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Trial record **1 of 1** for: MSA-RAS-202

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Clinical Trial to Assess Efficacy, Safety, and Tolerability of Rasagiline Mesylate 1 mg in Patients With Multiple System Atrophy of the Parkinsonian Subtype (MSA-P)

This study has been completed.

Sponsor:
Teva Pharmaceutical Industries

Collaborator:
H. Lundbeck A/S

Information provided by (Responsible Party):
Teva Pharmaceutical Industries

ClinicalTrials.gov Identifier:
NCT00977665

First received: September 15, 2009
Last updated: February 10, 2015
Last verified: February 2015
History of Changes

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Purpose

To test the clinical effect of rasagiline on subjects with MSA of the parkinsonian subtype.

Condition	Intervention	Phase
Multiple System Atrophy	Drug: rasagiline mesylate Drug: placebo	Phase 2

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

Official Title: A Multi-centered, Randomized, Double-blind, Placebo-controlled Clinical Trial to Assess the Efficacy, Safety, and Tolerability of Rasagiline Mesylate 1 mg in Patients With Multiple System Atrophy of the Parkinsonian Subtype (MSA-P)

Resource links provided by NLM:

Genetics Home Reference related topics: multiple system atrophy

Drug Information available for: Rasagiline mesylate

Genetic and Rare Diseases Information Center resources: Multiple System Atrophy Multiple System Atrophy (MSA) With Orthostatic Hypotension Proximal Spinal Muscular Atrophy

U.S. FDA Resources

Further study details as provided by Teva Pharmaceutical Industries:

Primary Outcome Measures:

- Change From Baseline to Week 48/Termination Visit in the Total Unified Multiple System Atrophy Rating Scale (UMSARS Part I and II) [Time Frame: Day 0 (baseline), Week 48] [Designated as safety issue: No]

  This outcome represents the sum of 2 UMSARS sub-scales: Part I: Historical Review that includes 12 items and Part II: Motor Examination that includes 14 items. All items range from 0 to 4. Each subscale score is the sum of its items and the total UMSARS score is the sum of all 26 items. Hence the total UMSARS score can range from 0 to 104, with 0 meaning no impairment and 104 indicating severe impairment. Negative

change from baseline scores indicate improvement.In the case that 6 items or more (out of 26) were missing at a certain visit, the UMSARS score for that visit was assigned a missing value.

Secondary Outcome Measures:

- Clinical Global Impression Improvement (CGI-I) at Week 48/Termination Visit [Time Frame: Week 48] [Designated as safety issue: No]

  Outcome measures the investigator's clinical impression of the participants' improvement at Week 48 as compared to Week 12. CGI scale range from 1-7, with 1=very much improved, 4= no change, and 7=very much worse.In order to maintain the overall (hypotheses about primary and key secondary endpoints) type I error at the 0.05 level an hierarchy will be employed as follows: If the primary endpoint will be found to be significant at a significance level of 0.05 then the first key secondary endpoint will be tested, if this endpoint will be found to be significant in a significance level of 0.05 then the second key secondary endpoint will be tested and so on. The 'key' secondary endpoints are outcomes 2-6.

- Change From Baseline to Week 24 in Total Unified Multiple System Atrophy Rating Scale (UMSARS) Score [Time Frame: Day 0 (baseline), Week 24] [Designated as safety issue: No]

  The UMSARS is composed of 2 sub-scales: Part I: Historical Review that includes 12 items and Part II: Motor Examination that includes 14 items. All items range from 0 to 4. Each subscale score is the sum of its items and the total UMSARS score is the sum of all 26 items. Hence the total UMSARS score can range from 0 to 104, with 0 meaning no impairment and 104 indicating severe impairment. Negative change from baseline scores indicate improvement.In the case that 6 items or more (out of 26) were missing at a certain visit, the UMSARS score for that visit was assigned a missing value.

- Percentage of Participants Who Achieved a Score of >=3 on the Unified Multiple System Atrophy Rating Scale (UMSARS) Question #7 Regarding Ambulation [Time Frame: up to week 48] [Designated as safety issue: No]

  UMSARS' Question #7 concerns the participant's ability to walk, rated on a scale of 0=normal to 4=cannot walk at all even with assistance. This endpoint counts participants rated a 3 or worse. Rating 3 = Severely impaired; assistance and/or walking aid needed occasionally.

- Mean Score of the Composite Autonomic Symptom Scale Select (COMPASS_Select Change) at Week 48/Termination Visit [Time Frame: 48 weeks] [Designated as safety issue: No]

  COMPASS_Select change is comprised of 5 of the 11 domains in the COMPASS scale: Orthostatic Intolerance, Bladder Disorder, Sweating, Vasomotor, and Sleep Disorder COMPASS_Select change has a range of -150 to 150, with -150 indicating symptoms are much better and 150 indicating symptoms are much worse.

- Change From Baseline to Week 48/Termination Visit in the Multiple System Atrophy (MSA) Health-related Quality of Life (QoL) Scale [Time Frame: Day 0 (baseline), Week 48] [Designated as safety issue: No]

  The Multiple System Atrophy Quality of Life questionnaire (MSA-QoL) is a self-reported questionnaire focusing on MSA-specific symptoms and has a scale ranging from 0 - 160, with 0= 'no problem' and 160= "extreme problem".

- Rate of Progression in Total Unified Multiple System Atrophy Rating Scale (UMSARS) Score From Baseline to Weeks 12-48 [Time Frame: Day 0 (baseline), Weeks 12-48] [Designated as safety issue: No]

  The UMSARS is composed of 2 sub-scales: Part I: Historical Review that includes 12 items and Part II: Motor Examination that includes 14 items. All items range from 0 to 4. Each subscale score is the sum of its items and the total UMSARS score is the sum of all 26 items. Hence the total UMSARS score can range from 0 to 104, with 0 meaning no impairment and 104 indicating severe impairment.The rate of progression of atrophy is represented by the slope of change from baseline scores for visits between Weeks 12 and 48.

- Change From Baseline to Week 48 or Termination in UMSARS Subscores for Parts I, II and IV [Time Frame: Day 0 (baseline), Week 48 or termination visit] [Designated as safety issue: No]

  UMSARS Part I is an historical review and scores symptoms of neurological and autonomic dysfunction with 12 items rated on a scale of 0 (normal) to 4 (extreme dysfunction). The full scale for Part 1 is therefore 0 (normal) to 48 (extreme dysfunction). Part II is a motor examination and has 14 items also rated on a scale of 0 to 4 for a full scale of 0 (normal) to 56 (extreme dysfunction). Part IV is a global disability scale with rates the extent of disease from 1 (normal) to 5 (severe disease).

- Change From Baseline to Week 12 in Total UMSARS Score for Symptomatic Effect [Time Frame: Day 0 (baseline), Week 12] [Designated as safety issue: No]

  This outcome represents the sum of 2 UMSARS sub-scales: Part I: Historical Review that includes 12 items and Part II: Motor Examination that includes 14 items. All items range from 0 to 4. Each subscale score is the sum of its items and the total UMSARS score is the sum of all 26 items. Hence the total UMSARS score can range from 0 to 104, with 0 meaning no impairment and 104 indicating severe impairment. Negative change from baseline scores indicate improvement.

