Safety and Efficacy Study of Suvorexant in Participants With Primary Insomnia - Study B (MK-4305-029)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

Information provided by (Responsible Party):
Merck Sharp & Dohme Corp.

ClinicalTrials.gov Identifier:
NCT01097629

First received: March 26, 2010
Last updated: February 26, 2016
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History of Changes

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Purpose

This is a multicenter study to test the hypothesis that suvorexant (MK-4305) is superior to placebo in improving insomnia as measured by change from baseline in: subjective total sleep time and time to sleep onset, wake time after persistent sleep onset, and latency to onset of persistent sleep.

Condition	Intervention	Phase
Primary Insomnia	Drug: Suvorexant High Dose (HD) Drug: Suvorexant Low Dose (LD) Drug: Comparator: Placebo	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Investigator)
Primary Purpose: Treatment

Official Title: A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study to Evaluate the Safety and Efficacy of MK-4305 in Patients With Primary Insomnia - Study B

Resource links provided by NLM:

Drug Information available for: Suvorexant

U.S. FDA Resources

Further study details as provided by Merck Sharp & Dohme Corp.:

Primary Outcome Measures:

Suvorexant HD Versus Placebo: Change From Baseline in Mean Subjective Total Sleep Time (sTSTm) at Month 1 [Time Frame: Baseline and Month 1] [Designated as safety issue: No]

sTSTm is the average over a defined day range of the participant's report of the total amount of time spent asleep before waking for the day, as recorded in a daily electronic diary (e-diary). Averages were derived by taking the mean of all available daily measurements (excluding the mornings following any polysomnography [PSG] nights) falling within the day range; Month 1 range is Days 23-30 (Day 1 is day of first double-blind dose). A participant must have at least 3 days of data during the defined day range to calculate an average for the day range; otherwise, the mean value was considered missing for that day range. The baseline value is the mean of the last 7 daily measurements obtained during the placebo Run-in period.

- Suvorexant HD Versus Placebo: Change From Baseline in sTSTm at Month 3 [Time Frame: Baseline and Month 3] [Designated as safety issue: No]

  sTSTm is the average over a defined day range of the participant's report of the total amount of time spent asleep before waking for the day, as recorded in a daily e-diary. Averages were derived by taking the mean of all available daily measurements (excluding the mornings following any PSG nights) falling within the day range; Month 3 range is Days 76-90 (Day 1 is day of first double-blind dose). A participant must have at least 3 days of data during the defined day range to calculate an average for the day range; otherwise, the mean value was considered missing for that day range. The baseline value is the mean of the last 7 daily measurements obtained during the placebo Run-in period.

- Suvorexant HD Versus Placebo: Change From Baseline in Wakefulness After Persistent Sleep Onset (WASO) at Month 1 [Time Frame: Baseline and Month 1] [Designated as safety issue: No]

  WASO is measured during overnight sleep laboratory (PSG) assessments at baseline, Night 1, Month 1 and Month 3, and is defined as the duration of wakefulness from the onset of persistent sleep (i.e., 10 consecutive minutes of sleep) to the end of PSG assessment the following morning. Beginning of PSG assessment ("Lights-Off") is at approximately the participant's habitual bedtime. The participant is awakened, or allowed to get out of bed if already awake, after 8 hours of PSG recording ("Lights-On"). PSG assessments consist of electronic measurement of brain activity and eye and muscle movements. PSG data was scored by a Centralized PSG reading center.

- Suvorexant HD Versus Placebo: Change From Baseline in WASO at Month 3 [Time Frame: Baseline and Month 3] [Designated as safety issue: No]

  WASO is measured during overnight sleep laboratory (PSG) assessments at baseline, Night 1, Month 1 and Month 3, and is defined as the duration of wakefulness from the onset of persistent sleep (i.e., 10 consecutive minutes of sleep) to the end of PSG assessment the following morning. Beginning of PSG assessment ("Lights-Off") is at approximately the participant's habitual bedtime. The participant is awakened, or allowed to get out of bed if already awake, after 8 hours of PSG recording ("Lights-On"). PSG assessments consist of electronic measurement of brain activity and eye and muscle movements. PSG data was scored by a Centralized PSG reading center.

- Suvorexant HD Versus Placebo: Change From Baseline in Mean Subjective Time to Sleep Onset (sTSOm) at Month 1 [Time Frame: Baseline and Month 1] [Designated as safety issue: No]

  sTSOm is the average over a defined day range of the participant's report of the duration of time that it took to fall asleep, as recorded in a daily e-diary. Averages were derived by taking the mean of all available daily measurements (excluding the mornings following any PSG nights) falling within the day range; Month 1 range is Days 23-30 (Day 1 is day of first double-blind dose). A participant must have at least 3 days of data during the defined day range to calculate an average for the day range; otherwise, the mean value was considered missing for that day range. The baseline value is the mean of the last 7 daily measurements obtained during the placebo Run-in period.

- Suvorexant HD Versus Placebo: Change From Baseline in sTSOm at Month 3 [Time Frame: Baseline and Month 3] [Designated as safety issue: No]

  sTSOm is the average over a defined day range of the participant's report of the duration of time that it took to fall asleep, as recorded in a daily e-diary. Averages were derived by taking the mean of all available daily measurements (excluding the mornings following any PSG nights) falling within the day range; Month 3 range is Days 76-90 (Day 1 is day of first double-blind dose). A participant must have at least 3 days of data during the defined day range to calculate an average for the day range; otherwise, the mean value was considered missing for that day range. The baseline value is the mean of the last 7 daily measurements obtained during the placebo Run-in period.

- Suvorexant HD Versus Placebo: Change From Baseline in Latency to Onset of Persistent Sleep (LPS) at Month 1 [Time Frame: Baseline and Month 1] [Designated as safety issue: No]

  LPS is measured during overnight sleep laboratory (PSG) assessments at baseline, Night 1, Month 1 and Month 3, and is defined as the duration of time from the beginning of PSG assessment ("Lights-Off") to the first interval of 10 consecutive minutes of sleep. Beginning of PSG assessment ("Lights-Off") is at approximately the participant's habitual bedtime. The participant is awakened, or allowed to get out of bed if already awake, after 8 hours of PSG recording ("Lights-On"). PSG assessments consist of electronic measurement of brain activity and eye and muscle movements. PSG data was scored by a Centralized PSG reading center.

- Suvorexant HD Versus Placebo: Change From Baseline in LPS at Month 3 [Time Frame: Baseline and Month 3]

[Designated as safety issue: No]

LPS is measured during overnight sleep laboratory (PSG) assessments at baseline, Night 1, Month 1 and Month 3, and is defined as the duration of time from the beginning of PSG assessment ("Lights-Off") to the first interval of 10 consecutive minutes of sleep. Beginning of PSG assessment ("Lights-Off") is at approximately the participant's habitual bedtime. The participant is awakened, or allowed to get out of bed if already awake, after 8 hours of PSG recording ("Lights-On"). PSG assessments consist of electronic measurement of brain activity and eye and muscle movements. PSG data was scored by a Centralized PSG reading center.

- Number of Participants With an Adverse Event (AE) During 3-Month DB TRT Phase [Time Frame: Up to 3 months]
  [Designated as safety issue: Yes]

  An AE is any unfavorable and unintended change in the structure, function or chemistry of the body temporally associated with study drug administration, whether or not considered related to the study drug. Participants with an AE occurring during the 3-month DB TRT Phase are counted once in this summary.

- Number of Participants Who Discontinued Study Drug Due to an AE Occurring During 3-Month DB TRT Phase [Time Frame: Up to 3 months]
  [Designated as safety issue: Yes]

  An AE is any unfavorable and unintended change in the structure, function or chemistry of the body temporally associated with study drug administration, whether or not considered related to the study drug. Participants who discontinued study drug treatment due to an AE occurring during the 3-month DB TRT Phase are counted once in this summary.

Secondary Outcome Measures:

- Suvorexant HD Versus Placebo: Change From Baseline in sTSTm at Week 1 [Time Frame: Baseline and Week 1]
  [Designated as safety issue: No]

  sTSTm is the average over a defined day range of the participant's report of the total amount of time spent asleep before waking for the day, as recorded in a daily e-diary. Averages were derived by taking the mean of all available daily measurements (excluding the mornings following any PSG nights) falling within the day range; Week 1 range is Days 2-8 (Day 1 is day of first double-blind dose). A participant must have at least 3 days of data during the defined day range to calculate an average for the day range; otherwise, the mean value was considered missing for that day range. The baseline value is the mean of the last 7 daily measurements obtained during the placebo Run-in period.

- Suvorexant HD Versus Placebo: Change From Baseline in WASO at Night 1 [Time Frame: Baseline and Night 1]
  [Designated as safety issue: No]

  WASO is measured during overnight sleep laboratory (PSG) assessments at baseline, Night 1, Month 1 and Month 3, and is defined as the duration of wakefulness from the onset of persistent sleep (i.e., 10 consecutive minutes of sleep) to the end of PSG assessment the following morning. Beginning of PSG assessment ("Lights-Off") is at approximately the participant's habitual bedtime. The participant is awakened, or allowed to get out of bed if already awake, after 8 hours of PSG recording ("Lights-On"). PSG assessments consist of electronic measurement of brain activity and eye and muscle movements. PSG data was scored by a Centralized PSG reading center.

- Suvorexant HD Versus Placebo: Change From Baseline in sTSOm at Week 1 [Time Frame: Baseline and Week 1]
  [Designated as safety issue: No]

  sTSOm is the average over a defined day range of the participant's report of the duration of time that it took to fall asleep, as recorded in a daily e-diary. Averages were derived by taking the mean of all available daily measurements (excluding the mornings following any PSG nights) falling within the day range; Week 1 range is Days 2-8 (Day 1 is day of first double-blind dose). A participant must have at least 3 days of data during the defined day range to calculate an average for the day range; otherwise, the mean value was considered missing for that day range. The baseline value is the mean of the last 7 daily measurements obtained during the placebo Run-in period.

- Suvorexant HD Versus Placebo: Change From Baseline in LPS at Night 1 [Time Frame: Baseline and Night 1]
  [Designated as safety issue: No]

  LPS is measured during overnight sleep laboratory (PSG) assessments at baseline, Night 1, Month 1 and Month 3, and is defined as the duration of time from the beginning of PSG assessment ("Lights-Off") to the first interval of 10 consecutive minutes of sleep. Beginning of PSG assessment ("Lights-Off") is at approximately the participant's habitual bedtime. The participant is awakened, or allowed to get out of bed if already awake, after 8 hours of PSG recording ("Lights-On"). PSG assessments consist of electronic measurement of brain activity and eye and muscle movements. PSG data was scored by a Centralized PSG reading center.

