



MAP Pharmaceuticals Announces FDA will not Require a Second Pivotal Efficacy Study for LEVADEX(TM) NDA Submission

MOUNTAIN VIEW, Calif., Jan 11, 2010 /PRNewswire via COMTEX News Network/ -- MAP Pharmaceuticals, Inc. (Nasdaq: MAPP) today announced that the U.S. Food and Drug Administration (FDA) has informed the Company that a second pivotal efficacy study is not required for the Company's LEVADEX(TM) new drug application (NDA) submission for the acute treatment of migraine. The Company announced in May 2009 that the efficacy portion of its Phase 3 FREEDOM-301 clinical study of LEVADEX met all four primary endpoints. The Company had previously anticipated initiating a second pivotal efficacy study in the first quarter of 2010.

"We are pleased that the LEVADEX program can move forward without a second pivotal efficacy study; this news underscores our confidence in the program and allows us to focus our resources and efforts on completing our remaining clinical studies to support our NDA submission," said Timothy S. Nelson, president and chief executive officer of MAP Pharmaceuticals. "We believe that LEVADEX has the potential to provide rapid and sustained relief of migraine symptoms to many of the approximately 30 million migraine sufferers in the U.S., including many who are not helped by currently available migraine therapies and we are committed to rapidly moving this program forward."

The remaining clinical studies include the ongoing 12 month open-label safety extension of the FREEDOM-301 study, a pharmacokinetic (PK) study and a pharmacodynamic (PD) study. The Company anticipates that patients in these studies will complete treatment in 2010.

The goal of the long-term safety extension is to evaluate overall safety, including pulmonary and cardiovascular safety, of LEVADEX in 300 patients for six months and 150 patients, including asthmatics, for 12 months. The study is being conducted under a Special Protocol Assessment with the FDA. As previously announced, as of October 2009, more than 400 patients had completed at least six months of treatment and over 7,800 headaches had been treated, with no drug-related serious adverse events reported.

The PK study will compare the safety, PK and metabolic profiles of LEVADEX with IV dihydroergotamine (DHE) in smokers. The PD study will evaluate pulmonary artery pressure in healthy volunteers.

About LEVADEX(TM)

LEVADEX orally inhaled migraine therapy is a novel migraine therapy in Phase 3 development. 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 ($p = 0.02$). 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 and those treating late in their migraine cycle responded well to LEVADEX.

LEVADEX is designed to be differentiated from existing migraine treatments. It is a novel formulation of dihydroergotamine (DHE), a drug used intravenously in clinical settings to effectively and safely treat migraines. Based on clinical results, the company believes that LEVADEX has the potential to provide both 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 DHE 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>.

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