Trial record **1 of 1** for: CIGE025A2432

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Efficacy of Omalizumab in Adults (18-60 Years of Age) With Moderate-Severe, Persistent Allergic Asthma, Despite Receiving Inhaled Corticosteroids and Long Acting Beta-agonists (eXplore)

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

Collaborator:
Genentech, Inc.

Information provided by (Responsible Party):
Novartis (Novartis Pharmaceuticals)

ClinicalTrials.gov Identifier:
NCT00670930

First received: April 30, 2008
Last updated: December 12, 2012
Last verified: November 2012
History of Changes

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Results First Received: November 16, 2012

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator); Primary Purpose: Treatment
Condition:	Allergic Asthma
Interventions:	Drug: omalizumab at a dose of 0.016mg/kg/IU/mL

	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
No text entered.

Reporting Groups

	Description
Omalizumab	Omalizumab was supplied as lyophilized, sterile powder in a single use, 5 ml vial that was designed to deliver 150 mg of omalizumab for subcutaneous (SQ) administration upon reconstitution with 1.4 ml sterile water for injection. The dose administered was individualized for each patient based on the patient's body weight and total serum Immunoglobulin E (IgE) level at Visit 1 and the number of injections and injection volume was determined using protocol-specified dosing tables. Omalizumab 75 to 375 mg was administered SQ every 2 or 4 weeks depending on the dose for the 78 weeks duration of double-blinded treatment.
Placebo	Omalizumab matching placebo was supplied as lyophilized, sterile powder in a single-use, 5 ml vial that was designed to deliver omalizumab matching placebo for subcutaneous (SQ) administration upon reconstitution with 1.4 ml sterile water for injection. The number of injections and injection volume was individualized for each patient based on the patient's body weight and total serum Immunoglobulin E (IgE) level at Visit 1 and was determined using protocol-specified dosing tables. Placebo was administered SQ every 2 or 4 weeks for the 78 weeks duration of double-blinded treatment.

Participant Flow: Overall Study

	Omalizumab	Placebo

STARTED	**23** [1]	**13**
Intent to Treat (ITT) Population	**23**	**12**
COMPLETED	**22**	**12**
NOT COMPLETED	**1**	**1**
Adminstrative Problem	**0**	**1**
Lost to Follow-up	**1**	**0**

[1] "Started" indicates Randomized and Safety populaiton

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
Omalizumab	Omalizumab was supplied as lyophilized, sterile powder in a single use, 5 ml vial that was designed to deliver 150 mg of omalizumab for subcutaneous (SQ) administration upon reconstitution with 1.4 ml sterile water for injection. The dose administered was individualized for each patient based on the patient's body weight and total serum Immunoglobulin E (IgE) level at Visit 1 and the number of injections and injection volume was determined using protocol-specified dosing tables. Omalizumab 75 to 375 mg was administered SQ every 2 or 4 weeks depending on the dose for the 78 weeks duration of double-blinded treatment.
Placebo	Omalizumab matching placebo was supplied as lyophilized, sterile powder in a single-use, 5 ml vial that was designed to deliver omalizumab matching placebo for subcutaneous (SQ) administration upon reconstitution with 1.4 ml sterile water for injection. The number of injections and injection volume was individualized for each patient based on the patient's body weight and total serum Immunoglobulin E (IgE) level at Visit 1 and was determined using protocol-specified dosing tables. Placebo

	was administered SQ every 2 or 4 weeks for the 78 weeks duration of double-blinded treatment.
Total	Total of all reporting groups

Baseline Measures

	Omalizumab	Placebo	Total
Number of Participants [units: participants]	**23**	**12**	**35**
Age [1] [units: Years] Mean (Standard Deviation)	**43.7 (9.66)**	**41.8 (10.43)**	**43.1 (9.8)**
Gender [units: Participants]			
Female	**13**	**6**	**19**
Male	**10**	**6**	**16**

[1] Demographics analysis based on Intent to treat population.

