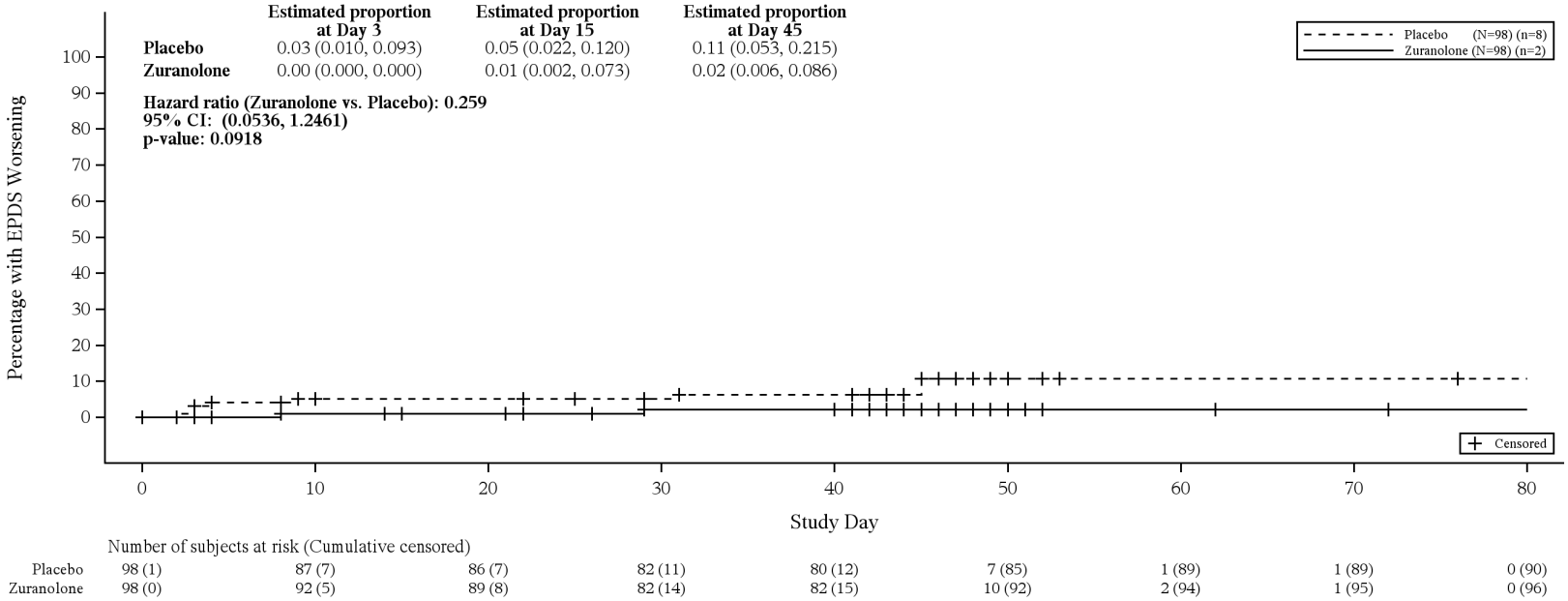
Nicht zutreffend.

2.3.3.2 TTE-Analysen

2.3.3.2 .1 ITT-Population

Kaplan-Meier Plot for Time to First Edinburgh Postpartum Depression Scale (EPDS) Worsening (>=15% of total scale range increase from baseline): 217-PPD-301 - ITT population

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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-301-ovr.sas:f-epds-wors15-tte-301-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-301 - ITT population

Page: 1 of 1

	Placebo (N=101)	Zuranolone (N=99)
Number of evaluable subjects [1]	98	98
Number of subjects with response, n (%) [2]	8 (8.2)	2 (2.0)
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]		0.259
95% CI for the HR		(0.0536 , 1.2461)
p-value for the HR		0.0918

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-301-ovr.sas:t-epds-wors15-tte-301-ovr-itta.rtf **Run Date:** 18JUL2025

2.3.3.2 .2 Subgruppen

2.3.3.2 .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-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	98	98	
Number of subjects with response, n (%)	8 (8.2)	2 (2.0)	
Age Group (years)			
18 - 24, n / N (%)	2/12 (16.7)	0/19	NA
25 - 45, n / N (%)	6/86 (7.0)	2/79 (2.5)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	5/32 (15.6)	1/33 (3.0)	NA
>=28, n / N (%)	3/66 (4.5)	1/65 (1.5)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	2/18 (11.1)	0/25	NA
White, n / N (%)	6/69 (8.7)	2/68 (2.9)	
Antidepressant Use at Baseline			
Yes, n / N (%)	3/15 (20.0)	2/15 (13.3)	NA
No, n / N (%)	5/83 (6.0)	0/83	

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-301-int.sas:t-epds-wors15-tte-301-int-itta.rtf **Run Date:** 24JUL2025

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-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9, n / N (%)	1/22 (4.5)	0/20	NA(a)
25-29.9, n / N (%)	2/34 (5.9)	0/24	NA(b)
>=30, n / N (%)	5/42 (11.9)	2/53 (3.8)	NA(c)
Onset of PPD			
3rd Trimester, n / N (%)	2/31 (6.5)	0/34	NA
Postpartum, n / N (%)	6/67 (9.0)	2/64 (3.1)	
Family History of PPD			
Yes, n / N (%)	4/16 (25.0)	0/21	NA
No/Unknown, n / N (%)	4/82 (4.9)	2/77 (2.6)	
History of PPD			
1st Episode, n / N (%)	7/87 (8.0)	0/81	NA
Recurrent Episode, n / N (%)	1/11 (9.1)	2/17 (11.8)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	0/21	0/24	NA
>=20, n / N (%)	8/77 (10.4)	2/74 (2.7)	

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-301-int.sas:t-epds-wors15-tte-301-int-itta.rtf **Run Date:** 24JUL2025

2.3.3.2 .2 .2 Subgruppenanalysen

Nicht zutreffend.

2.3.3.2 .2 .3 Kaplan-Meier-Plots

Nicht zutreffend.

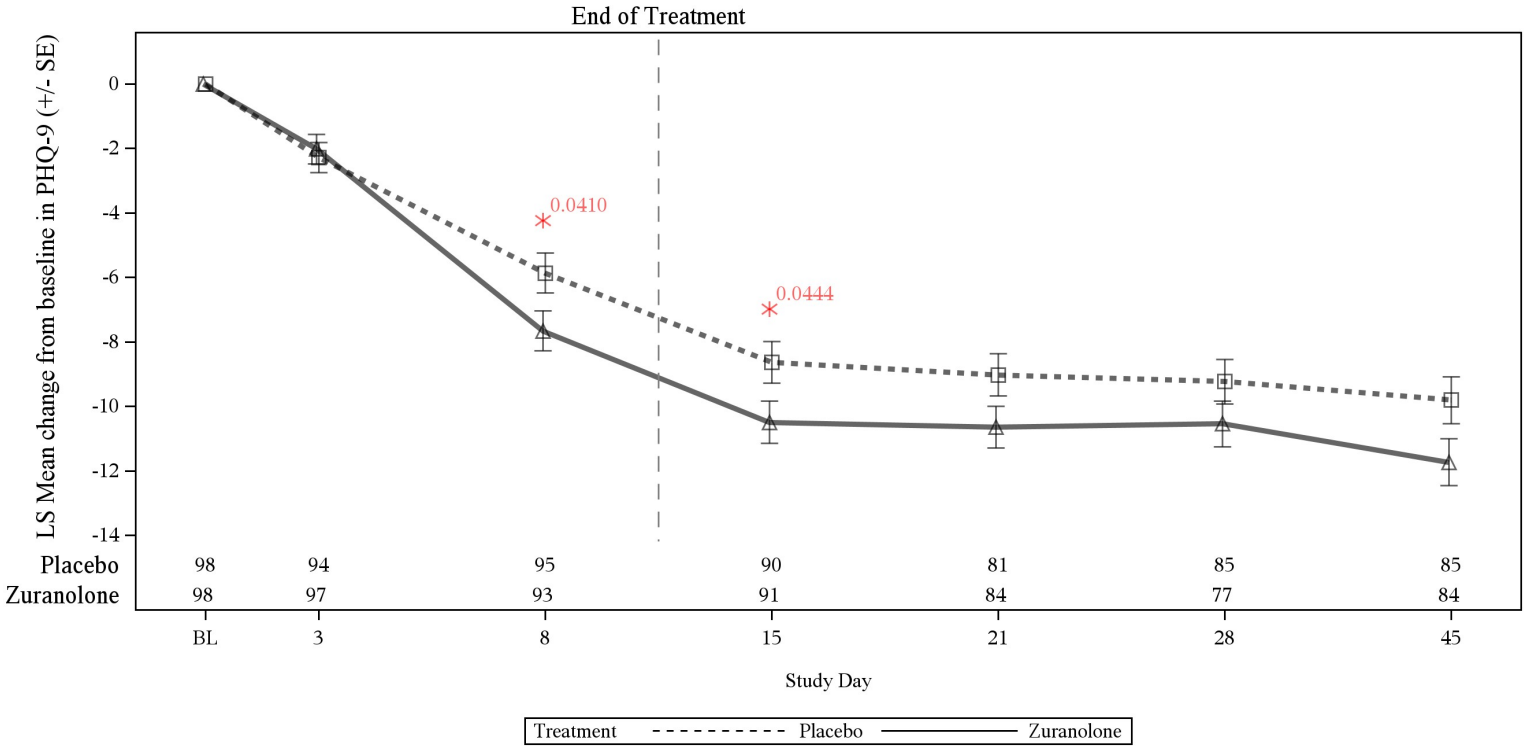
2.4 PHQ-9

2.4.1 MMRM

2.4.1.1 ITT-Population

Line Plot of LS Mean (+/- SE) Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score over Time: 217-PPD-301 - 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-301-ovr.sas:f-phq9-mmrm-301-ovr-itta.rtf **Run Date:** 18JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score: 217-PPD-301 - ITT population

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	Placebo (N=101)	Zuranolone (N=99)
Day 3		
n	94	97
LS Mean (SE)	-2.28 (0.462)	-2.02 (0.456)
95% CI for the LS Mean	-3.19, -1.37	-2.92, -1.12
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.26 (0.649)
95% CI for the LS Mean		-1.02, 1.54
p-value		0.6912
Hedges' g (Zuranolone vs. Placebo)		0.057
95% CI for Hedges' g		-0.2264, 0.3411
Day 8		
n	95	93
LS Mean (SE)	-5.86 (0.617)	-7.66 (0.620)
95% CI for the LS Mean	-7.07, -4.64	-8.88, -6.43
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.80 (0.874)
95% CI for the LS Mean		-3.52, -0.07
p-value		0.0410
Hedges' g (Zuranolone vs. Placebo)		-0.299
95% CI for Hedges' g		-0.5864, -0.0114

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-301-ovr.sas:t-phq9-mmrm-301-ovr-itta.rtf **Run Date:** 18JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score: 217-PPD-301 - ITT population

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	Placebo (N=101)	Zuranolone (N=99)
Day 15		
n	90	91
LS Mean (SE)	-8.63 (0.652)	-10.49 (0.651)
95% CI for the LS Mean	-9.91, -7.34	-11.78, -9.21
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.87 (0.922)
95% CI for the LS Mean		-3.68, -0.05
p-value		0.0444
Hedges' g (Zuranolone vs. Placebo)		-0.300
95% CI for Hedges' g		-0.5927, -0.0067
Day 21		
n	81	84
LS Mean (SE)	-9.02 (0.655)	-10.64 (0.651)
95% CI for the LS Mean	-10.31, -7.73	-11.92, -9.35
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.62 (0.924)
95% CI for the LS Mean		-3.44, 0.20
p-value		0.0811
Hedges' g (Zuranolone vs. Placebo)		-0.272
95% CI for Hedges' g		-0.5785, 0.0347

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-301-ovr.sas:t-phq9-mmrm-301-ovr-itta.rtf **Run Date:** 18JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score: 217-PPD-301 - ITT population

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	Placebo (N=101)	Zuranolone (N=99)
Day 28		
n	85	77
LS Mean (SE)	-9.23 (0.692)	-10.54 (0.703)
95% CI for the LS Mean	-10.59, -7.86	-11.93, -9.15
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.31 (0.987)
95% CI for the LS Mean		-3.26, 0.63
p-value		0.1846
Hedges' g (Zuranolone vs. Placebo)		-0.209
95% CI for Hedges' g		-0.5177, 0.1006
Day 45		
n	85	84
LS Mean (SE)	-9.80 (0.728)	-11.73 (0.731)
95% CI for the LS Mean	-11.23, -8.36	-13.17, -10.29
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.93 (1.031)
95% CI for the LS Mean		-3.97, 0.10
p-value		0.0625
Hedges' g (Zuranolone vs. Placebo)		-0.287
95% CI for Hedges' g		-0.5901, 0.0160

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-301-ovr.sas:t-phq9-mmrm-301-ovr-itta.rtf **Run Date:** 18JUL2025

2.4.1.2 Subgruppen

2.4.1.2 .1 Interaktionstest

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score: Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Age Group (years)			
18 - 24	12	19	0.9493
25 - 45	86	79	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28	32	33	0.6946
>=28	66	65	
Race Group (Black or African American, White)			
Black or African American	18	25	0.1415
White	69	68	
Antidepressant Use at Baseline			
Yes	15	15	0.3560
No	83	83	

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-301-int.sas:t-phq9-mmrm-301-int-itta.rtf **Run Date:** 18JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score: Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9	22	20	0.1508(a)
25-29.9	34	24	0.3054(b)
>=30	42	53	0.5401(c)
Onset of PPD			
3rd Trimester	31	34	0.6274
Postpartum	67	64	
Family History of PPD			
Yes	16	21	0.2277
No/Unknown	82	77	
History of PPD			
1st Episode	87	81	0.4606
Recurrent Episode	11	17	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20	21	24	0.9451
>=20	77	74	

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-301-int.sas:t-phq9-mmrm-301-int-itta.rtf **Run Date:** 18JUL2025

2.4.1.2 .2 Subgruppenanalysen

2.4.1.2 .2 .1 Alter

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 18-24

	Placebo (N=13)	Zuranolone (N=19)
Day 3		
n	12	19
LS Mean (SE)	-5.14 (1.366)	-3.52 (1.083)
95% CI for the LS Mean	-7.94, -2.34	-5.74, -1.29
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.62 (1.746)
95% CI for the LS Mean		-1.96, 5.20
p-value		0.3605
Hedges' g (Zuranolone vs. Placebo)		0.334
95% CI for Hedges' g		-0.3935, 1.0614
Day 8		
n	12	19
LS Mean (SE)	-8.39 (2.100)	-10.78 (1.668)
95% CI for the LS Mean	-12.70, -4.08	-14.20, -7.36
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.39 (2.684)
95% CI for the LS Mean		-7.89, 3.11
p-value		0.3810
Hedges' g (Zuranolone vs. Placebo)		-0.320
95% CI for Hedges' g		-1.0468, 0.4073

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-301-by.sas:t-phq9-mmrm-301-by-age-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 18-24

	Placebo (N=13)	Zuranolone (N=19)
Day 15		
n	12	19
LS Mean (SE)	-11.14 (1.844)	-12.15 (1.464)
95% CI for the LS Mean	-14.92, -7.36	-15.15, -9.15
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.01 (2.357)
95% CI for the LS Mean		-5.84, 3.82
p-value		0.6722
Hedges' g (Zuranolone vs. Placebo)		-0.154
95% CI for Hedges' g		-0.8773, 0.5701
Day 21		
n	9	18
LS Mean (SE)	-12.33 (1.650)	-13.56 (1.266)
95% CI for the LS Mean	-15.71, -8.95	-16.16, -10.95
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.23 (2.082)
95% CI for the LS Mean		-5.49, 3.04
p-value		0.5609
Hedges' g (Zuranolone vs. Placebo)		-0.233
95% CI for Hedges' g		-1.0356, 0.5695

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-301-by.sas:t-phq9-mmrm-301-by-age-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 18-24

	Placebo (N=13)	Zuranolone (N=19)
Day 28		
n	12	17
LS Mean (SE)	-10.56 (2.006)	-12.34 (1.627)
95% CI for the LS Mean	-14.67, -6.44	-15.67, -9.01
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.79 (2.584)
95% CI for the LS Mean		-7.08, 3.51
p-value		0.4952
Hedges' g (Zuranolone vs. Placebo)		-0.253
95% CI for Hedges' g		-0.9952, 0.4885
Day 45		
n	11	18
LS Mean (SE)	-10.79 (1.891)	-13.86 (1.490)
95% CI for the LS Mean	-14.66, -6.92	-16.91, -10.81
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.07 (2.410)
95% CI for the LS Mean		-8.00, 1.86
p-value		0.2133
Hedges' g (Zuranolone vs. Placebo)		-0.473
95% CI for Hedges' g		-1.2332, 0.2866

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-301-by.sas:t-phq9-mmrm-301-by-age-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 25-45

	Placebo (N=88)	Zuranolone (N=80)
Day 3		
n	82	78
LS Mean (SE)	-1.84 (0.488)	-1.69 (0.502)
95% CI for the LS Mean	-2.80, -0.87	-2.68, -0.70
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.15 (0.700)
95% CI for the LS Mean		-1.23, 1.53
p-value		0.8306
Hedges' g (Zuranolone vs. Placebo)		0.034
95% CI for Hedges' g		-0.2763, 0.3437
Day 8		
n	83	74
LS Mean (SE)	-5.47 (0.625)	-6.89 (0.658)
95% CI for the LS Mean	-6.71, -4.24	-8.19, -5.59
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.41 (0.908)
95% CI for the LS Mean		-3.21, 0.38
p-value		0.1210
Hedges' g (Zuranolone vs. Placebo)		-0.248
95% CI for Hedges' g		-0.5626, 0.0665

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-301-by.sas:t-phq9-mmrm-301-by-age-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 25-45

	Placebo (N=88)	Zuranolone (N=80)
Day 15		
n	78	72
LS Mean (SE)	-8.24 (0.703)	-10.12 (0.734)
95% CI for the LS Mean	-9.63, -6.85	-11.57, -8.67
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.87 (1.016)
95% CI for the LS Mean		-3.88, 0.13
p-value		0.0670
Hedges' g (Zuranolone vs. Placebo)		-0.300
95% CI for Hedges' g		-0.6221, 0.0221
Day 21		
n	72	66
LS Mean (SE)	-8.55 (0.713)	-9.93 (0.746)
95% CI for the LS Mean	-9.96, -7.15	-11.40, -8.45
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.37 (1.032)
95% CI for the LS Mean		-3.41, 0.66
p-value		0.1848
Hedges' g (Zuranolone vs. Placebo)		-0.226
95% CI for Hedges' g		-0.5608, 0.1093

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-301-by.sas:t-phq9-mmrm-301-by-age-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 25-45

	Placebo (N=88)	Zuranolone (N=80)
Day 28		
n	73	60
LS Mean (SE)	-9.03 (0.739)	-10.18 (0.786)
95% CI for the LS Mean	-10.49, -7.57	-11.73, -8.63
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.15 (1.079)
95% CI for the LS Mean		-3.28, 0.99
p-value		0.2898
Hedges' g (Zuranolone vs. Placebo)		-0.184
95% CI for Hedges' g		-0.5263, 0.1582
Day 45		
n	74	66
LS Mean (SE)	-9.63 (0.794)	-11.25 (0.836)
95% CI for the LS Mean	-11.20, -8.06	-12.90, -9.60
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.62 (1.153)
95% CI for the LS Mean		-3.90, 0.66
p-value		0.1613
Hedges' g (Zuranolone vs. Placebo)		-0.237
95% CI for Hedges' g		-0.5700, 0.0960

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-301-by.sas:t-phq9-mmrm-301-by-age-itta.rtf **Run Date:** 25JUL2025

2.4.1.2 .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-301 - ITT population

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

	Placebo (N=32)	Zuranolone (N=33)
Day 3		
n	32	32
LS Mean (SE)	-1.87 (0.661)	-1.60 (0.659)
95% CI for the LS Mean	-3.19, -0.55	-2.91, -0.28
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.28 (0.934)
95% CI for the LS Mean		-1.59, 2.15
p-value		0.7668
Hedges' g (Zuranolone vs. Placebo)		0.074
95% CI for Hedges' g		-0.4166, 0.5637
Day 8		
n	32	32
LS Mean (SE)	-5.09 (1.137)	-6.40 (1.133)
95% CI for the LS Mean	-7.37, -2.82	-8.67, -4.14
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.31 (1.605)
95% CI for the LS Mean		-4.52, 1.90
p-value		0.4171
Hedges' g (Zuranolone vs. Placebo)		-0.202
95% CI for Hedges' g		-0.6931, 0.2894

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-301-by.sas:t-phq9-mmrm-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Baseline HAMD-17 Total Score: 217-PPD-301 - ITT population

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

	Placebo (N=32)	Zuranolone (N=33)
Day 15		
n	30	32
LS Mean (SE)	-7.46 (1.165)	-9.93 (1.142)
95% CI for the LS Mean	-9.79, -5.12	-12.22, -7.65
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.48 (1.632)
95% CI for the LS Mean		-5.75, 0.79
p-value		0.1340
Hedges' g (Zuranolone vs. Placebo)		-0.381
95% CI for Hedges' g		-0.8838, 0.1214
Day 21		
n	27	31
LS Mean (SE)	-7.33 (1.212)	-10.34 (1.171)
95% CI for the LS Mean	-9.75, -4.91	-12.68, -8.00
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.01 (1.685)
95% CI for the LS Mean		-6.38, 0.36
p-value		0.0789
Hedges' g (Zuranolone vs. Placebo)		-0.464
95% CI for Hedges' g		-0.9870, 0.0587

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-301-by.sas:t-phq9-mmrm-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Baseline HAMD-17 Total Score: 217-PPD-301 - ITT population

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

	Placebo (N=32)	Zuranolone (N=33)
Day 28		
n	26	28
LS Mean (SE)	-7.61 (1.388)	-9.53 (1.347)
95% CI for the LS Mean	-10.38, -4.83	-12.22, -6.83
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.92 (1.934)
95% CI for the LS Mean		-5.79, 1.95
p-value		0.3250
Hedges' g (Zuranolone vs. Placebo)		-0.266
95% CI for Hedges' g		-0.8026, 0.2697
Day 45		
n	27	30
LS Mean (SE)	-7.92 (1.352)	-10.79 (1.306)
95% CI for the LS Mean	-10.62, -5.22	-13.40, -8.17
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.87 (1.880)
95% CI for the LS Mean		-6.63, 0.89
p-value		0.1324
Hedges' g (Zuranolone vs. Placebo)		-0.399
95% CI for Hedges' g		-0.9242, 0.1260

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-301-by.sas:t-phq9-mmrm-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Baseline HAMD-17 Total Score: 217-PPD-301 - ITT population

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

	Placebo (N=66)	Zuranolone (N=65)
Day 3		
n	62	65
LS Mean (SE)	-2.51 (0.609)	-2.21 (0.598)
95% CI for the LS Mean	-3.71, -1.30	-3.40, -1.03
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.29 (0.854)
95% CI for the LS Mean		-1.40, 1.98
p-value		0.7324
Hedges' g (Zuranolone vs. Placebo)		0.060
95% CI for Hedges' g		-0.2875, 0.4085
Day 8		
n	63	61
LS Mean (SE)	-6.27 (0.743)	-8.28 (0.751)
95% CI for the LS Mean	-7.74, -4.80	-9.77, -6.80
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.02 (1.057)
95% CI for the LS Mean		-4.11, 0.07
p-value		0.0584
Hedges' g (Zuranolone vs. Placebo)		-0.341
95% CI for Hedges' g		-0.6957, 0.0136

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-301-by.sas:t-phq9-mmrm-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Baseline HAMD-17 Total Score: 217-PPD-301 - ITT population

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

	Placebo (N=66)	Zuranolone (N=65)
Day 15		
n	60	59
LS Mean (SE)	-9.21 (0.799)	-10.73 (0.806)
95% CI for the LS Mean	-10.79, -7.63	-12.33, -9.14
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.52 (1.135)
95% CI for the LS Mean		-3.77, 0.72
p-value		0.1823
Hedges' g (Zuranolone vs. Placebo)		-0.244
95% CI for Hedges' g		-0.6051, 0.1163
Day 21		
n	54	53
LS Mean (SE)	-9.88 (0.784)	-10.71 (0.794)
95% CI for the LS Mean	-11.44, -8.33	-12.28, -9.13
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.82 (1.116)
95% CI for the LS Mean		-3.03, 1.39
p-value		0.4633
Hedges' g (Zuranolone vs. Placebo)		-0.141
95% CI for Hedges' g		-0.5207, 0.2382

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-301-by.sas:t-phq9-mmrm-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Baseline HAMD-17 Total Score: 217-PPD-301 - ITT population

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

	Placebo (N=66)	Zuranolone (N=65)
Day 28		
n	59	49
LS Mean (SE)	-9.90 (0.805)	-11.03 (0.839)
95% CI for the LS Mean	-11.50, -8.31	-12.69, -9.37
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.13 (1.163)
95% CI for the LS Mean		-3.43, 1.17
p-value		0.3329
Hedges' g (Zuranolone vs. Placebo)		-0.187
95% CI for Hedges' g		-0.5662, 0.1930
Day 45		
n	58	54
LS Mean (SE)	-10.55 (0.866)	-12.25 (0.893)
95% CI for the LS Mean	-12.27, -8.84	-14.02, -10.48
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.70 (1.244)
95% CI for the LS Mean		-4.16, 0.76
p-value		0.1746
Hedges' g (Zuranolone vs. Placebo)		-0.257
95% CI for Hedges' g		-0.6287, 0.1156

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-301-by.sas:t-phq9-mmrm-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

2.4.1.2 .2 .3 Abstammung

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Race Group: 217-PPD-301 - ITT population

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Race Group = Black or African American

	Placebo (N=20)	Zuranolone (N=26)
Day 3		
n	17	25
LS Mean (SE)	-2.90 (1.378)	-2.68 (1.141)
95% CI for the LS Mean	-5.69, -0.11	-4.99, -0.37
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.22 (1.794)
95% CI for the LS Mean		-3.41, 3.85
p-value		0.9027
Hedges' g (Zuranolone vs. Placebo)		0.038
95% CI for Hedges' g		-0.5782, 0.6541
Day 8		
n	16	23
LS Mean (SE)	-4.44 (1.696)	-7.91 (1.414)
95% CI for the LS Mean	-7.89, -1.00	-10.78, -5.04
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.47 (2.214)
95% CI for the LS Mean		-7.97, 1.02
p-value		0.1259
Hedges' g (Zuranolone vs. Placebo)		-0.500
95% CI for Hedges' g		-1.1477, 0.1475

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-301-by.sas:t-phq9-mmrm-301-by-race-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Race Group: 217-PPD-301 - ITT population

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Race Group = Black or African American

	Placebo (N=20)	Zuranolone (N=26)
Day 15		
n	14	21
LS Mean (SE)	-9.43 (1.906)	-11.37 (1.575)
95% CI for the LS Mean	-13.30, -5.56	-14.58, -8.17
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.94 (2.478)
95% CI for the LS Mean		-6.98, 3.09
p-value		0.4385
Hedges' g (Zuranolone vs. Placebo)		-0.264
95% CI for Hedges' g		-0.9434, 0.4148
Day 21		
n	11	18
LS Mean (SE)	-7.81 (1.611)	-11.82 (1.308)
95% CI for the LS Mean	-11.08, -4.54	-14.48, -9.17
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-4.02 (2.086)
95% CI for the LS Mean		-8.25, 0.21
p-value		0.0621
Hedges' g (Zuranolone vs. Placebo)		-0.717
95% CI for Hedges' g		-1.4892, 0.0557

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-301-by.sas:t-phq9-mmrm-301-by-race-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Race Group: 217-PPD-301 - ITT population

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Race Group = Black or African American

	Placebo (N=20)	Zuranolone (N=26)
Day 28		
n	11	19
LS Mean (SE)	-8.46 (1.843)	-12.37 (1.480)
95% CI for the LS Mean	-12.19, -4.73	-15.37, -9.36
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.91 (2.371)
95% CI for the LS Mean		-8.72, 0.90
p-value		0.1079
Hedges' g (Zuranolone vs. Placebo)		-0.608
95% CI for Hedges' g		-1.3658, 0.1508
Day 45		
n	13	22
LS Mean (SE)	-7.29 (1.834)	-13.56 (1.456)
95% CI for the LS Mean	-11.00, -3.57	-16.52, -10.60
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-6.28 (2.350)
95% CI for the LS Mean		-11.04, -1.51
p-value		0.0113
Hedges' g (Zuranolone vs. Placebo)		-0.913
95% CI for Hedges' g		-1.6309, -0.1944

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-301-by.sas:t-phq9-mmrm-301-by-race-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Race Group: 217-PPD-301 - ITT population

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Race Group = White

	Placebo (N=70)	Zuranolone (N=68)
Day 3		
n	67	68
LS Mean (SE)	-1.71 (0.438)	-1.37 (0.436)
95% CI for the LS Mean	-2.57, -0.84	-2.23, -0.51
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.34 (0.618)
95% CI for the LS Mean		-0.89, 1.56
p-value		0.5869
Hedges' g (Zuranolone vs. Placebo)		0.093
95% CI for Hedges' g		-0.2443, 0.4308
Day 8		
n	69	65
LS Mean (SE)	-6.10 (0.700)	-7.29 (0.716)
95% CI for the LS Mean	-7.48, -4.72	-8.71, -5.88
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.19 (1.002)
95% CI for the LS Mean		-3.17, 0.79
p-value		0.2360
Hedges' g (Zuranolone vs. Placebo)		-0.205
95% CI for Hedges' g		-0.5443, 0.1350

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-301-by.sas:t-phq9-mmrm-301-by-race-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Race Group: 217-PPD-301 - ITT population

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Race Group = White

	Placebo (N=70)	Zuranolone (N=68)
Day 15		
n	66	65
LS Mean (SE)	-8.36 (0.726)	-10.03 (0.735)
95% CI for the LS Mean	-9.80, -6.93	-11.49, -8.58
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.67 (1.033)
95% CI for the LS Mean		-3.71, 0.38
p-value		0.1087
Hedges' g (Zuranolone vs. Placebo)		-0.281
95% CI for Hedges' g		-0.6249, 0.0635
Day 21		
n	60	61
LS Mean (SE)	-9.09 (0.772)	-10.29 (0.779)
95% CI for the LS Mean	-10.62, -7.56	-11.83, -8.74
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.19 (1.097)
95% CI for the LS Mean		-3.36, 0.98
p-value		0.2784
Hedges' g (Zuranolone vs. Placebo)		-0.197
95% CI for Hedges' g		-0.5539, 0.1606

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-301-by.sas:t-phq9-mmrm-301-by-race-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Race Group: 217-PPD-301 - ITT population

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Race Group = White

	Placebo (N=70)	Zuranolone (N=68)
Day 28		
n	64	53
LS Mean (SE)	-9.46 (0.816)	-9.61 (0.851)
95% CI for the LS Mean	-11.07, -7.84	-11.29, -7.93
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.15 (1.179)
95% CI for the LS Mean		-2.49, 2.18
p-value		0.8973
Hedges' g (Zuranolone vs. Placebo)		-0.024
95% CI for Hedges' g		-0.3879, 0.3402
Day 45		
n	62	58
LS Mean (SE)	-10.30 (0.856)	-11.06 (0.881)
95% CI for the LS Mean	-12.00, -8.61	-12.80, -9.32
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.76 (1.229)
95% CI for the LS Mean		-3.19, 1.68
p-value		0.5398
Hedges' g (Zuranolone vs. Placebo)		-0.112
95% CI for Hedges' g		-0.4699, 0.2467

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-301-by.sas:t-phq9-mmrm-301-by-race-itta.rtf **Run Date:** 25JUL2025

2.4.1.2 .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-301 - ITT population

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Antidepressant Use at Baseline = Yes

	Placebo (N=15)	Zuranolone (N=15)
Day 3		
n	13	15
LS Mean (SE)	-0.69 (1.080)	-1.22 (1.033)
95% CI for the LS Mean	-2.91, 1.52	-3.34, 0.90
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.53 (1.500)
95% CI for the LS Mean		-3.60, 2.54
p-value		0.7266
Hedges' g (Zuranolone vs. Placebo)		-0.130
95% CI for Hedges' g		-0.8734, 0.6135
Day 8		
n	15	14
LS Mean (SE)	-5.44 (1.586)	-6.16 (1.612)
95% CI for the LS Mean	-8.69, -2.18	-9.47, -2.86
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.73 (2.266)
95% CI for the LS Mean		-5.37, 3.92
p-value		0.7512
Hedges' g (Zuranolone vs. Placebo)		-0.116
95% CI for Hedges' g		-0.8446, 0.6133

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-301-by.sas:t-phq9-mmrm-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Baseline Antidepressant Use: 217-PPD-301 - ITT population

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Antidepressant Use at Baseline = Yes

	Placebo (N=15)	Zuranolone (N=15)
Day 15		
n	15	14
LS Mean (SE)	-8.77 (1.725)	-7.91 (1.759)
95% CI for the LS Mean	-12.31, -5.23	-11.51, -4.30
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.86 (2.468)
95% CI for the LS Mean		-4.20, 5.93
p-value		0.7292
Hedges' g (Zuranolone vs. Placebo)		0.126
95% CI for Hedges' g		-0.6027, 0.8554
Day 21		
n	14	14
LS Mean (SE)	-9.23 (1.720)	-8.74 (1.721)
95% CI for the LS Mean	-12.76, -5.70	-12.27, -5.21
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.49 (2.437)
95% CI for the LS Mean		-4.52, 5.49
p-value		0.8425
Hedges' g (Zuranolone vs. Placebo)		0.074
95% CI for Hedges' g		-0.6674, 0.8147

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-301-by.sas:t-phq9-mmrm-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Baseline Antidepressant Use: 217-PPD-301 - ITT population

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Antidepressant Use at Baseline = Yes

	Placebo (N=15)	Zuranolone (N=15)
Day 28		
n	13	14
LS Mean (SE)	-9.87 (1.837)	-8.94 (1.822)
95% CI for the LS Mean	-13.63, -6.11	-12.68, -5.21
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.93 (2.592)
95% CI for the LS Mean		-4.38, 6.24
p-value		0.7233
Hedges' g (Zuranolone vs. Placebo)		0.134
95% CI for Hedges' g		-0.6222, 0.8893
Day 45		
n	14	15
LS Mean (SE)	-8.01 (2.264)	-9.09 (2.241)
95% CI for the LS Mean	-12.65, -3.37	-13.69, -4.49
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.08 (3.189)
95% CI for the LS Mean		-7.62, 5.45
p-value		0.7372
Hedges' g (Zuranolone vs. Placebo)		-0.122
95% CI for Hedges' g		-0.8515, 0.6066

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-301-by.sas:t-phq9-mmrm-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Baseline Antidepressant Use: 217-PPD-301 - ITT population

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Antidepressant Use at Baseline = No

	Placebo (N=86)	Zuranolone (N=84)
Day 3		
n	81	82
LS Mean (SE)	-2.57 (0.509)	-2.18 (0.507)
95% CI for the LS Mean	-3.57, -1.56	-3.18, -1.18
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.39 (0.719)
95% CI for the LS Mean		-1.03, 1.81
p-value		0.5918
Hedges' g (Zuranolone vs. Placebo)		0.084
95% CI for Hedges' g		-0.2234, 0.3910
Day 8		
n	80	79
LS Mean (SE)	-5.94 (0.672)	-7.97 (0.675)
95% CI for the LS Mean	-7.27, -4.61	-9.30, -6.63
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.02 (0.953)
95% CI for the LS Mean		-3.91, -0.14
p-value		0.0351
Hedges' g (Zuranolone vs. Placebo)		-0.335
95% CI for Hedges' g		-0.6485, -0.0224

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-301-by.sas:t-phq9-mmrm-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Baseline Antidepressant Use: 217-PPD-301 - ITT population

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Antidepressant Use at Baseline = No

	Placebo (N=86)	Zuranolone (N=84)
Day 15		
n	75	77
LS Mean (SE)	-8.59 (0.703)	-11.03 (0.700)
95% CI for the LS Mean	-9.98, -7.20	-12.41, -9.64
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.44 (0.992)
95% CI for the LS Mean		-4.40, -0.48
p-value		0.0152
Hedges' g (Zuranolone vs. Placebo)		-0.396
95% CI for Hedges' g		-0.7174, -0.0752
Day 21		
n	67	70
LS Mean (SE)	-8.96 (0.709)	-11.02 (0.704)
95% CI for the LS Mean	-10.36, -7.56	-12.41, -9.63
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.06 (0.999)
95% CI for the LS Mean		-4.03, -0.08
p-value		0.0412
Hedges' g (Zuranolone vs. Placebo)		-0.350
95% CI for Hedges' g		-0.6874, -0.0124

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-301-by.sas:t-phq9-mmrm-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Baseline Antidepressant Use: 217-PPD-301 - ITT population

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Antidepressant Use at Baseline = No

	Placebo (N=86)	Zuranolone (N=84)
Day 28		
n	72	63
LS Mean (SE)	-9.09 (0.742)	-10.90 (0.757)
95% CI for the LS Mean	-10.55, -7.62	-12.40, -9.41
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.82 (1.060)
95% CI for the LS Mean		-3.91, 0.28
p-value		0.0886
Hedges' g (Zuranolone vs. Placebo)		-0.294
95% CI for Hedges' g		-0.6339, 0.0460
Day 45		
n	71	69
LS Mean (SE)	-10.11 (0.756)	-12.29 (0.762)
95% CI for the LS Mean	-11.60, -8.62	-13.79, -10.78
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.18 (1.074)
95% CI for the LS Mean		-4.30, -0.05
p-value		0.0445
Hedges' g (Zuranolone vs. Placebo)		-0.341
95% CI for Hedges' g		-0.6743, -0.0069

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-301-by.sas:t-phq9-mmrm-301-by-adt-itta.rtf **Run Date:** 25JUL2025

2.4.1.2 .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-301 - ITT population

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

	Placebo (N=22)	Zuranolone (N=20)
Day 3		
n	21	20
LS Mean (SE)	-1.11 (0.987)	-1.39 (1.015)
95% CI for the LS Mean	-3.11, 0.89	-3.46, 0.67
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.28 (1.419)
95% CI for the LS Mean		-3.16, 2.60
p-value		0.8436
Hedges' g (Zuranolone vs. Placebo)		-0.061
95% CI for Hedges' g		-0.6734, 0.5516
Day 8		
n	22	18
LS Mean (SE)	-6.20 (1.249)	-4.30 (1.360)
95% CI for the LS Mean	-8.73, -3.66	-7.06, -1.54
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.90 (1.848)
95% CI for the LS Mean		-1.85, 5.64
p-value		0.3116
Hedges' g (Zuranolone vs. Placebo)		0.320
95% CI for Hedges' g		-0.3071, 0.9466

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-301-by.sas:t-phq9-mmrm-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Baseline BMI (kg/m^2)
Group: 217-PPD-301 - ITT population

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

	Placebo (N=22)	Zuranolone (N=20)
Day 15		
n	21	18
LS Mean (SE)	-8.84 (1.331)	-6.67 (1.449)
95% CI for the LS Mean	-11.54, -6.14	-9.61, -3.73
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.17 (1.969)
95% CI for the LS Mean		-1.82, 6.17
p-value		0.2775
Hedges' g (Zuranolone vs. Placebo)		0.347
95% CI for Hedges' g		-0.2871, 0.9814
Day 21		
n	17	16
LS Mean (SE)	-7.95 (1.045)	-8.37 (1.137)
95% CI for the LS Mean	-10.07, -5.82	-10.69, -6.06
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.43 (1.548)
95% CI for the LS Mean		-3.58, 2.72
p-value		0.7843
Hedges' g (Zuranolone vs. Placebo)		-0.094
95% CI for Hedges' g		-0.7768, 0.5893

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-301-by.sas:t-phq9-mmrm-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Baseline BMI (kg/m^2)
Group: 217-PPD-301 - ITT population

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

	Placebo (N=22)	Zuranolone (N=20)
Day 28		
n	21	12
LS Mean (SE)	-7.91 (1.321)	-9.15 (1.567)
95% CI for the LS Mean	-10.60, -5.23	-12.31, -5.98
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.23 (2.053)
95% CI for the LS Mean		-5.39, 2.93
p-value		0.5523
Hedges' g (Zuranolone vs. Placebo)		-0.212
95% CI for Hedges' g		-0.9228, 0.4994
Day 45		
n	22	15
LS Mean (SE)	-8.70 (1.260)	-10.22 (1.473)
95% CI for the LS Mean	-11.26, -6.13	-13.21, -7.24
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.53 (1.944)
95% CI for the LS Mean		-5.47, 2.42
p-value		0.4378
Hedges' g (Zuranolone vs. Placebo)		-0.257
95% CI for Hedges' g		-0.9161, 0.4017

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-301-by.sas:t-phq9-mmrm-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Baseline BMI (kg/m^2)
Group: 217-PPD-301 - ITT population

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

	Placebo (N=34)	Zuranolone (N=24)
Day 3		
n	33	23
LS Mean (SE)	-2.26 (0.713)	-2.56 (0.851)
95% CI for the LS Mean	-3.69, -0.83	-4.27, -0.86
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.30 (1.116)
95% CI for the LS Mean		-2.54, 1.94
p-value		0.7883
Hedges' g (Zuranolone vs. Placebo)		-0.072
95% CI for Hedges' g		-0.6048, 0.4603
Day 8		
n	32	23
LS Mean (SE)	-5.21 (0.997)	-8.81 (1.176)
95% CI for the LS Mean	-7.21, -3.21	-11.17, -6.45
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.60 (1.548)
95% CI for the LS Mean		-6.71, -0.50
p-value		0.0237
Hedges' g (Zuranolone vs. Placebo)		-0.627
95% CI for Hedges' g		-1.1757, -0.0788

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-301-by.sas:t-phq9-mmrm-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Baseline BMI (kg/m^2)
Group: 217-PPD-301 - ITT population
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BMI (kg/m2) Group 2 = 25-29.9

	Placebo (N=34)	Zuranolone (N=24)
Day 15		
n	30	23
LS Mean (SE)	-8.14 (1.090)	-11.98 (1.260)
95% CI for the LS Mean	-10.33, -5.95	-14.51, -9.45
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.84 (1.673)
95% CI for the LS Mean		-7.20, -0.49
p-value		0.0256
Hedges' g (Zuranolone vs. Placebo)		-0.628
95% CI for Hedges' g		-1.1838, -0.0714
Day 21		
n	27	21
LS Mean (SE)	-9.52 (1.151)	-12.51 (1.329)
95% CI for the LS Mean	-11.84, -7.21	-15.18, -9.84
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.99 (1.764)
95% CI for the LS Mean		-6.53, 0.56
p-value		0.0966
Hedges' g (Zuranolone vs. Placebo)		-0.485
95% CI for Hedges' g		-1.0631, 0.0938

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-301-by.sas:t-phq9-mmrm-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Baseline BMI (kg/m^2)
Group: 217-PPD-301 - ITT population

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

	Placebo (N=34)	Zuranolone (N=24)
Day 28		
n	29	20
LS Mean (SE)	-10.49 (1.171)	-12.53 (1.379)
95% CI for the LS Mean	-12.84, -8.13	-15.30, -9.75
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.04 (1.814)
95% CI for the LS Mean		-5.69, 1.61
p-value		0.2664
Hedges' g (Zuranolone vs. Placebo)		-0.322
95% CI for Hedges' g		-0.8948, 0.2517
Day 45		
n	28	20
LS Mean (SE)	-11.18 (1.200)	-13.33 (1.410)
95% CI for the LS Mean	-13.59, -8.77	-16.16, -10.50
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.15 (1.856)
95% CI for the LS Mean		-5.87, 1.58
p-value		0.2528
Hedges' g (Zuranolone vs. Placebo)		-0.333
95% CI for Hedges' g		-0.9108, 0.2445

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-301-by.sas:t-phq9-mmrm-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Baseline BMI (kg/m^2)
Group: 217-PPD-301 - ITT population

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

	Placebo (N=42)	Zuranolone (N=53)
Day 3		
n	40	53
LS Mean (SE)	-2.82 (0.786)	-2.05 (0.687)
95% CI for the LS Mean	-4.38, -1.26	-3.42, -0.69
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.77 (1.049)
95% CI for the LS Mean		-1.32, 2.85
p-value		0.4661
Hedges' g (Zuranolone vs. Placebo)		0.152
95% CI for Hedges' g		-0.2590, 0.5631
Day 8		
n	41	51
LS Mean (SE)	-6.12 (0.986)	-8.42 (0.879)
95% CI for the LS Mean	-8.08, -4.16	-10.16, -6.67
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.30 (1.324)
95% CI for the LS Mean		-4.93, 0.33
p-value		0.0862
Hedges' g (Zuranolone vs. Placebo)		-0.361
95% CI for Hedges' g		-0.7752, 0.0537

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-301-by.sas:t-phq9-mmrm-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Baseline BMI (kg/m^2)
Group: 217-PPD-301 - ITT population

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

	Placebo (N=42)	Zuranolone (N=53)
Day 15		
n	39	49
LS Mean (SE)	-8.83 (1.007)	-11.21 (0.895)
95% CI for the LS Mean	-10.83, -6.83	-12.98, -9.43
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.38 (1.351)
95% CI for the LS Mean		-5.06, 0.31
p-value		0.0822
Hedges' g (Zuranolone vs. Placebo)		-0.374
95% CI for Hedges' g		-0.7982, 0.0502
Day 21		
n	37	46
LS Mean (SE)	-8.99 (1.051)	-10.56 (0.934)
95% CI for the LS Mean	-11.08, -6.90	-12.41, -8.70
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.57 (1.410)
95% CI for the LS Mean		-4.37, 1.23
p-value		0.2694
Hedges' g (Zuranolone vs. Placebo)		-0.243
95% CI for Hedges' g		-0.6775, 0.1913

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-301-by.sas:t-phq9-mmrm-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Baseline BMI (kg/m^2)
Group: 217-PPD-301 - ITT population

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

	Placebo (N=42)	Zuranolone (N=53)
Day 28		
n	35	44
LS Mean (SE)	-8.88 (1.100)	-10.39 (0.970)
95% CI for the LS Mean	-11.07, -6.70	-12.32, -8.46
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.51 (1.470)
95% CI for the LS Mean		-4.43, 1.41
p-value		0.3068
Hedges' g (Zuranolone vs. Placebo)		-0.231
95% CI for Hedges' g		-0.6759, 0.2148
Day 45		
n	35	48
LS Mean (SE)	-9.23 (1.195)	-11.62 (1.035)
95% CI for the LS Mean	-11.60, -6.86	-13.68, -9.56
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.39 (1.584)
95% CI for the LS Mean		-5.54, 0.76
p-value		0.1348
Hedges' g (Zuranolone vs. Placebo)		-0.332
95% CI for Hedges' g		-0.7710, 0.1062

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-301-by.sas:t-phq9-mmrm-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

2.4.1.2 .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-301 - ITT population

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Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=35)
Day 3		
n	29	34
LS Mean (SE)	-3.12 (0.894)	-2.95 (0.827)
95% CI for the LS Mean	-4.90, -1.33	-4.60, -1.30
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.16 (1.217)
95% CI for the LS Mean		-2.27, 2.60
p-value		0.8931
Hedges' g (Zuranolone vs. Placebo)		0.034
95% CI for Hedges' g		-0.4618, 0.5291
Day 8		
n	28	32
LS Mean (SE)	-5.68 (1.154)	-8.10 (1.078)
95% CI for the LS Mean	-7.99, -3.38	-10.25, -5.94
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.41 (1.579)
95% CI for the LS Mean		-5.57, 0.74
p-value		0.1316
Hedges' g (Zuranolone vs. Placebo)		-0.390
95% CI for Hedges' g		-0.9024, 0.1216

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-301-by.sas:t-phq9-mmrm-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=35)
Day 15		
n	27	31
LS Mean (SE)	-8.63 (1.292)	-11.09 (1.206)
95% CI for the LS Mean	-11.22, -6.05	-13.51, -8.68
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.46 (1.768)
95% CI for the LS Mean		-6.00, 1.08
p-value		0.1690
Hedges' g (Zuranolone vs. Placebo)		-0.362
95% CI for Hedges' g		-0.8818, 0.1585
Day 21		
n	25	29
LS Mean (SE)	-8.68 (1.310)	-11.29 (1.224)
95% CI for the LS Mean	-11.30, -6.06	-13.74, -8.84
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.61 (1.793)
95% CI for the LS Mean		-6.20, 0.98
p-value		0.1510
Hedges' g (Zuranolone vs. Placebo)		-0.391
95% CI for Hedges' g		-0.9314, 0.1486

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-301-by.sas:t-phq9-mmrm-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=35)
Day 28		
n	25	26
LS Mean (SE)	-9.44 (1.281)	-11.41 (1.214)
95% CI for the LS Mean	-12.00, -6.87	-13.84, -8.98
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.97 (1.766)
95% CI for the LS Mean		-5.50, 1.56
p-value		0.2694
Hedges' g (Zuranolone vs. Placebo)		-0.307
95% CI for Hedges' g		-0.8597, 0.2448
Day 45		
n	25	27
LS Mean (SE)	-10.05 (1.346)	-12.80 (1.273)
95% CI for the LS Mean	-12.74, -7.35	-15.34, -10.25
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.75 (1.855)
95% CI for the LS Mean		-6.46, 0.96
p-value		0.1438
Hedges' g (Zuranolone vs. Placebo)		-0.405
95% CI for Hedges' g		-0.9546, 0.1445

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-301-by.sas:t-phq9-mmrm-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = Postpartum

	Placebo (N=69)	Zuranolone (N=64)
Day 3		
n	65	63
LS Mean (SE)	-1.92 (0.540)	-1.54 (0.549)
95% CI for the LS Mean	-2.98, -0.85	-2.63, -0.45
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.37 (0.770)
95% CI for the LS Mean		-1.15, 1.90
p-value		0.6277
Hedges' g (Zuranolone vs. Placebo)		0.085
95% CI for Hedges' g		-0.2612, 0.4321
Day 8		
n	67	61
LS Mean (SE)	-5.89 (0.737)	-7.43 (0.767)
95% CI for the LS Mean	-7.35, -4.43	-8.95, -5.91
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.54 (1.064)
95% CI for the LS Mean		-3.64, 0.57
p-value		0.1506
Hedges' g (Zuranolone vs. Placebo)		-0.254
95% CI for Hedges' g		-0.6027, 0.0938

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-301-by.sas:t-phq9-mmrm-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = Postpartum

	Placebo (N=69)	Zuranolone (N=64)
Day 15		
n	63	60
LS Mean (SE)	-8.56 (0.755)	-10.22 (0.778)
95% CI for the LS Mean	-10.06, -7.07	-11.76, -8.68
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.66 (1.085)
95% CI for the LS Mean		-3.80, 0.49
p-value		0.1296
Hedges' g (Zuranolone vs. Placebo)		-0.274
95% CI for Hedges' g		-0.6288, 0.0816
Day 21		
n	56	55
LS Mean (SE)	-9.11 (0.753)	-10.38 (0.771)
95% CI for the LS Mean	-10.60, -7.61	-11.90, -8.85
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.27 (1.078)
95% CI for the LS Mean		-3.41, 0.86
p-value		0.2409
Hedges' g (Zuranolone vs. Placebo)		-0.222
95% CI for Hedges' g		-0.5954, 0.1510

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-301-by.sas:t-phq9-mmrm-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = Postpartum

	Placebo (N=69)	Zuranolone (N=64)
Day 28		
n	60	51
LS Mean (SE)	-9.06 (0.830)	-10.19 (0.870)
95% CI for the LS Mean	-10.71, -7.42	-11.91, -8.47
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.13 (1.203)
95% CI for the LS Mean		-3.51, 1.25
p-value		0.3496
Hedges' g (Zuranolone vs. Placebo)		-0.178
95% CI for Hedges' g		-0.5516, 0.1964
Day 45		
n	60	57
LS Mean (SE)	-9.68 (0.866)	-11.16 (0.894)
95% CI for the LS Mean	-11.39, -7.97	-12.92, -9.39
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.48 (1.245)
95% CI for the LS Mean		-3.94, 0.99
p-value		0.2380
Hedges' g (Zuranolone vs. Placebo)		-0.218
95% CI for Hedges' g		-0.5815, 0.1457

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-301-by.sas:t-phq9-mmrm-301-by-onset-itta.rtf **Run Date:** 25JUL2025

2.4.1.2 .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-301 - ITT population

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Family History of PPD = Yes

	Placebo (N=16)	Zuranolone (N=21)
Day 3		
n	15	21
LS Mean (SE)	-3.07 (1.164)	-2.37 (0.985)
95% CI for the LS Mean	-5.44, -0.70	-4.38, -0.37
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.69 (1.533)
95% CI for the LS Mean		-2.43, 3.81
p-value		0.6540
Hedges' g (Zuranolone vs. Placebo)		0.150
95% CI for Hedges' g		-0.5139, 0.8130
Day 8		
n	15	21
LS Mean (SE)	-7.67 (1.441)	-7.33 (1.218)
95% CI for the LS Mean	-10.60, -4.73	-9.81, -4.85
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.34 (1.894)
95% CI for the LS Mean		-3.51, 4.20
p-value		0.8581
Hedges' g (Zuranolone vs. Placebo)		0.060
95% CI for Hedges' g		-0.6032, 0.7223

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-301-by.sas:t-phq9-mmrm-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Family History of PPD: 217-PPD-301 - ITT population

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Family History of PPD = Yes

	Placebo (N=16)	Zuranolone (N=21)
Day 15		
n	13	20
LS Mean (SE)	-11.43 (1.889)	-10.93 (1.549)
95% CI for the LS Mean	-15.28, -7.59	-14.08, -7.77
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.51 (2.449)
95% CI for the LS Mean		-4.47, 5.49
p-value		0.8371
Hedges' g (Zuranolone vs. Placebo)		0.072
95% CI for Hedges' g		-0.6264, 0.7705
Day 21		
n	13	20
LS Mean (SE)	-11.51 (1.705)	-11.27 (1.421)
95% CI for the LS Mean	-14.98, -8.03	-14.17, -8.37
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.24 (2.226)
95% CI for the LS Mean		-4.30, 4.78
p-value		0.9143
Hedges' g (Zuranolone vs. Placebo)		0.038
95% CI for Hedges' g		-0.6606, 0.7360

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-301-by.sas:t-phq9-mmrm-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Family History of PPD: 217-PPD-301 - ITT population

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Family History of PPD = Yes

	Placebo (N=16)	Zuranolone (N=21)
Day 28		
n	12	18
LS Mean (SE)	-12.16 (1.817)	-11.63 (1.503)
95% CI for the LS Mean	-15.87, -8.45	-14.71, -8.55
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.53 (2.364)
95% CI for the LS Mean		-4.30, 5.36
p-value		0.8245
Hedges' g (Zuranolone vs. Placebo)		0.081
95% CI for Hedges' g		-0.6496, 0.8119
Day 45		
n	13	19
LS Mean (SE)	-12.58 (1.857)	-11.09 (1.545)
95% CI for the LS Mean	-16.36, -8.81	-14.23, -7.95
Difference (Zuranolone - Placebo)		
LS Mean (SE)		1.49 (2.421)
95% CI for the LS Mean		-3.43, 6.42
p-value		0.5419
Hedges' g (Zuranolone vs. Placebo)		0.216
95% CI for Hedges' g		-0.4912, 0.9237

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-301-by.sas:t-phq9-mmrm-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Family History of PPD: 217-PPD-301 - ITT population

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Family History of PPD = No/Unknown

	Placebo (N=85)	Zuranolone (N=78)
Day 3		
n	79	76
LS Mean (SE)	-2.17 (0.504)	-1.91 (0.516)
95% CI for the LS Mean	-3.16, -1.17	-2.93, -0.89
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.25 (0.721)
95% CI for the LS Mean		-1.17, 1.68
p-value		0.7264
Hedges' g (Zuranolone vs. Placebo)		0.056
95% CI for Hedges' g		-0.2589, 0.3710
Day 8		
n	80	72
LS Mean (SE)	-5.53 (0.686)	-7.74 (0.720)
95% CI for the LS Mean	-6.89, -4.18	-9.16, -6.32
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.21 (0.995)
95% CI for the LS Mean		-4.17, -0.24
p-value		0.0281
Hedges' g (Zuranolone vs. Placebo)		-0.358
95% CI for Hedges' g		-0.6792, -0.0374

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-301-by.sas:t-phq9-mmrm-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Family History of PPD: 217-PPD-301 - ITT population

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Family History of PPD = No/Unknown

	Placebo (N=85)	Zuranolone (N=78)
Day 15		
n	77	71
LS Mean (SE)	-8.16 (0.683)	-10.34 (0.712)
95% CI for the LS Mean	-9.51, -6.81	-11.75, -8.94
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.19 (0.987)
95% CI for the LS Mean		-4.14, -0.24
p-value		0.0283
Hedges' g (Zuranolone vs. Placebo)		-0.363
95% CI for Hedges' g		-0.6877, -0.0375
Day 21		
n	68	64
LS Mean (SE)	-8.62 (0.714)	-10.43 (0.741)
95% CI for the LS Mean	-10.03, -7.21	-11.90, -8.96
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.81 (1.030)
95% CI for the LS Mean		-3.84, 0.23
p-value		0.0814
Hedges' g (Zuranolone vs. Placebo)		-0.304
95% CI for Hedges' g		-0.6471, 0.0395

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-301-by.sas:t-phq9-mmrm-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Family History of PPD: 217-PPD-301 - ITT population

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Family History of PPD = No/Unknown

	Placebo (N=85)	Zuranolone (N=78)
Day 28		
n	73	59
LS Mean (SE)	-8.71 (0.752)	-10.27 (0.798)
95% CI for the LS Mean	-10.19, -7.22	-11.85, -8.69
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.56 (1.097)
95% CI for the LS Mean		-3.73, 0.60
p-value		0.1560
Hedges' g (Zuranolone vs. Placebo)		-0.248
95% CI for Hedges' g		-0.5926, 0.0962
Day 45		
n	72	65
LS Mean (SE)	-9.32 (0.793)	-11.93 (0.833)
95% CI for the LS Mean	-10.89, -7.75	-13.57, -10.28
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.61 (1.150)
95% CI for the LS Mean		-4.88, -0.34
p-value		0.0248
Hedges' g (Zuranolone vs. Placebo)		-0.386
95% CI for Hedges' g		-0.7243, -0.0475

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-301-by.sas:t-phq9-mmrm-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

2.4.1.2 .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-301 - ITT population

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History of PPD = 1st Episode

	Placebo (N=90)	Zuranolone (N=82)
Day 3		
n	84	80
LS Mean (SE)	-1.64 (0.458)	-1.67 (0.471)
95% CI for the LS Mean	-2.54, -0.74	-2.60, -0.74
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.03 (0.657)
95% CI for the LS Mean		-1.33, 1.27
p-value		0.9632
Hedges' g (Zuranolone vs. Placebo)		-0.007
95% CI for Hedges' g		-0.3134, 0.2990
Day 8		
n	84	76
LS Mean (SE)	-5.36 (0.664)	-7.46 (0.694)
95% CI for the LS Mean	-6.67, -4.05	-8.83, -6.09
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.10 (0.961)
95% CI for the LS Mean		-3.99, -0.20
p-value		0.0306
Hedges' g (Zuranolone vs. Placebo)		-0.344
95% CI for Hedges' g		-0.6563, -0.0311

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-301-by.sas:t-phq9-mmrm-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by History of PPD: 217-PPD-301 - ITT population

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History of PPD = 1st Episode

	Placebo (N=90)	Zuranolone (N=82)
Day 15		
n	79	74
LS Mean (SE)	-8.04 (0.682)	-9.91 (0.707)
95% CI for the LS Mean	-9.39, -6.70	-11.30, -8.51
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.86 (0.983)
95% CI for the LS Mean		-3.80, 0.08
p-value		0.0599
Hedges' g (Zuranolone vs. Placebo)		-0.305
95% CI for Hedges' g		-0.6240, 0.0139
Day 21		
n	71	68
LS Mean (SE)	-8.50 (0.673)	-10.61 (0.696)
95% CI for the LS Mean	-9.83, -7.17	-11.99, -9.24
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.11 (0.969)
95% CI for the LS Mean		-4.03, -0.20
p-value		0.0308
Hedges' g (Zuranolone vs. Placebo)		-0.368
95% CI for Hedges' g		-0.7033, -0.0326

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-301-by.sas:t-phq9-mmrm-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by History of PPD: 217-PPD-301 - ITT population

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History of PPD = 1st Episode

	Placebo (N=90)	Zuranolone (N=82)
Day 28		
n	74	60
LS Mean (SE)	-9.06 (0.728)	-10.19 (0.772)
95% CI for the LS Mean	-10.50, -7.62	-11.72, -8.67
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.13 (1.062)
95% CI for the LS Mean		-3.23, 0.96
p-value		0.2877
Hedges' g (Zuranolone vs. Placebo)		-0.184
95% CI for Hedges' g		-0.5255, 0.1569
Day 45		
n	75	68
LS Mean (SE)	-9.68 (0.745)	-11.43 (0.778)
95% CI for the LS Mean	-11.16, -8.21	-12.97, -9.89
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.74 (1.078)
95% CI for the LS Mean		-3.87, 0.39
p-value		0.1079
Hedges' g (Zuranolone vs. Placebo)		-0.269
95% CI for Hedges' g		-0.5990, 0.0603

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-301-by.sas:t-phq9-mmrm-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by History of PPD: 217-PPD-301 - ITT population

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History of PPD = Recurrent Episode

	Placebo (N=11)	Zuranolone (N=17)
Day 3		
n	10	17
LS Mean (SE)	-6.62 (1.795)	-4.27 (1.370)
95% CI for the LS Mean	-10.32, -2.91	-7.11, -1.43
Difference (Zuranolone - Placebo)		
LS Mean (SE)		2.35 (2.331)
95% CI for the LS Mean		-2.47, 7.16
p-value		0.3238
Hedges' g (Zuranolone vs. Placebo)		0.389
95% CI for Hedges' g		-0.3986, 1.1774
Day 8		
n	11	17
LS Mean (SE)	-8.89 (1.789)	-9.15 (1.413)
95% CI for the LS Mean	-12.56, -5.22	-12.05, -6.25
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.26 (2.355)
95% CI for the LS Mean		-5.08, 4.57
p-value		0.9139
Hedges' g (Zuranolone vs. Placebo)		-0.041
95% CI for Hedges' g		-0.7995, 0.7175

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-301-by.sas:t-phq9-mmrm-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by History of PPD: 217-PPD-301 - ITT population

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History of PPD = Recurrent Episode

	Placebo (N=11)	Zuranolone (N=17)
Day 15		
n	11	17
LS Mean (SE)	-12.16 (2.011)	-13.74 (1.594)
95% CI for the LS Mean	-16.30, -8.03	-17.02, -10.46
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.57 (2.633)
95% CI for the LS Mean		-6.98, 3.83
p-value		0.5554
Hedges' g (Zuranolone vs. Placebo)		-0.224
95% CI for Hedges' g		-0.9850, 0.5363
Day 21		
n	10	16
LS Mean (SE)	-11.89 (2.301)	-11.66 (1.827)
95% CI for the LS Mean	-16.62, -7.16	-15.43, -7.90
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.22 (2.999)
95% CI for the LS Mean		-5.94, 6.38
p-value		0.9413
Hedges' g (Zuranolone vs. Placebo)		0.029
95% CI for Hedges' g		-0.7611, 0.8192

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-301-by.sas:t-phq9-mmrm-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by History of PPD: 217-PPD-301 - ITT population

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History of PPD = Recurrent Episode

	Placebo (N=11)	Zuranolone (N=17)
Day 28		
n	11	17
LS Mean (SE)	-9.71 (2.282)	-12.56 (1.816)
95% CI for the LS Mean	-14.39, -5.03	-16.29, -8.83
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.85 (2.975)
95% CI for the LS Mean		-8.95, 3.25
p-value		0.3463
Hedges' g (Zuranolone vs. Placebo)		-0.360
95% CI for Hedges' g		-1.1242, 0.4043
Day 45		
n	10	16
LS Mean (SE)	-9.86 (2.608)	-13.44 (2.073)
95% CI for the LS Mean	-15.21, -4.51	-17.69, -9.18
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-3.58 (3.383)
95% CI for the LS Mean		-10.51, 3.35
p-value		0.2995
Hedges' g (Zuranolone vs. Placebo)		-0.413
95% CI for Hedges' g		-1.2108, 0.3852

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-301-by.sas:t-phq9-mmrm-301-by-hist-itta.rtf **Run Date:** 25JUL2025

2.4.1.2 .2 .9 Depression mit Angst

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

Page: 1 of 6

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

	Placebo (N=21)	Zuranolone (N=24)
Day 3		
n	20	24
LS Mean (SE)	-1.99 (0.980)	-1.78 (0.894)
95% CI for the LS Mean	-3.97, -0.01	-3.59, 0.02
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.21 (1.329)
95% CI for the LS Mean		-2.48, 2.89
p-value		0.8772
Hedges' g (Zuranolone vs. Placebo)		0.046
95% CI for Hedges' g		-0.5472, 0.6397
Day 8		
n	20	23
LS Mean (SE)	-3.79 (1.221)	-6.12 (1.133)
95% CI for the LS Mean	-6.26, -1.32	-8.41, -3.83
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.33 (1.668)
95% CI for the LS Mean		-5.71, 1.04
p-value		0.1695
Hedges' g (Zuranolone vs. Placebo)		-0.420
95% CI for Hedges' g		-1.0257, 0.1859

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-301-by.sas:t-phq9-mmrm-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

Page: 2 of 6

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

	Placebo (N=21)	Zuranolone (N=24)
Day 15		
n	20	23
LS Mean (SE)	-7.34 (1.451)	-9.03 (1.351)
95% CI for the LS Mean	-10.28, -4.40	-11.76, -6.30
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.69 (1.985)
95% CI for the LS Mean		-5.71, 2.32
p-value		0.3997
Hedges' g (Zuranolone vs. Placebo)		-0.256
95% CI for Hedges' g		-0.8572, 0.3461
Day 21		
n	17	23
LS Mean (SE)	-8.25 (1.320)	-11.22 (1.204)
95% CI for the LS Mean	-10.92, -5.57	-13.66, -8.78
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.98 (1.790)
95% CI for the LS Mean		-6.60, 0.65
p-value		0.1044
Hedges' g (Zuranolone vs. Placebo)		-0.522
95% CI for Hedges' g		-1.1588, 0.1157

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-301-by.sas:t-phq9-mmrm-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

Page: 3 of 6

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

	Placebo (N=21)	Zuranolone (N=24)
Day 28		
n	19	19
LS Mean (SE)	-9.46 (1.558)	-9.62 (1.504)
95% CI for the LS Mean	-12.62, -6.29	-12.67, -6.57
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.16 (2.168)
95% CI for the LS Mean		-4.56, 4.24
p-value		0.9407
Hedges' g (Zuranolone vs. Placebo)		-0.024
95% CI for Hedges' g		-0.6597, 0.6121
Day 45		
n	20	21
LS Mean (SE)	-10.29 (1.447)	-11.63 (1.371)
95% CI for the LS Mean	-13.21, -7.36	-14.40, -8.86
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.34 (1.996)
95% CI for the LS Mean		-5.37, 2.69
p-value		0.5062
Hedges' g (Zuranolone vs. Placebo)		-0.206
95% CI for Hedges' g		-0.8195, 0.4085

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-301-by.sas:t-phq9-mmrm-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

	Placebo (N=77)	Zuranolone (N=74)
Day 3		
n	74	73
LS Mean (SE)	-2.40 (0.529)	-2.07 (0.535)
95% CI for the LS Mean	-3.44, -1.36	-3.13, -1.01
Difference (Zuranolone - Placebo)		
LS Mean (SE)		0.33 (0.752)
95% CI for the LS Mean		-1.16, 1.82
p-value		0.6605
Hedges' g (Zuranolone vs. Placebo)		0.072
95% CI for Hedges' g		-0.2512, 0.3956
Day 8		
n	75	70
LS Mean (SE)	-6.45 (0.711)	-8.12 (0.733)
95% CI for the LS Mean	-7.86, -5.05	-9.57, -6.68
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.67 (1.021)
95% CI for the LS Mean		-3.69, 0.35
p-value		0.1040
Hedges' g (Zuranolone vs. Placebo)		-0.270
95% CI for Hedges' g		-0.5977, 0.0567

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-301-by.sas:t-phq9-mmrm-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

Page: 5 of 6

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

	Placebo (N=77)	Zuranolone (N=74)
Day 15		
n	70	68
LS Mean (SE)	-9.00 (0.734)	-10.95 (0.748)
95% CI for the LS Mean	-10.45, -7.55	-12.43, -9.47
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.96 (1.048)
95% CI for the LS Mean		-4.03, 0.12
p-value		0.0641
Hedges' g (Zuranolone vs. Placebo)		-0.316
95% CI for Hedges' g		-0.6518, 0.0198
Day 21		
n	64	61
LS Mean (SE)	-9.26 (0.752)	-10.27 (0.771)
95% CI for the LS Mean	-10.75, -7.77	-11.79, -8.74
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.01 (1.077)
95% CI for the LS Mean		-3.14, 1.12
p-value		0.3511
Hedges' g (Zuranolone vs. Placebo)		-0.166
95% CI for Hedges' g		-0.5177, 0.1849

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-301-by.sas:t-phq9-mmrm-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Model-based Results on Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

Page: 6 of 6

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

	Placebo (N=77)	Zuranolone (N=74)
Day 28		
n	66	58
LS Mean (SE)	-9.15 (0.778)	-10.75 (0.806)
95% CI for the LS Mean	-10.69, -7.61	-12.34, -9.16
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.60 (1.121)
95% CI for the LS Mean		-3.81, 0.62
p-value		0.1568
Hedges' g (Zuranolone vs. Placebo)		-0.255
95% CI for Hedges' g		-0.6088, 0.0995
Day 45		
n	65	63
LS Mean (SE)	-9.67 (0.843)	-11.78 (0.864)
95% CI for the LS Mean	-11.34, -8.00	-13.49, -10.07
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.11 (1.208)
95% CI for the LS Mean		-4.50, 0.28
p-value		0.0827
Hedges' g (Zuranolone vs. Placebo)		-0.307
95% CI for Hedges' g		-0.6557, 0.0414

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.

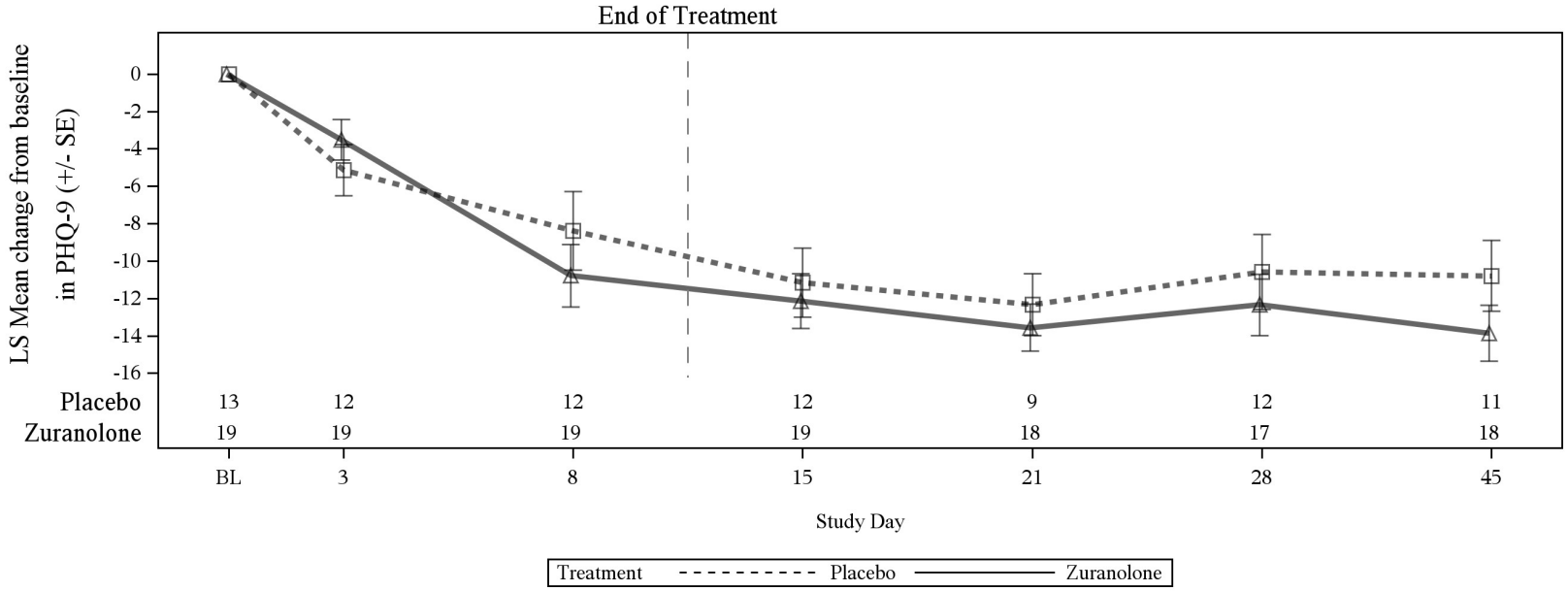
Source: biib125/v_a/germany_amnog/t-phq9-mmrm-301-by.sas:t-phq9-mmrm-301-by-hama-itta.rtf **Run Date:** 25JUL2025

2.4.1.2 .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-301 - ITT population

Page: 1 of 19

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.

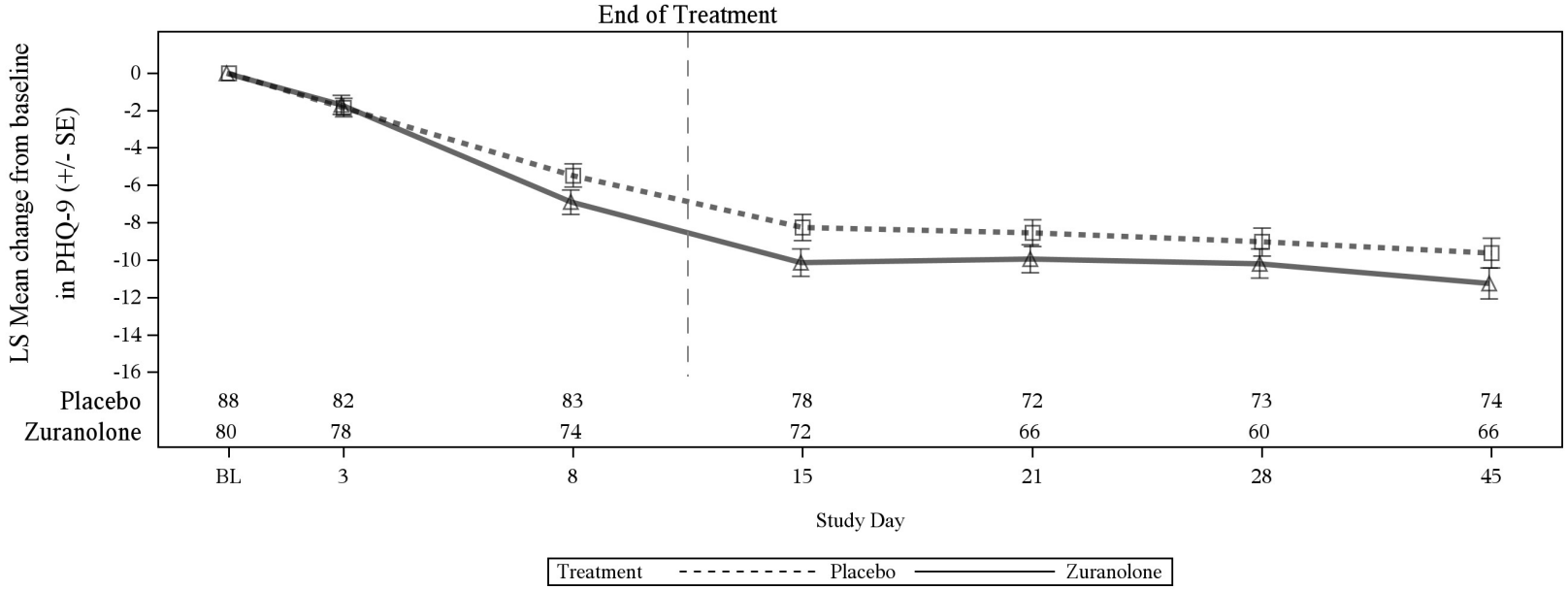
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.

Source: biib125/v_a/germany_amnog/f-phq9-mmrm-301-by.sas:f-phq9-mmrm-301-by-itta.rtf **Run Date:** 18JUL2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score over Time by Subgroup: 217-PPD-301 - ITT population

Page: 2 of 19

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.

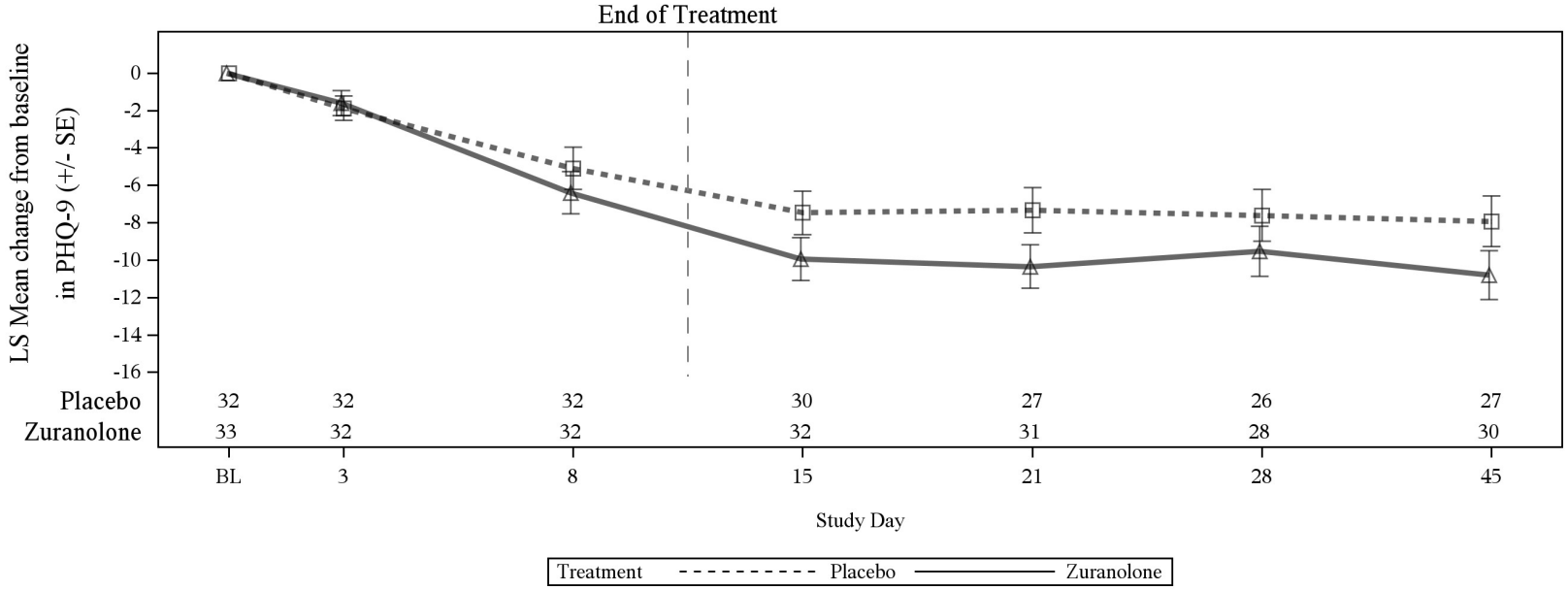
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.

Source: biib125/v_a/germany_amnog/f-phq9-mmrm-301-by.sas:f-phq9-mmrm-301-by-itta.rtf **Run Date:** 18JUL2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score over Time by Subgroup: 217-PPD-301 - 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.

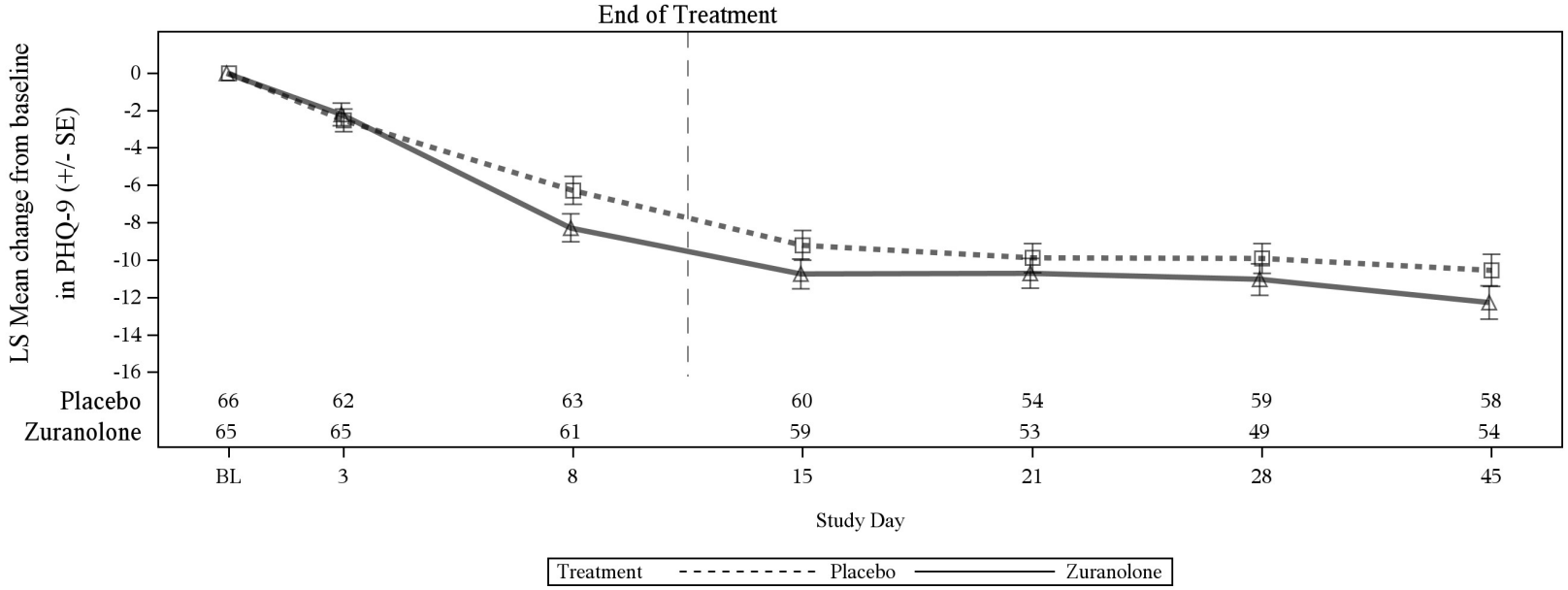
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.

Source: biib125/v_a/germany_amnog/f-phq9-mmrm-301-by.sas:f-phq9-mmrm-301-by-itta.rtf **Run Date:** 18JUL2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score over Time by Subgroup: 217-PPD-301 - 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.

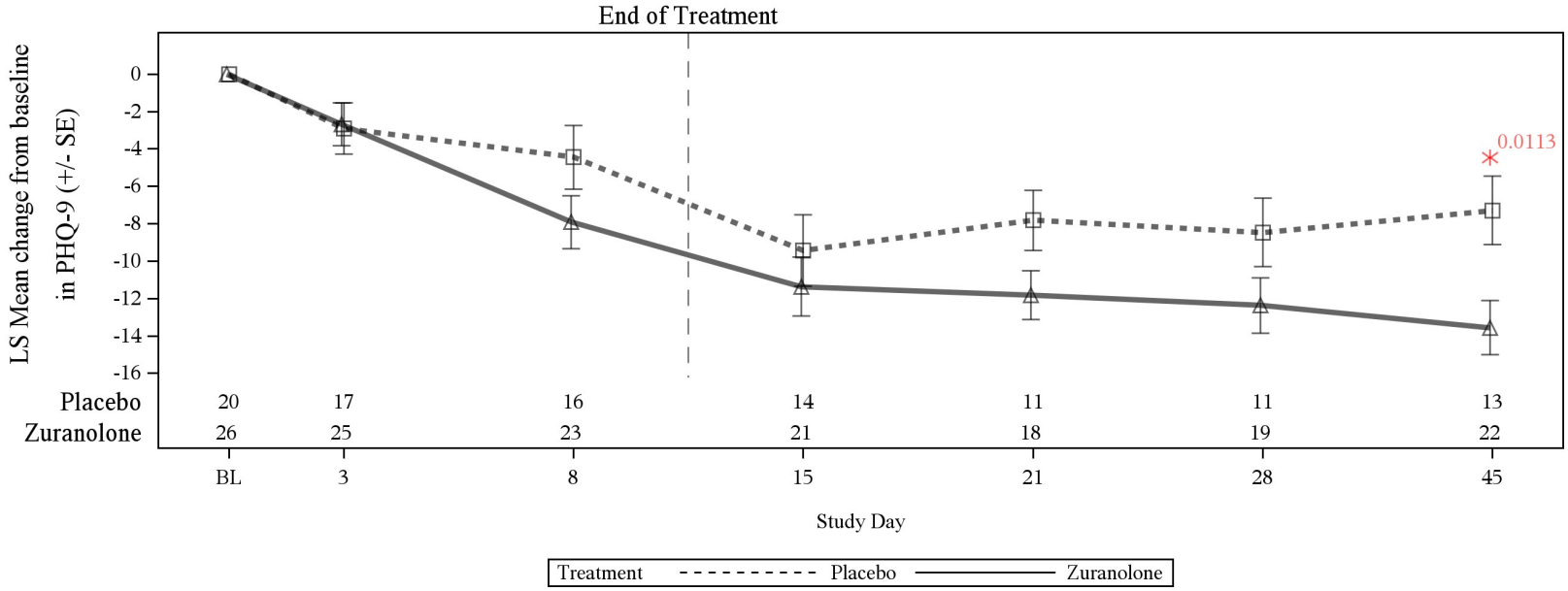
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.

Source: biib125/v_a/germany_amnog/f-phq9-mmrm-301-by.sas:f-phq9-mmrm-301-by-itta.rtf **Run Date:** 18JUL2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score over Time by Subgroup: 217-PPD-301 - 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.

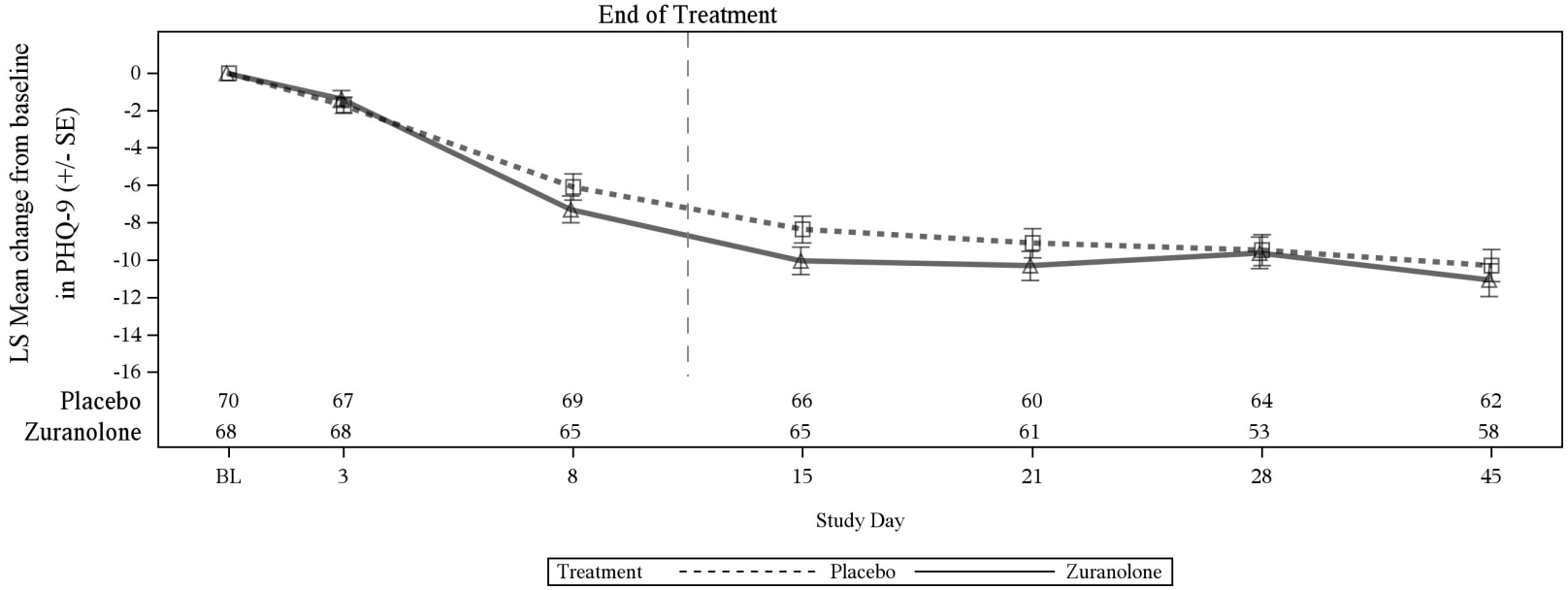
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.

Source: biib125/v_a/germany_amnog/f-phq9-mmrm-301-by.sas:f-phq9-mmrm-301-by-itta.rtf **Run Date:** 18JUL2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score over Time by Subgroup: 217-PPD-301 - ITT population

Page: 6 of 19

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.

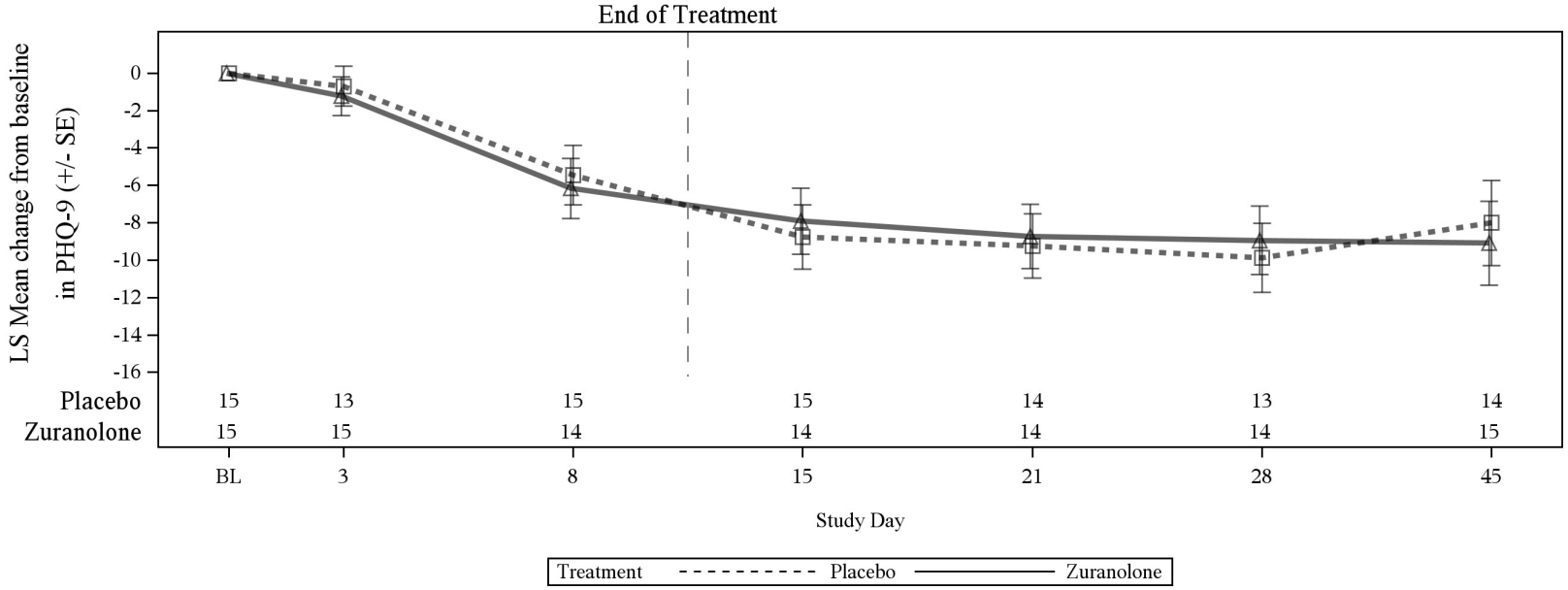
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.

Source: biib125/v_a/germany_amnog/f-phq9-mmrm-301-by.sas:f-phq9-mmrm-301-by-itta.rtf **Run Date:** 18JUL2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score over Time by Subgroup: 217-PPD-301 - 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.

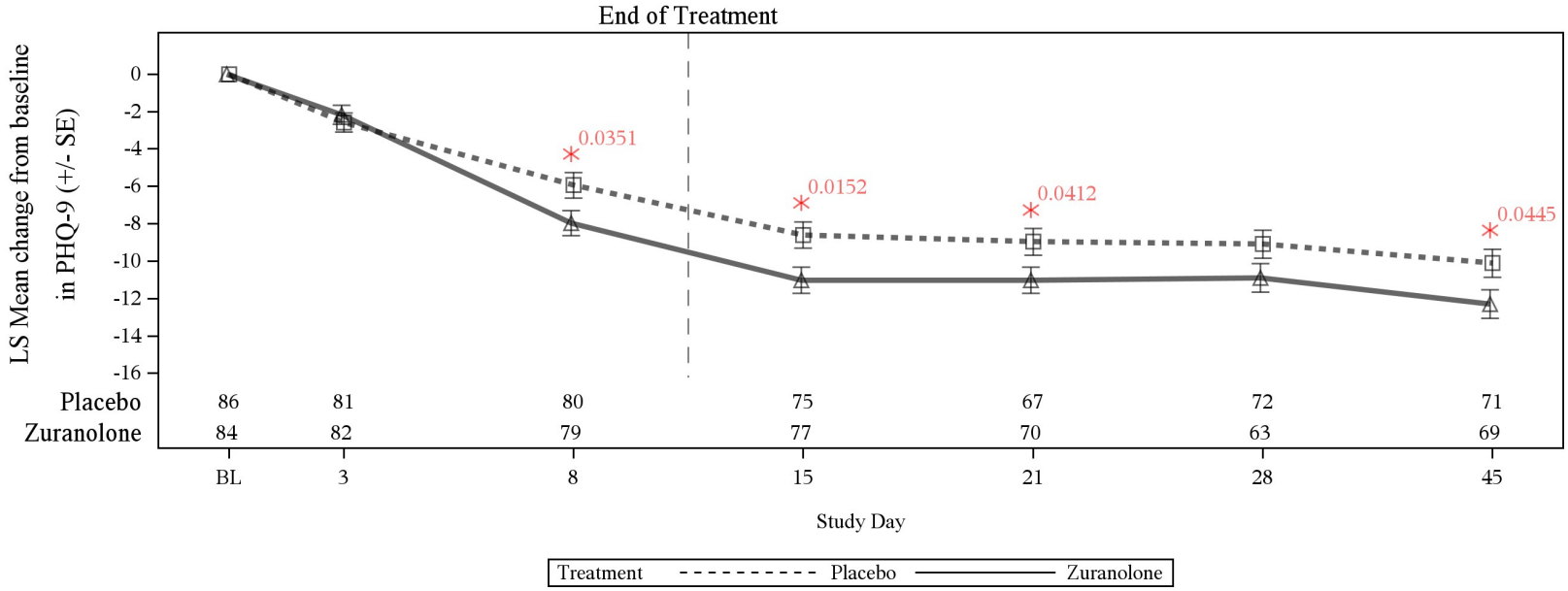
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.

Source: biib125/v_a/germany_amnog/f-phq9-mmrm-301-by.sas:f-phq9-mmrm-301-by-itta.rtf **Run Date:** 18JUL2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score over Time by Subgroup: 217-PPD-301 - ITT population

Page: 8 of 19

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.

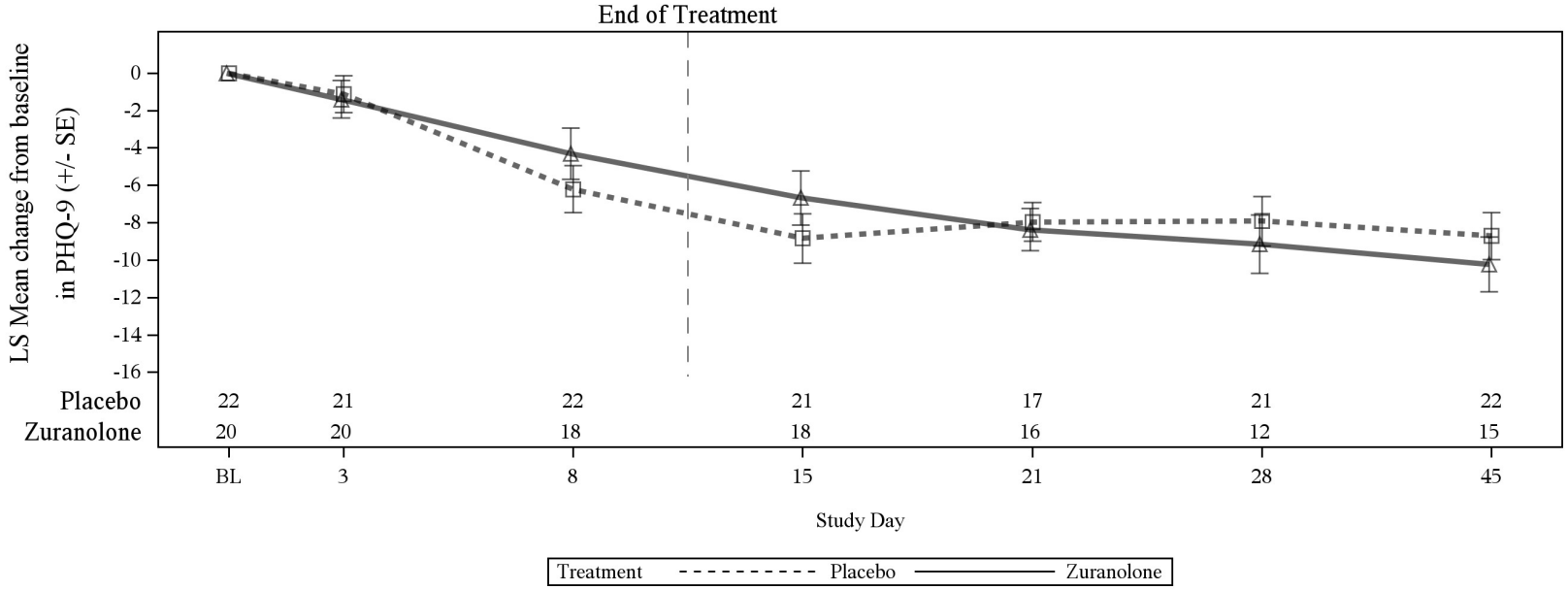
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.

Source: biib125/v_a/germany_amnog/f-phq9-mmrm-301-by.sas:f-phq9-mmrm-301-by-itta.rtf **Run Date:** 18JUL2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score over Time by Subgroup: 217-PPD-301 - 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.

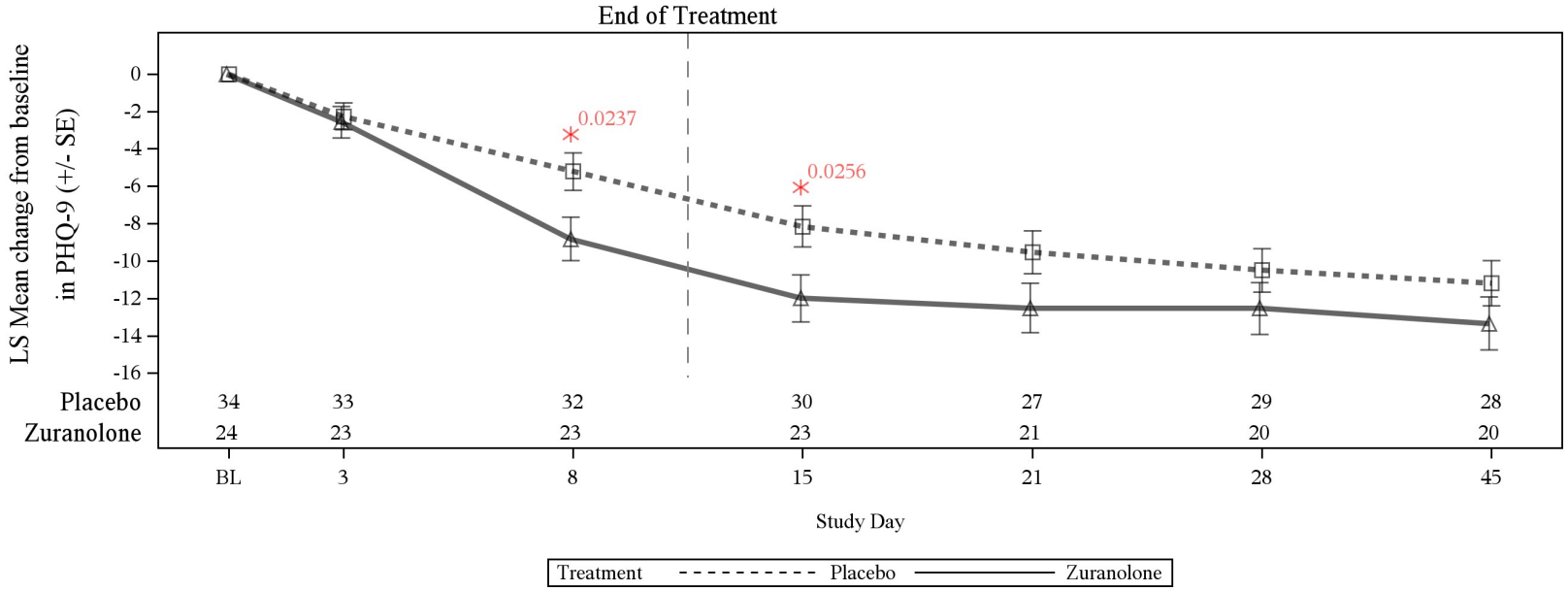
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.

Source: biib125/v_a/germany_amnog/f-phq9-mmrm-301-by.sas:f-phq9-mmrm-301-by-itta.rtf **Run Date:** 18JUL2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score over Time by Subgroup: 217-PPD-301 - 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.

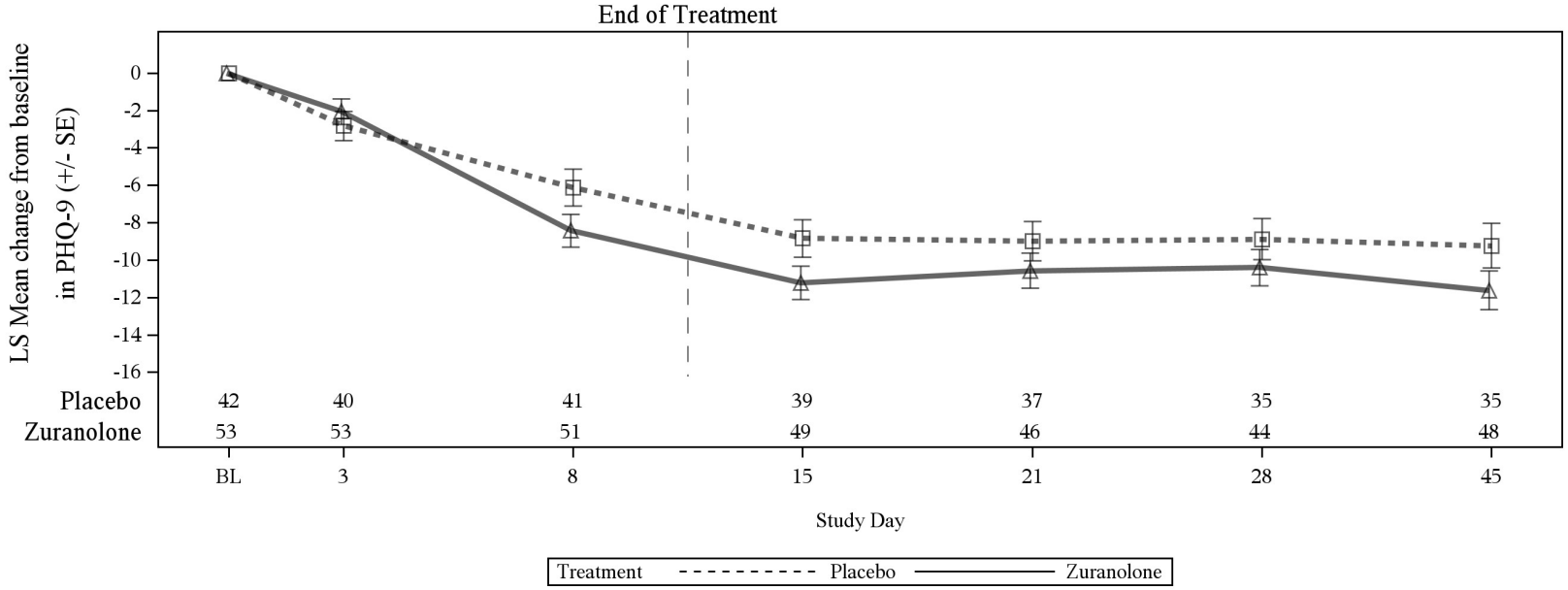
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.

Source: biib125/v_a/germany_amnog/f-phq9-mmrm-301-by.sas:f-phq9-mmrm-301-by-itta.rtf **Run Date:** 18JUL2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score over Time by Subgroup: 217-PPD-301 - 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.

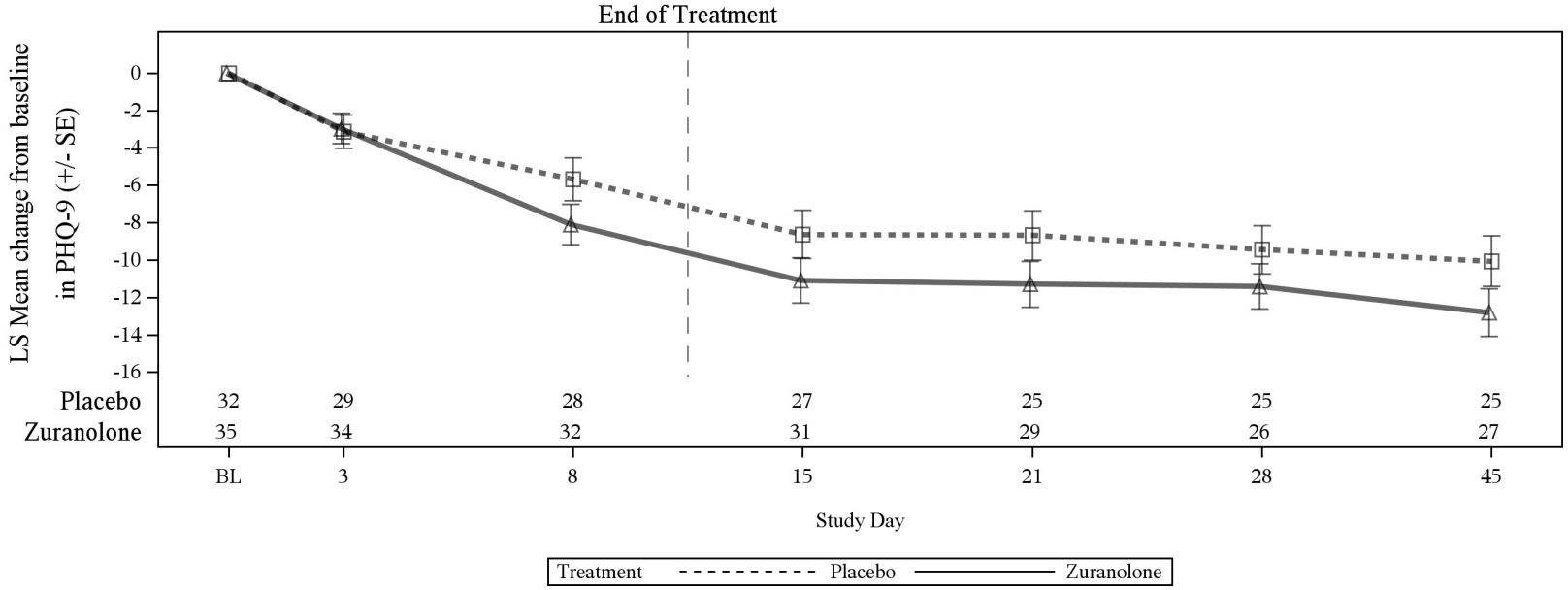
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.

