Efficacy and Long-Term Safety of Ragweed (Ambrosia Artemisiifolia) Sublingual Tablet (SCH 39641) in Adults With a History of Ragweed-Induced Rhinoconjunctivitis With or Without Asthma (Study P05234)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00770315

First received: October 9, 2008
Last updated: October 12, 2015
Last verified: October 2015
History of Changes

Purpose

This study will evaluate the efficacy and safety of ragweed sublingual tablet (SCH 39641/MK-3641/Amb a 1-U) compared with placebo in participants with ragweed-induced rhinoconjunctivitis over a one-year period. It is expected that ragweed allergic participants on one of the active arms of the trial will have decreased allergic rhinoconjunctivitis symptoms and require less allergy rescue medications during ragweed pollen season.

Condition	Intervention	Phase
Rhinitis, Allergic Conjunctivitis	Biological: Ambrosia artemisiifolia allergen extract (Amb a 1-U) Biological: Placebo	Phase 3

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

Official Title: A Multicenter, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group Study Evaluating the Efficacy and Long-Term Safety of Ragweed (Ambrosia Artemisiifolia) Sublingual Tablet (SCH 39641) in Adult Subjects With a History of Ragweed-Induced Rhinoconjunctivitis With or Without Asthma

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

Primary Outcome Measures:

- Combined (Sum of) Rhinoconjunctivitis Daily Symptom Score (DSS) and Daily Medication Score (DMS) Averaged Over the Peak Ragweed Season (RS) [Time Frame: The 15-day period during the ragweed season with the highest moving pollen average]
  [Designated as safety issue: No]

  The total combined score is a composite endpoint that combines the rhinoconjuntivitis DSS and the rhinoconjunctivitis DMS. The

rhinoconjunctivitis DSS consisted of a total of 6 symptoms (runny nose, blocked nose, sneezing, itchy nose, gritty feeling/red/itchy eyes and watery eyes) that were measured on a scale of 0 to 3 (0=no symptoms, 3=severe symptoms; score range: 0-18), with a lower score indicating less rhinoconjunctivitis symptoms. Rhinoconjunctivitis DMS was based on use of specific study-provided rescue medication, with different rescue medications being assigned different scores/dose unit (score range: 0-36), with a lower score indicating less rhinconjunctivitis medication use. The sum of the rhinoconjunctivitis DSS+DMS could range from 0 to 54, with a lower score indicating less rhinoconjuntivitis symptoms and medication use. Raw means were converted to adjusted means using an ANOVA model with baseline asthmatic condition, pollen region and treatment group as fixed effects.

Secondary Outcome Measures:

- Average Combined Rhinoconjunctivitis DSS and DMS Over the Entire RS [Time Frame: Approximately 5 weeks] [Designated as safety issue: No]

  The total combined score is a composite endpoint that combines the rhinoconjuntivitis DSS and the rhinoconjunctivitis DMS. The rhinoconjunctivitis DSS consisted of a total of 6 symptoms (runny nose, blocked nose, sneezing, itchy nose, gritty feeling/red/itchy eyes and watery eyes) that were measured on a scale of 0 to 3 (0=no symptoms, 3=severe symptoms; score range: 0-18), with a lower score indicating less rhinoconjunctivitis symptoms. Rhinoconjunctivitis DMS was based on use of specific study-provided rescue medication, with different rescue medications being assigned different scores/dose unit (score range: 0-36), with a lower score indicating less rhinconjunctivitis medication use. The sum of the rhinoconjunctivitis DSS+DMS could range from 0 to 54, with a lower score indicating less rhinoconjuntivitis symptoms and medication use. Raw means were converted to adjusted means using an ANOVA model with baseline asthmatic condition, pollen region and treatment group as fixed effects.

- Average Rhinoconjunctivitis DSS for the Peak RS [Time Frame: The 15-day period during the ragweed season with the highest moving pollen average] [Designated as safety issue: No]

  The rhinoconjunctivitis DSS consisted of a total of 6 symptoms (runny nose, blocked nose, sneezing, itchy nose, gritty feeling/red/itchy eyes and watery eyes) that were measured on a scale of 0 to 3 (0=no symptoms, 3=severe symptoms; score range: 0-18), with a lower score indicating less rhinoconjunctivitis symptoms. Raw means were converted to adjusted means using an ANOVA model with baseline asthmatic condition, pollen region and treatment group as fixed effects.

- Average Rhinoconjunctivitis DSS for the Entire RS [Time Frame: Approximately 5 weeks] [Designated as safety issue: No]

  The rhinoconjunctivitis DSS consisted of a total of 6 symptoms (runny nose, blocked nose, sneezing, itchy nose, gritty feeling/red/itchy eyes and watery eyes) that were measured on a scale of 0 to 3 (0=no symptoms, 3=severe symptoms; score range: 0-18), with a lower score indicating less rhinoconjunctivitis symptoms. Raw means were converted to adjusted means using an ANOVA model with baseline asthmatic condition, pollen region and treatment group as fixed effects.

- Average Rhinoconjunctivitis DMS for the Peak RS [Time Frame: The 15-day period during the ragweed season with the highest moving pollen average] [Designated as safety issue: No]

  Rhinoconjunctivitis DMS was based on participant use of specific study-provided rescue medication, with different rescue medications being assigned different scores/dose unit (score range: 0-36), with a lower score indicating less rhinconjunctivitis medication use. Raw means were converted to adjusted means using an ANOVA model with baseline asthmatic condition, pollen region and treatment group as fixed effects.

