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Trial record **1 of 1** for: C10953/3072

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Study to Evaluate the Efficacy and Safety of Armodafinil Treatment as Adjunctive Therapy in Adults With Major Depression Associated With Bipolar I Disorder

This study has been completed.

Sponsor:
Cephalon

Information provided by (Responsible Party):
Teva Pharmaceutical Industries (Cephalon)

ClinicalTrials.gov Identifier:
NCT01072630

First received: February 19, 2010
Last updated: January 15, 2015
Last verified: January 2015
History of Changes

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Purpose

The primary objective of the study is to determine whether armodafinil treatment, at a dosage of 150 mg/day, is more effective than placebo treatment as adjunctive therapy to mood stabilizers for treatment of adults with major depression associated with bipolar I disorder.

Condition	Intervention	Phase
Depression	Drug: Armodafinil Drug: Placebo	Phase 3

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

Official Title: A Double-Blind, Placebo-Controlled, Parallel-Group, Fixed-Dosage Study to Evaluate the Efficacy and Safety of Armodafinil Treatment (150 and 200 mg/Day) as Adjunctive Therapy in Adults With Major Depression Associated With Bipolar I Disorder

Resource links provided by NLM:

MedlinePlus related topics: Suicide

Drug Information available for: Modafinil Armodafinil

U.S. FDA Resources

Further study details as provided by Teva Pharmaceutical Industries:

Primary Outcome Measures:

- Change From Baseline to Week 8 in the Total Score From the 30-Item Inventory of Depressive Symptomatology-Clinician-Rated (IDS-C30) [Time Frame: Day 0 (baseline), Week 8] [Designated as safety issue: No]

  The IDS-C30 is a standardized 30-item, clinician-rated scale to assess the severity of a participant's depressive symptoms. Every effort was made to have the same rater evaluate a participant across all visits.Total scores range from 0-84, with a score of 0 indicating no depression and a score of 84 indicating the most severe depression. Negative change from baseline values indicate improvement in the severity of depression.

Secondary Outcome Measures:

- Percentage of Responders At Different Treatment Weeks According to the 30-Item Inventory of Depressive Symptomatology-Clinician Rated (IDS-C30) Total Score [Time Frame: Day 0 (baseline), Weeks 1, 2, 4, 6, 7, and 8, and last postbaseline observation]
  [Designated as safety issue: No]

  A responder is a participant with a ≥50% decrease or greater from baseline in the total score of the IDS-C30. The IDS-C30 is a standardized 30 -item, clinician-rated scale to assess the severity of a participant's depressive symptoms. Every effort was made to have the same rater evaluate a participant across all visits.Total scores range from 0-84, with a score of 0 indicating no depression and a score of 84 indicating the most severe depression.

- Percentage of Participants in Remission At Different Treatment Weeks According to the 30-Item Inventory of Depressive Symptomatology-Clinician Rated (IDS-C30) Total Score [Time Frame: Weeks 1, 2, 4, 6, 7, and 8, and last postbaseline observation]
  [Designated as safety issue: No]

  A participant in remission was defined as a participant with an IDS-C30 total score of 11 or less.The IDS-C30 is a standardized 30-item, clinician-rated scale to assess the severity of a participant's depressive symptoms. Every effort was made to have the same rater evaluate a participant across all visits.Total scores range from 0-84, with a score of 0 indicating no depression and a score of 84 indicating the most severe depression.

- Change From Baseline to Different Treatment Weeks in the Total Score From the 30-Item Inventory of Depressive Symptomatology-Clinician-Rated (IDS-C30) [Time Frame: Day 0 (baseline), Weeks 1, 2, 4, 6, 7, and 8, and last postbaseline observation]
  [Designated as safety issue: No]

  The IDS-C30 is a standardized 30-item, clinician-rated scale to assess the severity of a participant's depressive symptoms. Every effort was made to have the same rater evaluate a participant across all visits.Total scores range from 0-84, with a score of 0 indicating no depression and a score of 84 indicating the most severe depression. Negative change from baseline values indicate improvement in the severity of depression.

- Change From Baseline to Different Treatment Weeks in the Total Score From the 16-Item Quick Inventory of Depressive Symptomatology-Clinician-Rated (QIDS-C16) [Time Frame: Day 0 (baseline), Weeks 1, 2, 4, 6, 7, and 8, and last postbaseline observation]
  [Designated as safety issue: No]

  The QIDS-C16 was derived from specified items in the IDS-C30, clinician-rated scale to assess the severity of a participant's depressive symptoms. Total scores range from 0-27, with a score of 0 indicating no depression and a score of 27 indicating the most severe depression. Negative change from baseline values indicate improvement in the severity of depression.

- Change From Baseline to Different Treatment Weeks in the Clinical Global Impression of Severity (CGI-S) for Depression [Time Frame: Day 0 (baseline), Weeks 1, 2, 4, 6, 7, and 8, and last postbaseline observation] [Designated as safety issue: No]

  The CGI-S is an observer-rated scale that measures illness severity on a 7-point scale, with the severity of illness scale using a range of responses from 1 (normal) through to 7 (amongst the most severely ill patients). Negative change from baseline values indicate improvement in the severity of depression.

- Change From Baseline to Weeks 4, 8 and Endpoint in the Global Assessment for Functioning (GAF) Scale [Time Frame: Day 0 (baseline), Weeks 1, 2, 4, 6, 7, and 8, and last postbaseline observation] [Designated as safety issue: No]

  The Global Assessment of Functioning (GAF) is a numeric scale (1 through 100) used by mental health clinicians and physicians to rate subjectively the social, occupational, and psychological functioning of adults, e.g., how well or adaptively one is meeting various problems-in-living. Ratings of 1 - 10 mean the participant is in persistent danger of severely hurting self or others (e.g., recurrent violence) or persistent inability to maintain minimal personal hygiene or serious suicidal act with clear expectation of death. Ratings of 91 - 100 indicate no symptoms, and the participant exhibits superior functioning in a wide range of activities, life's problems never seem to get out of hand, is sought out by others because of his or her many positive qualities. Positive change from baseline values indicate improvement in functioning.

- Participants With Treatment-Emergent Adverse Events (TEAE) [Time Frame: Day 1 to Week 9] [Designated as safety issue: Yes]

  AEs were graded by the investigator for severity on a three-point scale: mild, moderate and severe. Causality is graded as either related or not related. A serious adverse event (SAE) is an AE resulting in death, a life-threatening adverse event, hospitalization, a persistent or significant disability/incapacity, a congenital anomaly/birth defect, or an important medical event that may require medical intervention to prevent any of the previous results.Protocol-defined adverse events requiring expedited reporting included skin rash, hypersensitivity reaction, emergent suicidal ideation or suicide attempt, and psychosis.

- Change From Baseline to Endpoint in the Young Mania Rating Scale Total Score [Time Frame: Day 0 (baseline), Week 8 or last postbaseline observation] [Designated as safety issue: Yes]

  The YMRS is a clinician-rated, 11-item checklist used to measure the severity of manic episodes. Information for assigning scores is gained from the participant's subjective reported symptoms over the previous 48 hours and from clinical observation during the interview. Seven items are ranked 0 through 4 and have descriptors associated with each severity level. Four items (irritability, speech, content, and disruptive-aggressive behavior) are scored 0 through 8 and have descriptors for every second increment. The total scale is 0-60. A score of ≤12 indicates remission of manic symptoms, and higher scores indicate greater severity of mania. Negative change from baseline scores indicate a decrease in severity of mania.

- Change From Baseline to Endpoint in the Hamilton Anxiety Scale (HAM-A) Total Score [Time Frame: Day 0 (baseline), Week 8 or last postbaseline observation] [Designated as safety issue: Yes]

  HAM-A measures the severity of anxiety symptoms. The scale consists of 14 items, each defined by a series of symptoms, and measures both psychic anxiety (mental agitation and psychological distress) and somatic anxiety (physical complaints related to anxiety). Each item is scored on a scale of 0 (not present) to 4 (severe), with a total score range of 0-56, where <17 indicates mild severity, 18-24 mild to moderate severity and 25-30 moderate to severe. Negative change from baseline scores indicate a decrease in severity of anxiety.

- Change From Baseline to Endpoint in the Insomnia Severity Index (ISI) Total Score [Time Frame: Day 0 (baseline), Week 8 or last postbaseline observation] [Designated as safety issue: Yes]

  The ISI is a participant-rated, 7-item questionnaire designed to assess the severity of the participant's insomnia. Each item is ranked 0 (none) through 4 (very severe) and has a descriptor associated with each severity level. Total range is 0 (no insomnia) to 28 (very severe insomnia). Responses to each item are added to obtain a total score to determine the severity of insomnia. Negative change from baseline scores indicate a decrease in severity of insomnia.

- Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Behavior - Actual Attempt Question [Time Frame: Weeks 1, 2, 4, 6, 7, 8, and Endpoint] [Designated as safety issue: Yes]

  The C-SSRS is a clinician-rated scale that assesses suicidality from ideation to behaviors and monitors the potential emergence of suicidality in clinical studies. The C-SSRS-B (baseline) was performed at screening and the C-SSRS-SLV ('Since Last Visit') was performed at baseline and weeks 1, 2, 4, 6, 7, and 8 or last postbaseline observation. The Suicidal Behavior - Actual Attempt question records whether the participant committed a potentially self-injurious act with at least some wish to die since the last visit.

- Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Behavior - Non-Suicidal Self-Injurious Behavior Question [Time Frame: Weeks 1, 2, 4, 6, 7, 8, and Endpoint]
  [Designated as safety issue: Yes]

  The C-SSRS is a clinician-rated scale that assesses suicidality from ideation to behaviors and monitors the potential emergence of suicidality in clinical studies. The C-SSRS-B (baseline) was performed at screening and the C-SSRS-SLV ('Since Last Visit') was performed at baseline and weeks 1, 2, 4, 6, 7, and 8 or last postbaseline observation.The Suicidal Behavior - Non-Suicidal Self-Injurious Behavior question records whether the participant committed a potentially self-injurious act that was not associated with a wish to die since the last visit.

- Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Behavior - Interrupted Attempt Question [Time Frame: Weeks 1, 2, 4, 6, 7, 8, and Endpoint] [Designated as safety issue: Yes]

  The C-SSRS is a clinician-rated scale that assesses suicidality from ideation to behaviors and monitors the potential emergence of suicidality in clinical studies. The C-SSRS-B (baseline) was performed at screening and the C-SSRS-SLV ('Since Last Visit') was performed at baseline and weeks 1, 2, 4, 6, 7, and 8 or last postbaseline observation.The Suicidal Behavior - Interrupted Attempt question records whether the participant was interrupted by an outside circumstance from starting the potentially self-injurious act with at least some wish to die since the last visit.

- Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Behavior - Aborted Attempt Question [Time Frame: Weeks 1, 2, 4, 6, 7, 8, and Endpoint] [Designated as safety issue: Yes]

  The C-SSRS is a clinician-rated scale that assesses suicidality from ideation to behaviors and monitors the potential emergence of suicidality in clinical studies. The C-SSRS-B (baseline) was performed at screening and the C-SSRS-SLV ('Since Last Visit') was performed at baseline and weeks 1, 2, 4, 6, 7, and 8 or last postbaseline observation.The Suicidal Behavior - Aborted Attempt question records whether the participant began to take steps toward making a suicide attempt but stops themselves before starting the potentially self-injurious act since the last visit.

- Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Behavior - Suicidal Behavior Question [Time Frame: Weeks 1, 2, 4, 6, 7, 8, and Endpoint] [Designated as safety issue: Yes]

  The C-SSRS is a clinician-rated scale that assesses suicidality from ideation to behaviors and monitors the potential emergence of suicidality in clinical studies. The C-SSRS-B (baseline) was performed at screening and the C-SSRS-SLV ('Since Last Visit') was performed at baseline and weeks 1, 2, 4, 6, 7, and 8 or last postbaseline observation.The Suicidal Behavior - Suicidal Behavior question records whether in the clinician's opinion, the participant exhibited suicidal behavior since the last visit.

- Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Behavior - Preparatory Acts or Behavior Question [Time Frame: Weeks 1, 2, 4, 6, 7, 8, and Endpoint] [Designated as safety issue: Yes]

  The C-SSRS is a clinician-rated scale that assesses suicidality from ideation to behaviors and monitors the potential emergence of suicidality in clinical studies. The C-SSRS-B (baseline) was performed at screening and the C-SSRS-SLV ('Since Last Visit') was performed at baseline and weeks 1, 2, 4, 6, 7, and 8 or last postbaseline observation.The Suicidal Behavior - Preparatory Acts or Behavior question records whether the participant exhibited acts or preparations towards imminently making a suicide attempt since the last visit..

- Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Behavior - Completed Suicide Question [Time Frame: Weeks 1, 2, 4, 6, 7, 8, and Endpoint] [Designated as safety issue: Yes]

  The C-SSRS is a clinician-rated scale that assesses suicidality from ideation to behaviors and monitors the potential emergence of suicidality in clinical studies. The C-SSRS-B (baseline) was performed at screening and the C-SSRS-SLV ('Since Last Visit') was performed at baseline and

weeks 1, 2, 4, 6, 7, and 8 or last postbaseline observation.The Suicidal Behavior - Completed Suicide question records whether the participant intentionally causing his/her's own death since the last visit.

- Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Ideation - Wish to Be Dead Question [Time Frame: Weeks 1, 2, 4, 6, 7, 8, and Endpoint] [Designated as safety issue: Yes]

  The C-SSRS is a clinician-rated scale that assesses suicidality from ideation to behaviors and monitors the potential emergence of suicidality in clinical studies. The C-SSRS-B (baseline) was performed at screening and the C-SSRS-SLV ('Since Last Visit') was performed at baseline and weeks 1, 2, 4, 6, 7, and 8 or last postbaseline observation.The Suicidal Ideation - Wish to Be Dead question records whether the participant endorses thoughts about a wish to dead or not alive anymore, or a wish to fall asleep and not wake up since the last visit.

- Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Ideation - Non-Specific Active Suicidal Thoughts Question [Time Frame: Weeks 1, 2, 4, 6, 7, 8, and Endpoint]
  [Designated as safety issue: Yes]

  The C-SSRS is a clinician-rated scale that assesses suicidality from ideation to behaviors and monitors the potential emergence of suicidality in clinical studies. The C-SSRS-B (baseline) was performed at screening and the C-SSRS-SLV ('Since Last Visit') was performed at baseline and weeks 1, 2, 4, 6, 7, and 8 or last postbaseline observation.The Suicidal Ideation - Non-Specific Active Suicidal Thoughts question records whether the participant shares general non-specific thoughts of wanting to end one's life/commit suicide since the last visit.

- Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Ideation - Any Methods (Not Plan) Without Intent to Act Question [Time Frame: Weeks 1, 2, 4, 6, 7, 8, and Endpoint]
  [Designated as safety issue: Yes]

  The C-SSRS is a clinician-rated scale that assesses suicidality from ideation to behaviors and monitors the potential emergence of suicidality in clinical studies. The C-SSRS-B (baseline) was performed at screening and the C-SSRS-SLV ('Since Last Visit') was performed at baseline and weeks 1, 2, 4, 6, 7, and 8 or last postbaseline observation.The Suicidal Ideation - Any Methods (Not Plan) Without Intent to Act question records whether the participant endorses thoughts of suicide and has thought of at least one method but has no specific plan of action since the last visit.

- Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Ideation - Some Intent to Act Without a Specific Plan Question [Time Frame: Weeks 1, 2, 4, 6, 7, 8, and Endpoint]
  [Designated as safety issue: Yes]

  The C-SSRS is a clinician-rated scale that assesses suicidality from ideation to behaviors and monitors the potential emergence of suicidality in clinical studies. The C-SSRS-B (baseline) was performed at screening and the C-SSRS-SLV ('Since Last Visit') was performed at baseline and weeks 1, 2, 4, 6, 7, and 8 or last postbaseline observation.The Suicidal Ideation - Some Intent to Act Without a Specific Plan question records whether the participant has active suicidal thoughts of killing oneself and reports having some intent to act on such thoughts since the last visit.

- Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Ideation - Specific Plan and Intent Question [Time Frame: Weeks 1, 2, 4, 6, 7, 8, and Endpoint] [Designated as safety issue: Yes]

  The C-SSRS is a clinician-rated scale that assesses suicidality from ideation to behaviors and monitors the potential emergence of suicidality in clinical studies. The C-SSRS-B (baseline) was performed at screening and the C-SSRS-SLV ('Since Last Visit') was performed at baseline and weeks 1, 2, 4, 6, 7, and 8 or last postbaseline observation.The Suicidal Ideation - Specific Plan and Intent question records whether the participant has active suicidal thoughts of killing oneself with details of plan fully or partially worked out and the participant has some intent to carry out the plan since the last visit.

Enrollment:	492
Study Start Date:	March 2010
Study Completion Date:	November 2012
Primary Completion Date:	November 2012 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Placebo Comparator: Placebo Participants were administered placebo and titrated to match the armodafinil treatment arms. Total treatment was 8 weeks.	Drug: Placebo Matching Placebo, also in tablet form taken orally, once daily in the morning. Other Name: placebo
Experimental: Armodafinil 150 mg/day Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 150 mg/day. The 150 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment.	Drug: Armodafinil Doses of either 150mg/day or 200 mg/day in tablet form taken orally, once daily in the morning. Other Names: • Nuvigil

	• CEP-10953
Experimental: Armodafinil 200 mg/day Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 200 mg/day. The 200 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment. This treatment arm was discontinued via a protocol amendment.	Drug: Armodafinil Doses of either 150mg/day or 200 mg/day in tablet form taken orally, once daily in the morning. Other Names: • Nuvigil • CEP-10953

Eligibility

Ages Eligible for Study: 18 Years to 65 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- The patient has a diagnosis of bipolar I disorder according to Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision (DSM-IV-TR) criteria and is currently experiencing a major depressive episode.
- Documentation that the patient has had at least 1 previous manic or mixed episode.
- The patient has had no more than 6 mood episodes in the last year.
- The patient's current major depressive episode must have started no less than 2 weeks and no more than 12 months prior to the screening visit. The current depressive episode must have begun after the patient's current mood stabilizer regime began.
- The patient must have been taking 1 (or 2) of the following protocol-allowed mood stabilizers: lithium, valproic acid, lamotrigine, aripiprazole, olanzapine, risperidone, or ziprasidone (only if taken in combination with lithium or valproic acid).
- Written informed consent is obtained.
- The patient is a man or woman 18 through 65 years of age.
- The patient is in good health (except for diagnosis of bipolar I disorder) as judged by the investigator, on the basis of medical and psychiatric history, medical examination, electrocardiography (ECG), serum chemistry, hematology, and urinalysis.
- Women of childbearing potential (women who have not reached menopause, women who are less than 2 years postmenopausal, and women who are not surgically sterile) who are sexually active must use a medically accepted method of contraception and must agree to continue use of this method for the duration of the study and for 30 days after participation in the study.
- The patient is willing and able to comply with study restrictions and to attend regularly scheduled clinic visits as specified in this protocol.
- The patient has permanent accommodations and means of being contacted by the study center.
- The patient understands that they may enroll in this clinical study only once and may not enroll in any other clinical study while participating in this trial.

Exclusion Criteria:

- The patient has any Axis I disorder apart from bipolar I disorder that was the primary focus of treatment within 6 months of the screening visit or during the screening period.
- The patient has psychotic symptoms or has had psychosis within 4 weeks of the screening visit or during the screening period.
- The patient has current active suicidal ideation, is at imminent risk of self-harm, or has a history of significant suicidal ideation or suicide attempt at any time in the past that causes concern at present.
- The patient has a history of an eating disorder or obsessive compulsive disorder (OCD) within 6 months of the screening visit or during the screening period.
- The patient has a history of alcohol or substance abuse or dependence (with the exception of nicotine dependence) within 3 months of the screening visit or during the screening period.
- The patient has a history of any cutaneous drug reaction or drug hypersensitivity reaction, a history of any clinically significant hypersensitivity reaction, or a history of multiple clinically relevant allergies.
- The patient has any clinically significant uncontrolled medical condition, treated or untreated.
- The patient has received modafinil or armodafinil within the past 5 years, or the patient has a known sensitivity to any ingredients in the study drug tablets.
- The patient has previously participated in a clinical study with armodafinil or has used any investigational product within 90 days of screening. The patient may not enroll in any other clinical study while participating in this study.
- The patient has ever been treated with vagus nerve stimulation (VNS) or deep brain stimulation (DBS), or has been treated with electroconvulsive therapy (ECT) or repetitive transcranial magnetic stimulation (rTMS) within 3 months of the screening visit.
- The patient is a pregnant or lactating woman.

Contacts and Locations

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

Please refer to this study by its ClinicalTrials.gov identifier: NCT01072630

Hide Study Locations

Locations

United States, Alabama

Birmingham Psychiatry Pharmaceutical Studies, Inc
Birmingham, Alabama, United States

United States, California

South Coast Medical Associates/SC Clinical Trials, Inc.
Anaheim, California, United States

Comprehensive NeuroScience
Cerritos, California, United States

Sun Valley Behavioral Medical
Imperial, California, United States

North County Clinical Research
Oceanside, California, United States

CNRI Los Angeles LLC
Pico Rivera, California, United States

CNRI-San Diego LLC
San Diego, California, United States

Clinical Innovations Inc.
Santa Ana, California, United States

Schuster Medical Research Institute
Sherman Oaks, California, United States

Stanford University Medical Center
Stanford, California, United States

Viking Clinical Research Center
Temecula, California, United States

United States, District of Columbia

Comprehensive NeuroScience
Washington DC, District of Columbia, United States

United States, Florida

Scientific Clinical Research, Inc.
Aventura, Florida, United States

Florida Clinical Research Center
Bradenton, Florida, United States

Clinical Neuroscience Solutions Inc
Jacksonville, Florida, United States

Fidelity Clinical Research
Lauderhill, Florida, United States

Compass Research, LLC
Orlando, Florida, United States

Stedman Clinical Trials, LLC
Tampa, Florida, United States

United States, Georgia

Atlanta Center for Medical Research
Atlanta, Georgia, United States

Carman Research
Smyrna, Georgia, United States

United States, Hawaii

Hawaii Clinical Research Center
Honolulu, Hawaii, United States

United States, Illinois

Midwest Center for Neurobehavioral Medicine
Oakbrook Terrace, Illinois, United States

CNS - Comprehensive Neuro Science
Park Ridge, Illinois, United States

United States, Kentucky

Community Research
Crestview Hills, Kentucky, United States

United States, Massachusetts

AccelRx Research
Fall River, Massachusetts, United States

United States, Minnesota

Mayo College of Medicine
Rochester, Minnesota, United States

United States, Mississippi

Precise Research Centers
Flowood, Mississippi, United States

United States, New Jersey

CRI Worldwide, LLC
Mount Laurel, New Jersey, United States

United States, New York

Behavioral Medical Research of Brooklyn
Brooklyn, New York, United States

Fieve Clinical Services, Inc.
New York, New York, United States

Medical and Behavioral Health Research
New York, New York, United States

Behavioral Medical Research of Staten Island
Staten Island, New York, United States