- Estimates for Time to Change in Anti-Parkinsonian or Anti-Orthostatis Hypotension Medications [Time Frame: Day 0 (baseline) to Week 48 or termination visit] [Designated as safety issue: No]

  Change in anti-parkinsonian or anti-orthostatic hypotension medication is defined by at least one of the following events:

a. An addition of a new anti-parkinsonian or anti-orthostatic hypotension medication during study.
b. Dose modification of anti-parkinsonian or anti-orthostatic hypotension concomitant medications reflecting disease progression.

The event of interest, determined on a by patient basis, therefore, is the earliest event of the two events defined above. Otherwise, patient is right censored according to his/her study termination date.Since less than 25% of participants had an event, median estimatation for time to change in medications is not possible.

- Change From Baseline to Week 48 or Termination in the Montreal Cognitive Assessment Scale (MoCA) Scale [Time Frame: Day 0 (baseline), Week 48 or termination visit] [Designated as safety issue: No]

  MoCA is a cognitive screening test which helps health professionals identify mild cognitive impairment. The total scale is 0 (significant cognitive impairment) to 30 (no impairment detected). Scores >=26 are considered normal. Positive change from baseline scores indicate improvement in cognition.

- Percentage of Participants Who Achieved a Score of >=3 on the Unified Multiple System Atrophy Rating Scale (UMSARS) Question #1 (Speech Impairment), Question #2 (Swallowing Impairment) and Question #8 (Falling) [Time Frame: up to week 48]
  [Designated as safety issue: No]

  UMSARS' questions are rated on a scale of 0=normal to 4=extreme impairment.This endpoint reports the percentage of participants rated a 3 or worse. Rating 3 = Severely impaired speech (Question #1), swallowing (Question #2) or falling more frequently than once per week (Question #8).

- Change From Baseline to Week 48 or Termination in the Beck Depression Inventory Scale (BDI-II) [Time Frame: Day 0 (baseline), Week 48 or termination visit] [Designated as safety issue: No]

  The Beck Depression Inventory (BDI-II), is a 21-question multiple-choice self-report inventory, one of the most widely used instruments for measuring the severity of depression. Participants are asked to pick the answer for each question that best describes the way they have been feeling in the past two weeks, including the day participants complete the questionnaire. Each question is rated on a scale of 0-3, with 0 meaning the participant does not feel the emotion described in the question, and 3 meaning the participant has extremely strong feelings. Total scale is 0 (no evidence of depression) to 63 (extreme depression). Negative change from baseline scores indicate improvement in level of depression.

- Total Number of Falls During the Study [Time Frame: Day 1 up to week 48] [Designated as safety issue: No]

  Participants recorded each time they fell during the study in a diary.

Enrollment:	174
Study Start Date:	December 2009
Study Completion Date:	October 2011
Primary Completion Date:	October 2011 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: rasagiline mesylate rasagiline tablet, 1 mg/day for up to 48 weeks.	Drug: rasagiline mesylate rasagiline 1 mg tablet/day for 48 weeks Other Names: • Azilect • TVP-1012
Placebo Comparator: placebo placebo tablet for up to 48 weeks.	Drug: placebo placebo tablet for 48 weeks Other Name: placebo

Eligibility

Ages Eligible for Study:	30 Years and older
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria
Inclusion Criteria:

- Subjects over 30 years old with a diagnosis of Possible or Probable MSA of the parkinsonian subtype (MSA-P) according to The Gilman Criteria (2008).
- Subjects who are less than 3 years from the time of documented MSA diagnosis.

- Subjects with an anticipated survival of at least 3 years in the opinion of the investigator.
- Subjects who are willing and able to give informed consent. Subjects who are not able to write may give verbal consent in the presence of at least one witness, and the witness should sign the informed consent form.

Exclusion Criteria:

- Subjects receiving treatment with midodrine or other sympathomimetics within 4 weeks prior to baseline visit.
- Subjects with severe orthostatic symptoms as assessed by a score of ≥ 3 on Unified Multiple System Atrophy Rating Scale (UMSARS) question 9.
- Subjects who meet any of the following criteria which tend to suggest advanced disease:
  a. Speech impairment as assessed by a score of ≥ 3 on UMSARS question 1
  b. Swallowing impairment as assessed by a score of ≥ 3 on UMSARS question 2
  c. Impairment in ambulation as assessed by a score of ≥ 3 on UMSARS question 7
  d. Falling more frequently than once per week as assessed by a score of ≥ 3 on UMSARS question 8
- Subjects taking disallowed medications according to the locally approved Azilect® label.
- Subjects taking monoamine oxidase (MAO) inhibitors within 3 months prior to baseline visit.
- Subjects with hypertension whose blood pressure, in the investigator's opinion, is not well controlled.
- Subjects who, based on the investigator's judgment, have a clinically significant or unstable medical or surgical condition that may preclude safe and complete study participation. Subjects with moderate or severe hepatic impairment.
- Subjects who have taken any investigational products within 60 days prior to baseline.
- Women of child-bearing potential who do not practice an acceptable method of birth control [acceptable methods of birth control in this study are: surgical sterilization, intrauterine devices, oral contraceptive, contraceptive patch, long-acting injectable contraceptive, partner's vasectomy, a double-protection method (condom or diaphragm with spermicide)].
- Pregnant or nursing women.

