ForPatients
by Roche

Chronic Obstructive Pulmonary Disease (COPD)

A Study to Evaluate the Efficacy and Safety of Astegolimab in Participants With Chronic Obstructive Pulmonary Disease

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	24 Countries	NCT05037929 GB43311

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Phase IIb, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Astegolimab in Patients With Chronic Obstructive Pulmonary Disease

Trial Summary:

This study will evaluate the efficacy, safety, and pharmacokinetics of astegolimab in combination with standard of care chronic obstructive pulmonary disease (COPD) maintenance therapy in patients with COPD who are former or current smokers and have a history of frequent exacerbations.

Genentech, Inc.
Sponsor

Phase 2
Phase

NCT05037929 GB43311
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#40 Years & # 90 Years	No

Inclusion Criteria:

- Documented physician diagnosis of COPD for at least 12 months
- History of frequent exacerbations, defined as having had two or more moderate or severe exacerbations occurring within a 12-month period in the 24 months prior to screening
- Post-bronchodilator FEV1 >=20 and <80% of predicted normal value at screening
- Modified Medical Research Council (dyspnea scale) (mMRC) score >=2
- Current or former smoker with a minimum of 10 pack-year history

- History of one of the following combinations of optimized, stable, standard-of-care COPD maintenance therapy for at least 4 weeks prior to screening, with no anticipated changes in therapy prior to initiation of study drug and throughout the study: Inhaled corticosteroid (ICS) plus long-acting beta-agonist (LABA); Long-acting muscarinic antagonist (LAMA) plus LABA; ICS plus LAMA plus LABA

Exclusion Criteria:

- Current documented diagnosis of asthma according to the Global Initiative for Asthma guidelines or other accepted guidelines within 5 years prior to screening
- History of clinically significant pulmonary disease other than COPD
- History of long-term treatment with oxygen at >4.0 liters/minute
- Lung volume reduction surgery or procedure within 12 months prior to screening
- Participation in or planned participation in a new pulmonary rehabilitation program. Patients who are in the maintenance phase of a rehabilitation program are eligible
- History of lung transplant
- Occurrence of moderate or severe COPD exacerbation, COVID-19, upper or lower respiratory infection, pneumonia, or hospitalization of 24 hours duration within 4 weeks prior to initiation of study drug
- Treatment with oral, IV, or IM corticosteroids within 4 weeks prior to initiation of study drug
- Initiation of a methylxanthine preparation, maintenance macrolide therapy, and/or PDE4 inhibitor within 4 weeks prior to screening
- Unstable cardiac disease, myocardial infarction, or New York Heart Association Class III or IV heart failure within 12 months prior to screening