ID: LuAA21004_311 Efficacy and Safety of Vortioxetine (Lu AA21004) for Treatment of Generalized Anxiety Disorder in Adults. NCT00744627

Uploaded Record
Results Preview

Close

Hide All

Participant Flow

Recruitment Details	Participants took part in the study at 47 investigative sites in Europe from 23 September 2008 to 07 July 2009.
Pre-Assignment Details	Participants with a diagnosis of generalized anxiety disorder were enrolled equally in one of two treatment groups, once a day placebo or 5 mg vortioxetine.

Arm/Group Title	**Placebo**	**Vortioxetine 5 mg**	Total (Not public)
Arm/Group Description	Vortioxetine placebo-matching capsules, orally, once daily for up to 8 weeks.	Vortioxetine 5 mg, encapsulated tablets, orally, once daily for up to 8 weeks.	
Period Title: Overall Study			
Started	151	150	301
Treated	150	150	300
Completed	126	128	254
Not Completed	25	22	47
Reason Not Completed			
Adverse Event	6	9	15
Lack of Efficacy	7	3	10
Noncompliance	0	1	1
Protocol Deviations	0	2	2
Voluntary Withdrawal	9	6	15
Lost to Follow-up	2	1	3
Other	1	0	1
NOTE : "Other" is not sufficiently descriptive for "Other" Reason Not Completed. Please provide a more descriptive label.			
(Not Public)	Not Completed = 25 Total from all reasons = 25	Not Completed = 22 Total from all reasons = 22	

Baseline Characteristics

Arm/Group Title	Placebo	Vortioxetine 5 mg	Total
Arm/Group Description	Vortioxetine placebo-matching capsules, orally, once daily for up to 8 weeks.	Vortioxetine 5 mg, encapsulated tablets, orally, once daily for up to 8 weeks.	
Overall Number of Baseline Participants	151	150	**301**
Baseline Analysis Population Description			
[Not specified]			
Age, Continuous			
Mean (Standard Deviation)			
Units: years	45.3 (13.49)	45.0 (14.07)	45.1 (13.76)
Age, Customized			
Measure Type: Number			
Units: participants			
≤55 years	112	111	223
>55 years	39	39	78
Gender, Male/Female			
Measure Type: Number			
Units: participants			
Female	93	103	196
Male	58	47	105
Race/Ethnicity, Customized			
Measure Type: Number			
Units: participants			
Caucasian (White, including Hispanic)	151	150	301
Black	0	0	0
Asian	0	0	0
American Indian or Alaska Native	0	0	0
Native Hawaiian/ Other Pacific Islander	0	0	0
Race/Ethnicity, Customized			
Measure Type: Number			
Units: participants			
Hispanic/Latino	8	5	13
Non-Hispanic/Non-Latino	143	145	288
Region of Enrollment			
Measure Type: Number			
Units: participants			
Estonia	7	3	10
Germany	34	37	71
Latvia	7	5	12
Lithuania	8	11	19
Poland	28	31	59
Romania	5	3	8
Russia	48	49	97
Ukraine	14	11	25
Weight			
Mean (Standard Deviation)			
Units: kg	75.76 (16.370)	72.97 (14.981)	74.37 (15.729)
Height			

Mean (Standard Deviation)			
Units: cm	169.56 (9.457)	168.21 (8.653)	168.89 (9.075)
Body Mass Index			
Mean (Standard Deviation)			
Units: kg/m^2	26.29 (4.980)	25.69 (4.419)	25.99 (4.710)
Smoking Classification			
Measure Type: Number			
Units: participants			
Never Smoked	99	90	189
Current Smoker	29	38	67
Ex-smoker	23	22	45
Alcohol Consumption			
Measure Type: Number			
Units: participants			
Never	49	47	96
Once monthly or less often	77	72	149
Once a week	15	18	33
2 to 6 times per week	6	10	16
Daily	4	3	7
Hamilton Anxiety Scale Total Score [1]			
Mean (Standard Deviation)			
Units: scores on a a scale	26.8 (3.95)	26.3 (3.92)	26.6 (3.94)

[1] Hamilton Anxiety Scale (HAM-A) is an anxiety rating scale consisting of 14 items that assess anxious mood, tension, fear, insomnia, intellectual (cognitive) symptoms, depressed mood, behavior at interview, somatic (sensory), cardiovascular, respiratory, gastrointestinal, genitourinary, autonomic and somatic (muscular) symptoms. Each symptom is rated from 0 (absent) to 4 (maximum severity). Total scores range from 0 (absent) to 56 (maximum severity).

Clinical Global Impression - Severity scale score [1]			
Mean (Standard Deviation)			
Units: scores on a scale	4.5 (0.67)	4.5 (0.70)	4.5 (0.69)

[1] The Clinical Global Impression - Severity scale (CGI-S) is a 7-point scale where the clinician rates the severity of the patient's illness at the time of assessment, relative to the clinician's past experience with patients who have the same diagnosis on the following scale: 1, normal, not at all ill; 2, borderline mentally ill; 3, mildly ill; 4, moderately ill; 5, markedly ill; 6, severely ill; or 7, extremely ill.

Hospital Anxiety and Depression – Anxiety subscale [1]			
Mean (Standard Deviation)			
Units: scores on a scale	14.4 (3.08)	13.8 (2.99)	14.1 (3.04)

[1] Hospital Anxiety and Depression (HAD) Anxiety sub-scale consists of 7 items that are assessed on a scale from 0 (no anxiety) to 3 (severe feeling of anxiety). The anxiety subscale determines a state of generalized anxiety including anxious mood, restlessness, anxious thoughts and panic attacks. Scores are summed and range from 0 to 21 (maximal severity).

Hospital Anxiety and Depression – Depression			

subscale [1]			
Mean (Standard Deviation) Units: scores on a scale	7.5 (4.03)	7.6 (3.89)	7.5 (3.96)

[1] Hospital Anxiety and Depression (HAD) Depression sub-scale consists of 7 items that are assessed on a scale from 0 (no depression) to 3 (severe feeling of depression). The depression subscale focuses on the state of lost interest and diminished pleasure response. Scores are summed and range from 0 to 21 (maximal severity).

Montgomery Åsberg Depression Rating Scale (MADRS) total score [1]			
Mean (Standard Deviation) Units: scores on a scale	12.12 (2.375)	12.25 (2.219)	12.18 (2.296)

[1] The Montgomery Åsberg Depression Rating Scale (MADRS) is a depression rating scale consisting of 10 items, each rated 0 to 6. The 10 items represent the core symptoms of depressive illness. The overall score ranges from 0 (symptoms absent) to 60 (severe depression).

