ID: LuAA21004/CCT-002 | Efficacy and Safety Study of Vortioxetine (Lu AA21004) for Treatment of Major Depressive Disorder | NCT01255787

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Participant Flow

Recruitment Details: Participants took part in the study at 90 investigative sites in Japan, Europe and Asia/Oceania from 18 November 2010 to 25 April 2012.

Pre-Assignment Details: Participants with a diagnosis of major depressive disorder were enrolled equally in 1 of 4 treatment groups, once a day placebo, 5 mg, 10 mg, or 20 mg vortioxetine.

Arm/Group Title	**Placebo**	**Vortioxetine 5 mg**	**Vortioxetine 10 mg**	**Vortioxetine 20 mg**	Total (Not public)
Arm/Group Description	Vortioxetine placebo-matching tablets, orally, once daily for up to 10 weeks.	Vortioxetine 5 mg, tablets, orally, once daily for 8 weeks, followed by vortioxetine placebo-matching tablets, orally, once daily for 2 weeks.	Vortioxetine 10 mg, tablets, orally, once daily for 8 weeks, followed by vortioxetine placebo-matching tablets, orally, once daily for 2 weeks.	Vortioxetine 10 mg, tablets, orally, once daily for 1 week, followed by vortioxetine 20 mg, tablets, orally, once daily for 7 weeks, followed by vortioxetine placebo-matching tablets, orally, once daily, for 2 weeks.	
Period Title: Overall Study					
Started	152	144	150	154	600
Treated	152	144	148	150	594
Completed	136	127	132	132	527
Not Completed	16	17	18	22	73
Reason Not Completed					
Pretreatment Event or Adverse Event (AE)	6	2	9	9	26
Major Protocol Deviation	1	1	0	4	6
Lost to Follow-up	1	2	4	2	9
Withdrawal of Consent	3	9	3	4	19
Pregnancy	0	0	0	1	1
Lack of Efficacy	2	2	2	2	8
Noncompliance with Study Drug	3	1	0	0	4
(Not Public)	Not Completed = 16 Total from all reasons = 16	Not Completed = 17 Total from all reasons = 17	Not Completed = 18 Total from all reasons = 18	Not Completed = 22 Total from all reasons = 22	

Baseline Characteristics

Arm/Group Title	**Placebo**	**Vortioxetine 5 mg**	**Vortioxetine 10 mg**	**Vortioxetine 20 mg**	**Total**
Arm/Group Description	Vortioxetine placebo-matching tablets, orally, once daily for up to 10 weeks.	Vortioxetine 5 mg, tablets, orally, once daily for 8 weeks, followed by vortioxetine placebo-matching tablets, orally, once daily for 2 weeks.	Vortioxetine 10 mg, tablets, orally, once daily for 8 weeks, followed by vortioxetine placebo-matching tablets, orally, once daily for 2 weeks.	Vortioxetine 10 mg, tablets, orally, once daily for 1 week, followed by vortioxetine 20 mg, tablets, orally, once daily for 7 weeks, followed by vortioxetine placebo-matching tablets, orally, once daily, for 2 weeks.	

Overall Number of Baseline Participants	152	144	150	154	**600**
Baseline Analysis Population Description [Not specified]					
Age, Continuous **Mean (Standard Deviation)** **Units: years**	43.6 (11.57)	44.2 (11.89)	45.7 (10.90)	44.0 (11.79)	44.4 (11.54)
Gender, Male/Female **Measure Type: Number** **Units: participants**					
Female	91	98	93	93	375
Male	61	46	57	61	225
Race/Ethnicity, Customized **Measure Type: Number** **Units: participants**					
Caucasian (or White, including Hispanic)	104	101	104	105	414
Asian	48	43	46	49	186
Region of Enrollment **Measure Type: Number** **Units: participants**					
Croatia	0	1	0	2	3
Finland	5	5	5	5	20
Germany	50	50	50	49	199
India	3	3	3	2	11
Japan	33	32	31	33	129
Latvia	3	2	2	3	10
Malaysia	2	0	0	2	4
Philippines	4	2	4	3	13
Poland	20	18	20	21	79
Romania	5	4	6	3	18
Russia	13	13	12	13	51
Serbia	2	2	3	2	9
South Korea	6	6	7	8	27
Ukraine	6	6	7	8	27
Height **Mean (Standard Deviation)** **Units: cm**	167.1 (8.75)	167.2 (9.64)	167.5 (9.40)	167.5 (9.61)	167.3 (9.33)
Weight [1] **Mean (Standard Deviation)** **Units: kg**	69.70 (16.901)	70.57 (18.214)	73.37 (19.014)	70.21 (18.189)	70.95 (18.095)
[1] Number of participants for whom weight data were available were 152, 144, 147 and 149 in each treatment group respectively.					
Body Mass Index (BMI) [1] **Mean (Standard Deviation)** **Units: kg/m^2**	24.82 (5.129)	25.06 (5.432)	25.93 (5.462)	24.82 (5.206)	25.15 (5.313)
[1] Number of participants for whom BMI data were available were 152, 144, 147 and 149 in each treatment group respectively.					
Smoking Classification **Measure Type: Number** **Units: participants**					
Current smoker	51	50	50	56	207
Ex-smoker	22	19	21	11	73
Never smoked	79	75	79	87	320
History of Alcohol Consumption **Measure Type: Number**					