Outcome Measures

Hide All Outcome Measures

1. Primary: Change From Baseline in Total Subepithelial Eosinophils at the End of Week 78 (End of Treatment) [Time Frame: Baseline, at end of week 78]

Measure Type	Primary
Measure Title	Change From Baseline in Total Subepithelial Eosinophils at the End of Week 78 (End of Treatment)
Measure Description	The primary variable of change from baseline in total epithelia eosinophils at end of Week 78 was analyzed on sub-population such as responders and non-responders. Responders are defined as all patients having a Global Evaluation of Treatment Effectiveness (GETE) outcome of excellent or good where as non-responders are with GETE

	outcome of poor, moderate or worsening. GETE categories are excellent, good, moderate, poor, worsening, and missing as determined by the investigator.
Time Frame	Baseline, at end of week 78
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent-to-treat (ITT) population: The ITT population consisted of all randomized patients. Following the intent-to-treat principle, patients were analyzed according to the treatment they were assigned to at randomization. Patients with both baseline and af end of week 78 data in each category have been reported.

Reporting Groups

	Description
Omalizumab	Omalizumab was supplied as lyophilized, sterile powder in a single use, 5 ml vial that was designed to deliver 150 mg of omalizumab for subcutaneous (SQ) administration upon reconstitution with 1.4 ml sterile water for injection. The dose administered was individualized for each patient based on the patient's body weight and total serum Immunoglobulin E (IgE) level at Visit 1 and the number of injections and injection volume was determined using protocol-specified dosing tables. Omalizumab 75 to 375 mg was administered SQ every 2 or 4 weeks depending on the dose for the 78 weeks duration of double-blinded treatment.
Placebo	Omalizumab matching placebo was supplied as lyophilized, sterile powder in a single-use, 5 ml vial that was designed to deliver omalizumab matching placebo for subcutaneous (SQ) administration upon reconstitution with 1.4 ml sterile water for injection. The number of injections and injection volume was individualized for each patient based on the patient's body weight and total serum Immunoglobulin E (IgE) level at Visit 1 and was determined using protocol-specified dosing tables. Placebo was administered SQ every 2 or 4 weeks for the 78 weeks duration of double-blinded treatment.

Measured Values

	Omalizumab	**Placebo**
Number of Participants Analyzed [units: participants]	**17**	**11**

Change From Baseline in Total Subepithelial Eosinophils at the End of Week 78 (End of Treatment) [units: cells/mm^2] Mean (Standard Deviation)		
Responder (n= 9, 3)	**-5.807 (13.921)**	**-5.890 (9.128)**
Non-responder (n = 8, 8)	**1.555 (11.065)**	**-5.626 (15.816)**

No statistical analysis provided for Change From Baseline in Total Subepithelial Eosinophils at the End of Week 78 (End of Treatment)

2. Secondary: Change From Baseline in Sub-epithelial Cell Count of Mast Cells Following 78 Weeks Treatment, as Assessed Biopsy Samples [Time Frame: Baseline, at end of week 78]

Measure Type	Secondary
Measure Title	Change From Baseline in Sub-epithelial Cell Count of Mast Cells Following 78 Weeks Treatment, as Assessed Biopsy Samples
Measure Description	The variable of change from baseline in Sub-epithelial cell count of mast cells at end of Week 78 was analyzed on sub-population such as responders and non-responders. Responders are defined as all patients having a Global Evaluation of Treatment Effectiveness (GETE) outcome of excellent or good where as non-responders are with GETE outcome of poor, moderate or worsening. GETE categories are excellent, good, moderate, poor, worsening, and missing as determined by the investigator.
Time Frame	Baseline, at end of week 78
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent-to-treat (ITT) population: The ITT population consisted of all randomized patients. Patients with both baseline and end of treatment (at the end of week 78) data were only included for the analysis under each category.

Reporting Groups

	Description
Omalizumab	Omalizumab was supplied as lyophilized, sterile powder in a single use, 5 ml vial that was designed to deliver 150 mg of omalizumab for subcutaneous (SQ) administration upon reconstitution with 1.4 ml sterile water for injection. The dose administered was individualized for each patient based on the patient's body weight and total serum Immunoglobulin E (IgE) level at Visit 1 and the number of injections and injection volume was determined using protocol-specified dosing tables. Omalizumab 75 to 375 mg was administered SQ every 2 or 4 weeks depending on the dose for the 78 weeks duration of double-blinded treatment.
Placebo	Omalizumab matching placebo was supplied as lyophilized, sterile powder in a single-use, 5 ml vial that was designed to deliver omalizumab matching placebo for subcutaneous (SQ) administration upon reconstitution with 1.4 ml sterile water for injection. The number of injections and injection volume was individualized for each patient based on the patient's body weight and total serum Immunoglobulin E (IgE) level at Visit 1 and was determined using protocol-specified dosing tables. Placebo was administered SQ every 2 or 4 weeks for the 78 weeks duration of double-blinded treatment.

