A Long Term Safety Study of Suvorexant in Participants With Primary Insomnia (MK-4305-009 AM3)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT01021813

First received: November 25, 2009
Last updated: August 14, 2015
Last verified: August 2015
History of Changes

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Purpose

This study will establish the safety and tolerability of suvorexant (MK-4305) when administered for up to 14 months. Participants will be randomized to receive suvorexant or placebo for a 12-month double-blind (DB) Treatment Phase. Participants who complete the 12-month DB Treatment Phase will enter a 2-month DB Randomized Discontinuation Phase. At the time of initial randomization, participants assigned to receive suvorexant during the initial 12-month Treatment Phase will be simultaneously randomized, in a 1:1 ratio, to receive either suvorexant or placebo during the 2-month Randomized Discontinuation Phase. Participants randomized to receive placebo in the initial 12-month Treatment Phase will continue to receive placebo during the 2-month Randomized Discontinuation Phase.

The first 3 nights of the Randomized Discontinuation Phase are referred to as the Run-Out Phase, and will assess rebound and withdrawal.

Condition	Intervention	Phase
Insomnia	Drug: Suvorexant Drug: Dose-matched Placebo to Suvorexant	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety 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, Long Term Safety Study of MK-4305 in Patients With Primary Insomnia

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:

- Percentage of Participants Who Experienced Cataplexy Adverse Events (AEs) During the Double-Blind (DB) Treatment Phase [Time Frame: From the first day of study treatment up to 12 months] [Designated as safety issue: Yes]

  Cataplexy is defined as a sudden loss of muscle tone while awake which prevents voluntary movement.

- Percentage of Participants Who Experienced Sleep Paralysis AEs During the DB Treatment Phase [Time Frame: From the first day of study treatment up to 12 months] [Designated as safety issue: Yes]

  Sleep paralysis was defined as the inability to perform voluntary muscle movements during sleep. Sleep paralysis adverse events included sleep-onset paralysis (paralysis as one is falling asleep).

- Percentage of Participants Who Experienced Complex Sleep-related Behaviors AEs During the DB Treatment Phase [Time Frame: From the first day of study treatment up to 12 months] [Designated as safety issue: Yes]

  Complex sleep-related behaviors were reported as ECIs and were characterized by patients engaging in specific activities while asleep (e.g., eating, drinking, preparing meals, making phone calls, having sex, driving, and sleep walking).

- Percentage of Participants Who Experienced Falls AEs During the DB Treatment Phase [Time Frame: From the first day of study treatment up to 12 months] [Designated as safety issue: Yes]

  Falls were adjudicated (to establish whether a fall event was due to cataplexy).

- Percentage of Participants Who Experienced Suicidal Ideation and/or Behavior AEs During the DB Treatment Phase [Time Frame: From the first day of study treatment up to 12 months] [Designated as safety issue: Yes]

  Suicidal ideation included suicidal plans, suicidal tendency, death wishes, life weariness, and suicidal intention. Suicidal behaviors included suicide attempts, suicide gesture, and self-injurious behaviour. Suicidal ideation and/or behavior was reported as an AE and considered an ECI.

- Percentage of Participants Who Experienced Hypnagogic/Hypnopompic Hallucinations AEs During the DB Treatment Phase [Time Frame: From the first day of study treatment up to 12 months] [Designated as safety issue: Yes]

  Perceptual distortions associated with transitions between wakefulness and sleep were termed as hypnagogic (occurring during the onset of sleep) or hypnopompic (occurring during onset of wakefulness) hallucinations.

- Percentage of Participants Who Experienced Selected AEs Associated With Potential for Abuse During the DB Treatment Phase [Time Frame: From the first day of study treatment up to 12 months] [Designated as safety issue: Yes]

  The pre-specified terms which were suggestive of abuse potential on this study included depersonalization (feeling of watching oneself act, while having no control over a situation), derealization (alteration in the perception or experience of the external world so that it seems unreal), dissociation (includes a wide array of experiences from mild detachment from immediate surroundings to more severe detachment from physical and emotional experience), euphoric mood (exaggerated feeling of physical and emotional well-being and optimism not consonant with apparent stimuli or events), mania (state of abnormally elevated or irritable mood, arousal, and/or energy levels), hallucination (perception in the absence of a stimulus which has qualities of real perception), and potential study medication misuse.

Secondary Outcome Measures:

- Percentage of Participants With Withdrawal Symptoms During the DB Run-Out Phase: Tyrer Withdrawal Symptom Questionnaire (WSQ) [Time Frame: Evening of Month 12 visit and next 3 consecutive days (Night 1, 2, and 3 of Discontinuation Phase [otherwise known as the Run-out])] [Designated as safety issue: Yes]

  Withdrawal effects assessed using Tyrer WSQ, which evaluated the presence/absence and severity of withdrawal symptoms with 20 items (i.e. sensitivity to noise, light, smell, touch, feeling unreal, etc). The Tyrer WSQ was completed as part of the evening e-diary prior to dosing on the Month 12 visit and on the 3 consecutive evenings of the DB Run-out Phase (first 3 nights of DB Discontinuation Phase). Responses rated 0 (No), 1 (Yes-moderate), or 2 (Yes-severe); range from 0 (no withdrawal) to 40 (severe withdrawal). A participant was defined to have a withdrawal symptom if an item during any of the 3 DB Run-out days had emerged for the first time, or had worsened compared to the measurement obtained at the end of the Treatment phase (Month 12). For single night analysis, a patient was defined to have withdrawal effects if the number of withdrawal symptoms (emergent or worsening) was ≥3. For across night analysis, withdrawal was defined as a total of ≥3 symptoms across the 3 nights.

- Percentage of Participants With Rebound As Defined By Decreased Subjective Total Sleep Time (sTST) During the DB Run-Out Phase [Time Frame: Baseline (Month 1) and first 3 days of Randomized Discontinuation Phase (otherwise known as the Run-out, Month 13)]

[Designated as safety issue: Yes]

Rebound insomnia was defined as insomnia that occurred following discontinuation of a sedative substance taken to relieve primary insomnia, and was assessed based on subjective total sleep time (sTST) as recorded in the participant's morning e-diary. A strict categorical analysis method (Yes/No) was used in which a participant was considered to have potentially experienced rebound (Yes) if the Morning Diary participant-reported sTST value (in minutes) on any of the 3 nights of the Run-out Phase (first 3 nights of the Discontinuation Phase) occurring after one year of treatment (Month 13) was less than the last value at baseline one year earlier (Month 1).

- Percentage of Participants With Rebound As Defined By Increased Subjective Time to Sleep Onset (sTSO) During the DB Run-Out Phase [Time Frame: Baseline (Month 1) and first 3 days of Randomized Discontinuation Phase (otherwise known as the Run-out, Month 13)] [Designated as safety issue: Yes]

  Rebound insomnia was defined as insomnia that occurred following discontinuation of a sedative substance taken to relieve primary insomnia, and was assessed based on subjective time to sleep onset (sTSO) as recorded in the participant's morning e-diary. A strict categorical analysis method (Yes/No) was used in which a participant was considered to have potentially experienced rebound (Yes) if the Morning Diary participant-reported sTSO value (in minutes) on any of the first 3 nights of the Run-out Phase occurring after one year of treatment (Month 13) was greater than the last value at baseline one year earlier (Month 1).

- Least Squares (LS) Mean Change From Baseline in Mean Subjective Total Sleep Time (sTSTm) During First Month of Treatment Phase [Time Frame: Baseline, Week 1, Week 2, Week 3, and Week 4] [Designated as safety issue: No]

  The sTSTm was defined as the average over time of daily e-diary values for a participant's report of the total amount of time spent asleep before waking for the day (measured in minutes). Weekly sTSTm values (Week 1, Week 2, etc.) were the average of the daily e-diary values for the week. A summary value of this measure for Month 1 was obtained by taking the average of weekly sTSTm values for Weeks 1 through 4; (Week 1 + Week 2 + Week 3 + Week 4) ÷ 4. LS Mean Change from Baseline in sTSTm was then calculated at Week 1, Week 2, Week 3, Week 4, and Month 1.

- Least Squares (LS) Mean Change From Baseline in Mean Subjective Time To Sleep Onset (sTSOm) During First Month of Treatment Phase [Time Frame: Baseline, Week 1, Week 2, Week 3, and Week 4] [Designated as safety issue: No]

  The sTSOm was defined as the average over time of daily e-diary values for a participant's report of the time he or she required to fall asleep (measured in minutes). Weekly sTSOm values (Week 1, Week 2, etc.) were the average of the daily e-diary values for the week. A summary value of this measure for Month 1 was obtained by taking the average of weekly sTSTm values for Weeks 1 through 4; (Week 1 + Week 2 + Week 3 + Week 4) ÷ 4. LS Mean Change from Baseline in sTSOm was then calculated at Week 1, Week 2, Week 3, Week 4, and Month 1.

Other Outcome Measures:

- Number of Participants Who Reported Suicidal Ideation and/or Behavior On Study Based on Responses to the Columbia Suicide Severity Rating Scale (C-SSRS) [Time Frame: From the first day of study treatment through study follow-up (up to 14 months)] [Designated as safety issue: Yes]

  Suicidal ideation and/or behavior that occurred on study was also assessed using the C-SSRS, a rater-administered questionnaire used to prospectively assess suicidal ideation and suicidal behavior. C-SSRS assessment was based upon a clinician's interpretation of the participant's responses to the C-SSRS questions, not by a numbered scale. Suicidal ideation and/or behaviors identified on the C-SSRS may not have been considered an adverse event, based on the investigator's judgment.

Enrollment:	781
Study Start Date:	December 2009
Study Completion Date:	August 2011
Primary Completion Date:	May 2011 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Suvorexant After a 1-week single-blind placebo run-in, participants received suvorexant (40 mg for participants aged 18 to <65 years; and 30 mg for participants aged ≥65 years) daily before bedtime for 12 months during the Treatment Phase.	Drug: Suvorexant Oral tablet (30 mg and 10 mg), administered daily before bedtime Other Name: MK-4305 Drug: Dose-matched Placebo to Suvorexant Oral tablet, administered daily before bedtime

Placebo Comparator: Placebo After a 1-week single-blind placebo run-in, participants received dose-matched placebo to suvorexant (administered according to age) daily before bedtime for 12 months during the Treatment Phase.	Drug: Dose-matched Placebo to Suvorexant Oral tablet, administered daily before bedtime

Eligibility

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

Criteria

Inclusion Criteria:

- Diagnosis of primary insomnia
- Participant is able to read, understand, and complete questionnaires and diaries
- If female, participant and partner both agree to use acceptable contraception. If male partner does not use an effective form of contraception, female participant must use 2 acceptable forms of contraception
- If ≥65 years of age, score of ≥25 on the Mini Mental State Examination (MMSE)

Exclusion Criteria:

- If female, participant is pregnant
- Participant expects to donate eggs or sperm during the study
- Recent and/or active history of a confounding neurological disorder
- History of clinically unstable cardiovascular disorder within the last 6 months
- Lifetime history of bipolar disorder
- Psychiatric condition that requires treatment with a medication prohibited by the study, or any other psychiatric condition that would interfere with the participant's ability to participate in the study
- History of substance abuse/dependence
- History of cancer ≤5 years prior to study participation except for adequately treated basal cell or squamous cell skin cancer or in situ cervical cancer
- Evidence of suicidality (based on a score of 2 on the Quick Inventory of Depressive Symptomatology Self-Report 16-Item ([QIDS-SR16] suicide item #12)
- Participant has travelled across >3 time zones or >3 hour time difference in the last 2 weeks
- History of permanent night shift work or rotating day/night shift work in the past 2 weeks
- Body Mass Index (BMI) >40 kg/m^2

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.

