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Trial record **1 of 1** for: CIGE025A2437

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An Exploratory Study to Assess Multiple Doses of Omalizumab in Patients With Cystic Fibrosis Complicated by Acute Bronchopulmonary Aspergillosis (ABPA)

This study has been terminated.

Sponsor:
Novartis Pharmaceuticals

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

ClinicalTrials.gov Identifier:
NCT00787917

First received: November 7, 2008
Last updated: September 22, 2011
Last verified: September 2011
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Results First Received: July 11, 2011

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
Conditions:	Cystic Fibrosis Allergic Bronchopulmonary Aspergillosis
	Drug: Omalizumab

Interventions:	Drug: Placebo Drug: Itraconazole

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	Eligible participants received a maximum dose of 600 mg omalizumab via subcutaneous injection for 6 months in the double-blind phase of the study. The study medication was to be administered at the same time of day. Study medication was injected subcutaneously into the upper arm in the area of the deltoid or to the thigh. A maximum 600 mg dose required 4 injections. All participants who entered the study received itraconazole twice daily, while receiving oral corticosteroids, with a maximum daily dose of 400 mg. Patients completed double-blinded phase, entered open-label treatment period of 6 months and continued the same regimen of omalizumab of double-blinded phase.
Placebo	Eligible participants received placebo comparator via subcutaneous injection for 6 months in the double-blind phase of the study. The study medication was to be administered at the same time of day. Study medication was injected subcutaneously into the upper arm in the area of the deltoid or to the thigh. All participants who entered the study received itraconazole twice daily, while on oral corticosteroids, with a maximum daily dose of 400 mg.

Participant Flow for 2 periods

Period 1: Blinded Treatment

	Omalizumab	Placebo
STARTED	9	5
COMPLETED	4	3
NOT COMPLETED	5	2
Adverse Event	1	0
Lack of Efficacy	1	0
Administrative problems	3	2

Period 2: Open Label

	Omalizumab	Placebo
STARTED	7	0 [1]
COMPLETED	3	0
NOT COMPLETED	4	0
Unsatisfactory therapeutic effect	1	0
Administrative problems	3	0

[1] "Placebo" was not an arm in open label treatment.

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	Eligible participants received a maximum dose of 600 mg omalizumab via subcutaneous injection for 6 months in the double-blind phase of the study. The study medication was to be administered at the same time of day. Study medication was injected subcutaneously into the upper arm in the area of the deltoid or to the thigh. A maximum 600 mg dose required 4 injections. All participants who entered the study received itraconazole twice daily, while receiving oral corticosteroids, with a maximum daily dose of 400 mg. Patients completed double-blinded phase, entered open-label treatment period of 6 months and continued the same regimen of omalizumab of double-blinded phase.
Placebo	Eligible participants received placebo comparator via subcutaneous injection for 6 months in the double-blind phase of the study. The study medication was to be administered at the same time of day. Study medication was injected subcutaneously into the upper arm in the area of the deltoid or to the thigh. All participants who entered the study received itraconazole twice daily, while on oral corticosteroids, with a maximum daily dose of 400 mg.
Total	Total of all reporting groups

Baseline Measures

	Omalizumab	Placebo	Total
Number of Participants [units: participants]	**9**	**5**	**14**
Age [units: years] Mean (Standard Deviation)	**21 (4.1)**	**28 (9.5)**	**23 (7.1)**
Gender [units: participants]			
Female	**5**	**1**	**6**
Male	**4**	**4**	**8**

Outcome Measures

Hide All Outcome Measures

1. Primary: Change From Baseline, as Measured by the Percentage of Participants Requiring Rescue With Corticosteroids, and as Measured by the Time to Deviation From the Protocol Prescribed Steroid Tapering Regimen [Time Frame: 6 months of blinded treatment]

Measure Type	Primary
Measure Title	Change From Baseline, as Measured by the Percentage of Participants Requiring Rescue With Corticosteroids, and as Measured by the Time to Deviation From the Protocol Prescribed Steroid Tapering Regimen
Measure Description	No text entered.
Time Frame	6 months of blinded treatment
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.
No statistical analysis was performed due to insufficient study enrollment

Reporting Groups

	Description
Omalizumab	Eligible participants received a maximum dose of 600 mg omalizumab via subcutaneous injection for 6 months in the double-blind phase of the study. The study medication was to be administered at the same time of day. Study medication was injected subcutaneously into the upper arm in the area of the deltoid or to the thigh. A maximum 600 mg dose required 4 injections. All participants who entered the study received itraconazole twice daily, while receiving oral corticosteroids, with a maximum daily dose of 400 mg.
Placebo	Eligible participants received placebo comparator via subcutaneous injection for 6 months in the double-blind phase of the study. The study medication was to be administered at the same time of day. Study medication was injected subcutaneously into the upper arm in the area of the deltoid or to the thigh. All participants who entered the study received itraconazole twice

	daily, while on oral corticosteroids, with a maximum daily dose of 400 mg.

