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6-Month Extension Trial of Asenapine With Olanzapine in Negative Symptom Patients Who Completed the Protocol 25543 (25544)(P05777)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00265343

First received: December 12, 2005
Last updated: February 20, 2015
Last verified: February 2015
History of Changes

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Purpose

This is an extension study to further test the efficacy and safety of asenapine compared with a marketed agent (olanzapine) in the treatment of patients with persistent negative symptoms of schizophrenia.

Condition	Intervention	Phase
Schizophrenia	Drug: asenapine Drug: olanzapine	Phase 3

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

Official Title: A Multicenter, Double-Blind, Flexible-Dose, 6-Month Extension Trial Comparing the Safety and Efficacy of Asenapine With Olanzapine in Subjects Who Completed the Protocol 25543 (NCT 00212836; P05817)

Resource links provided by NLM:

MedlinePlus related topics: Schizophrenia

Drug Information available for: Asenapine Olanzapine Olanzapine pamoate

U.S. FDA Resources

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

Primary Outcome Measures:

- Long-term Change in Negative Symptoms of Schizophrenia Measured by the Negative Symptom Assessment (NSA) Scale
  [Time Frame: Baseline of Protocol 25543 (NCT 00212836) to 365 days (total time for both protocols 25543 & 25544)]
  [Designated as safety issue: No]

  Decrease from baseline in the NSA scores indicates improvement of efficacy. Range NSA total score is 16 [best]-96 [worst].

Secondary Outcome Measures:

- Change in Quality of Life Measured by Quality of Life Scale (QLS) [Time Frame: Baseline of Protocol 25543 (NCT 00212836) to 365 days (total time for both protocols 25543 & 25544)] [Designated as safety issue: No]

  Increase from baseline in the QLS scores indicates improvement of efficacy. Range QLS total score is 0 [worst]-126 [best].

Enrollment:	306
Study Start Date:	December 2005
Study Completion Date:	January 2008
Primary Completion Date:	December 2007 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: 1 asenapine	Drug: asenapine 5-10 mg sublingually twice daily for 26 weeks
Active Comparator: 2 olanzapine	Drug: olanzapine 5-20 mg by mouth once daily for 26 weeks

Eligibility

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

Criteria

Inclusion Criteria:

- Continue to meet all demographic and procedural

inclusion criteria of the 25543 trial (NCT 00212836; P05817) to enter into

this extension trial.

- Have demonstrated an acceptable

degree of compliance and completed the 25543

trial, and would benefit from continued treatment

according to the investigator.

Exclusion Criteria:

- Have an uncontrolled, unstable clinically significant

medical condition.

- Have been judged to be medically

noncompliant in the management of their disease.

Contacts and Locations

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

information, see Learn About Clinical Studies.

No Contacts or Locations Provided

More Information

Publications:

Buchanan RW, Panagides J, Zhao J, Phiri P, den Hollander W, Ha X, Kouassi A, Alphs L, Schooler N, Szegedi A, Cazorla P. Asenapine versus olanzapine in people with persistent negative symptoms of schizophrenia. J Clin Psychopharmacol. 2012 Feb;32(1):36-45. doi: 10.1097/JCP.0b013e31823f880a.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00265343 History of Changes
Other Study ID Numbers:	P05777 25544 Aphrodite
Study First Received:	December 12, 2005
Results First Received:	February 17, 2010
Last Updated:	February 20, 2015
Health Authority:	Finland: Finnish Medicines Agency

Additional relevant MeSH terms:

Asenapine	Neurotransmitter Uptake Inhibitors
Olanzapine	Peripheral Nervous System Agents
Antiemetics	Pharmacologic Actions
Antipsychotic Agents	Physiological Effects of Drugs
Autonomic Agents	Psychotropic Drugs
Central Nervous System Agents	Serotonin Agents
Central Nervous System Depressants	Serotonin Uptake Inhibitors
Gastrointestinal Agents	Therapeutic Uses
Molecular Mechanisms of Pharmacological Action	Tranquilizing Agents
Neurotransmitter Agents	

