ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 04/16/2012

ClinicalTrials.gov ID: NCT00857584

Study Identification

Unique Protocol ID:	D1443L00058
Brief Title:	Quetiapine XR Versus Sertraline in Acute Bipolar Depression as add-on Therapy
Official Title:	Effectiveness of Quetiapine XR Versus Sertraline in Acute Depression as add-on Therapy to Previous Mood Stabilizer Treatment: a Pilot Study
Secondary IDs:	

Study Status

Record Verification:	March 2012
Overall Status:	Completed
Study Start:	May 2009
Primary Completion:	February 2011 [Actual]
Study Completion:	February 2011 [Actual]

Sponsor/Collaborators

Sponsor:	AstraZeneca
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	Yes
Applicable Trial?:	Section 801 Clinical Trial? Yes

	Delayed Posting? No
IND/IDE Protocol?:	No
Review Board:	Approval Status: Approved Approval Number: 2008-002649-22 Board Name: CEIC de Euskadi Board Affiliation: Hospital Santiago Apostol Phone: +34 94 500 79 01 Email:
Data Monitoring?:	No
Plan to Share Data?:	
Oversight Authorities:	Spain: Comité Ético de Investigación Clínica Spain: Spanish Agency of Medicines

Study Description

Brief Summary:	Prospective, open-label, controlled (active comparator), randomized study of 8 weeks follow-up for the evaluation of the efficacy of extended release quetiapine (quetiapine XR) versus Sertraline in addition to previous mood stabilizer treatment (lithium or valproate at stable and clinically therapeutic blood levels) in the treatment of the adult bipolar depression. This multicentric study will be featured in two sites in Spain.
Detailed Description:	

Conditions

Conditions:	Bipolar Disorder Bipolar Depression
Keywords:	Bipolar disorder Bipolar depression quetiapine sertraline

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 3
Intervention Model:	Parallel Assignment

Number of Arms:	2
Masking:	Open Label
Allocation:	Randomized
Endpoint Classification:	Efficacy Study
Enrollment:	27 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Quetiapine Extended Release Lithium or valproate at stable doses within seric therapeutic levels	Drug: Extended release quetiapine (quetiapine XR) Flexible dose from 300 to 600 mg/d (combination of tablets of 50mg, 200mg and 300mg) oral, daily, 8 weeks length. Quetiapine XR was initiated at 50 mg/day and titrated to 100 mg on day 2, 200 mg on day 3, 300 mg on day 4, and flexible doses of 300 to 600 mg/d from day 5 to the end of the study. Other Names: • SEROQUEL XR® Drug: adequate mood stabilizer An adequate mood stabilizer treatment with lithium or valproate(defined as a serum concentration of 0.5-1.2 mEq/L or 50-100 microg/ml, respectively).
Active Comparator: Sertraline Lithium or valproate at stable doses within seric therapeutic levels	Drug: Sertraline Flexible dose from 50 to 200 mg/d (combination of tablets of 50mg and 100mg) oral, daily, 8 weeks length. Sertraline titration: 50 mg on day 1-3, 100 mg on day 4, and flexible doses of 50 to 200 mg/d from day 5 to the end of the study. Other Names: • Zoloft Drug: adequate mood stabilizer An adequate mood stabilizer treatment with lithium or valproate(defined as a serum concentration of 0.5-1.2 mEq/L or 50-100 microg/ml, respectively).

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age: 65 Years

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- Adult ambulatory patients diagnosed of bipolar disorder I or II, current depressive episode (DSM-IV-TR 4ª Ed: 296.5x or 296.89 codes)
- Have been treated with only one mood stabilizer (lithium or valproate) in optimal and stable doses during at least the previous 4 weeks to randomization
- Hamilton Depression Rating Scale (HDRS-17) total score ≥ 20 and Young Mania Rating Scale (YMRS) total score ≤ 14 at the screening and randomization visits - Informed consent signed

Exclusion Criteria:

- Patients with any axis I or II Diagnostic and Statistical Manual of Mental Disorders, 4th edition, text revision (DSM-IV-TR) diagnoses different from bipolar disorder I or II - Length of current depressive episode less than 2 weeks or more than 12 months
- Having been treated with more than one mood stabilizer or any mood stabilizer other than Lithium or valproate, any antidepressant, any antipsychotic or any CP450-3A inductor/inhibitor within the 7 days period prior to randomization

