



## **New Study of Investigational Alzheimer's Disease Treatment Enrolling Patients in Australia**

August 31, 2009

### **New Study of Investigational Alzheimer's Disease Treatment Enrolling Patients in Australia**

**Sydney, Australia – 31, August 2009** – It was announced today that a new global clinical trial has begun enrolling patients with Alzheimer's disease in NSW, Victoria, Queensland, South Australia, and Western Australia.

The CONCERT study, is a new clinical trial that will test the efficacy of a unique investigational drug, dimebon (latrepirdine)\*, in patients currently taking Aricept® (donepezil HCl tablets), the leading Alzheimer's disease medication worldwide.

"Alzheimer's is a complex disease and while current medications address symptoms for some patients, the long-term management of this disease would benefit from new treatment options." said Professor Henry Brodaty, Professor of Ageing and Mental Health, University of New South Wales; Director, Aged Care Psychiatry and Head of the Memory Disorders Clinic, Prince of Wales Hospital.

"CONCERT is an important study because dimebon is thought to work differently than current medications and this study will evaluate whether adding it to one of the most commonly used Alzheimer's medications will provide more effective symptomatic treatment to patients," said Brodaty.

While a cure is still many years away, treatments that provide lasting effects, more complete symptomatic benefits or slow disease progression would be meaningful advances for patients and caregivers; for this reason there is an urgent need for patients to participate in clinical trials to help advance the understanding of how Alzheimer's disease can be better treated.

According to Alzheimer's Australia an estimated 230,000 Australians have dementia; of which 50-70% are Alzheimer's disease (1), a devastating disease that hinders a patient's ability to remember, learn, perform daily activities and relate to others. As the baby boomer population ages, the incidence of Alzheimer's is expected to increase dramatically.

(1) Alzheimer's Fact Sheet, Alzheimer's Australia <http://www.alzheimers.org.au/index.cfm>  
<http://www.alzheimers.org.au/upload/HS1.12.pdf>

For more information on eligibility and enrollment, patients and caregivers can call the CONCERT study hotline toll-free at **1 800 235 526** or visit [www.concertstudy.com](http://www.concertstudy.com).

### **About the CONCERT Study**

CONCERT is an international, randomized, double-blind, placebo-controlled study that will enroll approximately 1,050 patients with mild-to-moderate AD at approximately 100 sites in the United States, Australia, New Zealand and Western Europe. Patients on a stable dose of Aricept will be randomized to one of three treatment groups: dimebon 20 mg three times per day, dimebon 5 mg three times per day or placebo.

The primary endpoints are the Alzheimer's Disease Assessment Scale – cognitive subscale (ADAS-cog) and the Alzheimer's Disease Cooperative Study – Activities of Daily Living (ADCS-ADL), a measure of self-care and daily function.

The CONCERT study is sponsored by Pfizer and Medivation, Inc.

### **About Dimebon**

Dimebon (latrepirdine) is an investigational drug currently in Phase 3 development for the treatment of Alzheimer's disease and in clinical development for Huntington disease (HD). The comprehensive Phase 3 clinical development program for Alzheimer's disease is evaluating the potential for dimebon to be used in broad applications including use alone, in combination with existing medications and in patients at all stages of the disease.

Dimebon has a unique mechanism of action, distinct from currently available treatments. 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.

Mitochondria are critical to brain cell functioning as they are the primary source of energy for cells. Drugs that protect mitochondria or restore their function could potentially be a valuable treatment approach in AD.

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