Source: biib125/v_a/germany_amnog/f-phq9-mmrm-301-by.sas:f-phq9-mmrm-301-by-itta.rtf **Run Date:** 18JUL2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score over Time by Subgroup: 217-PPD-301 - 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.

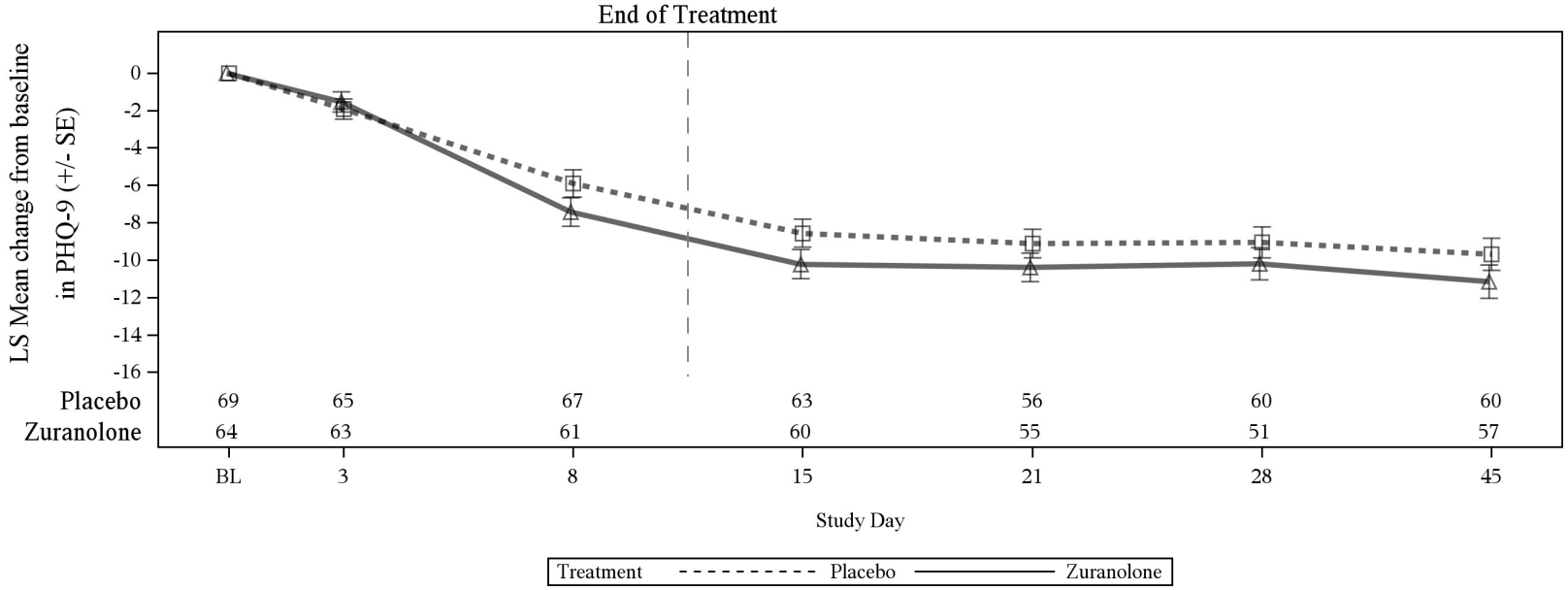
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.

Source: biib125/v_a/germany_amnog/f-phq9-mmrm-301-by.sas:f-phq9-mmrm-301-by-itta.rtf **Run Date:** 18JUL2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score over Time by Subgroup: 217-PPD-301 - 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 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.

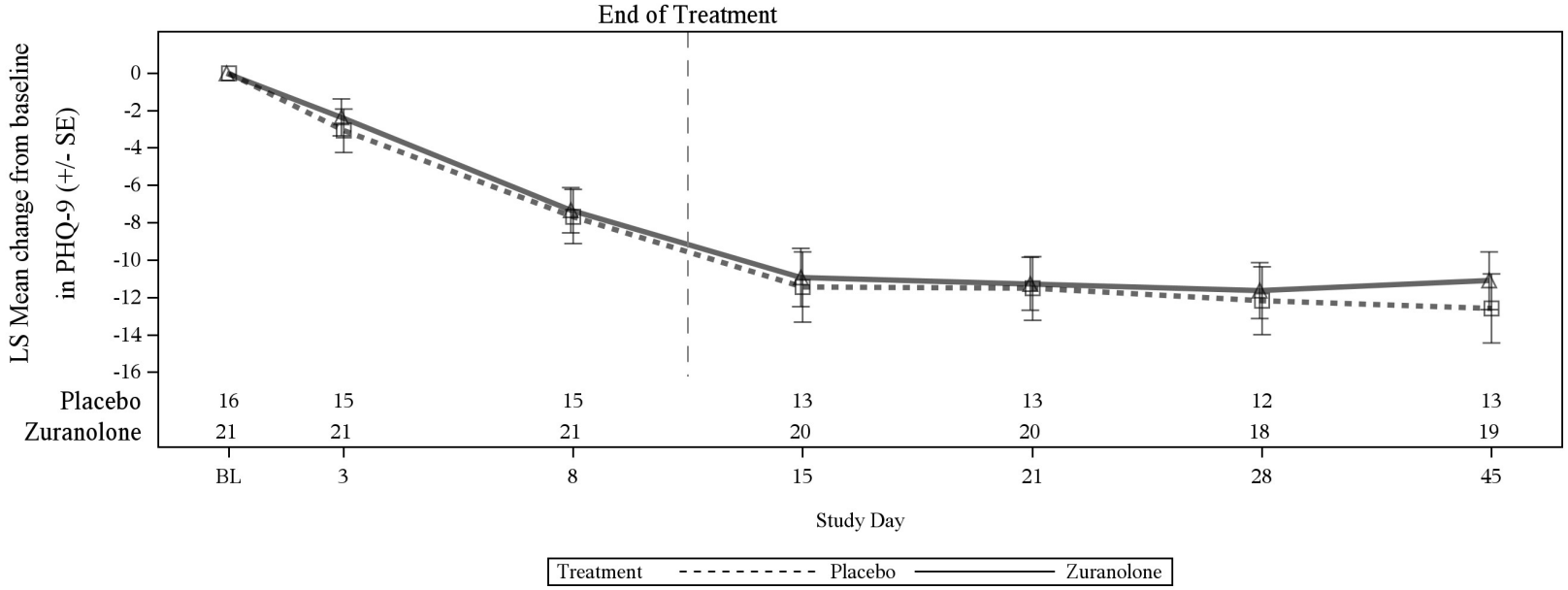
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.

Source: biib125/v_a/germany_amnog/f-phq9-mmrm-301-by.sas:f-phq9-mmrm-301-by-itta.rtf **Run Date:** 18JUL2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score over Time by Subgroup: 217-PPD-301 - 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.

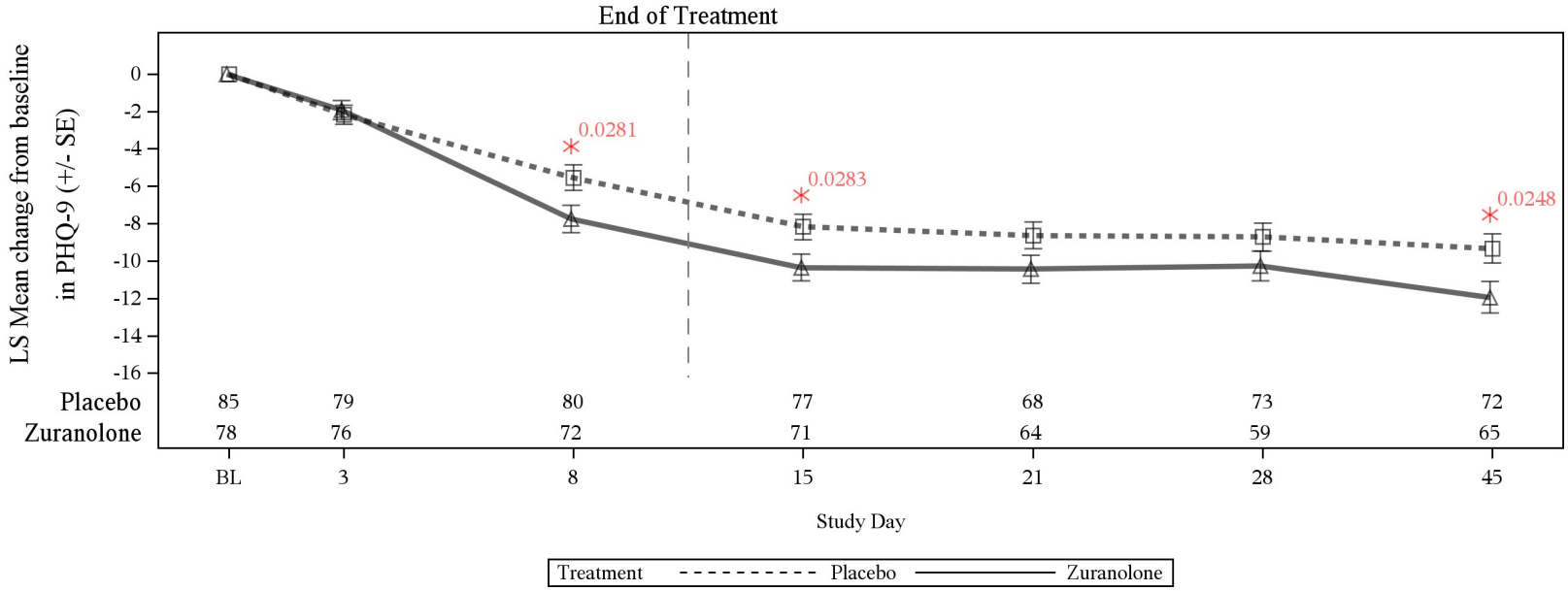
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.

Source: biib125/v_a/germany_amnog/f-phq9-mmrm-301-by.sas:f-phq9-mmrm-301-by-itta.rtf **Run Date:** 18JUL2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score over Time by Subgroup: 217-PPD-301 - 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.

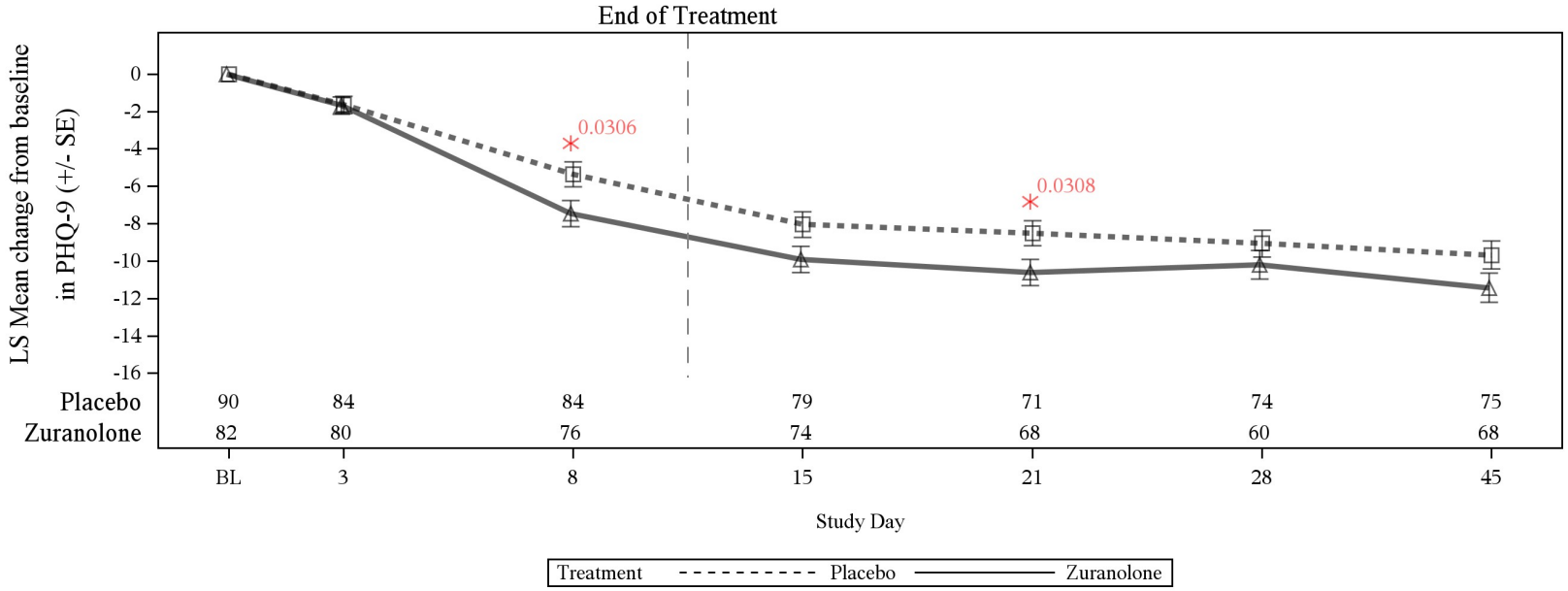
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.

Source: biib125/v_a/germany_amnog/f-phq9-mmrm-301-by.sas:f-phq9-mmrm-301-by-itta.rtf **Run Date:** 18JUL2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score over Time by Subgroup: 217-PPD-301 - 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.

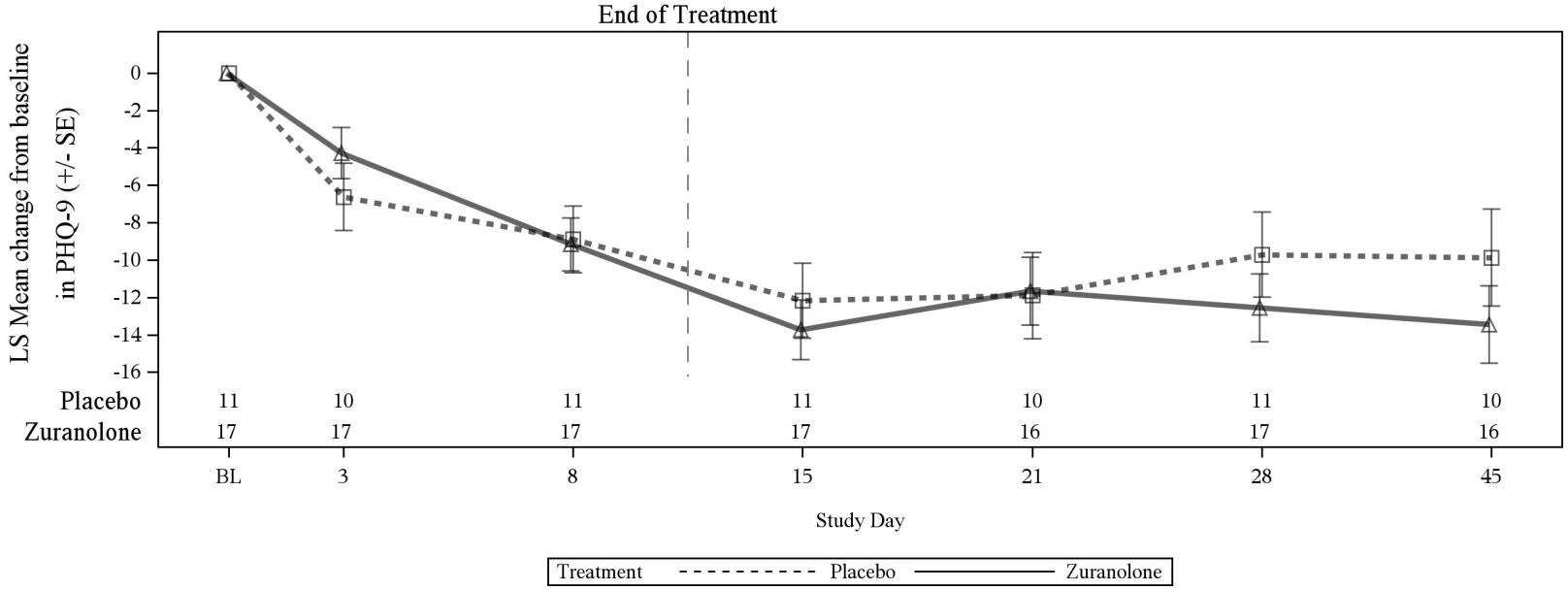
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.

Source: biib125/v_a/germany_amnog/f-phq9-mmrm-301-by.sas:f-phq9-mmrm-301-by-itta.rtf **Run Date:** 18JUL2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score over Time by Subgroup: 217-PPD-301 - 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.

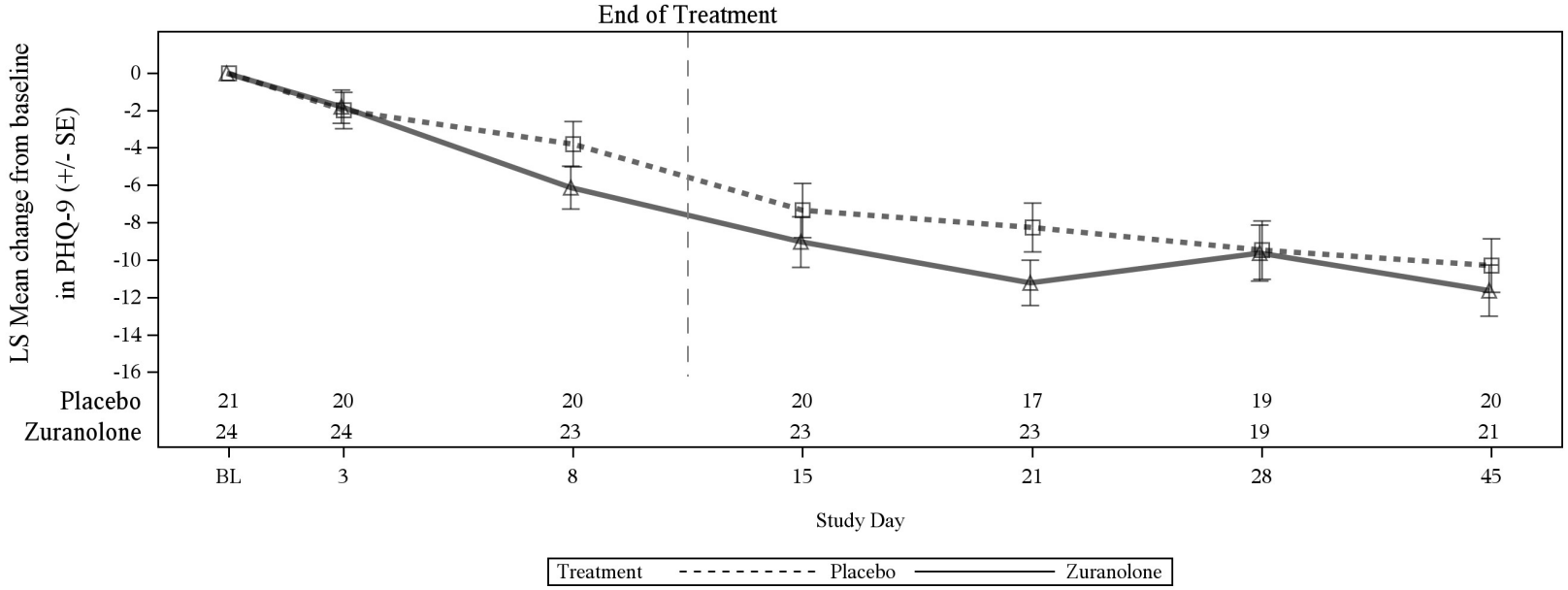
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.

Source: biib125/v_a/germany_amnog/f-phq9-mmrm-301-by.sas:f-phq9-mmrm-301-by-itta.rtf **Run Date:** 18JUL2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score over Time by Subgroup: 217-PPD-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20



Abbreviations: LS = Least-squares; SE = Standard 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.

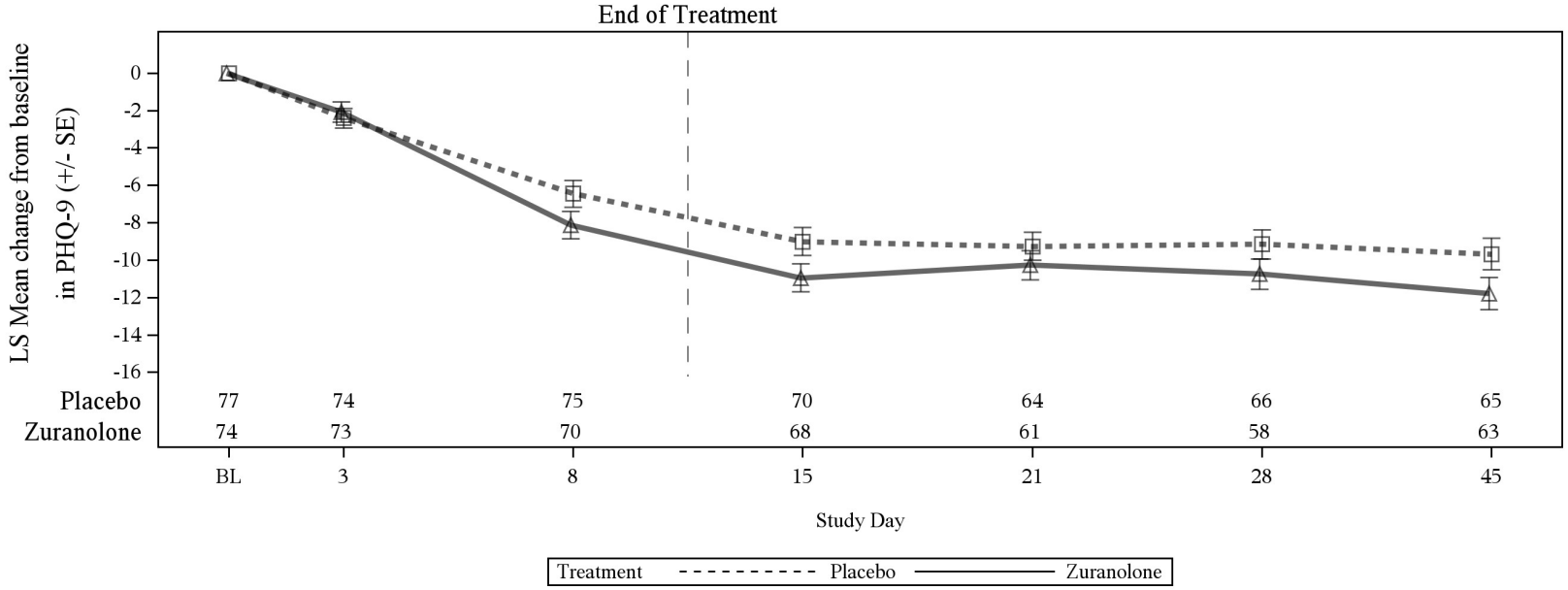
NOTE 2: The PHQ-9 total score was calculated as the sum of the 9 individual item scores. A lower value indicates better outcome.

Source: biib125/v_a/germany_amnog/f-phq9-mmrm-301-by.sas:f-phq9-mmrm-301-by-itta.rtf **Run Date:** 18JUL2025

Line Plot of LS Mean (+/- SE) Change from Baseline in Patient Health Questionnaire (PHQ-9) Total Score over Time by Subgroup: 217-PPD-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20



Abbreviations: LS = Least-squares; SE = Standard 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-301-by.sas:f-phq9-mmrm-301-by-itta.rtf **Run Date:** 18JUL2025

2.4.2 Ansprechen

2.4.2.1 Responder-Analysen

2.4.2.1 .1 ITT-Population

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline): 217-PPD-301 - ITT population

Page: 1 of 6

Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Number of evaluable subjects [1]	98	98
Day 3		
Number of subjects with a response, n (%) [2]	23 (23.5)	21 (21.4)
Number of subjects with missing evaluation, n (%)	4 (4.1)	1 (1.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.915
95% CI for the RR		(0.549, 1.525)
p-value for RR		0.7334
OR - Odds Ratio (Zuranolone vs. Placebo)		0.861
95% CI for the OR		(0.439, 1.689)
p-value for OR		0.6633
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. 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-resp15-301-ovr.sas:t-phq9-resp15-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline): 217-PPD-301 - ITT population

Page: 2 of 6

Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 8		
Number of subjects with a response, n (%) [2]	50 (51.0)	61 (62.2)
Number of subjects with missing evaluation, n (%)	3 (3.1)	5 (5.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.249
95% CI for the RR		(0.986, 1.581)
p-value for RR		0.0651
OR - Odds Ratio (Zuranolone vs. Placebo)		1.586
95% CI for the OR		(0.904, 2.784)
p-value for OR		0.1080
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. 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-resp15-301-ovr.sas:t-phq9-resp15-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline): 217-PPD-301 - ITT population

Page: 3 of 6

Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 15		
Number of subjects with a response, n (%) [2]	64 (65.3)	74 (75.5)
Number of subjects with missing evaluation, n (%)	8 (8.2)	7 (7.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.155
95% CI for the RR		(0.963, 1.385)
p-value for RR		0.1202
OR - Odds Ratio (Zuranolone vs. Placebo)		1.664
95% CI for the OR		(0.887, 3.120)
p-value for OR		0.1127
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. 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-resp15-301-ovr.sas:t-phq9-resp15-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline): 217-PPD-301 - ITT population

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Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 21		
Number of subjects with a response, n (%) [2]	58 (59.2)	68 (69.4)
Number of subjects with missing evaluation, n (%)	17 (17.3)	14 (14.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.161
95% CI for the RR		(0.937, 1.439)
p-value for RR		0.1722
OR - Odds Ratio (Zuranolone vs. Placebo)		1.570
95% CI for the OR		(0.850, 2.899)
p-value for OR		0.1497
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. 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-resp15-301-ovr.sas:t-phq9-resp15-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline): 217-PPD-301 - ITT population

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Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 28		
Number of subjects with a response, n (%) [2]	66 (67.3)	60 (61.2)
Number of subjects with missing evaluation, n (%)	13 (13.3)	21 (21.4)
RR - Relative Risk (Zuranolone vs. Placebo)		0.912
95% CI for the RR		(0.737, 1.128)
p-value for RR		0.3949
OR - Odds Ratio (Zuranolone vs. Placebo)		0.758
95% CI for the OR		(0.414, 1.386)
p-value for OR		0.3680
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. 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-resp15-301-ovr.sas:t-phq9-resp15-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline): 217-PPD-301 - ITT population

Page: 6 of 6

Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 45		
Number of subjects with a response, n (%) [2]	62 (63.3)	68 (69.4)
Number of subjects with missing evaluation, n (%)	13 (13.3)	14 (14.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.099
95% CI for the RR		(0.895, 1.350)
p-value for RR		0.3671
OR - Odds Ratio (Zuranolone vs. Placebo)		1.319
95% CI for the OR		(0.713, 2.439)
p-value for OR		0.3779
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. 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-resp15-301-ovr.sas:t-phq9-resp15-301-ovr-itta.rtf **Run Date:** 18JUL2025

2.4.2.1 .2 Subgruppen

2.4.2.1 .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-301 - ITT population

Page: 1 of 6

Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	98	98	
Number of subjects with response at Day 15, n (%)	64 (65.3)	74 (75.5)	
Number of subjects with response at Day 45, n (%)	62 (63.3)	68 (69.4)	
Age Group (years)			0.9002
Day 15			
18 - 24, n / N (%)	9/12 (75.0)	18/19 (94.7)	
25 - 45, n / N (%)	55/86 (64.0)	56/79 (70.9)	
Day 45			
18 - 24, n / N (%)	8/12 (66.7)	17/19 (89.5)	
25 - 45, n / N (%)	54/86 (62.8)	51/79 (64.6)	

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 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-resp15-301-int.sas:t-phq9-resp15-301-int-itta.rtf **Run Date:** 18JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

Page: 2 of 6

Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			0.0584
Day 15			
<28, n / N (%)	19/32 (59.4)	25/33 (75.8)	
>=28, n / N (%)	45/66 (68.2)	49/65 (75.4)	
Day 45			
<28, n / N (%)	17/32 (53.1)	25/33 (75.8)	
>=28, n / N (%)	45/66 (68.2)	43/65 (66.2)	
Race Group (Black or African American, White)			0.7023
Day 15			
Black or African American, n / N (%)	10/18 (55.6)	16/25 (64.0)	
White, n / N (%)	46/69 (66.7)	54/68 (79.4)	
Day 45			
Black or African American, n / N (%)	8/18 (44.4)	18/25 (72.0)	
White, n / N (%)	46/69 (66.7)	48/68 (70.6)	

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 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-resp15-301-int.sas:t-phq9-resp15-301-int-itta.rtf **Run Date:** 18JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			0.5147
Day 15			
Yes, n / N (%)	11/15 (73.3)	9/15 (60.0)	
No, n / N (%)	53/83 (63.9)	65/83 (78.3)	
Day 45			
Yes, n / N (%)	9/15 (60.0)	9/15 (60.0)	
No, n / N (%)	53/83 (63.9)	59/83 (71.1)	

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 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-resp15-301-int.sas:t-phq9-resp15-301-int-itta.rtf **Run Date:** 18JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			0.0405(a) 0.0699(b) 0.7103(c)
Day 15			
<=24.9, n / N (%)	15/22 (68.2)	11/20 (55.0)	
25-29.9, n / N (%)	21/34 (61.8)	20/24 (83.3)	
>=30, n / N (%)	28/42 (66.7)	42/53 (79.2)	
Day 45			
<=24.9, n / N (%)	15/22 (68.2)	12/20 (60.0)	
25-29.9, n / N (%)	23/34 (67.6)	18/24 (75.0)	
>=30, n / N (%)	24/42 (57.1)	37/53 (69.8)	

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-resp15-301-int.sas:t-phq9-resp15-301-int-itta.rtf **Run Date:** 18JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Onset of PPD			0.0927
Day 15			
3rd Trimester, n / N (%)	20/31 (64.5)	25/34 (73.5)	
Postpartum, n / N (%)	44/67 (65.7)	49/64 (76.6)	
Day 45			
3rd Trimester, n / N (%)	17/31 (54.8)	24/34 (70.6)	
Postpartum, n / N (%)	45/67 (67.2)	44/64 (68.8)	
Family History of PPD			0.6619
Day 15			
Yes, n / N (%)	11/16 (68.8)	15/21 (71.4)	
No/Unknown, n / N (%)	53/82 (64.6)	59/77 (76.6)	
Day 45			
Yes, n / N (%)	12/16 (75.0)	15/21 (71.4)	
No/Unknown, n / N (%)	50/82 (61.0)	53/77 (68.8)	

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-resp15-301-int.sas:t-phq9-resp15-301-int-itta.rtf **Run Date:** 18JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
History of PPD			0.6385
Day 15			
1st Episode, n / N (%)	54/87 (62.1)	60/81 (74.1)	
Recurrent Episode, n / N (%)	10/11 (90.9)	14/17 (82.4)	
Day 45			
1st Episode, n / N (%)	56/87 (64.4)	56/81 (69.1)	
Recurrent Episode, n / N (%)	6/11 (54.5)	12/17 (70.6)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			0.8409
Day 15			
<20, n / N (%)	12/21 (57.1)	17/24 (70.8)	
>=20, n / N (%)	52/77 (67.5)	57/74 (77.0)	
Day 45			
<20, n / N (%)	14/21 (66.7)	17/24 (70.8)	
>=20, n / N (%)	48/77 (62.3)	51/74 (68.9)	

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 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-resp15-301-int.sas:t-phq9-resp15-301-int-itta.rtf **Run Date:** 18JUL2025

2.4.2.1 .2 .2 Subgruppenanalysen

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Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =19)
Number of evaluable subjects [1]	12	19
Day 3		
Number of subjects with a response, n (%) [2]	6 (50.0)	5 (26.3)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.525
95% CI for the RR		(0.201, 1.369)
p-value for RR		0.1873
Day 8		
Number of subjects with a response, n (%) [2]	7 (58.3)	15 (78.9)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.349
95% CI for the RR		(0.797, 2.284)
p-value for RR		0.2653

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-resp15-301-by.sas:t-phq9-resp15-301-by-age-itta.rtf **Run Date:** 25JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =19)
Day 15		
Number of subjects with a response, n (%) [2]	9 (75.0)	18 (94.7)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.259
95% CI for the RR		(0.844, 1.877)
p-value for RR		0.2587
Day 21		
Number of subjects with a response, n (%) [2]	8 (66.7)	18 (94.7)
Number of subjects with missing evaluation, n (%)	3 (25.0)	1 (5.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.416
95% CI for the RR		(0.948, 2.117)
p-value for RR		0.0896

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-resp15-301-by.sas:t-phq9-resp15-301-by-age-itta.rtf **Run Date:** 25JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =19)
Day 28		
Number of subjects with a response, n (%) [2]	11 (91.7)	14 (73.7)
Number of subjects with missing evaluation, n (%)	0	2 (10.5)
RR - Relative Risk (Zuranolone vs. Placebo)		0.801
95% CI for the RR		(0.555, 1.156)
p-value for RR		0.2363
Day 45		
Number of subjects with a response, n (%) [2]	8 (66.7)	17 (89.5)
Number of subjects with missing evaluation, n (%)	1 (8.3)	1 (5.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.338
95% CI for the RR		(0.833, 2.149)
p-value for RR		0.2292

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-resp15-301-by.sas:t-phq9-resp15-301-by-age-itta.rtf **Run Date:** 25JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=88)	Zuranolone (N =80)
Number of evaluable subjects [1]	86	79
Day 3		
Number of subjects with a response, n (%) [2]	17 (19.8)	16 (20.3)
Number of subjects with missing evaluation, n (%)	4 (4.7)	1 (1.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.020
95% CI for the RR		(0.559, 1.861)
p-value for RR		0.9478
Day 8		
Number of subjects with a response, n (%) [2]	43 (50.0)	46 (58.2)
Number of subjects with missing evaluation, n (%)	3 (3.5)	5 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.160
95% CI for the RR		(0.884, 1.521)
p-value for RR		0.2839

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-resp15-301-by.sas:t-phq9-resp15-301-by-age-itta.rtf **Run Date:** 25JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=88)	Zuranolone (N =80)
Day 15		
Number of subjects with a response, n (%) [2]	55 (64.0)	56 (70.9)
Number of subjects with missing evaluation, n (%)	8 (9.3)	7 (8.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.104
95% CI for the RR		(0.893, 1.364)
p-value for RR		0.3606
Day 21		
Number of subjects with a response, n (%) [2]	50 (58.1)	50 (63.3)
Number of subjects with missing evaluation, n (%)	14 (16.3)	13 (16.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.084
95% CI for the RR		(0.846, 1.390)
p-value for RR		0.5244

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-resp15-301-by.sas:t-phq9-resp15-301-by-age-itta.rtf **Run Date:** 25JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=88)	Zuranolone (N =80)
Day 28		
Number of subjects with a response, n (%) [2]	55 (64.0)	46 (58.2)
Number of subjects with missing evaluation, n (%)	13 (15.1)	19 (24.1)
RR - Relative Risk (Zuranolone vs. Placebo)		0.907
95% CI for the RR		(0.709, 1.159)
p-value for RR		0.4346
Day 45		
Number of subjects with a response, n (%) [2]	54 (62.8)	51 (64.6)
Number of subjects with missing evaluation, n (%)	12 (14.0)	13 (16.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.024
95% CI for the RR		(0.811, 1.292)
p-value for RR		0.8427

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-resp15-301-by.sas:t-phq9-resp15-301-by-age-itta.rtf **Run Date:** 25JUL2025

2.4.2.1 .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-301 - 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=32)	Zuranolone (N =33)
Number of evaluable subjects [1]	32	33
Day 3		
Number of subjects with a response, n (%) [2]	4 (12.5)	8 (24.2)
Number of subjects with missing evaluation, n (%)	0	1 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		2.061
95% CI for the RR		(0.681, 6.243)
p-value for RR		0.2008
Day 8		
Number of subjects with a response, n (%) [2]	14 (43.8)	19 (57.6)
Number of subjects with missing evaluation, n (%)	0	1 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.346
95% CI for the RR		(0.835, 2.169)
p-value for RR		0.2228

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 and "Log" link function.
[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-resp15-301-by.sas:t-phq9-resp15-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Baseline HAMD-17 Total Score: 217-PPD-301 - ITT population

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

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =33)
Day 15		
Number of subjects with a response, n (%) [2]	19 (59.4)	25 (75.8)
Number of subjects with missing evaluation, n (%)	2 (6.3)	1 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.364
95% CI for the RR		(0.980, 1.896)
p-value for RR		0.0655
Day 21		
Number of subjects with a response, n (%) [2]	17 (53.1)	26 (78.8)
Number of subjects with missing evaluation, n (%)	5 (15.6)	2 (6.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.544
95% CI for the RR		(1.061, 2.246)
p-value for RR		0.0232

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 and "Log" link function.
[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-resp15-301-by.sas:t-phq9-resp15-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Baseline HAMD-17 Total Score: 217-PPD-301 - 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=32)	Zuranolone (N =33)
Day 28		
Number of subjects with a response, n (%) [2]	18 (56.3)	20 (60.6)
Number of subjects with missing evaluation, n (%)	6 (18.8)	5 (15.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.132
95% CI for the RR		(0.750, 1.709)
p-value for RR		0.5558
Day 45		
Number of subjects with a response, n (%) [2]	17 (53.1)	25 (75.8)
Number of subjects with missing evaluation, n (%)	5 (15.6)	3 (9.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.487
95% CI for the RR		(1.022, 2.164)
p-value for RR		0.0383

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 and "Log" link function.

[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-resp15-301-by.sas:t-phq9-resp15-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Baseline HAMD-17 Total Score: 217-PPD-301 - 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=66)	Zuranolone (N =65)
Number of evaluable subjects [1]	66	65
Day 3		
Number of subjects with a response, n (%) [2]	19 (28.8)	13 (20.0)
Number of subjects with missing evaluation, n (%)	4 (6.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.696
95% CI for the RR		(0.378, 1.280)
p-value for RR		0.2434
Day 8		
Number of subjects with a response, n (%) [2]	36 (54.5)	42 (64.6)
Number of subjects with missing evaluation, n (%)	3 (4.5)	4 (6.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.206
95% CI for the RR		(0.920, 1.582)
p-value for RR		0.1758

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 and "Log" link function.

[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-resp15-301-by.sas:t-phq9-resp15-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Baseline HAMD-17 Total Score: 217-PPD-301 - ITT population

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

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =65)
Day 15		
Number of subjects with a response, n (%) [2]	45 (68.2)	49 (75.4)
Number of subjects with missing evaluation, n (%)	6 (9.1)	6 (9.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.100
95% CI for the RR		(0.890, 1.359)
p-value for RR		0.3773
Day 21		
Number of subjects with a response, n (%) [2]	41 (62.1)	42 (64.6)
Number of subjects with missing evaluation, n (%)	12 (18.2)	12 (18.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.031
95% CI for the RR		(0.794, 1.337)
p-value for RR		0.8210

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 and "Log" link function.
[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-resp15-301-by.sas:t-phq9-resp15-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Baseline HAMD-17 Total Score: 217-PPD-301 - ITT population

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

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =65)
Day 28		
Number of subjects with a response, n (%) [2]	48 (72.7)	40 (61.5)
Number of subjects with missing evaluation, n (%)	7 (10.6)	16 (24.6)
RR - Relative Risk (Zuranolone vs. Placebo)		0.848
95% CI for the RR		(0.665, 1.081)
p-value for RR		0.1830
Day 45		
Number of subjects with a response, n (%) [2]	45 (68.2)	43 (66.2)
Number of subjects with missing evaluation, n (%)	8 (12.1)	11 (16.9)
RR - Relative Risk (Zuranolone vs. Placebo)		0.983
95% CI for the RR		(0.771, 1.253)
p-value for RR		0.8878

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 and "Log" link function.
[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-resp15-301-by.sas:t-phq9-resp15-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

2.4.2.1 .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-301 - ITT population

Page: 1 of 6

Race Group = Black or African American

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =26)
Number of evaluable subjects [1]	18	25
Day 3		
Number of subjects with a response, n (%) [2]	6 (33.3)	6 (24.0)
Number of subjects with missing evaluation, n (%)	1 (5.6)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.720
95% CI for the RR		(0.289, 1.795)
p-value for RR		0.4814
Day 8		
Number of subjects with a response, n (%) [2]	9 (50.0)	13 (52.0)
Number of subjects with missing evaluation, n (%)	2 (11.1)	2 (8.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.041
95% CI for the RR		(0.606, 1.788)
p-value for RR		0.8852

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-resp15-301-by.sas:t-phq9-resp15-301-by-race-itta.rtf **Run Date:** 25JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-301 - ITT population

Page: 2 of 6

Race Group = Black or African American

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =26)
Day 15		
Number of subjects with a response, n (%) [2]	10 (55.6)	16 (64.0)
Number of subjects with missing evaluation, n (%)	4 (22.2)	4 (16.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.153
95% CI for the RR		(0.704, 1.887)
p-value for RR		0.5719
Day 21		
Number of subjects with a response, n (%) [2]	8 (44.4)	14 (56.0)
Number of subjects with missing evaluation, n (%)	7 (38.9)	7 (28.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.261
95% CI for the RR		(0.664, 2.394)
p-value for RR		0.4788

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-resp15-301-by.sas:t-phq9-resp15-301-by-race-itta.rtf **Run Date:** 25JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-301 - ITT population

Page: 3 of 6

Race Group = Black or African American

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =26)
Day 28		
Number of subjects with a response, n (%) [2]	8 (44.4)	16 (64.0)
Number of subjects with missing evaluation, n (%)	7 (38.9)	6 (24.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.441
95% CI for the RR		(0.764, 2.717)
p-value for RR		0.2590
Day 45		
Number of subjects with a response, n (%) [2]	8 (44.4)	18 (72.0)
Number of subjects with missing evaluation, n (%)	5 (27.8)	3 (12.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.621
95% CI for the RR		(0.899, 2.922)
p-value for RR		0.1082

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-resp15-301-by.sas:t-phq9-resp15-301-by-race-itta.rtf **Run Date:** 25JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-301 - ITT population

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Race Group = White

Study Visit Statistics	Placebo (N=70)	Zuranolone (N =68)
Number of evaluable subjects [1]	69	68
Day 3		
Number of subjects with a response, n (%) [2]	13 (18.8)	13 (19.1)
Number of subjects with missing evaluation, n (%)	2 (2.9)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.006
95% CI for the RR		(0.506, 2.000)
p-value for RR		0.9854
Day 8		
Number of subjects with a response, n (%) [2]	36 (52.2)	44 (64.7)
Number of subjects with missing evaluation, n (%)	0	3 (4.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.230
95% CI for the RR		(0.931, 1.625)
p-value for RR		0.1448

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-resp15-301-by.sas:t-phq9-resp15-301-by-race-itta.rtf **Run Date:** 25JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-301 - ITT population

Race Group = White

Study Visit Statistics	Placebo (N=70)	Zuranolone (N =68)
Day 15		
Number of subjects with a response, n (%) [2]	46 (66.7)	54 (79.4)
Number of subjects with missing evaluation, n (%)	3 (4.3)	3 (4.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.181
95% CI for the RR		(0.964, 1.448)
p-value for RR		0.1079
Day 21		
Number of subjects with a response, n (%) [2]	42 (60.9)	50 (73.5)
Number of subjects with missing evaluation, n (%)	9 (13.0)	7 (10.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.198
95% CI for the RR		(0.946, 1.518)
p-value for RR		0.1344

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-resp15-301-by.sas:t-phq9-resp15-301-by-race-itta.rtf **Run Date:** 25JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-301 - ITT population

Race Group = White

Study Visit Statistics	Placebo (N=70)	Zuranolone (N =68)
Day 28		
Number of subjects with a response, n (%) [2]	50 (72.5)	40 (58.8)
Number of subjects with missing evaluation, n (%)	5 (7.2)	15 (22.1)
RR - Relative Risk (Zuranolone vs. Placebo)		0.805
95% CI for the RR		(0.630, 1.029)
p-value for RR		0.0838
Day 45		
Number of subjects with a response, n (%) [2]	46 (66.7)	48 (70.6)
Number of subjects with missing evaluation, n (%)	7 (10.1)	10 (14.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.050
95% CI for the RR		(0.838, 1.316)
p-value for RR		0.6703

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-resp15-301-by.sas:t-phq9-resp15-301-by-race-itta.rtf **Run Date:** 25JUL2025

2.4.2.1 .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-301 - ITT population

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Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=15)	Zuranolone (N =15)
Number of evaluable subjects [1]	15	15
Day 3		
Number of subjects with a response, n (%) [2]	2 (13.3)	2 (13.3)
Number of subjects with missing evaluation, n (%)	2 (13.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.053
95% CI for the RR		(0.173, 6.410)
p-value for RR		0.9553
Day 8		
Number of subjects with a response, n (%) [2]	8 (53.3)	8 (53.3)
Number of subjects with missing evaluation, n (%)	0	1 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.053
95% CI for the RR		(0.556, 1.996)
p-value for RR		0.8742

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 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-resp15-301-by.sas:t-phq9-resp15-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-301 - ITT population

Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=15)	Zuranolone (N =15)
Day 15		
Number of subjects with a response, n (%) [2]	11 (73.3)	9 (60.0)
Number of subjects with missing evaluation, n (%)	0	1 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.862
95% CI for the RR		(0.531, 1.399)
p-value for RR		0.5469
Day 21		
Number of subjects with a response, n (%) [2]	12 (80.0)	8 (53.3)
Number of subjects with missing evaluation, n (%)	1 (6.7)	1 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.702
95% CI for the RR		(0.412, 1.197)
p-value for RR		0.1938

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 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-resp15-301-by.sas:t-phq9-resp15-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-301 - ITT population

Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=15)	Zuranolone (N =15)
Day 28		
Number of subjects with a response, n (%) [2]	11 (73.3)	10 (66.7)
Number of subjects with missing evaluation, n (%)	2 (13.3)	1 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.957
95% CI for the RR		(0.625, 1.466)
p-value for RR		0.8410
Day 45		
Number of subjects with a response, n (%) [2]	9 (60.0)	9 (60.0)
Number of subjects with missing evaluation, n (%)	1 (6.7)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.053
95% CI for the RR		(0.600, 1.849)
p-value for RR		0.8572

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 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-resp15-301-by.sas:t-phq9-resp15-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-301 - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=86)	Zuranolone (N =84)
Number of evaluable subjects [1]	83	83
Day 3		
Number of subjects with a response, n (%) [2]	21 (25.3)	19 (22.9)
Number of subjects with missing evaluation, n (%)	2 (2.4)	1 (1.2)
RR - Relative Risk (Zuranolone vs. Placebo)		0.900
95% CI for the RR		(0.526, 1.540)
p-value for RR		0.7013
Day 8		
Number of subjects with a response, n (%) [2]	42 (50.6)	53 (63.9)
Number of subjects with missing evaluation, n (%)	3 (3.6)	4 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.256
95% CI for the RR		(0.967, 1.631)
p-value for RR		0.0880

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 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-resp15-301-by.sas:t-phq9-resp15-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-301 - ITT population

Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=86)	Zuranolone (N =84)
Day 15		
Number of subjects with a response, n (%) [2]	53 (63.9)	65 (78.3)
Number of subjects with missing evaluation, n (%)	8 (9.6)	6 (7.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.220
95% CI for the RR		(1.003, 1.485)
p-value for RR		0.0468
Day 21		
Number of subjects with a response, n (%) [2]	46 (55.4)	60 (72.3)
Number of subjects with missing evaluation, n (%)	16 (19.3)	13 (15.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.298
95% CI for the RR		(1.027, 1.640)
p-value for RR		0.0291

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 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-resp15-301-by.sas:t-phq9-resp15-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-301 - ITT population

Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=86)	Zuranolone (N =84)
Day 28		
Number of subjects with a response, n (%) [2]	55 (66.3)	50 (60.2)
Number of subjects with missing evaluation, n (%)	11 (13.3)	20 (24.1)
RR - Relative Risk (Zuranolone vs. Placebo)		0.905
95% CI for the RR		(0.717, 1.141)
p-value for RR		0.3970
Day 45		
Number of subjects with a response, n (%) [2]	53 (63.9)	59 (71.1)
Number of subjects with missing evaluation, n (%)	12 (14.5)	14 (16.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.108
95% CI for the RR		(0.895, 1.370)
p-value for RR		0.3463

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 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-resp15-301-by.sas:t-phq9-resp15-301-by-adt-itta.rtf **Run Date:** 25JUL2025

2.4.2.1 .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-301 - ITT population

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

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =20)
Number of evaluable subjects [1]	22	20
Day 3		
Number of subjects with a response, n (%) [2]	6 (27.3)	3 (15.0)
Number of subjects with missing evaluation, n (%)	1 (4.5)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.558
95% CI for the RR		(0.167, 1.870)
p-value for RR		0.3445
Day 8		
Number of subjects with a response, n (%) [2]	13 (59.1)	9 (45.0)
Number of subjects with missing evaluation, n (%)	0	2 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.773
95% CI for the RR		(0.445, 1.342)
p-value for RR		0.3601

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-resp15-301-by.sas:t-phq9-resp15-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =20)
Day 15		
Number of subjects with a response, n (%) [2]	15 (68.2)	11 (55.0)
Number of subjects with missing evaluation, n (%)	1 (4.5)	2 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.819
95% CI for the RR		(0.525, 1.276)
p-value for RR		0.3768
Day 21		
Number of subjects with a response, n (%) [2]	12 (54.5)	11 (55.0)
Number of subjects with missing evaluation, n (%)	5 (22.7)	4 (20.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.023
95% CI for the RR		(0.595, 1.759)
p-value for RR		0.9340

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-resp15-301-by.sas:t-phq9-resp15-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =20)
Day 28		
Number of subjects with a response, n (%) [2]	16 (72.7)	8 (40.0)
Number of subjects with missing evaluation, n (%)	1 (4.5)	8 (40.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.558
95% CI for the RR		(0.312, 0.997)
p-value for RR		0.0489
Day 45		
Number of subjects with a response, n (%) [2]	15 (68.2)	12 (60.0)
Number of subjects with missing evaluation, n (%)	0	5 (25.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.893
95% CI for the RR		(0.564, 1.413)
p-value for RR		0.6285

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-resp15-301-by.sas:t-phq9-resp15-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =24)
Number of evaluable subjects [1]	34	24
Day 3		
Number of subjects with a response, n (%) [2]	8 (23.5)	6 (25.0)
Number of subjects with missing evaluation, n (%)	1 (2.9)	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.049
95% CI for the RR		(0.413, 2.664)
p-value for RR		0.9197
Day 8		
Number of subjects with a response, n (%) [2]	17 (50.0)	15 (62.5)
Number of subjects with missing evaluation, n (%)	2 (5.9)	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.234
95% CI for the RR		(0.774, 1.969)
p-value for RR		0.3772

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-resp15-301-by.sas:t-phq9-resp15-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =24)
Day 15		
Number of subjects with a response, n (%) [2]	21 (61.8)	20 (83.3)
Number of subjects with missing evaluation, n (%)	4 (11.8)	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.332
95% CI for the RR		(0.965, 1.838)
p-value for RR		0.0810
Day 21		
Number of subjects with a response, n (%) [2]	21 (61.8)	18 (75.0)
Number of subjects with missing evaluation, n (%)	7 (20.6)	3 (12.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.199
95% CI for the RR		(0.848, 1.696)
p-value for RR		0.3051

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-resp15-301-by.sas:t-phq9-resp15-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =24)
Day 28		
Number of subjects with a response, n (%) [2]	24 (70.6)	18 (75.0)
Number of subjects with missing evaluation, n (%)	5 (14.7)	4 (16.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.049
95% CI for the RR		(0.760, 1.448)
p-value for RR		0.7706
Day 45		
Number of subjects with a response, n (%) [2]	23 (67.6)	18 (75.0)
Number of subjects with missing evaluation, n (%)	6 (17.6)	4 (16.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.095
95% CI for the RR		(0.802, 1.494)
p-value for RR		0.5682

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-resp15-301-by.sas:t-phq9-resp15-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

Study Visit Statistics	Placebo (N=42)	Zuranolone (N =53)
Number of evaluable subjects [1]	42	53
Day 3		
Number of subjects with a response, n (%) [2]	9 (21.4)	11 (20.8)
Number of subjects with missing evaluation, n (%)	2 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.942
95% CI for the RR		(0.434, 2.046)
p-value for RR		0.8799
Day 8		
Number of subjects with a response, n (%) [2]	20 (47.6)	36 (67.9)
Number of subjects with missing evaluation, n (%)	1 (2.4)	2 (3.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.387
95% CI for the RR		(0.976, 1.971)
p-value for RR		0.0678

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-resp15-301-by.sas:t-phq9-resp15-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

Study Visit Statistics	Placebo (N=42)	Zuranolone (N =53)
Day 15		
Number of subjects with a response, n (%) [2]	28 (66.7)	42 (79.2)
Number of subjects with missing evaluation, n (%)	3 (7.1)	4 (7.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.156
95% CI for the RR		(0.900, 1.486)
p-value for RR		0.2572
Day 21		
Number of subjects with a response, n (%) [2]	25 (59.5)	38 (71.7)
Number of subjects with missing evaluation, n (%)	5 (11.9)	7 (13.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.171
95% CI for the RR		(0.866, 1.584)
p-value for RR		0.3037

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-resp15-301-by.sas:t-phq9-resp15-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

Study Visit Statistics	Placebo (N=42)	Zuranolone (N =53)
Day 28		
Number of subjects with a response, n (%) [2]	26 (61.9)	33 (62.3)
Number of subjects with missing evaluation, n (%)	7 (16.7)	9 (17.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.978
95% CI for the RR		(0.713, 1.341)
p-value for RR		0.8911
Day 45		
Number of subjects with a response, n (%) [2]	24 (57.1)	37 (69.8)
Number of subjects with missing evaluation, n (%)	7 (16.7)	5 (9.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.188
95% CI for the RR		(0.872, 1.618)
p-value for RR		0.2739

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-resp15-301-by.sas:t-phq9-resp15-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

2.4.2.1 .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-301 - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =35)
Number of evaluable subjects [1]	31	34
Day 3		
Number of subjects with a response, n (%) [2]	6 (19.4)	10 (29.4)
Number of subjects with missing evaluation, n (%)	2 (6.5)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.541
95% CI for the RR		(0.648, 3.665)
p-value for RR		0.3276
Day 8		
Number of subjects with a response, n (%) [2]	13 (41.9)	21 (61.8)
Number of subjects with missing evaluation, n (%)	3 (9.7)	2 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.515
95% CI for the RR		(0.940, 2.443)
p-value for RR		0.0880

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 and "Log" link function.

[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-resp15-301-by.sas:t-phq9-resp15-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =35)
Day 15		
Number of subjects with a response, n (%) [2]	20 (64.5)	25 (73.5)
Number of subjects with missing evaluation, n (%)	4 (12.9)	3 (8.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.130
95% CI for the RR		(0.814, 1.569)
p-value for RR		0.4638
Day 21		
Number of subjects with a response, n (%) [2]	16 (51.6)	24 (70.6)
Number of subjects with missing evaluation, n (%)	6 (19.4)	5 (14.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.347
95% CI for the RR		(0.899, 2.019)
p-value for RR		0.1487

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 and "Log" link function.

[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-resp15-301-by.sas:t-phq9-resp15-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =35)
Day 28		
Number of subjects with a response, n (%) [2]	18 (58.1)	21 (61.8)
Number of subjects with missing evaluation, n (%)	6 (19.4)	8 (23.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.067
95% CI for the RR		(0.718, 1.586)
p-value for RR		0.7474
Day 45		
Number of subjects with a response, n (%) [2]	17 (54.8)	24 (70.6)
Number of subjects with missing evaluation, n (%)	6 (19.4)	7 (20.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.278
95% CI for the RR		(0.866, 1.886)
p-value for RR		0.2164

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 and "Log" link function.

[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-resp15-301-by.sas:t-phq9-resp15-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=69)	Zuranolone (N =64)
Number of evaluable subjects [1]	67	64
Day 3		
Number of subjects with a response, n (%) [2]	17 (25.4)	11 (17.2)
Number of subjects with missing evaluation, n (%)	2 (3.0)	1 (1.6)
RR - Relative Risk (Zuranolone vs. Placebo)		0.655
95% CI for the RR		(0.337, 1.271)
p-value for RR		0.2106
Day 8		
Number of subjects with a response, n (%) [2]	37 (55.2)	40 (62.5)
Number of subjects with missing evaluation, n (%)	0	3 (4.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.125
95% CI for the RR		(0.871, 1.453)
p-value for RR		0.3685

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 and "Log" link function.

[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-resp15-301-by.sas:t-phq9-resp15-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=69)	Zuranolone (N =64)
Day 15		
Number of subjects with a response, n (%) [2]	44 (65.7)	49 (76.6)
Number of subjects with missing evaluation, n (%)	4 (6.0)	4 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.129
95% CI for the RR		(0.931, 1.368)
p-value for RR		0.2183
Day 21		
Number of subjects with a response, n (%) [2]	42 (62.7)	44 (68.8)
Number of subjects with missing evaluation, n (%)	11 (16.4)	9 (14.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.081
95% CI for the RR		(0.848, 1.377)
p-value for RR		0.5286

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 and "Log" link function.

[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-resp15-301-by.sas:t-phq9-resp15-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=69)	Zuranolone (N =64)
Day 28		
Number of subjects with a response, n (%) [2]	48 (71.6)	39 (60.9)
Number of subjects with missing evaluation, n (%)	7 (10.4)	13 (20.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.869
95% CI for the RR		(0.678, 1.116)
p-value for RR		0.2717
Day 45		
Number of subjects with a response, n (%) [2]	45 (67.2)	44 (68.8)
Number of subjects with missing evaluation, n (%)	7 (10.4)	7 (10.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.029
95% CI for the RR		(0.806, 1.315)
p-value for RR		0.8183

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 and "Log" link function.

[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-resp15-301-by.sas:t-phq9-resp15-301-by-onset-itta.rtf **Run Date:** 25JUL2025

2.4.2.1 .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-301 - ITT population

Page: 1 of 6

Family History of PPD = Yes

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =21)
Number of evaluable subjects [1]	16	21
Day 3		
Number of subjects with a response, n (%) [2]	4 (25.0)	5 (23.8)
Number of subjects with missing evaluation, n (%)	1 (6.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.955
95% CI for the RR		(0.313, 2.911)
p-value for RR		0.9348
Day 8		
Number of subjects with a response, n (%) [2]	11 (68.8)	13 (61.9)
Number of subjects with missing evaluation, n (%)	1 (6.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.930
95% CI for the RR		(0.598, 1.447)
p-value for RR		0.7476

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 and "Log" link function.

[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-resp15-301-by.sas:t-phq9-resp15-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Family History of PPD: 217-PPD-301 - ITT population

Page: 2 of 6

Family History of PPD = Yes

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =21)
Day 15		
Number of subjects with a response, n (%) [2]	11 (68.8)	15 (71.4)
Number of subjects with missing evaluation, n (%)	3 (18.8)	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.044
95% CI for the RR		(0.676, 1.610)
p-value for RR		0.8469
Day 21		
Number of subjects with a response, n (%) [2]	12 (75.0)	15 (71.4)
Number of subjects with missing evaluation, n (%)	3 (18.8)	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		0.971
95% CI for the RR		(0.661, 1.429)
p-value for RR		0.8830

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 and "Log" link function.

[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-resp15-301-by.sas:t-phq9-resp15-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Family History of PPD: 217-PPD-301 - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =21)
Day 28		
Number of subjects with a response, n (%) [2]	12 (75.0)	15 (71.4)
Number of subjects with missing evaluation, n (%)	4 (25.0)	3 (14.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.967
95% CI for the RR		(0.664, 1.409)
p-value for RR		0.8622
Day 45		
Number of subjects with a response, n (%) [2]	12 (75.0)	15 (71.4)
Number of subjects with missing evaluation, n (%)	3 (18.8)	2 (9.5)
RR - Relative Risk (Zuranolone vs. Placebo)		0.952
95% CI for the RR		(0.650, 1.396)
p-value for RR		0.8026

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 and "Log" link function.

[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-resp15-301-by.sas:t-phq9-resp15-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Family History of PPD: 217-PPD-301 - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=85)	Zuranolone (N =78)
Number of evaluable subjects [1]	82	77
Day 3		
Number of subjects with a response, n (%) [2]	19 (23.2)	16 (20.8)
Number of subjects with missing evaluation, n (%)	3 (3.7)	1 (1.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.897
95% CI for the RR		(0.500, 1.607)
p-value for RR		0.7147
Day 8		
Number of subjects with a response, n (%) [2]	39 (47.6)	48 (62.3)
Number of subjects with missing evaluation, n (%)	2 (2.4)	5 (6.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.327
95% CI for the RR		(1.007, 1.749)
p-value for RR		0.0446

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 and "Log" link function.

[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-resp15-301-by.sas:t-phq9-resp15-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Family History of PPD: 217-PPD-301 - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=85)	Zuranolone (N =78)
Day 15		
Number of subjects with a response, n (%) [2]	53 (64.6)	59 (76.6)
Number of subjects with missing evaluation, n (%)	5 (6.1)	6 (7.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.184
95% CI for the RR		(0.972, 1.443)
p-value for RR		0.0938
Day 21		
Number of subjects with a response, n (%) [2]	46 (56.1)	53 (68.8)
Number of subjects with missing evaluation, n (%)	14 (17.1)	13 (16.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.208
95% CI for the RR		(0.946, 1.543)
p-value for RR		0.1293

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 and "Log" link function.

[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-resp15-301-by.sas:t-phq9-resp15-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Family History of PPD: 217-PPD-301 - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=85)	Zuranolone (N =78)
Day 28		
Number of subjects with a response, n (%) [2]	54 (65.9)	45 (58.4)
Number of subjects with missing evaluation, n (%)	9 (11.0)	18 (23.4)
RR - Relative Risk (Zuranolone vs. Placebo)		0.890
95% CI for the RR		(0.697, 1.137)
p-value for RR		0.3506
Day 45		
Number of subjects with a response, n (%) [2]	50 (61.0)	53 (68.8)
Number of subjects with missing evaluation, n (%)	10 (12.2)	12 (15.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.135
95% CI for the RR		(0.900, 1.431)
p-value for RR		0.2838

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 and "Log" link function.

[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-resp15-301-by.sas:t-phq9-resp15-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

2.4.2.1 .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-301 - ITT population

Page: 1 of 6

History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=90)	Zuranolone (N =82)
Number of evaluable subjects [1]	87	81
Day 3		
Number of subjects with a response, n (%) [2]	17 (19.5)	15 (18.5)
Number of subjects with missing evaluation, n (%)	3 (3.4)	1 (1.2)
RR - Relative Risk (Zuranolone vs. Placebo)		0.948
95% CI for the RR		(0.508, 1.770)
p-value for RR		0.8669
Day 8		
Number of subjects with a response, n (%) [2]	41 (47.1)	48 (59.3)
Number of subjects with missing evaluation, n (%)	3 (3.4)	5 (6.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.258
95% CI for the RR		(0.948, 1.670)
p-value for RR		0.1123

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-resp15-301-by.sas:t-phq9-resp15-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-301 - ITT population

Page: 2 of 6

History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=90)	Zuranolone (N =82)
Day 15		
Number of subjects with a response, n (%) [2]	54 (62.1)	60 (74.1)
Number of subjects with missing evaluation, n (%)	8 (9.2)	7 (8.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.194
95% CI for the RR		(0.967, 1.473)
p-value for RR		0.0990
Day 21		
Number of subjects with a response, n (%) [2]	49 (56.3)	56 (69.1)
Number of subjects with missing evaluation, n (%)	16 (18.4)	13 (16.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.228
95% CI for the RR		(0.969, 1.556)
p-value for RR		0.0893

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-resp15-301-by.sas:t-phq9-resp15-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-301 - ITT population

Page: 3 of 6

History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=90)	Zuranolone (N =82)
Day 28		
Number of subjects with a response, n (%) [2]	57 (65.5)	47 (58.0)
Number of subjects with missing evaluation, n (%)	13 (14.9)	21 (25.9)
RR - Relative Risk (Zuranolone vs. Placebo)		0.886
95% CI for the RR		(0.696, 1.127)
p-value for RR		0.3243
Day 45		
Number of subjects with a response, n (%) [2]	56 (64.4)	56 (69.1)
Number of subjects with missing evaluation, n (%)	12 (13.8)	13 (16.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.074
95% CI for the RR		(0.866, 1.333)
p-value for RR		0.5145

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-resp15-301-by.sas:t-phq9-resp15-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-301 - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=11)	Zuranolone (N =17)
Number of evaluable subjects [1]	11	17
Day 3		
Number of subjects with a response, n (%) [2]	6 (54.5)	6 (35.3)
Number of subjects with missing evaluation, n (%)	1 (9.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.829
95% CI for the RR		(0.362, 1.894)
p-value for RR		0.6557
Day 8		
Number of subjects with a response, n (%) [2]	9 (81.8)	13 (76.5)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.197
95% CI for the RR		(0.812, 1.765)
p-value for RR		0.3647

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-resp15-301-by.sas:t-phq9-resp15-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-301 - ITT population

Page: 5 of 6

History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=11)	Zuranolone (N =17)
Day 15		
Number of subjects with a response, n (%) [2]	10 (90.9)	14 (82.4)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.160
95% CI for the RR		(0.880, 1.529)
p-value for RR		0.2927
Day 21		
Number of subjects with a response, n (%) [2]	9 (81.8)	12 (70.6)
Number of subjects with missing evaluation, n (%)	1 (9.1)	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.105
95% CI for the RR		(0.739, 1.651)
p-value for RR		0.6270

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-resp15-301-by.sas:t-phq9-resp15-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-301 - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=11)	Zuranolone (N =17)
Day 28		
Number of subjects with a response, n (%) [2]	9 (81.8)	13 (76.5)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.197
95% CI for the RR		(0.819, 1.750)
p-value for RR		0.3541
Day 45		
Number of subjects with a response, n (%) [2]	6 (54.5)	12 (70.6)
Number of subjects with missing evaluation, n (%)	1 (9.1)	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.657
95% CI for the RR		(0.838, 3.278)
p-value for RR		0.1468

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-resp15-301-by.sas:t-phq9-resp15-301-by-hist-itta.rtf **Run Date:** 25JUL2025

2.4.2.1 .2 .2 .9 Depression mit Angst

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

Page: 1 of 6

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =24)
Number of evaluable subjects [1]	21	24
Day 3		
Number of subjects with a response, n (%) [2]	5 (23.8)	5 (20.8)
Number of subjects with missing evaluation, n (%)	1 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.917
95% CI for the RR		(0.316, 2.665)
p-value for RR		0.8734
Day 8		
Number of subjects with a response, n (%) [2]	9 (42.9)	13 (54.2)
Number of subjects with missing evaluation, n (%)	1 (4.8)	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.350
95% CI for the RR		(0.733, 2.485)
p-value for RR		0.3355

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 and "Log" link function.
[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-resp15-301-by.sas:t-phq9-resp15-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =24)
Day 15		
Number of subjects with a response, n (%) [2]	12 (57.1)	17 (70.8)
Number of subjects with missing evaluation, n (%)	1 (4.8)	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.319
95% CI for the RR		(0.857, 2.030)
p-value for RR		0.2083
Day 21		
Number of subjects with a response, n (%) [2]	12 (57.1)	19 (79.2)
Number of subjects with missing evaluation, n (%)	4 (19.0)	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.469
95% CI for the RR		(0.968, 2.231)
p-value for RR		0.0709

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 and "Log" link function.
[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-resp15-301-by.sas:t-phq9-resp15-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =24)
Day 28		
Number of subjects with a response, n (%) [2]	15 (71.4)	13 (54.2)
Number of subjects with missing evaluation, n (%)	2 (9.5)	5 (20.8)
RR - Relative Risk (Zuranolone vs. Placebo)		0.797
95% CI for the RR		(0.511, 1.243)
p-value for RR		0.3170
Day 45		
Number of subjects with a response, n (%) [2]	14 (66.7)	17 (70.8)
Number of subjects with missing evaluation, n (%)	1 (4.8)	3 (12.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.090
95% CI for the RR		(0.731, 1.624)
p-value for RR		0.6735

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 and "Log" link function.

[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-resp15-301-by.sas:t-phq9-resp15-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

Study Visit Statistics	Placebo (N=77)	Zuranolone (N =74)
Number of evaluable subjects [1]	77	74
Day 3		
Number of subjects with a response, n (%) [2]	18 (23.4)	16 (21.6)
Number of subjects with missing evaluation, n (%)	3 (3.9)	1 (1.4)
RR - Relative Risk (Zuranolone vs. Placebo)		0.922
95% CI for the RR		(0.511, 1.662)
p-value for RR		0.7869
Day 8		
Number of subjects with a response, n (%) [2]	41 (53.2)	48 (64.9)
Number of subjects with missing evaluation, n (%)	2 (2.6)	4 (5.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.226
95% CI for the RR		(0.947, 1.587)
p-value for RR		0.1219

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 and "Log" link function.

[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-resp15-301-by.sas:t-phq9-resp15-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

Study Visit Statistics	Placebo (N=77)	Zuranolone (N =74)
Day 15		
Number of subjects with a response, n (%) [2]	52 (67.5)	57 (77.0)
Number of subjects with missing evaluation, n (%)	7 (9.1)	6 (8.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.136
95% CI for the RR		(0.933, 1.383)
p-value for RR		0.2045
Day 21		
Number of subjects with a response, n (%) [2]	46 (59.7)	49 (66.2)
Number of subjects with missing evaluation, n (%)	13 (16.9)	13 (17.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.100
95% CI for the RR		(0.861, 1.406)
p-value for RR		0.4461

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 and "Log" link function.

[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-resp15-301-by.sas:t-phq9-resp15-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

Study Visit Statistics	Placebo (N=77)	Zuranolone (N =74)
Day 28		
Number of subjects with a response, n (%) [2]	51 (66.2)	47 (63.5)
Number of subjects with missing evaluation, n (%)	11 (14.3)	16 (21.6)
RR - Relative Risk (Zuranolone vs. Placebo)		0.954
95% CI for the RR		(0.752, 1.209)
p-value for RR		0.6946
Day 45		
Number of subjects with a response, n (%) [2]	48 (62.3)	51 (68.9)
Number of subjects with missing evaluation, n (%)	12 (15.6)	11 (14.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.110
95% CI for the RR		(0.880, 1.401)
p-value for RR		0.3768

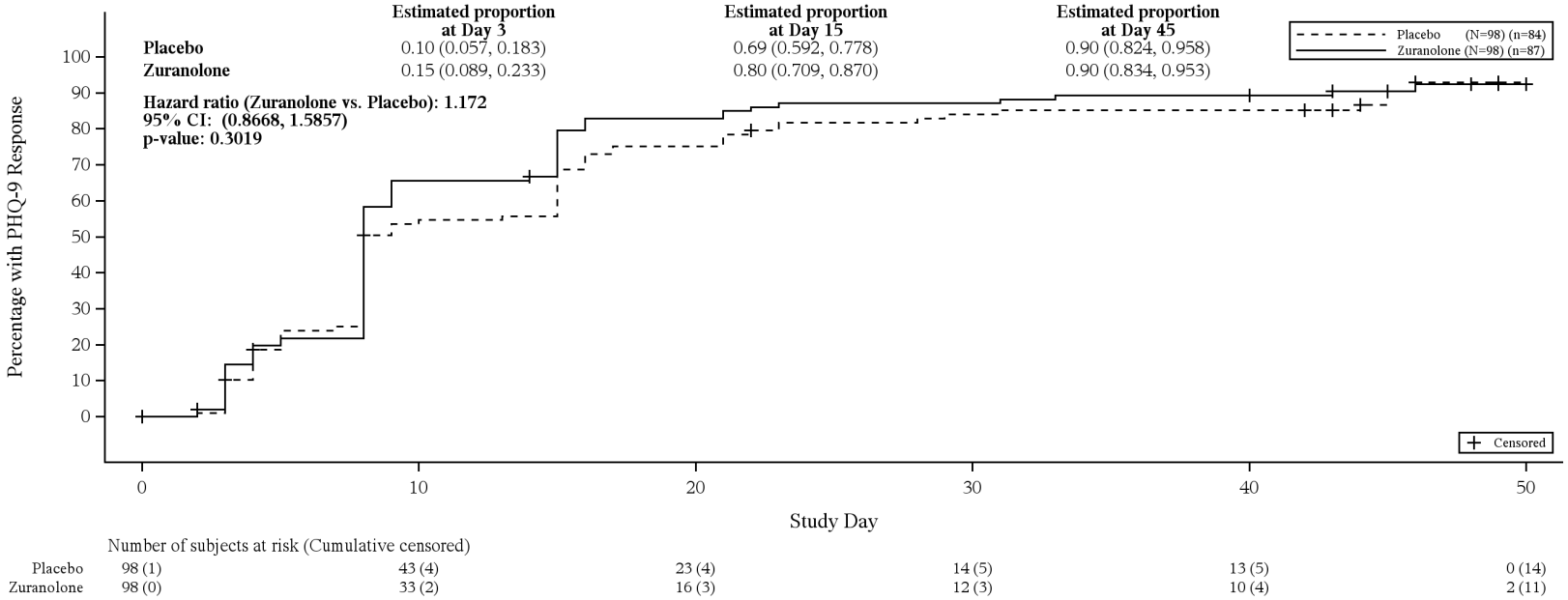
NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline PHQ-9 total score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure and "Log" link function.
[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-resp15-301-by.sas:t-phq9-resp15-301-by-hama-itta.rtf **Run Date:** 25JUL2025

2.4.2.2 TTE-Analysen

2.4.2.2 .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-301 - 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-301-ovr.sas:f-phq9-resp15-tte-301-ovr-itta.rtf **Run Date:** 12DEC2025

Summary of Time to First Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline): 217-PPD-301 - ITT population

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	Placebo (N=101)	Zuranolone (N=99)
Number of evaluable subjects [1]	98	98
Number of subjects with response, n (%) [2]	84 (85.7)	87 (88.8)
Time to first PHQ-9 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)	8.0 (8.0 , 15.0)	8.0 (8.0 , 9.0)
75th percentile - Q3 (95% CI)	17.0 (15.0 , 29.0)	15.0 (14.0 , 21.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.172
95% CI for the HR		(0.8668 , 1.5857)
p-value for the HR		0.3019

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-301-ovr.sas:t-phq9-resp15-tte-301-ovr-itta.rtf **Run Date:** 18JUL2025

2.4.2.2 .2 Subgruppen

2.4.2.2 .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-301 - ITT population

Page: 1 of 2

Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	98	98	
Number of subjects with response, n (%)	84 (85.7)	87 (88.8)	
Age Group (years)			
18 - 24, n / N (%)	12/12 (100.0)	19/19 (100.0)	0.6782
25 - 45, n / N (%)	72/86 (83.7)	68/79 (86.1)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	24/32 (75.0)	29/33 (87.9)	0.1903
>=28, n / N (%)	60/66 (90.9)	58/65 (89.2)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	13/18 (72.2)	24/25 (96.0)	0.5288
White, n / N (%)	61/69 (88.4)	59/68 (86.8)	
Antidepressant Use at Baseline			
Yes, n / N (%)	13/15 (86.7)	10/15 (66.7)	0.2355
No, n / N (%)	71/83 (85.5)	77/83 (92.8)	

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-301-int.sas:t-phq9-resp15-tte-301-int-itta.rtf **Run Date:** 18JUL2025

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-301 - ITT population

Page: 2 of 2

Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9, n / N (%)	19/22 (86.4)	16/20 (80.0)	0.3053(a)
25-29.9, n / N (%)	30/34 (88.2)	23/24 (95.8)	0.4414(b)
>=30, n / N (%)	35/42 (83.3)	47/53 (88.7)	0.7049(c)
Onset of PPD			
3rd Trimester, n / N (%)	25/31 (80.6)	31/34 (91.2)	0.1729
Postpartum, n / N (%)	59/67 (88.1)	56/64 (87.5)	
Family History of PPD			
Yes, n / N (%)	15/16 (93.8)	20/21 (95.2)	0.2163
No/Unknown, n / N (%)	69/82 (84.1)	67/77 (87.0)	
History of PPD			
1st Episode, n / N (%)	74/87 (85.1)	73/81 (90.1)	0.5653
Recurrent Episode, n / N (%)	10/11 (90.9)	14/17 (82.4)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	18/21 (85.7)	22/24 (91.7)	0.5145
>=20, n / N (%)	66/77 (85.7)	65/74 (87.8)	

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-301-int.sas:t-phq9-resp15-tte-301-int-itta.rtf **Run Date:** 18JUL2025

2.4.2.2 .2 .2 Subgruppenanalysen

2.4.2.2 .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-301 - ITT population

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Age Group (years) = 18-24

	Placebo (N=13)	Zuranolone (N=19)
Number of evaluable subjects [1]	12	19
Number of subjects with response, n (%) [2]	12 (100.0)	19 (100.0)
Time to first PHQ-9 response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 5.0)	5.0 (3.0 , 8.0)
50th percentile - median (95% CI)	6.5 (3.0 , 15.0)	8.0 (5.0 , 8.0)
75th percentile - Q3 (95% CI)	15.0 (5.0, NE)	9.0 (8.0 , 16.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.063
95% CI for the HR		(0.4992 , 2.2634)
p-value for the HR		0.8742

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-301-by.sas:t-phq9-resp15-tte-301-by-age-itta.rtf **Run Date:** 25JUL2025

Summary of Time to First Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 25-45

	Placebo (N=88)	Zuranolone (N=80)
Number of evaluable subjects [1]	86	79
Number of subjects with response, n (%) [2]	72 (83.7)	68 (86.1)
Time to first PHQ-9 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)	9.0 (8.0 , 15.0)	8.0 (8.0 , 9.0)
75th percentile - Q3 (95% CI)	21.0 (15.0 , 31.0)	15.0 (15.0 , 31.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.182
95% CI for the HR		(0.8462 , 1.6500)
p-value for the HR		0.3273

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-301-by.sas:t-phq9-resp15-tte-301-by-age-itta.rtf **Run Date:** 25JUL2025

2.4.2.2 .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-301 - ITT population

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

	Placebo (N=32)	Zuranolone (N=33)
Number of evaluable subjects [1]	32	33
Number of subjects with response, n (%) [2]	24 (75.0)	29 (87.9)
Time to first PHQ-9 response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (4.0 , 9.0)	8.0 (3.0 , 8.0)
50th percentile - median (95% CI)	15.0 (8.0 , 17.0)	9.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	46.0 (16.0, NE)	15.0 (9.0 , 46.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.582
95% CI for the HR		(0.9140 , 2.7385)
p-value for the HR		0.1013

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-301-by.sas:t-phq9-resp15-tte-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

Page: 2 of 2

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

	Placebo (N=66)	Zuranolone (N=65)
Number of evaluable subjects [1]	66	65
Number of subjects with response, n (%) [2]	60 (90.9)	58 (89.2)
Time to first PHQ-9 response (days) [3]		
25th percentile - Q1 (95% CI)	5.0 (4.0 , 8.0)	8.0 (4.0 , 8.0)
50th percentile - median (95% CI)	8.0 (8.0 , 15.0)	8.0 (NE, NE)
75th percentile - Q3 (95% CI)	16.0 (15.0 , 22.0)	15.0 (9.0 , 21.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.020
95% CI for the HR		(0.7074 , 1.4705)
p-value for the HR		0.9160

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-301-by.sas:t-phq9-resp15-tte-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

2.4.2.2 .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-301 - ITT population

Page: 1 of 2

Race Group = Black or African American

	Placebo (N=20)	Zuranolone (N=26)
Number of evaluable subjects [1]	18	25
Number of subjects with response, n (%) [2]	13 (72.2)	24 (96.0)
Time to first PHQ-9 response (days) [3]		
25th percentile - Q1 (95% CI)	5.0 (2.0 , 8.0)	8.0 (3.0 , 8.0)
50th percentile - median (95% CI)	8.0 (4.0 , 23.0)	8.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	23.0 (8.0, NE)	15.0 (9.0 , 33.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.995
95% CI for the HR		(0.5021 , 1.9733)
p-value for the HR		0.9894

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-301-by.sas:t-phq9-resp15-tte-301-by-race-itta.rtf **Run Date:** 25JUL2025

Summary of Time to First Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-301 - ITT population

Page: 2 of 2

Race Group = White

	Placebo (N=70)	Zuranolone (N=68)
Number of evaluable subjects [1]	69	68
Number of subjects with response, n (%) [2]	61 (88.4)	59 (86.8)
Time to first PHQ-9 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 , 15.0)	8.0 (8.0 , 9.0)
75th percentile - Q3 (95% CI)	17.0 (15.0 , 44.0)	15.0 (9.0 , 16.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.273
95% CI for the HR		(0.8845 , 1.8308)
p-value for the HR		0.1940

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-301-by.sas:t-phq9-resp15-tte-301-by-race-itta.rtf **Run Date:** 25JUL2025

2.4.2.2 .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-301 - ITT population

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Antidepressant Use at Baseline = Yes

	Placebo (N=15)	Zuranolone (N=15)
Number of evaluable subjects [1]	15	15
Number of subjects with response, n (%) [2]	13 (86.7)	10 (66.7)
Time to first PHQ-9 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 (7.0 , 16.0)	9.0 (8.0, NE)
75th percentile - Q3 (95% CI)	17.0 (8.0, NE)	NE (9.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.854
95% CI for the HR		(0.3633 , 2.0063)
p-value for the HR		0.7167

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-301-by.sas:t-phq9-resp15-tte-301-by-adt-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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Antidepressant Use at Baseline = No

	Placebo (N=86)	Zuranolone (N=84)
Number of evaluable subjects [1]	83	83
Number of subjects with response, n (%) [2]	71 (85.5)	77 (92.8)
Time to first PHQ-9 response (days) [3]		
25th percentile - Q1 (95% CI)	5.0 (4.0 , 8.0)	8.0 (4.0 , 8.0)
50th percentile - median (95% CI)	9.0 (8.0 , 15.0)	8.0 (NE, NE)
75th percentile - Q3 (95% CI)	21.0 (15.0 , 31.0)	15.0 (9.0 , 16.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.279
95% CI for the HR		(0.9232 , 1.7709)
p-value for the HR		0.1391

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-301-by.sas:t-phq9-resp15-tte-301-by-adt-itta.rtf **Run Date:** 25JUL2025

2.4.2.2 .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-301 - ITT population

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

	Placebo (N=22)	Zuranolone (N=20)
Number of evaluable subjects [1]	22	20
Number of subjects with response, n (%) [2]	19 (86.4)	16 (80.0)
Time to first PHQ-9 response (days) [3]		
25th percentile - Q1 (95% CI)	5.0 (3.0 , 8.0)	8.0 (4.0 , 8.0)
50th percentile - median (95% CI)	8.0 (5.0 , 15.0)	8.0 (8.0 , 23.0)
75th percentile - Q3 (95% CI)	21.0 (8.0, NE)	31.0 (8.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.926
95% CI for the HR		(0.4731 , 1.8116)
p-value for the HR		0.8219

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-301-by.sas:t-phq9-resp15-tte-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

	Placebo (N=34)	Zuranolone (N=24)
Number of evaluable subjects [1]	34	24
Number of subjects with response, n (%) [2]	30 (88.2)	23 (95.8)
Time to first PHQ-9 response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (4.0 , 8.0)	5.5 (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 (8.0 , 15.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.409
95% CI for the HR		(0.8005 , 2.4801)
p-value for the HR		0.2345

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-301-by.sas:t-phq9-resp15-tte-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

	Placebo (N=42)	Zuranolone (N=53)
Number of evaluable subjects [1]	42	53
Number of subjects with response, n (%) [2]	35 (83.3)	47 (88.7)
Time to first PHQ-9 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)	15.0 (8.0 , 16.0)	8.0 (8.0 , 9.0)
75th percentile - Q3 (95% CI)	23.0 (15.0 , 46.0)	15.0 (9.0 , 21.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.244
95% CI for the HR		(0.7968 , 1.9438)
p-value for the HR		0.3364

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-301-by.sas:t-phq9-resp15-tte-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

2.4.2.2 .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-301 - ITT population

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Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=35)
Number of evaluable subjects [1]	31	34
Number of subjects with response, n (%) [2]	25 (80.6)	31 (91.2)
Time to first PHQ-9 response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (4.0 , 8.0)	3.0 (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)	16.0 (15.0 , 45.0)	15.0 (9.0 , 22.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.585
95% CI for the HR		(0.9168 , 2.7400)
p-value for the HR		0.0991

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-301-by.sas:t-phq9-resp15-tte-301-by-onset-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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Onset of PPD = Postpartum

	Placebo (N=69)	Zuranolone (N=64)
Number of evaluable subjects [1]	67	64
Number of subjects with response, n (%) [2]	59 (88.1)	56 (87.5)
Time to first PHQ-9 response (days) [3]		
25th percentile - Q1 (95% CI)	5.0 (4.0 , 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)	21.0 (15.0 , 44.0)	15.0 (9.0 , 31.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.995
95% CI for the HR		(0.6881 , 1.4385)
p-value for the HR		0.9782

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-301-by.sas:t-phq9-resp15-tte-301-by-onset-itta.rtf **Run Date:** 25JUL2025

2.4.2.2 .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-301 - ITT population

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Family History of PPD = Yes

	Placebo (N=16)	Zuranolone (N=21)
Number of evaluable subjects [1]	16	21
Number of subjects with response, n (%) [2]	15 (93.8)	20 (95.2)
Time to first PHQ-9 response (days) [3]		
25th percentile - Q1 (95% CI)	5.0 (3.0 , 8.0)	8.0 (3.0 , 8.0)
50th percentile - median (95% CI)	8.0 (5.0 , 10.0)	8.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	15.0 (8.0, NE)	15.0 (8.0 , 43.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.751
95% CI for the HR		(0.3738 , 1.5094)
p-value for the HR		0.4216

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-301-by.sas:t-phq9-resp15-tte-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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Family History of PPD = No/Unknown

	Placebo (N=85)	Zuranolone (N=78)
Number of evaluable subjects [1]	82	77
Number of subjects with response, n (%) [2]	69 (84.1)	67 (87.0)
Time to first PHQ-9 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 , 15.0)	8.0 (8.0 , 9.0)
75th percentile - Q3 (95% CI)	21.0 (16.0 , 45.0)	15.0 (9.0 , 21.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.243
95% CI for the HR		(0.8844 , 1.7484)
p-value for the HR		0.2101

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-301-by.sas:t-phq9-resp15-tte-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

2.4.2.2 .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-301 - ITT population

Page: 1 of 2

History of PPD = 1st Episode

	Placebo (N=90)	Zuranolone (N=82)
Number of evaluable subjects [1]	87	81
Number of subjects with response, n (%) [2]	74 (85.1)	73 (90.1)
Time to first PHQ-9 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)	10.0 (8.0 , 15.0)	8.0 (8.0 , 9.0)
75th percentile - Q3 (95% CI)	21.0 (15.0 , 31.0)	15.0 (15.0 , 21.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.217
95% CI for the HR		(0.8786 , 1.6861)
p-value for the HR		0.2374

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-301-by.sas:t-phq9-resp15-tte-301-by-hist-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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History of PPD = Recurrent Episode

	Placebo (N=11)	Zuranolone (N=17)
Number of evaluable subjects [1]	11	17
Number of subjects with response, n (%) [2]	10 (90.9)	14 (82.4)
Time to first PHQ-9 response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 5.0)	5.0 (2.0 , 8.0)
50th percentile - median (95% CI)	5.0 (4.0 , 9.0)	8.0 (3.0 , 9.0)
75th percentile - Q3 (95% CI)	9.0 (5.0, NE)	9.0 (8.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.210
95% CI for the HR		(0.4941 , 2.9642)
p-value for the HR		0.6764

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-301-by.sas:t-phq9-resp15-tte-301-by-hist-itta.rtf **Run Date:** 25JUL2025

2.4.2.2 .2 .2 .9 Depression mit Angst

Summary of Time to First Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

Page: 1 of 2

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

	Placebo (N=21)	Zuranolone (N=24)
Number of evaluable subjects [1]	21	24
Number of subjects with response, n (%) [2]	18 (85.7)	22 (91.7)
Time to first PHQ-9 response (days) [3]		
25th percentile - Q1 (95% CI)	6.0 (3.0 , 8.0)	8.0 (3.0 , 8.0)
50th percentile - median (95% CI)	10.5 (4.0 , 22.0)	8.5 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	25.5 (13.0, NE)	16.0 (9.0 , 46.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.439
95% CI for the HR		(0.7385 , 2.8023)
p-value for the HR		0.2851

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-301-by.sas:t-phq9-resp15-tte-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Time to First Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

Page: 2 of 2

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

	Placebo (N=77)	Zuranolone (N=74)
Number of evaluable subjects [1]	77	74
Number of subjects with response, n (%) [2]	66 (85.7)	65 (87.8)
Time to first PHQ-9 response (days) [3]		
25th percentile - Q1 (95% CI)	7.0 (4.0 , 8.0)	8.0 (3.0 , 8.0)
50th percentile - median (95% CI)	8.0 (8.0 , 15.0)	8.0 (NE, NE)
75th percentile - Q3 (95% CI)	16.0 (15.0 , 28.0)	15.0 (9.0 , 21.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.115
95% CI for the HR		(0.7898 , 1.5742)
p-value for the HR		0.5362

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.

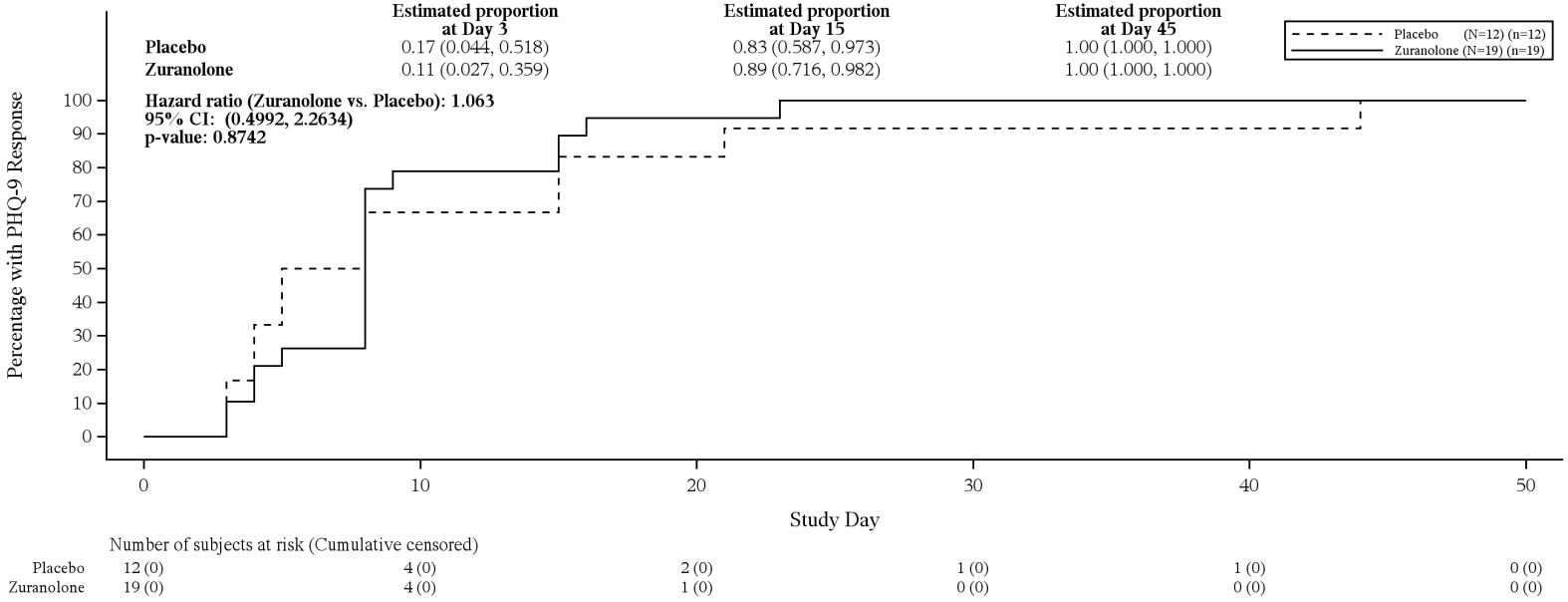
Source: biib125/v_a/germany_amnog/t-phq9-resp15-tte-301-by.sas:t-phq9-resp15-tte-301-by-hama-itta.rtf **Run Date:** 25JUL2025

2.4.2.2 .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-301 - 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.

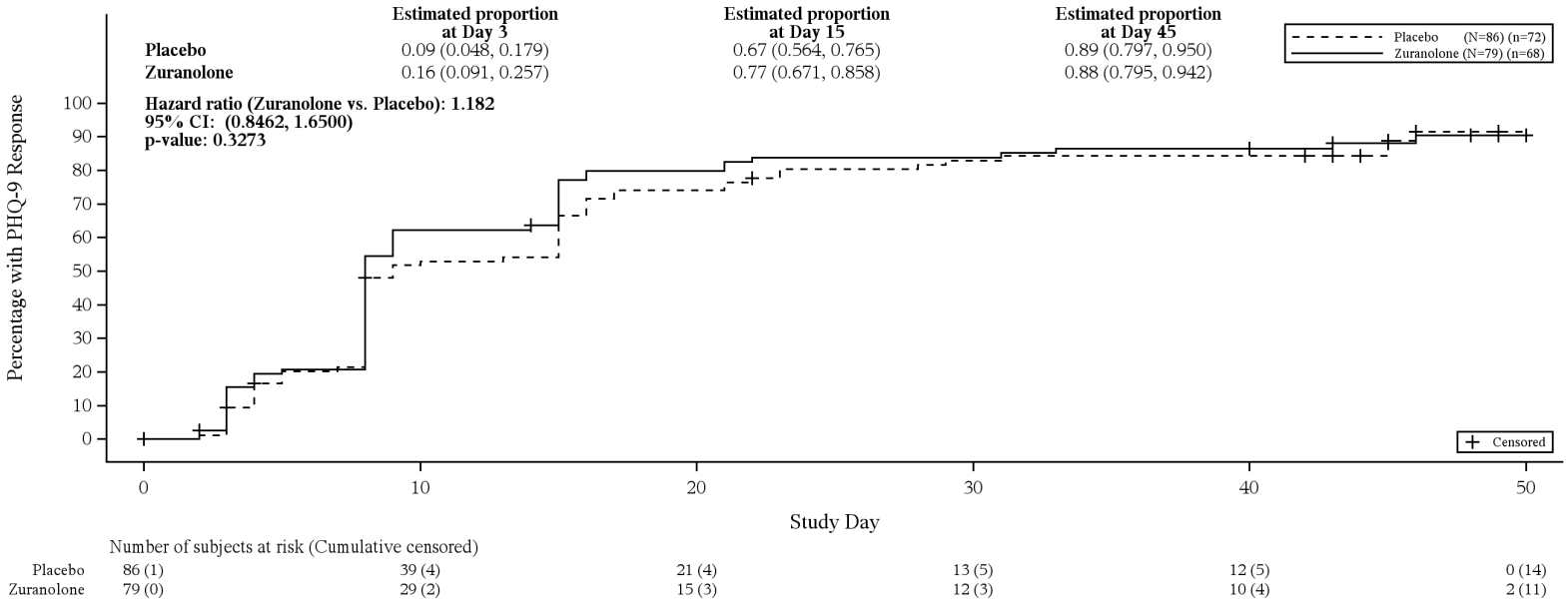
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline PHQ-9 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-phq9-resp15-tte-301-by.sas:f-phq9-resp15-tte-301-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-301 - 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.

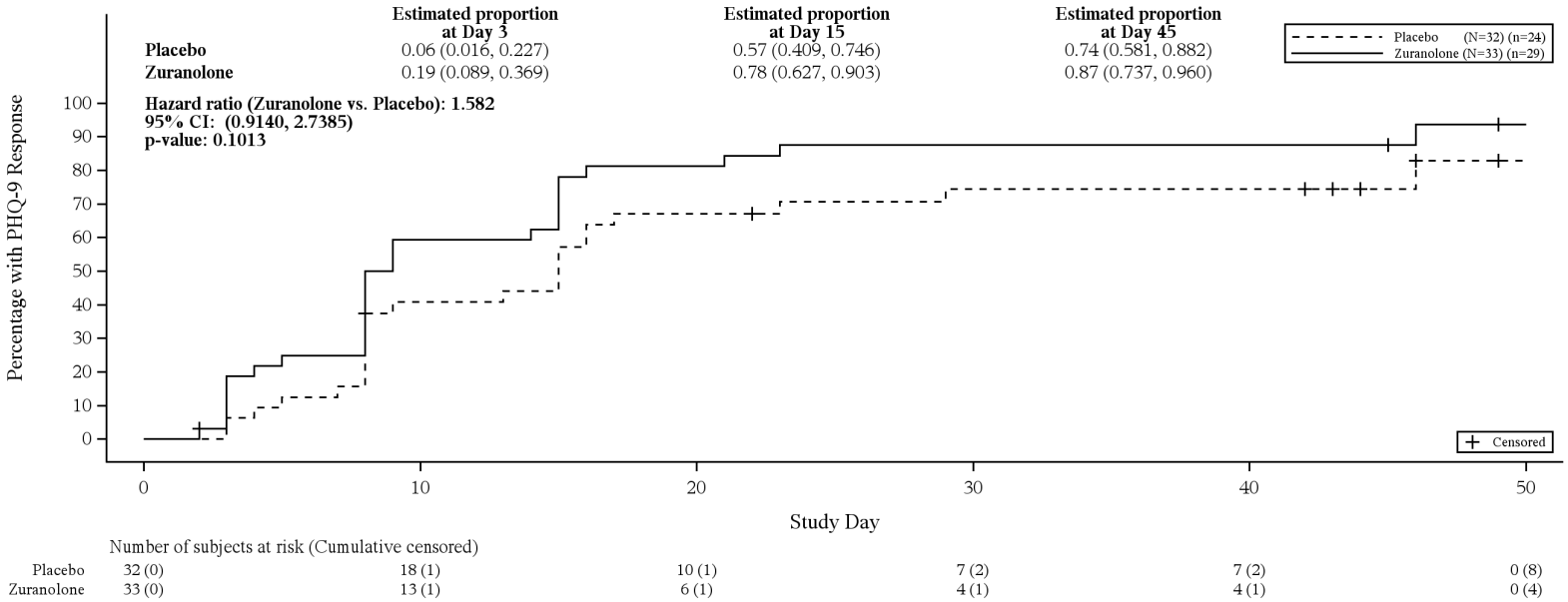
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline PHQ-9 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-phq9-resp15-tte-301-by.sas:f-phq9-resp15-tte-301-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-301 - 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	32 (0)	18 (1)	10 (1)	7 (2)	7 (2)	0 (8)
Zuranolone	33 (0)	13 (1)	6 (1)	4 (1)	4 (1)	0 (4)

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.

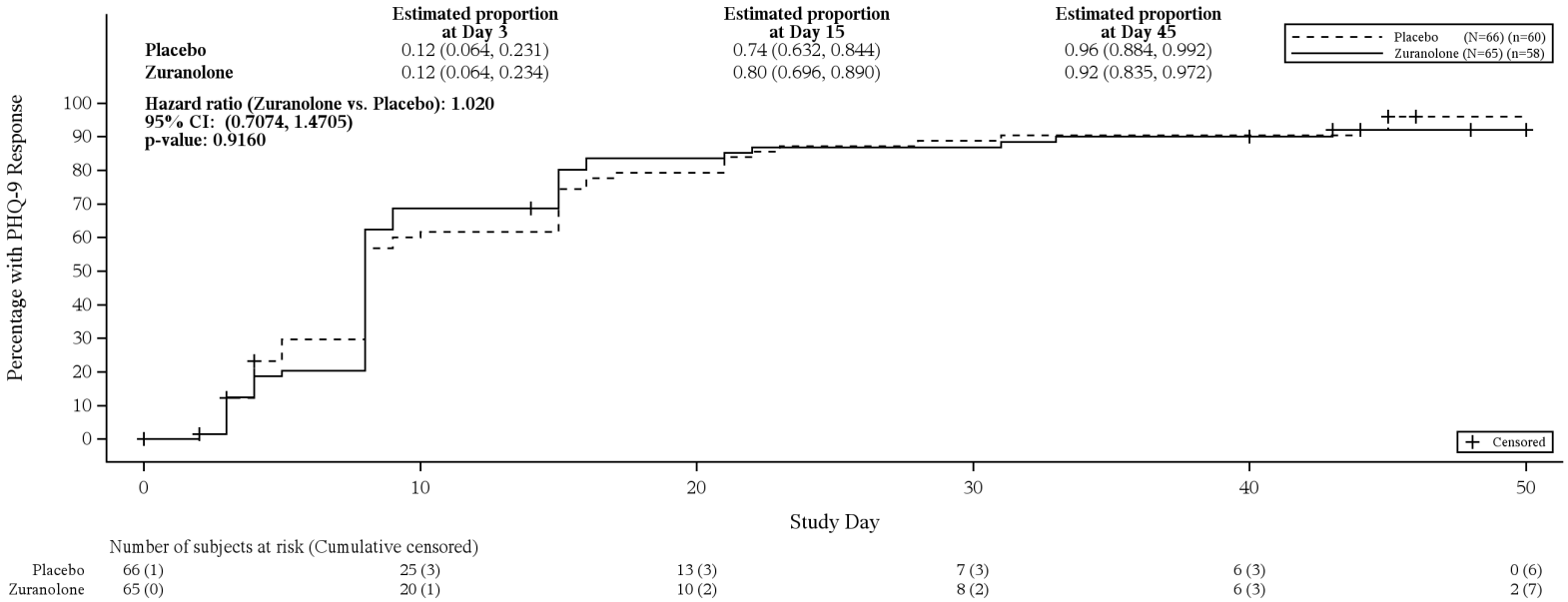
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline PHQ-9 total score, and treatment. Model covariate 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-301 - 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.

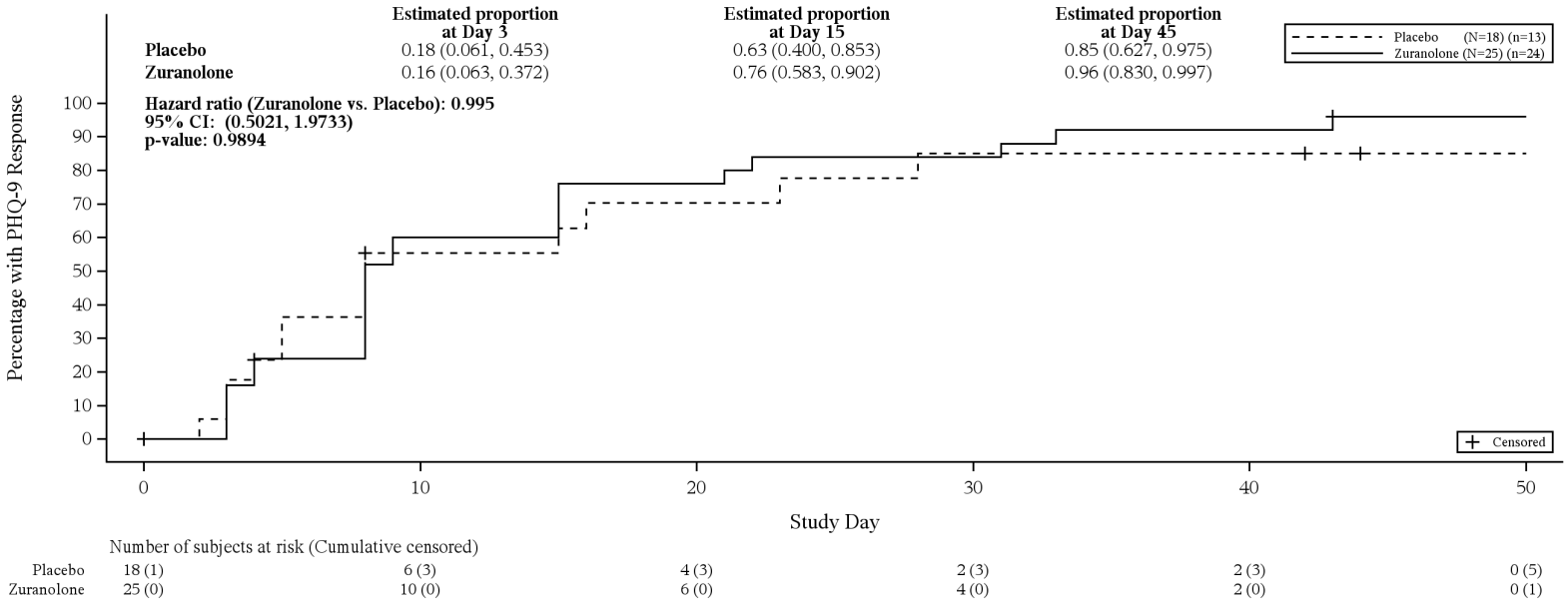
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline PHQ-9 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-phq9-resp15-tte-301-by.sas:f-phq9-resp15-tte-301-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-301 - ITT population

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Race Group = Black or African American



Number of subjects at risk (Cumulative censored)

Placebo	18 (1)	6 (3)	4 (3)	2 (3)	2 (3)	0 (5)
Zuranolone	25 (0)	10 (0)	6 (0)	4 (0)	2 (0)	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.

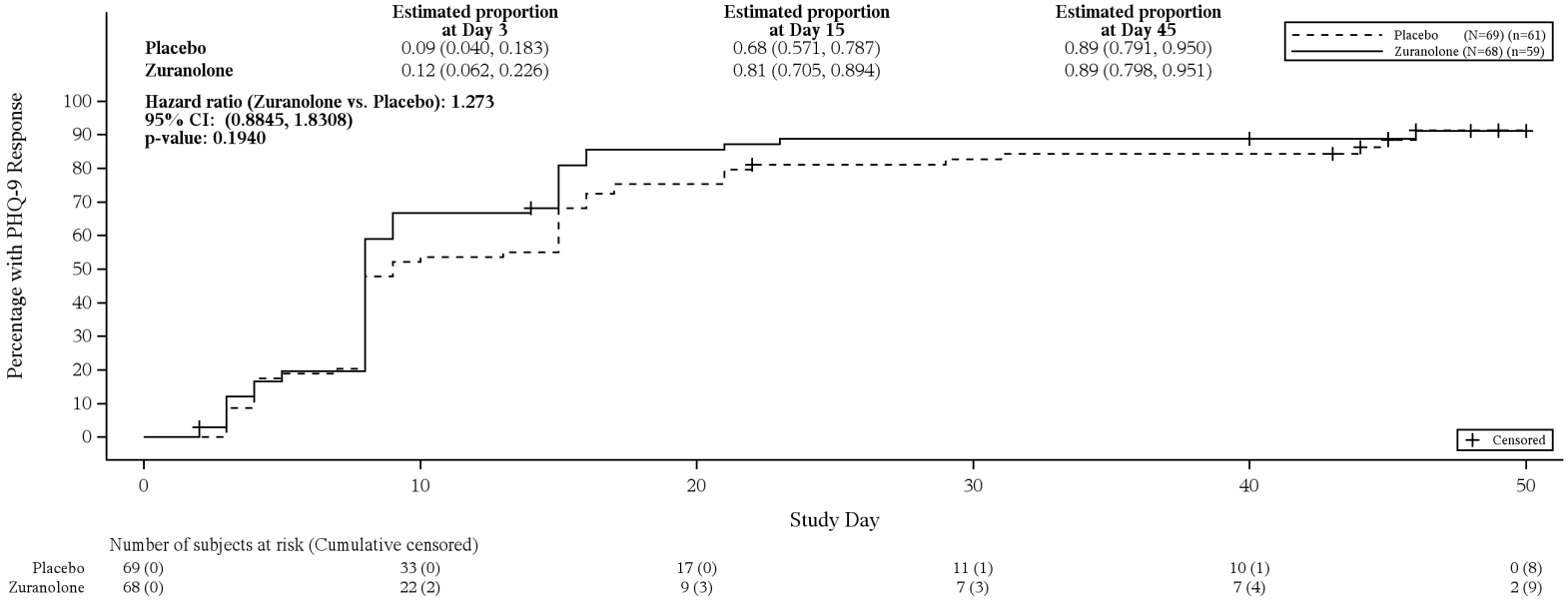
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline PHQ-9 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-phq9-resp15-tte-301-by.sas:f-phq9-resp15-tte-301-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-301 - 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 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.