Contacts/Locations

Study Officials:

Locations: Spain

Research Site
Vitoria, Pais Vasco, Spain

Research Site
Santander, Cantabria, Spain

Research Site
Vigo, Galicia, Spain

Research Site
Zamora, Castilla-León, Spain

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Reporting Groups

	Description
Quetiapine Extended Release	Extended release quetiapine (quetiapine XR) - flexible dose from 300 to 600 mg/d (combination of tablets of 50mg, 200mg and 300mg) oral, daily, 8 weeks length.
Setraline	Sertraline - flexible dose from 50 to 200 mg/d (combination of tablets of 50mg and 100mg) oral, daily, 8 weeks length.

Overall Study

	Quetiapine Extended Release	Setraline
Started	14	13
Week 1	14	13
Week 2	14	11
Week 4	11	9
Week 8	10	8
Completed	10	8
Not Completed	4	5
Lack of Efficacy	1	2
Adverse Event	2	2
Physician Decision	1	1

Baseline Characteristics

Reporting Groups

	Description
Quetiapine Extended Release	Extended release quetiapine (quetiapine XR) - flexible dose from 300 to 600 mg/d (combination of tablets of 50mg, 200mg and 300mg) oral, daily, 8 weeks length.
Setraline	Sertraline - flexible dose from 50 to 200 mg/d (combination of tablets of 50mg and 100mg) oral, daily, 8 weeks length.

Baseline Measures

	Quetiapine Extended Release	Setraline	Total
Number of Participants	14	13	27
Age, Continuous [units: years] Mean (Standard Deviation)	48.5 (12.5)	43.3 (12.6)	46.07 (12.6)
Gender, Male/Female [units: Participants]			
Female	6	4	10
Male	8	9	17
Montgomery Asberg Depression Rating Scale (MADRS) total score, Continuous [1] [units: score on a scale] Mean (Standard Deviation)	29.5 (5.0)	28.2 (5.8)	28.9 (5.3)
Clinical Impression Global Scale - Bipolar total score (CGI-BP-M), Continuous [2] [units: score on a scale] Mean (Standard Deviation)	5.1 (0.7)	5.3 (0.8)	5.2 (0.8)
Hamilton Anxiety Rating Scale (HARS) total score, Continuous [3] [units: score on a scale] Mean (Standard Deviation)	22.4 (4.03)	17.6 (4.46)	20.04 (7.38)

[1] MADRS assesses severity of depressive symptoms. It ranges from a minimum of 0 to a maximum of 60 (higher scores indicating a greater severity of depressive symptoms)

[2] CGI-BP-M assesses severity of clinical status. It ranges from a minimum of 1 to a maximum of 7 (higher scores indicating a greater clinical severity)

[3] HARS assesses severity of anxiety symptoms. It ranges from a minimum of 0 to a maximum of 56 (higher scores indicating a greater severity of anxiety symptoms)

Outcome Measures

1. Primary Outcome Measure:

Measure Title	The Mean Change From Baseline to Week 2 in the Montgomery Asberg Depression Rating Scale (MADRS) Total Score
Measure Description	MADRS assesses severity of depressive symptoms. It ranges from a minimum of 0 to a maximum of 60 (higher scores indicating a greater severity of depressive symptoms)
Time Frame	baseline, week 2
Safety Issue?	No

Analysis Population Description

Efficacy analyses of the intent-to-treat (ITT) population (those who received at least one dose of study medication and had at least one post-baseline efficacy assessment) were conducted using ANCOVA and last observation carried forward (LOCF) methodology. Safety data were analyzed for patients who received at least one dose of study medication.

Reporting Groups

	Description
Quetiapine Extended Release	Extended release quetiapine (quetiapine XR) - flexible dose from 300 to 600 mg/d (combination of tablets of 50mg, 200mg and 300mg) oral, daily, 8 weeks length.
Setraline	Sertraline - flexible dose from 50 to 200 mg/d (combination of tablets of 50mg and 100mg) oral, daily, 8 weeks length.

