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Mpex Pharmaceuticals Presents New Data on MP-376 in Cystic Fibrosis

Details to be presented at NACFC and ICAAC/IDSA meetings this week

San Diego, CA, October 23, 2008 – Mpex Pharmaceuticals, Inc. today announced additional clinical and preclinical results with MP-376, the company's novel formulation of levofloxacin inhaled solution delivered by an Investigational eFlow Nebulizer System for use in cystic fibrosis (CF) and chronic obstructive pulmonary disease (COPD). Clinical results show that aerosol dosing of MP-376 was well tolerated at all dose levels tested after 14 days of dosing. Encouraging signs of drug activity were also observed in this trial. New preclinical results demonstrate that MP-376 has potent activity against *Pseudomonas aeruginosa* (*P. aeruginosa)* infection under a wide array of conditions, avoids resistance development when used at high concentrations achievable with aerosol dosing and has anti-inflammatory properties in pulmonary tissues in addition and unrelated to its antibacterial effects. Detailed results are being presented at the North American Cystic Fibrosis Conference (NACFC) and ICAAC/IDSA meetings taking place this week in Orlando, Florida and Washington, D.C., respectively.

Clinical Results

The clinical results being presented at NACFC are from a Phase 1b safety, tolerability and pharmacokinetic (PK) study performed in 40 CF patients with stable disease at 11 U.S. clinical sites (Mpex 203). The study was a placebo-controlled, dose escalation trial to analyze the effects of 14 days of dosing at three different dose levels of MP-376 when administered by inhalation using an Investigational eFlow Nebulizer System.

All patients were required to be culture positive for *P. aeruginosa* at baseline. *P. aeruginosa* is a bacterial pathogen that is a leading cause of morbidity in CF patients. The great majority of CF patients over the age of 18 are chronically infected with this pathogen and chronic infection has been shown to lead to acute exacerbations and subsequent loss of lung function.

Results from this clinical trial indicated that MP-376 was well tolerated, with no serious drug related adverse events reported. Dose escalation proceeded successfully through the highest planned dose with no dose limiting toxicities. PK results also met expectations, with sputum drug levels increasing with increasing doses of inhaled MP-376.

Although this trial was not designed as an efficacy study, evidence of drug activity was observed in this trial. Patients receiving MP-376 experienced a reduction in *P. aeruginosa* counts well in excess of one log on average after 14 days of treatment, whereas counts in placebo treated patients increased slightly over the treatment period. In addition, FEV1, a standard measure of lung function, showed dose-related improvements in MP-376 treated patients, with the highest dose group experiencing increases in FEV1 of greater than 15%.

"The results from this study are very encouraging," stated Dr. Jeff Loutit, Chief Medical Officer of Mpex Pharmaceuticals. "The safety and PK results were consistent with our expectations and support advancing the compound into larger clinical trials. Furthermore, the effects seen on bacterial counts and pulmonary function give us confidence as we move MP-376 through development. This is particularly true given that the results were obtained in a patient population that had significant prior inhaled antibiotic experience and many patients were infected with multi-drug resistant *P. aeruginosa.*"

Based on these results Mpex initiated a 28-day Phase 2 study in 140 CF patients earlier this year at sites in the U.S., Germany and the Netherlands. This study is expected to complete enrollment in the second quarter of 2009. Results from this study, if successful, are expected to allow Mpex to choose the optimal dosing regimen for Phase 3 clinical trials anticipated to begin later in 2009.

Preclinical Results

MP-376 was designed to address many of the shortcomings of available inhaled antibiotic formulations for CF patients. These shortcomings include the following:

- Low potency against *P. aeruginosa*
- Lack of activity against other common CF pathogens
- Potential for rapid resistance development
- Suboptimal activity in biofilms, a factor that contributes to chronic infections in CF patients
- Reduced potency in anaerobic environments common in the CF lung from thickened mucous layers
- Reduced antibacterial activity in CF sputum

- Inconvenient dosing regimens that reduce patient compliance

Preclinical results presented at the meetings this week show MP-376 offers potentially substantial improvements in each of these areas:

- Potency: MIC90s for MP-376 against nearly 300 *P. aeruginosa* clinical isolates from CF patients were at least 4-fold lower than those obtained for tobramycin, amikacin and aztreonam.