Richmond Behavioral Associates
Staten Island, New York, United States

United States, Ohio

North Coast Clinical Trials, Inc.
Beachwood, Ohio, United States

Neuro-Behavioral Clinical Research, Inc
Canton, Ohio, United States

United States, Oklahoma

IPS Research Company
Oklahoma City, Oklahoma, United States

United States, Oregon

Oregon Center for Clinical Investigators, Inc. (OCCI, Inc.)
Portland, Oregon, United States

United States, Pennsylvania

Lehigh Center for Clinical Research
Allentown, Pennsylvania, United States

Belmont Center for Comprehensive Treatment
Philadelphia, Pennsylvania, United States

United States, Texas

FutureSearch Trials of Neurology
Austin, Texas, United States

Insite Clinical Research
Desoto, Texas, United States

Red Oak Psychiatry Associates, P.A.
Houston, Texas, United States

University Hills Clinical Research
Irving, Texas, United States

United States, Utah

Aspen Clinical Research, LLC
Orem, Utah, United States

Clinical Methods
Salt Lake City, Utah, United States

United States, Virginia

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Malvern, Victoria, Australia

Northern Area Mental Health Services Northern Psychiatric R
Melbourne, Victoria, Australia

Bulgaria

District Department of Psychiatric Disorders With Stationary
Bourgas, Bulgaria

State Psychiatric Hospital - Pazardjik
Pazardjik, Bulgaria

Psychiatric clinic for women UMHAT "Dr. Georgi Stranski"
Pleven, Bulgaria

ODPZS- EOOD, Plovdiv, Bulgaria
Plovdiv, Bulgaria

MHAT Doverie
Sofia, Bulgaria

Psychiatric clinic, University Hospital "Alexandrovska"
Sofia, Bulgaria

Diagnostic Consultative Center "Tchaika"
Varna, Bulgaria

MHAT - Sveta Marina
Varna, Bulgaria

Canada, Alberta

Grey Nuns Hospital
Edmonton, Alberta, Canada

Canada, British Columbia

Dr. Alexander McIntyre, Inc.
Penticton, British Columbia, Canada

Canada, Ontario

Providence Care Mental Health Services
Kingston, Ontario, Canada

Medical Research Associates
Mississauga, Ontario, Canada

Canada, Quebec

Hôpital Louis Hlafontaine
Montreal, Quebec, Canada

France

CMP/CHS du Jura
Dole, France

Centre Hospitalier de Jonzac
Jonzac, France

Hopital Universitaire Caremeau-Batiment Polyvalent, Service
Nîmes, France

Poland

Szpital Uniwersytecki im.dr.A.Jurasza w Bydgoszczy
Bydgoszcz, Poland

Klinika Chorob Psychicznych i Zaburzen Nerwicowych GUM
Gdansk, Poland

Wojewodzki Szpital Psychiatryczny im. prof. Tadeusza Bilikie
Gdansk, Poland

Malopolskie Centrum Medyczne
Krakow, Poland

South Africa

Cape Trial Centre
Cape Town, South Africa

Flexivest Fourteen Research Centre
Cape Town, South Africa

Knighton Surgery
Cape Town, South Africa

Vista Clinic
Centurion, South Africa

Dr Magnus & Dr Brink
Johannesburg, South Africa

Paarl Medical Centre
Paarl, South Africa

Dey Clinic
Pretoria, South Africa

Spain

Hospital del Henares
Coslada (Madrid), Spain

Clínica Universitaria de Navarra
Pamplona, Spain

Hospital Santiago Apostol
Vitoria, Spain

Hospital Psiquiátrico de Álava
Vitoria-Gasteiz, Spain

Ukraine

Odessa Regional Mental Hospital #2

s. Oleksandrivka, Odessa, Ukraine

Donetsk National Medical University n.a. M. Horkyy
Donetsk, Ukraine

Public Institution "Institute of Neurology, Psychiatry and N
Kharkiv, Ukraine

Kiev City Psychoneurological Hospital N 1, CNTRP
Kiev, Ukraine

Danylo Galitsky Lviv State Medical University
Lviv, Ukraine

Odessa Regional Psychoneurology Dispensary
Odessa, Ukraine

Vinnytsa National Medical University named by M.I. Pirogov
Vinnitsa, Ukraine

Sponsors and Collaborators

Cephalon

Investigators

Study Director: Sponsor's Medical Expert Cephalon

More Information

No publications provided

Responsible Party:	Teva Pharmaceutical Industries (Cephalon)
ClinicalTrials.gov Identifier:	NCT01072630 History of Changes
Other Study ID Numbers:	**C10953/3072**, 2009-016634-27
Study First Received:	February 19, 2010
Results First Received:	January 15, 2015
Last Updated:	January 15, 2015
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Keywords provided by Teva Pharmaceutical Industries:
Bipolar I Disorder

Additional relevant MeSH terms:

Depression	Modafinil
Depressive Disorder	Central Nervous System Agents
Depressive Disorder, Major	Central Nervous System Stimulants
Behavioral Symptoms	Pharmacologic Actions
Mental Disorders	Physiological Effects of Drugs
Mood Disorders	Therapeutic Uses
Armodafinil	Wakefulness-Promoting Agents

ClinicalTrials.gov processed this record on May 04, 2015

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Trial record **1 of 1** for: C10953/3072

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Study to Evaluate the Efficacy and Safety of Armodafinil Treatment as Adjunctive Therapy in Adults With Major Depression Associated With Bipolar I Disorder

This study has been completed.

Sponsor:
Cephalon

Information provided by (Responsible Party):
Teva Pharmaceutical Industries (Cephalon)

ClinicalTrials.gov Identifier:
NCT01072630

First received: February 19, 2010
Last updated: January 15, 2015
Last verified: January 2015
History of Changes

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Results First Received: January 15, 2015

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Depression
Interventions:	Drug: Armodafinil Drug: Placebo

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
Region 1: USA and Canada Region 2: Eastern European countries, Kyrgyzstan, Mongolia, Uzbekistan, Cyprus, Greece, and Turkey Region 3: Central and Northern European countries, Andorra, Australia, Iceland, Malta, Monaco, San Marino, and Vatican City Region 4: Rest of World

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Participants were randomized (1:1) to receive150 mg/day armodafinil or matching placebo. The 200-mg/day armodafinil treatment group was discontinued per protocol Amendment 03. Randomization was stratified on the basis of the mood-stabilizing medication and region of the world.

Reporting Groups

	Description
Placebo	Participants were administered placebo and titrated to match the armodafinil treatment arms. Total treatment was 8 weeks.
Armodafinil 150 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 150 mg/day. The 150 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment.

Armodafinil 200 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 200 mg/day. The 200 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment. This treatment arm was discontinued via a protocol amendment.

Participant Flow: Overall Study

	Placebo	Armodafinil 150 mg/Day	Armodafinil 200 mg/Day
STARTED	230	232	30
Safety Population	229 [1]	231 [1]	30 [2]
Full Analysis Population	224 [3]	230 [3]	28 [3]
COMPLETED	175	172	17
NOT COMPLETED	55	60	13
Adverse Event	11	19	2
Lack of Efficacy	10	10	1
Withdrawal by Subject	8	7	2
Protocol Violation	10	8	4
Lost to Follow-up	11	11	1
Noncompliance with study medication	1	1	1
Noncompliance with study procedures	1	2	1
Not specified	3	2	1

[1] Treated participants. One participant was randomized but not treated.
[2] Treated participants.
[3] Treated participants who have at least 1 postbaseline IDS-C30 efficacy assessment

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.
Randomized participants

Reporting Groups

	Description
Placebo	Participants were administered placebo and titrated to match the armodafinil treatment arms. Total treatment was 8 weeks.
Armodafinil 150 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 150 mg/day. The 150 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment.
Armodafinil 200 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 200 mg/day. The 200 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment. This treatment arm was discontinued via a protocol amendment.
Total	Total of all reporting groups

Baseline Measures

	Placebo	Armodafinil 150 mg/Day	Armodafinil 200 mg/Day	Total
Number of Participants [units: participants]	230	232	30	492

Age [units: years] Mean (Standard Deviation)	**43.8 (10.52)**	**44.4 (11.00)**	**41.2 (12.60)**	**43.9 (10.89)**
Gender [units: participants]				
Female	**125**	**128**	**20**	**273**
Male	**105**	**104**	**10**	**219**
Ethnicity (NIH/OMB) [units: participants]				
Hispanic or Latino	**18**	**16**	**2**	**36**
Not Hispanic or Latino	**203**	**206**	**28**	**437**
Unknown or Not Reported	**9**	**10**	**0**	**19**
Race (NIH/OMB) [units: participants]				
American Indian or Alaska Native	**1**	**0**	**0**	**1**
Asian	**3**	**2**	**2**	**7**
Native Hawaiian or Other Pacific Islander	**1**	**0**	**0**	**1**
Black or African American	**54**	**49**	**13**	**116**
White	**162**	**166**	**14**	**342**
More than one race	**0**	**0**	**0**	**0**
Unknown or Not Reported	**9**	**15**	**1**	**25**
Weight [units: kg] Mean (Standard Deviation)	**86.7 (20.21)**	**86.3 (19.21)**	**96.7 (21.91)**	**87.1 (19.96)**
Height [units: cm] Mean (Standard Deviation)	**169.6 (9.88)**	**169.9 (9.44)**	**170.4 (8.25)**	**169.7 (9.57)**
Body Mass Index [units: kg/m^2] Mean (Standard Deviation)	**30.2 (6.86)**	**29.9 (6.39)**	**33.6 (7.58)**	**30.3 (6.73)**
Time Since Start of Current Depressive Episode [units: weeks] Mean (Standard Deviation)	**11.2 (7.79)**	**12.4 (8.99)**	**14.7 (8.73)**	**12.0 (8.46)**
Time Since First Diagnosis for Bipolar [units: years] Mean (Standard Deviation)	**11.4 (9.57)**	**11.7 (9.49)**	**13.3 (10.96)**	**11.6 (9.62)**

Outcome Measures

Hide All Outcome Measures

1. Primary: Change From Baseline to Week 8 in the Total Score From the 30-Item Inventory of Depressive Symptomatology-Clinician-Rated (IDS-C30) [Time Frame: Day 0 (baseline), Week 8]

Measure Type	Primary
Measure Title	Change From Baseline to Week 8 in the Total Score From the 30-Item Inventory of Depressive Symptomatology-Clinician-Rated (IDS-C30)
Measure Description	The IDS-C30 is a standardized 30-item, clinician-rated scale to assess the severity of a participant's depressive symptoms. Every effort was made to have the same rater evaluate a participant across all visits.

	Total scores range from 0-84, with a score of 0 indicating no depression and a score of 84 indicating the most severe depression. Negative change from baseline values indicate improvement in the severity of depression.
Time Frame	Day 0 (baseline), Week 8
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 which includes participants who took 1 or more doses of study drug and who have at least 1 postbaseline IDS-C30 efficacy assessment.

Reporting Groups

	Description
Placebo	Participants were administered placebo and titrated to match the armodafinil treatment arms. Total treatment was 8 weeks.
Armodafinil 150 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 150 mg/day. The 150 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment.
All Armodafinil	This arm combines participants who took 150 mg/day and those in the discontinued treatment arm who took 200 mg/day of armodafinil for 8 weeks.