Enrollment:	1020
Study Start Date:	May 2010
Study Completion Date:	November 2011
Primary Completion Date:	November 2011 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Suvorexant HD Drug	Drug: Suvorexant High Dose (HD) Suvorexant 40 mg + placebo matching suvorexant 20 mg for participants <65 years old; Suvorexant 30 mg + placebo matching suvorexant 15 mg for participants ≥65 years old; all study drug is tablet for oral administration, taken once daily at bedtime. Participants receive this dose during the 3-month Treatment (TRT) Phase. During the 1-week double-blind (DB) Run-out (RO) following the TRT phase, participants in this study arm receive the noted suvorexant dose or placebo, in a 1:1 ratio. During the 2-week single-blind Run-in period prior to randomization all participants receive placebo to suvorexant once daily at bedtime. Other Name: MK-4305
Experimental: Suvorexant LD Drug	Drug: Suvorexant Low Dose (LD) Suvorexant 20 mg + placebo matching suvorexant 40 mg for participants <65 years old; Suvorexant 15 mg + placebo matching suvorexant 30 mg for participants ≥65 years old; all study drug is tablet for oral administration, taken once daily at bedtime. Participants receive this dose during the 3-month TRT Phase. During the 1-week DB RO following the TRT phase, participants in this study arm receive the noted suvorexant dose or placebo, in a 1:1 ratio. During the 2-week single-blind Run-in period prior to randomization all participants receive placebo to suvorexant once daily at bedtime. Other Name: MK-4305
Placebo Comparator: Placebo Placebo Comparator	Drug: Comparator: Placebo Matching placebos to suvorexant 40 mg and 20 mg for participants <65 years old; matching placebos to suvorexant 30 mg and 15 mg for participants ≥65 years old; all study drug is tablet for oral administration, taken once daily at bedtime. Placebo is a third treatment arm for comparison to the two active (suvorexant) treatment arms during the 3-month TRT Phase. During the 1-week DB RO following the TRT phase, participants in this study arm continue to receive placebo. During the 2-week single-blind Run-in period prior to randomization all participants receive placebo to suvorexant once daily at bedtime.

Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Must be ≥18 yrs old on the day of signing informed consent
- Diagnosed with Primary Insomnia
- Good physical and mental health
- Participant ≥65 yrs old score at least 25 on the Mini Mental State Examination
- A female participant who is of reproductive potential has a negative serum pregnancy test and agrees to use contraception
- Reports difficulty with initiating and maintaining sleep during the 4 weeks prior to Visit 1 (accordingly to specific protocol criteria)
- Reports spending 6.5 to 9 hours nightly in bed on at least 3 out of 7 nights prior to Visit 1
- Regular bedtime is between 9 pm-1 am
- Willing to refrain from napping while in study
- Able to read, understand and complete questionnaires and all diaries
- Willing to limit alcohol, caffeine, and nicotine consumption while in the study
- For a portion of participants: Must be willing to stay overnight in a sleep laboratory and must be willing to stay in bed for at least 8 hours each night while at the sleep laboratory

Exclusion Criteria:

- Female participant is pregnant and/or breastfeeding at Prestudy visit, or expecting to conceive while in study
- History or diagnosis of another sleep disorder
- Difficulty sleeping due to a medical condition
- History of a neurological disorder
- History of bipolar disorder, psychotic disorder, or posttraumatic stress disorder, or current psychiatric disorder that requires a prohibited medication
- Ongoing depression

- History of substance abuse or dependence
- History or current evidence of a clinically significant cardiovascular disorder or clinically significant electrocardiogram (ECG) at Prestudy Visit
- Taking certain prohibited medications
- Consumption of the equivalent of >15 cigarettes a day
- History of malignancy ≤5 years prior to signing informed consent, except for adequately treated basal cell or squamous cell skin cancer or in situ cervical cancer
- Participant is considered morbidly obese
- Previously randomized in another investigational study of suvorexant

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT01097629

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

Investigators

Study Director: Medical Monitor Merck Sharp & Dohme Corp.

More Information

Publications:

Herring WJ, Connor KM, Ivgy-May N, Snyder E, Liu K, Snavely DB, Krystal AD, Walsh JK, Benca RM, Rosenberg R, Sangal RB, Budd K, Hutzelmann J, Leibensperger H, Froman S, Lines C, Roth T, Michelson D. Suvorexant in Patients With Insomnia: Results From Two 3-Month Randomized Controlled Clinical Trials. Biol Psychiatry. 2016 Jan 15;79(2):136-48. doi: 10.1016/j.biopsych.2014.10.003. Epub 2014 Oct 23.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT01097629 History of Changes
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Study First Received:	March 26, 2010
Results First Received:	August 19, 2014
Last Updated:	February 26, 2016
Health Authority:	United States: Food and Drug Administration

Additional relevant MeSH terms:

Sleep Initiation and Maintenance Disorders	Nervous System Diseases
Dyssomnias	Sleep Disorders
Mental Disorders	Sleep Disorders, Intrinsic

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First received: March 26, 2010
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History of Changes

Results First Received: August 19, 2014

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Primary Insomnia
Interventions:	Drug: Suvorexant High Dose (HD) Drug: Suvorexant Low Dose (LD) Drug: Comparator: Placebo

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
A 2-week single-blind placebo Run-in occurred prior to randomization. 1 of the 1020 randomized participants enrolled in 2 separate suvorexant trials and is excluded from all summaries and analyses. 10 other randomized participants were not treated and are in Participant Flow Table below, but are excluded from all other summaries and analyses.

Reporting Groups

	Description
Suvorexant Low Dose (LD) (TRT Phase)	After a 2-week single-blind placebo Run-in, participants received suvorexant LD (20 mg for participants aged 18 to <65 years; and 15 mg for participants aged ≥65 years) daily before bedtime during the 3-month DB TRT Phase.
Suvorexant High Dose (HD) (TRT Phase)	After a 2-week single-blind placebo Run-in, participants received suvorexant HD (40 mg for participants aged 18 to <65 years; and 30 mg for participants aged ≥65 years) daily before bedtime during the 3-month DB TRT Phase.
Placebo (TRT Phase)	After a 2-week single-blind placebo Run-in, participants received placebo to suvorexant daily before bedtime during the 3-month double-blind DB TRT Phase.
Suvorexant LD (Run-out [RO], After Suvorexant LD in TRT)	After receiving suvorexant LD during the 3-Month DB TRT Phase, participants received their same dose of suvorexant during a 1-week DB RO Phase.
Placebo (RO, After Suvorexant LD in TRT)	After receiving suvorexant LD during the 3-Month DB TRT Phase, participants received placebo to suvorexant during a 1-week DB RO Phase.
Suvorexant HD (RO, After Suvorexant HD in TRT)	After receiving suvorexant HD during the 3-Month DB TRT Phase, participants received their same dose of suvorexant during a 1-week DB RO Phase.
Placebo (RO, After Suvorexant HD in TRT)	After receiving suvorexant HD during the 3-Month DB TRT Phase, participants received placebo to suvorexant during a 1-week DB RO Phase.

Placebo (RO, After Placebo in TRT)	After receiving placebo to suvorexant during the 3-Month DB TRT Phase, participants received placebo to suvorexant during a 1-week DB RO Phase.

Participant Flow for 2 periods

Period 1: Double-Blind (DB) Treatment (TRT) Phase

	Suvorexant Low Dose (LD) (TRT Phase)	Suvorexant High Dose (HD) (TRT Phase)	Placebo (TRT Phase)	Suvorexant LD (Run-out [RO], After Suvorexant LD in TRT)	Placebo (RO, After Suvorexant LD in TRT)	Suvorexant HD (RO, After Suvorexant HD in TRT)	Placebo (RO, After Suvorexant HD in TRT)	Placebo (RO, After Placebo in TRT)
STARTED	240	392	387	0	0	0	0	0
Treated	239	387	383	0	0	0	0	0
COMPLETED	205	346 [1]	330 [2]	0	0	0	0	0
NOT COMPLETED	35	46	57	0	0	0	0	0
Adverse Event	10	19	17	0	0	0	0	0
Withdrawal by Subject	8	9	19	0	0	0	0	0
Protocol Violation	5	4	8	0	0	0	0	0
Lost to Follow-up	2	4	1	0	0	0	0	0
Lack of Efficacy	7	4	8	0	0	0	0	0
Physician Decision	2	1	0	0	0	0	0	0
Not Treated	1	5	4	0	0	0	0	0

[1] 2 did not continue into RO
[2] 3 did not continue into RO

Period 2: DB RO Phase

	Suvorexant Low Dose (LD) (TRT Phase)	Suvorexant High Dose (HD) (TRT Phase)	Placebo (TRT Phase)	Suvorexant LD (Run-out [RO], After Suvorexant LD in TRT)	Placebo (RO, After Suvorexant LD in TRT)	Suvorexant HD (RO, After Suvorexant HD in TRT)	Placebo (RO, After Suvorexant HD in TRT)	Placebo (RO, After Placebo in TRT)
STARTED	0	0	0	97	108	173	171	327
COMPLETED	0	0	0	96	108	172	168	326
NOT COMPLETED	0	0	0	1	0	1	3	1
Withdrawal by Subject	0	0	0	0	0	0	0	1
Protocol Violation	0	0	0	1	0	1	1	0
Lost to Follow-up	0	0	0	0	0	0	2	0

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Suvorexant LD	After a 2-week single-blind placebo Run-in, participants received suvorexant LD (20 mg for participants aged 18 to <65 years; and 15 mg for participants aged ≥65 years) daily before bedtime during the 3-month DB TRT Phase.
Suvorexant HD	After a 2-week single-blind placebo Run-in, participants received suvorexant HD (40 mg for participants aged 18 to <65 years; and 30 mg for participants aged ≥65 years) daily before bedtime during the 3-month DB TRT Phase.