Outcome Measures

1. Primary Outcome

Title: Change From Baseline in the Hamilton Anxiety Scale (HAM-A) Total Score at Week 8

Description: The HAM-A is an anxiety rating scale consisting of 14 items that assess anxious mood, tension, fear, insomnia, intellectual (cognitive) symptoms, depressed mood, behavior at interview, somatic (sensory), cardiovascular, respiratory, gastrointestinal, genitourinary, autonomic and somatic (muscular) symptoms. Each symptom is rated from 0 (absent) to 4 (maximum severity). Total scores range from 0 to 56 where <17 indicates mild severity, 18-24 mild to moderate severity and 25-30 moderate to severe. Total scores above 30 are rare, but indicate very severe anxiety. Least Squares (LS) means were from a mixed model for repeated measurements (MMRM) with Baseline-by-week, center, week and week-by-treatment as factors in the analysis.

Time Frame: Baseline to Week 8

Safety Issue? No

Outcome Measure Data

Analysis Population Description

The Full Analysis Set included all patients who were randomized, received at least 1 dose of study drug, and had at least 1 post-baseline value for assessment of primary efficacy. A mixed model for repeated measurements (MMRM) based on observed cases was used.

Arm/Group Title	**Placebo**	**Vortioxetine 5 mg**
Arm/Group Description:	Vortioxetine placebo-matching capsules, orally, once daily for up to 8 weeks.	Vortioxetine 5 mg, encapsulated tablets, orally, once daily for up to 8 weeks.
Number of Participants Analyzed	126	128

Least Squares Mean (Standard Error) Units: scores on a scale	-10.49 (0.697)	-14.30 (0.695)

Statistical Analysis 1

Statistical Analysis Overview	**Comparison Groups**	Placebo, Vortioxetine 5 mg
	Comments	P-values were tested at the 5% level of significance (ie, statistical significance if P<0.05). To control for multiplicity, a pre-specified sequential testing procedure was applied to compare 5 mg vortioxetine to placebo; as soon as an endpoint was non-significant at 0.05, the testing procedure stopped for all subsequent endpoints.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	**P-Value**	<0.001
	Comments	Pre-specified sequential statistical testing procedure indicates that when p-value <0.05, hierarchical testing continues.
	Method	Other [Mixed model for repeated measurements]
	Comments	P-values were from a MMRM with Baseline-by-week, center, week and week-by-treatment as factors in the analysis.
Method of Estimation	**Estimation Parameter**	Other[LS Mean Difference]
	Estimated Value	-3.81
	Confidence Interval	(2-Sided) 95% -5.74 to -1.88
	Parameter Dispersion	Type: Standard Error of the mean Value: 0.981
	Estimation Comments	[Not specified]

2. Secondary Outcome

Title:	Change From Baseline in the Hospital Anxiety and Depression (HAD) Anxiety Subscale at Week 8
Description:	The Hospital Anxiety and Depression (HAD) Anxiety sub-scale consists of 7 items that are assessed on a scale from 0 (no anxiety) to 3 (severe feeling of anxiety). The anxiety subscale determines a state of generalized anxiety including anxious mood, restlessness, anxious thoughts and panic attacks. Scores are summed and range from 0 to 21 (maximal severity). LS means were from a MMRM with Baseline-by-week, center, week and week-by-treatment as factors in the analysis.
Time Frame:	Baseline to Week 8
Safety Issue?	No

Outcome Measure Data

Analysis Population Description

Full analysis set. A mixed model for repeated measurements (MMRM) based on observed cases was used.

Arm/Group Title	**Placebo**	**Vortioxetine 5 mg**
Arm/Group Description:	Vortioxetine placebo-matching capsules, orally, once daily for up to 8 weeks.	Vortioxetine 5 mg, encapsulated tablets, orally, once daily for up to 8 weeks.
Number of Participants Analyzed	128	129
Least Squares Mean (Standard Error)	-4.20 (0.396)	-6.49 (0.393)

Units: scores on a scale

Statistical Analysis 1

Statistical Analysis Overview	**Comparison Groups**	Placebo, Vortioxetine 5 mg
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	<0.001
	Comments	Pre-specified sequential statistical testing procedure indicates that when p-value <0.05, hierarchical testing continues.
	Method	Other [Mixed model for repeated measurements]
	Comments	P-values were from a MMRM with Baseline-by-week, center, week and

		week-by-treatment as factors in the analysis
Method of Estimation	**Estimation Parameter**	Other[LS Mean Difference]
	Estimated Value	-2.30
	Confidence Interval	(2-Sided) 95% -3.39 to -1.20
	Parameter Dispersion	Type: Standard Error of the mean Value: 0.555
	Estimation Comments	[Not specified]

3. Secondary Outcome

Title: Clinical Global Impression Scale-Global Improvement at Week 8

Description: The Clinical Global Impression-Global Improvement scale assesses the participant's improvement (or worsening) as assessed by the clinician relative to Baseline on a 7-point scale: 1, very much improved; 2, much improved; 3, minimally improved; 4, no change; 5, minimally worse; 6, much worse; or 7, very much worse. LS means were from a MMRM with baseline-by-week, center, week and week-by-treatment as factors in the analysis.

Time Frame: Baseline to Week 8

Safety Issue? No

Outcome Measure Data

Analysis Population Description

Full analysis set. A mixed model for repeated measurements (MMRM) based on observed cases was used.

Arm/Group Title	**Placebo**	**Vortioxetine 5 mg**
Arm/Group Description:	Vortioxetine placebo-matching capsules, orally, once daily for up to 8 weeks.	Vortioxetine 5 mg, encapsulated tablets, orally, once daily for up to 8 weeks.
Number of Participants Analyzed	126	128
Least Squares Mean (Standard Error) Units: scores on a scale	2.66 (0.098)	2.19 (0.098)

Statistical Analysis 1

Statistical Analysis Overview	**Comparison Groups**	Placebo, Vortioxetine 5 mg
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	**P-Value**	<0.001
	Comments	Pre-specified sequential statistical testing procedure indicates that when p-value <0.05, hierarchical testing continues.
	Method	Other [Mixed model for repeated measurements]
	Comments	P-values were from a MMRM with Baseline-by-week, center, week and week-by-treatment as factors in the analysis.
Method of Estimation	**Estimation Parameter**	Other[LS Mean Difference]
	Estimated Value	-0.46
	Confidence Interval	(2-Sided) 95% -0.73 to -0.19
	Parameter Dispersion	Type: Standard Error of the mean Value: 0.138
	Estimation Comments	[Not specified]

4. Secondary Outcome

Title: Change From Baseline in Sheehan Disability Scale (SDS) Total Score at Week 8

Description: The Sheehan Disability Scale assesses functional impairment in 3 domains: work/school, social life or leisure activities, and home life or family responsibilities. The participant rates the extent to which each aspect is impaired on a 10-point visual analog scale, from 0 (not at all) to 10 (extremely). The 3 scores are added together to calculate the total score, which ranges from 0 to 30, with higher scores indicating more impairment. LS means were from a MMRM with Baseline-by-week, center, week and week-by-treatment as factors in the analysis.