Enrollment:	784
Study Start Date:	September 2009
Study Completion Date:	May 2011
Primary Completion Date:	May 2011 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: SCH 39641 1.5 Amb a 1-U Participants receive Ambrosia artemisiifolia allergan extract (SCH 39641 1.5 Amb a 1-U) rapidly dissolving sublingual tablets, administered once daily for approximately 52 weeks	Biological: Ambrosia artemisiifolia allergen extract (Amb a 1-U) Rapidly dissolving tablet administered sublingually once daily, at a dose of 1.5, 6 or 12 units. Other Names: • SCH 39641 • MK-3641
Experimental: SCH 39641 6 Amb a 1-U Participants receive Ambrosia artemisiifolia allergan extract (SCH 39641 6 Amb a 1-	Biological: Ambrosia artemisiifolia allergen extract (Amb a 1-U)

U) rapidly dissolving sublingual tablets, administered once daily for approximately 52 weeks	Rapidly dissolving tablet administered sublingually once daily, at a dose of 1.5, 6 or 12 units. Other Names: • SCH 39641 • MK-3641
Experimental: SCH 39641 12 Amb a 1-U Participants receive Ambrosia artemisiifolia allergan extract (SCH 39641 12 Amb a 1-U) rapidly dissolving sublingual tablets, administered once daily for approximately 52 weeks	Biological: Ambrosia artemisiifolia allergen extract (Amb a 1-U) Rapidly dissolving tablet administered sublingually once daily, at a dose of 1.5, 6 or 12 units. Other Names: • SCH 39641 • MK-3641
Placebo Comparator: Placebo Participants receive matching placebo rapidly dissolving sublingual tablets, administered once daily for approximately 52 weeks	Biological: Placebo Placebo matching Ambrosia artemisiifolia allergen extract rapidly dissolving tablet, administered sublingually once daily

Eligibility

Ages Eligible for Study: 18 Years to 50 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Must have a clinical history of significant ragweed-induced allergic rhinoconjunctivitis of at least 2 years duration, with or without asthma and have received treatment during the previous ragweed season (RS).
- Must have a positive skin prick test response to Ambrosia artemisiifolia at Screening Visit.
- Must be positive for specific immunoglobulin E (IgE) against Ambrosia artemisiifolia at Screening Visit.
- Must have an forced expiratory volume in one second (FEV1) of at least 70% of predicted at Screening Visit.
- Safety laboratory tests and vital signs conducted at the Screening Visit must be within normal limits or clinically acceptable to the investigator/sponsor.
- Must be willing to give written informed consent and be able to adhere to dose and visit schedules.
- Female participants of childbearing potential must be using a medically acceptable and adequate form of birth control. These include: hormonal contraceptives as prescribed by a physician (oral, hormonal vaginal ring, hormonal implant or depot injectable); medically prescribed intra-uterine device; medically prescribed topically-applied transdermal contraceptive patch; double-barrier method (eg, condom in combination with a spermicide).
- Female participants of childbearing potential should be counseled in the appropriate use of birth control while in the study. Female participants who are not currently sexually active must and consent to use one of the above-mentioned methods if she becomes sexually active during the study.
- Female participants of childbearing potential must have a negative urine pregnancy test at Screening Visit. Women who have been surgically sterilized or at least 1 year postmenopausal are not considered to be of childbearing potential.

Exclusion Criteria:

- Clinical history of symptomatic seasonal allergic rhinitis and/or asthma having received regular medication, due to another during or potentially overlapping the RS.
- Clinical history of significant symptomatic perennial allergic rhinitis and/or asthma due to an allergen to which the participant is regularly exposed.
- Receipt of an immunosuppressive treatment within 3 months prior to the Screening Visit (except steroids for allergic and asthma symptoms).
- Clinical history of severe asthma.
- Asthma requiring medium or high dose inhaled corticosteroids (ICS).
- History of anaphylaxis with cardiorespiratory symptoms.
- History of chronic urticaria and angioedema.

- Clinical history of chronic sinusitis 2 years prior to the Screening Visit.
- Current severe atopic dermatitis.
- Breast-feeding, pregnancy, or intending to become pregnant.
- Had previous treatment by immunotherapy with ragweed allergen or any other allergen 5 years prior to Screening Visit.
- History of allergy, hypersensitivity or intolerance to the ingredients of the investigational medicinal products (except for Ambrosia artemisiifolia), rescue medications, or self-injectable epinephrine.
- Any clinically significant condition or situation, other than the condition being studied that, in the opinion of the investigator, would interfere with the study evaluations or optimal participation in the study.
- Use of any investigational drugs within 30 days of Screening Visit.
- Participation in any other clinical study.
- Being a family member of the study staff.
- Inability to meet medication washout requirements.
- Unlikely to be able to complete the trial, or likely to travel for an extended time during the RS.
- Clinically significant abnormal vital sign or lab value.
- Participation in this same study at another site.
- Randomized into this study more than once.
- Inability to or will not comply with the use of self-injectable epinephrine.
- Greater risk of developing adverse reactions after epinephrine administration.
- History of self-injectable epinephrine use

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:

Creticos PS, Maloney J, Bernstein DI, Casale T, Kaur A, Fisher R, Liu N, Murphy K, Nékám K, Nolte H. Randomized controlled trial of a ragweed allergy immunotherapy tablet in North American and European adults. J Allergy Clin Immunol. 2013 May;131(5):1342-9.e6. doi: 10.1016/j.jaci.2013.03.019.

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Christensen LH, Ipsen H, Nolte H, Maloney J, Nelson HS, Weber R, Lund K. Short ragweeds is highly cross-reactive with other ragweeds. Ann Allergy Asthma Immunol. 2015 Dec;115(6):490-495.e1. doi: 10.1016/j.anai.2015.09.016. Epub 2015 Oct 21.

