



# Pfizer And Medivation Announce Results From Two Phase 3 Studies In Dimebon (latrepirdine\*) Alzheimer's Disease Clinical Development Program

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In CONNECTION Study, Dimebon Does Not Meet Primary and Secondary Efficacy Endpoints Separate Phase 3 Safety Study Demonstrates Dimebon's Tolerability When Used Alone or in Combination with Approved Alzheimer's Disease Medicines Medivation to Hold Investor Call at 8:30 a.m. EST

(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) and Medivation, Inc. (NASDAQ: MDVN) today announced results from two Phase 3 trials of the investigational drug dimebon (latrepirdine\*) in patients with Alzheimer's disease (AD). In the CONNECTION trial, dimebon did not meet its co-primary or secondary efficacy endpoints compared to placebo. Co-primary endpoints were measures of cognition and global function.

"The results from the CONNECTION study are unexpected, and we are disappointed for the Alzheimer's community," said Dr. David Hung, president and chief executive officer of Medivation. "We are working with our colleagues at Pfizer to better understand the CONNECTION data and we plan to present these data at an upcoming medical meeting."

Dimebon was well tolerated in both the CONNECTION study and in a separate Phase 3 safety and tolerability study, which confirmed dimebon's tolerability when dosed alone or in combination with approved Alzheimer's disease medicines.

“We are evaluating the CONNECTION data with Medivation. After that review, Pfizer will be in a position to determine appropriate next steps regarding the dimebon program,” said Dr. Briggs W. Morrison, senior vice president, clinical development, Primary Care Business Unit at Pfizer. “We recognize the significant medical need, and we are committed to advancing treatment options for Alzheimer’s disease.”

### About the CONNECTION Study

CONNECTION is a Phase 3, multi-national, double-blind, placebo-controlled safety and efficacy trial involving 598 patients with mild-to-moderate AD at 63 sites in North America, Europe, and South America. Patients had a mean age of 74.4 years and a mean score of 17.7 on the Mini-Mental State Examination (MMSE) upon entry into the study. More than 40 percent of the patients enrolled were in the United States. In the study, patients were randomized to one of three treatment groups, receiving dimebon 20 mg three times a day (TID), dimebon 5 mg TID, or placebo TID for six months. The 5 mg arm was included in the study to help define the effective dose range for dimebon treatment.

No statistically significant improvements for the 20 mg TID group relative to placebo were achieved on the co-primary endpoints. One primary endpoint evaluated the effect of dimebon on cognition, as measured by the Alzheimer's Disease Assessment Scale-cognitive subscale (ADAS-cog), and showed that dimebon-treated patients achieved a 0.1 point difference from patients receiving placebo ( $p=0.86$ ). Neither group was significantly changed from baseline. The other primary endpoint evaluated the effect of dimebon on independently-rated global function over the course of the six-month trial, as measured by the Clinician's Interview-Based Impression of Change Plus Caregiver Input (CIBIC-plus;  $p=0.81$ ). According to the CIBIC-plus scale, 64.9 percent of the patients treated with dimebon 20 mg TID showed improvement or no change at Week 26 compared to 65.4 percent of placebo-treated patients. Results for the dimebon 5 mg dose were similar to the dimebon 20 mg and placebo, although they were numerically lower.

The 20 mg TID dimebon-treated patients also showed no statistically significant differences compared to placebo on the secondary efficacy endpoints. After six months of treatment, patients treated with dimebon showed a 0.4 point difference from patients taking placebo on activities of daily living ( $p=0.61$ ), as measured by the Alzheimer's Disease Cooperative Study Activities of Daily Living Scale (ADCS-ADL). Neither group was significantly changed from baseline. The dimebon-treated group showed a 1.6 point improvement on behavior compared to placebo ( $p=0.17$ ), as measured by the Neuropsychiatric Inventory (NPI). Compared to baseline, each group was improved, but this change was only significant for the dimebon group. On the Mini Mental State

Examination (MMSE), another measure of cognition, both groups improved significantly over baseline (dimebon 0.7; placebo 1.2). The difference favoring placebo was not significant ( $p=0.10$ ). Results for the dimebon 5 mg dose were similar to dimebon 20 mg and placebo, although they were numerically lower. Dimebon, 20 mg orally three-times daily, was well tolerated in the study. The number of patients with at least one adverse event was similar in the dimebon 20 mg and placebo groups (72.0% vs. 74.2%, respectively). The most frequently reported adverse events ( $>5\%$ ) in patients in the 20 mg dimebon group occurring more commonly than in the placebo group included somnolence (11.0% vs. 10.1%), dry mouth (8.5% vs. 6.6%), headache (9.5% vs. 5.6%), dizziness (7.5% vs. 5.1%), constipation (5.5% vs. 3.5%), cough (7.5% vs. 3.5%) and depression (6.0% vs. 3.5%). Similar rates of adverse events were observed for the 5 mg TID group. No clinically significant findings were noted in assessment of vital signs, clinical laboratories or on electrocardiography (ECG).