Measured Values

	Quetiapine Extended Release	Setraline
Number of Participants Analyzed	14	11
The Mean Change From Baseline to Week 2 in the Montgomery Asberg Depression Rating Scale (MADRS) Total Score [units: score on a scale] Mean (95% Confidence Interval)	-13.1 (-18.6 to -7.6)	-6.6 (-12.6 to -0.6)

2. Secondary Outcome Measure:

Measure Title	The Mean Change From Baseline to Week 1 in the Montgomery Asberg Depression Rating Scale (MADRS) Total Score
Measure Description	MADRS assesses severity of depressive symptoms. It ranges from a minimum of 0 to a maximum of 60 (higher scores indicating a greater severity of depressive symptoms)
Time Frame	baseline, week 1
Safety Issue?	No

Analysis Population Description

Efficacy analyses of the intent-to-treat (ITT) population (those who received at least one dose of the study medication and had at least one post-baseline efficacy assessment) were conducted using ANCOVA and last observation carried forward (LOCF) methodology.

Reporting Groups

	Description
Quetiapine Extended Release	Extended release quetiapine (quetiapine XR) - flexible dose from 300 to 600 mg/d (combination of tablets of 50mg, 200mg and 300mg) oral, daily, 8 weeks length.
Setraline	Sertraline - flexible dose from 50 to 200 mg/d (combination of tablets of 50mg and 100mg) oral, daily, 8 weeks length.

Measured Values

	Quetiapine Extended Release	Setraline
Number of Participants Analyzed	14	13
The Mean Change From Baseline to Week 1 in the Montgomery Asberg Depression Rating Scale (MADRS) Total Score [units: score on a scale] Mean (95% Confidence Interval)	-9.5 (-13.8 to -5.1)	-8.6 (-14.5 to -2.6)

3. Secondary Outcome Measure:

Measure Title	The Mean Change From Baseline to Week 4 in the Montgomery Asberg Depression Rating Scale (MADRS) Total Score
Measure Description	MADRS assesses severity of depressive symptoms. It ranges from a minimum of 0 to a maximum of 60 (higher scores indicating a greater severity of depressive symptoms)
Time Frame	baseline, week 4

Safety Issue?	No

Analysis Population Description

Efficacy analyses of the intent-to-treat (ITT) population (those who received at least one dose of the study medication and had at least one post-baseline efficacy assessment) were conducted using ANCOVA and last observation carried forward (LOCF) methodology.

Reporting Groups

	Description
Quetiapine Extended Release	Extended release quetiapine (quetiapine XR) - flexible dose from 300 to 600 mg/d (combination of tablets of 50mg, 200mg and 300mg) oral, daily, 8 weeks length.
Setraline	Sertraline - flexible dose from 50 to 200 mg/d (combination of tablets of 50mg and 100mg) oral, daily, 8 weeks length.

Measured Values

	Quetiapine Extended Release	Setraline
Number of Participants Analyzed	11	9
The Mean Change From Baseline to Week 4 in the Montgomery Asberg Depression Rating Scale (MADRS) Total Score [units: score on a scale] Mean (95% Confidence Interval)	-16.1 (-21.4 to -10.9)	-17.7 (-25.8 to -9.7)

4. Secondary Outcome Measure:

Measure Title	The Mean Change From Baseline to Week 8 in the Montgomery Asberg Depression Rating Scale (MADRS) Total Score
Measure Description	MADRS assesses severity of depressive symptoms. It ranges from a minimum of 0 to a maximum of 60 (higher scores indicating a greater severity of depressive symptoms)
Time Frame	baseline. week 8
Safety Issue?	No

Analysis Population Description

Efficacy analyses of the intent-to-treat (ITT) population (those who received at least one dose of the study medication and had at least one post-baseline efficacy assessment) were conducted using ANCOVA and last observation carried forward (LOCF) methodology.

Reporting Groups

	Description
Quetiapine Extended Release	Extended release quetiapine (quetiapine XR) - flexible dose from 300 to 600 mg/d (combination of tablets of 50mg, 200mg and 300mg) oral, daily, 8 weeks length.
Setraline	Sertraline - flexible dose from 50 to 200 mg/d (combination of tablets of 50mg and 100mg) oral, daily, 8 weeks length.

