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Protocol Registration and Results System

ID: C10953/2032/DP/US Armodafinil Treatment as Adjunctive Therapy in Adults With Major Depression Associated With Bipolar I Disorder NCT00481195

Protocol Registration and Results Preview

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:
NCT00481195

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Purpose

The primary objective of the study is to determine if armodafinil treatment, at a dosage of 150 mg/day, is more effective than placebo treatment as adjunctive therapy for adults who are experiencing a major depressive episode associated with Bipolar I Disorder and who are inadequately responsive to their current treatment for a current major depressive episode.

Condition	Intervention	Phase
Bipolar I Depression	Drug: Armodafinil Drug: Placebo	Phase 2

Study Type: Interventional
Study Design: Treatment, Parallel Assignment, Double Blind (Subject, Investigator), Randomized, Safety/Efficacy Study

Official Title: An 8 Week Double Blind, Placebo-Controlled, Parallel Group, Fixed Dosage Study to Evaluate the Efficacy and Safety of Armodafinil Treatment (150mg/Day) as Adjunctive Therapy in Adults With Major Depression Associated With Bipolar I Disorder

Further study details as provided by Teva Pharmaceutical Industries (Cephalon):

Primary Outcome Measure:

- The Mean Change From Baseline to Endpoint (Week 8 or Last Observation After Baseline) in the 30 Item Inventory of Depressive Symptomatology Clinician Rated (IDS C30) [Time Frame: Baseline and 8 weeks from start of study drug administration (or last observation after baseline)] [Designated as safety issue: No]

  The IDS C30 is a standardized 30 item, clinician rated scale to assess the severity of a patient's depressive symptoms. The scale uses the 9 symptom domains of the DSM-IV criteria to measure symptom severity. The scores range from a minimum of 0 to a maximum score of 84. The higher the score the more severe the symptoms of depression. The data presented here summarizes the change from baseline to Endpoint (either week 8 or the last observation after baseline) in the total score of the IDS-C30.

Secondary Outcome Measures:

- The Mean Change From Baseline to Week 1 in the 30 Item Inventory of Depressive Symptomatology Clinician Rated (IDS C30) [Time Frame: Baseline and 1 week following the start of study drug administration] [Designated as safety issue: No]

  The IDS C30 is a standardized 30 item, clinician rated, scale to assess the severity of a patient's depressive symptoms. The scale uses the 9 symptom domains of the DSM-IV criteria to measure symptom severity. The scores range from a minimum of 0 to a maximum score of 84. The higher the score the more severe the symptoms of depression. The data presented here summarizes the change from baseline to Week 1 in the total score of the IDS-C30.

- The Mean Change From Baseline to Week 2 in the 30 Item Inventory of Depressive Symptomatology Clinician Rated (IDS C30) [Time Frame: Baseline and 2 weeks following the start of study drug administration] [Designated as safety issue: No]

  The IDS C30 is a standardized 30 item, clinician rated, scale to assess the severity of a patient's depressive symptoms. The scale uses the 9 symptom domains of the DSM-IV criteria to measure symptom severity. The scores range from a minimum of 0 to a maximum score of 84. The higher the score the more severe the symptoms of depression. The data presented here summarizes the change from baseline to Week 2 in the total score of the IDS-C30.

- The Mean Change From Baseline to Week 3 in the 30 Item Inventory of Depressive Symptomatology Clinician Rated (IDS C30) [Time Frame: Baseline and 3 weeks following the start of study drug administration] [Designated as safety issue: No]

  The IDS C30 is a standardized 30 item, clinician rated, scale to assess the severity of a patient's depressive symptoms. The scale uses the 9 symptom domains of the DSM-IV criteria to measure symptom severity. The scores range from a minimum of 0 to a maximum score of 84. The higher the score the more severe the symptoms of depression. The data presented here summarizes the change from baseline to Week 3 in the total score of the IDS-C30.

- The Mean Change From Baseline to Week 4 in the 30 Item Inventory of Depressive Symptomatology Clinician Rated (IDS C30) [Time Frame: Baseline and 4 weeks following the start of study drug administration] [Designated as safety issue: No]

  The IDS C30 is a standardized 30 item, clinician rated, scale to assess the severity of a patient's depressive symptoms. The scale uses the 9 symptom domains of the DSM-IV criteria to measure symptom severity. The scores range from a minimum of 0 to a maximum score of 84. The higher the score the more severe the symptoms of depression. The data presented here summarizes the change from baseline to Week 4 in the total score of the IDS-C30.

- The Mean Change From Baseline to Week 6 in the 30 Item Inventory of Depressive Symptomatology Clinician Rated (IDS C30) [Time Frame: Baseline and 6 weeks following the start of study drug administration] [Designated as safety issue: No]

  The IDS C30 is a standardized 30 item, clinician rated, scale to assess the severity of a patient's depressive symptoms. The scale uses the 9 symptom domains of the DSM-IV criteria to measure symptom severity. The scores range from a minimum of 0 to a maximum score of 84. The higher the score the more severe the symptoms of depression. The data presented here summarizes the change from baseline to Week 6 in the total score of the IDS-C30.

- The Mean Change From Baseline to Week 8 in the 30 Item Inventory of Depressive Symptomatology Clinician Rated (IDS C30) [Time Frame: Baseline and 8 weeks following the start of study drug administration] [Designated as safety issue: No]

  The IDS C30 is a standardized 30 item, clinician rated, scale to assess the severity of a patient's depressive symptoms. The scale uses the 9 symptom domains of the DSM-IV criteria to measure symptom severity. The scores range from a minimum of 0 to a maximum score of 84. The higher the score the more severe the symptoms of depression. The data presented here summarizes the change from baseline to Week 8 in the total score of the IDS-C30.

- Number of Patients Achieving Remission at Endpoint According to the 30-item Inventory of Depressive Symptomatology-Clinician-Rated (IDS-C30) [Time Frame: Baseline, 4 and 8 weeks following start of study drug administration (or last observation after baseline)] [Designated as safety issue: No]

  The IDS C30 is a standardized 30 item, clinician rated, scale to assess the severity of a patient's depressive symptoms. The scale uses the 9 symptom domains of the DSM-IV criteria to measure symptom severity. The scores range from a minimum of 0 to a maximum score of 84. The higher the score the more severe the symptoms of depression. The data here summarizes the number of subjects in each treatment group who achieved a remission (total score <=11).

- Number of Patients Achieving "Response" at Endpoint According to the 30-item Inventory of Depressive Symptomatology-Clinician-Rated (IDS-C30) [Time Frame: Baseline, 4 and 8 weeks following start of study drug administration (or last observation after baseline)] [Designated as safety issue: No]

The IDS C30 is a standardized 30 item, clinician rated, scale to assess the severity of a patient's depressive symptoms. The scale uses the 9 symptom domains of the DSM-IV criteria to measure symptom severity. The scores range from a minimum of 0 to a maximum score of 84. The higher the score the more severe the symptoms of depression. The data here summarizes the number of subjects in each treatment group who achieved a "response" (> 50% decrease from baseline in total score).

- Number of Patients Achieving "Sustained Remission" at Endpoint According to the 30-item Inventory of Depressive Symptomatology-Clinician-Rated (IDS-C30) [Time Frame: Baseline, 4 and 8 weeks following start of study drug administration (or last observation after baseline)] [Designated as safety issue: No]

  The IDS C30 is a standardized 30 item, clinician rated, scale to assess the severity of a patient's depressive symptoms. The scale uses the 9 symptom domains of the DSM-IV criteria to measure symptom severity. The scores range from a minimum of 0 to a maximum score of 84. The higher the score the more severe the symptoms of depression. The data here summarizes the number of subjects in each treatment group who achieved a "sustained remission" (total score <= 11 that persists over the four week period from Week 4 to Week 8).

- Number of Patients Achieving "Sustained Response" at Endpoint According to the 30-item Inventory of Depressive Symptomatology-Clinician-Rated (IDS-C30) [Time Frame: Baseline, 4 and 8 weeks following start of study drug administration (or last observation after baseline)] [Designated as safety issue: No]

  The IDS C30 is a standardized 30 item, clinician rated, scale to assess the severity of a patient's depressive symptoms. The scale uses the 9 symptom domains of the DSM-IV criteria to measure symptom severity. The scores range from a minimum of 0 to a maximum score of 84. The higher the score the more severe the symptoms of depression. The data here summarizes the number of subjects in each treatment group who achieved a "sustained response" (> 50% decrease from baseline in total score that persisted over the four week period between Week 4 and Week 8).

- Change From Baseline to Endpoint (Week 8 or Last Observation After Baseline) on 30 Item Inventory of Depressive Symptomatology Clinician Rated (IDS C30) Combination of Items 1-3 [Time Frame: Baseline and 8 weeks (or last observation after baseline)] [Designated as safety issue: No]

  The IDS C30 is a standardized 30 item, clinician rated, scale to assess the severity of a patient's depressive symptoms. The scale uses the 9 symptom domains of the DSM-IV criteria to measure symptom severity. The scores range from a minimum of 0 to a maximum score of 84. The higher the score the more severe the symptoms of depression. Items 1 - 3 assess sleep onset insomnia, mid-nocturnal insomnia, and early morning insomnia respectively each on a 0 - 3 scale. The data presented here summarizes the change from baseline to Endpoint in the combined score of these three items assessing insomnia.

- Change From Baseline to Week 4 on 30 Item Inventory of Depressive Symptomatology Clinician Rated (IDS C30) Combination of Items 1-3 [Time Frame: Baseline and 4 weeks following the start of study drug administration] [Designated as safety issue: No]

The IDS C30 is a standardized 30 item, clinician rated, scale to assess the severity of a patient's depressive symptoms. The scale uses the 9 symptom domains of the DSM-IV criteria to measure symptom severity. The scores range from a minimum of 0 to a maximum score of 84. The higher the score the more severe the symptoms of depression. Items 1 - 3 assess sleep onset insomnia, mid-nocturnal insomnia, and early morning insomnia respectively each on a 0 - 3 scale. The data presented here summarizes the change from baseline to week 4 in the combined score of these three items assessing insomnia.

- Change From Baseline to Week 8 on 30 Item Inventory of Depressive Symptomatology Clinician Rated (IDS C30) Combination of Items 1-3 [Time Frame: Baseline and 8 weeks following the start of study drug administration] [Designated as safety issue: No]

  The IDS C30 is a standardized 30 item, clinician rated, scale to assess the severity of a patient's depressive symptoms. The scale uses the 9 symptom domains of the DSM-IV criteria to measure symptom severity. The scores range from a minimum of 0 to a maximum score of 84. The higher the score the more severe the symptoms of depression. Items 1 - 3 assess sleep onset insomnia, mid-nocturnal insomnia, and early morning insomnia respectively each on a 0 - 3 scale. The data presented here summarizes the change from baseline to week 8 in the combined score of these three items assessing insomnia.

- Change From Baseline to Endpoint (Week 8 or Last Observation After Baseline) on 30 Item Inventory of Depressive Symptomatology Clinician Rated (IDS C30) - Item 4 [Time Frame: Baseline and 8 weeks (or last observation after baseline)] [Designated as safety issue: No]

  The IDS C30 is a standardized 30 item, clinician rated, scale to assess the severity of a patient's depressive symptoms. The scale uses the 9 symptom domains of the DSM-IV criteria to measure symptom severity. The scores range from a minimum of 0 to a maximum score of 84. The higher the score the more severe the symptoms of depression. Item 4 assesses hypersomnia on a scale from 0 (sleeps no longer than 7-8 hours a night) to 3 (sleeps longer than 12 hours in 24 hour period). The data presented here summarizes the change from baseline to Endpoint in the score of Item 4 assessing hypersomnia.

- Change From Baseline to Week 4 on 30 Item Inventory of Depressive Symptomatology Clinician Rated (IDS C30) - Item 4 [Time Frame: Baseline and 4 weeks following the start of study drug administration] [Designated as safety issue: No]

  The IDS C30 is a standardized 30 item, clinician rated, scale to assess the severity of a patient's depressive symptoms. The scale uses the 9 symptom domains of the DSM-IV criteria to measure symptom severity. The scores range from a minimum of 0 to a maximum score of 84. The higher the score the more severe the symptoms of depression. Item 4 assesses hypersomnia on a scale from 0 (sleeps no longer than 7-8 hours a night) to 3 (sleeps longer than 12 hours in 24 hour period). The data presented here summarizes the change from baseline to week 4 in the score of Item 4 assessing hypersomnia.

- Change From Baseline to Week 8 on 30 Item Inventory of Depressive Symptomatology Clinician Rated (IDS C30) - Item 4 [Time Frame: Baseline and 8 weeks following the start of study drug administration] [Designated as safety issue: No]

The IDS C30 is a standardized 30 item, clinician rated, scale to assess the severity of a patient's depressive symptoms. The scale uses the 9 symptom domains of the DSM-IV criteria to measure symptom severity. The scores range from a minimum of 0 to a maximum score of 84. The higher the score the more severe the symptoms of depression. Item 4 assesses hypersomnia on a scale from 0 (sleeps no longer than 7-8 hours a night) to 3 (sleeps longer than 12 hours in 24 hour period). The data presented here summarizes the change from baseline to week 8 in the score of Item 4 assessing hypersomnia.

- Change From Baseline to Endpoint (Week 8 or Last Observation After Baseline) in the Montgomery-Asberg Depression Rating Scale (MADRS) Total Score [Time Frame: Baseline and Endpoint (8 weeks following the start of study drug administration or last observation after baseline)] [Designated as safety issue: No]

  The MADRS is a 10-item scale to evaluate the overall severity of a patient's depressive symptoms, that is completed by the physician. The rating scale makes use of both observational clues as to the subject's level of depression (eg. apparent sadness) and verbal indicators of depression expressed by the patient. Each of the 10 items is graded on a 6-point scale with anchors at 2 point intervals. Total scores range from 0 to 60, with the higher number indicating more severe symptoms of depression. Here we present data summarizing the change in MADRS from Baseline to Endpoint.

- Change From Baseline to Week 4 in the Montgomery-Asberg Depression Rating Scale (MADRS) Total Score [Time Frame: Baseline and 4 weeks following the start of study drug administration] [Designated as safety issue: No]

  The MADRS is a 10-item scale to evaluate the overall severity of a patient's depressive symptoms, that is completed by the physician. The rating scale makes use of both observational clues as to the subject's level of depression (eg. apparent sadness) and verbal indicators of depression expressed by the patient. Each of the 10 items is graded on a 6-point scale with anchors at 2 point intervals. Total scores range from 0 to 60, with the higher number indicating more severe symptoms of depression. Here we present data summarizing the difference in MADRS score from Baseline to Week 4.

- Change From Baseline to Week 8 in the Montgomery-Asberg Depression Rating Scale (MADRS) Total Score [Time Frame: Baseline and 8 weeks following the start of study drug administration] [Designated as safety issue: No]

  The MADRS is a 10-item scale to evaluate the overall severity of a patient's depressive symptoms, that is completed by the physician. The rating scale makes use of both observational clues as to the subject's level of depression (eg. apparent sadness) and verbal indicators of depression expressed by the patient. Each of the 10 items is graded on a 6-point scale with anchors at 2 point intervals. Total scores range from 0 to 60, with the higher number indicating more severe symptoms of depression. Here we present data summarizing the difference in MADRS score from Baseline to Week 8.

- Change From Baseline to Endpoint (Week 8 or Last Observation After Baseline) in the Quick Inventory of Depressive Symptomatology - 16 Items (QIDS-SR16) [Time Frame: Baseline and 8 weeks (or last observation after baseline)] [Designated as safety issue: No]

  The QIDS-SR16 is a 16-item rating scale of depressive symptoms completed by the patient at each visit. It is a shorter version of the IDS-C30 that is completed by the patient rather than the examiner. The total score ranges

from 0 to 27 (higher score signifies more severe depression) and is obtained by adding the scores for each of the 9 depression symptom domains of the DSM IV. The data presented here summarizes the change in QIDS-SR16 from Baseline to Endpoint (Week 8 or last observation after baseline).

- Change From Baseline to Week 1 in the Quick Inventory of Depressive Symptomatology - 16 Items (QIDS-SR16) [Time Frame: Baseline and 1 week following the start of study drug administration] [Designated as safety issue: No]
  The QIDS-SR16 is a 16-item rating scale of depressive symptoms completed by the patient at each visit. It is a shorter version of the IDS-C30 that is completed by the patient rather than the examiner. The total score ranges from 0 to 27 (higher score signifies more severe depression) and is obtained by adding the scores for each of the 9 depression symptom domains of the DSM IV. The data presented here summarizes the change in QIDS-SR16 from Baseline to Week 1

- Change From Baseline to Week 2 in the Quick Inventory of Depressive Symptomatology - 16 Items (QIDS-SR16) [Time Frame: Baseline and 2 weeks following the start of study drug administration] [Designated as safety issue: No]
  The QIDS-SR16 is a 16-item rating scale of depressive symptoms completed by the patient at each visit. It is a shorter version of the IDS-C30 that is completed by the patient rather than the examiner. The total score ranges from 0 to 27 (higher score signifies more severe depression) and is obtained by adding the scores for each of the 9 depression symptom domains of the DSM IV. The data presented here summarizes the change in QIDS-SR16 from Baseline to Week 2

- Change From Baseline to Week 3 in the Quick Inventory of Depressive Symptomatology - 16 Items (QIDS-SR16) [Time Frame: Baseline and 3 weeks following the start of study drug administration] [Designated as safety issue: No]
  The QIDS-SR16 is a 16-item rating scale of depressive symptoms completed by the patient at each visit. It is a shorter version of the IDS-C30 that is completed by the patient rather than the examiner. The total score ranges from 0 to 27 (higher score signifies more severe depression) and is obtained by adding the scores for each of the 9 depression symptom domains of the DSM IV. The data presented here summarizes the change in QIDS-SR16 from Baseline to Week 3.

- Change From Baseline to Week 4 in the Quick Inventory of Depressive Symptomatology - 16 Items (QIDS-SR16) [Time Frame: Baseline and 4 weeks following the start of study drug administration] [Designated as safety issue: No]
  The QIDS-SR16 is a 16-item rating scale of depressive symptoms completed by the patient at each visit. It is a shorter version of the IDS-C30 that is completed by the patient rather than the examiner. The total score ranges from 0 to 27 (higher score signifies more severe depression) and is obtained by adding the scores for each of the 9 depression symptom domains of the DSM IV. The data presented here summarizes the change in QIDS-SR16 from Baseline to Week 4.

