A Study of the Safety and Effectiveness of Benralizumab to Treat Patients With Severe Uncontrolled Asthma. (ANDHI)

ClinicalTrials.gov Identifier: NCT03170271

Recruitment Status: Recruiting
First Posted: May 31, 2017
Last Update Posted: August 29, 2018

See Contacts and Locations

Sponsor:
AstraZeneca

Information provided by (Responsible Party):
AstraZeneca

Study Details | Tabular View | No Results Posted | Disclaimer | How to Read a Study Record

Study Description

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Brief Summary:

The purpose of this study is to investigate the effect of benralizumab on the rate of asthma exacerbations, patient reported quality of life and lung function during the 24-week treatment in patients with uncontrolled, severe asthma with an eosinophilic phenotype. A subset of patients will be assessed for their ongoing chronic rhinosinusitis with nasal polyps.

Condition or disease	Intervention/treatment	Phase
Asthma	Drug: Benralizumab (Medi-563) Drug: Placebo	Phase 3

Study Design

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Study Type:	Interventional (Clinical Trial)
Estimated Enrollment:	630 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	Double (Participant, Investigator)
Primary Purpose:	Treatment
Official Title:	A Multicenter, Randomized, Double-blind, Parallel Group, Placebo Controlled, Phase 3b Study to Evaluate the Safety and Efficacy of Benralizumab 30 mg sc in Patients With Severe Asthma Uncontrolled on Standard of Care Treatment
Actual Study Start Date:	July 7, 2017
Estimated Primary Completion Date:	August 13, 2020
Estimated Study Completion Date:	August 13, 2020

Resource links provided by the National Library of Medicine

MedlinePlus related topics: Asthma

Drug Information available for: Benralizumab

U.S. FDA Resources

Arms and Interventions

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Arm	Intervention/treatment
Experimental: Benralizumab Administered subcutaneously at Visit 4 (day 0), Visit 6 (day 28 +/- 3 days), Visit 7 (day 56 +/- 3 days) and Visit 9 (day 112 +/- 3 days)	Drug: Benralizumab (Medi-563) 30mg Benralizumab administered as a subcutaneous injection at Visit 4 (day 0), Visit 6 (day 28 +/- 3 days), Visit 7 (day 56 +/- 3 days) and Visit 9 (day 112 +/- 3 days)
Placebo Comparator: Placebo Administered subcutaneously at Visit 4 (day 0), Visit 6 (day 28 +/- 3 days), Visit 7 (day 56 +/- 3 days) and Visit 9 (day 112 +/- 3 days)	Drug: Placebo Placebo administered as a subcutaneous injection at Visit 4 (day 0), Visit 6 (day 28 +/- 3 days), Visit 7 (day 56 +/- 3 days) and Visit 9 (day 112 +/- 3 days)

Outcome Measures

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Primary Outcome Measures:

1. Effect of benralizumab on the rate of asthma exacerbations and the annualized rate of asthma exacerbations between benralizumab and placebo. [Time Frame: 24 weeks after start of dosing.]

   The annualized rate of asthma exacerbations between benralizumab and placebo.

Secondary Outcome Measures:

1. Saint George Respiratory Questionnaire (SGRQ) [Time Frame: Baseline (Visit 4) to the end of treatment (EOT; Day 168/Week 24)]

The change from baseline in Saint George Respiratory Questionnaire (SGRQ) to the end of treatment

Eligibility Criteria

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Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:	18 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

1. Female and male patients aged 18 to 75 years inclusively at the time of Visit 1 with a history of physician-diagnosed asthma requiring treatment with medium-to-high dose Inhaled Corticosteroids (ICS) plus asthma controller, for at least 12 months prior to Visit 1.
2. Documented current treatment with high daily doses of ICS plus at least one other asthma controller for at least 3 months prior to Visit 1.
3. History of at least 2 asthma exacerbations while on ICS plus another asthma controller that required treatment with systemic corticosteroids (IM, IV, or oral) in the 12 months prior to Visit 1.
4. ACQ6 score ≥1.5 at Visit 1.
5. Screening pre-bronchodilator (pre-BD) FEV1 of <80% predicted at Visit 2.

