Prana Receives Approval For 12-Month Open Label Extension Study In Alzheimer's Disease

Melbourne – Wednesday, 3 July, 2013: Prana Biotechnology (NASDAQ:PRAN; ASX:PBT) today announced that it has received approval from the Austin Health Human Research Ethics Committee (HREC) to commence a 12-month open label extension study with Alzheimer's Disease patients participating in Prana's IMAGINE trial.

The approval follows a full review by Austin Health HREC of the potential benefit to patients and safety data collected during the ongoing IMAGINE trial, a 12-month double-blind Phase II clinical trial of PBT2 in Alzheimer's patients. Fifteen percent of participants in IMAGINE have now finished the full 12 months of treatment and one hundred percent have completed at least 6 months of treatment.

Patients who have completed the full 12-month term of the IMAGINE trial are eligible for participation in the open-label extension study. All participants in the extension study will receive a 250mg once daily oral dose of PBT2 for an additional 12 months, with the first patient expected to start next month.

Prana's Chairman and CEO, Geoffrey Kempler, said "We are keenly looking forward to the completion of the current IMAGINE trial to see the effects of PBT2 over 12 months, and we expect to report the results in March 2014. This will allow us to take the steps necessary to progress the commercialisation of PBT2 for Alzheimer's. What is so helpful about the open-label study is that it will provide ongoing information to support the safety, tolerability and efficacy of PBT2 over a 24 month period".

The open-label extension study protocol will closely follow the IMAGINE protocol, measuring amyloid burden and physical changes in the brain of Alzheimer's patients, through PET imaging, MRI and FDG-PET, as well as cognition and function. The protocol synopsis appears below in Appendix 1.

About Prana Biotechnology Limited

Prana Biotechnology was established to commercialise 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.

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 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.

Appendix 1:

Open Label Extension Trial Synopsis

Title	An open-label extension study to assess the safety and tolerability of PBT2, and its effect on amyloid deposition in the brains of Patients with prodromal or mild Alzheimer's disease.
Study Number	PBT2-204-Ext
Study Name/Acronym	IMAGINE Extension
Study Design	Open-label, non-randomised, extension study of the PBT2-204 IMAGINE Study.
Objectives	Prodromal or mild Alzheimer's disease patients were entered on IMAGINE. Following 52 weeks of treatment with either 250mg of PBT2 or placebo, they may now proceed to the extension study. <u>Primary objective</u>: To evaluate the effect after 52 weeks of treatment with 250mg of PBT2 on: • Safety and tolerability, and • Brain amyloid levels.

	Secondary objectives: To evaluate the effect after 52 weeks of treatment with 250mg of PBT2 on: • Brain metabolic activity • Brain volumes • Cognition • Functional abilities • Blood biomarkers.
Number of Patients	Approximately 40 Patients who have completed Visit 10 (Week 52) of the PBT2-204 clinical trial.
Key Patient Criteria	Must have completed Visit 10 (Week 52) of the PBT2-204 clinical trial.
Doses	250mg PBT2 capsules, once daily
Per Patient Duration	56+ weeks: Screening period (1 week, if required), Treatment Period (52 weeks) and Follow-up Period (4 weeks) post last dose of PBT2.
Endpoints	***Primary*** • ^{11}C-PiB PET neocortical SUVR • Safety and Tolerability assessments. ***Secondary*** • MRI: Total brain, hippocampal and ventricular volumes • ^{18}F-FDG PET: SUVR • Cognition: NTB and MMSE • Function: ADCS-ADL-23 • Blood biomarkers: A ☐ oligomer
Trial Locations	• Australia
Trial Standard	Study will be conducted according to ICH GCP

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