



Medivation Announces Publication in The Lancet of Dimebon Pivotal Trial Results in Alzheimer's Disease

- Dimebon Improved the Clinical Course of Alzheimer's Disease; Patients Experienced Statistically Significant Improvements in Memory and Thinking, Activities of Daily Living, Behavior and Overall Function -

SAN FRANCISCO, July 17, 2008 /PRNewswire-FirstCall via COMTEX News Network/ -- Medivation, Inc. (Nasdaq: MDVN) today announced publication of the results of its first Alzheimer's disease pivotal clinical trial of the investigational drug Dimebon in the July 19, 2008 issue of The Lancet. In this double-blind, placebo-controlled trial, patients with mild-to-moderate Alzheimer's disease treated with Dimebon experienced statistically significant improvements compared to placebo in all the key aspects of the disease: memory and thinking, activities of daily living, behavior and overall function.

After both six months and a full year of treatment, Dimebon-treated patients were significantly better than placebo-treated patients on all key aspects of the disease. The benefit on the primary endpoint, the Alzheimer's Disease Assessment Scale-cognitive subscale (ADAS-cog) at six months, was highly significant ($p < 0.0001$). Patients treated with Dimebon were also significantly improved at six months over baseline on all measures ($p = 0.005$ on ADAS-cog). Dimebon's benefit over placebo continued to increase throughout the 12-month treatment period. At the end of 12 months, Dimebon-treated patients preserved their starting level of function on each measure of Alzheimer's disease.

"In this study, Dimebon improved the clinical course of Alzheimer's disease, which is important given that the natural course is progressive deterioration over time," said Rachele Doody, M.D., Ph.D., lead author and the Effie Marie Cain Chair in Alzheimer's Disease Research at the Alzheimer's Disease and Memory Disorders Center, Baylor College of Medicine in Houston. "There is a clear need for new treatments that can add value and enduring benefit to the treatment of Alzheimer's disease. The results of this trial suggest that, if the findings are replicated, Dimebon could advance Alzheimer's treatment, offering more hope for patients and their caregivers."

Dimebon was well-tolerated throughout the trial. There was no difference between the Dimebon and placebo groups in the number of patients with adverse events, and the most common side effects seen were dry mouth (18 percent versus 1 percent for placebo) and depressed mood/depression (15 percent versus 5 percent for placebo). Importantly, fewer patients treated with Dimebon had serious adverse events than did patients on placebo at the end of the study (3 percent versus 12 percent; $p = 0.03$).

Additional analyses of the Dimebon pivotal study data presented at recent medical conferences showed that Dimebon's impact extended to caregivers. Behavioral improvements in Dimebon-treated patients resulted in a significant decrease in caregiver distress at six months and at one year compared to the distress of caregivers of placebo-treated patients. Further, after six months, caregivers of Dimebon-treated patients saved approximately one hour per day assisting patients with activities of daily living compared to caregivers of placebo-treated patients.

"The magnitude, consistency and duration of the beneficial effects of Dimebon demonstrated in this trial are striking," said Paul Aisen, M.D., Director, Alzheimer's Disease Cooperative Study (ADCS) and Professor in the Department of Neurosciences, University of California, San Diego (UCSD). "In addition, the drug has been well-tolerated to date and, if the safety profile is replicated in the ongoing international trial, it will be a substantial advance for this patient population prone to drug side effects."

"We are pleased to see our first pivotal trial culminate with publication of its significant findings in such a prestigious journal," said David Hung, M.D., President and Chief Executive Officer of Medivation. "Currently available therapies treat the symptoms of Alzheimer's disease with only modest effect. The Dimebon study is the first study in which a drug has achieved statistically significant benefits of this breadth, size and duration in a one year, well-controlled trial. These data, coupled with our recently announced positive results in Huntington's disease, suggest that Dimebon could be a novel therapy for the treatment of neurodegenerative diseases. We look forward to the completion of our confirmatory pivotal Phase 3 study of Dimebon in Alzheimer's disease."

About the Pivotal Study

In the trial, 183 patients with mild-to-moderate Alzheimer's disease were randomized to receive Dimebon (20 mg three times a day, administered orally) or placebo for six months. 134 patients continued treatment in a blinded manner for an additional six months (one year total treatment) in the same group to which they were originally randomized; 120 of these patients (90 percent) completed the trial.

Earlier this year, the U.S. Food and Drug Administration (FDA) informed Medivation that this study can be used as one of the pivotal studies required to support the approval of Dimebon to treat mild-to-moderate Alzheimer's disease, as long as a significant proportion of the sites in the confirmatory Phase 3 trial are located in the United States. The Company recently began a confirmatory pivotal Phase 3 trial of Dimebon in Alzheimer's disease known as the CONNECTION study. Patients and caregivers can learn more about the study by visiting <http://www.connectionstudy.com> or by calling 1-877-888-6386.

About Dimebon

Dimebon is an orally available small molecule that has been shown to inhibit brain cell death in preclinical models relevant to Alzheimer's and Huntington's diseases, making it a potential treatment for these and other neurodegenerative diseases. Preclinical data generated to date suggest that Dimebon operates through a novel mitochondrial mechanism of action.

On July 7, 2008, Medivation announced positive safety and efficacy results from its Phase 2 trial of Dimebon for the treatment of Huntington's disease, which was conducted in collaboration with the Huntington Study Group. The study met its primary endpoint of safety and tolerability; in addition, Dimebon showed statistically significant benefit versus placebo in cognition as measured by the Mini-Mental State Examination, a secondary endpoint in the study. Huntington's disease is a progressive neurodegenerative disease characterized by the gradual development of involuntary muscle movement, progressive deterioration of cognitive processes and memory and severe behavioral disturbances. There are currently no approved drugs in the United States to treat this uniformly fatal genetic disorder.

About Alzheimer's Disease

Alzheimer's disease is a progressive, neurodegenerative disease that destroys brain cells and affects areas of the brain involved in memory, cognition, judgment, language and behavior, eventually leading to severe impairments in cognition and function. The most common form of dementia, Alzheimer's disease affects as many as 5 million Americans.

About Medivation

Medivation, Inc. is a biopharmaceutical company focused on the rapid development of novel small molecule drugs to treat serious diseases for which there are limited treatment options. Medivation aims to transform the treatment of these diseases and offer hope to critically ill patients and their caregivers. The Company's current clinical development program includes a pivotal and confirmatory Phase 3 trial of Dimebon in Alzheimer's disease and a Phase 1-2 clinical trial of MDV3100 in patients with castration-resistant (also known as hormone-refractory) prostate cancer. Medivation recently announced that it plans to continue further development of Dimebon in patients with mild-to-moderate Huntington's disease based on the positive results seen in its Phase 2 trial. For more information, please visit us at <http://www.medivation.com>.

This press release contains forward-looking statements, including statements regarding future clinical development plans, which are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements involve risks and uncertainties that could cause actual results to differ significantly from those projected. You are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this release. None of the Company's product candidates has been approved for sale, significant additional animal and human testing is required in order to seek marketing approval for any of its product candidates, and Medivation cannot assure you that marketing approval can be obtained for any of its product candidates. Furthermore, as is typically the case at this stage of the regulatory review process, the FDA has not yet performed an in-depth review of Medivation's preclinical and clinical data, so its views remain subject to change. Medivation's filings with the Securities and Exchange Commission, including its current report on Form 8-K filed on June 23, 2008, include information about additional factors that could affect the Company's financial and operating results.

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