ARISE - A Randomized, Double-Blind, Placebo-Controlled, Active Comparator, Multicenter Study to Validate Patient-Reported Outcome Instruments 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 subjects with non-cavitary lung disease with new (initial or subsequent) MAC lung infections. This study aims to validate Patient Reported Outcomes (PRO) from the Quality Of Life (QOL)-B and PROMIS F-SF 7a Questionnaires within the MAC lung disease population .Subjects will be randomized in a 1:1 ratio to receive one of the two 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. Treatment will be administered continuously for 6 months followed by 1 month off treatment follow up and a final End of Study evaluation at Month 7.

Details

- **Condition:** Nontuberculous Mycobacterial Lung Infection (NTM) caused by Mycobacterium Avium Complex (MAC)
- **Drug:** Amikacin Liposome Inhalation Suspension (ALIS)
- **Clinical Trial Identifier:** NCT04677543
- **Sponsor:** Insmed Incorporated

Eligibility

Inclusion Criteria:

- Male or female, ≥ 18 years of age (20 years or older in Japan)
- Current diagnosis of Myobacterium avium Complex lung infection (initial, second, or third infection event)
- 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
- Refractory MAC lung infection and no documented successful treatment,
- Received any mycobacterial antibiotic treatment for current MAC lung infection
- ≤ 6 months of cessation of prior successful treatment
- Evidence of any pulmonary cavity ≥ 2 cm in diameter, 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 [COPD] or bronchiectasis) requiring treatment with antibiotics, or corticosteroids (intravenous [IV] or oral), within 4 weeks prior to and during Screening
- Prior exposure to amikacin liposome inhalation suspension (ALIS) (including clinical study)
- Acquired and primary immunodeficiency syndromes (eg, HIV-positive, regardless of CD4 counts)

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