ForPatients
by Roche

Chronic Obstructive Pulmonary Disease (COPD)

A Study Of ^{12}#XE MRI To Assess Disease Progression In Patients With COPD Treated With Or Without Azithromycin And Standard-of-Care Medications

Trial Status	Trial Runs In	Trial Identifier
Terminated	1 Country	NCT04353661 GE42063

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:

^{12}#XE MRI Assessment Of Disease Progression In Patients With Chronic Obstructive Pulmonary Disease Treated With Standard-of-Care Medications With Or Without Daily Open-Label Azithromycin Treatment To Prevent Acute Exacerbation

Trial Summary:

This study will test whether daily use of azithromycin will reduce the rate of exacerbations and improve lung ventilation and perfusion assessed by XE-MRI. The sensitivity of XE-MRI to detect COPD progression will be compared with standard clinical assessment measures including standard lung function tests, 6 minute walk test, and patient reported quality of life.

Genentech, Inc.
Sponsor

Phase 2
Phase

NCT04353661 GE42063
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#40 Years	No

Inclusion Criteria:

- Current or former smokers with years # 10 pack years
- mMRC dyspnea score > 1

- Post-bronchodilator FEV-1/forced vital capacity (FVC) <0.70 at Visit 1 or Visit 2
- Cohort A: GOLD Stage 2-4 COPD with a history of # 2 moderate/severe exacerbations within a 12-month period in the 24 months prior to screening
- Cohort B: GOLD Stage 1 COPD with a history of #1 moderate/severe exacerbations within a 12-month period in the 24 months prior to screening
- Receiving SOC background drug therapy as per GOLD or British Thoracic Society (BTS) guidance for COPD for 12 weeks prior to screening Visit 1
- On an eligible bronchodilator medication (LABA ± LAMA) ± ICS therapy for #12 weeks prior to Visit 1
- Chest X-ray or CT scan within 6 months prior to Visit 1, or during the screening period (prior to Visit 2), that confirms the absence of clinically significant lung disease besides COPD
- Use of contraceptive measures

Exclusion Criteria:

- Diagnosis of significant respiratory disease other than COPD
- Comorbid conditions that may interfere with the evaluation of an investigational medical product
- Known sensitivity or allergy to azithromycin
- A COPD exacerbation and or pneumonia within 4 weeks prior to Visit 1
- Use of systemic corticosteroids within 4 weeks (oral or intravenous) or within 12 weeks (intramuscular IM) prior to screening Visit 1
- MRI is contraindicated
- Any known arrhythmia, bradycardia or severe cardiac insufficiency
- Participant can not hold breath for 15 seconds
- Participant does not fit in the ^{12}#XE vest coil used for MRI
- Pregnant, lactating, or intending to become pregnant during the study or within 4 weeks after the last dose of the investigational medical product
- History or evidence of substance abuse that would pose a risk to participants safety, interfere with the conduct of the study, or have an impact on the study results
- For participants in Cohort A: Known significant hearing impairment as indicated by a score of # 26 on the Hearing Handicap Inventory in the Elderly-Screening Questionnaire or as determined by the investigator
- History of Clostridium difficile (C. difficile) diarrhea Clinically significant ECG changes, which in the opinion of investigator warrants further investigation or with a QTc interval > 450 ms