Measured Values

	Omalizumab	Placebo
Number of Participants Analyzed [units: participants]	**0**	**0**
Change From Baseline, as Measured by the Percentage of Participants Requiring Rescue With Corticosteroids, and as Measured by the Time to Deviation From the Protocol Prescribed Steroid Tapering Regimen [units: percentage] Least Squares Mean (Standard Error)		

No statistical analysis provided for Change From Baseline, as Measured by the Percentage of Participants Requiring Rescue With Corticosteroids, and as Measured by the Time to Deviation From the Protocol Prescribed Steroid Tapering Regimen

2. Secondary: Change in Allergic Bronchopulmonary Aspergillosis (ABPA) Exacerbation Rates During Double-blind Treatment Period and Open-label Treatment Period [Time Frame: 6 months, 12 months]

Measure Type	Secondary
Measure Title	Change in Allergic Bronchopulmonary Aspergillosis (ABPA) Exacerbation Rates During Double-blind Treatment Period and Open-label Treatment Period
Measure Description	No text entered.
Time Frame	6 months, 12 months
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.
No statistical analysis was performed due to insufficient study enrollment

Reporting Groups

	Description
Omalizumab	Eligible participants received a maximum dose of 600 mg omalizumab via subcutaneous injection for 6 months in the double-blind phase of the study. The study medication was to be administered at the same time of day. Study medication was injected subcutaneously into the upper arm in the area of the deltoid or to the thigh. A maximum 600 mg dose required 4 injections. All participants who entered the study received itraconazole twice daily, while receiving oral corticosteroids, with a maximum daily dose of 400 mg. Patients completed double-blinded phase, entered open-label treatment period of 6 months and continued the same regimen of omalizumab of double-blinded phase.
Placebo	Eligible participants received placebo comparator via subcutaneous injection for 6 months in the double-blind phase of the study. The study medication was to be administered at the same time of day. Study medication was injected subcutaneously into the upper arm in the area of the deltoid or to the thigh. All participants who entered the study received itraconazole twice daily, while on oral corticosteroids, with a maximum daily dose of 400 mg.

Measured Values

	Omalizumab	**Placebo**
Number of Participants Analyzed **[units: participants]**	**0**	**0**
Change in Allergic Bronchopulmonary Aspergillosis (ABPA) Exacerbation Rates During Double-blind Treatment Period and Open-label Treatment Period **[units: percentage]** **Least Squares Mean (Standard Error)**		

No statistical analysis provided for Change in Allergic Bronchopulmonary Aspergillosis (ABPA) Exacerbation Rates During Double-blind Treatment Period and Open-label Treatment Period

3. Secondary: Change in Forced Expiratory Volume in 1 Second (FEV1) From Baseline, Measured at 3 and 6 Months of Treatment [Time Frame: 3 months, 6 months]

Measure Type	Secondary
Measure Title	Change in Forced Expiratory Volume in 1 Second (FEV1) From Baseline, Measured at 3 and 6 Months of Treatment
Measure Description	No text entered.
Time Frame	3 months, 6 months
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.
No statistical analysis was performed due to insufficient study enrollment

Reporting Groups

	Description
Omalizumab	Eligible participants received a maximum dose of 600 mg omalizumab via subcutaneous injection for 6 months in the double-blind phase of the study. The study medication was to be administered at the same time of day. Study medication was injected subcutaneously into the upper arm in the area of the deltoid or to the thigh. A maximum 600 mg dose required 4 injections. All participants who entered the study received itraconazole twice daily, while receiving oral corticosteroids, with a maximum daily dose of 400 mg.
Placebo	Eligible participants received placebo comparator via subcutaneous injection for 6 months in the double-blind phase of the study. The study medication was to be administered at the same time of day. Study medication was injected subcutaneously into the upper arm in the area of the deltoid or to the thigh. All participants who entered the study received itraconazole twice daily, while on oral corticosteroids, with a maximum daily dose of 400 mg.

