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Contacts:

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

For Mpex Pharmaceuticals
Jennifer Larson
jlarson@labfive.com
(415) 725-2017

Mpex Pharmaceuticals Presents Positive Phase 2 Clinical Trial Results of Aeroquin™ (MP-376) Treatment in Cystic Fibrosis Patients

- Data Presented at the American Thoracic Society Annual Meeting -

San Diego, CA, May 17, 2010 - Mpex Pharmaceuticals, Inc. today announced the presentation of data from its Phase 2b clinical trial with Aeroquin™ (a proprietary aerosol formulation of levofloxacin, MP-376) in cystic fibrosis (CF) at the American Thoracic Society (ATS) Annual Meeting in New Orleans. Trial results demonstrated statistically significant improvements in bacterial load, respiratory function and time to need for anti-pseudomonal antibiotics (a measure of exacerbations) versus placebo in a heavily treated patient population. The results were presented by Dr. Douglas Conrad from the University of California at San Diego School of Medicine, the principal investigator for the study.

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 three dose levels of inhaled Aeroquin (120mg QD, 240 mg QD and 240 mg BID) administered for 28 days using an customized 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 the future Phase 3 program and consistent with current clinical practice, the study enrolled patients that had recently received multiple courses of inhaled antibiotics and in most cases were receiving concomitant medication such as dornase alpha, azithromycin and hypertonic saline that have been shown in previous studies to improve lung function and/or reduce exacerbations.

The trial met the primary endpoint of a reduction in sputum *Pseudomonas aeruginosa* density at Day 28, the end of treatment. All three doses of Aeroquin demonstrated statistical significance ($p < 0.01$ for each group versus placebo), with the highest dose (240 mg BID) showing the greatest effect of approximately 1 log reduction. There was no evidence for emergence of bacterial resistance during the study.

Improvements in respiratory function were also demonstrated in the trial. A greater proportion of patients had improvement in percent predicted FEV1 with any dose of Aeroquin compared to placebo, with a difference of 10.9% in percent predicted FEV1 between the 240mg BID group and placebo at day 28 ($p=0.0008$). Patients treated with 240 mg BID also had a 22% improvement in FEF25-75 ($p<0.0001$) and a 7.3% improvement in percent predicted FVC ($p=0.014$) at day 28 versus placebo. FEV1, FEF25-75 and FVC are standard measures of lung function in CF patients.

Consistent with these results, a statistically significant reduction in the need for other inhaled and/or systemic anti-pseudomonal antimicrobials was observed in all Aeroquin groups vs. placebo (risk reduction of 79% for 240mg BID vs. placebo; $p=0.0007$). The percent of patients with adverse events (AEs) was similar across all treatment groups, with no evidence of increasing incidence or severity of AEs with increasing Aeroquin dose.

"The results from the Aeroquin Phase 2b CF trial are very encouraging both in terms of the improvement in lung function and the reduction in the need for other anti-pseudomonal antimicrobials," stated Dr. Conrad. "The combination of these outcomes with an attractive safety profile to date and a convenient dosing regimen makes Aeroquin a potentially important new agent. These results were especially impressive because they were obtained in a heavily treated patient population, where demonstrating benefit can be more difficult."

"I am impressed with both the strength and quality of the data from this Aeroquin trial", stated Dr. Patrick Flume, Professor of Medicine and Pediatrics at the Medical University of South Carolina and Co-Chair of the Pulmonary Guidelines Committee of the Cystic Fibrosis Foundation. "Importantly, Aeroquin represents a new class of inhaled antibiotics for the treatment of CF. If we are to achieve our treatment objective of reducing bacterial exacerbations over the long term, it is critical that chronically infected patients be treated frequently with inhaled antibiotics. Having multiple classes of aerosol antibiotics available will give clinicians the ability to rotate classes and tailor treatment to the needs of each individual patient. Clinicians believe this is the best way to maximize efficacy and tolerability while minimizing resistance and side effects over the long term."

Mpex has been cleared to proceed to Phase 3 trials with Aeroquin by the U.S. FDA and is scheduled to meet with European regulatory authorities later this quarter. Phase 3 studies are expected to begin shortly thereafter.

About Cystic Fibrosis

Patients with CF suffer from chronic infections of the lower respiratory tract that can be caused by multiple bacteria, including *Pseudomonas 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 (requiring antibacterial intervention), and these exacerbations are implicated as a major cause of morbidity and mortality in CF patients.

About Aeroquin (MP-376)

Aeroquin 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 *Pseuomonas aeruginosa*. Administration of Aeroquin 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.

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 cystic fibrosis. 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**.

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.