No Contacts or Locations Provided

More Information

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Michelson D, Snyder E, Paradis E, Chengan-Liu M, Snavely DB, Hutzelmann J, Walsh JK, Krystal AD, Benca RM, Cohn M, Lines C, Roth T, Herring WJ. Safety and efficacy of suvorexant during 1-year treatment of insomnia with subsequent abrupt treatment discontinuation: a phase 3 randomised, double-blind, placebo-controlled trial. Lancet Neurol. 2014 May;13(5):461-71. doi: 10.1016/S1474-4422(14)70053-5. Epub 2014 Mar 27.

Responsible Party: Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier: NCT01021813 History of Changes

Other Study ID Numbers:	4305-009 2009_696
Study First Received:	November 25, 2009
Results First Received:	August 19, 2014
Last Updated:	August 14, 2015
Health Authority:	United States: Food and Drug Administration

ClinicalTrials.gov processed this record on May 08, 2016

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A Long Term Safety Study of Suvorexant in Participants With Primary Insomnia (MK-4305-009 AM3)

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ClinicalTrials.gov Identifier:
NCT01021813

First received: November 25, 2009
Last updated: August 14, 2015
Last verified: August 2015
History of Changes

Results First Received: August 19, 2014

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Insomnia
Interventions:	Drug: Suvorexant Drug: Dose-matched Placebo to Suvorexant

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

Of the 781 participants randomized into the Treatment Phase, 522 were randomized to suvorexant and 259 were randomized to placebo. Two participants were randomized, but not treated (one from each treatment group); therefore, the total number of participants evaluated for safety was 779.

Reporting Groups

	Description
Suvorexant	After a 1-week single-blind placebo run-in, participants received suvorexant (40 mg for participants aged 18 to <65 years; and 30 mg for participants aged ≥65 years) daily before bedtime for 12 months during the double-blind (DB) Treatment Phase.
Placebo	After a 1-week single-blind placebo run-in, participants received dose-matched placebo to suvorexant (administered according to age) daily before bedtime for 12 months during the DB Treatment Phase.
Suvorexant (DB Treatment)/Suvorexant (DB Discontinuation)	Following treatment with suvorexant during the 12-Month DB Treatment Phase, participants received their same dose of suvorexant during a 2-month DB Randomized Discontinuation Phase.
Suvorexant (DB Treatment)/Placebo (DB Discontinuation)	Following treatment with suvorexant during the 12-Month DB Treatment Phase, participants received dose-matched placebo to suvorexant during a 2-month DB Randomized Discontinuation Phase.
Placebo (DB Treatment)/Placebo (DB Discontinuation)	Following treatment with dose-matched placebo to suvorexant during the 12-Month DB Treatment Phase, participants continued to receive dose-matched placebo to suvorexant during a 2-month DB Randomized Discontinuation Phase.

Participant Flow for 2 periods

Period 1: DB Treatment Phase

	Suvorexant	Placebo	Suvorexant (DB Treatment)/Suvorexant (DB Discontinuation)	Suvorexant (DB Treatment)/Placebo (DB Discontinuation)	Placebo (DB Treatment)/Placebo (DB Discontinuation)
STARTED	522	259	0	0	0
Treated	521	258	0	0	0
COMPLETED	322	162	0	0	0
NOT COMPLETED	200	97	0	0	0
Adverse Event	60	22	0	0	0
Lack of Efficacy	44	28	0	0	0
Lost to Follow-up	14	12	0	0	0
Physician Decision	17	8	0	0	0
Pregnancy	1	0	0	0	0
Protocol Violation	4	3	0	0	0
Withdrawal by Subject	60	24	0	0	0

Period 2: DB Randomized Discontinuation Phase

	Suvorexant	Placebo	Suvorexant (DB Treatment)/Suvorexant (DB Discontinuation)	Suvorexant (DB Treatment)/Placebo (DB Discontinuation)	Placebo (DB Treatment)/Placebo (DB Discontinuation)
STARTED	0	0	156	166	162
COMPLETED	0	0	152	161	157
NOT COMPLETED	0	0	4	5	5
Adverse Event	0	0	0	3	1
Lack of Efficacy	0	0	0	1	0
Lost to Follow-up	0	0	0	0	1
Protocol Violation	0	0	1	0	0
Withdrawal by Subject	0	0	3	1	3

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.
781 participants were randomized on study (suvorexant=522, placebo=259). 2 participants were randomized but not treated, thus the total number of participants evaluated for baseline age and gender was 779 (suvorexant=521, placebo=258). 771 participants had data available for evaluation of baseline sleep parameters (suvorexant=517, placebo=254)

Reporting Groups

	Description
Suvorexant	After a 1-week single-blind placebo run-in, participants received suvorexant (40 mg for participants aged 18 to <65 years; and 30 mg for participants aged ≥65 years) daily before bedtime for 12 months during the double-blind (DB) Treatment Phase.
Placebo	After a 1-week single-blind placebo run-in, participants received dose-matched placebo to suvorexant (administered according to age) daily before bedtime for 12 months during the DB Treatment Phase.
Total	Total of all reporting groups

Baseline Measures

	Suvorexant	Placebo	Total
Number of Participants [units: participants]	521	258	779

Age **[units: years]** **Mean (Standard Deviation)**	**61.3 (14.5)**	**62.0 (14.6)**	**61.5 (14.5)**
Gender **[units: participants]**			
Female	**287**	**149**	**436**
Male	**234**	**109**	**343**
Mean Subjective Total Sleep Time (sTSTm) [1] **[units: minutes]** **Mean (Standard Deviation)**	**320.4 (76.1)**	**329.9 (79.4)**	**323.5 (77.3)**
Mean Subjective Time to Sleep Onset in minutes (sTSOm) [2] **[units: minutes]** **Mean (Standard Deviation)**	**65.9 (63.8)**	**65.0 (60.6)**	**65.6 (62.7)**

[1] The baseline sTSTm was defined as the participant's reported total amount of time spent asleep before waking for the day (measured in minutes), calculated as the mean of the last 7 (non-missing) daily e-diary values obtained during the placebo run-in phase.

(n=517, n=254)

[2] The baseline sTSOm was defined as the participant's reported time that he or she required to fall asleep (measured in minutes), calculated as the mean of the last 7 (non-missing) daily e-diary values obtained during the placebo run-in phase.

(n=517, n=254)

Outcome Measures

Hide All Outcome Measures

1. Primary: Percentage of Participants Who Experienced Cataplexy Adverse Events (AEs) During the Double-Blind (DB) Treatment Phase [Time Frame: From the first day of study treatment up to 12 months]

Measure Type	Primary
Measure Title	Percentage of Participants Who Experienced Cataplexy Adverse Events (AEs) During the Double-Blind (DB) Treatment Phase
Measure Description	Cataplexy is defined as a sudden loss of muscle tone while awake which prevents voluntary movement.
Time Frame	From the first day of study treatment up to 12 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 Participants as Treated (APaT) population; all randomized participants who received at least one dose of study treatment.

Reporting Groups

	Description

Suvorexant	After a 1-week single-blind placebo run-in, participants received suvorexant (40 mg for participants aged 18 to <65 years; and 30 mg for participants aged ≥65 years) daily before bedtime for 12 months during the double-blind (DB) Treatment Phase.
Placebo	After a 1-week single-blind placebo run-in, participants received dose-matched placebo to suvorexant (administered according to age) daily before bedtime for 12 months during the DB Treatment Phase.

Measured Values

	Suvorexant	Placebo
Number of Participants Analyzed [units: participants]	**521**	**258**
Percentage of Participants Who Experienced Cataplexy Adverse Events (AEs) During the Double-Blind (DB) Treatment Phase [units: percentage of participants]	**0.0**	**0.0**

No statistical analysis provided for Percentage of Participants Who Experienced Cataplexy Adverse Events (AEs) During the Double-Blind (DB) Treatment Phase

2. Primary: Percentage of Participants Who Experienced Sleep Paralysis AEs During the DB Treatment Phase [Time Frame: From the first day of study treatment up to 12 months]

Measure Type	Primary
Measure Title	Percentage of Participants Who Experienced Sleep Paralysis AEs During the DB Treatment Phase
Measure Description	Sleep paralysis was defined as the inability to perform voluntary muscle movements during sleep. Sleep paralysis adverse events included sleep-onset paralysis (paralysis as one is falling asleep).
Time Frame	From the first day of study treatment up to 12 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 Participants as Treated (APaT) population; all randomized participants who received at least one dose of study treatment

Reporting Groups

	Description
Suvorexant	After a 1-week single-blind placebo run-in, participants received suvorexant (40 mg for participants aged 18 to <65 years; and 30 mg for participants aged ≥65 years) daily before bedtime for 12 months during the double-blind (DB) Treatment Phase.
Placebo	After a 1-week single-blind placebo run-in, participants received dose-matched placebo to suvorexant (administered according to age) daily before bedtime for 12 months during the DB Treatment Phase.

Measured Values

	Suvorexant	Placebo
Number of Participants Analyzed		

[units: participants]	**521**	**258**
Percentage of Participants Who Experienced Sleep Paralysis AEs During the DB Treatment Phase [units: percentage of participants]	**0.4**	**0.0**

Statistical Analysis 1 for Percentage of Participants Who Experienced Sleep Paralysis AEs During the DB Treatment Phase

Groups [1]	All groups
Method [2]	Miettinen & Nurminen Method.
Difference in Percentage [3]	0.4
95% Confidence Interval	-1.1 to 1.4

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The method of Miettinen and Nurminen was used to construct the confidence interval for the difference in the percentage of participants with any sleep paralysis AEs between the Suvorexant group and Placebo group .
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Other relevant estimation information:
	No text entered.