Placebo	After a 2-week single-blind placebo Run-in, participants received placebo to suvorexant daily before bedtime during the 3-month double-blind DB TRT Phase.
Total	Total of all reporting groups

Baseline Measures

	Suvorexant LD	Suvorexant HD	Placebo	Total
Number of Participants [units: participants]	239	387	383	1009
Age [units: years] Mean (Standard Deviation)	56 (16)	57 (15)	57 (15)	56 (15)
Gender [units: participants]				
Female	157	267	247	671
Male	82	120	136	338
Mean Subjective Total Sleep Time (sTSTm) [1] [units: minutes] Mean (Standard Deviation)	298.3 (81.9)	315.3 (77.0)	309.7 (77.1)	309.2 (78.4)
Wakefulness After Persistent Sleep Onset (WASO) [2] [units: minutes] Mean (Standard Deviation)	119.6 (50.8)	119.4 (51.3)	118.4 (49.1)	119.0 (50.3)
Mean Subjective Time to Sleep Onset (sTSOm) [1] [units: minutes] Mean (Standard Deviation)	86.0 (77.6)	74.4 (61.9)	81.3 (76.2)	79.8 (71.5)
Latency to Onset of Persistent Sleep (LPS) [3] [units: minutes] Mean (Standard Deviation)	65.3 (47.8)	67.3 (48.8)	68.0 (42.8)	67.2 (46.2)

[1] N=238, 386, 383, 1007 for Suvorexant Low Dose, Suvorexant High Dose, Placebo and Total, respectively.
[2] N=150, 299, 295, 744 for Suvorexant Low Dose, Suvorexant High Dose, Placebo and Total, respectively. WASO was assessed during sleep laboratory (polysomnography [PSG]) assessment, which was conducted in a subset of the study population.
[3] N=150, 299, 295, 744 for Suvorexant Low Dose, Suvorexant High Dose, Placebo and Total, respectively. LPS was assessed during sleep laboratory (PSG) assessment, which was conducted in a subset of the study population.

Outcome Measures

Hide All Outcome Measures

1. Primary: Suvorexant HD Versus Placebo: Change From Baseline in Mean Subjective Total Sleep Time (sTSTm) at Month 1 [Time Frame: Baseline and Month 1]

Measure Type	Primary
Measure Title	Suvorexant HD Versus Placebo: Change From Baseline in Mean Subjective Total Sleep Time (sTSTm) at Month 1
Measure Description	sTSTm is the average over a defined day range of the participant's report of the total amount of time spent asleep before waking for the day, as recorded in a daily electronic diary (e-diary). Averages were derived by taking the mean of all available daily measurements (excluding the mornings following any polysomnography [PSG] nights) falling within the day range; Month 1 range is Days 23-30 (Day 1 is day of first double-blind dose). A participant must have at least 3 days of data during the defined day range to calculate an average for the day range; otherwise, the mean value was considered missing for that day range. The baseline value is the mean of the last 7 daily measurements obtained during the placebo Run-in period.
Time Frame	Baseline and Month 1
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Randomized participants with ≥1 post-randomization e-diary observation after ≥1 dose of study drug, and baseline data were included in this analysis. The hypothesis included only the suvorexant HD-placebo comparison.

Reporting Groups

	Description
Suvorexant HD	After a 2-week single-blind placebo Run-in, participants received suvorexant HD (40 mg for participants aged 18 to <65 years; and 30 mg for participants aged ≥65 years) daily before bedtime during the 3-month DB TRT Phase.
Placebo	After a 2-week single-blind placebo Run-in, participants received placebo to suvorexant daily before bedtime during the 3-month double-blind DB TRT Phase.

Measured Values

	Suvorexant HD	Placebo

Number of Participants Analyzed [units: participants]	**365**	**350**
Suvorexant HD Versus Placebo: Change From Baseline in Mean Subjective Total Sleep Time (sTSTm) at Month 1 [units: minutes] Least Squares Mean (95% Confidence Interval)	**48.7 (43.1 to 54.3)**	**22.4 (16.7 to 28.1)**

Statistical Analysis 1 for Suvorexant HD Versus Placebo: Change From Baseline in Mean Subjective Total Sleep Time (sTSTm) at Month 1

Groups [1]	All groups
Method [2]	Longitudinal Data Analysis
P Value [3]	<0.00001
Difference in Least Squares Means [4]	26.3
95% Confidence Interval	18.3 to 34.3

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The null hypothesis, that suvorexant HD did not differ from placebo for Month 1 sTSTm, had planned marginal power of 97.6%. Sleep maintenance (sTSTm, WASO) and sleep onset (sTSOm, LPS) endpoints were tested at two-sided 2.5% significance level. Both Month 1 endpoints for sleep maintenance must be significant to test Month 3 endpoints; the same approach was used for sleep onset endpoints.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Model terms: baseline value, age group, region, gender, treatment, time, time by treatment interaction, and cohort (e-diary only, PSG-plus-e-diary).
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	By multiplicity strategy above, overall Type I error among primary hypotheses was controlled at two-sided 5% significance level.
[4]	Other relevant estimation information:
	No text entered.

2. Primary: Suvorexant HD Versus Placebo: Change From Baseline in sTSTm at Month 3 [Time Frame: Baseline and Month 3]

Measure Type	Primary
Measure Title	Suvorexant HD Versus Placebo: Change From Baseline in sTSTm at Month 3
Measure Description	sTSTm is the average over a defined day range of the participant's report of the total amount of time spent asleep before waking for the day, as recorded in a daily e-diary. Averages were derived by taking the mean of all available daily measurements (excluding the mornings following any PSG nights) falling within the day range; Month 3 range is Days 76-90 (Day 1 is day of first double-blind dose). A participant must have at least 3 days of data during the defined day range to calculate an average for the day range; otherwise, the mean value was considered missing for that day range. The baseline value is the mean of the last 7 daily measurements obtained during the placebo Run-in period.
Time Frame	Baseline and Month 3
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Randomized participants with ≥1 post-randomization e-diary observation after ≥1 dose of study drug, and baseline data were included in this analysis. The hypothesis included only the suvorexant HD-placebo comparison.

Reporting Groups

	Description
Suvorexant HD	After a 2-week single-blind placebo Run-in, participants received suvorexant HD (40 mg for participants aged 18 to <65 years; and 30 mg for participants aged ≥65 years) daily before bedtime during the 3-month DB TRT Phase.
Placebo	After a 2-week single-blind placebo Run-in, participants received placebo to suvorexant daily before bedtime during the 3-month double-blind DB TRT Phase.

Measured Values

	Suvorexant HD	**Placebo**
Number of Participants Analyzed [units: participants]	**340**	**325**
Suvorexant HD Versus Placebo: Change From Baseline in sTSTm at Month 3 [units: minutes]	**62.8 (56.4 to 69.2)**	**37.7 (31.2 to 44.2)**

Least Squares Mean (95% Confidence Interval)		

Statistical Analysis 1 for Suvorexant HD Versus Placebo: Change From Baseline in sTSTm at Month 3

Groups [1]	All groups
Method [2]	Longitudinal Data Analysis
P Value [3]	<0.00001
Difference in Least Squares Means [4]	25.1
95% Confidence Interval	16.0 to 34.2

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The null hypothesis, that suvorexant HD did not differ from placebo for Month 3 sTSTm, had planned marginal power of 95.7%. Sleep maintenance (sTSTm, WASO) and sleep onset (sTSOm, LPS) endpoints were tested at two-sided 2.5% significance level. Both Month 1 endpoints for sleep maintenance must be significant to test Month 3 endpoints; the same approach was used for sleep onset endpoints.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Model terms: baseline value, age group, region, gender, treatment, time, time by treatment interaction, and cohort (e-diary only, PSG-plus-e-diary).
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	By multiplicity strategy above, overall Type I error among primary hypotheses was controlled at two-sided 5% significance level.
[4]	Other relevant estimation information:
	No text entered.

3. Primary: Suvorexant HD Versus Placebo: Change From Baseline in Wakefulness After Persistent Sleep Onset (WASO) at Month 1 [Time Frame: Baseline and Month 1]

Measure Type	Primary
Measure Title	Suvorexant HD Versus Placebo: Change From Baseline in Wakefulness After Persistent Sleep Onset (WASO) at Month 1
Measure Description	WASO is measured during overnight sleep laboratory (PSG) assessments at baseline, Night 1, Month 1 and Month 3, and is defined as the duration of wakefulness from the onset of persistent sleep (i.e., 10 consecutive minutes of sleep) to the end of PSG assessment the following morning. Beginning of PSG assessment ("Lights-Off") is at approximately the participant's habitual bedtime. The participant is awakened, or allowed to get out of bed if already awake, after 8 hours of PSG recording ("Lights-On"). PSG assessments consist of electronic measurement of brain activity and eye and muscle movements. PSG data was scored by a Centralized PSG reading center.
Time Frame	Baseline and Month 1
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Randomized participants with ≥1 post-randomization PSG observation after ≥1 dose of study drug, and baseline data were included in this analysis. The hypothesis included only the suvorexant HD-placebo comparison.

Reporting Groups

	Description
Suvorexant HD	After a 2-week single-blind placebo Run-in, participants received suvorexant HD (40 mg for participants aged 18 to <65 years; and 30 mg for participants aged ≥65 years) daily before bedtime during the 3-month DB TRT Phase.
Placebo	After a 2-week single-blind placebo Run-in, participants received placebo to suvorexant daily before bedtime during the 3-month double-blind DB TRT Phase.

Measured Values

	Suvorexant HD	**Placebo**
Number of Participants Analyzed [units: participants]	**278**	**270**
Suvorexant HD Versus Placebo: Change From Baseline in Wakefulness After Persistent Sleep Onset (WASO) at Month 1 [units: minutes] Least Squares Mean (95% Confidence Interval)	**-51.9 (-56.9 to -46.9)**	**-22.5 (-27.5 to -17.4)**

Statistical Analysis 1 for Suvorexant HD Versus Placebo: Change From Baseline in Wakefulness After Persistent Sleep Onset (WASO) at Month 1

Groups [1]	All groups
Method [2]	Longitudinal Data Analysis

P Value [3]	<0.00001
Difference in Least Squares Means [4]	-29.4
95% Confidence Interval	-36.6 to -22.3

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The null hypothesis, that suvorexant HD did not differ from placebo for Month 1 WASO, had planned marginal power of 99.2%. Sleep maintenance (sTSTm, WASO) and sleep onset (sTSOm, LPS) endpoints were tested at two-sided 2.5% significance level. Both Month 1 endpoints for sleep maintenance must be significant to test Month 3 endpoints; the same approach was used for sleep onset endpoints.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Model terms: baseline value, age group, region, gender, treatment, time, and time by treatment interaction.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	By multiplicity strategy above, overall Type I error among primary hypotheses was controlled at two-sided 5% significance level.
[4]	Other relevant estimation information:
	No text entered.