ClinicalTrials.gov processed this record on April 24, 2016

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First received: December 12, 2005
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Results First Received: February 17, 2010

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

Participant Flow

Hide Participant Flow

Recruitment Details

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

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description
Asenapine	5-10 mg twice daily (bid) sublingual (SL)
Olanzapine	5-20 mg daily (QD) orally (PO)

Participant Flow: Overall Study

	Asenapine	Olanzapine
STARTED	**134**	**172**
COMPLETED	**113**	**153**
NOT COMPLETED	**21**	**19**
Adverse Event	**10**	**7**
Withdrawal by Subject	**3**	**9**
Unknown	**8**	**3**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

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

Reporting Groups

	Description
Asenapine	5-10 mg twice daily (bid) sublingual (SL)
Olanzapine	5-20 mg daily (QD) orally (PO)
Total	Total of all reporting groups

Baseline Measures

	Asenapine	Olanzapine	Total
Number of Participants [units: participants]	**134**	**172**	**306**
Age [units: years] Mean (Standard Deviation)	**39.9 (12.2)**	**40.7 (11.7)**	**40.4 (11.9)**
Gender [units: participants]			
Female	**43**	**53**	**96**
Male	**91**	**119**	**210**

Outcome Measures

Hide All Outcome Measures

1. Primary: Long-term Change in Negative Symptoms of Schizophrenia Measured by the Negative Symptom Assessment (NSA) Scale [Time Frame: Baseline of Protocol 25543 (NCT 00212836) to 365 days (total time for both protocols 25543 & 25544)]

Measure Type	Primary
Measure Title	Long-term Change in Negative Symptoms of Schizophrenia Measured by the Negative Symptom Assessment (NSA) Scale
Measure Description	Decrease from baseline in the NSA scores indicates improvement of efficacy. Range NSA total score is 16 [best]-96 [worst].
Time Frame	Baseline of Protocol 25543 (NCT 00212836) to 365 days (total time for both protocols 25543 & 25544)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent-to-treat population

Reporting Groups

	Description
Asenapine	5-10 mg twice daily (bid) sublingual (SL)
Olanzapine	5-20 mg daily (QD) orally (PO)

Measured Values

	Asenapine	**Olanzapine**
Number of Participants Analyzed [units: participants]	**122**	**157**
Long-term Change in Negative Symptoms of Schizophrenia Measured by the Negative Symptom Assessment (NSA) Scale [units: Units on a Scale] Least Squares Mean (Standard Error)	**-16.9 (0.98)**	**-15.4 (0.85)**

No statistical analysis provided for Long-term Change in Negative Symptoms of Schizophrenia Measured by the Negative Symptom Assessment (NSA) Scale

2. Secondary: Change in Quality of Life Measured by Quality of Life Scale (QLS) [Time Frame: Baseline of Protocol 25543 (NCT 00212836) to 365 days (total time for both protocols 25543 & 25544)]

Measure Type	Secondary
Measure Title	Change in Quality of Life Measured by Quality of Life Scale (QLS)
Measure Description	Increase from baseline in the QLS scores indicates improvement of efficacy. Range QLS total score is 0 [worst]-126 [best].

Time Frame	Baseline of Protocol 25543 (NCT 00212836) to 365 days (total time for both protocols 25543 & 25544)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent-to-treat population

Reporting Groups

	Description
Asenapine	5-10 mg twice daily (bid) sublingual (SL)
Olanzapine	5-20 mg daily (QD) orally (PO)

Measured Values

	Asenapine	**Olanzapine**
Number of Participants Analyzed [units: participants]	**122**	**157**
Change in Quality of Life Measured by Quality of Life Scale (QLS) [units: Units on a Scale] Least Squares Mean (Standard Error)	**18.7 (1.64)**	**16.4 (1.4)**

No statistical analysis provided for Change in Quality of Life Measured by Quality of Life Scale (QLS)

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
Asenapine	No text entered.
Olanzapine	No text entered.