Measured Values

	Omalizumab	Placebo
Number of Participants Analyzed [units: participants]	**0**	**0**
Change in Forced Expiratory Volume in 1 Second (FEV1) From Baseline, Measured at 3 and 6 Months of Treatment [units: Liters] Least Squares Mean (Standard Error)		

No statistical analysis provided for Change in Forced Expiratory Volume in 1 Second (FEV1) From Baseline, Measured at 3 and 6 Months of Treatment

4. Secondary: Time to Steroid Free State. [Time Frame: 12 months]

Measure Type	Secondary
Measure Title	Time to Steroid Free State.
Measure Description	No text entered.
Time Frame	12 months
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.
No statistical analysis was performed due to insufficient study enrollment

Reporting Groups

	Description

Omalizumab	Eligible participants received a maximum dose of 600 mg omalizumab via subcutaneous injection for 6 months in the double-blind phase of the study. The study medication was to be administered at the same time of day. Study medication was injected subcutaneously into the upper arm in the area of the deltoid or to the thigh. A maximum 600 mg dose required 4 injections. All participants who entered the study received itraconazole twice daily, while receiving oral corticosteroids, with a maximum daily dose of 400 mg. Patients completed double-blinded phase, entered open-label treatment period of 6 months and continued the same regimen of omalizumab of double-blinded phase.
Placebo	Eligible participants received placebo comparator via subcutaneous injection for 6 months in the double-blind phase of the study. The study medication was to be administered at the same time of day. Study medication was injected subcutaneously into the upper arm in the area of the deltoid or to the thigh. All participants who entered the study received itraconazole twice daily, while on oral corticosteroids, with a maximum daily dose of 400 mg.

Measured Values

	Omalizumab	**Placebo**
Number of Participants Analyzed [units: participants]	**0**	**0**
Time to Steroid Free State. [units: days] Mean (Standard Deviation)		

No statistical analysis provided for Time to Steroid Free State.

5. Secondary: Change From Baseline in Average Oral Corticosteroid Use. [Time Frame: 6 months, 12 months]

Measure Type	Secondary
Measure Title	Change From Baseline in Average Oral Corticosteroid Use.
Measure Description	No text entered.
Time Frame	6 months, 12 months

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.
No statistical analysis was performed due to insufficient study enrollment

Reporting Groups

	Description
Omalizumab	Eligible participants received a maximum dose of 600 mg omalizumab via subcutaneous injection for 6 months in the double-blind phase of the study. The study medication was to be administered at the same time of day. Study medication was injected subcutaneously into the upper arm in the area of the deltoid or to the thigh. A maximum 600 mg dose required 4 injections. All participants who entered the study received itraconazole twice daily, while receiving oral corticosteroids, with a maximum daily dose of 400 mg. Patients completed double-blinded phase, entered open-label treatment period of 6 months and continued the same regimen of omalizumab of double-blinded phase.
Placebo	Eligible participants received placebo comparator via subcutaneous injection for 6 months in the double-blind phase of the study. The study medication was to be administered at the same time of day. Study medication was injected subcutaneously into the upper arm in the area of the deltoid or to the thigh. All participants who entered the study received itraconazole twice daily, while on oral corticosteroids, with a maximum daily dose of 400 mg.

Measured Values

	Omalizumab	**Placebo**
Number of Participants Analyzed [units: participants]	**0**	**0**
Change From Baseline in Average Oral Corticosteroid Use. [units: mg/day] Mean (Standard Deviation)		

No statistical analysis provided for Change From Baseline in Average Oral Corticosteroid Use.

