FDA Approval to Commence Huntington's Disease Clinical Trial Using Prana's PBT2

Huntington Study Group appointed to coordinate the trial and start recruitment

Melbourne – 4 January, 2012: Prana Biotechnology (NASDAQ:PRAN; ASX:PBT) today announced that it has received approval from the United States Food and Drug Administration (FDA) to start recruiting patients for the company's first clinical trial using PBT2 in patients with Huntington's Disease (HD).

Prana's Investigational New Drug Application (IND) is now open. "The opening of this IND for a Phase 2 study follows an extensive review of PBT2 data by the FDA and reflects a favourable analysis from the FDA to support the study of PBT2 in Huntington's Disease patients", commented Geoffrey Kempler, Prana's Executive Chairman.

Huntington's 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 Company has appointed the Huntington Study Group (HSG) to coordinate the trial. HSG will commence recruitment of patients for the trial, named "Reach2HD, at clinical sites across USA and in Australia. The randomised, double-blind, placebo-controlled trial will enrol 100 patients with early to mid-stage Huntington's Disease. The Principal Investigator on the study is Dr. Raymond Dorsey of Johns Hopkins University Medical Center. The protocol synopsis appears below in Appendix 1.

Professor Ira Shoulson, Professor of Neurology, Pharmacology and Human Science at Georgetown University (Washington DC) and the Chair of the Executive Committee of the Huntington Study Group said "PBT2 attracted our attention as an experimental drug with the potential to bring real benefit to Huntington's Disease patients who suffer from a range of motor, behavioural and cognitive symptoms. The favourable signals from the PBT2 trial in Alzheimer's Disease are particularly promising".

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. Prana aims, in this trial, to demonstrate safety, motor benefits and the same cognitive benefits for Huntington's patients that it has already demonstrated in Alzheimer's patients treated with PBT2.

Appendix 1 - Protocol synopsis

Title	A randomised, double-blind, placebo-controlled study to assess the safety and tolerability, and efficacy of PBT2 in patients with early to mid-stage Huntington's disease (HD)
Study Number	PBT2-204
Study Name/Acronym	Reach2HD
Study Design	Randomised, double-blind, placebo-controlled, parallel group, multi-centre, Phase 2a study.
Objectives	Primary objective: To evaluate the safety and tolerability of two dose levels of PBT2 when administered orally once daily over 26 weeks in patients with HD. Secondary objectives: Determine the effect of PBT2 after 26 weeks in patients with HD on: 1. Cognition 2. Motor function 3. Behaviour 4. Functional abilities 5. Global function 6. Plasma and urine biomarkers 7. Brain volumes and function (imaging), and 8. To evaluate the Pharmacokinetics of PBT2 in patients with HD.
Number of Patients	It is planned that 100 patients will be randomised in to the study.
Key Patient Criteria	• Men and women with Total Functional Capacity (TFC) 6-13, inclusive, and a CAG repeat number of ≥ 36 • Montreal Cognitive Assessment (MoCA) score ≥ 12
Doses	Placebo (0mg PBT2), 100mg PBT2 and 250mg PBT2, once daily capsules.
Per Patient Duration	34 weeks: Four week Screening period, 6 months (26 weeks) treatment period and Follow-up 4 weeks post treatment.
Endpoints	***Primary*** • Safety and Tolerability assessments. ***Secondary*** • Cognition Tests: Cognitive Test Battery (consisting of Category Fluency Test, Trail Making Test parts A and B, Map Search, Symbol Digit Modalities Test and Unified Huntington Disease Rating Scale (UHDRS) Stroop Word Reading). MoCA. • Motor Function Tests: UHDRS '99 Motor component; Speeded

	Tapping Task. • Behaviour: UHDRS Behavioural component. • Functional Abilities: Total Functional Capacity and Independence Scale from UHDRS '99; Schwab & England Activities of Daily Living Scale (SEADL). • Subject and investigator global assessments: Patient Reported Outcomes; Clinical Global Impression – Severity Scale. • Biomarkers: small molecule markers of metabolic and oxidative stress in blood and urine; blood levels of total and mutant huntingtin; gene expression markers of HD progression; plasma selenium. • Brain Imaging: volumetric and functional measures. • Pharmacokinetics: sparse sampling.
Trial Locations	• Australia • USA
Trial Standard	Study will be conducted according to ICH GCP

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.

The Huntington Study Group

(www.huntington-study-group.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 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.

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