- Change From Baseline to Week 6 in the Quick Inventory of Depressive Symptomatology - 16 Items (QIDS-SR16) [Time Frame: Baseline and 6 weeks following the start of study drug administration] [Designated as safety issue: No]
  The QIDS-SR16 is a 16-item rating scale of depressive symptoms completed by the patient at each visit. It is a shorter version of the IDS-C30 that is completed by the patient rather than the examiner. The total score ranges

from 0 to 27 (higher score signifies more severe depression) and is obtained by adding the scores for each of the 9 depression symptom domains of the DSM IV. The data presented here summarizes the change in QIDS-SR16 from Baseline to Week 6.

- Change From Baseline to Week 8 in the Quick Inventory of Depressive Symptomatology - 16 Items (QIDS-SR16) [Time Frame: Baseline and 8 weeks following the start of study drug administration] [Designated as safety issue: No]
  The QIDS-SR16 is a 16-item rating scale of depressive symptoms completed by the patient at each visit. It is a shorter version of the IDS-C30 that is completed by the patient rather than the examiner. The total score ranges from 0 to 27 (higher score signifies more severe depression) and is obtained by adding the scores for each of the 9 depression symptom domains of the DSM IV. The data presented here summarizes the change in QIDS-SR16 from Baseline to Week 8.

- Change From Baseline to Endpoint (Week 8 or Last Observation After Baseline) in the Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (Q-LES-Q-SF) [Time Frame: Baseline and 8 weeks (or last observation after baseline)] [Designated as safety issue: No]
  The Q-LES-Q-SF is an instrument designed to measure general activities of daily living. It is a patient-rated quality of life questionnaire and consists of 16 items, but only the first 14 are included in the total score. Each item is rated by the patient on a scale from 1 - 5 (1=very poor, 2=poor, 3=fair, 4=good, and 5=very good). The minimum score is 14 and the maximum score is 70, with lower scores indicating poorer quality of life. The data presented here summarizes the change in score from baseline to endpoint (8 weeks or last observation after baseline).

- Change From Baseline to Week 4 in the Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (Q-LES-Q-SF) [Time Frame: Baseline and 4 weeks following the start of study drug administration] [Designated as safety issue: No]
  The Q-LES-Q-SF is an instrument designed to measure general activities of daily living. It is a patient-rated quality of life questionnaire and consists of 16 items, but only the first 14 are included in the total score. Each item is rated by the patient on a scale from 1 - 5 (1=very poor, 2=poor, 3=fair, 4=good, and 5=very good). The minimum score is 14 and the maximum score is 70, with lower scores indicating poorer quality of life. The data presented here summarizes the change in score from baseline to 4 weeks.

- Change From Baseline to Week 8 in the Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (Q-LES-Q-SF) [Time Frame: Baseline and 8 weeks following the start of study drug administration] [Designated as safety issue: No]
  The Q-LES-Q-SF is an instrument designed to measure general activities of daily living. It is a patient-rated quality of life questionnaire and consists of 16 items, but only the first 14 are included in the total score. Each item is rated by the patient on a scale from 1 - 5 (1=very poor, 2=poor, 3=fair, 4=good, and 5=very good). The minimum score is 14 and the maximum score is 70, with lower scores indicating poorer quality of life. The data presented here summarizes the change in score from baseline to 8 weeks.

- Change From Baseline to Endpoint (8 Weeks or Last Observation After Baseline) in Hamilton Anxiety Scale (HAM-A) Total Score [Time Frame: baseline and 8 weeks (or last observation after baseline)] [Designated as safety issue: No]
  The HAM-A is a clinician-rated 14 item scale that provides an overall measure of global anxiety, including psychic (mental agitation and psychological distress) and somatic (physical complaints related to anxiety) symptoms. Each item is scored on a scale of 0 (not present) to 4 (severe), with a total score range of 0 - 56, where less than 17 indicates mild anxiety, 18 - 24 mild to moderate anxiety, 25-30 moderate to severe, >30 very severe. The data presented here summarizes the change in HAM-A score from Baseline to Endpoint (8 weeks or last observation after baseline).

- Change From Baseline to 4 Weeks in the Hamilton Anxiety Scale (HAM A) Total Score [Time Frame: Baseline and 4 weeks following the start of study drug administration] [Designated as safety issue: No]
  The HAM-A is a clinician-rated 14 item scale that provides an overall measure of global anxiety, including psychic (mental agitation and psychological distress) and somatic (physical complaints related to anxiety) symptoms. Each item is scored on a scale of 0 (not present) to 4 (severe), with a total score range of 0 - 56, where less than 17 indicates mild anxiety, 18 - 24 mild to moderate anxiety and 25-30 moderate to severe. The data presented here summarizes the change in HAM-A score from Baseline to 4 Weeks

- Change From Baseline to 8 Weeks in the Hamilton Anxiety Scale (HAM A) Total Score [Time Frame: Baseline and 8 weeks following the start of study drug administration] [Designated as safety issue: No]
  The HAM-A is a clinician-rated 14 item scale that provides an overall measure of global anxiety, including psychic (mental agitation and psychological distress) and somatic (physical complaints related to anxiety) symptoms. Each item is scored on a scale of 0 (not present) to 4 (severe), with a total score range of 0 - 56, where less than 17 indicates mild anxiety, 18 - 24 mild to moderate anxiety and 25-30 moderate to severe. The data presented here summarizes the change in HAM-A score from Baseline to 8 Weeks

- The Number of Responders According to the Clinical Global Impression of Change - Bipolar Version (CGI BP) Measure of Depression at Endpoint (Week 8 or Last Observation After Baseline) [Time Frame: Baseline and 8 weeks (or last observation after baseline)] [Designated as safety issue: No]
  CGI-BP is a standardized, clinician-rated assessment which allows the clinician to rate the bipolar illness at various time points compared with baseline. At Screening and Baseline visits the physician rated the severity of the illness using 7 categories (1=normal through 7=very severely ill). At subsequent visits the clinician assessed the change in severity of the condition using 7 categories (1=very much improved through 7=very much worse). Subjects were considered responders if they had a rating of "much improved" or "very much improved". The number of responders at Endpoint are presented.

- The Number of Responders According to the Clinical Global Impression of Change - Bipolar Version (CGI BP) Measure of Depression at Week 1 [Time Frame: Baseline and 1 week following the start of study drug administration] [Designated as safety issue: No]
  CGI-BP is a standardized, clinician-rated assessment which allows the clinician to rate the bipolar illness at various time points compared with baseline. At Screening and Baseline visits the physician rated the severity of

the illness using 7 categories (1=normal through 7=very severely ill). At subsequent visits the clinician assessed the change in severity of the condition using 7 categories (1=very much improved through 7=very much worse). Subjects were considered responders if they had a rating of "much improved" or "very much improved". The number of responders at Week 1 are presented.

- The Number of Responders According to the Clinical Global Impression of Change - Bipolar Version (CGI BP) Measure of Depression at Week 2 [Time Frame: Baseline and 2 weeks following the start of study drug administration] [Designated as safety issue: No]

  CGI-BP is a standardized, clinician-rated assessment which allows the clinician to rate the bipolar illness at various time points compared with baseline. At Screening and Baseline visits the physician rated the severity of the illness using 7 categories (1=normal through 7=very severely ill). At subsequent visits the clinician assessed the change in severity of the condition using 7 categories (1=very much improved through 7=very much worse). Subjects were considered responders if they had a rating of "much improved" or "very much improved". The number of responders at Week 2 are presented.

- The Number of Responders According to the Clinical Global Impression of Change - Bipolar Version (CGI BP) Measure of Depression at Week 3 [Time Frame: Baseline and 3 weeks following the start of study drug administration] [Designated as safety issue: No]

  CGI-BP is a standardized, clinician-rated assessment which allows the clinician to rate the bipolar illness at various time points compared with baseline. At Screening and Baseline visits the physician rated the severity of the illness using 7 categories (1=normal through 7=very severely ill). At subsequent visits the clinician assessed the change in severity of the condition using 7 categories (1=very much improved through 7=very much worse). Subjects were considered responders if they had a rating of "much improved" or "very much improved". The number of responders at Week 3 are presented.

- The Number of Responders According to the Clinical Global Impression of Change - Bipolar Version (CGI BP) Measure of Depression at Week 4 [Time Frame: Baseline and 4 weeks following the start of study drug administration] [Designated as safety issue: No]

  CGI-BP is a standardized, clinician-rated assessment which allows the clinician to rate the bipolar illness at various time points compared with baseline. At Screening and Baseline visits the physician rated the severity of the illness using 7 categories (1=normal through 7=very severely ill). At subsequent visits the clinician assessed the change in severity of the condition using 7 categories (1=very much improved through 7=very much worse). Subjects were considered responders if they had a rating of "much improved" or "very much improved". The number of responders at Week 4 are presented.

- The Number of Responders According to the Clinical Global Impression of Change - Bipolar Version (CGI BP) Measure of Depression at Week 6 [Time Frame: Baseline and 6 weeks following the start of study drug administration] [Designated as safety issue: No]

  CGI-BP is a standardized, clinician-rated assessment which allows the clinician to rate the bipolar illness at various time points compared with baseline. At Screening and Baseline visits the physician rated the severity of

the illness using 7 categories (1=normal through 7=very severely ill). At subsequent visits the clinician assessed the change in severity of the condition using 7 categories (1=very much improved through 7=very much worse). Subjects were considered responders if they had a rating of "much improved" or "very much improved". The number of responders at Week 6 are presented.

- The Number of Responders According to the Clinical Global Impression of Change - Bipolar Version (CGI BP) Measure of Depression at Week 8 [Time Frame: Baseline and 8 weeks following the start of study drug administration] [Designated as safety issue: No]
  CGI-BP is a standardized, clinician-rated assessment which allows the clinician to rate the bipolar illness at various time points compared with baseline. At Screening and Baseline visits the physician rated the severity of the illness using 7 categories (1=normal through 7=very severely ill). At subsequent visits the clinician assessed the change in severity of the condition using 7 categories (1=very much improved through 7=very much worse). Subjects were considered responders if they had a rating of "much improved" or "very much improved". The number of responders at Week 8 are presented.

Enrollment: 257
Study Start Date: June 2007
Study Completion Date: December 2008
Primary Completion Date: December 2008

Arms	Assigned Interventions
Active Comparator: Armodafinil	Drug: Armodafinil Patients were randomly assigned to begin oral treatment with armodafinil, which was titrated to 150 mg/day (3 tablets). Armodafinil was titrated up to the target dosage of 150 mg/day (daily dose was administered each morning). Patients began taking blinded armodafinil at a dose of 50 mg/day (1 tablet) on the day following the baseline visit. Doses were increased by 50 mg/day (1 tablet) to a dose of 100 mg/day on Day 2 and 3, and then again by 50 mg /day on day 4 for a target dose of 150 mg/day. Following titration, patients continued taking 150 mg/day of armodafinil for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 100 mg/day [2 tablets]) was allowed. The dosage could not be increased after it was decreased.
Placebo Comparator: Placebo	Drug: Placebo Patients were randomly assigned to begin oral treatment with placebo, which was titrated to 3 tablets. Placebo tablets matching the 50 mg armodafinil tablet were used in a manner identical to that of the armodafinil tablets. Study drug was titrated up to the target dosage of 3 tablets / day (daily dose was administered each morning). Patients began taking blinded study drug at a dose of 1 tablet daily on the day following the baseline visit. Doses were increased by 1 tablet to a dose of 2 tablets/day on Day 2 and 3, and then again by 1 tablet /day on day 4 for a target dose

	of 3 tablets/day. Following titration, patients continued taking 3 tablets/day of study drug for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 2 tablets/day) was allowed. The dosage could not be increased after it was decreased.

Eligibility

Ages Eligible for Study: 18 Years to 65 Years
Genders Eligible for Study: Both
Key Inclusion Criteria:

- The patient has a diagnosis of Bipolar I Disorder and is currently experiencing a major depressive episode.
- The patient is currently being treated with 1 or 2 of the following drugs: lithium, olanzapine, or valproic acid.

Key Exclusion Criteria:

- The patient has any Axis I disorder apart from Bipolar I Disorder that was the primary focus of treatment within 6 months before the screening visit (with the exception of nicotine dependence).
- The patient has any clinically significant uncontrolled medical or surgical condition.
- The patient has previously received modafinil or armodafinil, or the patient has a known sensitivity to any ingredients in the study drug tablets.
- The patient is a pregnant or lactating woman. (Any woman becoming pregnant during the study will be withdrawn from the study.)

Contacts and Locations

Locations

United States, Alabama

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Birmingham, Alabama, United States, 35216
Birmingham Psychiatry Pharmaceutical Studies, Inc
Birmingham, Alabama, United States, 35226

United States, California

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Escondido, California, United States, 92025
Bay Area Research Institute
Lafayette, California, United States, 94549
Synergy Clinical Research Center
National City, California, United States, 91950

Excell Research
Oceanside, California, United States, 92056
Pacific Clinical Research Medical Group
Orange, California, United States, 92868
CNRI Los Angeles LLC
Pico Rivera, California, United States, 90660
Pacific Clinical Research Medical Group
Riverside, California, United States, 92506
California Neuropsychopharmacology Clinical Research Inst
San Diego, California, United States, 92126
Stanford University
Stanford, California, United States, 94305

United States, Florida

Clinical Neuroscience Solutions Inc
Jacksonville, Florida, United States, 32216
Fidelity Clinical Research
Lauderhill, Florida, United States, 33319
Stedman Clinical Trials, LLC
Tampa, Florida, United States, 33613
Janus Center for Psychiatric Research
West Palm Beach, Florida, United States, 33407

United States, Georgia

Atlanta Center for Clinical Research
Atlanta, Georgia, United States, 30308
Carman Research
Smyrna, Georgia, United States, 30080

United States, Illinois

Psychiatric Medicine Associates
Skokie, Illinois, United States, 60076

United States, Maryland

Capital Clinical Research Associates
Rockville, Maryland, United States, 20852

United States, New Jersey

CNS Research Institute
Clementon, New Jersey, United States, 08021

United States, New York

Social Psychiatry Research Institute
Brooklyn, New York, United States, 11235
Behavioral Medical Research of Brooklyn
Brooklyn, New York, United States, 11201
Social Psychiatry Research Institute
New York, New York, United States, 10021
Medical & Behavioral Health Research
New York, New York, United States, 10023
Behavioral Medical Research of Staten Island
Staten Island, New York, United States, 10305

United States, North Carolina

Richard Weisler, MD and Associates
Raleigh, North Carolina, United States, 27609
Piedmont Clinical Trials, Inc.
Winston-Salem, North Carolina, United States, 27104

United States, Ohio

Mood Disorders Program
Cleveland, Ohio, United States, 44106
Midwest Clinical Research Center
Dayton, Ohio, United States, 45408

United States, Oklahoma

Sooner Clinical Research
Oklahoma City, Oklahoma, United States, 73112

United States, Oregon

Oregon Center for Clinical Investigations, Inc.
Salem, Oregon, United States, 97301

United States, Pennsylvania

Dubois Regional Medical Center - Behavioral Health Services
Dubois, Pennsylvania, United States, 15801
Keystone Clinical Studies LLC

Norristown, Pennsylvania, United States, 19401

University of Pennsylvania

Philadelphia, Pennsylvania, United States, 19104

CRI Worldwide

Philadelphia, Pennsylvania, United States, 19139

United States, Tennessee

Clinical Neuroscience Solutions, Inc.

Memphis, Tennessee, United States, 38119

United States, Texas

Community Clinical Research

Austin, Texas, United States, 78754

Claghorn-Lesem Research Clinic, LTD

Bellaire, Texas, United States, 77401

University Hills Clinical Research

Irving, Texas, United States, 75062

Grayline Clinical Drug Trials

Wichita Falls, Texas, United States, 76309

United States, Washington

Northwest Clinical Research Center

Bellevue, Washington, United States, 98004

Eastside Therapeutic Resource

Kirkland, Washington, United States, 98033

Bulgaria

Call For Information

Burgas, Bulgaria, 8000

Call For Information

Plovdiv, Bulgaria, 4002

Call For Information - Center Site #2

Plovdiv, Bulgaria, 4002

Call For Information

Sofia, Bulgaria, 1113

Call For Information - Center Site #2

Sofia, Bulgaria, 1113

Hungary

Call For Information

Budapest, Hungary, H-1135

Call For Information

Nagykálló, Hungary, H-4321

Romania

Call For Information

Bucuresti, Romania, 030455

Call For Information

Bucuresti, Romania, 010604

Call For Information

Bucuresti, Romania, 041915

Call For Information - Center Site #2

Bucuresti, Romania, 041915

Call For Information

Pitesti, Romania, 110069

Call For Information

Targoviste, Romania, 190081

More Information

Responsible Party: Cephalon

Study ID Numbers: C10953/2032/DP/US

Health Authority: United States: Food and Drug Administration

Study Results

Participant Flow

Recruitment Details	42 centers in the US, Romania, Bulgaria, and Hungary. First participant enrolled: June 2007/ Last participant last visit: December 2008

Pre-Assignment Details	The study consisted of a 1 to 2 week screening period, an 8 week double blind treatment period, and a 1 week follow up period.

Arm/Group Title	Armodafinil 150 mg/Day	Placebo	Total (Not public)
▼ Arm/Group Description	Armodafinil was titrated up to the target dosage of 150 mg/day (daily dose was administered each morning). Patients began taking blinded armodafinil at a dose of 50 mg/day (1 tablet) on the day following the baseline visit. Doses were increased by 50 mg/day (1 tablet) to a dose of 100 mg/day on Day 2 and 3, and then again by 50 mg /day on day 4 for a target dose of 150 mg/day. Following titration, patients continued taking 150 mg/day of armodafinil for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 100 mg/day [2 tablets]) was allowed. The dosage could not be increased after it was decreased.	Placebo tablets matching the 50 mg armodafinil tablet were used in a manner identical to that of the armodafinil tablets. Study drug was titrated up to the target dosage of 3 tablets / day (daily dose was administered each morning). Patients began taking blinded study drug at a dose of 1 tablet daily on the day following the baseline visit. Doses were increased by 1 tablet to a dose of 2 tablets/day on Day 2 and 3, and then again by 1 tablet /day on day 4 for a target dose of 3 tablets/day. Following titration, patients continued taking 3 tablets/day of study drug for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 2 tablets/day) was allowed. The dosage could not be increased after it was decreased.	
Period Title: **Overall Study**			
Started	128 [1]	129 [2]	257
Completed	89	90	179
Not Completed	39	39	78
Reason Not Completed			

Adverse Event	16	11	27
Lack of Efficacy	1	3	4
Lost to Follow-up	4	6	10
Physician Decision	3	1	4
Protocol Violation	10	7	17
Withdrawal by Subject	3	9	12
Miscellaneous	2	2	4
(Not Public)	Not Completed =39 Total from all reasons =39	Not Completed =39 Total from all reasons =39	

[1] Two of these subjects were randomized but never received study medication.