Contacts and Locations

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

Please refer to this study by its ClinicalTrials.gov identifier: NCT00977665

Hide Study Locations

Locations

United States, California

Teva Investigational Site 1004
Irvine, California, United States

Teva Investigational Site 1014
La Jolla, California, United States

Teva Investigational Site 1006
Sunnyvale, California, United States

United States, District of Columbia

Teva Investigational Site 1010
Washington, District of Columbia, United States

United States, Florida

Teva Investigational Site 1061
Boca Raton, Florida, United States

Teva Investigational Site 1012
Tampa, Florida, United States

United States, Massachusetts

Teva Investigational Site 1009
Worcester, Massachusetts, United States

United States, Michigan

Teva Investigational Site 1003
Ann Arbor, Michigan, United States

United States, Minnesota

Teva Investigational Site 1007
Rochester, Minnesota, United States

United States, Missouri

Teva Investigational Site 1011
St. Louis, Missouri, United States

United States, New York

Teva Investigational Site 1008
Rochester, New York, United States

United States, Ohio

Teva Investigational Site 1001
Cleveland, Ohio, United States

United States, Pennsylvania

Teva Investigational Site 1002
Philadelphia, Pennsylvania, United States

United States, Tennessee

Teva Investigational Site 1013
Nashville, Tennessee, United States

United States, Texas

Teva Investigational Site 1005
Houston, Texas, United States

Austria

Teva Investigational Site 3305
Graz, Austria

Teva Investigational Site 3304
Innsbruck, Austria

Canada, Ontario

Teva Investigational Site 1109
Ottawa, Ontario, Canada

Canada, Quebec

Teva Investigational Site 1111
Greenfield Park, Quebec, Canada

Teva Investigational Site 1108
Montréal, Quebec, Canada

Teva Investigational Site 1110
Québec, Quebec, Canada

France

Teva Investigational Site 3503
Lille Cedex, France

Teva Investigational Site 3502
Pessac, France

Germany

Teva Investigational Site 3206
Dresden, Germany

Teva Investigational Site 3203
Kiel, Germany

Teva Investigational Site 3201
Marburg, Germany

Teva Investigational Site 3205
Muenchen, Germany

Teva Investigational Site 3204
Tuebingen, Germany

Teva Investigational Site 3202

Ulm, Germany

Hungary

Teva Investigational Site 5101
Budapest, Hungary

Teva Investigational Site 5102
Debrecen, Hungary

Teva Investigational Site 5103
Miskolc, Hungary

Israel

Teva Investigational Site 8002
Ramat -Gan, IL, Israel

Teva Investigational Site 8004
Haifa, Israel

Teva Investigational Site 8003
Tel Aviv, Israel

Italy

Teva Investigational Site 3006
Bologna, Italy

Teva Investigational Site 3004
Roma, Italy

Teva Investigational Site 3005
Venezia - Lido, Italy

Netherlands

Teva Investigational Site 3801
Amersfoort, Netherlands

Teva Investigational Site 3802
Sittard-Geleen, Netherlands

Portugal

Teva Investigational Site 3603
Lisbon, Portugal

Spain

Teva Investigational Site 3101
Barcelona, Spain

Teva Investigational Site 3102
Barcelona, Spain

Teva Investigational Site 3103
Sevilla, Spain

United Kingdom

Teva Investigational Site 3403
Cardiff, Wales, United Kingdom

Teva Investigational Site 3401
London, United Kingdom

Teva Investigational Site 3402
Newcastle-Upon-Tyne, United Kingdom

Sponsors and Collaborators

Teva Pharmaceutical Industries

H. Lundbeck A/S

Investigators

Principal Investigator: Werner Poewe, Prof Innsbruck Medical University, Innsbruck, Austria

More Information

No publications provided

Responsible Party:	Teva Pharmaceutical Industries
ClinicalTrials.gov Identifier:	NCT00977665 History of Changes
Other Study ID Numbers:	**MSA-RAS-202**, 2009-014644-11
Study First Received:	September 15, 2009
Results First Received:	February 10, 2015
Last Updated:	February 10, 2015
Health Authority:	United States: Food and Drug Administration

Additional relevant MeSH terms:

Atrophy
Multiple System Atrophy
Shy-Drager Syndrome
Autonomic Nervous System Diseases
Basal Ganglia Diseases
Brain Diseases
Cardiovascular Diseases
Central Nervous System Diseases
Hypotension
Movement Disorders
Nervous System Diseases
Neurodegenerative Diseases
Pathological Conditions, Anatomical
Primary Dysautonomias
Vascular Diseases
Rasagiline
Central Nervous System Agents
Enzyme Inhibitors
Molecular Mechanisms of Pharmacological Action
Monoamine Oxidase Inhibitors
Neuroprotective Agents
Pharmacologic Actions
Physiological Effects of Drugs
Protective Agents
Therapeutic Uses

ClinicalTrials.gov processed this record on May 04, 2015

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Clinical Trial to Assess Efficacy, Safety, and Tolerability of Rasagiline Mesylate 1 mg in Patients With Multiple System Atrophy of the Parkinsonian Subtype (MSA-P)

This study has been completed.

Sponsor:
Teva Pharmaceutical Industries

Collaborator:
H. Lundbeck A/S

Information provided by (Responsible Party):
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ClinicalTrials.gov Identifier:
NCT00977665

First received: September 15, 2009
Last updated: February 10, 2015
Last verified: February 2015
History of Changes

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Results First Received: February 10, 2015

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Multiple System Atrophy
Interventions:	Drug: rasagiline mesylate Drug: placebo

Participant Flow

Hide Participant Flow

Recruitment Details

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

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Eligible participants were randomized in a 1:1 ratio to either active treatment or placebo.

Reporting Groups

	Description
Rasagiline Mesylate	rasagiline tablet, 1 mg/day for up to 48 weeks.
Placebo	placebo tablet for up to 48 weeks.

Participant Flow: Overall Study

	Rasagiline Mesylate	**Placebo**
STARTED	**84**	**90**
COMPLETED	**63**	**75**

NOT COMPLETED	**21**	**15**
Withdrawal by Subject	**1**	**3**
Physician Decision	**2**	**1**
Sponsor requested withdrawal	**0**	**1**
Lost to Follow-up	**1**	**0**
Death	**3**	**2**
Adverse Event	**14**	**7**
Treatment failure	**0**	**1**

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
Rasagiline Mesylate	rasagiline tablet, 1 mg/day for up to 48 weeks.
Placebo	placebo tablet for up to 48 weeks.
Total	Total of all reporting groups

Baseline Measures

	Rasagiline Mesylate	**Placebo**	**Total**
Number of Participants [units: participants]	**84**	**90**	**174**
Age [units: years] Mean (Standard Deviation)	**64.9 (8.5)**	**65.1 (8.6)**	**65.0 (8.5)**
Gender [units: participants]			
Female	**35**	**39**	**74**
Male	**49**	**51**	**100**
Race/Ethnicity, Customized [units: participants]			
Asian/Oriental	**0**	**2**	**2**
Black of African Heritage	**2**	**0**	**2**
Black or African American	**0**	**2**	**2**
Caucasian	**81**	**85**	**166**
Unknown	**1**	**1**	**2**
Region of Enrollment [units: participants]			
Portugal	**2**	**3**	**5**
United States	**16**	**16**	**32**

France	**9**	**8**	**17**
Hungary	**11**	**10**	**21**
Canada	**10**	**10**	**20**
Spain	**4**	**3**	**7**
Austria	**3**	**4**	**7**
Israel	**9**	**12**	**21**
Germany	**7**	**12**	**19**
Netherlands	**3**	**2**	**5**
Italy	**8**	**8**	**16**
United Kingdom	**2**	**2**	**4**
Weight [units: kg] Mean (Standard Deviation)	**76.9 (15.9)**	**76.8 (15.5)**	**76.9 (15.6)**
Height [units: cm] Mean (Standard Deviation)	**168.0 (10.2)**	**169.0 (8.9)**	**168.5 (9.6)**
Body Mass Index [units: kg/m^2] Mean (Standard Deviation)	**27.2 (4.4)**	**26.8 (4.4)**	**27.0 (4.4)**
Multiple System Atrophy of the Parkinsonian Subtype (MSA-P) [1] **[units: participants]**			
Possible MSA-P	**38**	**55**	**93**
Probable MSA-P	**46**	**35**	**81**

[1] Possible or Probable MSA of the parkinsonian subtype (MSA-P) is according to The Gilman Criteria (2008).

- Possible MSA requires a sporadic, progressive adult-onset disease including parkinsonism and at least one feature suggesting autonomic dysfunction plus one other feature that may be a clinical or a neuroimaging abnormality.
- Probable MSA requires a sporadic, progressive adult-onset disorder including rigorously defined autonomic failure and poorly levodopa-responsive parkinsonism.

Outcome Measures

Hide All Outcome Measures

1. Primary: Change From Baseline to Week 48/Termination Visit in the Total Unified Multiple System Atrophy Rating Scale (UMSARS Part I and II) [Time Frame: Day 0 (baseline), Week 48]

Measure Type	Primary
Measure Title	Change From Baseline to Week 48/Termination Visit in the Total Unified Multiple System Atrophy Rating Scale (UMSARS Part I and II)
Measure Description	This outcome represents the sum of 2 UMSARS sub-scales: Part I: Historical Review that includes 12 items and Part II: Motor Examination that includes 14 items. All items range from 0 to 4. Each subscale score is the sum of its items and the total UMSARS score is the sum of all 26 items. Hence the total UMSARS score can range from 0 to 104, with 0 meaning no impairment and 104 indicating severe impairment. Negative change from baseline scores indicate improvement. In the case that 6 items or more (out of 26) were missing at a certain visit, the UMSARS score for that visit was assigned a missing value.
Time Frame	Day 0 (baseline), Week 48
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.
Modified Intention-To-Treat Analysis Set (mITT): all randomized participants who took at least one dose of the study drug and who had at least one post-baseline efficacy assessment were included in the principal efficacy analysis, according to the treatment group to which they were originally assigned.

