ForPatients
by Roche

Chronic Obstructive Pulmonary Disease (COPD)Non#cystic fibrosis bronchiectasis

A Study to Test the Safety and Effects of Inhaled GDC-6988 in Participants With Muco-Obstructive Disease

Trial Status	Trial Runs In	Trial Identifier
Terminated	1 Country	NCT06603246 GB45429

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 Ic, Open-label, Multicenter Study to Evaluate the Safety, Tolerability, and Activity of Inhaled GDC-6988 in Patients With Muco-obstructive Disease

Trial Summary:

This study evaluates the safety, tolerability, and activity of inhaled GDC-6988 in participants with muco-obstructive disease.

Genentech, Inc.
Sponsor

Phase 1
Phase

NCT06603246 GB45429
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Percent predicted FEV1 # 40% by spirometry during screening
- Ability to demonstrate correct use of the smart DPI at screening, in the investigator's judgment
- On a stable treatment regimen for muco-obstructive diseases for # 28 days prior to initiation of study treatment and willingness to remain on the stable treatment regimen through completion of study
- Stable disease for # 28 days prior to screening and through to initiation of study treatment

Additional Inclusion Criteria for Participants in Part B

© 2022 F. Hoffmann-La Roche Ltd

- Chronic sputum production of #1 teaspoon per day as reported in the sputum volume item
- Ability to produce a sputum sample that is suitable for central laboratory determination of mucus percent solids and sialic acid concentration exploratory biomarker research, and biomarker assay development
- Availability of a representative blood sample for exploratory biomarker research and biomarker assay development

Additional Inclusion Criteria for Participants With Non-cystic Fibrosis Bronchiectasis (NCFB) (Cohort 1, Cohort 2, and Cohort 3):

- Diagnosis of bronchiectasis on the basis of prior chest computed tomography (CT), involving at least 2 lobes, with at least one lobe of involvement in the right lung as assessed by the investigator

Additional Inclusion Criteria for Participants With Chronic Obstructive Pulmonary Disease (COPD) (Cohort 1, Cohort 2, and Cohort 4):

- COPD defined as post-bronchodilator FEV1/FVC ratio of <0.7
- Chronic bronchitis, with a definition including chronic cough and excessive sputum production for more than 3 months per year for at least 2 years prior to screening
- Former smoker with a minimum of 10 pack-year history (e.g., 20 cigarettes/day for 10 years) or non-smoker with at least one documented COPD risk factor

Exclusion Criteria:

- Pregnant or breastfeeding, or intention of becoming pregnant during the study or within the timeframe in which contraception is required
- Known significant bronchodilator response of >10% predicted change in FEV1 or FVC, in the investigator's judgment
- Use of any prohibited medications
- Acute respiratory infection within 28 days of screening
- Significant hemoptysis greater than 60 milliliter (mL) within 3 months prior to screening
- Known immunodeficiency that, in the investigator's judgment, is clinically significant and places the individual at a substantially elevated risk for opportunistic infections.
- Known substance abuse, in the investigator's judgment, within 12 months prior to screening
- Poor peripheral venous access
- Receipt of blood products within 120 days prior to screening
- Any medical condition or abnormal clinical laboratory finding that, in the investigator's judgment, would preclude the individual's safe participation in and completion of the study or could affect the interpretation of the results
- History of thoracic or metastatic malignancy within 5 years prior to screening
- Known history of a clinically significant abnormal electrocardiogram (ECG), or presence of an abnormal ECG that is deemed clinically significant by the investigator
- QT interval corrected through use of Fridericia's formula (QTcF) >450 milliseconds (ms) for males or >470 ms for females

Additional Exclusion Criteria for Participants in Part B -More than 2 chest CTs or other procedures known to expose the lungs to greater than 100 millisievert (mSv) within 12 months prior to screening

Additional Exclusion Criteria for Participants With NCFB (Cohort 1, Cohort 2, and Cohort 3)

© 2022 F. Hoffmann-La Roche Ltd

- Bronchiectasis primarily due to cystic fibrosis, primary ciliary dyskinesia, non-tuberculous mycobacterial infection, chronic aspiration, or predominantly traction bronchiectasis due to interstitial lung disease (ILD), in the investigator's judgment
- Diagnosis of asthma, that in the investigator's judgment, is the primary driver of the individual's respiratory disease (e.g., primary asthma with incidental bronchiectasis findings)
- NCFB exacerbation within 28 days prior to screening or that has not returned to baseline
- Current smoker: Current smoking is defined as any use of inhaled tobacco products or inhaled marijuana within 3 months prior to screening, through use of cigarettes, cigars, electronic cigarettes, vaporizing devices, or pipes.

Additional Exclusion Criteria for Participants with NCFB in Cohort 3

- Diagnosis of COPD that, in the investigator's judgment, is the primary driver of the individual's respiratory disease (e.g., primary COPD with incidental bronchiectasis findings)

Additional Exclusion Criteria for Participants With COPD (Cohort 1, Cohort 2, and Cohort 4):

- COPD exacerbation within 28 days prior to screening or that has not returned to baseline
- Asthma/COPD overlap syndrome

© 2022 F. Hoffmann-La Roche Ltd