Time Frame: Baseline to Week 8

Safety Issue? No

Outcome Measure Data

Analysis Population Description

Full analysis set. A mixed model for repeated measurements (MMRM) based on observed cases was used.

Arm/Group Title	**Placebo**	**Vortioxetine 5 mg**
Arm/Group Description:	Vortioxetine placebo-matching capsules, orally, once daily for up to 8 weeks.	Vortioxetine 5 mg, encapsulated tablets, orally, once daily for up to 8 weeks.
Number of Participants Analyzed	109	102

Least Squares Mean (Standard Error) Units: scores on a scale	-6.14 (0.631)	-8.10 (0.656)

Statistical Analysis 1

Statistical Analysis Overview	**Comparison Groups**	Placebo, Vortioxetine 5 mg
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	0.031
	Comments	Pre-specified sequential statistical testing procedure indicates that when p-value <0.05, hierarchical testing continues.
	Method	Other [Mixed model for repeated measurements]
	Comments	P-values were from a MMRM with Baseline-by-week, center, week and

week-by-treatment as factors in the analysis.

Method of Estimation	**Estimation Parameter**	Other[LS Mean Difference]
	Estimated Value	-1.96
	Confidence Interval	(2-Sided) 95% -3.74 to -0.18
	Parameter Dispersion	Type: Standard Error of the mean Value: 0.901
	Estimation Comments	[Not specified]

5. Secondary Outcome

Title:	Percentage of Responders in HAM-A Total Score at Week 8
Description:	Response was defined as participants with a ≥ 50% decrease from Baseline in the Hamilton Anxiety Scale (HAM-A) total score. The HAM-A is an anxiety rating scale consisting of 14 items that assess anxious mood, tension, fear, insomnia, intellectual (cognitive) symptoms, depressed mood, behavior at interview, somatic (sensory), cardiovascular, respiratory, gastrointestinal, genitourinary, autonomic and somatic (muscular) symptoms. Each symptom is rated from 0 (absent) to 4 (maximum severity). Total scores range from 0 (symptoms absent) to 56 (maximum severity).
Time Frame:	Baseline and Week 8
Safety Issue?	No

Outcome Measure Data

Analysis Population Description

Full analysis set; Last observation carried forward was used.

Arm/Group Title	**Placebo**	**Vortioxetine 5 mg**
Arm/Group Description:	Vortioxetine placebo-matching capsules, orally, once daily for up to 8 weeks.	Vortioxetine 5 mg, encapsulated tablets, orally, once daily for up to 8 weeks.
Number of Participants Analyzed	148	149
Measure Type: Number Units: percentage of participants	39.9	61.7

Statistical Analysis 1

Statistical Analysis Overview	**Comparison Groups**	Placebo, Vortioxetine 5 mg
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No

	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	<0.001
	Comments	Pre-specified sequential statistical testing procedure indicates that when p-value <0.05, hierarchical testing continues.
	Method	Regression, Logistic
	Comments	Logistic regression with explanatory variables for treatment and Baseline HAM-A score.
Method of Estimation	**Estimation Parameter**	Odds Ratio (OR)
	Estimated Value	2.393
	Confidence Interval	(2-Sided) 95% 1.496 to 3.830
	Estimation Comments	[Not specified]

6. Secondary Outcome

Title: Change From Baseline in the Hamilton Anxiety Scale (HAM-A) Total Score at Week 8 in Participants With Baseline HAM-A ≥25

Description: The HAM-A is an anxiety rating scale consisting of 14 items that assess anxious mood, tension, fear, insomnia, intellectual (cognitive) symptoms, depressed mood, behavior at interview, somatic (sensory), cardiovascular, respiratory, gastrointestinal, genitourinary, autonomic and somatic (muscular) symptoms. Each symptom is rated from 0 (absent) to 4 (maximum severity). Total scores range from 0 to 56 where <17 indicates mild severity, 18-24 mild to moderate severity and 25-30 moderate to severe. Total scores above 30 are rare, but indicate very severe anxiety. LS means were from a MMRM with Baseline-by-week, center, week and week-by-treatment as factors in the analysis.

Time Frame: Baseline to Week 8

Safety Issue? No

Outcome Measure Data

Analysis Population Description

Full analysis set patients with a HAM-A Baseline score ≥25. A mixed model for repeated measurements (MMRM) based on observed cases was used.

Arm/Group Title	**Placebo**	**Vortioxetine 5 mg**
Arm/Group Description:	Vortioxetine placebo-matching capsules, orally, once daily for up to 8 weeks.	Vortioxetine 5 mg, encapsulated tablets, orally, once daily for up to 8 weeks.
Number of Participants Analyzed	82	82
Least Squares Mean (Standard Error)	-10.44 (0.895)	-15.55 (0.904)

Units: scores on a scale

Statistical Analysis 1

Statistical Analysis Overview	**Comparison Groups**	Placebo, Vortioxetine 5 mg
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	<0.001
	Comments	Pre-specified sequential statistical testing procedure indicates that when p-value <0.05, hierarchical testing continues.
	Method	Other [Mixed model for repeated measurements]

	Comments	P-values were from a MMRM with Baseline-by-week, center, week and week-by-treatment as factors in the analysis.
Method of Estimation	**Estimation Parameter**	Other[LS Mean Difference]
	Estimated Value	-5.10
	Confidence Interval	(2-Sided) 95% -7.61 to -2.60
	Parameter Dispersion	Type: Standard Error of the mean Value: 1.267
	Estimation Comments	[Not specified]

7. Secondary Outcome

Title:	Change From Baseline in 36-Item Short-Form Health Survey (SF-36) Social Functioning Subscore at Week 8
Description:	The Medical Outcomes Study SF-36 is a participant self-rated questionnaire that is a general measure of perceived health status comprising 36 questions, which yields an 8-scale health profile. The social functioning subscale assesses limitations in social activities because of physical or emotional problems. The sub-score scale ranges from 0 (best) - 100 (worst). LS means were from a MMRM with Baseline-by-week, center, week and week-by-treatment as factors in the analysis.
Time Frame:	Baseline to Week 8
Safety Issue?	No

Outcome Measure Data

Analysis Population Description

The Full Analysis Set. A mixed model for repeated measurements (MMRM) based on observed cases was used.