Reporting Groups

	Description
Rasagiline Mesylate	rasagiline tablet, 1 mg/day for up to 48 weeks.
Placebo	placebo tablet for up to 48 weeks.

Measured Values

	Rasagiline Mesylate	**Placebo**
Number of Participants Analyzed [units: participants]	**81**	**90**
Change From Baseline to Week 48/Termination Visit in the Total Unified Multiple System Atrophy Rating Scale (UMSARS Part I and II) [units: units on a scale] Least Squares Mean (Standard Error)	**7.2 (1.186)**	**7.8 (1.091)**

Statistical Analysis 1 for Change From Baseline to Week 48/Termination Visit in the Total Unified Multiple System Atrophy Rating Scale (UMSARS Part I and II)

Groups [1]	All groups
Method [2]	repeated measures model
P Value [3]	0.6984
Mean Difference (Final Values) [4]	-0.603
95% Confidence Interval	-3.677 to 2.470

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Fixed effects: categorical week in trial by treatment interaction, center, and baseline UMSARS score.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	A priori threshold for statistical significance is 0.05.
[4]	Other relevant estimation information:
	No text entered.

2. Secondary: Clinical Global Impression Improvement (CGI-I) at Week 48/Termination Visit [Time Frame: Week 48]

Measure Type	Secondary
Measure Title	Clinical Global Impression Improvement (CGI-I) at Week 48/Termination Visit

Measure Description	Outcome measures the investigator's clinical impression of the participants' improvement at Week 48 as compared to Week 12. CGI scale range from 1-7, with 1=very much improved, 4= no change, and 7=very much worse. In order to maintain the overall (hypotheses about primary and key secondary endpoints) type I error at the 0.05 level an hierarchy will be employed as follows: If the primary endpoint will be found to be significant at a significance level of 0.05 then the first key secondary endpoint will be tested, if this endpoint will be found to be significant in a significance level of 0.05 then the second key secondary endpoint will be tested and so on. The 'key' secondary endpoints are outcomes 2 -6.
Time Frame	Week 48
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.
Modified Intention-To-Treat Analysis Set (mITT): all randomized participants who took at least one dose of the study drug and who had at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Rasagiline Mesylate	rasagiline tablet, 1 mg/day for up to 48 weeks.
Placebo	placebo tablet for up to 48 weeks.

Measured Values

	Rasagiline Mesylate	**Placebo**
Number of Participants Analyzed [units: participants]	**80**	**88**
Clinical Global Impression Improvement (CGI-I) at Week 48/Termination Visit [units: units on a scale] Least Squares Mean (Standard Error)	**4.9 (0.152)**	**4.8 (0.139)**

No statistical analysis provided for Clinical Global Impression Improvement (CGI-I) at Week 48/Termination Visit

3. Secondary: Change From Baseline to Week 24 in Total Unified Multiple System Atrophy Rating Scale (UMSARS) Score [Time Frame: Day 0 (baseline), Week 24]

Measure Type	Secondary
Measure Title	Change From Baseline to Week 24 in Total Unified Multiple System Atrophy Rating Scale (UMSARS) Score
Measure Description	The UMSARS is composed of 2 sub-scales: Part I: Historical Review that includes 12 items and Part II: Motor Examination that includes 14 items. All items range from 0 to 4. Each subscale score is the sum of its items and the total UMSARS score is the sum of all 26 items. Hence the total UMSARS score can range from 0 to 104, with 0 meaning no impairment and 104 indicating severe impairment. Negative change from baseline scores indicate improvement. In the case that 6 items or more (out of 26) were missing at a certain visit, the UMSARS score for that visit was assigned a missing value.
Time Frame	Day 0 (baseline), Week 24
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.
Modified Intention-To-Treat Analysis Set (mITT): all randomized participants who took at least one dose of the study drug and who had at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Rasagiline Mesylate	rasagiline tablet, 1 mg/day for up to 48 weeks.
Placebo	placebo tablet for up to 48 weeks.

Measured Values

	Rasagiline Mesylate	Placebo
Number of Participants Analyzed [units: participants]	**81**	**90**
Change From Baseline to Week 24 in Total Unified Multiple System Atrophy Rating Scale (UMSARS) Score [units: units on a scale] Least Squares Mean (Standard Error)	**3.8 (0.811)**	**3.0 (0.760)**

No statistical analysis provided for Change From Baseline to Week 24 in Total Unified Multiple System Atrophy Rating Scale (UMSARS) Score

4. Secondary: Percentage of Participants Who Achieved a Score of >=3 on the Unified Multiple System Atrophy Rating Scale (UMSARS) Question #7 Regarding Ambulation [Time Frame: up to week 48]

Measure Type	Secondary
Measure Title	Percentage of Participants Who Achieved a Score of >=3 on the Unified Multiple System Atrophy Rating Scale (UMSARS) Question #7 Regarding Ambulation
Measure Description	UMSARS' Question #7 concerns the participant's ability to walk, rated on a scale of 0=normal to 4=cannot walk at all even with assistance. This endpoint counts participants rated a 3 or worse. Rating 3 = Severely impaired; assistance and/or walking aid needed occasionally.
Time Frame	up to week 48
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.
Modified Intention-To-Treat Analysis Set (mITT): all randomized participants who took at least one dose of the study drug and who had at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Rasagiline Mesylate	rasagiline tablet, 1 mg/day for up to 48 weeks.
Placebo	placebo tablet for up to 48 weeks.

Measured Values

	Rasagiline Mesylate	Placebo
Number of Participants Analyzed [units: participants]	**81**	**90**
Percentage of Participants Who Achieved a Score of >=3 on the Unified Multiple System Atrophy Rating Scale (UMSARS) Question #7 Regarding Ambulation [units: percentage of participants]	**46.4**	**52.2**

No statistical analysis provided for Percentage of Participants Who Achieved a Score of >=3 on the Unified Multiple System Atrophy Rating

Scale (UMSARS) Question #7 Regarding Ambulation

5. Secondary: Mean Score of the Composite Autonomic Symptom Scale Select (COMPASS_Select Change) at Week 48/Termination Visit [Time Frame: 48 weeks]

Measure Type	Secondary
Measure Title	Mean Score of the Composite Autonomic Symptom Scale Select (COMPASS_Select Change) at Week 48/Termination Visit
Measure Description	COMPASS_Select change is comprised of 5 of the 11 domains in the COMPASS scale: Orthostatic Intolerance, Bladder Disorder, Sweating, Vasomotor, and Sleep Disorder COMPASS_Select change has a range of -150 to 150, with -150 indicating symptoms are much better and 150 indicating symptoms are much worse.
Time Frame	48 weeks
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.
Modified Intention-To-Treat Analysis Set (mITT): all randomized participants who took at least one dose of the study drug and who had at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Rasagiline Mesylate	rasagiline tablet, 1 mg/day for up to 48 weeks.
Placebo	placebo tablet for up to 48 weeks.

