



## **Medivation Completes Enrollment in Confirmatory, Pivotal Phase 3 'CONNECTION' Trial of Dimebon in Patients With Alzheimer's Disease**

SAN FRANCISCO, June 11, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Medivation, Inc. (Nasdaq: MDVN) today announced the completion of patient enrollment in the CONNECTION study, a six-month, confirmatory, pivotal Phase 3 trial of the investigational drug dimebon in patients with mild-to-moderate Alzheimer's disease.

The international, double-blind, placebo-controlled, pivotal Phase 3 study enrolled 598 patients, exceeding the enrollment target of 525 patients. More than 40 percent of the patients enrolled were in the United States. The six-month study is evaluating the effect of dimebon on the Alzheimer's Disease Assessment Scale-cognitive subscale (ADAS-cog) and the Clinician's Interview-Based Impression of Change plus caregiver interview (CIBIC-plus) -- the two endpoints have historically been accepted by the U.S. Food and Drug Administration (FDA) to support registration of currently approved drugs for mild-to-moderate Alzheimer's disease.

"Completion of patient enrollment in this second pivotal trial moves us closer to our goal of submitting a marketing application to the FDA and bringing dimebon to market for the many Alzheimer's patients suffering from this devastating disease," said Lynn Seely, M.D., chief medical officer of Medivation. "We are gratified by the strong interest in this trial as indicated by our exceeding the enrollment goal. Together with our partner Pfizer, we are executing a comprehensive clinical plan to support an NDA filing, currently targeted for 2011, with a broad and differentiated label for dimebon in Alzheimer's disease. We are also conducting a Phase 3 safety study, which will provide us and Pfizer the opportunity to seek marketing approval earlier if results of the CONNECTION study confirm our previously completed first pivotal study, which was published in the Lancet last year."

### **About Dimebon**

Dimebon is an investigational compound currently in Phase 3 development for the treatment of Alzheimer's disease and in clinical development for Huntington disease. In preclinical models of Alzheimer's disease and Huntington disease explored thus far, dimebon has been shown to inhibit brain cell death, potentially by stabilizing and improving mitochondrial function in a way that prevents neuron death and dysfunction. The dimebon mechanism is thought to be distinct from that of currently available Alzheimer's disease medications.

In addition to CONNECTION, dimebon is being studied in the 12-month Phase 3 CONCERT trial, which is evaluating the efficacy of dimebon when added to ongoing treatment with donepezil (Aricept(R)) in patients with mild-to-moderate Alzheimer's disease, and in a Phase 3 safety study. Two Phase 3 studies in moderate-to-severe Alzheimer's disease are also planned to start this year.

In Huntington disease, a Phase 2 study has been completed. Medivation and Pfizer expect to initiate a Phase 3 trial this year to evaluate the potential benefits of dimebon on cognition in patients with Huntington disease.

### **About Alzheimer's Disease**

Alzheimer's disease is a progressive degenerative brain disorder that gradually destroys a person's memory and ability to learn, reason, make judgments, communicate and carry out daily activities. As the disease progresses, patients may experience changes in personality and behavior, such as anxiety, suspiciousness or agitation, as well as delusions or hallucinations.

### **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. In September 2008, Medivation announced a global agreement with Pfizer Inc to develop and commercialize dimebon for the treatment of Alzheimer's and Huntington diseases. With Pfizer, the Company is conducting a broad dimebon clinical development program that includes several Phase 3 trials assessing the efficacy and safety of dimebon taken alone or in combination with other Alzheimer's medications in patients with mild, moderate or severe Alzheimer's disease. Further development of dimebon in patients with Huntington disease is also planned. In addition, a Phase 1-2 clinical trial of MDV3100 in patients with castration-resistant (also known as hormone-refractory) prostate cancer is

ongoing, and a Phase 3 trial is expected to begin this year. For more information, please visit us at <http://www.medivation.com>.

This press release contains forward-looking statements, including statements regarding the timing and potential results of clinical trials, and the anticipated timing of regulatory filings, which are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Any statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements. Forward-looking statements involve risks and uncertainties that could cause Medivation's actual results to differ significantly from those projected, including, without limitation, risks related to progress, timing and results of Medivation's clinical trials, difficulties or delays in obtaining regulatory approval, enrollment of patients in Medivation's clinical trials, partnering of Medivation's product candidates, manufacturing of Medivation's product candidates, competition with Medivation's product candidates should they receive marketing approval, the adequacy of Medivation's financial resources, unanticipated expenditures or liabilities, intellectual property matters, and other risks detailed in Medivation's filings with the Securities and Exchange Commission, including its quarterly report on Form 10-Q for the quarter ended March 31, 2009, filed on May 11, 2009, with the SEC. You are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this release. Medivation disclaims any obligation or undertaking to update or revise any forward-looking statements contained in this press release.

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