Measured Values

	Omalizumab	Placebo
Number of Participants Analyzed [units: participants]	**17**	**11**
Change From Baseline in Sub-epithelial Cell Count of Mast Cells Following 78 Weeks Treatment, as Assessed Biopsy Samples [units: cells/mm^2] Mean (Standard Deviation)		
Responder (n= 9, 3)	**-1.392 (13.123)**	**5.840 (19.809)**
Non-responder (n= 8, 8)	**10.140 (10.266)**	**1.114 (18.397)**

No statistical analysis provided for Change From Baseline in Sub-epithelial Cell Count of Mast Cells Following 78 Weeks Treatment, as Assessed Biopsy Samples

3. Secondary: Change From Baseline in Sub-epithelial CD4+ T-lymphocytes Following 78 Weeks Treatment, as Assessed Biopsy Samples [Time Frame: Baseline, at end of week 78]

Measure Type	Secondary
Measure Title	Change From Baseline in Sub-epithelial CD4+ T-lymphocytes Following 78 Weeks Treatment, as Assessed Biopsy Samples
Measure Description	The variable of change from baseline in Sub-epithelial CD4+ T-lymphocytes at end of Week 78 was analyzed on sub-population such as responders and non-responders. Responders are defined as all patients having a Global Evaluation of Treatment Effectiveness (GETE) outcome of excellent or good where as non-responders are with GETE outcome of poor, moderate or worsening. GETE categories are excellent, good, moderate, poor, worsening, and missing as determined by the investigator.
Time Frame	Baseline, at end of week 78
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent-to-treat (ITT) population: The ITT population consisted of all randomized patients. Patients with both baseline and end of treatment (at the end of week 78) data were only included for the analysis under each category.

Reporting Groups

	Description
Omalizumab	Omalizumab was supplied as lyophilized, sterile powder in a single use, 5 ml vial that was designed to deliver 150 mg of omalizumab for subcutaneous (SQ) administration upon reconstitution with 1.4 ml sterile water for injection. The dose administered was individualized for each patient based on the patient's body weight and total serum Immunoglobulin E (IgE) level at Visit 1 and the number of injections and injection volume was determined using protocol-specified dosing tables. Omalizumab 75 to 375 mg was administered SQ every 2 or 4 weeks depending on the dose for the 78 weeks duration of double-blinded treatment.
Placebo	Omalizumab matching placebo was supplied as lyophilized, sterile powder in a single-use, 5 ml vial that was designed to deliver omalizumab matching placebo for subcutaneous (SQ) administration upon reconstitution with 1.4 ml sterile water for

	injection. The number of injections and injection volume was individualized for each patient based on the patient's body weight and total serum Immunoglobulin E (IgE) level at Visit 1 and was determined using protocol-specified dosing tables. Placebo was administered SQ every 2 or 4 weeks for the 78 weeks duration of double-blinded treatment.

Measured Values

	Omalizumab	Placebo
Number of Participants Analyzed [units: participants]	**17**	**11**
Change From Baseline in Sub-epithelial CD4+ T-lymphocytes Following 78 Weeks Treatment, as Assessed Biopsy Samples [units: cells/mm^2] Mean (Standard Deviation)		
Responder (n= 9, 3)	**-5.820 (12.490)**	**-2.693 (8.117)**
Non-responder (n= 8, 8)	**-4.719 (11.021)**	**-7.320 (13.950)**

No statistical analysis provided for Change From Baseline in Sub-epithelial CD4+ T-lymphocytes Following 78 Weeks Treatment, as Assessed Biopsy Samples

4. Secondary: Change From Baseline in Thickness of the Lamina Reticularis Following 78 Weeks Treatment, as Assessed Biopsy Samples [Time Frame: Baseline, at end of week 78]

Measure Type	Secondary
Measure Title	Change From Baseline in Thickness of the Lamina Reticularis Following 78 Weeks Treatment, as Assessed Biopsy Samples
Measure Description	The variable of change from baseline in thickness of the lamina reticularis at end of Week 78 was analyzed on sub-population such as responders and non-responders. Responders are defined as all patients having a Global Evaluation of Treatment Effectiveness (GETE) outcome of excellent or good where as non-responders are with GETE

	outcome of poor, moderate or worsening. GETE categories are excellent, good, moderate, poor, worsening, and missing as determined by the investigator.
Time Frame	Baseline, at end of week 78
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent-to-treat (ITT) population: The ITT population consisted of all randomized patients. Patients with both baseline and end of treatment (at the end of week 78) data were only included for the analysis under each category.

