



Regulatory Approval to Start PBT2 Phase IIa Clinical Trial in Alzheimer's Disease Patients

Clinical trial strategy to accelerate PBT2's pathway to market in Europe

Melbourne, Australia – 5 October 2006 – Prana Biotechnology Limited (NASDAQ: PRAN, ASX: PBT), today announced that it has received regulatory approval from Sweden's Medical Products Agency (MPA) to start a Phase IIa clinical trial of its proprietary lead compound, PBT2, in patients with early Alzheimer's disease. The trial will be conducted in seven centres in Sweden.

The study, which will commence next month, will evaluate the safety and tolerability of PBT2. In addition, it will examine the drug's mechanism of action and indicators of potential efficacy in treating Alzheimer's disease. Results are expected to be announced in the fourth quarter of 2007.

"The earlier clinical finding with PBT1 (Prana's proof-of-concept compound), together with our recently announced 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. The best hope is that in the course of its development PBT2 could be shown to be disease modifying, offering real hope to Alzheimer's disease patients. Currently there are no approved disease modifying treatments available to patients," stated Professor Colin Masters of the University of Melbourne and the Mental Health Research Institute, and a director of Prana.

The Phase IIa study is a randomised, double blind, placebo-controlled design, in which 80 Alzheimer's disease patients will receive three months of either one of two oral dose levels 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 behavioural changes.

This trial forms part of Prana's strategy to assess the behaviour of PBT2 across a broad dose range, in a manner that is also consistent with the new European Medicines Agency (EMA) regulations that permit accelerated conditional marketing approval for treatments of seriously debilitating diseases such as Alzheimer's disease. These regulations enable marketing for such agents in parallel with pivotal, final stage clinical trials. Mr Geoffrey Kempler, Executive Chairman and CEO commented, "If we qualify under these regulations we could significantly accelerate PBT2's pathway to market in Europe."

"We are very pleased with PBT2's development to date. Besides having successfully completed Phase I, we have also demonstrated, in nonclinical 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. More recently we have announced that, in transgenic animal models,

(i) PBT2 can improve memory performance within 5 days of oral dosing, (ii) PBT2 rapidly reduces the levels of soluble A-beta in the brain, and (iii) PBT2 restores normal function of a-beta impaired synapses. 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," concluded Mr. Kempler.

About Prana Biotechnology Limited

Prana Biotechnology was established to commercialise 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.

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Contacts:

Investor and media relations

Rebecca Piercy

Buchan Consulting

Ph: 02 9237 280 / 0422 916 422