- Spectrum: MIC90s for MP-376 against clinical isolates for other common CF pathogens such as *B. cepacia, S. maltophilia and A. xylosoxidans* were substantially lower than for these other antibiotics. Previous in vitro work has also shown superior potency of MP-376 compared to other agents against gram positive bacteria commonly found in CF patients.

- Resistance: in an in vitro model of resistance development in *P. aeruginosa*, doses of levofloxacin formulated as MP-376 at levels consistent with that which can be achieved with aerosol administrations demonstrated rapid bacterial killing with no development of resistance over the course of 4 days. In contrast, doses of levofloxacin mimicking human exposures following systemic administration showed initial bacterial killing, but allowed for resistance development within 24 hours. This demonstrates the importance of achieving high Cmax:MIC ratios in pulmonary tissues to avoid resistance development in bacteria.

- Activity in biofilms: studies in an established in vitro biofilm system showed that levofloxacin potency was least affected compared to tobramycin or aztreonam.

- Activity in anaerobic environments: antimicrobial susceptibility in more than 100 *P. aeruginosa* isolates from CF patients was compared between aerobic and anaerobic testing conditions. The geometric mean of the MIC in levofloxacin treated isolates increased less than two fold under anaerobic conditions, whereas tobramycin, amikacin and aztreonam treated isolates increased 4-7 fold under anaerobic conditions. This implies that MP-376 may retain its potency in anaerobic environments in the lung more effectively compared to other classes of antibiotics.

- Activity in CF sputum: Studies of antibiotic activity in CF sputum showed that levofloxacin retained its full antibacterial activity against *P. aeruginosa* whereas tobramycin activity was decreased by 1-2 logs in the presence of CF sputum, consistent with previous studies.

- Convenient dosing regimen: In an in vivo model of a chronic lung infection due to *P. aeruginosa*, MP-376 showed comparable antibacterial activity when administered once or twice per day. In contrast, current treatment options must be administered at least 2-3 times per day for optimal activity.

In addition to these preclinical studies, Mpex is also presenting data at the NACFC meeting indicating that MP-376 has anti-inflammatory activity that is independent of its antibacterial effect. This was demonstrated in both in vitro and in vivo models and includes effects on both IL-6 and IL-8, cytokines which have both been implicated in destructive inflammatory processes in CF lungs. These beneficial anti-inflammatory effects were not observed with tobramycin or aztreonam.

“We believe that taken together these studies show a very attractive profile for MP-376 in the treatment of chronic bacterial infections in CF patients,” stated Dr. Michael Dudley, Senior VP of R&D and Chief Scientific Officer of Mpex Pharmaceuticals. “MP-376 has the potential to address many of the current shortcomings with inhaled antibiotic treatments in CF. The combination of the inherent potency of levofloxacin and the novel formulation we have developed for aerosol administration may allow us to achieve the desired pharmacokinetic and pharmacodynamic parameters that are necessary for long-term success in this indication. We look forward to working with CF patients and caregivers to move this potentially important new treatment option through development.”

About 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, Munich, Germany). 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 delivery of high concentrations of active drug directly to the site of infection, while minimizing systemic exposure. Mpex believes this approach has the potential to improve bacterial killing and reduce resistance development versus traditional oral or IV routes of administration.

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, MP-376, is a proprietary aerosol formulation of levofloxacin that is being developed clinically as a maintenance therapy for the prevention of bacterial exacerbations in patients with cystic fibrosis and COPD. The company has also built a 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 recently entered into a

collaboration with GlaxoSmithKline focused on developing multiple drug candidates utilizing Mpex's EPI technology. Company website: **www.mpexpharma.com**.

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