Measured Values

	Placebo	**Armodafinil 150 mg/Day**	**All Armodafinil**
Number of Participants Analyzed [units: participants]	**224**	**230**	**258**
Change From Baseline to Week 8 in the Total Score From the 30-Item Inventory of Depressive Symptomatology-Clinician-Rated (IDS-C30) [units: units on a scale] Least Squares Mean (Standard Error)	**-18.8 (1.02)**	**-20.9 (1.02)**	**-20.7 (0.98)**

Statistical Analysis 1 for Change From Baseline to Week 8 in the Total Score From the 30-Item Inventory of Depressive Symptomatology-Clinician-Rated (IDS-C30)

Groups [1]	Placebo vs. Armodafinil 150 mg/Day
Method [2]	mixed-model repeated measures (MMRM)
P Value [3]	0.1302
Mean Difference (Final Values) [4]	-2.1
95% Confidence Interval	-4.67 to 0.60

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Treatment, visit, treatment-by-visit interaction, concurrent mood-stabilizing medication, and region of the world used as fixed factors.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	All statistical tests were 2-tailed at the 0.05 level of significance.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Change From Baseline to Week 8 in the Total Score From the 30-Item Inventory of Depressive Symptomatology-Clinician-Rated (IDS-C30)

Groups [1]	Placebo vs. All Armodafinil
Method [2]	mixed-model repeated measures (MMRM)
P Value [3]	0.1350
Mean Difference (Final Values) [4]	-1.9
95% Confidence Interval	-4.51 to 0.61

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Treatment, visit, treatment-by-visit interaction, concurrent mood-stabilizing medication, and region of the world used as fixed factors.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	All statistical tests were 2-tailed at the 0.05 level of significance.
[4]	Other relevant estimation information:
	No text entered.

2. Secondary: Percentage of Responders At Different Treatment Weeks According to the 30-Item Inventory of Depressive Symptomatology-Clinician Rated (IDS-C30) Total Score [Time Frame: Day 0 (baseline), Weeks 1, 2, 4, 6, 7, and 8, and last postbaseline observation]

Measure Type	Secondary
Measure Title	Percentage of Responders At Different Treatment Weeks According to the 30-Item Inventory of Depressive Symptomatology-Clinician Rated (IDS-C30) Total Score
Measure Description	A responder is a participant with a ≥50% decrease or greater from baseline in the total score of the IDS-C30. The IDS-C30 is a standardized 30-item, clinician-rated scale to assess the severity of a participant's depressive symptoms. Every effort was made to have the same rater evaluate a participant across all visits. Total scores range from 0-84, with a score of 0 indicating no depression and a score of 84 indicating the most severe depression.
Time Frame	Day 0 (baseline), Weeks 1, 2, 4, 6, 7, and 8, and last postbaseline observation
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 which includes participants who took 1 or more doses of study drug and who have at least 1 postbaseline IDS-C30 efficacy assessment. The denominator for calculating the percentages at each visit is the number of participants with a nonmissing value at that visit. Endpoint was the last observed postbaseline data.

Reporting Groups

	Description
Placebo	Participants were administered placebo and titrated to match the armodafinil treatment arms. Total treatment was 8 weeks.
Armodafinil 150 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 150 mg/day. The 150 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment.

Armodafinil 200 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 200 mg/day. The 200 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment. This treatment arm was discontinued via a protocol amendment.

Measured Values

	Placebo	Armodafinil 150 mg/Day	Armodafinil 200 mg/Day
Number of Participants Analyzed [units: participants]	**224**	**230**	**28**
Percentage of Responders At Different Treatment Weeks According to the 30-Item Inventory of Depressive Symptomatology-Clinician Rated (IDS-C30) Total Score [units: percentage of participants]			
Week 1 (218, 223, 27)	**5**	**7**	**22**
Week 2 (209, 212, 25)	**16**	**17**	**20**
Week 4 (193, 190, 22)	**28**	**27**	**41**
Week 6 (182, 181, 18)	**36**	**41**	**56**
Week 7 (172, 178, 14)	**40**	**44**	**57**
Week 8 (172, 169, 17)	**47**	**49**	**59**
Endpoint (224, 230, 28)	**39**	**40**	**39**

No statistical analysis provided for Percentage of Responders At Different Treatment Weeks According to the 30-Item Inventory of Depressive Symptomatology-Clinician Rated (IDS-C30) Total Score

3. Secondary: Percentage of Participants in Remission At Different Treatment Weeks According to the 30-Item Inventory of Depressive Symptomatology-Clinician Rated (IDS-C30) Total Score [Time Frame: Weeks 1, 2, 4, 6, 7, and 8, and last postbaseline observation]

Measure Type	Secondary
Measure Title	Percentage of Participants in Remission At Different Treatment Weeks According to the 30-Item Inventory of Depressive Symptomatology-Clinician Rated (IDS-C30) Total Score
Measure Description	A participant in remission was defined as a participant with an IDS-C30 total score of 11 or less. The IDS-C30 is a standardized 30-item, clinician-rated scale to assess the severity of a participant's depressive symptoms. Every effort was made to have the same rater evaluate a participant across all visits. Total scores range from 0-84, with a score of 0 indicating no depression and a score of 84 indicating the most severe depression.
Time Frame	Weeks 1, 2, 4, 6, 7, and 8, and last postbaseline observation
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 which includes participants who took 1 or more doses of study drug and who have at least 1 postbaseline IDS-C30 efficacy assessment. The denominator for calculating the percentages at each visit is the number of participants with a nonmissing value at that visit. Endpoint was the last observed postbaseline data.

Reporting Groups

	Description
Placebo	Participants were administered placebo and titrated to match the armodafinil treatment arms. Total treatment was 8 weeks.

Armodafinil 150 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 150 mg/day. The 150 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment.
Armodafinil 200 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 200 mg/day. The 200 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment. This treatment arm was discontinued via a protocol amendment.

Measured Values

	Placebo	Armodafinil 150 mg/Day	Armodafinil 200 mg/Day
Number of Participants Analyzed [units: participants]	**224**	**230**	**28**
Percentage of Participants in Remission At Different Treatment Weeks According to the 30-Item Inventory of Depressive Symptomatology-Clinician Rated (IDS-C30) Total Score [units: percentage of participants]			
Week 1 (218, 223, 27)	**.5**	**1**	**7**
Week 2 (209, 212, 25)	**7**	**4**	**12**
Week 4 (193, 190, 22)	**11**	**8**	**18**
Week 6 (182, 181, 18)	**19**	**15**	**39**
Week 7 (172, 178, 14)	**19**	**17**	**43**
Week 8 (172, 169, 17)	**22**	**23**	**47**
Endpoint (224, 230, 28)	**17**	**18**	**29**

No statistical analysis provided for Percentage of Participants in Remission At Different Treatment Weeks According to the 30-Item Inventory of Depressive Symptomatology-Clinician Rated (IDS-C30) Total Score

4. Secondary: Change From Baseline to Different Treatment Weeks in the Total Score From the 30-Item Inventory of Depressive Symptomatology -Clinician-Rated (IDS-C30) [Time Frame: Day 0 (baseline), Weeks 1, 2, 4, 6, 7, and 8, and last postbaseline observation]

Measure Type	Secondary
Measure Title	Change From Baseline to Different Treatment Weeks in the Total Score From the 30-Item Inventory of Depressive Symptomatology-Clinician-Rated (IDS-C30)
Measure Description	The IDS-C30 is a standardized 30-item, clinician-rated scale to assess the severity of a participant's depressive symptoms. Every effort was made to have the same rater evaluate a participant across all visits. Total scores range from 0-84, with a score of 0 indicating no depression and a score of 84 indicating the most severe depression. Negative change from baseline values indicate improvement in the severity of depression.
Time Frame	Day 0 (baseline), Weeks 1, 2, 4, 6, 7, and 8, and last postbaseline observation
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 which includes participants who took 1 or more doses of study drug and who have at least 1 postbaseline IDS-C30 efficacy assessment. Participants are included in the analysis at each timepoint if they have a nonmissing value at that visit. Endpoint for analyses was the last observed postbaseline data.

Reporting Groups

	Description

Placebo	Participants were administered placebo and titrated to match the armodafinil treatment arms. Total treatment was 8 weeks.
Armodafinil 150 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 150 mg/day. The 150 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment.
Armodafinil 200 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 200 mg/day. The 200 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment. This treatment arm was discontinued via a protocol amendment.

Measured Values

	Placebo	Armodafinil 150 mg/Day	Armodafinil 200 mg/Day
Number of Participants Analyzed [units: participants]	**224**	**230**	**28**
Change From Baseline to Different Treatment Weeks in the Total Score From the 30-Item Inventory of Depressive Symptomatology-Clinician-Rated (IDS-C30) [units: units on a scale] Mean (Standard Deviation)			
Week 1 (218, 223, 27)	**-6.6 (7.59)**	**-7.2 (8.28)**	**-9.9 (12.92)**
Week 2 (209, 212, 25)	**-11.1 (10.72)**	**-11.8 (9.85)**	**-13.9 (11.99)**
Week 4 (193, 190, 22)	**-15.1 (12.14)**	**-16.7 (10.98)**	**-17.8 (12.82)**
Week 6 (182, 181, 18)	**-18.1 (12.60)**	**-19.1 (11.77)**	**-20.7 (12.30)**
Week 7 (172, 178, 14)	**-19.0 (13.38)**	**021.0 (12.12)**	**-22.8 (14.57)**
Week 8 (172, 169, 17)	**-20.2 (13.81)**	**-22.4 (12.63)**	**-21.8 (13.42)**
Endpoint (224, 230, 28)	**-17.5 (14.28)**	**-19.1 (13.55)**	**-18.6 (13.76)**

No statistical analysis provided for Change From Baseline to Different Treatment Weeks in the Total Score From the 30-Item Inventory of Depressive Symptomatology-Clinician-Rated (IDS-C30)

5. Secondary: Change From Baseline to Different Treatment Weeks in the Total Score From the 16-Item Quick Inventory of Depressive Symptomatology-Clinician-Rated (QIDS-C16) [Time Frame: Day 0 (baseline), Weeks 1, 2, 4, 6, 7, and 8, and last postbaseline observation]

Measure Type	Secondary
Measure Title	Change From Baseline to Different Treatment Weeks in the Total Score From the 16-Item Quick Inventory of Depressive Symptomatology-Clinician-Rated (QIDS-C16)
Measure Description	The QIDS-C16 was derived from specified items in the IDS-C30, clinician-rated scale to assess the severity of a participant's depressive symptoms. Total scores range from 0-27, with a score of 0 indicating no depression and a score of 27 indicating the most severe depression. Negative change from baseline values indicate improvement in the severity of depression.
Time Frame	Day 0 (baseline), Weeks 1, 2, 4, 6, 7, and 8, and last postbaseline observation
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 which includes participants who took 1 or more doses of study drug and who have at least 1 postbaseline IDS-C30 efficacy assessment. The number of participants at each visit is those with a nonmissing value at that visit. Endpoint was the last observed postbaseline data.

Reporting Groups

	Description
Placebo	Participants were administered placebo and titrated to match the armodafinil treatment arms. Total treatment was 8 weeks.
Armodafinil 150 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 150 mg/day. The 150 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment.
Armodafinil 200 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 200 mg/day. The 200 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment. This treatment arm was discontinued via a protocol amendment.

