



## **Prana Commences Alzheimer's Trial Recruitment**

*12 month Phase II Imaging study with PBT2 in early Alzheimer's patients*

**Melbourne – 15 December, 2011: Prana Biotechnology (NASDAQ:PRAN; ASX:PBT)** today announced that it has commenced recruitment and screening of patients for a 12 month Phase II Imaging trial testing PBT2, the Company's drug in development for Alzheimer's Disease.

Screening of patients began last week with psychological tests to measure cognition<sup>1</sup>. This week, the first patient was tested for evidence of significant levels of Abeta deposits in the brain<sup>2</sup>.

Professor Colin Masters, Director of the Mental Health Research Institute, explained that "we are selecting patients with established Alzheimer's Disease, as well as targeting those very early in the disease process. We are using the most modern techniques available for measuring PBT2's disease modifying effects to establish cognitive, functional and physical changes in the brain. By disease modifying, I mean modifying the rate of progress of Alzheimer's, slowing it down and delaying onset. We are using PiB-PET imaging to measure the drug's effects on the insoluble form of Abeta, and we are using a recently developed blood test to measure levels of the soluble oligomers of Abeta<sup>3</sup>. This week we have been taking pre-drug dosing measures of eligible patients to compare with measures that will be taken throughout the trial. Per protocol, each patient qualifying for entry to the trial will receive the first dose of drug or placebo on their second visit to the clinic."

"In my opinion PBT2 has the best and highest chance of all drugs currently in development to have a major impact on the disease process, and help avoid the global epidemic of Alzheimer's which, left untreated, is poised to become unmanageable. This trial that is now in progress will establish for the first time not only that PBT2 can improve cognition, as already shown, but that it can actually modify the course of the disease. It will be a major step forward if the drug demonstrates, as I think it will, its ability to affect both soluble and insoluble Abeta levels", concluded Professor Masters.

### **<sup>1</sup>Cognition Tests**

#### NTB

The NTB is a battery of commonly used and validated neuropsychological tests which includes tests of both amnesic and executive impairment.

#### ADCS-ADL-23

The ADCS-ADL-23 consists of a comprehensive battery of ADL questions used to measure the functional capabilities of Patients. Each ADL item is rated from the highest level of independent performance to complete loss.

#### MMSE

The MMSE is a brief test of cognitive function including orientation, immediate recall, delayed recall, constructional ability and language.

## **<sup>2</sup>Brain Imaging techniques**

### **PiB PET SUVR (measuring plaques or insoluble Abeta)**

PET is a sensitive molecular imaging technique that allows *in vivo* quantification of radiotracer concentrations. PET radiotracers are typically designed to bind a substrate known to be involved in the biological process being evaluated. This interaction allows the *in vivo* assessment of the molecular processes at their sites of action, permitting detection of disease at asymptomatic stages, when there is no evidence of anatomic changes on CT and MRI.

PiB is a PET radio tracer used to image *in vivo*, amyloid plaques which are one of the major histopathological hallmarks of AD. Quantitative analysis of C-PiB retention requires normalisation of the C-PiB uptake values, to allow inter- and intra- subject comparisons. The SUVR normalises the uptake values to the mean uptake value within a region containing nonspecific binding, the cerebellar grey matter in the case of Screening. For inclusion in the trial patients need a C-PiB PET neocortical retention ratio relative to the cerebellum (neocortical Standardised Uptake Value Ratios (SUVR)) of > 1.7.

### **F-FDG PET (measuring energy usage and brain activity)**

F-FDG PET is a glucose analogue and PET radio tracer that is used to measure metabolic activity non-invasively. F-FDG uptake thus reflects the regional consumption of glucose. In the brain, this regional metabolic activity is mainly related to neuronal/synaptic function.

### **MRI (measuring brain volume)**

MRI measures the volume of specific parts of the brain involved in cognition (cortical grey matter volume, hippocampal volume, and ventricular volume).

## **<sup>3</sup>Blood test for soluble Abeta levels**

This test utilises mass spectrometry to detect a variety of forms of soluble Abeta, the levels of which correlate with cognitive performance and brain amyloid in the Alzheimer's human brain. Villemagne *et al.* J Neurosci [2010] 30:6315-6322.

### **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.

**Contacts:**

*Australia*

Prana Biotechnology Ltd

T: +61 3 93494906

E: [info@pranabio.com](mailto:info@pranabio.com)

*US – Investor Relations*

Leslie Wolf-Creutzfeldt

T: 646-284-9472

E: [leslie.wolf-creutzfeldt@grayling.com](mailto:leslie.wolf-creutzfeldt@grayling.com)

*US - Media*

Ivette Almeida

T: 646-284-9455

E: [ivette.almeida@grayling.com](mailto:ivette.almeida@grayling.com)