6. Excessive variability in lung function by satisfying ≥ 1 of the following criteria:
    1. Airway reversibility (FEV1 ≥12%) using a short-acting bronchodilator demonstrated at Visit 2 or Visit 3.
    2. Airway reversibility to short-acting bronchodilator (FEV1 ≥12%) documented during the 12 months prior to enrolment Visit 1.
    3. Daily diurnal peak flow variability of >10% when averaged over 7 continuous days during the study run-in period
    4. An increase in FEV1 of ≥12% and 200 mL after a therapeutic trial of systemic corticosteroid (eg, OCS), given outside of an asthma exacerbation, documented in the 12 months prior enrolment Visit 1.
    5. Airway hyper-responsiveness (methacholine: PC20 of <8 mg/mL, histamine: PD20 of <7.8 µmol, mannitol: decrease in FEV1 as per the labelled product instructions) documented in the 24 months prior to randomization Visit 4.
7. Peripheral blood eosinophil count either:
    - 300 cells/µL assessed by central laboratory at either Visit 1 or Visit 2

OR

≥150 to <300 cells/µL assessed by central laboratory at either Visit 1 or Visit 2, IF ≥1 of the following 5 clinical criteria (a to e) is met:

1. Using maintenance OCS (daily or every other day OCS requirement in order to maintain asthma control; maximum total daily dose 20 mg prednisone or equivalent) at screening
2. History of nasal polyposis
3. Age of asthma onset ≥18 years
4. Three or more documented exacerbations requiring systemic corticosteroid treatment during the 12 months prior to screening
5. Pre-bronchodilator forced vital capacity <65% of predicted, as assessed at Visit 2 (note that screening pre-BD FEV1 Inclusion Criterion #6 must still be satisfied)

Exclusion Criteria:

1. Clinically important pulmonary disease other than asthma
2. Acute upper or lower respiratory infections within 30 days prior to the date informed consent.
3. A helminth parasitic infection diagnosed within 24 weeks prior to the date informed consent is obtained that has not been treated with, or has failed to respond to, standard of care therapy.

4. History of alcohol or drug abuse within 12 months prior to the date informed consent is obtained.
5. A history of known immunodeficiency disorder.
6. Current smokers or former smokers with a smoking history of ≥10 pack years.
7. Previously received benralizumab (MEDI-563).
8. Receipt of any investigational medication as part of a research study within approximately 5 half-lives prior to randomization.
9. Receipt of immunoglobulin or blood products within 30 days prior to the date informed consent is obtained.
10. Receipt of live attenuated vaccines 30 days prior to the date of randomization; other types of vaccines are allowed.
11. Concurrent enrolment in another interventional or post-authorization safety study

Contacts and Locations

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Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT03170271***

Contacts

Contact: AstraZeneca Clinical Study Information Center 1-877-240-9479 information.center@astrazeneca.com

Show 216 Study Locations

Sponsors and Collaborators

AstraZeneca

Investigators

Principal Investigator:	Brad Goodman, MD	Aero Allergy Research Lab of Savannah
Principal Investigator:	Vinay Sikand, MD	Sikand Institute of Pulmonary Research
Principal Investigator:	Willaim Cherry, MD	Riverside Medical Center

More Information

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Responsible Party:	AstraZeneca
ClinicalTrials.gov Identifier:	NCT03170271 History of Changes
Other Study ID Numbers:	D3250C00045
	2017-001040-35 (EudraCT Number)
First Posted:	May 31, 2017 Key Record Dates
Last Update Posted:	August 29, 2018
Last Verified:	August 2018

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD: Yes

Studies a U.S. FDA-regulated Drug Product:	Yes
Studies a U.S. FDA-regulated Device Product:	No
Product Manufactured in and Exported from the U.S.:	No

Keywords provided by AstraZeneca:

Asthma, Bronchial Diseases, Respiratory Tract Diseases, Lung Diseases, Obstructive Lung Diseases

Additional relevant MeSH terms:

Asthma

Inflammation

Bronchial Diseases

Respiratory Tract Diseases

Lung Diseases, Obstructive

Lung Diseases Respiratory Hypersensitivity

Hypersensitivity, Immediate

Hypersensitivity

Immune System Diseases

Pathologic Processes

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