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Dose-Range Finding Efficacy and Safety Study for QBW251 in COPD Patients *(NCT04072887)*

QBW251 is an investigational drug.
Efficacy and safety have not been established.

Official title

A 24-week multicenter, double-blind, placebo-controlled dose-range finding study to investigate the efficacy and safety of oral QBW251 in COPD patients on triple inhaled therapy (LABA/LAMA/ICS)

Purpose

To support the dose selection for future studies by evaluating the efficacy and safety of different QBW251 doses in COPD patients with chronic bronchitis and a history of exacerbations, compared with placebo, when added to a triple combination therapy of LABA, LAMA, and ICS

Primary outcome measure

- Change in trough FEV_1 from baseline to Week 12

Secondary outcome measures

- Change from baseline in overall COPD symptoms, cough, and sputum (E-RS, PGI-S score, and CASA-Q score) and health-related quality of life (SGRQ score) at Weeks 12 and 24
- Change from baseline in lung function (trough FEV_1) at Weeks 4, 8, 16, 20, and 24
- Pharmacokinetics of QBW251:
  - Trough concentration on all visits (up to Week 24)
  - C_{max} on Days 1 and 15, and Week 24
  - AUC and C_{max} on Days 1 and 15 in a subset of patients
  - C_{min} from Day 1 to Week 24

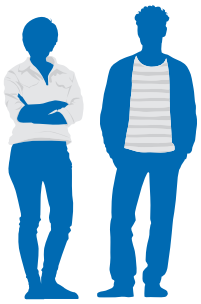
Study design

Multicenter, phase 2, double-blind, dose-range finding study of QBW251 (25, 75, 150, 300, 450 mg) versus placebo

Population

956

male and female patients aged ⩾40 years with diagnosed COPD



Key inclusion criteria

- Current or ex-smokers who have a smoking history of ⩾10 pack-years
- Patients who have been treated with a triple combination of LABA/LAMA/ICS for 3 months prior to screening
- Patients with chronic bronchitis

Key exclusion criteria

- Patients with a COPD exacerbation requiring treatment with antibiotics, oral corticosteroids and/or hospitalization, or a respiratory tract infection 4 weeks prior to screening, or between screening and randomization
- Patients with documented history of asthma, or an onset of chronic respiratory symptoms, including a COPD diagnosis, prior to age 40 years
- Patients with a BMI of >40 kg/m^2
- Use of other investigational drugs within 30 days or 5 half-lives prior to screening, or until the expected pharmacodynamic effect has returned to baseline, whichever is longer; or longer if required by local regulations
- Pregnant or nursing women, and women of childbearing potential not willing to use acceptable effective methods of contraception during study participation

Study sites

185

locations worldwide

Study timelines

Study start date: September 12, 2019

Estimated primary completion date: September 22, 2021

Estimated study completion date: January 13, 2022

Recruitment status: Recruiting

Abbreviations

AUC, area under curve; BMI, body mass index; CASA-Q, Cough and Sputum Assessment Questionnaire; C_{max}, maximum serum concentration; C_{min}, minimum serum concentration; COPD, chronic obstructive pulmonary disease; E-RS, Evaluating Respiratory Symptoms in COPD; FEV_1, forced expiratory volume in 1 second; ICS, inhaled corticosteroids; LABA, long-acting beta-agonist; LAMA, long-acting muscarinic antagonist; PGI-S, Patient Global Impression of Severity; SGRQ, St. George's Respiratory Questionnaire.

Reference

ClinicalTrials.gov. NCT04072887. https://clinicaltrials.gov/ct2/show/NCT04072887. Accessed May 7, 2021.

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