6. Secondary: Percentage of Participants Responding to Omalizumab, as Defined by a Reduction in Oral Corticosteroid Dose Use of 50% or More as Compared to Baseline [Time Frame: 6 months, 12 months]

Measure Type	Secondary
Measure Title	Percentage of Participants Responding to Omalizumab, as Defined by a Reduction in Oral Corticosteroid Dose Use of 50% or More as Compared to Baseline
Measure Description	No text entered.
Time Frame	6 months, 12 months
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.
No statistical analysis was performed due to insufficient study enrollment

Reporting Groups

	Description
Omalizumab	Eligible participants received a maximum dose of 600 mg omalizumab via subcutaneous injection for 6 months in the double-blind phase of the study. The study medication was to be administered at the same time of day. Study medication was injected subcutaneously into the upper arm in the area of the deltoid or to the thigh. A maximum 600 mg dose required 4 injections. All participants who entered the study received itraconazole twice daily, while receiving oral corticosteroids, with a maximum daily dose of 400 mg. Patients completed double-blinded phase, entered open-label treatment period of 6 months and continued the same regimen of omalizumab of double-blinded phase.
Placebo	Eligible participants received placebo comparator via subcutaneous injection for 6 months in the double-blind phase of the study. The study medication was to be administered at the same time of day. Study medication was injected subcutaneously

	into the upper arm in the area of the deltoid or to the thigh. All participants who entered the study received itraconazole twice daily, while on oral corticosteroids, with a maximum daily dose of 400 mg.

Measured Values

	Omalizumab	Placebo
Number of Participants Analyzed [units: participants]	**0**	**0**
Percentage of Participants Responding to Omalizumab, as Defined by a Reduction in Oral Corticosteroid Dose Use of 50% or More as Compared to Baseline [units: percentage of participants] Least Squares Mean (Standard Error)		

No statistical analysis provided for Percentage of Participants Responding to Omalizumab, as Defined by a Reduction in Oral Corticosteroid Dose Use of 50% or More as Compared to Baseline

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Blinded Omalizumab	Eligible participants received a maximum dose of 600 mg omalizumab via subcutaneous injection for 6 months in the double-blind phase of the study. The study medication was to be administered at the same time of day. Study medication was injected subcutaneously into the upper arm in the area of the deltoid or to the thigh. A maximum 600 mg dose required 4 injections. All participants who entered the study received itraconazole twice daily, while

	receiving oral corticosteroids, with a maximum daily dose of 400 mg.
Placebo	Eligible participants received placebo comparator via subcutaneous injection for 6 months in the double-blind phase of the study. The study medication was to be administered at the same time of day. Study medication was injected subcutaneously into the upper arm in the area of the deltoid or to the thigh. All participants who entered the study received itraconazole twice daily, while on oral corticosteroids, with a maximum daily dose of 400 mg.
Open Label Omalizumab	Patients who completed double-blinded phase of the study, enrolled into 6 months open label phase and continued in the same regimen of omalizumab as they were during double-blinded phase. A maximum dose of 600 mg omalizumab via subcutaneous injection for 6 months was to be administered at the same time of day. Study medication was injected subcutaneously into the upper arm in the area of the deltoid or to the thigh. A maximum 600 mg dose required 4 injections. All participants who entered the study received itraconazole twice daily, while receiving oral corticosteroids, with a maximum daily dose of 400 mg.

Serious Adverse Events

	Blinded Omalizumab	Placebo	Open Label Omalizumab
Total, serious adverse events			
# participants affected / at risk	**6/9 (66.67%)**	**1/5 (20.00%)**	**4/7 (57.14%)**
Gastrointestinal disorders			
Distal intestinal obstruction syndrome † 1			
# participants affected / at risk	**1/9 (11.11%)**	**0/5 (0.00%)**	**0/7 (0.00%)**
Infections and infestations			
Bronchopulmonary aspergillosis allergic † 1			
# participants affected / at risk	**2/9 (22.22%)**	**0/5 (0.00%)**	**0/7 (0.00%)**
Infective pulmonary exacerbation of cystic fibrosis † 1			
# participants affected / at risk	**5/9 (55.56%)**	**1/5 (20.00%)**	**4/7 (57.14%)**
Lower respiratory tract infection bacterial † 1			
# participants affected / at risk	**1/9 (11.11%)**	**0/5 (0.00%)**	**0/7 (0.00%)**
Pneumonia † 1			
# participants affected / at risk	**0/9 (0.00%)**	**0/5 (0.00%)**	**1/7 (14.29%)**