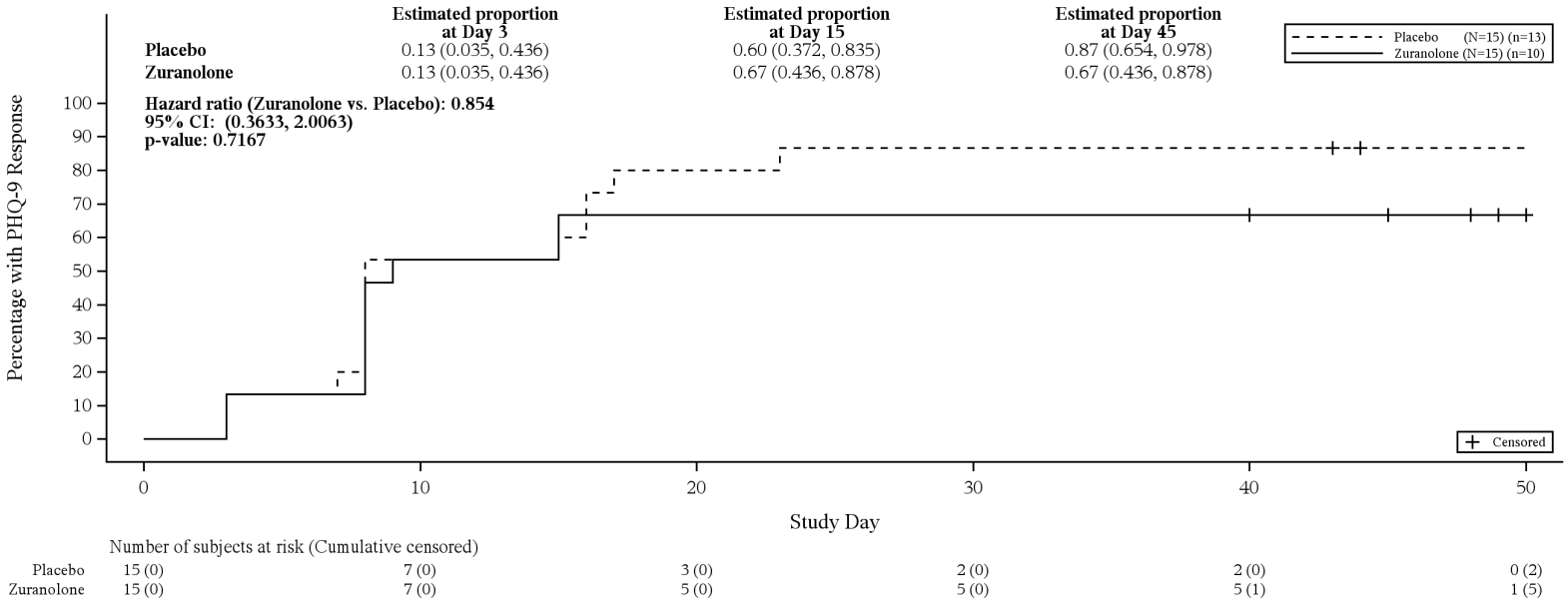
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline PHQ-9 total score, and treatment. Model covariate 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-301 - ITT population

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Antidepressant Use at Baseline = Yes



Number of subjects at risk (Cumulative censored)

Placebo	15 (0)	7 (0)	3 (0)	2 (0)	2 (0)	0 (2)
Zuranolone	15 (0)	7 (0)	5 (0)	5 (0)	5 (1)	1 (5)

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.

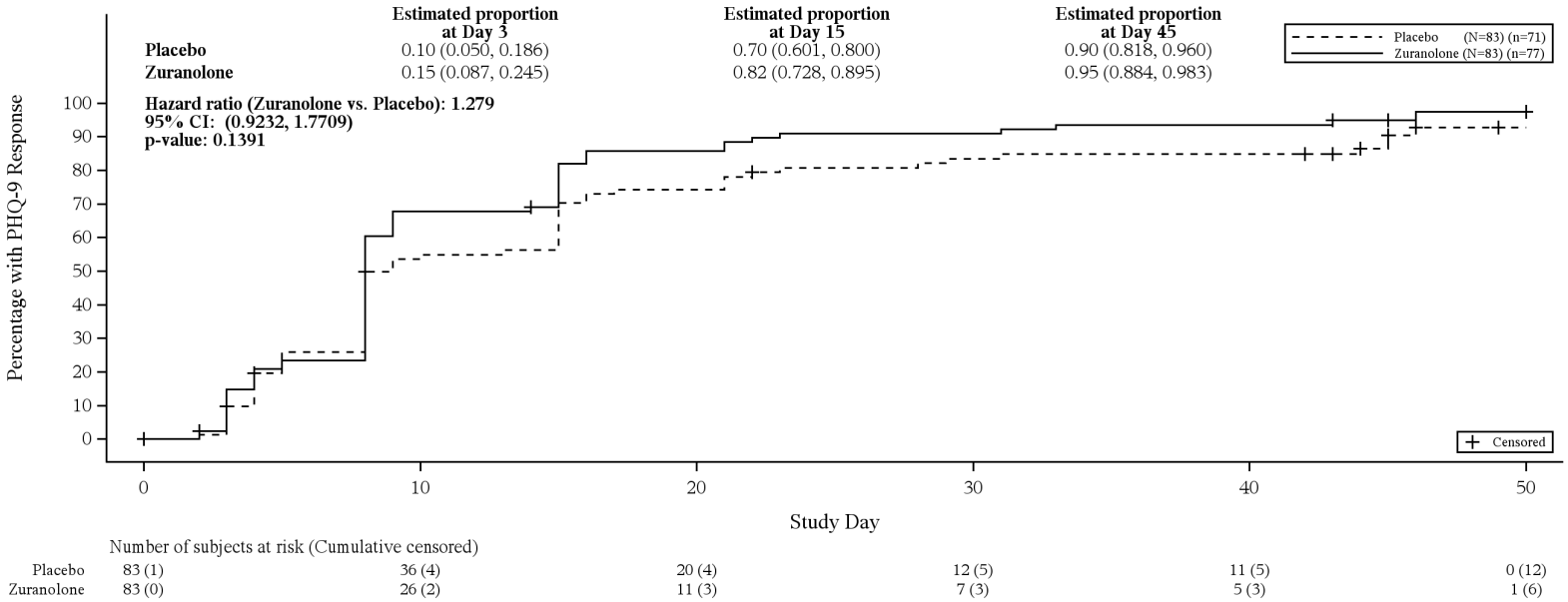
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline PHQ-9 total score, and treatment. Model covariate 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-301 - ITT population

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Antidepressant Use at Baseline = No



Number of subjects at risk (Cumulative censored)

Placebo	83 (1)	36 (4)	20 (4)	12 (5)	11 (5)	0 (12)
Zuranolone	83 (0)	26 (2)	11 (3)	7 (3)	5 (3)	1 (6)

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.

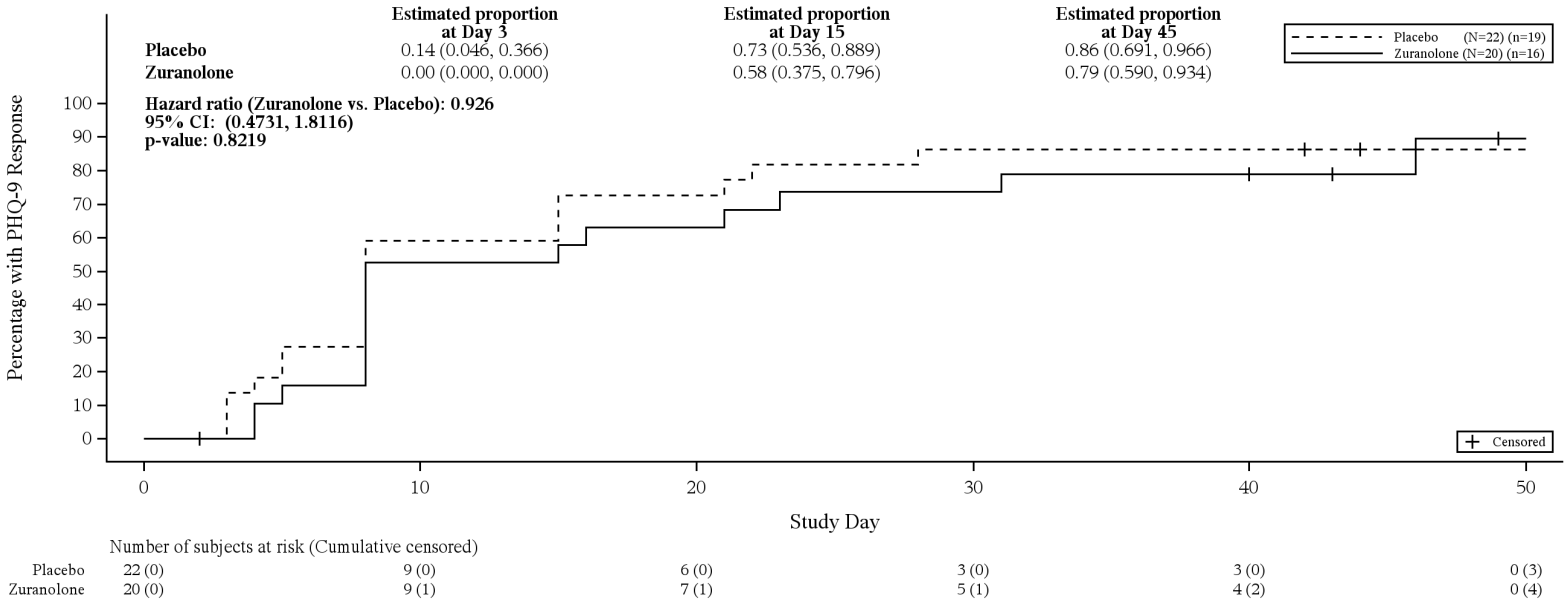
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline PHQ-9 total score, and treatment. Model covariate 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-301 - ITT population

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



Number of subjects at risk (Cumulative censored)

Placebo	22 (0)	9 (0)	6 (0)	3 (0)	3 (0)	0 (3)
Zuranolone	20 (0)	9 (1)	7 (1)	5 (1)	4 (2)	0 (4)

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.

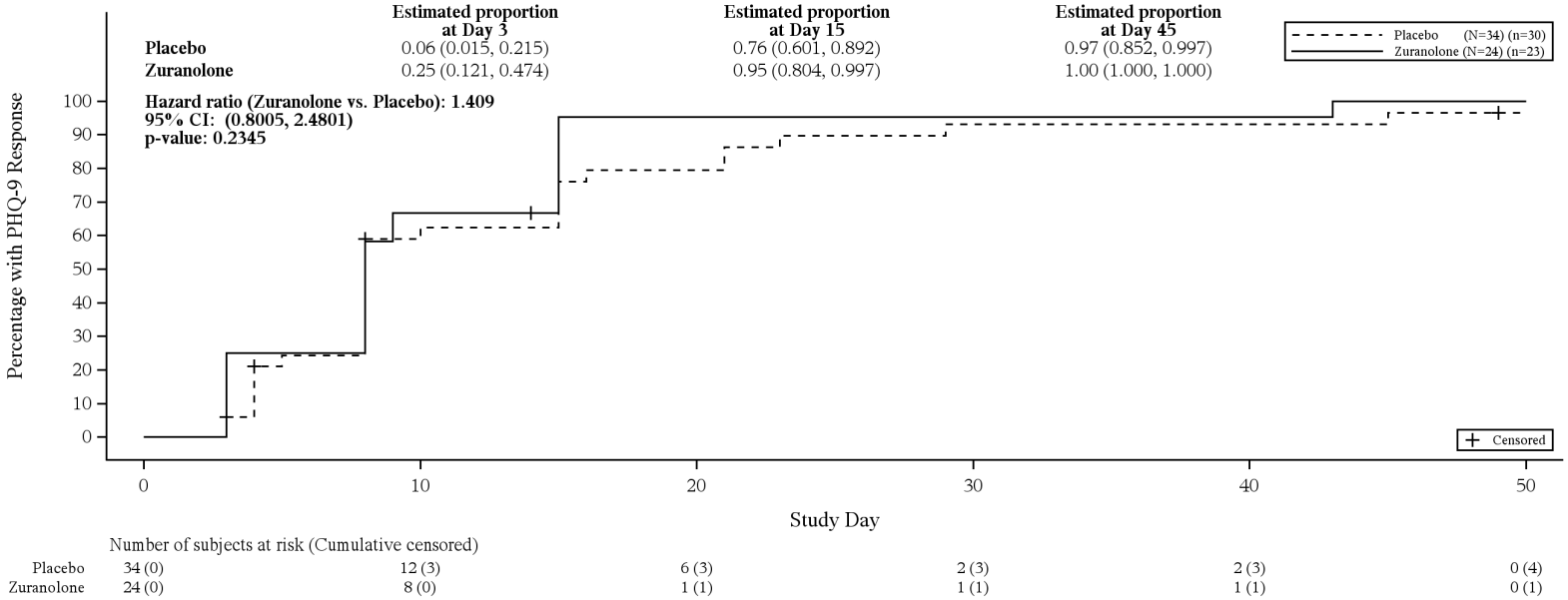
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline PHQ-9 total score, and treatment. Model covariate 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-301 - ITT population

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



Number of subjects at risk (Cumulative censored)

Placebo	34 (0)	12 (3)	6 (3)	2 (3)	2 (3)	0 (4)
Zuranolone	24 (0)	8 (0)	1 (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 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.

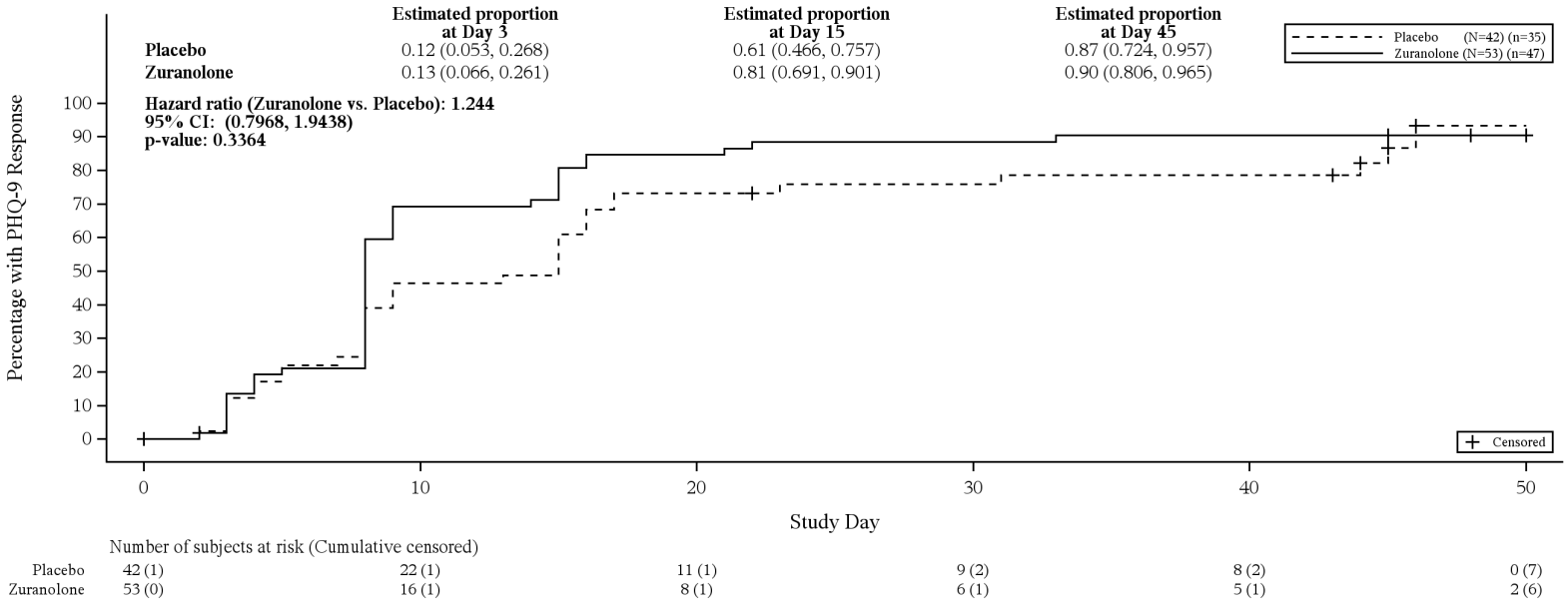
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline PHQ-9 total score, and treatment. Model covariate 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-301 - 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.

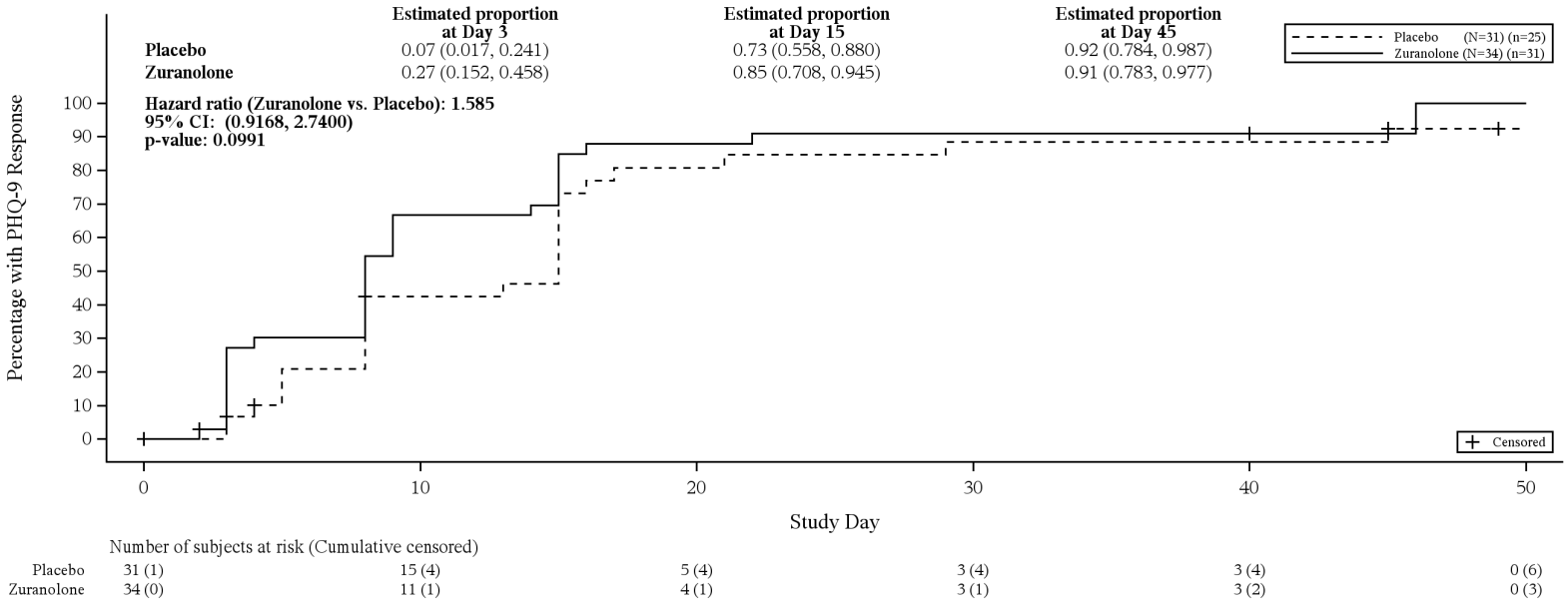
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline PHQ-9 total score, and treatment. Model covariate 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-301 - ITT population

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Onset of PPD = 3rd trimester



Number of subjects at risk (Cumulative censored)

Placebo	31 (1)	15 (4)	5 (4)	3 (4)	3 (4)	0 (6)
Zuranolone	34 (0)	11 (1)	4 (1)	3 (1)	3 (2)	0 (3)

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.

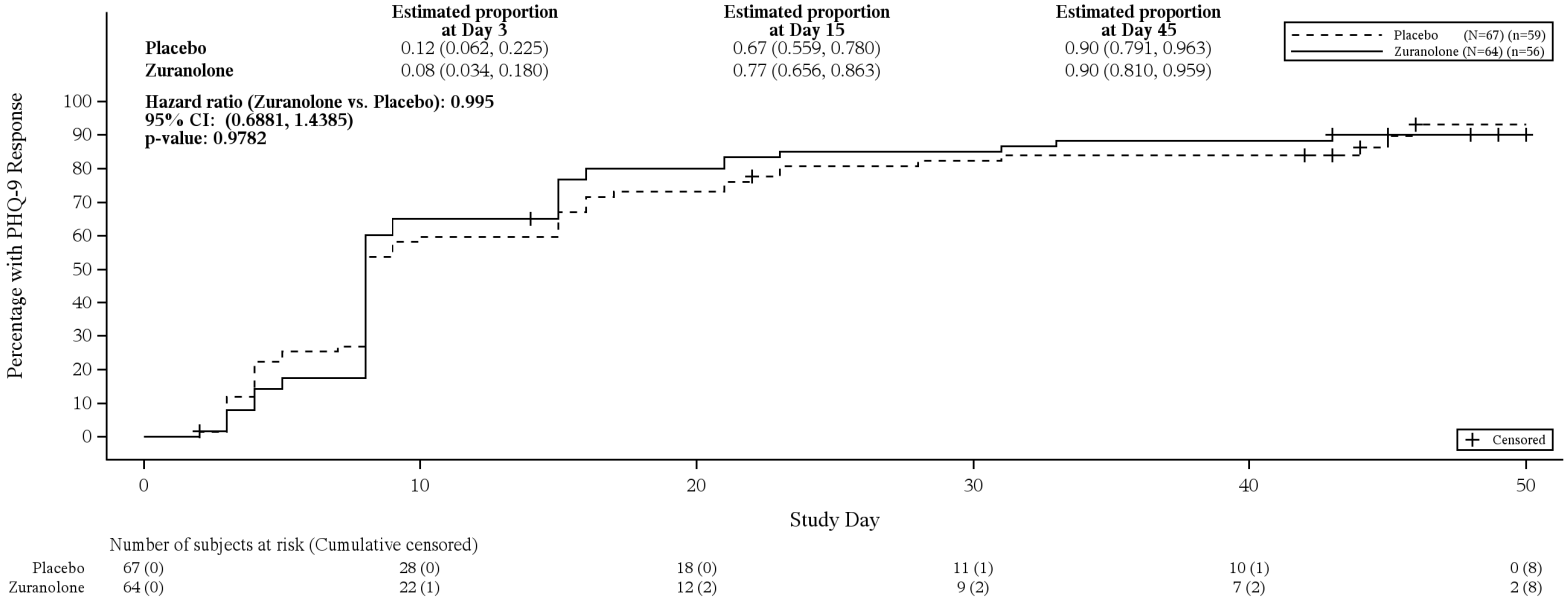
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Kaplan-Meier Plot for Time to First Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-301 - ITT population

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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.

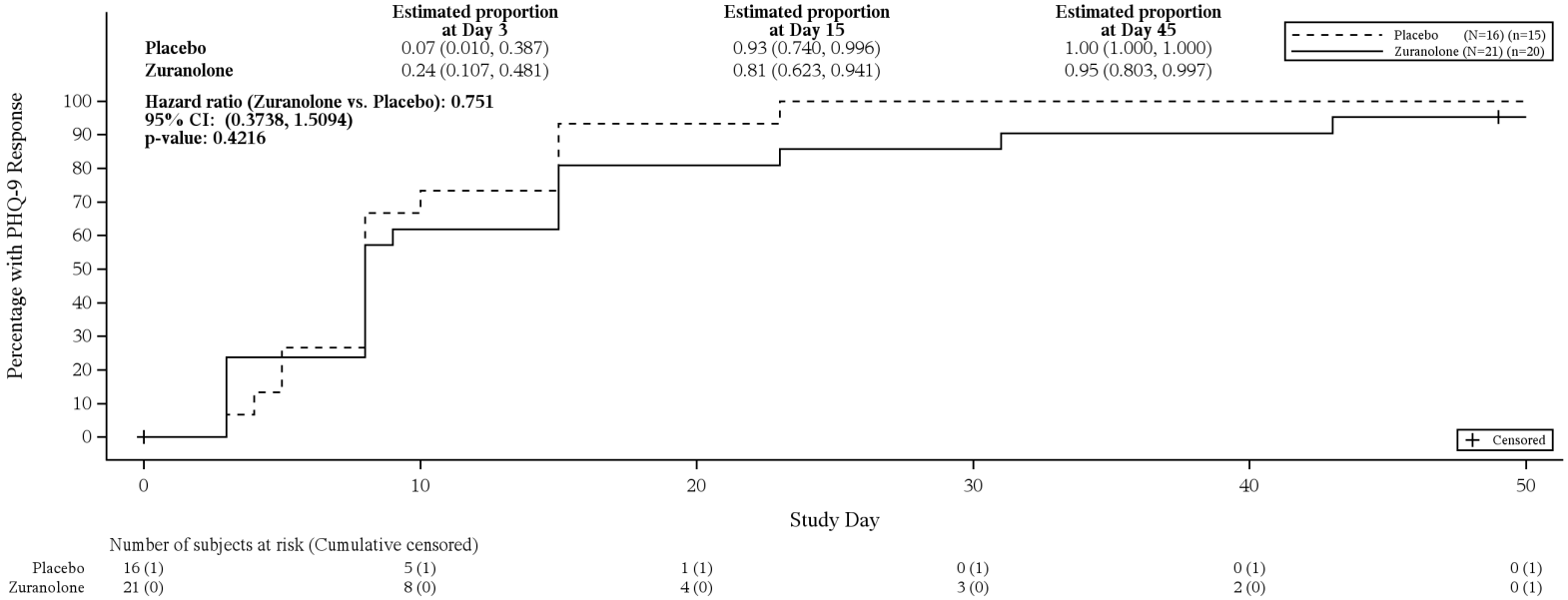
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline PHQ-9 total score, and treatment. Model covariate 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-301 - 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.

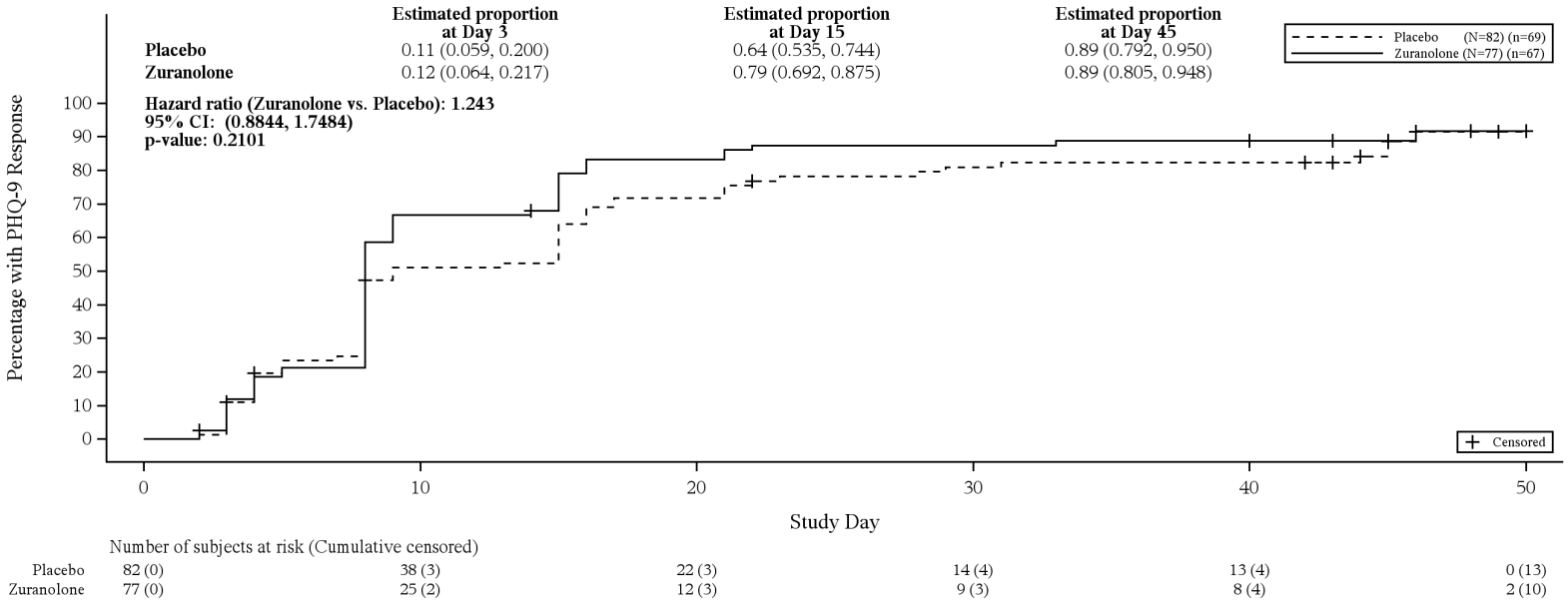
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Kaplan-Meier Plot for Time to First Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-301 - ITT population

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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.

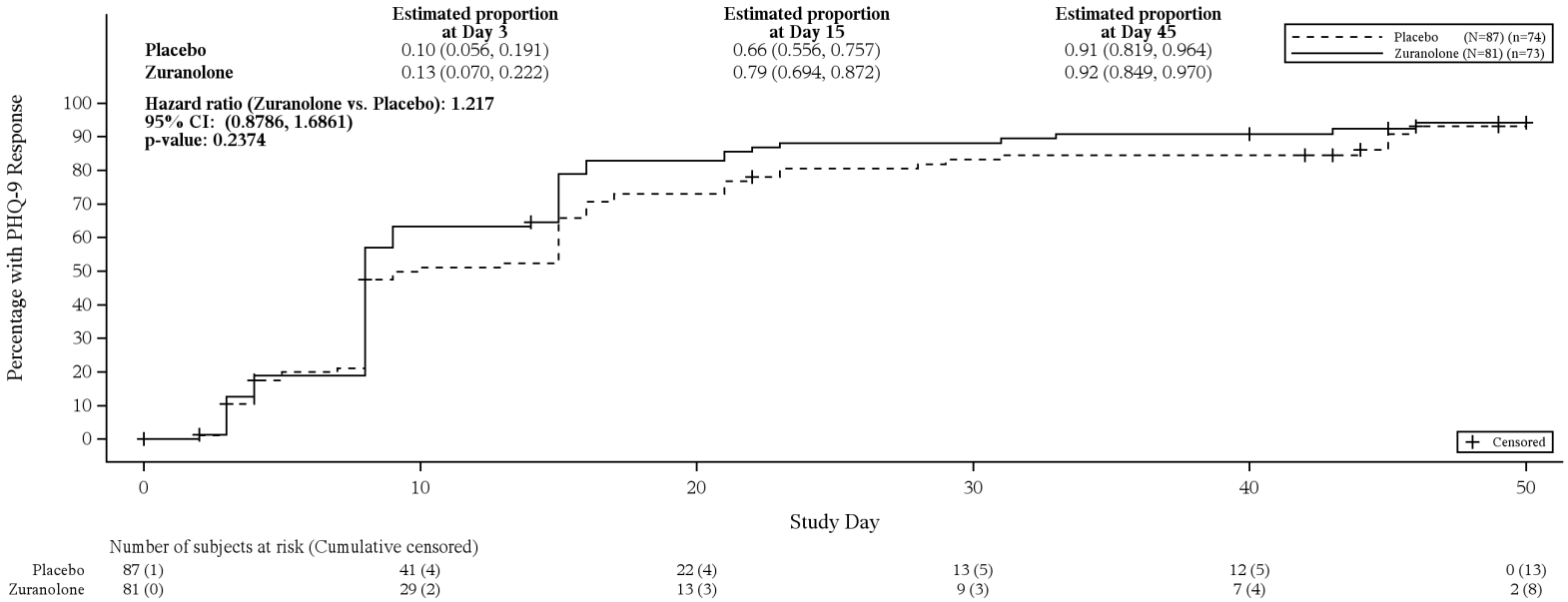
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Kaplan-Meier Plot for Time to First Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-301 - ITT population

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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.

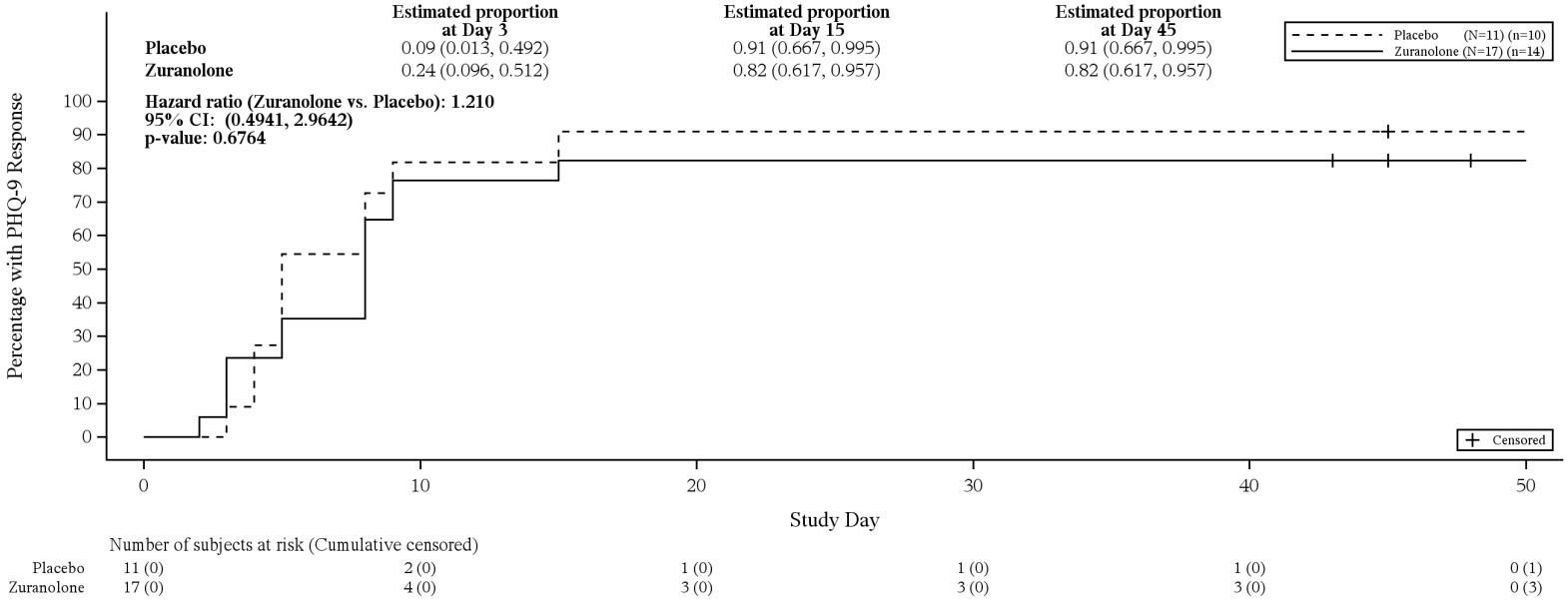
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Kaplan-Meier Plot for Time to First Patient Health Questionnaire (PHQ-9) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-301 - ITT population

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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.

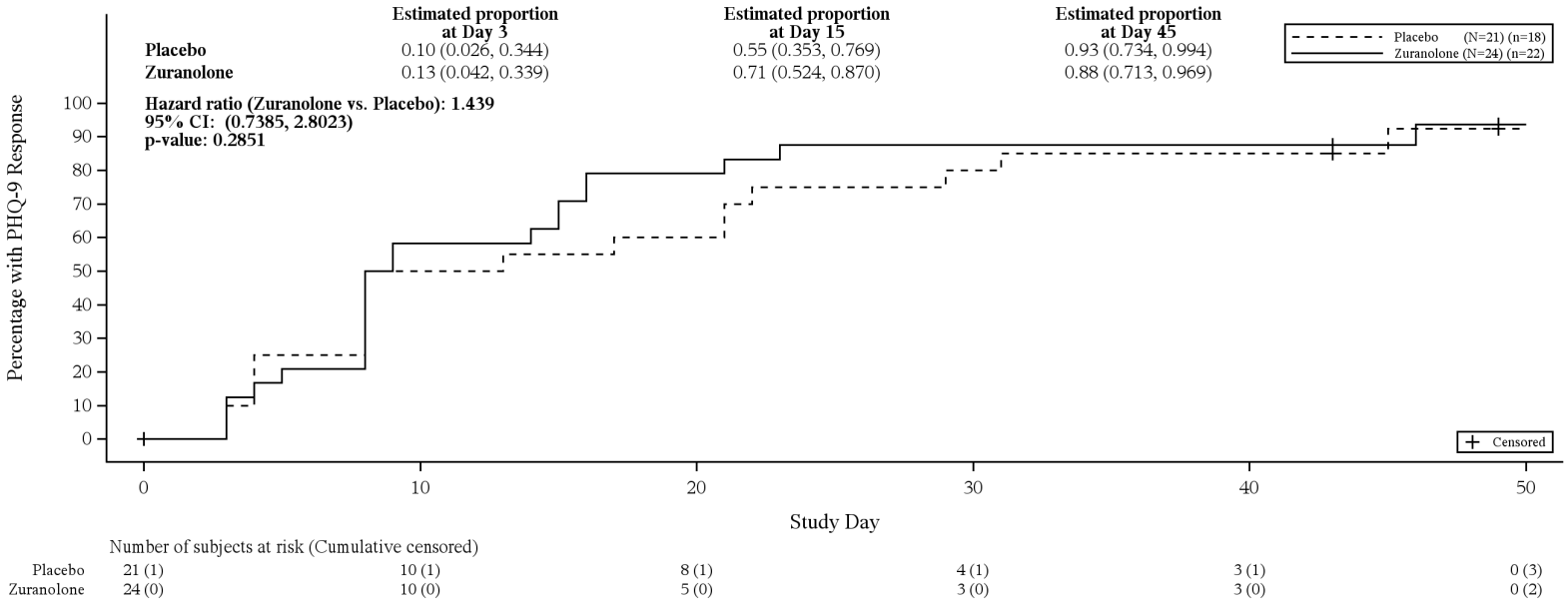
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline PHQ-9 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-phq9-resp15-tte-301-by.sas:f-phq9-resp15-tte-301-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-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20



Number of subjects at risk (Cumulative censored)

Placebo	21 (1)	10 (1)	8 (1)	4 (1)	3 (1)	0 (3)
Zuranolone	24 (0)	10 (0)	5 (0)	3 (0)	3 (0)	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.

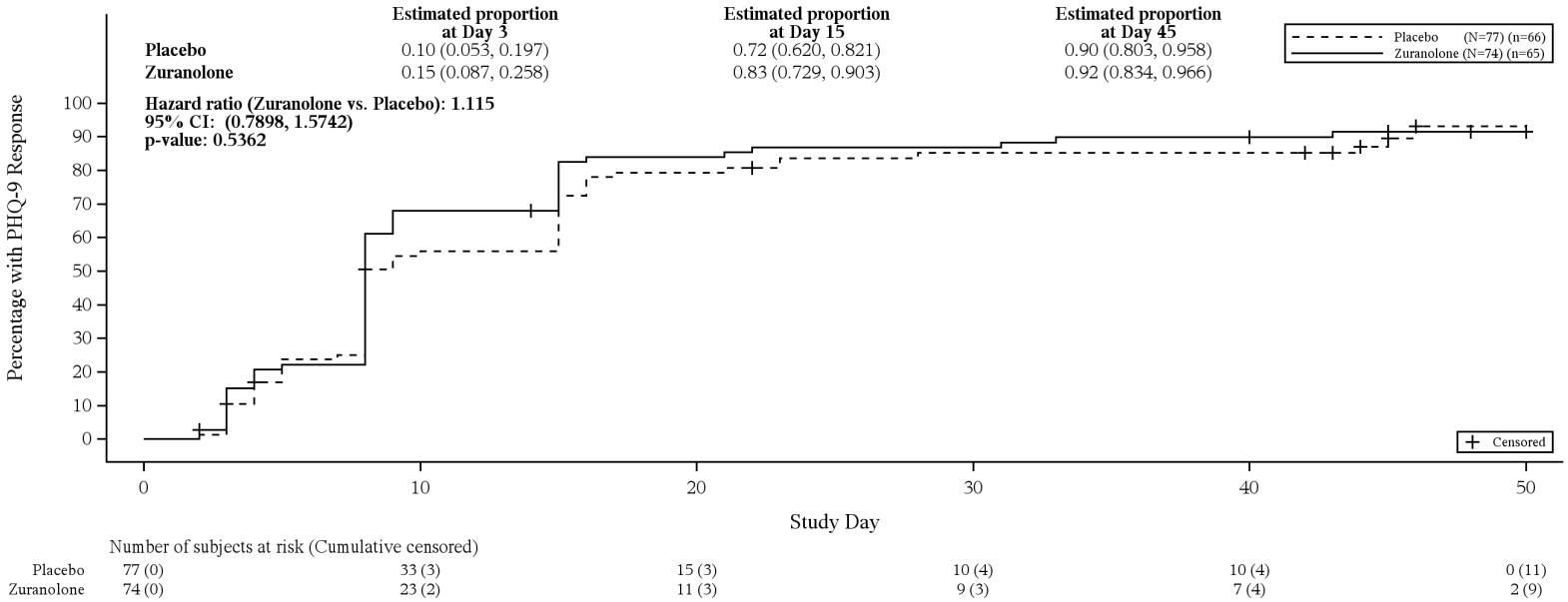
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline PHQ-9 total score, and treatment. Model covariate antidepressant use at baseline is removed from antidepressant use at baseline subgroup analysis.

Source: biib125/v_a/amnog_kmplots/f-phq9-resp15-tte-301-by.sas:f-phq9-resp15-tte-301-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-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20



Number of subjects at risk (Cumulative censored)

Placebo	77 (0)	33 (3)	15 (3)	10 (4)	10 (4)	0 (11)
Zuranolone	74 (0)	23 (2)	11 (3)	9 (3)	7 (4)	2 (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.

Source: biib125/v_a/amnog_kmplots/f-phq9-resp15-tte-301-by.sas:f-phq9-resp15-tte-301-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 Patient Health Questionnaire (PHQ-9) Worsening (>=15% of total scale range increase from baseline): 217-PPD-301 - ITT population

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Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Number of evaluable subjects [1]	98	98
Day 3		
Number of subjects with worsening, n (%) [2]	3 (3.1)	4 (4.1)
Number of subjects with missing evaluation, n (%)	4 (4.1)	1 (1.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.33
95% CI for the RR		(0.306, 5.802)
p-value for RR		0.7014
OR - Odds Ratio (Zuranolone vs. Placebo)		1.35
95% CI for the OR		(0.294, 6.185)
p-value for OR		0.7013
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.01
95% CI for the ARR		(-0.042, 0.062)
p-value for ARR		0.7002

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-wors15-301-ovr.sas:t-phq9-wors15-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Worsening (>=15% of total scale range increase from baseline): 217-PPD-301 - ITT population

Page: 2 of 6

Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 8		
Number of subjects with worsening, n (%) [2]	2 (2.0)	3 (3.1)
Number of subjects with missing evaluation, n (%)	3 (3.1)	5 (5.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.50
95% CI for the RR		(0.256, 8.781)
p-value for RR		0.6529
OR - Odds Ratio (Zuranolone vs. Placebo)		1.52
95% CI for the OR		(0.248, 9.276)
p-value for OR		0.6527
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.01
95% CI for the ARR		(-0.034, 0.054)
p-value for ARR		0.6504

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-wors15-301-ovr.sas:t-phq9-wors15-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Worsening (>=15% of total scale range increase from baseline): 217-PPD-301 - ITT population

Page: 3 of 6

Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 15		
Number of subjects with worsening, n (%) [2]	1 (1.0)	2 (2.0)
Number of subjects with missing evaluation, n (%)	8 (8.2)	7 (7.1)
RR - Relative Risk (Zuranolone vs. Placebo)		2.00
95% CI for the RR		(0.184, 21.698)
p-value for RR		0.5688
OR - Odds Ratio (Zuranolone vs. Placebo)		2.02
95% CI for the OR		(0.180, 22.658)
p-value for OR		0.5683
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.01
95% CI for the ARR		(-0.024, 0.045)
p-value for ARR		0.5603

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-wors15-301-ovr.sas:t-phq9-wors15-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Worsening (>=15% of total scale range increase from baseline): 217-PPD-301 - ITT population

Page: 4 of 6

Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 21		
Number of subjects with worsening, n (%) [2]	0	1 (1.0)
Number of subjects with missing evaluation, n (%)	17 (17.3)	14 (14.3)
RR - Relative Risk (Zuranolone vs. Placebo)		3.00
95% CI for the RR		(0.124, 72.753)
p-value for RR		0.4995
OR - Odds Ratio (Zuranolone vs. Placebo)		3.03
95% CI for the OR		(0.122, 75.313)
p-value for OR		0.4988
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.01
95% CI for the ARR		(-0.018, 0.038)
p-value for ARR		0.4767

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-wors15-301-ovr.sas:t-phq9-wors15-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Worsening (>=15% of total scale range increase from baseline): 217-PPD-301 - ITT population

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Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 28		
Number of subjects with worsening, n (%) [2]	1 (1.0)	1 (1.0)
Number of subjects with missing evaluation, n (%)	13 (13.3)	21 (21.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.00
95% CI for the RR		(0.063, 15.762)
p-value for RR		1.0000
OR - Odds Ratio (Zuranolone vs. Placebo)		1.00
95% CI for the OR		(0.062, 16.217)
p-value for OR		1.0000
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.00
95% CI for the ARR		(-0.028, 0.028)
p-value for ARR		1.0000

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-wors15-301-ovr.sas:t-phq9-wors15-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Worsening (>=15% of total scale range increase from baseline): 217-PPD-301 - ITT population

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Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 45		
Number of subjects with worsening, n (%) [2]	0	2 (2.0)
Number of subjects with missing evaluation, n (%)	13 (13.3)	14 (14.3)
RR - Relative Risk (Zuranolone vs. Placebo)		5.00
95% CI for the RR		(0.243, 102.822)
p-value for RR		0.2968
OR - Odds Ratio (Zuranolone vs. Placebo)		5.10
95% CI for the OR		(0.242, 107.691)
p-value for OR		0.2948
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.02
95% CI for the ARR		(-0.014, 0.054)
p-value for ARR		0.2430

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-wors15-301-ovr.sas:t-phq9-wors15-301-ovr-itta.rtf **Run Date:** 18JUL2025

2.4.3.1 .2 Subgruppen

2.4.3.1 .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-301 - ITT population

Page: 1 of 6

Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	98	98	
Number of subjects with response at Day 15, n (%)	1 (1.0)	2 (2.0)	
Number of subjects with response at Day 45, n (%)	0	2 (2.0)	
Age Group (years)			NA
Day 15			
18 - 24, n / N (%)	0/12	0/19	
25 - 45, n / N (%)	1/86 (1.2)	2/79 (2.5)	
Day 45			
18 - 24, n / N (%)	0/12	0/19	
25 - 45, n / N (%)	0/86	2/79 (2.5)	

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-wors15-301-int.sas:t-phq9-wors15-301-int-itta.rtf **Run Date:** 24JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Worsening (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	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 (%)	1/32 (3.1)	1/33 (3.0)	
>=28, n / N (%)	0/66	1/65 (1.5)	
Day 45			
<28, n / N (%)	0/32	2/33 (6.1)	
>=28, n / N (%)	0/66	0/65	
Race Group (Black or African American, White)			NA
Day 15			
Black or African American, n / N (%)	0/18	1/25 (4.0)	
White, n / N (%)	1/69 (1.4)	1/68 (1.5)	
Day 45			
Black or African American, n / N (%)	0/18	0/25	
White, n / N (%)	0/69	2/68 (2.9)	

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-wors15-301-int.sas:t-phq9-wors15-301-int-itta.rtf **Run Date:** 24JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Worsening (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			NA
Day 15			
Yes, n / N (%)	0/15	1/15 (6.7)	
No, n / N (%)	1/83 (1.2)	1/83 (1.2)	
Day 45			
Yes, n / N (%)	0/15	2/15 (13.3)	
No, n / N (%)	0/83	0/83	

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-wors15-301-int.sas:t-phq9-wors15-301-int-itta.rtf **Run Date:** 24JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Worsening (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	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 (%)	0/22	2/20 (10.0)	
25-29.9, n / N (%)	0/34	0/24	
>=30, n / N (%)	1/42 (2.4)	0/53	
Day 45			
<=24.9, n / N (%)	0/22	1/20 (5.0)	
25-29.9, n / N (%)	0/34	0/24	
>=30, n / N (%)	0/42	1/53 (1.9)	

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-wors15-301-int.sas:t-phq9-wors15-301-int-itta.rtf **Run Date:** 24JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Worsening (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Onset of PPD			NA
Day 15			
3rd Trimester, n / N (%)	0/31	0/34	
Postpartum, n / N (%)	1/67 (1.5)	2/64 (3.1)	
Day 45			
3rd Trimester, n / N (%)	0/31	0/34	
Postpartum, n / N (%)	0/67	2/64 (3.1)	
Family History of PPD			NA
Day 15			
Yes, n / N (%)	0/16	2/21 (9.5)	
No/Unknown, n / N (%)	1/82 (1.2)	0/77	
Day 45			
Yes, n / N (%)	0/16	1/21 (4.8)	
No/Unknown, n / N (%)	0/82	1/77 (1.3)	

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.
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-wors15-301-int.sas:t-phq9-wors15-301-int-itta.rtf **Run Date:** 24JUL2025

Summary of Patient Health Questionnaire (PHQ-9) Worsening (>=15% of total scale range increase from baseline): Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
History of PPD			NA
Day 15			
1st Episode, n / N (%)	1/87 (1.1)	2/81 (2.5)	
Recurrent Episode, n / N (%)	0/11	0/17	
Day 45			
1st Episode, n / N (%)	0/87	1/81 (1.2)	
Recurrent Episode, n / N (%)	0/11	1/17 (5.9)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			NA
Day 15			
<20, n / N (%)	0/21	1/24 (4.2)	
>=20, n / N (%)	1/77 (1.3)	1/74 (1.4)	
Day 45			
<20, n / N (%)	0/21	1/24 (4.2)	
>=20, n / N (%)	0/77	1/74 (1.4)	

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-wors15-301-int.sas:t-phq9-wors15-301-int-itta.rtf **Run Date:** 24JUL2025

2.4.3.1 .2 .2 Subgruppenanalysen

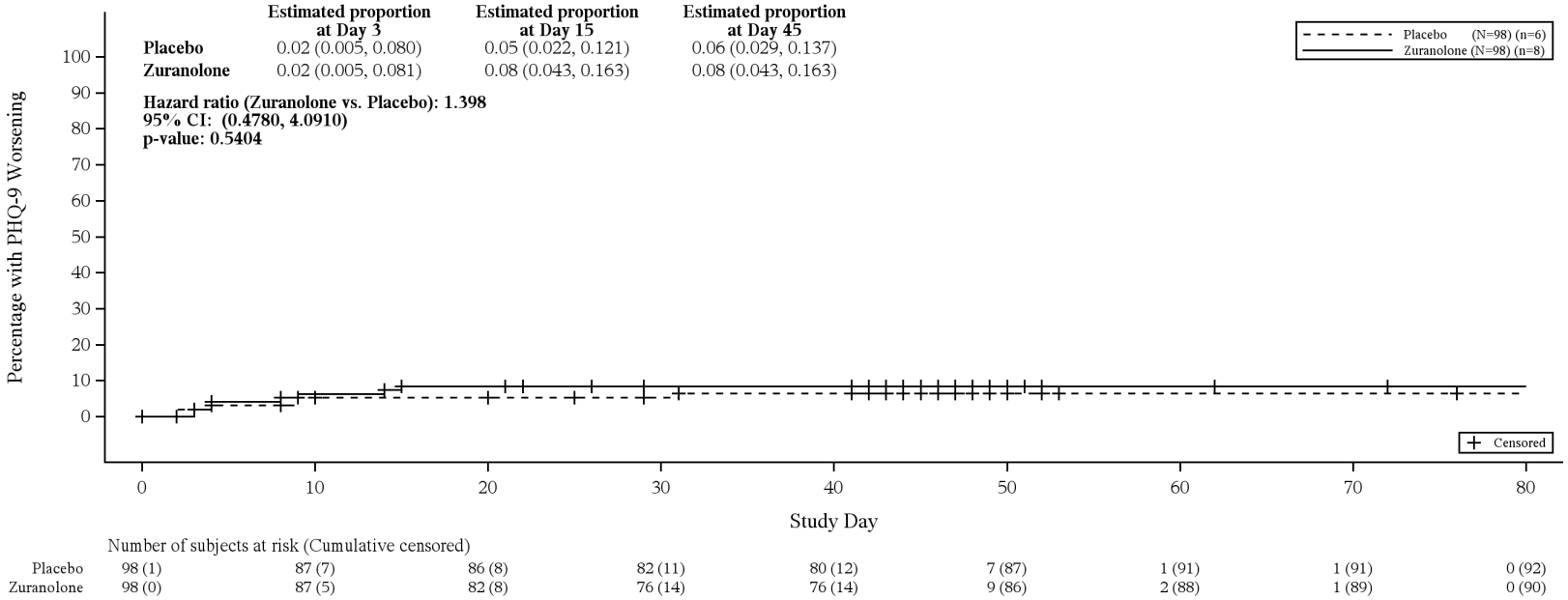
Nicht zutreffend.

2.4.3.2 TTE-Analysen

2.4.3.2 .1 ITT-Population

Kaplan-Meier Plot for Time to First Patient Health Questionnaire (PHQ-9) Worsening (>=15% of total scale range increase from baseline): 217-PPD-301 - ITT population

Page: 1 of 1



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-301-ovr.sas:f-phq9-wors15-tte-301-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-301 - ITT population

Page: 1 of 1

	Placebo (N=101)	Zuranolone (N=99)
Number of evaluable subjects [1]	98	98
Number of subjects with response, n (%) [2]	6 (6.1)	8 (8.2)
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]		1.398
95% CI for the HR		(0.4780 , 4.0910)
p-value for the HR		0.5404

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-301-ovr.sas:t-phq9-wors15-tte-301-ovr-itta.rtf **Run Date:** 18JUL2025

2.4.3.2 .2 Subgruppen

2.4.3.2 .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-301 - ITT population

Page: 1 of 2

Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	98	98	
Number of subjects with response, n (%)	6 (6.1)	8 (8.2)	
Age Group (years)			
18 - 24, n / N (%)	0/12	0/19	NA
25 - 45, n / N (%)	6/86 (7.0)	8/79 (10.1)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	5/32 (15.6)	4/33 (12.1)	NA
>=28, n / N (%)	1/66 (1.5)	4/65 (6.2)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	3/18 (16.7)	2/25 (8.0)	NA
White, n / N (%)	3/69 (4.3)	6/68 (8.8)	
Antidepressant Use at Baseline			
Yes, n / N (%)	1/15 (6.7)	3/15 (20.0)	NA
No, n / N (%)	5/83 (6.0)	5/83 (6.0)	

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-301-int.sas:t-phq9-wors15-tte-301-int-itta.rtf **Run Date:** 24JUL2025

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-301 - ITT population

Page: 2 of 2

Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9, n / N (%)	2/22 (9.1)	4/20 (20.0)	NA(a)
25-29.9, n / N (%)	0/34	0/24	NA(b)
>=30, n / N (%)	4/42 (9.5)	4/53 (7.5)	NA(c)
Onset of PPD			
3rd Trimester, n / N (%)	0/31	4/34 (11.8)	NA
Postpartum, n / N (%)	6/67 (9.0)	4/64 (6.3)	
Family History of PPD			
Yes, n / N (%)	1/16 (6.3)	3/21 (14.3)	NA
No/Unknown, n / N (%)	5/82 (6.1)	5/77 (6.5)	
History of PPD			
1st Episode, n / N (%)	6/87 (6.9)	7/81 (8.6)	NA
Recurrent Episode, n / N (%)	0/11	1/17 (5.9)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	1/21 (4.8)	3/24 (12.5)	NA
>=20, n / N (%)	5/77 (6.5)	5/74 (6.8)	

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-301-int.sas:t-phq9-wors15-tte-301-int-itta.rtf **Run Date:** 24JUL2025

2.4.3.2 .2 .2 Subgruppenanalysen

Nicht zutreffend.

2.4.3.2 .2 .3 Kaplan-Meier-Plots

Nicht zutreffend.

2.5 HAMA

2.5.1 MMRM

Model-based Results on Change from Baseline in Hamilton Rating Scale for Anxiety (HAM-A) Total Score: 217-PPD-301 - ITT population

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	Placebo (N=101)	Zuranolone (N=99)
Day 3		
n	96	98
LS Mean (SE)	-5.27 (0.614)	-7.08 (0.608)
95% CI for the LS Mean	-6.48, -4.06	-8.28, -5.88
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.81 (0.864)
95% CI for the LS Mean		-3.52, -0.11
p-value		0.0373
Hedges' g (Zuranolone vs. Placebo)		-0.300
95% CI for Hedges' g		-0.5829, -0.0169
Day 8		
n	95	93
LS Mean (SE)	-8.46 (0.702)	-10.47 (0.704)
95% CI for the LS Mean	-9.85, -7.08	-11.86, -9.08
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.00 (0.994)
95% CI for the LS Mean		-3.96, -0.04
p-value		0.0451
Hedges' g (Zuranolone vs. Placebo)		-0.293
95% CI for Hedges' g		-0.5805, -0.0056

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-301-ovr.sas:t-hama-mmrm-301-ovr-itta.rtf **Run Date:** 18JUL2025

Model-based Results on Change from Baseline in Hamilton Rating Scale for Anxiety (HAM-A) Total Score: 217-PPD-301 - ITT population

Page: 2 of 3

	Placebo (N=101)	Zuranolone (N=99)
Day 15		
n	90	92
LS Mean (SE)	-10.55 (0.697)	-12.80 (0.693)
95% CI for the LS Mean	-11.92, -9.18	-14.16, -11.43
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.24 (0.983)
95% CI for the LS Mean		-4.18, -0.31
p-value		0.0235
Hedges' g (Zuranolone vs. Placebo)		-0.337
95% CI for Hedges' g		-0.6299, -0.0446
Day 21		
n	83	84
LS Mean (SE)	-12.14 (0.739)	-13.58 (0.738)
95% CI for the LS Mean	-13.60, -10.69	-15.04, -12.12
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.44 (1.045)
95% CI for the LS Mean		-3.50, 0.63
p-value		0.1712
Hedges' g (Zuranolone vs. Placebo)		-0.212
95% CI for Hedges' g		-0.5159, 0.0925

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-301-ovr.sas:t-hama-mmrm-301-ovr-itta.rtf **Run Date:** 18JUL2025

Model-based Results on Change from Baseline in Hamilton Rating Scale for Anxiety (HAM-A) Total Score: 217-PPD-301 - ITT population

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	Placebo (N=101)	Zuranolone (N=99)
Day 28		
n	85	77
LS Mean (SE)	-12.45 (0.750)	-13.69 (0.759)
95% CI for the LS Mean	-13.93, -10.97	-15.18, -12.19
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-1.24 (1.067)
95% CI for the LS Mean		-3.34, 0.87
p-value		0.2478
Hedges' g (Zuranolone vs. Placebo)		-0.182
95% CI for Hedges' g		-0.4905, 0.1274
Day 45		
n	85	84
LS Mean (SE)	-12.50 (0.813)	-14.78 (0.814)
95% CI for the LS Mean	-14.11, -10.90	-16.38, -13.17
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-2.27 (1.150)
95% CI for the LS Mean		-4.54, -0.00
p-value		0.0496
Hedges' g (Zuranolone vs. Placebo)		-0.303
95% CI for Hedges' g		-0.6060, 0.0005

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-301-ovr.sas:t-hama-mmrm-301-ovr-itta.rtf **Run Date:** 18JUL2025

2.5.2 Ansprechen

2.5.2.1 Responder-Analysen

2.5.2.1 .1 ITT-Population

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline): 217-PPD-301 - ITT population

Page: 1 of 6

Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Number of evaluable subjects [1]	98	98
Day 3		
Number of subjects with a response, n (%) [2]	23 (23.5)	35 (35.7)
Number of subjects with missing evaluation, n (%)	2 (2.0)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.529
95% CI for the RR		(0.991, 2.358)
p-value for RR		0.0549
OR - Odds Ratio (Zuranolone vs. Placebo)		1.830
95% CI for the OR		(0.990, 3.385)
p-value for OR		0.0540
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.128
95% CI for the ARR		(0.019, 0.237)
p-value for ARR		0.0219

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.

[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-resp15-301-ovr.sas:t-hama-resp15-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline): 217-PPD-301 - ITT population

Page: 2 of 6

Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 8		
Number of subjects with a response, n (%) [2]	38 (38.8)	53 (54.1)
Number of subjects with missing evaluation, n (%)	3 (3.1)	5 (5.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.401
95% CI for the RR		(1.038, 1.891)
p-value for RR		0.0275
OR - Odds Ratio (Zuranolone vs. Placebo)		1.880
95% CI for the OR		(1.070, 3.304)
p-value for OR		0.0281
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.168
95% CI for the ARR		(0.037, 0.299)
p-value for ARR		0.0117

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.

[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-resp15-301-ovr.sas:t-hama-resp15-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline): 217-PPD-301 - ITT population

Page: 3 of 6

Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 15		
Number of subjects with a response, n (%) [2]	47 (48.0)	66 (67.3)
Number of subjects with missing evaluation, n (%)	8 (8.2)	6 (6.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.411
95% CI for the RR		(1.108, 1.796)
p-value for RR		0.0052
OR - Odds Ratio (Zuranolone vs. Placebo)		2.289
95% CI for the OR		(1.289, 4.066)
p-value for OR		0.0047
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.220
95% CI for the ARR		(0.094, 0.346)
p-value for ARR		0.0006

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.

[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-resp15-301-ovr.sas:t-hama-resp15-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline): 217-PPD-301 - ITT population

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Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 21		
Number of subjects with a response, n (%) [2]	53 (54.1)	59 (60.2)
Number of subjects with missing evaluation, n (%)	15 (15.3)	14 (14.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.118
95% CI for the RR		(0.879, 1.422)
p-value for RR		0.3622
OR - Odds Ratio (Zuranolone vs. Placebo)		1.288
95% CI for the OR		(0.718, 2.309)
p-value for OR		0.3955
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.070
95% CI for the ARR		(-0.064, 0.204)
p-value for ARR		0.3055

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.

[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-resp15-301-ovr.sas:t-hama-resp15-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline): 217-PPD-301 - ITT population

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Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 28		
Number of subjects with a response, n (%) [2]	57 (58.2)	59 (60.2)
Number of subjects with missing evaluation, n (%)	13 (13.3)	21 (21.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.040
95% CI for the RR		(0.821, 1.317)
p-value for RR		0.7461
OR - Odds Ratio (Zuranolone vs. Placebo)		1.092
95% CI for the OR		(0.599, 1.989)
p-value for OR		0.7745
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.020
95% CI for the ARR		(-0.121, 0.161)
p-value for ARR		0.7814

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.

[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-resp15-301-ovr.sas:t-hama-resp15-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline): 217-PPD-301 - ITT population

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Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 45		
Number of subjects with a response, n (%) [2]	56 (57.1)	62 (63.3)
Number of subjects with missing evaluation, n (%)	13 (13.3)	14 (14.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.112
95% CI for the RR		(0.882, 1.403)
p-value for RR		0.3697
OR - Odds Ratio (Zuranolone vs. Placebo)		1.302
95% CI for the OR		(0.712, 2.383)
p-value for OR		0.3917
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.060
95% CI for the ARR		(-0.079, 0.199)
p-value for ARR		0.3966

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.

[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-resp15-301-ovr.sas:t-hama-resp15-301-ovr-itta.rtf **Run Date:** 18JUL2025

2.5.2.1 .2 Subgruppen

2.5.2.1 .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-301 - ITT population

Page: 1 of 6

Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	98	98	
Number of subjects with response at Day 15, n (%)	47 (48.0)	66 (67.3)	
Number of subjects with response at Day 45, n (%)	56 (57.1)	62 (63.3)	
Age Group (years)			0.3239
Day 15			
18 - 24, n / N (%)	7/12 (58.3)	16/19 (84.2)	
25 - 45, n / N (%)	40/86 (46.5)	50/79 (63.3)	
Day 45			
18 - 24, n / N (%)	7/12 (58.3)	12/19 (63.2)	
25 - 45, n / N (%)	49/86 (57.0)	50/79 (63.3)	

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-resp15-301-int.sas:t-hama-resp15-301-int-itta.rtf **Run Date:** 18JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

Page: 2 of 6

Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			0.8044
Day 15			
<28, n / N (%)	15/32 (46.9)	17/33 (51.5)	
>=28, n / N (%)	32/66 (48.5)	49/65 (75.4)	
Day 45			
<28, n / N (%)	15/32 (46.9)	21/33 (63.6)	
>=28, n / N (%)	41/66 (62.1)	41/65 (63.1)	
Race Group (Black or African American, White)			0.5286
Day 15			
Black or African American, n / N (%)	8/18 (44.4)	18/25 (72.0)	
White, n / N (%)	34/69 (49.3)	47/68 (69.1)	
Day 45			
Black or African American, n / N (%)	5/18 (27.8)	16/25 (64.0)	
White, n / N (%)	46/69 (66.7)	44/68 (64.7)	

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 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-resp15-301-int.sas:t-hama-resp15-301-int-itta.rtf **Run Date:** 18JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			0.0256
Day 15			
Yes, n / N (%)	13/15 (86.7)	7/15 (46.7)	
No, n / N (%)	34/83 (41.0)	59/83 (71.1)	
Day 45			
Yes, n / N (%)	9/15 (60.0)	8/15 (53.3)	
No, n / N (%)	47/83 (56.6)	54/83 (65.1)	

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 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-resp15-301-int.sas:t-hama-resp15-301-int-itta.rtf **Run Date:** 18JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			0.5156(a) 0.3259(b) 0.7424(c)
Day 15			
<=24.9, n / N (%)	10/22 (45.5)	13/20 (65.0)	
25-29.9, n / N (%)	15/34 (44.1)	13/24 (54.2)	
>=30, n / N (%)	22/42 (52.4)	39/53 (73.6)	
Day 45			
<=24.9, n / N (%)	15/22 (68.2)	12/20 (60.0)	
25-29.9, n / N (%)	22/34 (64.7)	12/24 (50.0)	
>=30, n / N (%)	19/42 (45.2)	37/53 (69.8)	

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 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-resp15-301-int.sas:t-hama-resp15-301-int-itta.rtf **Run Date:** 18JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Onset of PPD			0.9747
Day 15			
3rd Trimester, n / N (%)	16/31 (51.6)	23/34 (67.6)	
Postpartum, n / N (%)	31/67 (46.3)	43/64 (67.2)	
Day 45			
3rd Trimester, n / N (%)	17/31 (54.8)	20/34 (58.8)	
Postpartum, n / N (%)	39/67 (58.2)	42/64 (65.6)	
Family History of PPD			0.7337
Day 15			
Yes, n / N (%)	10/16 (62.5)	12/21 (57.1)	
No/Unknown, n / N (%)	37/82 (45.1)	54/77 (70.1)	
Day 45			
Yes, n / N (%)	11/16 (68.8)	13/21 (61.9)	
No/Unknown, n / N (%)	45/82 (54.9)	49/77 (63.6)	

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 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-resp15-301-int.sas:t-hama-resp15-301-int-itta.rtf **Run Date:** 18JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
History of PPD			0.7400
Day 15			
1st Episode, n / N (%)	40/87 (46.0)	52/81 (64.2)	
Recurrent Episode, n / N (%)	7/11 (63.6)	14/17 (82.4)	
Day 45			
1st Episode, n / N (%)	50/87 (57.5)	50/81 (61.7)	
Recurrent Episode, n / N (%)	6/11 (54.5)	12/17 (70.6)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			0.2562
Day 15			
<20, n / N (%)	5/21 (23.8)	13/24 (54.2)	
>=20, n / N (%)	42/77 (54.5)	53/74 (71.6)	
Day 45			
<20, n / N (%)	13/21 (61.9)	15/24 (62.5)	
>=20, n / N (%)	43/77 (55.8)	47/74 (63.5)	

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 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.
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2.5.2.1 .2 .2 Subgruppenanalysen

2.5.2.1 .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-301 - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =19)
Number of evaluable subjects [1]	12	19
Day 3		
Number of subjects with a response, n (%) [2]	4 (33.3)	13 (68.4)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.080
95% CI for the RR		(0.973, 4.448)
p-value for RR		0.0590
Day 8		
Number of subjects with a response, n (%) [2]	5 (41.7)	14 (73.7)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.792
95% CI for the RR		(0.922, 3.484)
p-value for RR		0.0856

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-resp15-301-by.sas:t-hama-resp15-301-by-age-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =19)
Day 15		
Number of subjects with a response, n (%) [2]	7 (58.3)	16 (84.2)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.463
95% CI for the RR		(0.911, 2.348)
p-value for RR		0.1151
Day 21		
Number of subjects with a response, n (%) [2]	6 (50.0)	14 (73.7)
Number of subjects with missing evaluation, n (%)	2 (16.7)	1 (5.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.493
95% CI for the RR		(0.820, 2.719)
p-value for RR		0.1897

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-resp15-301-by.sas:t-hama-resp15-301-by-age-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =19)
Day 28		
Number of subjects with a response, n (%) [2]	9 (75.0)	15 (78.9)
Number of subjects with missing evaluation, n (%)	0	2 (10.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.067
95% CI for the RR		(0.692, 1.643)
p-value for RR		0.7699
Day 45		
Number of subjects with a response, n (%) [2]	7 (58.3)	12 (63.2)
Number of subjects with missing evaluation, n (%)	1 (8.3)	1 (5.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.097
95% CI for the RR		(0.591, 2.035)
p-value for RR		0.7688

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-resp15-301-by.sas:t-hama-resp15-301-by-age-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=88)	Zuranolone (N =80)
Number of evaluable subjects [1]	86	79
Day 3		
Number of subjects with a response, n (%) [2]	19 (22.1)	22 (27.8)
Number of subjects with missing evaluation, n (%)	2 (2.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.265
95% CI for the RR		(0.747, 2.142)
p-value for RR		0.3823
Day 8		
Number of subjects with a response, n (%) [2]	33 (38.4)	39 (49.4)
Number of subjects with missing evaluation, n (%)	3 (3.5)	5 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.291
95% CI for the RR		(0.916, 1.820)
p-value for RR		0.1449

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-resp15-301-by.sas:t-hama-resp15-301-by-age-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=88)	Zuranolone (N =80)
Day 15		
Number of subjects with a response, n (%) [2]	40 (46.5)	50 (63.3)
Number of subjects with missing evaluation, n (%)	8 (9.3)	6 (7.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.365
95% CI for the RR		(1.035, 1.801)
p-value for RR		0.0274
Day 21		
Number of subjects with a response, n (%) [2]	47 (54.7)	45 (57.0)
Number of subjects with missing evaluation, n (%)	13 (15.1)	13 (16.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.046
95% CI for the RR		(0.799, 1.370)
p-value for RR		0.7446

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-resp15-301-by.sas:t-hama-resp15-301-by-age-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=88)	Zuranolone (N =80)
Day 28		
Number of subjects with a response, n (%) [2]	48 (55.8)	44 (55.7)
Number of subjects with missing evaluation, n (%)	13 (15.1)	19 (24.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.001
95% CI for the RR		(0.762, 1.316)
p-value for RR		0.9926
Day 45		
Number of subjects with a response, n (%) [2]	49 (57.0)	50 (63.3)
Number of subjects with missing evaluation, n (%)	12 (14.0)	13 (16.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.115
95% CI for the RR		(0.868, 1.431)
p-value for RR		0.3951

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-resp15-301-by.sas:t-hama-resp15-301-by-age-itta.rtf **Run Date:** 25JUL2025

2.5.2.1 .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-301 - 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=32)	Zuranolone (N =33)
Number of evaluable subjects [1]	32	33
Day 3		
Number of subjects with a response, n (%) [2]	7 (21.9)	11 (33.3)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.606
95% CI for the RR		(0.714, 3.610)
p-value for RR		0.2517
Day 8		
Number of subjects with a response, n (%) [2]	12 (37.5)	14 (42.4)
Number of subjects with missing evaluation, n (%)	0	1 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.192
95% CI for the RR		(0.667, 2.130)
p-value for RR		0.5525

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-resp15-301-by.sas:t-hama-resp15-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =33)
Day 15		
Number of subjects with a response, n (%) [2]	15 (46.9)	17 (51.5)
Number of subjects with missing evaluation, n (%)	2 (6.3)	1 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.158
95% CI for the RR		(0.706, 1.899)
p-value for RR		0.5603
Day 21		
Number of subjects with a response, n (%) [2]	16 (50.0)	18 (54.5)
Number of subjects with missing evaluation, n (%)	5 (15.6)	2 (6.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.150
95% CI for the RR		(0.716, 1.847)
p-value for RR		0.5639

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-resp15-301-by.sas:t-hama-resp15-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

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-301 - 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=32)	Zuranolone (N =33)
Day 28		
Number of subjects with a response, n (%) [2]	14 (43.8)	19 (57.6)
Number of subjects with missing evaluation, n (%)	6 (18.8)	5 (15.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.387
95% CI for the RR		(0.843, 2.282)
p-value for RR		0.1978
Day 45		
Number of subjects with a response, n (%) [2]	15 (46.9)	21 (63.6)
Number of subjects with missing evaluation, n (%)	5 (15.6)	3 (9.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.431
95% CI for the RR		(0.899, 2.278)
p-value for RR		0.1312

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-resp15-301-by.sas:t-hama-resp15-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

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-301 - 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=66)	Zuranolone (N =65)
Number of evaluable subjects [1]	66	65
Day 3		
Number of subjects with a response, n (%) [2]	16 (24.2)	24 (36.9)
Number of subjects with missing evaluation, n (%)	2 (3.0)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.494
95% CI for the RR		(0.891, 2.507)
p-value for RR		0.1280
Day 8		
Number of subjects with a response, n (%) [2]	26 (39.4)	39 (60.0)
Number of subjects with missing evaluation, n (%)	3 (4.5)	4 (6.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.494
95% CI for the RR		(1.052, 2.124)
p-value for RR		0.0251

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-resp15-301-by.sas:t-hama-resp15-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

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-301 - 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=66)	Zuranolone (N =65)
Day 15		
Number of subjects with a response, n (%) [2]	32 (48.5)	49 (75.4)
Number of subjects with missing evaluation, n (%)	6 (9.1)	5 (7.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.526
95% CI for the RR		(1.153, 2.018)
p-value for RR		0.0031
Day 21		
Number of subjects with a response, n (%) [2]	37 (56.1)	41 (63.1)
Number of subjects with missing evaluation, n (%)	10 (15.2)	12 (18.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.104
95% CI for the RR		(0.833, 1.462)
p-value for RR		0.4903

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-resp15-301-by.sas:t-hama-resp15-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

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-301 - 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=66)	Zuranolone (N =65)
Day 28		
Number of subjects with a response, n (%) [2]	43 (65.2)	40 (61.5)
Number of subjects with missing evaluation, n (%)	7 (10.6)	16 (24.6)
RR - Relative Risk (Zuranolone vs. Placebo)		0.927
95% CI for the RR		(0.707, 1.215)
p-value for RR		0.5817
Day 45		
Number of subjects with a response, n (%) [2]	41 (62.1)	41 (63.1)
Number of subjects with missing evaluation, n (%)	8 (12.1)	11 (16.9)
RR - Relative Risk (Zuranolone vs. Placebo)		0.996
95% CI for the RR		(0.759, 1.307)
p-value for RR		0.9787

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-resp15-301-by.sas:t-hama-resp15-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

2.5.2.1 .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-301 - ITT population

Page: 1 of 6

Race Group = Black or African American

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =26)
Number of evaluable subjects [1]	18	25
Day 3		
Number of subjects with a response, n (%) [2]	4 (22.2)	6 (24.0)
Number of subjects with missing evaluation, n (%)	1 (5.6)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.119
95% CI for the RR		(0.384, 3.259)
p-value for RR		0.8373
Day 8		
Number of subjects with a response, n (%) [2]	7 (38.9)	13 (52.0)
Number of subjects with missing evaluation, n (%)	2 (11.1)	2 (8.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.385
95% CI for the RR		(0.665, 2.883)
p-value for RR		0.3840

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-resp15-301-by.sas:t-hama-resp15-301-by-race-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-301 - ITT population

Race Group = Black or African American

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =26)
Day 15		
Number of subjects with a response, n (%) [2]	8 (44.4)	18 (72.0)
Number of subjects with missing evaluation, n (%)	4 (22.2)	3 (12.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.678
95% CI for the RR		(0.959, 2.934)
p-value for RR		0.0696
Day 21		
Number of subjects with a response, n (%) [2]	7 (38.9)	15 (60.0)
Number of subjects with missing evaluation, n (%)	7 (38.9)	7 (28.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.598
95% CI for the RR		(0.836, 3.055)
p-value for RR		0.1564

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-resp15-301-by.sas:t-hama-resp15-301-by-race-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-301 - ITT population

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Race Group = Black or African American

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =26)
Day 28		
Number of subjects with a response, n (%) [2]	7 (38.9)	16 (64.0)
Number of subjects with missing evaluation, n (%)	7 (38.9)	6 (24.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.705
95% CI for the RR		(0.883, 3.291)
p-value for RR		0.1122
Day 45		
Number of subjects with a response, n (%) [2]	5 (27.8)	16 (64.0)
Number of subjects with missing evaluation, n (%)	5 (27.8)	3 (12.0)
RR - Relative Risk (Zuranolone vs. Placebo)		2.386
95% CI for the RR		(1.041, 5.470)
p-value for RR		0.0399

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-resp15-301-by.sas:t-hama-resp15-301-by-race-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-301 - ITT population

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Race Group = White

Study Visit Statistics	Placebo (N=70)	Zuranolone (N =68)
Number of evaluable subjects [1]	69	68
Day 3		
Number of subjects with a response, n (%) [2]	15 (21.7)	28 (41.2)
Number of subjects with missing evaluation, n (%)	1 (1.4)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.887
95% CI for the RR		(1.123, 3.172)
p-value for RR		0.0165
Day 8		
Number of subjects with a response, n (%) [2]	27 (39.1)	39 (57.4)
Number of subjects with missing evaluation, n (%)	0	3 (4.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.460
95% CI for the RR		(1.030, 2.071)
p-value for RR		0.0336

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-resp15-301-by.sas:t-hama-resp15-301-by-race-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-301 - ITT population

Race Group = White

Study Visit Statistics	Placebo (N=70)	Zuranolone (N =68)
Day 15		
Number of subjects with a response, n (%) [2]	34 (49.3)	47 (69.1)
Number of subjects with missing evaluation, n (%)	3 (4.3)	3 (4.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.398
95% CI for the RR		(1.055, 1.851)
p-value for RR		0.0196
Day 21		
Number of subjects with a response, n (%) [2]	39 (56.5)	43 (63.2)
Number of subjects with missing evaluation, n (%)	7 (10.1)	7 (10.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.115
95% CI for the RR		(0.849, 1.464)
p-value for RR		0.4348

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-resp15-301-by.sas:t-hama-resp15-301-by-race-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-301 - ITT population

Race Group = White

Study Visit Statistics	Placebo (N=70)	Zuranolone (N =68)
Day 28		
Number of subjects with a response, n (%) [2]	44 (63.8)	41 (60.3)
Number of subjects with missing evaluation, n (%)	5 (7.2)	15 (22.1)
RR - Relative Risk (Zuranolone vs. Placebo)		0.942
95% CI for the RR		(0.723, 1.228)
p-value for RR		0.6587
Day 45		
Number of subjects with a response, n (%) [2]	46 (66.7)	44 (64.7)
Number of subjects with missing evaluation, n (%)	7 (10.1)	10 (14.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.967
95% CI for the RR		(0.755, 1.238)
p-value for RR		0.7902

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-resp15-301-by.sas:t-hama-resp15-301-by-race-itta.rtf **Run Date:** 25JUL2025

2.5.2.1 .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-301 - ITT population

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Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=15)	Zuranolone (N =15)
Number of evaluable subjects [1]	15	15
Day 3		
Number of subjects with a response, n (%) [2]	4 (26.7)	2 (13.3)
Number of subjects with missing evaluation, n (%)	1 (6.7)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.318
95% CI for the RR		(0.028, 3.613)
p-value for RR		0.3554
Day 8		
Number of subjects with a response, n (%) [2]	7 (46.7)	5 (33.3)
Number of subjects with missing evaluation, n (%)	0	1 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.454
95% CI for the RR		(0.069, 3.008)
p-value for RR		0.4132

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-resp15-301-by.sas:t-hama-resp15-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-301 - ITT population

Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=15)	Zuranolone (N =15)
Day 15		
Number of subjects with a response, n (%) [2]	13 (86.7)	7 (46.7)
Number of subjects with missing evaluation, n (%)	0	1 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.342
95% CI for the RR		(0.067, 1.762)
p-value for RR		0.1997
Day 21		
Number of subjects with a response, n (%) [2]	12 (80.0)	8 (53.3)
Number of subjects with missing evaluation, n (%)	1 (6.7)	1 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.424
95% CI for the RR		(0.081, 2.226)
p-value for RR		0.3105

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-resp15-301-by.sas:t-hama-resp15-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-301 - ITT population

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Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=15)	Zuranolone (N =15)
Day 28		
Number of subjects with a response, n (%) [2]	10 (66.7)	8 (53.3)
Number of subjects with missing evaluation, n (%)	2 (13.3)	1 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.509
95% CI for the RR		(0.117, 2.213)
p-value for RR		0.3675
Day 45		
Number of subjects with a response, n (%) [2]	9 (60.0)	8 (53.3)
Number of subjects with missing evaluation, n (%)	1 (6.7)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.565
95% CI for the RR		(0.103, 3.087)
p-value for RR		0.5100

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-resp15-301-by.sas:t-hama-resp15-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-301 - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=86)	Zuranolone (N =84)
Number of evaluable subjects [1]	83	83
Day 3		
Number of subjects with a response, n (%) [2]	19 (22.9)	33 (39.8)
Number of subjects with missing evaluation, n (%)	1 (1.2)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.722
95% CI for the RR		(1.087, 2.728)
p-value for RR		0.0205
Day 8		
Number of subjects with a response, n (%) [2]	31 (37.3)	48 (57.8)
Number of subjects with missing evaluation, n (%)	3 (3.6)	4 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.535
95% CI for the RR		(1.110, 2.125)
p-value for RR		0.0097

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-resp15-301-by.sas:t-hama-resp15-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-301 - ITT population

Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=86)	Zuranolone (N =84)
Day 15		
Number of subjects with a response, n (%) [2]	34 (41.0)	59 (71.1)
Number of subjects with missing evaluation, n (%)	8 (9.6)	5 (6.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.721
95% CI for the RR		(1.295, 2.286)
p-value for RR		0.0002
Day 21		
Number of subjects with a response, n (%) [2]	41 (49.4)	51 (61.4)
Number of subjects with missing evaluation, n (%)	14 (16.9)	13 (15.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.233
95% CI for the RR		(0.941, 1.616)
p-value for RR		0.1283

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-resp15-301-by.sas:t-hama-resp15-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-301 - ITT population

Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=86)	Zuranolone (N =84)
Day 28		
Number of subjects with a response, n (%) [2]	47 (56.6)	51 (61.4)
Number of subjects with missing evaluation, n (%)	11 (13.3)	20 (24.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.076
95% CI for the RR		(0.832, 1.391)
p-value for RR		0.5758
Day 45		
Number of subjects with a response, n (%) [2]	47 (56.6)	54 (65.1)
Number of subjects with missing evaluation, n (%)	12 (14.5)	14 (16.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.139
95% CI for the RR		(0.886, 1.465)
p-value for RR		0.3089

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-resp15-301-by.sas:t-hama-resp15-301-by-adt-itta.rtf **Run Date:** 25JUL2025

2.5.2.1 .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-301 - ITT population

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

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =20)
Number of evaluable subjects [1]	22	20
Day 3		
Number of subjects with a response, n (%) [2]	5 (22.7)	5 (25.0)
Number of subjects with missing evaluation, n (%)	1 (4.5)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.112
95% CI for the RR		(0.414, 2.988)
p-value for RR		0.8334
Day 8		
Number of subjects with a response, n (%) [2]	8 (36.4)	9 (45.0)
Number of subjects with missing evaluation, n (%)	0	2 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.251
95% CI for the RR		(0.665, 2.352)
p-value for RR		0.4870

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-resp15-301-by.sas:t-hama-resp15-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =20)
Day 15		
Number of subjects with a response, n (%) [2]	10 (45.5)	13 (65.0)
Number of subjects with missing evaluation, n (%)	1 (4.5)	2 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.445
95% CI for the RR		(0.905, 2.309)
p-value for RR		0.1233
Day 21		
Number of subjects with a response, n (%) [2]	13 (59.1)	10 (50.0)
Number of subjects with missing evaluation, n (%)	4 (18.2)	4 (20.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.855
95% CI for the RR		(0.507, 1.443)
p-value for RR		0.5582

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-resp15-301-by.sas:t-hama-resp15-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =20)
Day 28		
Number of subjects with a response, n (%) [2]	13 (59.1)	10 (50.0)
Number of subjects with missing evaluation, n (%)	1 (4.5)	8 (40.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.855
95% CI for the RR		(0.477, 1.534)
p-value for RR		0.6001
Day 45		
Number of subjects with a response, n (%) [2]	15 (68.2)	12 (60.0)
Number of subjects with missing evaluation, n (%)	0	5 (25.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.890
95% CI for the RR		(0.542, 1.460)
p-value for RR		0.6435

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-resp15-301-by.sas:t-hama-resp15-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =24)
Number of evaluable subjects [1]	34	24
Day 3		
Number of subjects with a response, n (%) [2]	7 (20.6)	8 (33.3)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.643
95% CI for the RR		(0.678, 3.982)
p-value for RR		0.2712
Day 8		
Number of subjects with a response, n (%) [2]	12 (35.3)	13 (54.2)
Number of subjects with missing evaluation, n (%)	2 (5.9)	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.558
95% CI for the RR		(0.871, 2.786)
p-value for RR		0.1349

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-resp15-301-by.sas:t-hama-resp15-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =24)
Day 15		
Number of subjects with a response, n (%) [2]	15 (44.1)	13 (54.2)
Number of subjects with missing evaluation, n (%)	4 (11.8)	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.246
95% CI for the RR		(0.742, 2.093)
p-value for RR		0.4054
Day 21		
Number of subjects with a response, n (%) [2]	19 (55.9)	17 (70.8)
Number of subjects with missing evaluation, n (%)	6 (17.6)	3 (12.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.287
95% CI for the RR		(0.874, 1.894)
p-value for RR		0.2017

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-resp15-301-by.sas:t-hama-resp15-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =24)
Day 28		
Number of subjects with a response, n (%) [2]	23 (67.6)	16 (66.7)
Number of subjects with missing evaluation, n (%)	5 (14.7)	4 (16.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.000
95% CI for the RR		(0.692, 1.446)
p-value for RR		0.9985
Day 45		
Number of subjects with a response, n (%) [2]	22 (64.7)	12 (50.0)
Number of subjects with missing evaluation, n (%)	6 (17.6)	4 (16.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.784
95% CI for the RR		(0.490, 1.255)
p-value for RR		0.3112

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-resp15-301-by.sas:t-hama-resp15-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

Study Visit Statistics	Placebo (N=42)	Zuranolone (N =53)
Number of evaluable subjects [1]	42	53
Day 3		
Number of subjects with a response, n (%) [2]	11 (26.2)	22 (41.5)
Number of subjects with missing evaluation, n (%)	1 (2.4)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.576
95% CI for the RR		(0.869, 2.859)
p-value for RR		0.1345
Day 8		
Number of subjects with a response, n (%) [2]	18 (42.9)	31 (58.5)
Number of subjects with missing evaluation, n (%)	1 (2.4)	2 (3.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.357
95% CI for the RR		(0.897, 2.054)
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 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-resp15-301-by.sas:t-hama-resp15-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

Study Visit Statistics	Placebo (N=42)	Zuranolone (N =53)
Day 15		
Number of subjects with a response, n (%) [2]	22 (52.4)	39 (73.6)
Number of subjects with missing evaluation, n (%)	3 (7.1)	3 (5.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.397
95% CI for the RR		(1.003, 1.945)
p-value for RR		0.0479
Day 21		
Number of subjects with a response, n (%) [2]	21 (50.0)	31 (58.5)
Number of subjects with missing evaluation, n (%)	5 (11.9)	7 (13.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.163
95% CI for the RR		(0.797, 1.698)
p-value for RR		0.4335

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-resp15-301-by.sas:t-hama-resp15-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

Study Visit Statistics	Placebo (N=42)	Zuranolone (N =53)
Day 28		
Number of subjects with a response, n (%) [2]	21 (50.0)	32 (60.4)
Number of subjects with missing evaluation, n (%)	7 (16.7)	9 (17.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.201
95% CI for the RR		(0.826, 1.746)
p-value for RR		0.3384
Day 45		
Number of subjects with a response, n (%) [2]	19 (45.2)	37 (69.8)
Number of subjects with missing evaluation, n (%)	7 (16.7)	5 (9.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.534
95% CI for the RR		(1.048, 2.246)
p-value for RR		0.0276

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-resp15-301-by.sas:t-hama-resp15-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

2.5.2.1 .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-301 - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =35)
Number of evaluable subjects [1]	31	34
Day 3		
Number of subjects with a response, n (%) [2]	10 (32.3)	15 (44.1)
Number of subjects with missing evaluation, n (%)	1 (3.2)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.376
95% CI for the RR		(0.731, 2.589)
p-value for RR		0.3226
Day 8		
Number of subjects with a response, n (%) [2]	11 (35.5)	20 (58.8)
Number of subjects with missing evaluation, n (%)	3 (9.7)	2 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.668
95% CI for the RR		(0.965, 2.881)
p-value for RR		0.0667

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-resp15-301-by.sas:t-hama-resp15-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-301 - ITT population

Page: 2 of 6

Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =35)
Day 15		
Number of subjects with a response, n (%) [2]	16 (51.6)	23 (67.6)
Number of subjects with missing evaluation, n (%)	4 (12.9)	3 (8.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.319
95% CI for the RR		(0.872, 1.995)
p-value for RR		0.1906
Day 21		
Number of subjects with a response, n (%) [2]	17 (54.8)	22 (64.7)
Number of subjects with missing evaluation, n (%)	6 (19.4)	5 (14.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.187
95% CI for the RR		(0.790, 1.784)
p-value for RR		0.4098

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-resp15-301-by.sas:t-hama-resp15-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =35)
Day 28		
Number of subjects with a response, n (%) [2]	17 (54.8)	20 (58.8)
Number of subjects with missing evaluation, n (%)	6 (19.4)	8 (23.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.079
95% CI for the RR		(0.706, 1.648)
p-value for RR		0.7247
Day 45		
Number of subjects with a response, n (%) [2]	17 (54.8)	20 (58.8)
Number of subjects with missing evaluation, n (%)	6 (19.4)	7 (20.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.079
95% CI for the RR		(0.705, 1.651)
p-value for RR		0.7257

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-resp15-301-by.sas:t-hama-resp15-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=69)	Zuranolone (N =64)
Number of evaluable subjects [1]	67	64
Day 3		
Number of subjects with a response, n (%) [2]	13 (19.4)	20 (31.3)
Number of subjects with missing evaluation, n (%)	1 (1.5)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.629
95% CI for the RR		(0.897, 2.959)
p-value for RR		0.1091
Day 8		
Number of subjects with a response, n (%) [2]	27 (40.3)	33 (51.6)
Number of subjects with missing evaluation, n (%)	0	3 (4.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.294
95% CI for the RR		(0.899, 1.864)
p-value for RR		0.1658

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-resp15-301-by.sas:t-hama-resp15-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=69)	Zuranolone (N =64)
Day 15		
Number of subjects with a response, n (%) [2]	31 (46.3)	43 (67.2)
Number of subjects with missing evaluation, n (%)	4 (6.0)	3 (4.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.469
95% CI for the RR		(1.092, 1.975)
p-value for RR		0.0109
Day 21		
Number of subjects with a response, n (%) [2]	36 (53.7)	37 (57.8)
Number of subjects with missing evaluation, n (%)	9 (13.4)	9 (14.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.088
95% CI for the RR		(0.806, 1.470)
p-value for RR		0.5812

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-resp15-301-by.sas:t-hama-resp15-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=69)	Zuranolone (N =64)
Day 28		
Number of subjects with a response, n (%) [2]	40 (59.7)	39 (60.9)
Number of subjects with missing evaluation, n (%)	7 (10.4)	13 (20.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.032
95% CI for the RR		(0.779, 1.369)
p-value for RR		0.8245
Day 45		
Number of subjects with a response, n (%) [2]	39 (58.2)	42 (65.6)
Number of subjects with missing evaluation, n (%)	7 (10.4)	7 (10.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.140
95% CI for the RR		(0.869, 1.496)
p-value for RR		0.3430

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-resp15-301-by.sas:t-hama-resp15-301-by-onset-itta.rtf **Run Date:** 25JUL2025

2.5.2.1 .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-301 - ITT population

Page: 1 of 6

Family History of PPD = Yes

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =21)
Number of evaluable subjects [1]	16	21
Day 3		
Number of subjects with a response, n (%) [2]	4 (25.0)	10 (47.6)
Number of subjects with missing evaluation, n (%)	1 (6.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.021
95% CI for the RR		(0.819, 4.982)
p-value for RR		0.1266
Day 8		
Number of subjects with a response, n (%) [2]	9 (56.3)	13 (61.9)
Number of subjects with missing evaluation, n (%)	1 (6.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.167
95% CI for the RR		(0.698, 1.954)
p-value for RR		0.5556

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-resp15-301-by.sas:t-hama-resp15-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =21)
Day 15		
Number of subjects with a response, n (%) [2]	10 (62.5)	12 (57.1)
Number of subjects with missing evaluation, n (%)	3 (18.8)	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		0.970
95% CI for the RR		(0.592, 1.589)
p-value for RR		0.9034
Day 21		
Number of subjects with a response, n (%) [2]	11 (68.8)	16 (76.2)
Number of subjects with missing evaluation, n (%)	3 (18.8)	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.176
95% CI for the RR		(0.790, 1.749)
p-value for RR		0.4249

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-resp15-301-by.sas:t-hama-resp15-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =21)
Day 28		
Number of subjects with a response, n (%) [2]	11 (68.8)	15 (71.4)
Number of subjects with missing evaluation, n (%)	4 (25.0)	3 (14.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.102
95% CI for the RR		(0.724, 1.677)
p-value for RR		0.6497
Day 45		
Number of subjects with a response, n (%) [2]	11 (68.8)	13 (61.9)
Number of subjects with missing evaluation, n (%)	3 (18.8)	2 (9.5)
RR - Relative Risk (Zuranolone vs. Placebo)		0.955
95% CI for the RR		(0.595, 1.532)
p-value for RR		0.8493

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-resp15-301-by.sas:t-hama-resp15-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=85)	Zuranolone (N =78)
Number of evaluable subjects [1]	82	77
Day 3		
Number of subjects with a response, n (%) [2]	19 (23.2)	25 (32.5)
Number of subjects with missing evaluation, n (%)	1 (1.2)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.398
95% CI for the RR		(0.846, 2.312)
p-value for RR		0.1914
Day 8		
Number of subjects with a response, n (%) [2]	29 (35.4)	40 (51.9)
Number of subjects with missing evaluation, n (%)	2 (2.4)	5 (6.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.466
95% CI for the RR		(1.025, 2.097)
p-value for RR		0.0363

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-resp15-301-by.sas:t-hama-resp15-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=85)	Zuranolone (N =78)
Day 15		
Number of subjects with a response, n (%) [2]	37 (45.1)	54 (70.1)
Number of subjects with missing evaluation, n (%)	5 (6.1)	5 (6.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.551
95% CI for the RR		(1.178, 2.042)
p-value for RR		0.0018
Day 21		
Number of subjects with a response, n (%) [2]	42 (51.2)	43 (55.8)
Number of subjects with missing evaluation, n (%)	12 (14.6)	13 (16.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.088
95% CI for the RR		(0.816, 1.450)
p-value for RR		0.5648

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-resp15-301-by.sas:t-hama-resp15-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=85)	Zuranolone (N =78)
Day 28		
Number of subjects with a response, n (%) [2]	46 (56.1)	44 (57.1)
Number of subjects with missing evaluation, n (%)	9 (11.0)	18 (23.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.017
95% CI for the RR		(0.773, 1.337)
p-value for RR		0.9069
Day 45		
Number of subjects with a response, n (%) [2]	45 (54.9)	49 (63.6)
Number of subjects with missing evaluation, n (%)	10 (12.2)	12 (15.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.157
95% CI for the RR		(0.891, 1.503)
p-value for RR		0.2743

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-resp15-301-by.sas:t-hama-resp15-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

2.5.2.1 .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-301 - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=90)	Zuranolone (N =82)
Number of evaluable subjects [1]	87	81
Day 3		
Number of subjects with a response, n (%) [2]	18 (20.7)	27 (33.3)
Number of subjects with missing evaluation, n (%)	2 (2.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.613
95% CI for the RR		(0.972, 2.676)
p-value for RR		0.0643
Day 8		
Number of subjects with a response, n (%) [2]	32 (36.8)	42 (51.9)
Number of subjects with missing evaluation, n (%)	3 (3.4)	5 (6.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.411
95% CI for the RR		(1.002, 1.987)
p-value for RR		0.0486

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-resp15-301-by.sas:t-hama-resp15-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-301 - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=90)	Zuranolone (N =82)
Day 15		
Number of subjects with a response, n (%) [2]	40 (46.0)	52 (64.2)
Number of subjects with missing evaluation, n (%)	8 (9.2)	6 (7.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.398
95% CI for the RR		(1.062, 1.839)
p-value for RR		0.0169
Day 21		
Number of subjects with a response, n (%) [2]	46 (52.9)	48 (59.3)
Number of subjects with missing evaluation, n (%)	14 (16.1)	13 (16.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.122
95% CI for the RR		(0.860, 1.463)
p-value for RR		0.3963

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-resp15-301-by.sas:t-hama-resp15-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-301 - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=90)	Zuranolone (N =82)
Day 28		
Number of subjects with a response, n (%) [2]	51 (58.6)	46 (56.8)
Number of subjects with missing evaluation, n (%)	13 (14.9)	21 (25.9)
RR - Relative Risk (Zuranolone vs. Placebo)		0.970
95% CI for the RR		(0.744, 1.264)
p-value for RR		0.8198
Day 45		
Number of subjects with a response, n (%) [2]	50 (57.5)	50 (61.7)
Number of subjects with missing evaluation, n (%)	12 (13.8)	13 (16.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.075
95% CI for the RR		(0.833, 1.387)
p-value for RR		0.5776

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-resp15-301-by.sas:t-hama-resp15-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-301 - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=11)	Zuranolone (N =17)
Number of evaluable subjects [1]	11	17
Day 3		
Number of subjects with a response, n (%) [2]	5 (45.5)	8 (47.1)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.260
95% CI for the RR		(0.570, 2.789)
p-value for RR		0.5678
Day 8		
Number of subjects with a response, n (%) [2]	6 (54.5)	11 (64.7)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.444
95% CI for the RR		(0.739, 2.822)
p-value for RR		0.2820

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-resp15-301-by.sas:t-hama-resp15-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-301 - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=11)	Zuranolone (N =17)
Day 15		
Number of subjects with a response, n (%) [2]	7 (63.6)	14 (82.4)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.576
95% CI for the RR		(0.954, 2.603)
p-value for RR		0.0759
Day 21		
Number of subjects with a response, n (%) [2]	7 (63.6)	11 (64.7)
Number of subjects with missing evaluation, n (%)	1 (9.1)	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.238
95% CI for the RR		(0.708, 2.166)
p-value for RR		0.4545

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-resp15-301-by.sas:t-hama-resp15-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-301 - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=11)	Zuranolone (N =17)
Day 28		
Number of subjects with a response, n (%) [2]	6 (54.5)	13 (76.5)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.707
95% CI for the RR		(0.959, 3.037)
p-value for RR		0.0689
Day 45		
Number of subjects with a response, n (%) [2]	6 (54.5)	12 (70.6)
Number of subjects with missing evaluation, n (%)	1 (9.1)	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.576
95% CI for the RR		(0.845, 2.939)
p-value for RR		0.1528

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-resp15-301-by.sas:t-hama-resp15-301-by-hist-itta.rtf **Run Date:** 25JUL2025

2.5.2.1 .2 .2 .9 Depression mit Angst

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =24)
Number of evaluable subjects [1]	21	24
Day 3		
Number of subjects with a response, n (%) [2]	2 (9.5)	5 (20.8)
Number of subjects with missing evaluation, n (%)	1 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.232
95% CI for the RR		(0.504, 9.893)
p-value for RR		0.2905
Day 8		
Number of subjects with a response, n (%) [2]	2 (9.5)	9 (37.5)
Number of subjects with missing evaluation, n (%)	1 (4.8)	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		4.018
95% CI for the RR		(1.025, 15.744)
p-value for RR		0.0459

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-resp15-301-by.sas:t-hama-resp15-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =24)
Day 15		
Number of subjects with a response, n (%) [2]	5 (23.8)	13 (54.2)
Number of subjects with missing evaluation, n (%)	1 (4.8)	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		2.321
95% CI for the RR		(1.018, 5.296)
p-value for RR		0.0454
Day 21		
Number of subjects with a response, n (%) [2]	8 (38.1)	14 (58.3)
Number of subjects with missing evaluation, n (%)	3 (14.3)	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.563
95% CI for the RR		(0.852, 2.864)
p-value for RR		0.1489

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-resp15-301-by.sas:t-hama-resp15-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =24)
Day 28		
Number of subjects with a response, n (%) [2]	11 (52.4)	13 (54.2)
Number of subjects with missing evaluation, n (%)	2 (9.5)	5 (20.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.055
95% CI for the RR		(0.613, 1.817)
p-value for RR		0.8464
Day 45		
Number of subjects with a response, n (%) [2]	13 (61.9)	15 (62.5)
Number of subjects with missing evaluation, n (%)	1 (4.8)	3 (12.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.030
95% CI for the RR		(0.664, 1.599)
p-value for RR		0.8944

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-resp15-301-by.sas:t-hama-resp15-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

Study Visit Statistics	Placebo (N=77)	Zuranolone (N =74)
Number of evaluable subjects [1]	77	74
Day 3		
Number of subjects with a response, n (%) [2]	21 (27.3)	30 (40.5)
Number of subjects with missing evaluation, n (%)	1 (1.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.485
95% CI for the RR		(0.944, 2.338)
p-value for RR		0.0874
Day 8		
Number of subjects with a response, n (%) [2]	36 (46.8)	44 (59.5)
Number of subjects with missing evaluation, n (%)	2 (2.6)	4 (5.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.271
95% CI for the RR		(0.939, 1.721)
p-value for RR		0.1210

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-resp15-301-by.sas:t-hama-resp15-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

Study Visit Statistics	Placebo (N=77)	Zuranolone (N =74)
Day 15		
Number of subjects with a response, n (%) [2]	42 (54.5)	53 (71.6)
Number of subjects with missing evaluation, n (%)	7 (9.1)	5 (6.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.312
95% CI for the RR		(1.024, 1.682)
p-value for RR		0.0318
Day 21		
Number of subjects with a response, n (%) [2]	45 (58.4)	45 (60.8)
Number of subjects with missing evaluation, n (%)	12 (15.6)	13 (17.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.040
95% CI for the RR		(0.801, 1.351)
p-value for RR		0.7697

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-resp15-301-by.sas:t-hama-resp15-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

Study Visit Statistics	Placebo (N=77)	Zuranolone (N =74)
Day 28		
Number of subjects with a response, n (%) [2]	46 (59.7)	46 (62.2)
Number of subjects with missing evaluation, n (%)	11 (14.3)	16 (21.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.040
95% CI for the RR		(0.803, 1.346)
p-value for RR		0.7666
Day 45		
Number of subjects with a response, n (%) [2]	43 (55.8)	47 (63.5)
Number of subjects with missing evaluation, n (%)	12 (15.6)	11 (14.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.137
95% CI for the RR		(0.872, 1.481)
p-value for RR		0.3435

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.