Nolte H, Amar N, Bernstein DI, Lanier BQ, Creticos P, Berman G, Kaur A, Hébert J, Maloney J. Safety and tolerability of a short ragweed sublingual immunotherapy tablet. Ann Allergy Asthma Immunol. 2014 Jul;113(1):93-100.e3. doi: 10.1016/j.anai.2014.04.018. Epub 2014 May 14.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00770315 History of Changes
Other Study ID Numbers:	P05234 3810249 2008-003864-20 MK-3641-002
Study First Received:	October 9, 2008
Results First Received:	April 25, 2014
Last Updated:	October 12, 2015
Health Authority:	United States: Food and Drug Administration

Additional relevant MeSH terms:
Conjunctivitis
Conjunctival Diseases
Eye Diseases

ClinicalTrials.gov processed this record on May 08, 2016

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Efficacy and Long-Term Safety of Ragweed (Ambrosia Artemisiifolia) Sublingual Tablet (SCH 39641) in Adults With a History of Ragweed-Induced Rhinoconjunctivitis With or Without Asthma (Study P05234)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00770315

First received: October 9, 2008
Last updated: October 12, 2015
Last verified: October 2015
History of Changes

Results First Received: April 25, 2014

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Conditions:	Rhinitis, Allergic Conjunctivitis
Interventions:	Biological: Ambrosia artemisiifolia allergen extract (Amb a 1-U) Biological: 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
No text entered.

Reporting Groups

	Description
SCH 39641 1.5 Amb a 1-U	Participants receive Ambrosia artemisiifolia allergan extract (SCH 39641 1.5 Amb a 1-U) rapidly dissolving sublingual tablets, administered once daily for approximately 52 weeks
SCH 39641 6 Amb a 1-U	Participants receive Ambrosia artemisiifolia allergan extract (SCH 39641 6 Amb a 1-U) rapidly dissolving sublingual tablets, administered once daily for approximately 52 weeks
SCH 39641 12 Amb a 1-U	Participants receive Ambrosia artemisiifolia allergan extract (SCH 39641 12 Amb a 1-U) rapidly dissolving sublingual tablets, administered once daily for approximately 52 weeks
Placebo	Participants receive placebo matching Ambrosia artemisiifolia allergan extract rapidly dissolving sublingual tablets, administered once daily for approximately 52 weeks

Participant Flow: Overall Study

	SCH 39641 1.5 Amb a 1-U	SCH 39641 6 Amb a 1-U	SCH 39641 12 Amb a 1-U	Placebo
STARTED	197	195	194	198
COMPLETED	157	152	137	160
NOT COMPLETED	40	43	57	38
Adverse Event	11	17	16	6
Lost to Follow-up	9	5	10	3
Withdrawal by Subject	13	17	24	20
Noncompliance with Protocol	7	4	7	9

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
SCH 39641 1.5 Amb a 1-U	Participants receive Ambrosia artemisiifolia allergan extract (SCH 39641 1.5 Amb a 1-U) rapidly dissolving sublingual tablets, administered once daily for approximately 52 weeks
SCH 39641 6 Amb a 1-U	Participants receive Ambrosia artemisiifolia allergan extract (SCH 39641 6 Amb a 1-U) rapidly dissolving sublingual tablets, administered once daily for approximately 52 weeks
SCH 39641 12 Amb a 1-U	Participants receive Ambrosia artemisiifolia allergan extract (SCH 39641 12 Amb a 1-U) rapidly dissolving sublingual tablets, administered once daily for approximately 52 weeks
Placebo	Participants receive placebo matching Ambrosia artemisiifolia allergan extract rapidly dissolving sublingual tablets, administered once daily for approximately 52 weeks
Total	Total of all reporting groups

Baseline Measures

	SCH 39641 1.5 Amb a 1-	SCH 39641 6 Amb a 1-	SCH 39641 12 Amb a 1-		

	U	U	U	Placebo	Total
Number of Participants [units: participants]	197	195	194	198	784
Age [units: years] Mean (Standard Deviation)	36.2 (8.83)	36.9 (8.80)	35.6 (8.75)	36.7 (8.54)	36.4 (8.73)
Gender [units: participants]					
Female	110	103	91	96	400
Male	87	92	103	102	384

Outcome Measures

Hide All Outcome Measures

1. Primary: Combined (Sum of) Rhinoconjunctivitis Daily Symptom Score (DSS) and Daily Medication Score (DMS) Averaged Over the Peak Ragweed Season (RS) [Time Frame: The 15-day period during the ragweed season with the highest moving pollen average]

Measure Type	Primary
Measure Title	Combined (Sum of) Rhinoconjunctivitis Daily Symptom Score (DSS) and Daily Medication Score (DMS) Averaged Over the Peak Ragweed Season (RS)
Measure Description	The total combined score is a composite endpoint that combines the rhinoconjuntivitis DSS and the rhinoconjunctivitis DMS. The rhinoconjunctivitis DSS consisted of a total of 6 symptoms (runny nose, blocked nose, sneezing, itchy nose, gritty feeling/red/itchy eyes and watery eyes) that were measured on a scale of 0 to 3 (0=no symptoms, 3=severe symptoms; score range: 0-18), with a lower score indicating less rhinoconjunctivitis symptoms. Rhinoconjunctivitis DMS was based on use of specific study-provided rescue medication, with different rescue medications being assigned different scores/dose unit (score range: 0-36), with a lower score indicating less rhinconjunctivitis medication use. The sum of the rhinoconjunctivitis DSS+DMS could range from 0 to 54, with a lower score indicating less rhinoconjuntivitis symptoms and medication use. Raw means were converted to adjusted means using an ANOVA model with baseline asthmatic condition, pollen region and treatment group as fixed effects.
Time Frame	The 15-day period during the ragweed season with the highest moving pollen average
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.
The Full Analysis Set (FAS) population consisted of all randomized participants who took at least one dose of study medication and had at least one post-randomization efficacy measurement.