Respiratory tract infection † 1			
# participants affected / at risk	**0/9 (0.00%)**	**0/5 (0.00%)**	**1/7 (14.29%)**
Respiratory, thoracic and mediastinal disorders			
Dyspnoea exertional † 1			
# participants affected / at risk	**1/9 (11.11%)**	**0/5 (0.00%)**	**0/7 (0.00%)**
Haemoptysis † 1			
# participants affected / at risk	**1/9 (11.11%)**	**0/5 (0.00%)**	**0/7 (0.00%)**
Rhonchi † 1			
# participants affected / at risk	**1/9 (11.11%)**	**0/5 (0.00%)**	**0/7 (0.00%)**
Vascular disorders			
Hypertension † 1			
# participants affected / at risk	**0/9 (0.00%)**	**0/5 (0.00%)**	**1/7 (14.29%)**

† 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
Blinded Omalizumab	Eligible participants received a maximum dose of 600 mg omalizumab via subcutaneous injection for 6 months in the double-blind phase of the study. The study medication was to be administered at the same time of day. Study medication was injected subcutaneously into the upper arm in the area of the deltoid or to the thigh. A maximum 600 mg dose required 4 injections. All participants who entered the study received itraconazole twice daily, while receiving oral corticosteroids, with a maximum daily dose of 400 mg.
Placebo	Eligible participants received placebo comparator via subcutaneous injection for 6 months in the double-blind phase of the study. The study medication was to be administered at the same time of day. Study medication was injected subcutaneously into the upper arm in the area of the deltoid or to the thigh. All participants who entered the study received itraconazole twice daily, while on oral corticosteroids, with a maximum daily dose of 400 mg.
Open Label Omalizumab	Patients who completed double-blinded phase of the study, enrolled into 6 months open label phase and continued in the same regimen of omalizumab as they were during double-blinded phase. A maximum dose of 600 mg omalizumab via subcutaneous injection for 6 months was to be administered at the same time of day. Study medication was injected subcutaneously into the upper arm in the area of the deltoid or to the thigh. A maximum 600 mg dose required 4 injections. All participants who entered the study received itraconazole twice daily, while receiving oral corticosteroids, with a maximum daily dose of 400 mg.

Other Adverse Events

	Blinded Omalizumab	Placebo	Open Label Omalizumab
Total, other (not including serious) adverse events			
# participants affected / at risk	**9/9 (100.00%)**	**5/5 (100.00%)**	**6/7 (85.71%)**
Congenital, familial and genetic disorders			
Cystic fibrosis lung † [1]			
# participants affected / at risk	**1/9 (11.11%)**	**0/5 (0.00%)**	**0/7 (0.00%)**
Endocrine disorders			
Adrenal insufficiency † [1]			
# participants affected / at risk	**0/9 (0.00%)**	**1/5 (20.00%)**	**0/7 (0.00%)**

Eye disorders			
Conjunctivitis † 1			
# participants affected / at risk	**0/9 (0.00%)**	**1/5 (20.00%)**	**0/7 (0.00%)**
Retinopathy hypertensive † 1			
# participants affected / at risk	**0/9 (0.00%)**	**0/5 (0.00%)**	**1/7 (14.29%)**
Gastrointestinal disorders			
Constipation † 1			
# participants affected / at risk	**0/9 (0.00%)**	**0/5 (0.00%)**	**1/7 (14.29%)**
Diarrhoea † 1			
# participants affected / at risk	**1/9 (11.11%)**	**0/5 (0.00%)**	**0/7 (0.00%)**
Nausea † 1			
# participants affected / at risk	**1/9 (11.11%)**	**0/5 (0.00%)**	**1/7 (14.29%)**
Vomiting † 1			
# participants affected / at risk	**0/9 (0.00%)**	**1/5 (20.00%)**	**3/7 (42.86%)**
General disorders			
Chills † 1			
# participants affected / at risk	**0/9 (0.00%)**	**1/5 (20.00%)**	**0/7 (0.00%)**
Device occlusion † 1			
# participants affected / at risk	**1/9 (11.11%)**	**0/5 (0.00%)**	**0/7 (0.00%)**
Exercise tolerance decreased † 1			
# participants affected / at risk	**1/9 (11.11%)**	**0/5 (0.00%)**	**0/7 (0.00%)**
Influenza like illness † 1			
# participants affected / at risk	**0/9 (0.00%)**	**0/5 (0.00%)**	**1/7 (14.29%)**
Injection site erythema † 1			
# participants affected / at risk	**3/9 (33.33%)**	**0/5 (0.00%)**	**0/7 (0.00%)**