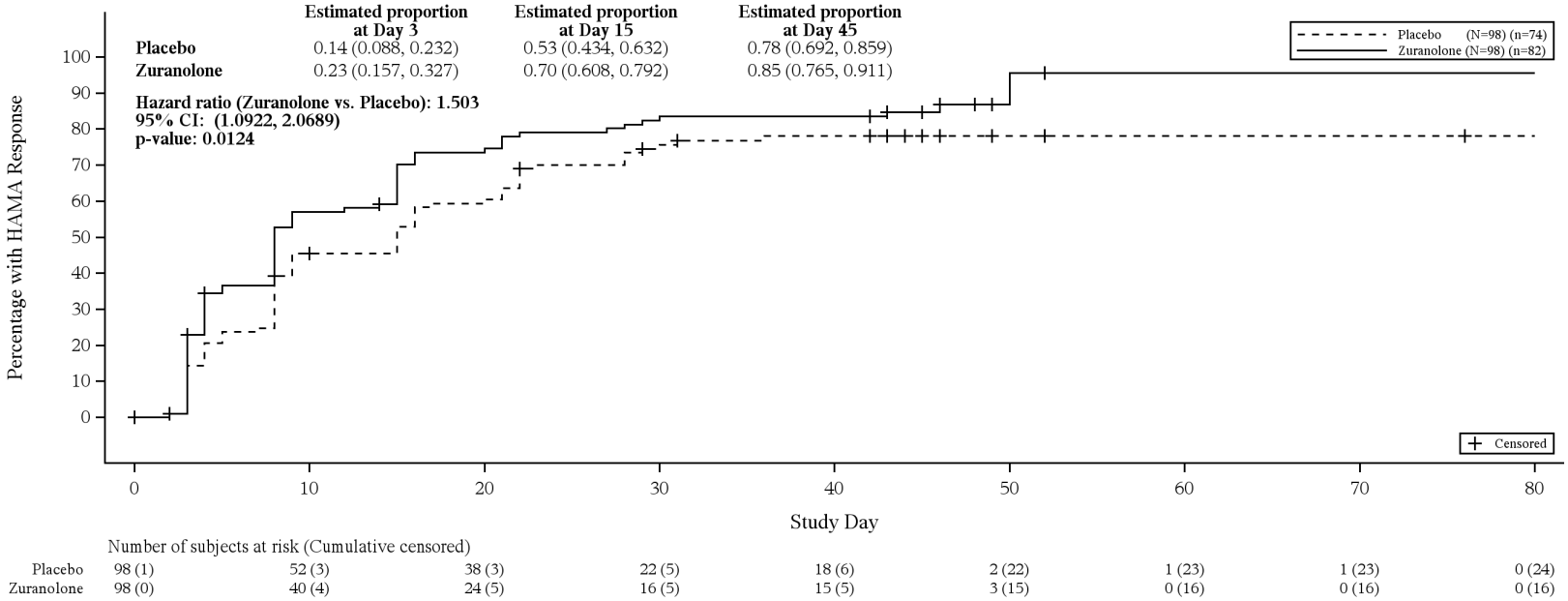
Source: biib125/v_a/germany_amnog/t-hama-resp15-301-by.sas:t-hama-resp15-301-by-hama-itta.rtf **Run Date:** 25JUL2025

2.5.2.2 TTE-Analysen

2.5.2.2 .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-301 - 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-301-ovr.sas:f-hama-resp15-tte-301-ovr-itta.rtf **Run Date:** 16DEC2025

Summary of Time to First Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline): 217-PPD-301 - ITT population

Page: 1 of 1

	Placebo (N=101)	Zuranolone (N=99)
Number of evaluable subjects [1]	98	98
Number of subjects with response, n (%) [2]	74 (75.5)	82 (83.7)
Time to first HAMA 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 (9.0 , 20.0)	8.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	30.0 (22.0, NE)	21.0 (15.0 , 30.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.503
95% CI for the HR		(1.0922 , 2.0689)
p-value for the HR		0.0124

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-301-ovr.sas:t-hama-resp15-tte-301-ovr-itta.rtf **Run Date:** 18JUL2025

2.5.2.2 .2 Subgruppen

2.5.2.2 .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-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	98	98	
Number of subjects with response, n (%)	74 (75.5)	82 (83.7)	
Age Group (years)			
18 - 24, n / N (%)	10/12 (83.3)	17/19 (89.5)	0.5665
25 - 45, n / N (%)	64/86 (74.4)	65/79 (82.3)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	19/32 (59.4)	25/33 (75.8)	0.6561
>=28, n / N (%)	55/66 (83.3)	57/65 (87.7)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	11/18 (61.1)	21/25 (84.0)	0.9501
White, n / N (%)	54/69 (78.3)	58/68 (85.3)	
Antidepressant Use at Baseline			
Yes, n / N (%)	13/15 (86.7)	10/15 (66.7)	0.0288
No, n / N (%)	61/83 (73.5)	72/83 (86.7)	

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-301-int.sas:t-hama-resp15-tte-301-int-itta.rtf **Run Date:** 18JUL2025

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-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9, n / N (%)	17/22 (77.3)	16/20 (80.0)	0.7931(a)
25-29.9, n / N (%)	28/34 (82.4)	18/24 (75.0)	0.6520(b)
>=30, n / N (%)	29/42 (69.0)	47/53 (88.7)	0.4199(c)
Onset of PPD			
3rd Trimester, n / N (%)	24/31 (77.4)	29/34 (85.3)	0.8020
Postpartum, n / N (%)	50/67 (74.6)	53/64 (82.8)	
Family History of PPD			
Yes, n / N (%)	13/16 (81.3)	18/21 (85.7)	0.4801
No/Unknown, n / N (%)	61/82 (74.4)	64/77 (83.1)	
History of PPD			
1st Episode, n / N (%)	65/87 (74.7)	68/81 (84.0)	0.5816
Recurrent Episode, n / N (%)	9/11 (81.8)	14/17 (82.4)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	13/21 (61.9)	17/24 (70.8)	0.8332
>=20, n / N (%)	61/77 (79.2)	65/74 (87.8)	

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-301-int.sas:t-hama-resp15-tte-301-int-itta.rtf **Run Date:** 18JUL2025

2.5.2.2 .2 .2 Subgruppenanalysen

2.5.2.2 .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-301 - ITT population

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Age Group (years) = 18-24

	Placebo (N=13)	Zuranolone (N=19)
Number of evaluable subjects [1]	12	19
Number of subjects with response, n (%) [2]	10 (83.3)	17 (89.5)
Time to first HAMA response (days) [3]		
25th percentile - Q1 (95% CI)	4.5 (3.0 , 9.0)	4.0 (3.0 , 4.0)
50th percentile - median (95% CI)	12.0 (3.0 , 22.0)	4.0 (4.0 , 8.0)
75th percentile - Q3 (95% CI)	22.0 (9.0, NE)	8.0 (4.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.171
95% CI for the HR		(0.9184 , 5.1314)
p-value for the HR		0.0774

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-301-by.sas:t-hama-resp15-tte-301-by-age-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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Age Group (years) = 25-45

	Placebo (N=88)	Zuranolone (N=80)
Number of evaluable subjects [1]	86	79
Number of subjects with response, n (%) [2]	64 (74.4)	65 (82.3)
Time to first HAMA 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 , 21.0)	9.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	31.0 (22.0, NE)	21.0 (15.0 , 46.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.434
95% CI for the HR		(1.0093 , 2.0361)
p-value for the HR		0.0443

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-301-by.sas:t-hama-resp15-tte-301-by-age-itta.rtf **Run Date:** 25JUL2025

2.5.2.2 .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-301 - ITT population

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

	Placebo (N=32)	Zuranolone (N=33)
Number of evaluable subjects [1]	32	33
Number of subjects with response, n (%) [2]	19 (59.4)	25 (75.8)
Time to first HAMA response (days) [3]		
25th percentile - Q1 (95% CI)	7.5 (3.0 , 8.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	16.0 (8.0, NE)	15.0 (4.0 , 28.0)
75th percentile - Q3 (95% CI)	NE (36.0, NE)	43.0 (21.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.799
95% CI for the HR		(0.9651 , 3.3543)
p-value for the HR		0.0646

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-301-by.sas:t-hama-resp15-tte-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

Page: 2 of 2

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

	Placebo (N=66)	Zuranolone (N=65)
Number of evaluable subjects [1]	66	65
Number of subjects with response, n (%) [2]	55 (83.3)	57 (87.7)
Time to first HAMA response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 8.0)	3.5 (3.0 , 5.0)
50th percentile - median (95% CI)	15.0 (9.0 , 16.0)	8.0 (5.0 , 9.0)
75th percentile - Q3 (95% CI)	23.0 (20.0 , 31.0)	15.0 (12.0 , 21.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.471
95% CI for the HR		(1.0035 , 2.1560)
p-value for the HR		0.0479

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-301-by.sas:t-hama-resp15-tte-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

2.5.2.2 .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-301 - ITT population

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Race Group = Black or African American

	Placebo (N=20)	Zuranolone (N=26)
Number of evaluable subjects [1]	18	25
Number of subjects with response, n (%) [2]	11 (61.1)	21 (84.0)
Time to first HAMA 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 (4.0, NE)	9.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	NE (9.0, NE)	15.0 (12.0 , 21.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.442
95% CI for the HR		(0.6758 , 3.0759)
p-value for the HR		0.3439

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-301-by.sas:t-hama-resp15-tte-301-by-race-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

Page: 2 of 2

Race Group = White

	Placebo (N=70)	Zuranolone (N=68)
Number of evaluable subjects [1]	69	68
Number of subjects with response, n (%) [2]	54 (78.3)	58 (85.3)
Time to first HAMA 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 , 21.0)	8.0 (4.0 , 9.0)
75th percentile - Q3 (95% CI)	29.0 (22.0, NE)	21.0 (14.0 , 46.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.557
95% CI for the HR		(1.0628 , 2.2809)
p-value for the HR		0.0230

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-301-by.sas:t-hama-resp15-tte-301-by-race-itta.rtf **Run Date:** 25JUL2025

2.5.2.2 .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-301 - ITT population

Page: 1 of 2

Antidepressant Use at Baseline = Yes

	Placebo (N=15)	Zuranolone (N=15)
Number of evaluable subjects [1]	15	15
Number of subjects with response, n (%) [2]	13 (86.7)	10 (66.7)
Time to first HAMA 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 , 15.0)	21.0 (8.0, NE)
75th percentile - Q3 (95% CI)	16.0 (8.0, NE)	50.0 (21.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.473
95% CI for the HR		(0.1910 , 1.1691)
p-value for the HR		0.1048

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-301-by.sas:t-hama-resp15-tte-301-by-adt-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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Antidepressant Use at Baseline = No

	Placebo (N=86)	Zuranolone (N=84)
Number of evaluable subjects [1]	83	83
Number of subjects with response, n (%) [2]	61 (73.5)	72 (86.7)
Time to first HAMA 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)	16.0 (9.0 , 22.0)	8.0 (4.0 , 9.0)
75th percentile - Q3 (95% CI)	36.0 (22.0, NE)	16.0 (15.0 , 27.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.765
95% CI for the HR		(1.2474 , 2.4962)
p-value for the HR		0.0013

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-301-by.sas:t-hama-resp15-tte-301-by-adt-itta.rtf **Run Date:** 25JUL2025

2.5.2.2 .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-301 - ITT population

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

	Placebo (N=22)	Zuranolone (N=20)
Number of evaluable subjects [1]	22	20
Number of subjects with response, n (%) [2]	17 (77.3)	16 (80.0)
Time to first HAMA response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (2.0 , 15.0)	5.0 (3.0 , 8.0)
50th percentile - median (95% CI)	18.0 (8.0 , 22.0)	15.0 (5.0 , 16.0)
75th percentile - Q3 (95% CI)	36.0 (20.0, NE)	28.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.878
95% CI for the HR		(0.9118 , 3.8665)
p-value for the HR		0.0874

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-301-by.sas:t-hama-resp15-tte-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

	Placebo (N=34)	Zuranolone (N=24)
Number of evaluable subjects [1]	34	24
Number of subjects with response, n (%) [2]	28 (82.4)	18 (75.0)
Time to first HAMA response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 8.0)	3.0 (3.0 , 8.0)
50th percentile - median (95% CI)	15.0 (8.0 , 16.0)	8.0 (3.0 , 21.0)
75th percentile - Q3 (95% CI)	23.0 (15.0, NE)	21.0 (9.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.281
95% CI for the HR		(0.6846 , 2.3974)
p-value for the HR		0.4384

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-301-by.sas:t-hama-resp15-tte-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

	Placebo (N=42)	Zuranolone (N=53)
Number of evaluable subjects [1]	42	53
Number of subjects with response, n (%) [2]	29 (69.0)	47 (88.7)
Time to first HAMA response (days) [3]		
25th percentile - Q1 (95% CI)	5.0 (3.0 , 8.0)	4.0 (3.0 , 4.0)
50th percentile - median (95% CI)	15.0 (8.0 , 28.0)	8.0 (4.0 , 15.0)
75th percentile - Q3 (95% CI)	NE (21.0, NE)	16.0 (15.0 , 43.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.718
95% CI for the HR		(1.0733 , 2.7496)
p-value for the HR		0.0241

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-301-by.sas:t-hama-resp15-tte-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

2.5.2.2 .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-301 - ITT population

Page: 1 of 2

Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=35)
Number of evaluable subjects [1]	31	34
Number of subjects with response, n (%) [2]	24 (77.4)	29 (85.3)
Time to first HAMA response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	3.0 (NE, NE)
50th percentile - median (95% CI)	9.0 (5.0 , 21.0)	8.0 (3.0 , 15.0)
75th percentile - Q3 (95% CI)	22.0 (15.0, NE)	15.0 (9.0 , 46.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.522
95% CI for the HR		(0.8752 , 2.6456)
p-value for the HR		0.1369

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-301-by.sas:t-hama-resp15-tte-301-by-onset-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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Onset of PPD = Postpartum

	Placebo (N=69)	Zuranolone (N=64)
Number of evaluable subjects [1]	67	64
Number of subjects with response, n (%) [2]	50 (74.6)	53 (82.8)
Time to first HAMA 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)	16.0 (9.0 , 22.0)	8.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	36.0 (22.0, NE)	21.0 (15.0 , 50.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.456
95% CI for the HR		(0.9844 , 2.1550)
p-value for the HR		0.0600

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-301-by.sas:t-hama-resp15-tte-301-by-onset-itta.rtf **Run Date:** 25JUL2025

2.5.2.2 .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-301 - ITT population

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Family History of PPD = Yes

	Placebo (N=16)	Zuranolone (N=21)
Number of evaluable subjects [1]	16	21
Number of subjects with response, n (%) [2]	13 (81.3)	18 (85.7)
Time to first HAMA response (days) [3]		
25th percentile - Q1 (95% CI)	5.0 (3.0 , 8.0)	3.0 (3.0 , 4.0)
50th percentile - median (95% CI)	8.0 (4.0 , 15.0)	8.0 (3.0 , 20.0)
75th percentile - Q3 (95% CI)	15.5 (8.0, NE)	21.0 (8.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.259
95% CI for the HR		(0.5989 , 2.6468)
p-value for the HR		0.5434

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-301-by.sas:t-hama-resp15-tte-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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Family History of PPD = No/Unknown

	Placebo (N=85)	Zuranolone (N=78)
Number of evaluable subjects [1]	82	77
Number of subjects with response, n (%) [2]	61 (74.4)	64 (83.1)
Time to first HAMA response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (4.0 , 9.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	16.0 (9.0 , 22.0)	8.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	36.0 (22.0, NE)	16.0 (15.0 , 46.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.538
95% CI for the HR		(1.0763 , 2.1988)
p-value for the HR		0.0181

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-301-by.sas:t-hama-resp15-tte-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

2.5.2.2 .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-301 - ITT population

Page: 1 of 2

History of PPD = 1st Episode

	Placebo (N=90)	Zuranolone (N=82)
Number of evaluable subjects [1]	87	81
Number of subjects with response, n (%) [2]	65 (74.7)	68 (84.0)
Time to first HAMA response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (4.0 , 8.0)	4.0 (3.0 , 5.0)
50th percentile - median (95% CI)	15.0 (9.0 , 21.0)	8.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	31.0 (22.0, NE)	21.0 (15.0 , 43.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.463
95% CI for the HR		(1.0374 , 2.0621)
p-value for the HR		0.0300

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-301-by.sas:t-hama-resp15-tte-301-by-hist-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

Page: 2 of 2

History of PPD = Recurrent Episode

	Placebo (N=11)	Zuranolone (N=17)
Number of evaluable subjects [1]	11	17
Number of subjects with response, n (%) [2]	9 (81.8)	14 (82.4)
Time to first HAMA response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 8.0)	3.0 (2.0 , 5.0)
50th percentile - median (95% CI)	8.0 (4.0 , 28.0)	8.0 (3.0 , 15.0)
75th percentile - Q3 (95% CI)	28.0 (5.0, NE)	15.0 (8.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.899
95% CI for the HR		(0.7359 , 4.8982)
p-value for the HR		0.1849

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-301-by.sas:t-hama-resp15-tte-301-by-hist-itta.rtf **Run Date:** 25JUL2025

2.5.2.2 .2 .2 .9 Depression mit Angst

Summary of Time to First Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

Page: 1 of 2

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

	Placebo (N=21)	Zuranolone (N=24)
Number of evaluable subjects [1]	21	24
Number of subjects with response, n (%) [2]	13 (61.9)	17 (70.8)
Time to first HAMA response (days) [3]		
25th percentile - Q1 (95% CI)	19.5 (3.0 , 28.0)	8.0 (3.0 , 15.0)
50th percentile - median (95% CI)	29.0 (17.0, NE)	15.0 (8.0 , 30.0)
75th percentile - Q3 (95% CI)	NE (30.0, NE)	46.0 (16.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.042
95% CI for the HR		(0.9160 , 4.5500)
p-value for the HR		0.0809

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-301-by.sas:t-hama-resp15-tte-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Time to First Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

Page: 2 of 2

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

	Placebo (N=77)	Zuranolone (N=74)
Number of evaluable subjects [1]	77	74
Number of subjects with response, n (%) [2]	61 (79.2)	65 (87.8)
Time to first HAMA response (days) [3]		
25th percentile - Q1 (95% CI)	5.0 (3.0 , 8.0)	4.0 (3.0 , 4.0)
50th percentile - median (95% CI)	9.0 (8.0 , 15.0)	8.0 (4.0 , 9.0)
75th percentile - Q3 (95% CI)	22.0 (16.0, NE)	15.0 (12.0 , 22.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.458
95% CI for the HR		(1.0238 , 2.0752)
p-value for the HR		0.0366

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.

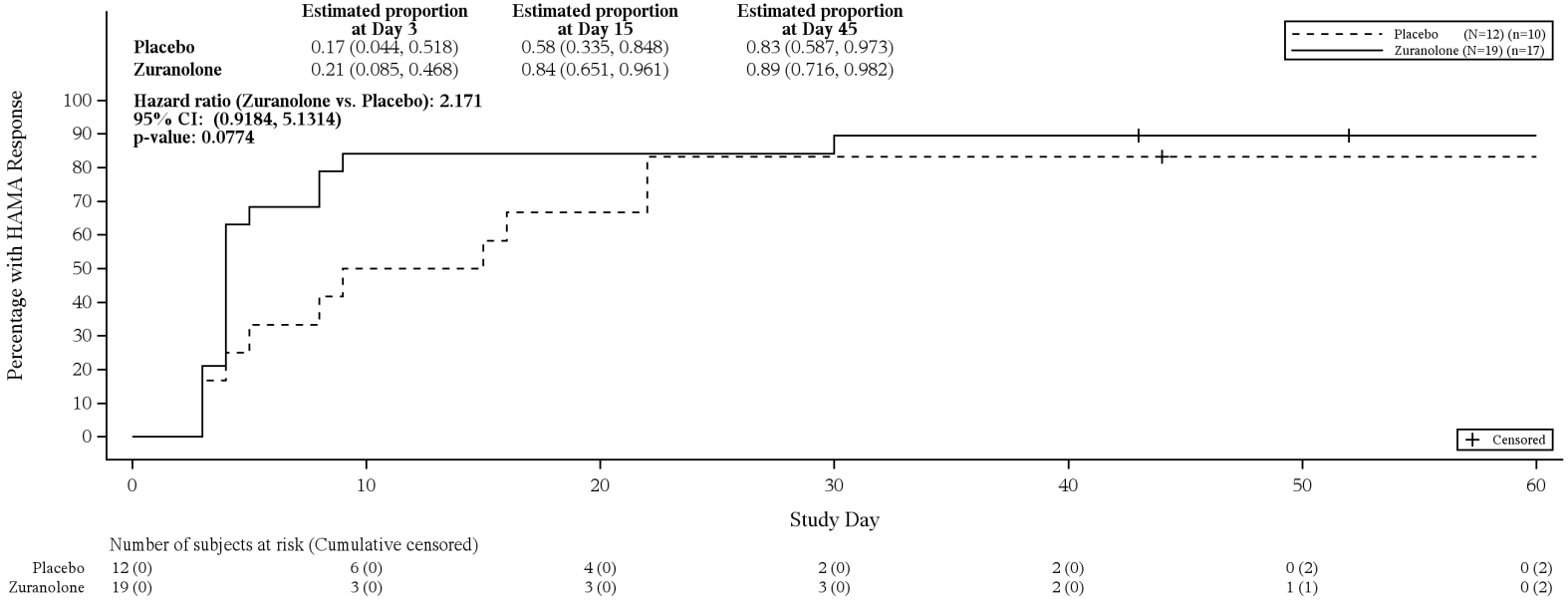
Source: biib125/v_a/germany_amnog/t-hama-resp15-tte-301-by.sas:t-hama-resp15-tte-301-by-hama-itta.rtf **Run Date:** 25JUL2025

2.5.2.2 .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-301 - 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 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.

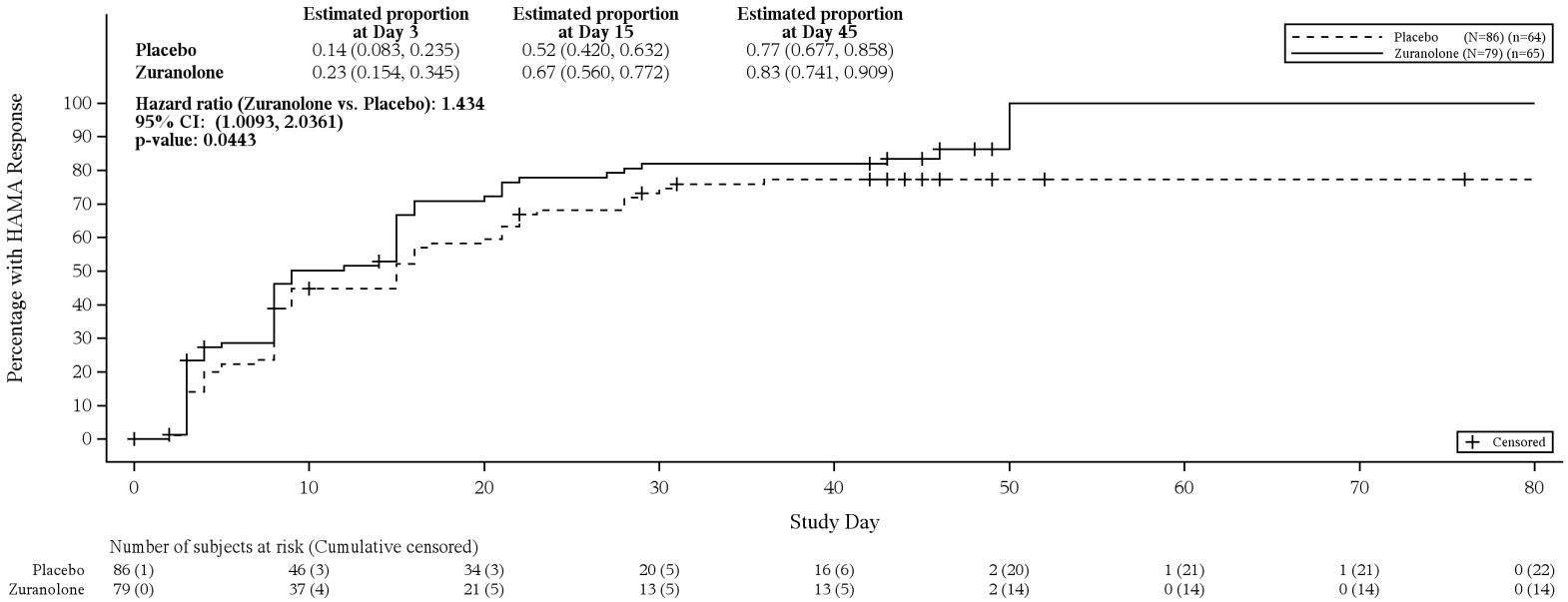
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAM-A total score, and treatment. Model covariate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

Source: biib125/v_a/amnog_kmplots/f-hama-resp15-tte-301-by.sas:f-hama-resp15-tte-301-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-301 - 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 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.

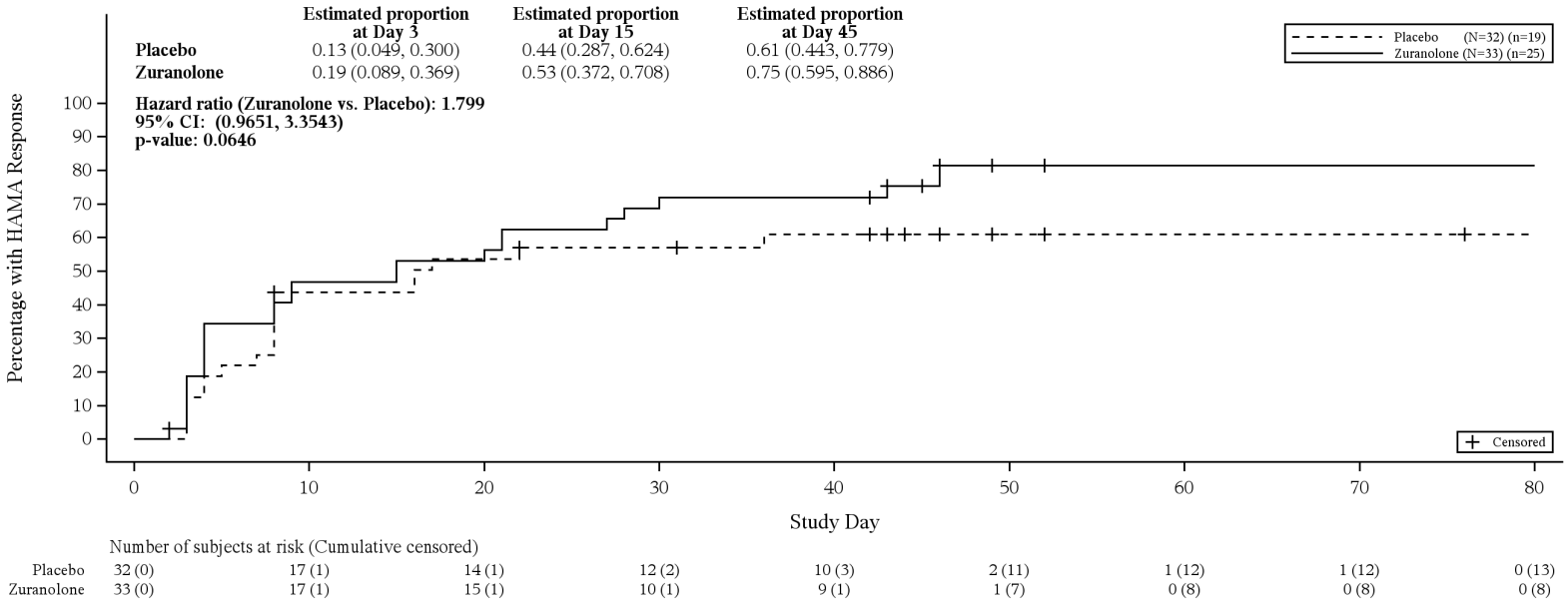
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Source: biib125/v_a/amnog_kmplots/f-hama-resp15-tte-301-by.sas:f-hama-resp15-tte-301-by-itta.rtf **Run Date:** 08JAN2026

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-301 - 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 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.

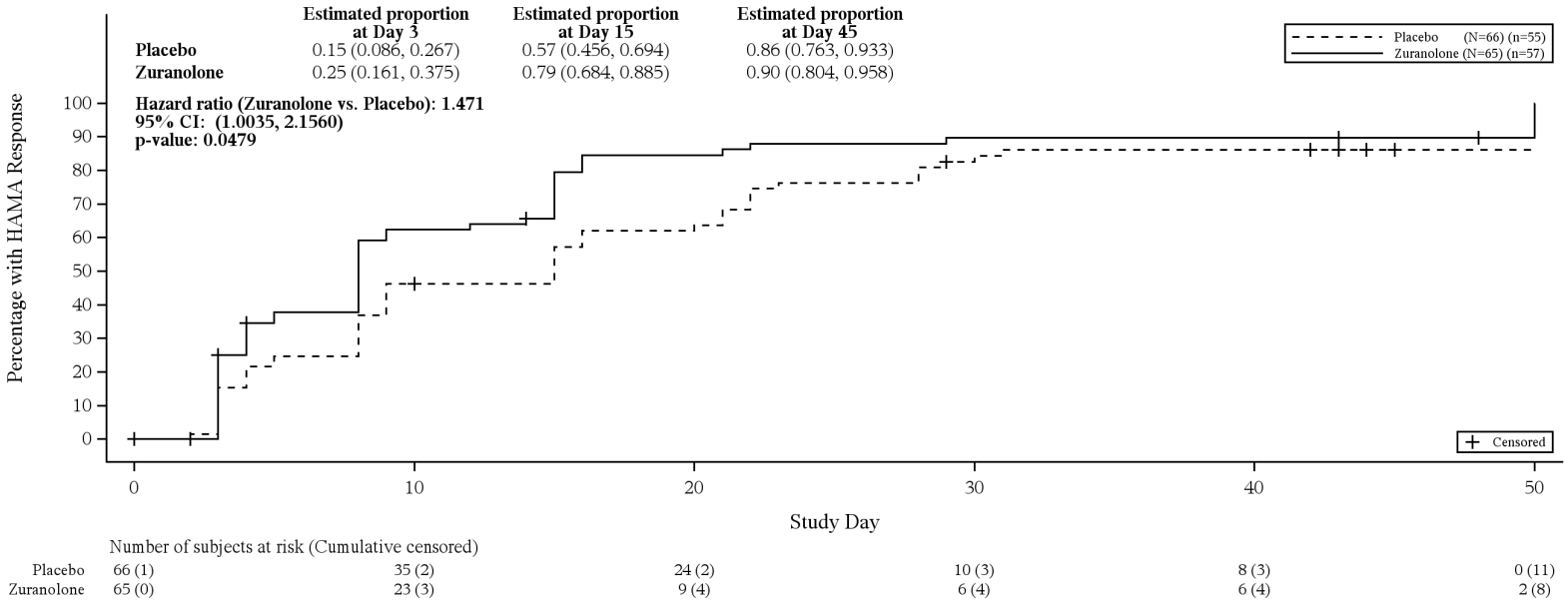
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAM-A total score, and treatment. Model covariate 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-301 - 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 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.

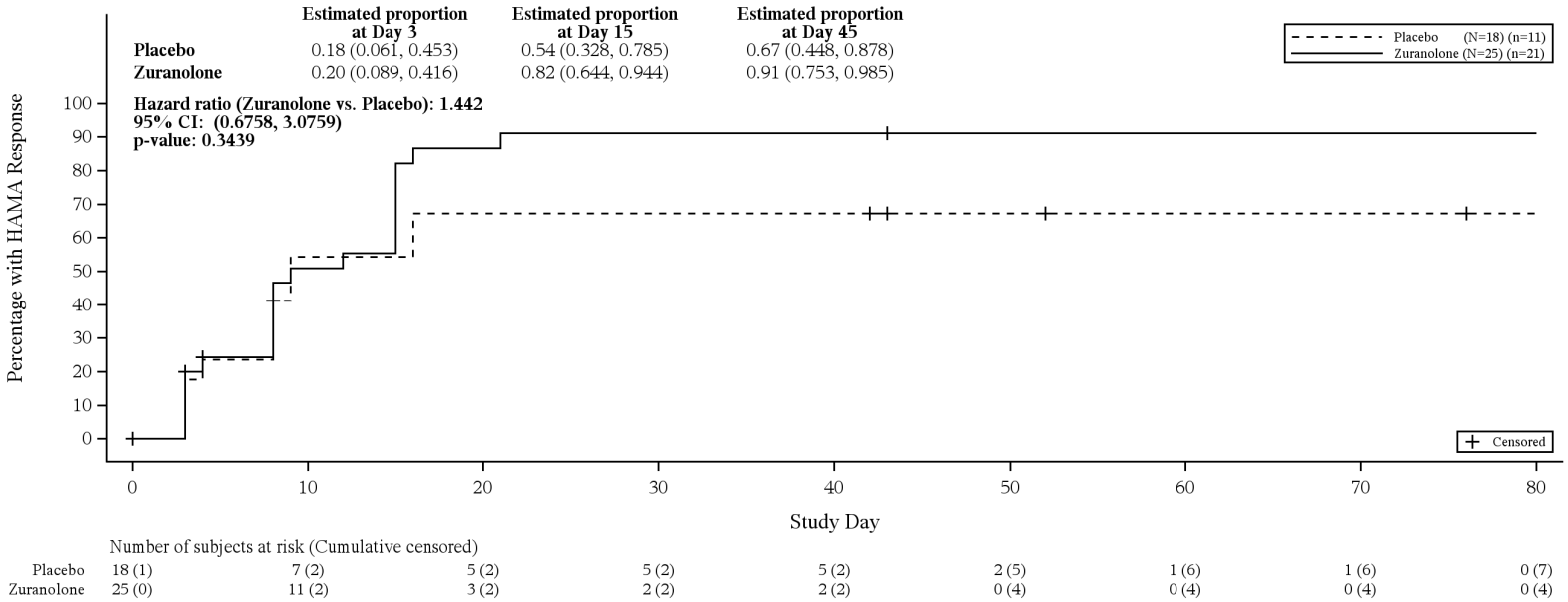
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAM-A total score, and treatment. Model covariate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

Source: biib125/v_a/amnog_kmplots/f-hama-resp15-tte-301-by.sas:f-hama-resp15-tte-301-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-301 - ITT population

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Race Group = Black or African American



Number of subjects at risk (Cumulative censored)

Placebo	18 (1)	7 (2)	5 (2)	5 (2)	5 (2)	2 (5)	1 (6)	1 (6)	0 (7)
Zuranolone	25 (0)	11 (2)	3 (2)	2 (2)	2 (2)	0 (4)	0 (4)	0 (4)	0 (4)

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.

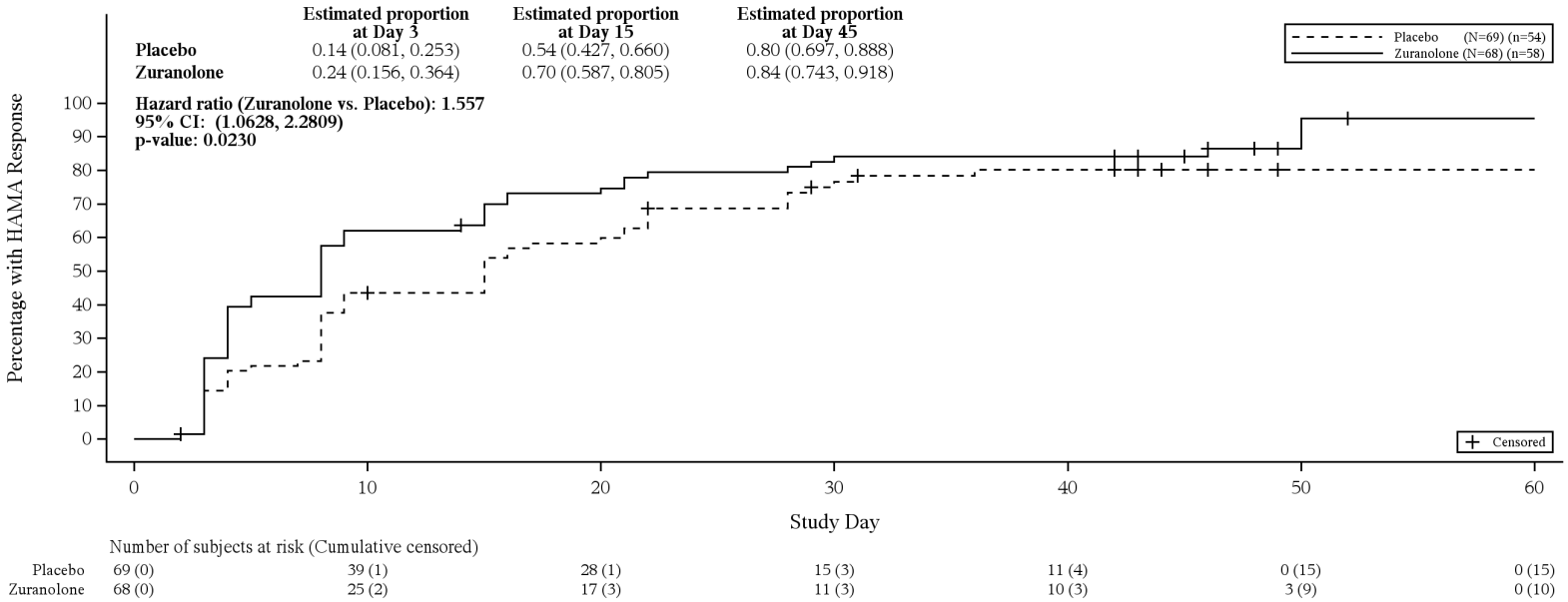
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Source: biib125/v_a/amnog_kmplots/f-hama-resp15-tte-301-by.sas:f-hama-resp15-tte-301-by-itta.rtf **Run Date:** 08JAN2026

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-301 - ITT population

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Race Group = White



Number of subjects at risk (Cumulative censored)

Placebo	69 (0)	39 (1)	28 (1)	15 (3)	11 (4)	0 (15)	0 (15)
Zuranolone	68 (0)	25 (2)	17 (3)	11 (3)	10 (3)	3 (9)	0 (10)

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.

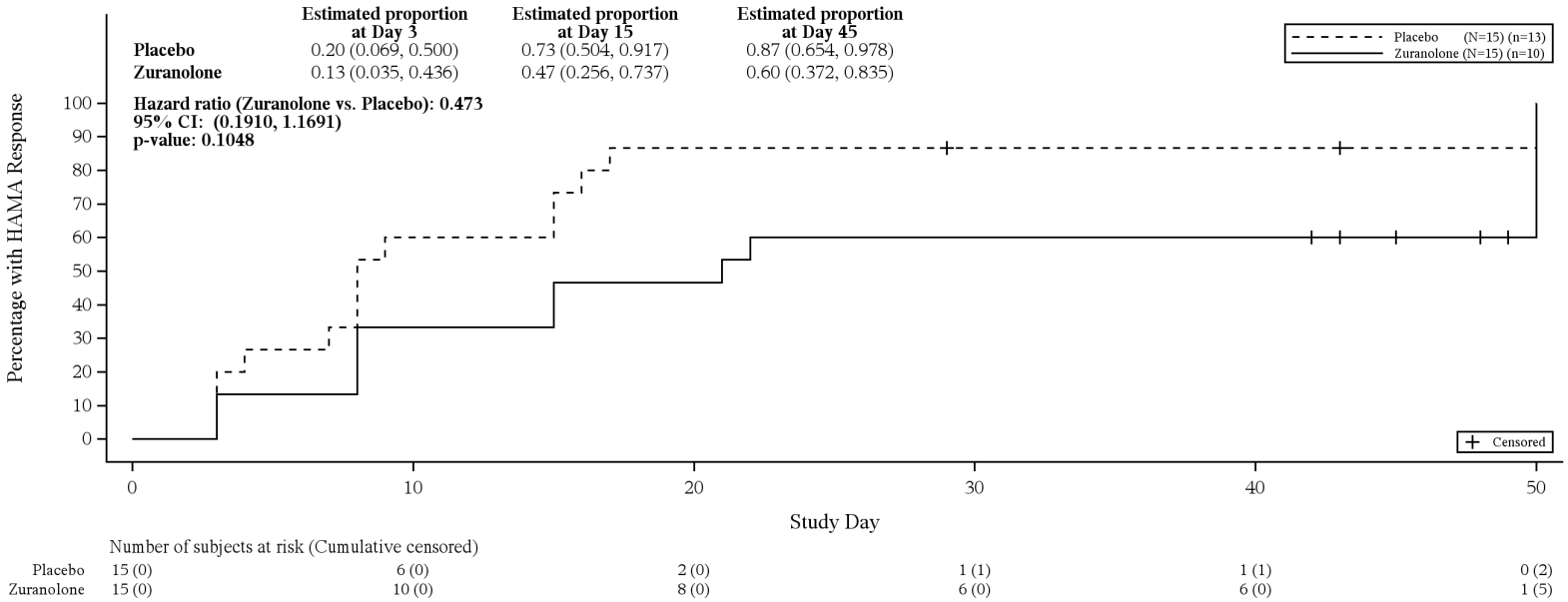
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Source: biib125/v_a/amnog_kmplots/f-hama-resp15-tte-301-by.sas:f-hama-resp15-tte-301-by-itta.rtf **Run Date:** 08JAN2026

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-301 - 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.

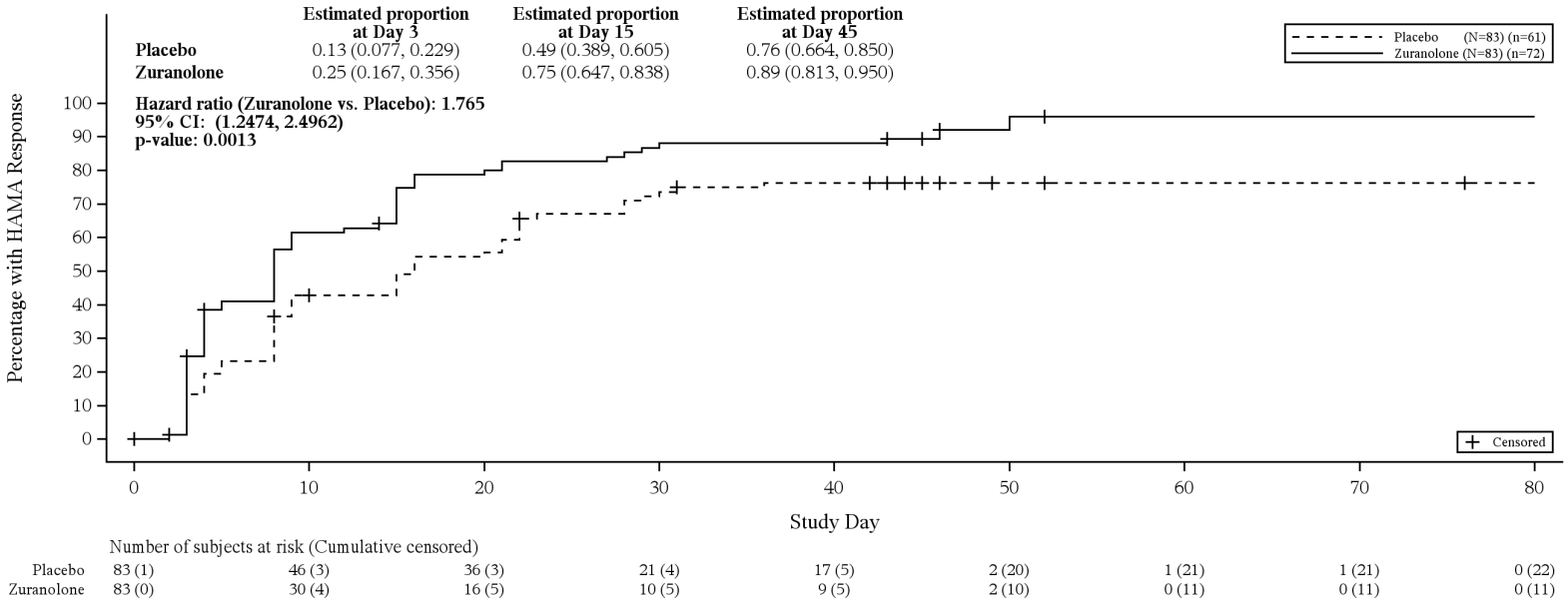
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Source: biib125/v_a/amnog_kmplots/f-hama-resp15-tte-301-by.sas:f-hama-resp15-tte-301-by-itta.rtf **Run Date:** 08JAN2026

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-301 - ITT population

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Antidepressant Use at Baseline = No



Number of subjects at risk (Cumulative censored)

Placebo	83 (1)	46 (3)	36 (3)	21 (4)	17 (5)	2 (20)	1 (21)	1 (21)	0 (22)
Zuranolone	83 (0)	30 (4)	16 (5)	10 (5)	9 (5)	2 (10)	0 (11)	0 (11)	0 (11)

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.

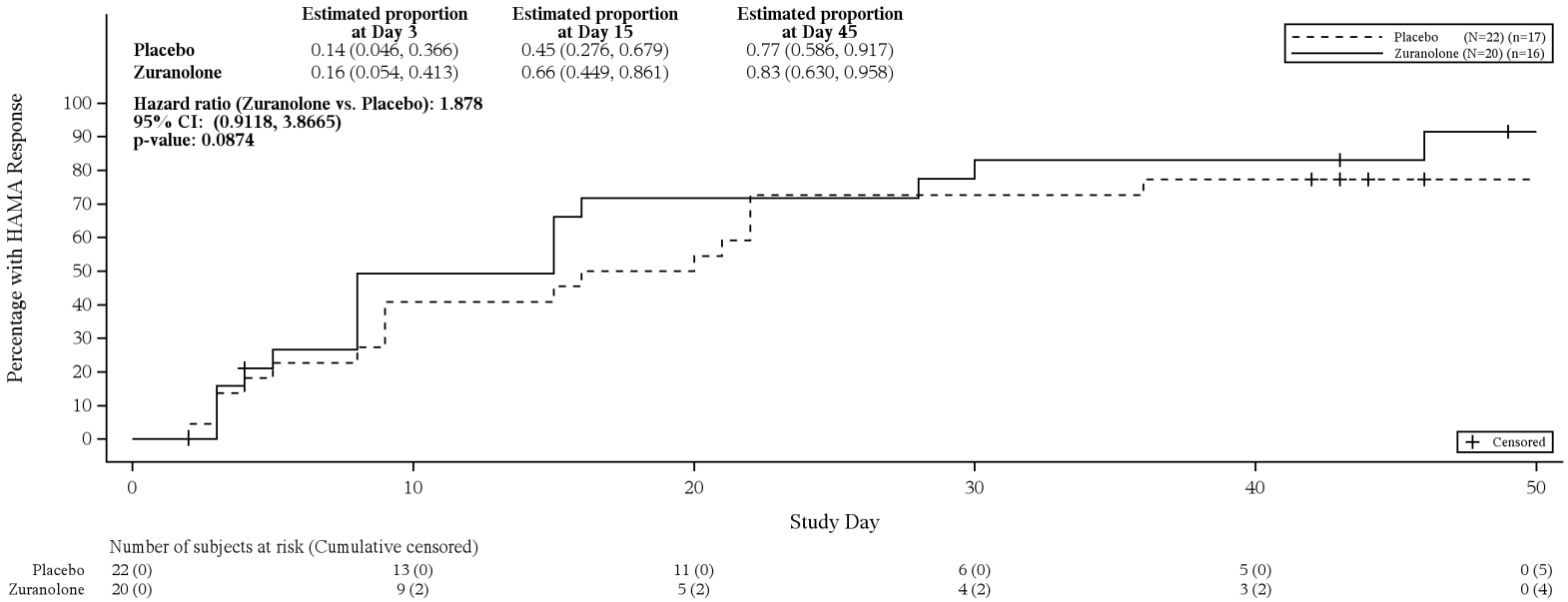
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Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-301 - ITT population

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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.

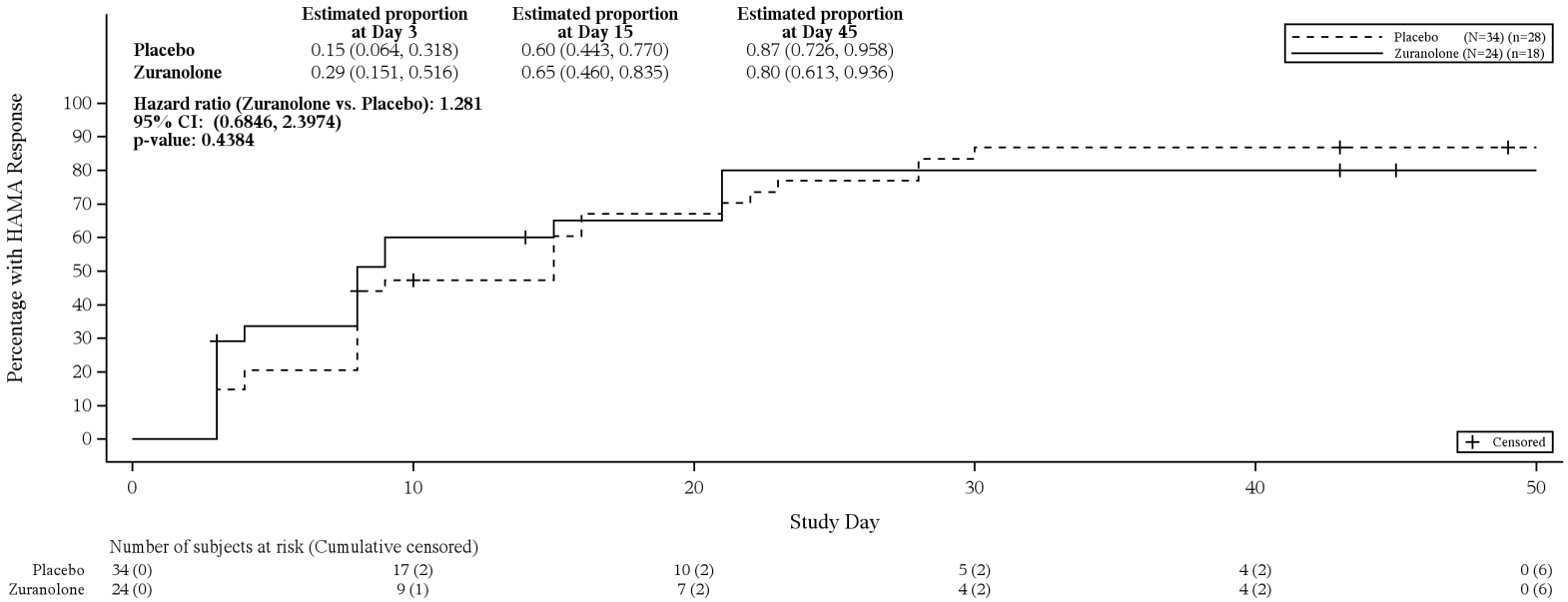
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Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-301 - ITT population

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



Number of subjects at risk (Cumulative censored)

Placebo	34 (0)	17 (2)	10 (2)	5 (2)	4 (2)	0 (6)
Zuranolone	24 (0)	9 (1)	7 (2)	4 (2)	4 (2)	0 (6)

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.

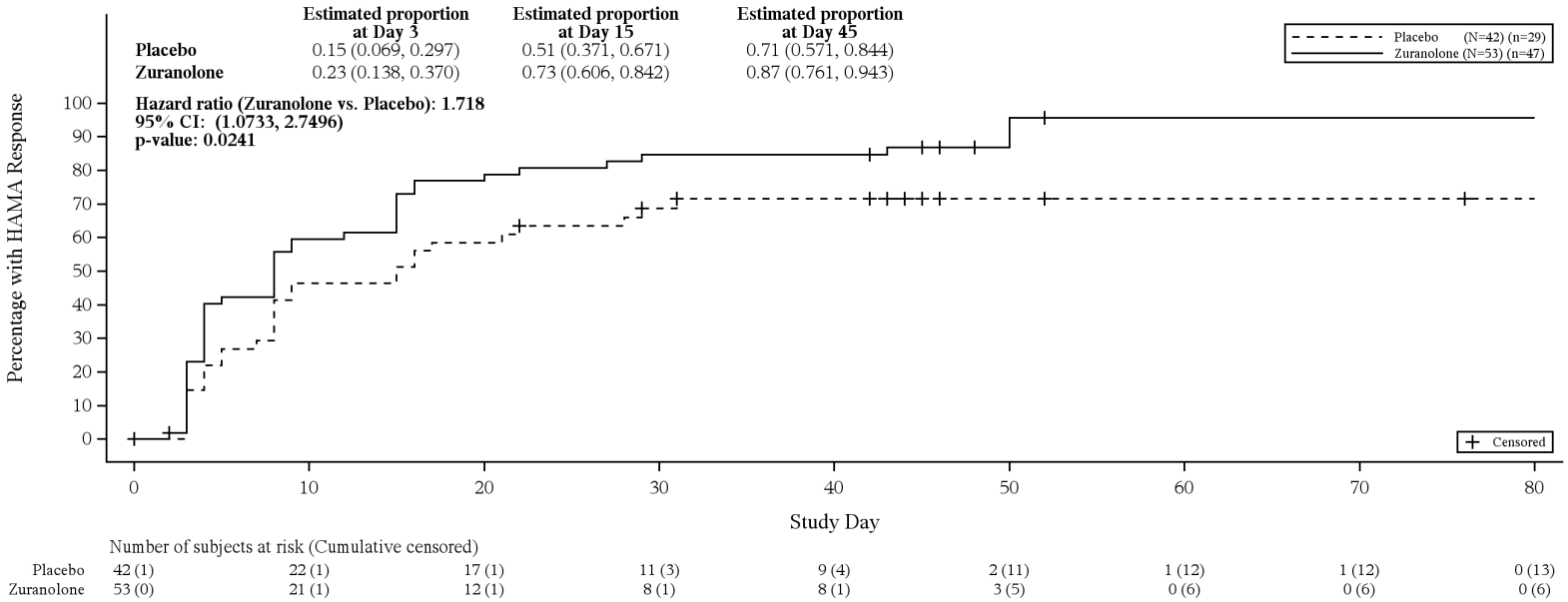
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Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-301 - ITT population

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



Number of subjects at risk (Cumulative censored)

Placebo	42 (1)	22 (1)	17 (1)	11 (3)	9 (4)	2 (11)	1 (12)	1 (12)	0 (13)
Zuranolone	53 (0)	21 (1)	12 (1)	8 (1)	8 (1)	3 (5)	0 (6)	0 (6)	0 (6)

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.

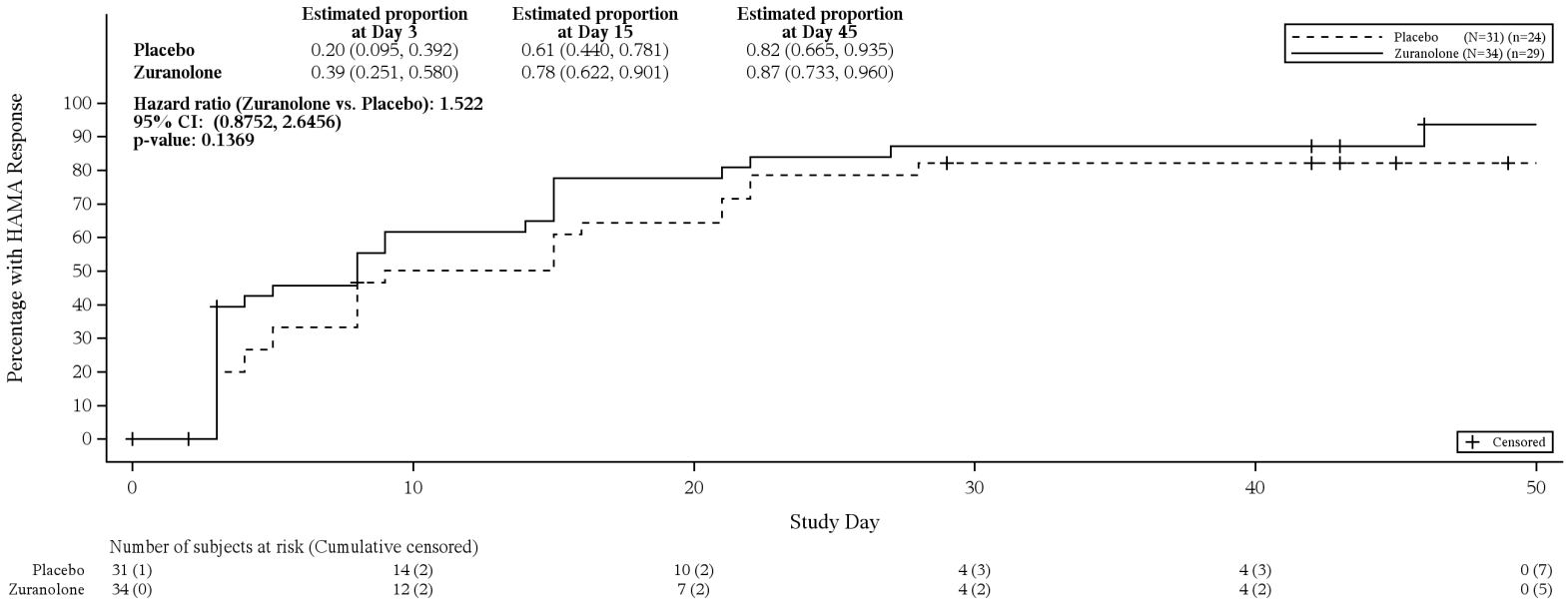
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Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-301 - ITT population

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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.

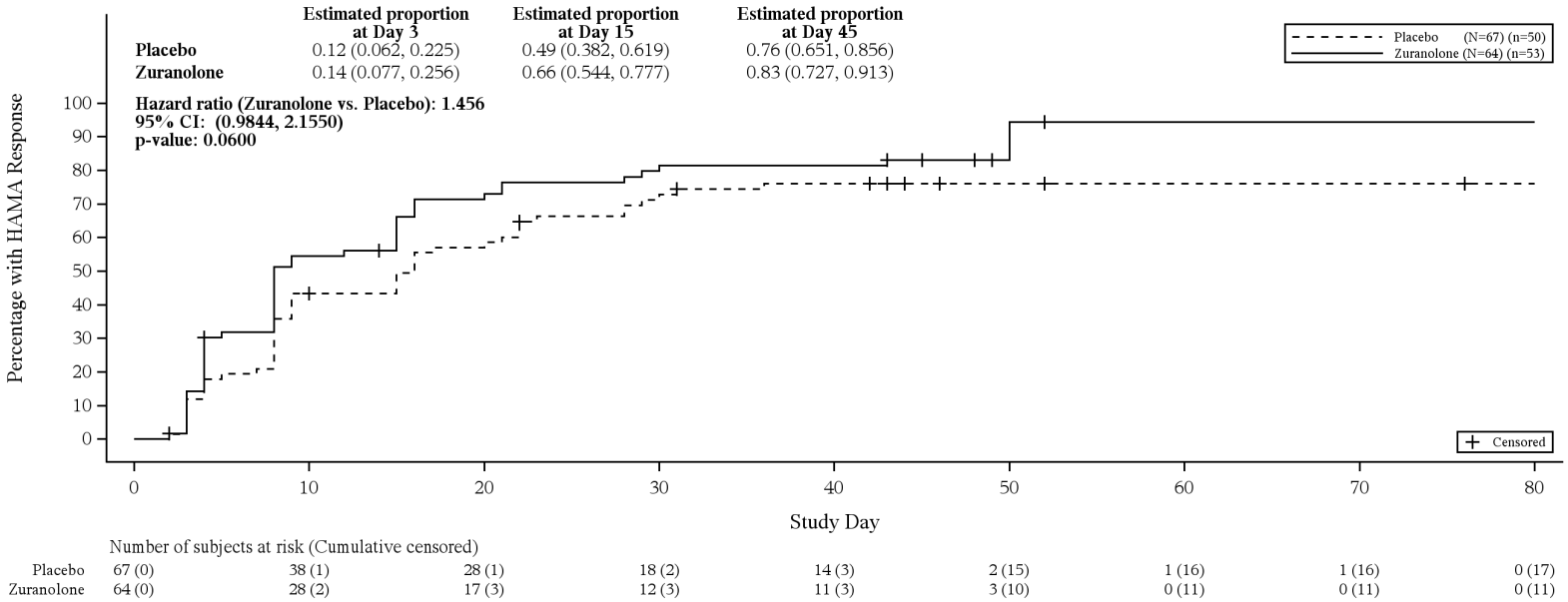
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Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-301 - ITT population

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Onset of PPD = Postpartum



Number of subjects at risk (Cumulative censored)

Placebo	67 (0)	38 (1)	28 (1)	18 (2)	14 (3)	2 (15)	1 (16)	1 (16)	0 (17)
Zuranolone	64 (0)	28 (2)	17 (3)	12 (3)	11 (3)	3 (10)	0 (11)	0 (11)	0 (11)

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.

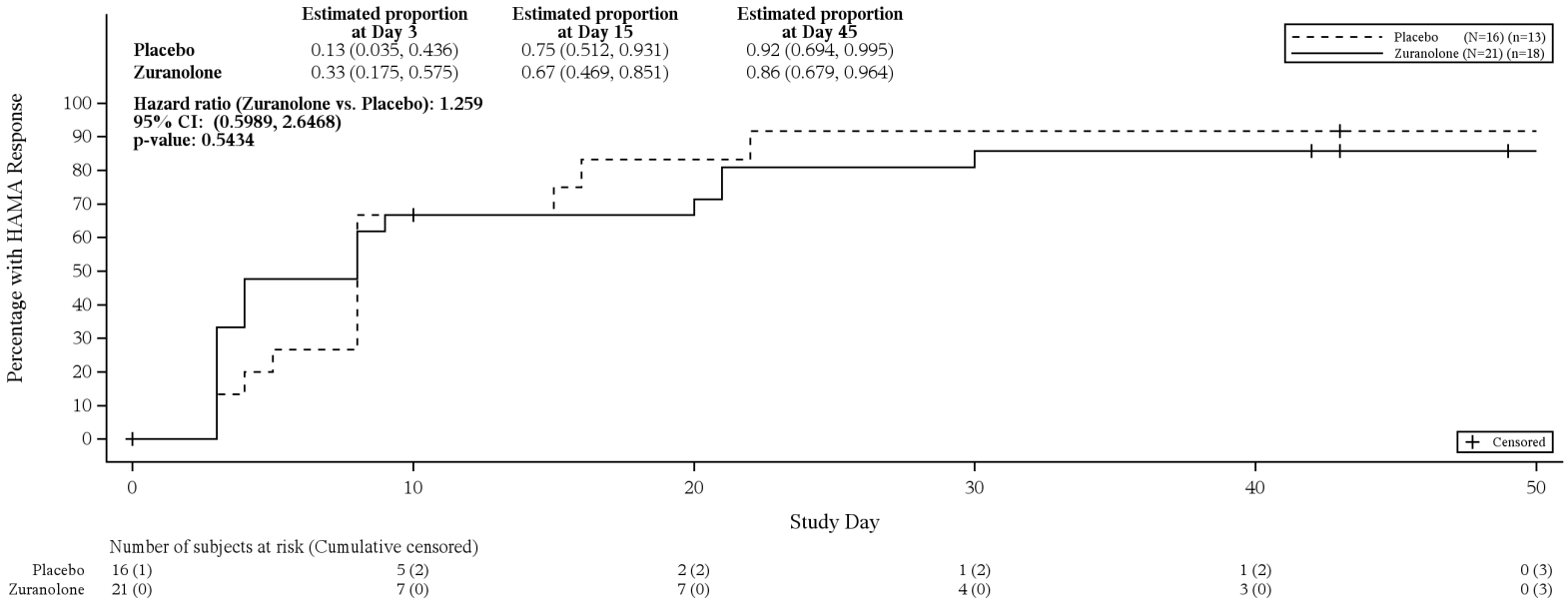
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Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-301 - ITT population

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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 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.

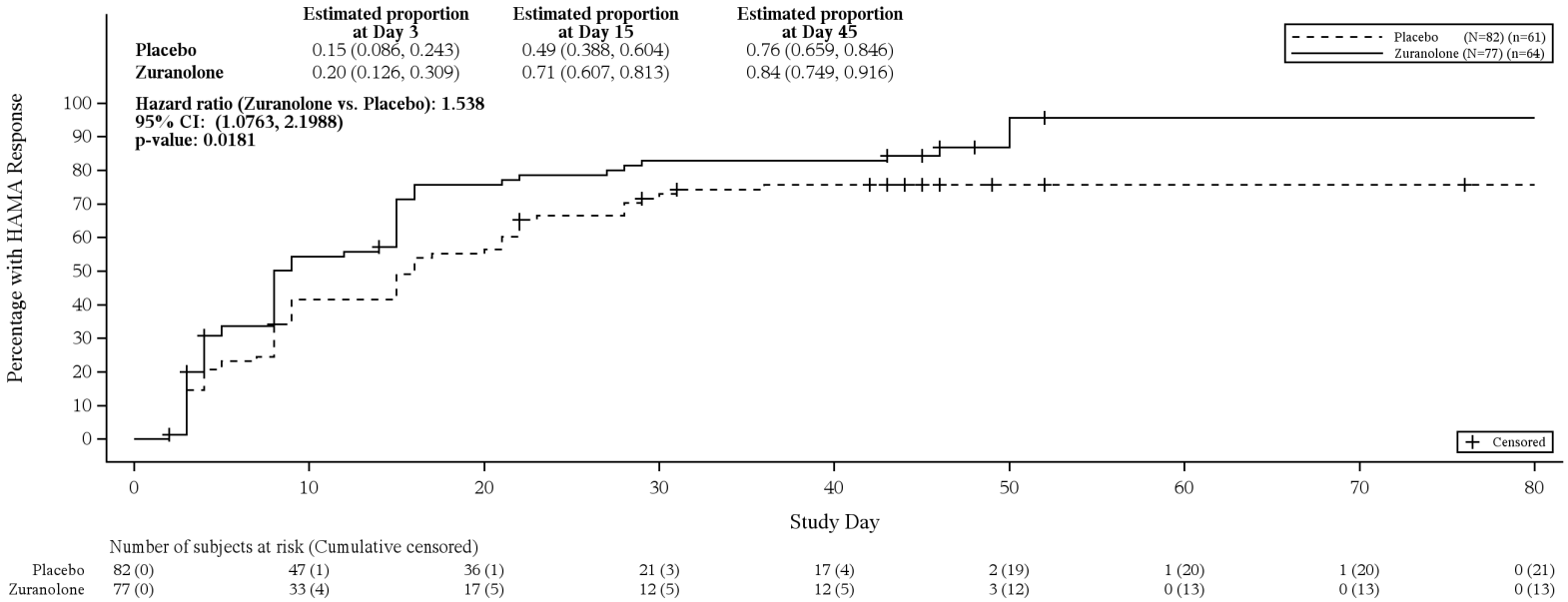
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Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-301 - ITT population

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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.

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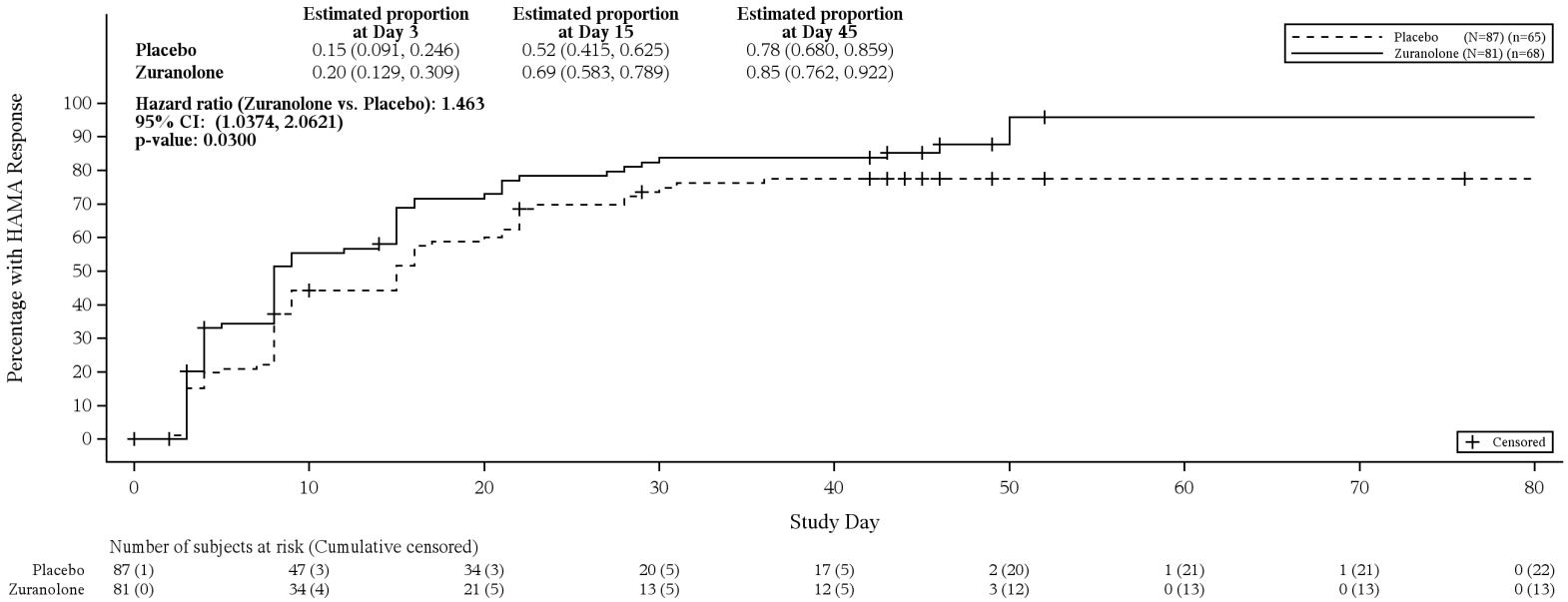
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Kaplan-Meier Plot for Time to First Hamilton Rating Scale for Anxiety (HAM-A) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-301 - ITT population

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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.

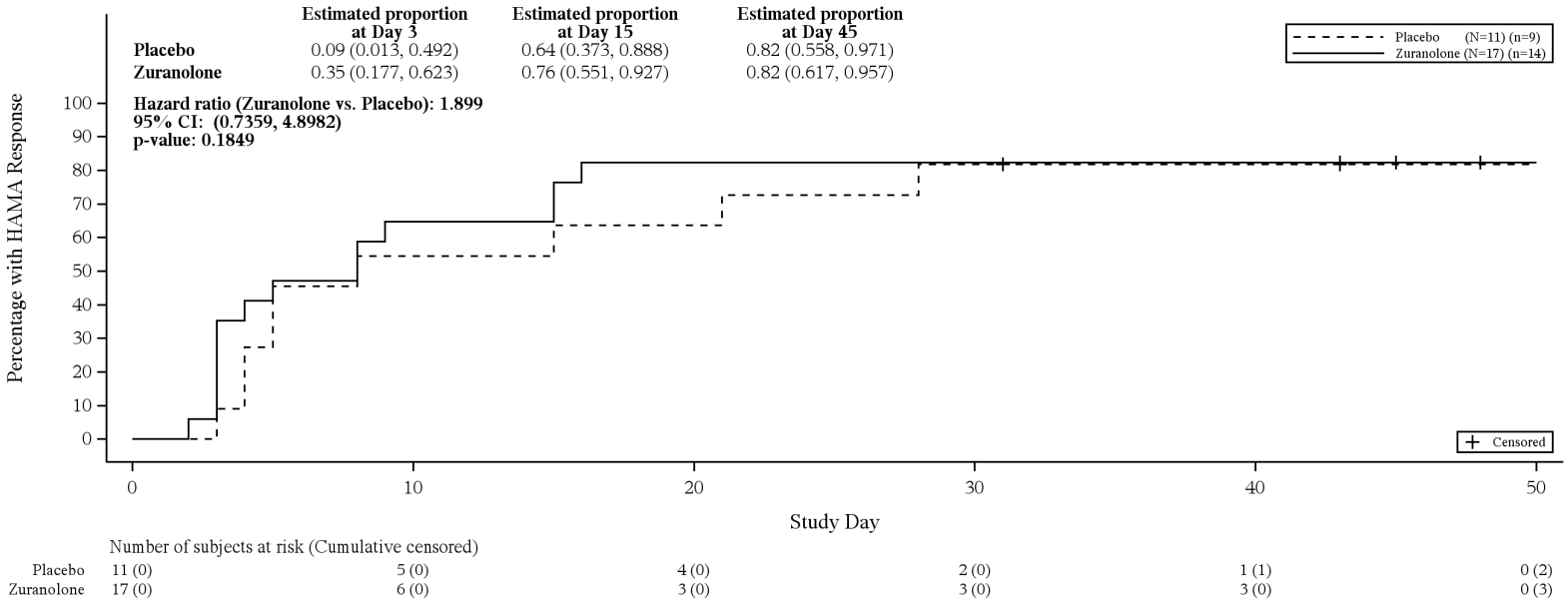
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAM-A total score, and treatment. Model covariate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

Source: biib125/v_a/amnog_kmplots/f-hama-resp15-tte-301-by.sas:f-hama-resp15-tte-301-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-301 - ITT population

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History of PPD = Recurrent Episode



Number of subjects at risk (Cumulative censored)

Placebo	11 (0)	5 (0)	4 (0)	2 (0)	1 (1)	0 (2)
Zuranolone	17 (0)	6 (0)	3 (0)	3 (0)	3 (0)	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.

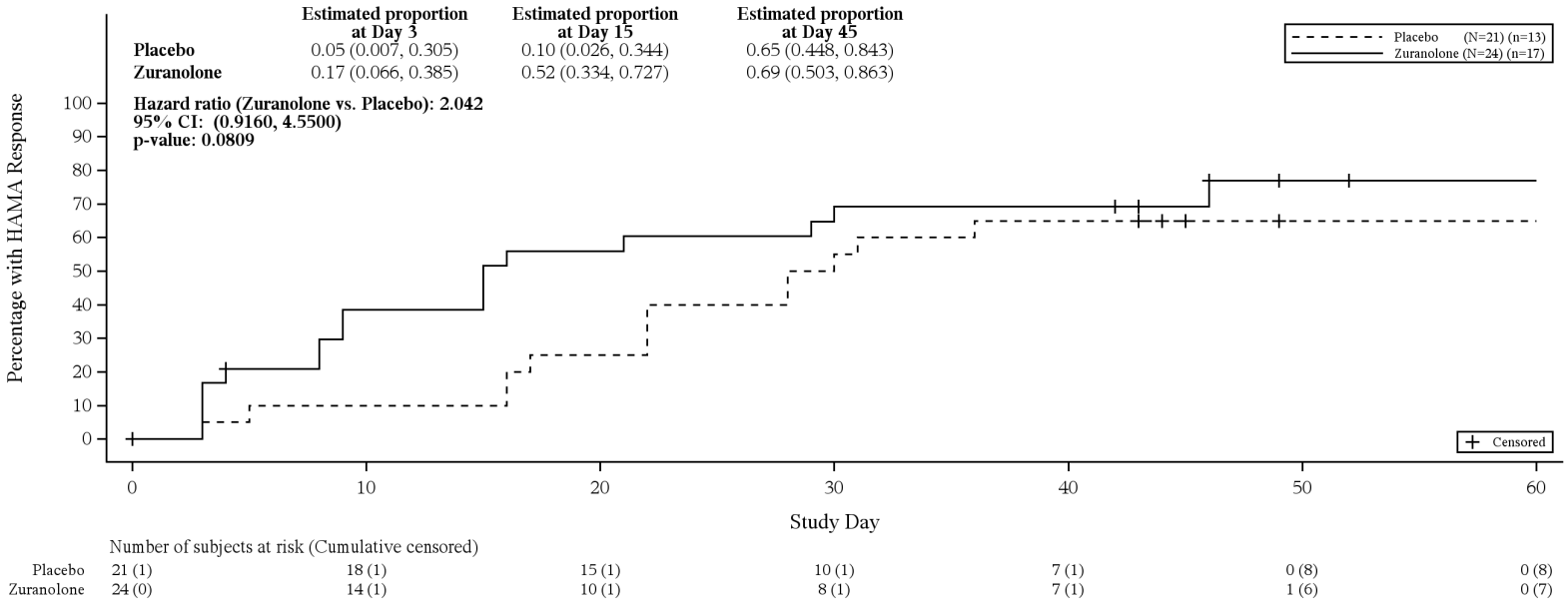
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAM-A total score, and treatment. Model covariate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

Source: biib125/v_a/amnog_kmplots/f-hama-resp15-tte-301-by.sas:f-hama-resp15-tte-301-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-301 - 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 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.

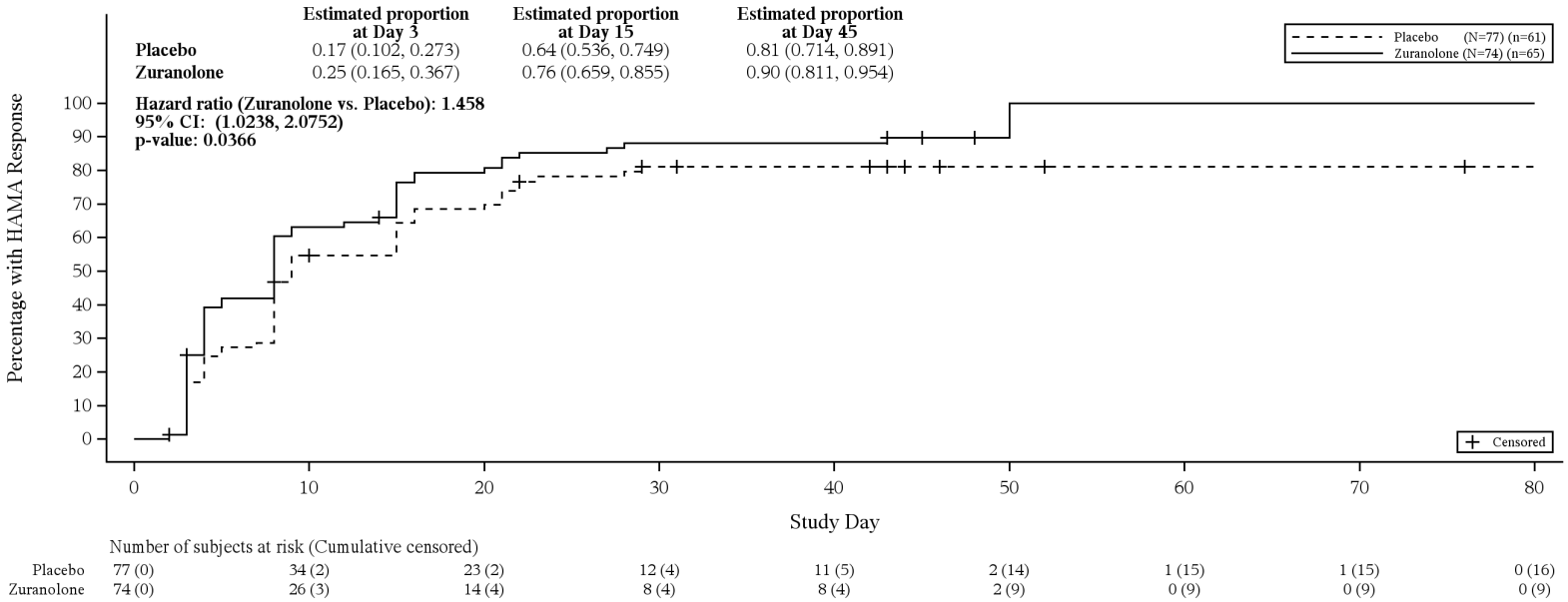
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline HAM-A total score, and treatment. Model covariate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

Source: biib125/v_a/amnog_kmplots/f-hama-resp15-tte-301-by.sas:f-hama-resp15-tte-301-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-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20



Number of subjects at risk (Cumulative censored)

Placebo	77 (0)	34 (2)	23 (2)	12 (4)	11 (5)	2 (14)	1 (15)	1 (15)	0 (16)
Zuranolone	74 (0)	26 (3)	14 (4)	8 (4)	8 (4)	2 (9)	0 (9)	0 (9)	0 (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.

Source: biib125/v_a/amnog_kmplots/f-hama-resp15-tte-301-by.sas:f-hama-resp15-tte-301-by-itta.rtf **Run Date:** 08JAN2026

2.6 CGI-S

2.6.1 MMRM

Model-based Results on Change from Baseline in Clinical Global Impression - Severity (CGI-S): 217-PPD-301 - ITT population

Page: 1 of 3

	Placebo (N=101)	Zuranolone (N=99)
Day 3		
n	96	98
LS Mean (SE)	-0.71 (0.103)	-0.96 (0.103)
95% CI for the LS Mean	-0.92, -0.51	-1.16, -0.76
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.25 (0.146)
95% CI for the LS Mean		-0.53, 0.04
p-value		0.0925
Hedges' g (Zuranolone vs. Placebo)		-0.242
95% CI for Hedges' g		-0.5244, 0.0406
Day 8		
n	95	93
LS Mean (SE)	-1.12 (0.117)	-1.73 (0.118)
95% CI for the LS Mean	-1.35, -0.89	-1.96, -1.49
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.60 (0.166)
95% CI for the LS Mean		-0.93, -0.28
p-value		0.0004
Hedges' g (Zuranolone vs. Placebo)		-0.528
95% CI for Hedges' g		-0.8188, -0.2371

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-301-ovr.sas:t-cgis-mmrm-301-ovr-itta.rtf **Run Date:** 18JUL2025

Model-based Results on Change from Baseline in Clinical Global Impression - Severity (CGI-S): 217-PPD-301 - ITT population

Page: 2 of 3

	Placebo (N=101)	Zuranolone (N=99)
Day 15		
n	90	93
LS Mean (SE)	-1.61 (0.139)	-2.17 (0.138)
95% CI for the LS Mean	-1.89, -1.34	-2.44, -1.90
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.55 (0.196)
95% CI for the LS Mean		-0.94, -0.17
p-value		0.0052
Hedges' g (Zuranolone vs. Placebo)		-0.416
95% CI for Hedges' g		-0.7092, -0.1233
Day 21		
n	83	84
LS Mean (SE)	-1.87 (0.142)	-2.34 (0.141)
95% CI for the LS Mean	-2.15, -1.59	-2.61, -2.06
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.46 (0.200)
95% CI for the LS Mean		-0.86, -0.07
p-value		0.0218
Hedges' g (Zuranolone vs. Placebo)		-0.356
95% CI for Hedges' g		-0.6622, -0.0507

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-301-ovr.sas:t-cgis-mmrm-301-ovr-itta.rtf **Run Date:** 18JUL2025

Model-based Results on Change from Baseline in Clinical Global Impression - Severity (CGI-S): 217-PPD-301 - ITT population

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	Placebo (N=101)	Zuranolone (N=99)
Day 28		
n	85	77
LS Mean (SE)	-1.89 (0.142)	-2.30 (0.144)
95% CI for the LS Mean	-2.17, -1.61	-2.58, -2.01
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.41 (0.202)
95% CI for the LS Mean		-0.81, -0.01
p-value		0.0437
Hedges' g (Zuranolone vs. Placebo)		-0.318
95% CI for Hedges' g		-0.6284, -0.0078
Day 45		
n	85	84
LS Mean (SE)	-2.07 (0.142)	-2.58 (0.143)
95% CI for the LS Mean	-2.35, -1.79	-2.86, -2.30
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.51 (0.202)
95% CI for the LS Mean		-0.91, -0.12
p-value		0.0116
Hedges' g (Zuranolone vs. Placebo)		-0.390
95% CI for Hedges' g		-0.6948, -0.0860

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-301-ovr.sas:t-cgis-mmrm-301-ovr-itta.rtf **Run Date:** 18JUL2025

2.6.2 Ansprechen

2.6.2.1 Responder-Analysen

2.6.2.1 .1 ITT-Population

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline): 217-PPD-301 - ITT population

Page: 1 of 6

Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Number of evaluable subjects [1]	98	98
Day 3		
Number of subjects with a response, n (%) [2]	16 (16.3)	26 (26.5)
Number of subjects with missing evaluation, n (%)	2 (2.0)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.626
95% CI for the RR		(0.947, 2.791)
p-value for RR		0.0780
OR - Odds Ratio (Zuranolone vs. Placebo)		1.799
95% CI for the OR		(0.892, 3.627)
p-value for OR		0.1007
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. 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-resp15-301-ovr.sas:t-cgis-resp15-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline): 217-PPD-301 - ITT population

Page: 2 of 6

Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 8		
Number of subjects with a response, n (%) [2]	29 (29.6)	49 (50.0)
Number of subjects with missing evaluation, n (%)	3 (3.1)	5 (5.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.687
95% CI for the RR		(1.188, 2.395)
p-value for RR		0.0035
OR - Odds Ratio (Zuranolone vs. Placebo)		2.411
95% CI for the OR		(1.332, 4.362)
p-value for OR		0.0036
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. 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-resp15-301-ovr.sas:t-cgis-resp15-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline): 217-PPD-301 - ITT population

Page: 3 of 6

Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 15		
Number of subjects with a response, n (%) [2]	44 (44.9)	59 (60.2)
Number of subjects with missing evaluation, n (%)	8 (8.2)	5 (5.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.342
95% CI for the RR		(1.035, 1.742)
p-value for RR		0.0267
OR - Odds Ratio (Zuranolone vs. Placebo)		1.885
95% CI for the OR		(1.051, 3.381)
p-value for OR		0.0335
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. 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-resp15-301-ovr.sas:t-cgis-resp15-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline): 217-PPD-301 - ITT population

Page: 4 of 6

Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 21		
Number of subjects with a response, n (%) [2]	45 (45.9)	61 (62.2)
Number of subjects with missing evaluation, n (%)	15 (15.3)	14 (14.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.333
95% CI for the RR		(1.034, 1.719)
p-value for RR		0.0264
OR - Odds Ratio (Zuranolone vs. Placebo)		1.981
95% CI for the OR		(1.096, 3.583)
p-value for OR		0.0237
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. 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-resp15-301-ovr.sas:t-cgis-resp15-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline): 217-PPD-301 - ITT population

Page: 5 of 6

Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 28		
Number of subjects with a response, n (%) [2]	50 (51.0)	51 (52.0)
Number of subjects with missing evaluation, n (%)	13 (13.3)	21 (21.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.016
95% CI for the RR		(0.787, 1.312)
p-value for RR		0.9015
OR - Odds Ratio (Zuranolone vs. Placebo)		1.028
95% CI for the OR		(0.577, 1.833)
p-value for OR		0.9255
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. 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-resp15-301-ovr.sas:t-cgis-resp15-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline): 217-PPD-301 - ITT population

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Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 45		
Number of subjects with a response, n (%) [2]	54 (55.1)	62 (63.3)
Number of subjects with missing evaluation, n (%)	13 (13.3)	14 (14.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.123
95% CI for the RR		(0.893, 1.413)
p-value for RR		0.3220
OR - Odds Ratio (Zuranolone vs. Placebo)		1.416
95% CI for the OR		(0.777, 2.582)
p-value for OR		0.2557
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. 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-resp15-301-ovr.sas:t-cgis-resp15-301-ovr-itta.rtf **Run Date:** 18JUL2025

2.6.2.1 .2 Subgruppen

2.6.2.1 .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-301 - ITT population

Page: 1 of 5

Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	98	98	
Number of subjects with response at Day 15, n (%)	44 (44.9)	59 (60.2)	
Number of subjects with response at Day 45, n (%)	54 (55.1)	62 (63.3)	
Age Group (years)			0.4157
Day 15			
18 - 24, n / N (%)	5/12 (41.7)	16/19 (84.2)	
25 - 45, n / N (%)	39/86 (45.3)	43/79 (54.4)	
Day 45			
18 - 24, n / N (%)	7/12 (58.3)	15/19 (78.9)	
25 - 45, n / N (%)	47/86 (54.7)	47/79 (59.5)	

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-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-resp15-301-int.sas:t-cgis-resp15-301-int-itta.rtf **Run Date:** 18JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

Page: 2 of 5

Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			0.5007
Day 15			
<28, n / N (%)	15/32 (46.9)	17/33 (51.5)	
>=28, n / N (%)	29/66 (43.9)	42/65 (64.6)	
Day 45			
<28, n / N (%)	14/32 (43.8)	22/33 (66.7)	
>=28, n / N (%)	40/66 (60.6)	40/65 (61.5)	
Race Group (Black or African American, White)			0.1096
Day 15			
Black or African American, n / N (%)	6/18 (33.3)	14/25 (56.0)	
White, n / N (%)	35/69 (50.7)	44/68 (64.7)	
Day 45			
Black or African American, n / N (%)	5/18 (27.8)	16/25 (64.0)	
White, n / N (%)	44/69 (63.8)	43/68 (63.2)	

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 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-resp15-301-int.sas:t-cgis-resp15-301-int-itta.rtf **Run Date:** 18JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			0.2698
Day 15			
Yes, n / N (%)	9/15 (60.0)	8/15 (53.3)	
No, n / N (%)	35/83 (42.2)	51/83 (61.4)	
Day 45			
Yes, n / N (%)	9/15 (60.0)	9/15 (60.0)	
No, n / N (%)	45/83 (54.2)	53/83 (63.9)	
BMI (kg/m^2) Group			0.0356(a) 0.1126(b) 0.5349(c)
Day 15			
<=24.9, n / N (%)	11/22 (50.0)	10/20 (50.0)	
25-29.9, n / N (%)	15/34 (44.1)	15/24 (62.5)	
>=30, n / N (%)	18/42 (42.9)	34/53 (64.2)	
Day 45			
<=24.9, n / N (%)	15/22 (68.2)	11/20 (55.0)	
25-29.9, n / N (%)	22/34 (64.7)	17/24 (70.8)	
>=30, n / N (%)	17/42 (40.5)	33/53 (62.3)	

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 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-resp15-301-int.sas:t-cgis-resp15-301-int-itta.rtf **Run Date:** 18JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Onset of PPD			0.6723
Day 15			
3rd Trimester, n / N (%)	15/31 (48.4)	19/34 (55.9)	
Postpartum, n / N (%)	29/67 (43.3)	40/64 (62.5)	
Day 45			
3rd Trimester, n / N (%)	16/31 (51.6)	23/34 (67.6)	
Postpartum, n / N (%)	38/67 (56.7)	39/64 (60.9)	
Family History of PPD			0.8129
Day 15			
Yes, n / N (%)	8/16 (50.0)	12/21 (57.1)	
No/Unknown, n / N (%)	36/82 (43.9)	47/77 (61.0)	
Day 45			
Yes, n / N (%)	10/16 (62.5)	13/21 (61.9)	
No/Unknown, n / N (%)	44/82 (53.7)	49/77 (63.6)	

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-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-resp15-301-int.sas:t-cgis-resp15-301-int-itta.rtf **Run Date:** 18JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline): Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
History of PPD			0.8267
Day 15			
1st Episode, n / N (%)	39/87 (44.8)	47/81 (58.0)	
Recurrent Episode, n / N (%)	5/11 (45.5)	12/17 (70.6)	
Day 45			
1st Episode, n / N (%)	49/87 (56.3)	50/81 (61.7)	
Recurrent Episode, n / N (%)	5/11 (45.5)	12/17 (70.6)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			0.6731
Day 15			
<20, n / N (%)	12/21 (57.1)	13/24 (54.2)	
>=20, n / N (%)	32/77 (41.6)	46/74 (62.2)	
Day 45			
<20, n / N (%)	14/21 (66.7)	16/24 (66.7)	
>=20, n / N (%)	40/77 (51.9)	46/74 (62.2)	

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 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-resp15-301-int.sas:t-cgis-resp15-301-int-itta.rtf **Run Date:** 18JUL2025

2.6.2.1 .2 .2 Subgruppenanalysen

2.6.2.1 .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-301 - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =19)
Number of evaluable subjects [1]	12	19
Day 3		
Number of subjects with a response, n (%) [2]	4 (33.3)	8 (42.1)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.269
95% CI for the RR		(0.501, 3.214)
p-value for RR		0.6155
Day 8		
Number of subjects with a response, n (%) [2]	5 (41.7)	15 (78.9)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.903
95% CI for the RR		(0.977, 3.708)
p-value for RR		0.0585

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-resp15-301-by.sas:t-cgis-resp15-301-by-age-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =19)
Day 15		
Number of subjects with a response, n (%) [2]	5 (41.7)	16 (84.2)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.030
95% CI for the RR		(1.053, 3.914)
p-value for RR		0.0345
Day 21		
Number of subjects with a response, n (%) [2]	6 (50.0)	16 (84.2)
Number of subjects with missing evaluation, n (%)	2 (16.7)	1 (5.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.692
95% CI for the RR		(0.916, 3.126)
p-value for RR		0.0932

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-resp15-301-by.sas:t-cgis-resp15-301-by-age-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =19)
Day 28		
Number of subjects with a response, n (%) [2]	9 (75.0)	14 (73.7)
Number of subjects with missing evaluation, n (%)	0	2 (10.5)
RR - Relative Risk (Zuranolone vs. Placebo)		0.987
95% CI for the RR		(0.651, 1.497)
p-value for RR		0.9506
Day 45		
Number of subjects with a response, n (%) [2]	7 (58.3)	15 (78.9)
Number of subjects with missing evaluation, n (%)	1 (8.3)	1 (5.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.360
95% CI for the RR		(0.804, 2.299)
p-value for RR		0.2520

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-resp15-301-by.sas:t-cgis-resp15-301-by-age-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=88)	Zuranolone (N =80)
Number of evaluable subjects [1]	86	79
Day 3		
Number of subjects with a response, n (%) [2]	12 (14.0)	18 (22.8)
Number of subjects with missing evaluation, n (%)	2 (2.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.612
95% CI for the RR		(0.838, 3.101)
p-value for RR		0.1524
Day 8		
Number of subjects with a response, n (%) [2]	24 (27.9)	34 (43.0)
Number of subjects with missing evaluation, n (%)	3 (3.5)	5 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.523
95% CI for the RR		(1.005, 2.308)
p-value for RR		0.0476

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-resp15-301-by.sas:t-cgis-resp15-301-by-age-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=88)	Zuranolone (N =80)
Day 15		
Number of subjects with a response, n (%) [2]	39 (45.3)	43 (54.4)
Number of subjects with missing evaluation, n (%)	8 (9.3)	5 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.185
95% CI for the RR		(0.875, 1.605)
p-value for RR		0.2733
Day 21		
Number of subjects with a response, n (%) [2]	39 (45.3)	45 (57.0)
Number of subjects with missing evaluation, n (%)	13 (15.1)	13 (16.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.240
95% CI for the RR		(0.923, 1.666)
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 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-resp15-301-by.sas:t-cgis-resp15-301-by-age-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=88)	Zuranolone (N =80)
Day 28		
Number of subjects with a response, n (%) [2]	41 (47.7)	37 (46.8)
Number of subjects with missing evaluation, n (%)	13 (15.1)	19 (24.1)
RR - Relative Risk (Zuranolone vs. Placebo)		0.970
95% CI for the RR		(0.707, 1.330)
p-value for RR		0.8497
Day 45		
Number of subjects with a response, n (%) [2]	47 (54.7)	47 (59.5)
Number of subjects with missing evaluation, n (%)	12 (14.0)	13 (16.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.075
95% CI for the RR		(0.825, 1.399)
p-value for RR		0.5926

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-resp15-301-by.sas:t-cgis-resp15-301-by-age-itta.rtf **Run Date:** 25JUL2025

2.6.2.1 .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-301 - 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=32)	Zuranolone (N =33)
Number of evaluable subjects [1]	32	33
Day 3		
Number of subjects with a response, n (%) [2]	4 (12.5)	8 (24.2)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.022
95% CI for the RR		(0.695, 5.878)
p-value for RR		0.1962
Day 8		
Number of subjects with a response, n (%) [2]	9 (28.1)	12 (36.4)
Number of subjects with missing evaluation, n (%)	0	1 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.348
95% CI for the RR		(0.688, 2.640)
p-value for RR		0.3844

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-resp15-301-by.sas:t-cgis-resp15-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

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-301 - 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=32)	Zuranolone (N =33)
Day 15		
Number of subjects with a response, n (%) [2]	15 (46.9)	17 (51.5)
Number of subjects with missing evaluation, n (%)	2 (6.3)	1 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.146
95% CI for the RR		(0.706, 1.860)
p-value for RR		0.5824
Day 21		
Number of subjects with a response, n (%) [2]	13 (40.6)	21 (63.6)
Number of subjects with missing evaluation, n (%)	5 (15.6)	2 (6.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.633
95% CI for the RR		(1.012, 2.635)
p-value for RR		0.0446

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-resp15-301-by.sas:t-cgis-resp15-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

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-301 - 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=32)	Zuranolone (N =33)
Day 28		
Number of subjects with a response, n (%) [2]	12 (37.5)	17 (51.5)
Number of subjects with missing evaluation, n (%)	6 (18.8)	5 (15.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.432
95% CI for the RR		(0.829, 2.474)
p-value for RR		0.1979
Day 45		
Number of subjects with a response, n (%) [2]	14 (43.8)	22 (66.7)
Number of subjects with missing evaluation, n (%)	5 (15.6)	3 (9.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.588
95% CI for the RR		(1.006, 2.508)
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 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-resp15-301-by.sas:t-cgis-resp15-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

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-301 - 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=66)	Zuranolone (N =65)
Number of evaluable subjects [1]	66	65
Day 3		
Number of subjects with a response, n (%) [2]	12 (18.2)	18 (27.7)
Number of subjects with missing evaluation, n (%)	2 (3.0)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.476
95% CI for the RR		(0.783, 2.782)
p-value for RR		0.2292
Day 8		
Number of subjects with a response, n (%) [2]	20 (30.3)	37 (56.9)
Number of subjects with missing evaluation, n (%)	3 (4.5)	4 (6.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.820
95% CI for the RR		(1.200, 2.760)
p-value for RR		0.0048

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-resp15-301-by.sas:t-cgis-resp15-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

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-301 - 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=66)	Zuranolone (N =65)
Day 15		
Number of subjects with a response, n (%) [2]	29 (43.9)	42 (64.6)
Number of subjects with missing evaluation, n (%)	6 (9.1)	4 (6.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.425
95% CI for the RR		(1.033, 1.965)
p-value for RR		0.0311
Day 21		
Number of subjects with a response, n (%) [2]	32 (48.5)	40 (61.5)
Number of subjects with missing evaluation, n (%)	10 (15.2)	12 (18.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.230
95% CI for the RR		(0.901, 1.678)
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 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-resp15-301-by.sas:t-cgis-resp15-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

Study Visit Statistics	Placebo (N=66)	Zuranolone (N =65)
Day 28		
Number of subjects with a response, n (%) [2]	38 (57.6)	34 (52.3)
Number of subjects with missing evaluation, n (%)	7 (10.6)	16 (24.6)
RR - Relative Risk (Zuranolone vs. Placebo)		0.880
95% CI for the RR		(0.650, 1.193)
p-value for RR		0.4103
Day 45		
Number of subjects with a response, n (%) [2]	40 (60.6)	40 (61.5)
Number of subjects with missing evaluation, n (%)	8 (12.1)	11 (16.9)
RR - Relative Risk (Zuranolone vs. Placebo)		0.984
95% CI for the RR		(0.749, 1.291)
p-value for RR		0.9060

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-resp15-301-by.sas:t-cgis-resp15-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

2.6.2.1 .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-301 - ITT population

Page: 1 of 6

Race Group = Black or African American

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =26)
Number of evaluable subjects [1]	18	25
Day 3		
Number of subjects with a response, n (%) [2]	1 (5.6)	7 (28.0)
Number of subjects with missing evaluation, n (%)	1 (5.6)	0
RR - Relative Risk (Zuranolone vs. Placebo)		4.838
95% CI for the RR		(0.627, 37.366)
p-value for RR		0.1306
Day 8		
Number of subjects with a response, n (%) [2]	4 (22.2)	10 (40.0)
Number of subjects with missing evaluation, n (%)	2 (11.1)	2 (8.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.728
95% CI for the RR		(0.635, 4.705)
p-value for RR		0.2845

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-resp15-301-by.sas:t-cgis-resp15-301-by-race-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-301 - ITT population

Page: 2 of 6

Race Group = Black or African American

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =26)
Day 15		
Number of subjects with a response, n (%) [2]	6 (33.3)	14 (56.0)
Number of subjects with missing evaluation, n (%)	4 (22.2)	3 (12.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.613
95% CI for the RR		(0.797, 3.264)
p-value for RR		0.1839
Day 21		
Number of subjects with a response, n (%) [2]	4 (22.2)	13 (52.0)
Number of subjects with missing evaluation, n (%)	7 (38.9)	7 (28.0)
RR - Relative Risk (Zuranolone vs. Placebo)		2.246
95% CI for the RR		(0.868, 5.811)
p-value for RR		0.0951

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-resp15-301-by.sas:t-cgis-resp15-301-by-race-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-301 - ITT population

Page: 3 of 6

Race Group = Black or African American

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =26)
Day 28		
Number of subjects with a response, n (%) [2]	4 (22.2)	14 (56.0)
Number of subjects with missing evaluation, n (%)	7 (38.9)	6 (24.0)
RR - Relative Risk (Zuranolone vs. Placebo)		2.419
95% CI for the RR		(0.902, 6.489)
p-value for RR		0.0793
Day 45		
Number of subjects with a response, n (%) [2]	5 (27.8)	16 (64.0)
Number of subjects with missing evaluation, n (%)	5 (27.8)	3 (12.0)
RR - Relative Risk (Zuranolone vs. Placebo)		2.212
95% CI for the RR		(0.926, 5.286)
p-value for RR		0.0741

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-resp15-301-by.sas:t-cgis-resp15-301-by-race-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-301 - ITT population

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Race Group = White

Study Visit Statistics	Placebo (N=70)	Zuranolone (N =68)
Number of evaluable subjects [1]	69	68
Day 3		
Number of subjects with a response, n (%) [2]	12 (17.4)	18 (26.5)
Number of subjects with missing evaluation, n (%)	1 (1.4)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.539
95% CI for the RR		(0.811, 2.917)
p-value for RR		0.1869
Day 8		
Number of subjects with a response, n (%) [2]	23 (33.3)	38 (55.9)
Number of subjects with missing evaluation, n (%)	0	3 (4.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.695
95% CI for the RR		(1.157, 2.483)
p-value for RR		0.0068

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-resp15-301-by.sas:t-cgis-resp15-301-by-race-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-301 - ITT population

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Race Group = White

Study Visit Statistics	Placebo (N=70)	Zuranolone (N =68)
Day 15		
Number of subjects with a response, n (%) [2]	35 (50.7)	44 (64.7)
Number of subjects with missing evaluation, n (%)	3 (4.3)	2 (2.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.289
95% CI for the RR		(0.970, 1.715)
p-value for RR		0.0804
Day 21		
Number of subjects with a response, n (%) [2]	38 (55.1)	45 (66.2)
Number of subjects with missing evaluation, n (%)	7 (10.1)	7 (10.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.215
95% CI for the RR		(0.930, 1.586)
p-value for RR		0.1532

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-resp15-301-by.sas:t-cgis-resp15-301-by-race-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Race Group: 217-PPD-301 - ITT population

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Race Group = White

Study Visit Statistics	Placebo (N=70)	Zuranolone (N =68)
Day 28		
Number of subjects with a response, n (%) [2]	41 (59.4)	34 (50.0)
Number of subjects with missing evaluation, n (%)	5 (7.2)	15 (22.1)
RR - Relative Risk (Zuranolone vs. Placebo)		0.851
95% CI for the RR		(0.630, 1.149)
p-value for RR		0.2918
Day 45		
Number of subjects with a response, n (%) [2]	44 (63.8)	43 (63.2)
Number of subjects with missing evaluation, n (%)	7 (10.1)	10 (14.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.002
95% CI for the RR		(0.780, 1.288)
p-value for RR		0.9853

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-resp15-301-by.sas:t-cgis-resp15-301-by-race-itta.rtf **Run Date:** 25JUL2025

2.6.2.1 .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-301 - ITT population

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Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=15)	Zuranolone (N =15)
Number of evaluable subjects [1]	15	15
Day 3		
Number of subjects with a response, n (%) [2]	2 (13.3)	2 (13.3)
Number of subjects with missing evaluation, n (%)	1 (6.7)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.733
95% CI for the RR		(0.129, 4.166)
p-value for RR		0.7260
Day 8		
Number of subjects with a response, n (%) [2]	5 (33.3)	6 (40.0)
Number of subjects with missing evaluation, n (%)	0	1 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.879
95% CI for the RR		(0.348, 2.222)
p-value for RR		0.7860

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-resp15-301-by.sas:t-cgis-resp15-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-301 - ITT population

Page: 2 of 6

Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=15)	Zuranolone (N =15)
Day 15		
Number of subjects with a response, n (%) [2]	9 (60.0)	8 (53.3)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.651
95% CI for the RR		(0.289, 1.470)
p-value for RR		0.3019
Day 21		
Number of subjects with a response, n (%) [2]	9 (60.0)	9 (60.0)
Number of subjects with missing evaluation, n (%)	1 (6.7)	1 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.733
95% CI for the RR		(0.331, 1.624)
p-value for RR		0.4441

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-resp15-301-by.sas:t-cgis-resp15-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-301 - ITT population

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Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=15)	Zuranolone (N =15)
Day 28		
Number of subjects with a response, n (%) [2]	7 (46.7)	9 (60.0)
Number of subjects with missing evaluation, n (%)	2 (13.3)	1 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.942
95% CI for the RR		(0.399, 2.225)
p-value for RR		0.8922
Day 45		
Number of subjects with a response, n (%) [2]	9 (60.0)	9 (60.0)
Number of subjects with missing evaluation, n (%)	1 (6.7)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.733
95% CI for the RR		(0.374, 1.435)
p-value for RR		0.3646

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-resp15-301-by.sas:t-cgis-resp15-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-301 - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=86)	Zuranolone (N =84)
Number of evaluable subjects [1]	83	83
Day 3		
Number of subjects with a response, n (%) [2]	14 (16.9)	24 (28.9)
Number of subjects with missing evaluation, n (%)	1 (1.2)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.707
95% CI for the RR		(0.962, 3.027)
p-value for RR		0.0676
Day 8		
Number of subjects with a response, n (%) [2]	24 (28.9)	43 (51.8)
Number of subjects with missing evaluation, n (%)	3 (3.6)	4 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.784
95% CI for the RR		(1.211, 2.628)
p-value for RR		0.0034

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-resp15-301-by.sas:t-cgis-resp15-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-301 - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=86)	Zuranolone (N =84)
Day 15		
Number of subjects with a response, n (%) [2]	35 (42.2)	51 (61.4)
Number of subjects with missing evaluation, n (%)	8 (9.6)	5 (6.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.451
95% CI for the RR		(1.077, 1.954)
p-value for RR		0.0144
Day 21		
Number of subjects with a response, n (%) [2]	36 (43.4)	52 (62.7)
Number of subjects with missing evaluation, n (%)	14 (16.9)	13 (15.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.438
95% CI for the RR		(1.073, 1.927)
p-value for RR		0.0149

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-resp15-301-by.sas:t-cgis-resp15-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Baseline Antidepressant Use: 217-PPD-301 - ITT population

Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=86)	Zuranolone (N =84)
Day 28		
Number of subjects with a response, n (%) [2]	43 (51.8)	42 (50.6)
Number of subjects with missing evaluation, n (%)	11 (13.3)	20 (24.1)
RR - Relative Risk (Zuranolone vs. Placebo)		0.972
95% CI for the RR		(0.728, 1.299)
p-value for RR		0.8500
Day 45		
Number of subjects with a response, n (%) [2]	45 (54.2)	53 (63.9)
Number of subjects with missing evaluation, n (%)	12 (14.5)	14 (16.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.173
95% CI for the RR		(0.908, 1.514)
p-value for RR		0.2218

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-resp15-301-by.sas:t-cgis-resp15-301-by-adt-itta.rtf **Run Date:** 25JUL2025

2.6.2.1 .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-301 - ITT population

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

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =20)
Number of evaluable subjects [1]	22	20
Day 3		
Number of subjects with a response, n (%) [2]	5 (22.7)	5 (25.0)
Number of subjects with missing evaluation, n (%)	1 (4.5)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.997
95% CI for the RR		(0.280, 3.553)
p-value for RR		0.9960
Day 8		
Number of subjects with a response, n (%) [2]	8 (36.4)	6 (30.0)
Number of subjects with missing evaluation, n (%)	0	2 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.748
95% CI for the RR		(0.277, 2.016)
p-value for RR		0.5654

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-resp15-301-by.sas:t-cgis-resp15-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =20)
Day 15		
Number of subjects with a response, n (%) [2]	11 (50.0)	10 (50.0)
Number of subjects with missing evaluation, n (%)	1 (4.5)	2 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.906
95% CI for the RR		(0.431, 1.906)
p-value for RR		0.7950
Day 21		
Number of subjects with a response, n (%) [2]	10 (45.5)	13 (65.0)
Number of subjects with missing evaluation, n (%)	4 (18.2)	4 (20.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.296
95% CI for the RR		(0.661, 2.539)
p-value for RR		0.4502

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-resp15-301-by.sas:t-cgis-resp15-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =20)
Day 28		
Number of subjects with a response, n (%) [2]	14 (63.6)	9 (45.0)
Number of subjects with missing evaluation, n (%)	1 (4.5)	8 (40.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.641
95% CI for the RR		(0.307, 1.339)
p-value for RR		0.2368
Day 45		
Number of subjects with a response, n (%) [2]	15 (68.2)	11 (55.0)
Number of subjects with missing evaluation, n (%)	0	5 (25.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.731
95% CI for the RR		(0.380, 1.404)
p-value for RR		0.3468

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-resp15-301-by.sas:t-cgis-resp15-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =24)
Number of evaluable subjects [1]	34	24
Day 3		
Number of subjects with a response, n (%) [2]	4 (11.8)	8 (33.3)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.931
95% CI for the RR		(1.017, 8.446)
p-value for RR		0.0465
Day 8		
Number of subjects with a response, n (%) [2]	9 (26.5)	15 (62.5)
Number of subjects with missing evaluation, n (%)	2 (5.9)	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		2.442
95% CI for the RR		(1.322, 4.513)
p-value for RR		0.0044

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-resp15-301-by.sas:t-cgis-resp15-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =24)
Day 15		
Number of subjects with a response, n (%) [2]	15 (44.1)	15 (62.5)
Number of subjects with missing evaluation, n (%)	4 (11.8)	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.465
95% CI for the RR		(0.911, 2.356)
p-value for RR		0.1148
Day 21		
Number of subjects with a response, n (%) [2]	19 (55.9)	18 (75.0)
Number of subjects with missing evaluation, n (%)	6 (17.6)	3 (12.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.388
95% CI for the RR		(0.951, 2.027)
p-value for RR		0.0895

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-resp15-301-by.sas:t-cgis-resp15-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =24)
Day 28		
Number of subjects with a response, n (%) [2]	20 (58.8)	17 (70.8)
Number of subjects with missing evaluation, n (%)	5 (14.7)	4 (16.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.246
95% CI for the RR		(0.852, 1.820)
p-value for RR		0.2570
Day 45		
Number of subjects with a response, n (%) [2]	22 (64.7)	17 (70.8)
Number of subjects with missing evaluation, n (%)	6 (17.6)	4 (16.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.132
95% CI for the RR		(0.787, 1.628)
p-value for RR		0.5026

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-resp15-301-by.sas:t-cgis-resp15-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

Study Visit Statistics	Placebo (N=42)	Zuranolone (N =53)
Number of evaluable subjects [1]	42	53
Day 3		
Number of subjects with a response, n (%) [2]	7 (16.7)	13 (24.5)
Number of subjects with missing evaluation, n (%)	1 (2.4)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.372
95% CI for the RR		(0.612, 3.074)
p-value for RR		0.4428
Day 8		
Number of subjects with a response, n (%) [2]	12 (28.6)	28 (52.8)
Number of subjects with missing evaluation, n (%)	1 (2.4)	2 (3.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.723
95% CI for the RR		(1.016, 2.923)
p-value for RR		0.0435

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-resp15-301-by.sas:t-cgis-resp15-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