Units: participants					
Never	58	62	54	56	230
Once monthly or less often	52	41	54	53	200
Once a week	17	22	22	22	83
2 to 6 times per week	14	9	10	13	46
Daily	11	10	10	10	41

Status of Major Depressive Episode (MDE) [1]
Measure Type: Number
Units: participants

Single episode	51	55	49	49	204
Recurrent episode	101	89	101	105	396

[1] An MDE is a period marked by depressed mood, loss of interest or pleasure, disturbed sleep or appetite, low energy, feelings of guilt or low self-worth, and poor concentration.

Pharmacotherapy for Current Major Depressive Episode
Measure Type: Number
Units: participants

Yes	73	60	69	75	277
No	79	84	81	79	323

Montgomery Åsberg Depression Rating Scale (MADRS) Total Score [1]
Mean (Standard Deviation)

Units: scores on a scale	31.6 (3.56)	31.6 (3.67)	31.8 (4.02)	31.7 (3.73)	31.7 (3.74)

[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). Number of participants for whom MADRS data were available were 152, 144, 147 and 149 in each treatment arm respectively.

Clinical Global Impression - Severity scale score [1]
Mean (Standard Deviation)

Units: scores on a scale	4.7 (0.66)	4.7 (0.65)	4.7 (0.66)	4.7 (0.65)	4.70 (0.65)

[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. Number of participants for whom CGI-S data were available were 152, 144, 147 and 149 in each treatment arm respectively.

Sheehan Disability Scale (SDS) - Total score [1]
Mean (Standard Deviation)

Units: scores on a scale	18.2 (5.28)	17.9 (6.27)	18.5 (5.42)	18.2 (5.70)	18.2 (5.65)

[1] 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. Number of participants for whom SDS data were available were 132, 116, 119 and 121 in each treatment arm respectively.

Hamilton Anxiety Scale Total Score [1]
Mean (Standard Deviation)

Units: scores on a scale	18.6 (6.83)	18.9 (6.55)	18.8 (6.66)	18.5 (6.12)	18.7 (6.53)

[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). Number of participants for whom HAM-A data were available were 152, 144, 148 and 150 in each treatment arm respectively.

Outcome Measures

1. Primary Outcome

Title: Change From Baseline in Montgomery-Åsberg Depression Rating Scale (MADRS) Total Score

Description: The MADRS is a depression rating scale consisting of 10 items, each rated 0 (normal) to 6 (most abnormal). The 10 items represent the core symptoms of depressive illness. The overall score ranges from 0 (symptoms absent) to 60 (severe depression). A decrease in the total score or on individual items indicates improvement. Least squares (LS) means were from an Analysis of Covariance (ANCOVA) model with treatment as a fixed factor and the Baseline value as a covariate.

Time Frame: Baseline and Week 8

Safety Issue? No

Outcome Measure Data

Analysis Population Description

The full analysis set included all randomized participants who received at least 1 dose of study drug. One patient in the placebo arm was excluded from all datasets due to enrollment in another clinical study. Only participants with Baseline and at least 1 post-baseline value are included. Last observation carried forward (LOCF) was used.

