Long-Term Safety Follow-up Design
- All patients with NTM lung infection who failed to consent to participate in the long-term safety follow-up phase were scheduled to be contacted by telephone once every 12 months for 2 years for a total of 3 telephone calls.
- Twenty-eight-day follow-up of patients with culture conversion was completed by the MDR-TB treatment coordinator, 1 year after the last dose of study drug.
- After completing LAI treatment, 65 patients (LAI, 29; placebo, 36) entered the long-term safety follow-up phase (Figure 2).
- Of those 65 patients, 32 patients discontinued before the final 12-month follow-up visit: 18 patients in the LAI group and 14 patients in the placebo group.
- Of the 23 patients who achieved culture conversion by the 28-day end-of-study follow-up visit, 6 converted at baseline (Day 0), 15 converted after the 28-day follow-up visit, and 2 patients who did not achieve culture conversion at the 28-day follow-up visit became culture converted during the long-term safety follow-up phase.
- The long-term safety follow-up phase did not have a control group, and no patient received study drug during that time.
- A 12-month, preferably blinded, randomized, placebo-controlled, double-blind, phase 2 study was conducted at 171 sites in North America to evaluate the efficacy and safety of liposomal amikacin for inhalation in patients with NTM lung infection.

RESULTS

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INTRODUCTION
- The increasing rate of nontuberculous mycobacterial (NTM) lung infection worldwide represents an important public health concern.
- NTM lung infections can often be may be refractory to current multidrug-based antibiotic therapy, and no specific diagnostic and therapeutic guidelines have been established for many nontuberculous mycobacterial strains.
- Liposomal amikacin for inhalation (LAI) is a novel inhalation formulation of amikacin designed for the treatment of nontuberculous mycobacterial lung infection (NTMLI), a complex disease of chronic lung disease.
- The primary endpoint of change from baseline on the SQS in the LAI group vs. placebo did not reach statistical significance (Figure 1).
- The results of this study are consistent with the findings of the Arikace clinical trial, and the current study underscores the potential of LAI for the treatment of NTM lung infection.
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