Study Visit Statistics	Placebo (N=42)	Zuranolone (N =53)
Day 15		
Number of subjects with a response, n (%) [2]	18 (42.9)	34 (64.2)
Number of subjects with missing evaluation, n (%)	3 (7.1)	2 (3.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.395
95% CI for the RR		(0.942, 2.065)
p-value for RR		0.0961
Day 21		
Number of subjects with a response, n (%) [2]	16 (38.1)	29 (54.7)
Number of subjects with missing evaluation, n (%)	5 (11.9)	7 (13.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.339
95% CI for the RR		(0.865, 2.072)
p-value for RR		0.1905

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-resp15-301-by.sas:t-cgis-resp15-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

Study Visit Statistics	Placebo (N=42)	Zuranolone (N =53)
Day 28		
Number of subjects with a response, n (%) [2]	16 (38.1)	25 (47.2)
Number of subjects with missing evaluation, n (%)	7 (16.7)	9 (17.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.154
95% CI for the RR		(0.729, 1.826)
p-value for RR		0.5407
Day 45		
Number of subjects with a response, n (%) [2]	17 (40.5)	33 (62.3)
Number of subjects with missing evaluation, n (%)	7 (16.7)	5 (9.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.434
95% CI for the RR		(0.951, 2.161)
p-value for RR		0.0853

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-resp15-301-by.sas:t-cgis-resp15-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

2.6.2.1 .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-301 - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =35)
Number of evaluable subjects [1]	31	34
Day 3		
Number of subjects with a response, n (%) [2]	7 (22.6)	12 (35.3)
Number of subjects with missing evaluation, n (%)	1 (3.2)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.613
95% CI for the RR		(0.727, 3.580)
p-value for RR		0.2395
Day 8		
Number of subjects with a response, n (%) [2]	9 (29.0)	17 (50.0)
Number of subjects with missing evaluation, n (%)	3 (9.7)	2 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.778
95% CI for the RR		(0.936, 3.376)
p-value for RR		0.0788

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-resp15-301-by.sas:t-cgis-resp15-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =35)
Day 15		
Number of subjects with a response, n (%) [2]	15 (48.4)	19 (55.9)
Number of subjects with missing evaluation, n (%)	4 (12.9)	3 (8.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.192
95% CI for the RR		(0.748, 1.899)
p-value for RR		0.4596
Day 21		
Number of subjects with a response, n (%) [2]	14 (45.2)	22 (64.7)
Number of subjects with missing evaluation, n (%)	6 (19.4)	5 (14.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.479
95% CI for the RR		(0.936, 2.337)
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 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-resp15-301-by.sas:t-cgis-resp15-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =35)
Day 28		
Number of subjects with a response, n (%) [2]	14 (45.2)	17 (50.0)
Number of subjects with missing evaluation, n (%)	6 (19.4)	8 (23.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.143
95% CI for the RR		(0.699, 1.869)
p-value for RR		0.5949
Day 45		
Number of subjects with a response, n (%) [2]	16 (51.6)	23 (67.6)
Number of subjects with missing evaluation, n (%)	6 (19.4)	7 (20.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.353
95% CI for the RR		(0.897, 2.041)
p-value for RR		0.1497

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-resp15-301-by.sas:t-cgis-resp15-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=69)	Zuranolone (N =64)
Number of evaluable subjects [1]	67	64
Day 3		
Number of subjects with a response, n (%) [2]	9 (13.4)	14 (21.9)
Number of subjects with missing evaluation, n (%)	1 (1.5)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.552
95% CI for the RR		(0.738, 3.260)
p-value for RR		0.2463
Day 8		
Number of subjects with a response, n (%) [2]	20 (29.9)	32 (50.0)
Number of subjects with missing evaluation, n (%)	0	3 (4.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.596
95% CI for the RR		(1.045, 2.437)
p-value for RR		0.0305

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-resp15-301-by.sas:t-cgis-resp15-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=69)	Zuranolone (N =64)
Day 15		
Number of subjects with a response, n (%) [2]	29 (43.3)	40 (62.5)
Number of subjects with missing evaluation, n (%)	4 (6.0)	2 (3.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.376
95% CI for the RR		(0.991, 1.909)
p-value for RR		0.0564
Day 21		
Number of subjects with a response, n (%) [2]	31 (46.3)	39 (60.9)
Number of subjects with missing evaluation, n (%)	9 (13.4)	9 (14.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.255
95% CI for the RR		(0.909, 1.733)
p-value for RR		0.1681

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-resp15-301-by.sas:t-cgis-resp15-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=69)	Zuranolone (N =64)
Day 28		
Number of subjects with a response, n (%) [2]	36 (53.7)	34 (53.1)
Number of subjects with missing evaluation, n (%)	7 (10.4)	13 (20.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.942
95% CI for the RR		(0.686, 1.294)
p-value for RR		0.7121
Day 45		
Number of subjects with a response, n (%) [2]	38 (56.7)	39 (60.9)
Number of subjects with missing evaluation, n (%)	7 (10.4)	7 (10.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.024
95% CI for the RR		(0.769, 1.363)
p-value for RR		0.8728

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-resp15-301-by.sas:t-cgis-resp15-301-by-onset-itta.rtf **Run Date:** 25JUL2025

2.6.2.1 .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-301 - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =21)
Number of evaluable subjects [1]	16	21
Day 3		
Number of subjects with a response, n (%) [2]	2 (12.5)	6 (28.6)
Number of subjects with missing evaluation, n (%)	1 (6.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.209
95% CI for the RR		(0.517, 9.443)
p-value for RR		0.2851
Day 8		
Number of subjects with a response, n (%) [2]	6 (37.5)	8 (38.1)
Number of subjects with missing evaluation, n (%)	1 (6.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.004
95% CI for the RR		(0.436, 2.313)
p-value for RR		0.9919

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-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-resp15-301-by.sas:t-cgis-resp15-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Family History of PPD: 217-PPD-301 - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =21)
Day 15		
Number of subjects with a response, n (%) [2]	8 (50.0)	12 (57.1)
Number of subjects with missing evaluation, n (%)	3 (18.8)	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.107
95% CI for the RR		(0.606, 2.022)
p-value for RR		0.7414
Day 21		
Number of subjects with a response, n (%) [2]	10 (62.5)	14 (66.7)
Number of subjects with missing evaluation, n (%)	3 (18.8)	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.021
95% CI for the RR		(0.644, 1.619)
p-value for RR		0.9293

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-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-resp15-301-by.sas:t-cgis-resp15-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Family History of PPD: 217-PPD-301 - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =21)
Day 28		
Number of subjects with a response, n (%) [2]	8 (50.0)	13 (61.9)
Number of subjects with missing evaluation, n (%)	4 (25.0)	3 (14.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.231
95% CI for the RR		(0.677, 2.237)
p-value for RR		0.4953
Day 45		
Number of subjects with a response, n (%) [2]	10 (62.5)	13 (61.9)
Number of subjects with missing evaluation, n (%)	3 (18.8)	2 (9.5)
RR - Relative Risk (Zuranolone vs. Placebo)		0.957
95% CI for the RR		(0.574, 1.597)
p-value for RR		0.8672

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-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-resp15-301-by.sas:t-cgis-resp15-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Family History of PPD: 217-PPD-301 - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=85)	Zuranolone (N =78)
Number of evaluable subjects [1]	82	77
Day 3		
Number of subjects with a response, n (%) [2]	14 (17.1)	20 (26.0)
Number of subjects with missing evaluation, n (%)	1 (1.2)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.499
95% CI for the RR		(0.832, 2.702)
p-value for RR		0.1780
Day 8		
Number of subjects with a response, n (%) [2]	23 (28.0)	41 (53.2)
Number of subjects with missing evaluation, n (%)	2 (2.4)	5 (6.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.856
95% CI for the RR		(1.255, 2.744)
p-value for RR		0.0019

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-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-resp15-301-by.sas:t-cgis-resp15-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Family History of PPD: 217-PPD-301 - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=85)	Zuranolone (N =78)
Day 15		
Number of subjects with a response, n (%) [2]	36 (43.9)	47 (61.0)
Number of subjects with missing evaluation, n (%)	5 (6.1)	4 (5.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.387
95% CI for the RR		(1.043, 1.846)
p-value for RR		0.0247
Day 21		
Number of subjects with a response, n (%) [2]	35 (42.7)	47 (61.0)
Number of subjects with missing evaluation, n (%)	12 (14.6)	13 (16.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.386
95% CI for the RR		(1.035, 1.856)
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 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-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-resp15-301-by.sas:t-cgis-resp15-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Family History of PPD: 217-PPD-301 - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=85)	Zuranolone (N =78)
Day 28		
Number of subjects with a response, n (%) [2]	42 (51.2)	38 (49.4)
Number of subjects with missing evaluation, n (%)	9 (11.0)	18 (23.4)
RR - Relative Risk (Zuranolone vs. Placebo)		0.965
95% CI for the RR		(0.725, 1.284)
p-value for RR		0.8066
Day 45		
Number of subjects with a response, n (%) [2]	44 (53.7)	49 (63.6)
Number of subjects with missing evaluation, n (%)	10 (12.2)	12 (15.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.157
95% CI for the RR		(0.900, 1.486)
p-value for RR		0.2556

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-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-resp15-301-by.sas:t-cgis-resp15-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

2.6.2.1 .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-301 - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=90)	Zuranolone (N =82)
Number of evaluable subjects [1]	87	81
Day 3		
Number of subjects with a response, n (%) [2]	12 (13.8)	23 (28.4)
Number of subjects with missing evaluation, n (%)	2 (2.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.062
95% CI for the RR		(1.113, 3.819)
p-value for RR		0.0214
Day 8		
Number of subjects with a response, n (%) [2]	26 (29.9)	39 (48.1)
Number of subjects with missing evaluation, n (%)	3 (3.4)	5 (6.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.614
95% CI for the RR		(1.099, 2.368)
p-value for RR		0.0145

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-resp15-301-by.sas:t-cgis-resp15-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-301 - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=90)	Zuranolone (N =82)
Day 15		
Number of subjects with a response, n (%) [2]	39 (44.8)	47 (58.0)
Number of subjects with missing evaluation, n (%)	8 (9.2)	5 (6.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.296
95% CI for the RR		(0.965, 1.741)
p-value for RR		0.0845
Day 21		
Number of subjects with a response, n (%) [2]	40 (46.0)	51 (63.0)
Number of subjects with missing evaluation, n (%)	14 (16.1)	13 (16.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.372
95% CI for the RR		(1.037, 1.814)
p-value for RR		0.0267

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-resp15-301-by.sas:t-cgis-resp15-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-301 - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=90)	Zuranolone (N =82)
Day 28		
Number of subjects with a response, n (%) [2]	46 (52.9)	40 (49.4)
Number of subjects with missing evaluation, n (%)	13 (14.9)	21 (25.9)
RR - Relative Risk (Zuranolone vs. Placebo)		0.935
95% CI for the RR		(0.698, 1.254)
p-value for RR		0.6551
Day 45		
Number of subjects with a response, n (%) [2]	49 (56.3)	50 (61.7)
Number of subjects with missing evaluation, n (%)	12 (13.8)	13 (16.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.098
95% CI for the RR		(0.852, 1.415)
p-value for RR		0.4715

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-resp15-301-by.sas:t-cgis-resp15-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-301 - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=11)	Zuranolone (N =17)
Number of evaluable subjects [1]	11	17
Day 3		
Number of subjects with a response, n (%) [2]	4 (36.4)	3 (17.6)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.416
95% CI for the RR		(0.090, 1.916)
p-value for RR		0.2602
Day 8		
Number of subjects with a response, n (%) [2]	3 (27.3)	10 (58.8)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.848
95% CI for the RR		(0.515, 6.633)
p-value for RR		0.3464

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-resp15-301-by.sas:t-cgis-resp15-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-301 - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=11)	Zuranolone (N =17)
Day 15		
Number of subjects with a response, n (%) [2]	5 (45.5)	12 (70.6)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.330
95% CI for the RR		(0.462, 3.831)
p-value for RR		0.5968
Day 21		
Number of subjects with a response, n (%) [2]	5 (45.5)	10 (58.8)
Number of subjects with missing evaluation, n (%)	1 (9.1)	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.109
95% CI for the RR		(0.351, 3.501)
p-value for RR		0.8605

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-resp15-301-by.sas:t-cgis-resp15-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by History of PPD: 217-PPD-301 - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=11)	Zuranolone (N =17)
Day 28		
Number of subjects with a response, n (%) [2]	4 (36.4)	11 (64.7)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.524
95% CI for the RR		(0.504, 4.610)
p-value for RR		0.4552
Day 45		
Number of subjects with a response, n (%) [2]	5 (45.5)	12 (70.6)
Number of subjects with missing evaluation, n (%)	1 (9.1)	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.330
95% CI for the RR		(0.432, 4.100)
p-value for RR		0.6191

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-resp15-301-by.sas:t-cgis-resp15-301-by-hist-itta.rtf **Run Date:** 25JUL2025

2.6.2.1 .2 .2 .9 Depression mit Angst

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =24)
Number of evaluable subjects [1]	21	24
Day 3		
Number of subjects with a response, n (%) [2]	1 (4.8)	5 (20.8)
Number of subjects with missing evaluation, n (%)	1 (4.8)	0
RR - Relative Risk (Zuranolone vs. Placebo)		4.369
95% CI for the RR		(0.548, 34.858)
p-value for RR		0.1641
Day 8		
Number of subjects with a response, n (%) [2]	3 (14.3)	10 (41.7)
Number of subjects with missing evaluation, n (%)	1 (4.8)	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		2.916
95% CI for the RR		(0.925, 9.198)
p-value for RR		0.0678

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-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-resp15-301-by.sas:t-cgis-resp15-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =24)
Day 15		
Number of subjects with a response, n (%) [2]	12 (57.1)	13 (54.2)
Number of subjects with missing evaluation, n (%)	1 (4.8)	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		0.938
95% CI for the RR		(0.560, 1.571)
p-value for RR		0.8084
Day 21		
Number of subjects with a response, n (%) [2]	11 (52.4)	17 (70.8)
Number of subjects with missing evaluation, n (%)	3 (14.3)	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.362
95% CI for the RR		(0.839, 2.211)
p-value for RR		0.2119

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-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-resp15-301-by.sas:t-cgis-resp15-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =24)
Day 28		
Number of subjects with a response, n (%) [2]	13 (61.9)	13 (54.2)
Number of subjects with missing evaluation, n (%)	2 (9.5)	5 (20.8)
RR - Relative Risk (Zuranolone vs. Placebo)		0.865
95% CI for the RR		(0.527, 1.422)
p-value for RR		0.5683
Day 45		
Number of subjects with a response, n (%) [2]	14 (66.7)	16 (66.7)
Number of subjects with missing evaluation, n (%)	1 (4.8)	3 (12.5)
RR - Relative Risk (Zuranolone vs. Placebo)		0.990
95% CI for the RR		(0.649, 1.510)
p-value for RR		0.9614

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-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-resp15-301-by.sas:t-cgis-resp15-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

Study Visit Statistics	Placebo (N=77)	Zuranolone (N =74)
Number of evaluable subjects [1]	77	74
Day 3		
Number of subjects with a response, n (%) [2]	15 (19.5)	21 (28.4)
Number of subjects with missing evaluation, n (%)	1 (1.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.417
95% CI for the RR		(0.810, 2.476)
p-value for RR		0.2216
Day 8		
Number of subjects with a response, n (%) [2]	26 (33.8)	39 (52.7)
Number of subjects with missing evaluation, n (%)	2 (2.6)	4 (5.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.524
95% CI for the RR		(1.062, 2.185)
p-value for RR		0.0221

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-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-resp15-301-by.sas:t-cgis-resp15-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

Study Visit Statistics	Placebo (N=77)	Zuranolone (N =74)
Day 15		
Number of subjects with a response, n (%) [2]	32 (41.6)	46 (62.2)
Number of subjects with missing evaluation, n (%)	7 (9.1)	4 (5.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.460
95% CI for the RR		(1.086, 1.962)
p-value for RR		0.0122
Day 21		
Number of subjects with a response, n (%) [2]	34 (44.2)	44 (59.5)
Number of subjects with missing evaluation, n (%)	12 (15.6)	13 (17.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.274
95% CI for the RR		(0.948, 1.710)
p-value for RR		0.1079

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-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-resp15-301-by.sas:t-cgis-resp15-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

Study Visit Statistics	Placebo (N=77)	Zuranolone (N =74)
Day 28		
Number of subjects with a response, n (%) [2]	37 (48.1)	38 (51.4)
Number of subjects with missing evaluation, n (%)	11 (14.3)	16 (21.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.094
95% CI for the RR		(0.818, 1.463)
p-value for RR		0.5439
Day 45		
Number of subjects with a response, n (%) [2]	40 (51.9)	46 (62.2)
Number of subjects with missing evaluation, n (%)	12 (15.6)	11 (14.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.166
95% CI for the RR		(0.913, 1.491)
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 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-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.

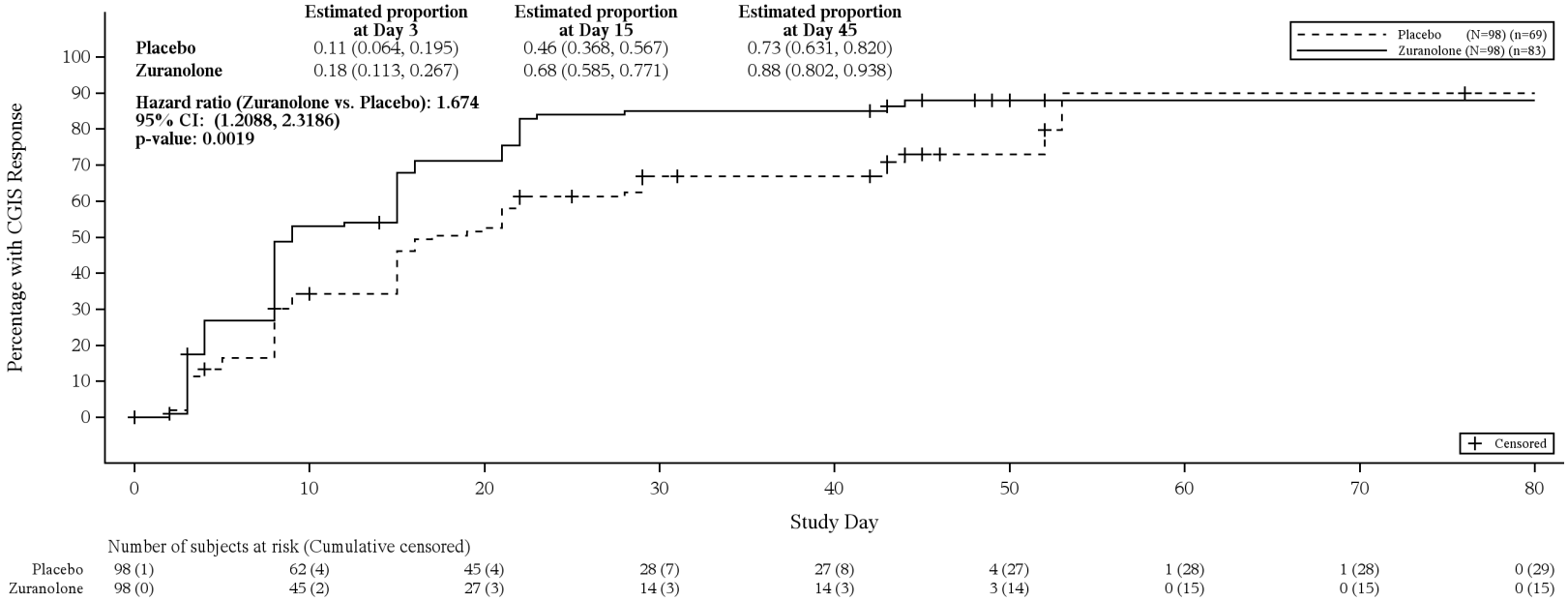
Source: biib125/v_a/germany_amnog/t-cgis-resp15-301-by.sas:t-cgis-resp15-301-by-hama-itta.rtf **Run Date:** 25JUL2025

2.6.2.2 TTE-Analysen

2.6.2.2 .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-301 - 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-301-ovr.sas:f-cgis-resp15-tte-301-ovr-itta.rtf **Run Date:** 16DEC2025

Summary of Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline): 217-PPD-301 - ITT population

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	Placebo (N=101)	Zuranolone (N=99)
Number of evaluable subjects [1]	98	98
Number of subjects with response, n (%) [2]	69 (70.4)	83 (84.7)
Time to first CGI-S response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (5.0 , 9.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	17.0 (15.0 , 22.0)	9.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	52.0 (29.0, NE)	21.0 (15.0 , 23.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.674
95% CI for the HR		(1.2088 , 2.3186)
p-value for the HR		0.0019

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-301-ovr.sas:t-cgis-resp15-tte-301-ovr-itta.rtf **Run Date:** 18JUL2025

2.6.2.2 .2 Subgruppen

2.6.2.2 .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-301 - ITT population

Page: 1 of 2

Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	98	98	
Number of subjects with response, n (%)	69 (70.4)	83 (84.7)	
Age Group (years)			
18 - 24, n / N (%)	10/12 (83.3)	18/19 (94.7)	0.3343
25 - 45, n / N (%)	59/86 (68.6)	65/79 (82.3)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	20/32 (62.5)	27/33 (81.8)	0.8256
>=28, n / N (%)	49/66 (74.2)	56/65 (86.2)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	8/18 (44.4)	21/25 (84.0)	0.5260
White, n / N (%)	54/69 (78.3)	58/68 (85.3)	
Antidepressant Use at Baseline			
Yes, n / N (%)	12/15 (80.0)	10/15 (66.7)	0.0486
No, n / N (%)	57/83 (68.7)	73/83 (88.0)	

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-301-int.sas:t-cgis-resp15-tte-301-int-itta.rtf **Run Date:** 18JUL2025

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-301 - ITT population

Page: 2 of 2

Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9, n / N (%)	20/22 (90.9)	16/20 (80.0)	0.1199(a)
25-29.9, n / N (%)	26/34 (76.5)	20/24 (83.3)	0.0487(b)
>=30, n / N (%)	23/42 (54.8)	46/53 (86.8)	0.7252(c)
Onset of PPD			
3rd Trimester, n / N (%)	21/31 (67.7)	31/34 (91.2)	0.4496
Postpartum, n / N (%)	48/67 (71.6)	52/64 (81.3)	
Family History of PPD			
Yes, n / N (%)	12/16 (75.0)	18/21 (85.7)	0.4252
No/Unknown, n / N (%)	57/82 (69.5)	65/77 (84.4)	
History of PPD			
1st Episode, n / N (%)	64/87 (73.6)	69/81 (85.2)	0.6435
Recurrent Episode, n / N (%)	5/11 (45.5)	14/17 (82.4)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	17/21 (81.0)	20/24 (83.3)	0.4486
>=20, n / N (%)	52/77 (67.5)	63/74 (85.1)	

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-301-int.sas:t-cgis-resp15-tte-301-int-itta.rtf **Run Date:** 18JUL2025

2.6.2.2 .2 .2 Subgruppenanalysen

2.6.2.2 .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-301 - ITT population

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Age Group (years) = 18-24

	Placebo (N=13)	Zuranolone (N=19)
Number of evaluable subjects [1]	12	19
Number of subjects with response, n (%) [2]	10 (83.3)	18 (94.7)
Time to first CGI-S response (days) [3]		
25th percentile - Q1 (95% CI)	4.0 (3.0 , 21.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	21.0 (3.0 , 29.0)	8.0 (4.0 , 8.0)
75th percentile - Q3 (95% CI)	25.5 (21.0, NE)	9.0 (8.0 , 23.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.301
95% CI for the HR		(0.9758 , 5.4276)
p-value for the HR		0.0569

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-301-by.sas:t-cgis-resp15-tte-301-by-age-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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Age Group (years) = 25-45

	Placebo (N=88)	Zuranolone (N=80)
Number of evaluable subjects [1]	86	79
Number of subjects with response, n (%) [2]	59 (68.6)	65 (82.3)
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)	16.0 (15.0 , 28.0)	15.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	52.0 (43.0, NE)	22.0 (16.0 , 43.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.573
95% CI for the HR		(1.0973 , 2.2547)
p-value for the HR		0.0137

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-301-by.sas:t-cgis-resp15-tte-301-by-age-itta.rtf **Run Date:** 25JUL2025

2.6.2.2 .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-301 - ITT population

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

	Placebo (N=32)	Zuranolone (N=33)
Number of evaluable subjects [1]	32	33
Number of subjects with response, n (%) [2]	20 (62.5)	27 (81.8)
Time to first CGI-S response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (4.0 , 15.0)	8.0 (3.0 , 9.0)
50th percentile - median (95% CI)	17.0 (9.0 , 53.0)	15.0 (8.0 , 22.0)
75th percentile - Q3 (95% CI)	53.0 (29.0, NE)	28.0 (22.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.801
95% CI for the HR		(0.9908 , 3.2722)
p-value for the HR		0.0537

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-301-by.sas:t-cgis-resp15-tte-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

	Placebo (N=66)	Zuranolone (N=65)
Number of evaluable subjects [1]	66	65
Number of subjects with response, n (%) [2]	49 (74.2)	56 (86.2)
Time to first CGI-S response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (4.0 , 9.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	16.0 (15.0 , 22.0)	8.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	43.0 (22.0, NE)	16.0 (15.0 , 21.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.669
95% CI for the HR		(1.1239 , 2.4794)
p-value for the HR		0.0111

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-301-by.sas:t-cgis-resp15-tte-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

2.6.2.2 .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-301 - ITT population

Page: 1 of 2

Race Group = Black or African American

	Placebo (N=20)	Zuranolone (N=26)
Number of evaluable subjects [1]	18	25
Number of subjects with response, n (%) [2]	8 (44.4)	21 (84.0)
Time to first CGI-S response (days) [3]		
25th percentile - Q1 (95% CI)	9.0 (3.0 , 43.0)	4.0 (3.0 , 12.0)
50th percentile - median (95% CI)	43.0 (9.0, NE)	15.0 (4.0 , 21.0)
75th percentile - Q3 (95% CI)	NE (43.0, NE)	22.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.308
95% CI for the HR		(0.9541 , 5.5825)
p-value for the HR		0.0635

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-301-by.sas:t-cgis-resp15-tte-301-by-race-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

Page: 2 of 2

Race Group = White

	Placebo (N=70)	Zuranolone (N=68)
Number of evaluable subjects [1]	69	68
Number of subjects with response, n (%) [2]	54 (78.3)	58 (85.3)
Time to first CGI-S response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (4.0 , 9.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	16.0 (15.0 , 21.0)	8.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	43.0 (21.0, NE)	16.0 (15.0 , 23.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.757
95% CI for the HR		(1.1962 , 2.5817)
p-value for the HR		0.0041

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-301-by.sas:t-cgis-resp15-tte-301-by-race-itta.rtf **Run Date:** 25JUL2025

2.6.2.2 .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-301 - ITT population

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Antidepressant Use at Baseline = Yes

	Placebo (N=15)	Zuranolone (N=15)
Number of evaluable subjects [1]	15	15
Number of subjects with response, n (%) [2]	12 (80.0)	10 (66.7)
Time to first CGI-S response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (2.0 , 15.0)	8.0 (3.0 , 15.0)
50th percentile - median (95% CI)	16.0 (8.0 , 22.0)	15.0 (8.0, NE)
75th percentile - Q3 (95% CI)	53.0 (16.0, NE)	NE (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.816
95% CI for the HR		(0.3450 , 1.9322)
p-value for the HR		0.6445

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-301-by.sas:t-cgis-resp15-tte-301-by-adt-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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Antidepressant Use at Baseline = No

	Placebo (N=86)	Zuranolone (N=84)
Number of evaluable subjects [1]	83	83
Number of subjects with response, n (%) [2]	57 (68.7)	73 (88.0)
Time to first CGI-S response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (5.0 , 15.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	20.0 (15.0 , 29.0)	8.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	52.0 (29.0, NE)	21.0 (15.0 , 22.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.916
95% CI for the HR		(1.3461 , 2.7267)
p-value for the HR		0.0003

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-301-by.sas:t-cgis-resp15-tte-301-by-adt-itta.rtf **Run Date:** 25JUL2025

2.6.2.2 .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-301 - ITT population

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

	Placebo (N=22)	Zuranolone (N=20)
Number of evaluable subjects [1]	22	20
Number of subjects with response, n (%) [2]	20 (90.9)	16 (80.0)
Time to first CGI-S response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (2.0 , 15.0)	4.0 (3.0 , 15.0)
50th percentile - median (95% CI)	15.0 (8.0 , 21.0)	15.0 (4.0 , 22.0)
75th percentile - Q3 (95% CI)	22.0 (15.0 , 43.0)	22.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		0.996
95% CI for the HR		(0.5132 , 1.9320)
p-value for the HR		0.9900

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-301-by.sas:t-cgis-resp15-tte-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

	Placebo (N=34)	Zuranolone (N=24)
Number of evaluable subjects [1]	34	24
Number of subjects with response, n (%) [2]	26 (76.5)	20 (83.3)
Time to first CGI-S 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)	20.0 (8.0 , 22.0)	8.0 (3.0 , 15.0)
75th percentile - Q3 (95% CI)	29.0 (21.0, NE)	22.0 (8.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.842
95% CI for the HR		(0.9964 , 3.4038)
p-value for the HR		0.0514

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-301-by.sas:t-cgis-resp15-tte-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

	Placebo (N=42)	Zuranolone (N=53)
Number of evaluable subjects [1]	42	53
Number of subjects with response, n (%) [2]	23 (54.8)	46 (86.8)
Time to first CGI-S response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (4.0 , 15.0)	8.0 (3.0 , 8.0)
50th percentile - median (95% CI)	29.0 (9.0, NE)	8.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	53.0 (52.0, NE)	16.0 (15.0 , 44.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.110
95% CI for the HR		(1.2544 , 3.5477)
p-value for the HR		0.0049

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-301-by.sas:t-cgis-resp15-tte-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

2.6.2.2 .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-301 - ITT population

Page: 1 of 2

Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=35)
Number of evaluable subjects [1]	31	34
Number of subjects with response, n (%) [2]	21 (67.7)	31 (91.2)
Time to first CGI-S response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 8.0)	3.0 (3.0 , 8.0)
50th percentile - median (95% CI)	15.0 (8.0 , 29.0)	8.0 (3.0 , 15.0)
75th percentile - Q3 (95% CI)	44.0 (21.0, NE)	21.0 (15.0 , 28.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.879
95% CI for the HR		(1.0560 , 3.3451)
p-value for the HR		0.0319

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-301-by.sas:t-cgis-resp15-tte-301-by-onset-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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Onset of PPD = Postpartum

	Placebo (N=69)	Zuranolone (N=64)
Number of evaluable subjects [1]	67	64
Number of subjects with response, n (%) [2]	48 (71.6)	52 (81.3)
Time to first CGI-S response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (8.0 , 15.0)	8.0 (4.0 , 8.0)
50th percentile - median (95% CI)	20.0 (15.0 , 28.0)	9.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	52.0 (29.0, NE)	21.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.534
95% CI for the HR		(1.0291 , 2.2876)
p-value for the HR		0.0356

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-301-by.sas:t-cgis-resp15-tte-301-by-onset-itta.rtf **Run Date:** 25JUL2025

2.6.2.2 .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-301 - ITT population

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Family History of PPD = Yes

	Placebo (N=16)	Zuranolone (N=21)
Number of evaluable subjects [1]	16	21
Number of subjects with response, n (%) [2]	12 (75.0)	18 (85.7)
Time to first CGI-S response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 15.0)	4.0 (3.0 , 9.0)
50th percentile - median (95% CI)	15.0 (8.0 , 22.0)	15.0 (4.0 , 22.0)
75th percentile - Q3 (95% CI)	22.0 (15.0, NE)	22.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.218
95% CI for the HR		(0.5763 , 2.5763)
p-value for the HR		0.6050

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-301-by.sas:t-cgis-resp15-tte-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

Page: 2 of 2

Family History of PPD = No/Unknown

	Placebo (N=85)	Zuranolone (N=78)
Number of evaluable subjects [1]	82	77
Number of subjects with response, n (%) [2]	57 (69.5)	65 (84.4)
Time to first CGI-S response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (5.0 , 15.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	20.0 (15.0 , 29.0)	8.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	52.0 (29.0, NE)	21.0 (15.0 , 22.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.763
95% CI for the HR		(1.2240 , 2.5393)
p-value for the HR		0.0023

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-301-by.sas:t-cgis-resp15-tte-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

2.6.2.2 .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-301 - ITT population

Page: 1 of 2

History of PPD = 1st Episode

	Placebo (N=90)	Zuranolone (N=82)
Number of evaluable subjects [1]	87	81
Number of subjects with response, n (%) [2]	64 (73.6)	69 (85.2)
Time to first CGI-S response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (8.0 , 15.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	17.0 (15.0 , 22.0)	9.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	44.0 (29.0, NE)	21.0 (15.0 , 22.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.692
95% CI for the HR		(1.1968 , 2.3918)
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-301-by.sas:t-cgis-resp15-tte-301-by-hist-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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History of PPD = Recurrent Episode

	Placebo (N=11)	Zuranolone (N=17)
Number of evaluable subjects [1]	11	17
Number of subjects with response, n (%) [2]	5 (45.5)	14 (82.4)
Time to first CGI-S response (days) [3]		
25th percentile - Q1 (95% CI)	5.0 (3.0, NE)	8.0 (3.0 , 8.0)
50th percentile - median (95% CI)	NE (4.0, NE)	8.0 (8.0 , 16.0)
75th percentile - Q3 (95% CI)	NE (8.0, NE)	16.0 (8.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.773
95% CI for the HR		(0.5797 , 5.4242)
p-value for the HR		0.3153

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-301-by.sas:t-cgis-resp15-tte-301-by-hist-itta.rtf **Run Date:** 25JUL2025

2.6.2.2 .2 .2 .9 Depression mit Angst

Summary of Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

Page: 1 of 2

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

	Placebo (N=21)	Zuranolone (N=24)
Number of evaluable subjects [1]	21	24
Number of subjects with response, n (%) [2]	17 (81.0)	20 (83.3)
Time to first CGI-S response (days) [3]		
25th percentile - Q1 (95% CI)	15.0 (5.0 , 16.0)	8.0 (3.0 , 8.0)
50th percentile - median (95% CI)	18.0 (15.0 , 29.0)	15.0 (8.0 , 21.0)
75th percentile - Q3 (95% CI)	36.0 (19.0, NE)	22.5 (16.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.347
95% CI for the HR		(0.6929 , 2.6191)
p-value for the HR		0.3797

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-301-by.sas:t-cgis-resp15-tte-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

Page: 2 of 2

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

	Placebo (N=77)	Zuranolone (N=74)
Number of evaluable subjects [1]	77	74
Number of subjects with response, n (%) [2]	52 (67.5)	63 (85.1)
Time to first CGI-S response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (4.0 , 9.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	16.0 (9.0 , 29.0)	8.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	53.0 (29.0, NE)	16.0 (15.0 , 22.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.711
95% CI for the HR		(1.1761 , 2.4900)
p-value for the HR		0.0050

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.

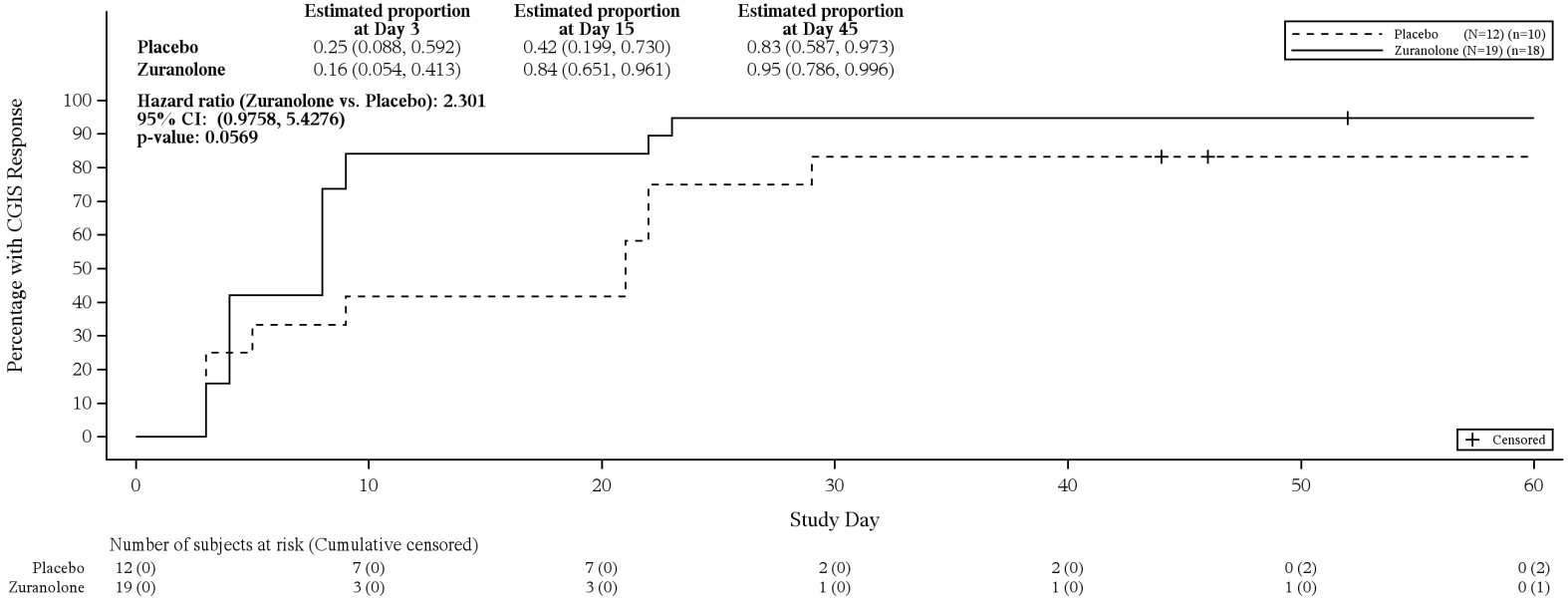
Source: biib125/v_a/germany_amnog/t-cgis-resp15-tte-301-by.sas:t-cgis-resp15-tte-301-by-hama-itta.rtf **Run Date:** 25JUL2025

2.6.2.2 .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-301 - 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 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.

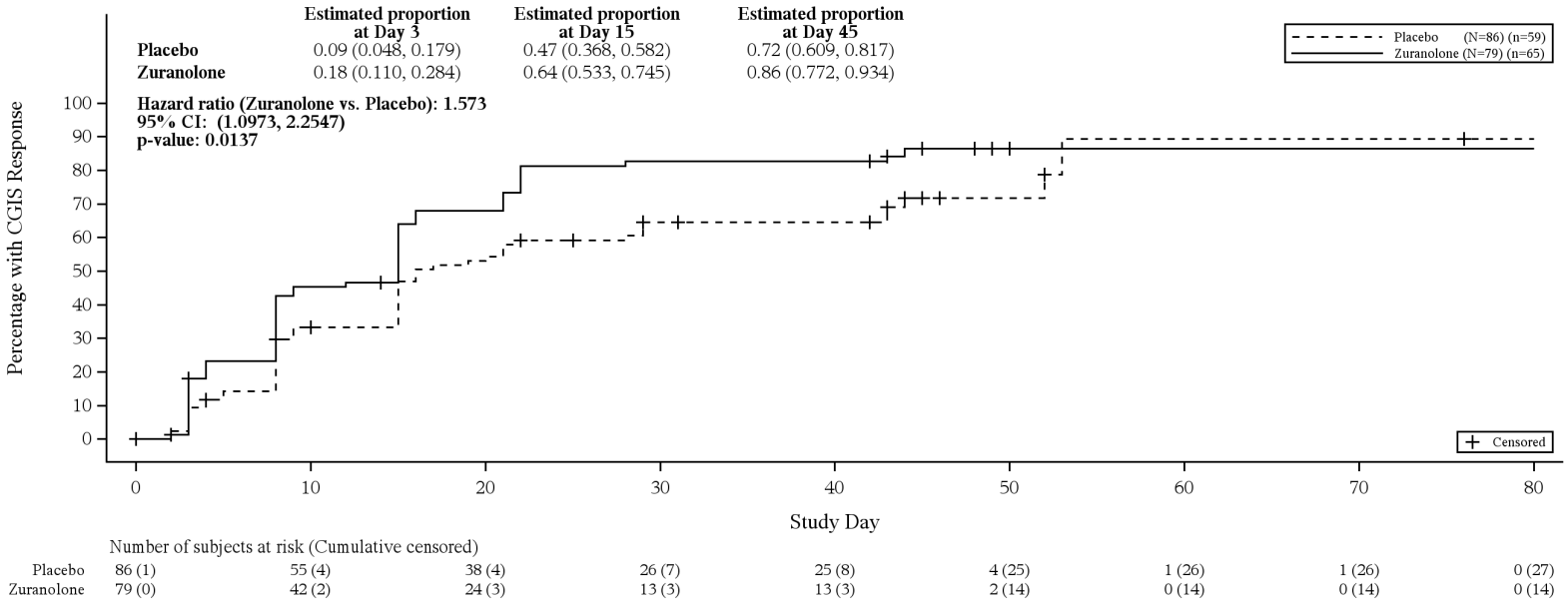
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant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

Source: biib125/v_a/amnog_kmplots/f-cgis-resp15-tte-301-by.sas:f-cgis-resp15-tte-301-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-301 - ITT population

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Age Group (years) = 25-45



Number of subjects at risk (Cumulative censored)

Placebo	86 (1)	55 (4)	38 (4)	26 (7)	25 (8)	4 (25)	1 (26)	1 (26)	0 (27)
Zuranolone	79 (0)	42 (2)	24 (3)	13 (3)	13 (3)	2 (14)	0 (14)	0 (14)	0 (14)

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.

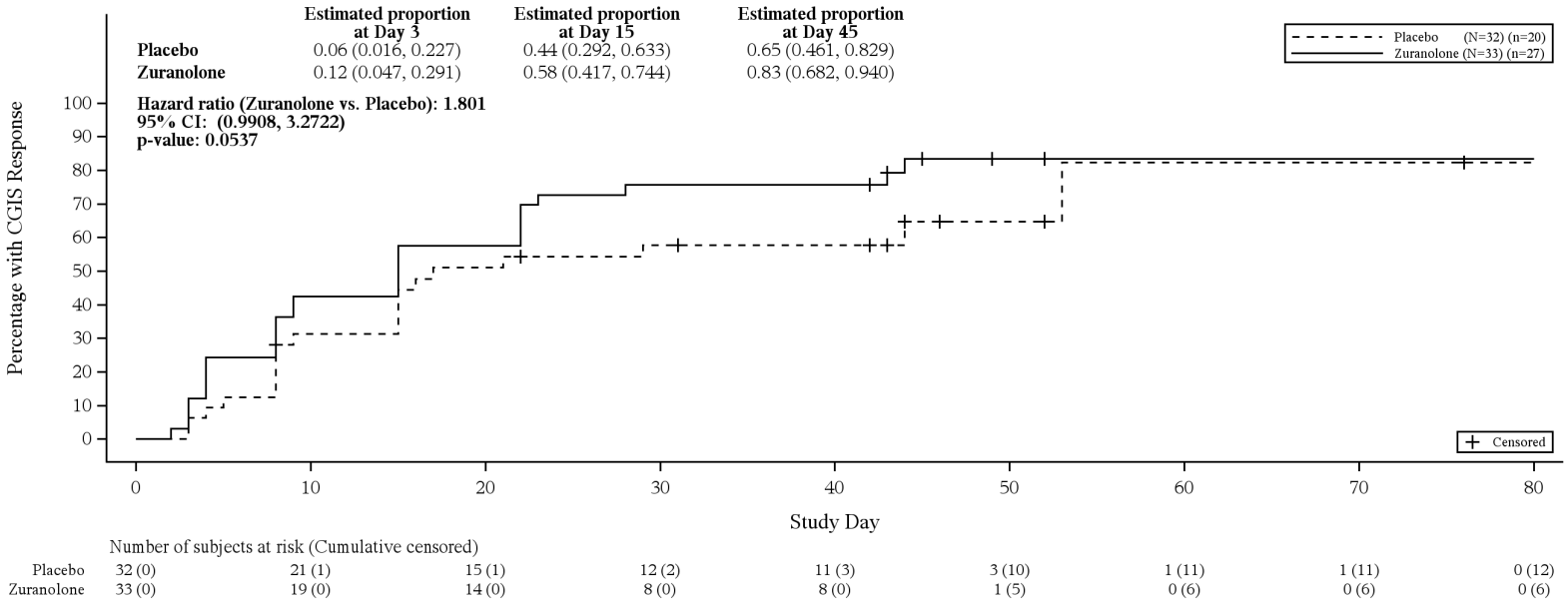
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant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

Source: biib125/v_a/amnog_kmplots/f-cgis-resp15-tte-301-by.sas:f-cgis-resp15-tte-301-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-301 - 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	32 (0)	21 (1)	15 (1)	12 (2)	11 (3)	3 (10)	1 (11)	1 (11)	0 (12)
Zuranolone	33 (0)	19 (0)	14 (0)	8 (0)	8 (0)	1 (5)	0 (6)	0 (6)	0 (6)

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.

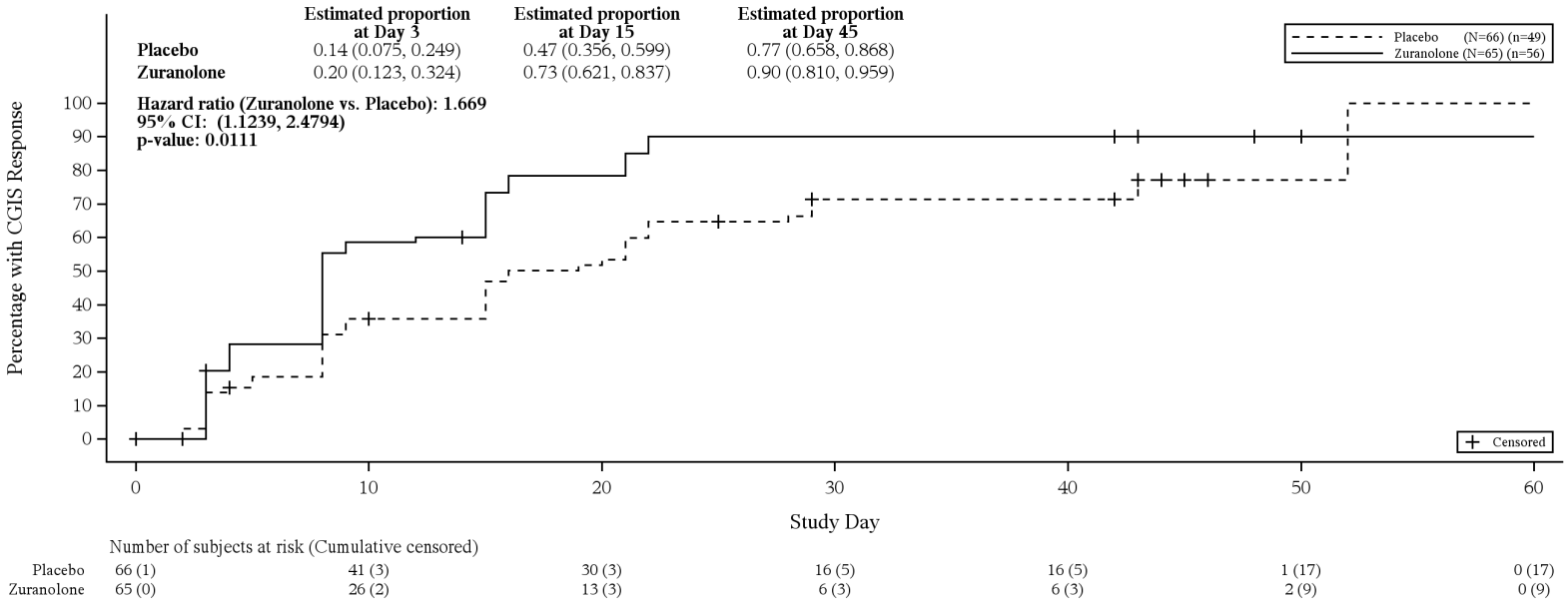
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant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

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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-301 - 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.

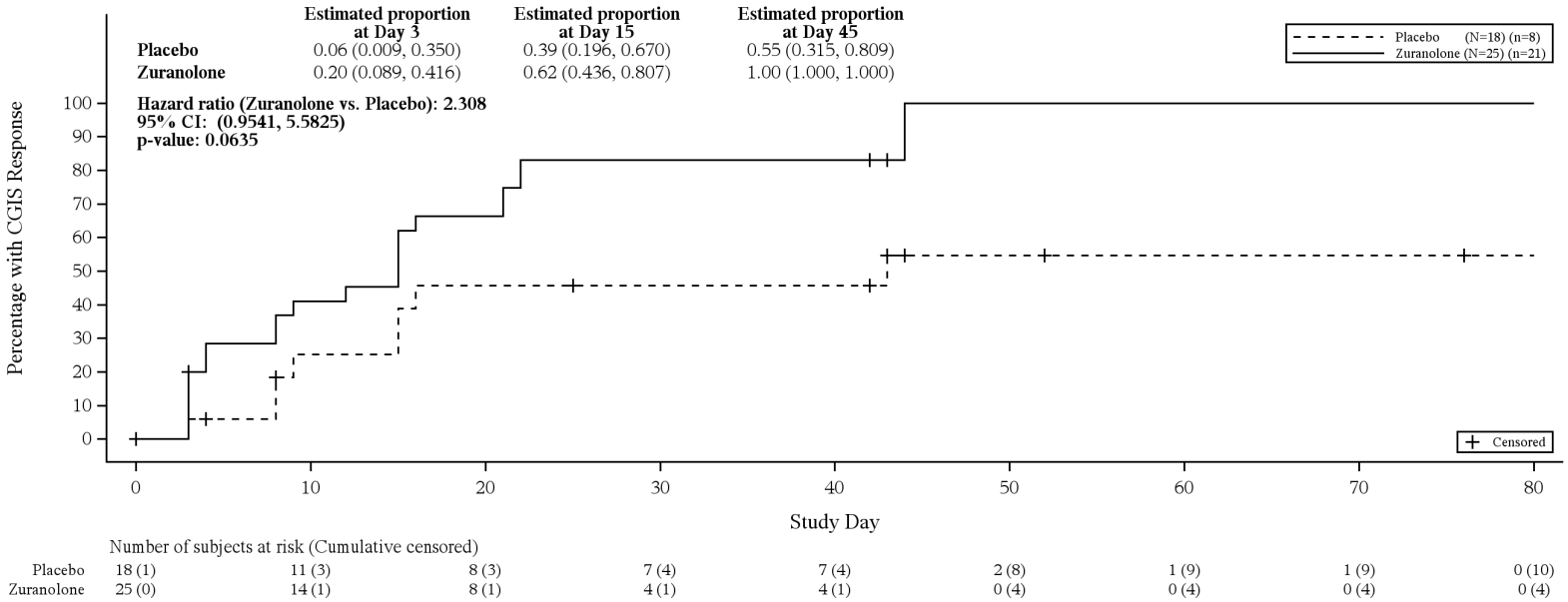
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Kaplan-Meier Plot for Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-301 - ITT population

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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.

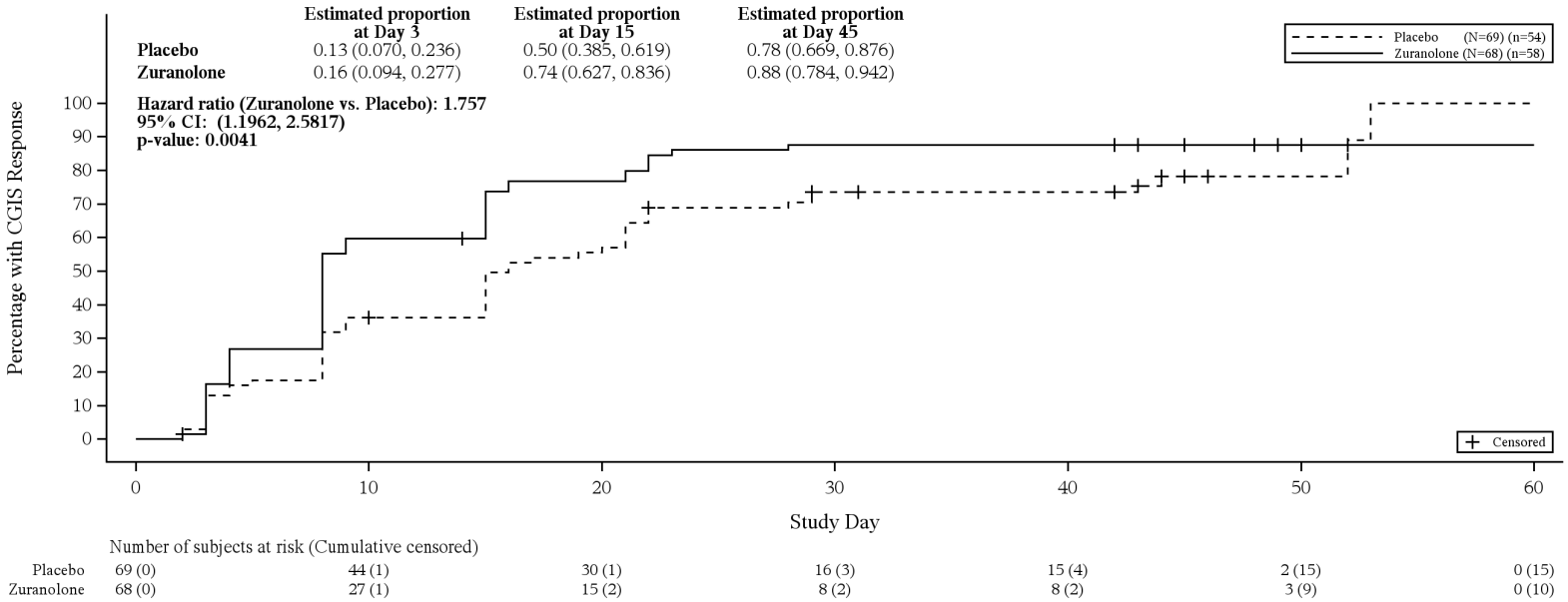
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Kaplan-Meier Plot for Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-301 - ITT population

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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.

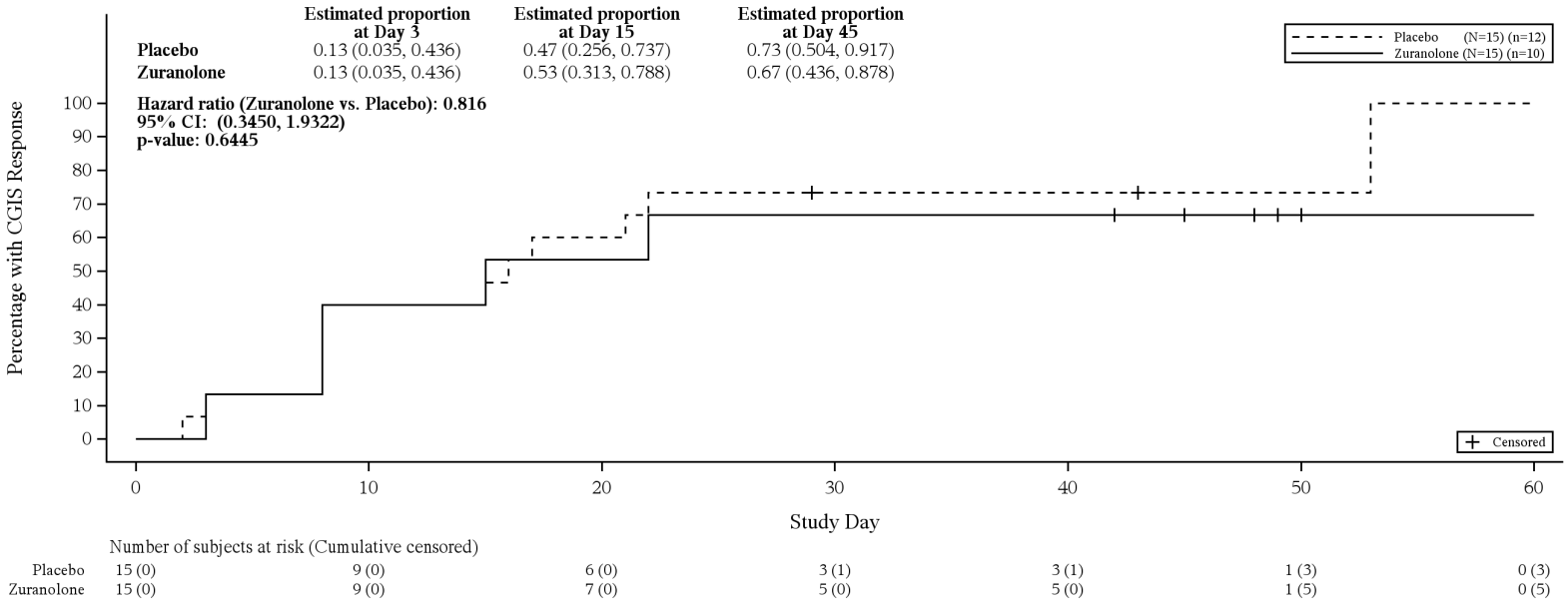
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Kaplan-Meier Plot for Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-301 - ITT population

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Antidepressant Use at Baseline = Yes



Number of subjects at risk (Cumulative censored)

Placebo	15 (0)	9 (0)	6 (0)	3 (1)	3 (1)	1 (3)	0 (3)
Zuranolone	15 (0)	9 (0)	7 (0)	5 (0)	5 (0)	1 (5)	0 (5)

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.

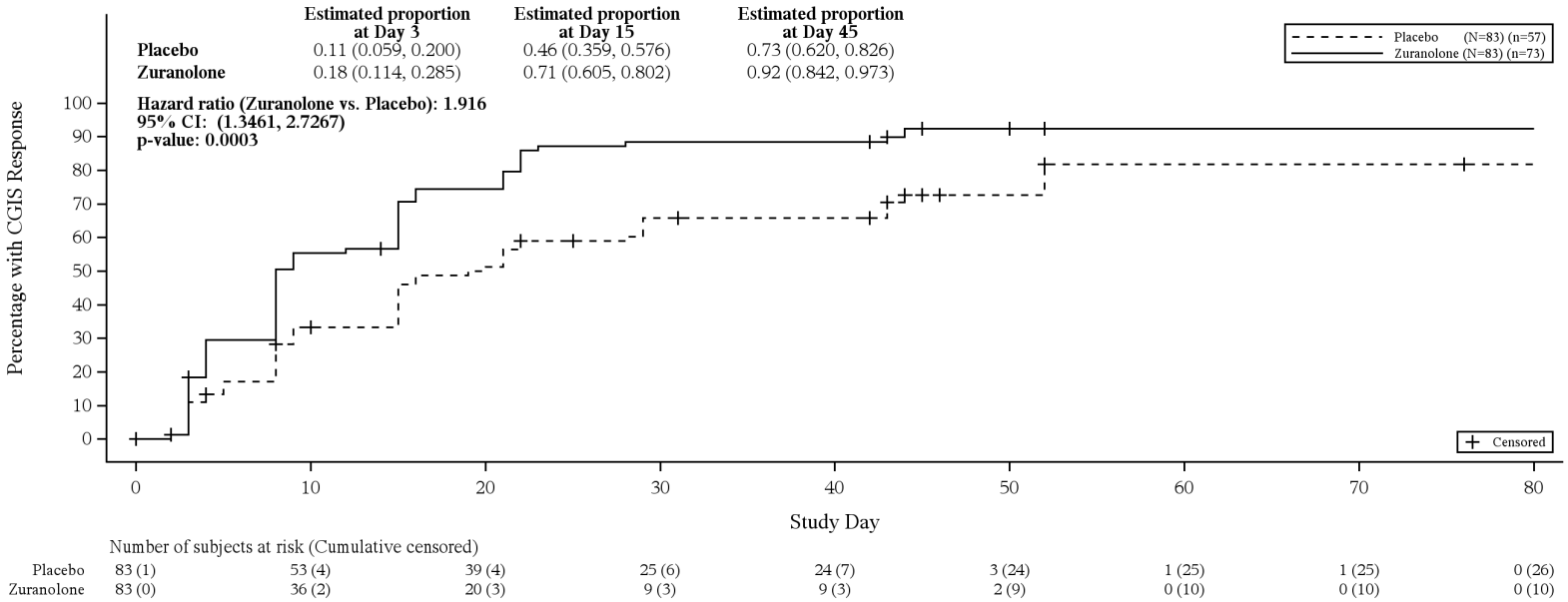
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Kaplan-Meier Plot for Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-301 - ITT population

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Antidepressant Use at Baseline = No



Number of subjects at risk (Cumulative censored)

Placebo	83 (1)	53 (4)	39 (4)	25 (6)	24 (7)	3 (24)	1 (25)	1 (25)	0 (26)
Zuranolone	83 (0)	36 (2)	20 (3)	9 (3)	9 (3)	2 (9)	0 (10)	0 (10)	0 (10)

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.

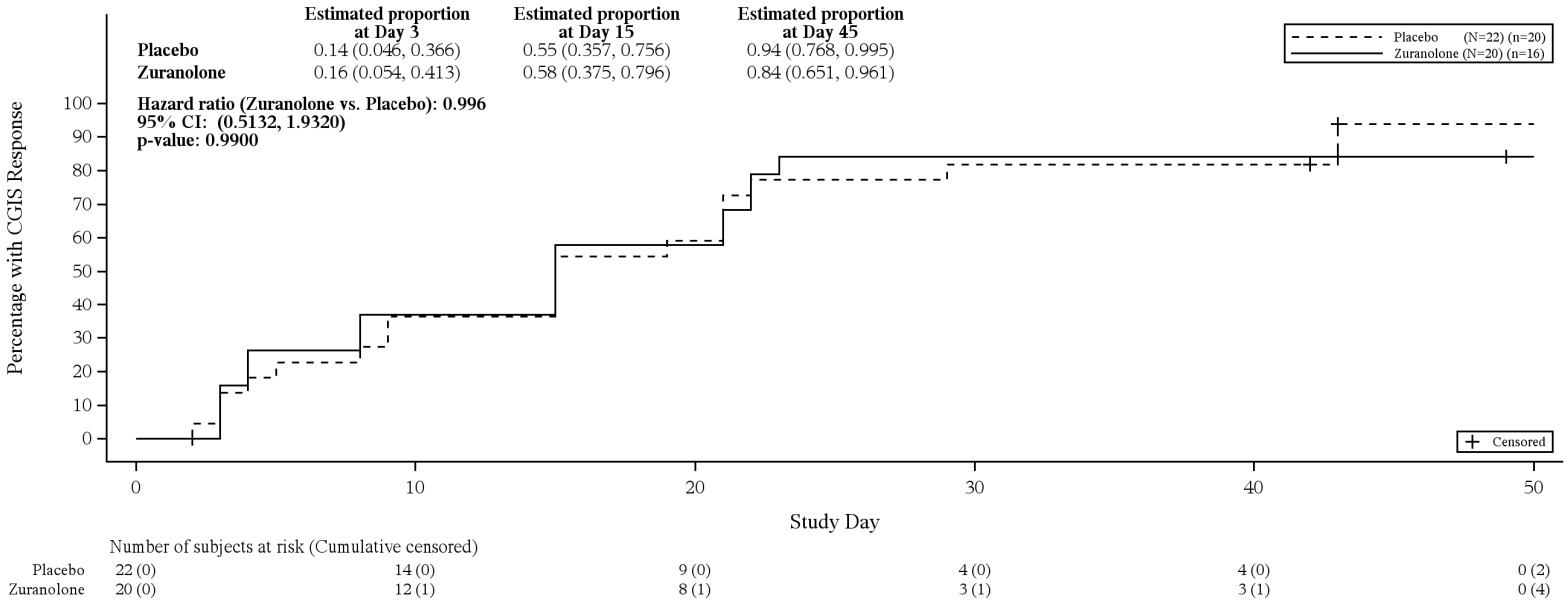
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Kaplan-Meier Plot for Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-301 - ITT population

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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.

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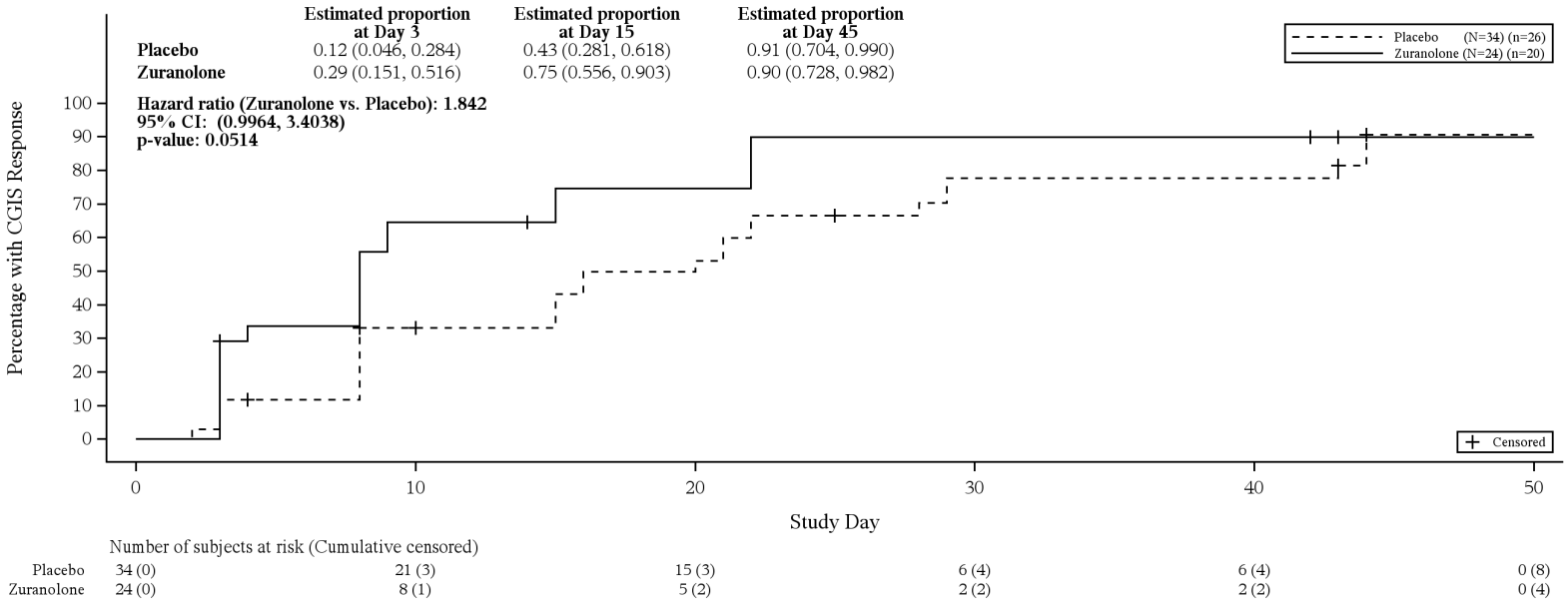
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant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

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Kaplan-Meier Plot for Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-301 - 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.

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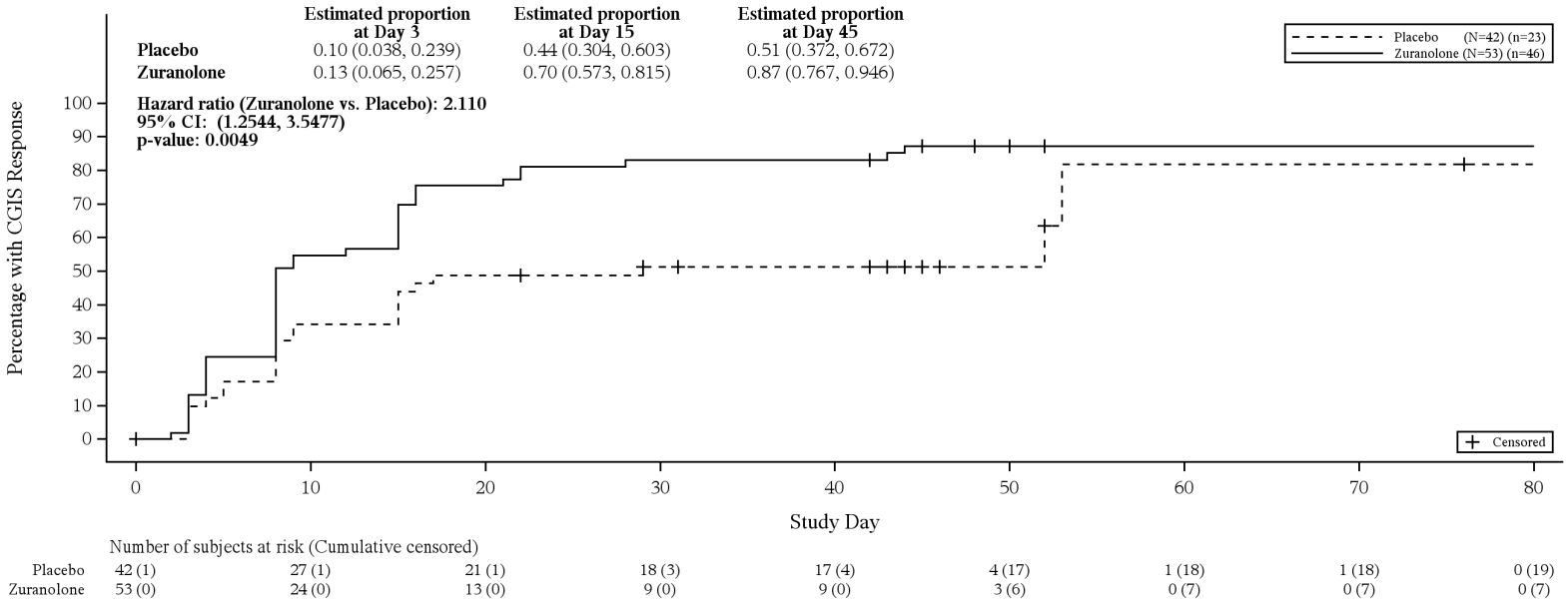
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Kaplan-Meier Plot for Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-301 - ITT population

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



Number of subjects at risk (Cumulative censored)

Placebo	42 (1)	27 (1)	21 (1)	18 (3)	17 (4)	4 (17)	1 (18)	1 (18)	0 (19)
Zuranolone	53 (0)	24 (0)	13 (0)	9 (0)	9 (0)	3 (6)	0 (7)	0 (7)	0 (7)

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.

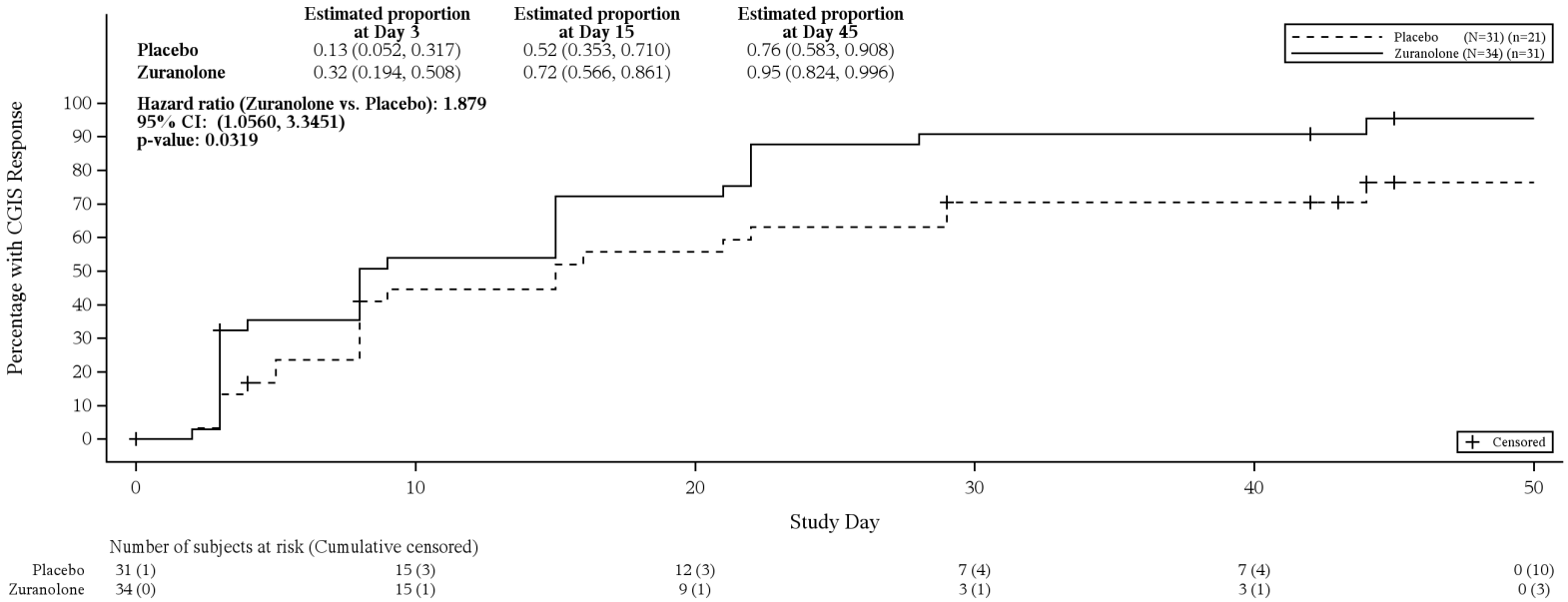
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant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

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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-301 - 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.

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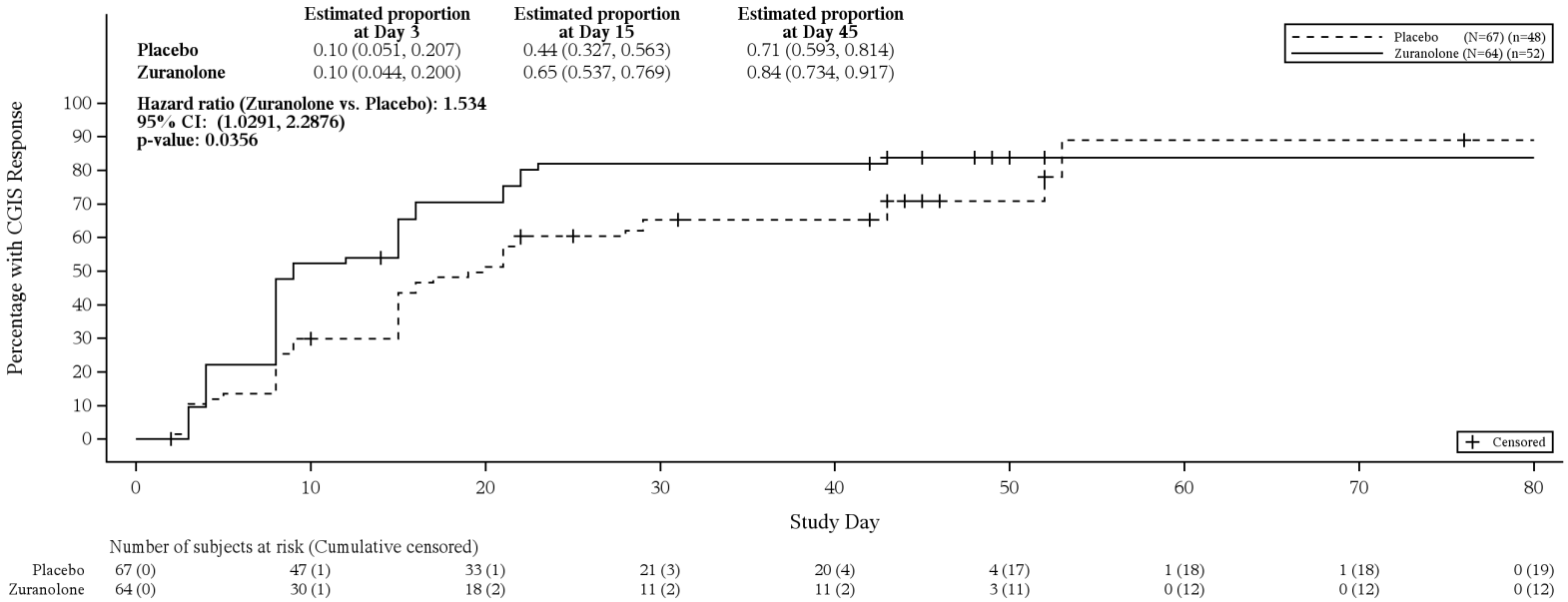
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Kaplan-Meier Plot for Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-301 - ITT population

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Onset of PPD = Postpartum



Number of subjects at risk (Cumulative censored)

Placebo	67 (0)	47 (1)	33 (1)	21 (3)	20 (4)	4 (17)	1 (18)	1 (18)	0 (19)
Zuranolone	64 (0)	30 (1)	18 (2)	11 (2)	11 (2)	3 (11)	0 (12)	0 (12)	0 (12)

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.

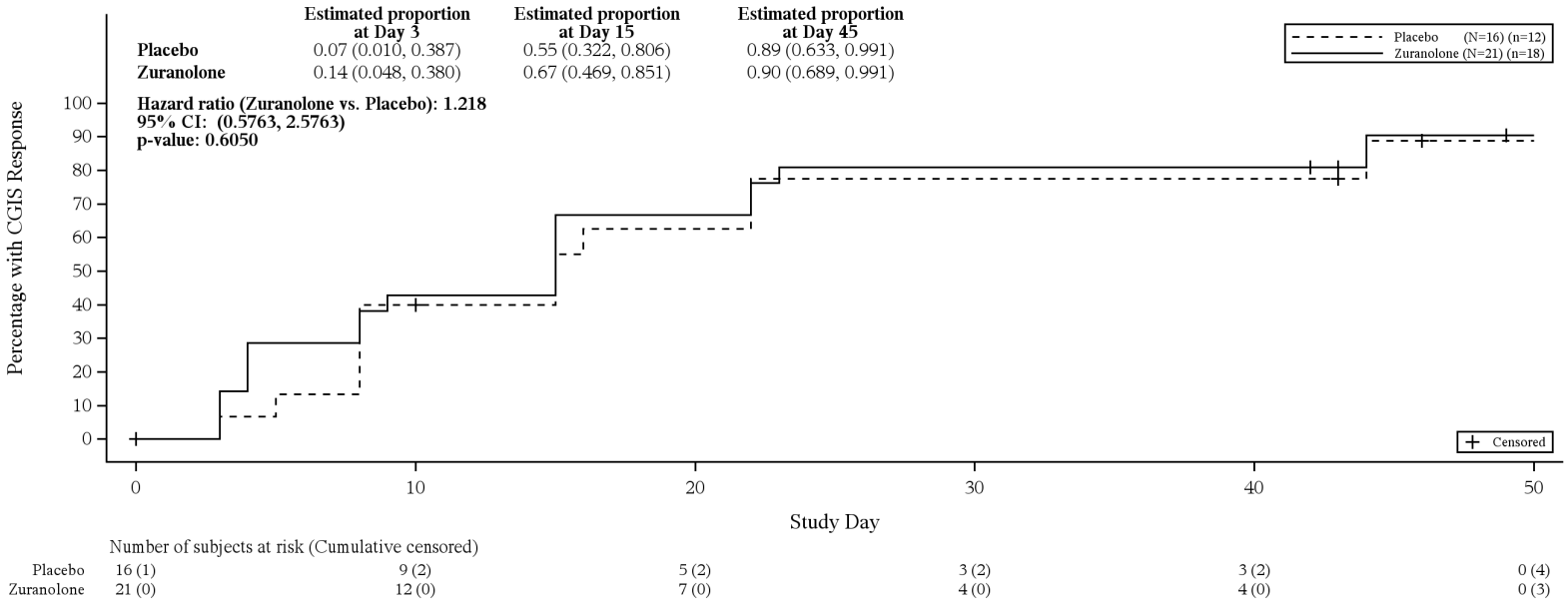
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant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

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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-301 - 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.

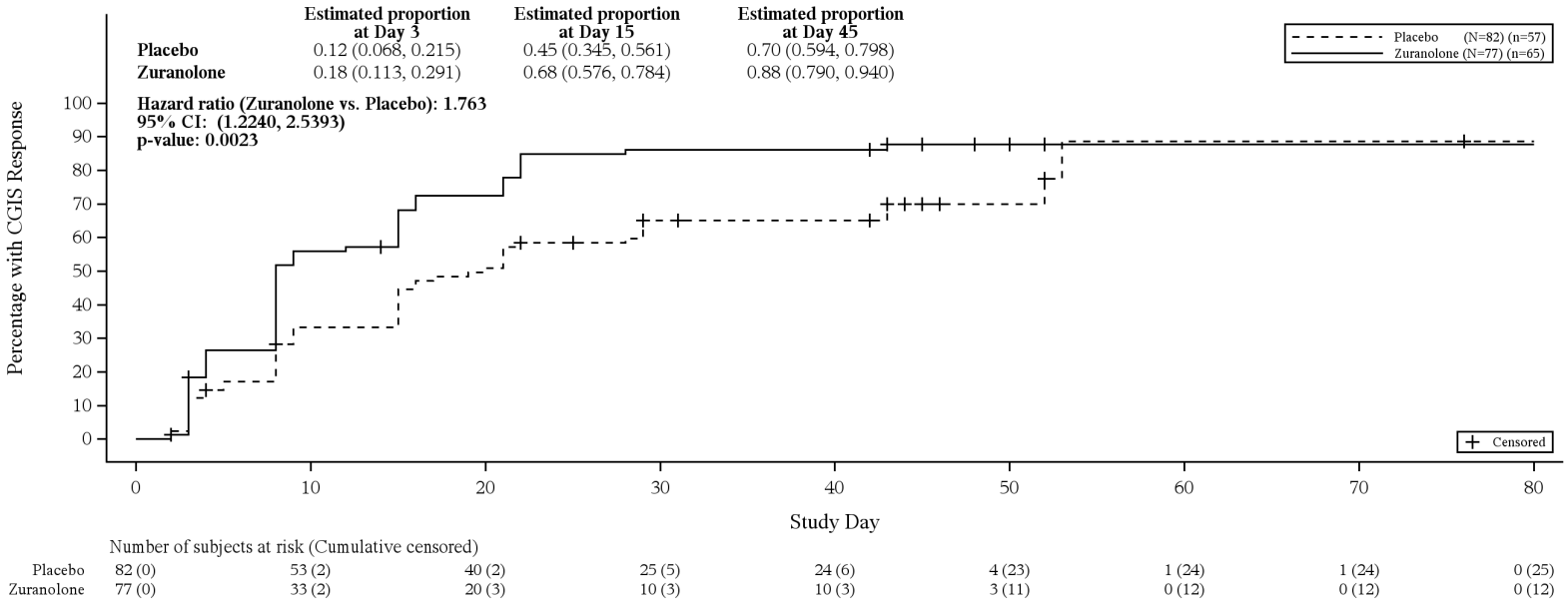
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Kaplan-Meier Plot for Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-301 - ITT population

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Family History of PPD = No/Unknown



Number of subjects at risk (Cumulative censored)

Placebo	82 (0)	53 (2)	40 (2)	25 (5)	24 (6)	4 (23)	1 (24)	1 (24)	0 (25)
Zuranolone	77 (0)	33 (2)	20 (3)	10 (3)	10 (3)	3 (11)	0 (12)	0 (12)	0 (12)

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.

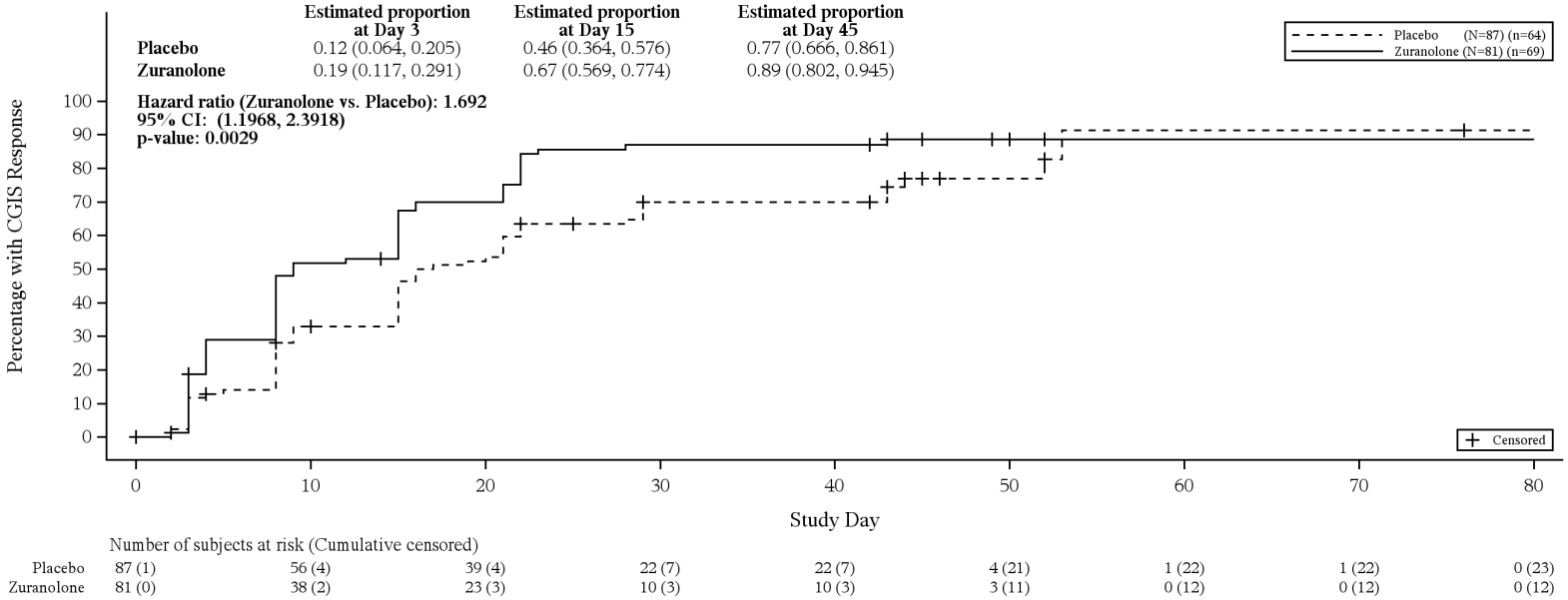
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Kaplan-Meier Plot for Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-301 - ITT population

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History of PPD = 1st Episode



Number of subjects at risk (Cumulative censored)

Placebo	87 (1)	56 (4)	39 (4)	22 (7)	22 (7)	4 (21)	1 (22)	1 (22)	0 (23)
Zuranolone	81 (0)	38 (2)	23 (3)	10 (3)	10 (3)	3 (11)	0 (12)	0 (12)	0 (12)

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.

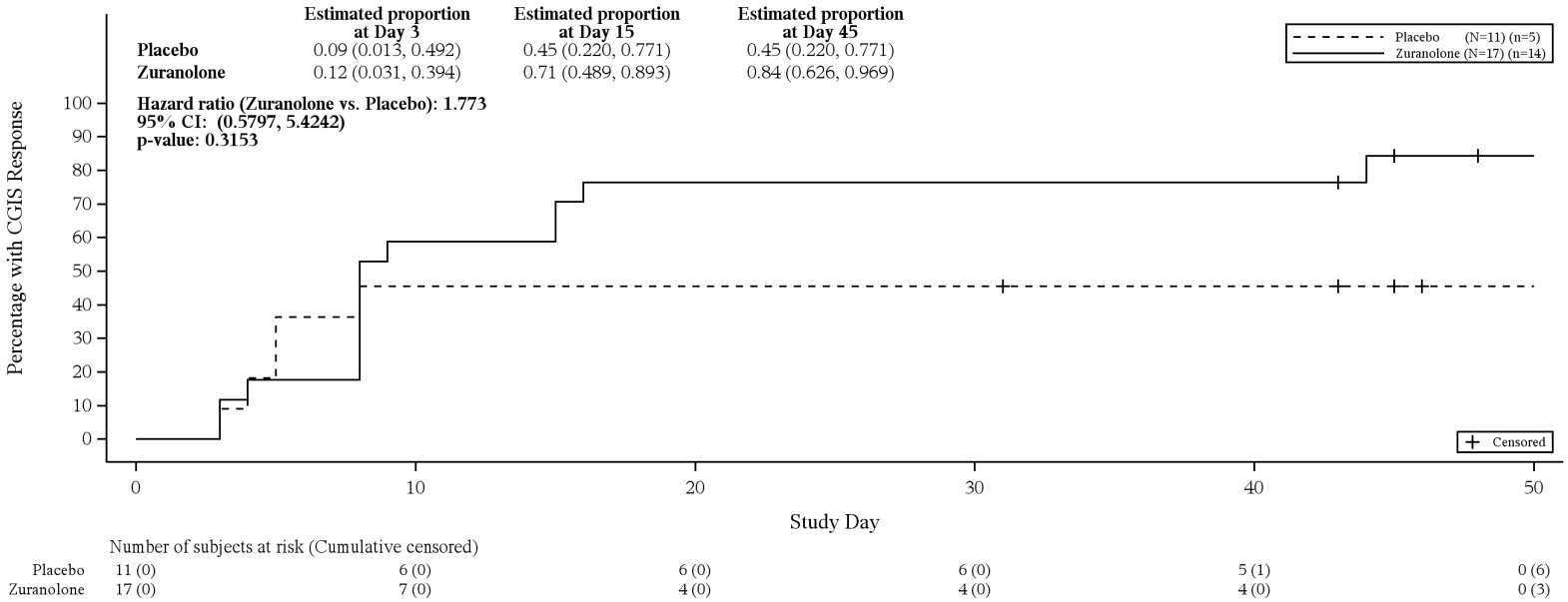
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Kaplan-Meier Plot for Time to First Clinical Global Impression - Severity (CGI-S) Response (>=15% of total scale range reduction from baseline) by Subgroup: 217-PPD-301 - ITT population

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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.

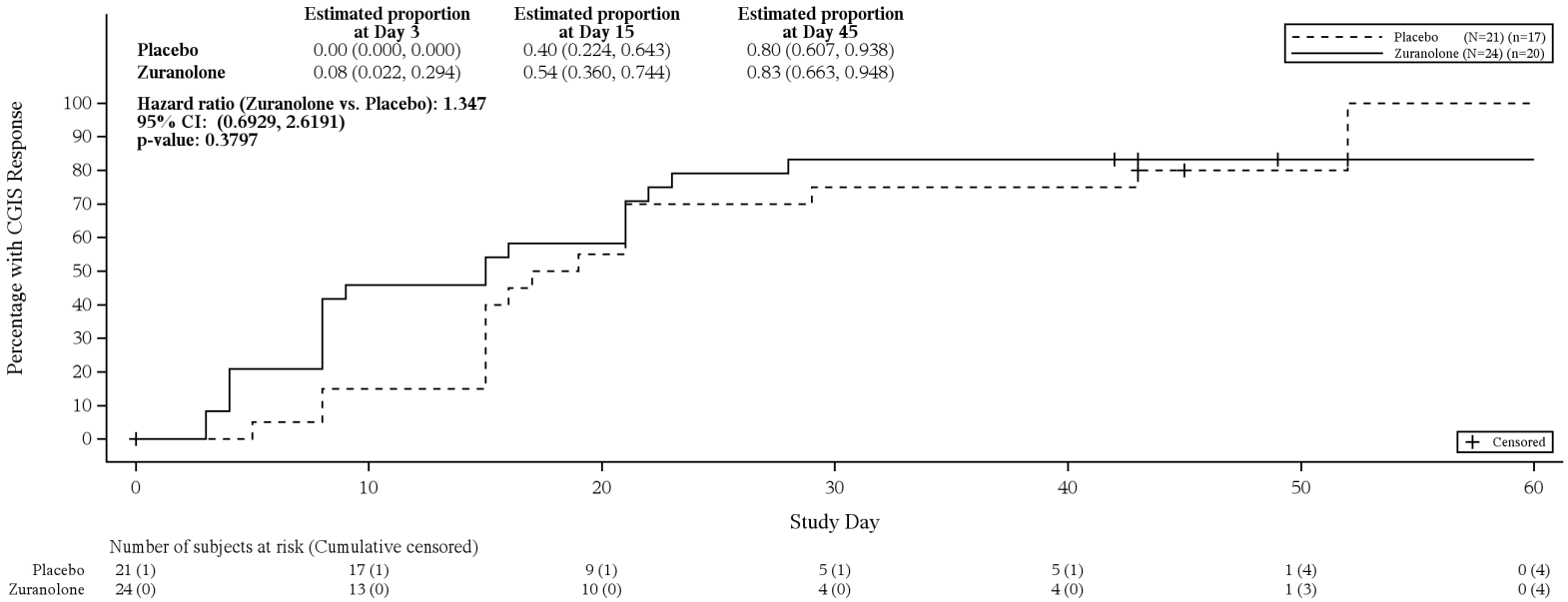
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant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

Source: biib125/v_a/amnog_kmplots/f-cgis-resp15-tte-301-by.sas:f-cgis-resp15-tte-301-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-301 - 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 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.