Reporting Groups

	Description
Omalizumab	Omalizumab was supplied as lyophilized, sterile powder in a single use, 5 ml vial that was designed to deliver 150 mg of omalizumab for subcutaneous (SQ) administration upon reconstitution with 1.4 ml sterile water for injection. The dose administered was individualized for each patient based on the patient's body weight and total serum Immunoglobulin E (IgE) level at Visit 1 and the number of injections and injection volume was determined using protocol-specified dosing tables. Omalizumab 75 to 375 mg was administered SQ every 2 or 4 weeks depending on the dose for the 78 weeks duration of double-blinded treatment.
Placebo	Omalizumab matching placebo was supplied as lyophilized, sterile powder in a single-use, 5 ml vial that was designed to deliver omalizumab matching placebo for subcutaneous (SQ) administration upon reconstitution with 1.4 ml sterile water for injection. The number of injections and injection volume was individualized for each patient based on the patient's body weight and total serum Immunoglobulin E (IgE) level at Visit 1 and was determined using protocol-specified dosing tables. Placebo was administered SQ every 2 or 4 weeks for the 78 weeks duration of double-blinded treatment.

Measured Values

	Omalizumab	**Placebo**
Number of Participants Analyzed [units: participants]	**16**	**11**

Change From Baseline in Thickness of the Lamina Reticularis Following 78 Weeks Treatment, as Assessed Biopsy Samples [units: micrometer(µm)] Mean (Standard Deviation)		
Responder (n= 8, 3)	**-1.300 (2.926)**	**-1.603 (0.258)**
Non-responder (n= 8, 8)	**0.098 (2.276)**	**-0.659 (2.288)**

No statistical analysis provided for Change From Baseline in Thickness of the Lamina Reticularis Following 78 Weeks Treatment, as Assessed Biopsy Samples

5. Secondary: Number of Participants With Adverse Events, Serious Adverse Events and Death as an Assessment of Safety and Tolerability of 78 Weeks Therapy [Time Frame: 78 weeks]

Measure Type	Secondary
Measure Title	Number of Participants With Adverse Events, Serious Adverse Events and Death as an Assessment of Safety and Tolerability of 78 Weeks Therapy
Measure Description	No text entered.
Time Frame	78 weeks
Safety Issue	Yes

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 safety population consisted of all patients in the intent to treat (ITT) population that received at least one dose of study drug and had at least one post-baseline safety assessment.

Reporting Groups

	Description
Omalizumab	Omalizumab was supplied as lyophilized, sterile powder in a single use, 5 ml vial that was designed to deliver 150 mg of omalizumab for subcutaneous (SQ) administration upon reconstitution with 1.4 ml sterile water for injection. The dose administered was individualized for each patient based on the patient's body weight and total serum Immunoglobulin E (IgE) level at Visit 1 and the number of injections and injection volume was determined using protocol-specified dosing tables. Omalizumab 75 to 375 mg was administered SQ every 2 or 4 weeks depending on the dose for the 78 weeks duration of double-blinded treatment.
Placebo	Omalizumab matching placebo was supplied as lyophilized, sterile powder in a single-use, 5 ml vial that was designed to deliver omalizumab matching placebo for subcutaneous (SQ) administration upon reconstitution with 1.4 ml sterile water for injection. The number of injections and injection volume was individualized for each patient based on the patient's body weight and total serum Immunoglobulin E (IgE) level at Visit 1 and was determined using protocol-specified dosing tables. Placebo was administered SQ every 2 or 4 weeks for the 78 weeks duration of double-blinded treatment.