Measured Values

	Quetiapine Extended Release	Setraline
Number of Participants Analyzed	10	8
The Mean Change From Baseline to Week 8 in the Montgomery Asberg Depression Rating Scale (MADRS) Total Score [units: score on a scale] Mean (95% Confidence Interval)	-19.4 (-24.2 to -14.5)	-18.2 (-24.8 to -11.6)

5. Secondary Outcome Measure:

Measure Title	The Mean Change From Baseline to Week 1 in the Clinical Impression Global Scale - Bipolar (CGI-BP-M) Total Score
Measure Description	CGI-BP-M assesses severity of clinical status. It ranges from a minimum of 1 to a maximum of 7 (higher scores indicating a greater clinical severity)
Time Frame	baseline, week 1
Safety Issue?	No

Analysis Population Description

Efficacy analyses of the intent-to-treat (ITT) population (those who received at least one dose of the study medication and had at least one post-baseline efficacy assessment) were conducted using ANCOVA and last observation carried forward (LOCF) methodology

Reporting Groups

	Description
Quetiapine Extended Release	Extended release quetiapine (quetiapine XR) - flexible dose from 300 to 600 mg/d (combination of tablets of 50mg, 200mg and 300mg) oral, daily, 8 weeks length.
Setraline	Sertraline - flexible dose from 50 to 200 mg/d (combination of tablets of 50mg and 100mg) oral, daily, 8 weeks length.

Measured Values

	Quetiapine Extended Release	Setraline
Number of Participants Analyzed	14	13
The Mean Change From Baseline to Week 1 in the Clinical Impression Global Scale - Bipolar (CGI-BP-M) Total Score [units: score on a scale] Mean (95% Confidence Interval)	-0.79 (-1.47 to -0.10)	-1.08 (-2.14 to -0.02)

6. Secondary Outcome Measure:

Measure Title	The Mean Change From Baseline to Week 2 in the Clinical Impression Global Scale - Bipolar (CGI-BP-M) Total Score
Measure Description	CGI-BP-M assesses severity of clinical status. It ranges from a minimum of 1 to a maximum of 7 (higher scores indicating a greater clinical severity)
Time Frame	baseline, week 2
Safety Issue?	No

Analysis Population Description

Efficacy analyses of the intent-to-treat (ITT) population (those who received at least one dose of the study medication and had at least one post-baseline efficacy assessment) were conducted using ANCOVA and last observation carried forward (LOCF) methodology.

Reporting Groups

	Description
Quetiapine Extended Release	Extended release quetiapine (quetiapine XR) - flexible dose from 300 to 600 mg/d (combination of tablets of 50mg, 200mg and 300mg) oral, daily, 8 weeks length.
Setraline	Sertraline - flexible dose from 50 to 200 mg/d (combination of tablets of 50mg and 100mg) oral, daily, 8 weeks length.

Measured Values

	Quetiapine Extended Release	Setraline
Number of Participants Analyzed	14	11
The Mean Change From Baseline to Week 2 in the Clinical Impression Global Scale - Bipolar (CGI-BP-M) Total Score [units: score on a scale] Mean (95% Confidence Interval)	-1.36 (-2.19 to -0.52)	-1.00 (-2.20 to -0.20)

7. Secondary Outcome Measure:

Measure Title	The Mean Change From Baseline to Week 4 in the Clinical Impression Global Scale - Bipolar (CGI-BP-M) Total Score
Measure Description	CGI-BP-M assesses severity of clinical status. It ranges from a minimum of 1 to a maximum of 7 (higher scores indicating a greater clinical severity)
Time Frame	baseline, week 4
Safety Issue?	No

Analysis Population Description

Efficacy analyses of the intent-to-treat (ITT) population (those who received at least one dose of the study medication and had at least one post-baseline efficacy assessment) were conducted using ANCOVA and last observation carried forward (LOCF) methodology.

Reporting Groups

	Description
Quetiapine Extended Release	Extended release quetiapine (quetiapine XR) - flexible dose from 300 to 600 mg/d (combination of tablets of 50mg, 200mg and 300mg) oral, daily, 8 weeks length.
Setraline	Sertraline - flexible dose from 50 to 200 mg/d (combination of tablets of 50mg and 100mg) oral, daily, 8 weeks length.