3. Primary: Percentage of Participants Who Experienced Complex Sleep-related Behaviors AEs During the DB Treatment Phase [Time Frame: From the first day of study treatment up to 12 months]

Measure Type	Primary
Measure Title	Percentage of Participants Who Experienced Complex Sleep-related Behaviors AEs During the DB Treatment Phase
Measure Description	Complex sleep-related behaviors were reported as ECIs and were characterized by patients engaging in specific activities while asleep (e.g., eating, drinking, preparing meals, making phone calls, having sex, driving, and sleep walking).
Time Frame	From the first day of study treatment up to 12 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 Participants as Treated (APaT) population; all randomized participants who received at least one dose of study treatment.

Reporting Groups

	Description

Suvorexant	After a 1-week single-blind placebo run-in, participants received suvorexant (40 mg for participants aged 18 to <65 years; and 30 mg for participants aged ≥65 years) daily before bedtime for 12 months during the double-blind (DB) Treatment Phase.
Placebo	After a 1-week single-blind placebo run-in, participants received dose-matched placebo to suvorexant (administered according to age) daily before bedtime for 12 months during the DB Treatment Phase.

Measured Values

	Suvorexant	Placebo
Number of Participants Analyzed [units: participants]	**521**	**258**
Percentage of Participants Who Experienced Complex Sleep-related Behaviors AEs During the DB Treatment Phase [units: percentage of participants]		
any complex sleep-related behaviors	**0.2**	**0.0**
somnambulism	**0.2**	**0.0**

Statistical Analysis 1 for Percentage of Participants Who Experienced Complex Sleep-related Behaviors AEs During the DB Treatment Phase

Groups [1]	All groups
Method [2]	Miettinen & Nurminen Method.
P Value [3]	0.482
Difference in Percentage [4]	0.2
95% Confidence Interval	-1.3 to 1.1

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The method of Miettinen and Nurminen was used to construct the confidence interval for the difference in the percentage of participants with any complex sleep-related behaviors AEs between the Suvorexant group and Placebo group.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[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.

4. Primary: Percentage of Participants Who Experienced Falls AEs During the DB Treatment Phase [Time Frame: From the first day of study treatment up to 12 months]

Measure Type	Primary

Measure Title	Percentage of Participants Who Experienced Falls AEs During the DB Treatment Phase
Measure Description	Falls were adjudicated (to establish whether a fall event was due to cataplexy).
Time Frame	From the first day of study treatment up to 12 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 Participants as Treated (APaT) population; all randomized participants who received at least one dose of study treatment.

Reporting Groups

	Description
Suvorexant	After a 1-week single-blind placebo run-in, participants received suvorexant (40 mg for participants aged 18 to <65 years; and 30 mg for participants aged ≥65 years) daily before bedtime for 12 months during the double-blind (DB) Treatment Phase.
Placebo	After a 1-week single-blind placebo run-in, participants received dose-matched placebo to suvorexant (administered according to age) daily before bedtime for 12 months during the DB Treatment Phase.

Measured Values

	Suvorexant	**Placebo**
Number of Participants Analyzed [units: participants]	**521**	**258**
Percentage of Participants Who Experienced Falls AEs During the DB Treatment Phase [units: percentage of participants]	**2.3**	**3.1**

Statistical Analysis 1 for Percentage of Participants Who Experienced Falls AEs During the DB Treatment Phase

Groups [1]	All groups
Method [2]	Miettinen & Nurminen Method
P Value [3]	0.508
Difference in Percentage [4]	-0.8
95% Confidence Interval	-3.9 to 1.5

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The method of Miettinen and Nurminen was used to calculate the p-value and construct the confidence interval for the difference in the percentage of participants with any falls AEs between the Suvorexant group and Placebo group.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.

[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.

5. Primary: Percentage of Participants Who Experienced Suicidal Ideation and/or Behavior AEs During the DB Treatment Phase [Time Frame: From the first day of study treatment up to 12 months]

Measure Type	Primary
Measure Title	Percentage of Participants Who Experienced Suicidal Ideation and/or Behavior AEs During the DB Treatment Phase
Measure Description	Suicidal ideation included suicidal plans, suicidal tendency, death wishes, life weariness, and suicidal intention. Suicidal behaviors included suicide attempts, suicide gesture, and self-injurious behaviour. Suicidal ideation and/or behavior was reported as an AE and considered an ECI.
Time Frame	From the first day of study treatment up to 12 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 Participants as Treated (APaT) population; all randomized participants who received at least one dose of study treatment.

Reporting Groups

	Description
Suvorexant	After a 1-week single-blind placebo run-in, participants received suvorexant (40 mg for participants aged 18 to <65 years; and 30 mg for participants aged ≥65 years) daily before bedtime for 12 months during the double-blind (DB) Treatment Phase.
Placebo	After a 1-week single-blind placebo run-in, participants received dose-matched placebo to suvorexant (administered according to age) daily before bedtime for 12 months during the DB Treatment Phase.

Measured Values

	Suvorexant	**Placebo**
Number of Participants Analyzed [units: participants]	**521**	**258**
Percentage of Participants Who Experienced Suicidal Ideation and/or Behavior AEs During the DB Treatment Phase [units: percentage of participants]	**0.8**	**0.0**

Statistical Analysis 1 for Percentage of Participants Who Experienced Suicidal Ideation and/or Behavior AEs During the DB Treatment Phase

Groups [1]	All groups

Method [2]	Miettinen & Nurminen Method
P Value [3]	0.159
Difference in Percentage of AEs [4]	0.8
95% Confidence Interval	-0.7 to 2.0

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The method of Miettinen and Nurminen was used to calculate the p-value and construct the confidence interval for the difference in the percentage of participants with any suicidal ideation/behavior AEs considered an ECI between the Suvorexant group and Placebo group.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[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.

6. Primary: Percentage of Participants Who Experienced Hypnagogic/Hypnopompic Hallucinations AEs During the DB Treatment Phase [Time Frame: From the first day of study treatment up to 12 months]

Measure Type	Primary
Measure Title	Percentage of Participants Who Experienced Hypnagogic/Hypnopompic Hallucinations AEs During the DB Treatment Phase
Measure Description	Perceptual distortions associated with transitions between wakefulness and sleep were termed as hypnagogic (occurring during the onset of sleep) or hypnopompic (occurring during onset of wakefulness) hallucinations.
Time Frame	From the first day of study treatment up to 12 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 Participants as Treated (APaT) population; all randomized participants who received at least one dose of study treatment.

Reporting Groups

	Description
Suvorexant	After a 1-week single-blind placebo run-in, participants received suvorexant (40 mg for participants aged 18 to <65 years; and 30 mg for participants aged ≥65 years) daily before bedtime for 12 months during the double-blind (DB) Treatment Phase.
Placebo	After a 1-week single-blind placebo run-in, participants received dose-matched placebo to suvorexant (administered according to age) daily before bedtime for 12 months during the DB Treatment Phase.

Measured Values

	Suvorexant	Placebo
Number of Participants Analyzed [units: participants]	**521**	**258**
Percentage of Participants Who Experienced Hypnagogic/Hypnopompic Hallucinations AEs During the DB Treatment Phase [units: percentage of participants]		
Any hypnagogic/hypnopompic hallucinations AEs	**0.8**	**0.0**
Hypnagogic hallucination	**0.6**	**0.0**
Hypnopompic hallucination	**0.2**	**0.0**

Statistical Analysis 1 for Percentage of Participants Who Experienced Hypnagogic/Hypnopompic Hallucinations AEs During the DB Treatment Phase

Groups [1]	All groups
Method [2]	Miettinen & Nurminen Method
P Value [3]	0.159
Difference in Percentage [4]	0.8
95% Confidence Interval	-0.7 to 2.0

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The method of Miettinen and Nurminen was used to calculate the p-value and construct the confidence interval for the difference in the percentage of participants with any Hypnagogic/hypnopompic hallucinations AEs between the Suvorexant group and Placebo group.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[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.

7. Primary: Percentage of Participants Who Experienced Selected AEs Associated With Potential for Abuse During the DB Treatment Phase [Time Frame: From the first day of study treatment up to 12 months]

Measure Type	Primary
Measure Title	Percentage of Participants Who Experienced Selected AEs Associated With Potential for Abuse During the DB Treatment Phase
Measure Description	The pre-specified terms which were suggestive of abuse potential on this study included depersonalization (feeling of watching oneself act, while having no control over a situation), derealization (alteration in the perception or experience of the external world so that it seems unreal), dissociation (includes a wide

	array of experiences from mild detachment from immediate surroundings to more severe detachment from physical and emotional experience), euphoric mood (exaggerated feeling of physical and emotional well-being and optimism not consonant with apparent stimuli or events), mania (state of abnormally elevated or irritable mood, arousal, and/or energy levels), hallucination (perception in the absence of a stimulus which has qualities of real perception), and potential study medication misuse.
Time Frame	From the first day of study treatment up to 12 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 Participants as Treated (APaT) population; all randomized participants who received at least one dose of study treatment.

Reporting Groups

	Description
Suvorexant	After a 1-week single-blind placebo run-in, participants received suvorexant (40 mg for participants aged 18 to <65 years; and 30 mg for participants aged ≥65 years) daily before bedtime for 12 months during the double-blind (DB) Treatment Phase.
Placebo	After a 1-week single-blind placebo run-in, participants received dose-matched placebo to suvorexant (administered according to age) daily before bedtime for 12 months during the DB Treatment Phase.

Measured Values

	Suvorexant	**Placebo**
Number of Participants Analyzed [units: participants]	**521**	**258**
Percentage of Participants Who Experienced Selected AEs Associated With Potential for Abuse During the DB Treatment Phase [units: percentage of participants]		
any selected AE of potential abuse	**3.5**	**3.9**
Drug maladministration	**2.3**	**3.9**
Derealisation	**0.2**	**0.0**
Hallucination, auditory	**0.2**	**0.0**
Hallucination, visual	**0.2**	**0.0**
Hypnagogic hallucination	**0.6**	**0.0**
Hypnopompic hallucination	**0.2**	**0.0**

Statistical Analysis 1 for Percentage of Participants Who Experienced Selected AEs Associated With Potential for Abuse During the DB Treatment Phase

Groups [1]	All groups
Method [2]	Miettinen & Nurminen Method
P Value [3]	0.767

Difference in Percentage [4]	-0.4
95% Confidence Interval	-3.8 to 2.2

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The method of Miettinen and Nurminen was used to calculate the p-value and construct the confidence interval for the difference in the percentage of participants with any selected AEs associated with potential abuse between the Suvorexant group and Placebo group.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[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.