Arm/Group Title	**Placebo**	**Vortioxetine 5 mg**
Arm/Group Description:	Vortioxetine placebo-matching capsules, orally, once daily for up to 8 weeks.	Vortioxetine 5 mg, encapsulated tablets, orally, once daily for up to 8 weeks.
Number of Participants Analyzed	128	129
Least Squares Mean (Standard Error) Units: scores on a scale	18.02 (1.991)	26.80 (1.974)

Statistical Analysis 1

Statistical Analysis Overview	**Comparison Groups**	Placebo, Vortioxetine 5 mg
	Comments	Results presented are for the number of participants at week 8 only.

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	0.002
	Comments	SF-36 social functioning subscore was the last endpoint to be tested in the hierarchical testing sequence.
	Method	Other [Mixed model for repeated measurements]
	Comments	P-values were from a MMRM with Baseline-by-week, center, week and week-by-treatment as factors in the analysis.
Method of Estimation	**Estimation Parameter**	Other[LS Mean Difference]
	Estimated Value	8.78
	Confidence Interval	(2-Sided) 95% 3.32 to 14.25
	Parameter Dispersion	Type: Standard Error of the mean Value: 2.774
	Estimation Comments	[Not specified]

8. Secondary Outcome

Title:	Change From Baseline in Hamilton Anxiety Scale (HAM-A) Total Score at Other Weeks Assessed
Description:	The HAM-A is an anxiety rating scale consisting of 14 items that assess anxious mood, tension, fear, insomnia, intellectual (cognitive) symptoms, depressed mood, behavior at interview, somatic (sensory), cardiovascular, respiratory, gastrointestinal, genitourinary, autonomic and somatic (muscular) symptoms. Each symptom is rated from 0 (absent) to 4 (maximum severity). Total scores range from 0 to 56 where <17 indicates mild severity, 18-24 mild to moderate severity and 25-30 moderate to severe. Total scores above 30 are rare, but indicate very severe anxiety. LS means were from a MMRM with Baseline-by-week, center, week and week-by-treatment as factors in the analysis.
Time Frame:	Baseline to Weeks 1, 2, 4 and 6.
Safety Issue?	No

Outcome Measure Data

Analysis Population Description

The Full Analysis Set. A mixed model for repeated measurements (MMRM) based on observed cases was used; "n" indicates the number of patients included in the analysis at each time point.

Arm/Group Title	**Placebo**	**Vortioxetine 5 mg**

Arm/Group Description:	Vortioxetine placebo-matching capsules, orally, once daily for up to 8 weeks.	Vortioxetine 5 mg, encapsulated tablets, orally, once daily for up to 8 weeks.
Number of Participants Analyzed	148	149
Least Squares Mean (Standard Error) Units: scores on a scale		
Week 1 (n=146, 148)	-2.46 (0.272)	-2.50 (0.270)
Week 2 (n=147, 144)	-5.05 (0.407)	-6.21 (0.408)
Week 4 (n=136, 137)	-7.43 (0.539)	-9.62 (0.538)
Week 6 (n=128, 129)	-9.17 (0.609)	-11.93 (0.608)

9. Secondary Outcome

Title:	Change From Baseline in the Hospital Anxiety and Depression (HAD) Anxiety Subscale at Other Weeks Assessed
Description:	The Hospital Anxiety and Depression (HAD) Anxiety sub-scale consists of 7 items that are assessed on a scale from 0 (no anxiety) to 3 (severe feeling of anxiety). The anxiety subscale determines a state of generalized anxiety including anxious mood, restlessness, anxious thoughts and panic attacks. Scores are summed and range from 0 to 21 (maximal severity). LS means were from a MMRM with Baseline-by-week, center, week and week-by-treatment as factors in the analysis.
Time Frame:	Baseline to Weeks 1 and 4
Safety Issue?	No

Outcome Measure Data

Analysis Population Description

The Full Analysis Set. A mixed model for repeated measurements (MMRM) based on observed cases was used; "n" indicates the number of patients included in the analysis at each time point.

Arm/Group Title	**Placebo**	**Vortioxetine 5 mg**
Arm/Group Description:	Vortioxetine placebo-matching capsules, orally, once daily for up to 8 weeks.	Vortioxetine 5 mg, encapsulated tablets, orally, once daily for up to 8 weeks.
Number of Participants Analyzed	148	149
Least Squares Mean (Standard Error) Units: scores on a scale		
Week 1 (n=146, 148)	-1.42 (0.226)	-1.14 (0.223)
Week 4 (n=140, 140)	-3.13 (0.298)	-4.07 (0.296)

10. Secondary Outcome

Title: Clinical Global Impression Scale-Global Improvement at Other Weeks Assessed

Description: The Clinical Global Impression-Global Improvement scale assesses the participant's improvement (or worsening) as assessed by the clinician relative to Baseline on a 7-point scale: 1, very much improved; 2, much improved; 3, minimally improved; 4, no change; 5, minimally worse; 6, much worse; or 7, very much worse. LS means were from a MMRM with Baseline-by-week, center, week and week-by-treatment as factors in the analysis.

Time Frame: Baseline to Weeks 1, 2, 4 and 6

Safety Issue? No

Outcome Measure Data

Analysis Population Description

Full analysis set. A mixed model for repeated measurements (MMRM) based on observed cases was used; "n" indicates the number of patients included in the analysis at each time point.

Arm/Group Title	**Placebo**	**Vortioxetine 5 mg**
Arm/Group Description:	Vortioxetine placebo-matching capsules, orally, once daily for up to 8 weeks.	Vortioxetine 5 mg, encapsulated tablets, orally, once daily for up to 8 weeks.
Number of Participants Analyzed	148	149
Least Squares Mean (Standard Error) Units: scores on a scale		
Week 1 (n=146, 148)	3.58 (0.053)	3.67 (0.053)
Week 2 (n=147, 144)	3.31 (0.070)	3.10 (0.070)
Week 4 (n=136, 137)	2.99 (0.080)	2.66 (0.080)
Week 6 (n=128, 129)	2.74 (0.086)	2.43 (0.086)

11. Secondary Outcome

Title: Change From Baseline in Sheehan Disability Scale (SDS) Total Score at Other Weeks Assessed

Description: The Sheehan Disability Scale assesses functional impairment in 3 domains: work/school, social life or leisure activities, and home life or family responsibilities. The participant rates the extent to which each aspect is impaired on a 10-point visual analog scale, from 0 (not at all) to 10 (extremely). The 3 scores are added together to calculate the total score, which ranges from 0 to 30, with higher scores indicating more impairment. LS means were from a MMRM with Baseline-by-week, center, week and week-by-treatment as factors in the analysis.