4. Primary: Suvorexant HD Versus Placebo: Change From Baseline in WASO at Month 3 [Time Frame: Baseline and Month 3]

Measure Type	Primary
Measure Title	Suvorexant HD Versus Placebo: Change From Baseline in WASO at Month 3
Measure Description	WASO is measured during overnight sleep laboratory (PSG) assessments at baseline, Night 1, Month 1 and Month 3, and is defined as the duration of wakefulness from the onset of persistent sleep (i.e., 10 consecutive minutes of sleep) to the end of PSG assessment the following morning. Beginning of PSG assessment ("Lights-Off") is at approximately the participant's habitual bedtime. The participant is awakened, or allowed to get out of bed if already awake, after 8 hours of PSG recording ("Lights-On"). PSG assessments consist of electronic measurement of brain activity and eye and muscle movements. PSG data was scored by a Centralized PSG reading center.
Time Frame	Baseline and Month 3
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Randomized participants with ≥1 post-randomization PSG observation after ≥1 dose of study drug, and baseline data were included in this analysis. The hypothesis included only the suvorexant HD-placebo comparison.

Reporting Groups

	Description
Suvorexant HD	After a 2-week single-blind placebo Run-in, participants received suvorexant HD (40 mg for participants aged 18 to <65 years; and 30 mg for participants aged ≥65 years) daily before bedtime during the 3-month DB TRT Phase.
Placebo	After a 2-week single-blind placebo Run-in, participants received placebo to suvorexant daily before bedtime during the 3-month double-blind DB TRT Phase.

Measured Values

	Suvorexant HD	**Placebo**
Number of Participants Analyzed [units: participants]	**260**	**252**
Suvorexant HD Versus Placebo: Change From Baseline in WASO at Month 3 [units: minutes] Least Squares Mean (95% Confidence Interval)	**-54.2 (-59.3 to -49.1)**	**-24.8 (-30.0 to -19.6)**

Statistical Analysis 1 for Suvorexant HD Versus Placebo: Change From Baseline in WASO at Month 3

Groups [1]	All groups
Method [2]	Longitudinal Data Analysis
P Value [3]	<0.00001
Difference in Least Squares Means [4]	-29.4
95% Confidence Interval	-36.7 to -22.1

[1]	Additional details about the analysis, such as null hypothesis and power calculation:

	The null hypothesis, that suvorexant HD did not differ from placebo for Month 3 WASO, had planned marginal power of 98.3%. Sleep maintenance (sTSTm, WASO) and sleep onset (sTSOm, LPS) endpoints were tested at two-sided 2.5% significance level. Both Month 1 endpoints for sleep maintenance must be significant to test Month 3 endpoints; the same approach was used for sleep onset endpoints.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Model terms: baseline value, age group, region, gender, treatment, time, and time by treatment interaction.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	By multiplicity strategy above, overall Type I error among primary hypotheses was controlled at two-sided 5% significance level.
[4]	Other relevant estimation information:
	No text entered.

5. Primary: Suvorexant HD Versus Placebo: Change From Baseline in Mean Subjective Time to Sleep Onset (sTSOm) at Month 1 [Time Frame: Baseline and Month 1]

Measure Type	Primary
Measure Title	Suvorexant HD Versus Placebo: Change From Baseline in Mean Subjective Time to Sleep Onset (sTSOm) at Month 1
Measure Description	sTSOm is the average over a defined day range of the participant's report of the duration of time that it took to fall asleep, as recorded in a daily e-diary. Averages were derived by taking the mean of all available daily measurements (excluding the mornings following any PSG nights) falling within the day range; Month 1 range is Days 23-30 (Day 1 is day of first double-blind dose). A participant must have at least 3 days of data during the defined day range to calculate an average for the day range; otherwise, the mean value was considered missing for that day range. The baseline value is the mean of the last 7 daily measurements obtained during the placebo Run-in period.
Time Frame	Baseline and Month 1
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Randomized participants with ≥1 post-randomization e-diary observation after ≥1 dose of study drug, and baseline data were included in this analysis. The hypothesis included only the suvorexant HD-placebo comparison.

Reporting Groups

	Description
Suvorexant HD	After a 2-week single-blind placebo Run-in, participants received suvorexant HD (40 mg for participants aged 18 to <65 years; and 30 mg for participants aged ≥65 years) daily before bedtime during the 3-month DB TRT Phase.
Placebo	After a 2-week single-blind placebo Run-in, participants received placebo to suvorexant daily before bedtime during the 3-month double-blind DB TRT Phase.

Measured Values

	Suvorexant HD	**Placebo**
Number of Participants Analyzed [units: participants]	**365**	**350**
Suvorexant HD Versus Placebo: Change From Baseline in Mean Subjective Time to Sleep Onset (sTSOm) at Month 1 [units: minutes] Least Squares Mean (95% Confidence Interval)	**-26.9 (-31.1 to -22.8)**	**-14.1 (-18.4 to -9.9)**

Statistical Analysis 1 for Suvorexant HD Versus Placebo: Change From Baseline in Mean Subjective Time to Sleep Onset (sTSOm) at Month 1

Groups [1]	All groups
Method [2]	Longitudinal Data Analysis
P Value [3]	0.00003
Difference in Least Squares Means [4]	-12.8
95% Confidence Interval	-18.8 to -6.9

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The null hypothesis, that suvorexant HD did not differ from placebo for Month 1 sTSOm, had planned marginal power of 99.9%. Sleep maintenance (sTSTm, WASO) and sleep onset (sTSOm, LPS) endpoints were tested at two-sided 2.5% significance level. Both Month 1 endpoints for sleep maintenance must be significant to test Month 3 endpoints; the same approach was used for sleep onset endpoints.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Model terms: baseline value, age group, region, gender, treatment, time, time by treatment interaction, and cohort (e-diary only, PSG-plus-e-diary).
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	By multiplicity strategy above, overall Type I error among primary hypotheses was controlled at two-sided 5% significance level.

[4]	Other relevant estimation information:
	No text entered.

6. Primary: Suvorexant HD Versus Placebo: Change From Baseline in sTSOm at Month 3 [Time Frame: Baseline and Month 3]

Measure Type	Primary
Measure Title	Suvorexant HD Versus Placebo: Change From Baseline in sTSOm at Month 3
Measure Description	sTSOm is the average over a defined day range of the participant's report of the duration of time that it took to fall asleep, as recorded in a daily e-diary. Averages were derived by taking the mean of all available daily measurements (excluding the mornings following any PSG nights) falling within the day range; Month 3 range is Days 76-90 (Day 1 is day of first double-blind dose). A participant must have at least 3 days of data during the defined day range to calculate an average for the day range; otherwise, the mean value was considered missing for that day range. The baseline value is the mean of the last 7 daily measurements obtained during the placebo Run-in period.
Time Frame	Baseline and Month 3
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Randomized participants with ≥1 post-randomization e-diary observation after ≥1 dose of study drug, and baseline data were included in this analysis. The hypothesis included only the suvorexant HD-placebo comparison.

Reporting Groups

	Description
Suvorexant HD	After a 2-week single-blind placebo Run-in, participants received suvorexant HD (40 mg for participants aged 18 to <65 years; and 30 mg for participants aged ≥65 years) daily before bedtime during the 3-month DB TRT Phase.
Placebo	After a 2-week single-blind placebo Run-in, participants received placebo to suvorexant daily before bedtime during the 3-month double-blind DB TRT Phase.

Measured Values

	Suvorexant HD	**Placebo**
Number of Participants Analyzed [units: participants]	**340**	**325**
Suvorexant HD Versus Placebo: Change From Baseline in sTSOm at Month 3 [units: minutes] Least Squares Mean (95% Confidence Interval)	**-33.7 (-38.0 to -29.3)**	**-20.5 (-24.9 to -16.1)**

Statistical Analysis 1 for Suvorexant HD Versus Placebo: Change From Baseline in sTSOm at Month 3

Groups [1]	All groups
Method [2]	Longitudinal Data Analysis
P Value [3]	0.00003
Difference in Least Squares Means [4]	-13.2
95% Confidence Interval	-19.4 to -7.0

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The null hypothesis, that suvorexant HD did not differ from placebo for Month 3 sTSOm, had planned marginal power of 99.6%. Sleep maintenance (sTSTm, WASO) and sleep onset (sTSOm, LPS) endpoints were tested at two-sided 2.5% significance level. Both Month 1 endpoints for sleep maintenance must be significant to test Month 3 endpoints; the same approach was used for sleep onset endpoints.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Model terms: baseline value, age group, region, gender, treatment, time, time by treatment interaction, and cohort (e-diary only, PSG-plus-e-diary).
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	By multiplicity strategy above, overall Type I error among primary hypotheses was controlled at two-sided 5% significance level.
[4]	Other relevant estimation information:
	No text entered.

7. Primary: Suvorexant HD Versus Placebo: Change From Baseline in Latency to Onset of Persistent Sleep (LPS) at Month 1 [Time Frame: Baseline and Month 1]

Measure Type	Primary
Measure Title	Suvorexant HD Versus Placebo: Change From Baseline in Latency to Onset of Persistent Sleep (LPS) at Month 1
Measure Description	LPS is measured during overnight sleep laboratory (PSG) assessments at baseline, Night 1, Month 1 and Month 3, and is defined as the duration of time from the beginning of PSG assessment ("Lights-Off") to the first interval of 10 consecutive minutes of sleep. Beginning of PSG assessment ("Lights-Off") is at approximately the participant's habitual bedtime. The participant is awakened, or allowed to get out of bed if already awake, after 8 hours of PSG recording ("Lights-On"). PSG assessments consist of electronic measurement of brain activity and eye and muscle movements. PSG data was scored by a Centralized PSG reading center.
Time Frame	Baseline and Month 1
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Randomized participants with ≥1 post-randomization PSG observation after ≥1 dose of study drug, and baseline data were included in this analysis. The hypothesis included only the suvorexant HD-placebo comparison.