Arm/Group Title	**Placebo**	**Vortioxetine 5 mg**	**Vortioxetine 10 mg**	**Vortioxetine 20 mg**
Arm/Group Description:	Vortioxetine placebo-matching tablets, orally, once daily for up to 10 weeks.	Vortioxetine 5 mg, tablets, orally, once daily for 8 weeks, followed by vortioxetine placebo-matching tablets, orally, once daily for 2 weeks.	Vortioxetine 10 mg, tablets, orally, once daily for 8 weeks, followed by vortioxetine placebo-matching tablets, orally, once daily for 2 weeks.	Vortioxetine 10 mg, tablets, orally, once daily for 1 week, followed by vortioxetine 20 mg, tablets, orally, once daily for 7 weeks, followed by vortioxetine placebo-matching tablets, orally, once daily, for 2 weeks.
Number of Participants Analyzed	150	142	147	149
Least Squares Mean (Standard Error) Units: scores on a scale	-13.99 (0.783)	-14.61 (0.805)	-15.68 (0.791)	-15.82 (0.786)

Statistical Analysis 1

Statistical Analysis Overview	**Comparison Groups**	Placebo, Vortioxetine 5 mg
	Comments	All statistical tests were 2-sided with the estimated P-values at the 5% level of significance.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	0.9070
	Comments	Adjustment for multiplicity for the comparisons was based on the Dunnett-Hsu procedure.
	Method	ANCOVA
	Comments	Analysis of covariance (ANCOVA), with treatment as a fixed factors and baseline MADRS as a covariate.
Method of Estimation	**Estimation Parameter**	Other[LS Mean Difference]
	Estimated Value	-0.61
	Confidence Interval	(2-Sided) 95% -3.258 to 2.035
	Parameter Dispersion	Type: Standard Error of the mean

		Value: 1.123
	Estimation Comments	[Not specified]

Statistical Analysis 2

Statistical Analysis Overview	**Comparison Groups**	Placebo, Vortioxetine 10 mg
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	0.3006
	Comments	[Not specified]
	Method	ANCOVA
	Comments	Analysis of covariance (ANCOVA), with treatment as a fixed factors and baseline MADRS as a covariate.
Method of Estimation	**Estimation Parameter**	Other[LS Mean Difference]
	Estimated Value	-1.69
	Confidence Interval	(2-Sided) 95% -4.310 to 0.938
	Parameter Dispersion	Type: Standard Error of the mean Value: 1.114
	Estimation Comments	[Not specified]

Statistical Analysis 3

Statistical Analysis Overview	**Comparison Groups**	Placebo, Vortioxetine 20 mg
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	0.2399
	Comments	[Not specified]
	Method	ANCOVA
	Comments	Analysis of covariance (ANCOVA), with treatment as a fixed factors and baseline MADRS as a covariate.
Method of Estimation	**Estimation Parameter**	Other[LS Mean Difference]
	Estimated Value	-1.82
	Confidence Interval	(2-Sided) 95% -4.436 to 0.794
	Parameter Dispersion	Type: Standard Error of the mean

Value: 1.110

Estimation Comments [Not specified]

2. Secondary Outcome

Title: Percentage of Participants With a MADRS Response at Week 8

Description: Response is defined as a participant with a ≥50% decrease in Montgomery Åsberg Depression Rating Scale (MADRS) total score from Baseline. The 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). Decrease in the total score or on individual items indicates improvement.

Time Frame: Baseline and Week 8

Safety Issue? No

Outcome Measure Data

Analysis Population Description

Full analysis set, only participants with Baseline and at least 1 post-baseline value are included. LOCF was used.

Arm/Group Title	**Placebo**	**Vortioxetine 5 mg**	**Vortioxetine 10 mg**	**Vortioxetine 20 mg**
Arm/Group Description:	Vortioxetine placebo-matching tablets, orally, once daily for up to 10 weeks.	Vortioxetine 5 mg, tablets, orally, once daily for 8 weeks, followed by vortioxetine placebo-matching tablets, orally, once daily for 2 weeks.	Vortioxetine 10 mg, tablets, orally, once daily for 8 weeks, followed by vortioxetine placebo-matching tablets, orally, once daily for 2 weeks.	Vortioxetine 10 mg, tablets, orally, once daily for 1 week, followed by vortioxetine 20 mg, tablets, orally, once daily for 7 weeks, followed by vortioxetine placebo-matching tablets, orally, once daily, for 2 weeks.
Number of Participants Analyzed	150	142	147	149
Measure Type: Number Units: percentage of participants	39.3	49.3	54.4	51.0

3. Secondary Outcome

Title: Percentage of Participants in MADRS Remission at Week 8

Description: Remission is defined as a participant with a Montgomery Åsberg Depression Rating Scale (MADRS) total score ≤10. The 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). Decrease in the total score or on individual items indicates improvement.

