Prana receives FDA Orphan Drug Designation for PBT2 for Huntington Disease

MELBOURNE, AUSTRALIA, SEPTEMBER 5, 2014: Prana Biotechnology (ASX:PBT) has today announced the US Food and Drug Administration (FDA) has granted Orphan Drug designation to PBT2 for the treatment of Huntington Disease.

Orphan drug designation is granted by the FDA to promote the development of drugs for diseases affecting less than 200,000 people in the United States. Orphan drug designation entitles Prana to seven years of market exclusivity for the use of PBT2 in the treatment of Huntington disease; protocol assistance by the FDA to optimize drug development in the preparation of a dossier that will meet regulatory requirements; and reduced fees associated with applying for market approval.

The company will also be applying for Orphan Drug designation in Europe and other jurisdictions.

Huntington disease is a neurodegenerative genetic disorder that affects muscle coordination and leads to cognitive decline and behavioral symptoms. More than 30,000 people in the US have Huntington disease and there are currently no treatments for the cognition or executive function symptoms of the disease.

Prana announced in February 2014 that its lead MPAC (Metal Protein Attenuating Compound) 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.

“The FDA’s decision to grant Orphan Drug designation is a reflection of the high unmet need for neurological drugs that can slow, halt or improve the decline of cognition and allow sufferers to have a better quality of life,” said Prana Chairman and CEO Geoffrey Kempler.

“We are very pleased to have received Orphan Drug designation from the FDA, which is a highly important input to determining the commercialisation pathway for PBT2 for the treatment of Huntington disease, and to bring to market as quickly as possible an improved treatment for people suffering from Huntington disease.”

Prana is preparing its Post Phase 2 Trial dossier for submission to the FDA to commence discussions on the next development steps for PBT2.

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About Prana Biotechnology Limited

Prana Biotechnology was established to commercialise research into Alzheimer's disease, Huntington disease and other neurodegenerative and movement 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.

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.