Injection site inflammation † 1			
# participants affected / at risk	**1/9 (11.11%)**	**0/5 (0.00%)**	**0/7 (0.00%)**
Injection site pain † 1			
# participants affected / at risk	**1/9 (11.11%)**	**0/5 (0.00%)**	**0/7 (0.00%)**
Injection site swelling † 1			
# participants affected / at risk	**4/9 (44.44%)**	**0/5 (0.00%)**	**0/7 (0.00%)**
Injection site warmth † 1			
# participants affected / at risk	**4/9 (44.44%)**	**0/5 (0.00%)**	**0/7 (0.00%)**
Medical device pain † 1			
# participants affected / at risk	**1/9 (11.11%)**	**0/5 (0.00%)**	**0/7 (0.00%)**
Non-cardiac chest pain † 1			
# participants affected / at risk	**1/9 (11.11%)**	**1/5 (20.00%)**	**1/7 (14.29%)**
Oedema peripheral † 1			
# participants affected / at risk	**1/9 (11.11%)**	**0/5 (0.00%)**	**0/7 (0.00%)**
Pyrexia † 1			
# participants affected / at risk	**3/9 (33.33%)**	**2/5 (40.00%)**	**2/7 (28.57%)**
Vessel puncture site haematoma † 1			
# participants affected / at risk	**1/9 (11.11%)**	**0/5 (0.00%)**	**0/7 (0.00%)**
Immune system disorders			
Food allergy † 1			
# participants affected / at risk	**0/9 (0.00%)**	**1/5 (20.00%)**	**0/7 (0.00%)**
Infections and infestations			
Gastroenteritis † 1			
# participants affected / at risk	**1/9 (11.11%)**	**0/5 (0.00%)**	**0/7 (0.00%)**
Gastrointestinal viral infection † 1			

# participants affected / at risk	0/9 (0.00%)	1/5 (20.00%)	0/7 (0.00%)
Infective pulmonary exacerbation of cystic fibrosis † 1			
# participants affected / at risk	6/9 (66.67%)	4/5 (80.00%)	3/7 (42.86%)
Lower respiratory tract infection † 1			
# participants affected / at risk	1/9 (11.11%)	0/5 (0.00%)	0/7 (0.00%)
Lung infection † 1			
# participants affected / at risk	0/9 (0.00%)	1/5 (20.00%)	0/7 (0.00%)
Nasopharyngitis † 1			
# participants affected / at risk	2/9 (22.22%)	0/5 (0.00%)	2/7 (28.57%)
Oral candidiasis † 1			
# participants affected / at risk	1/9 (11.11%)	0/5 (0.00%)	1/7 (14.29%)
Oral herpes † 1			
# participants affected / at risk	1/9 (11.11%)	0/5 (0.00%)	1/7 (14.29%)
Pharyngitis † 1			
# participants affected / at risk	0/9 (0.00%)	0/5 (0.00%)	1/7 (14.29%)
Pseudomonas infection † 1			
# participants affected / at risk	0/9 (0.00%)	1/5 (20.00%)	0/7 (0.00%)
Respiratory tract infection † 1			
# participants affected / at risk	0/9 (0.00%)	0/5 (0.00%)	1/7 (14.29%)
Sinusitis † 1			
# participants affected / at risk	0/9 (0.00%)	0/5 (0.00%)	1/7 (14.29%)
Upper respiratory tract infection † 1			
# participants affected / at risk	1/9 (11.11%)	0/5 (0.00%)	1/7 (14.29%)
Injury, poisoning and procedural complications			
Procedural pain † 1			

# participants affected / at risk	0/9 (0.00%)	0/5 (0.00%)	1/7 (14.29%)
Rib fracture † 1			
# participants affected / at risk	0/9 (0.00%)	1/5 (20.00%)	0/7 (0.00%)
Investigations			
Blood glucose increased † 1			
# participants affected / at risk	0/9 (0.00%)	0/5 (0.00%)	1/7 (14.29%)
Blood sodium decreased † 1			
# participants affected / at risk	0/9 (0.00%)	0/5 (0.00%)	1/7 (14.29%)
Liver function test abnormal † 1			
# participants affected / at risk	0/9 (0.00%)	0/5 (0.00%)	1/7 (14.29%)
Weight decreased † 1			
# participants affected / at risk	1/9 (11.11%)	0/5 (0.00%)	0/7 (0.00%)
Metabolism and nutrition disorders			
Decreased appetite † 1			
# participants affected / at risk	1/9 (11.11%)	0/5 (0.00%)	1/7 (14.29%)
Hypokalaemia † 1			
# participants affected / at risk	2/9 (22.22%)	0/5 (0.00%)	2/7 (28.57%)
Iron deficiency † 1			
# participants affected / at risk	0/9 (0.00%)	0/5 (0.00%)	1/7 (14.29%)
Vitamin K deficiency † 1			
# participants affected / at risk	1/9 (11.11%)	0/5 (0.00%)	0/7 (0.00%)
Musculoskeletal and connective tissue disorders			
Myalgia † 1			
# participants affected / at risk	0/9 (0.00%)	1/5 (20.00%)	0/7 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and			