Reporting Groups

	Description
Suvorexant HD	After a 2-week single-blind placebo Run-in, participants received suvorexant HD (40 mg for participants aged 18 to <65 years; and 30 mg for participants aged ≥65 years) daily before bedtime during the 3-month DB TRT Phase.
Placebo	After a 2-week single-blind placebo Run-in, participants received placebo to suvorexant daily before bedtime during the 3-month double-blind DB TRT Phase.

Measured Values

	Suvorexant HD	**Placebo**
Number of Participants Analyzed [units: participants]	**280**	**271**
Suvorexant HD Versus Placebo: Change From Baseline in Latency to Onset of Persistent Sleep (LPS) at Month 1 [units: minutes] Least Squares Mean (95% Confidence Interval)	**-36.7 (-40.8 to -32.7)**	**-24.6 (-28.7 to -20.6)**

Statistical Analysis 1 for Suvorexant HD Versus Placebo: Change From Baseline in Latency to Onset of Persistent Sleep (LPS) at Month 1

Groups [1]	All groups
Method [2]	Longitudinal Data Analysis
P Value [3]	0.00004
Difference in Least Squares Means [4]	-12.1
95% Confidence Interval	-17.8 to -6.4

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The null hypothesis, that suvorexant HD did not differ from placebo for Month 1 LPS, had planned marginal power of 81.4%. Sleep maintenance (sTSTm, WASO) and sleep onset (sTSOm, LPS) endpoints were tested at two-sided 2.5% significance level. Both Month 1 endpoints for sleep maintenance must be significant to test Month 3 endpoints; the same approach was used for sleep onset endpoints.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Model terms: baseline value, age group, region, gender, treatment, time, and time by treatment interaction.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	By multiplicity strategy above, overall Type I error among primary hypotheses was controlled at two-sided 5% significance level.
[4]	Other relevant estimation information:
	No text entered.

8. Primary: Suvorexant HD Versus Placebo: Change From Baseline in LPS at Month 3 [Time Frame: Baseline and Month 3]

Measure Type	Primary
Measure Title	Suvorexant HD Versus Placebo: Change From Baseline in LPS at Month 3
Measure Description	LPS is measured during overnight sleep laboratory (PSG) assessments at baseline, Night 1, Month 1 and Month 3, and is defined as the duration of time from the beginning of PSG assessment ("Lights-Off") to the first interval of 10 consecutive minutes of sleep. Beginning of PSG assessment ("Lights-Off") is at approximately the participant's habitual bedtime. The participant is awakened, or allowed to get out of bed if already awake, after 8 hours of PSG recording ("Lights-On"). PSG assessments consist of electronic measurement of brain activity and eye and muscle movements. PSG data was scored by a Centralized PSG reading center.
Time Frame	Baseline and Month 3

Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Randomized participants with ≥1 post-randomization PSG observation after ≥1 dose of study drug, and baseline data were included in this analysis. The hypothesis included only the suvorexant HD-placebo comparison.

Reporting Groups

	Description
Suvorexant HD	After a 2-week single-blind placebo Run-in, participants received suvorexant HD (40 mg for participants aged 18 to <65 years; and 30 mg for participants aged ≥65 years) daily before bedtime during the 3-month DB TRT Phase.
Placebo	After a 2-week single-blind placebo Run-in, participants received placebo to suvorexant daily before bedtime during the 3-month double-blind DB TRT Phase.

Measured Values

	Suvorexant HD	**Placebo**
Number of Participants Analyzed [units: participants]	**262**	**255**
Suvorexant HD Versus Placebo: Change From Baseline in LPS at Month 3 [units: minutes] Least Squares Mean (95% Confidence Interval)	**-32.2 (-36.7 to -27.7)**	**-28.6 (-33.1 to -24.0)**

Statistical Analysis 1 for Suvorexant HD Versus Placebo: Change From Baseline in LPS at Month 3

Groups [1]	All groups
Method [2]	Longitudinal Data Analysis
P Value [3]	0.26510
Difference in Least Squares Means [4]	-3.6
95% Confidence Interval	-10.1 to 2.8

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The null hypothesis, that suvorexant HD did not differ from placebo for Month 3 LPS, had planned marginal power of 76.2%. Sleep maintenance (sTSTm, WASO) and sleep onset (sTSOm, LPS) endpoints were tested at two-sided 2.5% significance level. Both Month 1 endpoints for sleep maintenance must be significant to test Month 3 endpoints; the same approach was used for sleep onset endpoints.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Model terms: baseline value, age group, region, gender, treatment, time, and time by treatment interaction.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	By multiplicity strategy above, overall Type I error among primary hypotheses was controlled at two-sided 5% significance level.
[4]	Other relevant estimation information:
	No text entered.

9. Primary: Number of Participants With an Adverse Event (AE) During 3-Month DB TRT Phase [Time Frame: Up to 3 months]

Measure Type	Primary
Measure Title	Number of Participants With an Adverse Event (AE) During 3-Month DB TRT Phase
Measure Description	An AE is any unfavorable and unintended change in the structure, function or chemistry of the body temporally associated with study drug administration, whether or not considered related to the study drug. Participants with an AE occurring during the 3-month DB TRT Phase are counted once in this summary.
Time Frame	Up to 3 months
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All Patients as Treated (APaT) population, consisting of all randomized participants who received at least one dose of study medication

Reporting Groups

	Description
Suvorexant LD	After a 2-week single-blind placebo Run-in, participants received suvorexant LD (20 mg for participants aged 18 to <65 years; and 15 mg for participants aged ≥65 years) daily before bedtime during the 3-month DB TRT Phase.
Suvorexant HD	After a 2-week single-blind placebo Run-in, participants received suvorexant HD (40 mg for participants aged 18 to <65 years; and 30 mg for participants aged ≥65 years) daily before bedtime during the 3-month DB TRT Phase.
Placebo	After a 2-week single-blind placebo Run-in, participants received placebo to suvorexant daily before bedtime during the 3-month double-blind DB TRT Phase.

Measured Values

	Suvorexant LD	Suvorexant HD	Placebo
Number of Participants Analyzed [units: participants]	**239**	**387**	**383**
Number of Participants With an Adverse Event (AE) During 3-Month DB TRT Phase [units: participants]	**103**	**189**	**167**

No statistical analysis provided for Number of Participants With an Adverse Event (AE) During 3-Month DB TRT Phase

10. Primary: Number of Participants Who Discontinued Study Drug Due to an AE Occurring During 3-Month DB TRT Phase [Time Frame: Up to 3 months]

Measure Type	Primary
Measure Title	Number of Participants Who Discontinued Study Drug Due to an AE Occurring During 3-Month DB TRT Phase
Measure Description	An AE is any unfavorable and unintended change in the structure, function or chemistry of the body temporally associated with study drug administration, whether or not considered related to the study drug. Participants who discontinued study drug treatment due to an AE occurring during the 3-month DB TRT Phase are counted once in this summary.
Time Frame	Up to 3 months
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All Patients as Treated (APaT) population, consisting of all randomized participants who received at least one dose of study medication

Reporting Groups

	Description
Suvorexant LD	After a 2-week single-blind placebo Run-in, participants received suvorexant LD (20 mg for participants aged 18 to <65 years; and 15 mg for participants aged ≥65 years) daily before bedtime during the 3-month DB TRT Phase.
Suvorexant HD	After a 2-week single-blind placebo Run-in, participants received suvorexant HD (40 mg for participants aged 18 to <65 years; and 30 mg for participants aged ≥65 years) daily before bedtime during the 3-month DB TRT Phase.
Placebo	After a 2-week single-blind placebo Run-in, participants received placebo to suvorexant daily before bedtime during the 3-month double-blind DB TRT Phase.

Measured Values

	Suvorexant LD	Suvorexant HD	Placebo
Number of Participants Analyzed [units: participants]	**239**	**387**	**383**
Number of Participants Who Discontinued Study Drug Due to an AE Occurring During 3-Month DB TRT Phase [units: participants]	**9**	**18**	**17**

No statistical analysis provided for Number of Participants Who Discontinued Study Drug Due to an AE Occurring During 3-Month DB TRT Phase

11. Secondary: Suvorexant HD Versus Placebo: Change From Baseline in sTSTm at Week 1 [Time Frame: Baseline and Week 1]

Measure Type	Secondary
Measure Title	Suvorexant HD Versus Placebo: Change From Baseline in sTSTm at Week 1
Measure Description	sTSTm is the average over a defined day range of the participant's report of the total amount of time spent asleep before waking for the day, as recorded in a daily e-diary. Averages were derived by taking the mean of all available

	daily measurements (excluding the mornings following any PSG nights) falling within the day range; Week 1 range is Days 2-8 (Day 1 is day of first double-blind dose). A participant must have at least 3 days of data during the defined day range to calculate an average for the day range; otherwise, the mean value was considered missing for that day range. The baseline value is the mean of the last 7 daily measurements obtained during the placebo Run-in period.
Time Frame	Baseline and Week 1
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Randomized participants with ≥1 post-randomization e-diary observation after ≥1 dose of study drug, and baseline data were included in this analysis. The hypothesis included only the suvorexant HD-placebo comparison.

Reporting Groups

	Description
Suvorexant HD	After a 2-week single-blind placebo Run-in, participants received suvorexant HD (40 mg for participants aged 18 to <65 years; and 30 mg for participants aged ≥65 years) daily before bedtime during the 3-month DB TRT Phase.
Placebo	After a 2-week single-blind placebo Run-in, participants received placebo to suvorexant daily before bedtime during the 3-month double-blind DB TRT Phase.

