

## **European Commission Approves PBT2 Orphan Designation for Huntington's Disease**

**MELBOURNE, June 1st, 2015:** Prana Biotechnology Limited (ASX:PBT/NASDAQ:PRAN) has today announced that the European Commission has approved orphan designation for PBT2 for the treatment of Huntington's disease, stating that Prana has shown that PBT2 might be of significant benefit for patients with Huntington's disease.

The approval was based on the recommendation of a positive opinion from the European Medicines Agency's (EMA) Committee for Orphan Medicinal Products (COMP). The COMP assessed the scientific documentation for PBT2 against the key criteria for orphan designation. The criteria require that PBT2 be intended for the treatment, prevention or diagnosis of a disease that is life-threatening or chronically debilitating; have a prevalence in the EU not more than five in 10,000, and no satisfactory method of diagnosis, prevention or treatment of the condition concerned, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

Orphan designation provides for ten years of market exclusivity in the European Union (EU) from the granting of a marketing authorisation (approval for sale). Other benefits relate to assistance in developing clinical protocols, reduced fees, and access to EU-funded research grants.

Last year Prana announced positive findings in its Phase 2 clinical trial for Huntington's disease (Reach2HD) and is planning for further clinical trials. The company has Orphan Drug designation with the US Food and Drug Administration. Further opportunities for the development of PBT2 in the US can commence on the removal of the current Partial Clinical Hold.

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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](http://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.*