Measured Values

	Omalizumab	Placebo
Number of Participants Analyzed [units: participants]	**23**	**13**
Number of Participants With Adverse Events, Serious Adverse Events and Death as an Assessment of Safety and Tolerability of 78 Weeks Therapy [units: Participants]		
At least one adverse event	**19**	**12**
At least one serious adverse event	**1**	**0**
Death	**0**	**0**

No statistical analysis provided for Number of Participants With Adverse Events, Serious Adverse Events and Death as an Assessment of Safety and Tolerability of 78 Weeks Therapy

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Omalizumab	Omalizumab
Placebo	Placebo

Serious Adverse Events

	Omalizumab	Placebo
Total, serious adverse events		
# participants affected / at risk	**1/23 (4.35%)**	**0/13 (0.00%)**
Hepatobiliary disorders		
Biliary colic † 1		
# participants affected / at risk	**1/23 (4.35%)**	**0/13 (0.00%)**

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

Other Adverse Events

Hide Other Adverse Events

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

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Omalizumab	Omalizumab
Placebo	Placebo

Other Adverse Events

	Omalizumab	Placebo
Total, other (not including serious) adverse events		
# participants affected / at risk	**16/23 (69.57%)**	**12/13 (92.31%)**
Blood and lymphatic system disorders		
Lymphadenopathy † [1]		
# participants affected / at risk	**0/23 (0.00%)**	**1/13 (7.69%)**
Cardiac disorders		
Palpitations † [1]		
# participants affected / at risk	**2/23 (8.70%)**	**0/13 (0.00%)**
Ear and labyrinth disorders		
Tinnitus † [1]		
# participants affected / at risk	**0/23 (0.00%)**	**1/13 (7.69%)**
Eye disorders		

Photopsia † 1		
# participants affected / at risk	**0/23 (0.00%)**	**1/13 (7.69%)**
Gastrointestinal disorders		
Abdominal distension † 1		
# participants affected / at risk	**0/23 (0.00%)**	**1/13 (7.69%)**
Abdominal pain † 1		
# participants affected / at risk	**0/23 (0.00%)**	**1/13 (7.69%)**
Diarrhoea † 1		
# participants affected / at risk	**1/23 (4.35%)**	**3/13 (23.08%)**
Dyspepsia † 1		
# participants affected / at risk	**2/23 (8.70%)**	**0/13 (0.00%)**
Gastrooesophageal reflux disease † 1		
# participants affected / at risk	**0/23 (0.00%)**	**1/13 (7.69%)**
Nausea † 1		
# participants affected / at risk	**3/23 (13.04%)**	**2/13 (15.38%)**
Vomiting † 1		
# participants affected / at risk	**1/23 (4.35%)**	**1/13 (7.69%)**
General disorders		
Chest pain † 1		
# participants affected / at risk	**2/23 (8.70%)**	**0/13 (0.00%)**
Fatigue † 1		
# participants affected / at risk	**2/23 (8.70%)**	**0/13 (0.00%)**
Injection site erythema † 1		
# participants affected / at risk	**2/23 (8.70%)**	**0/13 (0.00%)**
Injection site rash † 1		

# participants affected / at risk	0/23 (0.00%)	1/13 (7.69%)
Injection site swelling † 1		
# participants affected / at risk	2/23 (8.70%)	0/13 (0.00%)
Pain † 1		
# participants affected / at risk	2/23 (8.70%)	0/13 (0.00%)
Immune system disorders		
Allergy to arthropod bite † 1		
# participants affected / at risk	0/23 (0.00%)	1/13 (7.69%)
Infections and infestations		
Acute sinusitis † 1		
# participants affected / at risk	0/23 (0.00%)	1/13 (7.69%)
Alveolar osteitis † 1		
# participants affected / at risk	0/23 (0.00%)	1/13 (7.69%)
Bronchitis † 1		
# participants affected / at risk	0/23 (0.00%)	1/13 (7.69%)
Influenza † 1		
# participants affected / at risk	2/23 (8.70%)	2/13 (15.38%)
Lower respiratory tract infection † 1		
# participants affected / at risk	3/23 (13.04%)	2/13 (15.38%)
Nasopharyngitis † 1		
# participants affected / at risk	4/23 (17.39%)	2/13 (15.38%)
Pneumonia † 1		
# participants affected / at risk	3/23 (13.04%)	0/13 (0.00%)
Sinusitis † 1		
# participants affected / at risk	2/23 (8.70%)	3/13 (23.08%)

