



## **MAP Pharmaceuticals Announces Initiation of LEVADEX(TM) Pharmacokinetics Trial**

### **Trial to be used in support of NDA submission--**

MOUNTAIN VIEW, Calif., Feb 16, 2010 /PRNewswire via COMTEX News Network/ -- MAP Pharmaceuticals, Inc. (Nasdaq: MAPP) today announced that the Company initiated a trial to compare the pharmacokinetics (PK), safety and metabolic profiles of LEVADEX(TM) orally inhaled migraine therapy with intravenous dihydroergotamine mesylate (DHE) in smokers and non-smokers. LEVADEX is a novel orally inhaled migraine therapy that has completed Phase 3 efficacy development for the acute treatment of migraine.

This PK trial is one of two remaining trials to be initiated in support of a New Drug Application (NDA) submission for LEVADEX as previously requested by the U.S. Food and Drug Administration (FDA). In addition to the PK trial, the Company is conducting an ongoing 12 month open-label safety extension of its Phase 3 FREEDOM-301 trial, which has completed enrollment, and also plans to conduct a pharmacodynamic trial. The Company anticipates that patients in these trials will complete treatment in 2010.

"Earlier this year, we announced that a second pivotal efficacy trial is not required for our NDA submission," said Timothy S. Nelson, president and chief executive officer of MAP Pharmaceuticals. "The initiation of this PK trial is an important step for the Company as we continue to focus on completing our remaining clinical trials to support our NDA submission for LEVADEX."

This PK trial is a single dose, open-label, crossover trial designed to compare the PK of LEVADEX to intravenous DHE in both smokers and non-smokers. The trial includes healthy adult volunteers, 24 of whom are smokers and 24 of whom are non-smokers.

### **About LEVADEX(TM)**

LEVADEX orally inhaled migraine therapy is in Phase 3 development for the potential acute treatment of migraine. Patients administer LEVADEX themselves using the Company's proprietary TEMPO(R) inhaler. In the Phase 3 FREEDOM-301 trial, LEVADEX met all four co-primary endpoints at two hours: pain relief ( $p < 0.0001$ ); phonophobia free ( $p < 0.0001$ ); photophobia free ( $p < 0.0001$ ); and nausea free ( $p = 0.02$ ). LEVADEX was well tolerated and there were no drug related serious adverse events reported in the trial. Data from this Phase 3 trial show the potential for LEVADEX to be effective in treating acute migraine, as well as a broad spectrum of migraine subpopulations that are often difficult to treat with current therapies, including triptans. For example, in this trial, patients with allodynia, menstrual migraine, migraine with nausea and vomiting, severe migraine or who treated late in their migraine cycle responded well to LEVADEX.

LEVADEX is a novel formulation of dihydroergotamine mesylate (DHE), a drug used intravenously in clinical settings, to effectively and safely treat migraines. It is designed to be differentiated from existing migraine treatments. Based on clinical results, the Company believes that LEVADEX has the potential to provide fast onset of action, sustained pain relief and other migraine symptom relief in an easy-to-use and non-invasive at-home therapy.

LEVADEX is designed to incorporate the multiple beneficial mechanisms of action that allow DHE to block initiation of migraine, limit pain, reduce inflammation and stop a migraine at any point in the migraine cycle. Based on research to date, including the efficacy portion of the FREEDOM-301 trial, the Company believes the unique pharmacokinetic profile of LEVADEX has the potential to effectively treat migraines, while minimizing the side effects commonly seen with other DHE-based products and other currently available medicines.

### **About Migraine**

Common symptoms of migraine include recurrent headaches, nausea, vomiting, photophobia (sensitivity to light) and phonophobia (sensitivity to sound). According to the National Headache Foundation, most migraines last between four and 24 hours, but some last as long as three days. On average, migraine sufferers experience 1.5 migraine attacks monthly, although 25 percent of them experience one or more attacks weekly, according to published studies. Migraine patients report that currently approved drugs do not fully meet their needs due to slow onset of action, short duration of effect, inconsistent response and unacceptable side effect profiles. The economic burden of migraine remains substantial despite existing

treatments, with the direct and indirect costs of migraine in the United States estimated at over \$20 billion annually.

#### About MAP Pharmaceuticals

MAP Pharmaceuticals is dedicated to developing and commercializing new therapies for patients suffering from conditions that are not adequately treated by currently available medicines. The Company is developing LEVADEX orally inhaled therapy for the potential treatment of migraine and has reported positive results from the efficacy portion of the first Phase 3 trial of LEVADEX. In addition, MAP Pharmaceuticals generates new pipeline opportunities by applying its proprietary drug particle and inhalation technologies to enhance the therapeutic benefits of proven drugs, while minimizing risk by capitalizing on their known safety, efficacy and commercialization history.

Additional information about MAP Pharmaceuticals can be found at <http://www.mappharma.com>.

#### Forward-Looking Statements

In addition to statements of historical facts or statements of current conditions, this press release contains forward-looking statements, including with respect to MAP Pharmaceuticals' LEVADEX product candidate. Actual results may differ materially from current expectations based on risks and uncertainties affecting the company's business, including, without limitation, risks and uncertainties relating to the enrollment, conduct and completion of clinical trials, failure to achieve favorable clinical outcomes and to have the company's LEVADEX product candidate approved for commercial use. The reader is cautioned not to unduly rely on the forward-looking statements contained in this press release. MAP Pharmaceuticals expressly disclaims any intent or obligation to update these forward-looking statements, except as required by law. Additional information on potential factors that could affect MAP Pharmaceuticals' results and other risks and uncertainties are detailed in its Annual Report on Form 10-K for the year ended December 31, 2008, as amended, and its Quarterly Report on Form 10-Q for the quarter ended September 30, 2009, available at <http://edgar.sec.gov>.

#### CONTACTS:

Lisa Borland  
MAP Pharmaceuticals, Inc.  
(650) 386-3122  
[lborland@mappharma.com](mailto:lborland@mappharma.com)

Nicole Foderaro  
WCG  
(415) 946-1058  
[nfoderaro@wcgworld.com](mailto:nfoderaro@wcgworld.com)

SOURCE MAP Pharmaceuticals, Inc.

Copyright (C) 2010 PR Newswire. All rights reserved