Reporting Groups

	Description
SCH 39641 1.5 Amb a 1-U	Participants receive Ambrosia artemisiifolia allergan extract (SCH 39641 1.5 Amb a 1-U) rapidly dissolving sublingual tablets, administered once daily for approximately 52 weeks
SCH 39641 6 Amb a 1-U	Participants receive Ambrosia artemisiifolia allergan extract (SCH 39641 6 Amb a 1-U) rapidly dissolving sublingual tablets, administered once daily for approximately 52 weeks
SCH 39641 12 Amb a 1-U	Participants receive Ambrosia artemisiifolia allergan extract (SCH 39641 12 Amb a 1-U) rapidly dissolving sublingual tablets, administered once daily for approximately 52 weeks

Placebo	Participants receive matching placebo rapidly dissolving sublingual tablets, administered once daily for approximately 52 weeks

Measured Values

	SCH 39641 1.5 Amb a 1-U	SCH 39641 6 Amb a 1-U	SCH 39641 12 Amb a 1-U	Placebo
Number of Participants Analyzed [units: participants]	**169**	**167**	**152**	**169**
Combined (Sum of) Rhinoconjunctivitis Daily Symptom Score (DSS) and Daily Medication Score (DMS) Averaged Over the Peak Ragweed Season (RS) [units: score on a scale] Mean (Standard Error)	**7.70 (0.517)**	**6.88 (0.526)**	**6.41 (0.534)**	**8.46 (0.535)**

Statistical Analysis 1 for Combined (Sum of) Rhinoconjunctivitis Daily Symptom Score (DSS) and Daily Medication Score (DMS) Averaged Over the Peak Ragweed Season (RS)

Groups [1]	SCH 39641 1.5 Amb a 1-U vs. Placebo
Method [2]	ANOVA
P Value [3]	0.2192
Mean Difference (Final Values) [4]	-0.76
95% Confidence Interval	-1.98 to 0.45

[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:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	ANOVA model with baseline asthmatic condition, pollen region and treatment group as fixed effects

Statistical Analysis 2 for Combined (Sum of) Rhinoconjunctivitis Daily Symptom Score (DSS) and Daily Medication Score (DMS) Averaged Over the Peak Ragweed Season (RS)

Groups [1]	SCH 39641 6 Amb a 1-U vs. Placebo
Method [2]	ANOVA
P Value [3]	0.0113
Mean Difference (Final Values) [4]	-1.58
95% Confidence Interval	-2.80 to -0.36

[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:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	ANOVA model with baseline asthmatic condition, pollen region and treatment group as fixed effects

Statistical Analysis 3 for Combined (Sum of) Rhinoconjunctivitis Daily Symptom Score (DSS) and Daily Medication Score (DMS) Averaged Over the Peak Ragweed Season (RS)

Groups [1]	SCH 39641 12 Amb a 1-U vs. Placebo
Method [2]	ANOVA
P Value [3]	0.0015
Mean Difference (Final Values) [4]	-2.04
95% Confidence Interval	-3.30 to -0.79

[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:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	ANOVA model with baseline asthmatic condition, pollen region and treatment group as fixed effects

2. Secondary: Average Combined Rhinoconjunctivitis DSS and DMS Over the Entire RS [Time Frame: Approximately 5 weeks]

Measure Type	Secondary
Measure Title	Average Combined Rhinoconjunctivitis DSS and DMS Over the Entire RS
Measure Description	The total combined score is a composite endpoint that combines the rhinoconjuntivitis DSS and the rhinoconjunctivitis DMS. The rhinoconjunctivitis DSS consisted of a total of 6 symptoms (runny nose, blocked nose, sneezing, itchy nose, gritty feeling/red/itchy eyes and watery eyes) that were measured on a scale of 0 to 3 (0=no symptoms, 3=severe symptoms; score range: 0-18), with a lower score indicating less rhinoconjunctivitis symptoms. Rhinoconjunctivitis DMS was based on use of specific study-provided rescue medication, with different rescue medications being assigned different scores/dose unit (score range: 0-36), with a lower score indicating less rhinconjunctivitis medication use. The sum of the rhinoconjunctivitis DSS+DMS could range from 0 to 54, with a lower score indicating less rhinoconjuntivitis symptoms and medication use. Raw means were converted to adjusted means using an ANOVA model with baseline asthmatic condition, pollen region and treatment group as fixed effects.
Time Frame	Approximately 5 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.
The FAS population consisted of all randomized participants who took at least one dose of study medication and had at least one post-randomization efficacy measurement.

Reporting Groups

	Description
SCH 39641 1.5 Amb a 1-U	Participants receive Ambrosia artemisiifolia allergan extract (SCH 39641 1.5 Amb a 1-U) rapidly dissolving sublingual tablets, administered once daily for approximately 52 weeks
SCH 39641 6 Amb a 1-U	Participants receive Ambrosia artemisiifolia allergan extract (SCH 39641 6 Amb a 1-U) rapidly dissolving sublingual tablets, administered once daily for approximately 52 weeks
SCH 39641 12 Amb a 1-U	Participants receive Ambrosia artemisiifolia allergan extract (SCH 39641 12 Amb a 1-U) rapidly dissolving sublingual tablets, administered once daily for approximately 52 weeks
Placebo	Participants receive matching placebo rapidly dissolving sublingual tablets, administered once daily for approximately 52 weeks

Measured Values

	SCH 39641 1.5 Amb a 1-U	SCH 39641 6 Amb a 1-U	SCH 39641 12 Amb a 1-U	Placebo
Number of Participants Analyzed [units: participants]	**171**	**172**	**158**	**174**
Average Combined Rhinoconjunctivitis DSS and DMS Over the Entire RS [units: score on a scale] Mean (Standard Error)	**6.22 (0.432)**	**5.81 (0.433)**	**5.18 (0.439)**	**7.09 (0.441)**

Statistical Analysis 1 for Average Combined Rhinoconjunctivitis DSS and DMS Over the Entire RS

