ForPatients
by Roche

Chronic Obstructive Pulmonary Disease (COPD)

A Study of RO7830698 in Healthy Participants and Participants With Chronic Obstructive Pulmonary Disease

Trial Status	Trial Runs In	Trial Identifier
Not yet recruiting		NCT07822334 WP46321

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 I, Randomized, Investigator and Participant-blind, Placebo-controlled, Single and Multiple Ascending Dose Study to Investigate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, and Pharmacodynamics of RO7830698 in Healthy Participants (Part 1) and in Participants With Chronic Obstructive Pulmonary Disease (Part 2)

Trial Summary:

This study will evaluate the safety, tolerability, pharmacokinetics (PK), immunogenicity, and pharmacodynamics (PD) of single and multiple doses of RO7830698 in healthy participants and participants with chronic obstructive pulmonary disease (COPD).

Hoffmann-La Roche Sponsor	**Phase 1/Phase 2** Phase

NCT07822334 WP46321
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years & # 80 Years	Accepts Healthy Volunteers

Inclusion Criteria:

All participants:

- Body mass index (BMI) between 18 and 32 kilograms per meter square (kg/m2)
- Agreement to adhere to the contraception requirements

Part 1:

- Absence of evidence of any active or chronic disease

Part 2:

- Confirmed diagnosis of COPD for > 6 months, as defined by the Global Initiative for Chronic obstructive Lung Disease (GOLD) guidelines
- Using maintenance inhaled therapy that may include inhaled corticosteroids (ICS) and/or long-acting #-agonist (LABA) and/or long-acting muscarinic antagonist (LAMA) as separate inhaler(s) or in combination preparation(s)
- Current smoker or ex-smoker with a tobacco history of >= 10 pack years

Exclusion Criteria:

- Pregnant or breastfeeding, or planning to become pregnant during the study or within the timeframe in which contraception is required
- Current or chronic history of clinically significant liver disease or known hepatic or biliary abnormalities (with the exception of Gilbert syndrome or asymptomatic gallstones) or cirrhosis
- Known history of allergy to drugs or other substances, or clinically significant, acute, and/or uncontrolled allergic disease
- Known or suspected history of immunosuppression
- History of recurrent severe infections and underlying conditions predisposing participant to infections
- History of disseminated herpes simplex infection, or recurrent (> 1 episode) or disseminated herpes zoster
- Autoimmune disease requiring systemic immunosuppressive therapy
- History of or presence of any clinically significant unstable cardiovascular disease
- Treatment with medications targeting the same pathways as RO7830698, immunomodulatory/ immunosuppressive therapy, or licensed biologics for COPD and asthma within protocol-defined periods
- Positive results for hepatitis B infection, human immunodeficiency virus infection, or hepatitis C infection at the Screening visit
- Evidence of tuberculosis infection or disease
- Participation in any clinical study of a drug or medical device within protocol-defined periods
- Any other conditions that may affect providing informed consent or study protocol adherence, or if study participation may affect study results or participant safety