Efficacy of QAX576 in Asthma

This study is currently recruiting participants.

Verified by Novartis, May 2010

First Received: May 24, 2010 Last Updated: June 10, 2010 History of Changes

Sponsor:	Novartis
Information provided by:	Novartis
ClinicalTrials.gov Identifier:	NCT01130064

Purpose

The purpose of this study is to investigate the efficacy of 24 weeks intravenous treatment with **QAX576** in patients with persistent asthma not adequately controlled with inhaled corticosteroids and long acting beta2-agonists.

Condition	Intervention	Phase
Asthma	Biological: **QAX576** Drug: Placebo	Phase II

Study Type: Interventional

Study Design: Allocation: Randomized
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Primary Purpose: Treatment

Official Title: A Multi-center, Randomized, Double Blind, Placebo-controlled, 'add-on' Study to Investigate the Efficacy and Safety of 24 Weeks Intravenous Treatment With **QAX576** in Patients (≥18-75 Years) With Persistent Asthma Not Adequately Controlled With Inhaled Corticosteroids and Long Acting β2-agonists

Resource links provided by NLM:

MedlinePlus related topics: Asthma
U.S. FDA Resources

Further study details as provided by Novartis:

Primary Outcome Measures:

- Asthma Control Questionnaire [Time Frame: 24 weeks]
  [Designated as safety issue: No]

Secondary Outcome Measures:

- Incidence rate of clinically significant asthma exacerbations [Time Frame: 24 weeks] [Designated as safety issue: No]

Estimated Enrollment:	256
Study Start Date:	May 2010
Estimated Primary Completion Date:	October 2011 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
QAX576: Experimental **QAX576** Intervention: Biological: **QAX576**	Biological: **QAX576** every 3 weeks via intravenous infusion
Placebo: Placebo Comparator Placebo Intervention: Drug: Placebo	Drug: Placebo every 3 weeks via intravenous infusion

Eligibility

Ages Eligible for Study: 18 Years to 75 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Male and female patients
- Female patients must be surgically sterilized or postmenopausal
- Male patients must use two forms of contraception
- Body mass index must be between 18 and 39 kg/m2
- Diagnosis of asthma for at least one year, which is not adequately controlled by inhaled corticosteroids and long acting beta-2 agonists

Exclusion Criteria:

- Smoking history >10 pack-years
- Patients with a diagnosis of chronic obstructive pulmonary disease (COPD)

- Patients who have experienced a severe asthma attack/exacerbation requiring systemic corticosteroids or an increase in maintenance doses, within 6 weeks of screening
- Patients who have had a respiratory tract infection within 6 weeks prior to screening
- History of schistosomiasis, within 6 months of screening, or traveling to a country endemic with schistosomiasis within 6 months of completing the study

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT01130064

Contacts

Contact: Novartis Pharmaceuticals +41-61-324-1111

Locations

Belgium

Novartis Investigative Site Bruxelles, Belgium	**Recruiting**
Novartis Investigative Site Gent, Belgium	**Recruiting**
Novartis Investigative Site Laeken, Belgium	**Recruiting**
Novartis Investigative Site Leuven, Belgium	**Recruiting**
Novartis Investigative Site Liège, Belgium	**Recruiting**

Sponsors and Collaborators

Novartis

Investigators

Study Director: Novartis Pharmaceuticals Novartis Pharmaceuticals

More Information

No publications provided

Responsible Party:	Novartis Pharmaceuticals (External Affairs)
ClinicalTrials.gov Identifier:	NCT01130064 History of Changes
Other Study ID Numbers:	CQAX576A2207, 2009-011590-32
Study First Received:	May 24, 2010
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Health Authority:	Argentina: Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica; Belgium: Federal Agency for Medicinal Products and Health

Products; Germany: The Bavarian State Ministry of the Environment and Public Health; Poland: Office for Registration of Medicinal Products, Medical Devices and Biocidal Products

Keywords provided by Novartis:
Asthma
QAX576

Additional relevant MeSH terms:

Asthma	Respiratory Hypersensitivity
Bronchial Diseases	Hypersensitivity, Immediate
Respiratory Tract Diseases	Hypersensitivity
Lung Diseases, Obstructive	Immune System Diseases
Lung Diseases	

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