



## **Prana Doses First Patient in the “IMAGINE” Phase II Alzheimer’s Disease Trial**

**Melbourne – 6 March, 2012: Prana Biotechnology (NASDAQ:PRAN; ASX:PBT)** today announced that the first patient has been dosed in the “IMAGINE Trial” - 12 month Phase II Imaging trial testing PBT2, the Company’s drug in development for Alzheimer’s Disease.

In the “IMAGINE trial” PBT2, a drug that significantly changed Abeta levels in spinal fluid and significantly improved the cognition of Alzheimer’s Disease patients in an earlier 12 week clinical trial, is now being assessed in a 12 month study for its effects on the distribution of amyloid in the brain and cognitive and functional improvement. The data on PBT2 from the preceding clinical trial has been published in *Lancet Neurology* and *Journal of Alzheimer’s Disease*.<sup>1,2,3</sup>

“We believe that in this 12 month trial PBT2 will establish its credentials as a safe and effective treatment for Alzheimer’s Disease”, commented Prana’s Executive Chairman, Mr Geoffrey Kempler.

The double blind placebo controlled trial is being conducted on 40 patients with prodromal or mild Alzheimer’s Disease. Patients on the trial have been screened using PiB-PET scanning to confirm pre-dosing levels of amyloid in the brain before receiving a single oral capsule of either PBT2 or placebo per day. The Protocol Synopsis can be viewed [here](#)<sup>a</sup>.

The trial has received funding from the Alzheimer’s Drug Discovery Foundation (ADDF). Howard Fillit, MD, the ADDF’s Executive Director commented that “PBT2 stands out as one of the few remaining orally available agents with clinical trial evidence of cognitive benefit for Alzheimer’s patients. Success in this trial will demonstrate target engagement by PBT2 in the brains of people with Alzheimer’s Disease, and accelerate the clinical development of PBT2 to patients”.

The scientific data supporting the belief that PBT2 will bring meaningful clinical benefit to patients is extensive. PBT2 restores neuronal health by selectively binding and redistributing brain metals (copper, zinc) that have become imbalanced due to disease or the ageing process. Furthermore PBT2 is able to prevent Abeta induced toxicity and promote its disaggregation in the brain. A position paper on PBT2’s differentiated mechanism of action relative to other drugs in development can be viewed [here](#)<sup>b</sup>.

Alzheimer’s Disease and dementia affects over 26 million people worldwide. The cost to society has been reported as \$600 billion per annum. Currently all available treatments are approved to provide some degree of symptomatic relief. None change the course of the disease and the eventual decline in patient’s cognition and health. PBT2 has the potential to be an effective treatment for AD that is supported by an extensive body of scientific and clinical work.

Patient enquiries should be directed to a dedicated IMAGINE Trial telephone number (Australia) 1800 83 76 83. The trial is being conducted at sites in Melbourne, Australia.

#### Links

- a. Clinical data available at: <http://www.anzctr.org.au/ACTRN12611001008910.aspx>
- b. Mechanism paper available at: <http://www.pranabio.com/downloads/Prana%20Positioning%20statement%20November%202010%20FINAL.pdf>

#### References

1. Lannfelt *et al.* "Safety, Efficacy, and biomarker findings of PBT2 in targeting Abeta modifying therapy for Alzheimer's disease: a controlled phase IIa, double-blind, randomized, placebo-controlled trial", *Lancet Neurology* (2008) vol. 7, pp. 779-86.
2. Lannfelt *et al.* **Errata:** *Lancet Neurology* (2009) vol. 8, pp. 981.
3. Faux *et al.* "PBT2 Rapidly Improves Cognition in Alzheimer's Disease: Additional Phase II Analyses", *Journal of Alzheimer's Disease* (2010) vol. 20 pp. 509-516

#### **About Prana Biotechnology Limited**

Prana Biotechnology was established to commercialize research into age-related neurodegenerative disorders. The Company was incorporated in 1997 and listed on the Australian Securities 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 (Melbourne) and Massachusetts General Hospital, a teaching hospital of Harvard Medical School, contributed to the discovery of Prana's technology.

For further information please visit the Company's web site at [www.pranabio.com](http://www.pranabio.com).

#### **About the Alzheimer's Drug Discovery Foundation**

The Alzheimer's Drug Discovery Foundation (ADDF) is the only non-profit organization whose sole mission is to accelerate the discovery and development of drugs to prevent, treat and cure Alzheimer's Disease, related dementias and cognitive aging. Since 1998, the ADDF has granted more than \$50 million to fund over 325 Alzheimer's drug discovery programs in academic centers and biotechnology companies in 18 countries. For more information about the Foundation, please visit [www.AlzDiscovery.org](http://www.AlzDiscovery.org).

#### **Forward Looking Statements**

*This press release contains "forward-looking statements" within the meaning of section 27A of the Securities Act of 1933 and section 21E of the Securities Exchange Act of 1934. The Company has tried to identify such forward-looking statements by use of such words as "expects," "intends," "hopes," "anticipates," "believes," "could," "may," "evidences" and "estimates," and other similar expressions, but these words are not the exclusive means of identifying such statements. Such statements include, but are not limited to any statements relating to the Company's drug development program, including, but not limited to the initiation, progress and outcomes of clinical trials of the Company's drug development program, including, but not limited to, PBT2, and any other statements that are not historical facts. Such statements involve risks and uncertainties, including, but not limited to, those risks and uncertainties relating to the difficulties or delays in financing, development, testing, regulatory approval, production and marketing of the Company's drug components, including, but not limited to, PBT2, the ability of the Company to procure additional future sources of financing, unexpected adverse side effects or inadequate therapeutic efficacy of the Company's drug compounds, including, but not limited to, PBT2, that could slow or prevent products coming to market, the uncertainty of patent protection for the Company's intellectual property or trade secrets, including, but not limited to, the intellectual property relating to PBT2, and other risks detailed from time to time in the filings the Company makes with Securities and Exchange Commission including its annual reports on Form 20-F and its reports on Form 6-K. Such statements are based on management's current expectations, but actual results may differ materially due to various factors including those risks*

*and uncertainties mentioned or referred to in this press release. Accordingly, you should not rely on those forward-looking statements as a prediction of actual future results.*

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