Measured Values

	Placebo	Armodafinil 150 mg/Day	Armodafinil 200 mg/Day
Number of Participants Analyzed [units: participants]	**224**	**230**	**28**
Change From Baseline to Different Treatment Weeks in the Total Score From the 16-Item Quick Inventory of Depressive Symptomatology-Clinician-Rated (QIDS-C16) [units: units on a scale] Mean (Standard Deviation)			
Week 1 (218, 223, 27)	**-2.7 (3.05)**	**-2.9 (3.51)**	**-4.5 (5.16)**
Week 2 (209, 212, 25)	**-4.2 (4.02)**	**-4.5 (3.97)**	**-6.0 (4.63)**
Week 4 (193, 190, 22)	**-5.7 (4.68)**	**-6.5 (4.29)**	**-7.4 (4.80)**
Week 6 (182, 181, 18)	**-6.8 (4.87)**	**-7.5 (4.58)**	**-8.8 (5.05)**
Week 7 (172, 178, 14)	**-7.2 (5.13)**	**-8.1 (4.68)**	**-9.6 (5.50)**
Week 8 (172, 169, 17)	**-7.7 (5.42)**	**-8.6 (4.88)**	**-9.8 (5.68)**
Endpoint (224, 230, 28)	**-6.7 (5.51)**	**-7.4 (5.24)**	**-8.1 (5.47)**

No statistical analysis provided for Change From Baseline to Different Treatment Weeks in the Total Score From the 16-Item Quick Inventory of Depressive Symptomatology-Clinician-Rated (QIDS-C16)

6. Secondary: Change From Baseline to Different Treatment Weeks in the Clinical Global Impression of Severity (CGI-S) for Depression [Time Frame: Day 0 (baseline), Weeks 1, 2, 4, 6, 7, and 8, and last postbaseline observation]

Measure Type	Secondary
Measure Title	Change From Baseline to Different Treatment Weeks in the Clinical Global Impression of Severity (CGI-S) for Depression
Measure Description	The CGI-S is an observer-rated scale that measures illness severity on a 7-point scale, with the severity of illness scale using a range of responses from 1 (normal) through to 7 (amongst the most severely ill patients). Negative change from baseline values indicate improvement in the severity of depression.
Time Frame	Day 0 (baseline), Weeks 1, 2, 4, 6, 7, and 8, and last postbaseline observation

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 which includes participants who took 1 or more doses of study drug and who have at least 1 postbaseline IDS-C30 efficacy assessment. The number of participants is those with a nonmissing value at that visit. Endpoint was the last observed postbaseline data.

Reporting Groups

	Description
Placebo	Participants were administered placebo and titrated to match the armodafinil treatment arms. Total treatment was 8 weeks.
Armodafinil 150 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 150 mg/day. The 150 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment.
Armodafinil 200 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 200 mg/day. The 200 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment. This treatment arm was discontinued via a protocol amendment.

Measured Values

	Placebo	**Armodafinil 150 mg/Day**	**Armodafinil 200 mg/Day**
Number of Participants Analyzed [units: participants]	**224**	**230**	**28**
Change From Baseline to Different Treatment Weeks in the Clinical Global Impression of Severity (CGI-S) for Depression [units: units on a scale] Mean (Standard Deviation)			
Week 1 (218, 223, 27)	**-0.2 (0.48)**	**-0.3 (0.58)**	**-0.6 (0.97)**
Week 2 (209, 212, 25)	**-0.6 (0.83)**	**-0.6 (0.74)**	**-0.8 (1.00)**
Week 4 (193, 190, 22)	**-0.9 (0.99)**	**-0.9 (0.90)**	**-1.1 (1.02)**
Week 6 (182, 181, 18)	**-1.1 (1.14)**	**-1.1 (1.04)**	**-1.3 (0.97)**
Week 7 (172, 178, 14)	**-1.3 (1.14)**	**-1.3 (1.08)**	**-1.4 (1.22)**
Week 8 (174, 171, 17)	**-1.4 (1.24)**	**-1.5 (1.13)**	**-1.8 (1.15)**
Endpoint (224, 230, 28)	**-1.2 (1.27)**	**-1.2 (1.19)**	**-1.3 (1.21)**

No statistical analysis provided for Change From Baseline to Different Treatment Weeks in the Clinical Global Impression of Severity (CGI-S) for Depression

7. Secondary: Change From Baseline to Weeks 4, 8 and Endpoint in the Global Assessment for Functioning (GAF) Scale [Time Frame: Day 0 (baseline), Weeks 1, 2, 4, 6, 7, and 8, and last postbaseline observation]

Measure Type	Secondary
Measure Title	Change From Baseline to Weeks 4, 8 and Endpoint in the Global Assessment for Functioning (GAF) Scale

Measure Description	The Global Assessment of Functioning (GAF) is a numeric scale (1 through 100) used by mental health clinicians and physicians to rate subjectively the social, occupational, and psychological functioning of adults, e.g., how well or adaptively one is meeting various problems-in-living. Ratings of 1 - 10 mean the participant is in persistent danger of severely hurting self or others (e.g., recurrent violence) or persistent inability to maintain minimal personal hygiene or serious suicidal act with clear expectation of death. Ratings of 91 - 100 indicate no symptoms, and the participant exhibits superior functioning in a wide range of activities, life's problems never seem to get out of hand, is sought out by others because of his or her many positive qualities. Positive change from baseline values indicate improvement in functioning.
Time Frame	Day 0 (baseline), Weeks 1, 2, 4, 6, 7, and 8, and last postbaseline observation
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 which includes participants who took 1 or more doses of study drug and who have at least 1 postbaseline IDS-C30 efficacy assessment. The number of participants is those with a nonmissing value at that visit. Endpoint was the last observed postbaseline data.

Reporting Groups

	Description
Placebo	Participants were administered placebo and titrated to match the armodafinil treatment arms. Total treatment was 8 weeks.
Armodafinil 150 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 150 mg/day. The 150 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment.
Armodafinil 200 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 200 mg/day. The 200 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment. This treatment arm was discontinued via a protocol amendment.

Measured Values

	Placebo	**Armodafinil 150 mg/Day**	**Armodafinil 200 mg/Day**
Number of Participants Analyzed [units: participants]	**224**	**230**	**28**
Change From Baseline to Weeks 4, 8 and Endpoint in the Global Assessment for Functioning (GAF) Scale [units: units on a scale] Mean (Standard Deviation)			
Week 4 (193, 190, 22)	**6.4 (8.74)**	**7.2 (10.63)**	**10.0 (9.74)**
Week 8 (172, 171, 17)	**10.8 (11.01)**	**11.6 (11.22)**	**13.4 (11.14)**
Endpoint (213, 219, 25)	**9.6 (11.44)**	**9.3 (11.85)**	**10.5 (10.60)**

No statistical analysis provided for Change From Baseline to Weeks 4, 8 and Endpoint in the Global Assessment for Functioning (GAF) Scale

8. Secondary: Participants With Treatment-Emergent Adverse Events (TEAE) [Time Frame: Day 1 to Week 9]

Measure Type	Secondary
Measure Title	Participants With Treatment-Emergent Adverse Events (TEAE)
Measure Description	AEs were graded by the investigator for severity on a three-point scale: mild, moderate and severe. Causality is graded as either related or not related. A serious adverse event (SAE) is an AE resulting in death, a life-threatening adverse event, hospitalization, a persistent or significant disability/incapacity, a congenital anomaly/birth defect, or an important medical event that may require medical intervention to prevent any of the previous results.

	Protocol-defined adverse events requiring expedited reporting included skin rash, hypersensitivity reaction, emergent suicidal ideation or suicide attempt, and psychosis.
Time Frame	Day 1 to Week 9
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.
The safety analysis set includes randomized participants who took 1 or more doses of study drug

Reporting Groups

	Description
Placebo	Participants were administered placebo and titrated to match the armodafinil treatment arms. Total treatment was 8 weeks.
Armodafinil 150 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 150 mg/day. The 150 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment.
Armodafinil 200 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 200 mg/day. The 200 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment. This treatment arm was discontinued via a protocol amendment.

Measured Values

	Placebo	**Armodafinil 150 mg/Day**	**Armodafinil 200 mg/Day**
Number of Participants Analyzed [units: participants]	**299**	**123**	**21**
Participants With Treatment-Emergent Adverse Events (TEAE) [units: participants]			
>=1 adverse event	**102**	**123**	**21**
Severe adverse event	**7**	**7**	**1**
Treatment-related adverse event	**59**	**78**	**16**
Deaths	**0**	**1**	**0**
Other serious adverse events	**1**	**5**	**2**
Withdrawn from study due to adverse events	**11**	**19**	**2**
Protocol-defined adverse events	**5**	**3**	**3**

No statistical analysis provided for Participants With Treatment-Emergent Adverse Events (TEAE)

9. Secondary: Change From Baseline to Endpoint in the Young Mania Rating Scale Total Score [Time Frame: Day 0 (baseline), Week 8 or last postbaseline observation]

Measure Type	Secondary
Measure Title	Change From Baseline to Endpoint in the Young Mania Rating Scale Total Score
Measure Description	The YMRS is a clinician-rated, 11-item checklist used to measure the severity of manic episodes. Information for assigning scores is gained from the participant's subjective reported symptoms over the previous 48 hours and from clinical observation during the interview. Seven items are ranked 0 through 4 and have descriptors associated with each severity level. Four items (irritability, speech, content, and disruptive-aggressive behavior) are scored 0 through 8 and have descriptors for every second increment. The total scale is 0-60. A score of ≤12 indicates remission of manic symptoms, and higher scores indicate greater severity of mania. Negative change from baseline scores indicate a decrease in severity of mania.
Time Frame	Day 0 (baseline), Week 8 or last postbaseline observation

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.
The safety analysis set includes randomized participants who took 1 or more doses of study drug.

Reporting Groups

	Description
Placebo	Participants were administered placebo and titrated to match the armodafinil treatment arms. Total treatment was 8 weeks.
Armodafinil 150 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 150 mg/day. The 150 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment.
Armodafinil 200 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 200 mg/day. The 200 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment. This treatment arm was discontinued via a protocol amendment.

Measured Values

	Placebo	**Armodafinil 150 mg/Day**	**Armodafinil 200 mg/Day**
Number of Participants Analyzed [units: participants]	**226**	**230**	**28**
Change From Baseline to Endpoint in the Young Mania Rating Scale Total Score [units: units on a scale] Mean (Standard Deviation)	**-0.6 (2.76)**	**-0.5 (3.47)**	**-0.5 (2.71)**

No statistical analysis provided for Change From Baseline to Endpoint in the Young Mania Rating Scale Total Score

10. Secondary: Change From Baseline to Endpoint in the Hamilton Anxiety Scale (HAM-A) Total Score [Time Frame: Day 0 (baseline), Week 8 or last postbaseline observation]

Measure Type	Secondary
Measure Title	Change From Baseline to Endpoint in the Hamilton Anxiety Scale (HAM-A) Total Score
Measure Description	HAM-A measures the severity of anxiety symptoms. The scale consists of 14 items, each defined by a series of symptoms, and measures both psychic anxiety (mental agitation and psychological distress) and somatic anxiety (physical complaints related to anxiety). Each item is scored on a scale of 0 (not present) to 4 (severe), with a total score range of 0-56, where <17 indicates mild severity, 18-24 mild to moderate severity and 25-30 moderate to severe. Negative change from baseline scores indicate a decrease in severity of anxiety.
Time Frame	Day 0 (baseline), Week 8 or last postbaseline observation
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.
The safety analysis set includes randomized participants who took 1 or more doses of study drug. The number analyzed includes participants with both baseline and during treatment assessments.