Time Frame: Week 8

Safety Issue? No

Outcome Measure Data

Analysis Population Description

Full analysis set, only participants with Baseline and at least 1 post-baseline value are included. LOCF was used.

Arm/Group Title	**Placebo**	**Vortioxetine 5 mg**	**Vortioxetine 10 mg**	**Vortioxetine 20 mg**
Arm/Group Description:	Vortioxetine placebo-matching tablets, orally, once daily for up to 10 weeks.	Vortioxetine 5 mg, tablets, orally, once daily for 8 weeks, followed by vortioxetine placebo-matching tablets, orally, once daily for 2 weeks.	Vortioxetine 10 mg, tablets, orally, once daily for 8 weeks, followed by vortioxetine placebo-matching tablets, orally, once daily for 2 weeks.	Vortioxetine 10 mg, tablets, orally, once daily for 1 week, followed by vortioxetine 20 mg, tablets, orally, once daily for 7 weeks, followed by vortioxetine placebo-matching tablets, orally, once daily, for 2 weeks.

Number of Participants Analyzed	150	142	147	149
Measure Type: Number Units: percentage of participants	26.7	24.6	29.3	30.9

4. Secondary Outcome

Title: Mean Clinical Global Impression Scale - Improvement (CGI-I) Score 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 an ANCOVA model with treatment as a fixed factor and the Baseline Clinical Global Impression-Severity of Illness (CGI-S) score as a covariate.

Time Frame: Week 8

Safety Issue? No

Outcome Measure Data

Analysis Population Description

Full analysis set, only participants with Baseline and at least 1 post-baseline value are included. LOCF was used.

Arm/Group Title	**Placebo**	**Vortioxetine 5 mg**	**Vortioxetine 10 mg**	**Vortioxetine 20 mg**
Arm/Group Description:	Vortioxetine placebo-matching tablets, orally, once daily for up to 10 weeks.	Vortioxetine 5 mg, tablets, orally, once daily for 8 weeks, followed by vortioxetine placebo-matching tablets, orally, once daily for 2 weeks.	Vortioxetine 10 mg, tablets, orally, once daily for 8 weeks, followed by vortioxetine placebo-matching tablets, orally, once daily for 2 weeks.	Vortioxetine 10 mg, tablets, orally, once daily for 1 week, followed by vortioxetine 20 mg, tablets, orally, once daily for 7 weeks, followed by vortioxetine placebo-matching tablets, orally, once daily, for 2 weeks.
Number of Participants Analyzed	150	142	148	150
Least Squares Mean				

(Standard Error) **Units: scores on a scale**	2.54 (0.087)	2.37 (0.089)	2.27 (0.088)	2.36 (0.087)

5. 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 family life or home 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 an ANCOVA model with treatment as a fixed factor and the Baseline value as a covariate.

Time Frame: Baseline and Week 8

Safety Issue? No

Outcome Measure Data

Analysis Population Description

Full analysis set, only participants with Baseline and at least 1 post-baseline value are included. LOCF was used.

Arm/Group Title	**Placebo**	**Vortioxetine 5 mg**	**Vortioxetine 10 mg**	**Vortioxetine 20 mg**
Arm/Group Description:	Vortioxetine placebo-matching tablets, orally, once daily for up to 10 weeks.	Vortioxetine 5 mg, tablets, orally, once daily for 8 weeks, followed by vortioxetine placebo-matching tablets, orally, once daily for 2 weeks.	Vortioxetine 10 mg, tablets, orally, once daily for 8 weeks, followed by vortioxetine placebo-matching tablets, orally, once daily for 2 weeks.	Vortioxetine 10 mg, tablets, orally, once daily for 1 week, followed by vortioxetine 20 mg, tablets, orally, once daily for 7 weeks, followed by vortioxetine placebo-matching tablets, orally, once daily, for 2 weeks.
Number of Participants Analyzed	126	109	114	118