8. Secondary: Percentage of Participants With Withdrawal Symptoms During the DB Run-Out Phase: Tyrer Withdrawal Symptom Questionnaire (WSQ) [Time Frame: Evening of Month 12 visit and next 3 consecutive days (Night 1, 2, and 3 of Discontinuation Phase [otherwise known as the Run-out])]

Measure Type	Secondary
Measure Title	Percentage of Participants With Withdrawal Symptoms During the DB Run-Out Phase: Tyrer Withdrawal Symptom Questionnaire (WSQ)
Measure Description	Withdrawal effects assessed using Tyrer WSQ, which evaluated the presence/absence and severity of withdrawal symptoms with 20 items (i.e. sensitivity to noise, light, smell, touch, feeling unreal, etc). The Tyrer WSQ was completed as part of the evening e-diary prior to dosing on the Month 12 visit and on the 3 consecutive evenings of the DB Run-out Phase (first 3 nights of DB Discontinuation Phase). Responses rated 0 (No), 1 (Yes-moderate), or 2 (Yes-severe); range from 0 (no withdrawal) to 40 (severe withdrawal). A participant was defined to have a withdrawal symptom if an item during any of the 3 DB Run-out days had emerged for the first time, or had worsened compared to the measurement obtained at the end of the Treatment phase (Month 12). For single night analysis, a patient was defined to have withdrawal effects if the number of withdrawal symptoms (emergent or worsening) was ≥3. For across night analysis, withdrawal was defined as a total of ≥3 symptoms across the 3 nights.
Time Frame	Evening of Month 12 visit and next 3 consecutive days (Night 1, 2, and 3 of Discontinuation Phase [otherwise known as the Run-out])
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.
Participants in the APaT population who completed the entire DB Treatment Phase, had at least one measurement at the end of the DB Treatment Phase (Month 12), had taken at least one dose of Run-out study medication, and had a measurement on at least one of the nights of the DB Run-out Phase.

Reporting Groups

	Description
Suvorexant (DB Treatment)/Suvorexant (DB Discontinuation)	Following treatment with suvorexant during the 12-Month DB Treatment Period, participants received their same dose of suvorexant during a 2-month DB Discontinuation Period.

Suvorexant (DB Treatment)/Placebo (DB Discontinuation)	Following treatment with suvorexant during the 12-Month DB Treatment Period, participants received dose-matched placebo to suvorexant during a 2-month DB Discontinuation Period.
Placebo (DB Treatment)/Placebo (DB Discontinuation)	Following treatment with dose-matched placebo to suvorexant during the 12-Month DB Treatment Period, participants continued to receive dose-matched placebo to suvorexant during a 2-month DB Discontinuation Period.

Measured Values

	Suvorexant (DB Treatment)/Suvorexant (DB Discontinuation)	Suvorexant (DB Treatment)/Placebo (DB Discontinuation)	Placebo (DB Treatment)/Placebo (DB Discontinuation)
Number of Participants Analyzed [units: participants]	**129**	**129**	**136**
Percentage of Participants With Withdrawal Symptoms During the DB Run-Out Phase: Tyrer Withdrawal Symptom Questionnaire (WSQ) [units: percentage of participants]			
Withdrawal Symptoms on Night 1 (n=121, 122, 131)	**0.8**	**1.6**	**1.5**
Withdrawal Symptoms on Night 2 (n=121, 124, 125)	**0.8**	**3.2**	**2.4**
Withdrawal Symptoms on Night 3 (n=116, 120, 128)	**1.7**	**2.5**	**0.8**
Symptoms Across Nights 1, 2, & 3 (n=129, 129, 136)	**6.2**	**6.2**	**5.1**

Statistical Analysis 1 for Percentage of Participants With Withdrawal Symptoms During the DB Run-Out Phase: Tyrer Withdrawal Symptom Questionnaire (WSQ)

Groups [1]	Suvorexant (DB Treatment)/Suvorexant (DB Discontinuation) vs. Suvorexant (DB Treatment)/Placebo (DB Discontinuation)
Method [2]	Miettinen & Nurminen Method
P Value [3]	0.567
Difference in Percentage: Night 1 [4]	-0.81
95% Confidence Interval	-5.1 to 3.1

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The method of Miettinen and Nurminen was used to calculate the p-value and compute the confidence interval for the point difference in a pairwise comparison of the percentage of participants with withdrawal symptoms during Night 1 in the Suvorexant (DB Treatment)/Suvorexant (DB Discontinuation) group vs. the Suvorexant (DB Treatment)/Placebo (DB Discontinuation) group.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[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.

Statistical Analysis 2 for Percentage of Participants With Withdrawal Symptoms During the DB Run-Out Phase: Tyrer Withdrawal Symptom Questionnaire (WSQ)

Groups [1]	Suvorexant (DB Treatment)/Suvorexant (DB Discontinuation) vs. Suvorexant (DB Treatment)/Placebo (DB Discontinuation)
Method [2]	Miettinen & Nurminen Method
P Value [3]	0.185
Difference in Percentage: Night 2 [4]	-2.40
95% Confidence Interval	-7.3 to 1.6

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The method of Miettinen and Nurminen was used to calculate the p-value and compute the confidence interval for the point difference in a pairwise comparison of the percentage of participants with withdrawal symptoms during Night 2 in the Suvorexant (DB Treatment)/Suvorexant (DB Discontinuation) group vs. the Suvorexant (DB Treatment)/Placebo (DB Discontinuation) group.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[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.

Statistical Analysis 3 for Percentage of Participants With Withdrawal Symptoms During the DB Run-Out Phase: Tyrer Withdrawal Symptom Questionnaire (WSQ)

Groups [1]	Suvorexant (DB Treatment)/Suvorexant (DB Discontinuation) vs. Suvorexant (DB Treatment)/Placebo (DB Discontinuation)
Method [2]	Miettinen & Nurminen Method
P Value [3]	0.680
Difference in Percentage: Night 3 [4]	-0.78
95% Confidence Interval	-5.6 to 3.9

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The method of Miettinen and Nurminen was used to calculate the p-value and compute the confidence interval for the point difference in a pairwise comparison of the percentage of participants with withdrawal symptoms during Night 3 in the Suvorexant (DB Treatment)/Suvorexant (DB Discontinuation) group vs. the Suvorexant (DB Treatment)/Placebo (DB Discontinuation) group.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[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.

Statistical Analysis 4 for Percentage of Participants With Withdrawal Symptoms During the DB Run-Out Phase: Tyrer Withdrawal Symptom Questionnaire (WSQ)

Groups [1]	Suvorexant (DB Treatment)/Suvorexant (DB Discontinuation) vs. Suvorexant (DB Treatment)/Placebo (DB Discontinuation)
Method [2]	Miettinen & Nurminen Method
P Value [3]	1.000
Difference in Percentage: Across Nights [4]	0.00
95% Confidence Interval	-6.4 to 6.4

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The method of Miettinen and Nurminen was used to calculate the p-value and compute the confidence interval for the point difference in a pairwise comparison of the percentage of participants with withdrawal symptoms across Nights 1, 2, and 3 in the Suvorexant (DB Treatment)/Suvorexant (DB Discontinuation) group vs. the Suvorexant (DB Treatment)/Placebo (DB Discontinuation) group.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[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.

9. Secondary: Percentage of Participants With Rebound As Defined By Decreased Subjective Total Sleep Time (sTST) During the DB Run-Out Phase [Time Frame: Baseline (Month 1) and first 3 days of Randomized Discontinuation Phase (otherwise known as the Run-out, Month 13)]

Measure Type	Secondary
Measure Title	Percentage of Participants With Rebound As Defined By Decreased Subjective Total Sleep Time (sTST) During the DB Run-Out Phase
Measure Description	Rebound insomnia was defined as insomnia that occurred following discontinuation of a sedative substance taken to relieve primary insomnia, and was assessed based on subjective total sleep time (sTST) as recorded in the participant's morning e-diary. A strict categorical analysis method (Yes/No) was used in which a participant was considered to have potentially experienced rebound (Yes) if the Morning Diary participant-reported sTST value (in minutes) on any of the 3 nights of the Run-out Phase (first 3 nights of the Discontinuation Phase) occurring after one year of treatment (Month 13) was less than the last value at baseline one year earlier (Month 1).
Time Frame	Baseline (Month 1) and first 3 days of Randomized Discontinuation Phase (otherwise known as the Run-out, Month 13)
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.
Participants in the APaT population who completed the entire DB Treatment Phase, had a baseline measurement, had taken at least one dose of DB Run-out study medication, and had a measurement on at least one of the nights of the DB Run-out Phase.

Reporting Groups

	Description
Suvorexant (DB Treatment)/Suvorexant (DB Discontinuation)	Following treatment with suvorexant during the 12-Month DB Treatment Period, participants received their same dose of suvorexant during a 2-month DB Discontinuation Period.
Suvorexant (DB Treatment)/Placebo (DB Discontinuation)	Following treatment with suvorexant during the 12-Month DB Treatment Period, participants received dose-matched placebo to suvorexant during a 2-month DB Discontinuation Period.
Placebo (DB Treatment)/Placebo (DB Discontinuation)	Following treatment with dose-matched placebo to suvorexant during the 12-Month DB Treatment Period, participants continued to receive dose-matched placebo to suvorexant during a 2-month DB Discontinuation Period.

Measured Values

	Suvorexant (DB Treatment)/Suvorexant (DB Discontinuation)	Suvorexant (DB Treatment)/Placebo (DB Discontinuation)	Placebo (DB Treatment)/Placebo (DB Discontinuation)
Number of Participants Analyzed [units: participants]	**152**	**157**	**152**
Percentage of Participants With Rebound As Defined By Decreased Subjective Total Sleep Time (sTST) During the DB Run-Out Phase [units: percentage of participants]			
Rebound on Night 1 (n=137, 142, 139)	**17.5**	**33.8**	**28.8**
Rebound on Night 2 (n=138, 146, 145)	**19.6**	**35.6**	**26.9**
Rebound on Night 3 (n=131, 146, 139)	**16.8**	**37.7**	**31.7**
Rebound on Nights 1, 2 or 3 (n=152, 157, 152)	**28.9**	**51.0**	**40.1**

Statistical Analysis 1 for Percentage of Participants With Rebound As Defined By Decreased Subjective Total Sleep Time (sTST) During the DB Run-Out Phase

Groups [1]	Suvorexant (DB Treatment)/Suvorexant (DB Discontinuation) vs. Placebo (DB Treatment)/Placebo (DB Discontinuation)
Method [2]	Miettinen & Nurminen Method
P Value [3]	0.365
Difference in Percentage: Night 1 [4]	5.03
95% Confidence Interval	-5.8 to 15.8

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The method of Miettinen and Nurminen was used to calculate the p-value and compute the confidence interval for the point difference in a pairwise comparison of the percentage of participants with sTST rebound effects during Night 1 in the Suvorexant (DB Treatment)/Suvorexant (DB Discontinuation) group vs. the Placebo (DB Treatment)/Placebo (DB Discontinuation) group.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[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.