[2] Four of these subjects were randomized but never received study medication.

Baseline Characteristics

Arm/Group Title	Armodafinil 150 mg/Day	Placebo	Total
▼ Arm/Group Description	Armodafinil was titrated up to the target dosage of 150 mg/day (daily dose was administered each morning). Patients began taking blinded armodafinil at a dose of 50 mg/day (1 tablet) on the day following the baseline visit. Doses were increased by 50 mg/day (1 tablet) to a dose of 100 mg/day on Day 2 and 3, and then again by 50 mg /day on day 4 for a target dose of 150 mg/day. Following titration, patients continued taking 150 mg/day of armodafinil for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in	Placebo tablets matching the 50 mg armodafinil tablet were used in a manner identical to that of the armodafinil tablets. Study drug was titrated up to the target dosage of 3 tablets / day (daily dose was administered each morning). Patients began taking blinded study drug at a dose of 1 tablet daily on the day following the baseline visit. Doses were increased by 1 tablet to a dose of 2 tablets/day on Day 2 and 3, and then again by 1 tablet /day on day 4 for a target dose of 3 tablets/day. Following titration, patients continued taking 3 tablets/day of study drug for	

		dosage (ie, minimum dosage 100 mg/day [2 tablets]) was allowed. The dosage could not be increased after it was decreased.	the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 2 tablets/day) was allowed. The dosage could not be increased after it was decreased.	
Overall Number of Baseline Participants		128	129	257
▼ Baseline Analysis Population Description [Not specified]				
Age, Categorical Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	128 participants	129 participants	257 participants
	<=18 years	0 0%	0 0%	0 0%
	Between 18 and 65 years	128 100%	129 100%	257 100%
	>=65 years	0 0%	0 0%	0 0%
Age, Continuous Mean (Standard Deviation) Unit of measure: years	Number Analyzed	128 participants	129 participants	257 participants
		42.6 (11.34)	44.9 (11.53)	43.7 (11.47)
Gender, Male/Female Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	128 participants	129 participants	257 participants
	Female	64 50%	76 58.91%	140 54.47%
	Male	64 50%	53 41.09%	117 45.53%
Region of Enrollment Measure Type: Number	Number Analyzed	128 participants	129 participants	257 participants

Unit of measure: participants				
United States		115	105	220
Hungary		0	2	2
Romania		5	7	12
Bulgaria		8	15	23

Outcome Measures

1. Primary Outcome

Title:	The Mean Change From Baseline to Endpoint (Week 8 or Last Observation After Baseline) in the 30 Item Inventory of Depressive Symptomatology Clinician Rated (IDS C30)
Description:	The IDS C30 is a standardized 30 item, clinician rated scale to assess the severity of a patient's depressive symptoms. The scale uses the 9 symptom domains of the DSM-IV criteria to measure symptom severity. The scores range from a minimum of 0 to a maximum score of 84. The higher the score the more severe the symptoms of depression. The data presented here summarizes the change from baseline to Endpoint (either week 8 or the last observation after baseline) in the total score of the IDS-C30.
Time Frame:	Baseline and 8 weeks from start of study drug administration (or last observation after baseline)
Safety Issue?	No

Outcome Measure Data

Analysis Population Description

Full analysis set defined as subjects who were assessed with the IDS-C30 at both baseline and at least one time point after baseline

Arm/Group Title	Armodafinil 150 mg/Day	Placebo

▼ Arm/Group Description:	Armodafinil was titrated up to the target dosage of 150 mg/day (daily dose was administered each morning). Patients began taking blinded armodafinil at a dose of 50 mg/day (1 tablet) on the day following the baseline visit. Doses were increased by 50 mg/day (1 tablet) to a dose of 100 mg/day on Day 2 and 3, and then again by 50 mg /day on day 4 for a target dose of 150 mg/day. Following titration, patients continued taking 150 mg/day of armodafinil for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 100 mg/day [2 tablets]) was allowed. The dosage could not be increased after it was decreased.	Placebo tablets matching the 50 mg armodafinil tablet were used in a manner identical to that of the armodafinil tablets. Study drug was titrated up to the target dosage of 3 tablets / day (daily dose was administered each morning). Patients began taking blinded study drug at a dose of 1 tablet daily on the day following the baseline visit. Doses were increased by 1 tablet to a dose of 2 tablets/day on Day 2 and 3, and then again by 1 tablet /day on day 4 for a target dose of 3 tablets/day. Following titration, patients continued taking 3 tablets/day of study drug for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 2 tablets/day) was allowed. The dosage could not be increased after it was decreased.
Number of Participants Analyzed	124	123
Least Squares Mean (Standard Error) Unit of measure: Units on a scale	-15.6 (1.32)	-12.5 (1.34)

▼ Statistical Analysis 1 ✓

Statistical Analysis Overview	Comparison Groups	Armodafinil 150 mg/Day, Placebo

	Comments	Least square (LS) mean and standard error of the LS mean for each treatment group and the p-value for the treatment comparison is from an analysis of variance (ANOVA) with treatment ands concurrent treatment for bipolar disorders as factors. A significant treatment-by baseline interaction was observed in the total score that violates the assumption of parallelism on which an ANCOVA is based, so the data was analyzed using ANOVA without baseline as a covariate rather than ANCOVA.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.0439
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]

2. Secondary Outcome

Title:	The Mean Change From Baseline to Week 1 in the 30 Item Inventory of Depressive Symptomatology Clinician Rated (IDS C30)
▼ Description:	The IDS C30 is a standardized 30 item, clinician rated, scale to assess the severity of a patient's depressive symptoms. The scale uses the 9 symptom domains of the DSM-IV criteria to measure symptom severity. The scores range from a minimum of 0 to a maximum score of 84. The higher the score the more severe the symptoms of depression. The data presented here summarizes the change from baseline to Week 1 in the total score of the IDS-C30.
Time Frame:	Baseline and 1 week following the start of study drug administration
Safety Issue?	No

▼ Outcome Measure Data 

▼ Analysis Population Description

Full analysis set defined as subjects who were assessed with the IDS-C30 at both baseline and at week 1 after start of study drug administration

Arm/Group Title	Armodafinil 150 mg/Day	Placebo
▼ Arm/Group Description:	Armodafinil was titrated up to the target dosage of 150 mg/day (daily dose was administered each morning). Patients began taking blinded armodafinil at a dose of 50 mg/day (1 tablet) on the day following the baseline visit. Doses were increased by 50 mg/day (1 tablet) to a dose of 100 mg/day on Day 2 and 3, and then again by 50 mg /day on day 4 for a target dose of 150 mg/day. Following titration, patients continued taking 150 mg/day of armodafinil for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 100 mg/day [2 tablets]) was allowed. The dosage could not be increased after it was decreased.	Placebo tablets matching the 50 mg armodafinil tablet were used in a manner identical to that of the armodafinil tablets. Study drug was titrated up to the target dosage of 3 tablets / day (daily dose was administered each morning). Patients began taking blinded study drug at a dose of 1 tablet daily on the day following the baseline visit. Doses were increased by 1 tablet to a dose of 2 tablets/day on Day 2 and 3, and then again by 1 tablet /day on day 4 for a target dose of 3 tablets/day. Following titration, patients continued taking 3 tablets/day of study drug for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 2 tablets/day) was allowed. The dosage could not be increased after it was decreased.
Number of Participants Analyzed	120	118
Least Squares Mean (Standard Error) Unit of measure: Units on a scale	-6.5 (0.84)	-4.8 (0.85)

▼ Statistical Analysis 1 ✔

Statistical Analysis Overview	Comparison Groups	Armodafinil 150 mg/Day, Placebo

	Comments	Least square (LS) mean and standard error of the LS mean for each treatment group and the p-value for the treatment comparison is from an ANCOVA with treatment and concurrent treatment for bipolar disorder as factors, and the baseline value as covariate.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.0795
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

3. Secondary Outcome

Title:	The Mean Change From Baseline to Week 2 in the 30 Item Inventory of Depressive Symptomatology Clinician Rated (IDS C30)
▼ Description:	The IDS C30 is a standardized 30 item, clinician rated, scale to assess the severity of a patient's depressive symptoms. The scale uses the 9 symptom domains of the DSM-IV criteria to measure symptom severity. The scores range from a minimum of 0 to a maximum score of 84. The higher the score the more severe the symptoms of depression. The data presented here summarizes the change from baseline to Week 2 in the total score of the IDS-C30.
Time Frame:	Baseline and 2 weeks following the start of study drug administration
Safety Issue?	No

▼ Outcome Measure Data 

▼ Analysis Population Description

Full analysis set defined as subjects who were assessed with the IDS-C30 at baseline and at 2 weeks

Arm/Group Title	Armodafinil 150 mg/Day	Placebo

▼ Arm/Group Description:	Armodafinil was titrated up to the target dosage of 150 mg/day (daily dose was administered each morning). Patients began taking blinded armodafinil at a dose of 50 mg/day (1 tablet) on the day following the baseline visit. Doses were increased by 50 mg/day (1 tablet) to a dose of 100 mg/day on Day 2 and 3, and then again by 50 mg /day on day 4 for a target dose of 150 mg/day. Following titration, patients continued taking 150 mg/day of armodafinil for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 100 mg/day [2 tablets]) was allowed. The dosage could not be increased after it was decreased.	Placebo tablets matching the 50 mg armodafinil tablet were used in a manner identical to that of the armodafinil tablets. Study drug was titrated up to the target dosage of 3 tablets / day (daily dose was administered each morning). Patients began taking blinded study drug at a dose of 1 tablet daily on the day following the baseline visit. Doses were increased by 1 tablet to a dose of 2 tablets/day on Day 2 and 3, and then again by 1 tablet /day on day 4 for a target dose of 3 tablets/day. Following titration, patients continued taking 3 tablets/day of study drug for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 2 tablets/day) was allowed. The dosage could not be increased after it was decreased.
Number of Participants Analyzed	108	112
Least Squares Mean (Standard Error) Unit of measure: Units on a scale	-10.0 (1.04)	-7.3 (1.05)

▼ Statistical Analysis 1 ✓

Statistical Analysis Overview	Comparison Groups	Armodafinil 150 mg/Day, Placebo
	Comments	Least square (LS) mean and standard error of the LS mean for each treatment group and the p-value for the treatment comparison is from an ANCOVA with treatment and concurrent treatment for bipolar disorder as factors, and the baseline value as covariate.

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.0272
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

4. Secondary Outcome

Title:	The Mean Change From Baseline to Week 3 in the 30 Item Inventory of Depressive Symptomatology Clinician Rated (IDS C30)
▼ Description:	The IDS C30 is a standardized 30 item, clinician rated, scale to assess the severity of a patient's depressive symptoms. The scale uses the 9 symptom domains of the DSM-IV criteria to measure symptom severity. The scores range from a minimum of 0 to a maximum score of 84. The higher the score the more severe the symptoms of depression. The data presented here summarizes the change from baseline to Week 3 in the total score of the IDS-C30.
Time Frame:	Baseline and 3 weeks following the start of study drug administration
Safety Issue?	No

▼ Outcome Measure Data 

▼ Analysis Population Description

Full analysis set defined as subjects who were assessed with the IDS-C30 at baseline and at 3 weeks

Arm/Group Title	Armodafinil 150 mg/Day	Placebo

▼ Arm/Group Description:	Armodafinil was titrated up to the target dosage of 150 mg/day (daily dose was administered each morning). Patients began taking blinded armodafinil at a dose of 50 mg/day (1 tablet) on the day following the baseline visit. Doses were increased by 50 mg/day (1 tablet) to a dose of 100 mg/day on Day 2 and 3, and then again by 50 mg /day on day 4 for a target dose of 150 mg/day. Following titration, patients continued taking 150 mg/day of armodafinil for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 100 mg/day [2 tablets]) was allowed. The dosage could not be increased after it was decreased.	Placebo tablets matching the 50 mg armodafinil tablet were used in a manner identical to that of the armodafinil tablets. Study drug was titrated up to the target dosage of 3 tablets / day (daily dose was administered each morning). Patients began taking blinded study drug at a dose of 1 tablet daily on the day following the baseline visit. Doses were increased by 1 tablet to a dose of 2 tablets/day on Day 2 and 3, and then again by 1 tablet /day on day 4 for a target dose of 3 tablets/day. Following titration, patients continued taking 3 tablets/day of study drug for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 2 tablets/day) was allowed. The dosage could not be increased after it was decreased.
Number of Participants Analyzed	102	100
Least Squares Mean (Standard Error) Unit of measure: Units on a scale	-13.1 (1.16)	-10.7 (1.20)

▼ Statistical Analysis 1 ✓

Statistical Analysis Overview	Comparison Groups	Armodafinil 150 mg/Day, Placebo
	Comments	Least square (LS) mean and standard error of the LS mean for each treatment group and the p-value for the treatment comparison is from an ANCOVA with treatment and concurrent treatment for bipolar disorder as factors, and the baseline value as covariate.

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.0802
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

5. Secondary Outcome

Title:	The Mean Change From Baseline to Week 4 in the 30 Item Inventory of Depressive Symptomatology Clinician Rated (IDS C30)
▼ Description:	The IDS C30 is a standardized 30 item, clinician rated, scale to assess the severity of a patient's depressive symptoms. The scale uses the 9 symptom domains of the DSM-IV criteria to measure symptom severity. The scores range from a minimum of 0 to a maximum score of 84. The higher the score the more severe the symptoms of depression. The data presented here summarizes the change from baseline to Week 4 in the total score of the IDS-C30.
Time Frame:	Baseline and 4 weeks following the start of study drug administration
Safety Issue?	No

▼ Outcome Measure Data 

▼ Analysis Population Description

Full analysis set defined as subjects who were assessed with the IDS-C30 at baseline and at 4 weeks

Arm/Group Title	Armodafinil 150 mg/Day	Placebo

▼ Arm/Group Description:	Armodafinil was titrated up to the target dosage of 150 mg/day (daily dose was administered each morning). Patients began taking blinded armodafinil at a dose of 50 mg/day (1 tablet) on the day following the baseline visit. Doses were increased by 50 mg/day (1 tablet) to a dose of 100 mg/day on Day 2 and 3, and then again by 50 mg /day on day 4 for a target dose of 150 mg/day. Following titration, patients continued taking 150 mg/day of armodafinil for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 100 mg/day [2 tablets]) was allowed. The dosage could not be increased after it was decreased.	Placebo tablets matching the 50 mg armodafinil tablet were used in a manner identical to that of the armodafinil tablets. Study drug was titrated up to the target dosage of 3 tablets / day (daily dose was administered each morning). Patients began taking blinded study drug at a dose of 1 tablet daily on the day following the baseline visit. Doses were increased by 1 tablet to a dose of 2 tablets/day on Day 2 and 3, and then again by 1 tablet /day on day 4 for a target dose of 3 tablets/day. Following titration, patients continued taking 3 tablets/day of study drug for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 2 tablets/day) was allowed. The dosage could not be increased after it was decreased.
Number of Participants Analyzed	99	97
Least Squares Mean (Standard Error) Unit of measure: Units on a scale	-13.7 (1.19)	-12.1 (1.25)

▼ Statistical Analysis 1 ✓

Statistical Analysis Overview	Comparison Groups	Armodafinil 150 mg/Day, Placebo
	Comments	Least square (LS) mean and standard error of the LS mean for each treatment group and the p-value for the treatment comparison is from an ANCOVA with treatment and concurrent treatment for bipolar disorder as factors, and the baseline value as covariate.

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.2407
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

6. Secondary Outcome

Title:	The Mean Change From Baseline to Week 6 in the 30 Item Inventory of Depressive Symptomatology Clinician Rated (IDS C30)
▼ Description:	The IDS C30 is a standardized 30 item, clinician rated, scale to assess the severity of a patient's depressive symptoms. The scale uses the 9 symptom domains of the DSM-IV criteria to measure symptom severity. The scores range from a minimum of 0 to a maximum score of 84. The higher the score the more severe the symptoms of depression. The data presented here summarizes the change from baseline to Week 6 in the total score of the IDS-C30.
Time Frame:	Baseline and 6 weeks following the start of study drug administration
Safety Issue?	No

▼ Outcome Measure Data 

▼ Analysis Population Description

Full analysis set defined as subjects who were assessed with the IDS-C30 at baseline and at 6 weeks

Arm/Group Title	Armodafinil 150 mg/Day	Placebo

▼ Arm/Group Description:	Armodafinil was titrated up to the target dosage of 150 mg/day (daily dose was administered each morning). Patients began taking blinded armodafinil at a dose of 50 mg/day (1 tablet) on the day following the baseline visit. Doses were increased by 50 mg/day (1 tablet) to a dose of 100 mg/day on Day 2 and 3, and then again by 50 mg /day on day 4 for a target dose of 150 mg/day. Following titration, patients continued taking 150 mg/day of armodafinil for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 100 mg/day [2 tablets]) was allowed. The dosage could not be increased after it was decreased.	Placebo tablets matching the 50 mg armodafinil tablet were used in a manner identical to that of the armodafinil tablets. Study drug was titrated up to the target dosage of 3 tablets / day (daily dose was administered each morning). Patients began taking blinded study drug at a dose of 1 tablet daily on the day following the baseline visit. Doses were increased by 1 tablet to a dose of 2 tablets/day on Day 2 and 3, and then again by 1 tablet /day on day 4 for a target dose of 3 tablets/day. Following titration, patients continued taking 3 tablets/day of study drug for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 2 tablets/day) was allowed. The dosage could not be increased after it was decreased.
Number of Participants Analyzed	92	92
Least Squares Mean (Standard Error) Unit of measure: Units on a scale	-16.7 (1.36)	-13.7 (1.40)

▼ Statistical Analysis 1 ✓

Statistical Analysis Overview	Comparison Groups	Armodafinil 150 mg/Day, Placebo
	Comments	Least square (LS) mean and standard error of the LS mean for each treatment group and the p-value for the treatment comparison is from an ANCOVA with treatment and concurrent treatment for bipolar disorder as factors, and the baseline value as covariate.

