

**FOR IMMEDIATE RELEASE**

**Contacts:**

**Mpex Pharmaceuticals**

Daniel Burgess, President &  
CEO  
(858) 875-6675

**For Mpex Pharmaceuticals**

Jennifer Larson  
[jlaron@labfive.com](mailto:jlaron@labfive.com)  
(415) 725-2017

**Mpex Pharmaceuticals Announces Positive Phase 2b Clinical Trial Results with Aeroquin™ (MP-376) Treatment in Cystic Fibrosis Patients**

**San Diego, CA, September 10, 2009** - Mpex Pharmaceuticals, Inc. today announced positive data from its Phase 2b clinical trial with Aeroquin™ (a novel aerosol formulation of levofloxacin, MP-376) in cystic fibrosis (CF). Trial results showed that nebulized Aeroquin met the primary endpoint of reducing bacterial counts of *Pseudomonas aeruginosa* (*P. aeruginosa*) in sputum after 28 days of dosing versus placebo. Clinically and statistically significant improvements versus placebo were also seen in a number of important clinical endpoints, including FEV1, percent predicted FEV1, FEF25-75 (all measures of respiratory function) and time to need for anti-pseudomonal antibiotics (a measure of exacerbations). Both once and twice-daily dosing of Aeroquin showed activity in this trial, with higher doses showing improved responses. Aeroquin was well tolerated and no significant change in antibiotic resistance was observed in this study. Detailed results will be presented at a major respiratory meeting in the near future.

The Phase 2b, multi-center randomized, double-blind, placebo-controlled trial (Mpex 204) studied 151 CF patients to evaluate the safety, tolerability and efficacy of inhaled Aeroquin administered for 28 days using an Investigational eFlow Nebulizer System (PARI Pharma GmbH). Patients were then followed for an additional 28 days after completion of dosing. The trial was conducted in the U.S., Germany and the Netherlands.

To ensure that results from this trial were as predictive as possible for a future Phase 3 program, Mpex 204 enrolled patients that have recently received multiple courses of inhaled antibiotics and in most cases were already receiving other medication shown to improve lung function and reduce exacerbations. To be eligible for the trial, CF patients had to have received at least three 28 day cycles of other inhaled antibiotic therapy over the previous 12 months. Patients were also allowed to remain on all other stable CF therapies during the study.

“The results of this study are very gratifying, particularly given the heavily treated nature of the patients included in this trial,” stated Dr. Jeff Loutit, Chief Medical Officer of Mpex Pharmaceuticals. “It is difficult for new agents to show benefit on top of state-of-the-art care in CF, and generating statistically significant results across a broad range of key endpoints in this Phase 2b study bodes well for success in Phase 3.”

“We thank the participating CF patients and physicians for helping make this trial a success”, stated Daniel Burgess, President and CEO of Mpex Pharmaceuticals. “We are eager to meet with CF experts and regulatory authorities in the U.S. and Europe to discuss these results and determine the most expeditious path to move Aeroquin through Phase 3 development.”

Patients with CF suffer from chronic infections of the lower respiratory tract that can be caused by multiple bacteria, including *P. aeruginosa*. Chronic pulmonary infection is associated with a decrease in lung function over time caused by inflammation arising from bacteria and their toxins. Periodic exacerbations in the lung result from bacterial overgrowth, and these exacerbations are implicated as a major cause of morbidity and mortality in CF patients.

### **About Aeroquin (MP-376)**

MP-376 is a proprietary formulation of levofloxacin that has been optimized for aerosol delivery using a customized Investigational eFlow® Nebulizer System (PARI Pharma GmbH). Levofloxacin is a fluoroquinolone antibiotic that has been widely used in a variety of indications for over a decade and has established safety and efficacy when administered orally or intravenously against many bacterial pathogens, including *P. aeruginosa*. Administration of MP-376 with a high efficiency nebulizer to the lungs allows for the rapid delivery of high concentrations of active drug directly to the site of infection, while minimizing systemic exposure. In addition to the trial described above in CF, Mpex is also conducting a large Phase 2 study in COPD that is now fully enrolled, with results expected to be available in the first half of 2010.

### **About Mpex Pharmaceuticals**

Mpex Pharmaceuticals is a clinical stage biopharmaceutical company whose mission is to develop important new therapies to combat the growing issue of antibiotic resistance. The company's internal development pipeline focuses on combining proprietary formulations, PK/PD strategies and novel potentiating agents with proven antibiotics to overcome or directly inhibit the molecular mechanisms in bacteria responsible for antibiotic resistance. Mpex's most advanced product candidate, Aeroquin™ (MP-376), is a proprietary aerosol formulation of levofloxacin that is being developed clinically as a maintenance therapy for patients with CF or COPD. The company has also built a separate discovery and development platform and intellectual property estate around inhibitors of multi-drug resistant (MDR) efflux pumps (EPIs) found in many gram-negative bacterial pathogens. Bacterial efflux of antibiotics is a leading source of multi-drug resistance, particularly in gram-negative organisms. Mpex compounds have been shown in both *in vitro* and *in vivo* studies to overcome efflux-based resistance to multiple classes of antibiotics. Mpex has established a collaboration with GlaxoSmithKline focused on developing multiple drug candidates utilizing Mpex's EPI technology. Company website: [www.mpexpharma.com](http://www.mpexpharma.com).

### **About the Investigational eFlow Nebulizer System and PARI Pharma**

Aeroquin (MP-376) is delivered via an Investigational eFlow Nebulizer System, an inhalation delivery device optimized specifically for Aeroquin. The Investigational eFlow Nebulizer System uses eFlow Technology to enable highly efficient aerosolization of

medication via a vibrating, perforated membrane that includes thousands of small holes to produce the aerosol mist. Compared to other nebulization technologies, eFlow Technology produces aerosols with a very high density of active drug, a precisely defined droplet size, and a high proportion of respirable droplets delivered in the shortest possible period of time. Combined with its quiet mode of operation, small size (it fits in the palm of the patient's hand), light weight and battery use, eFlow Technology reduces the burden of taking daily, inhaled treatments. PARI Pharma focuses on the development of aerosol delivery devices and comprehensive inhalation drug development to advance aerosol therapies where drug and device can be optimized together.