Efficacy and Safety Study of Benralizumab Added to High-dose Inhaled Corticosteroid Plus LABA in Patients With Uncontrolled Asthma

This study is currently recruiting participants.

Sponsor: AstraZeneca

ClinicalTrials.gov Identifier: NCT01928771

Purpose

The purpose of this study is to determine whether **Benralizumab** reduces the number of asthma exacerbations in patients who remain uncontrolled on high doses of ICS-LABA.

Condition	Intervention	Phase
Asthma	Biological: **Benralizumab** Biological: Placebo	Phase 3

Study Type: Interventional

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

Official Title: A Multicentre, Randomized, Double-blind, Parallel Group, Placebo-controlled, Phase III Efficacy and Safety Study of **Benralizumab** (MEDI-563) Added to High-dose Inhaled Corticosteroid Plus Long-acting β2 Agonist in Patients With Uncontrolled Asthma

Primary Outcome Measures:

- To evaluate the effect of **benralizumab** on asthma exacerbations in adult patients with uncontrolled asthma [Time Frame: Immediately following the first administration of study drug through Study Week 48.] [Designated as safety issue: No]

Estimated Enrollment: 1890

Arms	Assigned Interventions
Experimental: **Benralizumab** Arm A **Benralizumab** administered subcutaneously.	Biological: **Benralizumab** **Benralizumab** subcutaneously on study week 0 until study week 44 inclusive.
Experimental: **Benralizumab** Arm B **Benralizumab** administered subcutaneously.	Biological: **Benralizumab** **Benralizumab** subcutaneously on study week 0 until study week 44 inclusive.
Placebo Comparator: Placebo Placebo administered subcutaneously	Biological: Placebo Placebo subcutaneously on study week 0 until study week 44 inclusive. Other Name: Placebo

Eligibility

Ages Eligible for Study: 18 Years to 75 Years

Inclusion Criteria:

1. Female and male aged from 18 to 75 years, inclusively
2. History of physician-diagnosed asthma requiring treatment with medium-to-high dose ICS
3. Documented treatment with high-dose ICS (>500 µg fluticasone dry powder formulation equivalents total daily dose) and LABA for at least 3 month prior to Visit 1 -

Exclusion criteria:

1. Clinically important pulmonary disease other than asthma (e.g. active lung infection, COPD, bronchiectasis, pulmonary fibrosis, cystic fibrosis,)
2. Any disorder, including, but not limited to, cardiovascular, gastrointestinal, hepatic, renal, neurological, musculoskeletal or major physical impairment that is not stable in the opinion of the Investigator
3. Acute upper or lower respiratory infections requiring antibiotics or antiviral medication within 30 days prior to the date informed
4. Any clinically significant abnormal findings in physical examination, vital signs, haematology, clinical chemistry, or urinalysis during screening/run-in period