Time Frame: Baseline to Weeks 1, 2 and 4

Safety Issue? No

Outcome Measure Data

Analysis Population Description

Full analysis set where Baseline data were available. A mixed model for repeated measurements

(MMRM) based on observed cases was used. "n" indicates the number of patients included in the analysis at each time point.

Arm/Group Title	**Placebo**	**Vortioxetine 5 mg**
Arm/Group Description:	Vortioxetine placebo-matching capsules, orally, once daily for up to 8 weeks.	Vortioxetine 5 mg, encapsulated tablets, orally, once daily for up to 8 weeks.
Number of Participants Analyzed	124	120
Least Squares Mean (Standard Error) Units: scores on a scale		
Week 1 (n=121, 117)	-1.32 (0.314)	-1.12 (0.329)
Week 2 (n=122, 114)	-2.93 (0.440)	-3.04 (0.459)
Week 4 (n=112, 107)	-4.35 (0.546)	-5.13 (0.566)

12. Secondary Outcome

Title: Percentage of Responders in HAM-A Total Score at Other Weeks Assessed

Description: Response was defined as participants with a ≥ 50% decrease from Baseline in the Hamilton Anxiety Scale (HAM-A) total score. The HAM-A is an anxiety rating scale consisting of 14 items that assess anxious mood, tension, fear, insomnia, intellectual (cognitive) symptoms, depressed mood, behavior at interview, somatic (sensory), cardiovascular, respiratory, gastrointestinal, genitourinary, autonomic and somatic (muscular) symptoms. Each symptom is rated from 0 (absent) to 4 (maximum severity). Total scores range from 0 (symptoms absent) to 56 (maximum severity).

Time Frame: Baseline and Weeks 1, 2, 4 and 6

Safety Issue? No

Outcome Measure Data

Analysis Population Description

Full analysis set; Last observation carried forward was used. "n" indicates the number of patients included in the analysis at each time point.

Arm/Group Title	**Placebo**	**Vortioxetine 5 mg**
Arm/Group Description:	Vortioxetine placebo-matching capsules, orally, once daily for up to 8 weeks.	Vortioxetine 5 mg, encapsulated tablets, orally, once daily for up to 8 weeks.
Number of Participants Analyzed	148	149
Measure Type: Number Units: percentage of participants		
Week 1 (n=146, 148)	2.7	2.0
Week 2 (n=148, 149)	12.2	12.1
Week 4 (n=148, 149)	20.3	28.9
Week 6 (n=148, 149)	29.7	43.6

13. Secondary Outcome

Title: Change From Baseline in the Hamilton Anxiety Scale (HAM-A) Total Score at Other Weeks Assessed in Participants With Baseline HAM-A ≥25

Description: The HAM-A is an anxiety rating scale consisting of 14 items that assess anxious mood, tension, fear, insomnia, intellectual (cognitive) symptoms, depressed mood, behavior at interview, somatic (sensory), cardiovascular, respiratory, gastrointestinal, genitourinary, autonomic and somatic (muscular) symptoms. Each symptom is rated from 0 (absent) to 4 (maximum severity). Total scores range from 0 to 56 where <17 indicates mild severity, 18-24 mild to moderate severity and 25-30 moderate to severe. Total scores above 30 are rare, but indicate very severe anxiety. LS means were from a MMRM with Baseline-by-week, center, week and week-by-treatment as factors in the analysis.

Time Frame: Baseline to Weeks 1, 2, 4 and 6

Safety Issue? No

Outcome Measure Data

Analysis Population Description

Full analysis set patients with a HAM-A Baseline score ≥25. A mixed model for repeated measurements (MMRM) based on observed cases was used; "n" indicates the number of patients included in the analysis at each time point.

Arm/Group Title	**Placebo**	**Vortioxetine 5 mg**
Arm/Group Description:	Vortioxetine placebo-matching capsules, orally, once daily for up to 8 weeks.	Vortioxetine 5 mg, encapsulated tablets, orally, once daily for up to 8 weeks.
Number of Participants Analyzed	100	96
Least Squares Mean (Standard Error) Units: scores on a scale		
Week 1 (n=100, 95)	-2.64 (0.332)	-2.62 (0.341)
Week 2 (n=99, 92)	-4.89 (0.507)	-6.43 (0.522)
Week 4 (n=89, 89)	-7.33 (0.694)	-10.08 (0.702)
Week 6 (n=83, 83)	-9.02 (0.763)	-12.90 (0.771)

14. Secondary Outcome

Title: Percentage of Participants in HAM-A Remission at Each Week Assessed

Description: Remission is defined as a Hamilton Anxiety Scale (HAM-A) total score ≤ 7. The HAM-A is an anxiety rating scale consisting of 14 items that assess anxious mood, tension, fear, insomnia, intellectual (cognitive) symptoms, depressed mood, behavior at interview, somatic (sensory), cardiovascular, respiratory, gastrointestinal, genitourinary, autonomic and somatic (muscular) symptoms. Each symptom is rated from 0 (absent) to 4 (maximum severity). Total scores range from 0 (symptoms absent) to 56 (maximum severity).

Time Frame: Weeks 1, 2, 4, 6 and 8

Safety Issue? No

Outcome Measure Data

Analysis Population Description

Full analysis set; Last observation carried forward was used. "n" indicates the number of patients included in the analysis at each time point.

