



## **MAP Pharmaceuticals' Analysis of Positive Phase 3 LEVADEX(TM) Data To Be Presented in Late-Breaking Session at 14th Congress of the International Headache Society**

**-- Analysis Shows Potential of LEVADEX to Treat a Broad Spectrum of Migraine --  
-- Company to Host Webcast on Monday, September 14th at 7:15 a.m. ET --**

MOUNTAIN VIEW, Calif., Sept 10, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- MAP Pharmaceuticals, Inc. (Nasdaq: MAPP) announced today that it will present analysis of data from the efficacy portion of the first Phase 3 trial of its novel LEVADEX(TM) orally inhaled migraine therapy, currently in development, at the 14th Congress of the International Headache Society. Data from this Phase 3 trial show the potential of LEVADEX to be effective in treating acute migraine as well as a broad spectrum of migraine, including migraine subpopulations that are often resistant to current therapies such as triptans, migraine with moderate and severe pain, migraine with nausea and vomiting and migraine with and without aura.

"A majority of patients are dissatisfied with their current migraine treatment due in part to inconsistent response, high rates of recurrence of the migraine attack within 24 hours and slow onset of action," said Stewart Tepper, M.D., Director of Research for the Center for Headache and Pain, Cleveland Clinic. "Based on these Phase 3 data, LEVADEX has the potential to provide rapid and sustained pain relief, along with a favorable tolerability profile. In addition, LEVADEX showed efficacy in a broad spectrum of migraine subpopulations that are often unresponsive to current migraine therapies."

As previously reported, LEVADEX met all four co-primary endpoints, as well as a number of secondary endpoints, in the first of two Phase 3 clinical trials. The four co-primary endpoints at two hours were:

- pain relief ( $p < 0.0001$ );
- phonophobia free ( $p < 0.0001$ );
- photophobia free ( $p < 0.0001$ ); and
  
- nausea free ( $p = 0.02$ ).

Results from the post-hoc analyses reported today found that LEVADEX also was effective compared to placebo in treating migraine:

- in patients with or without allodynia;
- at any time during the migraine attack, regardless of how long patients had waited to treat a migraine;
- that occurs in the early morning, also known as "morning migraine";
- in severely disabled and non disabled patients, as defined by a HIT-6 score;
- with severe as well as moderate intensity of baseline pain;
- with severe intensity of pain, providing pain relief at 10 minutes; and
  
- with and without nausea, vomiting and aura.

Additional LEVADEX data from the Phase 3 trial showed rapid and sustained efficacy in treating migraine with:

- pain relief at 10 minutes ( $p = 0.16$ ) and time to pain relief at 30 minutes ( $p = 0.03$ );
- sustained pain relief from two to 24 hours in 44 percent of patients compared to 20 percent for placebo ( $p < 0.0001$ );
- sustained pain relief from two to 48 hours in 36 percent of patients compared to 17 percent for placebo ( $p < 0.0001$ , unadjusted for

multiplicity); and

- sustained pain free from two to 24 hours in 23 percent of patients compared to 7 percent for placebo, and from two to 48 hours in 18 percent of patients compared to 6 percent for placebo ( $p < 0.0001$  for both timepoints, unadjusted for multiplicity).

There were no drug-related serious adverse events reported in the trial. LEVADEX was well tolerated, with the most common adverse event reported being medication aftertaste at six percent, with two percent of patients receiving placebo also reporting medication aftertaste. The next most common adverse event was nausea at five percent, compared with two percent for placebo. Symptoms or sensitivities typically associated with commonly used triptan migraine treatments, such as chest discomfort (one percent) or chest pain (0 percent), were rare and comparable to placebo. There were no decreases in lung function, as measured by spirometry, between the active and placebo groups.

"These sub-analyses further heighten our enthusiasm for LEVADEX and its potential to help the many patients who suffer from the debilitating effects of migraine, including the potential to provide benefit to a number of significant subpopulations of migraine patients who are not well served by currently available therapies," said Timothy S. Nelson, President and Chief Executive Officer of MAP Pharmaceuticals. "We look forward to continuing development of LEVADEX and initiating a confirmatory Phase 3 trial in the first quarter of 2010."

LEVADEX data are being presented in a late-breaking oral platform presentation titled "LEVADEX(TM), a novel orally inhaled treatment for acute migraine: efficacy and tolerability results of a Phase 3 study" on Saturday, September 12, 2009 at the 14th Congress of the International Headache Society in Philadelphia, PA by clinical trial investigator Stephen Silberstein, M.D., F.A.C.P., director of the Jefferson Headache Center, and professor in the Department of Neurology at Jefferson Medical College of Thomas Jefferson University. In addition, three poster presentations titled 1) "Efficacy and tolerability of MAP0004, a novel inhaled therapy, in treating acute migraine", 2) "Efficacy evaluation of LEVADEX(TM) (previously MAP0004) in treating resistant migraine including migraine with allodynia, migraine treated late in its cycle, morning migraine and disabling migraine" and 3) "Efficacy evaluation of LEVADEX(TM) (previously MAP0004) in treating a broad spectrum of acute migraine attacks including patients using triptans and patients not using triptans" will be available for review at the conference.

#### Webcast Information

MAP Pharmaceuticals will host a webcast on Monday, September 14, 2009 at 7:15 a.m. ET to review the data presented at the 14th Congress of the International Headache Society. The webcast will be accessible in the Investor Relations section of the company's website at [www.mappharma.com](http://www.mappharma.com).

#### About LEVADEX(TM)

LEVADEX orally inhaled migraine therapy is a novel migraine therapy candidate in Phase 3 development. Patients administer LEVADEX themselves using the company's proprietary TEMPO(R) inhaler. 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 and 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 FREEDOM-301 trial, which was the first Phase 3 trial of LEVADEX, the company believes the unique pharmacokinetic profile of LEVADEX has the potential to effectively treat migraine, while minimizing the side effects commonly seen with DHE and other currently available medicines.

#### About Migraine

Migraine is a common, debilitating neurological disorder that affects approximately 30 million people in the United States, according to the National Headache Foundation. Limitations of oral triptans, the class of prescription drugs widely used for migraines, include slow onset of significant pain relief between 45 and 90 minutes, substantial variability in patient response and side effects such as heightened blood pressure.

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 often 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>.

LEVADEX and TEMPO are trademarks of MAP Pharmaceuticals, Inc.

#### 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 following: the enrollment of clinical trials, risks related to the 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 June 30, 2009 and available at <http://edgar.sec.gov>.

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