European Cystic Fibrosis Society

Journal of Cystic Fibrosis
The Official Journal of the European Cystic Fibrosis Society

Cystic Fibrosis Research News

Title:

A Phase 3, Multi-center, Multinational, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of Levofloxacin Inhalation Solution (APT-1026) in Stable Cystic Fibrosis Patients

Authors:

Patrick A. Flume[1], Donald R. VanDevanter[2], Elizabeth E. Morgan[3], Michael N. Dudley[3], Jeffery S. Loutit[3], Scott C. Bell[4], Eitan Kerem[5], Rainald Fischer[6], Alan R. Smyth[7], Shawn D. Aaron[8], Douglas Conrad[9], David E. Geller[10], J. Stuart Elborn[11] on behalf of the APT investigators

Affiliations:

[1]Departments of medicine and Pediatrics, Medical University of South Carolina, Charleston, SC
[2]Department of Pediatrics, Case Western Reserve University School of Medicine, Cleveland Ohio
[3]The Medicines Company, San Diego, CA
[4]The Prince Charles Hospital and QIMR Berghofer Medical Research Institute, Queensland, Australia
[5]Department of Pediatrics, Hadassah Medical Center, Jerusalem, Israel
[6]Pneumologische Praxis München-Pasing, Munich, Germany
[7]Division of Child Health, Obstetrics & Gynaecology, School of Medicine, University of Nottingham, UK.
[8]The Ottawa Hospital Research Institute, University of Ottawa, Ottawa, Ontario, Canada.
[9]Department of Medicine, University of California, San Diego
[10]Florida State University College of Medicine, Orlando, FL
[11]Centre for Infection and Immunity, Queens University Belfast, BT9 7AE

What was your research question?

We wanted to see if a new inhaled formulation of an antibiotic, levofloxacin, would improve lung function and decrease the likelihood of a pulmonary exacerbation (a flare up of symptoms) in patients with cystic fibrosis. Levofloxacin is available as an oral antibiotic, i.e. to be swallowed.

Why is this important?

Many people with cystic fibrosis have long-term infection of their airways, most commonly with Pseudomonas aeruginosa. Long-term P. aeruginosa infection is usually treated with

inhaled antibiotics to suppress the infection, reduce the risk of pulmonary exacerbations, improve a person's quality of life, and preserve lung function. Although there are several inhaled antibiotics available, more safe and effective alternative options are needed, as patients may not be able to tolerate them or they may become less effective.

What did you do?

We compared the new antibiotic, levofloxacin inhalation solution, to a placebo (inhaled treatment but without the active drug), given twice daily for 28 days followed by an observation period of 28 days. We measured lung function, quality of life, and the time to a pulmonary exacerbation in 330 patients with cystic fibrosis.

What did you find?

Although we did not find a difference in the number of pulmonary exacerbations between the two groups, there was a small but important improvement in lung function in the patients treated with the new antibiotics compared to those treated with placebo. The medication was generally well-tolerated with the main complaint from some patients being an unpleasant taste of the medication.

What does this mean and reasons for caution?

This means that the new inhaled antibiotic may have a role in the treatment of CF patients with Pseudomonas infection of the airways.

What's next?

The drug has been approved in some countries, so now we can assess the long-term safety and benefits in patients who are treated with it.