Groups [1]	SCH 39641 1.5 Amb a 1-U vs. Placebo
Method [2]	ANOVA
P Value [3]	0.0878
Mean Difference (Final Values) [4]	-0.88
95% Confidence Interval	-1.88 to 0.13

[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:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	ANOVA model with baseline asthmatic condition, pollen region and treatment group as fixed effects

Statistical Analysis 2 for Average Combined Rhinoconjunctivitis DSS and DMS Over the Entire RS

Groups [1]	SCH 39641 6 Amb a 1-U vs. Placebo
Method [2]	ANOVA
P Value [3]	0.0125
Mean Difference (Final Values) [4]	-1.28
95% Confidence Interval	-2.29 to -0.28

[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:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	ANOVA model with baseline asthmatic condition, pollen region and treatment group as fixed effects

Statistical Analysis 3 for Average Combined Rhinoconjunctivitis DSS and DMS Over the Entire RS

Groups [1]	SCH 39641 12 Amb a 1-U vs. Placebo
Method [2]	ANOVA
P Value [3]	0.0003
Mean Difference (Final Values) [4]	-1.92
95% Confidence Interval	-2.95 to -0.88

[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:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	ANOVA model with baseline asthmatic condition, pollen region and treatment group as fixed effects

3. Secondary: Average Rhinoconjunctivitis DSS for the Peak RS [Time Frame: The 15-day period during the ragweed season with the highest moving pollen average]

Measure Type	Secondary
Measure Title	Average Rhinoconjunctivitis DSS for the Peak RS

Measure Description	The rhinoconjunctivitis DSS consisted of a total of 6 symptoms (runny nose, blocked nose, sneezing, itchy nose, gritty feeling/red/itchy eyes and watery eyes) that were measured on a scale of 0 to 3 (0=no symptoms, 3=severe symptoms; score range: 0-18), with a lower score indicating less rhinoconjunctivitis symptoms. Raw means were converted to adjusted means using an ANOVA model with baseline asthmatic condition, pollen region and treatment group as fixed effects.
Time Frame	The 15-day period during the ragweed season with the highest moving pollen average
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.
The FAS population consisted of all randomized participants who took at least one dose of study medication and had at least one post-randomization efficacy measurement.

Reporting Groups

	Description
SCH 39641 1.5 Amb a 1-U	Participants receive Ambrosia artemisiifolia allergan extract (SCH 39641 1.5 Amb a 1-U) rapidly dissolving sublingual tablets, administered once daily for approximately 52 weeks
SCH 39641 6 Amb a 1-U	Participants receive Ambrosia artemisiifolia allergan extract (SCH 39641 6 Amb a 1-U) rapidly dissolving sublingual tablets, administered once daily for approximately 52 weeks
SCH 39641 12 Amb a 1-U	Participants receive Ambrosia artemisiifolia allergan extract (SCH 39641 12 Amb a 1-U) rapidly dissolving sublingual tablets, administered once daily for approximately 52 weeks
Placebo	Participants receive matching placebo rapidly dissolving sublingual tablets, administered once daily for approximately 52 weeks

Measured Values

	SCH 39641 1.5 Amb a 1-U	**SCH 39641 6 Amb a 1-U**	**SCH 39641 12 Amb a 1-U**	**Placebo**
Number of Participants Analyzed [units: participants]	**169**	**167**	**152**	**169**
Average Rhinoconjunctivitis DSS for the Peak RS [units: score on a scale] Mean (Standard Error)	**5.11 (0.301)**	**4.87 (0.306)**	**4.43 (0.311)**	**5.37 (0.311)**

Statistical Analysis 1 for Average Rhinoconjunctivitis DSS for the Peak RS

Groups [1]	SCH 39641 1.5 Amb a 1-U vs. Placebo
Method [2]	ANOVA
P Value [3]	0.4781
Mean Difference (Final Values) [4]	-0.26
95% Confidence Interval	-0.96 to 0.45

[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:

	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	ANOVA model with baseline asthmatic condition, pollen region and treatment group as fixed effects

Statistical Analysis 2 for Average Rhinoconjunctivitis DSS for the Peak RS

Groups [1]	SCH 39641 6 Amb a 1-U vs. Placebo
Method [2]	ANOVA
P Value [3]	0.1695
Mean Difference (Final Values) [4]	-0.50
95% Confidence Interval	-1.21 to 0.21

[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:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	ANOVA model with baseline asthmatic condition, pollen region and treatment group as fixed effects

Statistical Analysis 3 for Average Rhinoconjunctivitis DSS for the Peak RS

Groups [1]	SCH 39641 12 Amb a 1-U vs. Placebo
Method [2]	ANOVA
P Value [3]	0.0118
Mean Difference (Final Values) [4]	-0.94
95% Confidence Interval	-1.67 to -0.21

[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:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:

	ANOVA model with baseline asthmatic condition, pollen region and treatment group as fixed effects

4. Secondary: Average Rhinoconjunctivitis DSS for the Entire RS [Time Frame: Approximately 5 weeks]

Measure Type	Secondary
Measure Title	Average Rhinoconjunctivitis DSS for the Entire RS
Measure Description	The rhinoconjunctivitis DSS consisted of a total of 6 symptoms (runny nose, blocked nose, sneezing, itchy nose, gritty feeling/red/itchy eyes and watery eyes) that were measured on a scale of 0 to 3 (0=no symptoms, 3=severe symptoms; score range: 0-18), with a lower score indicating less rhinoconjunctivitis symptoms. Raw means were converted to adjusted means using an ANOVA model with baseline asthmatic condition, pollen region and treatment group as fixed effects.
Time Frame	Approximately 5 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.
The FAS population consisted of all randomized participants who took at least one dose of study medication and had at least one post-randomization efficacy measurement.