Measured Values

	Quetiapine Extended Release	Setraline
Number of Participants Analyzed	11	9
The Mean Change From Baseline to Week 4 in the Clinical Impression Global Scale - Bipolar (CGI-BP-M) Total Score [units: score on a scale] Mean (95% Confidence Interval)	-2.09 (-3.19 to -0.99)	-2.56 (-4.15 to -0.97)

8. Secondary Outcome Measure:

Measure Title	The Mean Change From Baseline to Week 8 in the Clinical Impression Global Scale - Bipolar (CGI-BP-M) Total Score
Measure Description	CGI-BP-M assesses severity of clinical status. It ranges from a minimum of 1 to a maximum of 7 (higher scores indicating a greater clinical severity)
Time Frame	baseline, week 8

Safety Issue?	No

Analysis Population Description

Efficacy analyses of the intent-to-treat (ITT) population (those who received at least one dose of the study medication and had at least one post-baseline efficacy assessment) were conducted using ANCOVA and last observation carried forward (LOCF) methodology.

Reporting Groups

	Description
Quetiapine Extended Release	Extended release quetiapine (quetiapine XR) - flexible dose from 300 to 600 mg/d (combination of tablets of 50mg, 200mg and 300mg) oral, daily, 8 weeks length.
Setraline	Sertraline - flexible dose from 50 to 200 mg/d (combination of tablets of 50mg and 100mg) oral, daily, 8 weeks length.

Measured Values

	Quetiapine Extended Release	Setraline
Number of Participants Analyzed	10	8
The Mean Change From Baseline to Week 8 in the Clinical Impression Global Scale - Bipolar (CGI-BP-M) Total Score [units: score on a scale] Mean (95% Confidence Interval)	-2.9 (-4.14 to -1.66)	-2.88 (-4.25 to -1.50)

9. Secondary Outcome Measure:

Measure Title	The Mean Change From Baseline to Week 4 in the Hamilton Anxiety Rating Scale (HARS) Total Score
Measure Description	HARS assesses severity of anxiety symptoms. It ranges from a minimum of 0 to a maximum of 56 (higher scores indicating a greater severity of anxiety symptoms)
Time Frame	baseline, week 4
Safety Issue?	No

Analysis Population Description

Efficacy analyses of the intent-to-treat (ITT) population (those who received at least one dose of the study medication and had at least one post-baseline efficacy assessment) were conducted using ANCOVA and last observation carried forward (LOCF) methodology.

Reporting Groups

	Description
Quetiapine Extended Release	Extended release quetiapine (quetiapine XR) - flexible dose from 300 to 600 mg/d (combination of tablets of 50mg, 200mg and 300mg) oral, daily, 8 weeks length.
Setraline	Sertraline - flexible dose from 50 to 200 mg/d (combination of tablets of 50mg and 100mg) oral, daily, 8 weeks length.

Measured Values

	Quetiapine Extended Release	Setraline
Number of Participants Analyzed	11	9
The Mean Change From Baseline to Week 4 in the Hamilton Anxiety Rating Scale (HARS) Total Score [units: score on a scale] Mean (95% Confidence Interval)	-13.4 (-17.6 to -9.1)	-8.9 (-14.3 to -3.4)

10. Secondary Outcome Measure:

Measure Title	The Mean Change From Baseline to Week 8 in the Hamilton Anxiety Rating Scale (HARS) Total Score
Measure Description	HARS assesses severity of anxiety symptoms. It ranges from a minimum of 0 to a maximum of 56 (higher scores indicating a greater severity of anxiety symptoms)
Time Frame	baseline, week 8
Safety Issue?	No

Analysis Population Description

Efficacy analyses of the intent-to-treat (ITT) population (those who received at least one dose of the study medication and had at least one post-baseline efficacy assessment) were conducted using ANCOVA and last observation carried forward (LOCF) methodology.

Reporting Groups

	Description
Quetiapine Extended Release	Extended release quetiapine (quetiapine XR) - flexible dose from 300 to 600 mg/d (combination of tablets of 50mg, 200mg and 300mg) oral, daily, 8 weeks length.
Setraline	Sertraline - flexible dose from 50 to 200 mg/d (combination of tablets of 50mg and 100mg) oral, daily, 8 weeks length.

