

Pfizer And Medivation Initiate Two Phase 3 Trials Of Dimebon In Patients With Moderate-To-Severe Alzheimer's Disease

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International Studies to Evaluate Effects of Dimebon in Combination Therapy: One in Patients on Background Donepezil, One in Patients on Background Memantine

[\(BUSINESS WIRE\)](#)--Pfizer Inc (NYSE: PFE) and Medivation, Inc. (NASDAQ: MDVN) today announced the initiation of CONTACT and CONSTELLATION, two Phase 3 trials of the investigational drug dimebon (latrepirdine)* in patients with moderate-to-severe Alzheimer's disease (AD).

The CONTACT study will assess as primary endpoints the potential benefits of adding dimebon to ongoing treatment with donepezil HCl tablets, the leading AD medication worldwide, on neuropsychiatric symptoms and activities of daily living. The CONSTELLATION study will evaluate as primary endpoints the effects of adding dimebon to memantine HCl, another standard of care, on cognition, memory and activities of daily living.

"Alzheimer's disease is a growing global epidemic with an unmet clinical need. Many patients with moderate-to-severe Alzheimer's disease experience behavioral and neuropsychiatric symptoms, which are among the leading causes of placement in care facilities for these patients," said Pierre N. Tariot, MD, director of the Memory Disorders Center at the Banner Alzheimer's Institute and study investigator. "These studies are intended to evaluate the potential added benefits of dimebon in combination with current standards of Alzheimer's care."

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 medications.

"Pfizer and Medivation are committed to developing dimebon as a treatment that may meaningfully improve the lives of patients across the full spectrum of Alzheimer's disease severity," said Lynn Seely, M.D., chief medical officer for Medivation. "The initiation of the CONTACT and CONSTELLATION studies is an important milestone in the broad clinical development of dimebon."

These studies are part of a comprehensive Phase 3 clinical development program, currently consisting of seven trials, to assess the safety and efficacy of dimebon across all stages of Alzheimer's disease, as monotherapy and in combination with currently available Alzheimer's treatments, and in Huntington disease.

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

About the CONTACT Study

This Phase 3 randomized, double-blind, placebo-controlled study will enroll approximately 600 patients with moderate-to-severe AD and neuropsychiatric symptoms at approximately 75 sites in Europe and South America. Patients who are already taking donepezil will be randomized to also receive either dimebon 20 mg three times daily or placebo for six months.

The CONTACT study is designed to assess patients' behavioral difficulties and their ability to perform routine activities of daily living. Behavior will be measured by the Neuropsychiatric Inventory (NPI), while self-care and daily function will be measured by the Alzheimer's Disease Cooperative Study – Activities of Daily Living (severe) (ADCS-ADLsev). Secondary endpoints include measures of cognition, memory, global function, pharmacoeconomic impact, quality of life and safety and tolerability.

For more information about the CONTACT study, please visit www.ContactStudy.com or email contactstudy@medivation.com.

About the CONSTELLATION Study

This Phase 3 randomized, double-blind, placebo-controlled study will enroll approximately 570 patients with moderate-to-severe AD at approximately 80 sites in the United States, Canada and Europe. Patients already taking memantine will be randomized to also receive either dimebon 20 mg three times daily or placebo for six months.

The CONSTELLATION study will evaluate the potential benefits of adding dimebon to ongoing memantine therapy on cognition, memory and activities of daily living. Cognition and memory will be measured by the Severe Impairment Battery (SIB), while self-care and daily function will be measured by the Alzheimer's Disease Cooperative Study – Activities of Daily Living (severe) (ADCS-ADLsev). Secondary endpoints include measures of cognitive and behavioral symptoms, global function, resource utilization, quality of life, safety and tolerability.

For more information about the CONSTELLATION study, please visit www.ConstellationStudy.com or call 1-877-377-4476.

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 delusions, hallucinations, anxiety, and agitation.

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 advance the Phase 3 development program with the goal of submitting a new drug application to the FDA and bringing dimebon to market in the United States. In addition, pending 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 November 3, 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. -5-

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 June 30, 2009, filed on August 5, 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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