Reporting Groups

	Description
SCH 39641 1.5 Amb a 1-U	Participants receive Ambrosia artemisiifolia allergan extract (SCH 39641 1.5 Amb a 1-U) rapidly dissolving sublingual tablets, administered once daily for approximately 52 weeks
SCH 39641 6 Amb a 1-U	Participants receive Ambrosia artemisiifolia allergan extract (SCH 39641 6 Amb a 1-U) rapidly dissolving sublingual tablets, administered once daily for approximately 52 weeks
SCH 39641 12 Amb a 1-U	Participants receive Ambrosia artemisiifolia allergan extract (SCH 39641 12 Amb a 1-U) rapidly dissolving sublingual tablets, administered once daily for approximately 52 weeks
Placebo	Participants receive matching placebo rapidly dissolving sublingual tablets, administered once daily for approximately 52 weeks

Measured Values

	SCH 39641 1.5 Amb a 1-U	**SCH 39641 6 Amb a 1-U**	**SCH 39641 12 Amb a 1-U**	**Placebo**
Number of Participants Analyzed [units: participants]	**171**	**172**	**158**	**174**
Average Rhinoconjunctivitis DSS for the Entire RS [units: score on a scale] Mean (Standard Error)	**4.24 (0.255)**	**4.19 (0.256)**	**3.62 (0.259)**	**4.58 (0.261)**

Statistical Analysis 1 for Average Rhinoconjunctivitis DSS for the Entire RS

Groups [1]	SCH 39641 1.5 Amb a 1-U vs. Placebo
Method [2]	ANOVA
[3]	

P Value	0.2622
Mean Difference (Final Values) [4]	-0.34
95% Confidence Interval	-0.93 to 0.25

[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:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	ANOVA model with baseline asthmatic condition, pollen region and treatment group as fixed effects

Statistical Analysis 2 for Average Rhinoconjunctivitis DSS for the Entire RS

Groups [1]	SCH 39641 6 Amb a 1-U vs. Placebo
Method [2]	ANOVA
P Value [3]	0.1914
Mean Difference (Final Values) [4]	-0.40
95% Confidence Interval	-0.99 to 0.20

[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:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	ANOVA model with baseline asthmatic condition, pollen region and treatment group as fixed effects

Statistical Analysis 3 for Average Rhinoconjunctivitis DSS for the Entire RS

Groups [1]	SCH 39641 12 Amb a 1-U vs. Placebo
Method [2]	ANOVA
P Value [3]	0.0021
Mean Difference (Final Values) [4]	-0.96
95% Confidence Interval	-1.57 to -0.35

[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:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	ANOVA model with baseline asthmatic condition, pollen region and treatment group as fixed effects

5. Secondary: Average Rhinoconjunctivitis DMS for the Peak RS [Time Frame: The 15-day period during the ragweed season with the highest moving pollen average]

Measure Type	Secondary
Measure Title	Average Rhinoconjunctivitis DMS for the Peak RS
Measure Description	Rhinoconjunctivitis DMS was based on participant use of specific study-provided rescue medication, with different rescue medications being assigned different scores/dose unit (score range: 0-36), with a lower score indicating less rhinconjunctivitis medication use. Raw means were converted to adjusted means using an ANOVA model with baseline asthmatic condition, pollen region and treatment group as fixed effects.
Time Frame	The 15-day period during the ragweed season with the highest moving pollen average
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.
The FAS population consisted of all randomized participants who took at least one dose of study medication and had at least one post-randomization efficacy measurement.

Reporting Groups

	Description
SCH 39641 1.5 Amb a 1-U	Participants receive Ambrosia artemisiifolia allergan extract (SCH 39641 1.5 Amb a 1-U) rapidly dissolving sublingual tablets, administered once daily for approximately 52 weeks
SCH 39641 6 Amb a 1-U	Participants receive Ambrosia artemisiifolia allergan extract (SCH 39641 6 Amb a 1-U) rapidly dissolving sublingual tablets, administered once daily for approximately 52 weeks
SCH 39641 12 Amb a 1-U	Participants receive Ambrosia artemisiifolia allergan extract (SCH 39641 12 Amb a 1-U) rapidly dissolving sublingual tablets, administered once daily for approximately 52 weeks
Placebo	Participants receive matching placebo rapidly dissolving sublingual tablets, administered once daily for approximately 52 weeks

Measured Values

	SCH 39641 1.5 Amb a 1-U	**SCH 39641 6 Amb a 1-U**	**SCH 39641 12 Amb a 1-U**	**Placebo**
Number of Participants Analyzed [units: participants]	**169**	**167**	**152**	**169**
Average Rhinoconjunctivitis DMS for the Peak RS [units: score on a scale]	**2.58 (0.322)**	**2.01 (0.328)**	**1.99 (0.333)**	**3.09 (0.333)**

Mean (Standard Error)				

Statistical Analysis 1 for Average Rhinoconjunctivitis DMS for the Peak RS

Groups [1]	SCH 39641 1.5 Amb a 1-U vs. Placebo
Method [2]	ANOVA
P Value [3]	0.1900
Mean Difference (Final Values) [4]	-0.51
95% Confidence Interval	-1.26 to 0.25

[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:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	ANOVA model with baseline asthmatic condition, pollen region and treatment group as fixed effects

Statistical Analysis 2 for Average Rhinoconjunctivitis DMS for the Peak RS

Groups [1]	SCH 39641 6 Amb a 1-U vs. Placebo
Method [2]	ANOVA
P Value [3]	0.0053
Mean Difference (Final Values) [4]	-1.08
95% Confidence Interval	-1.84 to -0.32

[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:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	ANOVA model with baseline asthmatic condition, pollen region and treatment group as fixed effects

Statistical Analysis 3 for Average Rhinoconjunctivitis DMS for the Peak RS

Groups [1]	SCH 39641 12 Amb a 1-U vs. Placebo
[2]	ANOVA

Method	
P Value [3]	0.0058
Mean Difference (Final Values) [4]	-1.10
95% Confidence Interval	-1.89 to -0.32

[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:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	ANOVA model with baseline asthmatic condition, pollen region and treatment group as fixed effects

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Up to 53 weeks
Additional Description	The population consisted of all randomized participants who took at least one dose of study medication.