Measured Values

	Rasagiline Mesylate	**Placebo**
Number of Participants Analyzed [units: participants]	**79**	**90**
Mean Score of the Composite Autonomic Symptom Scale Select (COMPASS_Select Change) at Week 48/Termination Visit [units: units on a scale] Least Squares Mean (Standard Error)	**34.1 (4.342)**	**42.7 (4.025)**

No statistical analysis provided for Mean Score of the Composite Autonomic Symptom Scale Select (COMPASS_Select Change) at Week 48/Termination Visit

6. Secondary: Change From Baseline to Week 48/Termination Visit in the Multiple System Atrophy (MSA) Health-related Quality of Life (QoL) Scale [Time Frame: Day 0 (baseline), Week 48]

Measure Type	Secondary
Measure Title	Change From Baseline to Week 48/Termination Visit in the Multiple System Atrophy (MSA) Health-related Quality of Life (QoL) Scale
Measure Description	The Multiple System Atrophy Quality of Life questionnaire (MSA-QoL) is a self-reported questionnaire focusing on MSA-specific symptoms and has a scale ranging from 0 - 160, with 0= 'no problem' and 160= "extreme problem".
Time Frame	Day 0 (baseline), Week 48
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.
Modified Intention-To-Treat Analysis Set (mITT): all randomized participants who took at least one dose of the study drug and who had at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Rasagiline Mesylate	rasagiline tablet, 1 mg/day for up to 48 weeks.
Placebo	placebo tablet for up to 48 weeks.

Measured Values

	Rasagiline Mesylate	**Placebo**
Number of Participants Analyzed [units: participants]	**74**	**82**
Change From Baseline to Week 48/Termination Visit in the Multiple System Atrophy (MSA) Health-related Quality of Life (QoL) Scale [units: units on a scale] Least Squares Mean (Standard Error)	**4.6 (2.877)**	**9.3 (2.720)**

No statistical analysis provided for Change From Baseline to Week 48/Termination Visit in the Multiple System Atrophy (MSA) Health-related Quality of Life (QoL) Scale

7. Secondary: Rate of Progression in Total Unified Multiple System Atrophy Rating Scale (UMSARS) Score From Baseline to Weeks 12-48 [Time Frame: Day 0 (baseline), Weeks 12-48]

Measure Type	Secondary
Measure Title	Rate of Progression in Total Unified Multiple System Atrophy Rating Scale (UMSARS) Score From Baseline to Weeks 12-48
Measure Description	The UMSARS is composed of 2 sub-scales: Part I: Historical Review that includes 12 items and Part II: Motor Examination that includes 14 items. All items range from 0 to 4. Each subscale score is the sum of its items and the total UMSARS score is the sum of all 26 items. Hence the total UMSARS score can range from 0 to 104, with 0 meaning no impairment and 104 indicating severe impairment. The rate of progression of atrophy is represented by the slope of change from baseline scores for visits between Weeks 12 and 48.
Time Frame	Day 0 (baseline), Weeks 12-48
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.
Modified Intention-To-Treat Analysis Set (mITT): all randomized participants who took at least one dose of the study drug and who had at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Rasagiline Mesylate	rasagiline tablet, 1 mg/day for up to 48 weeks.
Placebo	placebo tablet for up to 48 weeks.

Measured Values

	Rasagiline Mesylate	Placebo
Number of Participants Analyzed [units: participants]	**81**	**90**
Rate of Progression in Total Unified Multiple System Atrophy Rating Scale (UMSARS) Score From Baseline to Weeks 12-48 [units: units on a scale/week] Mean (Standard Error)	**0.1496 (0.02843)**	**0.1788 (0.02591)**

No statistical analysis provided for Rate of Progression in Total Unified Multiple System Atrophy Rating Scale (UMSARS) Score From Baseline to Weeks 12-48

8. Secondary: Change From Baseline to Week 48 or Termination in UMSARS Subscores for Parts I, II and IV [Time Frame: Day 0 (baseline), Week 48 or termination visit]

Measure Type	Secondary
Measure Title	Change From Baseline to Week 48 or Termination in UMSARS Subscores for Parts I, II and IV
Measure Description	UMSARS Part I is an historical review and scores symptoms of neurological and autonomic dysfunction with 12 items rated on a scale of 0 (normal) to 4 (extreme dysfunction). The full scale for Part 1 is therefore 0 (normal) to 48 (extreme dysfunction). Part II is a motor examination and has 14 items also rated on a scale of 0 to 4 for a full scale of 0 (normal) to 56 (extreme dysfunction). Part IV is a global disability scale with rates the extent of disease from 1 (normal) to 5 (severe disease).
Time Frame	Day 0 (baseline), Week 48 or termination visit
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.
Modified Intention-To-Treat Analysis Set (mITT): all randomized participants who took at least one dose of the study drug and who had at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Rasagiline Mesylate	rasagiline tablet, 1 mg/day for up to 48 weeks.
Placebo	placebo tablet for up to 48 weeks.

Measured Values

	Rasagiline Mesylate	Placebo
Number of Participants Analyzed [units: participants]	**81**	**90**
Change From Baseline to Week 48 or Termination in UMSARS Subscores for Parts I, II and IV [units: units on a scale] Least Squares Mean (Standard Error)		
UMSARS Part I	**3.8233 (0.6339)**	**4.3785 (0.5808)**
UMSARS Part II	**3.6478 (0.7017)**	**3.5068 (0.6445)**
UMSARS Part IV	**0.7100 (0.1040)**	**0.6763 (0.09523)**

No statistical analysis provided for Change From Baseline to Week 48 or Termination in UMSARS Subscores for Parts I, II and IV

9. Secondary: Change From Baseline to Week 12 in Total UMSARS Score for Symptomatic Effect [Time Frame: Day 0 (baseline), Week 12]

Measure Type	Secondary
Measure Title	Change From Baseline to Week 12 in Total UMSARS Score for Symptomatic Effect
Measure Description	This outcome represents the sum of 2 UMSARS sub-scales: Part I: Historical Review that includes 12 items and Part II: Motor Examination that includes 14 items. All items range from 0 to 4. Each subscale score is the sum of its items and the total UMSARS score is the sum of all 26 items. Hence the total UMSARS score can range from 0 to 104, with 0 meaning no impairment and 104 indicating severe impairment. Negative change from baseline scores indicate improvement.
Time Frame	Day 0 (baseline), Week 12
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.
Modified Intention-To-Treat Analysis Set (mITT): all randomized participants who took at least one dose of the study drug and who had at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Rasagiline Mesylate	rasagiline tablet, 1 mg/day for up to 48 weeks.
Placebo	placebo tablet for up to 48 weeks.

Measured Values

	Rasagiline Mesylate	**Placebo**
Number of Participants Analyzed [units: participants]	**79**	**88**
Change From Baseline to Week 12 in Total UMSARS Score for Symptomatic Effect [units: units on a scale] Mean (Standard Deviation)	**1.875 (0.693)**	**1.574 (0.678)**

No statistical analysis provided for Change From Baseline to Week 12 in Total UMSARS Score for Symptomatic Effect

10. Secondary: Estimates for Time to Change in Anti-Parkinsonian or Anti-Orthostatis Hypotension Medications [Time Frame: Day 0 (baseline) to Week 48 or termination visit]

Measure Type	Secondary
Measure Title	Estimates for Time to Change in Anti-Parkinsonian or Anti-Orthostatis Hypotension Medications
Measure Description	Change in anti-parkinsonian or anti-orthostatic hypotension medication is defined by at least one of the following events: 1. An addition of a new anti-parkinsonian or anti-orthostatic hypotension medication during study. 2. Dose modification of anti-parkinsonian or anti-orthostatic hypotension concomitant medications reflecting disease progression. The event of interest, determined on a by patient basis, therefore, is the earliest event of the two events defined above. Otherwise, patient is right censored according to his/her study termination date. Since less than 25% of participants had an event, median estimatation for time to change in medications is not possible.