Statistical Analysis 2 for Percentage of Participants With Rebound As Defined By Decreased Subjective Total Sleep Time (sTST) During the DB Run-Out Phase

Groups [1]	Suvorexant (DB Treatment)/Suvorexant (DB Discontinuation) vs. Placebo (DB Treatment)/Placebo (DB Discontinuation)
Method [2]	Miettinen & Nurminen Method
P Value [3]	0.109
Difference in Percentage: Night 2 [4]	8.72
95% Confidence Interval	-2.0 to 19.2

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The method of Miettinen and Nurminen was used to calculate the p-value and compute the confidence interval for the point difference in a pairwise comparison of the percentage of participants with sTST rebound effects during Night 2 in the Suvorexant (DB Treatment)/Suvorexant (DB Discontinuation) group vs. the Placebo (DB Treatment)/Placebo (DB Discontinuation) group.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[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.

Statistical Analysis 3 for Percentage of Participants With Rebound As Defined By Decreased Subjective Total Sleep Time (sTST) During the DB Run-Out Phase

Groups [1]	Suvorexant (DB Treatment)/Suvorexant (DB Discontinuation) vs. Placebo (DB Treatment)/Placebo (DB Discontinuation)
Method [2]	Miettinen & Nurminen Method
P Value [3]	0.287
Difference in Percentage: Night 3 [4]	6.02
95% Confidence Interval	-5.1 to 16.9

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The method of Miettinen and Nurminen was used to calculate the p-value and compute the confidence interval for the point difference in a pairwise comparison of the percentage of participants with sTST rebound effects during Night 3 in the Suvorexant (DB Treatment)/Suvorexant (DB Discontinuation) group vs. the Placebo (DB Treatment)/Placebo (DB Discontinuation) group.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[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.

Statistical Analysis 4 for Percentage of Participants With Rebound As Defined By Decreased Subjective Total Sleep Time (sTST) During the DB Run-Out Phase

Groups [1]	Suvorexant (DB Treatment)/Suvorexant (DB Discontinuation) vs. Placebo (DB Treatment)/Placebo (DB Discontinuation)
Method [2]	Miettinen & Nurminen Method
P Value [3]	0.057
Difference in Percentage:Night 1, 2 or 3 [4]	10.82
95% Confidence Interval	-0.3 to 21.7

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The method of Miettinen and Nurminen was used to calculate the p-value and compute the confidence interval for the point difference in a pairwise comparison of the percentage of participants with sTST rebound effects during Nights 1, 2, or 3 in the Suvorexant (DB Treatment)/Suvorexant (DB Discontinuation) group vs. the Placebo (DB Treatment)/Placebo (DB Discontinuation) group.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[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.

10. Secondary: Percentage of Participants With Rebound As Defined By Increased Subjective Time to Sleep Onset (sTSO) During the DB Run-Out Phase [Time Frame: Baseline (Month 1) and first 3 days of Randomized Discontinuation Phase (otherwise known as the Run-out, Month 13)]

Measure Type	Secondary
Measure Title	Percentage of Participants With Rebound As Defined By Increased Subjective Time to Sleep Onset (sTSO) During the DB Run-Out Phase
Measure Description	Rebound insomnia was defined as insomnia that occurred following discontinuation of a sedative substance taken to relieve primary insomnia, and was assessed based on subjective time to sleep onset (sTSO) as recorded in the participant's morning e-diary. A strict categorical analysis method (Yes/No) was used in which a participant was considered to have potentially experienced rebound (Yes) if the Morning Diary participant-reported sTSO value (in minutes) on any of the first 3 nights of the Run-out Phase occurring after one year of treatment (Month 13) was greater than the last value at baseline one year earlier (Month 1).
Time Frame	Baseline (Month 1) and first 3 days of Randomized Discontinuation Phase (otherwise known as the Run-out, Month 13)
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.

Participants in the APaT population who completed the entire DB Treatment Phase, had a baseline measurement, had taken at least one dose of DB Run-out study medication, and had a measurement on at least one of the nights of the DB Run-out Phase.

Reporting Groups

	Description
Suvorexant (DB Treatment)/Suvorexant (DB Discontinuation)	Following treatment with suvorexant during the 12-Month DB Treatment Period, participants received their same dose of suvorexant during a 2-month DB Discontinuation Period.
Suvorexant (DB Treatment)/Placebo (DB Discontinuation)	Following treatment with suvorexant during the 12-Month DB Treatment Period, participants received dose-matched placebo to suvorexant during a 2-month DB Discontinuation Period.
Placebo (DB Treatment)/Placebo (DB Discontinuation)	Following treatment with dose-matched placebo to suvorexant during the 12-Month DB Treatment Period, participants continued to receive dose-matched placebo to suvorexant during a 2-month DB Discontinuation Period.

Measured Values

	Suvorexant (DB Treatment)/Suvorexant (DB Discontinuation)	Suvorexant (DB Treatment)/Placebo (DB Discontinuation)	Placebo (DB Treatment)/Placebo (DB Discontinuation)
Number of Participants Analyzed [units: participants]	**152**	**157**	**152**
Percentage of Participants With Rebound As Defined By Increased Subjective Time to Sleep Onset (sTSO) During the DB Run-Out Phase [units: percentage of participants]			
Rebound on Night 1 (n=137, 142, 139)	**16.8**	**26.8**	**22.3**
Rebound on Night 2 (n=138, 146, 145)	**18.8**	**30.1**	**24.8**
Rebound on Night 3 (n=131, 146, 139)	**19.1**	**30.1**	**25.2**
Rebound on Nights 1, 2 or 3 (n=152, 157, 152)	**31.6**	**40.8**	**36.2**

Statistical Analysis 1 for Percentage of Participants With Rebound As Defined By Increased Subjective Time to Sleep Onset (sTSO) During the DB Run-Out Phase

Groups [1]	Suvorexant (DB Treatment)/Suvorexant (DB Discontinuation) vs. Placebo (DB Treatment)/Placebo (DB Discontinuation)
Method [2]	Miettinen & Nurminen Method
P Value [3]	0.386
Difference in Percentage: Night 1 [4]	4.46
95% Confidence Interval	-5.7 to 14.5

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The method of Miettinen and Nurminen was used to calculate the p-value and compute the confidence interval for the point difference in a pairwise comparison of the percentage of participants with sTSO rebound effects during Night 1 in the Suvorexant (DB Treatment)/Suvorexant (DB Discontinuation) group vs. the Placebo (DB Treatment)/Placebo (DB Discontinuation) group.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.

[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.

Statistical Analysis 2 for Percentage of Participants With Rebound As Defined By Increased Subjective Time to Sleep Onset (sTSO) During the DB Run-Out Phase

Groups [1]	Suvorexant (DB Treatment)/Suvorexant (DB Discontinuation) vs. Placebo (DB Treatment)/Placebo (DB Discontinuation)
Method [2]	Miettinen & Nurminen Method
P Value [3]	0.311
Difference in Percentage: Night 2 [4]	5.31
95% Confidence Interval	-5.0 to 15.5

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The method of Miettinen and Nurminen was used to calculate the p-value and compute the confidence interval for the point difference in a pairwise comparison of the percentage of participants with sTSO rebound effects during Night 2 in the Suvorexant (DB Treatment)/Suvorexant (DB Discontinuation) group vs. the Placebo (DB Treatment)/Placebo (DB Discontinuation) group.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[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.

Statistical Analysis 3 for Percentage of Participants With Rebound As Defined By Increased Subjective Time to Sleep Onset (sTSO) During the DB Run-Out Phase

Groups [1]	Suvorexant (DB Treatment)/Suvorexant (DB Discontinuation) vs. Placebo (DB Treatment)/Placebo (DB Discontinuation)
Method [2]	Miettinen & Nurminen Method
P Value [3]	0.351
Difference in Percentage: Night 3 [4]	4.96
95% Confidence Interval	-5.5 to 15.3

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The method of Miettinen and Nurminen was used to calculate the p-value and compute the confidence interval for the point difference in a pairwise comparison of the percentage of participants with sTSO rebound effects during Night 3 in the Suvorexant (DB Treatment)/Suvorexant (DB Discontinuation) group vs. the Placebo (DB Treatment)/Placebo (DB Discontinuation) group.
[2]	Other relevant method information, such as adjustments or degrees of freedom:

	No text entered.
[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.

Statistical Analysis 4 for Percentage of Participants With Rebound As Defined By Increased Subjective Time to Sleep Onset (sTSO) During the DB Run-Out Phase

Groups [1]	Suvorexant (DB Treatment)/Suvorexant (DB Discontinuation) vs. Placebo (DB Treatment)/Placebo (DB Discontinuation)
Method [2]	Miettinen & Nurminen Method
P Value [3]	0.409
Difference in Percentage:Night 1, 2 or 3 [4]	4.58
95% Confidence Interval	-6.3 to 15.3

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The method of Miettinen and Nurminen was used to calculate the p-value and compute the confidence interval for the point difference in a pairwise comparison of the percentage of participants with sTSO rebound effects during Nights 1, 2, or 3 in the Suvorexant (DB Treatment)/Suvorexant (DB Discontinuation) group vs. the Placebo (DB Treatment)/Placebo (DB Discontinuation) group.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[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.

11. Secondary: Least Squares (LS) Mean Change From Baseline in Mean Subjective Total Sleep Time (sTSTm) During First Month of Treatment Phase [Time Frame: Baseline, Week 1, Week 2, Week 3, and Week 4]

Measure Type	Secondary
Measure Title	Least Squares (LS) Mean Change From Baseline in Mean Subjective Total Sleep Time (sTSTm) During First Month of Treatment Phase
Measure Description	The sTSTm was defined as the average over time of daily e-diary values for a participant's report of the total amount of time spent asleep before waking for the day (measured in minutes). Weekly sTSTm values (Week 1, Week 2, etc.) were the average of the daily e-diary values for the week. A summary value of this measure for Month 1 was obtained by taking the average of weekly sTSTm values for Weeks 1 through 4; (Week 1 + Week 2 + Week 3 + Week 4) ÷ 4. LS Mean Change from Baseline in sTSTm was then calculated at Week 1, Week 2, Week 3, Week 4, and Month 1.
Time Frame	Baseline, Week 1, Week 2, Week 3, and Week 4
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.
Full Analysis Set (FAS)-Efficacy; all randomized participants who had ≥1 post-randomization observation for the analysis endpoint subsequent to ≥1 dose of study treatment, and baseline data for those analyses that required baseline data. The number included in the FAS may vary across endpoints due to the degree of missing data for each endpoint.

Reporting Groups

	Description
Suvorexant	After a 1-week single-blind placebo run-in, participants received suvorexant (40 mg for participants aged 18 to <65 years; and 30 mg for participants aged ≥65 years) daily before bedtime for 12 months during the double-blind (DB) Treatment Phase.
Placebo	After a 1-week single-blind placebo run-in, participants received dose-matched placebo to suvorexant (administered according to age) daily before bedtime for 12 months during the DB Treatment Phase.