Measured Values

	Suvorexant HD	**Placebo**
Number of Participants Analyzed [units: participants]	**373**	**364**
Suvorexant HD Versus Placebo: Change From Baseline in sTSTm at Week 1 [units: minutes] Least Squares Mean (95% Confidence Interval)	**40.4 (35.7 to 45.1)**	**14.0 (9.2 to 18.7)**

Statistical Analysis 1 for Suvorexant HD Versus Placebo: Change From Baseline in sTSTm at Week 1

Groups [1]	All groups
Method [2]	Longitudinal Data Analysis
P Value [3]	<0.00001
Difference in Least Squares Means [4]	26.4
95% Confidence Interval	19.8 to 33.1

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The null hypothesis, that suvorexant HD did not differ from placebo for Week 1 sTSTm, had planned marginal power of 98.3%. Sleep maintenance (sTSTm, WASO) and sleep onset (sTSOm, LPS) endpoints were tested at two-sided 2.5% significance level. Both Month 1 endpoints for sleep maintenance must be significant to test Month 3 endpoints and either subjective or objective Month 3 endpoint must be significant to test Week 1/Night 1 endpoints. The same approach was used for sleep onset endpoints.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Model terms: baseline value, age group, region, gender, treatment, time, time by treatment interaction, and cohort (e-diary only, PSG-plus-e-diary).
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

12. Secondary: Suvorexant HD Versus Placebo: Change From Baseline in WASO at Night 1 [Time Frame: Baseline and Night 1]

Measure Type	Secondary
Measure Title	Suvorexant HD Versus Placebo: Change From Baseline in WASO at Night 1
Measure Description	WASO is measured during overnight sleep laboratory (PSG) assessments at baseline, Night 1, Month 1 and Month 3, and is defined as the duration of wakefulness from the onset of persistent sleep (i.e., 10 consecutive minutes of sleep) to the end of PSG assessment the following morning. Beginning of PSG assessment ("Lights-Off") is at approximately the participant's habitual bedtime. The participant is awakened, or allowed to get out of bed if already awake, after 8 hours of PSG recording ("Lights-On"). PSG assessments consist of electronic measurement of brain activity and eye and muscle movements. PSG data was scored by a Centralized PSG reading center.
Time Frame	Baseline and Night 1
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Randomized participants with ≥1 post-randomization PSG observation after ≥1 dose of study drug, and baseline data were included in this analysis. The hypothesis included only the suvorexant HD-placebo comparison.

Reporting Groups

	Description
Suvorexant HD	After a 2-week single-blind placebo Run-in, participants received suvorexant HD (40 mg for participants aged 18 to <65 years; and 30 mg for participants aged ≥65 years) daily before bedtime during the 3-month DB TRT Phase.
Placebo	After a 2-week single-blind placebo Run-in, participants received placebo to suvorexant daily before bedtime during the 3-month double-blind DB TRT Phase.

Measured Values

	Suvorexant HD	Placebo
Number of Participants Analyzed [units: participants]	**285**	**283**
Suvorexant HD Versus Placebo: Change From Baseline in WASO at Night 1 [units: minutes] Least Squares Mean (95% Confidence Interval)	**-63.3 (-68.0 to -58.6)**	**-21.3 (-26.1 to -16.6)**

Statistical Analysis 1 for Suvorexant HD Versus Placebo: Change From Baseline in WASO at Night 1

Groups [1]	All groups
Method [2]	Longitudinal Data Analysis
P Value [3]	<0.00001
Difference in Least Squares Means [4]	-42.0
95% Confidence Interval	-48.6 to -35.3

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The null hypothesis, that suvorexant HD did not differ from placebo for Night 1 WASO, had planned marginal power of 100.0%. Sleep maintenance (sTSTm, WASO) and sleep onset (sTSOm, LPS) endpoints were tested at two-sided 2.5% significance level. Both Month 1 endpoints for sleep maintenance must be significant to test Month 3 endpoints and either subjective or objective Month 3 endpoint must be significant to test Week 1/Night 1 endpoints. The same approach was used for sleep onset endpoints.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Model terms: baseline value, age group, region, gender, treatment, time, and time by treatment interaction.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

13. Secondary: Suvorexant HD Versus Placebo: Change From Baseline in sTSOm at Week 1 [Time Frame: Baseline and Week 1]

Measure Type	Secondary
Measure Title	Suvorexant HD Versus Placebo: Change From Baseline in sTSOm at Week 1
Measure Description	sTSOm is the average over a defined day range of the participant's report of the duration of time that it took to fall asleep, as recorded in a daily e-diary. Averages were derived by taking the mean of all available daily measurements (excluding the mornings following any PSG nights) falling within the day range; Week 1 range is Days 2-8 (Day 1 is day of first double-blind dose). A participant must have at least 3 days of data during the defined day range to calculate an average for the day range; otherwise, the mean value was considered missing for that day range. The baseline value is the mean of the last 7 daily measurements obtained during the placebo Run-in period.
Time Frame	Baseline and Week 1
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Randomized participants with ≥1 post-randomization e-diary observation after ≥1 dose of study drug, and baseline data were included in this analysis. The hypothesis included only the suvorexant HD-placebo comparison.

Reporting Groups

	Description
Suvorexant HD	After a 2-week single-blind placebo Run-in, participants received suvorexant HD (40 mg for participants aged 18 to <65 years; and 30 mg for participants aged ≥65 years) daily before bedtime during the 3-month DB TRT Phase.
Placebo	After a 2-week single-blind placebo Run-in, participants received placebo to suvorexant daily before bedtime during the 3-month double-blind DB TRT Phase.

Measured Values

	Suvorexant HD	Placebo
Number of Participants Analyzed [units: participants]	**373**	**364**
Suvorexant HD Versus Placebo: Change From Baseline in sTSOm at Week 1 [units: minutes] Least Squares Mean (95% Confidence Interval)	**-19.7 (-23.0 to -16.4)**	**-6.7 (-10.0 to -3.3)**

Statistical Analysis 1 for Suvorexant HD Versus Placebo: Change From Baseline in sTSOm at Week 1

Groups [1]	All groups
Method [2]	Longitudinal Data Analysis
P Value [3]	<0.00001
Difference in Least Squares Means [4]	-13.1
95% Confidence Interval	-17.7 to -8.4

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The null hypothesis, that suvorexant HD did not differ from placebo for Week 1 sTSOm, had planned marginal power of 99.6%. Sleep maintenance (sTSTm, WASO) and sleep onset (sTSOm, LPS) endpoints were tested at two-sided 2.5% significance level. Both Month 1 endpoints for sleep maintenance must be significant to test Month 3 endpoints and either subjective or objective Month 3 endpoint must be significant to test Week 1/Night 1 endpoints. The same approach was used for sleep onset endpoints.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Model terms: baseline value, age group, region, gender, treatment, time, time by treatment interaction, and cohort (e-diary only, PSG-plus-e-diary).
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

14. Secondary: Suvorexant HD Versus Placebo: Change From Baseline in LPS at Night 1 [Time Frame: Baseline and Night 1]

Measure Type	Secondary
Measure Title	Suvorexant HD Versus Placebo: Change From Baseline in LPS at Night 1
Measure Description	LPS is measured during overnight sleep laboratory (PSG) assessments at baseline, Night 1, Month 1 and Month 3, and is defined as the duration of time from the beginning of PSG assessment ("Lights-Off") to the first interval of 10 consecutive minutes of sleep. Beginning of PSG assessment ("Lights-Off") is at approximately the participant's habitual bedtime. The participant is awakened, or allowed to get out of bed if already awake, after 8 hours of PSG recording ("Lights-On"). PSG assessments consist of electronic measurement of brain activity and eye and muscle movements. PSG data was scored by a Centralized PSG reading center.
Time Frame	Baseline and Night 1
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Randomized participants with ≥1 post-randomization PSG observation after ≥1 dose of study drug, and baseline data were included in this analysis. The hypothesis included only the suvorexant HD-placebo comparison.

Reporting Groups

	Description
Suvorexant HD	After a 2-week single-blind placebo Run-in, participants received suvorexant HD (40 mg for participants aged 18 to <65 years; and 30 mg for participants aged ≥65 years) daily before bedtime during the 3-month DB TRT Phase.
Placebo	After a 2-week single-blind placebo Run-in, participants received placebo to suvorexant daily before bedtime during the 3-month double-blind DB TRT Phase.

Measured Values

	Suvorexant HD	Placebo
Number of Participants Analyzed [units: participants]	**289**	**284**
Suvorexant HD Versus Placebo: Change From Baseline in LPS at Night 1 [units: minutes] Least Squares Mean (95% Confidence Interval)	**-34.7 (-39.5 to -29.9)**	**-13.0 (-17.8 to -8.1)**

Statistical Analysis 1 for Suvorexant HD Versus Placebo: Change From Baseline in LPS at Night 1

Groups [1]	All groups
Method [2]	Longitudinal Data Analysis
P Value [3]	<0.00001
Difference in Least Squares Means [4]	-21.7
95% Confidence Interval	-28.6 to -14.9

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The null hypothesis, that suvorexant HD did not differ from placebo for Night 1 LPS, had planned marginal power of 100.0%. Sleep maintenance (sTSTm, WASO) and sleep onset (sTSOm, LPS) endpoints were tested at two-sided 2.5% significance level. Both Month 1 endpoints for sleep maintenance must be significant to test Month 3 endpoints and either subjective or objective Month 3 endpoint must be significant to test Week 1/Night 1 endpoints. The same approach was used for sleep onset endpoints.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Model terms: baseline value, age group, region, gender, treatment, time, and time by treatment interaction.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Up to 14 days after the last dose of study drug
Additional Description	The 3 TRT Phase reporting groups include total population; other groups present same or subsets of this population in other study phases. Events are reported by phase. Phases are: - TRT - RO - Follow-up (enter directly from TRT Phase, or from RO)