Tooth abscess † 1		
# participants affected / at risk	**0/23 (0.00%)**	**1/13 (7.69%)**
Tracheobronchitis † 1		
# participants affected / at risk	**0/23 (0.00%)**	**1/13 (7.69%)**
Upper respiratory tract infection † 1		
# participants affected / at risk	**3/23 (13.04%)**	**2/13 (15.38%)**
Upper respiratory tract infection bacterial † 1		
# participants affected / at risk	**0/23 (0.00%)**	**1/13 (7.69%)**
Injury, poisoning and procedural complications		
Concussion † 1		
# participants affected / at risk	**0/23 (0.00%)**	**1/13 (7.69%)**
Eye injury † 1		
# participants affected / at risk	**0/23 (0.00%)**	**1/13 (7.69%)**
Joint sprain † 1		
# participants affected / at risk	**1/23 (4.35%)**	**1/13 (7.69%)**
Muscle injury † 1		
# participants affected / at risk	**1/23 (4.35%)**	**1/13 (7.69%)**
Muscle rupture † 1		
# participants affected / at risk	**0/23 (0.00%)**	**1/13 (7.69%)**
Investigations		
Alanine aminotransferase increased † 1		
# participants affected / at risk	**0/23 (0.00%)**	**1/13 (7.69%)**
Aspartate aminotransferase increased † 1		
# participants affected / at risk	**0/23 (0.00%)**	**1/13 (7.69%)**
Metabolism and nutrition disorders		

Vitamin D deficiency † 1		
# participants affected / at risk	**0/23 (0.00%)**	**1/13 (7.69%)**
Musculoskeletal and connective tissue disorders		
Arthralgia † 1		
# participants affected / at risk	**3/23 (13.04%)**	**0/13 (0.00%)**
Back pain † 1		
# participants affected / at risk	**2/23 (8.70%)**	**2/13 (15.38%)**
Muscle spasms † 1		
# participants affected / at risk	**0/23 (0.00%)**	**1/13 (7.69%)**
Neck pain † 1		
# participants affected / at risk	**0/23 (0.00%)**	**1/13 (7.69%)**
Osteoporosis † 1		
# participants affected / at risk	**0/23 (0.00%)**	**1/13 (7.69%)**
Pain in extremity † 1		
# participants affected / at risk	**2/23 (8.70%)**	**1/13 (7.69%)**
Pain in jaw † 1		
# participants affected / at risk	**0/23 (0.00%)**	**1/13 (7.69%)**
Nervous system disorders		
Dizziness † 1		
# participants affected / at risk	**2/23 (8.70%)**	**1/13 (7.69%)**
Headache † 1		
# participants affected / at risk	**5/23 (21.74%)**	**0/13 (0.00%)**
Respiratory, thoracic and mediastinal disorders		
Cough † 1		
# participants affected / at risk	**2/23 (8.70%)**	**2/13 (15.38%)**

Increased bronchial secretion † 1		
# participants affected / at risk	**0/23 (0.00%)**	**1/13 (7.69%)**
Nasal congestion † 1		
# participants affected / at risk	**0/23 (0.00%)**	**1/13 (7.69%)**
Oropharyngeal pain † 1		
# participants affected / at risk	**1/23 (4.35%)**	**1/13 (7.69%)**
Productive cough † 1		
# participants affected / at risk	**2/23 (8.70%)**	**0/13 (0.00%)**
Skin and subcutaneous tissue disorders		
Dermatitis contact † 1		
# participants affected / at risk	**0/23 (0.00%)**	**1/13 (7.69%)**

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

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 terms and conditions of Novartis' agreements with its investigators may vary. However, Novartis does not prohibit any investigator from publishing. Any publications from a single-site are postponed until the publication of the pooled data (i.e., data from all sites) in the clinical trial or disclosure of trial results in their entirety.

Results Point of Contact:

Name/Title: Study Director
Organization: Novartis Pharmaceuticals
phone: 862-778-8300

No publications provided

Responsible Party:	Novartis (Novartis Pharmaceuticals)
ClinicalTrials.gov Identifier:	NCT00670930 History of Changes
Other Study ID Numbers:	**CIGE025A2432**
	2007-004653-29 (EudraCT Number)
Study First Received:	April 30, 2008
Results First Received:	November 16, 2012
Last Updated:	December 12, 2012
Health Authority:	United States: Food and Drug Administration

United Kingdom: Medicines and Healthcare Products Regulatory Agency
Canada: Health Canada
France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis)
Germany: Federal Institute for Drugs and Medical Devices
Sweden: Medical Products Agency
Netherlands: The Central Committee on Research Involving Human Subjects (CCMO)