Measured Values

	Quetiapine Extended Release	Setraline
Number of Participants Analyzed	10	8
The Mean Change From Baseline to Week 8 in the Hamilton Anxiety Rating Scale (HARS) Total Score [units: score on a scale] Mean (95% Confidence Interval)	-13.1 (-18.01 to -8.2)	-10.6 (-15.5 to -5.7)

11. Secondary Outcome Measure:

Measure Title	Number of Patients Response at Week 1
Measure Description	Number of patients responded to the treatment at week 1, where response is defined as ≥ 50% reduction in the Montgomery Asberg Depression Rating Scale (MADRS) total score from baseline to week 1. MADRS assesses severity of depressive symptoms. It ranges from a minimum of 0 to a maximum of 60 (higher scores indicating a greater severity of depressive symptoms.
Time Frame	week 1
Safety Issue?	No

Analysis Population Description

Efficacy analyses of the intent-to-treat (ITT) population (those who received at least one dose of the study medication and had at least one post-baseline efficacy assessment) were conducted using ANCOVA and last observation carried forward (LOCF) methodology.

Reporting Groups

	Description
Quetiapine Extended Release	Extended release quetiapine (quetiapine XR) - flexible dose from 300 to 600 mg/d (combination of tablets of 50mg, 200mg and 300mg) oral, daily, 8 weeks length.
Setraline	Sertraline - flexible dose from 50 to 200 mg/d (combination of tablets of 50mg and 100mg) oral, daily, 8 weeks length.

Measured Values

	Quetiapine Extended Release	Setraline
Number of Participants Analyzed	14	13
Number of Patients Response at Week 1 [units: Participants]	4	4

12. Secondary Outcome Measure:

Measure Title	Number of Patients With Response at Week 2
Measure Description	Number of patients responded to the treatment at week 2, where response is defined as ≥ 50% reduction in the Montgomery Asberg Depression Rating Scale (MADRS) total score from baseline to week 2. MADRS assesses severity of depressive symptoms. It ranges from a minimum of 0 to a maximum of 60 (higher scores indicating a greater severity of depressive symptoms.
Time Frame	week 2
Safety Issue?	No

Analysis Population Description

Efficacy analyses of the intent-to-treat (ITT) population (those who received at least one dose of the study medication and had at least one post-baseline efficacy assessment) were conducted using ANCOVA and last observation carried forward (LOCF) methodology.

Reporting Groups

	Description
Quetiapine Extended Release	Extended release quetiapine (quetiapine XR) - flexible dose from 300 to 600 mg/d (combination of tablets of 50mg, 200mg and 300mg) oral, daily, 8 weeks length.
Setraline	Sertraline - flexible dose from 50 to 200 mg/d (combination of tablets of 50mg and 100mg) oral, daily, 8 weeks length.

Measured Values

	Quetiapine Extended Release	Setraline
Number of Participants Analyzed	14	11
Number of Patients With Response at Week 2 [units: Participants]	8	2

13. Secondary Outcome Measure:

Measure Title	Number of Patients With Response at Week 4.
Measure Description	Number of patients responded to the treatment at week 4, where response is defined as ≥ 50% reduction in the Montgomery Asberg Depression Rating Scale (MADRS) total score from baseline to week 4. MADRS assesses severity of depressive symptoms. It ranges from a minimum of 0 to a maximum of 60 (higher scores indicating a greater severity of depressive symptoms.

Time Frame	week 4
Safety Issue?	No

Analysis Population Description

Efficacy analyses of the intent-to-treat (ITT) population (those who received at least one dose of the study medication and had at least one post-baseline efficacy assessment) were conducted using ANCOVA and last observation carried forward (LOCF) methodology.

Reporting Groups

	Description
Quetiapine Extended Release	Extended release quetiapine (quetiapine XR) - flexible dose from 300 to 600 mg/d (combination of tablets of 50mg, 200mg and 300mg) oral, daily, 8 weeks length.
Setraline	Sertraline - flexible dose from 50 to 200 mg/d (combination of tablets of 50mg and 100mg) oral, daily, 8 weeks length.

