



## **Prana Completes Recruitment in Huntington Trial**

*6 month Phase II study with PBT2 in Huntington patients*

**Melbourne – 19 December, 2012: Prana Biotechnology (NASDAQ:PRAN; ASX:PBT)** today announced that it has completed recruitment in the Reach2HD Phase IIa clinical trial using PBT2 in patients with Huntington Disease (HD).

The 6 month double-blind, placebo-controlled Phase II trial in patients with early to mid-stage Huntington Disease met its enrolment target of 100 patients ahead of schedule. Additional patients may be included in the trial, subject to final procedures this week.

The Principal Investigator on the study, Dr Ray Dorsey of Johns Hopkins University Medical Center, commented that “interest in PBT2 is high in part because PBT2 offers a novel mechanistic approach to the treatment of HD. We thank the clinical sites and the Huntington community for their wonderful support”. The Reach2HD trial was coordinated in conjunction with the Huntington Study Group (HSG) across 20 clinical sites in the USA and Australia.

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. At this time there is only one marketed drug for the alleviation of some of the involuntary motor symptoms associated with the disease.

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 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. In this trial, Prana is studying the safety and tolerability of PBT2 in Huntington patients and investigating potential benefits in cognition, motor coordination, behavioural, functional and psychiatric effects. In addition the trial will pilot biomarker and imaging assessments. The protocol synopsis appears below in Appendix 1.

## Appendix 1 - Protocol synopsis

<b>Title</b>	A randomized, double-blind, placebo-controlled study to assess the safety and tolerability, and efficacy of PBT2 in patients with early to mid-stage Huntington disease (HD)
<b>Study Number</b>	PBT2-203
<b>Study Name/Acronym</b>	Reach2HD
<b>Study Design</b>	Randomised, double-blind, placebo-controlled, parallel group, multi-centre, Phase 2a study.
<b>Objectives</b>	<p><u>Primary objective:</u></p> <p>To evaluate the safety and tolerability of two dose levels of PBT2 when administered orally once daily over 26 weeks in patients with HD.</p> <p><u>Secondary objectives:</u></p> <p>Determine the effect of PBT2 after 26 weeks in patients with HD on:</p> <ol style="list-style-type: none"> <li>1. Cognition</li> <li>2. Motor function</li> <li>3. Behavior</li> <li>4. Functional abilities</li> <li>5. Global function</li> <li>6. Plasma and urine biomarkers</li> <li>7. Brain volumes and function (imaging), and</li> <li>8. To evaluate the Pharmacokinetics of PBT2 in patients with HD.</li> </ol>
<b>Number of Patients</b>	100 patients (original target)
<b>Key Patient Criteria</b>	<ul style="list-style-type: none"> <li>• Men and women with Total Functional Capacity (TFC) 6-13, inclusive, and a CAG repeat number of <math>\geq 36</math></li> <li>• Montreal Cognitive Assessment (MoCA) score <math>\geq 12</math></li> </ul>
<b>Doses</b>	Placebo (0mg PBT2), 100mg PBT2 and 250mg PBT2, once daily capsules.
<b>Per Patient Duration</b>	34 weeks: Four week Screening period, 6 months (26 weeks) treatment period and Follow-up 4 weeks post treatment.
<b>Endpoints</b>	<p><b>Primary</b></p> <ul style="list-style-type: none"> <li>• <u>Safety and Tolerability</u> assessments.</li> </ul> <p><b>Secondary</b></p> <ul style="list-style-type: none"> <li>• <u>Cognition</u> 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.</li> <li>• <u>Motor Function</u> Tests: UHDRS '99 Motor component; Speeded Tapping Task.</li> <li>• <u>Behavior</u>: UHDRS Behavioral component.</li> </ul>

	<ul style="list-style-type: none"> <li>• <u>Functional Abilities</u>: Total Functional Capacity and Independence Scale from UHDRS '99; Schwab &amp; England Activities of Daily Living Scale (SEADL).</li> <li>• Subject and investigator <u>global</u> assessments: Patient Reported Outcomes; Clinical Global Impression – Severity Scale.</li> <li>• <u>Biomarkers</u>: 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.</li> <li>• <u>Brain Imaging</u>: volumetric and functional measures.</li> <li>• <u>Pharmacokinetics</u>: sparse sampling.</li> </ul>
<b>Trial Locations</b>	<ul style="list-style-type: none"> <li>• Australia</li> <li>• USA</li> </ul>
<b>Trial Standard</b>	Study being 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](http://www.pranabio.com).

### The Huntington Study Group

([www.huntington-study-group.org](http://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 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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