Time Frame	Day 0 (baseline) to Week 48 or termination visit
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.
Modified Intention-To-Treat Analysis Set (mITT): all randomized participants who took at least one dose of the study drug and who had at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Rasagiline Mesylate	rasagiline tablet, 1 mg/day for up to 48 weeks.
Placebo	placebo tablet for up to 48 weeks.

Measured Values

	Rasagiline Mesylate	**Placebo**
Number of Participants Analyzed [units: participants]	**84**	**90**
Estimates for Time to Change in Anti-Parkinsonian or Anti-Orthostatis Hypotension Medications [units: days] Median (95% Confidence Interval)	**246 (162 to NA)** [1]	**294 (226 to NA)** [1]

[1] Not enough participants had an event for which to a median or upper 95% CI for the 25th percentile can be estimated, hence only the 25th percentile estimate and the lower 95% CI for the 25th percentile are presented

Statistical Analysis 1 for Estimates for Time to Change in Anti-Parkinsonian or Anti-Orthostatis Hypotension Medications

Groups [1]	All groups
Hazard Ratio (HR) [2]	1.189
95% Confidence Interval	0.646 to 2.186

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant estimation information:
	No text entered.

11. Secondary: Change From Baseline to Week 48 or Termination in the Montreal Cognitive Assessment Scale (MoCA) Scale [Time Frame: Day 0 (baseline), Week 48 or termination visit]

Measure Type	Secondary
Measure Title	Change From Baseline to Week 48 or Termination in the Montreal Cognitive Assessment Scale (MoCA) Scale
Measure Description	MoCA is a cognitive screening test which helps health professionals identify mild cognitive impairment. The total scale is 0 (significant cognitive impairment) to 30 (no impairment detected). Scores >=26 are considered normal. Positive change from baseline scores indicate improvement in cognition.
Time Frame	Day 0 (baseline), Week 48 or termination visit
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.
Modified Intention-To-Treat Analysis Set (mITT): all randomized participants who took at least one dose of the study drug and who had at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Rasagiline Mesylate	rasagiline tablet, 1 mg/day for up to 48 weeks.
Placebo	placebo tablet for up to 48 weeks.

Measured Values

	Rasagiline Mesylate	**Placebo**
Number of Participants Analyzed [units: participants]	**73**	**82**
Change From Baseline to Week 48 or Termination in the Montreal Cognitive Assessment Scale (MoCA) Scale [units: units on a scale] Least Squares Mean (Standard Error)	**-1.1572 (0.4590)**	**-0.5786 (0.4186)**

No statistical analysis provided for Change From Baseline to Week 48 or Termination in the Montreal Cognitive Assessment Scale (MoCA) Scale

12. Secondary: Percentage of Participants Who Achieved a Score of >=3 on the Unified Multiple System Atrophy Rating Scale (UMSARS) Question #1 (Speech Impairment), Question #2 (Swallowing Impairment) and Question #8 (Falling) [Time Frame: up to week 48]

Measure Type	Secondary
Measure Title	Percentage of Participants Who Achieved a Score of >=3 on the Unified Multiple System Atrophy Rating Scale (UMSARS) Question #1 (Speech Impairment), Question #2 (Swallowing Impairment) and Question #8 (Falling)
Measure Description	UMSARS' questions are rated on a scale of 0=normal to 4=extreme impairment. This endpoint reports the percentage of participants rated a 3 or worse. Rating 3 = Severely impaired speech (Question #1), swallowing (Question #2) or falling more frequently than once per week (Question #8).
Time Frame	up to week 48
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.
Modified Intention-To-Treat Analysis Set (mITT): all randomized participants who took at least one dose of the study drug and who had at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Rasagiline Mesylate	rasagiline tablet, 1 mg/day for up to 48 weeks.
Placebo	placebo tablet for up to 48 weeks.

Measured Values

	Rasagiline Mesylate	Placebo
Number of Participants Analyzed [units: participants]	**81**	**90**
Percentage of Participants Who Achieved a Score of >=3 on the Unified Multiple System Atrophy Rating Scale (UMSARS) Question #1 (Speech Impairment), Question #2 (Swallowing Impairment) and Question #8 (Falling) [units: percentage of participants]		
Q1. Speech Impairment	**35.7**	**30.0**
Q2. Swallowing Impairment	**3.6**	**6.7**
Q8. Falling	**19.0**	**15.6**

No statistical analysis provided for Percentage of Participants Who Achieved a Score of >=3 on the Unified Multiple System Atrophy Rating Scale (UMSARS) Question #1 (Speech Impairment), Question #2 (Swallowing Impairment) and Question #8 (Falling)

13. Secondary: Change From Baseline to Week 48 or Termination in the Beck Depression Inventory Scale (BDI-II) [Time Frame: Day 0 (baseline), Week 48 or termination visit]

Measure Type	Secondary
Measure Title	Change From Baseline to Week 48 or Termination in the Beck Depression Inventory Scale (BDI-II)
Measure Description	The Beck Depression Inventory (BDI-II), is a 21-question multiple-choice self-report inventory, one of the most widely used instruments for measuring the severity of depression. Participants are asked to pick the answer for each question that best describes the way they have been feeling in the past two weeks, including the day participants complete the questionnaire. Each question is rated on a scale of 0-3, with 0 meaning the participant does not feel the emotion described in the question, and 3 meaning the participant has extremely strong feelings. Total scale is 0 (no evidence of depression) to 63 (extreme depression). Negative change from baseline scores indicate improvement in level of depression.
Time Frame	Day 0 (baseline), Week 48 or termination visit
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.
Modified Intention-To-Treat Analysis Set (mITT): all randomized participants who took at least one dose of the study drug and who had at least one post-baseline efficacy assessment.

Reporting Groups

	Description
Rasagiline Mesylate	rasagiline tablet, 1 mg/day for up to 48 weeks.
Placebo	placebo tablet for up to 48 weeks.

Measured Values

	Rasagiline Mesylate	Placebo
Number of Participants Analyzed [units: participants]	**72**	**82**
Change From Baseline to Week 48 or Termination in the Beck Depression Inventory Scale (BDI-II) [units: units on a scale] Least Squares Mean (Standard Error)	**0.4894 (0.9988)**	**0.7145 (0.9241)**

No statistical analysis provided for Change From Baseline to Week 48 or Termination in the Beck Depression Inventory Scale (BDI-II)

14. Secondary: Total Number of Falls During the Study [Time Frame: Day 1 up to week 48]

Measure Type	Secondary
Measure Title	Total Number of Falls During the Study
Measure Description	Participants recorded each time they fell during the study in a diary.
Time Frame	Day 1 up to week 48
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.
Modified Intention-To-Treat Analysis Set (mITT): all randomized participants who took at least one dose of the study drug and who had at least one post-baseline efficacy assessment, and who maintained diaries.

Reporting Groups

	Description
Rasagiline Mesylate	rasagiline tablet, 1 mg/day for up to 48 weeks.
Placebo	placebo tablet for up to 48 weeks.

Measured Values

	Rasagiline Mesylate	**Placebo**
Number of Participants Analyzed [units: participants]	**79**	**89**
Total Number of Falls During the Study [units: falls] Median (Inter-Quartile Range)	**4.00 (1.00 to 14.00)**	**5.00 (1.00 to 10.00)**

No statistical analysis provided for Total Number of Falls During the Study

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Day 1 to Week 48
Additional Description	No text entered.