Measured Values

	Suvorexant	**Placebo**
Number of Participants Analyzed [units: participants]	**517**	**254**
Least Squares (LS) Mean Change From Baseline in Mean Subjective Total Sleep Time (sTSTm) During First Month of Treatment Phase [units: minutes] Least Squares Mean (95% Confidence Interval)		
Change From BL at Week 1 (N=508, 252)	**41.1 (36.9 to 45.3)**	**14.1 (8.2 to 20.1)**
Change From BL at Week 2 (N=495, 248)	**32.4 (28.1 to 36.7)**	**14.7 (8.6 to 20.8)**
Change From BL at Week 3 (N=488, 241)	**39.6 (35.3 to 44.0)**	**16.4 (10.3 to 22.6)**
Change From BL at Week 4 (N=473, 238)	**41.6 (37.1 to 46.1)**	**18.7 (12.3 to 25.1)**
Change From BL at Month 1 Average (N=517, 254)	**38.7 (35.0 to 42.3)**	**16.0 (10.8 to 21.2)**

Statistical Analysis 1 for Least Squares (LS) Mean Change From Baseline in Mean Subjective Total Sleep Time (sTSTm) During First Month of Treatment Phase

Groups [1]	All groups
Method [2]	Longitudinal Data Analysis
P Value [3]	<0.0001

Difference in LS Means: Month 1 [4]	22.7
95% Confidence Interval	16.4 to 29.0

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	A Longitudinal Data Analysis Model was used to test the difference in LS mean change from baseline in sTSTm for Month 1 (Average of Weeks 1, 2, 3, 4) in the Suvorexant group vs. the Placebo group.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	To account for multiplicity, Hochberg's procedure was used to control the overall Type I error rate at the 5% level.
[4]	Other relevant estimation information:
	No text entered.

12. Secondary: Least Squares (LS) Mean Change From Baseline in Mean Subjective Time To Sleep Onset (sTSOm) During First Month of Treatment Phase [Time Frame: Baseline, Week 1, Week 2, Week 3, and Week 4]

Measure Type	Secondary
Measure Title	Least Squares (LS) Mean Change From Baseline in Mean Subjective Time To Sleep Onset (sTSOm) During First Month of Treatment Phase
Measure Description	The sTSOm was defined as the average over time of daily e-diary values for a participant's report of the time he or she required to fall asleep (measured in minutes). Weekly sTSOm values (Week 1, Week 2, etc.) were the average of the daily e-diary values for the week. A summary value of this measure for Month 1 was obtained by taking the average of weekly sTSTm values for Weeks 1 through 4; (Week 1 + Week 2 + Week 3 + Week 4) ÷ 4. LS Mean Change from Baseline in sTSOm was then calculated at Week 1, Week 2, Week 3, Week 4, and Month 1.
Time Frame	Baseline, Week 1, Week 2, Week 3, and Week 4
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.
Full Analysis Set (FAS)-Efficacy; all randomized participants who had ≥1 post-randomization observation for the analysis endpoint subsequent to ≥1 dose of study treatment, and baseline data for those analyses that required baseline data. The number included in the FAS may vary across endpoints due to the degree of missing data for each endpoint.

Reporting Groups

	Description
Suvorexant	After a 1-week single-blind placebo run-in, participants received suvorexant (40 mg for participants aged 18 to <65 years; and 30 mg for participants aged ≥65 years) daily before bedtime for 12 months during the double-blind (DB) Treatment Phase.
Placebo	After a 1-week single-blind placebo run-in, participants received dose-matched placebo to suvorexant (administered according to age) daily before bedtime for 12 months during the DB Treatment Phase.

Measured Values

	Suvorexant	Placebo
Number of Participants Analyzed [units: participants]	**517**	**254**
Least Squares (LS) Mean Change From Baseline in Mean Subjective Time To Sleep Onset (sTSOm) During First Month of Treatment Phase [units: minutes] Least Squares Mean (95% Confidence Interval)		
Change From BL at Week 1 (N=508, 252)	**-17.7 (-20.9 to -14.5)**	**-6.8 (-11.4 to -2.3)**
Change From BL at Week 2 (N=495, 248)	**-15.7 (-19.2 to -12.2)**	**-7.5 (-12.4 to -2.6)**
Change From BL at Week 3 (N=488, 241)	**-18.7 (-22.2 to -15.2)**	**-10.0 (-14.9 to -5.0)**
Change From BL at Week 4 (N=473, 238)	**-19.9 (-23.1 to -16.6)**	**-9.4 (-14.1 to -4.8)**
Change From BL at Month 1 Average (N=517, 254)	**-18.0 (-20.9 to -15.1)**	**-8.4 (-12.5 to -4.3)**

Statistical Analysis 1 for Least Squares (LS) Mean Change From Baseline in Mean Subjective Time To Sleep Onset (sTSOm) During First Month of Treatment Phase

Groups [1]	All groups
Method [2]	Longitudinal Data Analysis
P Value [3]	0.0002
Difference in LS Means: Month 1 [4]	-9.5
95% Confidence Interval	-14.6 to -4.5

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	A Longitudinal Data Analysis Model was used to test the difference in LS mean change from baseline in sTSOm for Month 1 (Average of Weeks 1, 2, 3, 4) in the Suvorexant group vs. the Placebo group.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	To account for multiplicity, Hochberg's procedure was used to control the overall Type I error rate at the 5% level.
[4]	Other relevant estimation information:
	No text entered.

13. Other Pre-specified: Number of Participants Who Reported Suicidal Ideation and/or Behavior On Study Based on Responses to the Columbia Suicide Severity Rating Scale (C-SSRS) [Time Frame: From the first day of study treatment through study follow-up (up to 14 months)]

Measure Type	Other Pre-specified
Measure Title	Number of Participants Who Reported Suicidal Ideation and/or Behavior On Study Based on Responses to the Columbia Suicide Severity Rating Scale (C-SSRS)
Measure Description	Suicidal ideation and/or behavior that occurred on study was also assessed using the C-SSRS, a rater-administered questionnaire used to prospectively assess suicidal ideation and suicidal behavior. C-SSRS assessment was based upon a clinician's interpretation of the participant's responses to the C-SSRS questions, not by a numbered scale. Suicidal ideation and/or behaviors identified on the C-SSRS may not have been considered an adverse event, based on the investigator's judgment.
Time Frame	From the first day of study treatment through study follow-up (up to 14 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 Participants as Treated (APaT) population; all randomized participants who received at least one dose of study treatment.

Reporting Groups

	Description
Suvorexant	After a 1-week single-blind placebo run-in, participants received suvorexant (40 mg for participants aged 18 to <65 years; and 30 mg for participants aged ≥65 years) daily before bedtime for 12 months during the double-blind (DB) Treatment Phase. Following the Treatment Phase, these participants were randomized (at baseline) to suvorexant or placebo during the 2-month Randomized Discontinuation Phase.
Placebo	After a 1-week single-blind placebo run-in, participants received dose-matched placebo to suvorexant (administered according to age) daily before bedtime for 12 months during the DB Treatment Phase. Following the Treatment Phase, these participants continued on placebo during the 2-month Randomized Discontinuation Phase.

Measured Values

	Suvorexant	**Placebo**
Number of Participants Analyzed [units: participants]	**521**	**258**
Number of Participants Who Reported Suicidal Ideation and/or Behavior On Study Based on Responses to the Columbia Suicide Severity Rating Scale (C-SSRS) [units: participants]	**6**	**0**

No statistical analysis provided for Number of Participants Who Reported Suicidal Ideation and/or Behavior On Study Based on Responses to the Columbia Suicide Severity Rating Scale (C-SSRS)

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	AEs were monitored from the time of the Prestudy Visit (~Study Day -14) up to the completion of the Follow-up call, occurring 14 days after Randomized Discontinuation Phase (~Study Day 420) or after the last dose of medication, whichever point was later.
Additional Description	No text entered.

Reporting Groups

	Description
Suvorexant	After a 1-week single-blind placebo run-in, participants received suvorexant (40 mg for participants aged 18 to <65 years; and 30 mg for participants aged ≥65 years) daily before bedtime for 12 months during the double-blind (DB) Treatment Phase.
Placebo	After a 1-week single-blind placebo run-in, participants received dose-matched placebo to suvorexant (administered according to age) daily before bedtime for 12 months during the DB Treatment Phase.
Suvorexant (DB Treatment)/Suvorexant (DB Discontinuation)	Following treatment with suvorexant during the 12-Month DB Treatment Phase, participants received their same dose of suvorexant during a 2-month DB Randomized Discontinuation Phase.
Suvorexant (DB Treatment)/Placebo (DB Discontinuation)	Following treatment with suvorexant during the 12-Month DB Treatment Phase, participants received dose-matched placebo to suvorexant during a 2-month DB Randomized Discontinuation Phase.
Placebo (DB Treatment)/Placebo (DB Discontinuation)	Following treatment with dose-matched placebo to suvorexant during the 12-Month DB Treatment Phase, participants continued to receive dose-matched placebo to suvorexant during a 2-month DB Randomized Discontinuation Phase.
Suvorexant (DB Treatment)/Suvorexant (DB Run-out)/Follow-up	Following treatment with suvorexant during both the 12-Month DB Treatment Period and the DB Run-out period, participants entered a Follow-up Phase which concluded with a follow-up phone call 14 days after the last dose of study medication (or 14 days after the Discontinuation visit, whichever time point was later) to report AEs.
Suvorexant (DB Treatment)/Placebo (DB Run-out)/Follow-up	Following treatment with suvorexant during the 12-Month DB Treatment Period and treatment with dose-matched placebo during the DB the Run-out period, participants entered a Follow-up Phase which concluded with a follow-up phone call 14 days after the last dose of study medication (or 14 days after the Discontinuation visit, whichever time point was later) to report AEs.
Placebo (DB Treatment)/Placebo (DB Run-out)/Follow-up	Following treatment with dose-matched placebo during both the 12-Month DB Treatment Period and the DB Run-out period, participants entered a Follow-up Phase which concluded with a follow-up phone call 14 days after the last dose of study medication (or 14 days after the Discontinuation visit, whichever time point was later) to report AEs.