Reporting Groups

	Description

Placebo	Participants were administered placebo and titrated to match the armodafinil treatment arms. Total treatment was 8 weeks.
Armodafinil 150 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 150 mg/day. The 150 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment.
Armodafinil 200 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 200 mg/day. The 200 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment. This treatment arm was discontinued via a protocol amendment.

Measured Values

	Placebo	**Armodafinil 150 mg/Day**	**Armodafinil 200 mg/Day**
Number of Participants Analyzed [units: participants]	**218**	**221**	**25**
Change From Baseline to Endpoint in the Hamilton Anxiety Scale (HAM-A) Total Score [units: units on a scale] Mean (Standard Deviation)	**-4.3 (4.95)**	**-4.0 (5.50)**	**-2.6 (5.67)**

No statistical analysis provided for Change From Baseline to Endpoint in the Hamilton Anxiety Scale (HAM-A) Total Score

11. Secondary: Change From Baseline to Endpoint in the Insomnia Severity Index (ISI) Total Score [Time Frame: Day 0 (baseline), Week 8 or last postbaseline observation]

Measure Type	Secondary
Measure Title	Change From Baseline to Endpoint in the Insomnia Severity Index (ISI) Total Score
Measure Description	The ISI is a participant-rated, 7-item questionnaire designed to assess the severity of the participant's insomnia. Each item is ranked 0 (none) through 4 (very severe) and has a descriptor associated with each severity level. Total range is 0 (no insomnia) to 28 (very severe insomnia). Responses to each item are added to obtain a total score to determine the severity of insomnia. Negative change from baseline scores indicate a decrease in severity of insomnia.
Time Frame	Day 0 (baseline), Week 8 or last postbaseline observation
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.
The safety analysis set includes randomized participants who took 1 or more doses of study drug. The number analyzed includes participants with both baseline and during treatment assessments.

Reporting Groups

	Description
Placebo	Participants were administered placebo and titrated to match the armodafinil treatment arms. Total treatment was 8 weeks.
Armodafinil 150 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 150 mg/day. The 150 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment.
Armodafinil 200 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 200 mg/day. The 200 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment. This treatment arm was discontinued via a protocol amendment.

Measured Values

	Placebo	**Armodafinil 150 mg/Day**	**Armodafinil 200 mg/Day**

Number of Participants Analyzed [units: participants]	**217**	**219**	**25**
Change From Baseline to Endpoint in the Insomnia Severity Index (ISI) Total Score [units: units on a scale] Mean (Standard Deviation)	**-5.2 (6.89)**	**-6.7 (7.18)**	**-6.2 (6.93)**

No statistical analysis provided for Change From Baseline to Endpoint in the Insomnia Severity Index (ISI) Total Score

12. Secondary: Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Behavior - Actual Attempt Question [Time Frame: Weeks 1, 2, 4, 6, 7, 8, and Endpoint]

Measure Type	Secondary
Measure Title	Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Behavior - Actual Attempt Question
Measure Description	The C-SSRS is a clinician-rated scale that assesses suicidality from ideation to behaviors and monitors the potential emergence of suicidality in clinical studies. The C-SSRS-B (baseline) was performed at screening and the C-SSRS-SLV ('Since Last Visit') was performed at baseline and weeks 1, 2, 4, 6, 7, and 8 or last postbaseline observation. The Suicidal Behavior - Actual Attempt question records whether the participant committed a potentially self-injurious act with at least some wish to die since the last visit.
Time Frame	Weeks 1, 2, 4, 6, 7, 8, and Endpoint
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.
The safety analysis set includes randomized participants who took 1 or more doses of study drug. The number analyzed includes participants with treatment assessments at the indicated time period.

Reporting Groups

	Description
Placebo	Participants were administered placebo and titrated to match the armodafinil treatment arms. Total treatment was 8 weeks.
Armodafinil 150 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 150 mg/day. The 150 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment.
Armodafinil 200 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 200 mg/day. The 200 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment. This treatment arm was discontinued via a protocol amendment.

Measured Values

	Placebo	**Armodafinil 150 mg/Day**	**Armodafinil 200 mg/Day**
Number of Participants Analyzed [units: participants]	**229**	**231**	**30**
Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Behavior - Actual Attempt Question [units: participants]			
Week 1 (218, 223, 27)	**0**	**0**	**0**
Week 2 (209, 212, 25)	**0**	**0**	**0**

Week 4 (193, 190, 22)	**0**	**0**	**0**
Week 6 (182, 181, 18)	**0**	**0**	**0**
Week 7 (172, 178, 14)	**0**	**0**	**0**
Week 8 (174, 171, 17)	**0**	**0**	**0**
Endpoint (226, 230, 28)	**0**	**0**	**0**

No statistical analysis provided for Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Behavior - Actual Attempt Question

13. Secondary: Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Behavior - Non-Suicidal Self-Injurious Behavior Question [Time Frame: Weeks 1, 2, 4, 6, 7, 8, and Endpoint]

Measure Type	Secondary
Measure Title	Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Behavior - Non-Suicidal Self-Injurious Behavior Question
Measure Description	The C-SSRS is a clinician-rated scale that assesses suicidality from ideation to behaviors and monitors the potential emergence of suicidality in clinical studies. The C-SSRS-B (baseline) was performed at screening and the C-SSRS-SLV ('Since Last Visit') was performed at baseline and weeks 1, 2, 4, 6, 7, and 8 or last postbaseline observation. The Suicidal Behavior - Non-Suicidal Self-Injurious Behavior question records whether the participant committed a potentially self-injurious act that was not associated with a wish to die since the last visit.
Time Frame	Weeks 1, 2, 4, 6, 7, 8, and Endpoint
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.
The safety analysis set includes randomized participants who took 1 or more doses of study drug. The number analyzed includes participants with treatment assessments at the indicated time period.

Reporting Groups

	Description
Placebo	Participants were administered placebo and titrated to match the armodafinil treatment arms. Total treatment was 8 weeks.
Armodafinil 150 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 150 mg/day. The 150 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment.
Armodafinil 200 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 200 mg/day. The 200 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment. This treatment arm was discontinued via a protocol amendment.

Measured Values

	Placebo	**Armodafinil 150 mg/Day**	**Armodafinil 200 mg/Day**
Number of Participants Analyzed [units: participants]	**229**	**231**	**30**
Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Behavior - Non-Suicidal Self-Injurious Behavior Question [units: participants]			
Week 1 (218, 223, 27)	**0**	**0**	**0**

Week 2 (209, 212, 25)	**0**	**0**	**0**
Week 4 (193, 190, 22)	**0**	**0**	**0**
Week 6 (182, 181, 18)	**0**	**0**	**0**
Week 7 (172, 178, 14)	**0**	**0**	**0**
Week 8 (174, 171, 17)	**0**	**0**	**0**
Endpoint (226, 230, 28)	**0**	**0**	**0**

No statistical analysis provided for Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Behavior - Non-Suicidal Self-Injurious Behavior Question

14. Secondary: Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Behavior - Interrupted Attempt Question [Time Frame: Weeks 1, 2, 4, 6, 7, 8, and Endpoint]

Measure Type	Secondary
Measure Title	Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Behavior - Interrupted Attempt Question
Measure Description	The C-SSRS is a clinician-rated scale that assesses suicidality from ideation to behaviors and monitors the potential emergence of suicidality in clinical studies. The C-SSRS-B (baseline) was performed at screening and the C-SSRS-SLV ('Since Last Visit') was performed at baseline and weeks 1, 2, 4, 6, 7, and 8 or last postbaseline observation. The Suicidal Behavior - Interrupted Attempt question records whether the participant was interrupted by an outside circumstance from starting the potentially self-injurious act with at least some wish to die since the last visit.
Time Frame	Weeks 1, 2, 4, 6, 7, 8, and Endpoint
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.
The safety analysis set includes randomized participants who took 1 or more doses of study drug. The number analyzed includes participants with treatment assessments at the indicated time period.

Reporting Groups

	Description
Placebo	Participants were administered placebo and titrated to match the armodafinil treatment arms. Total treatment was 8 weeks.
Armodafinil 150 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 150 mg/day. The 150 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment.
Armodafinil 200 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 200 mg/day. The 200 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment. This treatment arm was discontinued via a protocol amendment.

Measured Values

	Placebo	**Armodafinil 150 mg/Day**	**Armodafinil 200 mg/Day**
Number of Participants Analyzed [units: participants]	**229**	**231**	**30**
Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Behavior - Interrupted Attempt Question [units: participants]			

Week 1 (218, 223, 27)	**0**	**0**	**0**
Week 2 (209, 212, 25)	**0**	**0**	**0**
Week 4 (193, 190, 22)	**0**	**0**	**0**
Week 6 (182, 181, 18)	**0**	**0**	**0**
Week 7 (172, 178, 14)	**0**	**0**	**0**
Week 8 (174, 171, 17)	**0**	**0**	**0**
Endpoint (226, 230, 28)	**1**	**0**	**0**

No statistical analysis provided for Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Behavior - Interrupted Attempt Question

15. Secondary: Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Behavior - Aborted Attempt Question [Time Frame: Weeks 1, 2, 4, 6, 7, 8, and Endpoint]

Measure Type	Secondary
Measure Title	Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Behavior - Aborted Attempt Question
Measure Description	The C-SSRS is a clinician-rated scale that assesses suicidality from ideation to behaviors and monitors the potential emergence of suicidality in clinical studies. The C-SSRS-B (baseline) was performed at screening and the C-SSRS-SLV ('Since Last Visit') was performed at baseline and weeks 1, 2, 4, 6, 7, and 8 or last postbaseline observation. The Suicidal Behavior - Aborted Attempt question records whether the participant began to take steps toward making a suicide attempt but stops themselves before starting the potentially self-injurious act since the last visit.
Time Frame	Weeks 1, 2, 4, 6, 7, 8, and Endpoint
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.
The safety analysis set includes randomized participants who took 1 or more doses of study drug. The number analyzed includes participants with treatment assessments at the indicated time period.

Reporting Groups

	Description
Placebo	Participants were administered placebo and titrated to match the armodafinil treatment arms. Total treatment was 8 weeks.
Armodafinil 150 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 150 mg/day. The 150 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment.
Armodafinil 200 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 200 mg/day. The 200 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment. This treatment arm was discontinued via a protocol amendment.

Measured Values

	Placebo	**Armodafinil 150 mg/Day**	**Armodafinil 200 mg/Day**
Number of Participants Analyzed [units: participants]	**229**	**231**	**30**
Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Behavior - Aborted Attempt			

Question [units: participants]			
Week 1 (218, 223, 27)	0	0	0
Week 2 (209, 212, 25)	0	0	0
Week 4 (193, 190, 22)	0	0	0
Week 6 (182, 181, 18)	0	0	0
Week 7 (172, 178, 14)	0	0	0
Week 8 (174, 171, 17)	0	0	0
Endpoint (226, 230, 28)	0	0	0

No statistical analysis provided for Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Behavior - Aborted Attempt Question

16. Secondary: Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Behavior - Suicidal Behavior Question [Time Frame: Weeks 1, 2, 4, 6, 7, 8, and Endpoint]

Measure Type	Secondary
Measure Title	Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Behavior - Suicidal Behavior Question
Measure Description	The C-SSRS is a clinician-rated scale that assesses suicidality from ideation to behaviors and monitors the potential emergence of suicidality in clinical studies. The C-SSRS-B (baseline) was performed at screening and the C-SSRS-SLV ('Since Last Visit') was performed at baseline and weeks 1, 2, 4, 6, 7, and 8 or last postbaseline observation. The Suicidal Behavior - Suicidal Behavior question records whether in the clinician's opinion, the participant exhibited suicidal behavior since the last visit.
Time Frame	Weeks 1, 2, 4, 6, 7, 8, and Endpoint
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.
The safety analysis set includes randomized participants who took 1 or more doses of study drug. The number analyzed includes participants with treatment assessments at the indicated time period.