Reporting Groups

	Description
SCH 39641 1.5 Amb a 1-U	Participants receive Ambrosia artemisiifolia allergan extract (SCH 39641 1.5 Amb a 1-U) rapidly dissolving sublingual tablets, administered once daily for approximately 52 weeks
SCH 39641 6 Amb a 1-U	Participants receive Ambrosia artemisiifolia allergan extract (SCH 39641 6 Amb a 1-U) rapidly dissolving sublingual tablets, administered once daily for approximately 52 weeks
SCH 39641 12 Amb a 1-U	Participants receive Ambrosia artemisiifolia allergan extract (SCH 39641 12 Amb a 1-U) rapidly dissolving sublingual tablets, administered once daily for approximately 52 weeks
Placebo	Participants receive placebo matching Ambrosia artemisiifolia allergan extract rapidly dissolving sublingual tablets, administered once daily for approximately 52 weeks

Serious Adverse Events

	SCH 39641 1.5 Amb a 1-U	SCH 39641 6 Amb a 1-U	SCH 39641 12 Amb a 1-U	Placebo
Total, serious adverse events				
# participants affected / at risk	**5/196 (2.55%)**	**4/195 (2.05%)**	**4/194 (2.06%)**	**1/198 (0.51%)**
Congenital, familial and genetic disorders				
Hydrocele † 1				

# participants affected / at risk	0/196 (0.00%)	0/195 (0.00%)	1/194 (0.52%)	0/198 (0.00%)
# events	0	0	1	0
Gastrointestinal disorders				
Abdominal hernia obstructive † 1				
# participants affected / at risk	0/196 (0.00%)	1/195 (0.51%)	0/194 (0.00%)	0/198 (0.00%)
# events	0	1	0	0
Pancreatitis acute † 1				
# participants affected / at risk	1/196 (0.51%)	0/195 (0.00%)	0/194 (0.00%)	0/198 (0.00%)
# events	2	0	0	0
Hepatobiliary disorders				
Cholelithiasis † 1				
# participants affected / at risk	1/196 (0.51%)	0/195 (0.00%)	0/194 (0.00%)	0/198 (0.00%)
# events	1	0	0	0
Immune system disorders				
Hypersensitivity † 1				
# participants affected / at risk	0/196 (0.00%)	0/195 (0.00%)	1/194 (0.52%)	0/198 (0.00%)
# events	0	0	1	0
Infections and infestations				
Bronchitis † 1				
# participants affected / at risk	0/196 (0.00%)	1/195 (0.51%)	0/194 (0.00%)	0/198 (0.00%)
# events	0	1	0	0
Pneumonia chlamydial † 1				
# participants affected / at risk	0/196 (0.00%)	0/195 (0.00%)	0/194 (0.00%)	1/198 (0.51%)
# events	0	0	0	1
Postoperative abscess † 1				
# participants affected / at risk	0/196 (0.00%)	1/195 (0.51%)	0/194 (0.00%)	0/198 (0.00%)
# events	0	1	0	0
Injury, poisoning and procedural complications				
Ligament rupture † 1				
# participants affected / at risk	1/196 (0.51%)	0/195 (0.00%)	0/194 (0.00%)	0/198 (0.00%)
# events	1	0	0	0
Metabolism and nutrition disorders				

Diabetes mellitus inadequate control † 1				
# participants affected / at risk	**0/196 (0.00%)**	**0/195 (0.00%)**	**1/194 (0.52%)**	**0/198 (0.00%)**
# events	**0**	**0**	**1**	**0**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Breast cancer † 1				
# participants affected / at risk	**1/196 (0.51%)**	**1/195 (0.51%)**	**0/194 (0.00%)**	**0/198 (0.00%)**
# events	**1**	**1**	**0**	**0**
Pregnancy, puerperium and perinatal conditions				
Abortion spontaneous † 1				
# participants affected / at risk	**1/196 (0.51%)**	**1/195 (0.51%)**	**0/194 (0.00%)**	**0/198 (0.00%)**
# events	**1**	**1**	**0**	**0**
Reproductive system and breast disorders				
Ovarian cyst † 1				
# participants affected / at risk	**0/196 (0.00%)**	**0/195 (0.00%)**	**1/194 (0.52%)**	**0/198 (0.00%)**
# events	**0**	**0**	**1**	**0**
Surgical and medical procedures				
Abortion induced † 1				
# participants affected / at risk	**1/196 (0.51%)**	**0/195 (0.00%)**	**0/194 (0.00%)**	**0/198 (0.00%)**
# events	**1**	**0**	**0**	**0**

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

Other Adverse Events

Hide Other Adverse Events

Time Frame	Up to 53 weeks
Additional Description	The population consisted of all randomized participants who took at least one dose of study medication.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
SCH 39641 1.5 Amb a 1-U	Participants receive Ambrosia artemisiifolia allergan extract (SCH 39641 1.5 Amb a 1-U) rapidly dissolving

	sublingual tablets, administered once daily for approximately 52 weeks
SCH 39641 6 Amb a 1-U	Participants receive Ambrosia artemisiifolia allergan extract (SCH 39641 6 Amb a 1-U) rapidly dissolving sublingual tablets, administered once daily for approximately 52 weeks
SCH 39641 12 Amb a 1-U	Participants receive Ambrosia artemisiifolia allergan extract (SCH 39641 12 Amb a 1-U) rapidly dissolving sublingual tablets, administered once daily for approximately 52 weeks
Placebo	Participants receive placebo matching Ambrosia artemisiifolia allergan extract rapidly dissolving sublingual tablets, administered once daily for approximately 52 weeks