Reporting Groups

	Description
Suvorexant LD (TRT Phase)	After a 2-week single-blind placebo Run-in, participants received suvorexant LD (20 mg for participants aged 18 to <65 years; and 15 mg for participants aged ≥65 years) daily before bedtime during the 3-month DB TRT Phase.
Suvorexant HD (TRT Phase)	After a 2-week single-blind placebo Run-in, participants received suvorexant HD (40 mg for participants aged 18 to <65 years; and 30 mg for participants aged ≥65 years) daily before bedtime during the 3-month DB TRT Phase.
Placebo (TRT Phase)	After a 2-week single-blind placebo Run-in, participants received placebo to suvorexant daily before bedtime during the 3-month double-blind DB TRT Phase.
Suvorexant LD (RO, After Suvorexant LD in TRT)	After receiving suvorexant LD during the 3-Month DB TRT Phase, participants received their same dose of suvorexant during a 1-week DB RO Phase.
Placebo (RO, After Suvorexant LD in TRT)	After receiving suvorexant LD during the 3-Month DB TRT Phase, participants received placebo to suvorexant during a 1-week DB RO Phase.
Suvorexant HD (RO, After Suvorexant HD in TRT)	After receiving suvorexant HD during the 3-Month DB TRT Phase, participants received their same dose of suvorexant during a 1-week DB RO Phase.
Placebo (RO, After Suvorexant HD in TRT)	After receiving suvorexant HD during the 3-Month DB TRT Phase, participants received placebo to suvorexant during a 1-week DB RO Phase.
Placebo (RO, After Placebo in TRT)	After receiving placebo to suvorexant during the 3-Month DB TRT Phase, participants received placebo to suvorexant during a 1-week DB RO Phase.
Suvorexant LD (TRT Phase): Follow-up	During 14-day Follow-up after last dose no study drug was administered. Follow-up AE data is presented for TRT Phase participants who entered Follow-up directly from TRT Phase and had received suvorexant LD during TRT Phase.
Suvorexant HD (TRT Phase): Follow-up	During 14-day Follow-up after last dose no study drug was administered. Follow-up AE data is presented for TRT Phase participants who entered Follow-up directly from TRT Phase and had received suvorexant HD during TRT Phase.
Placebo (TRT Phase): Follow-up	During 14-day Follow-up after last dose no study drug was administered. Follow-up AE data is presented for TRT Phase participants who entered Follow-up directly from TRT Phase and had

	received placebo during TRT Phase.
Suvorexant LD (RO, After Suvorexant LD in TRT): Follow-up	During 14-day Follow-up after last dose no study drug was administered. Follow-up AE data is presented for RO participants who entered Follow-up from RO Phase, and had received suvorexant LD during TRT and RO Phases.
Placebo (RO, After Suvorexant LD in TRT): Follow-up	During 14-day Follow-up after last dose no study drug was administered. Follow-up AE data is presented for RO participants who entered Follow-up from RO Phase, and had received suvorexant LD during TRT Phase and placebo during RO Phase.
Suvorexant HD (RO, After Suvorexant HD in TRT): Follow-up	During 14-day Follow-up after last dose no study drug was administered. Follow-up AE data is presented for RO participants who entered Follow-up from RO Phase, and had received suvorexant HD during TRT and RO Phases.
Placebo (RO, After Suvorexant HD in TRT): Follow-up	During 14-day Follow-up after last dose no study drug was administered. Follow-up AE data is presented for RO participants who entered Follow-up from RO Phase, and had received suvorexant HD during TRT Phase and placebo during RO Phase.
Placebo (RO, After Placebo in TRT): Follow-up	During 14-day Follow-up after last dose no study drug was administered. Follow-up AE data is presented for RO participants who entered Follow-up from RO Phase, and had received placebo during TRT and RO Phases.

Serious Adverse Events

	Suvorexant LD (TRT Phase)	Suvorexant HD (TRT Phase)	Placebo (TRT Phase)	Suvorexant LD (RO, After Suvorexant LD in TRT)	Placebo (RO, After Suvorexant LD in TRT)	Suvorexant HD (RO, After Suvorexant HD in TRT)	Placebo (RO, After Suvorexant HD in TRT)	Placebo (RO, After Placebo in TRT)	Suvorexant LD (TRT Phase): Follow-up	Suvorexant HD (TRT Phase): Follow-up	Placebo (TRT Phase): Follow-up	Suvorexant LD (RO, After Suvorexant LD in TRT): Follow-up	Placebo (RO, After Suvorexant LD in TRT): Follow-up	Suvorexant HD (RO, After Suvorexant HD in TRT): Follow-up	Placebo (RO, After Suvorexant HD in TRT): Follow-up	Placebo (RO, After Placebo in TRT): Follow-up
Total, serious adverse events																
# participants affected / at risk	2/239 (0.84%)	6/387 (1.55%)	5/383 (1.31%)	0/97 (0.00%)	1/108 (0.93%)	0/173 (0.00%)	0/171 (0.00%)	0/327 (0.00%)	0/239 (0.00%)	1/387 (0.26%)	0/383 (0.00%)	0/97 (0.00%)	0/108 (0.00%)	0/173 (0.00%)	0/171 (0.00%)	0/327 (0.00%)
Cardiac disorders																
atrial fibrillation [1]																
# participants affected / at risk	1/239 (0.42%)	0/387 (0.00%)	0/383 (0.00%)	0/97 (0.00%)	0/108 (0.00%)	0/173 (0.00%)	0/171 (0.00%)	0/327 (0.00%)	0/239 (0.00%)	0/387 (0.00%)	0/383 (0.00%)	0/97 (0.00%)	0/108 (0.00%)	0/173 (0.00%)	0/171 (0.00%)	0/327 (0.00%)
# events	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Ear and labyrinth disorders																
Meniere's disease [1]																
# participants affected / at risk	0/239 (0.00%)	1/387 (0.26%)	0/383 (0.00%)	0/97 (0.00%)	0/108 (0.00%)	0/173 (0.00%)	0/171 (0.00%)	0/327 (0.00%)	0/239 (0.00%)	0/387 (0.00%)	0/383 (0.00%)	0/97 (0.00%)	0/108 (0.00%)	0/173 (0.00%)	0/171 (0.00%)	0/327 (0.00%)
# events	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Endocrine disorders																
autoimmune thyroiditis [1]																
# participants affected / at risk	0/239 (0.00%)	1/387 (0.26%)	0/383 (0.00%)	0/97 (0.00%)	0/108 (0.00%)	0/173 (0.00%)	0/171 (0.00%)	0/327 (0.00%)	0/239 (0.00%)	0/387 (0.00%)	0/383 (0.00%)	0/97 (0.00%)	0/108 (0.00%)	0/173 (0.00%)	0/171 (0.00%)	0/327 (0.00%)
# events	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Infections and infestations																
endometritis [1]																
# participants affected / at risk	0/239 (0.00%)	0/387 (0.00%)	1/383 (0.26%)	0/97 (0.00%)	0/108 (0.00%)	0/173 (0.00%)	0/171 (0.00%)	0/327 (0.00%)	0/239 (0.00%)	0/387 (0.00%)	0/383 (0.00%)	0/97 (0.00%)	0/108 (0.00%)	0/173 (0.00%)	0/171 (0.00%)	0/327 (0.00%)
# events	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0
gastroenteritis [1]																
# participants affected / at	0/239 (0.00%)	0/387 (0.00%)	1/383 (0.26%)	0/97 (0.00%)	0/108 (0.00%)	0/173 (0.00%)	0/171 (0.00%)	0/327 (0.00%)	0/239 (0.00%)	0/387 (0.00%)	0/383 (0.00%)	0/97 (0.00%)	0/108 (0.00%)	0/173 (0.00%)	0/171 (0.00%)	0/327 (0.00%)

risk																
# events	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0
meningitis [1]																
# participants affected / at risk	0/239 (0.00%)	0/387 (0.00%)	0/383 (0.00%)	0/97 (0.00%)	1/108 (0.93%)	0/173 (0.00%)	0/171 (0.00%)	0/327 (0.00%)	0/239 (0.00%)	0/387 (0.00%)	0/383 (0.00%)	0/97 (0.00%)	0/108 (0.00%)	0/173 (0.00%)	0/171 (0.00%)	0/327 (0.00%)
# events	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Injury, poisoning and procedural complications																
ankle fracture [1]																
# participants affected / at risk	1/239 (0.42%)	0/387 (0.00%)	0/383 (0.00%)	0/97 (0.00%)	0/108 (0.00%)	0/173 (0.00%)	0/171 (0.00%)	0/327 (0.00%)	0/239 (0.00%)	0/387 (0.00%)	0/383 (0.00%)	0/97 (0.00%)	0/108 (0.00%)	0/173 (0.00%)	0/171 (0.00%)	0/327 (0.00%)
# events	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
compression fracture [1]																
# participants affected / at risk	0/239 (0.00%)	1/387 (0.26%)	0/383 (0.00%)	0/97 (0.00%)	0/108 (0.00%)	0/173 (0.00%)	0/171 (0.00%)	0/327 (0.00%)	0/239 (0.00%)	0/387 (0.00%)	0/383 (0.00%)	0/97 (0.00%)	0/108 (0.00%)	0/173 (0.00%)	0/171 (0.00%)	0/327 (0.00%)
# events	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
fall [1]																
# participants affected / at risk	0/239 (0.00%)	1/387 (0.26%)	0/383 (0.00%)	0/97 (0.00%)	0/108 (0.00%)	0/173 (0.00%)	0/171 (0.00%)	0/327 (0.00%)	0/239 (0.00%)	0/387 (0.00%)	0/383 (0.00%)	0/97 (0.00%)	0/108 (0.00%)	0/173 (0.00%)	0/171 (0.00%)	0/327 (0.00%)
# events	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ulna fracture [1]																
# participants affected / at risk	0/239 (0.00%)	1/387 (0.26%)	0/383 (0.00%)	0/97 (0.00%)	0/108 (0.00%)	0/173 (0.00%)	0/171 (0.00%)	0/327 (0.00%)	0/239 (0.00%)	0/387 (0.00%)	0/383 (0.00%)	0/97 (0.00%)	0/108 (0.00%)	0/173 (0.00%)	0/171 (0.00%)	0/327 (0.00%)
# events	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Musculoskeletal and connective tissue disorders																
musculoskeletal chest pain [1]																
# participants affected / at risk	0/239 (0.00%)	1/387 (0.26%)	0/383 (0.00%)	0/97 (0.00%)	0/108 (0.00%)	0/173 (0.00%)	0/171 (0.00%)	0/327 (0.00%)	0/239 (0.00%)	0/387 (0.00%)	0/383 (0.00%)	0/97 (0.00%)	0/108 (0.00%)	0/173 (0.00%)	0/171 (0.00%)	0/327 (0.00%)
# events	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)																
bladder neoplasm [1]																
# participants affected / at risk	0/239 (0.00%)	0/387 (0.00%)	1/383 (0.26%)	0/97 (0.00%)	0/108 (0.00%)	0/173 (0.00%)	0/171 (0.00%)	0/327 (0.00%)	0/239 (0.00%)	0/387 (0.00%)	0/383 (0.00%)	0/97 (0.00%)	0/108 (0.00%)	0/173 (0.00%)	0/171 (0.00%)	0/327 (0.00%)
# events	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0
malignant melanoma [1]																
# participants affected / at risk	0/239 (0.00%)	0/387 (0.00%)	1/383 (0.26%)	0/97 (0.00%)	0/108 (0.00%)	0/173 (0.00%)	0/171 (0.00%)	0/327 (0.00%)	0/239 (0.00%)	0/387 (0.00%)	0/383 (0.00%)	0/97 (0.00%)	0/108 (0.00%)	0/173 (0.00%)	0/171 (0.00%)	0/327 (0.00%)
# events	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0
uterine leiomyoma [1]																

