ÍENCORE - A Randomized, Double-Blind, Placebo-Controlled, Active Comparator, Multicenter Study to Evaluate the Efficacy and Safety of an Amikacin Liposome Inhalation Suspension (ALIS)-Based Regimen in Adult Subjects With Newly Diagnosed Nontuberculous Mycobacterial (NTM) Lung Infection Caused by Mycobacterium Avium Complex (MAC)
STATUS: Recruiting

STUDY DETAILS

Summary

This is a randomized, double-blind, placebo-controlled, active comparator study in eligible subjects with a new diagnosis (initial or subsequent) of MAC lung infection who have not started treatment. Subjects will be randomized at Baseline in a 1:1 ratio to receive one of the 2 treatment regimens: Amikacin Liposome Inhalation Suspension (ALIS) 590 mg daily + Azithromycin (AZI) 250 mg daily + Ethambutol (ETH) 15 mg/kg daily or Empty Liposome Control (ELC) (matching placebo for ALIS) + AZI + ETH for 12 months. This study aims to evaluate the efficacy and safety of ALIS-based regimen in patient reported symptoms and the rate of durable sputum culture conversion in off-treatment adults diagnosed with non-cavitary lung disease caused by new MAC lung infections who have not started treatment.

Details

- **Condition**: Nontuberculous Mycobacterial Lung Infection caused by Mycobacterium Avium Complex
- **Drug**: Amikacin Liposome Inhalation Suspension (ALIS)
- **Clinical Trial Identifier:** NCT04677569
- **Sponsor**: Insmed Incorporated

Eligibility

Inclusion Criteria:

- Male or female, ≥ 18 years of age (20 years or older in Japan)
- Current diagnosis of Mycobacterial avium Complex (MAC) lung infection. MAC or mixed infection with MAC as the dominant species allowed, with MAC as the intended organism for treatment.
- Ability to produce (spontaneously or with induction) approximately 2mL of sputum for mycobacteriology at screening
- Women of child-bearing potential agree to practice an acceptable method of birth control (eg, true abstinence, copper intrauterine device (IUD), hormonal methods (levonorgestrel-releasing intrauterine system, progestogen implant, combined oral contraceptive pillor double barrier method plus a spermicidal agent, exclusive homosexual relationship, or sole male partner who has undergone surgical sterilization with confirmation of azoospermia at least 3 months post procedure) while participating in the study

Exclusion Criteria:

- Diagnosis of cystic fibrosis (CF)
- History of 3 or more prior MAC lung infections
- Disseminated MAC infection
- Received any mycobacterial antibiotic treatment for current MAC lung infection.
- Refractory MAC lung infections and no documented successful treatment
- Relapse of prior MAC lung infection
- Evidence of any pulmonary cavity ≥ 2 cm in diameter, as determined within 6 months prior to Screening.
- Radiographic finding of new lobar consolidation, atelectasis, significant pleural effusion, or pneumothorax within 2 months prior to Screening.
- Active pulmonary malignancy (primary or metastatic) or any malignancy requiring chemotherapy or radiation therapy within 1 year prior to Screening or anticipated during the study.
- Acute pulmonary exacerbation (eg, chronic obstructive pulmonary disease or bronchiectasis) requiring treatment with antibiotics, or corticosteroids (intravenous or oral), within 4 weeks prior to and during Screening.
- Acquired and primary immunodeficiency syndromes (eg, HIV-positive, regardless of CD4 counts).

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