Arm/Group Title	**Placebo**	**Vortioxetine 5 mg**
Arm/Group Description:	Vortioxetine placebo-matching capsules, orally, once daily for up to 8 weeks.	Vortioxetine 5 mg, encapsulated tablets, orally, once daily for up to 8 weeks.
Number of Participants Analyzed	148	149
Measure Type: Number Units: percentage of participants		
Week 1 (n=146, 148)	0	0
Week 2 (n=148, 149)	2.7	2.7
Week 4 (n=148, 149)	6.8	8.7
Week 6 (n=148, 149)	12.2	16.8
Week 8 (n=148, 149)	17.6	30.2

15. Secondary Outcome

Title: Change From Baseline in Clinical Global Impression Scale-Severity of Illness at Each Week Assessed

Description: The Clinical Global Impression-Severity scale (CGI-S) is a 7-point scale that requires the clinician to rate the severity of the patient's illness at the time of assessment, relative to the clinician's past experience with patients who have the same diagnosis. Considering total clinical experience, a patient is assessed on severity of mental illness on the following scale: 1, normal, not at all ill; 2, borderline mentally ill; 3, mildly ill; 4, moderately ill; 5, markedly ill; 6, severely ill; or 7, extremely ill. LS means were from a MMRM with Baseline-by-week, center, week and week-by-treatment as factors in the analysis.

Time Frame: Baseline to Weeks 1, 2, 4, 6 and 8

Safety Issue? No

Outcome Measure Data

Analysis Population Description

Full analysis set. A mixed model for repeated measurements (MMRM) based on observed cases was used; "n" indicates the number of patients included in the analysis at each time point.

Arm/Group Title	**Placebo**	**Vortioxetine 5 mg**
Arm/Group Description:	Vortioxetine placebo-matching capsules, orally, once daily for up to 8 weeks.	Vortioxetine 5 mg, encapsulated tablets, orally, once daily for up to 8 weeks.
Number of Participants Analyzed	148	149
Least Squares Mean (Standard Error) Units: scores on a scale		
Week 1 (n=146, 148)	-0.23 (0.039)	-0.19 (0.039)
Week 2 (n=147, 144)	-0.53 (0.060)	-0.60 (0.060)
Week 4 (n=136, 137)	-0.87 (0.071)	-1.04 (0.071)
Week 6 (n=128, 129)	-1.09 (0.080)	-1.40 (0.080)
Week 8 (n=126, 128)	-1.26 (0.096)	-1.78 (0.095)

16. Secondary Outcome

Title:	Change From Baseline in the Hospital Anxiety and Depression (HAD) Depression Subscale at Each Week Assessed
Description:	The HAD-Depression subscale is completed by the participant and measures depression, focusing on the state of lost interest and diminished pleasure response. The subscale is made up of 7 items that are assessed on a scale from 0 (no depression) to 3 (severe feeling of depression). Participants are required to indicate the response which most accurately reflects the way they have felt over the last few days. The item scores are summed and the total subscore ranges from 0 to 21 (maximal severity). LS means were from a MMRM with Baseline-by-week, center, week and week-by-treatment as factors in the analysis.
Time Frame:	Baseline to Weeks 1, 4 and 8
Safety Issue?	No

Outcome Measure Data

Analysis Population Description

The Full Analysis Set. A mixed model for repeated measurements (MMRM) based on observed cases was used; "n" indicates the number of patients included in the analysis at each time point.

Arm/Group Title	**Placebo**	**Vortioxetine 5 mg**
Arm/Group Description:	Vortioxetine placebo-matching capsules, orally, once daily for up to 8 weeks.	Vortioxetine 5 mg, encapsulated tablets, orally, once daily for up to 8 weeks.
Number of Participants Analyzed	148	149
Least Squares Mean (Standard Error) Units: scores on a scale		
Week 1 (n=146, 148)	-0.18 (0.178)	-0.28 (0.176)
Week 4 (n=140, 140)	-1.08 (0.245)	-1.62 (0.245)
Week 8 (n=128, 129)	-1.50 (0.297)	-3.18 (0.295)

17. Secondary Outcome

Title: Change From Baseline in 36-Item Short-Form Health Survey (SF-36) Social Functioning Subscore at Other Weeks Assessed

Description: The Medical Outcomes Study SF-36 is a participant self-rated questionnaire that is a general measure of perceived health status comprising 36 questions, which yields an 8-scale health profile. The social functioning subscale assesses limitations in social activities because of physical or emotional problems. The sub-score scale ranges from 0 (best) - 100 (worst). LS means were from a MMRM with Baseline-by-week, center, week and week-by-treatment as factors in the analysis.

Time Frame: Baseline to Weeks 2 and 4

Safety Issue? No

Outcome Measure Data

Analysis Population Description

The Full Analysis Set with available data at Baseline. A mixed model for repeated measurements (MMRM) based on observed cases was used; "n" indicates the number of patients included in the analysis at each time point.

Arm/Group Title	**Placebo**	**Vortioxetine 5 mg**
Arm/Group Description:	Vortioxetine placebo-matching capsules, orally, once daily for up to 8 weeks.	Vortioxetine 5 mg, encapsulated tablets, orally, once daily for up to 8 weeks.
Number of Participants Analyzed	147	149
Least Squares Mean (Standard Error) Units: scores on a scale		
Week 2 (n=147, 149)	8.50 (1.536)	8.83 (1.519)
Week 4 (n=136, 137)	11.41 (1.773)	18.45 (1.758)

18. Secondary Outcome

Title: Change From Baseline in 36-Item Short-Form Health Survey (SF-36) Physical Functioning Subscore at Each Week Assessed

Description: The Medical Outcomes Study SF-36 is a participant self-rated questionnaire that is a general measure of perceived health status comprising 36 questions, which yields an 8-scale health profile. The physical functioning subscale assesses limitations in physical activities because of health problems. The sub-score scale ranges from 0 (best) - 100 (worst). LS means were from a MMRM with Baseline-by-week, center, week and week-by-treatment as factors in the analysis.

Time Frame: Baseline to Weeks 2, 4 and 8

Safety Issue? No

Outcome Measure Data

Analysis Population Description

The Full Analysis Set with available data at Baseline. A mixed model for repeated measurements (MMRM) based on observed cases was used; "n" indicates the number of patients included in

the analysis at each time point.

Arm/Group Title	Placebo	Vortioxetine 5 mg
Arm/Group Description:	Vortioxetine placebo-matching capsules, orally, once daily for up to 8 weeks.	Vortioxetine 5 mg, encapsulated tablets, orally, once daily for up to 8 weeks.
Number of Participants Analyzed	147	149
Least Squares Mean (Standard Error) Units: scores on a scale		
Week 2 (n=147, 149)	2.54 (1.160)	3.39 (1.146)
Week 4 (n=136, 137)	2.15 (1.149)	8.34 (1.137)
Week 8 (n=128, 129)	4.48 (1.271)	10.69 (1.258)

19. Secondary Outcome

Title: Change From Baseline in 36-Item Short-Form Health Survey (SF-36) Role-Physical Subscore at Each Week Assessed

Description: The Medical Outcomes Study SF-36 is a participant self-rated questionnaire that is a general measure of perceived health status comprising 36 questions, which yields an 8-scale health profile. The role-physical subscale assesses limitations in usual role activities because of physical health problems. The sub-score scale ranges from 0 (best) - 100 (worst). LS means were from a MMRM with Baseline-by-week, center, week and week-by-treatment as factors in the analysis.

