

Prana completes PBT2 dosing in IMAGINE Alzheimer's Disease clinical trial

95% patient retention level achieved in IMAGINE trial

MELBOURNE, December 9, 2013: Prana Biotechnology (ASX:PBT; NASDAQ:PRAN), a developer of best-in-class treatments for neurodegenerative disease, today announced the completion of the treatment phase of its IMAGINE Alzheimer's Disease (AD) clinical trial.

There were 42 patients with prodromal or mild AD enrolled in the Phase II double-blind placebo-controlled clinical trial of Prana's novel drug, PBT2. A total of 40 patients completed the planned 12 months of treatment with PBT2, or placebo, bringing the treatment phase of the trial to a close.

The IMAGINE trial received funding from the New York based Alzheimer's Drug Discovery Foundation (ADDF). ADDF's Executive Director Howard Fillit, MD, said the results were now keenly anticipated.

"At the time of initiating the trial, we noted that PBT2 stood out as one of the few remaining orally available agents with clinical trial evidence of cognitive benefit for Alzheimer's patients," Dr Fillit said.

"Since then the relevance of this trial and its design has only increased, in light of the changing competitive and regulatory landscape for Alzheimer's drugs in development."

"The ADDF is proud to have supported this PBT2 trial design that reflects the US Food and Drug Administration's new guidelines encouraging companies to look at treating patients earlier in the disease process."

The primary outcome of IMAGINE is the effect of 12 months of treatment with a daily oral dose of 250mg of PBT2 on beta amyloid deposits in the brain.

Other outcomes include the effects of PBT2 on increasing brain activity (F-FDG PET), brain volume (MRI) and cognition, measured by a Neuropsychological Test Battery (NTB). The IMAGINE protocol can be accessed <u>here*</u>.

To qualify for participation in the trial, patients completed a PiB-PET brain scan to confirm a level of beta amyloid deposit consistent with prodromal or early disease.

Only two patients withdrew during the trial representing a trial retention rate of 95%. An independent Data Safety Advisory Board met five times during the course of the trial and on no occasion made any recommendations to vary the original trial protocol.

The data compilation and statistical analysis will commence shortly after the last few patients complete their follow up visit, with results expected in March 2014.

Currently all available treatments for AD 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. The IMAGINE study design aims to demonstrate PBT2's potential as an effective disease modifying treatment available to patients.

* IMAGINE protocol: https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=12611001008910



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About Prana Biotechnology Limited

Prana Biotechnology was established to commercialise research into Alzheimer's disease and other major age-related neurodegenerative 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 (Melbourne) and Massachusetts General Hospital, a teaching hospital of Harvard Medical School, contributed to the discovery of Prana's technology.

PBT2 is currently the subject of the Phase II IMAGINE trial in AD and the Phase II Reach2HD trial in Huntington's disease. Both trials are expected to report results in Q1 2014.

For further information please visit the Company's web site at <u>www.pranabio.com</u>.

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 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 factions 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.