



## **PBT2 -Phase IIa Clinical Trial in Alzheimer's Disease Patients**

**Melbourne, Australia – Thursday 11<sup>th</sup> May 2006: Prana Biotechnology Limited (NASDAQ: PRAN, ASX: PBT)**, today announced that it plans to move forward with a Phase IIa clinical trial of its proprietary lead compound, PBT2, in patients with Alzheimer's Disease.

The study, to be conducted in several sites in Sweden, will evaluate the safety and tolerability of PBT2, as well as measures of the drug's mechanism of action and indicators of potential efficacy in Alzheimer's Disease. The study is expected to commence enrollment in the fourth quarter of 2006, subject to final regulatory approval. Results are expected to be reported by the end of 2007.

The Phase IIa study is a randomized, double-blind, placebo-controlled design, in which Alzheimer's Disease patients will receive three (3) months of either one of three oral doses of PBT2, or placebo. In addition to examining safety and tolerability, the study will investigate the ability of PBT2 to affect multiple cerebrospinal fluid (CSF) and blood biomarkers of Alzheimer's Disease during the treatment period. Outcomes will include measures of CSF a-beta and tau levels as well as neurocognitive and behavioral changes.

Prana intends to utilize data from this Phase IIa trial, along with data from a planned larger, pivotal clinical trial, to capitalize on new European Medicines Agency (EMA) regulations that allow for Conditional Marketing Authorization of treatments for seriously debilitating or life-threatening diseases for which there are otherwise no, or only limited, treatment options. Geoffrey Kempler, Executive Chairman and CEO commented, "Based on these new regulations, Prana hopes to accelerate PBT2's path to market in Europe by qualifying for Conditional Marketing Authorization.

Previously, Prana scientists discovered a pathological interaction of metals and proteins leading to toxic a-beta oligomer formation in the brain that is characteristic of patients with Alzheimer's Disease. PBT1, Prana's proof-of-concept MPAC (Metal Protein Attenuating Compound), both lowered plasma a-beta levels and slowed cognitive deterioration, compared to placebo, in a nine-month Phase II pilot study of moderately to severely affected patients, as reported in *Archives of Neurology*, 2003.

"The earlier clinical finding with PBT1, together with our (unpublished) data that there is a rapid and potent onset of benefits in transgenic mice treated with PBT2, leads us to believe that we may see biochemical, and possibly cognitive, benefit in the relatively short time frame of our Phase IIa trial of mildly affected patients," stated Professor Colin Masters of the University of Melbourne and the Mental Health Research Institute, and a director of Prana.

Mr. Kempler concluded, "PBT2 performed very well in the Phase I trials. We also have demonstrated in non-clinical studies that PBT2 can prevent the formation of the toxic oligomers of the a-beta protein, dissolve existing oligomers, and attenuate the production of free radicals. This gives us great confidence in our commitment to the strategic development plan for PBT2 as a treatment for the underlying causes of Alzheimer's disease".

## **Conference Call**

Prana will conduct a teleconference to discuss the Phase I clinical trials data and its plans for the Phase IIa trial on Monday, May 15, at 7.00 am Melbourne Time on Tuesday, May 16 (5:00 p.m. US Eastern Time).

Dial +1-877-270-4109 from the US or Canada (toll-free), +800 00 20 92 from Australia (toll-free) or +1-706-679-0560 from other locations, at least 10 minutes prior to commencement to access the call. Reference Prana or conference ID #9023810. The call also will be web cast and available on the Prana web site, [www.pranabio.com](http://www.pranabio.com).

A replay of the call also will be available 2 hours later until 11:59 PM US Eastern Time on Monday, May 22 (2pm Melbourne Time on Tuesday, May 23). To access the replay, dial +1-800-642-1687 from the US or Canada (toll-free), +800 766 700 from Australia (toll-free) or +1-706-645-9291 from other locations, and enter conference ID#9023810. An archived replay of the conference web cast will be available on the Prana site.

## **Upcoming Management Presentation**

Geoffrey Kempler, Executive Chairman and Chief Executive Officer, will present at the Rodman & Renshaw Third Annual Global Healthcare Conference in Monaco on Tuesday, May 16 at 11.55 Central Europe Time (5:55 a.m. Eastern Time and 19.55 Melbourne Time). During the presentation, Mr. Kempler will address the current status of Prana's development program.

The Company's audio and slide presentation will be web cast live on May 16. A replay will be available one hour following the presentation and archived on the Company's web site for 90 days. To access the live and replay presentations, visit the Prana Biotechnology web site, [www.pranabio.com](http://www.pranabio.com).

## **About Prana Biotechnology Limited**

Prana Biotechnology was established to commercialize research into Alzheimer's disease and other major age-related degenerative disorders. The company was incorporated in 1997 and listed on the Australian Stock Exchange in March 2000 and listed on NASDAQ in September 2002. Researchers at prominent international institutions including the University of Melbourne, The Mental Health Research Institute and Massachusetts General Hospital, a teaching hospital of Harvard Medical School, discovered Prana's technology.

For further information, please visit our web site at [www.pranabio.com](http://www.pranabio.com).

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