Reporting Groups

	Description
Placebo	Placebo tablet for up to 48 weeks.
Rasagiline Mesylate	Rasagiline tablet, 1 mg/day for up to 48 weeks.

Serious Adverse Events

	Placebo	**Rasagiline Mesylate**
Total, serious adverse events		

# participants affected / at risk	23/90 (25.56%)	29/84 (34.52%)
Blood and lymphatic system disorders		
ANAEMIA † 1		
# participants affected / at risk	1/90 (1.11%)	0/84 (0.00%)
# events	1	0
Cardiac disorders		
CARDIAC FAILURE † 1		
# participants affected / at risk	1/90 (1.11%)	0/84 (0.00%)
# events	1	0
CARDIOVASCULAR INSUFFICIENCY † 1		
# participants affected / at risk	0/90 (0.00%)	1/84 (1.19%)
# events	0	1
CORONARY ARTERY DISEASE † 1		
# participants affected / at risk	1/90 (1.11%)	0/84 (0.00%)
# events	1	0
LEFT VENTRICULAR FAILURE † 1		
# participants affected / at risk	1/90 (1.11%)	0/84 (0.00%)
# events	1	0
SUPRAVENTRICULAR TACHYCARDIA † 1		
# participants affected / at risk	0/90 (0.00%)	1/84 (1.19%)
# events	0	1
Gastrointestinal disorders		
ABDOMINAL PAIN UPPER † 1		
# participants affected / at risk	1/90 (1.11%)	0/84 (0.00%)
# events	1	0
ABDOMINAL RIGIDITY † 1		
# participants affected / at risk	0/90 (0.00%)	1/84 (1.19%)
# events	0	1
ACUTE ABDOMEN † 1		
# participants affected / at risk	0/90 (0.00%)	1/84 (1.19%)
# events	0	1
CONSTIPATION † 1		
# participants affected / at risk	1/90 (1.11%)	1/84 (1.19%)
# events	1	1
CROHN'S DISEASE † 1		
# participants affected / at risk	0/90 (0.00%)	1/84 (1.19%)
# events	0	1
GASTRIC ULCER † 1		
# participants affected / at risk	1/90 (1.11%)	0/84 (0.00%)
# events	1	0
HAEMATEMESIS † 1		
# participants affected / at risk	0/90 (0.00%)	1/84 (1.19%)
# events	0	1
General disorders		
ASTHENIA † 1		
# participants affected / at risk	1/90 (1.11%)	0/84 (0.00%)
# events	1	0
CHEST PAIN † 1		

# participants affected / at risk	0/90 (0.00%)	1/84 (1.19%)
# events	0	1
CHILLS [†1]		
# participants affected / at risk	1/90 (1.11%)	0/84 (0.00%)
# events	1	0
FATIGUE [†1]		
# participants affected / at risk	1/90 (1.11%)	0/84 (0.00%)
# events	1	0
OEDEMA PERIPHERAL [†1]		
# participants affected / at risk	1/90 (1.11%)	0/84 (0.00%)
# events	1	0
PYREXIA [†1]		
# participants affected / at risk	1/90 (1.11%)	1/84 (1.19%)
# events	1	2
Hepatobiliary disorders		
CHOLECYSTITIS [†1]		
# participants affected / at risk	1/90 (1.11%)	0/84 (0.00%)
# events	1	0
Infections and infestations		
ARTHRITIS INFECTIVE [†1]		
# participants affected / at risk	0/90 (0.00%)	1/84 (1.19%)
# events	0	1
CARBUNCLE [†1]		
# participants affected / at risk	0/90 (0.00%)	1/84 (1.19%)
# events	0	1
CYSTITIS [†1]		
# participants affected / at risk	0/90 (0.00%)	1/84 (1.19%)
# events	0	1
DEVICE RELATED INFECTION [†1]		
# participants affected / at risk	1/90 (1.11%)	0/84 (0.00%)
# events	1	0
HERPES ZOSTER [†1]		
# participants affected / at risk	1/90 (1.11%)	0/84 (0.00%)
# events	1	0
LOWER RESPIRATORY TRACT INFECTION [†1]		
# participants affected / at risk	0/90 (0.00%)	1/84 (1.19%)
# events	0	1
LUNG INFECTION [†1]		
# participants affected / at risk	0/90 (0.00%)	1/84 (1.19%)
# events	0	1
NASOPHARYNGITIS [†1]		
# participants affected / at risk	0/90 (0.00%)	1/84 (1.19%)
# events	0	1
PNEUMONIA [†1]		
# participants affected / at risk	1/90 (1.11%)	1/84 (1.19%)
# events	1	1
URINARY TRACT INFECTION [†1]		
# participants affected / at risk	1/90 (1.11%)	4/84 (4.76%)
# events	1	6

Injury, poisoning and procedural complications		
FALL [† 1]		
# participants affected / at risk	**3/90 (3.33%)**	**2/84 (2.38%)**
# events	**3**	**2**
FEMUR FRACTURE [† 1]		
# participants affected / at risk	**2/90 (2.22%)**	**2/84 (2.38%)**
# events	**2**	**2**
HEAD INJURY [† 1]		
# participants affected / at risk	**0/90 (0.00%)**	**2/84 (2.38%)**
# events	**0**	**2**
HIP FRACTURE [† 1]		
# participants affected / at risk	**1/90 (1.11%)**	**1/84 (1.19%)**
# events	**1**	**1**
LACERATION [† 1]		
# participants affected / at risk	**0/90 (0.00%)**	**1/84 (1.19%)**
# events	**0**	**1**
LUMBAR VERTEBRAL FRACTURE [† 1]		
# participants affected / at risk	**1/90 (1.11%)**	**0/84 (0.00%)**
# events	**1**	**0**
PUBIS FRACTURE [† 1]		
# participants affected / at risk	**1/90 (1.11%)**	**0/84 (0.00%)**
# events	**1**	**0**
Investigations		
WEIGHT DECREASED [† 1]		
# participants affected / at risk	**1/90 (1.11%)**	**0/84 (0.00%)**
# events	**1**	**0**
Metabolism and nutrition disorders		
DECREASED APPETITE [† 1]		
# participants affected / at risk	**1/90 (1.11%)**	**0/84 (0.00%)**
# events	**1**	**0**
HYPERGLYCAEMIA [† 1]		
# participants affected / at risk	**1/90 (1.11%)**	**0/84 (0.00%)**
# events	**1**	**0**
Musculoskeletal and connective tissue disorders		
ARTHRALGIA [† 1]		
# participants affected / at risk	**1/90 (1.11%)**	**0/84 (0.00%)**
# events	**1**	**0**
BACK PAIN [† 1]		
# participants affected / at risk	**1/90 (1.11%)**	**0/84 (0.00%)**
# events	**1**	**0**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
PROSTATE CANCER [† 1]		
# participants affected / at risk	**1/90 (1.11%)**	**0/84 (0.00%)**
# events	**1**	**0**
Nervous system disorders		
HEADACHE [† 1]		
# participants affected / at risk	**1/90 (1.11%)**	**0/84 (0.00%)**
# events	**1**	**0**