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.0502
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

7. Secondary Outcome

Title:	The Mean Change From Baseline to Week 8 in the 30 Item Inventory of Depressive Symptomatology Clinician Rated (IDS C30)
▼ Description:	The IDS C30 is a standardized 30 item, clinician rated, scale to assess the severity of a patient's depressive symptoms. The scale uses the 9 symptom domains of the DSM-IV criteria to measure symptom severity. The scores range from a minimum of 0 to a maximum score of 84. The higher the score the more severe the symptoms of depression. The data presented here summarizes the change from baseline to Week 8 in the total score of the IDS-C30.
Time Frame:	Baseline and 8 weeks following the start of study drug administration
Safety Issue?	No

▼ Outcome Measure Data 

▼ Analysis Population Description

Full analysis set defined as subjects who were assessed at baseline and at 8 weeks with the IDS-C30.

Arm/Group Title	Armodafinil 150 mg/Day	Placebo

▼ Arm/Group Description:	Armodafinil was titrated up to the target dosage of 150 mg/day (daily dose was administered each morning). Patients began taking blinded armodafinil at a dose of 50 mg/day (1 tablet) on the day following the baseline visit. Doses were increased by 50 mg/day (1 tablet) to a dose of 100 mg/day on Day 2 and 3, and then again by 50 mg /day on day 4 for a target dose of 150 mg/day. Following titration, patients continued taking 150 mg/day of armodafinil for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 100 mg/day [2 tablets]) was allowed. The dosage could not be increased after it was decreased.	Placebo tablets matching the 50 mg armodafinil tablet were used in a manner identical to that of the armodafinil tablets. Study drug was titrated up to the target dosage of 3 tablets / day (daily dose was administered each morning). Patients began taking blinded study drug at a dose of 1 tablet daily on the day following the baseline visit. Doses were increased by 1 tablet to a dose of 2 tablets/day on Day 2 and 3, and then again by 1 tablet /day on day 4 for a target dose of 3 tablets/day. Following titration, patients continued taking 3 tablets/day of study drug for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 2 tablets/day) was allowed. The dosage could not be increased after it was decreased.
Number of Participants Analyzed	89	90
Least Squares Mean (Standard Error) Unit of measure: Units on a scale	-17.8 (1.41)	-14.8 (1.45)

▼ Statistical Analysis 1 ✓

Statistical Analysis Overview	Comparison Groups	Armodafinil 150 mg/Day, Placebo
	Comments	Least square (LS) mean and standard error of the LS mean for each treatment group and the p-value for the treatment comparison is from an ANCOVA with treatment and concurrent treatment for bipolar disorder as factors, and the baseline value as covariate.

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.0612
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

8. Secondary Outcome

Title:	Number of Patients Achieving Remission at Endpoint According to the 30-item Inventory of Depressive Symptomatology-Clinician-Rated (IDS-C30)
▼ Description:	The IDS C30 is a standardized 30 item, clinician rated, scale to assess the severity of a patient's depressive symptoms. The scale uses the 9 symptom domains of the DSM-IV criteria to measure symptom severity. The scores range from a minimum of 0 to a maximum score of 84. The higher the score the more severe the symptoms of depression. The data here summarizes the number of subjects in each treatment group who achieved a remission (total score <=11).
Time Frame:	Baseline, 4 and 8 weeks following start of study drug administration (or last observation after baseline)
Safety Issue?	No

▼ Outcome Measure Data 

▼ Analysis Population Description

Full analysis set defined as subjects who had completed IDS-C30 at baseline and at least one observation after baseline

Arm/Group Title	Armodafinil 150 mg/Day	Placebo

▼ Arm/Group Description:	Armodafinil was titrated up to the target dosage of 150 mg/day (daily dose was administered each morning). Patients began taking blinded armodafinil at a dose of 50 mg/day (1 tablet) on the day following the baseline visit. Doses were increased by 50 mg/day (1 tablet) to a dose of 100 mg/day on Day 2 and 3, and then again by 50 mg /day on day 4 for a target dose of 150 mg/day. Following titration, patients continued taking 150 mg/day of armodafinil for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 100 mg/day [2 tablets]) was allowed. The dosage could not be increased after it was decreased.	Placebo tablets matching the 50 mg armodafinil tablet were used in a manner identical to that of the armodafinil tablets. Study drug was titrated up to the target dosage of 3 tablets / day (daily dose was administered each morning). Patients began taking blinded study drug at a dose of 1 tablet daily on the day following the baseline visit. Doses were increased by 1 tablet to a dose of 2 tablets/day on Day 2 and 3, and then again by 1 tablet /day on day 4 for a target dose of 3 tablets/day. Following titration, patients continued taking 3 tablets/day of study drug for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 2 tablets/day) was allowed. The dosage could not be increased after it was decreased.
Number of Participants Analyzed	124	123
Measure Type: Number Unit of measure: Participants		
Row Title: Remission	30	22
Row Title: No Remission	94	101

▼ Statistical Analysis 1 ✓

Statistical Analysis Overview	Comparison Groups	Armodafinil 150 mg/Day, Placebo
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.1980
	Comments	P-value is from a Cochran-Mantel-Haenzel chi-square test adjusted for concurrent treatment for bipolar disorder
	Method	Cochran-Mantel-Haenszel
	Comments	[Not specified]

9. Secondary Outcome

Title:	Number of Patients Achieving "Response" at Endpoint According to the 30-item Inventory of Depressive Symptomatology-Clinician-Rated (IDS-C30)
▼ Description:	The IDS C30 is a standardized 30 item, clinician rated, scale to assess the severity of a patient's depressive symptoms. The scale uses the 9 symptom domains of the DSM-IV criteria to measure symptom severity. The scores range from a minimum of 0 to a maximum score of 84. The higher the score the more severe the symptoms of depression. The data here summarizes the number of subjects in each treatment group who achieved a "response" (> 50% decrease from baseline in total score).
Time Frame:	Baseline, 4 and 8 weeks following start of study drug administration (or last observation after baseline)
Safety Issue?	No

▼ Outcome Measure Data

▼ Analysis Population Description

Full analysis set defined as subjects who were assessed by IDS-C30 at baseline, and at least one observation after baseline

Arm/Group Title	Armodafinil 150 mg/Day	Placebo

▼ Arm/Group Description:	Armodafinil was titrated up to the target dosage of 150 mg/day (daily dose was administered each morning). Patients began taking blinded armodafinil at a dose of 50 mg/day (1 tablet) on the day following the baseline visit. Doses were increased by 50 mg/day (1 tablet) to a dose of 100 mg/day on Day 2 and 3, and then again by 50 mg /day on day 4 for a target dose of 150 mg/day. Following titration, patients continued taking 150 mg/day of armodafinil for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 100 mg/day [2 tablets]) was allowed. The dosage could not be increased after it was decreased.	Placebo tablets matching the 50 mg armodafinil tablet were used in a manner identical to that of the armodafinil tablets. Study drug was titrated up to the target dosage of 3 tablets / day (daily dose was administered each morning). Patients began taking blinded study drug at a dose of 1 tablet daily on the day following the baseline visit. Doses were increased by 1 tablet to a dose of 2 tablets/day on Day 2 and 3, and then again by 1 tablet /day on day 4 for a target dose of 3 tablets/day. Following titration, patients continued taking 3 tablets/day of study drug for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 2 tablets/day) was allowed. The dosage could not be increased after it was decreased.
Number of Participants Analyzed	124	123
Measure Type: Number Unit of measure: Participants		
Row Title: Response	46	47
Row Title: No Response	78	76

▼ Statistical Analysis 1 ✓

Statistical Analysis Overview	Comparison Groups	Armodafinil 150 mg/Day, Placebo
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.8960
	Comments	P-value is from a Cochran-Mantel-Haenzel chi-square test adjusted for concurrent treatment for bipolar disorder
	Method	Cochran-Mantel-Haenszel
	Comments	[Not specified]

10. Secondary Outcome

Title:	Number of Patients Achieving "Sustained Remission" at Endpoint According to the 30-item Inventory of Depressive Symptomatology-Clinician-Rated (IDS-C30)
▼ Description:	The IDS C30 is a standardized 30 item, clinician rated, scale to assess the severity of a patient's depressive symptoms. The scale uses the 9 symptom domains of the DSM-IV criteria to measure symptom severity. The scores range from a minimum of 0 to a maximum score of 84. The higher the score the more severe the symptoms of depression. The data here summarizes the number of subjects in each treatment group who achieved a "sustained remission" (total score <= 11 that persists over the four week period from Week 4 to Week 8).
Time Frame:	Baseline, 4 and 8 weeks following start of study drug administration (or last observation after baseline)
Safety Issue?	No

▼ Outcome Measure Data

▼ Analysis Population Description

Full analysis set defined as subjects who were assessed by IDS-C30 at baseline, and at least one observation after baseline

Arm/Group Title	Armodafinil 150 mg/Day	Placebo

▼ Arm/Group Description:	Armodafinil was titrated up to the target dosage of 150 mg/day (daily dose was administered each morning). Patients began taking blinded armodafinil at a dose of 50 mg/day (1 tablet) on the day following the baseline visit. Doses were increased by 50 mg/day (1 tablet) to a dose of 100 mg/day on Day 2 and 3, and then again by 50 mg /day on day 4 for a target dose of 150 mg/day. Following titration, patients continued taking 150 mg/day of armodafinil for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 100 mg/day [2 tablets]) was allowed. The dosage could not be increased after it was decreased.	Placebo tablets matching the 50 mg armodafinil tablet were used in a manner identical to that of the armodafinil tablets. Study drug was titrated up to the target dosage of 3 tablets / day (daily dose was administered each morning). Patients began taking blinded study drug at a dose of 1 tablet daily on the day following the baseline visit. Doses were increased by 1 tablet to a dose of 2 tablets/day on Day 2 and 3, and then again by 1 tablet /day on day 4 for a target dose of 3 tablets/day. Following titration, patients continued taking 3 tablets/day of study drug for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 2 tablets/day) was allowed. The dosage could not be increased after it was decreased.
Number of Participants Analyzed	124	123
Measure Type: Number Unit of measure: Participants		
Row Title: Sustained Remission	13	8
Row Title: No Sustained Remission	111	115

▼ Statistical Analysis 1 ✓

Statistical Analysis Overview	Comparison Groups	Armodafinil 150 mg/Day, Placebo
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No

	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.2575
	Comments	P-value is from a Cochran-Mantel-Haenzel chi-square test adjusted for concurrent treatment for bipolar disorder
	Method	Cochran-Mantel-Haenszel
	Comments	[Not specified]

11. Secondary Outcome

Title:	Number of Patients Achieving "Sustained Response" at Endpoint According to the 30-item Inventory of Depressive Symptomatology-Clinician-Rated (IDS-C30)
▼ Description:	The IDS C30 is a standardized 30 item, clinician rated, scale to assess the severity of a patient's depressive symptoms. The scale uses the 9 symptom domains of the DSM-IV criteria to measure symptom severity. The scores range from a minimum of 0 to a maximum score of 84. The higher the score the more severe the symptoms of depression. The data here summarizes the number of subjects in each treatment group who achieved a "sustained response" (> 50% decrease from baseline in total score that persisted over the four week period between Week 4 and Week 8).
Time Frame:	Baseline, 4 and 8 weeks following start of study drug administration (or last observation after baseline)
Safety Issue?	No

▼ Outcome Measure Data

▼ Analysis Population Description

Full analysis set defined as subjects who were assessed by IDS-C30 at baseline, and at least one observation after baseline

Arm/Group Title	Armodafinil 150 mg/Day	Placebo

▼ Arm/Group Description:	Armodafinil was titrated up to the target dosage of 150 mg/day (daily dose was administered each morning). Patients began taking blinded armodafinil at a dose of 50 mg/day (1 tablet) on the day following the baseline visit. Doses were increased by 50 mg/day (1 tablet) to a dose of 100 mg/day on Day 2 and 3, and then again by 50 mg /day on day 4 for a target dose of 150 mg/day. Following titration, patients continued taking 150 mg/day of armodafinil for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 100 mg/day [2 tablets]) was allowed. The dosage could not be increased after it was decreased.	Placebo tablets matching the 50 mg armodafinil tablet were used in a manner identical to that of the armodafinil tablets. Study drug was titrated up to the target dosage of 3 tablets / day (daily dose was administered each morning). Patients began taking blinded study drug at a dose of 1 tablet daily on the day following the baseline visit. Doses were increased by 1 tablet to a dose of 2 tablets/day on Day 2 and 3, and then again by 1 tablet /day on day 4 for a target dose of 3 tablets/day. Following titration, patients continued taking 3 tablets/day of study drug for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 2 tablets/day) was allowed. The dosage could not be increased after it was decreased.
Number of Participants Analyzed	124	123
Measure Type: Number Unit of measure: Participants		
Row Title: Sustained Response	23	17
Row Title: No Sustained Response	101	106

▼ Statistical Analysis 1 ✓

Statistical Analysis Overview	Comparison Groups	Armodafinil 150 mg/Day, Placebo
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No

	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.3129
	Comments	P-value is from a Cochran-Mantel-Haenzel chi-square test adjusted for concurrent treatment for bipolar disorder
	Method	Cochran-Mantel-Haenszel
	Comments	[Not specified]

12. Secondary Outcome

Title:	Change From Baseline to Endpoint (Week 8 or Last Observation After Baseline) on 30 Item Inventory of Depressive Symptomatology Clinician Rated (IDS C30) Combination of Items 1-3
▼ Description:	The IDS C30 is a standardized 30 item, clinician rated, scale to assess the severity of a patient's depressive symptoms. The scale uses the 9 symptom domains of the DSM-IV criteria to measure symptom severity. The scores range from a minimum of 0 to a maximum score of 84. The higher the score the more severe the symptoms of depression. Items 1 - 3 assess sleep onset insomnia, mid-nocturnal insomnia, and early morning insomnia respectively each on a 0 - 3 scale. The data presented here summarizes the change from baseline to Endpoint in the combined score of these three items assessing insomnia.
Time Frame:	Baseline and 8 weeks (or last observation after baseline)
Safety Issue?	No

▼ Outcome Measure Data

▼ Analysis Population Description

Full analysis set defined as subjects who were assessed by IDS-C30 at baseline and at least one observation after baseline

Arm/Group Title	Armodafinil 150 mg/Day	Placebo

▼ Arm/Group Description:	Armodafinil was titrated up to the target dosage of 150 mg/day (daily dose was administered each morning). Patients began taking blinded armodafinil at a dose of 50 mg/day (1 tablet) on the day following the baseline visit. Doses were increased by 50 mg/day (1 tablet) to a dose of 100 mg/day on Day 2 and 3, and then again by 50 mg /day on day 4 for a target dose of 150 mg/day. Following titration, patients continued taking 150 mg/day of armodafinil for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 100 mg/day [2 tablets]) was allowed. The dosage could not be increased after it was decreased.	Placebo tablets matching the 50 mg armodafinil tablet were used in a manner identical to that of the armodafinil tablets. Study drug was titrated up to the target dosage of 3 tablets / day (daily dose was administered each morning). Patients began taking blinded study drug at a dose of 1 tablet daily on the day following the baseline visit. Doses were increased by 1 tablet to a dose of 2 tablets/day on Day 2 and 3, and then again by 1 tablet /day on day 4 for a target dose of 3 tablets/day. Following titration, patients continued taking 3 tablets/day of study drug for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 2 tablets/day) was allowed. The dosage could not be increased after it was decreased.
Number of Participants Analyzed	124	123
Least Squares Mean (Standard Error) Unit of measure: Units on a scale	-1.6 (0.24)	-1.2 (0.25)

▼ Statistical Analysis 1 ✓

Statistical Analysis Overview	Comparison Groups	Armodafinil 150 mg/Day, Placebo
	Comments	Least square (LS) mean and standard error of the LS mean for each treatment group and the p-value for the treatment comparison is from an ANCOVA with treatment and concurrent treatment for bipolar disorder as factors, and the baseline value as covariate.

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.1565
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

13. Secondary Outcome

Title:	Change From Baseline to Week 4 on 30 Item Inventory of Depressive Symptomatology Clinician Rated (IDS C30) Combination of Items 1-3
▼ Description:	The IDS C30 is a standardized 30 item, clinician rated, scale to assess the severity of a patient's depressive symptoms. The scale uses the 9 symptom domains of the DSM-IV criteria to measure symptom severity. The scores range from a minimum of 0 to a maximum score of 84. The higher the score the more severe the symptoms of depression. Items 1 - 3 assess sleep onset insomnia, mid-nocturnal insomnia, and early morning insomnia respectively each on a 0 - 3 scale. The data presented here summarizes the change from baseline to week 4 in the combined score of these three items assessing insomnia.
Time Frame:	Baseline and 4 weeks following the start of study drug administration
Safety Issue?	No

▼ Outcome Measure Data

▼ Analysis Population Description

Full analysis set defined as subjects who were assessed by IDS C30 at baseline and Week 4

Arm/Group Title	Armodafinil 150 mg/Day	Placebo

▼ Arm/Group Description:	Armodafinil was titrated up to the target dosage of 150 mg/day (daily dose was administered each morning). Patients began taking blinded armodafinil at a dose of 50 mg/day (1 tablet) on the day following the baseline visit. Doses were increased by 50 mg/day (1 tablet) to a dose of 100 mg/day on Day 2 and 3, and then again by 50 mg /day on day 4 for a target dose of 150 mg/day. Following titration, patients continued taking 150 mg/day of armodafinil for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 100 mg/day [2 tablets]) was allowed. The dosage could not be increased after it was decreased.	Placebo tablets matching the 50 mg armodafinil tablet were used in a manner identical to that of the armodafinil tablets. Study drug was titrated up to the target dosage of 3 tablets / day (daily dose was administered each morning). Patients began taking blinded study drug at a dose of 1 tablet daily on the day following the baseline visit. Doses were increased by 1 tablet to a dose of 2 tablets/day on Day 2 and 3, and then again by 1 tablet /day on day 4 for a target dose of 3 tablets/day. Following titration, patients continued taking 3 tablets/day of study drug for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 2 tablets/day) was allowed. The dosage could not be increased after it was decreased.
Number of Participants Analyzed	99	97
Least Squares Mean (Standard Error) Unit of measure: Units on a scale	-1.2 (0.26)	-1.1 (0.27)

▼ Statistical Analysis 1 ✓

Statistical Analysis Overview	Comparison Groups	Armodafinil 150 mg/Day, Placebo
	Comments	Least square (LS) mean and standard error of the LS mean for each treatment group and the p-value for the treatment comparison is from an ANCOVA with treatment and concurrent treatment for bipolar disorder as factors, and the baseline value as covariate.