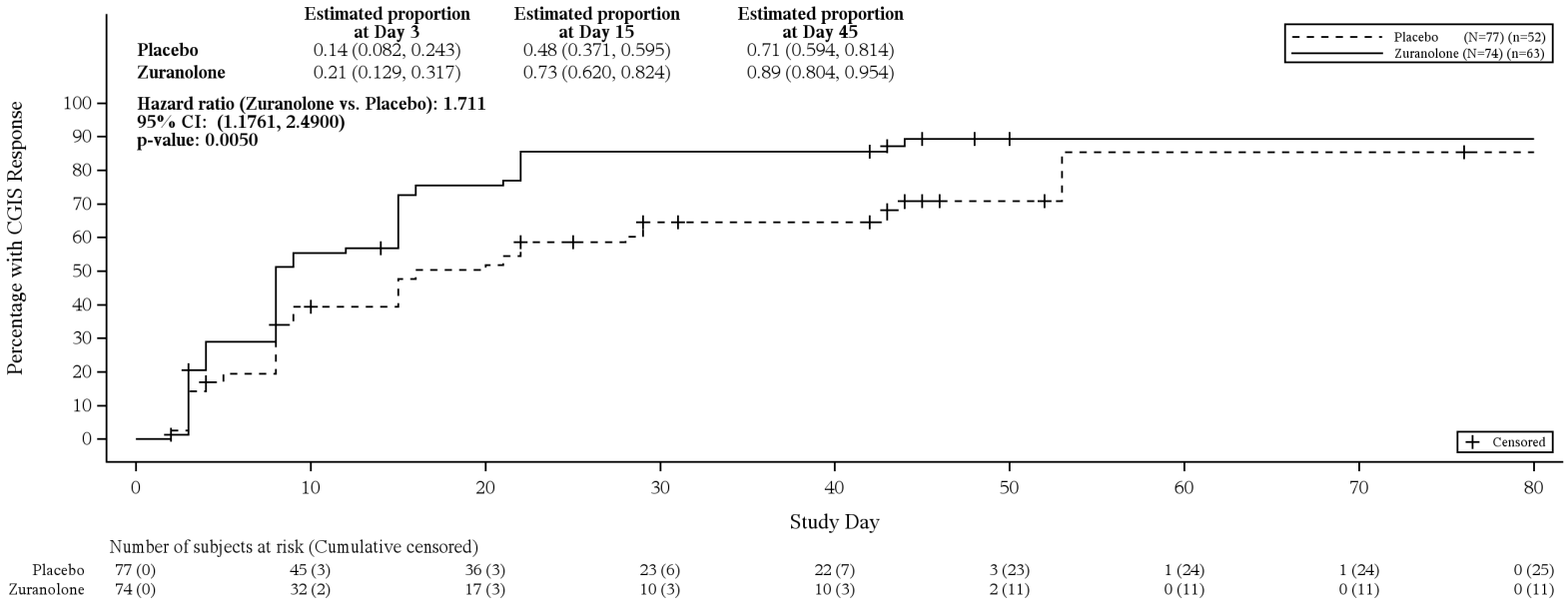
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant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

Source: biib125/v_a/amnog_kmplots/f-cgis-resp15-tte-301-by.sas:f-cgis-resp15-tte-301-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-301 - 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 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-301-by.sas:f-cgis-resp15-tte-301-by-itta.rtf **Run Date:** 08JAN2026

2.7 CGI-I

2.7.1 MMRM

Model-based Results on Change from Baseline in Clinical Global Impression - Improvement (CGI-I): 217-PPD-301 - ITT population

Page: 1 of 3

	Placebo (N=101)	Zuranolone (N=99)
Day 3		
n	95	98
LS Mean (SE)	-0.60 (0.092)	-1.02 (0.091)
95% CI for the LS Mean	-0.78, -0.42	-1.20, -0.84
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.42 (0.129)
95% CI for the LS Mean		-0.67, -0.16
p-value		0.0015
Hedges' g (Zuranolone vs. Placebo)		-0.462
95% CI for Hedges' g		-0.7478, -0.1759
Day 8		
n	95	93
LS Mean (SE)	-1.12 (0.105)	-1.59 (0.106)
95% CI for the LS Mean	-1.33, -0.92	-1.80, -1.38
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.47 (0.149)
95% CI for the LS Mean		-0.76, -0.17
p-value		0.0020
Hedges' g (Zuranolone vs. Placebo)		-0.455
95% CI for Hedges' g		-0.7447, -0.1656

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-301-ovr.sas:t-cgii-mmrm-301-ovr-itta.rtf **Run Date:** 18JUL2025

Model-based Results on Change from Baseline in Clinical Global Impression - Improvement (CGI-I): 217-PPD-301 - ITT population

Page: 2 of 3

	Placebo (N=101)	Zuranolone (N=99)
Day 15		
n	90	93
LS Mean (SE)	-1.38 (0.116)	-1.94 (0.115)
95% CI for the LS Mean	-1.61, -1.16	-2.17, -1.71
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.55 (0.163)
95% CI for the LS Mean		-0.88, -0.23
p-value		0.0008
Hedges' g (Zuranolone vs. Placebo)		-0.501
95% CI for Hedges' g		-0.7950, -0.2063
Day 21		
n	83	84
LS Mean (SE)	-1.59 (0.119)	-1.93 (0.119)
95% CI for the LS Mean	-1.82, -1.35	-2.17, -1.70
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.34 (0.169)
95% CI for the LS Mean		-0.68, -0.01
p-value		0.0426
Hedges' g (Zuranolone vs. Placebo)		-0.315
95% CI for Hedges' g		-0.6198, -0.0094

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-301-ovr.sas:t-cgii-mmrm-301-ovr-itta.rtf **Run Date:** 18JUL2025

Model-based Results on Change from Baseline in Clinical Global Impression - Improvement (CGI-I): 217-PPD-301 - ITT population

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	Placebo (N=101)	Zuranolone (N=99)
Day 28		
n	85	77
LS Mean (SE)	-1.56 (0.122)	-1.95 (0.125)
95% CI for the LS Mean	-1.80, -1.32	-2.20, -1.70
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.39 (0.174)
95% CI for the LS Mean		-0.73, -0.05
p-value		0.0264
Hedges' g (Zuranolone vs. Placebo)		-0.351
95% CI for Hedges' g		-0.6613, -0.0399
Day 45		
n	85	84
LS Mean (SE)	-1.83 (0.113)	-2.17 (0.113)
95% CI for the LS Mean	-2.05, -1.61	-2.39, -1.94
Difference (Zuranolone - Placebo)		
LS Mean (SE)		-0.33 (0.160)
95% CI for the LS Mean		-0.65, -0.02
p-value		0.0377
Hedges' g (Zuranolone vs. Placebo)		-0.321
95% CI for Hedges' g		-0.6241, -0.0172

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-301-ovr.sas:t-cgii-mmrm-301-ovr-itta.rtf **Run Date:** 18JUL2025

2.7.2 Ansprechen

2.7.2.1 Responder-Analysen

2.7.2.1 .1 ITT-Population

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved): 217-PPD-301 - ITT population

Page: 1 of 6

Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Number of evaluable subjects [1]	97	98
Day 3		
Number of subjects with a response, n (%) [2]	13 (13.4)	29 (29.6)
Number of subjects with missing evaluation, n (%)	2 (2.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.205
95% CI for the RR		(1.221, 3.982)
p-value for RR		0.0087
OR - Odds Ratio (Zuranolone vs. Placebo)		2.716
95% CI for the OR		(1.310, 5.631)
p-value for OR		0.0072
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.161
95% CI for the ARR		(0.048, 0.274)
p-value for ARR		0.0052

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-resp12-301-ovr.sas:t-cgii-resp12-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved): 217-PPD-301 - ITT population

Page: 2 of 6

Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 8		
Number of subjects with a response, n (%) [2]	30 (30.9)	55 (56.1)
Number of subjects with missing evaluation, n (%)	2 (2.1)	5 (5.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.812
95% CI for the RR		(1.282, 2.561)
p-value for RR		0.0008
OR - Odds Ratio (Zuranolone vs. Placebo)		2.857
95% CI for the OR		(1.588, 5.141)
p-value for OR		0.0005
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.252
95% CI for the ARR		(0.117, 0.387)
p-value for ARR		0.0002

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-resp12-301-ovr.sas:t-cgii-resp12-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved): 217-PPD-301 - ITT population

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Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 15		
Number of subjects with a response, n (%) [2]	42 (43.3)	62 (63.3)
Number of subjects with missing evaluation, n (%)	7 (7.2)	5 (5.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.452
95% CI for the RR		(1.105, 1.908)
p-value for RR		0.0074
OR - Odds Ratio (Zuranolone vs. Placebo)		2.253
95% CI for the OR		(1.267, 4.007)
p-value for OR		0.0057
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.199
95% CI for the ARR		(0.062, 0.337)
p-value for ARR		0.0044

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-resp12-301-ovr.sas:t-cgii-resp12-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved): 217-PPD-301 - ITT population

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Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 21		
Number of subjects with a response, n (%) [2]	45 (46.4)	60 (61.2)
Number of subjects with missing evaluation, n (%)	14 (14.4)	14 (14.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.317
95% CI for the RR		(1.010, 1.718)
p-value for RR		0.0418
OR - Odds Ratio (Zuranolone vs. Placebo)		1.822
95% CI for the OR		(1.031, 3.220)
p-value for OR		0.0388
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.148
95% CI for the ARR		(0.010, 0.287)
p-value for ARR		0.0356

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-resp12-301-ovr.sas:t-cgii-resp12-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved): 217-PPD-301 - ITT population

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Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 28		
Number of subjects with a response, n (%) [2]	48 (49.5)	56 (57.1)
Number of subjects with missing evaluation, n (%)	12 (12.4)	21 (21.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.152
95% CI for the RR		(0.884, 1.501)
p-value for RR		0.2945
OR - Odds Ratio (Zuranolone vs. Placebo)		1.359
95% CI for the OR		(0.772, 2.393)
p-value for OR		0.2884
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.076
95% CI for the ARR		(-0.063, 0.216)
p-value for ARR		0.2836

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-resp12-301-ovr.sas:t-cgii-resp12-301-ovr-itta.rtf **Run Date:** 18JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved): 217-PPD-301 - ITT population

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Study Visit Statistics	Placebo (N=101)	Zuranolone (N =99)
Day 45		
Number of subjects with a response, n (%) [2]	56 (57.7)	62 (63.3)
Number of subjects with missing evaluation, n (%)	12 (12.4)	14 (14.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.094
95% CI for the RR		(0.871, 1.373)
p-value for RR		0.4395
OR - Odds Ratio (Zuranolone vs. Placebo)		1.259
95% CI for the OR		(0.706, 2.245)
p-value for OR		0.4349
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.055
95% CI for the ARR		(-0.082, 0.192)
p-value for ARR		0.4321

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-resp12-301-ovr.sas:t-cgii-resp12-301-ovr-itta.rtf **Run Date:** 18JUL2025

2.7.2.1 .2 Subgruppen

2.7.2.1 .2 .1 Interaktionstest

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved): Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

Page: 1 of 6

Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	97	98	
Number of subjects with response at Day 15, n (%)	42 (43.3)	62 (63.3)	
Number of subjects with response at Day 45, n (%)	56 (57.7)	62 (63.3)	
Age Group (years)			0.6813
Day 15			
18 - 24, n / N (%)	6/12 (50.0)	12/19 (63.2)	
25 - 45, n / N (%)	36/85 (42.4)	50/79 (63.3)	
Day 45			
18 - 24, n / N (%)	7/12 (58.3)	16/19 (84.2)	
25 - 45, n / N (%)	49/85 (57.6)	46/79 (58.2)	

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 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.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-301-int.sas:t-cgii-resp12-301-int-itta.rtf **Run Date:** 18JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved): Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

Page: 2 of 6

Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			0.9781
Day 15			
<28, n / N (%)	16/32 (50.0)	18/33 (54.5)	
>=28, n / N (%)	26/65 (40.0)	44/65 (67.7)	
Day 45			
<28, n / N (%)	15/32 (46.9)	24/33 (72.7)	
>=28, n / N (%)	41/65 (63.1)	38/65 (58.5)	
Race Group (Black or African American, White)			0.1967
Day 15			
Black or African American, n / N (%)	7/17 (41.2)	14/25 (56.0)	
White, n / N (%)	31/69 (44.9)	47/68 (69.1)	
Day 45			
Black or African American, n / N (%)	6/17 (35.3)	15/25 (60.0)	
White, n / N (%)	44/69 (63.8)	44/68 (64.7)	

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.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-301-int.sas:t-cgii-resp12-301-int-itta.rtf **Run Date:** 18JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved): Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

Page: 3 of 6

Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			0.3767
Day 15			
Yes, n / N (%)	10/15 (66.7)	8/15 (53.3)	
No, n / N (%)	32/82 (39.0)	54/83 (65.1)	
Day 45			
Yes, n / N (%)	10/15 (66.7)	9/15 (60.0)	
No, n / N (%)	46/82 (56.1)	53/83 (63.9)	

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 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.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-301-int.sas:t-cgii-resp12-301-int-itta.rtf **Run Date:** 18JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved): Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

Page: 4 of 6

Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			0.2081(a) 0.3146(b) 0.6987(c)
Day 15			
<=24.9, n / N (%)	9/22 (40.9)	10/20 (50.0)	
25-29.9, n / N (%)	14/34 (41.2)	14/24 (58.3)	
>=30, n / N (%)	19/41 (46.3)	37/53 (69.8)	
Day 45			
<=24.9, n / N (%)	16/22 (72.7)	11/20 (55.0)	
25-29.9, n / N (%)	22/34 (64.7)	17/24 (70.8)	
>=30, n / N (%)	18/41 (43.9)	33/53 (62.3)	

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 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.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-301-int.sas:t-cgii-resp12-301-int-itta.rtf **Run Date:** 18JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved): Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Onset of PPD			0.5230
Day 15			
3rd Trimester, n / N (%)	14/30 (46.7)	21/34 (61.8)	
Postpartum, n / N (%)	28/67 (41.8)	41/64 (64.1)	
Day 45			
3rd Trimester, n / N (%)	16/30 (53.3)	22/34 (64.7)	
Postpartum, n / N (%)	40/67 (59.7)	40/64 (62.5)	
Family History of PPD			0.4732
Day 15			
Yes, n / N (%)	9/15 (60.0)	12/21 (57.1)	
No/Unknown, n / N (%)	33/82 (40.2)	50/77 (64.9)	
Day 45			
Yes, n / N (%)	11/15 (73.3)	13/21 (61.9)	
No/Unknown, n / N (%)	45/82 (54.9)	49/77 (63.6)	

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.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-301-int.sas:t-cgii-resp12-301-int-itta.rtf **Run Date:** 18JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved): Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
History of PPD			0.6782
Day 15			
1st Episode, n / N (%)	36/86 (41.9)	50/81 (61.7)	
Recurrent Episode, n / N (%)	6/11 (54.5)	12/17 (70.6)	
Day 45			
1st Episode, n / N (%)	51/86 (59.3)	50/81 (61.7)	
Recurrent Episode, n / N (%)	5/11 (45.5)	12/17 (70.6)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			0.4664
Day 15			
<20, n / N (%)	9/20 (45.0)	17/24 (70.8)	
>=20, n / N (%)	33/77 (42.9)	45/74 (60.8)	
Day 45			
<20, n / N (%)	15/20 (75.0)	18/24 (75.0)	
>=20, n / N (%)	41/77 (53.2)	44/74 (59.5)	

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.
Source: biib125/v_a/germany_amnog/t-cgii-resp12-301-int.sas:t-cgii-resp12-301-int-itta.rtf **Run Date:** 18JUL2025

2.7.2.1 .2 .2 Subgruppenanalysen

2.7.2.1 .2 .2 .1 Alter

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =19)
Number of evaluable subjects [1]	12	19
Day 3		
Number of subjects with a response, n (%) [2]	2 (16.7)	8 (42.1)
Number of subjects with missing evaluation, n (%)	1 (8.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.530
95% CI for the RR		(0.646, 9.904)
p-value for RR		0.1826
Day 8		
Number of subjects with a response, n (%) [2]	5 (41.7)	13 (68.4)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.644
95% CI for the RR		(0.794, 3.406)
p-value for RR		0.1807

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-resp12-301-by.sas:t-cgii-resp12-301-by-age-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =19)
Day 15		
Number of subjects with a response, n (%) [2]	6 (50.0)	12 (63.2)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.265
95% CI for the RR		(0.653, 2.451)
p-value for RR		0.4864
Day 21		
Number of subjects with a response, n (%) [2]	6 (50.0)	16 (84.2)
Number of subjects with missing evaluation, n (%)	2 (16.7)	1 (5.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.686
95% CI for the RR		(0.926, 3.070)
p-value for RR		0.0874

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-resp12-301-by.sas:t-cgii-resp12-301-by-age-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 18-24

Study Visit Statistics	Placebo (N=13)	Zuranolone (N =19)
Day 28		
Number of subjects with a response, n (%) [2]	8 (66.7)	14 (73.7)
Number of subjects with missing evaluation, n (%)	0	2 (10.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.107
95% CI for the RR		(0.681, 1.799)
p-value for RR		0.6824
Day 45		
Number of subjects with a response, n (%) [2]	7 (58.3)	16 (84.2)
Number of subjects with missing evaluation, n (%)	1 (8.3)	1 (5.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.446
95% CI for the RR		(0.858, 2.437)
p-value for RR		0.1667

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-resp12-301-by.sas:t-cgii-resp12-301-by-age-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=88)	Zuranolone (N =80)
Number of evaluable subjects [1]	85	79
Day 3		
Number of subjects with a response, n (%) [2]	11 (12.9)	21 (26.6)
Number of subjects with missing evaluation, n (%)	1 (1.2)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.054
95% CI for the RR		(1.058, 3.990)
p-value for RR		0.0335
Day 8		
Number of subjects with a response, n (%) [2]	25 (29.4)	42 (53.2)
Number of subjects with missing evaluation, n (%)	2 (2.4)	5 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.808
95% CI for the RR		(1.223, 2.672)
p-value for RR		0.0030

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-resp12-301-by.sas:t-cgii-resp12-301-by-age-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=88)	Zuranolone (N =80)
Day 15		
Number of subjects with a response, n (%) [2]	36 (42.4)	50 (63.3)
Number of subjects with missing evaluation, n (%)	7 (8.2)	5 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.495
95% CI for the RR		(1.108, 2.016)
p-value for RR		0.0084
Day 21		
Number of subjects with a response, n (%) [2]	39 (45.9)	44 (55.7)
Number of subjects with missing evaluation, n (%)	12 (14.1)	13 (16.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.214
95% CI for the RR		(0.897, 1.644)
p-value for RR		0.2092

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-resp12-301-by.sas:t-cgii-resp12-301-by-age-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 25-45

Study Visit Statistics	Placebo (N=88)	Zuranolone (N =80)
Day 28		
Number of subjects with a response, n (%) [2]	40 (47.1)	42 (53.2)
Number of subjects with missing evaluation, n (%)	12 (14.1)	19 (24.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.130
95% CI for the RR		(0.832, 1.535)
p-value for RR		0.4344
Day 45		
Number of subjects with a response, n (%) [2]	49 (57.6)	46 (58.2)
Number of subjects with missing evaluation, n (%)	11 (12.9)	13 (16.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.010
95% CI for the RR		(0.778, 1.312)
p-value for RR		0.9388

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-resp12-301-by.sas:t-cgii-resp12-301-by-age-itta.rtf **Run Date:** 25JUL2025

2.7.2.1 .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-301 - 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=32)	Zuranolone (N =33)
Number of evaluable subjects [1]	32	33
Day 3		
Number of subjects with a response, n (%) [2]	5 (15.6)	8 (24.2)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.568
95% CI for the RR		(0.568, 4.330)
p-value for RR		0.3853
Day 8		
Number of subjects with a response, n (%) [2]	10 (31.3)	16 (48.5)
Number of subjects with missing evaluation, n (%)	0	1 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.568
95% CI for the RR		(0.841, 2.925)
p-value for RR		0.1571

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-resp12-301-by.sas:t-cgii-resp12-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Baseline HAMD-17 Total Score: 217-PPD-301 - 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=32)	Zuranolone (N =33)
Day 15		
Number of subjects with a response, n (%) [2]	16 (50.0)	18 (54.5)
Number of subjects with missing evaluation, n (%)	2 (6.3)	1 (3.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.103
95% CI for the RR		(0.691, 1.761)
p-value for RR		0.6824
Day 21		
Number of subjects with a response, n (%) [2]	14 (43.8)	22 (66.7)
Number of subjects with missing evaluation, n (%)	5 (15.6)	2 (6.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.540
95% CI for the RR		(0.972, 2.440)
p-value for RR		0.0658

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-resp12-301-by.sas:t-cgii-resp12-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Baseline HAMD-17 Total Score: 217-PPD-301 - 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=32)	Zuranolone (N =33)
Day 28		
Number of subjects with a response, n (%) [2]	12 (37.5)	19 (57.6)
Number of subjects with missing evaluation, n (%)	6 (18.8)	5 (15.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.552
95% CI for the RR		(0.911, 2.642)
p-value for RR		0.1055
Day 45		
Number of subjects with a response, n (%) [2]	15 (46.9)	24 (72.7)
Number of subjects with missing evaluation, n (%)	5 (15.6)	3 (9.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.568
95% CI for the RR		(1.026, 2.398)
p-value for RR		0.0378

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-resp12-301-by.sas:t-cgii-resp12-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Baseline HAMD-17 Total Score: 217-PPD-301 - 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=66)	Zuranolone (N =65)
Number of evaluable subjects [1]	65	65
Day 3		
Number of subjects with a response, n (%) [2]	8 (12.3)	21 (32.3)
Number of subjects with missing evaluation, n (%)	2 (3.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.630
95% CI for the RR		(1.258, 5.497)
p-value for RR		0.0102
Day 8		
Number of subjects with a response, n (%) [2]	20 (30.8)	39 (60.0)
Number of subjects with missing evaluation, n (%)	2 (3.1)	4 (6.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.954
95% CI for the RR		(1.286, 2.967)
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 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-resp12-301-by.sas:t-cgii-resp12-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Baseline HAMD-17 Total Score: 217-PPD-301 - 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=66)	Zuranolone (N =65)
Day 15		
Number of subjects with a response, n (%) [2]	26 (40.0)	44 (67.7)
Number of subjects with missing evaluation, n (%)	5 (7.7)	4 (6.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.695
95% CI for the RR		(1.203, 2.389)
p-value for RR		0.0026
Day 21		
Number of subjects with a response, n (%) [2]	31 (47.7)	38 (58.5)
Number of subjects with missing evaluation, n (%)	9 (13.8)	12 (18.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.228
95% CI for the RR		(0.884, 1.705)
p-value for RR		0.2200

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-resp12-301-by.sas:t-cgii-resp12-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Baseline HAMD-17 Total Score: 217-PPD-301 - 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=66)	Zuranolone (N =65)
Day 28		
Number of subjects with a response, n (%) [2]	36 (55.4)	37 (56.9)
Number of subjects with missing evaluation, n (%)	6 (9.2)	16 (24.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.030
95% CI for the RR		(0.759, 1.398)
p-value for RR		0.8514
Day 45		
Number of subjects with a response, n (%) [2]	41 (63.1)	38 (58.5)
Number of subjects with missing evaluation, n (%)	7 (10.8)	11 (16.9)
RR - Relative Risk (Zuranolone vs. Placebo)		0.928
95% CI for the RR		(0.702, 1.227)
p-value for RR		0.6024

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-resp12-301-by.sas:t-cgii-resp12-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

2.7.2.1 .2 .2 .3 Abstammung

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Race Group: 217-PPD-301 - ITT population

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Race Group = Black or African American

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =26)
Number of evaluable subjects [1]	17	25
Day 3		
Number of subjects with a response, n (%) [2]	1 (5.9)	9 (36.0)
Number of subjects with missing evaluation, n (%)	1 (5.9)	0
RR - Relative Risk (Zuranolone vs. Placebo)		4.770
95% CI for the RR		(0.279, 81.523)
p-value for RR		0.2807
Day 8		
Number of subjects with a response, n (%) [2]	4 (23.5)	13 (52.0)
Number of subjects with missing evaluation, n (%)	1 (5.9)	2 (8.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.722
95% CI for the RR		(0.232, 12.781)
p-value for RR		0.5949

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-resp12-301-by.sas:t-cgii-resp12-301-by-race-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Race Group: 217-PPD-301 - ITT population

Page: 2 of 6

Race Group = Black or African American

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =26)
Day 15		
Number of subjects with a response, n (%) [2]	7 (41.2)	14 (56.0)
Number of subjects with missing evaluation, n (%)	3 (17.6)	3 (12.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.060
95% CI for the RR		(0.164, 6.851)
p-value for RR		0.9513
Day 21		
Number of subjects with a response, n (%) [2]	6 (35.3)	12 (48.0)
Number of subjects with missing evaluation, n (%)	6 (35.3)	7 (28.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.060
95% CI for the RR		(0.155, 7.271)
p-value for RR		0.9528

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-resp12-301-by.sas:t-cgii-resp12-301-by-race-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Race Group: 217-PPD-301 - ITT population

Page: 3 of 6

Race Group = Black or African American

Study Visit Statistics	Placebo (N=20)	Zuranolone (N =26)
Day 28		
Number of subjects with a response, n (%) [2]	5 (29.4)	15 (60.0)
Number of subjects with missing evaluation, n (%)	6 (35.3)	6 (24.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.590
95% CI for the RR		(0.212, 11.937)
p-value for RR		0.6521
Day 45		
Number of subjects with a response, n (%) [2]	6 (35.3)	15 (60.0)
Number of subjects with missing evaluation, n (%)	4 (23.5)	3 (12.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.325
95% CI for the RR		(0.186, 9.423)
p-value for RR		0.7787

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-resp12-301-by.sas:t-cgii-resp12-301-by-race-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Race Group: 217-PPD-301 - ITT population

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Race Group = White

Study Visit Statistics	Placebo (N=70)	Zuranolone (N =68)
Number of evaluable subjects [1]	69	68
Day 3		
Number of subjects with a response, n (%) [2]	10 (14.5)	19 (27.9)
Number of subjects with missing evaluation, n (%)	1 (1.4)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.928
95% CI for the RR		(0.969, 3.839)
p-value for RR		0.0616
Day 8		
Number of subjects with a response, n (%) [2]	23 (33.3)	41 (60.3)
Number of subjects with missing evaluation, n (%)	0	3 (4.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.809
95% CI for the RR		(1.231, 2.658)
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 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-resp12-301-by.sas:t-cgii-resp12-301-by-race-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Race Group: 217-PPD-301 - ITT population

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Race Group = White

Study Visit Statistics	Placebo (N=70)	Zuranolone (N =68)
Day 15		
Number of subjects with a response, n (%) [2]	31 (44.9)	47 (69.1)
Number of subjects with missing evaluation, n (%)	3 (4.3)	2 (2.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.539
95% CI for the RR		(1.134, 2.088)
p-value for RR		0.0057
Day 21		
Number of subjects with a response, n (%) [2]	35 (50.7)	46 (67.6)
Number of subjects with missing evaluation, n (%)	7 (10.1)	7 (10.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.334
95% CI for the RR		(1.002, 1.775)
p-value for RR		0.0482

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-resp12-301-by.sas:t-cgii-resp12-301-by-race-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Race Group: 217-PPD-301 - ITT population

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Race Group = White

Study Visit Statistics	Placebo (N=70)	Zuranolone (N =68)
Day 28		
Number of subjects with a response, n (%) [2]	38 (55.1)	38 (55.9)
Number of subjects with missing evaluation, n (%)	5 (7.2)	15 (22.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.015
95% CI for the RR		(0.753, 1.368)
p-value for RR		0.9227
Day 45		
Number of subjects with a response, n (%) [2]	44 (63.8)	44 (64.7)
Number of subjects with missing evaluation, n (%)	7 (10.1)	10 (14.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.015
95% CI for the RR		(0.792, 1.300)
p-value for RR		0.9067

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-resp12-301-by.sas:t-cgii-resp12-301-by-race-itta.rtf **Run Date:** 25JUL2025

2.7.2.1 .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-301 - ITT population

Page: 1 of 6

Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=15)	Zuranolone (N =15)
Number of evaluable subjects [1]	15	15
Day 3		
Number of subjects with a response, n (%) [2]	2 (13.3)	4 (26.7)
Number of subjects with missing evaluation, n (%)	1 (6.7)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.039
95% CI for the RR		(0.435, 9.549)
p-value for RR		0.3657
Day 8		
Number of subjects with a response, n (%) [2]	5 (33.3)	8 (53.3)
Number of subjects with missing evaluation, n (%)	0	1 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.631
95% CI for the RR		(0.666, 3.994)
p-value for RR		0.2841

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, "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-resp12-301-by.sas:t-cgii-resp12-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Baseline Antidepressant Use: 217-PPD-301 - ITT population

Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=15)	Zuranolone (N =15)
Day 15		
Number of subjects with a response, n (%) [2]	10 (66.7)	8 (53.3)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.816
95% CI for the RR		(0.448, 1.486)
p-value for RR		0.5057
Day 21		
Number of subjects with a response, n (%) [2]	9 (60.0)	10 (66.7)
Number of subjects with missing evaluation, n (%)	1 (6.7)	1 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.133
95% CI for the RR		(0.645, 1.990)
p-value for RR		0.6642

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, "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-resp12-301-by.sas:t-cgii-resp12-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Baseline Antidepressant Use: 217-PPD-301 - ITT population

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Antidepressant Use at Baseline = Yes

Study Visit Statistics	Placebo (N=15)	Zuranolone (N =15)
Day 28		
Number of subjects with a response, n (%) [2]	8 (53.3)	8 (53.3)
Number of subjects with missing evaluation, n (%)	2 (13.3)	1 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.020
95% CI for the RR		(0.518, 2.009)
p-value for RR		0.9553
Day 45		
Number of subjects with a response, n (%) [2]	10 (66.7)	9 (60.0)
Number of subjects with missing evaluation, n (%)	1 (6.7)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.918
95% CI for the RR		(0.525, 1.605)
p-value for RR		0.7631

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, "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-resp12-301-by.sas:t-cgii-resp12-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Baseline Antidepressant Use: 217-PPD-301 - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=86)	Zuranolone (N =84)
Number of evaluable subjects [1]	82	83
Day 3		
Number of subjects with a response, n (%) [2]	11 (13.4)	25 (30.1)
Number of subjects with missing evaluation, n (%)	1 (1.2)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.245
95% CI for the RR		(1.184, 4.259)
p-value for RR		0.0133
Day 8		
Number of subjects with a response, n (%) [2]	25 (30.5)	47 (56.6)
Number of subjects with missing evaluation, n (%)	2 (2.4)	4 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.857
95% CI for the RR		(1.274, 2.707)
p-value for RR		0.0013

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, "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-resp12-301-by.sas:t-cgii-resp12-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Baseline Antidepressant Use: 217-PPD-301 - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=86)	Zuranolone (N =84)
Day 15		
Number of subjects with a response, n (%) [2]	32 (39.0)	54 (65.1)
Number of subjects with missing evaluation, n (%)	7 (8.5)	5 (6.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.667
95% CI for the RR		(1.219, 2.280)
p-value for RR		0.0014
Day 21		
Number of subjects with a response, n (%) [2]	36 (43.9)	50 (60.2)
Number of subjects with missing evaluation, n (%)	13 (15.9)	13 (15.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.372
95% CI for the RR		(1.016, 1.853)
p-value for RR		0.0390

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, "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-resp12-301-by.sas:t-cgii-resp12-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Baseline Antidepressant Use: 217-PPD-301 - ITT population

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Antidepressant Use at Baseline = No

Study Visit Statistics	Placebo (N=86)	Zuranolone (N =84)
Day 28		
Number of subjects with a response, n (%) [2]	40 (48.8)	48 (57.8)
Number of subjects with missing evaluation, n (%)	10 (12.2)	20 (24.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.185
95% CI for the RR		(0.889, 1.581)
p-value for RR		0.2472
Day 45		
Number of subjects with a response, n (%) [2]	46 (56.1)	53 (63.9)
Number of subjects with missing evaluation, n (%)	11 (13.4)	14 (16.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.138
95% CI for the RR		(0.885, 1.463)
p-value for RR		0.3124

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, "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-resp12-301-by.sas:t-cgii-resp12-301-by-adt-itta.rtf **Run Date:** 25JUL2025

2.7.2.1 .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-301 - ITT population

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

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =20)
Number of evaluable subjects [1]	22	20
Day 3		
Number of subjects with a response, n (%) [2]	3 (13.6)	6 (30.0)
Number of subjects with missing evaluation, n (%)	1 (4.5)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.217
95% CI for the RR		(0.634, 7.758)
p-value for RR		0.2128
Day 8		
Number of subjects with a response, n (%) [2]	8 (36.4)	8 (40.0)
Number of subjects with missing evaluation, n (%)	0	2 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.109
95% CI for the RR		(0.506, 2.430)
p-value for RR		0.7968

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-resp12-301-by.sas:t-cgii-resp12-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Baseline BMI (kg/m^2) Group: 217-PPD-301 - ITT population

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

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =20)
Day 15		
Number of subjects with a response, n (%) [2]	9 (40.9)	10 (50.0)
Number of subjects with missing evaluation, n (%)	1 (4.5)	2 (10.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.232
95% CI for the RR		(0.628, 2.415)
p-value for RR		0.5440
Day 21		
Number of subjects with a response, n (%) [2]	11 (50.0)	14 (70.0)
Number of subjects with missing evaluation, n (%)	4 (18.2)	4 (20.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.411
95% CI for the RR		(0.838, 2.375)
p-value for RR		0.1950

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-resp12-301-by.sas:t-cgii-resp12-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Baseline BMI (kg/m^2) Group: 217-PPD-301 - ITT population

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

Study Visit Statistics	Placebo (N=22)	Zuranolone (N =20)
Day 28		
Number of subjects with a response, n (%) [2]	12 (54.5)	8 (40.0)
Number of subjects with missing evaluation, n (%)	1 (4.5)	8 (40.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.739
95% CI for the RR		(0.380, 1.438)
p-value for RR		0.3732
Day 45		
Number of subjects with a response, n (%) [2]	16 (72.7)	11 (55.0)
Number of subjects with missing evaluation, n (%)	0	5 (25.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.762
95% CI for the RR		(0.469, 1.240)
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 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-resp12-301-by.sas:t-cgii-resp12-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Baseline BMI (kg/m^2) Group: 217-PPD-301 - ITT population

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

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =24)
Number of evaluable subjects [1]	34	24
Day 3		
Number of subjects with a response, n (%) [2]	2 (5.9)	7 (29.2)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		4.935
95% CI for the RR		(1.119, 21.753)
p-value for RR		0.0349
Day 8		
Number of subjects with a response, n (%) [2]	10 (29.4)	14 (58.3)
Number of subjects with missing evaluation, n (%)	2 (5.9)	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.974
95% CI for the RR		(1.064, 3.661)
p-value for RR		0.0310

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-resp12-301-by.sas:t-cgii-resp12-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Baseline BMI (kg/m^2) Group: 217-PPD-301 - ITT population

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

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =24)
Day 15		
Number of subjects with a response, n (%) [2]	14 (41.2)	14 (58.3)
Number of subjects with missing evaluation, n (%)	4 (11.8)	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.410
95% CI for the RR		(0.843, 2.358)
p-value for RR		0.1903
Day 21		
Number of subjects with a response, n (%) [2]	18 (52.9)	16 (66.7)
Number of subjects with missing evaluation, n (%)	6 (17.6)	3 (12.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.253
95% CI for the RR		(0.837, 1.876)
p-value for RR		0.2726

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-resp12-301-by.sas:t-cgii-resp12-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Baseline BMI (kg/m^2) Group: 217-PPD-301 - ITT population

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

Study Visit Statistics	Placebo (N=34)	Zuranolone (N =24)
Day 28		
Number of subjects with a response, n (%) [2]	19 (55.9)	17 (70.8)
Number of subjects with missing evaluation, n (%)	5 (14.7)	4 (16.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.262
95% CI for the RR		(0.858, 1.855)
p-value for RR		0.2374
Day 45		
Number of subjects with a response, n (%) [2]	22 (64.7)	17 (70.8)
Number of subjects with missing evaluation, n (%)	6 (17.6)	4 (16.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.089
95% CI for the RR		(0.774, 1.533)
p-value for RR		0.6228

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-resp12-301-by.sas:t-cgii-resp12-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Baseline BMI (kg/m^2) Group: 217-PPD-301 - ITT population

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

Study Visit Statistics	Placebo (N=42)	Zuranolone (N =53)
Number of evaluable subjects [1]	41	53
Day 3		
Number of subjects with a response, n (%) [2]	8 (19.5)	16 (30.2)
Number of subjects with missing evaluation, n (%)	1 (2.4)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.521
95% CI for the RR		(0.721, 3.209)
p-value for RR		0.2711
Day 8		
Number of subjects with a response, n (%) [2]	12 (29.3)	32 (60.4)
Number of subjects with missing evaluation, n (%)	0	2 (3.8)
RR - Relative Risk (Zuranolone vs. Placebo)		2.028
95% CI for the RR		(1.200, 3.428)
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 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-resp12-301-by.sas:t-cgii-resp12-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Baseline BMI (kg/m^2) Group: 217-PPD-301 - ITT population

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

Study Visit Statistics	Placebo (N=42)	Zuranolone (N =53)
Day 15		
Number of subjects with a response, n (%) [2]	19 (46.3)	37 (69.8)
Number of subjects with missing evaluation, n (%)	2 (4.9)	2 (3.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.481
95% CI for the RR		(1.018, 2.155)
p-value for RR		0.0402
Day 21		
Number of subjects with a response, n (%) [2]	16 (39.0)	29 (54.7)
Number of subjects with missing evaluation, n (%)	4 (9.8)	7 (13.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.378
95% CI for the RR		(0.873, 2.175)
p-value for RR		0.1680

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-resp12-301-by.sas:t-cgii-resp12-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Baseline BMI (kg/m^2) Group: 217-PPD-301 - ITT population

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

Study Visit Statistics	Placebo (N=42)	Zuranolone (N =53)
Day 28		
Number of subjects with a response, n (%) [2]	17 (41.5)	30 (56.6)
Number of subjects with missing evaluation, n (%)	6 (14.6)	9 (17.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.342
95% CI for the RR		(0.868, 2.074)
p-value for RR		0.1855
Day 45		
Number of subjects with a response, n (%) [2]	18 (43.9)	33 (62.3)
Number of subjects with missing evaluation, n (%)	6 (14.6)	5 (9.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.394
95% CI for the RR		(0.924, 2.104)
p-value for RR		0.1136

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-resp12-301-by.sas:t-cgii-resp12-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

2.7.2.1 .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-301 - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =35)
Number of evaluable subjects [1]	30	34
Day 3		
Number of subjects with a response, n (%) [2]	5 (16.7)	13 (38.2)
Number of subjects with missing evaluation, n (%)	1 (3.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.346
95% CI for the RR		(0.939, 5.860)
p-value for RR		0.0680
Day 8		
Number of subjects with a response, n (%) [2]	9 (30.0)	22 (64.7)
Number of subjects with missing evaluation, n (%)	2 (6.7)	2 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		2.205
95% CI for the RR		(1.213, 4.009)
p-value for RR		0.0095

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-resp12-301-by.sas:t-cgii-resp12-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =35)
Day 15		
Number of subjects with a response, n (%) [2]	14 (46.7)	21 (61.8)
Number of subjects with missing evaluation, n (%)	3 (10.0)	3 (8.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.353
95% CI for the RR		(0.849, 2.156)
p-value for RR		0.2030
Day 21		
Number of subjects with a response, n (%) [2]	13 (43.3)	24 (70.6)
Number of subjects with missing evaluation, n (%)	5 (16.7)	5 (14.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.666
95% CI for the RR		(1.044, 2.657)
p-value for RR		0.0322

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-resp12-301-by.sas:t-cgii-resp12-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = 3rd trimester

Study Visit Statistics	Placebo (N=32)	Zuranolone (N =35)
Day 28		
Number of subjects with a response, n (%) [2]	12 (40.0)	19 (55.9)
Number of subjects with missing evaluation, n (%)	5 (16.7)	8 (23.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.429
95% CI for the RR		(0.844, 2.419)
p-value for RR		0.1845
Day 45		
Number of subjects with a response, n (%) [2]	16 (53.3)	22 (64.7)
Number of subjects with missing evaluation, n (%)	5 (16.7)	7 (20.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.241
95% CI for the RR		(0.818, 1.881)
p-value for RR		0.3102

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-resp12-301-by.sas:t-cgii-resp12-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=69)	Zuranolone (N =64)
Number of evaluable subjects [1]	67	64
Day 3		
Number of subjects with a response, n (%) [2]	8 (11.9)	16 (25.0)
Number of subjects with missing evaluation, n (%)	1 (1.5)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.112
95% CI for the RR		(0.970, 4.602)
p-value for RR		0.0598
Day 8		
Number of subjects with a response, n (%) [2]	21 (31.3)	33 (51.6)
Number of subjects with missing evaluation, n (%)	0	3 (4.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.660
95% CI for the RR		(1.079, 2.553)
p-value for RR		0.0211

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-resp12-301-by.sas:t-cgii-resp12-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=69)	Zuranolone (N =64)
Day 15		
Number of subjects with a response, n (%) [2]	28 (41.8)	41 (64.1)
Number of subjects with missing evaluation, n (%)	4 (6.0)	2 (3.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.547
95% CI for the RR		(1.103, 2.168)
p-value for RR		0.0114
Day 21		
Number of subjects with a response, n (%) [2]	32 (47.8)	36 (56.3)
Number of subjects with missing evaluation, n (%)	9 (13.4)	9 (14.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.188
95% CI for the RR		(0.851, 1.658)
p-value for RR		0.3108

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-resp12-301-by.sas:t-cgii-resp12-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Onset of PPD: 217-PPD-301 - ITT population

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Onset of PPD = Postpartum

Study Visit Statistics	Placebo (N=69)	Zuranolone (N =64)
Day 28		
Number of subjects with a response, n (%) [2]	36 (53.7)	37 (57.8)
Number of subjects with missing evaluation, n (%)	7 (10.4)	13 (20.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.085
95% CI for the RR		(0.798, 1.477)
p-value for RR		0.6018
Day 45		
Number of subjects with a response, n (%) [2]	40 (59.7)	40 (62.5)
Number of subjects with missing evaluation, n (%)	7 (10.4)	7 (10.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.056
95% CI for the RR		(0.802, 1.390)
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 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-resp12-301-by.sas:t-cgii-resp12-301-by-onset-itta.rtf **Run Date:** 25JUL2025

2.7.2.1 .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-301 - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =21)
Number of evaluable subjects [1]	15	21
Day 3		
Number of subjects with a response, n (%) [2]	2 (13.3)	7 (33.3)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.483
95% CI for the RR		(0.598, 10.307)
p-value for RR		0.2105
Day 8		
Number of subjects with a response, n (%) [2]	6 (40.0)	11 (52.4)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.301
95% CI for the RR		(0.618, 2.737)
p-value for RR		0.4888

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-resp12-301-by.sas:t-cgii-resp12-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Family History of PPD: 217-PPD-301 - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =21)
Day 15		
Number of subjects with a response, n (%) [2]	9 (60.0)	12 (57.1)
Number of subjects with missing evaluation, n (%)	2 (13.3)	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		0.946
95% CI for the RR		(0.544, 1.643)
p-value for RR		0.8434
Day 21		
Number of subjects with a response, n (%) [2]	9 (60.0)	15 (71.4)
Number of subjects with missing evaluation, n (%)	2 (13.3)	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.182
95% CI for the RR		(0.727, 1.923)
p-value for RR		0.4999

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-resp12-301-by.sas:t-cgii-resp12-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Family History of PPD: 217-PPD-301 - ITT population

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Family History of PPD = Yes

Study Visit Statistics	Placebo (N=16)	Zuranolone (N =21)
Day 28		
Number of subjects with a response, n (%) [2]	9 (60.0)	14 (66.7)
Number of subjects with missing evaluation, n (%)	3 (20.0)	3 (14.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.103
95% CI for the RR		(0.660, 1.844)
p-value for RR		0.7069
Day 45		
Number of subjects with a response, n (%) [2]	11 (73.3)	13 (61.9)
Number of subjects with missing evaluation, n (%)	2 (13.3)	2 (9.5)
RR - Relative Risk (Zuranolone vs. Placebo)		0.838
95% CI for the RR		(0.542, 1.297)
p-value for RR		0.4280

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-resp12-301-by.sas:t-cgii-resp12-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Family History of PPD: 217-PPD-301 - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=85)	Zuranolone (N =78)
Number of evaluable subjects [1]	82	77
Day 3		
Number of subjects with a response, n (%) [2]	11 (13.4)	22 (28.6)
Number of subjects with missing evaluation, n (%)	2 (2.4)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.122
95% CI for the RR		(1.104, 4.081)
p-value for RR		0.0241
Day 8		
Number of subjects with a response, n (%) [2]	24 (29.3)	44 (57.1)
Number of subjects with missing evaluation, n (%)	2 (2.4)	5 (6.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.946
95% CI for the RR		(1.318, 2.871)
p-value for RR		0.0008

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.
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Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Family History of PPD: 217-PPD-301 - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=85)	Zuranolone (N =78)
Day 15		
Number of subjects with a response, n (%) [2]	33 (40.2)	50 (64.9)
Number of subjects with missing evaluation, n (%)	5 (6.1)	4 (5.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.608
95% CI for the RR		(1.177, 2.196)
p-value for RR		0.0028
Day 21		
Number of subjects with a response, n (%) [2]	36 (43.9)	45 (58.4)
Number of subjects with missing evaluation, n (%)	12 (14.6)	13 (16.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.327
95% CI for the RR		(0.974, 1.806)
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 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-resp12-301-by.sas:t-cgii-resp12-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Family History of PPD: 217-PPD-301 - ITT population

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Family History of PPD = No

Study Visit Statistics	Placebo (N=85)	Zuranolone (N =78)
Day 28		
Number of subjects with a response, n (%) [2]	39 (47.6)	42 (54.5)
Number of subjects with missing evaluation, n (%)	9 (11.0)	18 (23.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.143
95% CI for the RR		(0.841, 1.552)
p-value for RR		0.3928
Day 45		
Number of subjects with a response, n (%) [2]	45 (54.9)	49 (63.6)
Number of subjects with missing evaluation, n (%)	10 (12.2)	12 (15.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.156
95% CI for the RR		(0.890, 1.500)
p-value for RR		0.2773

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-resp12-301-by.sas:t-cgii-resp12-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

2.7.2.1 .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-301 - ITT population

Page: 1 of 6

History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=90)	Zuranolone (N =82)
Number of evaluable subjects [1]	86	81
Day 3		
Number of subjects with a response, n (%) [2]	9 (10.5)	25 (30.9)
Number of subjects with missing evaluation, n (%)	2 (2.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.969
95% CI for the RR		(1.475, 5.979)
p-value for RR		0.0023
Day 8		
Number of subjects with a response, n (%) [2]	26 (30.2)	45 (55.6)
Number of subjects with missing evaluation, n (%)	2 (2.3)	5 (6.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.850
95% CI for the RR		(1.269, 2.696)
p-value for RR		0.0014

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-resp12-301-by.sas:t-cgii-resp12-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by History of PPD: 217-PPD-301 - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=90)	Zuranolone (N =82)
Day 15		
Number of subjects with a response, n (%) [2]	36 (41.9)	50 (61.7)
Number of subjects with missing evaluation, n (%)	7 (8.1)	5 (6.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.485
95% CI for the RR		(1.098, 2.008)
p-value for RR		0.0103
Day 21		
Number of subjects with a response, n (%) [2]	40 (46.5)	51 (63.0)
Number of subjects with missing evaluation, n (%)	13 (15.1)	13 (16.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.363
95% CI for the RR		(1.031, 1.802)
p-value for RR		0.0299

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-resp12-301-by.sas:t-cgii-resp12-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by History of PPD: 217-PPD-301 - ITT population

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History of PPD = 1st Episode

Study Visit Statistics	Placebo (N=90)	Zuranolone (N =82)
Day 28		
Number of subjects with a response, n (%) [2]	44 (51.2)	43 (53.1)
Number of subjects with missing evaluation, n (%)	12 (14.0)	21 (25.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.045
95% CI for the RR		(0.781, 1.398)
p-value for RR		0.7689
Day 45		
Number of subjects with a response, n (%) [2]	51 (59.3)	50 (61.7)
Number of subjects with missing evaluation, n (%)	11 (12.8)	13 (16.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.048
95% CI for the RR		(0.820, 1.339)
p-value for RR		0.7079

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-resp12-301-by.sas:t-cgii-resp12-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by History of PPD: 217-PPD-301 - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=11)	Zuranolone (N =17)
Number of evaluable subjects [1]	11	17
Day 3		
Number of subjects with a response, n (%) [2]	4 (36.4)	4 (23.5)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.654
95% CI for the RR		(0.199, 2.145)
p-value for RR		0.4832
Day 8		
Number of subjects with a response, n (%) [2]	4 (36.4)	10 (58.8)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.634
95% CI for the RR		(0.687, 3.890)
p-value for RR		0.2669

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-resp12-301-by.sas:t-cgii-resp12-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by History of PPD: 217-PPD-301 - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=11)	Zuranolone (N =17)
Day 15		
Number of subjects with a response, n (%) [2]	6 (54.5)	12 (70.6)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.308
95% CI for the RR		(0.725, 2.357)
p-value for RR		0.3724
Day 21		
Number of subjects with a response, n (%) [2]	5 (45.5)	9 (52.9)
Number of subjects with missing evaluation, n (%)	1 (9.1)	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.177
95% CI for the RR		(0.574, 2.412)
p-value for RR		0.6567

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-resp12-301-by.sas:t-cgii-resp12-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by History of PPD: 217-PPD-301 - ITT population

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History of PPD = Recurrent Episode

Study Visit Statistics	Placebo (N=11)	Zuranolone (N =17)
Day 28		
Number of subjects with a response, n (%) [2]	4 (36.4)	13 (76.5)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		2.125
95% CI for the RR		(0.994, 4.542)
p-value for RR		0.0518
Day 45		
Number of subjects with a response, n (%) [2]	5 (45.5)	12 (70.6)
Number of subjects with missing evaluation, n (%)	1 (9.1)	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.569
95% CI for the RR		(0.811, 3.037)
p-value for RR		0.1812

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-resp12-301-by.sas:t-cgii-resp12-301-by-hist-itta.rtf **Run Date:** 25JUL2025

2.7.2.1 .2 .2 .9 Depression mit Angst

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =24)
Number of evaluable subjects [1]	20	24
Day 3		
Number of subjects with a response, n (%) [2]	1 (5.0)	6 (25.0)
Number of subjects with missing evaluation, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		4.991
95% CI for the RR		(0.658, 37.873)
p-value for RR		0.1200
Day 8		
Number of subjects with a response, n (%) [2]	4 (20.0)	13 (54.2)
Number of subjects with missing evaluation, n (%)	0	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		2.704
95% CI for the RR		(1.048, 6.972)
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 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-resp12-301-by.sas:t-cgii-resp12-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =24)
Day 15		
Number of subjects with a response, n (%) [2]	9 (45.0)	17 (70.8)
Number of subjects with missing evaluation, n (%)	0	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.571
95% CI for the RR		(0.915, 2.698)
p-value for RR		0.1014
Day 21		
Number of subjects with a response, n (%) [2]	10 (50.0)	20 (83.3)
Number of subjects with missing evaluation, n (%)	2 (10.0)	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.664
95% CI for the RR		(1.048, 2.642)
p-value for RR		0.0310

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-resp12-301-by.sas:t-cgii-resp12-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

Study Visit Statistics	Placebo (N=21)	Zuranolone (N =24)
Day 28		
Number of subjects with a response, n (%) [2]	13 (65.0)	13 (54.2)
Number of subjects with missing evaluation, n (%)	1 (5.0)	5 (20.8)
RR - Relative Risk (Zuranolone vs. Placebo)		0.832
95% CI for the RR		(0.511, 1.353)
p-value for RR		0.4582
Day 45		
Number of subjects with a response, n (%) [2]	15 (75.0)	18 (75.0)
Number of subjects with missing evaluation, n (%)	0	3 (12.5)
RR - Relative Risk (Zuranolone vs. Placebo)		0.998
95% CI for the RR		(0.723, 1.379)
p-value for RR		0.9915

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-resp12-301-by.sas:t-cgii-resp12-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

Study Visit Statistics	Placebo (N=77)	Zuranolone (N =74)
Number of evaluable subjects [1]	77	74
Day 3		
Number of subjects with a response, n (%) [2]	12 (15.6)	23 (31.1)
Number of subjects with missing evaluation, n (%)	2 (2.6)	0
RR - Relative Risk (Zuranolone vs. Placebo)		1.990
95% CI for the RR		(1.068, 3.707)
p-value for RR		0.0301
Day 8		
Number of subjects with a response, n (%) [2]	26 (33.8)	42 (56.8)
Number of subjects with missing evaluation, n (%)	2 (2.6)	4 (5.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.677
95% CI for the RR		(1.158, 2.430)
p-value for RR		0.0063

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-resp12-301-by.sas:t-cgii-resp12-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

Study Visit Statistics	Placebo (N=77)	Zuranolone (N =74)
Day 15		
Number of subjects with a response, n (%) [2]	33 (42.9)	45 (60.8)
Number of subjects with missing evaluation, n (%)	7 (9.1)	4 (5.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.416
95% CI for the RR		(1.031, 1.944)
p-value for RR		0.0314
Day 21		
Number of subjects with a response, n (%) [2]	35 (45.5)	40 (54.1)
Number of subjects with missing evaluation, n (%)	12 (15.6)	13 (17.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.187
95% CI for the RR		(0.861, 1.635)
p-value for RR		0.2955

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-resp12-301-by.sas:t-cgii-resp12-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

Study Visit Statistics	Placebo (N=77)	Zuranolone (N =74)
Day 28		
Number of subjects with a response, n (%) [2]	35 (45.5)	43 (58.1)
Number of subjects with missing evaluation, n (%)	11 (14.3)	16 (21.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.276
95% CI for the RR		(0.934, 1.743)
p-value for RR		0.1264
Day 45		
Number of subjects with a response, n (%) [2]	41 (53.2)	44 (59.5)
Number of subjects with missing evaluation, n (%)	12 (15.6)	11 (14.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.114
95% CI for the RR		(0.840, 1.478)
p-value for RR		0.4531

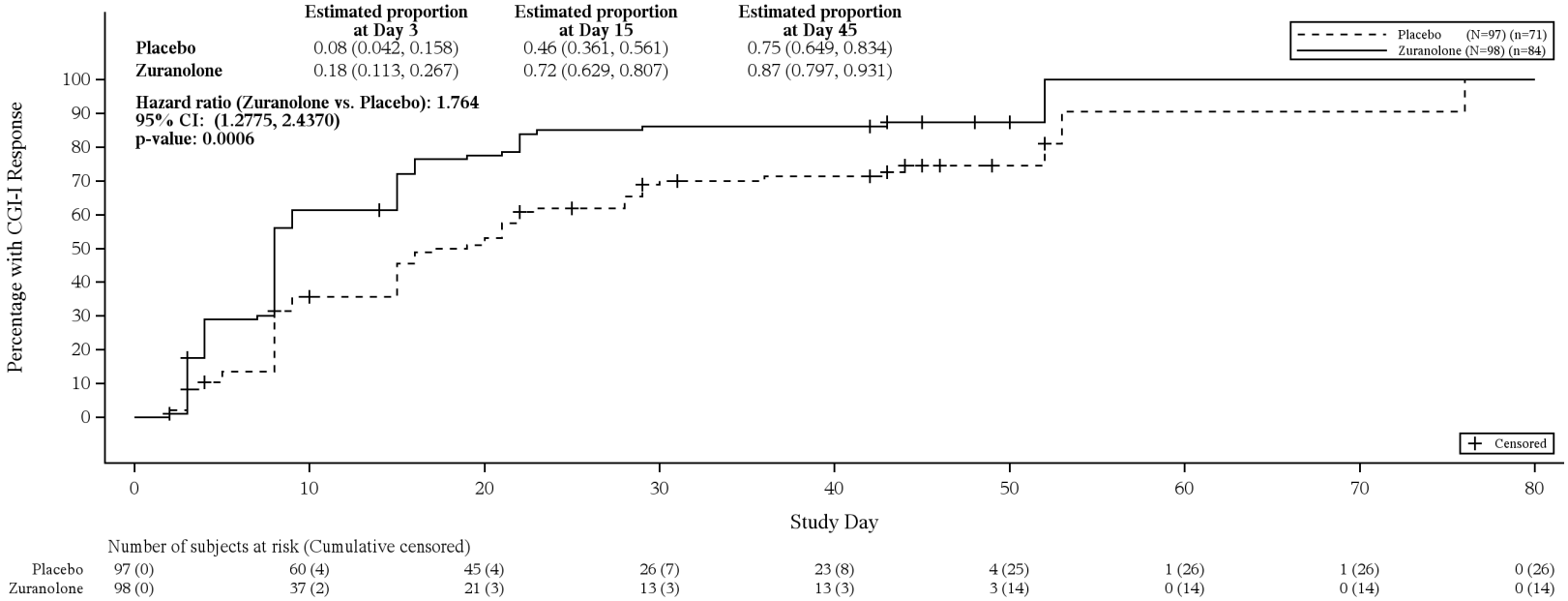
NOTE 1: Model used is a generalized estimating equation (GEE) for binary response model, with factors for antidepressant use at baseline, baseline CGI-S score, treatment, assessment time point, and time point-by-treatment interaction with exchangeable covariance structure, "Log" link function and Poisson 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-resp12-301-by.sas:t-cgii-resp12-301-by-hama-itta.rtf **Run Date:** 25JUL2025

2.7.2.2 TTE-Analysen

2.7.2.2 .1 ITT-Population

Kaplan-Meier Plot for First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved): 217-PPD-301 - 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-301-ovr.sas:f-cgii-resp12-tte-301-ovr-itta.rtf **Run Date:** 16DEC2025

Summary of Time to First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved): 217-PPD-301 - ITT population

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	Placebo (N=101)	Zuranolone (N=99)
Number of evaluable subjects [1]	97	98
Number of subjects with response, n (%) [2]	71 (73.2)	84 (85.7)
Time to first CGI-I response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (8.0 , 9.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	19.0 (15.0 , 22.0)	8.0 (8.0 , 9.0)
75th percentile - Q3 (95% CI)	52.0 (29.0, NE)	16.0 (15.0 , 22.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.764
95% CI for the HR		(1.2775 , 2.4370)
p-value for the HR		0.0006

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-301-ovr.sas:t-cgii-resp12-tte-301-ovr-itta.rtf **Run Date:** 18JUL2025

2.7.2.2 .2 Subgruppen

2.7.2.2 .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-301 - ITT population

Page: 1 of 2

Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
Number of evaluable subjects	97	98	
Number of subjects with response, n (%)	71 (73.2)	84 (85.7)	
Age Group (years)			
18 - 24, n / N (%)	10/12 (83.3)	19/19 (100.0)	0.6872
25 - 45, n / N (%)	61/85 (71.8)	65/79 (82.3)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	23/32 (71.9)	29/33 (87.9)	0.8556
>=28, n / N (%)	48/65 (73.8)	55/65 (84.6)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	10/17 (58.8)	20/25 (80.0)	0.5784
White, n / N (%)	54/69 (78.3)	60/68 (88.2)	
Antidepressant Use at Baseline			
Yes, n / N (%)	12/15 (80.0)	11/15 (73.3)	0.1638
No, n / N (%)	59/82 (72.0)	73/83 (88.0)	

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-301-int.sas:t-cgii-resp12-tte-301-int-itta.rtf **Run Date:** 18JUL2025

Summary of Time to First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved): Treatment by Subgroup Interaction: 217-PPD-301 - ITT population

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Subgroup Subgroup Category	Placebo (N=101)	Zuranolone (N=99)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2) Group			
<=24.9, n / N (%)	19/22 (86.4)	17/20 (85.0)	0.6349(a)
25-29.9, n / N (%)	25/34 (73.5)	19/24 (79.2)	0.1689(b)
>=30, n / N (%)	27/41 (65.9)	47/53 (88.7)	0.3608(c)
Onset of PPD			
3rd Trimester, n / N (%)	20/30 (66.7)	31/34 (91.2)	0.2380
Postpartum, n / N (%)	51/67 (76.1)	53/64 (82.8)	
Family History of PPD			
Yes, n / N (%)	12/15 (80.0)	18/21 (85.7)	0.3775
No/Unknown, n / N (%)	59/82 (72.0)	66/77 (85.7)	
History of PPD			
1st Episode, n / N (%)	65/86 (75.6)	70/81 (86.4)	0.9759
Recurrent Episode, n / N (%)	6/11 (54.5)	14/17 (82.4)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	17/20 (85.0)	22/24 (91.7)	0.8329
>=20, n / N (%)	54/77 (70.1)	62/74 (83.8)	

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-301-int.sas:t-cgii-resp12-tte-301-int-itta.rtf **Run Date:** 18JUL2025

2.7.2.2 .2 .2 Subgruppenanalysen

2.7.2.2 .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-301 - ITT population

Page: 1 of 2

Age Group (years) = 18-24

	Placebo (N=13)	Zuranolone (N=19)
Number of evaluable subjects [1]	12	19
Number of subjects with response, n (%) [2]	10 (83.3)	19 (100.0)
Time to first CGI-I response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (3.0 , 16.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	18.5 (5.0 , 29.0)	8.0 (4.0 , 9.0)
75th percentile - Q3 (95% CI)	25.5 (16.0, NE)	15.0 (8.0 , 23.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.225
95% CI for the HR		(0.9920 , 4.9898)
p-value for the HR		0.0523

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-301-by.sas:t-cgii-resp12-tte-301-by-age-itta.rtf **Run Date:** 25JUL2025

Summary of Time to First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Age Group: 217-PPD-301 - ITT population

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Age Group (years) = 25-45

	Placebo (N=88)	Zuranolone (N=80)
Number of evaluable subjects [1]	85	79
Number of subjects with response, n (%) [2]	61 (71.8)	65 (82.3)
Time to first CGI-I response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (8.0 , 9.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	19.0 (15.0 , 28.0)	8.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	52.0 (29.0, NE)	19.0 (15.0 , 43.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.686
95% CI for the HR		(1.1783 , 2.4133)
p-value for the HR		0.0043

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-301-by.sas:t-cgii-resp12-tte-301-by-age-itta.rtf **Run Date:** 25JUL2025

2.7.2.2 .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-301 - ITT population

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

	Placebo (N=32)	Zuranolone (N=33)
Number of evaluable subjects [1]	32	33
Number of subjects with response, n (%) [2]	23 (71.9)	29 (87.9)
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)	15.0 (8.0 , 36.0)	9.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	53.0 (28.0, NE)	22.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.674
95% CI for the HR		(0.9468 , 2.9587)
p-value for the HR		0.0764

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-301-by.sas:t-cgii-resp12-tte-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

Page: 2 of 2

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

	Placebo (N=66)	Zuranolone (N=65)
Number of evaluable subjects [1]	65	65
Number of subjects with response, n (%) [2]	48 (73.8)	55 (84.6)
Time to first CGI-I response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (8.0 , 9.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	20.0 (15.0 , 22.0)	8.0 (8.0 , 9.0)
75th percentile - Q3 (95% CI)	44.0 (23.0, NE)	16.0 (9.0 , 22.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.849
95% CI for the HR		(1.2410 , 2.7542)
p-value for the HR		0.0025

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-301-by.sas:t-cgii-resp12-tte-301-by-hamd-itta.rtf **Run Date:** 25JUL2025

2.7.2.2 .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-301 - ITT population

Page: 1 of 2

Race Group = Black or African American

	Placebo (N=20)	Zuranolone (N=26)
Number of evaluable subjects [1]	17	25
Number of subjects with response, n (%) [2]	10 (58.8)	20 (80.0)
Time to first CGI-I response (days) [3]		
25th percentile - Q1 (95% CI)	9.0 (2.0 , 16.0)	3.0 (3.0 , 8.0)
50th percentile - median (95% CI)	16.0 (8.0, NE)	8.0 (4.0 , 16.0)
75th percentile - Q3 (95% CI)	76.0 (16.0, NE)	21.0 (9.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.133
95% CI for the HR		(0.8997 , 5.0571)
p-value for the HR		0.0854

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-301-by.sas:t-cgii-resp12-tte-301-by-race-itta.rtf **Run Date:** 25JUL2025

Summary of Time to First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Race Group: 217-PPD-301 - ITT population

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Race Group = White

	Placebo (N=70)	Zuranolone (N=68)
Number of evaluable subjects [1]	69	68
Number of subjects with response, n (%) [2]	54 (78.3)	60 (88.2)
Time to first CGI-I response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (5.0 , 9.0)	4.0 (4.0 , 8.0)
50th percentile - median (95% CI)	17.0 (15.0 , 22.0)	8.0 (8.0 , 9.0)
75th percentile - Q3 (95% CI)	36.0 (22.0, NE)	15.0 (9.0 , 22.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.893
95% CI for the HR		(1.2918 , 2.7742)
p-value for the HR		0.0011

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-301-by.sas:t-cgii-resp12-tte-301-by-race-itta.rtf **Run Date:** 25JUL2025

2.7.2.2 .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-301 - ITT population

Page: 1 of 2

Antidepressant Use at Baseline = Yes

	Placebo (N=15)	Zuranolone (N=15)
Number of evaluable subjects [1]	15	15
Number of subjects with response, n (%) [2]	12 (80.0)	11 (73.3)
Time to first CGI-I response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (2.0 , 15.0)	7.0 (3.0 , 8.0)
50th percentile - median (95% CI)	15.0 (8.0 , 22.0)	8.0 (3.0 , 22.0)
75th percentile - Q3 (95% CI)	53.0 (15.0, NE)	NE (8.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.044
95% CI for the HR		(0.4488 , 2.4297)
p-value for the HR		0.9199

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-301-by.sas:t-cgii-resp12-tte-301-by-adt-itta.rtf **Run Date:** 25JUL2025

Summary of Time to First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Baseline Antidepressant Use: 217-PPD-301 - ITT population

Page: 2 of 2

Antidepressant Use at Baseline = No

	Placebo (N=86)	Zuranolone (N=84)
Number of evaluable subjects [1]	82	83
Number of subjects with response, n (%) [2]	59 (72.0)	73 (88.0)
Time to first CGI-I response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (8.0 , 9.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	20.0 (15.0 , 28.0)	8.0 (8.0 , 9.0)
75th percentile - Q3 (95% CI)	52.0 (29.0, NE)	16.0 (15.0 , 22.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.960
95% CI for the HR		(1.3797 , 2.7840)
p-value for the HR		0.0002

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-301-by.sas:t-cgii-resp12-tte-301-by-adt-itta.rtf **Run Date:** 25JUL2025

2.7.2.2 .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-301 - ITT population

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

	Placebo (N=22)	Zuranolone (N=20)
Number of evaluable subjects [1]	22	20
Number of subjects with response, n (%) [2]	19 (86.4)	17 (85.0)
Time to first CGI-I 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)	17.0 (8.0 , 22.0)	15.0 (4.0 , 22.0)
75th percentile - Q3 (95% CI)	23.0 (19.0, NE)	22.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.337
95% CI for the HR		(0.6846 , 2.6121)
p-value for the HR		0.3950

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-301-by.sas:t-cgii-resp12-tte-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

	Placebo (N=34)	Zuranolone (N=24)
Number of evaluable subjects [1]	34	24
Number of subjects with response, n (%) [2]	25 (73.5)	19 (79.2)
Time to first CGI-I response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (8.0 , 15.0)	3.5 (3.0 , 8.0)
50th percentile - median (95% CI)	20.0 (8.0 , 28.0)	8.0 (4.0 , 15.0)
75th percentile - Q3 (95% CI)	30.0 (21.0, NE)	15.0 (9.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.549
95% CI for the HR		(0.8333 , 2.8790)
p-value for the HR		0.1666

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-301-by.sas:t-cgii-resp12-tte-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

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-301 - ITT population

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

	Placebo (N=42)	Zuranolone (N=53)
Number of evaluable subjects [1]	41	53
Number of subjects with response, n (%) [2]	27 (65.9)	47 (88.7)
Time to first CGI-I 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)	17.0 (9.0 , 53.0)	8.0 (8.0 , 9.0)
75th percentile - Q3 (95% CI)	53.0 (52.0, NE)	15.0 (9.0 , 43.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.107
95% CI for the HR		(1.2790 , 3.4726)
p-value for the HR		0.0034

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-301-by.sas:t-cgii-resp12-tte-301-by-bmi-itta.rtf **Run Date:** 25JUL2025

2.7.2.2 .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-301 - ITT population

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Onset of PPD = 3rd trimester

	Placebo (N=32)	Zuranolone (N=35)
Number of evaluable subjects [1]	30	34
Number of subjects with response, n (%) [2]	20 (66.7)	31 (91.2)
Time to first CGI-I response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (4.0 , 15.0)	3.0 (3.0 , 8.0)
50th percentile - median (95% CI)	15.0 (8.0 , 30.0)	8.0 (3.0 , 9.0)
75th percentile - Q3 (95% CI)	44.0 (21.0, NE)	15.0 (8.0 , 22.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		2.308
95% CI for the HR		(1.2775 , 4.1692)
p-value for the HR		0.0056

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-301-by.sas:t-cgii-resp12-tte-301-by-onset-itta.rtf **Run Date:** 25JUL2025

Summary of Time to First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Onset of PPD: 217-PPD-301 - ITT population

Page: 2 of 2

Onset of PPD = Postpartum

	Placebo (N=69)	Zuranolone (N=64)
Number of evaluable subjects [1]	67	64
Number of subjects with response, n (%) [2]	51 (76.1)	53 (82.8)
Time to first CGI-I response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (8.0 , 15.0)	7.0 (4.0 , 8.0)
50th percentile - median (95% CI)	20.0 (15.0 , 23.0)	8.0 (8.0 , 15.0)
75th percentile - Q3 (95% CI)	52.0 (28.0, NE)	21.0 (15.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.562
95% CI for the HR		(1.0555 , 2.3117)
p-value for the HR		0.0257

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-301-by.sas:t-cgii-resp12-tte-301-by-onset-itta.rtf **Run Date:** 25JUL2025

2.7.2.2 .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-301 - ITT population

Page: 1 of 2

Family History of PPD = Yes

	Placebo (N=16)	Zuranolone (N=21)
Number of evaluable subjects [1]	15	21
Number of subjects with response, n (%) [2]	12 (80.0)	18 (85.7)
Time to first CGI-I 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 (8.0 , 22.0)	8.0 (4.0 , 15.0)
75th percentile - Q3 (95% CI)	22.0 (15.0, NE)	15.0 (9.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.264
95% CI for the HR		(0.6070 , 2.6331)
p-value for the HR		0.5311

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-301-by.sas:t-cgii-resp12-tte-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

Summary of Time to First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Family History of PPD: 217-PPD-301 - ITT population

Page: 2 of 2

Family History of PPD = No/Unknown

	Placebo (N=85)	Zuranolone (N=78)
Number of evaluable subjects [1]	82	77
Number of subjects with response, n (%) [2]	59 (72.0)	66 (85.7)
Time to first CGI-I response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (8.0 , 9.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	20.0 (15.0 , 28.0)	8.0 (8.0 , 9.0)
75th percentile - Q3 (95% CI)	52.0 (29.0, NE)	16.0 (15.0 , 22.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.886
95% CI for the HR		(1.3137 , 2.7080)
p-value for the HR		0.0006

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-301-by.sas:t-cgii-resp12-tte-301-by-fhist-itta.rtf **Run Date:** 25JUL2025

2.7.2.2 .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-301 - ITT population

Page: 1 of 2

History of PPD = 1st Episode

	Placebo (N=90)	Zuranolone (N=82)
Number of evaluable subjects [1]	86	81
Number of subjects with response, n (%) [2]	65 (75.6)	70 (86.4)
Time to first CGI-I response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (8.0 , 9.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	19.0 (15.0 , 22.0)	8.0 (8.0 , 9.0)
75th percentile - Q3 (95% CI)	43.0 (28.0, NE)	16.0 (15.0 , 22.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.816
95% CI for the HR		(1.2844 , 2.5690)
p-value for the HR		0.0007

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-301-by.sas:t-cgii-resp12-tte-301-by-hist-itta.rtf **Run Date:** 25JUL2025

Summary of Time to First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by History of PPD: 217-PPD-301 - ITT population

Page: 2 of 2

History of PPD = Recurrent Episode

	Placebo (N=11)	Zuranolone (N=17)
Number of evaluable subjects [1]	11	17
Number of subjects with response, n (%) [2]	6 (54.5)	14 (82.4)
Time to first CGI-I response (days) [3]		
25th percentile - Q1 (95% CI)	5.0 (3.0 , 15.0)	8.0 (3.0 , 8.0)
50th percentile - median (95% CI)	15.0 (4.0, NE)	8.0 (4.0 , 16.0)
75th percentile - Q3 (95% CI)	NE (8.0, NE)	16.0 (8.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.631
95% CI for the HR		(0.5481 , 4.8507)
p-value for the HR		0.3794

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-301-by.sas:t-cgii-resp12-tte-301-by-hist-itta.rtf **Run Date:** 25JUL2025

2.7.2.2 .2 .2 .9 Depression mit Angst

Summary of Time to First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

Page: 1 of 2

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

	Placebo (N=21)	Zuranolone (N=24)
Number of evaluable subjects [1]	20	24
Number of subjects with response, n (%) [2]	17 (85.0)	22 (91.7)
Time to first CGI-I response (days) [3]		
25th percentile - Q1 (95% CI)	15.5 (5.0 , 19.0)	7.5 (3.0 , 8.0)
50th percentile - median (95% CI)	21.0 (15.0 , 29.0)	8.5 (8.0 , 16.0)
75th percentile - Q3 (95% CI)	32.5 (21.0, NE)	18.5 (9.0, NE)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.780
95% CI for the HR		(0.9273 , 3.4152)
p-value for the HR		0.0831

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-301-by.sas:t-cgii-resp12-tte-301-by-hama-itta.rtf **Run Date:** 25JUL2025

Summary of Time to First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - ITT population

Page: 2 of 2

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

	Placebo (N=77)	Zuranolone (N=74)
Number of evaluable subjects [1]	77	74
Number of subjects with response, n (%) [2]	54 (70.1)	62 (83.8)
Time to first CGI-I response (days) [3]		
25th percentile - Q1 (95% CI)	8.0 (5.0 , 9.0)	4.0 (3.0 , 8.0)
50th percentile - median (95% CI)	15.0 (9.0 , 23.0)	8.0 (8.0 , 9.0)
75th percentile - Q3 (95% CI)	53.0 (29.0, NE)	16.0 (15.0 , 29.0)
HR - Hazard Ratio (Zuranolone vs. Placebo) [4]		1.713
95% CI for the HR		(1.1803 , 2.4854)
p-value for the HR		0.0046

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.

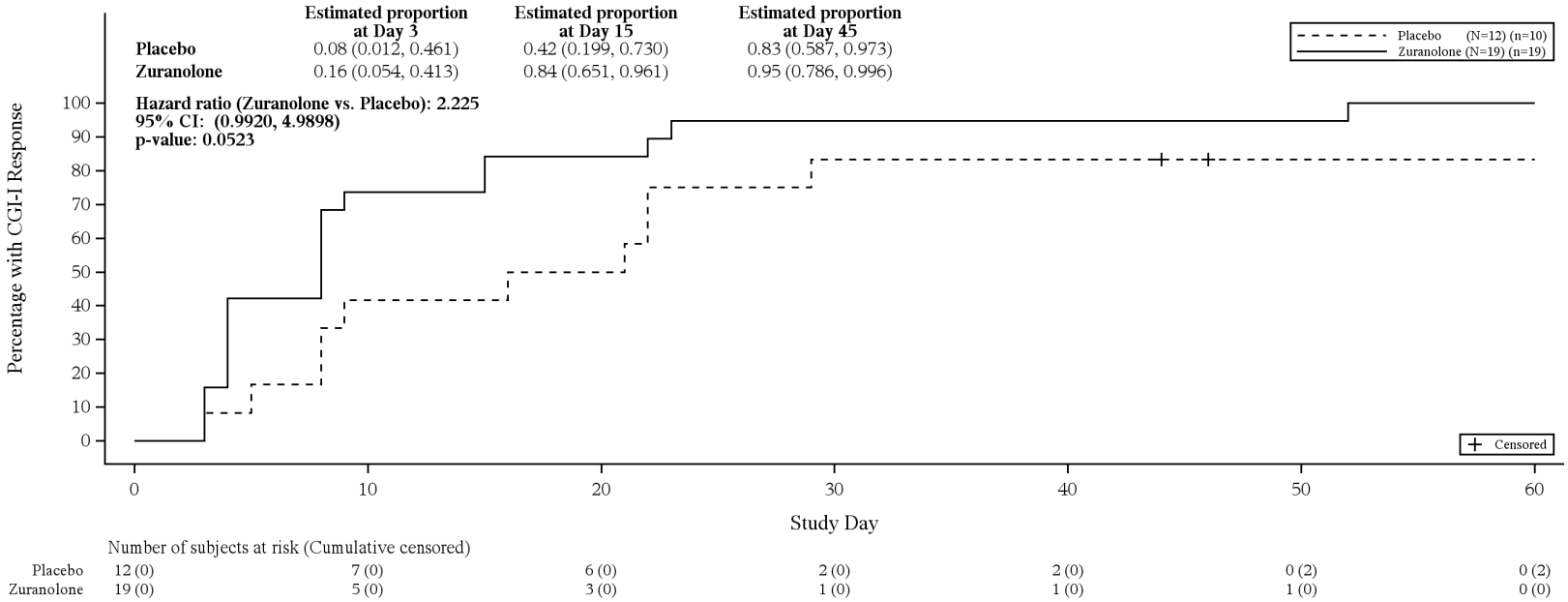
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2.7.2.2 .2 .3 Kaplan-Meier-Plots

Kaplan-Meier Plot for First Clinical Global Impression - Improvement (CGI-I) Response (much and very much improved) by Subgroup: 217-PPD-301 - ITT population

Page: 1 of 19

Age Group (years) = 18-24

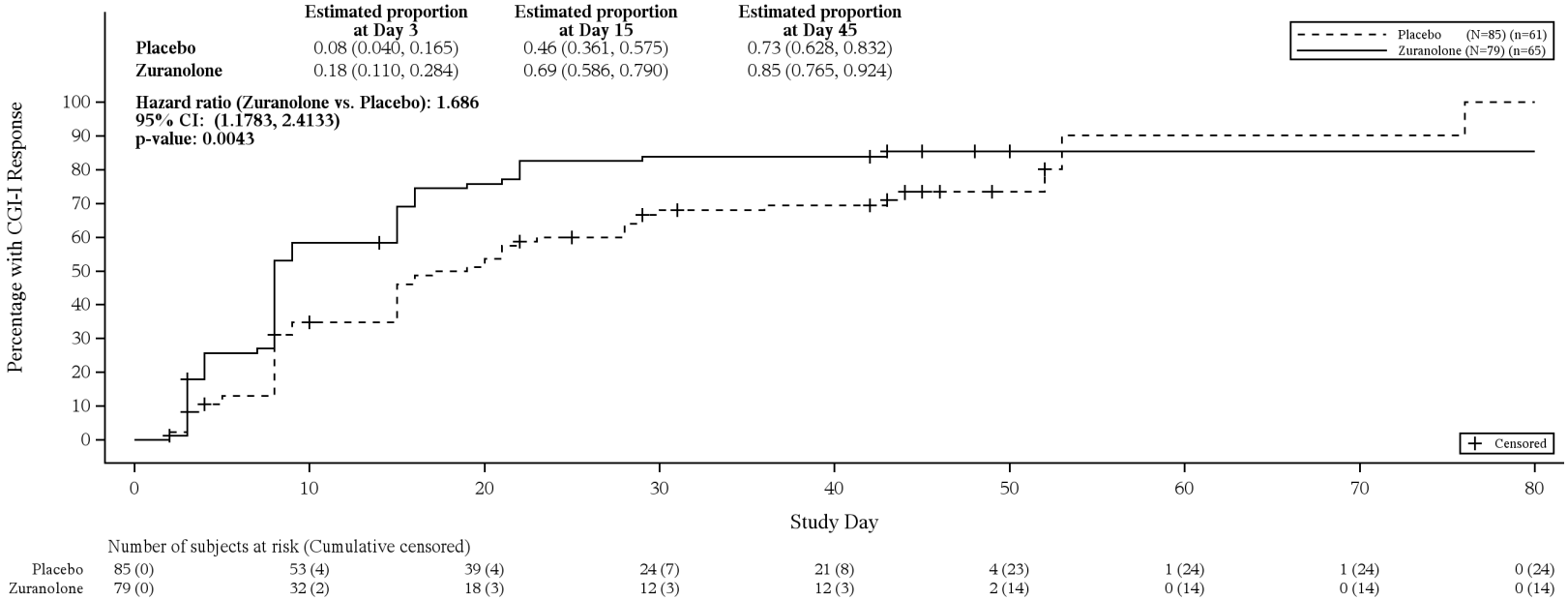


Abbreviations: N=number of evaluable subjects; n=number of subjects with response.
NOTE 1: Subjects with non-missing CGI-I score at any visit.
NOTE 2: CGI-I response is defined as having a CGI-I score of "much improved" or "very much improved". Days are calculated from the date of the first dose. Subjects 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-301-by.sas:f-cgii-resp12-tte-301-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-301 - ITT population

Page: 2 of 19

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.

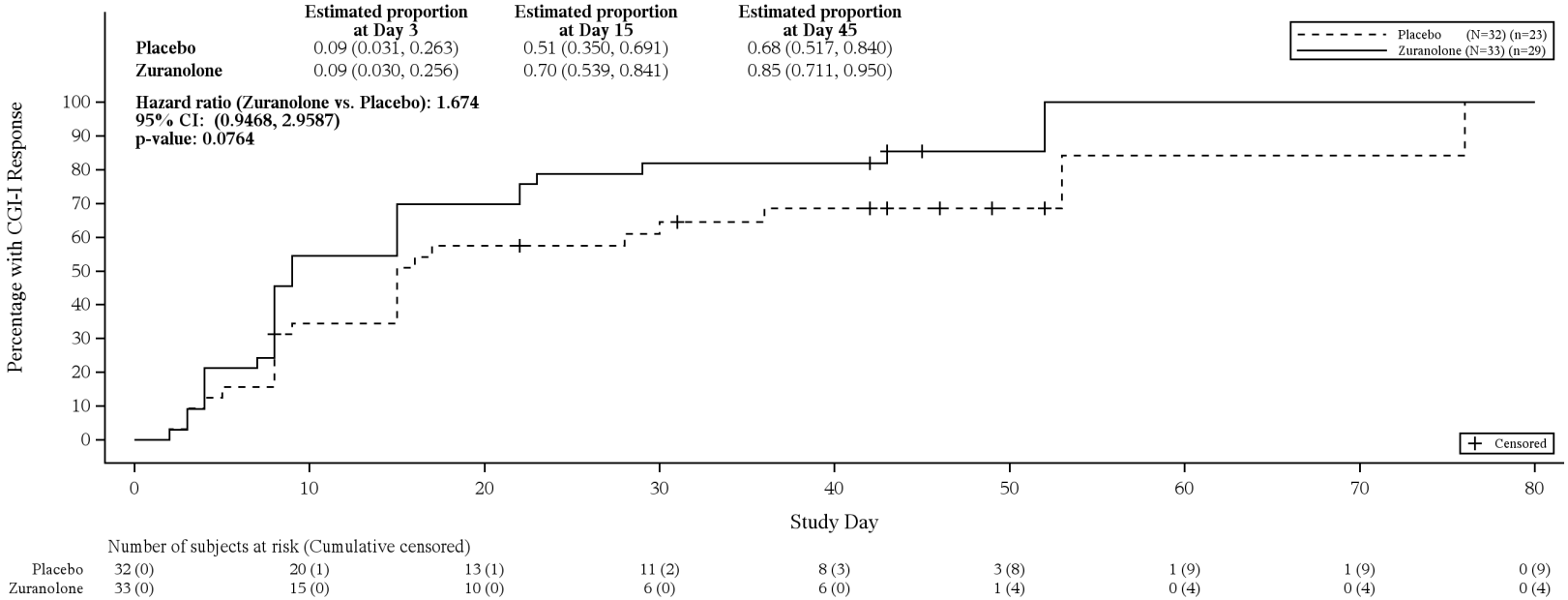
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant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

Source: biib125/v_a/amnog_kmplots/f-cgii-resp12-tte-301-by.sas:f-cgii-resp12-tte-301-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-301 - 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.

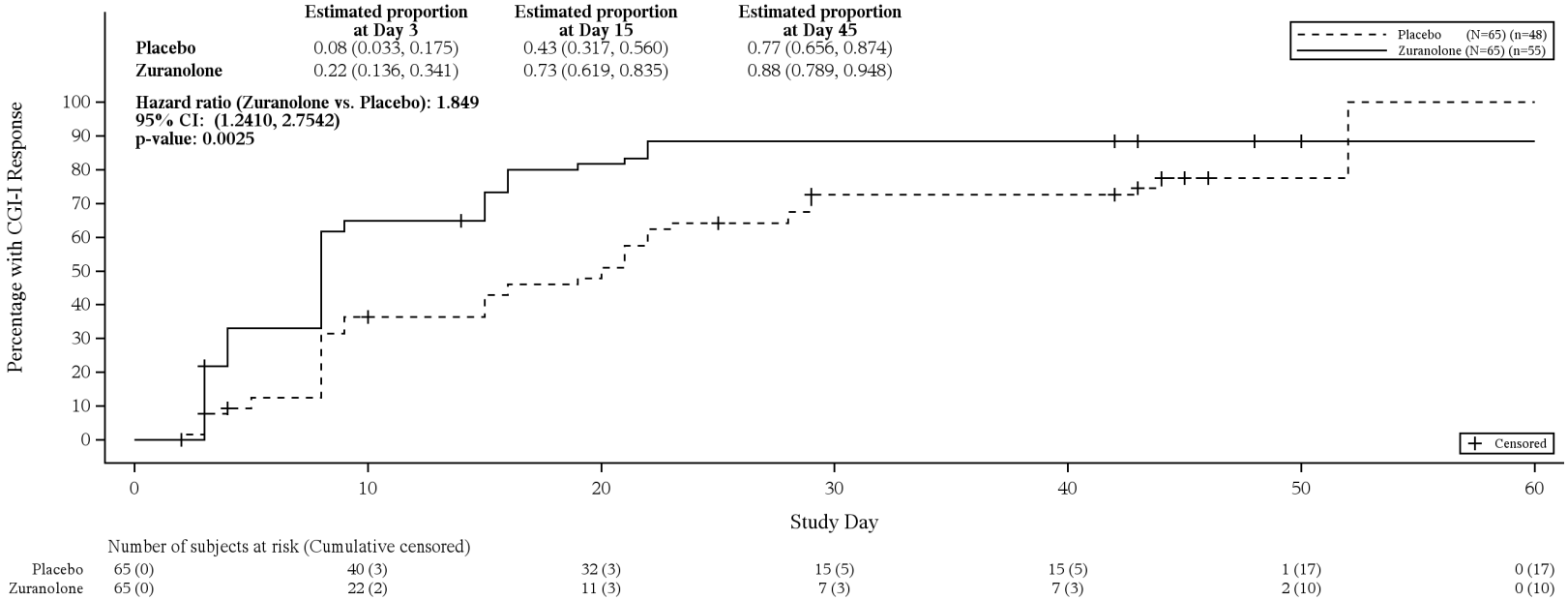
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant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

Source: biib125/v_a/amnog_kmplots/f-cgii-resp12-tte-301-by.sas:f-cgii-resp12-tte-301-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-301 - 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.

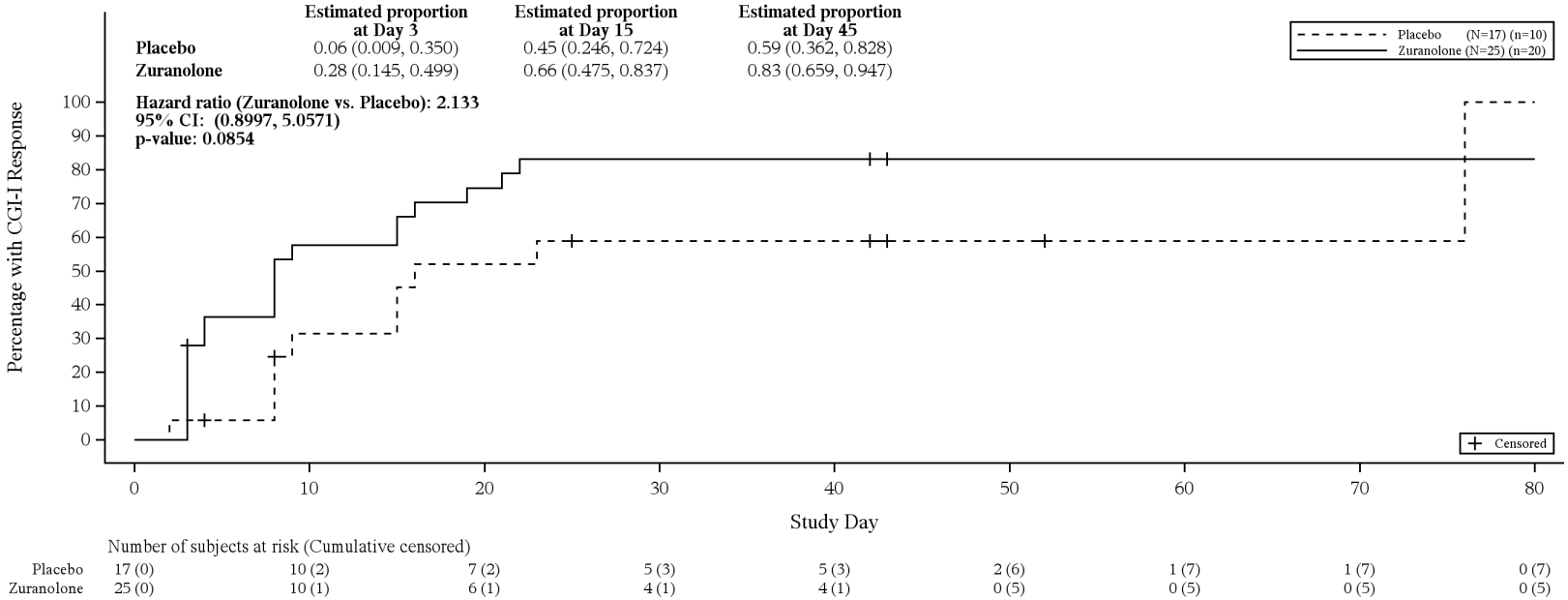
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant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

Source: biib125/v_a/amnog_kmplots/f-cgii-resp12-tte-301-by.sas:f-cgii-resp12-tte-301-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-301 - 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.

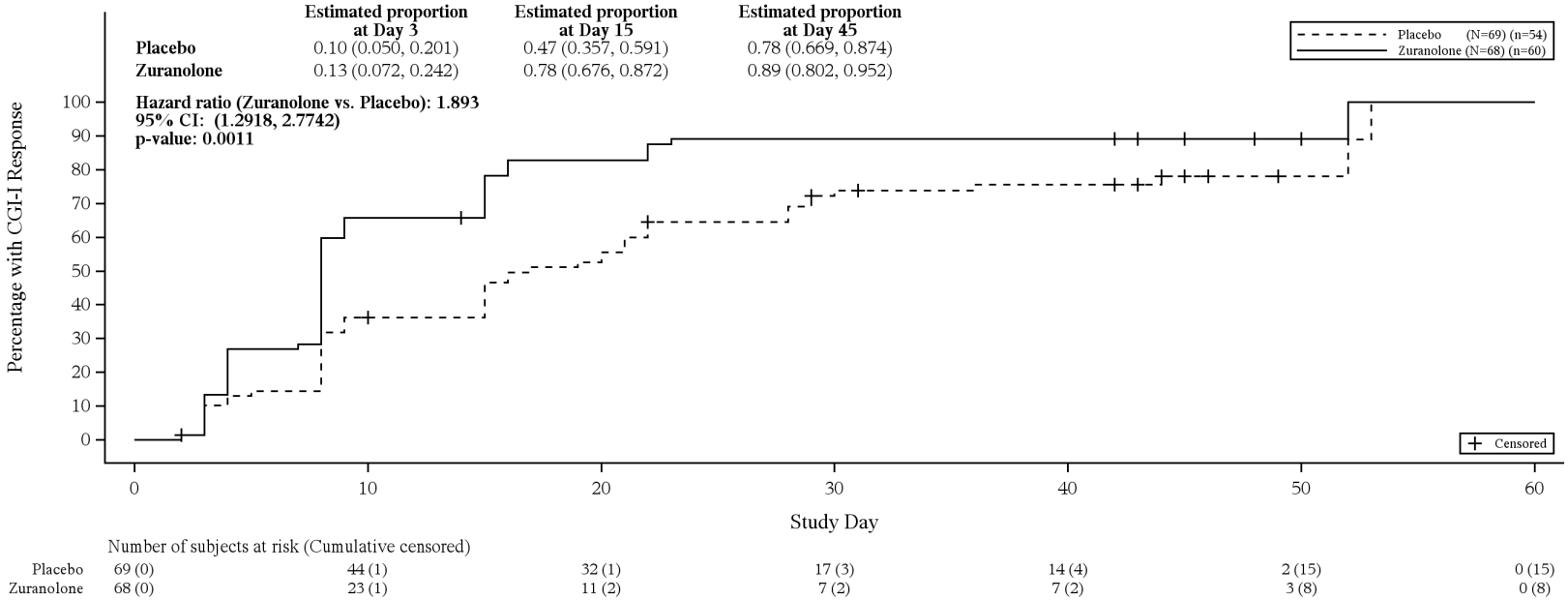
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant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

Source: biib125/v_a/amnog_kmplots/f-cgii-resp12-tte-301-by.sas:f-cgii-resp12-tte-301-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-301 - 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.

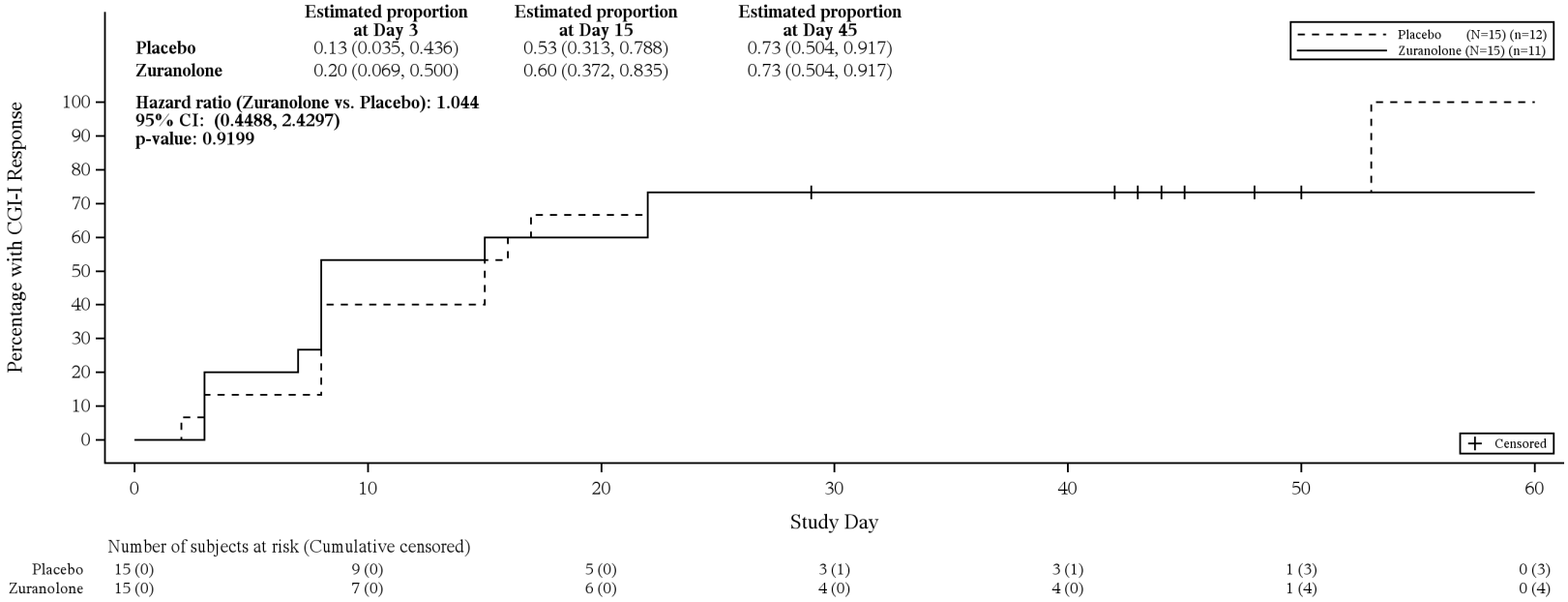
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant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

Source: biib125/v_a/amnog_kmplots/f-cgii-resp12-tte-301-by.sas:f-cgii-resp12-tte-301-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-301 - 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.

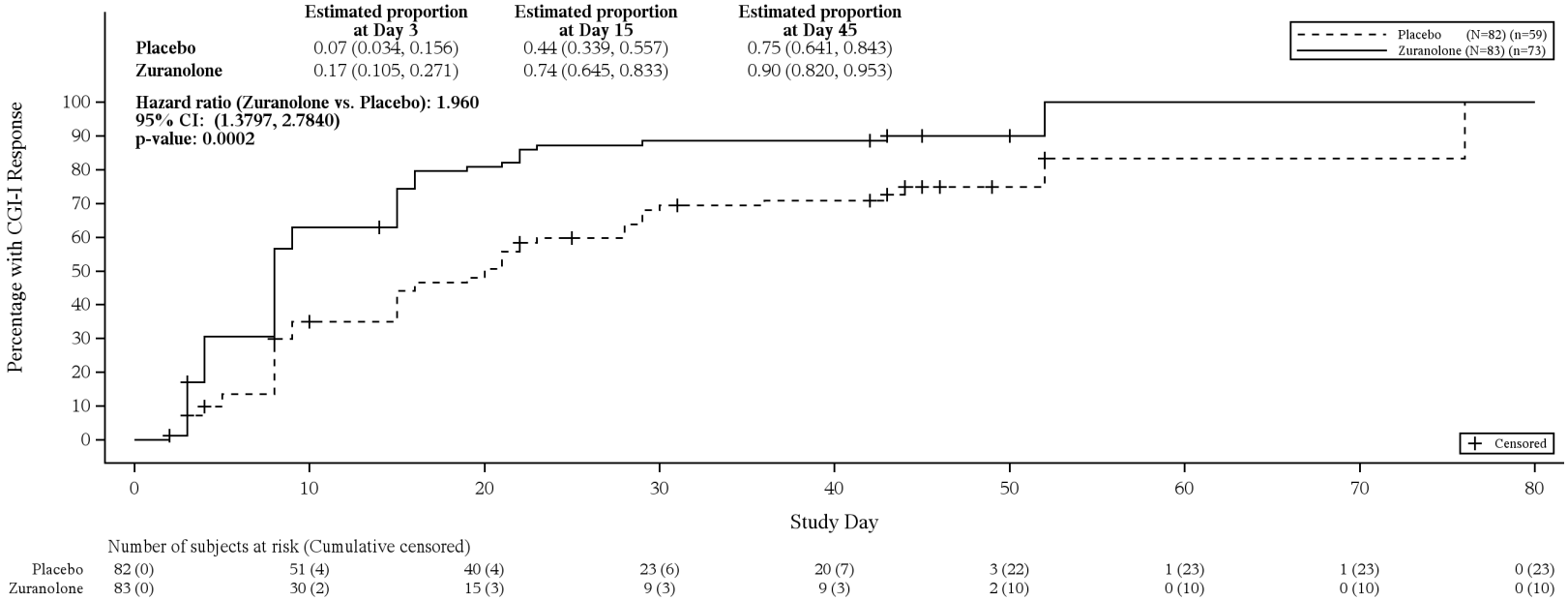
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant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

Source: biib125/v_a/amnog_kmplots/f-cgii-resp12-tte-301-by.sas:f-cgii-resp12-tte-301-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-301 - ITT population

Page: 8 of 19

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.

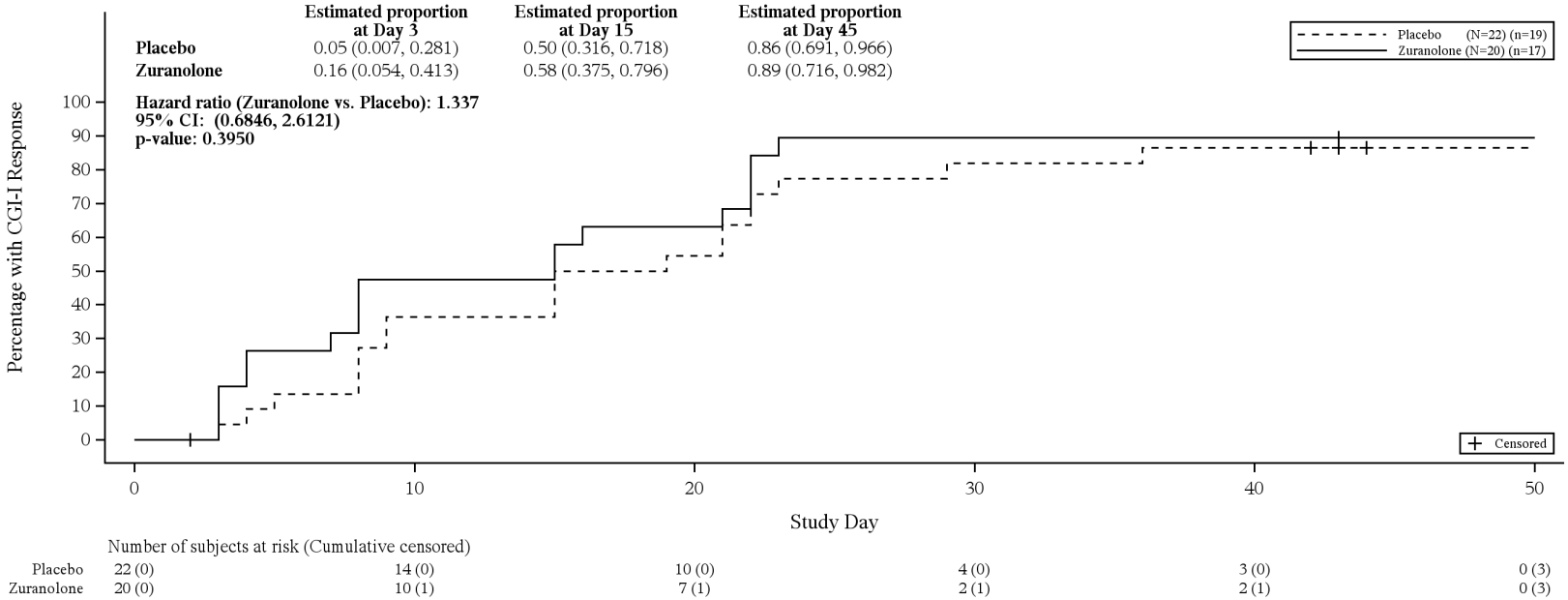
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant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

Source: biib125/v_a/amnog_kmplots/f-cgii-resp12-tte-301-by.sas:f-cgii-resp12-tte-301-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-301 - ITT population

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



Number of subjects at risk (Cumulative censored)

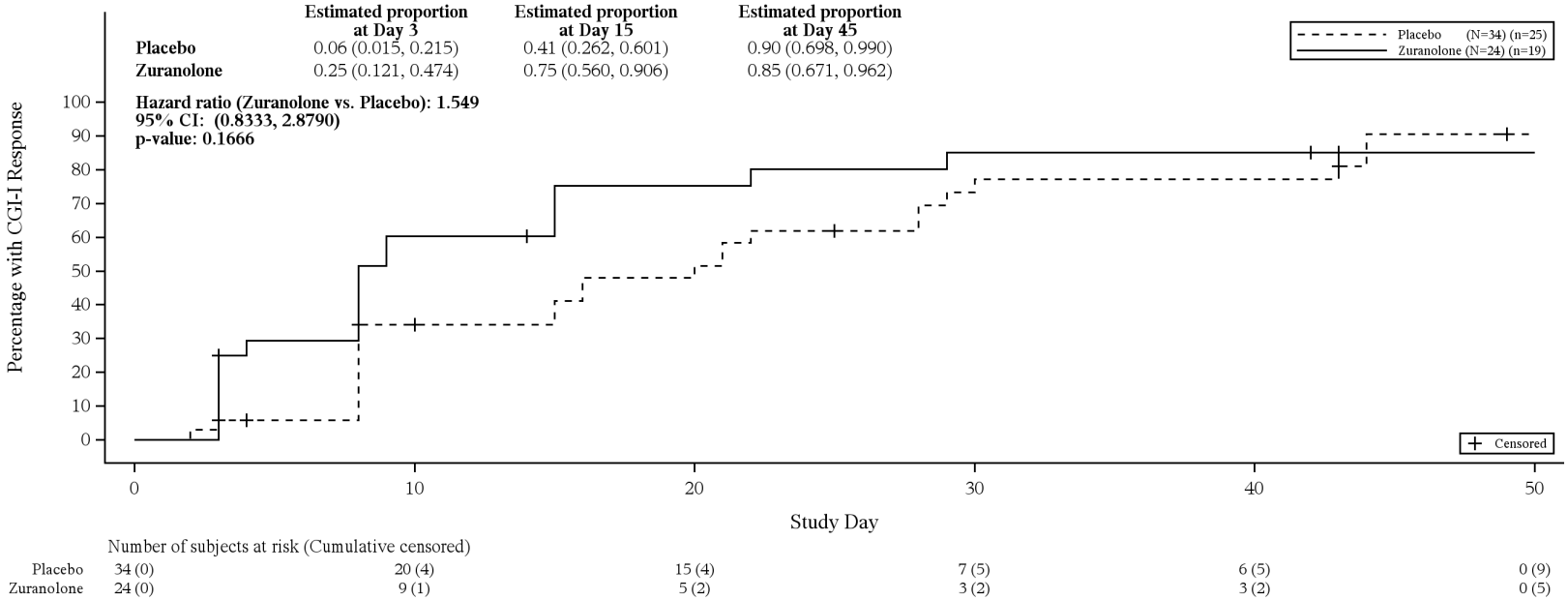
Placebo	22 (0)	14 (0)	10 (0)	4 (0)	3 (0)	0 (3)
Zuranolone	20 (0)	10 (1)	7 (1)	2 (1)	2 (1)	0 (3)

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-301-by.sas:f-cgii-resp12-tte-301-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-301 - 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.

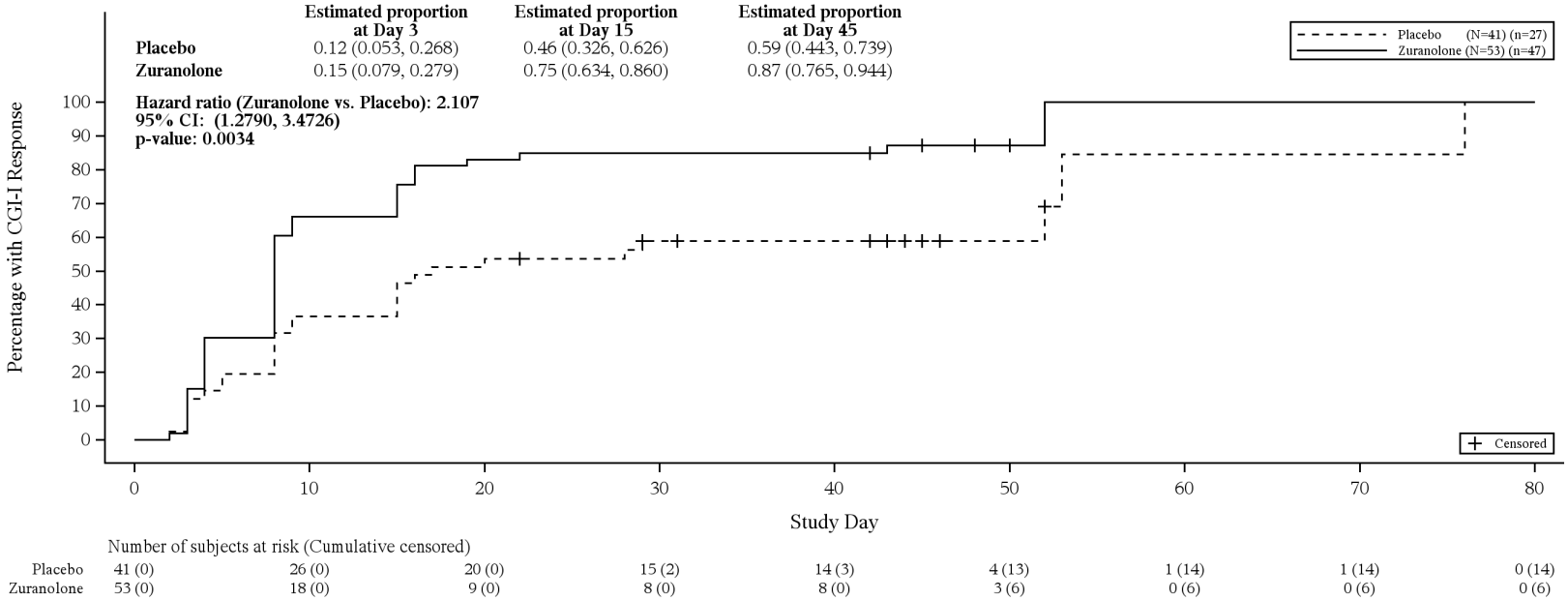
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant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

Source: biib125/v_a/amnog_kmplots/f-cgii-resp12-tte-301-by.sas:f-cgii-resp12-tte-301-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-301 - 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.

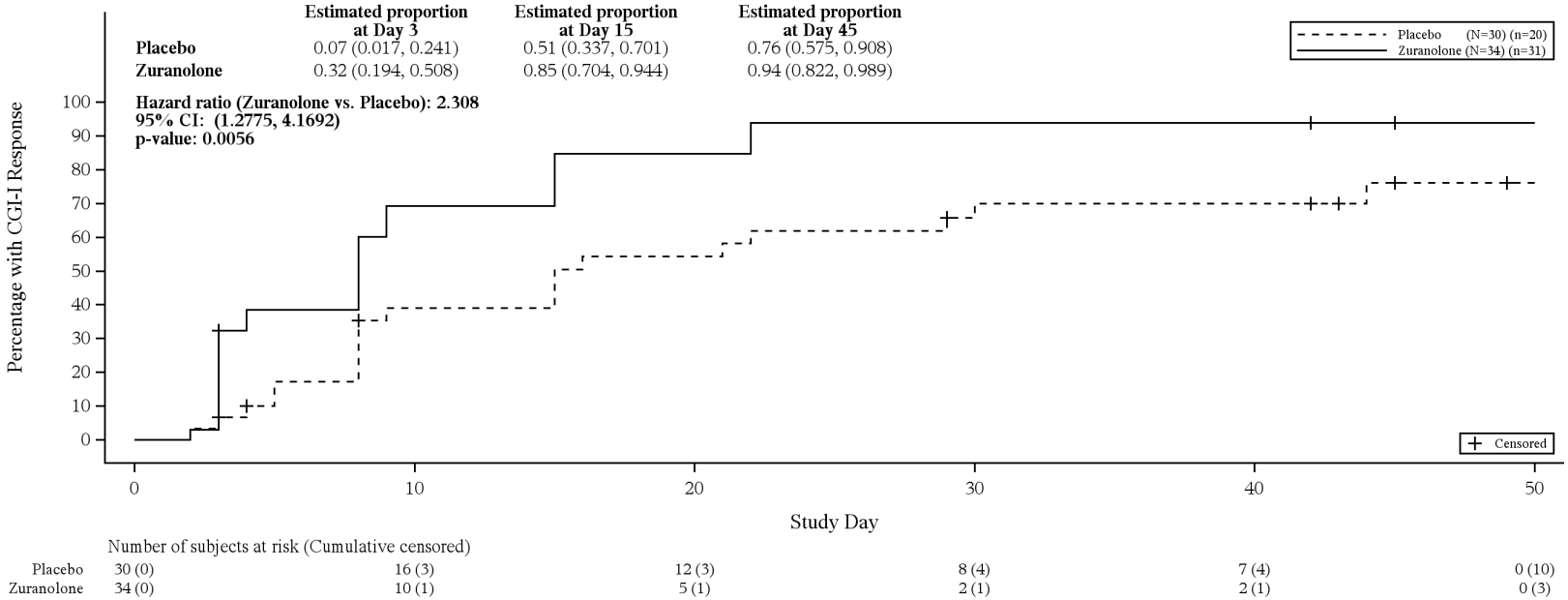
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant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

Source: biib125/v_a/amnog_kmplots/f-cgii-resp12-tte-301-by.sas:f-cgii-resp12-tte-301-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-301 - 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.

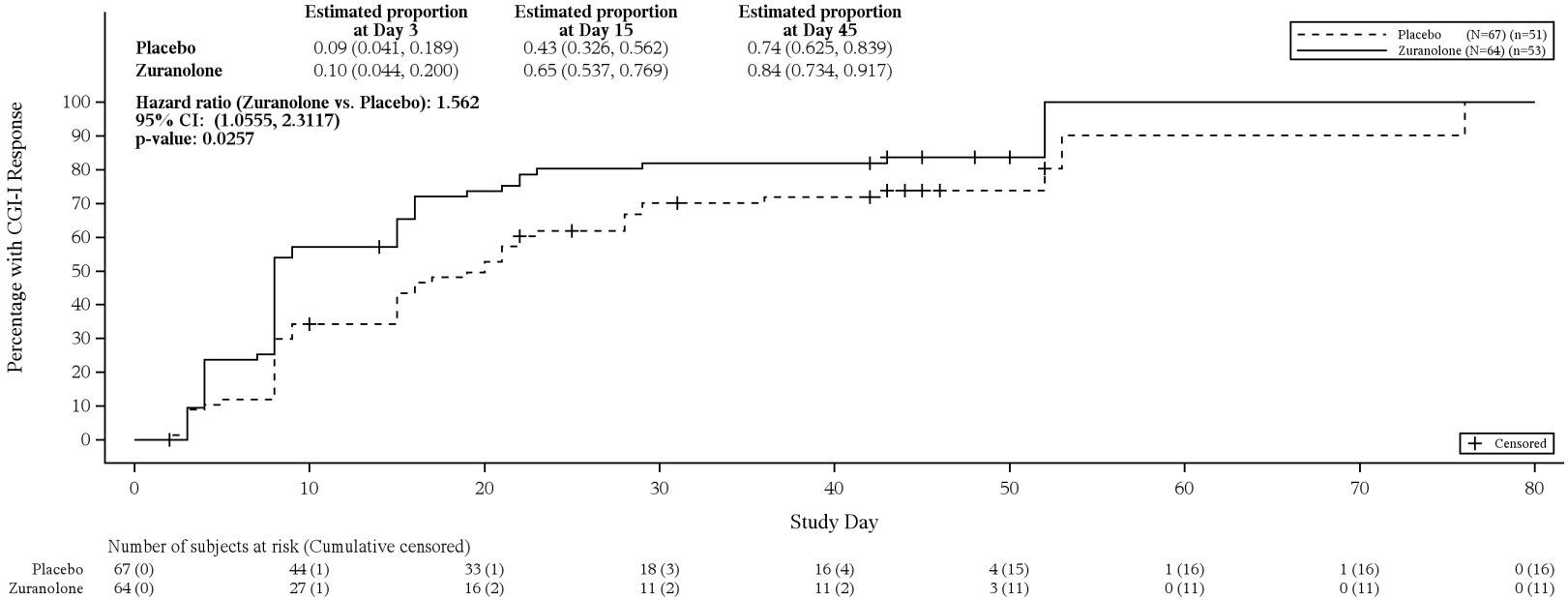
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant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

Source: biib125/v_a/amnog_kmplots/f-cgii-resp12-tte-301-by.sas:f-cgii-resp12-tte-301-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-301 - 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.

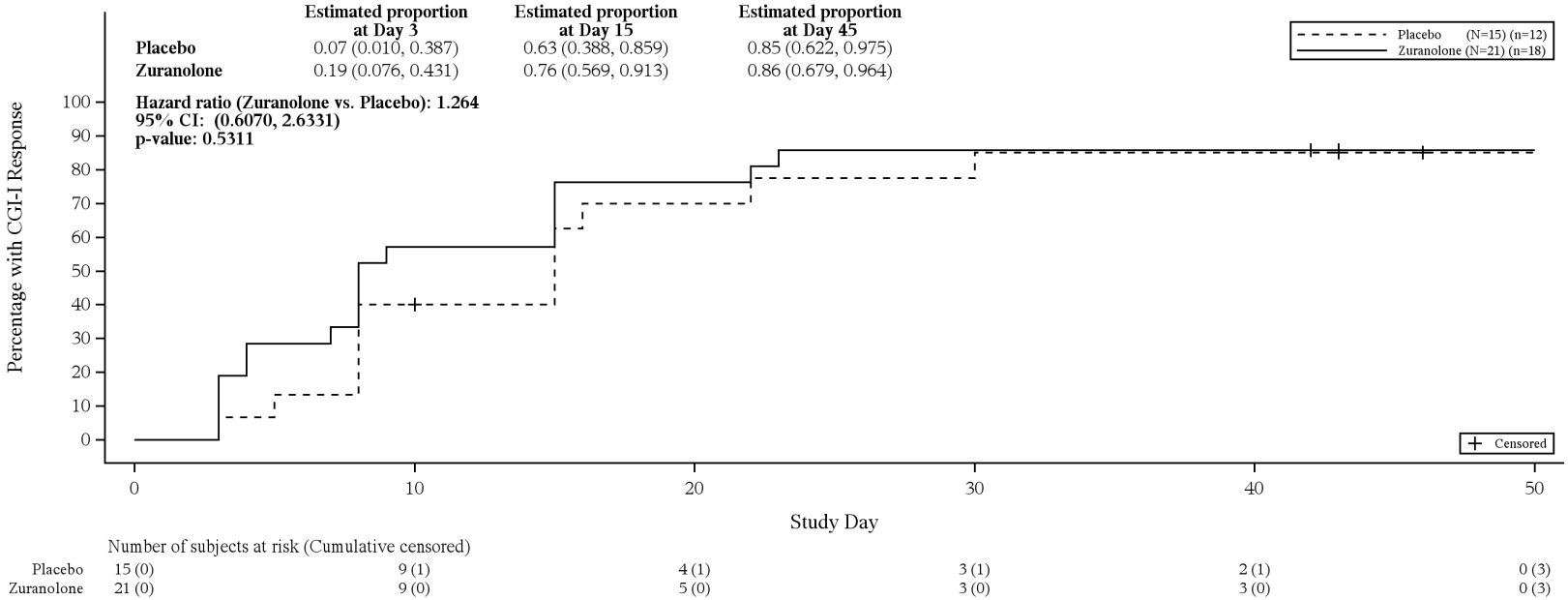
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant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

Source: biib125/v_a/amnog_kmplots/f-cgii-resp12-tte-301-by.sas:f-cgii-resp12-tte-301-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-301 - ITT population

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Family History of PPD = Yes

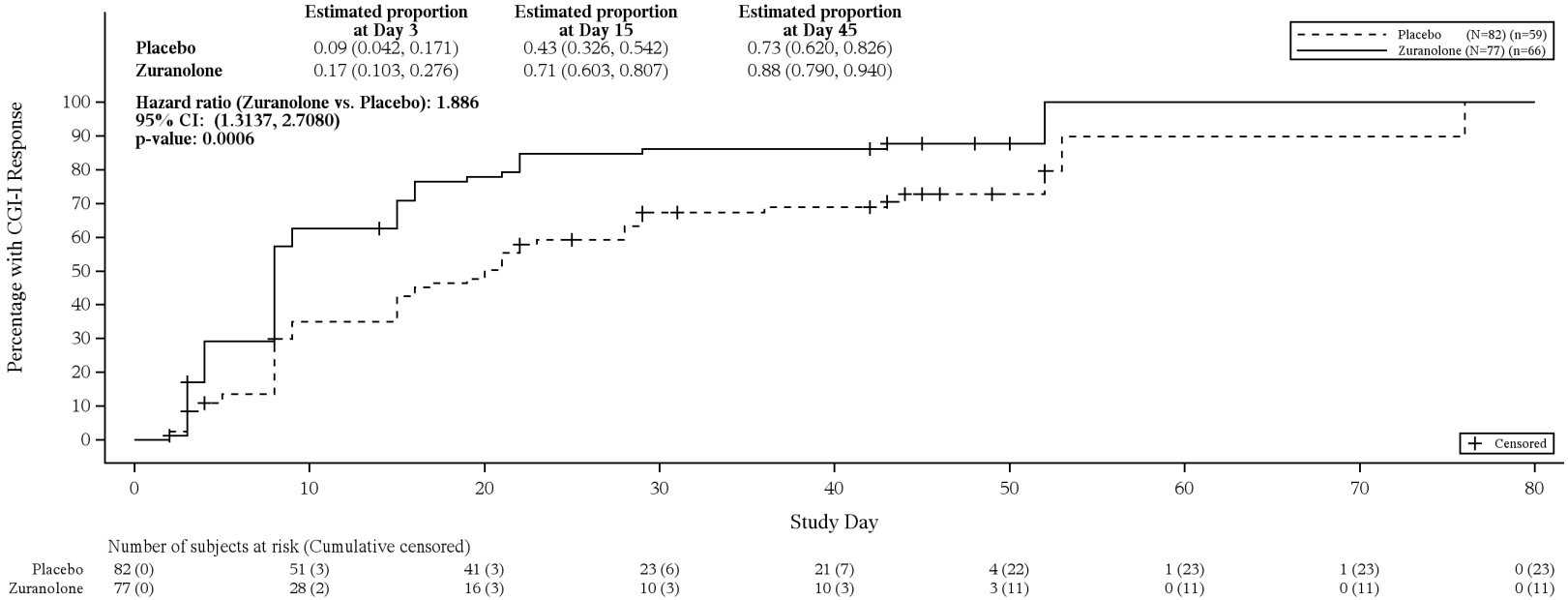


Abbreviations: N=number of evaluable subjects; n=number of subjects with response.
NOTE 1: Subjects with non-missing CGI-I score at any visit.
NOTE 2: CGI-I response is defined as having a CGI-I score of "much improved" or "very much improved". Days are calculated from the date of the first dose. Subjects 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-301-by.sas:f-cgii-resp12-tte-301-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-301 - 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.