Measured Values

	Quetiapine Extended Release	Setraline
Number of Participants Analyzed	11	9
Number of Patients With Response at Week 4. [units: Participants]	8	6

14. Secondary Outcome Measure:

Measure Title	Number of Patients With Response at Week 8.
Measure Description	Number of patients responded to the treatment at week 8, where response is defined as ≥ 50% reduction in the Montgomery Asberg Depression Rating Scale (MADRS) total score from baseline to week 8. MADRS assesses severity of depressive symptoms. It ranges from a minimum of 0 to a maximum of 60 (higher scores indicating a greater severity of depressive symptoms.
Time Frame	week 8
Safety Issue?	No

Analysis Population Description

Efficacy analyses of the intent-to-treat (ITT) population (those who received at least one dose of the study medication and had at least one post-baseline efficacy assessment) were conducted using ANCOVA and last observation carried forward (LOCF) methodology.

Reporting Groups

	Description
Quetiapine Extended Release	Extended release quetiapine (quetiapine XR) - flexible dose from 300 to 600 mg/d (combination of tablets of 50mg, 200mg and 300mg) oral, daily, 8 weeks length.
Setraline	Sertraline - flexible dose from 50 to 200 mg/d (combination of tablets of 50mg and 100mg) oral, daily, 8 weeks length.

Measured Values

	Quetiapine Extended Release	Setraline
Number of Participants Analyzed	10	8
Number of Patients With Response at Week 8. [units: Participants]	8	5

15. Secondary Outcome Measure:

Measure Title	Number of Patients With Remission at Week 1.
Measure Description	Number of patients who achieved remission at week 1, where remission is defined as Montgomery Asberg Depression Rating Scale (MADRS) total score ≤ 10. MADRS assesses severity of depressive symptoms. It ranges from a minimum of 0 to a maximum of 60 (higher scores indicating a greater severity of depressive symptoms.
Time Frame	week 1
Safety Issue?	No

Analysis Population Description

Efficacy analyses of the intent-to-treat (ITT) population (those who received at least one dose of the study medication and had at least one post-baseline efficacy assessment) were conducted using ANCOVA and last observation carried forward (LOCF) methodology.

Reporting Groups

	Description
Quetiapine Extended Release	Extended release quetiapine (quetiapine XR) - flexible dose from 300 to 600 mg/d (combination of tablets of 50mg, 200mg and 300mg) oral, daily, 8 weeks length.
Setraline	Sertraline - flexible dose from 50 to 200 mg/d (combination of tablets of 50mg and 100mg) oral, daily, 8 weeks length.

Measured Values

	Quetiapine Extended Release	Setraline
Number of Participants Analyzed	14	13
Number of Patients With Remission at Week 1. [units: Participants]	6	5

16. Secondary Outcome Measure:

Measure Title	Number of Patients With Remission at Week 2.
Measure Description	Number of patients who achieved remission at week 2, where remission is defined as Montgomery Asberg Depression Rating Scale (MADRS) total score ≤ 10. MADRS assesses severity of depressive symptoms. It ranges from a minimum of 0 to a maximum of 60 (higher scores indicating a greater severity of depressive symptoms.
Time Frame	week 2
Safety Issue?	No

Analysis Population Description

Efficacy analyses of the intent-to-treat (ITT) population (those who received at least one dose of the study medication and had at least one post-baseline efficacy assessment) were conducted using ANCOVA and last observation carried forward (LOCF) methodology.

Reporting Groups

	Description
Quetiapine Extended Release	Extended release quetiapine (quetiapine XR) - flexible dose from 300 to 600 mg/d (combination of tablets of 50mg, 200mg and 300mg) oral, daily, 8 weeks length.
Setraline	Sertraline - flexible dose from 50 to 200 mg/d (combination of tablets of 50mg and 100mg) oral, daily, 8 weeks length.

Measured Values

	Quetiapine Extended Release	Setraline
Number of Participants Analyzed	14	11
Number of Patients With Remission at Week 2. [units: Participants]	6	5

17. Secondary Outcome Measure:

Measure Title	Number of Patients With Remission at Week 4.
Measure Description	Number of patients who achieved remission at week 4, where remission is defined as Montgomery Asberg Depression Rating Scale (MADRS) total score ≤ 10. MADRS assesses severity of depressive symptoms. It ranges from a minimum of 0 to a maximum of 60 (higher scores indicating a greater severity of depressive symptoms.
Time Frame	week 4
Safety Issue?	No

Analysis Population Description

Efficacy analyses of the intent-to-treat (ITT) population (those who received at least one dose of the study medication and had at least one post-baseline efficacy assessment) were conducted using ANCOVA and last observation carried forward (LOCF) methodology.