Reporting Groups

	Description
Placebo	Participants were administered placebo and titrated to match the armodafinil treatment arms. Total treatment was 8 weeks.
Armodafinil 150 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 150 mg/day. The 150 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment.
Armodafinil 200 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 200 mg/day. The 200 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment. This treatment arm was discontinued via a protocol amendment.

Measured Values

	Placebo	**Armodafinil 150 mg/Day**	**Armodafinil 200 mg/Day**
Number of Participants Analyzed [units: participants]	**229**	**231**	**30**

Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Behavior - Suicidal Behavior Question [units: participants]			
Week 1 (218, 223, 27)	0	0	0
Week 2 (209, 212, 25)	0	0	0
Week 4 (193, 190, 22)	0	0	0
Week 6 (182, 181, 18)	0	0	0
Week 7 (172, 178, 14)	0	0	0
Week 8 (174, 171, 17)	0	0	0
Endpoint (226, 230, 28)	0	0	0

No statistical analysis provided for Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Behavior - Suicidal Behavior Question

17. Secondary: Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Behavior - Preparatory Acts or Behavior Question [Time Frame: Weeks 1, 2, 4, 6, 7, 8, and Endpoint]

Measure Type	Secondary
Measure Title	Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Behavior - Preparatory Acts or Behavior Question
Measure Description	The C-SSRS is a clinician-rated scale that assesses suicidality from ideation to behaviors and monitors the potential emergence of suicidality in clinical studies. The C-SSRS-B (baseline) was performed at screening and the C-SSRS-SLV ('Since Last Visit') was performed at baseline and weeks 1, 2, 4, 6, 7, and 8 or last postbaseline observation. The Suicidal Behavior - Preparatory Acts or Behavior question records whether the participant exhibited acts or preparations towards imminently making a suicide attempt since the last visit. .
Time Frame	Weeks 1, 2, 4, 6, 7, 8, and Endpoint
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.
The safety analysis set includes randomized participants who took 1 or more doses of study drug. The number analyzed includes participants with treatment assessments at the indicated time period.

Reporting Groups

	Description
Placebo	Participants were administered placebo and titrated to match the armodafinil treatment arms. Total treatment was 8 weeks.
Armodafinil 150 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 150 mg/day. The 150 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment.
Armodafinil 200 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 200 mg/day. The 200 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment. This treatment arm was discontinued via a protocol amendment.

Measured Values

	Placebo	**Armodafinil 150 mg/Day**	**Armodafinil 200 mg/Day**

Number of Participants Analyzed [units: participants]	**229**	**231**	**30**
Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Behavior - Preparatory Acts or Behavior Question [units: participants]			
Week 1 (218, 223, 27)	**0**	**0**	**0**
Week 2 (209, 212, 25)	**0**	**0**	**0**
Week 4 (193, 190, 22)	**0**	**0**	**0**
Week 6 (182, 181, 18)	**0**	**0**	**0**
Week 7 (172, 178, 14)	**0**	**0**	**0**
Week 8 (174, 171, 17)	**0**	**0**	**0**
Endpoint (226, 230, 28)	**0**	**0**	**0**

No statistical analysis provided for Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Behavior - Preparatory Acts or Behavior Question

18. Secondary: Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Behavior - Completed Suicide Question [Time Frame: Weeks 1, 2, 4, 6, 7, 8, and Endpoint]

Measure Type	Secondary
Measure Title	Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Behavior - Completed Suicide Question
Measure Description	The C-SSRS is a clinician-rated scale that assesses suicidality from ideation to behaviors and monitors the potential emergence of suicidality in clinical studies. The C-SSRS-B (baseline) was performed at screening and the C-SSRS-SLV ('Since Last Visit') was performed at baseline and weeks 1, 2, 4, 6, 7, and 8 or last postbaseline observation. The Suicidal Behavior - Completed Suicide question records whether the participant intentionally causing his/her's own death since the last visit.
Time Frame	Weeks 1, 2, 4, 6, 7, 8, and Endpoint
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.
The safety analysis set includes randomized participants who took 1 or more doses of study drug. The number analyzed includes participants with treatment assessments at the indicated time period.

Reporting Groups

	Description
Placebo	Participants were administered placebo and titrated to match the armodafinil treatment arms. Total treatment was 8 weeks.
Armodafinil 150 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 150 mg/day. The 150 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment.
Armodafinil 200 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 200 mg/day. The 200 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment. This treatment arm was discontinued via a protocol amendment.

Measured Values

	Placebo	Armodafinil 150 mg/Day	Armodafinil 200 mg/Day
Number of Participants Analyzed [units: participants]	**229**	**231**	**30**
Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Behavior - Completed Suicide Question [units: participants]			
Week 1 (218, 223, 27)	**0**	**0**	**0**
Week 2 (209, 212, 25)	**0**	**0**	**0**
Week 4 (193, 190, 22)	**0**	**0**	**0**
Week 6 (182, 181, 18)	**0**	**0**	**0**
Week 7 (172, 178, 14)	**0**	**0**	**0**
Week 8 (174, 171, 17)	**0**	**0**	**0**
Endpoint (226, 230, 28)	**0**	**0**	**0**

No statistical analysis provided for Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Behavior - Completed Suicide Question

19. Secondary: Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Ideation - Wish to Be Dead Question [Time Frame: Weeks 1, 2, 4, 6, 7, 8, and Endpoint]

Measure Type	Secondary
Measure Title	Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Ideation - Wish to Be Dead Question
Measure Description	The C-SSRS is a clinician-rated scale that assesses suicidality from ideation to behaviors and monitors the potential emergence of suicidality in clinical studies. The C-SSRS-B (baseline) was performed at screening and the C-SSRS-SLV ('Since Last Visit') was performed at baseline and weeks 1, 2, 4, 6, 7, and 8 or last postbaseline observation. The Suicidal Ideation - Wish to Be Dead question records whether the participant endorses thoughts about a wish to dead or not alive anymore, or a wish to fall asleep and not wake up since the last visit.
Time Frame	Weeks 1, 2, 4, 6, 7, 8, and Endpoint
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.
The safety analysis set includes randomized participants who took 1 or more doses of study drug. The number analyzed includes participants with treatment assessments at the indicated time period.

Reporting Groups

	Description
Placebo	Participants were administered placebo and titrated to match the armodafinil treatment arms. Total treatment was 8 weeks.
Armodafinil 150 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 150 mg/day. The 150 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment.
Armodafinil 200 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 200 mg/day. The 200 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment. This treatment arm was discontinued via a protocol amendment.

Measured Values

	Placebo	Armodafinil 150 mg/Day	Armodafinil 200 mg/Day
Number of Participants Analyzed [units: participants]	**229**	**231**	**30**
Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Ideation - Wish to Be Dead Question [units: participants]			
Week 1 (218, 223, 27)	**10**	**11**	**2**
Week 2 (209, 212, 25)	**7**	**11**	**0**
Week 4 (193, 190, 22)	**4**	**9**	**0**
Week 6 (182, 181, 18)	**6**	**6**	**0**
Week 7 (172, 178, 14)	**3**	**3**	**0**
Week 8 (174, 171, 17)	**3**	**5**	**1**
Endpoint (226, 230, 28)	**7**	**10**	**2**

No statistical analysis provided for Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Ideation - Wish to Be Dead Question

20. Secondary: Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Ideation - Non-Specific Active Suicidal Thoughts Question [Time Frame: Weeks 1, 2, 4, 6, 7, 8, and Endpoint]

Measure Type	Secondary
Measure Title	Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Ideation - Non-Specific Active Suicidal Thoughts Question
Measure Description	The C-SSRS is a clinician-rated scale that assesses suicidality from ideation to behaviors and monitors the potential emergence of suicidality in clinical studies. The C-SSRS-B (baseline) was performed at screening and the C-SSRS-SLV ('Since Last Visit') was performed at baseline and weeks 1, 2, 4, 6, 7, and 8 or last postbaseline observation. The Suicidal Ideation - Non-Specific Active Suicidal Thoughts question records whether the participant shares general non-specific thoughts of wanting to end one's life/commit suicide since the last visit.
Time Frame	Weeks 1, 2, 4, 6, 7, 8, and Endpoint
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.
The safety analysis set includes randomized participants who took 1 or more doses of study drug. The number analyzed includes participants with treatment assessments at the indicated time period.

Reporting Groups

	Description
Placebo	Participants were administered placebo and titrated to match the armodafinil treatment arms. Total treatment was 8 weeks.
Armodafinil 150 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 150 mg/day. The 150 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment.

Armodafinil 200 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 200 mg/day. The 200 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment. This treatment arm was discontinued via a protocol amendment.

Measured Values

	Placebo	Armodafinil 150 mg/Day	Armodafinil 200 mg/Day
Number of Participants Analyzed [units: participants]	**229**	**231**	**30**
Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Ideation - Non-Specific Active Suicidal Thoughts Question [units: participants]			
Week 1 (218, 223, 27)	**0**	**2**	**1**
Week 2 (209, 212, 25)	**0**	**1**	**0**
Week 4 (193, 190, 22)	**1**	**1**	**0**
Week 6 (182, 181, 18)	**0**	**3**	**0**
Week 7 (172, 178, 14)	**0**	**0**	**0**
Week 8 (174, 171, 17)	**0**	**1**	**0**
Endpoint (226, 230, 28)	**2**	**2**	**1**

No statistical analysis provided for Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Ideation - Non-Specific Active Suicidal Thoughts Question

21. Secondary: Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Ideation - Any Methods (Not Plan) Without Intent to Act Question [Time Frame: Weeks 1, 2, 4, 6, 7, 8, and Endpoint]

Measure Type	Secondary
Measure Title	Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Ideation - Any Methods (Not Plan) Without Intent to Act Question
Measure Description	The C-SSRS is a clinician-rated scale that assesses suicidality from ideation to behaviors and monitors the potential emergence of suicidality in clinical studies. The C-SSRS-B (baseline) was performed at screening and the C-SSRS-SLV ('Since Last Visit') was performed at baseline and weeks 1, 2, 4, 6, 7, and 8 or last postbaseline observation. The Suicidal Ideation - Any Methods (Not Plan) Without Intent to Act question records whether the participant endorses thoughts of suicide and has thought of at least one method but has no specific plan of action since the last visit.
Time Frame	Weeks 1, 2, 4, 6, 7, 8, and Endpoint
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.
The safety analysis set includes randomized participants who took 1 or more doses of study drug. This question is asked only if the answer to the 'Non-Specific Active Suicidal Thoughts' question was YES. The number analyzed includes participants with treatment assessments at the indicated time period.

Reporting Groups

	Description
Placebo	Participants were administered placebo and titrated to match the armodafinil treatment arms. Total treatment was 8 weeks.

Armodafinil 150 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 150 mg/day. The 150 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment.
Armodafinil 200 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 200 mg/day. The 200 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment. This treatment arm was discontinued via a protocol amendment.