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.6737
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

14. Secondary Outcome

Title:	Change From Baseline to Week 8 on 30 Item Inventory of Depressive Symptomatology Clinician Rated (IDS C30) Combination of Items 1-3
▼ Description:	The IDS C30 is a standardized 30 item, clinician rated, scale to assess the severity of a patient's depressive symptoms. The scale uses the 9 symptom domains of the DSM-IV criteria to measure symptom severity. The scores range from a minimum of 0 to a maximum score of 84. The higher the score the more severe the symptoms of depression. Items 1 - 3 assess sleep onset insomnia, mid-nocturnal insomnia, and early morning insomnia respectively each on a 0 - 3 scale. The data presented here summarizes the change from baseline to week 8 in the combined score of these three items assessing insomnia.
Time Frame:	Baseline and 8 weeks following the start of study drug administration
Safety Issue?	No

▼ Outcome Measure Data ✔

▼ Analysis Population Description

Full analysis set defined as subjects who were assessed with IDS-C30 at baseline and at week 8

Arm/Group Title	Armodafinil 150 mg/Day	Placebo

▼ Arm/Group Description:	Armodafinil was titrated up to the target dosage of 150 mg/day (daily dose was administered each morning). Patients began taking blinded armodafinil at a dose of 50 mg/day (1 tablet) on the day following the baseline visit. Doses were increased by 50 mg/day (1 tablet) to a dose of 100 mg/day on Day 2 and 3, and then again by 50 mg /day on day 4 for a target dose of 150 mg/day. Following titration, patients continued taking 150 mg/day of armodafinil for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 100 mg/day [2 tablets]) was allowed. The dosage could not be increased after it was decreased.	Placebo tablets matching the 50 mg armodafinil tablet were used in a manner identical to that of the armodafinil tablets. Study drug was titrated up to the target dosage of 3 tablets / day (daily dose was administered each morning). Patients began taking blinded study drug at a dose of 1 tablet daily on the day following the baseline visit. Doses were increased by 1 tablet to a dose of 2 tablets/day on Day 2 and 3, and then again by 1 tablet /day on day 4 for a target dose of 3 tablets/day. Following titration, patients continued taking 3 tablets/day of study drug for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 2 tablets/day) was allowed. The dosage could not be increased after it was decreased.
Number of Participants Analyzed	89	90
Least Squares Mean (Standard Error) Unit of measure: Units on a scale	-2.0 (0.28)	-1.6 (0.28)

▼ Statistical Analysis 1 ✓

Statistical Analysis Overview	Comparison Groups	Armodafinil 150 mg/Day, Placebo
	Comments	Least square (LS) mean and standard error of the LS mean for each treatment group and the p-value for the treatment comparison is from an ANCOVA with treatment and concurrent treatment for bipolar disorder as factors, and the baseline value as covariate.

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.2249
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

15. Secondary Outcome

Title:	Change From Baseline to Endpoint (Week 8 or Last Observation After Baseline) on 30 Item Inventory of Depressive Symptomatology Clinician Rated (IDS C30) - Item 4
▼ Description:	The IDS C30 is a standardized 30 item, clinician rated, scale to assess the severity of a patient's depressive symptoms. The scale uses the 9 symptom domains of the DSM-IV criteria to measure symptom severity. The scores range from a minimum of 0 to a maximum score of 84. The higher the score the more severe the symptoms of depression. Item 4 assesses hypersomnia on a scale from 0 (sleeps no longer than 7-8 hours a night) to 3 (sleeps longer than 12 hours in 24 hour period). The data presented here summarizes the change from baseline to Endpoint in the score of Item 4 assessing hypersomnia.
Time Frame:	Baseline and 8 weeks (or last observation after baseline)
Safety Issue?	No

▼ Outcome Measure Data

▼ Analysis Population Description

Full analysis set defined as subjects assessed with IDS-C30 at baseline and at least one observation after baseline

Arm/Group Title	Armodafinil 150 mg/Day	Placebo

▼ Arm/Group Description:	Armodafinil was titrated up to the target dosage of 150 mg/day (daily dose was administered each morning). Patients began taking blinded armodafinil at a dose of 50 mg/day (1 tablet) on the day following the baseline visit. Doses were increased by 50 mg/day (1 tablet) to a dose of 100 mg/day on Day 2 and 3, and then again by 50 mg /day on day 4 for a target dose of 150 mg/day. Following titration, patients continued taking 150 mg/day of armodafinil for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 100 mg/day [2 tablets]) was allowed. The dosage could not be increased after it was decreased.	Placebo tablets matching the 50 mg armodafinil tablet were used in a manner identical to that of the armodafinil tablets. Study drug was titrated up to the target dosage of 3 tablets / day (daily dose was administered each morning). Patients began taking blinded study drug at a dose of 1 tablet daily on the day following the baseline visit. Doses were increased by 1 tablet to a dose of 2 tablets/day on Day 2 and 3, and then again by 1 tablet /day on day 4 for a target dose of 3 tablets/day. Following titration, patients continued taking 3 tablets/day of study drug for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 2 tablets/day) was allowed. The dosage could not be increased after it was decreased.
Number of Participants Analyzed	124	123
Least Squares Mean (Standard Error) Unit of measure: Units on a scale	-0.4 (0.06)	-0.2 (0.07)

▼ Statistical Analysis 1 ✓

Statistical Analysis Overview	Comparison Groups	Armodafinil 150 mg/Day, Placebo
	Comments	Least square (LS) mean and standard error of the LS mean for each treatment group and the p-value for the treatment comparison is from an ANCOVA with treatment and concurrent treatment for bipolar disorder as factors, and the baseline value as covariate.

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.0862
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

16. Secondary Outcome

Title:	Change From Baseline to Week 4 on 30 Item Inventory of Depressive Symptomatology Clinician Rated (IDS C30) - Item 4
▼ Description:	The IDS C30 is a standardized 30 item, clinician rated, scale to assess the severity of a patient's depressive symptoms. The scale uses the 9 symptom domains of the DSM-IV criteria to measure symptom severity. The scores range from a minimum of 0 to a maximum score of 84. The higher the score the more severe the symptoms of depression. Item 4 assesses hypersomnia on a scale from 0 (sleeps no longer than 7-8 hours a night) to 3 (sleeps longer than 12 hours in 24 hour period). The data presented here summarizes the change from baseline to week 4 in the score of Item 4 assessing hypersomnia.
Time Frame:	Baseline and 4 weeks following the start of study drug administration
Safety Issue?	No

▼ Outcome Measure Data

▼ Analysis Population Description

Full analysis set defined as subjects assessed with IDS-C30 at baseline and at week 4

Arm/Group Title	Armodafinil 150 mg/Day	Placebo

▼ Arm/Group Description:	Armodafinil was titrated up to the target dosage of 150 mg/day (daily dose was administered each morning). Patients began taking blinded armodafinil at a dose of 50 mg/day (1 tablet) on the day following the baseline visit. Doses were increased by 50 mg/day (1 tablet) to a dose of 100 mg/day on Day 2 and 3, and then again by 50 mg /day on day 4 for a target dose of 150 mg/day. Following titration, patients continued taking 150 mg/day of armodafinil for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 100 mg/day [2 tablets]) was allowed. The dosage could not be increased after it was decreased.	Placebo tablets matching the 50 mg armodafinil tablet were used in a manner identical to that of the armodafinil tablets. Study drug was titrated up to the target dosage of 3 tablets / day (daily dose was administered each morning). Patients began taking blinded study drug at a dose of 1 tablet daily on the day following the baseline visit. Doses were increased by 1 tablet to a dose of 2 tablets/day on Day 2 and 3, and then again by 1 tablet /day on day 4 for a target dose of 3 tablets/day. Following titration, patients continued taking 3 tablets/day of study drug for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 2 tablets/day) was allowed. The dosage could not be increased after it was decreased.
Number of Participants Analyzed	99	97
Least Squares Mean (Standard Error) Unit of measure: Units on a scale	-0.2 (0.07)	-0.2 (0.07)

▼ Statistical Analysis 1 ✓

Statistical Analysis Overview	Comparison Groups	Armodafinil 150 mg/Day, Placebo
	Comments	Least square (LS) mean and standard error of the LS mean for each treatment group and the p-value for the treatment comparison is from an ANCOVA with treatment and concurrent treatment for bipolar disorder as factors, and the baseline value as covariate.

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.9281
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

17. Secondary Outcome

Title:	Change From Baseline to Week 8 on 30 Item Inventory of Depressive Symptomatology Clinician Rated (IDS C30) - Item 4
▼ Description:	The IDS C30 is a standardized 30 item, clinician rated, scale to assess the severity of a patient's depressive symptoms. The scale uses the 9 symptom domains of the DSM-IV criteria to measure symptom severity. The scores range from a minimum of 0 to a maximum score of 84. The higher the score the more severe the symptoms of depression. Item 4 assesses hypersomnia on a scale from 0 (sleeps no longer than 7-8 hours a night) to 3 (sleeps longer than 12 hours in 24 hour period). The data presented here summarizes the change from baseline to week 8 in the score of Item 4 assessing hypersomnia.
Time Frame:	Baseline and 8 weeks following the start of study drug administration
Safety Issue?	No

▼ Outcome Measure Data

▼ Analysis Population Description

Full analysis set defined as subjects who were assessed with IDS-C30 at baseline and at week 8

Arm/Group Title	Armodafinil 150 mg/Day	Placebo

▼ Arm/Group Description:	Armodafinil was titrated up to the target dosage of 150 mg/day (daily dose was administered each morning). Patients began taking blinded armodafinil at a dose of 50 mg/day (1 tablet) on the day following the baseline visit. Doses were increased by 50 mg/day (1 tablet) to a dose of 100 mg/day on Day 2 and 3, and then again by 50 mg /day on day 4 for a target dose of 150 mg/day. Following titration, patients continued taking 150 mg/day of armodafinil for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 100 mg/day [2 tablets]) was allowed. The dosage could not be increased after it was decreased.	Placebo tablets matching the 50 mg armodafinil tablet were used in a manner identical to that of the armodafinil tablets. Study drug was titrated up to the target dosage of 3 tablets / day (daily dose was administered each morning). Patients began taking blinded study drug at a dose of 1 tablet daily on the day following the baseline visit. Doses were increased by 1 tablet to a dose of 2 tablets/day on Day 2 and 3, and then again by 1 tablet /day on day 4 for a target dose of 3 tablets/day. Following titration, patients continued taking 3 tablets/day of study drug for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 2 tablets/day) was allowed. The dosage could not be increased after it was decreased.
Number of Participants Analyzed	89	90
Least Squares Mean (Standard Error) Unit of measure: Units on a scale	-0.3 (0.08)	-0.2 (0.08)

▼ Statistical Analysis 1 ✓

Statistical Analysis Overview	Comparison Groups	Armodafinil 150 mg/Day, Placebo
	Comments	Least square (LS) mean and standard error of the LS mean for each treatment group and the p-value for the treatment comparison is from an ANCOVA with treatment and concurrent treatment for bipolar disorder as factors, and the baseline value as covariate.

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.4428
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

18. Secondary Outcome

Title:	Change From Baseline to Endpoint (Week 8 or Last Observation After Baseline) in the Montgomery-Asberg Depression Rating Scale (MADRS) Total Score
▼ Description:	The MADRS is a 10-item scale to evaluate the overall severity of a patient's depressive symptoms, that is completed by the physician. The rating scale makes use of both observational clues as to the subject's level of depression (eg. apparent sadness) and verbal indicators of depression expressed by the patient. Each of the 10 items is graded on a 6-point scale with anchors at 2 point intervals. Total scores range from 0 to 60, with the higher number indicating more severe symptoms of depression. Here we present data summarizing the change in MADRS from Baseline to Endpoint.
Time Frame:	Baseline and Endpoint (8 weeks following the start of study drug administration or last observation after baseline)
Safety Issue?	No

▼ Outcome Measure Data

▼ Analysis Population Description

Full analysis set defined as subjects who had both a baseline observation and at least one observation after baseline

Arm/Group Title	Armodafinil 150 mg/Day	Placebo

▼ Arm/Group Description:	Armodafinil was titrated up to the target dosage of 150 mg/day (daily dose was administered each morning). Patients began taking blinded armodafinil at a dose of 50 mg/day (1 tablet) on the day following the baseline visit. Doses were increased by 50 mg/day (1 tablet) to a dose of 100 mg/day on Day 2 and 3, and then again by 50 mg /day on day 4 for a target dose of 150 mg/day. Following titration, patients continued taking 150 mg/day of armodafinil for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 100 mg/day [2 tablets]) was allowed. The dosage could not be increased after it was decreased.	Placebo tablets matching the 50 mg armodafinil tablet were used in a manner identical to that of the armodafinil tablets. Study drug was titrated up to the target dosage of 3 tablets / day (daily dose was administered each morning). Patients began taking blinded study drug at a dose of 1 tablet daily on the day following the baseline visit. Doses were increased by 1 tablet to a dose of 2 tablets/day on Day 2 and 3, and then again by 1 tablet /day on day 4 for a target dose of 3 tablets/day. Following titration, patients continued taking 3 tablets/day of study drug for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 2 tablets/day) was allowed. The dosage could not be increased after it was decreased.
Number of Participants Analyzed	118	116
Least Squares Mean (Standard Error) Unit of measure: Units on a scale	-12.3 (1.10)	-10.2 (1.12)

▼ Statistical Analysis 1 ✓

Statistical Analysis Overview	Comparison Groups	Armodafinil 150 mg/Day, Placebo
	Comments	Least square (LS) mean and standard error of the LS mean for each treatment group and the p-value for the treatment comparison is from an ANCOVA with treatment and concurrent treatment for bipolar disorder as factors, and the baseline value as covariate.

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.0965
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

19. Secondary Outcome

Title:	Change From Baseline to Week 4 in the Montgomery-Asberg Depression Rating Scale (MADRS) Total Score
▼ Description:	The MADRS is a 10-item scale to evaluate the overall severity of a patient's depressive symptoms, that is completed by the physician. The rating scale makes use of both observational clues as to the subject's level of depression (eg. apparent sadness) and verbal indicators of depression expressed by the patient. Each of the 10 items is graded on a 6-point scale with anchors at 2 point intervals. Total scores range from 0 to 60, with the higher number indicating more severe symptoms of depression. Here we present data summarizing the difference in MADRS score from Baseline to Week 4.
Time Frame:	Baseline and 4 weeks following the start of study drug administration
Safety Issue?	No

▼ Outcome Measure Data

▼ Analysis Population Description

Full analysis set defined as subjects who were assessed by MADRS at both baseline and at Week 4

Arm/Group Title	Armodafinil 150 mg/Day	Placebo

▼ Arm/Group Description:	Armodafinil was titrated up to the target dosage of 150 mg/day (daily dose was administered each morning). Patients began taking blinded armodafinil at a dose of 50 mg/day (1 tablet) on the day following the baseline visit. Doses were increased by 50 mg/day (1 tablet) to a dose of 100 mg/day on Day 2 and 3, and then again by 50 mg /day on day 4 for a target dose of 150 mg/day. Following titration, patients continued taking 150 mg/day of armodafinil for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 100 mg/day [2 tablets]) was allowed. The dosage could not be increased after it was decreased.	Placebo tablets matching the 50 mg armodafinil tablet were used in a manner identical to that of the armodafinil tablets. Study drug was titrated up to the target dosage of 3 tablets / day (daily dose was administered each morning). Patients began taking blinded study drug at a dose of 1 tablet daily on the day following the baseline visit. Doses were increased by 1 tablet to a dose of 2 tablets/day on Day 2 and 3, and then again by 1 tablet /day on day 4 for a target dose of 3 tablets/day. Following titration, patients continued taking 3 tablets/day of study drug for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 2 tablets/day) was allowed. The dosage could not be increased after it was decreased.
Number of Participants Analyzed	99	97
Least Squares Mean (Standard Error) Unit of measure: Units on a scale	-9.6 (1.03)	-8.9 (1.08)

▼ Statistical Analysis 1 ✓

Statistical Analysis Overview	Comparison Groups	Armodafinil 150 mg/Day, Placebo
	Comments	Least square (LS) mean and standard error of the LS mean for each treatment group and the p-value for the treatment comparison is from an ANCOVA with treatment and concurrent treatment for bipolar disorder as factors, and the baseline value as covariate.

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.5389
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

20. Secondary Outcome

Title:	Change From Baseline to Week 8 in the Montgomery-Asberg Depression Rating Scale (MADRS) Total Score
▼ Description:	The MADRS is a 10-item scale to evaluate the overall severity of a patient's depressive symptoms, that is completed by the physician. The rating scale makes use of both observational clues as to the subject's level of depression (eg. apparent sadness) and verbal indicators of depression expressed by the patient. Each of the 10 items is graded on a 6-point scale with anchors at 2 point intervals. Total scores range from 0 to 60, with the higher number indicating more severe symptoms of depression. Here we present data summarizing the difference in MADRS score from Baseline to Week 8.
Time Frame:	Baseline and 8 weeks following the start of study drug administration
Safety Issue?	No

▼ Outcome Measure Data

▼ Analysis Population Description

Full analysis set defined as subjects who were assessed by MADRS at both baseline and at Week 8

Arm/Group Title	Armodafinil 150 mg/Day	Placebo

▼ Arm/Group Description:	Armodafinil was titrated up to the target dosage of 150 mg/day (daily dose was administered each morning). Patients began taking blinded armodafinil at a dose of 50 mg/day (1 tablet) on the day following the baseline visit. Doses were increased by 50 mg/day (1 tablet) to a dose of 100 mg/day on Day 2 and 3, and then again by 50 mg /day on day 4 for a target dose of 150 mg/day. Following titration, patients continued taking 150 mg/day of armodafinil for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 100 mg/day [2 tablets]) was allowed. The dosage could not be increased after it was decreased.	Placebo tablets matching the 50 mg armodafinil tablet were used in a manner identical to that of the armodafinil tablets. Study drug was titrated up to the target dosage of 3 tablets / day (daily dose was administered each morning). Patients began taking blinded study drug at a dose of 1 tablet daily on the day following the baseline visit. Doses were increased by 1 tablet to a dose of 2 tablets/day on Day 2 and 3, and then again by 1 tablet /day on day 4 for a target dose of 3 tablets/day. Following titration, patients continued taking 3 tablets/day of study drug for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 2 tablets/day) was allowed. The dosage could not be increased after it was decreased.
Number of Participants Analyzed	89	90
Least Squares Mean (Standard Error) Unit of measure: Units on a scale	-13.4 (1.20)	-11.0 (1.24)

▼ Statistical Analysis 1 ✓

Statistical Analysis Overview	Comparison Groups	Armodafinil 150 mg/Day, Placebo
	Comments	Least square (LS) mean and standard error of the LS mean for each treatment group and the p-value for the treatment comparison is from an ANCOVA with treatment and concurrent treatment for bipolar disorder as factors, and the baseline value as covariate.