Serious Adverse Events

	Asenapine	**Olanzapine**
Total, serious adverse events		
	9/134 (6.72%)	**6/172 (3.49%)**

# participants affected / at risk		
Cardiac disorders		
Myocardial infarction † 1		
# participants affected / at risk	0/134 (0.00%)	1/172 (0.58%)
# events	0	1
Gastrointestinal disorders		
Nausea † 1		
# participants affected / at risk	0/134 (0.00%)	1/172 (0.58%)
# events	0	1
Vomiting † 1		
# participants affected / at risk	0/134 (0.00%)	1/172 (0.58%)
# events	0	1
Infections and infestations		
Salmonellosis † 1		
# participants affected / at risk	1/134 (0.75%)	0/172 (0.00%)
# events	1	0
Injury, poisoning and procedural complications		
Fall † 1		
# participants affected / at risk	1/134 (0.75%)	0/172 (0.00%)
# events	1	0
Fibula fracture † 1		
# participants affected / at risk	1/134 (0.75%)	0/172 (0.00%)
# events	1	0
Metabolism and nutrition disorders		
Dehydration † 1		
# participants affected / at risk	0/134 (0.00%)	1/172 (0.58%)
# events	0	1
Nervous system disorders		
Dementia † 1		
# participants affected / at risk	1/134 (0.75%)	0/172 (0.00%)
# events	1	0
Psychiatric disorders		
Anxiety † 1		
# participants affected / at risk	1/134 (0.75%)	0/172 (0.00%)
# events	1	0
Nervousness † 1		
# participants affected / at risk	1/134 (0.75%)	0/172 (0.00%)
# events	3	0
Psychotic disorder † 1		
# participants affected / at risk	1/134 (0.75%)	0/172 (0.00%)
# events	1	0
Schizophrenia † 1		

# participants affected / at risk	4/134 (2.99%)	3/172 (1.74%)
# events	4	3
Stress † 1		
# participants affected / at risk	1/134 (0.75%)	0/172 (0.00%)
# events	3	0
Surgical and medical procedures		
Surgery † 1		
# participants affected / at risk	0/134 (0.00%)	1/172 (0.58%)
# events	0	1

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 10.1

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Asenapine	No text entered.
Olanzapine	No text entered.

Other Adverse Events

	Asenapine	Olanzapine
Total, other (not including serious) adverse events		
# participants affected / at risk	19/134 (14.18%)	21/172 (12.21%)
Infections and infestations		
Influenza † 1		
# participants affected / at risk	7/134 (5.22%)	3/172 (1.74%)
# events	7	3
Investigations		
Weight increased † 1		
# participants affected / at risk	0/134 (0.00%)	11/172 (6.40%)
# events	0	11

Nervous system disorders		
Headache † 1		
# participants affected / at risk	**7/134 (5.22%)**	**7/172 (4.07%)**
# events	**8**	**8**
Psychiatric disorders		
Schizophrenia † 1		
# participants affected / at risk	**7/134 (5.22%)**	**1/172 (0.58%)**
# events	**8**	**1**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 10.1

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data

No text entered.

More Information

Hide More Information

Certain Agreements:

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

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

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

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

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

☑ **Restriction Description:** Publication/presentation of data may not be made without prior review and comment by the Sponsor; all reasonable comments of Sponsor will be incorporated as far as the scientific data content is not impaired. A complete copy shall be provided to the Sponsor at least 60 days prior to date of submission. Participation in the Study involves a commitment to publish data from the study in a cooperative publication prior to publication/presentation or on an individual basis.

Results Point of Contact:

Name/Title: Senior Vice President, Global Clinical Development
Organization: Merck Sharp & Dohme Corp.
e-mail: ClinicalTrialsDisclosure@merck.com

Publications of Results:

Buchanan RW, Panagides J, Zhao J, Phiri P, den Hollander W, Ha X, Kouassi A, Alphs L, Schooler N, Szegedi A, Cazorla P. Asenapine versus

olanzapine in people with persistent negative symptoms of schizophrenia. J Clin Psychopharmacol. 2012 Feb;32(1):36-45. doi: 10.1097/JCP.0b013e31823f880a.

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Health Authority:	Finland: Finnish Medicines Agency

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