Time Frame: Baseline to Weeks 2, 4 and 8

Safety Issue? No

Outcome Measure Data

Analysis Population Description

The Full Analysis Set with available data at Baseline. A mixed model for repeated measurements (MMRM) based on observed cases was used; "n" indicates the number of patients included in

the analysis at each time point.

Arm/Group Title	**Placebo**	**Vortioxetine 5 mg**
Arm/Group Description:	Vortioxetine placebo-matching capsules, orally, once daily for up to 8 weeks.	Vortioxetine 5 mg, encapsulated tablets, orally, once daily for up to 8 weeks.
Number of Participants Analyzed	147	149
Least Squares Mean (Standard Error) Units: scores on a scale		
Week 2 (n=147, 149)	4.72 (1.488)	5.99 (1.474)
Week 4 (n=136, 137)	6.89 (1.592)	11.89 (1.578)
Week 8 (n=128, 129)	8.96 (1.897)	18.39 (1.880)

20. Secondary Outcome

Title: Change From Baseline in 36-Item Short-Form Health Survey (SF-36) Bodily Pain Subscore at Each Week Assessed

Description: The Medical Outcomes Study SF-36 is a participant self-rated questionnaire that is a general measure of perceived health status comprising 36 questions, which yields an 8-scale health profile. The bodily pain sub-score scale ranges from 0 (best) - 100 (worst). LS means were from a MMRM with Baseline-by-week, center, week and week-by-treatment as factors in the analysis.

Time Frame: Baseline to Weeks 2, 4 and 8

Safety Issue? No

Outcome Measure Data

Analysis Population Description

The Full Analysis Set with available data at Baseline. A mixed model for repeated measurements (MMRM) based on observed cases was used; "n" indicates the number of patients included in the analysis at each time point.

Arm/Group Title	**Placebo**	**Vortioxetine 5 mg**
Arm/Group Description:	Vortioxetine placebo-matching capsules, orally, once daily for up to 8 weeks.	Vortioxetine 5 mg, encapsulated tablets, orally, once daily for up to 8 weeks.
Number of Participants Analyzed	147	149
Least Squares Mean (Standard Error) Units: scores on a scale		
Week 2 (n=147, 149)	6.49 (1.702)	7.40 (1.681)
Week 4 (n=136, 137)	6.81 (1.875)	10.62 (1.856)
Week 8 (n=128, 129)	10.90 (1.903)	15.38 (1.883)

21. Secondary Outcome

Title:	Change From Baseline in 36-Item Short-Form Health Survey (SF-36) General Health Subscore at Each Week Assessed
Description:	The Medical Outcomes Study SF-36 is a participant self-rated questionnaire that is a general measure of perceived health status comprising 36 questions, which yields an 8-scale health profile. The general health sub-score scale ranges from 0 (best) - 100 (worst). LS means were from a MMRM with Baseline-by-week, center, week and week-by-treatment as factors in the analysis.
Time Frame:	Baseline to Weeks 2, 4 and 8
Safety Issue?	No

Outcome Measure Data

Analysis Population Description

The Full Analysis Set with available data at Baseline. A mixed model for repeated measurements (MMRM) based on observed cases was used; "n" indicates the number of patients included in the analysis at each time point.

Arm/Group Title	**Placebo**	**Vortioxetine 5 mg**
Arm/Group Description:	Vortioxetine placebo-matching capsules, orally, once daily for up to 8 weeks.	Vortioxetine 5 mg, encapsulated tablets, orally, once daily for up to 8 weeks.
Number of Participants Analyzed	147	149
Least Squares Mean (Standard Error) Units: scores on a scale		
Week 2 (n=147, 149)	4.54 (0.992)	6.04 (0.979)
Week 4 (n=136, 137)	8.45 (1.292)	10.36 (1.280)
Week 8 (n=128, 129)	9.76 (1.409)	16.30 (1.396)

22. Secondary Outcome

Title:	Change From Baseline in 36-Item Short-Form Health Survey (SF-36) Vitality Subscore at Each Week Assessed
Description:	The Medical Outcomes Study SF-36 is a participant self-rated questionnaire that is a general measure of perceived health status comprising 36 questions, which yields an 8-scale health profile. The vitality sub-score assesses energy and fatigue, and ranges from 0 (best) - 100 (worst). LS means were from a MMRM with Baseline-by-week, center, week and week-by-treatment as factors in the analysis.
Time Frame:	Baseline to Weeks 2, 4 and 8
Safety Issue?	No

Outcome Measure Data

Analysis Population Description

The Full Analysis Set with available data at Baseline. A mixed model for repeated measurements (MMRM) based on observed cases was used; "n" indicates the number of patients included in the analysis at each time point.

Arm/Group Title	**Placebo**	**Vortioxetine 5 mg**
Arm/Group Description:	Vortioxetine placebo-matching capsules, orally, once daily for up to 8 weeks.	Vortioxetine 5 mg, encapsulated tablets, orally, once daily for up to 8 weeks.
Number of Participants Analyzed	147	149
Least Squares Mean (Standard Error) Units: scores on a scale		
Week 2 (n=147, 149)	5.44 (1.275)	8.11 (1.261)
Week 4 (n=136, 137)	8.36 (1.500)	13.38 (1.486)
Week 8 (n= 128, 129)	12.56 (1.686)	22.53 (1.671)

23. Secondary Outcome

Title:	Change From Baseline in 36-Item Short-Form Health Survey (SF-36) Role-Emotional Subscore at Each Week Assessed
Description:	The Medical Outcomes Study SF-36 is a participant self-rated questionnaire that is a general measure of perceived health status comprising 36 questions, which yields an 8-scale health profile. The role-emotional subscale assesses limitations in usual role activities because of emotional problems. The sub-score scale ranges from 0 (best) - 100 (worst). LS means were from a MMRM with Baseline-by-week, center, week and week-by-treatment as factors in the analysis.
Time Frame:	Baseline to Weeks 2, 4 and 8
Safety Issue?	No

Outcome Measure Data

Analysis Population Description

The Full Analysis Set with available data at Baseline. A mixed model for repeated measurements (MMRM) based on observed cases was used; "n" indicates the number of patients included in

the analysis at each time point.