HYPOKINESIA [†1]		
# participants affected / at risk	1/90 (1.11%)	0/84 (0.00%)
# events	1	0
LOSS OF CONSCIOUSNESS [†1]		
# participants affected / at risk	0/90 (0.00%)	1/84 (1.19%)
# events	0	1
SYNCOPE [†1]		
# participants affected / at risk	2/90 (2.22%)	2/84 (2.38%)
# events	2	2
TRANSIENT ISCHAEMIC ATTACK [†1]		
# participants affected / at risk	0/90 (0.00%)	1/84 (1.19%)
# events	0	1
Psychiatric disorders		
DELIRIUM [†1]		
# participants affected / at risk	0/90 (0.00%)	1/84 (1.19%)
# events	0	1
MENTAL STATUS CHANGES [†1]		
# participants affected / at risk	1/90 (1.11%)	0/84 (0.00%)
# events	1	0
SLEEP DISORDER [†1]		
# participants affected / at risk	1/90 (1.11%)	0/84 (0.00%)
# events	1	0
SUICIDE ATTEMPT [†1]		
# participants affected / at risk	1/90 (1.11%)	0/84 (0.00%)
# events	1	0
Renal and urinary disorders		
HAEMATURIA [†1]		
# participants affected / at risk	1/90 (1.11%)	0/84 (0.00%)
# events	1	0
URINARY RETENTION [†1]		
# participants affected / at risk	1/90 (1.11%)	1/84 (1.19%)
# events	1	1
URINARY TRACT OBSTRUCTION [†1]		
# participants affected / at risk	1/90 (1.11%)	0/84 (0.00%)
# events	1	0
Reproductive system and breast disorders		
BENIGN PROSTATIC HYPERPLASIA [†1]		
# participants affected / at risk	1/90 (1.11%)	1/84 (1.19%)
# events	1	1
PROSTATOMEGALY [†1]		
# participants affected / at risk	0/90 (0.00%)	1/84 (1.19%)
# events	0	1
Respiratory, thoracic and mediastinal disorders		
CHOKING [†1]		
# participants affected / at risk	1/90 (1.11%)	0/84 (0.00%)
# events	1	0
DYSPHONIA [†1]		
# participants affected / at risk	0/90 (0.00%)	1/84 (1.19%)

# events	0	1
DYSPNOEA † 1		
# participants affected / at risk	1/90 (1.11%)	2/84 (2.38%)
# events	1	3
PULMONARY EMBOLISM † 1		
# participants affected / at risk	1/90 (1.11%)	0/84 (0.00%)
# events	1	0
RESPIRATORY DISTRESS † 1		
# participants affected / at risk	0/90 (0.00%)	1/84 (1.19%)
# events	0	1
RESPIRATORY FAILURE † 1		
# participants affected / at risk	1/90 (1.11%)	3/84 (3.57%)
# events	1	3
Surgical and medical procedures		
CATARACT OPERATION † 1		
# participants affected / at risk	1/90 (1.11%)	0/84 (0.00%)
# events	2	0
GASTROSTOMY † 1		
# participants affected / at risk	0/90 (0.00%)	1/84 (1.19%)
# events	0	1
HIP ARTHROPLASTY † 1		
# participants affected / at risk	0/90 (0.00%)	1/84 (1.19%)
# events	0	1
INGUINAL HERNIA REPAIR † 1		
# participants affected / at risk	0/90 (0.00%)	1/84 (1.19%)
# events	0	1
KNEE ARTHROPLASTY † 1		
# participants affected / at risk	0/90 (0.00%)	1/84 (1.19%)
# events	0	1
PROSTATECTOMY † 1		
# participants affected / at risk	0/90 (0.00%)	1/84 (1.19%)
# events	0	1
TRACHEOSTOMY † 1		
# participants affected / at risk	0/90 (0.00%)	1/84 (1.19%)
# events	0	1
TRANSURETHRAL PROSTATECTOMY † 1		
# participants affected / at risk	0/90 (0.00%)	1/84 (1.19%)
# events	0	1
Vascular disorders		
HYPERTENSION † 1		
# participants affected / at risk	1/90 (1.11%)	0/84 (0.00%)
# events	1	0
LABILE BLOOD PRESSURE † 1		
# participants affected / at risk	0/90 (0.00%)	1/84 (1.19%)
# events	0	1
ORTHOSTATIC HYPOTENSION † 1		
# participants affected / at risk	0/90 (0.00%)	3/84 (3.57%)
# events	0	3

† Events were collected by systematic assessment

1 Term from vocabulary, MedDRA (14.0)

Other Adverse Events

Hide Other Adverse Events

Time Frame	Day 1 to Week 48
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Placebo	Placebo tablet for up to 48 weeks.
Rasagiline Mesylate	Rasagiline tablet, 1 mg/day for up to 48 weeks.

Other Adverse Events

	Placebo	Rasagiline Mesylate
Total, other (not including serious) adverse events		
# participants affected / at risk	**45/90 (50.00%)**	**41/84 (48.81%)**
Gastrointestinal disorders		
CONSTIPATION † 1		
# participants affected / at risk	**5/90 (5.56%)**	**5/84 (5.95%)**
# events	**6**	**5**
General disorders		
OEDEMA PERIPHERAL † 1		
# participants affected / at risk	**6/90 (6.67%)**	**9/84 (10.71%)**
# events	**6**	**9**
Infections and infestations		
NASOPHARYNGITIS † 1		
# participants affected / at risk	**6/90 (6.67%)**	**4/84 (4.76%)**
# events	**6**	**4**
URINARY TRACT INFECTION † 1		
# participants affected / at risk	**12/90 (13.33%)**	**6/84 (7.14%)**
# events	**22**	**14**
Injury, poisoning and procedural complications		
FALL † 1		
# participants affected / at risk	**9/90 (10.00%)**	**5/84 (5.95%)**
# events	**12**	**6**
Nervous system disorders		
DIZZINESS † 1		
# participants affected / at risk	**10/90 (11.11%)**	**10/84 (11.90%)**
# events	**14**	**11**
HEADACHE † 1		
# participants affected / at risk	**7/90 (7.78%)**	**3/84 (3.57%)**
# events	**7**	**3**

SOMNOLENCE † 1		
# participants affected / at risk	**5/90 (5.56%)**	**2/84 (2.38%)**
# events	**6**	**2**
Psychiatric disorders		
DEPRESSION † 1		
# participants affected / at risk	**5/90 (5.56%)**	**1/84 (1.19%)**
# events	**5**	**1**
Vascular disorders		
ORTHOSTATIC HYPOTENSION † 1		
# participants affected / at risk	**3/90 (3.33%)**	**6/84 (7.14%)**
# events	**3**	**8**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA (14.0)

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.
The agreement is: ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed. ☑ **Restriction Description:** Sponsor has the right 60 days before submission for publication to review/provide comments. If the Sponsor's review shows that potentially patentable subject matter would be disclosed, publication or public disclosure shall be delayed for up to 90 additional days in order for the Sponsor, or Sponsor's designees, to file the necessary patent applications. In multicenter trials, each PI will postpone single center publications until after disclosure or publication of multicenter data.

Results Point of Contact:

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No publications provided by Teva Pharmaceutical Industries

Publications automatically indexed to this study:

Poewe W, Seppi K, Fitzer-Attas CJ, Wenning GK, Gilman S, Low PA, Giladi N, Barone P, Sampaio C, Eyal E, Rascol O; Rasagiline-for-MSA investigators. Efficacy of rasagiline in patients with the parkinsonian variant of multiple system atrophy: a randomised, placebo-controlled trial. Lancet Neurol. 2015 Feb;14(2):145-52. doi: 10.1016/S1474-4422(14)70288-1. Epub 2014 Dec 8.

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