Serious Adverse Events

	Suvorexant	Placebo	Suvorexant (DB Treatment)/Suvorexant (DB Discontinuation)	Suvorexant (DB Treatment)/Placebo (DB Discontinuation)	Placebo (DB Treatment)/Placebo (DB Discontinuation)	Suvorexant (DB Treatment)/Suvorexant (DB Run-out)/Follow-up	Suvorexant (DB Treatment)/Placebo (DB Run-out)/Follow-up	Placebo (DB Treatment)/Placebo (DB Run-out)/Follow-up
Total, serious adverse events								
# participants affected / at risk	**27/521 (5.18%)**	**17/258 (6.59%)**	**3/156 (1.92%)**	**1/166 (0.60%)**	**1/162 (0.62%)**	**1/260 (0.38%)**	**0/261 (0.00%)**	**2/258 (0.78%)**

Cardiac disorders								
Atrial fibrillation [1]								
# participants affected / at risk	**1/521 (0.19%)**	**3/258 (1.16%)**	**0/156 (0.00%)**	**0/166 (0.00%)**	**0/162 (0.00%)**	**0/260 (0.00%)**	**0/261 (0.00%)**	**0/258 (0.00%)**
# events	**1**	**3**	**0**	**0**	**0**	**0**	**0**	**0**
Coronary artery disease [1]								
# participants affected / at risk	**1/521 (0.19%)**	**0/258 (0.00%)**	**0/156 (0.00%)**	**0/166 (0.00%)**	**0/162 (0.00%)**	**0/260 (0.00%)**	**0/261 (0.00%)**	**0/258 (0.00%)**
# events	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Ear and labyrinth disorders								
Vertigo positional [1]								
# participants affected / at risk	**1/521 (0.19%)**	**0/258 (0.00%)**	**1/156 (0.64%)**	**0/166 (0.00%)**	**0/162 (0.00%)**	**0/260 (0.00%)**	**0/261 (0.00%)**	**0/258 (0.00%)**
# events	**1**	**0**	**1**	**0**	**0**	**0**	**0**	**0**
Gastrointestinal disorders								
Gastrooesophageal reflux [1]								
# participants affected / at risk	**1/521 (0.19%)**	**0/258 (0.00%)**	**0/156 (0.00%)**	**0/166 (0.00%)**	**0/162 (0.00%)**	**0/260 (0.00%)**	**0/261 (0.00%)**	**0/258 (0.00%)**
# events	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Ileus [1]								
# participants affected / at risk	**0/521 (0.00%)**	**1/258 (0.39%)**	**0/156 (0.00%)**	**0/166 (0.00%)**	**0/162 (0.00%)**	**0/260 (0.00%)**	**0/261 (0.00%)**	**0/258 (0.00%)**
# events	**0**	**1**	**0**	**0**	**0**	**0**	**0**	**0**
Pancreatitis [1]								
# participants affected / at risk	**0/521 (0.00%)**	**1/258 (0.39%)**	**0/156 (0.00%)**	**0/166 (0.00%)**	**0/162 (0.00%)**	**0/260 (0.00%)**	**0/261 (0.00%)**	**0/258 (0.00%)**
# events	**0**	**1**	**0**	**0**	**0**	**0**	**0**	**0**
General disorders								
Non-cardiac chest pain [1]								
# participants affected / at risk	**1/521 (0.19%)**	**0/258 (0.00%)**	**0/156 (0.00%)**	**0/166 (0.00%)**	**0/162 (0.00%)**	**0/260 (0.00%)**	**0/261 (0.00%)**	**0/258 (0.00%)**
# events	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Infections and								

infestations								
Abdominal infection [1]								
# participants affected / at risk	**0/521 (0.00%)**	**1/258 (0.39%)**	**0/156 (0.00%)**	**0/166 (0.00%)**	**0/162 (0.00%)**	**0/260 (0.00%)**	**0/261 (0.00%)**	**0/258 (0.00%)**
# events	**0**	**1**	**0**	**0**	**0**	**0**	**0**	**0**
Cellulitis [1]								
# participants affected / at risk	**0/521 (0.00%)**	**0/258 (0.00%)**	**1/156 (0.64%)**	**0/166 (0.00%)**	**0/162 (0.00%)**	**0/260 (0.00%)**	**0/261 (0.00%)**	**0/258 (0.00%)**
# events	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**0**
Diverticulitis [1]								
# participants affected / at risk	**2/521 (0.38%)**	**1/258 (0.39%)**	**0/156 (0.00%)**	**0/166 (0.00%)**	**0/162 (0.00%)**	**0/260 (0.00%)**	**0/261 (0.00%)**	**0/258 (0.00%)**
# events	**2**	**1**	**0**	**0**	**0**	**0**	**0**	**0**
Erysipelas [1]								
# participants affected / at risk	**0/521 (0.00%)**	**1/258 (0.39%)**	**0/156 (0.00%)**	**0/166 (0.00%)**	**0/162 (0.00%)**	**0/260 (0.00%)**	**0/261 (0.00%)**	**0/258 (0.00%)**
# events	**0**	**1**	**0**	**0**	**0**	**0**	**0**	**0**
Pneumonia [1]								
# participants affected / at risk	**1/521 (0.19%)**	**0/258 (0.00%)**	**0/156 (0.00%)**	**0/166 (0.00%)**	**0/162 (0.00%)**	**0/260 (0.00%)**	**0/261 (0.00%)**	**0/258 (0.00%)**
# events	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Postoperative wound infection [1]								
# participants affected / at risk	**0/521 (0.00%)**	**0/258 (0.00%)**	**0/156 (0.00%)**	**0/166 (0.00%)**	**0/162 (0.00%)**	**0/260 (0.00%)**	**0/261 (0.00%)**	**1/258 (0.39%)**
# events	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**
Urinary tract infection [1]								
# participants affected / at risk	**1/521 (0.19%)**	**1/258 (0.39%)**	**0/156 (0.00%)**	**0/166 (0.00%)**	**0/162 (0.00%)**	**0/260 (0.00%)**	**0/261 (0.00%)**	**0/258 (0.00%)**
# events	**1**	**1**	**0**	**0**	**0**	**0**	**0**	**0**
Injury, poisoning and procedural complications								
Clavicle fracture [1]								
# participants affected / at risk	**1/521 (0.19%)**	**0/258 (0.00%)**	**0/156 (0.00%)**	**0/166 (0.00%)**	**0/162 (0.00%)**	**0/260 (0.00%)**	**0/261 (0.00%)**	**0/258 (0.00%)**

# events	1	0	0	0	0	0	0	0
Concussion [1]								
# participants affected / at risk	1/521 (0.19%)	0/258 (0.00%)	0/156 (0.00%)	0/166 (0.00%)	0/162 (0.00%)	0/260 (0.00%)	0/261 (0.00%)	0/258 (0.00%)
# events	1	0	0	0	0	0	0	0
Joint dislocation [1]								
# participants affected / at risk	0/521 (0.00%)	1/258 (0.39%)	0/156 (0.00%)	0/166 (0.00%)	0/162 (0.00%)	0/260 (0.00%)	0/261 (0.00%)	0/258 (0.00%)
# events	0	1	0	0	0	0	0	0
Tendon rupture [1]								
# participants affected / at risk	1/521 (0.19%)	0/258 (0.00%)	0/156 (0.00%)	0/166 (0.00%)	0/162 (0.00%)	0/260 (0.00%)	0/261 (0.00%)	0/258 (0.00%)
# events	1	0	0	0	0	0	0	0
Musculoskeletal and connective tissue disorders								
Arthralgia [1]								
# participants affected / at risk	1/521 (0.19%)	0/258 (0.00%)	0/156 (0.00%)	0/166 (0.00%)	0/162 (0.00%)	0/260 (0.00%)	0/261 (0.00%)	0/258 (0.00%)
# events	1	0	0	0	0	0	0	0
Back pain [1]								
# participants affected / at risk	0/521 (0.00%)	1/258 (0.39%)	0/156 (0.00%)	0/166 (0.00%)	0/162 (0.00%)	0/260 (0.00%)	0/261 (0.00%)	0/258 (0.00%)
# events	0	1	0	0	0	0	0	0
Meniscal degeneration [1]								
# participants affected / at risk	0/521 (0.00%)	1/258 (0.39%)	0/156 (0.00%)	0/166 (0.00%)	0/162 (0.00%)	0/260 (0.00%)	0/261 (0.00%)	0/258 (0.00%)
# events	0	1	0	0	0	0	0	0
Spinal column stenosis [1]								
# participants affected / at risk	1/521 (0.19%)	0/258 (0.00%)	0/156 (0.00%)	0/166 (0.00%)	0/162 (0.00%)	0/260 (0.00%)	0/261 (0.00%)	0/258 (0.00%)
# events	1	0	0	0	0	0	0	0
Spondylitis [1]								
# participants affected / at risk	1/521 (0.19%)	0/258 (0.00%)	0/156 (0.00%)	0/166 (0.00%)	0/162 (0.00%)	0/260 (0.00%)	0/261 (0.00%)	0/258 (0.00%)
# events	1	0	0	0	0	0	0	0

Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
B-cell lymphoma [1]								
# participants affected / at risk	**1/521 (0.19%)**	**0/258 (0.00%)**	**0/156 (0.00%)**	**0/166 (0.00%)**	**0/162 (0.00%)**	**0/260 (0.00%)**	**0/261 (0.00%)**	**0/258 (0.00%)**
# events	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Basal cell carcinoma [1]								
# participants affected / at risk	**2/521 (0.38%)**	**2/258 (0.78%)**	**0/156 (0.00%)**	**0/166 (0.00%)**	**1/162 (0.62%)**	**0/260 (0.00%)**	**0/261 (0.00%)**	**0/258 (0.00%)**
# events	**2**	**2**	**0**	**0**	**1**	**0**	**0**	**0**
Breast cancer in situ [1]								
# participants affected / at risk	**0/521 (0.00%)**	**0/258 (0.00%)**	**0/156 (0.00%)**	**1/166 (0.60%)**	**0/162 (0.00%)**	**0/260 (0.00%)**	**0/261 (0.00%)**	**0/258 (0.00%)**
# events	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**0**
Hodgkin's disease [1]								
# participants affected / at risk	**1/521 (0.19%)**	**0/258 (0.00%)**	**0/156 (0.00%)**	**0/166 (0.00%)**	**0/162 (0.00%)**	**0/260 (0.00%)**	**0/261 (0.00%)**	**0/258 (0.00%)**
# events	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Malignant melanoma [1]								
# participants affected / at risk	**0/521 (0.00%)**	**1/258 (0.39%)**	**0/156 (0.00%)**	**0/166 (0.00%)**	**0/162 (0.00%)**	**0/260 (0.00%)**	**0/261 (0.00%)**	**0/258 (0.00%)**
# events	**0**	**1**	**0**	**0**	**0**	**0**	**0**	**0**
Neoplasm skin [1]								
# participants affected / at risk	**1/521 (0.19%)**	**0/258 (0.00%)**	**0/156 (0.00%)**	**0/166 (0.00%)**	**0/162 (0.00%)**	**0/260 (0.00%)**	**0/261 (0.00%)**	**0/258 (0.00%)**
# events	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Squamous cell carcinoma [1]								
# participants affected / at risk	**1/521 (0.19%)**	**1/258 (0.39%)**	**1/156 (0.64%)**	**0/166 (0.00%)**	**0/162 (0.00%)**	**0/260 (0.00%)**	**0/261 (0.00%)**	**0/258 (0.00%)**
# events	**1**	**1**	**1**	**0**	**0**	**0**	**0**	**0**
Uterine cancer [1]								
# participants affected / at	**1/521 (0.19%)**	**0/258 (0.00%)**	**0/156 (0.00%)**	**0/166 (0.00%)**	**0/162 (0.00%)**	**0/260 (0.00%)**	**0/261 (0.00%)**	**0/258 (0.00%)**