Arm/Group Title	Placebo	Vortioxetine 5 mg
Arm/Group Description:	Vortioxetine placebo-matching capsules, orally, once daily for up to 8 weeks.	Vortioxetine 5 mg, encapsulated tablets, orally, once daily for up to 8 weeks.
Number of Participants Analyzed	147	149
Least Squares Mean (Standard Error) Units: scores on a scale		
Week 2 (n=147, 149)	7.27 (1.480)	9.62 (1.463)
Week 4 (n=136, 137)	13.41 (1.871)	19.04 (1.856)
Week 8 (n=128, 129)	18.96 (2.138)	28.13 (2.121)

24. Secondary Outcome

Title:	Change From Baseline in 36-Item Short-Form Health Survey (SF-36) Mental Health Subscore at Each Week Assessed
Description:	The Medical Outcomes Study SF-36 is a participant self-rated questionnaire that is a general measure of perceived health status comprising 36 questions, which yields an 8-scale health profile. The mental health sub-score assesses general mental health (psychological distress and well-being) and ranges from 0 (best) - 100 (worst). LS means were from a MMRM with Baseline-by-week, center, week and week-by-treatment as factors in the analysis.
Time Frame:	Baseline to Weeks 2, 4 and 8
Safety Issue?	No

Outcome Measure Data

Analysis Population Description

The Full Analysis Set with available data at Baseline. A mixed model for repeated measurements (MMRM) based on observed cases was used; "n" indicates the number of patients included in

the analysis at each time point.

Arm/Group Title	**Placebo**	**Vortioxetine 5 mg**
Arm/Group Description:	Vortioxetine placebo-matching capsules, orally, once daily for up to 8 weeks.	Vortioxetine 5 mg, encapsulated tablets, orally, once daily for up to 8 weeks.
Number of Participants Analyzed	147	149
Least Squares Mean (Standard Error) Units: scores on a scale		
Week 2 (n=147, 149)	5.58 (1.166)	8.90 (1.152)
Week 4 (n=136, 137)	9.79 (1.432)	14.73 (1.421)
Week 8 (n=128, 129)	13.51 (1.693)	21.75 (1.681)

25. Secondary Outcome

Title: Health Care Resource Utilization as Assessed by the Health Economic Assessment Questionnaire

Description: Healthcare resource utilization was assessed by the Health Economic Assessment (HEA) questionnaire, which monitors the participants absenteeism from work, as well as resource use such as visits to a general practitioner, outpatient and inpatient services, hospitalization, medications, and other relevant services over the past 8 weeks.

Time Frame: Baseline and Week 8

Safety Issue? No

Outcome Measure Data

Analysis Population Description

Full analysis set.

Arm/Group Title	**Placebo**	**Vortioxetine 5 mg**
Arm/Group Description:	Vortioxetine placebo-matching capsules, orally, once daily for up to 8 weeks.	Vortioxetine 5 mg, encapsulated tablets, orally, once daily for up to 8 weeks.
Number of Participants Analyzed	148	149
Measure Type: Number Units: participants		
Baseline: Any resource use	79	84
Baseline: Any hospitalization-related services	7	3
Baseline: Hospitalization related to anxiety	4	2
Baseline: Any sick leave	7	7
Baseline: Sick leave related to anxiety	4	4
Week 8: Any resource use	14	25
Week 8: Any hospitalization-related service	0	1
Week 8: Hospitalization related to anxiety	0	0
Week 8: Any sick leave	2	4
Week 8: Sick leave related to anxiety	2	3

Adverse Events

Time Frame	Safety was assessed during the 8-week treatment period and a 4-week follow-up period.
Additional Description	At each visit the investigator had to document any occurrence of adverse events and abnormal laboratory findings. Any event spontaneously reported by the participant or observed by the investigator was recorded, irrespective of the relation to study treatment.
Source Vocabulary Name	MedDRA Version 12.0
Assessment Type	Systematic Assessment

Arm/Group Title	Placebo	Vortioxetine 5 mg
Arm/Group Description	Vortioxetine placebo-matching capsules, orally, once daily for up to 8 weeks.	Vortioxetine 5 mg, encapsulated tablets, orally, once daily for up to 8 weeks.

Serious Adverse Events

	Placebo Affected / at Risk (%)	**Vortioxetine 5 mg** Affected / at Risk (%)
Total	1/150 (0.67%)	0/150 (0%)
Musculoskeletal and connective tissue disorders		
Intervertebral disc protrusion † A	1/150 (0.67%)	0/150 (0%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA Version 12.0

Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events	2%

	Placebo Affected / at Risk (%)	**Vortioxetine 5 mg** Affected / at Risk (%)
Total	36/150 (24%)	48/150 (32%)
Gastrointestinal disorders		
Abdominal pain † A	0/150 (0%)	3/150 (2%)
Diarrhoea † A	4/150 (2.67%)	3/150 (2%)
Dry mouth † A	4/150 (2.67%)	5/150 (3.33%)
Nausea † A	9/150 (6%)	18/150 (12%)
Vomiting † A	5/150 (3.33%)	2/150 (1.33%)
General disorders		
Fatigue † A	4/150 (2.67%)	1/150 (0.67%)
Infections and infestations		
Bronchitis † A	4/150 (2.67%)	0/150 (0%)
Influenza † A	1/150 (0.67%)	3/150 (2%)
Nasopharyngitis † A	1/150 (0.67%)	5/150 (3.33%)
Nervous system disorders		
Dizziness † A	4/150 (2.67%)	9/150 (6%)
Headache † A	13/150 (8.67%)	12/150 (8%)
Somnolence † A	2/150 (1.33%)	6/150 (4%)
Skin and subcutaneous tissue		

disorders		
Hyperhidrosis † A	1/150 (0.67%)	5/150 (3.33%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA Version 12.0

Limitations and Caveats

[Not Specified]

More Information

Certain Agreements

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The first study related publication will be a multi-center publication submitted within 24 months after conclusion or termination of a study at all sites. After such multi site publication, all proposed site publications and presentations will be submitted to sponsor for review 60 days in advance of publication. Site will remove Sponsor confidential information unrelated to study results. Sponsor can delay a proposed publication for another 60 days to preserve intellectual property.

Results Point of Contact

Name/Official Title:	Medical Director, Clinical Science
Organization:	Takeda
Phone:	800-778-2860
Email:	clinicaltrialregistry@tpna.com

Close