



## **Prana Provides Clinical Trials Safety and Progress Update**

### ***Alzheimer's and Huntington disease trials on track***

**Melbourne – 3 April, 2013; Prana Biotechnology (NASDAQ:PRAN; ASX:PBT)** today reported on the progress of its lead development asset PBT2 in Phase II trials for Huntington disease and Alzheimer's disease. Across the two trials approximately 37% have been dosed to 6 months or longer, twice the duration of the previous Phase II Alzheimer's trial.<sup>1,2</sup> PBT2 has been well tolerated and both trials are on schedule with very pleasing retention rates and compliance. Each Independent Data Safety Monitoring Board for the two trials met at the end of March and recommended that each trial continue as planned without any protocol changes.

Prana's PBT2 represents a novel and differentiated therapeutic action in the treatment of neurodegenerative diseases based on its specialized ability to prevent the toxic relationship between disease proteins and biological metals in the brain which otherwise can lead to protein amyloid formation. Moreover, the redistribution of such metals by PBT2 promotes neurotransmission and neuronal function.

#### **Alzheimer's disease Trial Update – the "IMAGINE" trial**

In an earlier 12 week trial PBT2 both significantly changed amyloid levels in spinal fluid and improved the cognition of patients with Alzheimer's disease.<sup>1,2</sup> The IMAGINE trial, with 12 months of treatment, aims to establish PBT2 as a safe and effective treatment for Alzheimer's disease. The following provides an update on the trial:

- Last Patient recruited November 2012;
- Last Patient to be Dosed November 2013;
- Trial will be completed in December, 2013;
- 7% of patients have completed 12 months of dosing, over 4 times longer than the previous longest exposure to PBT2;
- 50% of patients have reached 26 weeks of dosing;
- Data Safety Monitoring Board met on 27 March, 2013, with the recommendation to continue the trial without any changes to the original protocol.

The randomized, double-blind, placebo controlled trial has enrolled 41 patients with prodromal or mild Alzheimer's disease in five sites in Melbourne, Australia. Brain Imaging is being used to measure PBT2's effect on amyloid deposits in the brain (using PiB-PET scanning) and effects on increasing brain activity (FDG PET). Cognition effects are being measured by the Neuropsychological Test Battery (NTB).

The trial has received funding from the Alzheimer's Drug Discovery Foundation (ADDF).

Howard Fillit, MD, the ADDF's Executive Director commented, "PBT2 stands out as one of the few 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 brain of people with Alzheimer's disease, and accelerate the clinical development of PBT2 to patients."

The protocol for the IMAGINE trial is available by clicking [here](#).

### **Huntington Disease Trial Update – the “Reach2HD” trial**

The Reach2HD trial is a 6 month trial in 109 patients with early to mid-stage Huntington disease. The trial is being conducted across sites in the USA and Australia. The following provides an update on the trial:

- Last Patient recruited December 2012;
- Last Patient to be Dosed June, 2013;
- Results anticipated October, 2013;
- 97% of patients have completed 12 weeks of dosing (equal to previous longest exposure of PBT2);
- 32% of patients have completed 6 months of dosing;
- Data Safety Monitoring Board met on 28 March, 2013, with the recommendation to continue the trial without any changes to the original protocol.

Only one drug is marketed for Huntington disease and that is only for the relief of the severe motor or chorea symptoms. There are no approved treatments for the significant cognitive and behavioural components of the disease, which typically manifest before motor problems.

The protocol and site updates for the Reach2HD trial can be accessed by clicking [here](#).

### **References**

- <sup>1.</sup> Lannfelt *et al.* Lancet Neurology (2008) vol. 7, pp. 779-86;
- <sup>2.</sup> Lannfelt *et al.* Erratum: Lancet Neurology (2009) vol. 8, pp. 981.

### **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 Huntington disease**

Huntington disease is a complex and severely debilitating genetic, neurodegenerative disease, for which there is no cure. The disease often affects young adults and, whilst associated with severe physical movement symptoms, progressively impacts the mind and emotions as well. The disease causes incapacitation and death about 15-25 years after onset. The disease affects 30,000 people in the US and about 70,000 worldwide. There are no drugs in development that have established clinical evidence for treating cognitive decline.

### **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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