risk								
# events	1	0	0	0	0	0	0	0
Nervous system disorders								
Cerebral infarction [1]								
# participants affected / at risk	0/521 (0.00%)	1/258 (0.39%)	0/156 (0.00%)	0/166 (0.00%)	0/162 (0.00%)	0/260 (0.00%)	0/261 (0.00%)	0/258 (0.00%)
# events	0	1	0	0	0	0	0	0
Cervicobrachial syndrome [1]								
# participants affected / at risk	1/521 (0.19%)	0/258 (0.00%)	0/156 (0.00%)	0/166 (0.00%)	0/162 (0.00%)	0/260 (0.00%)	0/261 (0.00%)	0/258 (0.00%)
# events	1	0	0	0	0	0	0	0
Headache [1]								
# participants affected / at risk	1/521 (0.19%)	0/258 (0.00%)	0/156 (0.00%)	0/166 (0.00%)	0/162 (0.00%)	0/260 (0.00%)	0/261 (0.00%)	0/258 (0.00%)
# events	1	0	0	0	0	0	0	0
Migraine [1]								
# participants affected / at risk	1/521 (0.19%)	0/258 (0.00%)	0/156 (0.00%)	0/166 (0.00%)	0/162 (0.00%)	0/260 (0.00%)	0/261 (0.00%)	0/258 (0.00%)
# events	1	0	0	0	0	0	0	0
Transient ischaemic attack [1]								
# participants affected / at risk	1/521 (0.19%)	0/258 (0.00%)	0/156 (0.00%)	0/166 (0.00%)	0/162 (0.00%)	0/260 (0.00%)	0/261 (0.00%)	0/258 (0.00%)
# events	1	0	0	0	0	0	0	0
Pregnancy, puerperium and perinatal conditions								
Abortion spontaneous [1]								
# participants affected / at risk	0/521 (0.00%)	0/258 (0.00%)	0/156 (0.00%)	0/166 (0.00%)	0/162 (0.00%)	1/260 (0.38%)	0/261 (0.00%)	0/258 (0.00%)
# events	0	0	0	0	0	1	0	0
Psychiatric disorders								
Suicidal ideation [1]								
# participants affected / at	1/521 (0.19%)	0/258 (0.00%)	0/156 (0.00%)	0/166 (0.00%)	0/162 (0.00%)	0/260 (0.00%)	0/261 (0.00%)	0/258 (0.00%)

risk								
# events	1	0	0	0	0	0	0	0
Renal and urinary disorders								
Calculus ureteric [1]								
# participants affected / at risk	0/521 (0.00%)	1/258 (0.39%)	0/156 (0.00%)	0/166 (0.00%)	0/162 (0.00%)	0/260 (0.00%)	0/261 (0.00%)	0/258 (0.00%)
# events	0	1	0	0	0	0	0	0
Renal failure acute [1]								
# participants affected / at risk	0/521 (0.00%)	1/258 (0.39%)	0/156 (0.00%)	0/166 (0.00%)	0/162 (0.00%)	0/260 (0.00%)	0/261 (0.00%)	0/258 (0.00%)
# events	0	1	0	0	0	0	0	0
Reproductive system and breast disorders								
Vaginal prolapse [1]								
# participants affected / at risk	0/521 (0.00%)	1/258 (0.39%)	0/156 (0.00%)	0/166 (0.00%)	0/162 (0.00%)	0/260 (0.00%)	0/261 (0.00%)	0/258 (0.00%)
# events	0	1	0	0	0	0	0	0
Respiratory, thoracic and mediastinal disorders								
Lung disorder [1]								
# participants affected / at risk	1/521 (0.19%)	0/258 (0.00%)	0/156 (0.00%)	0/166 (0.00%)	0/162 (0.00%)	0/260 (0.00%)	0/261 (0.00%)	0/258 (0.00%)
# events	1	0	0	0	0	0	0	0
Vascular disorders								
Hypertension [1]								
# participants affected / at risk	0/521 (0.00%)	0/258 (0.00%)	0/156 (0.00%)	0/166 (0.00%)	0/162 (0.00%)	0/260 (0.00%)	0/261 (0.00%)	1/258 (0.39%)
# events	0	0	0	0	0	0	0	1

[1] Term from vocabulary, MedDRA 14.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	AEs were monitored from the time of the Prestudy Visit (~Study Day -14) up to the completion of the Follow-up call, occurring 14 days after Randomized

	Discontinuation Phase (~Study Day 420) or after the last dose of medication, whichever point was later.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Suvorexant	After a 1-week single-blind placebo run-in, participants received suvorexant (40 mg for participants aged 18 to <65 years; and 30 mg for participants aged ≥65 years) daily before bedtime for 12 months during the double-blind (DB) Treatment Phase.
Placebo	After a 1-week single-blind placebo run-in, participants received dose-matched placebo to suvorexant (administered according to age) daily before bedtime for 12 months during the DB Treatment Phase.
Suvorexant (DB Treatment)/Suvorexant (DB Discontinuation)	Following treatment with suvorexant during the 12-Month DB Treatment Phase, participants received their same dose of suvorexant during a 2-month DB Randomized Discontinuation Phase.
Suvorexant (DB Treatment)/Placebo (DB Discontinuation)	Following treatment with suvorexant during the 12-Month DB Treatment Phase, participants received dose-matched placebo to suvorexant during a 2-month DB Randomized Discontinuation Phase.
Placebo (DB Treatment)/Placebo (DB Discontinuation)	Following treatment with dose-matched placebo to suvorexant during the 12-Month DB Treatment Phase, participants continued to receive dose-matched placebo to suvorexant during a 2-month DB Randomized Discontinuation Phase.
Suvorexant (DB Treatment)/Suvorexant (DB Run-out)/Follow-up	Following treatment with suvorexant during both the 12-Month DB Treatment Period and the DB Run-out period, participants entered a Follow-up Phase which concluded with a follow-up phone call 14 days after the last dose of study medication (or 14 days after the Discontinuation visit, whichever time point was later) to report AEs.
Suvorexant (DB Treatment)/Placebo (DB Run-out)/Follow-up	Following treatment with suvorexant during the 12-Month DB Treatment Period and treatment with dose-matched placebo during the DB the Run-out period, participants entered a Follow-up Phase which concluded with a follow-up phone call 14 days after the last dose of study medication (or 14 days after the Discontinuation visit, whichever time point was later) to report AEs.
Placebo (DB Treatment)/Placebo (DB Run-out)/Follow-up	Following treatment with dose-matched placebo during both the 12-Month DB Treatment Period and the DB Run-out period, participants entered a Follow-up Phase which concluded with a follow-up phone call 14 days after the last dose of study medication (or 14 days after the Discontinuation visit, whichever time point was later) to report AEs.

Other Adverse Events

	Suvorexant	**Placebo**	**Suvorexant (DB Treatment)/Suvorexant (DB Discontinuation)**	**Suvorexant (DB Treatment)/Placebo (DB Discontinuation)**	**Placebo (DB Treatment)/Placebo (DB Discontinuation)**	**Suvorexant (DB Treatment)/Suvorexant (DB Run-out)/Follow-up**	**Suvorexant (DB Treatment)/Placebo (DB Run-out)/Follow-up**	**Placebo (DB Treatment)/Placebo (DB Run-out)/Follow-up**
Total, other (not including serious) adverse events								
# participants affected / at risk	**184/521 (35.32%)**	**63/258 (24.42%)**	**7/156 (4.49%)**	**5/166 (3.01%)**	**9/162 (5.56%)**	**2/260 (0.77%)**	**1/261 (0.38%)**	**2/258 (0.78%)**
General disorders								

Fatigue [1]								
# participants affected / at risk	**34/521 (6.53%)**	**5/258 (1.94%)**	**0/156 (0.00%)**	**0/166 (0.00%)**	**1/162 (0.62%)**	**0/260 (0.00%)**	**0/261 (0.00%)**	**0/258 (0.00%)**
# events	**40**	**5**	**0**	**0**	**1**	**0**	**0**	**0**
Infections and infestations								
Nasopharyngitis [1]								
# participants affected / at risk	**42/521 (8.06%)**	**20/258 (7.75%)**	**5/156 (3.21%)**	**2/166 (1.20%)**	**4/162 (2.47%)**	**2/260 (0.77%)**	**0/261 (0.00%)**	**1/258 (0.39%)**
# events	**53**	**25**	**5**	**2**	**4**	**2**	**0**	**1**
Upper respiratory tract infection [1]								
# participants affected / at risk	**28/521 (5.37%)**	**11/258 (4.26%)**	**1/156 (0.64%)**	**2/166 (1.20%)**	**1/162 (0.62%)**	**0/260 (0.00%)**	**0/261 (0.00%)**	**0/258 (0.00%)**
# events	**32**	**13**	**1**	**3**	**1**	**0**	**0**	**0**
Nervous system disorders								
Dizziness [1]								
# participants affected / at risk	**24/521 (4.61%)**	**16/258 (6.20%)**	**0/156 (0.00%)**	**0/166 (0.00%)**	**1/162 (0.62%)**	**0/260 (0.00%)**	**0/261 (0.00%)**	**0/258 (0.00%)**
# events	**29**	**19**	**0**	**0**	**1**	**0**	**0**	**0**
Headache [1]								
# participants affected / at risk	**43/521 (8.25%)**	**22/258 (8.53%)**	**2/156 (1.28%)**	**0/166 (0.00%)**	**2/162 (1.23%)**	**0/260 (0.00%)**	**1/261 (0.38%)**	**0/258 (0.00%)**
# events	**66**	**25**	**2**	**0**	**2**	**0**	**1**	**0**
Somnolence [1]								
# participants affected / at risk	**69/521 (13.24%)**	**7/258 (2.71%)**	**0/156 (0.00%)**	**1/166 (0.60%)**	**0/162 (0.00%)**	**0/260 (0.00%)**	**0/261 (0.00%)**	**1/258 (0.39%)**
# events	**76**	**7**	**0**	**1**	**0**	**0**	**0**	**1**

1 Term from vocabulary, MedDRA 14.0

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: The Sponsor must have the opportunity to review all proposed abstracts, manuscripts, or presentations regarding this study 60 days prior to submission for publication/presentation. Any information identified by the Sponsor as confidential must be deleted prior to submission. Sponsor review can be expedited to meet publication timelines.

Results Point of Contact:

Name/Title: Vice President, Late Stage Development Group Leader
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Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

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Responsible Party: Merck Sharp & Dohme Corp.
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