A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy, Safety, and Tolerability of Brensocatib Administered Once Daily for 52 Weeks in Subjects With Non-Cystic Fibrosis Bronchiectasis – The ASPEN Study

STATUS: Recruiting

STUDY DETAILS

Summary

This study will investigate the efficacy, safety, and tolerability of brensocatib in the clinical management of subjects with Non-Cystic Fibrous Bronchiectasis (NCFBE). Subjects will be randomized in a 1:1:1 ratio to 3 treatment arms to receive brensocatib 10 mg once daily (QD), brensocatib 25 mg QD, or matching placebo QD for 52 weeks. The goals are to confirm the findings from the phase two study, INS1007-201 and, if successful, to support marketing authorizations for brensocatib for the treatment of adult patients with NCFBE.

Details

- **Condition**: Non-Cystic Fibrous Bronchiectasis (NCFBE)
- **Drug**: Brensocatib
- **Clinical Trial Identifier:** NCT04594369
- **Sponsor:** Insmed Incorporated

Eligibility

Inclusion Criteria:

- Male or female, ≥ 18 years of age (20 years or older in Japan)
- Clinical history consistent with non-cystic fibrosis bronchiectasis (cough, chronic sputum production and/or recurrent respiratory infections) that is confirmed by chest computerized tomography (CT) scan
- At least 2 pulmonary exacerbations defined by need for antibiotic prescription by a physician for the signs and symptoms of respiratory infections in the past 12 months before the Screening Visit
- Women must be post-menopausal (defined as no menses for 12 months without an alternative medical cause), surgically sterile, or using highly effective double barrier contraception (ie, methods that in combination achieve <1% unintended pregnancy rates per year) from Day 1 to at least 90 days after the last dose
- Male participants with female partners of childbearing potential must be using effective contraception from Day 1 to at least 90 days after the last dose

Exclusion Criteria:

- A primary diagnosis of chronic obstructive pulmonary disease (COPD) or asthma as judged by the Investigator
- Bronchiectasis due to cystic fibrosis.
- Current smokers as defined per Centers for Disease Control (CDC)
- Known or suspected immunodeficiency disorder, including history of invasive opportunistic infections
- Known history of human immunodeficiency virus (HIV) infection
- Currently being treated for nontuberculous mycobacteria (NTM) lung infection, allergic bronchopulmonary aspergillosis, or tuberculosis (TB)
- Receiving medications or therapy that are prohibited as concomitant medications
- Suffering an exacerbation 4 weeks before Screening or during the Screening period
- History of alcohol or drug abuse within 6 months prior to the Screening Visit

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