Least Squares Mean (Standard Error) Units: scores on a scale	-6.20 (0.602)	-6.38 (0.647)	-7.97 (0.633)	-7.26 (0.622)

Adverse Events

Time Frame	A treatment-emergent adverse event is defined as any AE whose onset occurs or intensity increases after the first dose of double-blind study medication through 2 weeks after the last dose of double-blind study medication.
Additional Description	The safety analysis set included all patients who received at least 1 dose of study drug. One patient in the placebo arm was excluded due to enrollment in another clinical study. Any event spontaneously reported by the patient or observed by the investigator was recorded, irrespective of relation to study drug.
Source Vocabulary Name	MedDRA 15.0
Assessment Type	Systematic Assessment

Arm/Group Title	Placebo	Vortioxetine 5 mg	Vortioxetine 10 mg	Vortioxetine 20 mg
Arm/Group Description	Vortioxetine placebo-matching tablets, orally, once daily for up to 10 weeks.	Vortioxetine 5 mg, tablets, orally, once daily for 8 weeks, followed by vortioxetine placebo-matching tablets, orally, once daily for 2 weeks.	Vortioxetine 10 mg, tablets, orally, once daily for 8 weeks, followed by vortioxetine placebo-matching tablets, orally, once daily for 2 weeks.	Vortioxetine 10 mg, tablets, orally, once daily for 1 week, followed by vortioxetine 20 mg, tablets, orally, once daily for 7 weeks, followed by vortioxetine placebo-matching tablets, orally, once daily, for 2 weeks.

Serious Adverse Events

	Placebo	**Vortioxetine 5 mg**	**Vortioxetine 10 mg**	**Vortioxetine 20 mg**
	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)

Total	1/151 (0.66%)	2/144 (1.39%)	2/148 (1.35%)	3/150 (2%)
Infections and infestations				
Gastroenteritis † A	0/151 (0%)	0/144 (0%)	1/148 (0.68%)	0/150 (0%)
Pyelonephritis † A	0/151 (0%)	0/144 (0%)	0/148 (0%)	1/150 (0.67%)
Nervous system disorders				
Syncope † A	0/151 (0%)	1/144 (0.69%)	0/148 (0%)	0/150 (0%)
Pregnancy, puerperium and perinatal conditions				
Abortion missed † A	0/151 (0%)	0/144 (0%)	0/148 (0%)	1/150 (0.67%)
Psychiatric disorders				
Depression † A	0/151 (0%)	0/144 (0%)	1/148 (0.68%)	0/150 (0%)
Suicidal ideation † A	0/151 (0%)	0/144 (0%)	0/148 (0%)	1/150 (0.67%)
Suicide attempt † A	1/151 (0.66%)	0/144 (0%)	0/148 (0%)	1/150 (0.67%)
Renal and urinary disorders				
Renal colic † A	0/151 (0%)	1/144 (0.69%)	0/148 (0%)	0/150 (0%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 15.0

Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events	2%			
	Placebo	**Vortioxetine 5 mg**	**Vortioxetine 10 mg**	**Vortioxetine 20 mg**
	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)
Total	97/151 (64.24%)	96/144 (66.67%)	93/148 (62.84%)	106/150 (70.67%)
Cardiac disorders				
Palpitations † A	2/151 (1.32%)	0/144 (0%)	0/148 (0%)	3/150 (2%)
Ear and labyrinth disorders				
Tinnitus † A	3/151 (1.99%)	2/144 (1.39%)	1/148 (0.68%)	3/150 (2%)
Vertigo † A	3/151 (1.99%)	1/144 (0.69%)	2/148 (1.35%)	3/150 (2%)
Gastrointestinal disorders				
Abdominal discomfort † A	0/151 (0%)	2/144 (1.39%)	1/148 (0.68%)	3/150 (2%)
Abdominal distension † A	0/151 (0%)	3/144 (2.08%)	1/148 (0.68%)	0/150 (0%)
Abdominal pain † A	3/151 (1.99%)	2/144 (1.39%)	1/148 (0.68%)	0/150 (0%)
Abdominal pain upper † A	4/151 (2.65%)	2/144 (1.39%)	2/148 (1.35%)	3/150 (2%)
Constipation † A	3/151 (1.99%)	6/144 (4.17%)	5/148 (3.38%)	8/150 (5.33%)
Diarrhoea † A	14/151 (9.27%)	7/144 (4.86%)	6/148 (4.05%)	5/150 (3.33%)
Dry mouth † A	3/151 (1.99%)	3/144 (2.08%)	6/148 (4.05%)	9/150 (6%)
Dyspepsia † A	0/151 (0%)	3/144 (2.08%)	3/148 (2.03%)	4/150 (2.67%)
Nausea † A	11/151 (7.28%)	26/144 (18.06%)	27/148 (18.24%)	37/150 (24.67%)
Vomiting † A	3/151 (1.99%)	2/144 (1.39%)	1/148 (0.68%)	6/150 (4%)
General disorders				
Fatigue † A	2/151 (1.32%)	6/144 (4.17%)	4/148 (2.7%)	5/150 (3.33%)
Thirst † A	1/151 (0.66%)	0/144 (0%)	3/148 (2.03%)	0/150 (0%)
Hepatobiliary disorders				
Hepatic function abnormal † A	0/151 (0%)	0/144 (0%)	3/148 (2.03%)	0/150 (0%)
Infections and infestations				
Bronchitis † A	3/151 (1.99%)	1/144 (0.69%)	1/148 (0.68%)	1/150 (0.67%)
Nasopharyngitis † A	18/151 (11.92%)	24/144 (16.67%)	18/148 (12.16%)	21/150 (14%)
Respiratory tract infection † A	0/151 (0%)	3/144 (2.08%)	0/148 (0%)	1/150 (0.67%)
Metabolism and nutrition disorders				
Decreased appetite † A	1/151 (0.66%)	4/144 (2.78%)	0/148 (0%)	1/150 (0.67%)
Musculoskeletal and connective				

tissue disorders				
Arthralgia † A	1/151 (0.66%)	3/144 (2.08%)	0/148 (0%)	0/150 (0%)
Back pain † A	3/151 (1.99%)	2/144 (1.39%)	6/148 (4.05%)	1/150 (0.67%)
Pain in extremity † A	0/151 (0%)	0/144 (0%)	3/148 (2.03%)	1/150 (0.67%)
Nervous system disorders				
Dizziness † A	5/151 (3.31%)	7/144 (4.86%)	8/148 (5.41%)	10/150 (6.67%)
Headache † A	21/151 (13.91%)	16/144 (11.11%)	19/148 (12.84%)	23/150 (15.33%)
Hypoaesthesia † A	4/151 (2.65%)	1/144 (0.69%)	1/148 (0.68%)	1/150 (0.67%)
Sedation † A	1/151 (0.66%)	2/144 (1.39%)	0/148 (0%)	3/150 (2%)
Somnolence † A	2/151 (1.32%)	7/144 (4.86%)	7/148 (4.73%)	6/150 (4%)
Psychiatric disorders				
Depression † A	3/151 (1.99%)	1/144 (0.69%)	2/148 (1.35%)	1/150 (0.67%)
Insomnia † A	2/151 (1.32%)	4/144 (2.78%)	4/148 (2.7%)	9/150 (6%)
Libido decreased † A	0/151 (0%)	0/144 (0%)	0/148 (0%)	3/150 (2%)
Suicidal ideation † A	4/151 (2.65%)	2/144 (1.39%)	2/148 (1.35%)	2/150 (1.33%)
Reproductive system and breast disorders				
Dysmenorrhoea † A	0/151 (0%)	3/144 (2.08%)	0/148 (0%)	1/150 (0.67%)
Respiratory, thoracic and mediastinal disorders				
Oropharyngeal pain † A	0/151 (0%)	1/144 (0.69%)	0/148 (0%)	3/150 (2%)
Skin and subcutaneous tissue disorders				
Hyperhidrosis † A	2/151 (1.32%)	5/144 (3.47%)	4/148 (2.7%)	3/150 (2%)
Pruritus generalised † A	0/151 (0%)	0/144 (0%)	2/148 (1.35%)	3/150 (2%)
Vascular disorders				
Hypertension † A	0/151 (0%)	0/144 (0%)	0/148 (0%)	3/150 (2%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 15.0

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

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