Other Adverse Events

	SCH 39641 1.5 Amb a 1-U	SCH 39641 6 Amb a 1-U	SCH 39641 12 Amb a 1-U	Placebo
Total, other (not including serious) adverse events				
# participants affected / at risk	**105/196 (53.57%)**	**108/195 (55.38%)**	**125/194 (64.43%)**	**78/198 (39.39%)**
Ear and labyrinth disorders				
Ear pruritus † 1				
# participants affected / at risk	**14/196 (7.14%)**	**27/195 (13.85%)**	**25/194 (12.89%)**	**2/198 (1.01%)**
# events	**15**	**30**	**26**	**2**
Gastrointestinal disorders				
Oral pruritus † 1				
# participants affected / at risk	**11/196 (5.61%)**	**29/195 (14.87%)**	**16/194 (8.25%)**	**2/198 (1.01%)**
# events	**12**	**37**	**17**	**2**
Paraesthesia oral † 1				
# participants affected / at risk	**10/196 (5.10%)**	**15/195 (7.69%)**	**9/194 (4.64%)**	**5/198 (2.53%)**
# events	**11**	**18**	**14**	**9**
Swollen tongue † 1				
# participants affected / at risk	**11/196 (5.61%)**	**12/195 (6.15%)**	**15/194 (7.73%)**	**1/198 (0.51%)**
# events	**11**	**14**	**16**	**1**
Tongue oedema † 1				
# participants affected / at risk	**8/196 (4.08%)**	**15/195 (7.69%)**	**12/194 (6.19%)**	**0/198 (0.00%)**
# events	**8**	**16**	**14**	**0**
Tongue pruritus † 1				
# participants affected / at risk	**13/196 (6.63%)**	**19/195 (9.74%)**	**18/194 (9.28%)**	**3/198 (1.52%)**
# events	**14**	**26**	**21**	**3**
Infections and infestations				
Bronchitis † 1				
# participants affected / at risk	**5/196 (2.55%)**	**6/195 (3.08%)**	**8/194 (4.12%)**	**12/198 (6.06%)**
# events	**7**	**6**	**8**	**14**
Nasopharyngitis † 1				
# participants affected / at risk	**31/196 (15.82%)**	**28/195 (14.36%)**	**33/194 (17.01%)**	**35/198 (17.68%)**
# events	**40**	**35**	**42**	**45**
† 1				

Sinusitis				
# participants affected / at risk	**12/196 (6.12%)**	**9/195 (4.62%)**	**8/194 (4.12%)**	**7/198 (3.54%)**
# events	**13**	**10**	**9**	**10**
Upper respiratory tract infection † 1				
# participants affected / at risk	**9/196 (4.59%)**	**18/195 (9.23%)**	**9/194 (4.64%)**	**9/198 (4.55%)**
# events	**9**	**22**	**12**	**11**
Nervous system disorders				
Headache † 1				
# participants affected / at risk	**15/196 (7.65%)**	**12/195 (6.15%)**	**18/194 (9.28%)**	**20/198 (10.10%)**
# events	**33**	**17**	**49**	**34**
Respiratory, thoracic and mediastinal disorders				
Cough † 1				
# participants affected / at risk	**11/196 (5.61%)**	**10/195 (5.13%)**	**12/194 (6.19%)**	**6/198 (3.03%)**
# events	**13**	**10**	**14**	**8**
Oropharyngeal pain † 1				
# participants affected / at risk	**14/196 (7.14%)**	**5/195 (2.56%)**	**9/194 (4.64%)**	**4/198 (2.02%)**
# events	**17**	**5**	**10**	**4**
Sneezing † 1				
# participants affected / at risk	**10/196 (5.10%)**	**6/195 (3.08%)**	**8/194 (4.12%)**	**4/198 (2.02%)**
# events	**11**	**7**	**10**	**8**
Throat irritation † 1				
# participants affected / at risk	**28/196 (14.29%)**	**42/195 (21.54%)**	**41/194 (21.13%)**	**11/198 (5.56%)**
# events	**29**	**46**	**45**	**11**

† 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: The investigator agrees to provide to the sponsor 45 days prior to submission for publication or presentation, review copies of abstracts or manuscripts for publication that report any results of the study.

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:

Creticos PS, Maloney J, Bernstein DI, Casale T, Kaur A, Fisher R, Liu N, Murphy K, Nékám K, Nolte H. Randomized controlled trial of a ragweed allergy immunotherapy tablet in North American and European adults. J Allergy Clin Immunol. 2013 May;131(5):1342-9.e6. doi: 10.1016/j.jaci.2013.03.019.

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Christensen LH, Ipsen H, Nolte H, Maloney J, Nelson HS, Weber R, Lund K. Short ragweeds is highly cross-reactive with other ragweeds. Ann Allergy Asthma Immunol. 2015 Dec;115(6):490-495.e1. doi: 10.1016/j.anai.2015.09.016. Epub 2015 Oct 21.

Nolte H, Amar N, Bernstein DI, Lanier BQ, Creticos P, Berman G, Kaur A, Hébert J, Maloney J. Safety and tolerability of a short ragweed sublingual immunotherapy tablet. Ann Allergy Asthma Immunol. 2014 Jul;113(1):93-100.e3. doi: 10.1016/j.anai.2014.04.018. Epub 2014 May 14.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00770315 History of Changes
Other Study ID Numbers:	P05234 3810249 (Other Identifier: Schering-Plough Study Number) 2008-003864-20 (EudraCT Number) MK-3641-002 (Other Identifier: Merck Protocol Number)
Study First Received:	October 9, 2008
Results First Received:	April 25, 2014
Last Updated:	October 12, 2015
Health Authority:	United States: Food and Drug Administration

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