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.0793
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

21. Secondary Outcome

Title:	Change From Baseline to Endpoint (Week 8 or Last Observation After Baseline) in the Quick Inventory of Depressive Symptomatology - 16 Items (QIDS-SR16)
▼ Description:	The QIDS-SR16 is a 16-item rating scale of depressive symptoms completed by the patient at each visit. It is a shorter version of the IDS-C30 that is completed by the patient rather than the examiner. The total score ranges from 0 to 27 (higher score signifies more severe depression) and is obtained by adding the scores for each of the 9 depression symptom domains of the DSM IV. The data presented here summarizes the change in QIDS-SR16 from Baseline to Endpoint (Week 8 or last observation after baseline).
Time Frame:	Baseline and 8 weeks (or last observation after baseline)
Safety Issue?	No

▼ Outcome Measure Data

▼ Analysis Population Description

Full analysis set defined as subjects who completed the QIDS-SR16 at baseline and at least one observation after baseline.

Arm/Group Title	Armodafinil 150 mg/Day	Placebo

▼ Arm/Group Description:	Armodafinil was titrated up to the target dosage of 150 mg/day (daily dose was administered each morning). Patients began taking blinded armodafinil at a dose of 50 mg/day (1 tablet) on the day following the baseline visit. Doses were increased by 50 mg/day (1 tablet) to a dose of 100 mg/day on Day 2 and 3, and then again by 50 mg /day on day 4 for a target dose of 150 mg/day. Following titration, patients continued taking 150 mg/day of armodafinil for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 100 mg/day [2 tablets]) was allowed. The dosage could not be increased after it was decreased.	Placebo tablets matching the 50 mg armodafinil tablet were used in a manner identical to that of the armodafinil tablets. Study drug was titrated up to the target dosage of 3 tablets / day (daily dose was administered each morning). Patients began taking blinded study drug at a dose of 1 tablet daily on the day following the baseline visit. Doses were increased by 1 tablet to a dose of 2 tablets/day on Day 2 and 3, and then again by 1 tablet /day on day 4 for a target dose of 3 tablets/day. Following titration, patients continued taking 3 tablets/day of study drug for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 2 tablets/day) was allowed. The dosage could not be increased after it was decreased.
Number of Participants Analyzed	124	123
Least Squares Mean (Standard Error) Unit of measure: Units on a scale	-7.0 (0.55)	-6.5 (0.56)

▼ Statistical Analysis 1 ✓

Statistical Analysis Overview	Comparison Groups	Armodafinil 150 mg/Day, Placebo
	Comments	Least square (LS) mean and standard error of the LS mean for each treatment group and the p-value for the treatment comparison is from an ANCOVA with treatment and concurrent treatment for bipolar disorder as factors, and the baseline value as covariate.

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.3814
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

22. Secondary Outcome

Title:	Change From Baseline to Week 1 in the Quick Inventory of Depressive Symptomatology - 16 Items (QIDS-SR16)
▼ Description:	The QIDS-SR16 is a 16-item rating scale of depressive symptoms completed by the patient at each visit. It is a shorter version of the IDS-C30 that is completed by the patient rather than the examiner. The total score ranges from 0 to 27 (higher score signifies more severe depression) and is obtained by adding the scores for each of the 9 depression symptom domains of the DSM IV. The data presented here summarizes the change in QIDS-SR16 from Baseline to Week 1
Time Frame:	Baseline and 1 week following the start of study drug administration
Safety Issue?	No

▼ Outcome Measure Data 

▼ Analysis Population Description

Full analysis set defined as subjects who completed the QIDS-SR16 at baseline and at 1 week

Arm/Group Title	Armodafinil 150 mg/Day	Placebo

▼ Arm/Group Description:	Armodafinil was titrated up to the target dosage of 150 mg/day (daily dose was administered each morning). Patients began taking blinded armodafinil at a dose of 50 mg/day (1 tablet) on the day following the baseline visit. Doses were increased by 50 mg/day (1 tablet) to a dose of 100 mg/day on Day 2 and 3, and then again by 50 mg /day on day 4 for a target dose of 150 mg/day. Following titration, patients continued taking 150 mg/day of armodafinil for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 100 mg/day [2 tablets]) was allowed. The dosage could not be increased after it was decreased.	Placebo tablets matching the 50 mg armodafinil tablet were used in a manner identical to that of the armodafinil tablets. Study drug was titrated up to the target dosage of 3 tablets / day (daily dose was administered each morning). Patients began taking blinded study drug at a dose of 1 tablet daily on the day following the baseline visit. Doses were increased by 1 tablet to a dose of 2 tablets/day on Day 2 and 3, and then again by 1 tablet /day on day 4 for a target dose of 3 tablets/day. Following titration, patients continued taking 3 tablets/day of study drug for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 2 tablets/day) was allowed. The dosage could not be increased after it was decreased.
Number of Participants Analyzed	120	118
Least Squares Mean (Standard Error) Unit of measure: Units on a scale	-3.5 (0.42)	-3.7 (0.43)

▼ Statistical Analysis 1 ✓

Statistical Analysis Overview	Comparison Groups	Armodafinil 150 mg/Day, Placebo
	Comments	Least square (LS) mean and standard error of the LS mean for each treatment group and the p-value for the treatment comparison is from an ANCOVA with treatment and concurrent treatment for bipolar disorder as factors, and the baseline value as covariate.

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.8099
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

23. Secondary Outcome

Title:	Change From Baseline to Week 2 in the Quick Inventory of Depressive Symptomatology - 16 Items (QIDS-SR16)
▼ Description:	The QIDS-SR16 is a 16-item rating scale of depressive symptoms completed by the patient at each visit. It is a shorter version of the IDS-C30 that is completed by the patient rather than the examiner. The total score ranges from 0 to 27 (higher score signifies more severe depression) and is obtained by adding the scores for each of the 9 depression symptom domains of the DSM IV. The data presented here summarizes the change in QIDS-SR16 from Baseline to Week 2
Time Frame:	Baseline and 2 weeks following the start of study drug administration
Safety Issue?	No

▼ Outcome Measure Data 

▼ Analysis Population Description

Full analysis set defined as subjects who completed the QIDS-SR16 at baseline and at 2 weeks

Arm/Group Title	Armodafinil 150 mg/Day	Placebo

▼ Arm/Group Description:	Armodafinil was titrated up to the target dosage of 150 mg/day (daily dose was administered each morning). Patients began taking blinded armodafinil at a dose of 50 mg/day (1 tablet) on the day following the baseline visit. Doses were increased by 50 mg/day (1 tablet) to a dose of 100 mg/day on Day 2 and 3, and then again by 50 mg /day on day 4 for a target dose of 150 mg/day. Following titration, patients continued taking 150 mg/day of armodafinil for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 100 mg/day [2 tablets]) was allowed. The dosage could not be increased after it was decreased.	Placebo tablets matching the 50 mg armodafinil tablet were used in a manner identical to that of the armodafinil tablets. Study drug was titrated up to the target dosage of 3 tablets / day (daily dose was administered each morning). Patients began taking blinded study drug at a dose of 1 tablet daily on the day following the baseline visit. Doses were increased by 1 tablet to a dose of 2 tablets/day on Day 2 and 3, and then again by 1 tablet /day on day 4 for a target dose of 3 tablets/day. Following titration, patients continued taking 3 tablets/day of study drug for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 2 tablets/day) was allowed. The dosage could not be increased after it was decreased.
Number of Participants Analyzed	108	113
Least Squares Mean (Standard Error) Unit of measure: Units on a scale	-5.0 (0.44)	-4.1 (0.44)

▼ Statistical Analysis 1 ✓

Statistical Analysis Overview	Comparison Groups	Armodafinil 150 mg/Day, Placebo
	Comments	Least square (LS) mean and standard error of the LS mean for each treatment group and the p-value for the treatment comparison is from an ANCOVA with treatment and concurrent treatment for bipolar disorder as factors, and the baseline value as covariate.

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.0968
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

24. Secondary Outcome

Title:	Change From Baseline to Week 3 in the Quick Inventory of Depressive Symptomatology - 16 Items (QIDS-SR16)
▼ Description:	The QIDS-SR16 is a 16-item rating scale of depressive symptoms completed by the patient at each visit. It is a shorter version of the IDS-C30 that is completed by the patient rather than the examiner. The total score ranges from 0 to 27 (higher score signifies more severe depression) and is obtained by adding the scores for each of the 9 depression symptom domains of the DSM IV. The data presented here summarizes the change in QIDS-SR16 from Baseline to Week 3.
Time Frame:	Baseline and 3 weeks following the start of study drug administration
Safety Issue?	No

▼ Outcome Measure Data 

▼ Analysis Population Description

Full analysis set defined as subjects who completed the QIDS-SR16 at baseline and at week 3

Arm/Group Title	Armodafinil 150 mg/Day	Placebo

▼ Arm/Group Description:	Armodafinil was titrated up to the target dosage of 150 mg/day (daily dose was administered each morning). Patients began taking blinded armodafinil at a dose of 50 mg/day (1 tablet) on the day following the baseline visit. Doses were increased by 50 mg/day (1 tablet) to a dose of 100 mg/day on Day 2 and 3, and then again by 50 mg /day on day 4 for a target dose of 150 mg/day. Following titration, patients continued taking 150 mg/day of armodafinil for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 100 mg/day [2 tablets]) was allowed. The dosage could not be increased after it was decreased.	Placebo tablets matching the 50 mg armodafinil tablet were used in a manner identical to that of the armodafinil tablets. Study drug was titrated up to the target dosage of 3 tablets / day (daily dose was administered each morning). Patients began taking blinded study drug at a dose of 1 tablet daily on the day following the baseline visit. Doses were increased by 1 tablet to a dose of 2 tablets/day on Day 2 and 3, and then again by 1 tablet /day on day 4 for a target dose of 3 tablets/day. Following titration, patients continued taking 3 tablets/day of study drug for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 2 tablets/day) was allowed. The dosage could not be increased after it was decreased.
Number of Participants Analyzed	102	101
Least Squares Mean (Standard Error) Unit of measure: Units on a scale	-5.8 (0.52)	-5.0 (0.54)

▼ Statistical Analysis 1 ✓

Statistical Analysis Overview	Comparison Groups	Armodafinil 150 mg/Day, Placebo
	Comments	Least square (LS) mean and standard error of the LS mean for each treatment group and the p-value for the treatment comparison is from an ANCOVA with treatment and concurrent treatment for bipolar disorder as factors, and the baseline value as covariate.

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.1605
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

25. Secondary Outcome

Title:	Change From Baseline to Week 4 in the Quick Inventory of Depressive Symptomatology - 16 Items (QIDS-SR16)
▼ Description:	The QIDS-SR16 is a 16-item rating scale of depressive symptoms completed by the patient at each visit. It is a shorter version of the IDS-C30 that is completed by the patient rather than the examiner. The total score ranges from 0 to 27 (higher score signifies more severe depression) and is obtained by adding the scores for each of the 9 depression symptom domains of the DSM IV. The data presented here summarizes the change in QIDS-SR16 from Baseline to Week 4.
Time Frame:	Baseline and 4 weeks following the start of study drug administration
Safety Issue?	No

▼ Outcome Measure Data

▼ Analysis Population Description

Full analysis set defined as subjects who completed the QIDS-SR16 at baseline and at 4 weeks

Arm/Group Title	Armodafinil 150 mg/Day	Placebo

▼ Arm/Group Description:	Armodafinil was titrated up to the target dosage of 150 mg/day (daily dose was administered each morning). Patients began taking blinded armodafinil at a dose of 50 mg/day (1 tablet) on the day following the baseline visit. Doses were increased by 50 mg/day (1 tablet) to a dose of 100 mg/day on Day 2 and 3, and then again by 50 mg /day on day 4 for a target dose of 150 mg/day. Following titration, patients continued taking 150 mg/day of armodafinil for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 100 mg/day [2 tablets]) was allowed. The dosage could not be increased after it was decreased.	Placebo tablets matching the 50 mg armodafinil tablet were used in a manner identical to that of the armodafinil tablets. Study drug was titrated up to the target dosage of 3 tablets / day (daily dose was administered each morning). Patients began taking blinded study drug at a dose of 1 tablet daily on the day following the baseline visit. Doses were increased by 1 tablet to a dose of 2 tablets/day on Day 2 and 3, and then again by 1 tablet /day on day 4 for a target dose of 3 tablets/day. Following titration, patients continued taking 3 tablets/day of study drug for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 2 tablets/day) was allowed. The dosage could not be increased after it was decreased.
Number of Participants Analyzed	99	97
Least Squares Mean (Standard Error) Unit of measure: Units on a scale	-6.4 (0.53)	-5.6 (0.56)

▼ Statistical Analysis 1 ✓

Statistical Analysis Overview	Comparison Groups	Armodafinil 150 mg/Day, Placebo
	Comments	Least square (LS) mean and standard error of the LS mean for each treatment group and the p-value for the treatment comparison is from an ANCOVA with treatment and concurrent treatment for bipolar disorder as factors, and the baseline value as covariate.

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.1869
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

26. Secondary Outcome

Title:	Change From Baseline to Week 6 in the Quick Inventory of Depressive Symptomatology - 16 Items (QIDS-SR16)
▼ Description:	The QIDS-SR16 is a 16-item rating scale of depressive symptoms completed by the patient at each visit. It is a shorter version of the IDS-C30 that is completed by the patient rather than the examiner. The total score ranges from 0 to 27 (higher score signifies more severe depression) and is obtained by adding the scores for each of the 9 depression symptom domains of the DSM IV. The data presented here summarizes the change in QIDS-SR16 from Baseline to Week 6.
Time Frame:	Baseline and 6 weeks following the start of study drug administration
Safety Issue?	No

▼ Outcome Measure Data 

▼ Analysis Population Description

Full analysis set defined as subjects who completed the QIDS-SR16 at baseline and at 6 weeks

Arm/Group Title	Armodafinil 150 mg/Day	Placebo

▼ Arm/Group Description:	Armodafinil was titrated up to the target dosage of 150 mg/day (daily dose was administered each morning). Patients began taking blinded armodafinil at a dose of 50 mg/day (1 tablet) on the day following the baseline visit. Doses were increased by 50 mg/day (1 tablet) to a dose of 100 mg/day on Day 2 and 3, and then again by 50 mg /day on day 4 for a target dose of 150 mg/day. Following titration, patients continued taking 150 mg/day of armodafinil for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 100 mg/day [2 tablets]) was allowed. The dosage could not be increased after it was decreased.	Placebo tablets matching the 50 mg armodafinil tablet were used in a manner identical to that of the armodafinil tablets. Study drug was titrated up to the target dosage of 3 tablets / day (daily dose was administered each morning). Patients began taking blinded study drug at a dose of 1 tablet daily on the day following the baseline visit. Doses were increased by 1 tablet to a dose of 2 tablets/day on Day 2 and 3, and then again by 1 tablet /day on day 4 for a target dose of 3 tablets/day. Following titration, patients continued taking 3 tablets/day of study drug for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 2 tablets/day) was allowed. The dosage could not be increased after it was decreased.
Number of Participants Analyzed	92	92
Least Squares Mean (Standard Error) Unit of measure: Units on a scale	-7.8 (0.58)	-6.7 (0.60)

▼ Statistical Analysis 1 ✓

Statistical Analysis Overview	Comparison Groups	Armodafinil 150 mg/Day, Placebo
	Comments	Least square (LS) mean and standard error of the LS mean for each treatment group and the p-value for the treatment comparison is from an ANCOVA with treatment and concurrent treatment for bipolar disorder as factors, and the baseline value as covariate.

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.0817
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

27. Secondary Outcome

Title:	Change From Baseline to Week 8 in the Quick Inventory of Depressive Symptomatology - 16 Items (QIDS-SR16)
▼ Description:	The QIDS-SR16 is a 16-item rating scale of depressive symptoms completed by the patient at each visit. It is a shorter version of the IDS-C30 that is completed by the patient rather than the examiner. The total score ranges from 0 to 27 (higher score signifies more severe depression) and is obtained by adding the scores for each of the 9 depression symptom domains of the DSM IV. The data presented here summarizes the change in QIDS-SR16 from Baseline to Week 8.
Time Frame:	Baseline and 8 weeks following the start of study drug administration
Safety Issue?	No

▼ Outcome Measure Data 

▼ Analysis Population Description

Full analysis set defined as subjects who completed the QIDS-SR16 at baseline and at 8 weeks

Arm/Group Title	Armodafinil 150 mg/Day	Placebo

▼ Arm/Group Description:	Armodafinil was titrated up to the target dosage of 150 mg/day (daily dose was administered each morning). Patients began taking blinded armodafinil at a dose of 50 mg/day (1 tablet) on the day following the baseline visit. Doses were increased by 50 mg/day (1 tablet) to a dose of 100 mg/day on Day 2 and 3, and then again by 50 mg /day on day 4 for a target dose of 150 mg/day. Following titration, patients continued taking 150 mg/day of armodafinil for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 100 mg/day [2 tablets]) was allowed. The dosage could not be increased after it was decreased.	Placebo tablets matching the 50 mg armodafinil tablet were used in a manner identical to that of the armodafinil tablets. Study drug was titrated up to the target dosage of 3 tablets / day (daily dose was administered each morning). Patients began taking blinded study drug at a dose of 1 tablet daily on the day following the baseline visit. Doses were increased by 1 tablet to a dose of 2 tablets/day on Day 2 and 3, and then again by 1 tablet /day on day 4 for a target dose of 3 tablets/day. Following titration, patients continued taking 3 tablets/day of study drug for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 2 tablets/day) was allowed. The dosage could not be increased after it was decreased.
Number of Participants Analyzed	89	90
Least Squares Mean (Standard Error) Unit of measure: Units on a scale	-8.2 (0.58)	-7.6 (0.60)

▼ Statistical Analysis 1 ✓

Statistical Analysis Overview	Comparison Groups	Armodafinil 150 mg/Day, Placebo
	Comments	Least square (LS) mean and standard error of the LS mean for each treatment group and the p-value for the treatment comparison is from an ANCOVA with treatment and concurrent treatment for bipolar disorder as factors, and the baseline value as covariate.