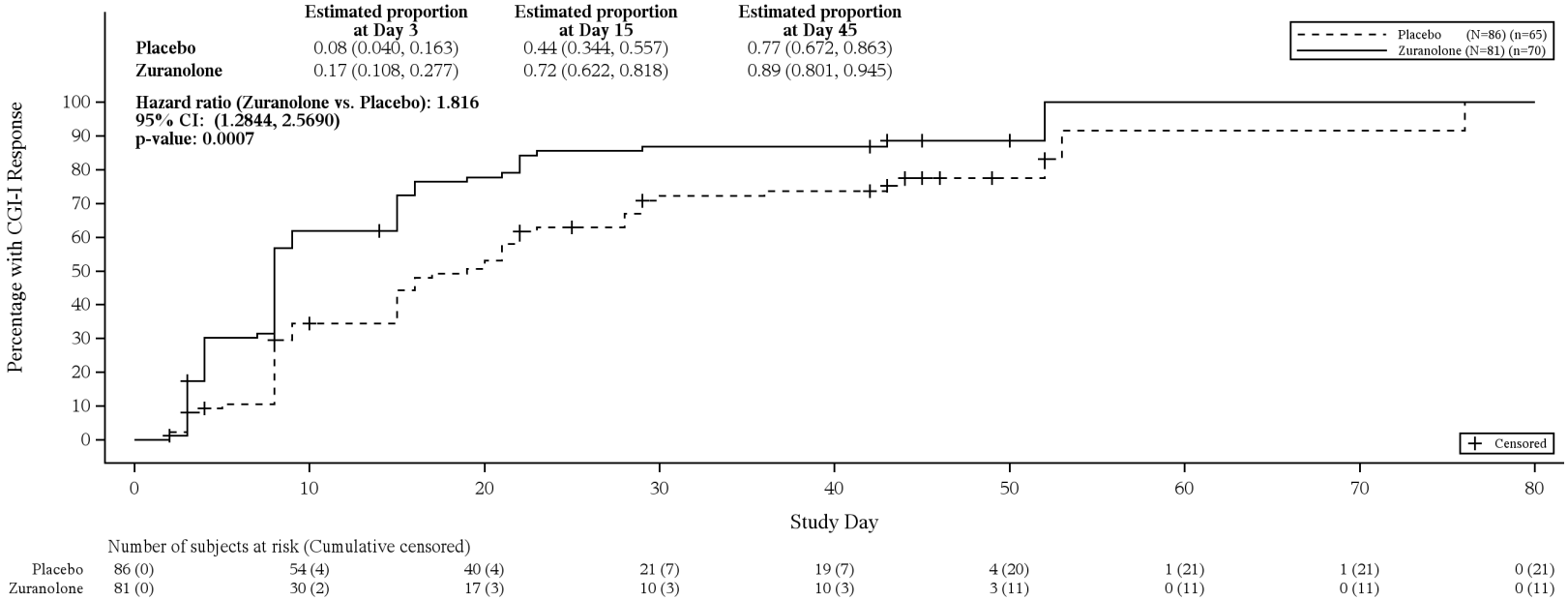
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant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

Source: biib125/v_a/amnog_kmplots/f-cgii-resp12-tte-301-by.sas:f-cgii-resp12-tte-301-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-301 - 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.

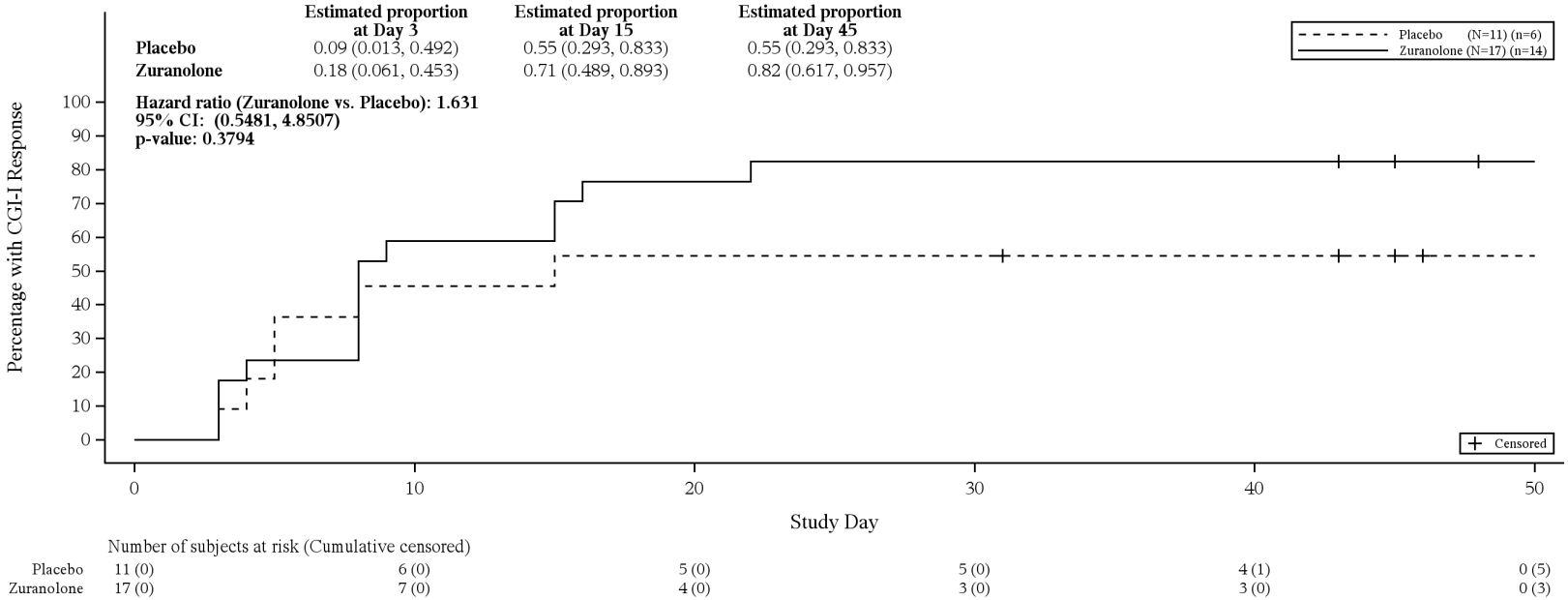
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant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

Source: biib125/v_a/amnog_kmplots/f-cgii-resp12-tte-301-by.sas:f-cgii-resp12-tte-301-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-301 - ITT population

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History of PPD = Recurrent Episode

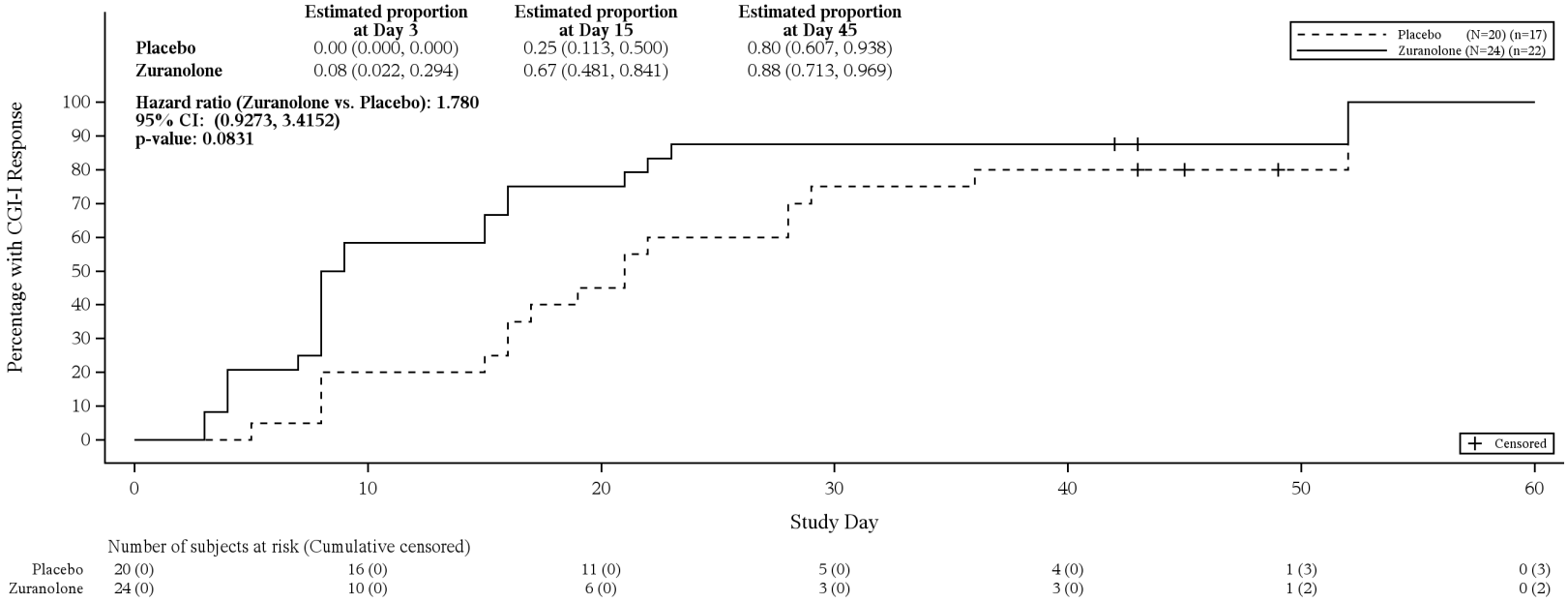


Abbreviations: N=number of evaluable subjects; n=number of subjects with response.
NOTE 1: Subjects with non-missing CGI-I score at any visit.
NOTE 2: CGI-I response is defined as having a CGI-I score of "much improved" or "very much improved". Days are calculated from the date of the first dose. Subjects 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-301-by.sas:f-cgii-resp12-tte-301-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-301 - 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 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.

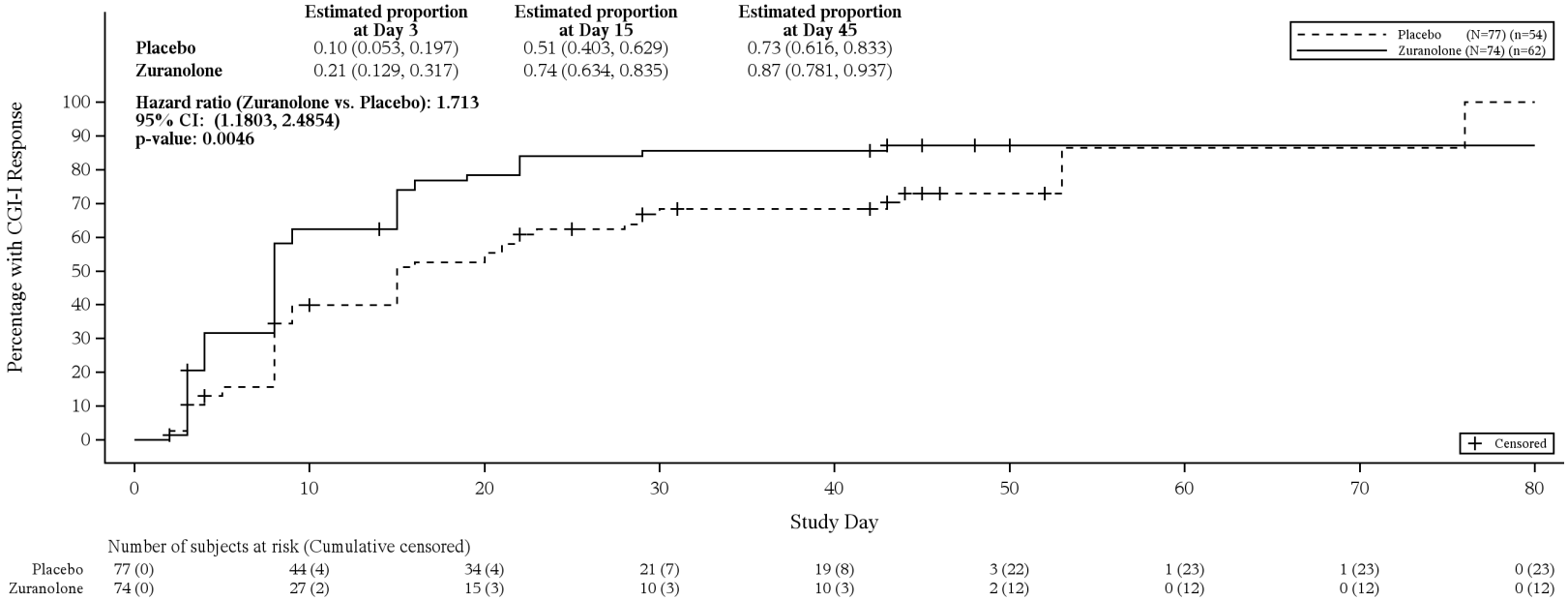
NOTE 3: The estimated proportion of subjects with event are based on Kaplan-Meier product limit method. Hazard ratio, 95% confidence interval and p-value are based on Cox proportional hazard model adjusted for antidepressant use at baseline, baseline CGI-S score, and treatment. Model covariate antidepressant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

Source: biib125/v_a/amnog_kmplots/f-cgii-resp12-tte-301-by.sas:f-cgii-resp12-tte-301-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-301 - 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 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-301-by.sas:f-cgii-resp12-tte-301-by-itta.rtf **Run Date:** 08JAN2026

3 Sicherheit

3.1 UE

3.1.1 Gesamtraten

3.1.1.1 ITT-Population

Number of Subjects with at Least One Treatment-Emergent Adverse Event: 217-PPD-301 - Safety population
Page: 1 of 1

	Placebo (N=98)	Zuranolone (N=98)
Number of subjects with >=1 TEAE, n (%)	52 (53.1)	65 (66.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.25
95% CI for the RR		(0.990, 1.579)
p-value for RR		0.0612
OR - Odds Ratio (Zuranolone vs. Placebo)		1.74
95% CI for the OR		(0.979, 3.103)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.13
95% CI for the ARR		(-0.003, 0.269)

NOTE 1: AEs were coded using MedDRA version 24.0.
Source: biib125/v_a/germany_amnog/t-ae-301-ovr.sas:t-ae-301-ovr-safc.rtf **Run Date:** 18JUL2025

3.1.1.2 Subgruppen

3.1.1.2 .1 Interaktionstest

Number of Subjects with at Least One Treatment-Emergent Adverse Event: Treatment by Subgroup Interaction: 217-PPD-301 - Safety population

Page: 1 of 2

Subgroup Subgroup Category	Placebo (N=98)	Zuranolone (N=98)	p-value for Treatment by Subgroup Interaction Test
Number of subjects with >=1 TEAE, n(%)	52 (53.1)	65 (66.3)	
Age Group (years)			
18 - 24, n / N (%)	6/12 (50.0)	16/19 (84.2)	0.2417
25 - 45, n / N (%)	46/86 (53.5)	49/79 (62.0)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	17/32 (53.1)	20/33 (60.6)	0.5766
>=28, n / N (%)	35/66 (53.0)	45/65 (69.2)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	11/18 (61.1)	17/25 (68.0)	0.4850
White, n / N (%)	34/69 (49.3)	46/68 (67.6)	
Antidepressant Use at Baseline			
Yes, n / N (%)	11/15 (73.3)	9/15 (60.0)	0.0820
No, n / N (%)	41/83 (49.4)	56/83 (67.5)	

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-301-int.sas:t-ae-301-int-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with at Least One Treatment-Emergent Adverse Event: Treatment by Subgroup Interaction: 217-PPD-301 - Safety population

Page: 2 of 2

Subgroup Subgroup Category	Placebo (N=98)	Zuranolone (N=98)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2}) Group 2			
<=24.9, n / N (%)	12/22 (54.5)	11/20 (55.0)	0.9721(a)
25-29.9, n / N (%)	18/34 (52.9)	13/24 (54.2)	0.2512(b)
>=30, n / N (%)	22/42 (52.4)	41/53 (77.4)	0.2179(c)
Onset of PPD			
3rd Trimester, n / N (%)	14/31 (45.2)	19/34 (55.9)	0.8957
Postpartum, n / N (%)	38/67 (56.7)	46/64 (71.9)	
Family History of PPD			
Yes, n / N (%)	5/16 (31.3)	15/21 (71.4)	0.0565
No/Unknown, n / N (%)	47/82 (57.3)	50/77 (64.9)	
History of PPD			
1st Episode, n / N (%)	45/87 (51.7)	53/81 (65.4)	0.6100
Recurrent Episode, n / N (%)	7/11 (63.6)	12/17 (70.6)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	6/21 (28.6)	13/24 (54.2)	0.2080
>=20, n / N (%)	46/77 (59.7)	52/74 (70.3)	

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%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=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-301-int.sas:t-ae-301-int-safc.rtf **Run Date:** 18JUL2025

3.1.1.2 .2 Subgruppenanalysen

3.1.1.2 .2 .1 Alter

Number of Subjects with at Least One Treatment-Emergent Adverse Event by Age Group: 217-PPD-301 - Safety Population

Page: 1 of 2

Age Group (years) = 18-24

	Placebo (N=12)	Zuranolone (N=19)
Number of subjects with >=1 TEAE, n (%)	6 (50.0)	16 (84.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.68
95% CI for the RR		(0.926, 3.064)
p-value for RR		0.0877
OR - Odds Ratio (Zuranolone vs. Placebo)		5.33
95% CI for the OR		(1.000, 28.435)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.34
95% CI for the ARR		(0.015, 0.669)

NOTE 1: AEs were coded using MedDRA version 24.0.

Source: biib125/v_a/germany_amnog/t-ae-301-by.sas:t-ae-301-by-age-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with at Least One Treatment-Emergent Adverse Event by Age Group: 217-PPD-301 - Safety Population

Page: 2 of 2

Age Group (years) = 25-45

	Placebo (N=86)	Zuranolone (N=79)
Number of subjects with >=1 TEAE, n (%)	46 (53.5)	49 (62.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.16
95% CI for the RR		(0.892, 1.507)
p-value for RR		0.2679
OR - Odds Ratio (Zuranolone vs. Placebo)		1.42
95% CI for the OR		(0.763, 2.644)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.09
95% CI for the ARR		(-0.065, 0.236)

NOTE 1: AEs were coded using MedDRA version 24.0.

Source: biib125/v_a/germany_amnog/t-ae-301-by.sas:t-ae-301-by-age-safc.rtf **Run Date:** 21JUL2025

3.1.1.2 .2 .2 Schwere der Erkrankung

Number of Subjects with at Least One Treatment-Emergent Adverse Event by Baseline HAMD-17 Total Score: 217-PPD-301 - Safety Population

Page: 1 of 2

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

	Placebo (N=32)	Zuranolone (N=33)
Number of subjects with >=1 TEAE, n (%)	17 (53.1)	20 (60.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.14
95% CI for the RR		(0.745, 1.747)
p-value for RR		0.5445
OR - Odds Ratio (Zuranolone vs. Placebo)		1.36
95% CI for the OR		(0.507, 3.634)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.07
95% CI for the ARR		(-0.165, 0.315)

NOTE 1: AEs were coded using MedDRA version 24.0.

Source: biib125/v_a/germany_amnog/t-ae-301-by.sas:t-ae-301-by-hamd-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with at Least One Treatment-Emergent Adverse Event by Baseline HAMD-17 Total Score: 217-PPD-301 - Safety Population

Page: 2 of 2

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

	Placebo (N=66)	Zuranolone (N=65)
Number of subjects with >=1 TEAE, n (%)	35 (53.0)	45 (69.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.31
95% CI for the RR		(0.988, 1.726)
p-value for RR		0.0611
OR - Odds Ratio (Zuranolone vs. Placebo)		1.99
95% CI for the OR		(0.975, 4.073)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.16
95% CI for the ARR		(-0.003, 0.327)

NOTE 1: AEs were coded using MedDRA version 24.0.

Source: biib125/v_a/germany_amnog/t-ae-301-by.sas:t-ae-301-by-hamd-safc.rtf **Run Date:** 21JUL2025

3.1.1.2 .2 .3 Abstammung

Number of Subjects with at Least One Treatment-Emergent Adverse Event by Race Group: 217-PPD-301 - Safety Population
Page: 1 of 2
Race Group = Black or African American

	Placebo (N=18)	Zuranolone (N=25)
Number of subjects with >=1 TEAE, n (%)	11 (61.1)	17 (68.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.11
95% CI for the RR		(0.705, 1.756)
p-value for RR		0.6463
OR - Odds Ratio (Zuranolone vs. Placebo)		1.35
95% CI for the OR		(0.381, 4.799)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.07
95% CI for the ARR		(-0.221, 0.359)

NOTE 1: AEs were coded using MedDRA version 24.0.
Source: biib125/v_a/germany_amnog/t-ae-301-by.sas:t-ae-301-by-race-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with at Least One Treatment-Emergent Adverse Event by Race Group: 217-PPD-301 - Safety Population
Page: 2 of 2
Race Group = White

	Placebo (N=69)	Zuranolone (N=68)
Number of subjects with >=1 TEAE, n (%)	34 (49.3)	46 (67.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.37
95% CI for the RR		(1.027, 1.835)
p-value for RR		0.0325
OR - Odds Ratio (Zuranolone vs. Placebo)		2.15
95% CI for the OR		(1.076, 4.306)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.18
95% CI for the ARR		(0.022, 0.346)

NOTE 1: AEs were coded using MedDRA version 24.0.
Source: biib125/v_a/germany_amnog/t-ae-301-by.sas:t-ae-301-by-race-safc.rtf **Run Date:** 21JUL2025

3.1.1.2 .2 .4 Antidepressiva-Nutzung

Number of Subjects with at Least One Treatment-Emergent Adverse Event by Baseline Antidepressant Use: 217-PPD-301 - Safety Population

Page: 1 of 2

Antidepressant Use at Baseline = Yes

	Placebo (N=15)	Zuranolone (N=15)
Number of subjects with >=1 TEAE, n (%)	11 (73.3)	9 (60.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.82
95% CI for the RR		(0.490, 1.368)
p-value for RR		0.4439
OR - Odds Ratio (Zuranolone vs. Placebo)		0.55
95% CI for the OR		(0.117, 2.549)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.13
95% CI for the ARR		(-0.467, 0.201)

NOTE 1: AEs were coded using MedDRA version 24.0.

Source: biib125/v_a/germany_amnog/t-ae-301-by.sas:t-ae-301-by-adt-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with at Least One Treatment-Emergent Adverse Event by Baseline Antidepressant Use: 217-PPD-301 - Safety Population

Page: 2 of 2

Antidepressant Use at Baseline = No

	Placebo (N=83)	Zuranolone (N=83)
Number of subjects with >=1 TEAE, n (%)	41 (49.4)	56 (67.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.37
95% CI for the RR		(1.049, 1.779)
p-value for RR		0.0207
OR - Odds Ratio (Zuranolone vs. Placebo)		2.12
95% CI for the OR		(1.132, 3.987)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.18
95% CI for the ARR		(0.033, 0.328)

NOTE 1: AEs were coded using MedDRA version 24.0.

Source: biib125/v_a/germany_amnog/t-ae-301-by.sas:t-ae-301-by-adt-safc.rtf **Run Date:** 21JUL2025

3.1.1.2 .2 .5 BMI

Number of Subjects with at Least One Treatment-Emergent Adverse Event by Baseline BMI (kg/m^2) Group: 217-PPD-301 - Safety Population

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

	Placebo (N=22)	Zuranolone (N=20)
Number of subjects with >=1 TEAE, n (%)	12 (54.5)	11 (55.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.01
95% CI for the RR		(0.582, 1.748)
p-value for RR		0.9764
OR - Odds Ratio (Zuranolone vs. Placebo)		1.02
95% CI for the OR		(0.302, 3.438)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.00
95% CI for the ARR		(-0.297, 0.306)

NOTE 1: AEs were coded using MedDRA version 24.0.

Source: biib125/v_a/germany_amnog/t-ae-301-by.sas:t-ae-301-by-bmi-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with at Least One Treatment-Emergent Adverse Event by Baseline BMI (kg/m^2) Group: 217-PPD-301 - Safety Population

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

	Placebo (N=34)	Zuranolone (N=24)
Number of subjects with >=1 TEAE, n (%)	18 (52.9)	13 (54.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.02
95% CI for the RR		(0.630, 1.663)
p-value for RR		0.9264
OR - Odds Ratio (Zuranolone vs. Placebo)		1.05
95% CI for the OR		(0.368, 2.996)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.01
95% CI for the ARR		(-0.248, 0.273)

NOTE 1: AEs were coded using MedDRA version 24.0.

Source: biib125/v_a/germany_amnog/t-ae-301-by.sas:t-ae-301-by-bmi-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with at Least One Treatment-Emergent Adverse Event by Baseline BMI (kg/m^2) Group: 217-PPD-301 - Safety Population

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

	Placebo (N=42)	Zuranolone (N=53)
Number of subjects with >=1 TEAE, n (%)	22 (52.4)	41 (77.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.48
95% CI for the RR		(1.069, 2.040)
p-value for RR		0.0180
OR - Odds Ratio (Zuranolone vs. Placebo)		3.11
95% CI for the OR		(1.284, 7.514)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.25
95% CI for the ARR		(0.061, 0.438)

NOTE 1: AEs were coded using MedDRA version 24.0.

Source: biib125/v_a/germany_amnog/t-ae-301-by.sas:t-ae-301-by-bmi-safc.rtf **Run Date:** 21JUL2025

3.1.1.2 .2 .6 Beginn der PPD

Number of Subjects with at Least One Treatment-Emergent Adverse Event by Onset of PPD: 217-PPD-301 - Safety Population
Page: 1 of 2
Onset of PPD = 3rd trimester

	Placebo (N=31)	Zuranolone (N=34)
Number of subjects with >=1 TEAE, n (%)	14 (45.2)	19 (55.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.24
95% CI for the RR		(0.758, 2.019)
p-value for RR		0.3938
OR - Odds Ratio (Zuranolone vs. Placebo)		1.54
95% CI for the OR		(0.578, 4.095)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.11
95% CI for the ARR		(-0.135, 0.349)

NOTE 1: AEs were coded using MedDRA version 24.0.
Source: biib125/v_a/germany_amnog/t-ae-301-by.sas:t-ae-301-by-onset-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with at Least One Treatment-Emergent Adverse Event by Onset of PPD: 217-PPD-301 - Safety Population
Page: 2 of 2
Onset of PPD = Postpartum

	Placebo (N=67)	Zuranolone (N=64)
Number of subjects with >=1 TEAE, n (%)	38 (56.7)	46 (71.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.27
95% CI for the RR		(0.978, 1.642)
p-value for RR		0.0734
OR - Odds Ratio (Zuranolone vs. Placebo)		1.95
95% CI for the OR		(0.941, 4.040)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.15
95% CI for the ARR		(-0.010, 0.313)

NOTE 1: AEs were coded using MedDRA version 24.0.
Source: biib125/v_a/germany_amnog/t-ae-301-by.sas:t-ae-301-by-onset-safc.rtf **Run Date:** 21JUL2025

3.1.1.2 .2 .7 PPD in der Familie

Number of Subjects with at Least One Treatment-Emergent Adverse Event by Family History of PPD: 217-PPD-301 - Safety Population

Page: 1 of 2

Family History of PPD = Yes

	Placebo (N=16)	Zuranolone (N=21)
Number of subjects with >=1 TEAE, n (%)	5 (31.3)	15 (71.4)
RR - Relative Risk (Zuranolone vs. Placebo)		2.29
95% CI for the RR		(1.053, 4.964)
p-value for RR		0.0367
OR - Odds Ratio (Zuranolone vs. Placebo)		5.50
95% CI for the OR		(1.331, 22.734)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.40
95% CI for the ARR		(0.104, 0.700)

NOTE 1: AEs were coded using MedDRA version 24.0.

Source: biib125/v_a/germany_amnog/t-ae-301-by.sas:t-ae-301-by-fhist-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with at Least One Treatment-Emergent Adverse Event by Family History of PPD: 217-PPD-301 - Safety Population

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Family History of PPD = No/Unknown

	Placebo (N=82)	Zuranolone (N=77)
Number of subjects with >=1 TEAE, n (%)	47 (57.3)	50 (64.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.13
95% CI for the RR		(0.884, 1.453)
p-value for RR		0.3253
OR - Odds Ratio (Zuranolone vs. Placebo)		1.38
95% CI for the OR		(0.727, 2.617)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.08
95% CI for the ARR		(-0.075, 0.227)

NOTE 1: AEs were coded using MedDRA version 24.0.

Source: biib125/v_a/germany_amnog/t-ae-301-by.sas:t-ae-301-by-fhist-safc.rtf **Run Date:** 21JUL2025

3.1.1.2 .2 .8 PPD in der Anamnese

Number of Subjects with at Least One Treatment-Emergent Adverse Event by History of PPD: 217-PPD-301 - Safety Population

Page: 1 of 2

History of PPD = 1st Episode

	Placebo (N=87)	Zuranolone (N=81)
Number of subjects with >=1 TEAE, n (%)	45 (51.7)	53 (65.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.27
95% CI for the RR		(0.978, 1.636)
p-value for RR		0.0735
OR - Odds Ratio (Zuranolone vs. Placebo)		1.77
95% CI for the OR		(0.949, 3.290)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.14
95% CI for the ARR		(-0.010, 0.285)

NOTE 1: AEs were coded using MedDRA version 24.0.

Source: biib125/v_a/germany_amnog/t-ae-301-by.sas:t-ae-301-by-hist-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with at Least One Treatment-Emergent Adverse Event by History of PPD: 217-PPD-301 - Safety Population

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History of PPD = Recurrent Episode

	Placebo (N=11)	Zuranolone (N=17)
Number of subjects with >=1 TEAE, n (%)	7 (63.6)	12 (70.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.11
95% CI for the RR		(0.645, 1.907)
p-value for RR		0.7077
OR - Odds Ratio (Zuranolone vs. Placebo)		1.37
95% CI for the OR		(0.274, 6.873)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.07
95% CI for the ARR		(-0.288, 0.427)

NOTE 1: AEs were coded using MedDRA version 24.0.

Source: biib125/v_a/germany_amnog/t-ae-301-by.sas:t-ae-301-by-hist-safc.rtf **Run Date:** 21JUL2025

3.1.1.2 .2 .9 Depression mit Angst

Number of Subjects with at Least One Treatment-Emergent Adverse Event by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - Safety Population

Page: 1 of 2

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

	Placebo (N=21)	Zuranolone (N=24)
Number of subjects with >=1 TEAE, n (%)	6 (28.6)	13 (54.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.90
95% CI for the RR		(0.878, 4.094)
p-value for RR		0.1034
OR - Odds Ratio (Zuranolone vs. Placebo)		2.95
95% CI for the OR		(0.854, 10.224)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.26
95% CI for the ARR		(-0.022, 0.534)

NOTE 1: AEs were coded using MedDRA version 24.0.

Source: biib125/v_a/germany_amnog/t-ae-301-by.sas:t-ae-301-by-hama-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with at Least One Treatment-Emergent Adverse Event by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - Safety Population

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Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

	Placebo (N=77)	Zuranolone (N=74)
Number of subjects with >=1 TEAE, n (%)	46 (59.7)	52 (70.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.18
95% CI for the RR		(0.929, 1.489)
p-value for RR		0.1771
OR - Odds Ratio (Zuranolone vs. Placebo)		1.59
95% CI for the OR		(0.811, 3.129)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.11
95% CI for the ARR		(-0.046, 0.256)

NOTE 1: AEs were coded using MedDRA version 24.0.

Source: biib125/v_a/germany_amnog/t-ae-301-by.sas:t-ae-301-by-hama-safc.rtf **Run Date:** 21JUL2025

3.1.2 nach SOC

3.1.2.1 ITT-Population

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class: 217-PPD-301 - Safety population

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Nervous system disorders

	Placebo (N=98)	Zuranolone (N=98)
Number of subjects with >=1 TEAE, n (%)	26 (26.5)	50 (51.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.92
95% CI for the RR		(1.312, 2.819)
p-value for RR		0.0008
OR - Odds Ratio (Zuranolone vs. Placebo)		2.88
95% CI for the OR		(1.586, 5.247)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.24
95% CI for the ARR		(0.113, 0.377)

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-301-ovr.sas:t-ae-soc-301-ovr-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class: 217-PPD-301 - Safety population

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Gastrointestinal disorders

	Placebo (N=98)	Zuranolone (N=98)
Number of subjects with >=1 TEAE, n (%)	14 (14.3)	13 (13.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.93
95% CI for the RR		(0.461, 1.872)
p-value for RR		0.8359
OR - Odds Ratio (Zuranolone vs. Placebo)		0.92
95% CI for the OR		(0.407, 2.069)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.01
95% CI for the ARR		(-0.107, 0.086)

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-301-ovr.sas:t-ae-soc-301-ovr-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class: 217-PPD-301 - Safety population

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Infections and infestations

	Placebo (N=98)	Zuranolone (N=98)
Number of subjects with >=1 TEAE, n (%)	8 (8.2)	13 (13.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.63
95% CI for the RR		(0.705, 3.745)
p-value for RR		0.2545
OR - Odds Ratio (Zuranolone vs. Placebo)		1.72
95% CI for the OR		(0.679, 4.358)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.05
95% CI for the ARR		(-0.035, 0.137)

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-301-ovr.sas:t-ae-soc-301-ovr-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class: 217-PPD-301 - Safety population

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General disorders and administration site conditions

	Placebo (N=98)	Zuranolone (N=98)
Number of subjects with >=1 TEAE, n (%)	3 (3.1)	11 (11.2)
RR - Relative Risk (Zuranolone vs. Placebo)		3.67
95% CI for the RR		(1.055, 12.741)
p-value for RR		0.0409
OR - Odds Ratio (Zuranolone vs. Placebo)		4.00
95% CI for the OR		(1.081, 14.829)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.08
95% CI for the ARR		(0.010, 0.153)

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-301-ovr.sas:t-ae-soc-301-ovr-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class: 217-PPD-301 - Safety population

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Psychiatric disorders

	Placebo (N=98)	Zuranolone (N=98)
Number of subjects with >=1 TEAE, n (%)	4 (4.1)	10 (10.2)
RR - Relative Risk (Zuranolone vs. Placebo)		2.50
95% CI for the RR		(0.811, 7.702)
p-value for RR		0.1105
OR - Odds Ratio (Zuranolone vs. Placebo)		2.67
95% CI for the OR		(0.808, 8.826)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.06
95% CI for the ARR		(-0.010, 0.133)

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-301-ovr.sas:t-ae-soc-301-ovr-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class: 217-PPD-301 - Safety population

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Investigations

	Placebo (N=98)	Zuranolone (N=98)
Number of subjects with >=1 TEAE, n (%)	12 (12.2)	5 (5.1)
RR - Relative Risk (Zuranolone vs. Placebo)		0.42
95% CI for the RR		(0.153, 1.138)
p-value for RR		0.0878
OR - Odds Ratio (Zuranolone vs. Placebo)		0.39
95% CI for the OR		(0.130, 1.139)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.07
95% CI for the ARR		(-0.150, 0.007)

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-301-ovr.sas:t-ae-soc-301-ovr-safc.rtf **Run Date:** 18JUL2025

3.1.2.2 Subgruppen

3.1.2.2 .1 Interaktionstest

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class: Treatment by Subgroup Interaction: 217-PPD-301 - Safety Population

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Nervous system disorders

Subgroup Subgroup Category	Placebo (N=98)	Zuranolone (N=98)	p-value for Treatment by Subgroup Interaction Test
Number of subjects with >=1 TEAE, n(%)	26 (26.5)	50 (51.0)	
Age Group (years)			
18 - 24, n / N (%)	2/12 (16.7)	11/19 (57.9)	0.3796
25 - 45, n / N (%)	24/86 (27.9)	39/79 (49.4)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	8/32 (25.0)	14/33 (42.4)	0.7152
>=28, n / N (%)	18/66 (27.3)	36/65 (55.4)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	9/18 (50.0)	12/25 (48.0)	0.0357
White, n / N (%)	12/69 (17.4)	36/68 (52.9)	

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-301-int.sas:t-ae-soc-301-int-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class: Treatment by Subgroup Interaction: 217-PPD-301 - Safety Population

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Nervous system disorders

Subgroup Subgroup Category	Placebo (N=98)	Zuranolone (N=98)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			
Yes, n / N (%)	2/15 (13.3)	7/15 (46.7)	0.4047
No, n / N (%)	24/83 (28.9)	43/83 (51.8)	
BMI (kg/m^2}) Group 2			
<=24.9, n / N (%)	6/22 (27.3)	10/20 (50.0)	0.9074(a)
25-29.9, n / N (%)	9/34 (26.5)	11/24 (45.8)	0.8627(b)
>=30, n / N (%)	11/42 (26.2)	29/53 (54.7)	0.7422(c)
Onset of PPD			
3rd Trimester, n / N (%)	9/31 (29.0)	12/34 (35.3)	0.2318
Postpartum, n / N (%)	17/67 (25.4)	38/64 (59.4)	
Family History of PPD			
Yes, n / N (%)	2/16 (12.5)	12/21 (57.1)	0.1769
No/Unknown, n / N (%)	24/82 (29.3)	38/77 (49.4)	

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 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-301-int.sas:t-ae-soc-301-int-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class: Treatment by Subgroup Interaction: 217-PPD-301 - Safety Population

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Nervous system disorders

Subgroup Subgroup Category	Placebo (N=98)	Zuranolone (N=98)	p-value for Treatment by Subgroup Interaction Test
History of PPD			
1st Episode, n / N (%)	22/87 (25.3)	40/81 (49.4)	0.8877
Recurrent Episode, n / N (%)	4/11 (36.4)	10/17 (58.8)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
>=20, n / N (%)	26/77 (33.8)	40/74 (54.1)	0.0873
<20, n / N (%)	0/21	10/24 (41.7)	

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-301-int.sas:t-ae-soc-301-int-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class: Treatment by Subgroup Interaction: 217-PPD-301 - Safety Population

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Gastrointestinal disorders

Subgroup Subgroup Category	Placebo (N=98)	Zuranolone (N=98)	p-value for Treatment by Subgroup Interaction Test
Number of subjects with >=1 TEAE, n(%)	14 (14.3)	13 (13.3)	
Age Group (years)			
18 - 24, n / N (%)	1/12 (8.3)	3/19 (15.8)	0.4824
25 - 45, n / N (%)	13/86 (15.1)	10/79 (12.7)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	4/32 (12.5)	5/33 (15.2)	0.5876
>=28, n / N (%)	10/66 (15.2)	8/65 (12.3)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	1/18 (5.6)	2/25 (8.0)	0.8599
White, n / N (%)	9/69 (13.0)	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 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-301-int.sas:t-ae-soc-301-int-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class: Treatment by Subgroup Interaction: 217-PPD-301 - Safety Population

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Gastrointestinal disorders

Subgroup Subgroup Category	Placebo (N=98)	Zuranolone (N=98)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			
Yes, n / N (%)	4/15 (26.7)	3/15 (20.0)	0.7444
No, n / N (%)	10/83 (12.0)	10/83 (12.0)	
BMI (kg/m^2}) Group 2			
<=24.9, n / N (%)	3/22 (13.6)	0/20	0.2443(a)
25-29.9, n / N (%)	4/34 (11.8)	3/24 (12.5)	0.2010(b)
>=30, n / N (%)	7/42 (16.7)	10/53 (18.9)	0.9401(c)
Onset of PPD			
3rd Trimester, n / N (%)	2/31 (6.5)	2/34 (5.9)	0.9195
Postpartum, n / N (%)	12/67 (17.9)	11/64 (17.2)	
Family History of PPD			
Yes, n / N (%)	0/16	2/21 (9.5)	0.3267
No/Unknown, n / N (%)	14/82 (17.1)	11/77 (14.3)	

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 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-301-int.sas:t-ae-soc-301-int-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class: Treatment by Subgroup Interaction: 217-PPD-301 - Safety Population

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Gastrointestinal disorders

Subgroup Subgroup Category	Placebo (N=98)	Zuranolone (N=98)	p-value for Treatment by Subgroup Interaction Test
History of PPD			
1st Episode, n / N (%)	12/87 (13.8)	10/81 (12.3)	0.8402
Recurrent Episode, n / N (%)	2/11 (18.2)	3/17 (17.6)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
>=20, n / N (%)	14/77 (18.2)	10/74 (13.5)	0.1673
<20, n / N (%)	0/21	3/24 (12.5)	

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 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-301-int.sas:t-ae-soc-301-int-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class: Treatment by Subgroup Interaction: 217-PPD-301 - Safety Population

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Infections and infestations

Subgroup Subgroup Category	Placebo (N=98)	Zuranolone (N=98)	p-value for Treatment by Subgroup Interaction Test
Number of subjects with >=1 TEAE, n(%)	8 (8.2)	13 (13.3)	
Age Group (years)			
18 - 24, n / N (%)	2/12 (16.7)	5/19 (26.3)	NA
25 - 45, n / N (%)	6/86 (7.0)	8/79 (10.1)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	4/32 (12.5)	3/33 (9.1)	0.2240
>=28, n / N (%)	4/66 (6.1)	10/65 (15.4)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	3/18 (16.7)	3/25 (12.0)	0.3903
White, n / N (%)	5/69 (7.2)	10/68 (14.7)	

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-301-int.sas:t-ae-soc-301-int-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class: Treatment by Subgroup Interaction: 217-PPD-301 - Safety Population

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Infections and infestations

Subgroup Subgroup Category	Placebo (N=98)	Zuranolone (N=98)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			
Yes, n / N (%)	5/15 (33.3)	3/15 (20.0)	0.0701
No, n / N (%)	3/83 (3.6)	10/83 (12.0)	
BMI (kg/m^2}) Group 2			
<=24.9, n / N (%)	2/22 (9.1)	0/20	0.1948(a)
25-29.9, n / N (%)	2/34 (5.9)	3/24 (12.5)	0.1734(b)
>=30, n / N (%)	4/42 (9.5)	10/53 (18.9)	0.9460(c)
Onset of PPD			
3rd Trimester, n / N (%)	3/31 (9.7)	3/34 (8.8)	0.3306
Postpartum, n / N (%)	5/67 (7.5)	10/64 (15.6)	
Family History of PPD			
Yes, n / N (%)	2/16 (12.5)	2/21 (9.5)	0.3995
No/Unknown, n / N (%)	6/82 (7.3)	11/77 (14.3)	

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 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-301-int.sas:t-ae-soc-301-int-safc.rtf **Run Date:** 18JUL2025

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Infections and infestations

Subgroup Subgroup Category	Placebo (N=98)	Zuranolone (N=98)	p-value for Treatment by Subgroup Interaction Test
History of PPD			
1st Episode, n / N (%)	7/87 (8.0)	9/81 (11.1)	NA
Recurrent Episode, n / N (%)	1/11 (9.1)	4/17 (23.5)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
>=20, n / N (%)	8/77 (10.4)	11/74 (14.9)	0.4777
<20, n / N (%)	0/21	2/24 (8.3)	

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 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-301-int.sas:t-ae-soc-301-int-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class: Treatment by Subgroup Interaction: 217-PPD-301 - Safety Population

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General disorders and administration site conditions

Subgroup Subgroup Category	Placebo (N=98)	Zuranolone (N=98)	p-value for Treatment by Subgroup Interaction Test
Number of subjects with >=1 TEAE, n(%)	3 (3.1)	11 (11.2)	
Age Group (years)			
18 - 24, n / N (%)	0/12	2/19 (10.5)	NA
25 - 45, n / N (%)	3/86 (3.5)	9/79 (11.4)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	2/32 (6.3)	0/33	0.0280
>=28, n / N (%)	1/66 (1.5)	11/65 (16.9)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	1/18 (5.6)	5/25 (20.0)	NA
White, n / N (%)	2/69 (2.9)	6/68 (8.8)	

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-301-int.sas:t-ae-soc-301-int-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class: Treatment by Subgroup Interaction: 217-PPD-301 - Safety Population

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General disorders and administration site conditions

Subgroup Subgroup Category	Placebo (N=98)	Zuranolone (N=98)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			
Yes, n / N (%)	0/15	2/15 (13.3)	NA
No, n / N (%)	3/83 (3.6)	9/83 (10.8)	
BMI (kg/m^2}) Group 2			
<=24.9, n / N (%)	0/22	1/20 (5.0)	NA(a)
25-29.9, n / N (%)	1/34 (2.9)	4/24 (16.7)	NA(b)
>=30, n / N (%)	2/42 (4.8)	6/53 (11.3)	NA(c)
Onset of PPD			
3rd Trimester, n / N (%)	2/31 (6.5)	0/34	0.0247
Postpartum, n / N (%)	1/67 (1.5)	11/64 (17.2)	
Family History of PPD			
Yes, n / N (%)	0/16	2/21 (9.5)	NA
No/Unknown, n / N (%)	3/82 (3.7)	9/77 (11.7)	

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-301-int.sas:t-ae-soc-301-int-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class: Treatment by Subgroup Interaction: 217-PPD-301 - Safety Population

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General disorders and administration site conditions

Subgroup Subgroup Category	Placebo (N=98)	Zuranolone (N=98)	p-value for Treatment by Subgroup Interaction Test
History of PPD			
1st Episode, n / N (%)	2/87 (2.3)	8/81 (9.9)	NA
Recurrent Episode, n / N (%)	1/11 (9.1)	3/17 (17.6)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
>=20, n / N (%)	3/77 (3.9)	10/74 (13.5)	0.8745
<20, n / N (%)	0/21	1/24 (4.2)	

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-301-int.sas:t-ae-soc-301-int-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class: Treatment by Subgroup Interaction: 217-PPD-301 - Safety Population

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Psychiatric disorders

Subgroup Subgroup Category	Placebo (N=98)	Zuranolone (N=98)	p-value for Treatment by Subgroup Interaction Test
Number of subjects with >=1 TEAE, n(%)	4 (4.1)	10 (10.2)	
Age Group (years)			
18 - 24, n / N (%)	0/12	1/19 (5.3)	NA
25 - 45, n / N (%)	4/86 (4.7)	9/79 (11.4)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	1/32 (3.1)	3/33 (9.1)	NA
>=28, n / N (%)	3/66 (4.5)	7/65 (10.8)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	0/18	3/25 (12.0)	NA
White, n / N (%)	4/69 (5.8)	6/68 (8.8)	

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-301-int.sas:t-ae-soc-301-int-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class: Treatment by Subgroup Interaction: 217-PPD-301 - Safety Population

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Psychiatric disorders

Subgroup Subgroup Category	Placebo (N=98)	Zuranolone (N=98)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			
Yes, n / N (%)	1/15 (6.7)	1/15 (6.7)	NA
No, n / N (%)	3/83 (3.6)	9/83 (10.8)	
BMI (kg/m^2}) Group 2			
<=24.9, n / N (%)	1/22 (4.5)	1/20 (5.0)	NA(a)
25-29.9, n / N (%)	0/34	1/24 (4.2)	NA(b)
>=30, n / N (%)	3/42 (7.1)	8/53 (15.1)	NA(c)
Onset of PPD			
3rd Trimester, n / N (%)	1/31 (3.2)	4/34 (11.8)	NA
Postpartum, n / N (%)	3/67 (4.5)	6/64 (9.4)	
Family History of PPD			
Yes, n / N (%)	0/16	2/21 (9.5)	NA
No/Unknown, n / N (%)	4/82 (4.9)	8/77 (10.4)	

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 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-301-int.sas:t-ae-soc-301-int-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class: Treatment by Subgroup Interaction: 217-PPD-301 - Safety Population

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Psychiatric disorders

Subgroup Subgroup Category	Placebo (N=98)	Zuranolone (N=98)	p-value for Treatment by Subgroup Interaction Test
History of PPD			
1st Episode, n / N (%)	3/87 (3.4)	8/81 (9.9)	NA
Recurrent Episode, n / N (%)	1/11 (9.1)	2/17 (11.8)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
>=20, n / N (%)	4/77 (5.2)	9/74 (12.2)	NA
<20, n / N (%)	0/21	1/24 (4.2)	

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-301-int.sas:t-ae-soc-301-int-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class: Treatment by Subgroup Interaction: 217-PPD-301 - Safety Population

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Investigations

Subgroup Subgroup Category	Placebo (N=98)	Zuranolone (N=98)	p-value for Treatment by Subgroup Interaction Test
Number of subjects with >=1 TEAE, n(%)	12 (12.2)	5 (5.1)	
Age Group (years)			
18 - 24, n / N (%)	3/12 (25.0)	1/19 (5.3)	NA
25 - 45, n / N (%)	9/86 (10.5)	4/79 (5.1)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	2/32 (6.3)	3/33 (9.1)	0.0900
>=28, n / N (%)	10/66 (15.2)	2/65 (3.1)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	1/18 (5.6)	1/25 (4.0)	0.6789
White, n / N (%)	11/69 (15.9)	4/68 (5.9)	

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-301-int.sas:t-ae-soc-301-int-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class: Treatment by Subgroup Interaction: 217-PPD-301 - Safety Population

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Investigations

Subgroup Subgroup Category	Placebo (N=98)	Zuranolone (N=98)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			
Yes, n / N (%)	1/15 (6.7)	1/15 (6.7)	0.5134
No, n / N (%)	11/83 (13.3)	4/83 (4.8)	
BMI (kg/m^2}) Group 2			
<=24.9, n / N (%)	7/22 (31.8)	1/20 (5.0)	NA(a)
25-29.9, n / N (%)	4/34 (11.8)	1/24 (4.2)	NA(b)
>=30, n / N (%)	1/42 (2.4)	3/53 (5.7)	NA(c)
Onset of PPD			
3rd Trimester, n / N (%)	2/31 (6.5)	1/34 (2.9)	0.9385
Postpartum, n / N (%)	10/67 (14.9)	4/64 (6.3)	
Family History of PPD			
Yes, n / N (%)	0/16	1/21 (4.8)	0.2681
No/Unknown, n / N (%)	12/82 (14.6)	4/77 (5.2)	

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-301-int.sas:t-ae-soc-301-int-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class: Treatment by Subgroup Interaction: 217-PPD-301 - Safety Population

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Investigations

Subgroup Subgroup Category	Placebo (N=98)	Zuranolone (N=98)	p-value for Treatment by Subgroup Interaction Test
History of PPD			
1st Episode, n / N (%)	12/87 (13.8)	4/81 (4.9)	0.3071
Recurrent Episode, n / N (%)	0/11	1/17 (5.9)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
>=20, n / N (%)	7/77 (9.1)	4/74 (5.4)	NA
<20, n / N (%)	5/21 (23.8)	1/24 (4.2)	

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-301-int.sas:t-ae-soc-301-int-safc.rtf **Run Date:** 18JUL2025

3.1.2.2 .2 Subgruppenanalysen

3.1.2.2 .2 .1 Alter

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Age Group: 217-PPD-301 - Safety Population

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Nervous system disorders

Age Group (years) = 18-24

	Placebo (N=12)	Zuranolone (N=19)
Number of subjects with >=1 TEAE, n (%)	2 (16.7)	11 (57.9)
RR - Relative Risk (Zuranolone vs. Placebo)		3.47
95% CI for the RR		(0.926, 13.029)
p-value for RR		0.0649
OR - Odds Ratio (Zuranolone vs. Placebo)		6.88
95% CI for the OR		(1.171, 40.378)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.41
95% CI for the ARR		(0.106, 0.718)

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-301-by.sas:t-ae-soc-301-by-age-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Age Group: 217-PPD-301 - Safety Population

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Nervous system disorders

Age Group (years) = 25-45

	Placebo (N=86)	Zuranolone (N=79)
Number of subjects with >=1 TEAE, n (%)	24 (27.9)	39 (49.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.77
95% CI for the RR		(1.178, 2.656)
p-value for RR		0.0060
OR - Odds Ratio (Zuranolone vs. Placebo)		2.52
95% CI for the OR		(1.321, 4.803)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.21
95% CI for the ARR		(0.069, 0.360)

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-301-by.sas:t-ae-soc-301-by-age-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Age Group: 217-PPD-301 - Safety Population

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Gastrointestinal disorders

Age Group (years) = 18-24

	Placebo (N=12)	Zuranolone (N=19)
Number of subjects with >=1 TEAE, n (%)	1 (8.3)	3 (15.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.89
95% CI for the RR		(0.222, 16.180)
p-value for RR		0.5592
OR - Odds Ratio (Zuranolone vs. Placebo)		2.06
95% CI for the OR		(0.189, 22.505)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.07
95% CI for the ARR		(-0.152, 0.301)

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-301-by.sas:t-ae-soc-301-by-age-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Age Group: 217-PPD-301 - Safety Population

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Gastrointestinal disorders

Age Group (years) = 25-45

	Placebo (N=86)	Zuranolone (N=79)
Number of subjects with >=1 TEAE, n (%)	13 (15.1)	10 (12.7)
RR - Relative Risk (Zuranolone vs. Placebo)		0.84
95% CI for the RR		(0.389, 1.801)
p-value for RR		0.6497
OR - Odds Ratio (Zuranolone vs. Placebo)		0.81
95% CI for the OR		(0.335, 1.977)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.02
95% CI for the ARR		(-0.130, 0.081)

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-301-by.sas:t-ae-soc-301-by-age-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Age Group: 217-PPD-301 - Safety Population

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Infections and infestations

Age Group (years) = 18-24

	Placebo (N=12)	Zuranolone (N=19)
Number of subjects with >=1 TEAE, n (%)	2 (16.7)	5 (26.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.58
95% CI for the RR		(0.362, 6.881)
p-value for RR		0.5431
OR - Odds Ratio (Zuranolone vs. Placebo)		1.79
95% CI for the OR		(0.287, 11.128)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.10
95% CI for the ARR		(-0.193, 0.386)

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-301-by.sas:t-ae-soc-301-by-age-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Age Group: 217-PPD-301 - Safety Population

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Infections and infestations

Age Group (years) = 25-45

	Placebo (N=86)	Zuranolone (N=79)
Number of subjects with >=1 TEAE, n (%)	6 (7.0)	8 (10.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.45
95% CI for the RR		(0.527, 3.999)
p-value for RR		0.4712
OR - Odds Ratio (Zuranolone vs. Placebo)		1.50
95% CI for the OR		(0.497, 4.539)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.03
95% CI for the ARR		(-0.054, 0.117)

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-301-by.sas:t-ae-soc-301-by-age-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Age Group: 217-PPD-301 - Safety Population

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General disorders and administration site conditions

Age Group (years) = 18-24

	Placebo (N=12)	Zuranolone (N=19)
Number of subjects with >=1 TEAE, n (%)	0	2 (10.5)
RR - Relative Risk (Zuranolone vs. Placebo)		3.25
95% CI for the RR		(0.169, 62.405)
p-value for RR		0.4343
OR - Odds Ratio (Zuranolone vs. Placebo)		3.57
95% CI for the OR		(0.157, 81.035)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.09
95% CI for the ARR		(-0.092, 0.265)

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-301-by.sas:t-ae-soc-301-by-age-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Age Group: 217-PPD-301 - Safety Population

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General disorders and administration site conditions

Age Group (years) = 25-45

	Placebo (N=86)	Zuranolone (N=79)
Number of subjects with >=1 TEAE, n (%)	3 (3.5)	9 (11.4)
RR - Relative Risk (Zuranolone vs. Placebo)		3.27
95% CI for the RR		(0.917, 11.634)
p-value for RR		0.0679
OR - Odds Ratio (Zuranolone vs. Placebo)		3.56
95% CI for the OR		(0.927, 13.650)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.08
95% CI for the ARR		(-0.001, 0.159)

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-301-by.sas:t-ae-soc-301-by-age-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Age Group: 217-PPD-301 - Safety Population

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Psychiatric disorders

Age Group (years) = 18-24

	Placebo (N=12)	Zuranolone (N=19)
Number of subjects with >=1 TEAE, n (%)	0	1 (5.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.95
95% CI for the RR		(0.086, 44.316)
p-value for RR		0.6752
OR - Odds Ratio (Zuranolone vs. Placebo)		2.03
95% CI for the OR		(0.076, 53.874)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.04
95% CI for the ARR		(-0.119, 0.192)

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-301-by.sas:t-ae-soc-301-by-age-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Age Group: 217-PPD-301 - Safety Population

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Psychiatric disorders

Age Group (years) = 25-45

	Placebo (N=86)	Zuranolone (N=79)
Number of subjects with >=1 TEAE, n (%)	4 (4.7)	9 (11.4)
RR - Relative Risk (Zuranolone vs. Placebo)		2.45
95% CI for the RR		(0.785, 7.639)
p-value for RR		0.1227
OR - Odds Ratio (Zuranolone vs. Placebo)		2.64
95% CI for the OR		(0.778, 8.930)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.07
95% CI for the ARR		(-0.016, 0.150)

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-301-by.sas:t-ae-soc-301-by-age-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Age Group: 217-PPD-301 - Safety Population

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Investigations

Age Group (years) = 18-24

	Placebo (N=12)	Zuranolone (N=19)
Number of subjects with >=1 TEAE, n (%)	3 (25.0)	1 (5.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.21
95% CI for the RR		(0.025, 1.798)
p-value for RR		0.1545
OR - Odds Ratio (Zuranolone vs. Placebo)		0.17
95% CI for the OR		(0.015, 1.838)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.20
95% CI for the ARR		(-0.462, 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-301-by.sas:t-ae-soc-301-by-age-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Age Group: 217-PPD-301 - Safety Population

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Investigations

Age Group (years) = 25-45

	Placebo (N=86)	Zuranolone (N=79)
Number of subjects with >=1 TEAE, n (%)	9 (10.5)	4 (5.1)
RR - Relative Risk (Zuranolone vs. Placebo)		0.48
95% CI for the RR		(0.155, 1.509)
p-value for RR		0.2109
OR - Odds Ratio (Zuranolone vs. Placebo)		0.46
95% CI for the OR		(0.135, 1.545)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.05
95% CI for the ARR		(-0.135, 0.027)

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-301-by.sas:t-ae-soc-301-by-age-safc.rtf **Run Date:** 21JUL2025

3.1.2.2 .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-301 - 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=32)	Zuranolone (N=33)
Number of subjects with >=1 TEAE, n (%)	8 (25.0)	14 (42.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.70
95% CI for the RR		(0.826, 3.486)
p-value for RR		0.1499
OR - Odds Ratio (Zuranolone vs. Placebo)		2.21
95% CI for the OR		(0.768, 6.360)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.17
95% CI for the ARR		(-0.051, 0.400)

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-301-by.sas:t-ae-soc-301-by-hamd-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline HAMD-17 Total Score: 217-PPD-301 - Safety Population

Page: 2 of 12

Nervous system disorders

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

	Placebo (N=66)	Zuranolone (N=65)
Number of subjects with >=1 TEAE, n (%)	18 (27.3)	36 (55.4)
RR - Relative Risk (Zuranolone vs. Placebo)		2.03
95% CI for the RR		(1.294, 3.186)
p-value for RR		0.0020
OR - Odds Ratio (Zuranolone vs. Placebo)		3.31
95% CI for the OR		(1.596, 6.868)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.28
95% CI for the ARR		(0.119, 0.443)

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-301-by.sas:t-ae-soc-301-by-hamd-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline HAMD-17 Total Score: 217-PPD-301 - Safety Population

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Gastrointestinal disorders

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

	Placebo (N=32)	Zuranolone (N=33)
Number of subjects with >=1 TEAE, n (%)	4 (12.5)	5 (15.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.21
95% CI for the RR		(0.357, 4.112)
p-value for RR		0.7576
OR - Odds Ratio (Zuranolone vs. Placebo)		1.25
95% CI for the OR		(0.304, 5.147)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.03
95% CI for the ARR		(-0.141, 0.194)

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-301-by.sas:t-ae-soc-301-by-hamd-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline HAMD-17 Total Score: 217-PPD-301 - Safety Population

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Gastrointestinal disorders

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

	Placebo (N=66)	Zuranolone (N=65)
Number of subjects with >=1 TEAE, n (%)	10 (15.2)	8 (12.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.81
95% CI for the RR		(0.342, 1.928)
p-value for RR		0.6374
OR - Odds Ratio (Zuranolone vs. Placebo)		0.79
95% CI for the OR		(0.289, 2.137)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.03
95% CI for the ARR		(-0.146, 0.089)

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-301-by.sas:t-ae-soc-301-by-hamd-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline HAMD-17 Total Score: 217-PPD-301 - 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=32)	Zuranolone (N=33)
Number of subjects with >=1 TEAE, n (%)	4 (12.5)	3 (9.1)
RR - Relative Risk (Zuranolone vs. Placebo)		0.73
95% CI for the RR		(0.177, 2.996)
p-value for RR		0.6593
OR - Odds Ratio (Zuranolone vs. Placebo)		0.70
95% CI for the OR		(0.144, 3.409)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.03
95% CI for the ARR		(-0.185, 0.117)

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-301-by.sas:t-ae-soc-301-by-hamd-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline HAMD-17 Total Score: 217-PPD-301 - 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=66)	Zuranolone (N=65)
Number of subjects with >=1 TEAE, n (%)	4 (6.1)	10 (15.4)
RR - Relative Risk (Zuranolone vs. Placebo)		2.54
95% CI for the RR		(0.838, 7.686)
p-value for RR		0.0993
OR - Odds Ratio (Zuranolone vs. Placebo)		2.82
95% CI for the OR		(0.836, 9.498)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.09
95% CI for the ARR		(-0.012, 0.198)

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-301-by.sas:t-ae-soc-301-by-hamd-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline HAMD-17 Total Score: 217-PPD-301 - Safety Population

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General disorders and administration site conditions

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

	Placebo (N=32)	Zuranolone (N=33)
Number of subjects with >=1 TEAE, n (%)	2 (6.3)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.19
95% CI for the RR		(0.010, 3.893)
p-value for RR		0.2839
OR - Odds Ratio (Zuranolone vs. Placebo)		0.18
95% CI for the OR		(0.008, 3.945)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.06
95% CI for the ARR		(-0.160, 0.038)

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-301-by.sas:t-ae-soc-301-by-hamd-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline HAMD-17 Total Score: 217-PPD-301 - Safety Population

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General disorders and administration site conditions

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

	Placebo (N=66)	Zuranolone (N=65)
Number of subjects with >=1 TEAE, n (%)	1 (1.5)	11 (16.9)
RR - Relative Risk (Zuranolone vs. Placebo)		11.17
95% CI for the RR		(1.484, 84.051)
p-value for RR		0.0191
OR - Odds Ratio (Zuranolone vs. Placebo)		13.24
95% CI for the OR		(1.656, 105.846)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.15
95% CI for the ARR		(0.058, 0.250)

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-301-by.sas:t-ae-soc-301-by-hamd-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline HAMD-17 Total Score: 217-PPD-301 - Safety Population

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Psychiatric disorders

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

	Placebo (N=32)	Zuranolone (N=33)
Number of subjects with >=1 TEAE, n (%)	1 (3.1)	3 (9.1)
RR - Relative Risk (Zuranolone vs. Placebo)		2.91
95% CI for the RR		(0.319, 26.527)
p-value for RR		0.3437
OR - Odds Ratio (Zuranolone vs. Placebo)		3.10
95% CI for the OR		(0.305, 31.487)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.06
95% CI for the ARR		(-0.055, 0.175)

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-301-by.sas:t-ae-soc-301-by-hamd-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline HAMD-17 Total Score: 217-PPD-301 - Safety Population

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Psychiatric disorders

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

	Placebo (N=66)	Zuranolone (N=65)
Number of subjects with >=1 TEAE, n (%)	3 (4.5)	7 (10.8)
RR - Relative Risk (Zuranolone vs. Placebo)		2.37
95% CI for the RR		(0.640, 8.767)
p-value for RR		0.1963
OR - Odds Ratio (Zuranolone vs. Placebo)		2.53
95% CI for the OR		(0.626, 10.265)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.06
95% CI for the ARR		(-0.028, 0.153)

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-301-by.sas:t-ae-soc-301-by-hamd-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline HAMD-17 Total Score: 217-PPD-301 - Safety Population

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Investigations

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

	Placebo (N=32)	Zuranolone (N=33)
Number of subjects with >=1 TEAE, n (%)	2 (6.3)	3 (9.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.45
95% CI for the RR		(0.260, 8.138)
p-value for RR		0.6697
OR - Odds Ratio (Zuranolone vs. Placebo)		1.50
95% CI for the OR		(0.234, 9.630)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.03
95% CI for the ARR		(-0.101, 0.157)

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-301-by.sas:t-ae-soc-301-by-hamd-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline HAMD-17 Total Score: 217-PPD-301 - Safety Population

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Investigations

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

	Placebo (N=66)	Zuranolone (N=65)
Number of subjects with >=1 TEAE, n (%)	10 (15.2)	2 (3.1)
RR - Relative Risk (Zuranolone vs. Placebo)		0.20
95% CI for the RR		(0.046, 0.891)
p-value for RR		0.0346
OR - Odds Ratio (Zuranolone vs. Placebo)		0.18
95% CI for the OR		(0.037, 0.846)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.12
95% CI for the ARR		(-0.217, -0.025)

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-301-by.sas:t-ae-soc-301-by-hamd-safc.rtf **Run Date:** 21JUL2025

3.1.2.2 .2 .3 Abstammung

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Race Group: 217-PPD-301 - Safety Population

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Nervous system disorders

Race Group = Black or African American

	Placebo (N=18)	Zuranolone (N=25)
Number of subjects with >=1 TEAE, n (%)	9 (50.0)	12 (48.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.96
95% CI for the RR		(0.518, 1.778)
p-value for RR		0.8967
OR - Odds Ratio (Zuranolone vs. Placebo)		0.92
95% CI for the OR		(0.275, 3.102)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.02
95% CI for the ARR		(-0.323, 0.283)

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-301-by.sas:t-ae-soc-301-by-race-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Race Group: 217-PPD-301 - Safety Population

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Nervous system disorders

Race Group = White

	Placebo (N=69)	Zuranolone (N=68)
Number of subjects with >=1 TEAE, n (%)	12 (17.4)	36 (52.9)
RR - Relative Risk (Zuranolone vs. Placebo)		3.04
95% CI for the RR		(1.737, 5.334)
p-value for RR		0.0001
OR - Odds Ratio (Zuranolone vs. Placebo)		5.34
95% CI for the OR		(2.440, 11.701)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.36
95% CI for the ARR		(0.207, 0.504)

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-301-by.sas:t-ae-soc-301-by-race-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Race Group: 217-PPD-301 - Safety Population

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Gastrointestinal disorders

Race Group = Black or African American

	Placebo (N=18)	Zuranolone (N=25)
Number of subjects with >=1 TEAE, n (%)	1 (5.6)	2 (8.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.44
95% CI for the RR		(0.141, 14.693)
p-value for RR		0.7583
OR - Odds Ratio (Zuranolone vs. Placebo)		1.48
95% CI for the OR		(0.124, 17.669)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.02
95% CI for the ARR		(-0.126, 0.174)

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-301-by.sas:t-ae-soc-301-by-race-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Race Group: 217-PPD-301 - Safety Population

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Gastrointestinal disorders

Race Group = White

	Placebo (N=69)	Zuranolone (N=68)
Number of subjects with >=1 TEAE, n (%)	9 (13.0)	11 (16.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.24
95% CI for the RR		(0.549, 2.801)
p-value for RR		0.6046
OR - Odds Ratio (Zuranolone vs. Placebo)		1.29
95% CI for the OR		(0.496, 3.335)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.03
95% CI for the ARR		(-0.087, 0.150)

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-301-by.sas:t-ae-soc-301-by-race-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Race Group: 217-PPD-301 - Safety Population

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Infections and infestations

Race Group = Black or African American

	Placebo (N=18)	Zuranolone (N=25)
Number of subjects with >=1 TEAE, n (%)	3 (16.7)	3 (12.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.72
95% CI for the RR		(0.164, 3.167)
p-value for RR		0.6638
OR - Odds Ratio (Zuranolone vs. Placebo)		0.68
95% CI for the OR		(0.121, 3.845)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.05
95% CI for the ARR		(-0.261, 0.167)

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-301-by.sas:t-ae-soc-301-by-race-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Race Group: 217-PPD-301 - Safety Population

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Infections and infestations

Race Group = White

	Placebo (N=69)	Zuranolone (N=68)
Number of subjects with >=1 TEAE, n (%)	5 (7.2)	10 (14.7)
RR - Relative Risk (Zuranolone vs. Placebo)		2.03
95% CI for the RR		(0.732, 5.628)
p-value for RR		0.1738
OR - Odds Ratio (Zuranolone vs. Placebo)		2.21
95% CI for the OR		(0.712, 6.837)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.07
95% CI for the ARR		(-0.029, 0.179)

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-301-by.sas:t-ae-soc-301-by-race-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Race Group: 217-PPD-301 - Safety Population

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General disorders and administration site conditions

Race Group = Black or African American

	Placebo (N=18)	Zuranolone (N=25)
Number of subjects with >=1 TEAE, n (%)	1 (5.6)	5 (20.0)
RR - Relative Risk (Zuranolone vs. Placebo)		3.60
95% CI for the RR		(0.459, 28.239)
p-value for RR		0.2229
OR - Odds Ratio (Zuranolone vs. Placebo)		4.25
95% CI for the OR		(0.451, 40.013)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.14
95% CI for the ARR		(-0.045, 0.334)

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-301-by.sas:t-ae-soc-301-by-race-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Race Group: 217-PPD-301 - Safety Population

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General disorders and administration site conditions

Race Group = White

	Placebo (N=69)	Zuranolone (N=68)
Number of subjects with >=1 TEAE, n (%)	2 (2.9)	6 (8.8)
RR - Relative Risk (Zuranolone vs. Placebo)		3.04
95% CI for the RR		(0.637, 14.557)
p-value for RR		0.1632
OR - Odds Ratio (Zuranolone vs. Placebo)		3.24
95% CI for the OR		(0.631, 16.665)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.06
95% CI for the ARR		(-0.019, 0.137)

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-301-by.sas:t-ae-soc-301-by-race-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Race Group: 217-PPD-301 - Safety Population

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Psychiatric disorders

Race Group = Black or African American

	Placebo (N=18)	Zuranolone (N=25)
Number of subjects with >=1 TEAE, n (%)	0	3 (12.0)
RR - Relative Risk (Zuranolone vs. Placebo)		5.12
95% CI for the RR		(0.280, 93.297)
p-value for RR		0.2705
OR - Odds Ratio (Zuranolone vs. Placebo)		5.76
95% CI for the OR		(0.279, 118.691)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.11
95% CI for the ARR		(-0.041, 0.258)

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-301-by.sas:t-ae-soc-301-by-race-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Race Group: 217-PPD-301 - Safety Population

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Psychiatric disorders

Race Group = White

	Placebo (N=69)	Zuranolone (N=68)
Number of subjects with >=1 TEAE, n (%)	4 (5.8)	6 (8.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.52
95% CI for the RR		(0.449, 5.156)
p-value for RR		0.4998
OR - Odds Ratio (Zuranolone vs. Placebo)		1.57
95% CI for the OR		(0.423, 5.841)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.03
95% CI for the ARR		(-0.057, 0.117)

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-301-by.sas:t-ae-soc-301-by-race-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Race Group: 217-PPD-301 - Safety Population

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Investigations

Race Group = Black or African American

	Placebo (N=18)	Zuranolone (N=25)
Number of subjects with >=1 TEAE, n (%)	1 (5.6)	1 (4.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.72
95% CI for the RR		(0.048, 10.765)
p-value for RR		0.8118
OR - Odds Ratio (Zuranolone vs. Placebo)		0.71
95% CI for the OR		(0.041, 12.131)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.02
95% CI for the ARR		(-0.146, 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-301-by.sas:t-ae-soc-301-by-race-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Race Group: 217-PPD-301 - Safety Population

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Investigations

Race Group = White

	Placebo (N=69)	Zuranolone (N=68)
Number of subjects with >=1 TEAE, n (%)	11 (15.9)	4 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		0.37
95% CI for the RR		(0.124, 1.102)
p-value for RR		0.0741
OR - Odds Ratio (Zuranolone vs. Placebo)		0.33
95% CI for the OR		(0.099, 1.092)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.10
95% CI for the ARR		(-0.203, 0.002)

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-301-by.sas:t-ae-soc-301-by-race-safc.rtf **Run Date:** 21JUL2025

3.1.2.2 .2 .4 Antidepressiva-Nutzung

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline Antidepressant Use: 217-PPD-301 - Safety Population

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Nervous system disorders

Antidepressant Use at Baseline = Yes

	Placebo (N=15)	Zuranolone (N=15)
Number of subjects with >=1 TEAE, n (%)	2 (13.3)	7 (46.7)
RR - Relative Risk (Zuranolone vs. Placebo)		3.50
95% CI for the RR		(0.864, 14.180)
p-value for RR		0.0793
OR - Odds Ratio (Zuranolone vs. Placebo)		5.69
95% CI for the OR		(0.939, 34.457)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.33
95% CI for the ARR		(0.028, 0.639)

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-301-by.sas:t-ae-soc-301-by-adt-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline Antidepressant Use: 217-PPD-301 - Safety Population

Page: 2 of 12

Nervous system disorders

Antidepressant Use at Baseline = No

	Placebo (N=83)	Zuranolone (N=83)
Number of subjects with >=1 TEAE, n (%)	24 (28.9)	43 (51.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.79
95% CI for the RR		(1.206, 2.662)
p-value for RR		0.0039
OR - Odds Ratio (Zuranolone vs. Placebo)		2.64
95% CI for the OR		(1.392, 5.016)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.23
95% CI for the ARR		(0.084, 0.374)

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-301-by.sas:t-ae-soc-301-by-adt-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline Antidepressant Use: 217-PPD-301 - Safety Population

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Gastrointestinal disorders

Antidepressant Use at Baseline = Yes

	Placebo (N=15)	Zuranolone (N=15)
Number of subjects with >=1 TEAE, n (%)	4 (26.7)	3 (20.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.75
95% CI for the RR		(0.201, 2.793)
p-value for RR		0.6680
OR - Odds Ratio (Zuranolone vs. Placebo)		0.69
95% CI for the OR		(0.125, 3.786)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.07
95% CI for the ARR		(-0.368, 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-301-by.sas:t-ae-soc-301-by-adt-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline Antidepressant Use: 217-PPD-301 - Safety Population

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Gastrointestinal disorders

Antidepressant Use at Baseline = No

	Placebo (N=83)	Zuranolone (N=83)
Number of subjects with >=1 TEAE, n (%)	10 (12.0)	10 (12.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.00
95% CI for the RR		(0.440, 2.275)
p-value for RR		1.0000
OR - Odds Ratio (Zuranolone vs. Placebo)		1.00
95% CI for the OR		(0.393, 2.546)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.00
95% CI for the ARR		(-0.099, 0.099)

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-301-by.sas:t-ae-soc-301-by-adt-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline Antidepressant Use: 217-PPD-301 - Safety Population

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Infections and infestations

Antidepressant Use at Baseline = Yes

	Placebo (N=15)	Zuranolone (N=15)
Number of subjects with >=1 TEAE, n (%)	5 (33.3)	3 (20.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.60
95% CI for the RR		(0.174, 2.073)
p-value for RR		0.4193
OR - Odds Ratio (Zuranolone vs. Placebo)		0.50
95% CI for the OR		(0.095, 2.628)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.13
95% CI for the ARR		(-0.446, 0.180)

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-301-by.sas:t-ae-soc-301-by-adt-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline Antidepressant Use: 217-PPD-301 - Safety Population

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Infections and infestations

Antidepressant Use at Baseline = No

	Placebo (N=83)	Zuranolone (N=83)
Number of subjects with >=1 TEAE, n (%)	3 (3.6)	10 (12.0)
RR - Relative Risk (Zuranolone vs. Placebo)		3.33
95% CI for the RR		(0.951, 11.679)
p-value for RR		0.0598
OR - Odds Ratio (Zuranolone vs. Placebo)		3.65
95% CI for the OR		(0.967, 13.793)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.08
95% CI for the ARR		(0.004, 0.165)

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-301-by.sas:t-ae-soc-301-by-adt-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline Antidepressant Use: 217-PPD-301 - Safety Population

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General disorders and administration site conditions

Antidepressant Use at Baseline = Yes

	Placebo (N=15)	Zuranolone (N=15)
Number of subjects with >=1 TEAE, n (%)	0	2 (13.3)
RR - Relative Risk (Zuranolone vs. Placebo)		5.00
95% CI for the RR		(0.260, 96.127)
p-value for RR		0.2860
OR - Odds Ratio (Zuranolone vs. Placebo)		5.74
95% CI for the OR		(0.253, 130.372)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.13
95% CI for the ARR		(-0.072, 0.322)

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-301-by.sas:t-ae-soc-301-by-adt-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline Antidepressant Use: 217-PPD-301 - Safety Population

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General disorders and administration site conditions

Antidepressant Use at Baseline = No

	Placebo (N=83)	Zuranolone (N=83)
Number of subjects with >=1 TEAE, n (%)	3 (3.6)	9 (10.8)
RR - Relative Risk (Zuranolone vs. Placebo)		3.00
95% CI for the RR		(0.842, 10.690)
p-value for RR		0.0902
OR - Odds Ratio (Zuranolone vs. Placebo)		3.24
95% CI for the OR		(0.846, 12.440)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.07
95% CI for the ARR		(-0.006, 0.150)

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-301-by.sas:t-ae-soc-301-by-adt-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline Antidepressant Use: 217-PPD-301 - Safety Population

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Psychiatric disorders

Antidepressant Use at Baseline = Yes

	Placebo (N=15)	Zuranolone (N=15)
Number of subjects with >=1 TEAE, n (%)	1 (6.7)	1 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.00
95% CI for the RR		(0.069, 14.553)
p-value for RR		1.0000
OR - Odds Ratio (Zuranolone vs. Placebo)		1.00
95% CI for the OR		(0.057, 17.621)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.00
95% CI for the ARR		(-0.179, 0.179)

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-301-by.sas:t-ae-soc-301-by-adt-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline Antidepressant Use: 217-PPD-301 - Safety Population

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Psychiatric disorders

Antidepressant Use at Baseline = No

	Placebo (N=83)	Zuranolone (N=83)
Number of subjects with >=1 TEAE, n (%)	3 (3.6)	9 (10.8)
RR - Relative Risk (Zuranolone vs. Placebo)		3.00
95% CI for the RR		(0.842, 10.690)
p-value for RR		0.0902
OR - Odds Ratio (Zuranolone vs. Placebo)		3.24
95% CI for the OR		(0.846, 12.440)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.07
95% CI for the ARR		(-0.006, 0.150)

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-301-by.sas:t-ae-soc-301-by-adt-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline Antidepressant Use: 217-PPD-301 - Safety Population

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Investigations

Antidepressant Use at Baseline = Yes

	Placebo (N=15)	Zuranolone (N=15)
Number of subjects with >=1 TEAE, n (%)	1 (6.7)	1 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.00
95% CI for the RR		(0.069, 14.553)
p-value for RR		1.0000
OR - Odds Ratio (Zuranolone vs. Placebo)		1.00
95% CI for the OR		(0.057, 17.621)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.00
95% CI for the ARR		(-0.179, 0.179)

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-301-by.sas:t-ae-soc-301-by-adt-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline Antidepressant Use: 217-PPD-301 - Safety Population

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Investigations

Antidepressant Use at Baseline = No

	Placebo (N=83)	Zuranolone (N=83)
Number of subjects with >=1 TEAE, n (%)	11 (13.3)	4 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		0.36
95% CI for the RR		(0.121, 1.096)
p-value for RR		0.0723
OR - Odds Ratio (Zuranolone vs. Placebo)		0.33
95% CI for the OR		(0.101, 1.087)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.08
95% CI for the ARR		(-0.171, 0.002)

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-301-by.sas:t-ae-soc-301-by-adt-safc.rtf **Run Date:** 21JUL2025

3.1.2.2 .2 .5 BMI

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline BMI (kg/m^2) Group: 217-PPD-301 - Safety Population

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Nervous system disorders

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

	Placebo (N=22)	Zuranolone (N=20)
Number of subjects with >=1 TEAE, n (%)	6 (27.3)	10 (50.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.83
95% CI for the RR		(0.815, 4.125)
p-value for RR		0.1430
OR - Odds Ratio (Zuranolone vs. Placebo)		2.67
95% CI for the OR		(0.738, 9.629)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.23
95% CI for the ARR		(-0.060, 0.515)

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-301-by.sas:t-ae-soc-301-by-bmi-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline BMI (kg/m^2) Group: 217-PPD-301 - Safety Population

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Nervous system disorders

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

	Placebo (N=34)	Zuranolone (N=24)
Number of subjects with >=1 TEAE, n (%)	9 (26.5)	11 (45.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.73
95% CI for the RR		(0.852, 3.519)
p-value for RR		0.1292
OR - Odds Ratio (Zuranolone vs. Placebo)		2.35
95% CI for the OR		(0.777, 7.110)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.19
95% CI for the ARR		(-0.055, 0.442)

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-301-by.sas:t-ae-soc-301-by-bmi-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline BMI (kg/m^2) Group: 217-PPD-301 - Safety Population

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Nervous system disorders

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

	Placebo (N=42)	Zuranolone (N=53)
Number of subjects with >=1 TEAE, n (%)	11 (26.2)	29 (54.7)
RR - Relative Risk (Zuranolone vs. Placebo)		2.09
95% CI for the RR		(1.189, 3.671)
p-value for RR		0.0104
OR - Odds Ratio (Zuranolone vs. Placebo)		3.41
95% CI for the OR		(1.420, 8.169)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.29
95% CI for the ARR		(0.096, 0.474)

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-301-by.sas:t-ae-soc-301-by-bmi-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline BMI (kg/m^2) Group: 217-PPD-301 - Safety Population

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Gastrointestinal disorders

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

	Placebo (N=22)	Zuranolone (N=20)
Number of subjects with >=1 TEAE, n (%)	3 (13.6)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.16
95% CI for the RR		(0.009, 2.854)
p-value for RR		0.2105
OR - Odds Ratio (Zuranolone vs. Placebo)		0.14
95% CI for the OR		(0.007, 2.805)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.13
95% CI for the ARR		(-0.289, 0.032)

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-301-by.sas:t-ae-soc-301-by-bmi-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline BMI (kg/m^2) Group: 217-PPD-301 - Safety Population

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Gastrointestinal disorders

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

	Placebo (N=34)	Zuranolone (N=24)
Number of subjects with >=1 TEAE, n (%)	4 (11.8)	3 (12.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.06
95% CI for the RR		(0.261, 4.321)
p-value for RR		0.9325
OR - Odds Ratio (Zuranolone vs. Placebo)		1.07
95% CI for the OR		(0.217, 5.293)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.01
95% CI for the ARR		(-0.164, 0.178)

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-301-by.sas:t-ae-soc-301-by-bmi-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline BMI (kg/m^2) Group: 217-PPD-301 - Safety Population

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Gastrointestinal disorders

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

	Placebo (N=42)	Zuranolone (N=53)
Number of subjects with >=1 TEAE, n (%)	7 (16.7)	10 (18.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.13
95% CI for the RR		(0.471, 2.721)
p-value for RR		0.7816
OR - Odds Ratio (Zuranolone vs. Placebo)		1.16
95% CI for the OR		(0.401, 3.370)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.02
95% CI for the ARR		(-0.132, 0.176)

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-301-by.sas:t-ae-soc-301-by-bmi-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline BMI (kg/m^2) Group: 217-PPD-301 - Safety Population

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Infections and infestations

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

	Placebo (N=22)	Zuranolone (N=20)
Number of subjects with >=1 TEAE, n (%)	2 (9.1)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.22
95% CI for the RR		(0.011, 4.305)
p-value for RR		0.3176
OR - Odds Ratio (Zuranolone vs. Placebo)		0.20
95% CI for the OR		(0.009, 4.428)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.08
95% CI for the ARR		(-0.228, 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-301-by.sas:t-ae-soc-301-by-bmi-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline BMI (kg/m^2) Group: 217-PPD-301 - Safety Population

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Infections and infestations

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

	Placebo (N=34)	Zuranolone (N=24)
Number of subjects with >=1 TEAE, n (%)	2 (5.9)	3 (12.5)
RR - Relative Risk (Zuranolone vs. Placebo)		2.13
95% CI for the RR		(0.384, 11.763)
p-value for RR		0.3879
OR - Odds Ratio (Zuranolone vs. Placebo)		2.29
95% CI for the OR		(0.352, 14.859)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.07
95% CI for the ARR		(-0.088, 0.220)

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-301-by.sas:t-ae-soc-301-by-bmi-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline BMI (kg/m^2) Group: 217-PPD-301 - Safety Population

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Infections and infestations

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

	Placebo (N=42)	Zuranolone (N=53)
Number of subjects with >=1 TEAE, n (%)	4 (9.5)	10 (18.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.98
95% CI for the RR		(0.668, 5.872)
p-value for RR		0.2175
OR - Odds Ratio (Zuranolone vs. Placebo)		2.21
95% CI for the OR		(0.640, 7.626)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.09
95% CI for the ARR		(-0.044, 0.231)

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-301-by.sas:t-ae-soc-301-by-bmi-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline BMI (kg/m^2) Group: 217-PPD-301 - Safety Population

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General disorders and administration site conditions

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

	Placebo (N=22)	Zuranolone (N=20)
Number of subjects with >=1 TEAE, n (%)	0	1 (5.0)
RR - Relative Risk (Zuranolone vs. Placebo)		3.29
95% CI for the RR		(0.141, 76.329)
p-value for RR		0.4585
OR - Odds Ratio (Zuranolone vs. Placebo)		3.46
95% CI for the OR		(0.133, 89.951)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.05
95% CI for the ARR		(-0.076, 0.175)

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-301-by.sas:t-ae-soc-301-by-bmi-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline BMI (kg/m^2) Group: 217-PPD-301 - Safety Population

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General disorders and administration site conditions

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

	Placebo (N=34)	Zuranolone (N=24)
Number of subjects with >=1 TEAE, n (%)	1 (2.9)	4 (16.7)
RR - Relative Risk (Zuranolone vs. Placebo)		5.67
95% CI for the RR		(0.675, 47.593)
p-value for RR		0.1101
OR - Odds Ratio (Zuranolone vs. Placebo)		6.60
95% CI for the OR		(0.688, 63.286)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.14
95% CI for the ARR		(-0.022, 0.297)

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-301-by.sas:t-ae-soc-301-by-bmi-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline BMI (kg/m^2) Group: 217-PPD-301 - Safety Population

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General disorders and administration site conditions

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

	Placebo (N=42)	Zuranolone (N=53)
Number of subjects with >=1 TEAE, n (%)	2 (4.8)	6 (11.3)
RR - Relative Risk (Zuranolone vs. Placebo)		2.38
95% CI for the RR		(0.505, 11.181)
p-value for RR		0.2730
OR - Odds Ratio (Zuranolone vs. Placebo)		2.55
95% CI for the OR		(0.488, 13.360)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.07
95% CI for the ARR		(-0.041, 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-301-by.sas:t-ae-soc-301-by-bmi-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline BMI (kg/m^2) Group: 217-PPD-301 - Safety Population

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Psychiatric disorders

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

	Placebo (N=22)	Zuranolone (N=20)
Number of subjects with >=1 TEAE, n (%)	1 (4.5)	1 (5.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.10
95% CI for the RR		(0.074, 16.447)
p-value for RR		0.9449
OR - Odds Ratio (Zuranolone vs. Placebo)		1.11
95% CI for the OR		(0.065, 18.926)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.00
95% CI for the ARR		(-0.125, 0.134)

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-301-by.sas:t-ae-soc-301-by-bmi-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline BMI (kg/m^2) Group: 217-PPD-301 - Safety Population

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Psychiatric disorders

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

	Placebo (N=34)	Zuranolone (N=24)
Number of subjects with >=1 TEAE, n (%)	0	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		4.20
95% CI for the RR		(0.178, 98.916)
p-value for RR		0.3733
OR - Odds Ratio (Zuranolone vs. Placebo)		4.40
95% CI for the OR		(0.172, 112.824)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.05
95% CI for the ARR		(-0.055, 0.147)

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-301-by.sas:t-ae-soc-301-by-bmi-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline BMI (kg/m^2) Group: 217-PPD-301 - Safety Population

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Psychiatric disorders

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

	Placebo (N=42)	Zuranolone (N=53)
Number of subjects with >=1 TEAE, n (%)	3 (7.1)	8 (15.1)
RR - Relative Risk (Zuranolone vs. Placebo)		2.11
95% CI for the RR		(0.597, 7.477)
p-value for RR		0.2458
OR - Odds Ratio (Zuranolone vs. Placebo)		2.31
95% CI for the OR		(0.573, 9.320)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.08
95% CI for the ARR		(-0.044, 0.203)

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-301-by.sas:t-ae-soc-301-by-bmi-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline BMI (kg/m^2) Group: 217-PPD-301 - Safety Population

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Investigations

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

	Placebo (N=22)	Zuranolone (N=20)
Number of subjects with >=1 TEAE, n (%)	7 (31.8)	1 (5.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.16
95% CI for the RR		(0.021, 1.168)
p-value for RR		0.0706
OR - Odds Ratio (Zuranolone vs. Placebo)		0.11
95% CI for the OR		(0.012, 1.020)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.27
95% CI for the ARR		(-0.485, -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-301-by.sas:t-ae-soc-301-by-bmi-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline BMI (kg/m^2) Group: 217-PPD-301 - Safety Population

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Investigations

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

	Placebo (N=34)	Zuranolone (N=24)
Number of subjects with >=1 TEAE, n (%)	4 (11.8)	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		0.35
95% CI for the RR		(0.042, 2.975)
p-value for RR		0.3391
OR - Odds Ratio (Zuranolone vs. Placebo)		0.33
95% CI for the OR		(0.034, 3.118)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.08
95% CI for the ARR		(-0.211, 0.059)

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-301-by.sas:t-ae-soc-301-by-bmi-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Baseline BMI (kg/m^2) Group: 217-PPD-301 - Safety Population

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Investigations

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

	Placebo (N=42)	Zuranolone (N=53)
Number of subjects with >=1 TEAE, n (%)	1 (2.4)	3 (5.7)
RR - Relative Risk (Zuranolone vs. Placebo)		2.38
95% CI for the RR		(0.256, 22.035)
p-value for RR		0.4459
OR - Odds Ratio (Zuranolone vs. Placebo)		2.46
95% CI for the OR		(0.247, 24.550)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.03
95% CI for the ARR		(-0.045, 0.110)

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-301-by.sas:t-ae-soc-301-by-bmi-safc.rtf **Run Date:** 21JUL2025

3.1.2.2 .2 .6 Beginn der PPD

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Onset of PPD: 217-PPD-301 - Safety Population

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Nervous system disorders

Onset of PPD = 3rd trimester

	Placebo (N=31)	Zuranolone (N=34)
Number of subjects with >=1 TEAE, n (%)	9 (29.0)	12 (35.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.22
95% CI for the RR		(0.595, 2.483)
p-value for RR		0.5920
OR - Odds Ratio (Zuranolone vs. Placebo)		1.33
95% CI for the OR		(0.468, 3.799)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.06
95% CI for the ARR		(-0.164, 0.289)

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-301-by.sas:t-ae-soc-301-by-onset-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Onset of PPD: 217-PPD-301 - Safety Population

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Nervous system disorders

Onset of PPD = Postpartum

	Placebo (N=67)	Zuranolone (N=64)
Number of subjects with >=1 TEAE, n (%)	17 (25.4)	38 (59.4)
RR - Relative Risk (Zuranolone vs. Placebo)		2.34
95% CI for the RR		(1.480, 3.699)
p-value for RR		0.0003
OR - Odds Ratio (Zuranolone vs. Placebo)		4.30
95% CI for the OR		(2.045, 9.034)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.34
95% CI for the ARR		(0.181, 0.499)

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-301-by.sas:t-ae-soc-301-by-onset-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Onset of PPD: 217-PPD-301 - Safety Population

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Gastrointestinal disorders

Onset of PPD = 3rd trimester

	Placebo (N=31)	Zuranolone (N=34)
Number of subjects with >=1 TEAE, n (%)	2 (6.5)	2 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		0.91
95% CI for the RR		(0.137, 6.087)
p-value for RR		0.9240
OR - Odds Ratio (Zuranolone vs. Placebo)		0.91
95% CI for the OR		(0.120, 6.855)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.01
95% CI for the ARR		(-0.123, 0.111)

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-301-by.sas:t-ae-soc-301-by-onset-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Onset of PPD: 217-PPD-301 - Safety Population

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Gastrointestinal disorders

Onset of PPD = Postpartum

	Placebo (N=67)	Zuranolone (N=64)
Number of subjects with >=1 TEAE, n (%)	12 (17.9)	11 (17.2)
RR - Relative Risk (Zuranolone vs. Placebo)		0.96
95% CI for the RR		(0.457, 2.017)
p-value for RR		0.9134
OR - Odds Ratio (Zuranolone vs. Placebo)		0.95
95% CI for the OR		(0.386, 2.342)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.01
95% CI for the ARR		(-0.138, 0.123)

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-301-by.sas:t-ae-soc-301-by-onset-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Onset of PPD: 217-PPD-301 - Safety Population

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Infections and infestations

Onset of PPD = 3rd trimester

	Placebo (N=31)	Zuranolone (N=34)
Number of subjects with >=1 TEAE, n (%)	3 (9.7)	3 (8.8)
RR - Relative Risk (Zuranolone vs. Placebo)		0.91
95% CI for the RR		(0.199, 4.188)
p-value for RR		0.9055
OR - Odds Ratio (Zuranolone vs. Placebo)		0.90
95% CI for the OR		(0.168, 4.846)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.01
95% CI for the ARR		(-0.150, 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-301-by.sas:t-ae-soc-301-by-onset-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Onset of PPD: 217-PPD-301 - Safety Population

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Infections and infestations

Onset of PPD = Postpartum

	Placebo (N=67)	Zuranolone (N=64)
Number of subjects with >=1 TEAE, n (%)	5 (7.5)	10 (15.6)
RR - Relative Risk (Zuranolone vs. Placebo)		2.09
95% CI for the RR		(0.757, 5.791)
p-value for RR		0.1546
OR - Odds Ratio (Zuranolone vs. Placebo)		2.30
95% CI for the OR		(0.739, 7.136)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.08
95% CI for the ARR		(-0.027, 0.191)

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-301-by.sas:t-ae-soc-301-by-onset-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Onset of PPD: 217-PPD-301 - Safety Population

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General disorders and administration site conditions

Onset of PPD = 3rd trimester

	Placebo (N=31)	Zuranolone (N=34)
Number of subjects with >=1 TEAE, n (%)	2 (6.5)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.18
95% CI for the RR		(0.009, 3.666)
p-value for RR		0.2667
OR - Odds Ratio (Zuranolone vs. Placebo)		0.17
95% CI for the OR		(0.008, 3.706)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.06
95% CI for the ARR		(-0.165, 0.037)

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-301-by.sas:t-ae-soc-301-by-onset-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Onset of PPD: 217-PPD-301 - Safety Population

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General disorders and administration site conditions

Onset of PPD = Postpartum

	Placebo (N=67)	Zuranolone (N=64)
Number of subjects with >=1 TEAE, n (%)	1 (1.5)	11 (17.2)
RR - Relative Risk (Zuranolone vs. Placebo)		11.52
95% CI for the RR		(1.530, 86.657)
p-value for RR		0.0176
OR - Odds Ratio (Zuranolone vs. Placebo)		13.70
95% CI for the OR		(1.713, 109.513)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.16
95% CI for the ARR		(0.060, 0.254)

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-301-by.sas:t-ae-soc-301-by-onset-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Onset of PPD: 217-PPD-301 - Safety Population

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Psychiatric disorders

Onset of PPD = 3rd trimester

	Placebo (N=31)	Zuranolone (N=34)
Number of subjects with >=1 TEAE, n (%)	1 (3.2)	4 (11.8)
RR - Relative Risk (Zuranolone vs. Placebo)		3.65
95% CI for the RR		(0.431, 30.892)
p-value for RR		0.2352
OR - Odds Ratio (Zuranolone vs. Placebo)		4.00
95% CI for the OR		(0.422, 37.912)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.09
95% CI for the ARR		(-0.039, 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-301-by.sas:t-ae-soc-301-by-onset-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Onset of PPD: 217-PPD-301 - Safety Population

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Psychiatric disorders

Onset of PPD = Postpartum

	Placebo (N=67)	Zuranolone (N=64)
Number of subjects with >=1 TEAE, n (%)	3 (4.5)	6 (9.4)
RR - Relative Risk (Zuranolone vs. Placebo)		2.09
95% CI for the RR		(0.547, 8.019)
p-value for RR		0.2808
OR - Odds Ratio (Zuranolone vs. Placebo)		2.21
95% CI for the OR		(0.528, 9.229)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.05
95% CI for the ARR		(-0.038, 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-301-by.sas:t-ae-soc-301-by-onset-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Onset of PPD: 217-PPD-301 - Safety Population

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Investigations

Onset of PPD = 3rd trimester

	Placebo (N=31)	Zuranolone (N=34)
Number of subjects with >=1 TEAE, n (%)	2 (6.5)	1 (2.9)
RR - Relative Risk (Zuranolone vs. Placebo)		0.46
95% CI for the RR		(0.043, 4.783)
p-value for RR		0.5125
OR - Odds Ratio (Zuranolone vs. Placebo)		0.44
95% CI for the OR		(0.038, 5.101)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.04
95% CI for the ARR		(-0.139, 0.068)

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-301-by.sas:t-ae-soc-301-by-onset-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Onset of PPD: 217-PPD-301 - Safety Population

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Investigations

Onset of PPD = Postpartum

	Placebo (N=67)	Zuranolone (N=64)
Number of subjects with >=1 TEAE, n (%)	10 (14.9)	4 (6.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.42
95% CI for the RR		(0.138, 1.268)
p-value for RR		0.1235
OR - Odds Ratio (Zuranolone vs. Placebo)		0.38
95% CI for the OR		(0.113, 1.281)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.09
95% CI for the ARR		(-0.191, 0.017)

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-301-by.sas:t-ae-soc-301-by-onset-safc.rtf **Run Date:** 21JUL2025

3.1.2.2 .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-301 - Safety Population

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Nervous system disorders

Family History of PPD = Yes

	Placebo (N=16)	Zuranolone (N=21)
Number of subjects with >=1 TEAE, n (%)	2 (12.5)	12 (57.1)
RR - Relative Risk (Zuranolone vs. Placebo)		4.57
95% CI for the RR		(1.187, 17.603)
p-value for RR		0.0272
OR - Odds Ratio (Zuranolone vs. Placebo)		9.33
95% CI for the OR		(1.679, 51.875)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.45
95% CI for the ARR		(0.180, 0.713)

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-301-by.sas:t-ae-soc-301-by-fhist-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Family History of PPD: 217-PPD-301 - Safety Population

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Nervous system disorders

Family History of PPD = No/Unknown

	Placebo (N=82)	Zuranolone (N=77)
Number of subjects with >=1 TEAE, n (%)	24 (29.3)	38 (49.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.69
95% CI for the RR		(1.124, 2.529)
p-value for RR		0.0116
OR - Odds Ratio (Zuranolone vs. Placebo)		2.35
95% CI for the OR		(1.226, 4.522)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.20
95% CI for the ARR		(0.052, 0.350)

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-301-by.sas:t-ae-soc-301-by-fhist-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Family History of PPD: 217-PPD-301 - Safety Population

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Gastrointestinal disorders

Family History of PPD = Yes

	Placebo (N=16)	Zuranolone (N=21)
Number of subjects with >=1 TEAE, n (%)	0	2 (9.5)
RR - Relative Risk (Zuranolone vs. Placebo)		3.86
95% CI for the RR		(0.198, 75.285)
p-value for RR		0.3724
OR - Odds Ratio (Zuranolone vs. Placebo)		4.23
95% CI for the OR		(0.189, 94.511)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.08
95% CI for the ARR		(-0.071, 0.239)

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-301-by.sas:t-ae-soc-301-by-fhist-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Family History of PPD: 217-PPD-301 - Safety Population

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Gastrointestinal disorders

Family History of PPD = No/Unknown

	Placebo (N=82)	Zuranolone (N=77)
Number of subjects with >=1 TEAE, n (%)	14 (17.1)	11 (14.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.84
95% CI for the RR		(0.405, 1.729)
p-value for RR		0.6303
OR - Odds Ratio (Zuranolone vs. Placebo)		0.81
95% CI for the OR		(0.343, 1.912)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.03
95% CI for the ARR		(-0.141, 0.085)

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-301-by.sas:t-ae-soc-301-by-fhist-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Family History of PPD: 217-PPD-301 - Safety Population

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Infections and infestations

Family History of PPD = Yes

	Placebo (N=16)	Zuranolone (N=21)
Number of subjects with >=1 TEAE, n (%)	2 (12.5)	2 (9.5)
RR - Relative Risk (Zuranolone vs. Placebo)		0.76
95% CI for the RR		(0.120, 4.840)
p-value for RR		0.7731
OR - Odds Ratio (Zuranolone vs. Placebo)		0.74
95% CI for the OR		(0.092, 5.886)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.03
95% CI for the ARR		(-0.235, 0.175)

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-301-by.sas:t-ae-soc-301-by-fhist-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Family History of PPD: 217-PPD-301 - Safety Population

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Infections and infestations

Family History of PPD = No/Unknown

	Placebo (N=82)	Zuranolone (N=77)
Number of subjects with >=1 TEAE, n (%)	6 (7.3)	11 (14.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.95
95% CI for the RR		(0.759, 5.022)
p-value for RR		0.1652
OR - Odds Ratio (Zuranolone vs. Placebo)		2.11
95% CI for the OR		(0.740, 6.021)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.07
95% CI for the ARR		(-0.027, 0.166)

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-301-by.sas:t-ae-soc-301-by-fhist-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Family History of PPD: 217-PPD-301 - Safety Population

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General disorders and administration site conditions

Family History of PPD = Yes

	Placebo (N=16)	Zuranolone (N=21)
Number of subjects with >=1 TEAE, n (%)	0	2 (9.5)
RR - Relative Risk (Zuranolone vs. Placebo)		3.86
95% CI for the RR		(0.198, 75.285)
p-value for RR		0.3724
OR - Odds Ratio (Zuranolone vs. Placebo)		4.23
95% CI for the OR		(0.189, 94.511)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.08
95% CI for the ARR		(-0.071, 0.239)

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-301-by.sas:t-ae-soc-301-by-fhist-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Family History of PPD: 217-PPD-301 - Safety Population

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General disorders and administration site conditions

Family History of PPD = No/Unknown

	Placebo (N=82)	Zuranolone (N=77)
Number of subjects with >=1 TEAE, n (%)	3 (3.7)	9 (11.7)
RR - Relative Risk (Zuranolone vs. Placebo)		3.19
95% CI for the RR		(0.898, 11.366)
p-value for RR		0.0728
OR - Odds Ratio (Zuranolone vs. Placebo)		3.49
95% CI for the OR		(0.907, 13.394)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.08
95% CI for the ARR		(-0.002, 0.163)

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-301-by.sas:t-ae-soc-301-by-fhist-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Family History of PPD: 217-PPD-301 - Safety Population

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Psychiatric disorders

Family History of PPD = Yes

	Placebo (N=16)	Zuranolone (N=21)
Number of subjects with >=1 TEAE, n (%)	0	2 (9.5)
RR - Relative Risk (Zuranolone vs. Placebo)		3.86
95% CI for the RR		(0.198, 75.285)
p-value for RR		0.3724
OR - Odds Ratio (Zuranolone vs. Placebo)		4.23
95% CI for the OR		(0.189, 94.511)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.08
95% CI for the ARR		(-0.071, 0.239)

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-301-by.sas:t-ae-soc-301-by-fhist-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Family History of PPD: 217-PPD-301 - Safety Population

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Psychiatric disorders

Family History of PPD = No/Unknown

	Placebo (N=82)	Zuranolone (N=77)
Number of subjects with >=1 TEAE, n (%)	4 (4.9)	8 (10.4)
RR - Relative Risk (Zuranolone vs. Placebo)		2.13
95% CI for the RR		(0.668, 6.789)
p-value for RR		0.2011
OR - Odds Ratio (Zuranolone vs. Placebo)		2.26
95% CI for the OR		(0.652, 7.837)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.06
95% CI for the ARR		(-0.027, 0.138)

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-301-by.sas:t-ae-soc-301-by-fhist-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Family History of PPD: 217-PPD-301 - Safety Population

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Investigations

Family History of PPD = Yes

	Placebo (N=16)	Zuranolone (N=21)
Number of subjects with >=1 TEAE, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		2.32
95% CI for the RR		(0.101, 53.420)
p-value for RR		0.5994
OR - Odds Ratio (Zuranolone vs. Placebo)		2.41
95% CI for the OR		(0.092, 63.253)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.04
95% CI for the ARR		(-0.094, 0.171)

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-301-by.sas:t-ae-soc-301-by-fhist-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Family History of PPD: 217-PPD-301 - Safety Population

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Investigations

Family History of PPD = No/Unknown

	Placebo (N=82)	Zuranolone (N=77)
Number of subjects with >=1 TEAE, n (%)	12 (14.6)	4 (5.2)
RR - Relative Risk (Zuranolone vs. Placebo)		0.35
95% CI for the RR		(0.120, 1.054)
p-value for RR		0.0621
OR - Odds Ratio (Zuranolone vs. Placebo)		0.32
95% CI for the OR		(0.098, 1.038)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.09
95% CI for the ARR		(-0.186, -0.003)

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-301-by.sas:t-ae-soc-301-by-fhist-safc.rtf **Run Date:** 21JUL2025

3.1.2.2 .2 .8 PPD in der Anamnese

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by History of PPD: 217-PPD-301 - Safety Population

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Nervous system disorders

History of PPD = 1st Episode

	Placebo (N=87)	Zuranolone (N=81)
Number of subjects with >=1 TEAE, n (%)	22 (25.3)	40 (49.4)
RR - Relative Risk (Zuranolone vs. Placebo)		1.95
95% CI for the RR		(1.279, 2.982)
p-value for RR		0.0019
OR - Odds Ratio (Zuranolone vs. Placebo)		2.88
95% CI for the OR		(1.504, 5.526)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.24
95% CI for the ARR		(0.099, 0.383)

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-301-by.sas:t-ae-soc-301-by-hist-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by History of PPD: 217-PPD-301 - Safety Population

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Nervous system disorders

History of PPD = Recurrent Episode

	Placebo (N=11)	Zuranolone (N=17)
Number of subjects with >=1 TEAE, n (%)	4 (36.4)	10 (58.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.62
95% CI for the RR		(0.673, 3.889)
p-value for RR		0.2825
OR - Odds Ratio (Zuranolone vs. Placebo)		2.50
95% CI for the OR		(0.524, 11.929)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.22
95% CI for the ARR		(-0.144, 0.593)

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-301-by.sas:t-ae-soc-301-by-hist-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by History of PPD: 217-PPD-301 - Safety Population

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Gastrointestinal disorders

History of PPD = 1st Episode

	Placebo (N=87)	Zuranolone (N=81)
Number of subjects with >=1 TEAE, n (%)	12 (13.8)	10 (12.3)
RR - Relative Risk (Zuranolone vs. Placebo)		0.90
95% CI for the RR		(0.409, 1.958)
p-value for RR		0.7813
OR - Odds Ratio (Zuranolone vs. Placebo)		0.88
95% CI for the OR		(0.358, 2.165)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.01
95% CI for the ARR		(-0.116, 0.087)

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-301-by.sas:t-ae-soc-301-by-hist-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by History of PPD: 217-PPD-301 - Safety Population

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Gastrointestinal disorders

History of PPD = Recurrent Episode

	Placebo (N=11)	Zuranolone (N=17)
Number of subjects with >=1 TEAE, n (%)	2 (18.2)	3 (17.6)
RR - Relative Risk (Zuranolone vs. Placebo)		0.97
95% CI for the RR		(0.192, 4.907)
p-value for RR		0.9712
OR - Odds Ratio (Zuranolone vs. Placebo)		0.96
95% CI for the OR		(0.134, 6.952)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.01
95% CI for the ARR		(-0.297, 0.286)

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-301-by.sas:t-ae-soc-301-by-hist-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by History of PPD: 217-PPD-301 - Safety Population

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Infections and infestations

History of PPD = 1st Episode

	Placebo (N=87)	Zuranolone (N=81)
Number of subjects with >=1 TEAE, n (%)	7 (8.0)	9 (11.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.38
95% CI for the RR		(0.539, 3.536)
p-value for RR		0.5010
OR - Odds Ratio (Zuranolone vs. Placebo)		1.43
95% CI for the OR		(0.506, 4.033)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.03
95% CI for the ARR		(-0.059, 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-301-by.sas:t-ae-soc-301-by-hist-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by History of PPD: 217-PPD-301 - Safety Population

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Infections and infestations

History of PPD = Recurrent Episode

	Placebo (N=11)	Zuranolone (N=17)
Number of subjects with >=1 TEAE, n (%)	1 (9.1)	4 (23.5)
RR - Relative Risk (Zuranolone vs. Placebo)		2.59
95% CI for the RR		(0.331, 20.224)
p-value for RR		0.3646
OR - Odds Ratio (Zuranolone vs. Placebo)		3.08
95% CI for the OR		(0.296, 31.982)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.14
95% CI for the ARR		(-0.119, 0.408)

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-301-by.sas:t-ae-soc-301-by-hist-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by History of PPD: 217-PPD-301 - Safety Population