# participants affected / at risk	0/239 (0.00%)	0/387 (0.00%)	1/383 (0.26%)	0/97 (0.00%)	0/108 (0.00%)	0/173 (0.00%)	0/171 (0.00%)	0/327 (0.00%)	0/239 (0.00%)	0/387 (0.00%)	0/383 (0.00%)	0/97 (0.00%)	0/108 (0.00%)	0/173 (0.00%)	0/171 (0.00%)	0/327 (0.00%)
# events	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0
Nervous system disorders																
cerebrovascular accident [1]																
# participants affected / at risk	0/239 (0.00%)	0/387 (0.00%)	1/383 (0.26%)	0/97 (0.00%)	0/108 (0.00%)	0/173 (0.00%)	0/171 (0.00%)	0/327 (0.00%)	0/239 (0.00%)	0/387 (0.00%)	0/383 (0.00%)	0/97 (0.00%)	0/108 (0.00%)	0/173 (0.00%)	0/171 (0.00%)	0/327 (0.00%)
# events	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0
hypoxic-ischaemic encephalopathy [1]																
# participants affected / at risk	0/239 (0.00%)	1/387 (0.26%)	0/383 (0.00%)	0/97 (0.00%)	0/108 (0.00%)	0/173 (0.00%)	0/171 (0.00%)	0/327 (0.00%)	0/239 (0.00%)	0/387 (0.00%)	0/383 (0.00%)	0/97 (0.00%)	0/108 (0.00%)	0/173 (0.00%)	0/171 (0.00%)	0/327 (0.00%)
# events	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Psychiatric disorders																
alcohol withdrawal syndrome [1]																
# participants affected / at risk	0/239 (0.00%)	0/387 (0.00%)	0/383 (0.00%)	0/97 (0.00%)	0/108 (0.00%)	0/173 (0.00%)	0/171 (0.00%)	0/327 (0.00%)	0/239 (0.00%)	1/387 (0.26%)	0/383 (0.00%)	0/97 (0.00%)	0/108 (0.00%)	0/173 (0.00%)	0/171 (0.00%)	0/327 (0.00%)
# events	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0

1 Term from vocabulary, MedDRA 14.1

Other Adverse Events

Hide Other Adverse Events

Time Frame	Up to 14 days after the last dose of study drug
Additional Description	The 3 TRT Phase reporting groups include total population; other groups present same or subsets of this population in other study phases. Events are reported by phase. Phases are: - TRT - RO - Follow-up (enter directly from TRT Phase, or from RO)

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Suvorexant LD (TRT Phase)	After a 2-week single-blind placebo Run-in, participants received suvorexant LD (20 mg for participants aged 18 to <65 years; and 15 mg for participants aged ≥65 years) daily before bedtime during the 3-month DB TRT Phase.
Suvorexant HD (TRT Phase)	After a 2-week single-blind placebo Run-in, participants received suvorexant HD (40 mg for participants aged 18 to <65 years; and 30 mg for participants aged ≥65 years) daily before bedtime during the 3-month DB TRT Phase.
Placebo (TRT Phase)	After a 2-week single-blind placebo Run-in, participants received placebo to suvorexant daily before bedtime during the 3-month double-blind DB TRT Phase.
Suvorexant LD (RO, After Suvorexant LD in TRT)	After receiving suvorexant LD during the 3-Month DB TRT Phase, participants received their same dose of suvorexant during a 1-week DB RO Phase.
Placebo (RO, After Suvorexant LD in TRT)	After receiving suvorexant LD during the 3-Month DB TRT Phase, participants received placebo to suvorexant during a 1-week DB RO Phase.
Suvorexant HD (RO, After Suvorexant HD in TRT)	After receiving suvorexant HD during the 3-Month DB TRT Phase, participants received their same dose of suvorexant during a 1-week DB RO Phase.
Placebo (RO, After Suvorexant HD in TRT)	After receiving suvorexant HD during the 3-Month DB TRT Phase, participants received placebo to suvorexant during a 1-week DB RO Phase.
Placebo (RO, After Placebo in TRT)	After receiving placebo to suvorexant during the 3-Month DB TRT Phase, participants received placebo to suvorexant during a 1-week DB RO Phase.
Suvorexant LD (TRT Phase): Follow-up	During 14-day Follow-up after last dose no study drug was administered. Follow-up AE data is presented for TRT Phase participants who entered Follow-up directly from TRT Phase and had received suvorexant LD during TRT Phase.

Suvorexant HD (TRT Phase): Follow-up	During 14-day Follow-up after last dose no study drug was administered. Follow-up AE data is presented for TRT Phase participants who entered Follow-up directly from TRT Phase and had received suvorexant HD during TRT Phase.
Placebo (TRT Phase): Follow-up	During 14-day Follow-up after last dose no study drug was administered. Follow-up AE data is presented for TRT Phase participants who entered Follow-up directly from TRT Phase and had received placebo during TRT Phase.
Suvorexant LD (RO, After Suvorexant LD in TRT): Follow-up	During 14-day Follow-up after last dose no study drug was administered. Follow-up AE data is presented for RO participants who entered Follow-up from RO Phase, and had received suvorexant LD during TRT and RO Phases.
Placebo (RO, After Suvorexant LD in TRT): Follow-up	During 14-day Follow-up after last dose no study drug was administered. Follow-up AE data is presented for RO participants who entered Follow-up from RO Phase, and had received suvorexant LD during TRT Phase and placebo during RO Phase.
Suvorexant HD (RO, After Suvorexant HD in TRT): Follow-up	During 14-day Follow-up after last dose no study drug was administered. Follow-up AE data is presented for RO participants who entered Follow-up from RO Phase, and had received suvorexant HD during TRT and RO Phases.
Placebo (RO, After Suvorexant HD in TRT): Follow-up	During 14-day Follow-up after last dose no study drug was administered. Follow-up AE data is presented for RO participants who entered Follow-up from RO Phase, and had received suvorexant HD during TRT Phase and placebo during RO Phase.
Placebo (RO, After Placebo in TRT): Follow-up	During 14-day Follow-up after last dose no study drug was administered. Follow-up AE data is presented for RO participants who entered Follow-up from RO Phase, and had received placebo during TRT and RO Phases.

Other Adverse Events

	Suvorexant LD (TRT Phase)	Suvorexant HD (TRT Phase)	Placebo (TRT Phase)	Suvorexant LD (RO, After Suvorexant LD in TRT)	Placebo (RO, After Suvorexant LD in TRT)	Suvorexant HD (RO, After Suvorexant HD in TRT)	Placebo (RO, After Suvorexant HD in TRT)	Placebo (RO, After Placebo in TRT)	Suvorexant LD (TRT Phase): Follow-up	Suvorexant HD (TRT Phase): Follow-up	Placebo (TRT Phase): Follow-up	Suvorexant LD (RO, After Suvorexant LD in TRT): Follow-up	Placebo (RO, After Suvorexant LD in TRT): Follow-up	Suvorexant HD (RO, After Suvorexant HD in TRT): Follow-up	Placebo (RO, After Suvorexant HD in TRT): Follow-up	Placebo (RO, After Placebo in TRT): Follow-up
Total, other (not including serious) adverse events																
# participants affected / at risk	33/239 (13.81%)	59/387 (15.25%)	33/383 (8.62%)	0/97 (0.00%)	1/108 (0.93%)	4/173 (2.31%)	1/171 (0.58%)	4/327 (1.22%)	0/239 (0.00%)	2/387 (0.52%)	0/383 (0.00%)	0/97 (0.00%)	1/108 (0.93%)	0/173 (0.00%)	0/171 (0.00%)	1/327 (0.31%)
Nervous system disorders																
headache [1]																
# participants affected / at risk	19/239 (7.95%)	29/387 (7.49%)	22/383 (5.74%)	0/97 (0.00%)	1/108 (0.93%)	3/173 (1.73%)	1/171 (0.58%)	4/327 (1.22%)	0/239 (0.00%)	2/387 (0.52%)	0/383 (0.00%)	0/97 (0.00%)	1/108 (0.93%)	0/173 (0.00%)	0/171 (0.00%)	1/327 (0.31%)
# events	22	32	22	0	1	3	1	4	0	2	0	0	1	0	0	1
somnolence [1]																
# participants affected / at risk	20/239 (8.37%)	40/387 (10.34%)	12/383 (3.13%)	0/97 (0.00%)	0/108 (0.00%)	1/173 (0.58%)	0/171 (0.00%)	0/327 (0.00%)	0/239 (0.00%)	0/387 (0.00%)	0/383 (0.00%)	0/97 (0.00%)	0/108 (0.00%)	0/173 (0.00%)	0/171 (0.00%)	0/327 (0.00%)
# events	21	44	13	0	0	1	0	0	0	0	0	0	0	0	0	0

1 Term from vocabulary, MedDRA 14.1

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.
The agreement is: The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot

☐ require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☑ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

Restriction Description: Investigator may publish results for his/her study site after publication of results of entire multicenter trial, or after public disclosure of the results online if a multicenter manuscript is not planned. Sponsor must be able to review all proposed results communications regarding study 60 days prior to submission for publication/presentation. Information identified by the Sponsor as confidential must be deleted prior to submission.

Results Point of Contact:

Name/Title: Senior Vice President, Global Clinical Development
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Publications of Results:

Herring WJ, Connor KM, Ivgy-May N, Snyder E, Liu K, Snavely DB, Krystal AD, Walsh JK, Benca RM, Rosenberg R, Sangal RB, Budd K, Hutzelmann J, Leibensperger H, Froman S, Lines C, Roth T, Michelson D. Suvorexant in Patients With Insomnia: Results From Two 3-Month Randomized Controlled Clinical Trials. Biol Psychiatry. 2016 Jan 15;79(2):136-48. doi: 10.1016/j.biopsych.2014.10.003. Epub 2014 Oct 23.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT01097629 History of Changes
Other Study ID Numbers:	4305-029 2010_521 (Other Identifier: Merck Registration Number) CTRI/2010/091/001177 (Registry Identifier: CTRI)
Study First Received:	March 26, 2010
Results First Received:	August 19, 2014
Last Updated:	February 26, 2016
Health Authority:	United States: Food and Drug Administration

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