polyps)			
Neoplasm skin † 1			
# participants affected / at risk	**1/9 (11.11%)**	**0/5 (0.00%)**	**0/7 (0.00%)**
Nervous system disorders			
Headache † 1			
# participants affected / at risk	**4/9 (44.44%)**	**1/5 (20.00%)**	**3/7 (42.86%)**
Psychiatric disorders			
Anxiety † 1			
# participants affected / at risk	**0/9 (0.00%)**	**1/5 (20.00%)**	**0/7 (0.00%)**
Respiratory, thoracic and mediastinal disorders			
Bronchostenosis † 1			
# participants affected / at risk	**1/9 (11.11%)**	**0/5 (0.00%)**	**0/7 (0.00%)**
Cough † 1			
# participants affected / at risk	**4/9 (44.44%)**	**1/5 (20.00%)**	**3/7 (42.86%)**
Haemoptysis † 1			
# participants affected / at risk	**3/9 (33.33%)**	**0/5 (0.00%)**	**0/7 (0.00%)**
Increased upper airway secretion † 1			
# participants affected / at risk	**1/9 (11.11%)**	**0/5 (0.00%)**	**0/7 (0.00%)**
Oropharyngeal pain † 1			
# participants affected / at risk	**0/9 (0.00%)**	**0/5 (0.00%)**	**1/7 (14.29%)**
Respiratory tract congestion † 1			
# participants affected / at risk	**1/9 (11.11%)**	**0/5 (0.00%)**	**0/7 (0.00%)**
Rhonchi † 1			
# participants affected / at risk	**0/9 (0.00%)**	**1/5 (20.00%)**	**0/7 (0.00%)**
Sputum increased † 1			

# participants affected / at risk	**1/9 (11.11%)**	**1/5 (20.00%)**	**2/7 (28.57%)**
Skin and subcutaneous tissue disorders			
Acne † 1			
# participants affected / at risk	**1/9 (11.11%)**	**0/5 (0.00%)**	**0/7 (0.00%)**
Erythema † 1			
# participants affected / at risk	**0/9 (0.00%)**	**1/5 (20.00%)**	**0/7 (0.00%)**
Rash † 1			
# participants affected / at risk	**0/9 (0.00%)**	**1/5 (20.00%)**	**0/7 (0.00%)**
Vascular disorders			
Deep vein thrombosis † 1			
# participants affected / at risk	**1/9 (11.11%)**	**0/5 (0.00%)**	**0/7 (0.00%)**
Flushing † 1			
# participants affected / at risk	**0/9 (0.00%)**	**0/5 (0.00%)**	**1/7 (14.29%)**
Hypertension † 1			
# participants affected / at risk	**0/9 (0.00%)**	**0/5 (0.00%)**	**1/7 (14.29%)**

† 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's agreements with it's investigators vary. However, Novartis does not prohibit any investigator from publishing. Any publication from a single-center site are postponed until the publication of the pooled data (i.e. data from all sites) in the clinical trial.

Results Point of Contact:

Name/Title: Study Director
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No publications provided

Responsible Party: Novartis (Novartis Pharmaceuticals)
ClinicalTrials.gov Identifier: NCT00787917 History of Changes
Other Study ID Numbers: **CIGE025A2437**

Study First Received:	November 7, 2008
Results First Received:	July 11, 2011
Last Updated:	September 22, 2011
Health Authority:	Belgium: Federal Agency for Medicinal Products and Health Products United Kingdom: Medicines and Healthcare Products Regulatory Agency Germany: Paul-Ehrlich-Institut Italy: Ministry of Health