

PBT2 recommended for orphan designation in Europe

MELBOURNE, 28th April, 2015: Prana Biotechnology (ASX: PBT/NASDAQ:PRAN) is pleased to announce the European Medicines Agency’s Committee for Orphan Medicinal Products (COMP) has adopted a positive opinion recommending designation of PBT2 for the treatment of Huntington disease as an orphan medicinal product to the European Commission (EC).

Following finalisation of relevant documents the European Medicines Agency forwards the opinion to the EC for its decision on the designation.

“We welcome the positive opinion from COMP for PBT2 to receive orphan designation to treat Huntington disease in Europe,” said Prana Chairman and CEO Geoffrey Kempler.

“Prana is dedicated to progressing development of PBT2 as a treatment for this terrible disease that devastates lives and families.”

Orphan designation is granted by the EC to encourage the development of medicines to treat rare diseases. Rare diseases are defined as life-threatening or chronically debilitating conditions that affect no more than five in 10,000 people in Europe.

Huntington disease is a neurodegenerative genetic disorder that affects muscle coordination and leads to cognitive decline and behavioral symptoms. The [Huntington’s Outreach Project for Education](#) estimates there are between 40-100 cases of Huntington disease per million people in Europe.

The EC offers orphan medicinal product developers incentives including scientific advice, market exclusivity for 10 years for approved drugs and reduced fees.

In September last year the US Food and Drug Administration granted PBT2 orphan drug status for the treatment of Huntington disease.

In February last year Prana announced that PBT2 had met its primary end point of safety and tolerability, and improved measures of cognitive performance – a secondary endpoint in its REACH2HD Phase 2 clinical trial involving 109 people with Huntington disease.

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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.

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 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.