Efficacy and Safety of QGE031(Ligelizumab) versus Placebo and Omalizumab in Patients Aged 18-75 Years With Asthma

This study is currently recruiting participants.

Sponsor: **Novartis** Pharmaceuticals
ClinicalTrials.gov Identifier: NCT01716754

Purpose

This study will assess the effect on **asthma** control of different dose levels and regimens of QGE031 in **asthma** patients that are inadequately controlled with inhaled steroid and beta-2 agonist medication. Safety will also be assessed. Comparison will be to placebo and omalizumab. Information from this study will inform the design of future studies.

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 Multi-Center, Randomized, Double-Blind, Placebo and Active-Controlled Study With Exploratory DR to Investigate the Efficacy and Safety of 16 Wks Treatment With s.c. QGE031 in **Asthma** Patients Not Adequately Controlled With High-dose Inhaled Corticosteroids and Long Acting β2-agonists

Primary Outcome Measures:

- QGE031 ACQ response rate compared to placebo [Time Frame: Baseline, Week 16] [Designated as safety issue: No]

Estimated Enrollment: 457

Study Start Date: December 2012

Estimated Study Completion Date: March 2015

Eligibility

Ages Eligible for Study: 18 Years to 75 Years

Criteria

Key Inclusion Criteria:

- A diagnosis of allergic asthma , uncontrolled on current medication.
- History of at least 1 asthma exacerbation during the last 1 year
- Forced Expiratory Volume in one second (FEV1) of ≥ 40% and ≤ 80% of the predicted normal Key Exclusion Criteria:
- Baseline IgE levels or body weight outside the omalizumab dosing table.
- Use of tobacco products within the previous 6 months (Social occasional smokers may be included).