**OBJECTIVE**

The aim of this study was to evaluate the safety and efficacy of ALIS + GBT in patients with active MAC lung disease.

**METHODS**

**Inclusion criteria**

- Age ≥ 18 years with MAC lung disease
- Underlying lung disease, n (%): bronchiectasis (22.2%), cystic fibrosis, active pulmonary tuberculosis, immunodeficiency
- Race, n (%): white (69.9%), black (18.3%), Asian (9.5%), Other Asian (1.5%), unknown (1.0%)
- Underlying lung disease, n (%): bronchiectasis (22.2%), cystic fibrosis, active pulmonary tuberculosis, immunodeficiency
- Randomized patients who received at least 1 dose of ALIS (ALIS + GBT arm) or GBT (GBT-alone arm)

**RESULTS**

- **Patients**
  - 224 patients were assigned to ALIS + GBT (ITT) or GBT-alone (ITT).
  - At the time of data analysis, 19.6% of patients in the ALIS + GBT arm and 27.7% in the GBT-alone arm completed 12 months of treatment.

- **Safety**
  - Treatment-emergent adverse events (TEAEs) were reported in 78.9% and 93.8% of patients, respectively.
  - The most common TEAEs were related to respiratory system (respiratory infections) and skin.
  - Serious TEAEs occurred in 20.2% and 17.9% of patients, respectively.

- **Efficacy**
  - Culture conversion, the primary endpoint, was achieved by 55.2% of patients in the ALIS + GBT arm and 46.4% in the GBT-alone arm.
  - The median time to culture conversion was 4.9 months (FAS) and 7.0 months (ITT).

**DISCUSSION**

- This study demonstrates the efficacy and safety of ALIS + GBT in patients with active MAC lung disease.
- Further research is needed to understand the long-term outcomes and potential for treatment discontinuation.