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.3712
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

28. Secondary Outcome

Title:	Change From Baseline to Endpoint (Week 8 or Last Observation After Baseline) in the Quality of Life Enjoyment and Satisfaction Questionnaire – Short Form (Q-LES-Q-SF)
▼ Description:	The Q-LES-Q-SF is an instrument designed to measure general activities of daily living. It is a patient-rated quality of life questionnaire and consists of 16 items, but only the first 14 are included in the total score. Each item is rated by the patient on a scale from 1 - 5 (1=very poor, 2=poor, 3=fair, 4=good, and 5=very good). The minimum score is 14 and the maximum score is 70, with lower scores indicating poorer quality of life. The data presented here summarizes the change in score from baseline to endpoint (8 weeks or last observation after baseline).
Time Frame:	Baseline and 8 weeks (or last observation after baseline)
Safety Issue?	No

▼ Outcome Measure Data

▼ Analysis Population Description

Full analysis set defined as subjects who completed the questionnaire at baseline and at any appropriate time point after baseline

Arm/Group Title	Armodafinil 150 mg/Day	Placebo

▼ Arm/Group Description:	Armodafinil was titrated up to the target dosage of 150 mg/day (daily dose was administered each morning). Patients began taking blinded armodafinil at a dose of 50 mg/day (1 tablet) on the day following the baseline visit. Doses were increased by 50 mg/day (1 tablet) to a dose of 100 mg/day on Day 2 and 3, and then again by 50 mg /day on day 4 for a target dose of 150 mg/day. Following titration, patients continued taking 150 mg/day of armodafinil for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 100 mg/day [2 tablets]) was allowed. The dosage could not be increased after it was decreased.	Placebo tablets matching the 50 mg armodafinil tablet were used in a manner identical to that of the armodafinil tablets. Study drug was titrated up to the target dosage of 3 tablets / day (daily dose was administered each morning). Patients began taking blinded study drug at a dose of 1 tablet daily on the day following the baseline visit. Doses were increased by 1 tablet to a dose of 2 tablets/day on Day 2 and 3, and then again by 1 tablet /day on day 4 for a target dose of 3 tablets/day. Following titration, patients continued taking 3 tablets/day of study drug for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 2 tablets/day) was allowed. The dosage could not be increased after it was decreased.
Number of Participants Analyzed	115	112
Least Squares Mean (Standard Error) Unit of measure: Units on a scale	8.2 (1.12)	7.4 (1.16)

▼ Statistical Analysis 1 ✓

Statistical Analysis Overview	Comparison Groups	Armodafinil 150 mg/Day, Placebo
	Comments	Least square (LS) mean and standard error of the LS mean for each treatment group and the p-value for the treatment comparison is from an ANCOVA with treatment and concurrent treatment for bipolar disorder as factors, and the baseline value as covariate.

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.5427
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

29. Secondary Outcome

Title:	Change From Baseline to Week 4 in the Quality of Life Enjoyment and Satisfaction Questionnaire – Short Form (Q-LES-Q-SF)
▼ Description:	The Q-LES-Q-SF is an instrument designed to measure general activities of daily living. It is a patient-rated quality of life questionnaire and consists of 16 items, but only the first 14 are included in the total score. Each item is rated by the patient on a scale from 1 - 5 (1=very poor, 2=poor, 3=fair, 4=good, and 5=very good). The minimum score is 14 and the maximum score is 70, with lower scores indicating poorer quality of life. The data presented here summarizes the change in score from baseline to 4 weeks.
Time Frame:	Baseline and 4 weeks following the start of study drug administration
Safety Issue?	No

▼ Outcome Measure Data

▼ Analysis Population Description

Full analysis set defined as subjects who completed the questionnaire at baseline and at 4 weeks.

Arm/Group Title	Armodafinil 150 mg/Day	Placebo

▼ Arm/Group Description:	Armodafinil was titrated up to the target dosage of 150 mg/day (daily dose was administered each morning). Patients began taking blinded armodafinil at a dose of 50 mg/day (1 tablet) on the day following the baseline visit. Doses were increased by 50 mg/day (1 tablet) to a dose of 100 mg/day on Day 2 and 3, and then again by 50 mg /day on day 4 for a target dose of 150 mg/day. Following titration, patients continued taking 150 mg/day of armodafinil for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 100 mg/day [2 tablets]) was allowed. The dosage could not be increased after it was decreased.	Placebo tablets matching the 50 mg armodafinil tablet were used in a manner identical to that of the armodafinil tablets. Study drug was titrated up to the target dosage of 3 tablets / day (daily dose was administered each morning). Patients began taking blinded study drug at a dose of 1 tablet daily on the day following the baseline visit. Doses were increased by 1 tablet to a dose of 2 tablets/day on Day 2 and 3, and then again by 1 tablet /day on day 4 for a target dose of 3 tablets/day. Following titration, patients continued taking 3 tablets/day of study drug for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 2 tablets/day) was allowed. The dosage could not be increased after it was decreased.
Number of Participants Analyzed	95	95
Least Squares Mean (Standard Error) Unit of measure: Units on a scale	5.9 (1.16)	4.6 (1.22)

▼ Statistical Analysis 1 ✓

Statistical Analysis Overview	Comparison Groups	Armodafinil 150 mg/Day, Placebo
	Comments	Least square (LS) mean and standard error of the LS mean for each treatment group and the p-value for the treatment comparison is from an ANCOVA with treatment and concurrent treatment for bipolar disorder as factors, and the baseline value as covariate.

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.3463
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

30. Secondary Outcome

Title:	Change From Baseline to Week 8 in the Quality of Life Enjoyment and Satisfaction Questionnaire – Short Form (Q-LES-Q-SF)
▼ Description:	The Q-LES-Q-SF is an instrument designed to measure general activities of daily living. It is a patient-rated quality of life questionnaire and consists of 16 items, but only the first 14 are included in the total score. Each item is rated by the patient on a scale from 1 - 5 (1=very poor, 2=poor, 3=fair, 4=good, and 5=very good). The minimum score is 14 and the maximum score is 70, with lower scores indicating poorer quality of life. The data presented here summarizes the change in score from baseline to 8 weeks.
Time Frame:	Baseline and 8 weeks following the start of study drug administration
Safety Issue?	No

▼ Outcome Measure Data

▼ Analysis Population Description

Full analysis set defined as subjects who completed questionnaire at baseline and at 8 weeks

Arm/Group Title	Armodafinil 150 mg/Day	Placebo

▼ Arm/Group Description:	Armodafinil was titrated up to the target dosage of 150 mg/day (daily dose was administered each morning). Patients began taking blinded armodafinil at a dose of 50 mg/day (1 tablet) on the day following the baseline visit. Doses were increased by 50 mg/day (1 tablet) to a dose of 100 mg/day on Day 2 and 3, and then again by 50 mg /day on day 4 for a target dose of 150 mg/day. Following titration, patients continued taking 150 mg/day of armodafinil for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 100 mg/day [2 tablets]) was allowed. The dosage could not be increased after it was decreased.	Placebo tablets matching the 50 mg armodafinil tablet were used in a manner identical to that of the armodafinil tablets. Study drug was titrated up to the target dosage of 3 tablets / day (daily dose was administered each morning). Patients began taking blinded study drug at a dose of 1 tablet daily on the day following the baseline visit. Doses were increased by 1 tablet to a dose of 2 tablets/day on Day 2 and 3, and then again by 1 tablet /day on day 4 for a target dose of 3 tablets/day. Following titration, patients continued taking 3 tablets/day of study drug for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 2 tablets/day) was allowed. The dosage could not be increased after it was decreased.
Number of Participants Analyzed	85	86
Least Squares Mean (Standard Error) Unit of measure: Units on a scale	10.1 (1.29)	8.5 (1.34)

▼ Statistical Analysis 1 ✓

Statistical Analysis Overview	Comparison Groups	Armodafinil 150 mg/Day, Placebo
	Comments	Least square (LS) mean and standard error of the LS mean for each treatment group and the p-value for the treatment comparison is from an ANCOVA with treatment and concurrent treatment for bipolar disorder as factors, and the baseline value as covariate.

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.2730
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

31. Secondary Outcome

Title:	Change From Baseline to Endpoint (8 Weeks or Last Observation After Baseline) in Hamilton Anxiety Scale (HAM-A) Total Score
▼ Description:	The HAM-A is a clinician-rated 14 item scale that provides an overall measure of global anxiety, including psychic (mental agitation and psychological distress) and somatic (physical complaints related to anxiety) symptoms. Each item is scored on a scale of 0 (not present) to 4 (severe), with a total score range of 0 - 56, where less than 17 indicates mild anxiety, 18 - 24 mild to moderate anxiety, 25-30 moderate to severe, >30 very severe. The data presented here summarizes the change in HAM-A score from Baseline to Endpoint (8 weeks or last observation after baseline).
Time Frame:	baseline and 8 weeks (or last observation after baseline)
Safety Issue?	No

▼ Outcome Measure Data

▼ Analysis Population Description

Full analysis set defined as subjects who completed the HAM-A at baseline and at least once after baseline

Arm/Group Title	Armodafinil 150 mg/Day	Placebo

▼ Arm/Group Description:	Armodafinil was titrated up to the target dosage of 150 mg/day (daily dose was administered each morning). Patients began taking blinded armodafinil at a dose of 50 mg/day (1 tablet) on the day following the baseline visit. Doses were increased by 50 mg/day (1 tablet) to a dose of 100 mg/day on Day 2 and 3, and then again by 50 mg /day on day 4 for a target dose of 150 mg/day. Following titration, patients continued taking 150 mg/day of armodafinil for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 100 mg/day [2 tablets]) was allowed. The dosage could not be increased after it was decreased.	Placebo tablets matching the 50 mg armodafinil tablet were used in a manner identical to that of the armodafinil tablets. Study drug was titrated up to the target dosage of 3 tablets / day (daily dose was administered each morning). Patients began taking blinded study drug at a dose of 1 tablet daily on the day following the baseline visit. Doses were increased by 1 tablet to a dose of 2 tablets/day on Day 2 and 3, and then again by 1 tablet /day on day 4 for a target dose of 3 tablets/day. Following titration, patients continued taking 3 tablets/day of study drug for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 2 tablets/day) was allowed. The dosage could not be increased after it was decreased.
Number of Participants Analyzed	117	116
Least Squares Mean (Standard Error) Unit of measure: Units on a scale	-4.1 (0.60)	-3.9 (0.61)

▼ Statistical Analysis 1 ✓

Statistical Analysis Overview	Comparison Groups	Armodafinil 150 mg/Day, Placebo
	Comments	Least square (LS) mean and standard error of the LS mean for each treatment group and the p-value for the treatment comparison is from an ANCOVA with treatment and concurrent treatment for bipolar disorder as factors, and the baseline value as covariate.

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.7791
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

32. Secondary Outcome

Title:	Change From Baseline to 4 Weeks in the Hamilton Anxiety Scale (HAM A) Total Score
▼ Description:	The HAM-A is a clinician-rated 14 item scale that provides an overall measure of global anxiety, including psychic (mental agitation and psychological distress) and somatic (physical complaints related to anxiety) symptoms. Each item is scored on a scale of 0 (not present) to 4 (severe), with a total score range of 0 - 56, where less than 17 indicates mild anxiety, 18 - 24 mild to moderate anxiety and 25-30 moderate to severe. The data presented here summarizes the change in HAM-A score from Baseline to 4 Weeks
Time Frame:	Baseline and 4 weeks following the start of study drug administration
Safety Issue?	No

▼ Outcome Measure Data 

▼ Analysis Population Description

Full analysis set defined as subjects who completed the HAM-A at baseline and at 4 weeks

Arm/Group Title	Armodafinil 150 mg/Day	Placebo

▼ Arm/Group Description:	Armodafinil was titrated up to the target dosage of 150 mg/day (daily dose was administered each morning). Patients began taking blinded armodafinil at a dose of 50 mg/day (1 tablet) on the day following the baseline visit. Doses were increased by 50 mg/day (1 tablet) to a dose of 100 mg/day on Day 2 and 3, and then again by 50 mg /day on day 4 for a target dose of 150 mg/day. Following titration, patients continued taking 150 mg/day of armodafinil for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 100 mg/day [2 tablets]) was allowed. The dosage could not be increased after it was decreased.	Placebo tablets matching the 50 mg armodafinil tablet were used in a manner identical to that of the armodafinil tablets. Study drug was titrated up to the target dosage of 3 tablets / day (daily dose was administered each morning). Patients began taking blinded study drug at a dose of 1 tablet daily on the day following the baseline visit. Doses were increased by 1 tablet to a dose of 2 tablets/day on Day 2 and 3, and then again by 1 tablet /day on day 4 for a target dose of 3 tablets/day. Following titration, patients continued taking 3 tablets/day of study drug for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 2 tablets/day) was allowed. The dosage could not be increased after it was decreased.
Number of Participants Analyzed	99	97
Least Squares Mean (Standard Error) Unit of measure: Units on a scale	-3.6 (0.58)	-3.5 (0.60)

▼ Statistical Analysis 1 ✓

Statistical Analysis Overview	Comparison Groups	Armodafinil 150 mg/Day, Placebo
	Comments	Least square (LS) mean and standard error of the LS mean for each treatment group and the p-value for the treatment comparison is from an ANCOVA with treatment and concurrent treatment for bipolar disorder as factors, and the baseline value as covariate.

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.9007
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

33. Secondary Outcome

Title:	Change From Baseline to 8 Weeks in the Hamilton Anxiety Scale (HAM A) Total Score
▼ Description:	The HAM-A is a clinician-rated 14 item scale that provides an overall measure of global anxiety, including psychic (mental agitation and psychological distress) and somatic (physical complaints related to anxiety) symptoms. Each item is scored on a scale of 0 (not present) to 4 (severe), with a total score range of 0 - 56, where less than 17 indicates mild anxiety, 18 - 24 mild to moderate anxiety and 25-30 moderate to severe. The data presented here summarizes the change in HAM-A score from Baseline to 8 Weeks
Time Frame:	Baseline and 8 weeks following the start of study drug administration
Safety Issue?	No

▼ Outcome Measure Data 

▼ Analysis Population Description

Full analysis set defined as subjects who completed the HAM-A at baseline and at 8 weeks

Arm/Group Title	Armodafinil 150 mg/Day	Placebo

▼ Arm/Group Description:	Armodafinil was titrated up to the target dosage of 150 mg/day (daily dose was administered each morning). Patients began taking blinded armodafinil at a dose of 50 mg/day (1 tablet) on the day following the baseline visit. Doses were increased by 50 mg/day (1 tablet) to a dose of 100 mg/day on Day 2 and 3, and then again by 50 mg /day on day 4 for a target dose of 150 mg/day. Following titration, patients continued taking 150 mg/day of armodafinil for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 100 mg/day [2 tablets]) was allowed. The dosage could not be increased after it was decreased.	Placebo tablets matching the 50 mg armodafinil tablet were used in a manner identical to that of the armodafinil tablets. Study drug was titrated up to the target dosage of 3 tablets / day (daily dose was administered each morning). Patients began taking blinded study drug at a dose of 1 tablet daily on the day following the baseline visit. Doses were increased by 1 tablet to a dose of 2 tablets/day on Day 2 and 3, and then again by 1 tablet /day on day 4 for a target dose of 3 tablets/day. Following titration, patients continued taking 3 tablets/day of study drug for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 2 tablets/day) was allowed. The dosage could not be increased after it was decreased.
Number of Participants Analyzed	89	90
Least Squares Mean (Standard Error) Unit of measure: Units on a scale	-4.7 (0.68)	-4.4 (0.70)

▼ Statistical Analysis 1 ✓

Statistical Analysis Overview	Comparison Groups	Armodafinil 150 mg/Day, Placebo
	Comments	Least square (LS) mean and standard error of the LS mean for each treatment group and the p-value for the treatment comparison is from an ANCOVA with treatment and concurrent treatment for bipolar disorder as factors, and the baseline value as covariate.

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.6431
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

34. Secondary Outcome

Title:	The Number of Responders According to the Clinical Global Impression of Change – Bipolar Version (CGI BP) Measure of Depression at Endpoint (Week 8 or Last Observation After Baseline)
▼ Description:	CGI-BP is a standardized, clinician-rated assessment which allows the clinician to rate the bipolar illness at various time points compared with baseline. At Screening and Baseline visits the physician rated the severity of the illness using 7 categories (1=normal through 7=very severely ill). At subsequent visits the clinician assessed the change in severity of the condition using 7 categories (1=very much improved through 7=very much worse). Subjects were considered responders if they had a rating of "much improved" or "very much improved". The number of responders at Endpoint are presented.
Time Frame:	Baseline and 8 weeks (or last observation after baseline)
Safety Issue?	No

▼ Outcome Measure Data

▼ Analysis Population Description

Full analysis set defined as subjects assessed by CGI-BP at Baseline and at least one observation after Baseline.

Arm/Group Title	Armodafinil 150 mg/Day	Placebo

▼ Arm/Group Description:	Armodafinil was titrated up to the target dosage of 150 mg/day (daily dose was administered each morning). Patients began taking blinded armodafinil at a dose of 50 mg/day (1 tablet) on the day following the baseline visit. Doses were increased by 50 mg/day (1 tablet) to a dose of 100 mg/day on Day 2 and 3, and then again by 50 mg /day on day 4 for a target dose of 150 mg/day. Following titration, patients continued taking 150 mg/day of armodafinil for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 100 mg/day [2 tablets]) was allowed. The dosage could not be increased after it was decreased.	Placebo tablets matching the 50 mg armodafinil tablet were used in a manner identical to that of the armodafinil tablets. Study drug was titrated up to the target dosage of 3 tablets / day (daily dose was administered each morning). Patients began taking blinded study drug at a dose of 1 tablet daily on the day following the baseline visit. Doses were increased by 1 tablet to a dose of 2 tablets/day on Day 2 and 3, and then again by 1 tablet /day on day 4 for a target dose of 3 tablets/day. Following titration, patients continued taking 3 tablets/day of study drug for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 2 tablets/day) was allowed. The dosage could not be increased after it was decreased.
Number of Participants Analyzed	124	122
Measure Type: Number Unit of measure: Participants		
Row Title: Responder	64	60
Row Title: Non Responder	60	62

▼ Statistical Analysis 1 ✓

Statistical Analysis Overview	Comparison Groups	Armodafinil 150 mg/Day, Placebo
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.6631
	Comments	[Not specified]
	Method	Cochran-Mantel-Haenszel
	Comments	Adjusted for concurrent treatment for bipolar disorder.

