ForPatients
by Roche

CRC With Atopic AsthmaCRC With Chronic Obstructive Pulmonary DiseaseCRC With Chronic Obstructive Pulmonary Disease With Chronic BronchitisChronic Refractory Cough (CRC) With Non-atopic AsthmaUnexplained Chronic Cough

A Study To Evaluate The Efficacy, Safety, Pharmacokinetics, And Pharmacodynamic Effects Of GDC-6599 In Patients With Chronic Cough

Trial Status	Trial Runs In	Trial Identifier
Completed	4 Countries	NCT05660850 GA43590

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 IIa, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Crossover Study To Evaluate The Efficacy, Safety, Pharmacokinetics, And Pharmacodynamic Effects Of GDC-6599 In Patients With Chronic Cough

Trial Summary:

This Phase IIa, multicenter, randomized, double-blind, placebo-controlled, crossover study will evaluate the efficacy, safety, pharmacokinetics, and pharmacodynamic (PD) effects of GDC-6599 compared with placebo in patients with a history of chronic cough.

Genentech, Inc.
Sponsor

Phase 2
Phase

NCT05660850 GA43590
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years & # 80 Years	No

Inclusion Criteria:

- Previous diagnosis of CRC, despite optimized treatment for asthma or COPD, or UCC for at least 1 year

- Chest X-ray or computed tomography (CT) scan thorax within 5 years prior to screening visit that confirms the absence of any clinically significant abnormality contributing to the chronic cough in the opinion of the investigator
- Cough severity VAS score # 40 at screening visit
- Pre-bronchodilator forced expiratory volume in 1 second (FEV1) # 60% of predicted at screening"
- Mannitol CDR # 12 coughs/100 mg determined at screening visit mannitol challenge test
- For women of childbearing potential: agreement to remain abstinent or use contraception For men: agreement to remain abstinent or use a condom, and agreement to refrain from donating sperm

Inclusion Criteria for Patients with CRC with Atopic Asthma or Patients with CRC with Non-Atopic Asthma (Part A)

- Physician diagnosis of asthma for # 12 months based upon GINA STEP 2-5
- Stable treatment with ICS therapy (GINA STEP 2) or ICS therapy and at least one additional controller (GINA STEP 3- 5) for # 3 months
- Patients with atopic asthma (n = 20), based upon historic record of positive test for atopy (if available), or confirmed at screening by positive fluorescence enzyme immunoassay for specific IgE against at least one of the following five perennial aeroallergens: animal (cat dander, dog dander, cockroach), dust mite (Dermatophagoides farinae, Dermatophagoides pteronyssinus), and mold mix
- Patients with non-atopic asthma (n = 20), based upon historic record of negative test for atopy (if available), or confirmed at screening by negative ImmunoCAP test result for all five perennial aeroallergens: animal (cat dander, dog dander, cockroach), dust mite (Dermatophagoides farinae, Dermatophagoides pteronyssinus), and mold mix, and relevant local allergens, and no history of symptoms suggesting atopy
- Never or former smoker (# 6 months prior to screening) with < 20 pack-years or equivalent history

Inclusion Criteria for Patients with CRC COPD-CB or Patients with CRC COPD (Part B)

- Diagnosis of COPD GOLD I-II ± CB
- Stable background treatment consisting of a bronchodilator medication and or stable ICS therapy for # 12 weeks prior to screening visit
- Former smoker with # 10 pack-years or equivalent history within 6 months of screening
- Post-bronchodilator FEV1/ forced vital capacity (FVC) ratio # 0.70 at screening
- Chest X-ray or CT scan within 6 months prior to screening visit or during the screening period (prior to randomization [Study Visit 2]), that confirms the absence of clinically significant lung disease besides COPD

Exclusion Criteria:

- Pregnant or breastfeeding, or intention of becoming pregnant during the study or within 28 days after the final dose of GDC-6599
- History of diagnosed bleeding diathesis or easy bruising or bleeding
- Post-bronchodilator FEV1/ FVC ratio < 0.60 at screening visit (patients with CRC asthma and UCC only: Part A)
- History of significant hepatic impairment
- History of aspiration or recurrent pneumonia
- Respiratory infection (including upper respiratory infection) within 8 weeks prior to screening
- Treatment with any strong inhibitor or inducer of CYP3A within 28 days or 5 drug-elimination half-lives, whichever is longer, prior to initiation of study drug
- Treatment with angiotensin-converting enzyme (ACE) inhibitor within 12 weeks prior to screening (Study Visit 1) through completion of the study

- Treatment with opioids (including codeine), pregabalin, gabapentin, amitriptyline, or nortriptyline for the treatment of cough within 2 weeks prior to screening (Study Visit 1) through completion of the study
- Treatment with cough suppressant medication within 2 weeks prior to screening (Study Visit 1) through completion of the study
- Known coronavirus 2019 (COVID-19) infection, persistent symptoms of known prior COVID-19 infection, and/or known positive COVID-19 test within at least 8 weeks prior to screening and randomization
- Clinical laboratory value outside the reference range for the test laboratory at screening
- Any serious medical condition or abnormality in clinical laboratory tests that, in the investigator's judgment, precludes the patient's safe participation in and completion of the study
- History of malignancy within 5 years prior to screening, except for appropriately treated carcinoma in situ of the cervix or non-melanoma skin carcinoma