Measured Values

	Placebo	Armodafinil 150 mg/Day	Armodafinil 200 mg/Day
Number of Participants Analyzed [units: participants]	**229**	**231**	**30**
Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Ideation - Any Methods (Not Plan) Without Intent to Act Question [units: participants]			
Week 1 (9, 10, 1)	**0**	**0**	**0**
Week 2 (6, 10, 0)	**0**	**1**	**0**
Week 4 (4, 8, 0)	**0**	**1**	**0**
Week 6 (5, 7, 0)	**0**	**2**	**0**
Week 7 (3, 3, 0)	**0**	**0**	**0**
Week 8 (2, 5, 0)	**0**	**0**	**0**
Endpoint (18, 21, 1)	**1**	**2**	**0**

No statistical analysis provided for Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Ideation - Any Methods (Not Plan) Without Intent to Act Question

22. Secondary: Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Ideation - Some Intent to Act Without a Specific Plan Question [Time Frame: Weeks 1, 2, 4, 6, 7, 8, and Endpoint]

Measure Type	Secondary
Measure Title	Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Ideation - Some Intent to Act Without a Specific Plan Question
Measure Description	The C-SSRS is a clinician-rated scale that assesses suicidality from ideation to behaviors and monitors the potential emergence of suicidality in clinical studies. The C-SSRS-B (baseline) was performed at screening and the C-SSRS-SLV ('Since Last Visit') was performed at baseline and weeks 1, 2, 4, 6, 7, and 8 or last postbaseline observation. The Suicidal Ideation - Some Intent to Act Without a Specific Plan question records whether the participant has active suicidal thoughts of killing oneself and reports having some intent to act on such thoughts since the last visit.
Time Frame	Weeks 1, 2, 4, 6, 7, 8, and Endpoint
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.
The safety analysis set includes randomized participants who took 1 or more doses of study drug. This question is asked only if the answer to the 'Non-Specific Active Suicidal Thoughts' question was YES. The number analyzed includes participants with treatment assessments at the indicated time period.

Reporting Groups

	Description

Placebo	Participants were administered placebo and titrated to match the armodafinil treatment arms. Total treatment was 8 weeks.
Armodafinil 150 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 150 mg/day. The 150 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment.
Armodafinil 200 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 200 mg/day. The 200 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment. This treatment arm was discontinued via a protocol amendment.

Measured Values

	Placebo	Armodafinil 150 mg/Day	Armodafinil 200 mg/Day
Number of Participants Analyzed [units: participants]	**229**	**231**	**30**
Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Ideation - Some Intent to Act Without a Specific Plan Question [units: participants]			
Week 1 (9, 10, 1)	**0**	**0**	**0**
Week 2 (6, 10, 0)	**0**	**0**	**0**
Week 4 (4, 8, 0)	**0**	**0**	**0**
Week 6 (5, 7, 0)	**0**	**0**	**0**
Week 7 (3, 3, 0)	**0**	**0**	**0**
Week 8 (2, 5, 0)	**0**	**0**	**0**
Endpoint (18, 21, 1)	**1**	**0**	**0**

No statistical analysis provided for Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Ideation - Some Intent to Act Without a Specific Plan Question

23. Secondary: Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Ideation - Specific Plan and Intent Question [Time Frame: Weeks 1, 2, 4, 6, 7, 8, and Endpoint]

Measure Type	Secondary
Measure Title	Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Ideation - Specific Plan and Intent Question
Measure Description	The C-SSRS is a clinician-rated scale that assesses suicidality from ideation to behaviors and monitors the potential emergence of suicidality in clinical studies. The C-SSRS-B (baseline) was performed at screening and the C-SSRS-SLV ('Since Last Visit') was performed at baseline and weeks 1, 2, 4, 6, 7, and 8 or last postbaseline observation. The Suicidal Ideation - Specific Plan and Intent question records whether the participant has active suicidal thoughts of killing oneself with details of plan fully or partially worked out and the participant has some intent to carry out the plan since the last visit.
Time Frame	Weeks 1, 2, 4, 6, 7, 8, and Endpoint
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.
The safety analysis set includes randomized participants who took 1 or more doses of study drug. This question is asked only if the answer to the 'Non-Specific Active Suicidal Thoughts' question was YES. The number analyzed includes participants with treatment assessments at the indicated time period.

Reporting Groups

	Description
Placebo	Participants were administered placebo and titrated to match the armodafinil treatment arms. Total treatment was 8 weeks.
Armodafinil 150 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 150 mg/day. The 150 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment.
Armodafinil 200 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 200 mg/day. The 200 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment. This treatment arm was discontinued via a protocol amendment.

Measured Values

	Placebo	Armodafinil 150 mg/Day	Armodafinil 200 mg/Day
Number of Participants Analyzed [units: participants]	**229**	**231**	**30**
Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Ideation - Specific Plan and Intent Question [units: participants]			
Week 1 (9, 10, 1)	**0**	**0**	**0**
Week 2 (6, 10, 0)	**0**	**0**	**0**
Week 4 (4, 8, 0)	**0**	**0**	**0**
Week 6 (5, 7, 0)	**0**	**0**	**0**
Week 7 (3, 3, 0)	**0**	**0**	**0**
Week 8 (2, 5, 0)	**0**	**0**	**0**
Endpoint (18, 21, 1)	**0**	**0**	**0**

No statistical analysis provided for Columbia-Suicide Severity Rating Scale 'Since Last Visit' Version (C-SSRS-SLV) For Weeks 1, 2, 4, 6, 7, 8, and Endpoint For the Suicidal Ideation - Specific Plan and Intent Question

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Day 1 to Week 9
Additional Description	No text entered.

Reporting Groups

	Description
Armodafinil 150 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 150 mg/day. The 150 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment.
Armodafinil 200 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 200 mg/day. The 200 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment. This treatment arm was discontinued via a protocol amendment.
Placebo	Participants were administered placebo and titrated to match the armodafinil treatment arms. Total treatment was 8 weeks.

Serious Adverse Events

	Armodafinil 150 mg/Day	Armodafinil 200 mg/Day	Placebo
Total, serious adverse events			
# participants affected / at risk	**5/231 (2.16%)**	**2/30 (6.67%)**	**1/229 (0.44%)**
Cardiac disorders			
Coronary artery disease † 1			
# participants affected / at risk	**1/231 (0.43%)**	**0/30 (0.00%)**	**0/229 (0.00%)**
# events	**1**	**0**	**0**
General disorders			
Non-cardiac chest pain † 1			
# participants affected / at risk	**1/231 (0.43%)**	**0/30 (0.00%)**	**0/229 (0.00%)**
# events	**1**	**0**	**0**
Injury, poisoning and procedural complications			
Accidental overdose † 1			
# participants affected / at risk	**1/231 (0.43%)**	**0/30 (0.00%)**	**0/229 (0.00%)**
# events	**1**	**0**	**0**
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous † 1			
# participants affected / at risk	**0/231 (0.00%)**	**1/30 (3.33%)**	**0/229 (0.00%)**
# events	**0**	**1**	**0**
Psychiatric disorders			
Mania † 1			
# participants affected / at risk	**2/231 (0.87%)**	**0/30 (0.00%)**	**0/229 (0.00%)**
# events	**2**	**0**	**0**
Psychotic disorder † 1			
# participants affected / at risk	**0/231 (0.00%)**	**1/30 (3.33%)**	**0/229 (0.00%)**
# events	**0**	**1**	**0**
Suicidal ideation † 1			
# participants affected / at risk	**0/231 (0.00%)**	**1/30 (3.33%)**	**1/229 (0.44%)**
# events	**0**	**1**	**1**
Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism † 1			
# participants affected / at risk	**1/231 (0.43%)**	**0/30 (0.00%)**	**0/229 (0.00%)**
# events	**1**	**0**	**0**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA (15.0)

Other Adverse Events

Hide Other Adverse Events

Time Frame	Day 1 to Week 9
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Armodafinil 150 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 150 mg/day. The 150 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment.
Armodafinil 200 mg/Day	Participants started the study at a dose of 50mg/day of armodafinil and titrated up in the first week to 200 mg/day. The 200 mg/day dosage was continued for 7 more weeks for a total of 8 weeks of treatment. This treatment arm was discontinued via a protocol amendment.
Placebo	Participants were administered placebo and titrated to match the armodafinil treatment arms. Total treatment was 8 weeks.

Other Adverse Events

	Armodafinil 150 mg/Day	Armodafinil 200 mg/Day	Placebo
Total, other (not including serious) adverse events			
# participants affected / at risk	**80/231 (34.63%)**	**18/30 (60.00%)**	**59/229 (25.76%)**
Gastrointestinal disorders			
Diarrhoea † 1			
# participants affected / at risk	**11/231 (4.76%)**	**5/30 (16.67%)**	**13/229 (5.68%)**
# events	**11**	**8**	**16**
Dry mouth † 1			
# participants affected / at risk	**10/231 (4.33%)**	**5/30 (16.67%)**	**3/229 (1.31%)**
# events	**10**	**6**	**3**
Dyspepsia † 1			
# participants affected / at risk	**0/231 (0.00%)**	**2/30 (6.67%)**	**0/229 (0.00%)**
# events	**0**	**2**	**0**
Nausea † 1			
# participants affected / at risk	**17/231 (7.36%)**	**4/30 (13.33%)**	**5/229 (2.18%)**
# events	**18**	**5**	**5**
Toothache † 1			
# participants affected / at risk	**2/231 (0.87%)**	**2/30 (6.67%)**	**0/229 (0.00%)**
# events	**2**	**3**	**0**
Infections and infestations			
Nasopharyngitis † 1			
# participants affected / at risk	**7/231 (3.03%)**	**2/30 (6.67%)**	**4/229 (1.75%)**
# events	**7**	**2**	**4**
Nervous system disorders			
Dizziness † 1			
# participants affected / at risk	**7/231 (3.03%)**	**3/30 (10.00%)**	**2/229 (0.87%)**
# events	**9**	**3**	**2**
Headache † 1			
# participants affected / at risk	**38/231 (16.45%)**	**4/30 (13.33%)**	**30/229 (13.10%)**
# events	**45**	**5**	**39**
Psychiatric disorders			
Anxiety † 1			
# participants affected / at risk	**6/231 (2.60%)**	**2/30 (6.67%)**	**6/229 (2.62%)**
# events	**6**	**2**	**6**
Insomnia † 1			
# participants affected / at risk	**12/231 (5.19%)**	**4/30 (13.33%)**	**8/229 (3.49%)**
# events	**12**	**5**	**8**
Suicidal ideation † 1			

# participants affected / at risk	1/231 (0.43%)	3/30 (10.00%)	2/229 (0.87%)
# events	1	3	2
Respiratory, thoracic and mediastinal disorders			
Cough † 1			
# participants affected / at risk	0/231 (0.00%)	3/30 (10.00%)	2/229 (0.87%)
# events	0	4	2

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA (15.0)

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:** Sponsor has the right 60 days before submission for publication to review/provide comments. If the Sponsor's review shows that potentially patentable subject matter would be disclosed, publication or public disclosure shall be delayed for up to 90 additional days in order for the Sponsor, or Sponsor's designees, to file the necessary patent applications. In multicenter trials, each PI will postpone single center publications until after disclosure or publication of multicenter data.

Results Point of Contact:

Name/Title: Director, Clinical Research
Organization: Teva Branded Pharmaceutical Products, R&D Inc.
phone: 215-591-3000
e-mail: ustevatrials@tevapharm.com

No publications provided by Teva Pharmaceutical Industries

Publications automatically indexed to this study:

Ketter TA, Yang R, Frye MA. Adjunctive armodafinil for major depressive episodes associated with bipolar I disorder. J Affect Disord. 2015 Aug 1;181:87-91. doi: 10.1016/j.jad.2015.04.012. Epub 2015 Apr 15.

Responsible Party: Teva Pharmaceutical Industries (Cephalon)
ClinicalTrials.gov Identifier: NCT01072630 History of Changes
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