35. Secondary Outcome

Title:	The Number of Responders According to the Clinical Global Impression of Change – Bipolar Version (CGI BP) Measure of Depression at Week 1
▼ Description:	CGI-BP is a standardized, clinician-rated assessment which allows the clinician to rate the bipolar illness at various time points compared with baseline. At Screening and Baseline visits the physician rated the severity of the illness using 7 categories (1=normal through 7=very severely ill). At subsequent visits the clinician assessed the change in severity of the condition using 7 categories (1=very much improved through 7=very much worse). Subjects were considered responders if they had a rating of "much improved" or "very much improved". The number of responders at Week 1 are presented.
Time Frame:	Baseline and 1 week following the start of study drug administration
Safety Issue?	No

▼ Outcome Measure Data

▼ Analysis Population Description

Full analysis set defined as subjects who were assessed by CGI-BP at Baseline and Week 1

Arm/Group Title	Armodafinil 150 mg/Day	Placebo

▼ Arm/Group Description:	Armodafinil was titrated up to the target dosage of 150 mg/day (daily dose was administered each morning). Patients began taking blinded armodafinil at a dose of 50 mg/day (1 tablet) on the day following the baseline visit. Doses were increased by 50 mg/day (1 tablet) to a dose of 100 mg/day on Day 2 and 3, and then again by 50 mg /day on day 4 for a target dose of 150 mg/day. Following titration, patients continued taking 150 mg/day of armodafinil for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 100 mg/day [2 tablets]) was allowed. The dosage could not be increased after it was decreased.	Placebo tablets matching the 50 mg armodafinil tablet were used in a manner identical to that of the armodafinil tablets. Study drug was titrated up to the target dosage of 3 tablets / day (daily dose was administered each morning). Patients began taking blinded study drug at a dose of 1 tablet daily on the day following the baseline visit. Doses were increased by 1 tablet to a dose of 2 tablets/day on Day 2 and 3, and then again by 1 tablet /day on day 4 for a target dose of 3 tablets/day. Following titration, patients continued taking 3 tablets/day of study drug for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 2 tablets/day) was allowed. The dosage could not be increased after it was decreased.
Number of Participants Analyzed	119	117
Measure Type: Number Unit of measure: Participants		
Row Title: Responder	12	12
Row Title: Non Responder	107	105

▼ Statistical Analysis 1 ✓

Statistical Analysis Overview	Comparison Groups	Armodafinil 150 mg/Day, Placebo
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.9768
	Comments	[Not specified]
	Method	Cochran-Mantel-Haenszel
	Comments	Adjusted for concurrent treatment for bipolar disorder

36. Secondary Outcome

Title:	The Number of Responders According to the Clinical Global Impression of Change – Bipolar Version (CGI BP) Measure of Depression at Week 2
▼ Description:	CGI-BP is a standardized, clinician-rated assessment which allows the clinician to rate the bipolar illness at various time points compared with baseline. At Screening and Baseline visits the physician rated the severity of the illness using 7 categories (1=normal through 7=very severely ill). At subsequent visits the clinician assessed the change in severity of the condition using 7 categories (1=very much improved through 7=very much worse). Subjects were considered responders if they had a rating of "much improved" or "very much improved". The number of responders at Week 2 are presented.
Time Frame:	Baseline and 2 weeks following the start of study drug administration
Safety Issue?	No

▼ Outcome Measure Data

▼ Analysis Population Description

Full analysis set defined as subjects who were assessed by CGI-BP at baseline and week 2

Arm/Group Title	Armodafinil 150 mg/Day	Placebo

▼ Arm/Group Description:	Armodafinil was titrated up to the target dosage of 150 mg/day (daily dose was administered each morning). Patients began taking blinded armodafinil at a dose of 50 mg/day (1 tablet) on the day following the baseline visit. Doses were increased by 50 mg/day (1 tablet) to a dose of 100 mg/day on Day 2 and 3, and then again by 50 mg /day on day 4 for a target dose of 150 mg/day. Following titration, patients continued taking 150 mg/day of armodafinil for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 100 mg/day [2 tablets]) was allowed. The dosage could not be increased after it was decreased.	Placebo tablets matching the 50 mg armodafinil tablet were used in a manner identical to that of the armodafinil tablets. Study drug was titrated up to the target dosage of 3 tablets / day (daily dose was administered each morning). Patients began taking blinded study drug at a dose of 1 tablet daily on the day following the baseline visit. Doses were increased by 1 tablet to a dose of 2 tablets/day on Day 2 and 3, and then again by 1 tablet /day on day 4 for a target dose of 3 tablets/day. Following titration, patients continued taking 3 tablets/day of study drug for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 2 tablets/day) was allowed. The dosage could not be increased after it was decreased.
Number of Participants Analyzed	108	110
Measure Type: Number Unit of measure: Participants		
Row Title: Responder	25	26
Row Title: Non Responder	83	84

▼ Statistical Analysis 1 ✓

Statistical Analysis Overview	Comparison Groups	Armodafinil 150 mg/Day, Placebo
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.9873
	Comments	[Not specified]
	Method	Cochran-Mantel-Haenszel
	Comments	Adjusted for concurrent treatment fro bipolar disorder

37. Secondary Outcome

Title:	The Number of Responders According to the Clinical Global Impression of Change – Bipolar Version (CGI BP) Measure of Depression at Week 3
▼ Description:	CGI-BP is a standardized, clinician-rated assessment which allows the clinician to rate the bipolar illness at various time points compared with baseline. At Screening and Baseline visits the physician rated the severity of the illness using 7 categories (1=normal through 7=very severely ill). At subsequent visits the clinician assessed the change in severity of the condition using 7 categories (1=very much improved through 7=very much worse). Subjects were considered responders if they had a rating of "much improved" or "very much improved". The number of responders at Week 3 are presented.
Time Frame:	Baseline and 3 weeks following the start of study drug administration
Safety Issue?	No

▼ Outcome Measure Data

▼ Analysis Population Description

Full analysis set defined as subjects who were assessed by CGI-BP at baseline and at 3 weeks

Arm/Group Title	Armodafinil 150 mg/Day	Placebo

▼ Arm/Group Description:	Armodafinil was titrated up to the target dosage of 150 mg/day (daily dose was administered each morning). Patients began taking blinded armodafinil at a dose of 50 mg/day (1 tablet) on the day following the baseline visit. Doses were increased by 50 mg/day (1 tablet) to a dose of 100 mg/day on Day 2 and 3, and then again by 50 mg /day on day 4 for a target dose of 150 mg/day. Following titration, patients continued taking 150 mg/day of armodafinil for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 100 mg/day [2 tablets]) was allowed. The dosage could not be increased after it was decreased.	Placebo tablets matching the 50 mg armodafinil tablet were used in a manner identical to that of the armodafinil tablets. Study drug was titrated up to the target dosage of 3 tablets / day (daily dose was administered each morning). Patients began taking blinded study drug at a dose of 1 tablet daily on the day following the baseline visit. Doses were increased by 1 tablet to a dose of 2 tablets/day on Day 2 and 3, and then again by 1 tablet /day on day 4 for a target dose of 3 tablets/day. Following titration, patients continued taking 3 tablets/day of study drug for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 2 tablets/day) was allowed. The dosage could not be increased after it was decreased.
Number of Participants Analyzed	102	100
Measure Type: Number Unit of measure: Participants		
Row Title: Responder	38	32
Row Title: Non Responder	64	68

▼ Statistical Analysis 1 ✓

Statistical Analysis Overview	Comparison Groups	Armodafinil 150 mg/Day, Placebo
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.4567
	Comments	[Not specified]
	Method	Cochran-Mantel-Haenszel
	Comments	Adjusted for concurrent treatment for bipolar disorder

38. Secondary Outcome

Title:	The Number of Responders According to the Clinical Global Impression of Change – Bipolar Version (CGI BP) Measure of Depression at Week 4
▼ Description:	CGI-BP is a standardized, clinician-rated assessment which allows the clinician to rate the bipolar illness at various time points compared with baseline. At Screening and Baseline visits the physician rated the severity of the illness using 7 categories (1=normal through 7=very severely ill). At subsequent visits the clinician assessed the change in severity of the condition using 7 categories (1=very much improved through 7=very much worse). Subjects were considered responders if they had a rating of "much improved" or "very much improved". The number of responders at Week 4 are presented.
Time Frame:	Baseline and 4 weeks following the start of study drug administration
Safety Issue?	No

▼ Outcome Measure Data

▼ Analysis Population Description

Full analysis set defined as subjects who were assessed with CGI-BP at baseline and at 4 weeks

Arm/Group Title	Armodafinil 150 mg/Day	Placebo

▼ Arm/Group Description:	Armodafinil was titrated up to the target dosage of 150 mg/day (daily dose was administered each morning). Patients began taking blinded armodafinil at a dose of 50 mg/day (1 tablet) on the day following the baseline visit. Doses were increased by 50 mg/day (1 tablet) to a dose of 100 mg/day on Day 2 and 3, and then again by 50 mg /day on day 4 for a target dose of 150 mg/day. Following titration, patients continued taking 150 mg/day of armodafinil for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 100 mg/day [2 tablets]) was allowed. The dosage could not be increased after it was decreased.	Placebo tablets matching the 50 mg armodafinil tablet were used in a manner identical to that of the armodafinil tablets. Study drug was titrated up to the target dosage of 3 tablets / day (daily dose was administered each morning). Patients began taking blinded study drug at a dose of 1 tablet daily on the day following the baseline visit. Doses were increased by 1 tablet to a dose of 2 tablets/day on Day 2 and 3, and then again by 1 tablet /day on day 4 for a target dose of 3 tablets/day. Following titration, patients continued taking 3 tablets/day of study drug for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 2 tablets/day) was allowed. The dosage could not be increased after it was decreased.
Number of Participants Analyzed	99	97
Measure Type: Number Unit of measure: Participants		
Row Title: Responder	46	42
Row Title: Non Responder	53	55

▼ Statistical Analysis 1 ✓

Statistical Analysis Overview	Comparison Groups	Armodafinil 150 mg/Day, Placebo
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.6475
	Comments	[Not specified]
	Method	Cochran-Mantel-Haenszel
	Comments	Adjusted for concurrent treatment for bipolar disorder

39. Secondary Outcome

Title:	The Number of Responders According to the Clinical Global Impression of Change – Bipolar Version (CGI BP) Measure of Depression at Week 6
▼ Description:	CGI-BP is a standardized, clinician-rated assessment which allows the clinician to rate the bipolar illness at various time points compared with baseline. At Screening and Baseline visits the physician rated the severity of the illness using 7 categories (1=normal through 7=very severely ill). At subsequent visits the clinician assessed the change in severity of the condition using 7 categories (1=very much improved through 7=very much worse). Subjects were considered responders if they had a rating of "much improved" or "very much improved". The number of responders at Week 6 are presented.
Time Frame:	Baseline and 6 weeks following the start of study drug administration
Safety Issue?	No

▼ Outcome Measure Data

▼ Analysis Population Description

Full analysis set defined as subjects who were assessed by CGI-BP at baseline and at Week 6

Arm/Group Title	Armodafinil 150 mg/Day	Placebo

▼ Arm/Group Description:	Armodafinil was titrated up to the target dosage of 150 mg/day (daily dose was administered each morning). Patients began taking blinded armodafinil at a dose of 50 mg/day (1 tablet) on the day following the baseline visit. Doses were increased by 50 mg/day (1 tablet) to a dose of 100 mg/day on Day 2 and 3, and then again by 50 mg /day on day 4 for a target dose of 150 mg/day. Following titration, patients continued taking 150 mg/day of armodafinil for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 100 mg/day [2 tablets]) was allowed. The dosage could not be increased after it was decreased.	Placebo tablets matching the 50 mg armodafinil tablet were used in a manner identical to that of the armodafinil tablets. Study drug was titrated up to the target dosage of 3 tablets / day (daily dose was administered each morning). Patients began taking blinded study drug at a dose of 1 tablet daily on the day following the baseline visit. Doses were increased by 1 tablet to a dose of 2 tablets/day on Day 2 and 3, and then again by 1 tablet /day on day 4 for a target dose of 3 tablets/day. Following titration, patients continued taking 3 tablets/day of study drug for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 2 tablets/day) was allowed. The dosage could not be increased after it was decreased.
Number of Participants Analyzed	92	92
Measure Type: Number Unit of measure: Participants		
Row Title: Responder	47	43
Row Title: Non Responder	45	49

▼ Statistical Analysis 1 ✓

Statistical Analysis Overview	Comparison Groups	Armodafinil 150 mg/Day, Placebo
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.5066
	Comments	[Not specified]
	Method	Cochran-Mantel-Haenszel
	Comments	Adjusted for concurrent treatment for bipolar disorder

40. Secondary Outcome

Title:	The Number of Responders According to the Clinical Global Impression of Change – Bipolar Version (CGI BP) Measure of Depression at Week 8
▼ Description:	CGI-BP is a standardized, clinician-rated assessment which allows the clinician to rate the bipolar illness at various time points compared with baseline. At Screening and Baseline visits the physician rated the severity of the illness using 7 categories (1=normal through 7=very severely ill). At subsequent visits the clinician assessed the change in severity of the condition using 7 categories (1=very much improved through 7=very much worse). Subjects were considered responders if they had a rating of "much improved" or "very much improved". The number of responders at Week 8 are presented.
Time Frame:	Baseline and 8 weeks following the start of study drug administration
Safety Issue?	No

▼ Outcome Measure Data 

▼ Analysis Population Description

Full analysis set defined as subjects who were assessed with CGI-BP at baseline and at week 8

Arm/Group Title	Armodafinil 150 mg/Day	Placebo

▼ Arm/Group Description:	Armodafinil was titrated up to the target dosage of 150 mg/day (daily dose was administered each morning). Patients began taking blinded armodafinil at a dose of 50 mg/day (1 tablet) on the day following the baseline visit. Doses were increased by 50 mg/day (1 tablet) to a dose of 100 mg/day on Day 2 and 3, and then again by 50 mg /day on day 4 for a target dose of 150 mg/day. Following titration, patients continued taking 150 mg/day of armodafinil for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 100 mg/day [2 tablets]) was allowed. The dosage could not be increased after it was decreased.	Placebo tablets matching the 50 mg armodafinil tablet were used in a manner identical to that of the armodafinil tablets. Study drug was titrated up to the target dosage of 3 tablets / day (daily dose was administered each morning). Patients began taking blinded study drug at a dose of 1 tablet daily on the day following the baseline visit. Doses were increased by 1 tablet to a dose of 2 tablets/day on Day 2 and 3, and then again by 1 tablet /day on day 4 for a target dose of 3 tablets/day. Following titration, patients continued taking 3 tablets/day of study drug for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 2 tablets/day) was allowed. The dosage could not be increased after it was decreased.
Number of Participants Analyzed	89	88
Measure Type: Number Unit of measure: Participants		
Row Title: Responder	52	47
Row Title: Non Responder	37	41

▼ Statistical Analysis 1 ✓

Statistical Analysis Overview	Comparison Groups	Armodafinil 150 mg/Day, Placebo
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.4438
	Comments	[Not specified]
	Method	Cochran-Mantel-Haenszel
	Comments	Adjusted for concurrent treatment for bipolar disorder

Adverse Events

Time Frame		
Additional Description		
Source Vocabulary Name	[Not specified]	
Assessment Type	[Not specified]	
Arm/Group Title	Armodafinil 150 mg/Day	Placebo
Arm/Group Description	Armodafinil was titrated up to the target dosage of 150 mg/day (daily dose was administered each morning). Patients began taking blinded armodafinil at a dose of 50 mg/day (1 tablet) on the day following the baseline visit. Doses were increased by 50 mg/day (1 tablet) to a dose of 100 mg/day on Day 2 and 3, and then again by 50 mg /day on day 4 for a target dose of 150 mg/day. Following titration, patients continued taking 150 mg/day of armodafinil for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study drug, 1 reduction in dosage (ie, minimum dosage 100 mg/day [2 tablets]) was	Placebo tablets matching the 50 mg armodafinil tablet were used in a manner identical to that of the armodafinil tablets. Study drug was titrated up to the target dosage of 3 tablets / day (daily dose was administered each morning). Patients began taking blinded study drug at a dose of 1 tablet daily on the day following the baseline visit. Doses were increased by 1 tablet to a dose of 2 tablets/day on Day 2 and 3, and then again by 1 tablet /day on day 4 for a target dose of 3 tablets/day. Following titration, patients continued taking 3 tablets/day of study drug for the duration of the study. If a patient was unable to tolerate (recurrent or persistent adverse events) the study

	allowed. The dosage could not be increased after it was decreased.	drug, 1 reduction in dosage (ie, minimum dosage 2 tablets/day) was allowed. The dosage could not be increased after it was decreased.

Serious Adverse Events

	Armodafinil 150 mg/Day		Placebo	
	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events
Total	3/126 (2.38%)		3/125 (2.4%)	
Gastrointestinal disorders				
Small intestinal obstruction *	1/126 (0.79%)	1	0/125 (0%)	0
Psychiatric disorders				
Depression *	1/126 (0.79%)	1	1/125 (0.8%)	1
Mania *	0/126 (0%)	0	2/125 (1.6%)	2
Reproductive system and breast disorders				
Epididymal cyst *	1/126 (0.79%)	1	0/125 (0%)	0

* Indicates events were collected by non-systematic methods.

Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events	3%

	Armodafinil 150 mg/Day		Placebo	
	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events
Total	56/126 (44.44%)		54/125 (43.2%)	
Gastrointestinal disorders				
Diarrhoea *	12/126 (9.52%)		8/125 (6.4%)	
Dry Mouth *	8/126 (6.35%)		5/125 (4%)	
Nausea *	9/126 (7.14%)		6/125 (4.8%)	
Toothache *	1/126 (0.79%)		5/125 (4%)	
Vomiting *	5/126 (3.97%)		4/125 (3.2%)	
General disorders				

Fatigue *	4/126 (3.17%)	1/125 (0.8%)
Infections and infestations		
Nasopharyngitis *	2/126 (1.59%)	4/125 (3.2%)
Upper respiratory tract infection *	6/126 (4.76%)	9/125 (7.2%)
Investigations		
Weight increased *	1/126 (0.79%)	6/125 (4.8%)
Nervous system disorders		
Headache *	14/126 (11.11%)	12/125 (9.6%)
Somnolence *	6/126 (4.76%)	2/125 (1.6%)
Tremor *	4/126 (3.17%)	3/125 (2.4%)
Psychiatric disorders		
Anxiety *	5/126 (3.97%)	2/125 (1.6%)
Initial insomnia *	0/126 (0%)	4/125 (3.2%)
Insomnia *	13/126 (10.32%)	10/125 (8%)
Mania *	1/126 (0.79%)	4/125 (3.2%)
Restlessness *	7/126 (5.56%)	1/125 (0.8%)
Respiratory, thoracic and mediastinal disorders		
Rhinorrhoea *	4/126 (3.17%)	1/125 (0.8%)

* Indicates events were collected by non-systematic methods.

Limitations and Caveats

[Not Specified]

More Information

Certain Agreements

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

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 from the time submitted to the sponsor for review. The sponsor cannot require changes to the communication and cannot extend the embargo.

Results Point of Contact

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