



Pfizer And Medivation Initiate Phase 3 Trial Of Dimebon In Patients With Huntington Disease

Wednesday, July 29, 2009 - 07:00pm

U.S. Orphan Drug Designation Granted for Dimebon for Treatment of Huntington Disease

(BUSINESS WIRE)--Pfizer Inc (NYSE: PFE) and Medivation, Inc. (NASDAQ: MDVN) today announced the initiation of a Phase 3 trial of the investigational drug dimebon (latrepirdine)* in patients with Huntington disease. The international safety and efficacy trial, known as HORIZON, is designed to evaluate the potential benefits of dimebon on cognition (thinking and memory) in patients with Huntington disease. The companies also announced that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation to dimebon for the treatment of Huntington disease.

“Based on the promising results of our Phase 2 trial of dimebon in Huntington disease, we are pleased to advance dimebon into late-stage clinical development,” said Lynn Seely, M.D., chief medical officer for Medivation. “Huntington disease is a fatal genetic disease for which no medications are currently approved by the FDA to treat the cognitive impairment associated with the condition.”

Orphan status is granted by the FDA to promote the development of products that demonstrate promise for the treatment of rare diseases affecting fewer than 200,000 Americans annually, such as Huntington disease, which affects 30,000 individuals in the United States, with another 150,000 at risk. Orphan drug designation entitles Pfizer and Medivation to a seven-year period of marketing exclusivity in the United States for dimebon if it is approved by the FDA for the treatment of Huntington disease. It also enables the companies to apply for research funding, tax credits for certain research expenses, and a waiver from the FDA's application user fee.

*Latrepidine is the proposed generic (nonproprietary) name for dimebon.

Design of the HORIZON Study

The double-blind, placebo-controlled Phase 3 trial will enroll approximately 350 patients with Huntington disease at approximately 50 sites in North America, Europe and Australia. Patients will be randomized to receive either dimebon (latrepirdine) 20 mg three times daily or placebo for six months.

The primary endpoints of the trial are the Mini Mental State Examination (MMSE), which measures cognition, and the Clinician's Interview-Based Impression of Change, plus caregiver input (CIBIC-plus), which measures global function. The trial will include only patients who have cognitive impairment, as subjectively assessed by an investigator and objectively by MMSE score.

Secondary endpoints include the Neuropsychiatric Inventory (NPI), which measures behavior; the Alzheimer's Disease Cooperative Study – Activities of Daily Living (ADCS-ADL), which measures self-care and daily function; and the Unified Huntington Disease Rating Scale (UHDRS'99) Total Motor Score, which measures motor impairment; and safety.

The trial is being conducted in collaboration with the Huntington Study Group (HSG) and the European Huntington's Disease Network (EHDN). The HSG is a non-profit group of experienced clinical trial investigators from medical centers in the United States and abroad dedicated to clinical research of Huntington disease. The EHDN is a non-profit network of professionals providing an infrastructure for large scale Huntington disease clinical trials throughout Europe.

For more information about the HORIZON study, please visit www.horizontrial.com or call 800-487-7671 or +49 731 5006 3103.

About Dimebon

Dimebon (latrepirdine) is an investigational drug in Phase 3 development for the treatment of Alzheimer's disease (AD) and Huntington disease (HD). In preclinical studies, dimebon has been shown to protect brain cells from damage and enhance brain cell survival, potentially by stabilizing and improving mitochondrial function. The dimebon mechanism is distinct from currently available AD and HD medications.

About Huntington Disease

Huntington disease is a rare, neurodegenerative disease that is caused by the death of specific brain cells. The genetic disorder is characterized by the gradual development of involuntary muscle movements, cognitive impairment and severe behavioral disturbances. No medications are currently approved to treat the cognitive impairment (thinking and memory) of Huntington disease.

About the Pfizer/Medivation Dimebon Collaboration

Medivation and Pfizer have a global collaboration to develop and commercialize dimebon for the treatment of Alzheimer's disease and Huntington disease. Under the terms of the agreement, the companies are working in partnership to seek FDA approval for dimebon and bring it to market in the United States. In addition, following FDA approval, Medivation will co-promote dimebon to specialty physicians in the U.S. Pfizer has responsibility for development, regulatory and commercialization outside of the U.S.

For more information about Pfizer, visit www.Pfizer.com.

For more information about Medivation, visit www.Medivation.com.

Forward-Looking Statements

PFIZER DISCLOSURE NOTICE: The information contained in this release is as of July 30, 2009. Pfizer assumes no obligation to update any forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about certain potential indications for dimebon, including their potential benefits, that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development; decisions by regulatory authorities regarding whether and when to approve any new drug applications that may be filed for such indications as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of any such indications; and competitive developments.

A further list and description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2008, and in its reports on Form 10-Q and Form 8-K.

MEDIVATION DISCLOSURE NOTICE: This press release contains forward-looking statements, including statements regarding potential clinical indications for dimebon, 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.

Pfizer Inc Media: Sally Beatty, 212-733-6566 or Investors: Jennifer Davis, 212-733-0717 or Medivation, Inc. Patrick Machado, CFO, 415-829-4101