



## **MAP Pharmaceuticals Announces FDA Acceptance for Filing of NDA for LEVADEX®**

MOUNTAIN VIEW, Calif., Aug. 2, 2011 /PRNewswire/ -- MAP Pharmaceuticals, Inc. (Nasdaq: MAPP) today announced that its New Drug Application (NDA) for LEVADEX® orally inhaled migraine drug for the potential acute treatment of migraine in adults has been accepted for filing by the U.S. Food and Drug Administration (FDA), with a goal date of March 26, 2012 under the Prescription Drug User Fee Act (PDUFA). In accordance with the Company's collaboration agreement with Allergan, Inc., the FDA's acceptance for filing of the NDA triggers a milestone payment to MAP Pharmaceuticals of \$20 million.

"We are very pleased with the FDA's acceptance of the filing of our LEVADEX NDA submission as it is a significant achievement in the development of LEVADEX," said Timothy S. Nelson, president and chief executive officer of MAP Pharmaceuticals. "This takes us another step forward in our effort to provide the underserved migraine patient population with a potential new treatment option."

The Company's 505(b)(2) NDA submission for LEVADEX includes efficacy and safety data from the pivotal Phase 3 FREEDOM-301 clinical trial and the open-label, safety extension which was designed to evaluate overall safety of LEVADEX over six and 12 months of exposure. In total, more than 475 patients completed six months of treatment and more than 250 patients completed 12 months of treatment. In total, nearly 10,000 migraines were treated. The NDA is also supported by data from a pharmacokinetics (PK) trial evaluating the PK and safety of LEVADEX in smokers and non-smokers, a pharmacodynamics (PD) trial evaluating the acute effects of LEVADEX on pulmonary artery pressure, a thorough QT trial comparing the acute effects of a supra-therapeutic dose of LEVADEX on the cardiac QT interval as measured by electrocardiogram, a safety trial in adult asthmatics and a drug interaction study assessing the impact of CYP3A4 inhibition on LEVADEX pharmacokinetics. There were no drug related serious adverse events reported in any LEVADEX trial.

### **About LEVADEX®**

LEVADEX is an investigational drug for the acute treatment of migraine in adults, for which the Company has submitted a New Drug Application to the U.S. Food and Drug Administration. In the clinical trial, patients administered LEVADEX themselves using the proprietary TEMPO® inhaler. LEVADEX contains a novel formulation of dihydroergotamine (DHE). LEVADEX was evaluated in the efficacy portion of FREEDOM-301, MAP Pharmaceuticals' Phase 3 pivotal trial, which included 395 patients in the LEVADEX arm and 397 patients in the placebo arm. In the Phase 3 trial, patients taking LEVADEX had statistically significant improvement at two hours compared to patients on placebo for all four co-primary endpoints:

- Pain relief: 58.7 percent of patients who received LEVADEX compared with 34.5 percent for placebo ( $p < 0.0001$ );
- Phonophobia free: 52.9 percent of patients who received LEVADEX compared with 33.8 percent for placebo ( $p < 0.0001$ );
- Photophobia free: 46.6 percent of patients who received LEVADEX compared with 27.2 percent for placebo ( $p < 0.0001$ ); and
- Nausea free: 67.1 percent of patients who received LEVADEX compared with 58.7 percent for placebo ( $p = 0.02$ ).

The most common adverse event reported in the trial was medication aftertaste at six percent versus two percent for placebo. The next most common adverse event was nausea at five percent compared with two percent for placebo. There were no decreases in lung function, as measured by spirometry, between the active and placebo groups.

### **About Migraine**

Migraine is estimated to occur in 18% of women and 6% of men in the United States. Over 30 million people are impacted by the often debilitating symptoms of migraine, including headache pain, nausea, sensitivity to light and sensitivity to sound. While triptans are considered the standard of care for migraine today, there are millions of patients who do not consistently respond to triptans, leaving a large number of patients without adequate treatment for their migraines. 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 three migraine attacks monthly, although 25 percent of them experience one or more attacks weekly. 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 an emerging biopharmaceutical company focused on developing and commercializing new therapies to

address undermet patient needs in neurology. The Company is developing LEVADEX, an orally inhaled investigational drug for the acute treatment of migraine. The U.S. Food and Drug Administration has accepted for filing the New Drug Application for LEVADEX for the potential acute treatment of migraine in adults. MAP Pharmaceuticals has entered into a collaboration agreement with Allergan, Inc. to co-promote LEVADEX to neurologists and pain specialists in the U.S. The Company also applies its proprietary drug particle and inhalation technologies to generate new pipeline opportunities by enhancing 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 the FDA goal date for 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 regulatory approval process for the Company's LEVADEX product candidate. 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2011, available at <http://edgar.sec.gov>.

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