Reporting Groups

	Description
Quetiapine Extended Release	Extended release quetiapine (quetiapine XR) - flexible dose from 300 to 600 mg/d (combination of tablets of 50mg, 200mg and 300mg) oral, daily, 8 weeks length.
Setraline	Sertraline - flexible dose from 50 to 200 mg/d (combination of tablets of 50mg and 100mg) oral, daily, 8 weeks length.

Measured Values

	Quetiapine Extended Release	Setraline
Number of Participants Analyzed	11	9
Number of Patients With Remission at Week 4. [units: Participants]	3	3

18. Secondary Outcome Measure:

Measure Title	Number of Patients With Remission at Week 8.
Measure Description	Number of patients who achieved remission at week 8, where remission is defined as Montgomery Asberg Depression Rating Scale (MADRS) total score ≤ 10. MADRS assesses severity of depressive symptoms. It ranges from a minimum of 0 to a maximum of 60 (higher scores indicating a greater severity of depressive symptoms.
Time Frame	week 8

Safety Issue?	No

Analysis Population Description

Efficacy analyses of the intent-to-treat (ITT) population (those who received at least one dose of the study medication and had at least one post-baseline efficacy assessment) were conducted using ANCOVA and last observation carried forward (LOCF) methodology

Reporting Groups

	Description
Quetiapine Extended Release	Extended release quetiapine (quetiapine XR) - flexible dose from 300 to 600 mg/d (combination of tablets of 50mg, 200mg and 300mg) oral, daily, 8 weeks length.
Setraline	Sertraline - flexible dose from 50 to 200 mg/d (combination of tablets of 50mg and 100mg) oral, daily, 8 weeks length.

Measured Values

	Quetiapine Extended Release	Setraline
Number of Participants Analyzed	10	8
Number of Patients With Remission at Week 8. [units: Participants]	3	4

Reported Adverse Events

Time Frame	[Not specified]
Additional Description	[Not specified]

Reporting Groups

	Description
Quetiapine Extended Release	Extended release quetiapine (quetiapine XR) - flexible dose from 300 to 600 mg/d (combination of tablets of 50mg, 200mg and 300mg) oral, daily, 8 weeks length.
Setraline	Sertraline - flexible dose from 50 to 200 mg/d (combination of tablets of 50mg and 100mg) oral, daily, 8 weeks length.

Serious Adverse Events

	Quetiapine Extended Release	Setraline
	Affected/At Risk (%)	Affected/At Risk (%)
Total	0/14 (0%)	0/13 (0%)

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Quetiapine Extended Release	Setraline
	Affected/At Risk (%)	Affected/At Risk (%)
Total	12/14 (85.71%)	9/13 (69.23%)
Gastrointestinal disorders		
Diarrhoea [A] †	0/14 (0%)	2/13 (15.38%)
Dry mouth [A] †	3/14 (21.43%)	0/13 (0%)
Dyspepsia [A] †	0/14 (0%)	2/13 (15.38%)
General disorders		
Chest discomfort [A] †	1/14 (7.14%)	0/13 (0%)
Metabolism and nutrition disorders		
Hyperphagia [A] †	1/14 (7.14%)	0/13 (0%)
Nervous system disorders		
Dysarthria [A] †	1/14 (7.14%)	0/13 (0%)
Somnolence [A] †	5/14 (35.71%)	1/13 (7.69%)
Tremor [A] †	2/14 (14.29%)	1/13 (7.69%)
Psychiatric disorders		
Anxiety [A] †	0/14 (0%)	1/13 (7.69%)
Decreased libido [A] †	0/14 (0%)	1/13 (7.69%)
Disorientation [A] †	1/14 (7.14%)	0/13 (0%)
Insomnia [A] †	0/14 (0%)	2/13 (15.38%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 10.0

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

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

There is NOT an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Results Point of Contact:

Name/Official Title: Gerard Lynch
Organization: AstraZeneca
Phone:
Email: aztrial_results_posting@astrazeneca.com