Transcript Details
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ReachMD
www.reachmd.com
info@reachmd.com
(866) 423-7849

Journal of Cystic Fibrosis: Efficacy and Safety of Levofloxacin Inhalation Solution (APT-1026) in Stable Cystic Fibrosis Patients

Interpretation:

In this study published in the *Journal of Cystic Fibrosis* in February 2016, Patrick Flume et al discuss a Phase III trial assessing the effectiveness of levofloxacin inhaled solution in cystic fibrosis patients.

Cystic fibrosis lung disease is characterized by chronic respiratory tract infection with multiple bacterial species frequently dominated by *Pseudomonas aeruginosa*, which has been associated with accelerated lung disease progression, increased morbidity, and decreased survival.

For patients with cystic fibrosis, the use of inhaled antibiotics has become the standard of care to suppress chronic *Pseudomonas* airways infection. There are limited antibiotic options formulated and approved for inhaled use, and because antibiotic efficacies attenuate over time, additional inhaled antibiotic classes are needed. Levofloxacin inhalation solution is a fluoroquinolone in development for management of chronic *P. aeruginosa* airways infection in patients with cystic fibrosis.

This study was a multinational, randomized, double-blinded study comparing levofloxacin inhalation solution and placebo over 28 days in cystic fibrosis patients at least 12 years old who have chronically suffered with *P. aeruginosa* infection. The primary end point was time to exacerbation. Forced expiratory volume and patient-reported quality of life were among secondary endpoints.

Baseline demographics were similar, although significantly more patients randomized to the levofloxacin inhalation solution group had experienced multiple exacerbations in the year prior to study entry.

There was no statistically significant difference in protocol-defined pulmonary exacerbations between treatment arms.

Relative change in forced expiratory volume from baseline was significantly greater for patients using levofloxacin inhalation solution compared to those randomized to placebo ($p = .01$). Levofloxacin inhalation solution was well-tolerated, with dysguesia the most frequent adverse event.

Levofloxacin inhalation solution demonstrated clinical efficacy by a reduction in bacterial density and an increase in lung function. Although it did not meet its primary endpoint of reduction in exacerbations overall, in those patients with a prior history of frequent exacerbations, it may also increase the time to antibiotic treatment for pulmonary exacerbations. Given its proven safety and tolerability record, levofloxacin inhalation solution demonstrates promise as a therapy for some patients with cystic fibrosis and chronic *P. aeruginosa* infection of the airways and is currently approved in the EU and Canada.