



PRANA BIOTECHNOLOGY RECEIVES CLINICAL TRIALS AUTHORISATION IN UK TO INITIATE PLACQUE PHASE II/III STUDY

- Enrolment of 435 Alzheimer's Patients to Begin in Q2 2005 -

Melbourne, Australia – January 4, 2005: Prana Biotechnology Limited (NASDAQ: PRAN, ASX: PBT), today announced it has received a Clinical Trials Authorisation (CTA) from the Medicines and Healthcare Products Regulatory Agency (MHRA) of the United Kingdom to initiate the potentially pivotal PLACQUE (Progression Limitation in Alzheimer's: ClioQUinol's Efficacy) Phase II/III clinical trial.

- CTA approval enables company to move forward
- Study enables Prana to progress to late stage development company
- Prana meets milestone outlined at Analyst Briefing
- PBT-1 may be first drug to modify the progression of Alzheimer's disease

Study Specifics

The PLACQUE trial will be conducted over 52 weeks and will enrol 435 patients in the United Kingdom, Australia and the Republic of South Africa. The purpose of the study is to assess the efficacy of two dose levels of PBT-1 (clioquinol) when added to the current therapy of patients with moderate Alzheimer's disease. The trial will be randomised, double blind and placebo-controlled. The primary endpoint of the study will be to demonstrate a reduction in the progression of Alzheimer's as measured by the Alzheimer's Disease Assessment Scale-cognition (ADAS-cog).

Significant Milestone

"Receiving CTA approval is a significant milestone for Prana," said Jon Alsenas, CEO of Prana. "When 2004 began, the future of PBT-1 was uncertain due in large part to patent litigation and other concerns. Now as we begin 2005, the patent litigation with P.N. Gerolymatos, S.A. is behind us and we are on the cusp of transforming Prana from an early stage development company to a late stage development company with the initiation of the potentially pivotal PLACQUE trial. The CTA approval allows us to clear the first regulatory hurdle to establishing PBT-1 as the first truly effective therapy for Alzheimer's sufferers.

"We are extremely hopeful that PBT-1 will be the first drug to target what is believed to be the root cause of Alzheimer's disease – the accumulation of amyloid plaques in the neocortex of the brain," continued Dr. Alsenas. "Clioquinol appears to be one of the lead candidates to have a significant impact on both clinical symptoms and disease progression."

Outlook for 2005

Prana expects to have two promising Alzheimer's drugs in the clinic, with the PBT-1 Phase II/III PLACQUE study initiating in the second quarter and the PBT-2 Phase I clinical trial also commencing in early 2005. Moreover, Prana continues to focus upon developing a pipeline of drugs for the treatment of other disorders where inappropriate protein aggregation plays a key role, such as in Parkinson's disease.

"The Metal Theory"

The prize-winning science behind PBT-1 is based upon what is known as "the metal theory" of Alzheimer's disease. The theory is based on the premise that key metals, such as zinc and copper, are required for the inappropriate aggregation of amyloid beta to form the amyloid plaques. These plaques are then thought to cause the neurodegeneration associated with Alzheimer's disease. PBT-1 is the first of Prana's Metal-Protein Attenuating Compounds (MPACs) to be studied in a potentially pivotal trial. The metal-mediated aggregation of proteins is also thought to be a key contributor to the development of a variety of other degenerative disorders.

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 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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