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General disorders and administration site conditions

History of PPD = 1st Episode

	Placebo (N=87)	Zuranolone (N=81)
Number of subjects with >=1 TEAE, n (%)	2 (2.3)	8 (9.9)
RR - Relative Risk (Zuranolone vs. Placebo)		4.30
95% CI for the RR		(0.940, 19.637)
p-value for RR		0.0601
OR - Odds Ratio (Zuranolone vs. Placebo)		4.66
95% CI for the OR		(0.959, 22.629)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.08
95% CI for the ARR		(0.004, 0.148)

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-301-by.sas:t-ae-soc-301-by-hist-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by History of PPD: 217-PPD-301 - Safety Population

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General disorders and administration site conditions

History of PPD = Recurrent Episode

	Placebo (N=11)	Zuranolone (N=17)
Number of subjects with >=1 TEAE, n (%)	1 (9.1)	3 (17.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.94
95% CI for the RR		(0.230, 16.373)
p-value for RR		0.5421
OR - Odds Ratio (Zuranolone vs. Placebo)		2.14
95% CI for the OR		(0.194, 23.722)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.09
95% CI for the ARR		(-0.163, 0.334)

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-301-by.sas:t-ae-soc-301-by-hist-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by History of PPD: 217-PPD-301 - Safety Population

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Psychiatric disorders

History of PPD = 1st Episode

	Placebo (N=87)	Zuranolone (N=81)
Number of subjects with >=1 TEAE, n (%)	3 (3.4)	8 (9.9)
RR - Relative Risk (Zuranolone vs. Placebo)		2.86
95% CI for the RR		(0.787, 10.425)
p-value for RR		0.1104
OR - Odds Ratio (Zuranolone vs. Placebo)		3.07
95% CI for the OR		(0.785, 11.997)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.06
95% CI for the ARR		(-0.011, 0.140)

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-301-by.sas:t-ae-soc-301-by-hist-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by History of PPD: 217-PPD-301 - Safety Population

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Psychiatric disorders

History of PPD = Recurrent Episode

	Placebo (N=11)	Zuranolone (N=17)
Number of subjects with >=1 TEAE, n (%)	1 (9.1)	2 (11.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.29
95% CI for the RR		(0.133, 12.621)
p-value for RR		0.8244
OR - Odds Ratio (Zuranolone vs. Placebo)		1.33
95% CI for the OR		(0.106, 16.743)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.03
95% CI for the ARR		(-0.202, 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-301-by.sas:t-ae-soc-301-by-hist-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by History of PPD: 217-PPD-301 - Safety Population

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Investigations

History of PPD = 1st Episode

	Placebo (N=87)	Zuranolone (N=81)
Number of subjects with >=1 TEAE, n (%)	12 (13.8)	4 (4.9)
RR - Relative Risk (Zuranolone vs. Placebo)		0.36
95% CI for the RR		(0.120, 1.065)
p-value for RR		0.0648
OR - Odds Ratio (Zuranolone vs. Placebo)		0.32
95% CI for the OR		(0.100, 1.052)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.09
95% CI for the ARR		(-0.175, -0.002)

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-301-by.sas:t-ae-soc-301-by-hist-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by History of PPD: 217-PPD-301 - Safety Population

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Investigations

History of PPD = Recurrent Episode

	Placebo (N=11)	Zuranolone (N=17)
Number of subjects with >=1 TEAE, n (%)	0	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		2.00
95% CI for the RR		(0.089, 45.118)
p-value for RR		0.6629
OR - Odds Ratio (Zuranolone vs. Placebo)		2.09
95% CI for the OR		(0.078, 56.012)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.04
95% CI for the ARR		(-0.129, 0.212)

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-301-by.sas:t-ae-soc-301-by-hist-safc.rtf **Run Date:** 21JUL2025

3.1.2.2 .2 .9 Depression mit Angst

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - Safety Population

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Nervous system disorders

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

	Placebo (N=21)	Zuranolone (N=24)
Number of subjects with >=1 TEAE, n (%)	0	10 (41.7)
RR - Relative Risk (Zuranolone vs. Placebo)		18.48
95% CI for the RR		(1.148, 297.456)
p-value for RR		0.0396
OR - Odds Ratio (Zuranolone vs. Placebo)		31.14
95% CI for the OR		(1.689, 573.980)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.40
95% CI for the ARR		(0.194, 0.601)

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-301-by.sas:t-ae-soc-301-by-hama-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - Safety Population

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Nervous system disorders

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

	Placebo (N=77)	Zuranolone (N=74)
Number of subjects with >=1 TEAE, n (%)	26 (33.8)	40 (54.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.60
95% CI for the RR		(1.098, 2.333)
p-value for RR		0.0144
OR - Odds Ratio (Zuranolone vs. Placebo)		2.31
95% CI for the OR		(1.196, 4.453)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.20
95% CI for the ARR		(0.048, 0.358)

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-301-by.sas:t-ae-soc-301-by-hama-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - Safety Population

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Gastrointestinal disorders

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

	Placebo (N=21)	Zuranolone (N=24)
Number of subjects with >=1 TEAE, n (%)	0	3 (12.5)
RR - Relative Risk (Zuranolone vs. Placebo)		6.16
95% CI for the RR		(0.336, 112.769)
p-value for RR		0.2203
OR - Odds Ratio (Zuranolone vs. Placebo)		7.00
95% CI for the OR		(0.341, 143.853)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.12
95% CI for the ARR		(-0.032, 0.267)

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-301-by.sas:t-ae-soc-301-by-hama-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - Safety Population

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Gastrointestinal disorders

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

	Placebo (N=77)	Zuranolone (N=74)
Number of subjects with >=1 TEAE, n (%)	14 (18.2)	10 (13.5)
RR - Relative Risk (Zuranolone vs. Placebo)		0.74
95% CI for the RR		(0.352, 1.567)
p-value for RR		0.4357
OR - Odds Ratio (Zuranolone vs. Placebo)		0.70
95% CI for the OR		(0.291, 1.700)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.05
95% CI for the ARR		(-0.163, 0.069)

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-301-by.sas:t-ae-soc-301-by-hama-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - Safety Population

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Infections and infestations

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

	Placebo (N=21)	Zuranolone (N=24)
Number of subjects with >=1 TEAE, n (%)	0	2 (8.3)
RR - Relative Risk (Zuranolone vs. Placebo)		4.40
95% CI for the RR		(0.223, 86.784)
p-value for RR		0.3301
OR - Odds Ratio (Zuranolone vs. Placebo)		4.78
95% CI for the OR		(0.217, 105.355)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.08
95% CI for the ARR		(-0.056, 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-301-by.sas:t-ae-soc-301-by-hama-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - Safety Population

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Infections and infestations

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

	Placebo (N=77)	Zuranolone (N=74)
Number of subjects with >=1 TEAE, n (%)	8 (10.4)	11 (14.9)
RR - Relative Risk (Zuranolone vs. Placebo)		1.43
95% CI for the RR		(0.610, 3.357)
p-value for RR		0.4105
OR - Odds Ratio (Zuranolone vs. Placebo)		1.51
95% CI for the OR		(0.569, 3.983)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.04
95% CI for the ARR		(-0.061, 0.151)

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-301-by.sas:t-ae-soc-301-by-hama-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - Safety Population

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General disorders and administration site conditions

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

	Placebo (N=21)	Zuranolone (N=24)
Number of subjects with >=1 TEAE, n (%)	0	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		2.64
95% CI for the RR		(0.113, 61.540)
p-value for RR		0.5457
OR - Odds Ratio (Zuranolone vs. Placebo)		2.74
95% CI for the OR		(0.106, 71.043)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.04
95% CI for the ARR		(-0.075, 0.149)

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-301-by.sas:t-ae-soc-301-by-hama-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - Safety Population

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General disorders and administration site conditions

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

	Placebo (N=77)	Zuranolone (N=74)
Number of subjects with >=1 TEAE, n (%)	3 (3.9)	10 (13.5)
RR - Relative Risk (Zuranolone vs. Placebo)		3.47
95% CI for the RR		(0.994, 12.108)
p-value for RR		0.0512
OR - Odds Ratio (Zuranolone vs. Placebo)		3.85
95% CI for the OR		(1.016, 14.615)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.10
95% CI for the ARR		(0.007, 0.185)

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-301-by.sas:t-ae-soc-301-by-hama-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - Safety Population

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Psychiatric disorders

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

	Placebo (N=21)	Zuranolone (N=24)
Number of subjects with >=1 TEAE, n (%)	0	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		2.64
95% CI for the RR		(0.113, 61.540)
p-value for RR		0.5457
OR - Odds Ratio (Zuranolone vs. Placebo)		2.74
95% CI for the OR		(0.106, 71.043)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.04
95% CI for the ARR		(-0.075, 0.149)

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-301-by.sas:t-ae-soc-301-by-hama-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - Safety Population

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Psychiatric disorders

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

	Placebo (N=77)	Zuranolone (N=74)
Number of subjects with >=1 TEAE, n (%)	4 (5.2)	9 (12.2)
RR - Relative Risk (Zuranolone vs. Placebo)		2.34
95% CI for the RR		(0.753, 7.275)
p-value for RR		0.1414
OR - Odds Ratio (Zuranolone vs. Placebo)		2.53
95% CI for the OR		(0.743, 8.596)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.07
95% CI for the ARR		(-0.020, 0.159)

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-301-by.sas:t-ae-soc-301-by-hama-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - Safety Population

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Investigations

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

	Placebo (N=21)	Zuranolone (N=24)
Number of subjects with >=1 TEAE, n (%)	5 (23.8)	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		0.18
95% CI for the RR		(0.022, 1.381)
p-value for RR		0.0982
OR - Odds Ratio (Zuranolone vs. Placebo)		0.14
95% CI for the OR		(0.015, 1.307)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.20
95% CI for the ARR		(-0.395, 0.003)

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-301-by.sas:t-ae-soc-301-by-hama-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by System Organ Class by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - Safety Population

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Investigations

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

	Placebo (N=77)	Zuranolone (N=74)
Number of subjects with >=1 TEAE, n (%)	7 (9.1)	4 (5.4)
RR - Relative Risk (Zuranolone vs. Placebo)		0.59
95% CI for the RR		(0.182, 1.947)
p-value for RR		0.3904
OR - Odds Ratio (Zuranolone vs. Placebo)		0.57
95% CI for the OR		(0.160, 2.040)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.04
95% CI for the ARR		(-0.119, 0.045)

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-301-by.sas:t-ae-soc-301-by-hama-safc.rtf **Run Date:** 21JUL2025

3.1.3 nach PT

3.1.3.1 ITT-Population

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term: 217-PPD-301 - Safety population

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Nervous system disorders/Somnolence

	Placebo (N=98)	Zuranolone (N=98)
Number of subjects with >=1 TEAE, n (%)	5 (5.1)	26 (26.5)
RR - Relative Risk (Zuranolone vs. Placebo)		5.20
95% CI for the RR		(2.082, 12.986)
p-value for RR		0.0004
OR - Odds Ratio (Zuranolone vs. Placebo)		6.72
95% CI for the OR		(2.458, 18.355)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.21
95% CI for the ARR		(0.117, 0.312)

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-301-ovr.sas:t-ae-pt-301-ovr-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term: 217-PPD-301 - Safety population

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Nervous system disorders/Dizziness

	Placebo (N=98)	Zuranolone (N=98)
Number of subjects with >=1 TEAE, n (%)	10 (10.2)	13 (13.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.30
95% CI for the RR		(0.599, 2.823)
p-value for RR		0.5072
OR - Odds Ratio (Zuranolone vs. Placebo)		1.35
95% CI for the OR		(0.560, 3.234)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.03
95% CI for the ARR		(-0.059, 0.121)

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-301-ovr.sas:t-ae-pt-301-ovr-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term: 217-PPD-301 - Safety population

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Nervous system disorders/Sedation

	Placebo (N=98)	Zuranolone (N=98)
Number of subjects with >=1 TEAE, n (%)	1 (1.0)	11 (11.2)
RR - Relative Risk (Zuranolone vs. Placebo)		11.00
95% CI for the RR		(1.448, 83.577)
p-value for RR		0.0205
OR - Odds Ratio (Zuranolone vs. Placebo)		12.26
95% CI for the OR		(1.552, 96.948)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.10
95% CI for the ARR		(0.036, 0.168)

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-301-ovr.sas:t-ae-pt-301-ovr-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term: 217-PPD-301 - Safety population

Nervous system disorders/Headache

	Placebo (N=98)	Zuranolone (N=98)
Number of subjects with >=1 TEAE, n (%)	13 (13.3)	9 (9.2)
RR - Relative Risk (Zuranolone vs. Placebo)		0.69
95% CI for the RR		(0.310, 1.545)
p-value for RR		0.3691
OR - Odds Ratio (Zuranolone vs. Placebo)		0.66
95% CI for the OR		(0.269, 1.627)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.04
95% CI for the ARR		(-0.129, 0.047)

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-301-ovr.sas:t-ae-pt-301-ovr-safc.rtf **Run Date:** 18JUL2025

3.1.3.2 Subgruppen

3.1.3.2 .1 Interaktionstest

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term: Treatment by Subgroup Interaction: 217-PPD-301 - Safety population

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Nervous system disorders/ Somnolence

Subgroup Subgroup Category	Placebo (N=98)	Zuranolone (N=98)	p-value for Treatment by Subgroup Interaction Test
Number of subjects with >=1 TEAE, n(%)	5 (5.1)	26 (26.5)	
Age Group (years)			
18 - 24, n / N (%)	1/12 (8.3)	5/19 (26.3)	0.6155
25 - 45, n / N (%)	4/86 (4.7)	21/79 (26.6)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	1/32 (3.1)	6/33 (18.2)	0.9255
>=28, n / N (%)	4/66 (6.1)	20/65 (30.8)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	2/18 (11.1)	9/25 (36.0)	0.1434
White, n / N (%)	0/69	16/68 (23.5)	

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%).
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-301-int.sas:t-ae-pt-301-int-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term: Treatment by Subgroup Interaction: 217-PPD-301 - Safety population

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Nervous system disorders/ Somnolence

Subgroup Subgroup Category	Placebo (N=98)	Zuranolone (N=98)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			
Yes, n / N (%)	0/15	3/15 (20.0)	0.7855
No, n / N (%)	5/83 (6.0)	23/83 (27.7)	
BMI (kg/m^2}) Group 2			
<=24.9, n / N (%)	1/22 (4.5)	5/20 (25.0)	0.7178(a)
25-29.9, n / N (%)	3/34 (8.8)	8/24 (33.3)	0.6938(b)
>=30, n / N (%)	1/42 (2.4)	13/53 (24.5)	0.3679(c)
Onset of PPD			
3rd Trimester, n / N (%)	3/31 (9.7)	6/34 (17.6)	0.0780
Postpartum, n / N (%)	2/67 (3.0)	20/64 (31.3)	
Family History of PPD			
Yes, n / N (%)	1/16 (6.3)	4/21 (19.0)	0.5958
No/Unknown, n / N (%)	4/82 (4.9)	22/77 (28.6)	

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-301-int.sas:t-ae-pt-301-int-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term: Treatment by Subgroup Interaction: 217-PPD-301 - Safety population

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Nervous system disorders/ Somnolence

Subgroup Subgroup Category	Placebo (N=98)	Zuranolone (N=98)	p-value for Treatment by Subgroup Interaction Test
History of PPD			
1st Episode, n / N (%)	4/87 (4.6)	20/81 (24.7)	0.8949
Recurrent Episode, n / N (%)	1/11 (9.1)	6/17 (35.3)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	0/21	6/24 (25.0)	0.5042
>=20, n / N (%)	5/77 (6.5)	20/74 (27.0)	

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. 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-301-int.sas:t-ae-pt-301-int-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term: Treatment by Subgroup Interaction: 217-PPD-301 - Safety population

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Nervous system disorders/ Dizziness

Subgroup Subgroup Category	Placebo (N=98)	Zuranolone (N=98)	p-value for Treatment by Subgroup Interaction Test
Number of subjects with >=1 TEAE, n(%)	10 (10.2)	13 (13.3)	
Age Group (years)			
18 - 24, n / N (%)	0/12	3/19 (15.8)	0.3492
25 - 45, n / N (%)	10/86 (11.6)	10/79 (12.7)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	4/32 (12.5)	5/33 (15.2)	NA
>=28, n / N (%)	6/66 (9.1)	8/65 (12.3)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	3/18 (16.7)	4/25 (16.0)	NA
White, n / N (%)	4/69 (5.8)	9/68 (13.2)	

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-301-int.sas:t-ae-pt-301-int-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term: Treatment by Subgroup Interaction: 217-PPD-301 - Safety population

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Nervous system disorders/ Dizziness

Subgroup Subgroup Category	Placebo (N=98)	Zuranolone (N=98)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			
Yes, n / N (%)	1/15 (6.7)	0/15	0.3727
No, n / N (%)	9/83 (10.8)	13/83 (15.7)	
BMI (kg/m^2}) Group 2			
<=24.9, n / N (%)	3/22 (13.6)	1/20 (5.0)	NA(a)
25-29.9, n / N (%)	3/34 (8.8)	3/24 (12.5)	NA(b)
>=30, n / N (%)	4/42 (9.5)	9/53 (17.0)	NA(c)
Onset of PPD			
3rd Trimester, n / N (%)	3/31 (9.7)	3/34 (8.8)	0.6508
Postpartum, n / N (%)	7/67 (10.4)	10/64 (15.6)	
Family History of PPD			
Yes, n / N (%)	1/16 (6.3)	3/21 (14.3)	0.5608
No/Unknown, n / N (%)	9/82 (11.0)	10/77 (13.0)	

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. 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-301-int.sas:t-ae-pt-301-int-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term: Treatment by Subgroup Interaction: 217-PPD-301 - Safety population

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Nervous system disorders/ Dizziness

Subgroup Subgroup Category	Placebo (N=98)	Zuranolone (N=98)	p-value for Treatment by Subgroup Interaction Test
History of PPD			
1st Episode, n / N (%)	9/87 (10.3)	11/81 (13.6)	0.8186
Recurrent Episode, n / N (%)	1/11 (9.1)	2/17 (11.8)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	0/21	3/24 (12.5)	0.2484
>=20, n / N (%)	10/77 (13.0)	10/74 (13.5)	

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%).
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-301-int.sas:t-ae-pt-301-int-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term: Treatment by Subgroup Interaction: 217-PPD-301 - Safety population

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Nervous system disorders/ Sedation

Subgroup Subgroup Category	Placebo (N=98)	Zuranolone (N=98)	p-value for Treatment by Subgroup Interaction Test
Number of subjects with >=1 TEAE, n(%)	1 (1.0)	11 (11.2)	
Age Group (years)			
18 - 24, n / N (%)	1/12 (8.3)	4/19 (21.1)	NA
25 - 45, n / N (%)	0/86	7/79 (8.9)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	0/32	5/33 (15.2)	NA
>=28, n / N (%)	1/66 (1.5)	6/65 (9.2)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	0/18	0/25	0.2384
White, n / N (%)	1/69 (1.4)	10/68 (14.7)	

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-301-int.sas:t-ae-pt-301-int-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term: Treatment by Subgroup Interaction: 217-PPD-301 - Safety population

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Nervous system disorders/ Sedation

Subgroup Subgroup Category	Placebo (N=98)	Zuranolone (N=98)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			
Yes, n / N (%)	0/15	5/15 (33.3)	NA
No, n / N (%)	1/83 (1.2)	6/83 (7.2)	
BMI (kg/m^2}) Group 2			
<=24.9, n / N (%)	1/22 (4.5)	3/20 (15.0)	NA(a)
25-29.9, n / N (%)	0/34	0/24	NA(b)
>=30, n / N (%)	0/42	8/53 (15.1)	NA(c)
Onset of PPD			
3rd Trimester, n / N (%)	1/31 (3.2)	3/34 (8.8)	NA
Postpartum, n / N (%)	0/67	8/64 (12.5)	
Family History of PPD			
Yes, n / N (%)	0/16	5/21 (23.8)	NA
No/Unknown, n / N (%)	1/82 (1.2)	6/77 (7.8)	

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%).

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-301-int.sas:t-ae-pt-301-int-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term: Treatment by Subgroup Interaction: 217-PPD-301 - Safety population

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Nervous system disorders/ Sedation

Subgroup Subgroup Category	Placebo (N=98)	Zuranolone (N=98)	p-value for Treatment by Subgroup Interaction Test
History of PPD			
1st Episode, n / N (%)	1/87 (1.1)	8/81 (9.9)	NA
Recurrent Episode, n / N (%)	0/11	3/17 (17.6)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	0/21	2/24 (8.3)	NA
>=20, n / N (%)	1/77 (1.3)	9/74 (12.2)	

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-301-int.sas:t-ae-pt-301-int-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term: Treatment by Subgroup Interaction: 217-PPD-301 - Safety population

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Nervous system disorders/ Headache

Subgroup Subgroup Category	Placebo (N=98)	Zuranolone (N=98)	p-value for Treatment by Subgroup Interaction Test
Number of subjects with >=1 TEAE, n(%)	13 (13.3)	9 (9.2)	
Age Group (years)			
18 - 24, n / N (%)	1/12 (8.3)	3/19 (15.8)	0.2588
25 - 45, n / N (%)	12/86 (14.0)	6/79 (7.6)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	2/32 (6.3)	2/33 (6.1)	0.7202
>=28, n / N (%)	11/66 (16.7)	7/65 (10.8)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	4/18 (22.2)	1/25 (4.0)	NA
White, n / N (%)	6/69 (8.7)	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-301-int.sas:t-ae-pt-301-int-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term: Treatment by Subgroup Interaction: 217-PPD-301 - Safety population

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Nervous system disorders/ Headache

Subgroup Subgroup Category	Placebo (N=98)	Zuranolone (N=98)	p-value for Treatment by Subgroup Interaction Test
Antidepressant Use at Baseline			
Yes, n / N (%)	1/15 (6.7)	1/15 (6.7)	0.7777
No, n / N (%)	12/83 (14.5)	8/83 (9.6)	
BMI (kg/m^2}) Group 2			
<=24.9, n / N (%)	4/22 (18.2)	3/20 (15.0)	NA(a)
25-29.9, n / N (%)	5/34 (14.7)	1/24 (4.2)	NA(b)
>=30, n / N (%)	4/42 (9.5)	5/53 (9.4)	NA(c)
Onset of PPD			
3rd Trimester, n / N (%)	2/31 (6.5)	4/34 (11.8)	0.1384
Postpartum, n / N (%)	11/67 (16.4)	5/64 (7.8)	
Family History of PPD			
Yes, n / N (%)	0/16	1/21 (4.8)	0.4453
No/Unknown, n / N (%)	13/82 (15.9)	8/77 (10.4)	

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%).

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-301-int.sas:t-ae-pt-301-int-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term: Treatment by Subgroup Interaction: 217-PPD-301 - Safety population

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Nervous system disorders/ Headache

Subgroup Subgroup Category	Placebo (N=98)	Zuranolone (N=98)	p-value for Treatment by Subgroup Interaction Test
History of PPD			
1st Episode, n / N (%)	12/87 (13.8)	5/81 (6.2)	0.0610
Recurrent Episode, n / N (%)	1/11 (9.1)	4/17 (23.5)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	0/21	0/24	0.9210
>=20, n / N (%)	13/77 (16.9)	9/74 (12.2)	

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-301-int.sas:t-ae-pt-301-int-safc.rtf **Run Date:** 18JUL2025

3.1.3.2 .2 Subgruppenanalysen

3.1.3.2 .2 .1 Alter

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Age Group: 217-PPD-301 - Safety Population

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Nervous system disorders/Somnolence

Age Group (years) = 18-24

	Placebo (N=12)	Zuranolone (N=19)
Number of subjects with >=1 TEAE, n (%)	1 (8.3)	5 (26.3)
RR - Relative Risk (Zuranolone vs. Placebo)		3.16
95% CI for the RR		(0.418, 23.847)
p-value for RR		0.2650
OR - Odds Ratio (Zuranolone vs. Placebo)		3.93
95% CI for the OR		(0.399, 38.704)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.18
95% CI for the ARR		(-0.072, 0.432)

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-301-by.sas:t-ae-pt-301-by-age-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Age Group: 217-PPD-301 - Safety Population

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Nervous system disorders/Somnolence

Age Group (years) = 25-45

	Placebo (N=86)	Zuranolone (N=79)
Number of subjects with >=1 TEAE, n (%)	4 (4.7)	21 (26.6)
RR - Relative Risk (Zuranolone vs. Placebo)		5.72
95% CI for the RR		(2.051, 15.924)
p-value for RR		0.0009
OR - Odds Ratio (Zuranolone vs. Placebo)		7.42
95% CI for the OR		(2.420, 22.769)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.22
95% CI for the ARR		(0.112, 0.326)

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-301-by.sas:t-ae-pt-301-by-age-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Age Group: 217-PPD-301 - Safety Population

Page: 3 of 8

Nervous system disorders/Dizziness

Age Group (years) = 18-24

	Placebo (N=12)	Zuranolone (N=19)
Number of subjects with >=1 TEAE, n (%)	0	3 (15.8)
RR - Relative Risk (Zuranolone vs. Placebo)		4.55
95% CI for the RR		(0.255, 81.034)
p-value for RR		0.3024
OR - Odds Ratio (Zuranolone vs. Placebo)		5.30
95% CI for the OR		(0.250, 112.308)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.14
95% CI for the ARR		(-0.060, 0.333)

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-301-by.sas:t-ae-pt-301-by-age-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Age Group: 217-PPD-301 - Safety Population

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Nervous system disorders/Dizziness

Age Group (years) = 25-45

	Placebo (N=86)	Zuranolone (N=79)
Number of subjects with >=1 TEAE, n (%)	10 (11.6)	10 (12.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.09
95% CI for the RR		(0.479, 2.476)
p-value for RR		0.8395
OR - Odds Ratio (Zuranolone vs. Placebo)		1.10
95% CI for the OR		(0.432, 2.806)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.01
95% CI for the ARR		(-0.090, 0.110)

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-301-by.sas:t-ae-pt-301-by-age-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Age Group: 217-PPD-301 - Safety Population

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Nervous system disorders/Sedation

Age Group (years) = 18-24

	Placebo (N=12)	Zuranolone (N=19)
Number of subjects with >=1 TEAE, n (%)	1 (8.3)	4 (21.1)
RR - Relative Risk (Zuranolone vs. Placebo)		2.53
95% CI for the RR		(0.319, 19.995)
p-value for RR		0.3799
OR - Odds Ratio (Zuranolone vs. Placebo)		2.93
95% CI for the OR		(0.287, 30.008)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.13
95% CI for the ARR		(-0.114, 0.368)

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-301-by.sas:t-ae-pt-301-by-age-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Age Group: 217-PPD-301 - Safety Population

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Nervous system disorders/Sedation

Age Group (years) = 25-45

	Placebo (N=86)	Zuranolone (N=79)
Number of subjects with >=1 TEAE, n (%)	0	7 (8.9)
RR - Relative Risk (Zuranolone vs. Placebo)		16.31
95% CI for the RR		(0.947, 281.040)
p-value for RR		0.0546
OR - Odds Ratio (Zuranolone vs. Placebo)		17.90
95% CI for the OR		(1.005, 318.709)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.09
95% CI for the ARR		(0.022, 0.154)

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-301-by.sas:t-ae-pt-301-by-age-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Age Group: 217-PPD-301 - Safety Population

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Nervous system disorders/Headache

Age Group (years) = 18-24

	Placebo (N=12)	Zuranolone (N=19)
Number of subjects with >=1 TEAE, n (%)	1 (8.3)	3 (15.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.89
95% CI for the RR		(0.222, 16.180)
p-value for RR		0.5592
OR - Odds Ratio (Zuranolone vs. Placebo)		2.06
95% CI for the OR		(0.189, 22.505)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.07
95% CI for the ARR		(-0.152, 0.301)

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-301-by.sas:t-ae-pt-301-by-age-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Age Group: 217-PPD-301 - Safety Population

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Nervous system disorders/Headache

Age Group (years) = 25-45

	Placebo (N=86)	Zuranolone (N=79)
Number of subjects with >=1 TEAE, n (%)	12 (14.0)	6 (7.6)
RR - Relative Risk (Zuranolone vs. Placebo)		0.54
95% CI for the RR		(0.215, 1.381)
p-value for RR		0.2005
OR - Odds Ratio (Zuranolone vs. Placebo)		0.51
95% CI for the OR		(0.181, 1.422)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.06
95% CI for the ARR		(-0.157, 0.030)

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-301-by.sas:t-ae-pt-301-by-age-safc.rtf **Run Date:** 21JUL2025

3.1.3.2 .2 .2 Schwere der Erkrankung

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Baseline HAMD-17 Total Score: 217-PPD-301 - 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=32)	Zuranolone (N=33)
Number of subjects with >=1 TEAE, n (%)	1 (3.1)	6 (18.2)
RR - Relative Risk (Zuranolone vs. Placebo)		5.82
95% CI for the RR		(0.741, 45.668)
p-value for RR		0.0939
OR - Odds Ratio (Zuranolone vs. Placebo)		6.89
95% CI for the OR		(0.780, 60.878)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.15
95% CI for the ARR		(0.006, 0.295)

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-301-by.sas:t-ae-pt-301-by-hamd-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Baseline HAMD-17 Total Score: 217-PPD-301 - 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=66)	Zuranolone (N=65)
Number of subjects with >=1 TEAE, n (%)	4 (6.1)	20 (30.8)
RR - Relative Risk (Zuranolone vs. Placebo)		5.08
95% CI for the RR		(1.835, 14.043)
p-value for RR		0.0017
OR - Odds Ratio (Zuranolone vs. Placebo)		6.89
95% CI for the OR		(2.203, 21.541)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.25
95% CI for the ARR		(0.121, 0.373)

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-301-by.sas:t-ae-pt-301-by-hamd-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Baseline HAMD-17 Total Score: 217-PPD-301 - Safety Population

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Nervous system disorders/Dizziness

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

	Placebo (N=32)	Zuranolone (N=33)
Number of subjects with >=1 TEAE, n (%)	4 (12.5)	5 (15.2)
RR - Relative Risk (Zuranolone vs. Placebo)		1.21
95% CI for the RR		(0.357, 4.112)
p-value for RR		0.7576
OR - Odds Ratio (Zuranolone vs. Placebo)		1.25
95% CI for the OR		(0.304, 5.147)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.03
95% CI for the ARR		(-0.141, 0.194)

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-301-by.sas:t-ae-pt-301-by-hamd-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Baseline HAMD-17 Total Score: 217-PPD-301 - Safety Population

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Nervous system disorders/Dizziness

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

	Placebo (N=66)	Zuranolone (N=65)
Number of subjects with >=1 TEAE, n (%)	6 (9.1)	8 (12.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.35
95% CI for the RR		(0.497, 3.686)
p-value for RR		0.5533
OR - Odds Ratio (Zuranolone vs. Placebo)		1.40
95% CI for the OR		(0.458, 4.297)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.03
95% CI for the ARR		(-0.074, 0.138)

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-301-by.sas:t-ae-pt-301-by-hamd-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Baseline HAMD-17 Total Score: 217-PPD-301 - Safety Population

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Nervous system disorders/Sedation

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

	Placebo (N=32)	Zuranolone (N=33)
Number of subjects with >=1 TEAE, n (%)	0	5 (15.2)
RR - Relative Risk (Zuranolone vs. Placebo)		10.68
95% CI for the RR		(0.614, 185.528)
p-value for RR		0.1040
OR - Odds Ratio (Zuranolone vs. Placebo)		12.54
95% CI for the OR		(0.664, 236.905)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.15
95% CI for the ARR		(0.016, 0.277)

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-301-by.sas:t-ae-pt-301-by-hamd-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Baseline HAMD-17 Total Score: 217-PPD-301 - Safety Population

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Nervous system disorders/Sedation

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

	Placebo (N=66)	Zuranolone (N=65)
Number of subjects with >=1 TEAE, n (%)	1 (1.5)	6 (9.2)
RR - Relative Risk (Zuranolone vs. Placebo)		6.09
95% CI for the RR		(0.754, 49.212)
p-value for RR		0.0900
OR - Odds Ratio (Zuranolone vs. Placebo)		6.61
95% CI for the OR		(0.773, 56.529)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.08
95% CI for the ARR		(0.001, 0.153)

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-301-by.sas:t-ae-pt-301-by-hamd-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Baseline HAMD-17 Total Score: 217-PPD-301 - 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=32)	Zuranolone (N=33)
Number of subjects with >=1 TEAE, n (%)	2 (6.3)	2 (6.1)
RR - Relative Risk (Zuranolone vs. Placebo)		0.97
95% CI for the RR		(0.145, 6.475)
p-value for RR		0.9747
OR - Odds Ratio (Zuranolone vs. Placebo)		0.97
95% CI for the OR		(0.128, 7.319)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.00
95% CI for the ARR		(-0.119, 0.115)

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-301-by.sas:t-ae-pt-301-by-hamd-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Baseline HAMD-17 Total Score: 217-PPD-301 - 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=66)	Zuranolone (N=65)
Number of subjects with >=1 TEAE, n (%)	11 (16.7)	7 (10.8)
RR - Relative Risk (Zuranolone vs. Placebo)		0.65
95% CI for the RR		(0.267, 1.563)
p-value for RR		0.3327
OR - Odds Ratio (Zuranolone vs. Placebo)		0.60
95% CI for the OR		(0.218, 1.668)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.06
95% CI for the ARR		(-0.176, 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-301-by.sas:t-ae-pt-301-by-hamd-safc.rtf **Run Date:** 21JUL2025

3.1.3.2 .2 .3 Abstammung

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Race Group: 217-PPD-301 - Safety Population

Page: 1 of 8

Nervous system disorders/Somnolence

Race Group = Black or African American

	Placebo (N=18)	Zuranolone (N=25)
Number of subjects with >=1 TEAE, n (%)	2 (11.1)	9 (36.0)
RR - Relative Risk (Zuranolone vs. Placebo)		3.24
95% CI for the RR		(0.793, 13.235)
p-value for RR		0.1016
OR - Odds Ratio (Zuranolone vs. Placebo)		4.50
95% CI for the OR		(0.837, 24.183)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.25
95% CI for the ARR		(0.011, 0.487)

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-301-by.sas:t-ae-pt-301-by-race-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Race Group: 217-PPD-301 - Safety Population

Page: 2 of 8

Nervous system disorders/Somnolence

Race Group = White

	Placebo (N=69)	Zuranolone (N=68)
Number of subjects with >=1 TEAE, n (%)	0	16 (23.5)
RR - Relative Risk (Zuranolone vs. Placebo)		33.48
95% CI for the RR		(2.049, 547.122)
p-value for RR		0.0138
OR - Odds Ratio (Zuranolone vs. Placebo)		43.69
95% CI for the OR		(2.562, 744.898)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.23
95% CI for the ARR		(0.129, 0.335)

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-301-by.sas:t-ae-pt-301-by-race-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Race Group: 217-PPD-301 - Safety Population

Page: 3 of 8

Nervous system disorders/Dizziness

Race Group = Black or African American

	Placebo (N=18)	Zuranolone (N=25)
Number of subjects with >=1 TEAE, n (%)	3 (16.7)	4 (16.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.96
95% CI for the RR		(0.244, 3.774)
p-value for RR		0.9534
OR - Odds Ratio (Zuranolone vs. Placebo)		0.95
95% CI for the OR		(0.185, 4.895)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.01
95% CI for the ARR		(-0.231, 0.218)

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-301-by.sas:t-ae-pt-301-by-race-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Race Group: 217-PPD-301 - Safety Population

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Nervous system disorders/Dizziness

Race Group = White

	Placebo (N=69)	Zuranolone (N=68)
Number of subjects with >=1 TEAE, n (%)	4 (5.8)	9 (13.2)
RR - Relative Risk (Zuranolone vs. Placebo)		2.28
95% CI for the RR		(0.738, 7.062)
p-value for RR		0.1519
OR - Odds Ratio (Zuranolone vs. Placebo)		2.48
95% CI for the OR		(0.725, 8.475)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.07
95% CI for the ARR		(-0.023, 0.172)

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-301-by.sas:t-ae-pt-301-by-race-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Race Group: 217-PPD-301 - Safety Population

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Nervous system disorders/Sedation

Race Group = Black or African American

	Placebo (N=18)	Zuranolone (N=25)
Number of subjects with >=1 TEAE, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		NA
95% CI for the RR		NA
p-value for RR		NA
OR - Odds Ratio (Zuranolone vs. Placebo)		NA
95% CI for the OR		NA
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NA
95% CI for the ARR		NA

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-301-by.sas:t-ae-pt-301-by-race-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Race Group: 217-PPD-301 - Safety Population

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Nervous system disorders/Sedation

Race Group = White

	Placebo (N=69)	Zuranolone (N=68)
Number of subjects with >=1 TEAE, n (%)	1 (1.4)	10 (14.7)
RR - Relative Risk (Zuranolone vs. Placebo)		10.15
95% CI for the RR		(1.335, 77.119)
p-value for RR		0.0251
OR - Odds Ratio (Zuranolone vs. Placebo)		11.72
95% CI for the OR		(1.457, 94.341)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.13
95% CI for the ARR		(0.044, 0.221)

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-301-by.sas:t-ae-pt-301-by-race-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Race Group: 217-PPD-301 - Safety Population

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Nervous system disorders/Headache

Race Group = Black or African American

	Placebo (N=18)	Zuranolone (N=25)
Number of subjects with >=1 TEAE, n (%)	4 (22.2)	1 (4.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.18
95% CI for the RR		(0.022, 1.479)
p-value for RR		0.1105
OR - Odds Ratio (Zuranolone vs. Placebo)		0.15
95% CI for the OR		(0.015, 1.438)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.18
95% CI for the ARR		(-0.389, 0.025)

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-301-by.sas:t-ae-pt-301-by-race-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Race Group: 217-PPD-301 - Safety Population

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Nervous system disorders/Headache

Race Group = White

	Placebo (N=69)	Zuranolone (N=68)
Number of subjects with >=1 TEAE, n (%)	6 (8.7)	7 (10.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.18
95% CI for the RR		(0.419, 3.342)
p-value for RR		0.7499
OR - Odds Ratio (Zuranolone vs. Placebo)		1.20
95% CI for the OR		(0.383, 3.790)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.02
95% CI for the ARR		(-0.082, 0.114)

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-301-by.sas:t-ae-pt-301-by-race-safc.rtf **Run Date:** 21JUL2025

3.1.3.2 .2 .4 Antidepressiva-Nutzung

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Baseline Antidepressant Use: 217-PPD-301 - Safety Population

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Nervous system disorders/Somnolence

Antidepressant Use at Baseline = Yes

	Placebo (N=15)	Zuranolone (N=15)
Number of subjects with >=1 TEAE, n (%)	0	3 (20.0)
RR - Relative Risk (Zuranolone vs. Placebo)		7.00
95% CI for the RR		(0.393, 124.828)
p-value for RR		0.1856
OR - Odds Ratio (Zuranolone vs. Placebo)		8.68
95% CI for the OR		(0.409, 184.278)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.19
95% CI for the ARR		(-0.032, 0.407)

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-301-by.sas:t-ae-pt-301-by-adt-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Baseline Antidepressant Use: 217-PPD-301 - Safety Population

Page: 2 of 8

Nervous system disorders/Somnolence

Antidepressant Use at Baseline = No

	Placebo (N=83)	Zuranolone (N=83)
Number of subjects with >=1 TEAE, n (%)	5 (6.0)	23 (27.7)
RR - Relative Risk (Zuranolone vs. Placebo)		4.60
95% CI for the RR		(1.837, 11.520)
p-value for RR		0.0011
OR - Odds Ratio (Zuranolone vs. Placebo)		5.98
95% CI for the OR		(2.148, 16.650)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.22
95% CI for the ARR		(0.108, 0.326)

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-301-by.sas:t-ae-pt-301-by-adt-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Baseline Antidepressant Use: 217-PPD-301 - Safety Population

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Nervous system disorders/Dizziness

Antidepressant Use at Baseline = Yes

	Placebo (N=15)	Zuranolone (N=15)
Number of subjects with >=1 TEAE, n (%)	1 (6.7)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.33
95% CI for the RR		(0.015, 7.584)
p-value for RR		0.4908
OR - Odds Ratio (Zuranolone vs. Placebo)		0.31
95% CI for the OR		(0.012, 8.285)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.06
95% CI for the ARR		(-0.229, 0.104)

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-301-by.sas:t-ae-pt-301-by-adt-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Baseline Antidepressant Use: 217-PPD-301 - Safety Population

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Nervous system disorders/Dizziness

Antidepressant Use at Baseline = No

	Placebo (N=83)	Zuranolone (N=83)
Number of subjects with >=1 TEAE, n (%)	9 (10.8)	13 (15.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.44
95% CI for the RR		(0.653, 3.194)
p-value for RR		0.3638
OR - Odds Ratio (Zuranolone vs. Placebo)		1.53
95% CI for the OR		(0.614, 3.796)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.05
95% CI for the ARR		(-0.055, 0.151)

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-301-by.sas:t-ae-pt-301-by-adt-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Baseline Antidepressant Use: 217-PPD-301 - Safety Population

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Nervous system disorders/Sedation

Antidepressant Use at Baseline = Yes

	Placebo (N=15)	Zuranolone (N=15)
Number of subjects with >=1 TEAE, n (%)	0	5 (33.3)
RR - Relative Risk (Zuranolone vs. Placebo)		11.00
95% CI for the RR		(0.662, 182.874)
p-value for RR		0.0945
OR - Odds Ratio (Zuranolone vs. Placebo)		16.24
95% CI for the OR		(0.809, 325.882)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.31
95% CI for the ARR		(0.065, 0.560)

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-301-by.sas:t-ae-pt-301-by-adt-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Baseline Antidepressant Use: 217-PPD-301 - Safety Population

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Nervous system disorders/Sedation

Antidepressant Use at Baseline = No

	Placebo (N=83)	Zuranolone (N=83)
Number of subjects with >=1 TEAE, n (%)	1 (1.2)	6 (7.2)
RR - Relative Risk (Zuranolone vs. Placebo)		6.00
95% CI for the RR		(0.738, 48.754)
p-value for RR		0.0937
OR - Odds Ratio (Zuranolone vs. Placebo)		6.39
95% CI for the OR		(0.752, 54.293)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.06
95% CI for the ARR		(0.000, 0.121)

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-301-by.sas:t-ae-pt-301-by-adt-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Baseline Antidepressant Use: 217-PPD-301 - Safety Population

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Nervous system disorders/Headache

Antidepressant Use at Baseline = Yes

	Placebo (N=15)	Zuranolone (N=15)
Number of subjects with >=1 TEAE, n (%)	1 (6.7)	1 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.00
95% CI for the RR		(0.069, 14.553)
p-value for RR		1.0000
OR - Odds Ratio (Zuranolone vs. Placebo)		1.00
95% CI for the OR		(0.057, 17.621)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.00
95% CI for the ARR		(-0.179, 0.179)

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-301-by.sas:t-ae-pt-301-by-adt-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Baseline Antidepressant Use: 217-PPD-301 - Safety Population

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Nervous system disorders/Headache

Antidepressant Use at Baseline = No

	Placebo (N=83)	Zuranolone (N=83)
Number of subjects with >=1 TEAE, n (%)	12 (14.5)	8 (9.6)
RR - Relative Risk (Zuranolone vs. Placebo)		0.67
95% CI for the RR		(0.287, 1.546)
p-value for RR		0.3448
OR - Odds Ratio (Zuranolone vs. Placebo)		0.63
95% CI for the OR		(0.244, 1.635)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.05
95% CI for the ARR		(-0.147, 0.051)

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-301-by.sas:t-ae-pt-301-by-adt-safc.rtf **Run Date:** 21JUL2025

3.1.3.2 .2 .5 BMI

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Baseline BMI (kg/m^2) Group: 217-PPD-301 - Safety Population

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Nervous system disorders/Somnolence

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

	Placebo (N=22)	Zuranolone (N=20)
Number of subjects with >=1 TEAE, n (%)	1 (4.5)	5 (25.0)
RR - Relative Risk (Zuranolone vs. Placebo)		5.50
95% CI for the RR		(0.701, 43.147)
p-value for RR		0.1048
OR - Odds Ratio (Zuranolone vs. Placebo)		7.00
95% CI for the OR		(0.740, 66.212)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.20
95% CI for the ARR		(-0.004, 0.413)

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-301-by.sas:t-ae-pt-301-by-bmi-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Baseline BMI (kg/m^2) Group: 217-PPD-301 - Safety Population

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Nervous system disorders/Somnolence

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

	Placebo (N=34)	Zuranolone (N=24)
Number of subjects with >=1 TEAE, n (%)	3 (8.8)	8 (33.3)
RR - Relative Risk (Zuranolone vs. Placebo)		3.78
95% CI for the RR		(1.116, 12.792)
p-value for RR		0.0327
OR - Odds Ratio (Zuranolone vs. Placebo)		5.17
95% CI for the OR		(1.203, 22.195)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.25
95% CI for the ARR		(0.034, 0.456)

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-301-by.sas:t-ae-pt-301-by-bmi-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Baseline BMI (kg/m^2) Group: 217-PPD-301 - Safety Population

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Nervous system disorders/Somnolence

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

	Placebo (N=42)	Zuranolone (N=53)
Number of subjects with >=1 TEAE, n (%)	1 (2.4)	13 (24.5)
RR - Relative Risk (Zuranolone vs. Placebo)		10.30
95% CI for the RR		(1.404, 75.608)
p-value for RR		0.0218
OR - Odds Ratio (Zuranolone vs. Placebo)		13.33
95% CI for the OR		(1.665, 106.667)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.22
95% CI for the ARR		(0.097, 0.346)

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-301-by.sas:t-ae-pt-301-by-bmi-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Baseline BMI (kg/m^2) Group: 217-PPD-301 - Safety Population

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Nervous system disorders/Dizziness

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

	Placebo (N=22)	Zuranolone (N=20)
Number of subjects with >=1 TEAE, n (%)	3 (13.6)	1 (5.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.37
95% CI for the RR		(0.041, 3.246)
p-value for RR		0.3672
OR - Odds Ratio (Zuranolone vs. Placebo)		0.33
95% CI for the OR		(0.032, 3.498)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.09
95% CI for the ARR		(-0.259, 0.086)

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-301-by.sas:t-ae-pt-301-by-bmi-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Baseline BMI (kg/m^2) Group: 217-PPD-301 - Safety Population

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Nervous system disorders/Dizziness

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

	Placebo (N=34)	Zuranolone (N=24)
Number of subjects with >=1 TEAE, n (%)	3 (8.8)	3 (12.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.42
95% CI for the RR		(0.312, 6.429)
p-value for RR		0.6518
OR - Odds Ratio (Zuranolone vs. Placebo)		1.48
95% CI for the OR		(0.271, 8.028)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.04
95% CI for the ARR		(-0.126, 0.200)

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-301-by.sas:t-ae-pt-301-by-bmi-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Baseline BMI (kg/m^2) Group: 217-PPD-301 - Safety Population

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Nervous system disorders/Dizziness

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

	Placebo (N=42)	Zuranolone (N=53)
Number of subjects with >=1 TEAE, n (%)	4 (9.5)	9 (17.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.78
95% CI for the RR		(0.590, 5.389)
p-value for RR		0.3054
OR - Odds Ratio (Zuranolone vs. Placebo)		1.94
95% CI for the OR		(0.554, 6.818)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.07
95% CI for the ARR		(-0.060, 0.209)

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-301-by.sas:t-ae-pt-301-by-bmi-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Baseline BMI (kg/m^2) Group: 217-PPD-301 - Safety Population

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Nervous system disorders/Sedation

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

	Placebo (N=22)	Zuranolone (N=20)
Number of subjects with >=1 TEAE, n (%)	1 (4.5)	3 (15.0)
RR - Relative Risk (Zuranolone vs. Placebo)		3.30
95% CI for the RR		(0.373, 29.212)
p-value for RR		0.2832
OR - Odds Ratio (Zuranolone vs. Placebo)		3.71
95% CI for the OR		(0.353, 38.927)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.10
95% CI for the ARR		(-0.075, 0.284)

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-301-by.sas:t-ae-pt-301-by-bmi-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Baseline BMI (kg/m^2) Group: 217-PPD-301 - Safety Population

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Nervous system disorders/Sedation

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

	Placebo (N=34)	Zuranolone (N=24)
Number of subjects with >=1 TEAE, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		NA
95% CI for the RR		NA
p-value for RR		NA
OR - Odds Ratio (Zuranolone vs. Placebo)		NA
95% CI for the OR		NA
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NA
95% CI for the ARR		NA

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-301-by.sas:t-ae-pt-301-by-bmi-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Baseline BMI (kg/m^2) Group: 217-PPD-301 - Safety Population

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Nervous system disorders/Sedation

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

	Placebo (N=42)	Zuranolone (N=53)
Number of subjects with >=1 TEAE, n (%)	0	8 (15.1)
RR - Relative Risk (Zuranolone vs. Placebo)		13.54
95% CI for the RR		(0.804, 227.995)
p-value for RR		0.0706
OR - Odds Ratio (Zuranolone vs. Placebo)		15.88
95% CI for the OR		(0.889, 283.626)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.15
95% CI for the ARR		(0.043, 0.248)

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-301-by.sas:t-ae-pt-301-by-bmi-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Baseline BMI (kg/m^2) Group: 217-PPD-301 - Safety Population

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Nervous system disorders/Headache

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

	Placebo (N=22)	Zuranolone (N=20)
Number of subjects with >=1 TEAE, n (%)	4 (18.2)	3 (15.0)
RR - Relative Risk (Zuranolone vs. Placebo)		0.83
95% CI for the RR		(0.210, 3.243)
p-value for RR		0.7830
OR - Odds Ratio (Zuranolone vs. Placebo)		0.79
95% CI for the OR		(0.154, 4.082)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.03
95% CI for the ARR		(-0.256, 0.193)

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-301-by.sas:t-ae-pt-301-by-bmi-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Baseline BMI (kg/m^2) Group: 217-PPD-301 - Safety Population

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Nervous system disorders/Headache

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

	Placebo (N=34)	Zuranolone (N=24)
Number of subjects with >=1 TEAE, n (%)	5 (14.7)	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		0.28
95% CI for the RR		(0.035, 2.274)
p-value for RR		0.2353
OR - Odds Ratio (Zuranolone vs. Placebo)		0.25
95% CI for the OR		(0.028, 2.312)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.11
95% CI for the ARR		(-0.249, 0.038)

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-301-by.sas:t-ae-pt-301-by-bmi-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Baseline BMI (kg/m^2) Group: 217-PPD-301 - Safety Population

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Nervous system disorders/Headache

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

	Placebo (N=42)	Zuranolone (N=53)
Number of subjects with >=1 TEAE, n (%)	4 (9.5)	5 (9.4)
RR - Relative Risk (Zuranolone vs. Placebo)		0.99
95% CI for the RR		(0.284, 3.460)
p-value for RR		0.9882
OR - Odds Ratio (Zuranolone vs. Placebo)		0.99
95% CI for the OR		(0.248, 3.941)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.00
95% CI for the ARR		(-0.120, 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-301-by.sas:t-ae-pt-301-by-bmi-safc.rtf **Run Date:** 21JUL2025

3.1.3.2 .2 .6 Beginn der PPD

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Onset of PPD: 217-PPD-301 - Safety Population

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Nervous system disorders/Somnolence

Onset of PPD = 3rd trimester

	Placebo (N=31)	Zuranolone (N=34)
Number of subjects with >=1 TEAE, n (%)	3 (9.7)	6 (17.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.82
95% CI for the RR		(0.498, 6.675)
p-value for RR		0.3642
OR - Odds Ratio (Zuranolone vs. Placebo)		2.00
95% CI for the OR		(0.455, 8.800)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.08
95% CI for the ARR		(-0.085, 0.245)

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-301-by.sas:t-ae-pt-301-by-onset-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Onset of PPD: 217-PPD-301 - Safety Population

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Nervous system disorders/Somnolence

Onset of PPD = Postpartum

	Placebo (N=67)	Zuranolone (N=64)
Number of subjects with >=1 TEAE, n (%)	2 (3.0)	20 (31.3)
RR - Relative Risk (Zuranolone vs. Placebo)		10.47
95% CI for the RR		(2.549, 42.991)
p-value for RR		0.0011
OR - Odds Ratio (Zuranolone vs. Placebo)		14.77
95% CI for the OR		(3.286, 66.410)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.28
95% CI for the ARR		(0.162, 0.403)

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-301-by.sas:t-ae-pt-301-by-onset-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Onset of PPD: 217-PPD-301 - Safety Population

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Nervous system disorders/Dizziness

Onset of PPD = 3rd trimester

	Placebo (N=31)	Zuranolone (N=34)
Number of subjects with >=1 TEAE, n (%)	3 (9.7)	3 (8.8)
RR - Relative Risk (Zuranolone vs. Placebo)		0.91
95% CI for the RR		(0.199, 4.188)
p-value for RR		0.9055
OR - Odds Ratio (Zuranolone vs. Placebo)		0.90
95% CI for the OR		(0.168, 4.846)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.01
95% CI for the ARR		(-0.150, 0.133)

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-301-by.sas:t-ae-pt-301-by-onset-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Onset of PPD: 217-PPD-301 - Safety Population

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Nervous system disorders/Dizziness

Onset of PPD = Postpartum

	Placebo (N=67)	Zuranolone (N=64)
Number of subjects with >=1 TEAE, n (%)	7 (10.4)	10 (15.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.50
95% CI for the RR		(0.606, 3.690)
p-value for RR		0.3824
OR - Odds Ratio (Zuranolone vs. Placebo)		1.59
95% CI for the OR		(0.565, 4.462)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.05
95% CI for the ARR		(-0.063, 0.167)

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-301-by.sas:t-ae-pt-301-by-onset-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Onset of PPD: 217-PPD-301 - Safety Population

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Nervous system disorders/Sedation

Onset of PPD = 3rd trimester

	Placebo (N=31)	Zuranolone (N=34)
Number of subjects with >=1 TEAE, n (%)	1 (3.2)	3 (8.8)
RR - Relative Risk (Zuranolone vs. Placebo)		2.74
95% CI for the RR		(0.300, 24.939)
p-value for RR		0.3722
OR - Odds Ratio (Zuranolone vs. Placebo)		2.90
95% CI for the OR		(0.286, 29.488)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.06
95% CI for the ARR		(-0.058, 0.170)

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-301-by.sas:t-ae-pt-301-by-onset-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Onset of PPD: 217-PPD-301 - Safety Population

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Nervous system disorders/Sedation

Onset of PPD = Postpartum

	Placebo (N=67)	Zuranolone (N=64)
Number of subjects with >=1 TEAE, n (%)	0	8 (12.5)
RR - Relative Risk (Zuranolone vs. Placebo)		17.78
95% CI for the RR		(1.048, 301.921)
p-value for RR		0.0464
OR - Odds Ratio (Zuranolone vs. Placebo)		20.31
95% CI for the OR		(1.147, 359.631)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.12
95% CI for the ARR		(0.039, 0.208)

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-301-by.sas:t-ae-pt-301-by-onset-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Onset of PPD: 217-PPD-301 - Safety Population

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Nervous system disorders/Headache

Onset of PPD = 3rd trimester

	Placebo (N=31)	Zuranolone (N=34)
Number of subjects with >=1 TEAE, n (%)	2 (6.5)	4 (11.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.82
95% CI for the RR		(0.359, 9.271)
p-value for RR		0.4690
OR - Odds Ratio (Zuranolone vs. Placebo)		1.93
95% CI for the OR		(0.329, 11.378)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.05
95% CI for the ARR		(-0.085, 0.192)

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-301-by.sas:t-ae-pt-301-by-onset-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Onset of PPD: 217-PPD-301 - Safety Population

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Nervous system disorders/Headache

Onset of PPD = Postpartum

	Placebo (N=67)	Zuranolone (N=64)
Number of subjects with >=1 TEAE, n (%)	11 (16.4)	5 (7.8)
RR - Relative Risk (Zuranolone vs. Placebo)		0.48
95% CI for the RR		(0.175, 1.294)
p-value for RR		0.1455
OR - Odds Ratio (Zuranolone vs. Placebo)		0.43
95% CI for the OR		(0.141, 1.320)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.09
95% CI for the ARR		(-0.196, 0.024)

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-301-by.sas:t-ae-pt-301-by-onset-safc.rtf **Run Date:** 21JUL2025

3.1.3.2 .2 .7 PPD in der Familie

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Family History of PPD: 217-PPD-301 - Safety Population

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Nervous system disorders/Somnolence

Family History of PPD = Yes

	Placebo (N=16)	Zuranolone (N=21)
Number of subjects with >=1 TEAE, n (%)	1 (6.3)	4 (19.0)
RR - Relative Risk (Zuranolone vs. Placebo)		3.05
95% CI for the RR		(0.376, 24.703)
p-value for RR		0.2966
OR - Odds Ratio (Zuranolone vs. Placebo)		3.53
95% CI for the OR		(0.354, 35.156)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.13
95% CI for the ARR		(-0.078, 0.334)

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-301-by.sas:t-ae-pt-301-by-fhist-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Family History of PPD: 217-PPD-301 - Safety Population

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Nervous system disorders/Somnolence

Family History of PPD = No/Unknown

	Placebo (N=82)	Zuranolone (N=77)
Number of subjects with >=1 TEAE, n (%)	4 (4.9)	22 (28.6)
RR - Relative Risk (Zuranolone vs. Placebo)		5.86
95% CI for the RR		(2.114, 16.226)
p-value for RR		0.0007
OR - Odds Ratio (Zuranolone vs. Placebo)		7.80
95% CI for the OR		(2.545, 23.902)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.24
95% CI for the ARR		(0.126, 0.348)

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-301-by.sas:t-ae-pt-301-by-fhist-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Family History of PPD: 217-PPD-301 - Safety Population

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Nervous system disorders/Dizziness

Family History of PPD = Yes

	Placebo (N=16)	Zuranolone (N=21)
Number of subjects with >=1 TEAE, n (%)	1 (6.3)	3 (14.3)
RR - Relative Risk (Zuranolone vs. Placebo)		2.29
95% CI for the RR		(0.262, 19.973)
p-value for RR		0.4548
OR - Odds Ratio (Zuranolone vs. Placebo)		2.50
95% CI for the OR		(0.235, 26.600)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.08
95% CI for the ARR		(-0.111, 0.271)

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-301-by.sas:t-ae-pt-301-by-fhist-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Family History of PPD: 217-PPD-301 - Safety Population

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Nervous system disorders/Dizziness

Family History of PPD = No/Unknown

	Placebo (N=82)	Zuranolone (N=77)
Number of subjects with >=1 TEAE, n (%)	9 (11.0)	10 (13.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.18
95% CI for the RR		(0.508, 2.755)
p-value for RR		0.6964
OR - Odds Ratio (Zuranolone vs. Placebo)		1.21
95% CI for the OR		(0.464, 3.161)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.02
95% CI for the ARR		(-0.081, 0.121)

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-301-by.sas:t-ae-pt-301-by-fhist-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Family History of PPD: 217-PPD-301 - Safety Population

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Nervous system disorders/Sedation

Family History of PPD = Yes

	Placebo (N=16)	Zuranolone (N=21)
Number of subjects with >=1 TEAE, n (%)	0	5 (23.8)
RR - Relative Risk (Zuranolone vs. Placebo)		8.50
95% CI for the RR		(0.504, 143.322)
p-value for RR		0.1376
OR - Odds Ratio (Zuranolone vs. Placebo)		11.00
95% CI for the OR		(0.562, 215.354)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.22
95% CI for the ARR		(0.023, 0.419)

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-301-by.sas:t-ae-pt-301-by-fhist-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Family History of PPD: 217-PPD-301 - Safety Population

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Nervous system disorders/Sedation

Family History of PPD = No/Unknown

	Placebo (N=82)	Zuranolone (N=77)
Number of subjects with >=1 TEAE, n (%)	1 (1.2)	6 (7.8)
RR - Relative Risk (Zuranolone vs. Placebo)		6.39
95% CI for the RR		(0.787, 51.868)
p-value for RR		0.0826
OR - Odds Ratio (Zuranolone vs. Placebo)		6.85
95% CI for the OR		(0.805, 58.229)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.07
95% CI for the ARR		(0.001, 0.130)

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-301-by.sas:t-ae-pt-301-by-fhist-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Family History of PPD: 217-PPD-301 - Safety Population

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Nervous system disorders/Headache

Family History of PPD = Yes

	Placebo (N=16)	Zuranolone (N=21)
Number of subjects with >=1 TEAE, n (%)	0	1 (4.8)
RR - Relative Risk (Zuranolone vs. Placebo)		2.32
95% CI for the RR		(0.101, 53.420)
p-value for RR		0.5994
OR - Odds Ratio (Zuranolone vs. Placebo)		2.41
95% CI for the OR		(0.092, 63.253)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.04
95% CI for the ARR		(-0.094, 0.171)

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-301-by.sas:t-ae-pt-301-by-fhist-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Family History of PPD: 217-PPD-301 - Safety Population

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Nervous system disorders/Headache

Family History of PPD = No/Unknown

	Placebo (N=82)	Zuranolone (N=77)
Number of subjects with >=1 TEAE, n (%)	13 (15.9)	8 (10.4)
RR - Relative Risk (Zuranolone vs. Placebo)		0.66
95% CI for the RR		(0.287, 1.494)
p-value for RR		0.3148
OR - Odds Ratio (Zuranolone vs. Placebo)		0.62
95% CI for the OR		(0.240, 1.578)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.05
95% CI for the ARR		(-0.159, 0.050)

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-301-by.sas:t-ae-pt-301-by-fhist-safc.rtf **Run Date:** 21JUL2025

3.1.3.2 .2 .8 PPD in der Anamnese

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by History of PPD: 217-PPD-301 - Safety Population

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Nervous system disorders/Somnolence

History of PPD = 1st Episode

	Placebo (N=87)	Zuranolone (N=81)
Number of subjects with >=1 TEAE, n (%)	4 (4.6)	20 (24.7)
RR - Relative Risk (Zuranolone vs. Placebo)		5.37
95% CI for the RR		(1.917, 15.042)
p-value for RR		0.0014
OR - Odds Ratio (Zuranolone vs. Placebo)		6.80
95% CI for the OR		(2.213, 20.919)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.20
95% CI for the ARR		(0.097, 0.305)

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-301-by.sas:t-ae-pt-301-by-hist-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by History of PPD: 217-PPD-301 - Safety Population

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Nervous system disorders/Somnolence

History of PPD = Recurrent Episode

	Placebo (N=11)	Zuranolone (N=17)
Number of subjects with >=1 TEAE, n (%)	1 (9.1)	6 (35.3)
RR - Relative Risk (Zuranolone vs. Placebo)		3.88
95% CI for the RR		(0.538, 28.020)
p-value for RR		0.1786
OR - Odds Ratio (Zuranolone vs. Placebo)		5.45
95% CI for the OR		(0.556, 53.523)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.26
95% CI for the ARR		(-0.022, 0.546)

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-301-by.sas:t-ae-pt-301-by-hist-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by History of PPD: 217-PPD-301 - Safety Population

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Nervous system disorders/Dizziness

History of PPD = 1st Episode

	Placebo (N=87)	Zuranolone (N=81)
Number of subjects with >=1 TEAE, n (%)	9 (10.3)	11 (13.6)
RR - Relative Risk (Zuranolone vs. Placebo)		1.31
95% CI for the RR		(0.574, 3.003)
p-value for RR		0.5191
OR - Odds Ratio (Zuranolone vs. Placebo)		1.36
95% CI for the OR		(0.533, 3.480)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.03
95% CI for the ARR		(-0.066, 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-301-by.sas:t-ae-pt-301-by-hist-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by History of PPD: 217-PPD-301 - Safety Population

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Nervous system disorders/Dizziness

History of PPD = Recurrent Episode

	Placebo (N=11)	Zuranolone (N=17)
Number of subjects with >=1 TEAE, n (%)	1 (9.1)	2 (11.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.29
95% CI for the RR		(0.133, 12.621)
p-value for RR		0.8244
OR - Odds Ratio (Zuranolone vs. Placebo)		1.33
95% CI for the OR		(0.106, 16.743)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.03
95% CI for the ARR		(-0.202, 0.255)

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-301-by.sas:t-ae-pt-301-by-hist-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by History of PPD: 217-PPD-301 - Safety Population

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Nervous system disorders/Sedation

History of PPD = 1st Episode

	Placebo (N=87)	Zuranolone (N=81)
Number of subjects with >=1 TEAE, n (%)	1 (1.1)	8 (9.9)
RR - Relative Risk (Zuranolone vs. Placebo)		8.59
95% CI for the RR		(1.099, 67.196)
p-value for RR		0.0404
OR - Odds Ratio (Zuranolone vs. Placebo)		9.42
95% CI for the OR		(1.152, 77.127)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.09
95% CI for the ARR		(0.019, 0.156)

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-301-by.sas:t-ae-pt-301-by-hist-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by History of PPD: 217-PPD-301 - Safety Population

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Nervous system disorders/Sedation

History of PPD = Recurrent Episode

	Placebo (N=11)	Zuranolone (N=17)
Number of subjects with >=1 TEAE, n (%)	0	3 (17.6)
RR - Relative Risk (Zuranolone vs. Placebo)		4.67
95% CI for the RR		(0.264, 82.450)
p-value for RR		0.2931
OR - Odds Ratio (Zuranolone vs. Placebo)		5.55
95% CI for the OR		(0.260, 118.712)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.15
95% CI for the ARR		(-0.062, 0.368)

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-301-by.sas:t-ae-pt-301-by-hist-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by History of PPD: 217-PPD-301 - Safety Population

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Nervous system disorders/Headache

History of PPD = 1st Episode

	Placebo (N=87)	Zuranolone (N=81)
Number of subjects with >=1 TEAE, n (%)	12 (13.8)	5 (6.2)
RR - Relative Risk (Zuranolone vs. Placebo)		0.45
95% CI for the RR		(0.165, 1.215)
p-value for RR		0.1145
OR - Odds Ratio (Zuranolone vs. Placebo)		0.41
95% CI for the OR		(0.138, 1.224)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.08
95% CI for the ARR		(-0.166, 0.013)

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-301-by.sas:t-ae-pt-301-by-hist-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by History of PPD: 217-PPD-301 - Safety Population

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Nervous system disorders/Headache

History of PPD = Recurrent Episode

	Placebo (N=11)	Zuranolone (N=17)
Number of subjects with >=1 TEAE, n (%)	1 (9.1)	4 (23.5)
RR - Relative Risk (Zuranolone vs. Placebo)		2.59
95% CI for the RR		(0.331, 20.224)
p-value for RR		0.3646
OR - Odds Ratio (Zuranolone vs. Placebo)		3.08
95% CI for the OR		(0.296, 31.982)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.14
95% CI for the ARR		(-0.119, 0.408)

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-301-by.sas:t-ae-pt-301-by-hist-safc.rtf **Run Date:** 21JUL2025

3.1.3.2 .2 .9 Depression mit Angst

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - Safety Population

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Nervous system disorders/Somnolence

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

	Placebo (N=21)	Zuranolone (N=24)
Number of subjects with >=1 TEAE, n (%)	0	6 (25.0)
RR - Relative Risk (Zuranolone vs. Placebo)		11.44
95% CI for the RR		(0.683, 191.697)
p-value for RR		0.0902
OR - Odds Ratio (Zuranolone vs. Placebo)		15.11
95% CI for the OR		(0.796, 286.592)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.24
95% CI for the ARR		(0.054, 0.420)

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-301-by.sas:t-ae-pt-301-by-hama-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - Safety Population

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Nervous system disorders/Somnolence

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

	Placebo (N=77)	Zuranolone (N=74)
Number of subjects with >=1 TEAE, n (%)	5 (6.5)	20 (27.0)
RR - Relative Risk (Zuranolone vs. Placebo)		4.16
95% CI for the RR		(1.648, 10.513)
p-value for RR		0.0026
OR - Odds Ratio (Zuranolone vs. Placebo)		5.33
95% CI for the OR		(1.882, 15.113)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.21
95% CI for the ARR		(0.090, 0.321)

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-301-by.sas:t-ae-pt-301-by-hama-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - Safety Population

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Nervous system disorders/Dizziness

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

	Placebo (N=21)	Zuranolone (N=24)
Number of subjects with >=1 TEAE, n (%)	0	3 (12.5)
RR - Relative Risk (Zuranolone vs. Placebo)		6.16
95% CI for the RR		(0.336, 112.769)
p-value for RR		0.2203
OR - Odds Ratio (Zuranolone vs. Placebo)		7.00
95% CI for the OR		(0.341, 143.853)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.12
95% CI for the ARR		(-0.032, 0.267)

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-301-by.sas:t-ae-pt-301-by-hama-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - Safety Population

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Nervous system disorders/Dizziness

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

	Placebo (N=77)	Zuranolone (N=74)
Number of subjects with >=1 TEAE, n (%)	10 (13.0)	10 (13.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.04
95% CI for the RR		(0.460, 2.354)
p-value for RR		0.9240
OR - Odds Ratio (Zuranolone vs. Placebo)		1.05
95% CI for the OR		(0.408, 2.683)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.01
95% CI for the ARR		(-0.103, 0.113)

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-301-by.sas:t-ae-pt-301-by-hama-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - Safety Population

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Nervous system disorders/Sedation

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

	Placebo (N=21)	Zuranolone (N=24)
Number of subjects with >=1 TEAE, n (%)	0	2 (8.3)
RR - Relative Risk (Zuranolone vs. Placebo)		4.40
95% CI for the RR		(0.223, 86.784)
p-value for RR		0.3301
OR - Odds Ratio (Zuranolone vs. Placebo)		4.78
95% CI for the OR		(0.217, 105.355)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.08
95% CI for the ARR		(-0.056, 0.210)

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-301-by.sas:t-ae-pt-301-by-hama-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - Safety Population

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Nervous system disorders/Sedation

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

	Placebo (N=77)	Zuranolone (N=74)
Number of subjects with >=1 TEAE, n (%)	1 (1.3)	9 (12.2)
RR - Relative Risk (Zuranolone vs. Placebo)		9.36
95% CI for the RR		(1.216, 72.108)
p-value for RR		0.0317
OR - Odds Ratio (Zuranolone vs. Placebo)		10.52
95% CI for the OR		(1.299, 85.278)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.11
95% CI for the ARR		(0.030, 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-301-by.sas:t-ae-pt-301-by-hama-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - Safety Population

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Nervous system disorders/Headache

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = <20

	Placebo (N=21)	Zuranolone (N=24)
Number of subjects with >=1 TEAE, n (%)	0	0
RR - Relative Risk (Zuranolone vs. Placebo)		NA
95% CI for the RR		NA
p-value for RR		NA
OR - Odds Ratio (Zuranolone vs. Placebo)		NA
95% CI for the OR		NA
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		NA
95% CI for the ARR		NA

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-301-by.sas:t-ae-pt-301-by-hama-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Preferred Term by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - Safety Population

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Nervous system disorders/Headache

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20

	Placebo (N=77)	Zuranolone (N=74)
Number of subjects with >=1 TEAE, n (%)	13 (16.9)	9 (12.2)
RR - Relative Risk (Zuranolone vs. Placebo)		0.72
95% CI for the RR		(0.328, 1.584)
p-value for RR		0.4145
OR - Odds Ratio (Zuranolone vs. Placebo)		0.68
95% CI for the OR		(0.272, 1.706)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.05
95% CI for the ARR		(-0.159, 0.065)

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-301-by.sas:t-ae-pt-301-by-hama-safc.rtf **Run Date:** 21JUL2025

3.2 Schwere UE

3.2.1 Gesamtraten

3.2.1.1 ITT-Population

Number of Subjects with Treatment-Emergent Adverse Event by Grade of Severity: 217-PPD-301 - Safety population

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Grade 3/4/5

	Placebo (N=98)	Zuranolone (N=98)
Number of subjects with >=1 TEAE, n (%)	1 (1.0)	3 (3.1)
RR - Relative Risk (Zuranolone vs. Placebo)		3.00
95% CI for the RR		(0.318, 28.343)
p-value for RR		0.3377
OR - Odds Ratio (Zuranolone vs. Placebo)		3.06
95% CI for the OR		(0.313, 29.971)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.02
95% CI for the ARR		(-0.019, 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-301-ovr.sas:t-ae-gr-301-ovr-safc.rtf **Run Date:** 18JUL2025

3.2.1.2 Subgruppen

3.2.1.2 .1 Interaktionstest

Number of Subjects with Treatment-Emergent Adverse Event by Grade of Severity: Treatment by Subgroup Interaction: 217-PPD-301 - Safety population

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Grade >=3

Subgroup Subgroup Category	Placebo (N=98)	Zuranolone (N=98)	p-value for Treatment by Subgroup Interaction Test
Number of subjects with >=1 TEAE, n(%)	1 (1.0)	3 (3.1)	
Age Group (years)			
18 - 24, n / N (%)	0/12	1/19 (5.3)	NA
25 - 45, n / N (%)	1/86 (1.2)	2/79 (2.5)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	0/32	0/33	NA
>=28, n / N (%)	1/66 (1.5)	3/65 (4.6)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	0/18	2/25 (8.0)	NA
White, n / N (%)	1/69 (1.4)	1/68 (1.5)	
Antidepressant Use at Baseline			
Yes, n / N (%)	1/15 (6.7)	1/15 (6.7)	NA
No, n / N (%)	0/83	2/83 (2.4)	

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-301-int.sas:t-ae-gr-301-int-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Grade of Severity: Treatment by Subgroup Interaction: 217-PPD-301 - Safety population

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Grade >=3

Subgroup Subgroup Category	Placebo (N=98)	Zuranolone (N=98)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2}) Group 2			
<=24.9, n / N (%)	0/22	0/20	NA(a)
25-29.9, n / N (%)	0/34	1/24 (4.2)	NA(b)
>=30, n / N (%)	1/42 (2.4)	2/53 (3.8)	NA(c)
Onset of PPD			
3rd Trimester, n / N (%)	1/31 (3.2)	0/34	NA
Postpartum, n / N (%)	0/67	3/64 (4.7)	
Family History of PPD			
Yes, n / N (%)	0/16	0/21	NA
No/Unknown, n / N (%)	1/82 (1.2)	3/77 (3.9)	
History of PPD			
1st Episode, n / N (%)	1/87 (1.1)	2/81 (2.5)	NA
Recurrent Episode, n / N (%)	0/11	1/17 (5.9)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	0/21	0/24	NA
>=20, n / N (%)	1/77 (1.3)	3/74 (4.1)	

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-gr-301-int.sas:t-ae-gr-301-int-safc.rtf **Run Date:** 18JUL2025

3.2.1.2 .2 Subgruppenanalysen

3.2.1.2 .2 .1 Alter

Number of Subjects with Treatment-Emergent Adverse Event by Grade of Severity by Age Group: 217-PPD-301 - Safety Population

Page: 3 of 6

Age Group (years) = 18-24

Grade 3/4/5

	Placebo (N=12)	Zuranolone (N=19)
Number of subjects with >=1 TEAE, n (%)	0	1 (5.3)
RR - Relative Risk (Zuranolone vs. Placebo)		1.95
95% CI for the RR		(0.086, 44.316)
p-value for RR		0.6752
OR - Odds Ratio (Zuranolone vs. Placebo)		2.03
95% CI for the OR		(0.076, 53.874)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.04
95% CI for the ARR		(-0.119, 0.192)

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-301-by.sas:t-ae-gr-301-by-age-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Grade of Severity by Age Group: 217-PPD-301 - Safety Population

Page: 6 of 6

Age Group (years) = 25-45

Grade 3/4/5

	Placebo (N=86)	Zuranolone (N=79)
Number of subjects with >=1 TEAE, n (%)	1 (1.2)	2 (2.5)
RR - Relative Risk (Zuranolone vs. Placebo)		2.18
95% CI for the RR		(0.201, 23.547)
p-value for RR		0.5219
OR - Odds Ratio (Zuranolone vs. Placebo)		2.21
95% CI for the OR		(0.196, 24.833)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.01
95% CI for the ARR		(-0.028, 0.055)

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-301-by.sas:t-ae-gr-301-by-age-safc.rtf **Run Date:** 21JUL2025

3.2.1.2 .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-301 - 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=66)	Zuranolone (N=65)
Number of subjects with >=1 TEAE, n (%)	1 (1.5)	3 (4.6)
RR - Relative Risk (Zuranolone vs. Placebo)		3.05
95% CI for the RR		(0.325, 28.531)
p-value for RR		0.3291
OR - Odds Ratio (Zuranolone vs. Placebo)		3.15
95% CI for the OR		(0.319, 31.051)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.03
95% CI for the ARR		(-0.028, 0.090)

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-301-by.sas:t-ae-gr-301-by-hamd-safc.rtf **Run Date:** 21JUL2025

3.2.1.2 .2 .3 Abstammung

Number of Subjects with Treatment-Emergent Adverse Event by Grade of Severity by Race Group: 217-PPD-301 - Safety Population

Page: 3 of 6

Race Group = Black or African American

Grade 3/4/5

	Placebo (N=18)	Zuranolone (N=25)
Number of subjects with >=1 TEAE, n (%)	0	2 (8.0)
RR - Relative Risk (Zuranolone vs. Placebo)		3.65
95% CI for the RR		(0.186, 71.806)
p-value for RR		0.3938
OR - Odds Ratio (Zuranolone vs. Placebo)		3.94
95% CI for the OR		(0.178, 87.102)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.07
95% CI for the ARR		(-0.064, 0.204)

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-301-by.sas:t-ae-gr-301-by-race-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Grade of Severity by Race Group: 217-PPD-301 - Safety Population

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Race Group = White

Grade 3/4/5

	Placebo (N=69)	Zuranolone (N=68)
Number of subjects with >=1 TEAE, n (%)	1 (1.4)	1 (1.5)
RR - Relative Risk (Zuranolone vs. Placebo)		1.01
95% CI for the RR		(0.065, 15.896)
p-value for RR		0.9917
OR - Odds Ratio (Zuranolone vs. Placebo)		1.01
95% CI for the OR		(0.062, 16.561)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.00
95% CI for the ARR		(-0.040, 0.040)

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-301-by.sas:t-ae-gr-301-by-race-safc.rtf **Run Date:** 21JUL2025

3.2.1.2 .2 .4 Antidepressiva-Nutzung

Number of Subjects with Treatment-Emergent Adverse Event by Grade of Severity by Baseline Antidepressant Use: 217-PPD-301 - Safety Population

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Antidepressant Use at Baseline = Yes

Grade 3/4/5

	Placebo (N=15)	Zuranolone (N=15)
Number of subjects with >=1 TEAE, n (%)	1 (6.7)	1 (6.7)
RR - Relative Risk (Zuranolone vs. Placebo)		1.00
95% CI for the RR		(0.069, 14.553)
p-value for RR		1.0000
OR - Odds Ratio (Zuranolone vs. Placebo)		1.00
95% CI for the OR		(0.057, 17.621)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.00
95% CI for the ARR		(-0.179, 0.179)

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-301-by.sas:t-ae-gr-301-by-adt-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Grade of Severity by Baseline Antidepressant Use: 217-PPD-301 - Safety Population

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Antidepressant Use at Baseline = No

Grade 3/4/5

	Placebo (N=83)	Zuranolone (N=83)
Number of subjects with >=1 TEAE, n (%)	0	2 (2.4)
RR - Relative Risk (Zuranolone vs. Placebo)		5.00
95% CI for the RR		(0.244, 102.586)
p-value for RR		0.2964
OR - Odds Ratio (Zuranolone vs. Placebo)		5.12
95% CI for the OR		(0.242, 108.347)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.02
95% CI for the ARR		(-0.016, 0.064)

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-301-by.sas:t-ae-gr-301-by-adt-safc.rtf **Run Date:** 21JUL2025

3.2.1.2 .2 .5 BMI

Number of Subjects with Treatment-Emergent Adverse Event by Grade of Severity by Baseline BMI (kg/m^2) Group: 217-PPD-301 - Safety Population

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

Grade 3/4/5

	Placebo (N=34)	Zuranolone (N=24)
Number of subjects with >=1 TEAE, n (%)	0	1 (4.2)
RR - Relative Risk (Zuranolone vs. Placebo)		4.20
95% CI for the RR		(0.178, 98.916)
p-value for RR		0.3733
OR - Odds Ratio (Zuranolone vs. Placebo)		4.40
95% CI for the OR		(0.172, 112.824)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.05
95% CI for the ARR		(-0.055, 0.147)

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-301-by.sas:t-ae-gr-301-by-bmi-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Grade of Severity by Baseline BMI (kg/m^2) Group: 217-PPD-301 - Safety Population

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

Grade 3/4/5

	Placebo (N=42)	Zuranolone (N=53)
Number of subjects with >=1 TEAE, n (%)	1 (2.4)	2 (3.8)
RR - Relative Risk (Zuranolone vs. Placebo)		1.58
95% CI for the RR		(0.149, 16.888)
p-value for RR		0.7028
OR - Odds Ratio (Zuranolone vs. Placebo)		1.61
95% CI for the OR		(0.141, 18.362)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.01
95% CI for the ARR		(-0.055, 0.083)

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-301-by.sas:t-ae-gr-301-by-bmi-safc.rtf **Run Date:** 21JUL2025

3.2.1.2 .2 .6 Beginn der PPD

Number of Subjects with Treatment-Emergent Adverse Event by Grade of Severity by Onset of PPD: 217-PPD-301 - Safety Population

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Onset of PPD = 3rd trimester

Grade 3/4/5

	Placebo (N=31)	Zuranolone (N=34)
Number of subjects with >=1 TEAE, n (%)	1 (3.2)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.30
95% CI for the RR		(0.013, 7.216)
p-value for RR		0.4618
OR - Odds Ratio (Zuranolone vs. Placebo)		0.29
95% CI for the OR		(0.012, 7.505)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.03
95% CI for the ARR		(-0.116, 0.051)

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-301-by.sas:t-ae-gr-301-by-onset-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Grade of Severity by Onset of PPD: 217-PPD-301 - Safety Population

Page: 6 of 6

Onset of PPD = Postpartum

Grade 3/4/5

	Placebo (N=67)	Zuranolone (N=64)
Number of subjects with >=1 TEAE, n (%)	0	3 (4.7)
RR - Relative Risk (Zuranolone vs. Placebo)		7.32
95% CI for the RR		(0.386, 139.024)
p-value for RR		0.1849
OR - Odds Ratio (Zuranolone vs. Placebo)		7.68
95% CI for the OR		(0.389, 151.754)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.05
95% CI for the ARR		(-0.012, 0.105)

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-301-by.sas:t-ae-gr-301-by-onset-safc.rtf **Run Date:** 21JUL2025

3.2.1.2 .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-301 - Safety Population

Page: 5 of 5

Family History of PPD = No/Unknown

Grade 3/4/5

	Placebo (N=82)	Zuranolone (N=77)
Number of subjects with >=1 TEAE, n (%)	1 (1.2)	3 (3.9)
RR - Relative Risk (Zuranolone vs. Placebo)		3.19
95% CI for the RR		(0.340, 30.061)
p-value for RR		0.3098
OR - Odds Ratio (Zuranolone vs. Placebo)		3.28
95% CI for the OR		(0.334, 32.266)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.03
95% CI for the ARR		(-0.023, 0.076)

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-301-by.sas:t-ae-gr-301-by-fhist-safc.rtf **Run Date:** 21JUL2025

3.2.1.2 .2 .8 PPD in der Anamnese

Number of Subjects with Treatment-Emergent Adverse Event by Grade of Severity by History of PPD: 217-PPD-301 - Safety Population

Page: 3 of 6

History of PPD = 1st Episode

Grade 3/4/5

	Placebo (N=87)	Zuranolone (N=81)
Number of subjects with >=1 TEAE, n (%)	1 (1.1)	2 (2.5)
RR - Relative Risk (Zuranolone vs. Placebo)		2.15
95% CI for the RR		(0.199, 23.241)
p-value for RR		0.5291
OR - Odds Ratio (Zuranolone vs. Placebo)		2.18
95% CI for the OR		(0.194, 24.480)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.01
95% CI for the ARR		(-0.027, 0.054)

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-301-by.sas:t-ae-gr-301-by-hist-safc.rtf **Run Date:** 21JUL2025

Number of Subjects with Treatment-Emergent Adverse Event by Grade of Severity by History of PPD: 217-PPD-301 - Safety Population

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History of PPD = Recurrent Episode

Grade 3/4/5

	Placebo (N=11)	Zuranolone (N=17)
Number of subjects with >=1 TEAE, n (%)	0	1 (5.9)
RR - Relative Risk (Zuranolone vs. Placebo)		2.00
95% CI for the RR		(0.089, 45.118)
p-value for RR		0.6629
OR - Odds Ratio (Zuranolone vs. Placebo)		2.09
95% CI for the OR		(0.078, 56.012)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.04
95% CI for the ARR		(-0.129, 0.212)

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-301-by.sas:t-ae-gr-301-by-hist-safc.rtf **Run Date:** 21JUL2025

3.2.1.2 .2 .9 Depression mit Angst

Number of Subjects with Treatment-Emergent Adverse Event by Grade of Severity by Depression with Elevated Anxiety (by Baseline HAMA Total Score): 217-PPD-301 - Safety Population

Page: 5 of 5

Depression with Elevated Anxiety (by Baseline HAMA Total Score) = >=20
Grade 3/4/5

	Placebo (N=77)	Zuranolone (N=74)
Number of subjects with >=1 TEAE, n (%)	1 (1.3)	3 (4.1)
RR - Relative Risk (Zuranolone vs. Placebo)		3.12
95% CI for the RR		(0.332, 29.339)
p-value for RR		0.3194
OR - Odds Ratio (Zuranolone vs. Placebo)		3.21
95% CI for the OR		(0.326, 31.590)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.03
95% CI for the ARR		(-0.024, 0.079)

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-301-by.sas:t-ae-gr-301-by-hama-safc.rtf **Run Date:** 21JUL2025

3.2.2 nach SOC

3.2.2.1 ITT-Population

Number of Subjects with Grade >=3 Treatment-Emergent Adverse Event by System Organ Class: 217-PPD-301 - Safety population

Page: 1 of 1

No data to report

	Placebo (N=98)	Zuranolone (N=98)
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-301-ovr.sas:t-ae-gr3-soc-301-ovr-safc.rtf **Run Date:** 18JUL2025

3.2.2.2 Subgruppen

3.2.2.2 .1 Interaktionstest

Number of Subjects with Grade >=3 Treatment-Emergent Adverse Event by System Organ Class: Treatment by Subgroup Interaction: 217-PPD-301 - 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.
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=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-301-int.sas:t-ae-gr3-soc-301-int-safc.rtf **Run Date:** 18JUL2025

3.2.2.2 .2 Subgruppenanalysen

Nicht zutreffend.

3.2.3 nach PT

3.2.3.1 ITT-Population

Number of Subjects with Grade >=3 Treatment-Emergent Adverse Event by Preferred Term: 217-PPD-301 - Safety population

Page: 1 of 1

No data to report

	Placebo (N=98)	Zuranolone (N=98)
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-301-ovr.sas:t-ae-gr3-pt-301-ovr-safc.rtf **Run Date:** 18JUL2025

3.2.3.2 Subgruppen

3.2.3.2 .1 Interaktionstest

Number of Subjects with Grade >=3 Treatment-Emergent Adverse Event by Preferred Term: Treatment by Subgroup Interaction: 217-PPD-301 - 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-301-int.sas:t-ae-gr3-pt-301-int-safc.rtf **Run Date:** 18JUL2025

3.2.3.2 .2 Subgruppenanalysen

Nicht zutreffend.

3.3 SUE

3.3.1 Gesamtraten

3.3.1.1 ITT-Population

Number of Subjects with at Least One Serious Treatment-Emergent Adverse Event: 217-PPD-301 - Safety population

Page: 1 of 1

	Placebo (N=98)	Zuranolone (N=98)
Number of subjects with >=1 TEAE, n (%)	0	2 (2.0)
RR - Relative Risk (Zuranolone vs. Placebo)		5.00
95% CI for the RR		(0.243, 102.822)
p-value for RR		0.2968
OR - Odds Ratio (Zuranolone vs. Placebo)		5.10
95% CI for the OR		(0.242, 107.691)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.02
95% CI for the ARR		(-0.014, 0.054)

NOTE 1: AEs were coded using MedDRA version 24.0.

Source: biib125/v_a/germany_amnog/t-sae-301-ovr.sas:t-sae-301-ovr-safc.rtf **Run Date:** 18JUL2025

3.3.1.2 Subgruppen

3.3.1.2 .1 Interaktionstest

Number of Subjects with at Least One Serious Treatment-Emergent Adverse Event: Treatment by Subgroup Interaction: 217-PPD-301 - Safety population

Page: 1 of 2

Subgroup Subgroup Category	Placebo (N=98)	Zuranolone (N=98)	p-value for Treatment by Subgroup Interaction Test
Number of subjects with >=1 TEAE, n(%)	0	2 (2.0)	
Age Group (years)			
18 - 24, n / N (%)	0/12	0/19	NA
25 - 45, n / N (%)	0/86	2/79 (2.5)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	0/32	0/33	NA
>=28, n / N (%)	0/66	2/65 (3.1)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	0/18	1/25 (4.0)	NA
White, n / N (%)	0/69	1/68 (1.5)	
Antidepressant Use at Baseline			
Yes, n / N (%)	0/15	1/15 (6.7)	NA
No, n / N (%)	0/83	1/83 (1.2)	

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-sae-301-int.sas:t-sae-301-int-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with at Least One Serious Treatment-Emergent Adverse Event: Treatment by Subgroup Interaction: 217-PPD-301 - Safety population

Page: 2 of 2

Subgroup Subgroup Category	Placebo (N=98)	Zuranolone (N=98)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2}) Group 2			
<=24.9, n / N (%)	0/22	0/20	NA(a)
25-29.9, n / N (%)	0/34	0/24	NA(b)
>=30, n / N (%)	0/42	2/53 (3.8)	NA(c)
Onset of PPD			
3rd Trimester, n / N (%)	0/31	0/34	NA
Postpartum, n / N (%)	0/67	2/64 (3.1)	
Family History of PPD			
Yes, n / N (%)	0/16	0/21	NA
No/Unknown, n / N (%)	0/82	2/77 (2.6)	
History of PPD			
1st Episode, n / N (%)	0/87	1/81 (1.2)	NA
Recurrent Episode, n / N (%)	0/11	1/17 (5.9)	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	0/21	0/24	NA
>=20, n / N (%)	0/77	2/74 (2.7)	

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%).
(a), (b), and (c) represent p-values from interaction tests comparing BMI groups: <=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-301-int.sas:t-sae-301-int-safc.rtf **Run Date:** 18JUL2025

3.3.1.2 .2 Subgruppenanalysen

Nicht zutreffend.

3.3.2 nach SOC

3.3.2.1 ITT-Population

Number of Subjects with Serious Treatment-Emergent Adverse Event by System Organ Class: 217-PPD-301 - Safety population

Page: 1 of 1

No data to report

	Placebo (N=98)	Zuranolone (N=98)
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-301-ovr.sas:t-sae-soc-301-ovr-safc.rtf **Run Date:** 18JUL2025

3.3.2.2 Subgruppen

3.3.2.2 .1 Interaktionstest

Number of Subjects with Serious Treatment-Emergent Adverse Event by System Organ Class: Treatment by Subgroup Interaction: 217-PPD-301 - 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-301-int.sas:t-sae-soc-301-int-safc.rtf **Run Date:** 18JUL2025

3.3.2.2 .2 Subgruppenanalysen

Nicht zutreffend.

3.3.3 nach PT

3.3.3.1 ITT-Population

Number of Subjects with Serious Treatment-Emergent Adverse Event by Preferred Term: 217-PPD-301 - Safety population

Page: 1 of 1

No data to report

	Placebo (N=98)	Zuranolone (N=98)
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-301-ovr.sas:t-sae-pt-301-ovr-safc.rtf **Run Date:** 18JUL2025

3.3.3.2 Subgruppen

3.3.3.2 .1 Interaktionstest

Number of Subjects with Serious Treatment-Emergent Adverse Event by Preferred Term: Treatment by Subgroup Interaction: 217-PPD-301 - 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-301-int.sas:t-sae-pt-301-int-safc.rtf **Run Date:** 18JUL2025

3.3.3.2 .2 Subgruppenanalysen

Nicht zutreffend.

3.4 Therapieabbruch aufgrund von UE

3.4.1 Gesamtraten

3.4.1.1 ITT-Population

Number of Subjects with Treatment Discontinuations Due to Treatment-Emergent Adverse Event: 217-PPD-301 - Safety population

Page: 1 of 1

	Placebo (N=98)	Zuranolone (N=98)
Number of subjects with >=1 TEAE, n (%)	2 (2.0)	4 (4.1)
RR - Relative Risk (Zuranolone vs. Placebo)		2.00
95% CI for the RR		(0.375, 10.668)
p-value for RR		0.4171
OR - Odds Ratio (Zuranolone vs. Placebo)		2.04
95% CI for the OR		(0.365, 11.419)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.02
95% CI for the ARR		(-0.028, 0.069)

NOTE 1: AEs were coded using MedDRA version 24.0.

Source: biib125/v_a/germany_amnog/t-ae-disc-301-ovr.sas:t-ae-disc-301-ovr-safc.rtf **Run Date:** 18JUL2025

3.4.1.2 Subgruppen

3.4.1.2 .1 Interaktionstest

Number of Subjects with Treatment Discontinuations Due to Treatment-Emergent Adverse Event: Treatment by Subgroup Interaction: 217-PPD-301 - Safety Population

Page: 1 of 2

Subgroup Subgroup Category	Placebo (N=98)	Zuranolone (N=98)	p-value for Treatment by Subgroup Interaction Test
Number of subjects with >=1 TEAE, n(%)	2 (2.0)	4 (4.1)	
Age Group (years)			
18 - 24, n / N (%)	0/12	0/19	NA
25 - 45, n / N (%)	2/86 (2.3)	4/79 (5.1)	
Baseline HAMD-17 Total Score Category, by median of baseline HAMD-17 total score			
<28, n / N (%)	1/32 (3.1)	1/33 (3.0)	NA
>=28, n / N (%)	1/66 (1.5)	3/65 (4.6)	
Race Group (Black or African American, White)			
Black or African American, n / N (%)	2/18 (11.1)	0/25	NA
White, n / N (%)	0/69	3/68 (4.4)	
Antidepressant Use at Baseline			
Yes, n / N (%)	0/15	1/15 (6.7)	NA
No, n / N (%)	2/83 (2.4)	3/83 (3.6)	

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-ae-disc-301-int.sas:t-ae-disc-301-int-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment Discontinuations Due to Treatment-Emergent Adverse Event: Treatment by Subgroup Interaction: 217-PPD-301 - Safety Population

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Subgroup Subgroup Category	Placebo (N=98)	Zuranolone (N=98)	p-value for Treatment by Subgroup Interaction Test
BMI (kg/m^2}) Group 2			
<=24.9, n / N (%)	0/22	2/20 (10.0)	NA(a)
25-29.9, n / N (%)	1/34 (2.9)	1/24 (4.2)	NA(b)
>=30, n / N (%)	1/42 (2.4)	1/53 (1.9)	NA(c)
Onset of PPD			
3rd Trimester, n / N (%)	1/31 (3.2)	1/34 (2.9)	NA
Postpartum, n / N (%)	1/67 (1.5)	3/64 (4.7)	
Family History of PPD			
Yes, n / N (%)	0/16	0/21	NA
No/Unknown, n / N (%)	2/82 (2.4)	4/77 (5.2)	
History of PPD			
1st Episode, n / N (%)	2/87 (2.3)	4/81 (4.9)	NA
Recurrent Episode, n / N (%)	0/11	0/17	
Depression with Elevated Anxiety , by Baseline HAMA Total Score			
<20, n / N (%)	0/21	1/24 (4.2)	NA
>=20, n / N (%)	2/77 (2.6)	3/74 (4.1)	

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-disc-301-int.sas:t-ae-disc-301-int-safc.rtf **Run Date:** 18JUL2025

3.4.1.2 .2 Subgruppenanalysen

Nicht zutreffend.

3.4.2 nach SOC

3.4.2.1 ITT-Population

Number of Subjects with Treatment Discontinuations Due to Treatment-Emergent Adverse Event by System Organ Class: 217-PPD-301 - Safety population

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Nervous system disorders

	Placebo (N=98)	Zuranolone (N=98)
Number of subjects with >=1 TEAE, n (%)	2 (2.0)	3 (3.1)
RR - Relative Risk (Zuranolone vs. Placebo)		1.50
95% CI for the RR		(0.256, 8.781)
p-value for RR		0.6529
OR - Odds Ratio (Zuranolone vs. Placebo)		1.52
95% CI for the OR		(0.248, 9.276)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.01
95% CI for the ARR		(-0.034, 0.054)

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-301-ovr.sas:t-ae-disc-soc-301-ovr-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment Discontinuations Due to Treatment-Emergent Adverse Event by System Organ Class: 217-PPD-301 - Safety population

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Gastrointestinal disorders

	Placebo (N=98)	Zuranolone (N=98)
Number of subjects with >=1 TEAE, n (%)	1 (1.0)	1 (1.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.00
95% CI for the RR		(0.063, 15.762)
p-value for RR		1.0000
OR - Odds Ratio (Zuranolone vs. Placebo)		1.00
95% CI for the OR		(0.062, 16.217)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.00
95% CI for the ARR		(-0.028, 0.028)

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-301-ovr.sas:t-ae-disc-soc-301-ovr-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment Discontinuations Due to Treatment-Emergent Adverse Event by System Organ Class: 217-PPD-301 - Safety population

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General disorders and administration site conditions

	Placebo (N=98)	Zuranolone (N=98)
Number of subjects with >=1 TEAE, n (%)	1 (1.0)	1 (1.0)
RR - Relative Risk (Zuranolone vs. Placebo)		1.00
95% CI for the RR		(0.063, 15.762)
p-value for RR		1.0000
OR - Odds Ratio (Zuranolone vs. Placebo)		1.00
95% CI for the OR		(0.062, 16.217)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.00
95% CI for the ARR		(-0.028, 0.028)

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-301-ovr.sas:t-ae-disc-soc-301-ovr-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment Discontinuations Due to Treatment-Emergent Adverse Event by System Organ Class: 217-PPD-301 - Safety population

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Musculoskeletal and connective tissue disorders

	Placebo (N=98)	Zuranolone (N=98)
Number of subjects with >=1 TEAE, n (%)	0	1 (1.0)
RR - Relative Risk (Zuranolone vs. Placebo)		3.00
95% CI for the RR		(0.124, 72.753)
p-value for RR		0.4995
OR - Odds Ratio (Zuranolone vs. Placebo)		3.03
95% CI for the OR		(0.122, 75.313)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.01
95% CI for the ARR		(-0.018, 0.038)

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-301-ovr.sas:t-ae-disc-soc-301-ovr-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment Discontinuations Due to Treatment-Emergent Adverse Event by System Organ Class: 217-PPD-301 - Safety population

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Reproductive system and breast disorders

	Placebo (N=98)	Zuranolone (N=98)
Number of subjects with >=1 TEAE, n (%)	0	1 (1.0)
RR - Relative Risk (Zuranolone vs. Placebo)		3.00
95% CI for the RR		(0.124, 72.753)
p-value for RR		0.4995
OR - Odds Ratio (Zuranolone vs. Placebo)		3.03
95% CI for the OR		(0.122, 75.313)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.01
95% CI for the ARR		(-0.018, 0.038)

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-301-ovr.sas:t-ae-disc-soc-301-ovr-safc.rtf **Run Date:** 18JUL2025

3.4.2.2 Subgruppen

3.4.2.2 .1 Interaktionstest

Nicht zutreffend.

3.4.2.2 .2 Subgruppenanalysen

Nicht zutreffend.

3.4.3 nach PT

3.4.3.1 ITT-Population

Number of Subjects with Treatment Discontinuations Due to Treatment-Emergent Adverse Event by Preferred Term: 217-PPD-301 - Safety population

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Nervous system disorders/Somnolence

	Placebo (N=98)	Zuranolone (N=98)
Number of subjects with >=1 TEAE, n (%)	0	2 (2.0)
RR - Relative Risk (Zuranolone vs. Placebo)		5.00
95% CI for the RR		(0.243, 102.822)
p-value for RR		0.2968
OR - Odds Ratio (Zuranolone vs. Placebo)		5.10
95% CI for the OR		(0.242, 107.691)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.02
95% CI for the ARR		(-0.014, 0.054)

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-301-ovr.sas:t-ae-disc-pt-301-ovr-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment Discontinuations Due to Treatment-Emergent Adverse Event by Preferred Term: 217-PPD-301 - Safety population

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Gastrointestinal disorders/Abdominal pain upper

	Placebo (N=98)	Zuranolone (N=98)
Number of subjects with >=1 TEAE, n (%)	0	1 (1.0)
RR - Relative Risk (Zuranolone vs. Placebo)		3.00
95% CI for the RR		(0.124, 72.753)
p-value for RR		0.4995
OR - Odds Ratio (Zuranolone vs. Placebo)		3.03
95% CI for the OR		(0.122, 75.313)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.01
95% CI for the ARR		(-0.018, 0.038)

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-301-ovr.sas:t-ae-disc-pt-301-ovr-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment Discontinuations Due to Treatment-Emergent Adverse Event by Preferred Term: 217-PPD-301 - Safety population

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Gastrointestinal disorders/Nausea

	Placebo (N=98)	Zuranolone (N=98)
Number of subjects with >=1 TEAE, n (%)	0	1 (1.0)
RR - Relative Risk (Zuranolone vs. Placebo)		3.00
95% CI for the RR		(0.124, 72.753)
p-value for RR		0.4995
OR - Odds Ratio (Zuranolone vs. Placebo)		3.03
95% CI for the OR		(0.122, 75.313)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.01
95% CI for the ARR		(-0.018, 0.038)

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-301-ovr.sas:t-ae-disc-pt-301-ovr-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment Discontinuations Due to Treatment-Emergent Adverse Event by Preferred Term: 217-PPD-301 - Safety population

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General disorders and administration site conditions/Feeling abnormal

	Placebo (N=98)	Zuranolone (N=98)
Number of subjects with >=1 TEAE, n (%)	0	1 (1.0)
RR - Relative Risk (Zuranolone vs. Placebo)		3.00
95% CI for the RR		(0.124, 72.753)
p-value for RR		0.4995
OR - Odds Ratio (Zuranolone vs. Placebo)		3.03
95% CI for the OR		(0.122, 75.313)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.01
95% CI for the ARR		(-0.018, 0.038)

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-301-ovr.sas:t-ae-disc-pt-301-ovr-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment Discontinuations Due to Treatment-Emergent Adverse Event by Preferred Term: 217-PPD-301 - Safety population

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Musculoskeletal and connective tissue disorders/Muscular weakness

	Placebo (N=98)	Zuranolone (N=98)
Number of subjects with >=1 TEAE, n (%)	0	1 (1.0)
RR - Relative Risk (Zuranolone vs. Placebo)		3.00
95% CI for the RR		(0.124, 72.753)
p-value for RR		0.4995
OR - Odds Ratio (Zuranolone vs. Placebo)		3.03
95% CI for the OR		(0.122, 75.313)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.01
95% CI for the ARR		(-0.018, 0.038)

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-301-ovr.sas:t-ae-disc-pt-301-ovr-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment Discontinuations Due to Treatment-Emergent Adverse Event by Preferred Term: 217-PPD-301 - Safety population

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Nervous system disorders/Dyskinesia

	Placebo (N=98)	Zuranolone (N=98)
Number of subjects with >=1 TEAE, n (%)	0	1 (1.0)
RR - Relative Risk (Zuranolone vs. Placebo)		3.00
95% CI for the RR		(0.124, 72.753)
p-value for RR		0.4995
OR - Odds Ratio (Zuranolone vs. Placebo)		3.03
95% CI for the OR		(0.122, 75.313)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.01
95% CI for the ARR		(-0.018, 0.038)

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-301-ovr.sas:t-ae-disc-pt-301-ovr-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment Discontinuations Due to Treatment-Emergent Adverse Event by Preferred Term: 217-PPD-301 - Safety population

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Nervous system disorders/Sedation

	Placebo (N=98)	Zuranolone (N=98)
Number of subjects with >=1 TEAE, n (%)	0	1 (1.0)
RR - Relative Risk (Zuranolone vs. Placebo)		3.00
95% CI for the RR		(0.124, 72.753)
p-value for RR		0.4995
OR - Odds Ratio (Zuranolone vs. Placebo)		3.03
95% CI for the OR		(0.122, 75.313)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.01
95% CI for the ARR		(-0.018, 0.038)

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-301-ovr.sas:t-ae-disc-pt-301-ovr-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment Discontinuations Due to Treatment-Emergent Adverse Event by Preferred Term: 217-PPD-301 - Safety population

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Reproductive system and breast disorders/Vaginal haemorrhage

	Placebo (N=98)	Zuranolone (N=98)
Number of subjects with >=1 TEAE, n (%)	0	1 (1.0)
RR - Relative Risk (Zuranolone vs. Placebo)		3.00
95% CI for the RR		(0.124, 72.753)
p-value for RR		0.4995
OR - Odds Ratio (Zuranolone vs. Placebo)		3.03
95% CI for the OR		(0.122, 75.313)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		0.01
95% CI for the ARR		(-0.018, 0.038)

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-301-ovr.sas:t-ae-disc-pt-301-ovr-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment Discontinuations Due to Treatment-Emergent Adverse Event by Preferred Term: 217-PPD-301 - Safety population

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Gastrointestinal disorders/Eructation

	Placebo (N=98)	Zuranolone (N=98)
Number of subjects with >=1 TEAE, n (%)	1 (1.0)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.33
95% CI for the RR		(0.014, 8.084)
p-value for RR		0.4995
OR - Odds Ratio (Zuranolone vs. Placebo)		0.33
95% CI for the OR		(0.013, 8.199)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.01
95% CI for the ARR		(-0.038, 0.018)

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-301-ovr.sas:t-ae-disc-pt-301-ovr-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment Discontinuations Due to Treatment-Emergent Adverse Event by Preferred Term: 217-PPD-301 - Safety population

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General disorders and administration site conditions/Asthenia

	Placebo (N=98)	Zuranolone (N=98)
Number of subjects with >=1 TEAE, n (%)	1 (1.0)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.33
95% CI for the RR		(0.014, 8.084)
p-value for RR		0.4995
OR - Odds Ratio (Zuranolone vs. Placebo)		0.33
95% CI for the OR		(0.013, 8.199)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.01
95% CI for the ARR		(-0.038, 0.018)

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-301-ovr.sas:t-ae-disc-pt-301-ovr-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment Discontinuations Due to Treatment-Emergent Adverse Event by Preferred Term: 217-PPD-301 - Safety population

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Nervous system disorders/Dizziness

	Placebo (N=98)	Zuranolone (N=98)
Number of subjects with >=1 TEAE, n (%)	1 (1.0)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.33
95% CI for the RR		(0.014, 8.084)
p-value for RR		0.4995
OR - Odds Ratio (Zuranolone vs. Placebo)		0.33
95% CI for the OR		(0.013, 8.199)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.01
95% CI for the ARR		(-0.038, 0.018)

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-301-ovr.sas:t-ae-disc-pt-301-ovr-safc.rtf **Run Date:** 18JUL2025

Number of Subjects with Treatment Discontinuations Due to Treatment-Emergent Adverse Event by Preferred Term: 217-PPD-301 - Safety population

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Nervous system disorders/Headache

	Placebo (N=98)	Zuranolone (N=98)
Number of subjects with >=1 TEAE, n (%)	1 (1.0)	0
RR - Relative Risk (Zuranolone vs. Placebo)		0.33
95% CI for the RR		(0.014, 8.084)
p-value for RR		0.4995
OR - Odds Ratio (Zuranolone vs. Placebo)		0.33
95% CI for the OR		(0.013, 8.199)
ARR - Absolute Risk Reduction (Zuranolone vs. Placebo)		-0.01
95% CI for the ARR		(-0.038, 0.018)

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-301-ovr.sas:t-ae-disc-pt-301-ovr-safc.rtf **Run Date:** 18JUL2025

3.4.3.2 Subgruppen

3.4.3.2 .1 Interaktionstest

Nicht zutreffend.

3.4.3.2 .2 Subgruppenanalysen

Nicht zutreffend.