#### About the Phase 3 Safety and Tolerability Study

In a separate multi-center, placebo-controlled Phase 3 safety and tolerability study, dimebon was well tolerated when given alone or in combination with a variety of other AD medicines, including cholinesterase inhibitors, memantine, or both. Previous studies have confirmed the tolerability of dimebon alone. The Phase 3 safety and tolerability study enrolled 742 patients with mild-to-moderate Alzheimer's disease in the United States and Canada. In this study, patients were randomized to either dimebon 20 mg three-times daily or placebo and were treated for a period of either three or six months. Approximately 85 percent of patients were taking one or more currently approved Alzheimer's disease medicines while participating in this study.

Dimebon was well tolerated in the study. The most frequently reported adverse events ( $>5\%$ ) in the dimebon group occurring more commonly than in the placebo group were somnolence (5.1% vs. 1.9%) and fatigue (5.1% vs. 2.4%). No clinically significant findings were noted in assessment of vital signs, clinical laboratories or on electrocardiography (ECG).

#### About Dimebon

Dimebon (latrepirdine\*) is an investigational oral medication being tested as a potential treatment for Alzheimer's disease and Huntington disease. Dimebon is being studied in four other ongoing randomized, double-blind, placebo-controlled Phase 3 studies, which currently are enrolling. The CONCERT trial is a 12-month study testing dimebon in patients with mild-to-moderate Alzheimer's disease who are taking donepezil, a

commonly prescribed Alzheimer's disease medication. The CONTACT and CONSTELLATION trials are six-month trials testing dimebon in patients with moderate-to-severe Alzheimer's disease taking currently approved AD medications. In CONTACT, subjects must also be taking donepezil, while in CONSTELLATION they must also be taking memantine, another commonly prescribed Alzheimer's disease medication. Dimebon is also being tested in the HORIZON trial, a six-month study evaluating dimebon in patients with Huntington disease.

For information on dimebon clinical trials, please visit [www.dimebontrials.com](http://www.dimebontrials.com) or [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

### 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 work together on the dimebon development program.

For more information about Pfizer, visit [www.Pfizer.com](http://www.Pfizer.com).

For more information about Medivation, visit [www.Medivation.com](http://www.Medivation.com).

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

### Medivation Investor Conference Call Details:

Medivation will hold a conference call today at 8:30 a.m. Eastern Time (5:30 a.m. Pacific Time) to discuss this announcement. To participate in the live call please dial 877-303-2523 for domestic callers and 1-253-237-1755 for international callers. In addition, the live conference call is being webcast and can be accessed on the "Events and Presentations" page of the "Investor Relations" section of the Company's website at [www.medivation.com](http://www.medivation.com). A replay also will be available for 30 days following the live call.

### Forward-Looking Statements

PFIZER DISCLOSURE NOTICE: The information contained in this release is as of March 3, 2010. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information that involves substantial risks and uncertainties about certain potential indications for dimebon, including their potential benefits; the continued clinical development of dimebon; and the continuing collaborative activities under our collaboration with Medivation. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development, including risks related to the progress, timing and results of the clinical trials for dimebon; decisions by regulatory authorities regarding whether and when to approve any new drug applications that may be filed for such indications, including the risk that such indications may never be approved for commercial sale in any jurisdiction, 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, 2009 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 the continued clinical development of dimebon, the continued effectiveness of, and continuing collaborative activities under, our collaboration with Pfizer, potential clinical indications for dimebon, including its potential benefits, and potential regulatory approval and commercialization of 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, including the risk that adverse clinical trial results could alone or together with other factors result in the delay or discontinuation of some or all of our dimebon development activities, difficulties or delays in obtaining regulatory approval, including the risk that dimebon may never be approved for commercial sale in any jurisdiction, enrollment of patients in Medivation's clinical trials, partnering of Medivation's product candidates, including Medivation's dependence on the efforts of and funding by Pfizer for the development of dimebon under its collaboration with Pfizer, which collaboration may be unilaterally terminated by Pfizer at its election at any time, the achievement of development, regulatory and commercial

milestones under Medivation's collaboration agreement with Pfizer, manufacturing of Medivation's product candidates, including Medivation's dependence on Pfizer for the manufacture of all clinical requirements of dimebon, 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 September 30, 2009, filed with the SEC on November 4, 2009. 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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