EMA publishes minutes recommending Orphan Drug Designation for PBT2

MELBOURNE, Thursday May 21st 2015: Prana Biotechnology Limited (ASX:PBT / NASDAQ:PRAN) today announced that the European Medicines Agency (EMA) has published the Minutes from the April 2015 Meeting of its Committee for Orphan Medicinal Products (COMP), detailing the recommendation from the COMP that PBT2 be granted Orphan Designation in Europe. Prana announced the positive COMP recommendation on 28 April, 2015.

The relevant extract of the Minutes states:

> "The Committee agreed that the condition, Huntington's disease, is a distinct medical entity and meets the criteria for orphan designation.
>
> The intention to treat the condition with the medicinal product containing 5,7-dichloro-2-dimethylaminomethyl-8-hydroxyquinoline hydrochloride* was considered justified based on pre-clinical in vivo data and preliminary clinical data showing improvement in parameters associated with the condition.
>
> The condition is life-threatening and chronically debilitating due to severe behavioural and cognitive disturbances, progressive motor dysfunction and potentially fatal complications.
> The condition was estimated to be affecting approximately 1 in 10,000 persons in the European Union, at the time the application was made.
>
> In addition, although satisfactory methods of treatment of the condition have been authorised in the European Union, the sponsor has provided sufficient justification for the assumption that the medicinal product containing 5,7-dichloro-2-dimethylaminomethyl-8-hydroxyquinoline hydrochloride may be of significant benefit to those affected by the condition. The sponsor has provided preliminary clinical data that demonstrate an improvement in a relevant parameter when the product is used in combination with tetrabenazine. The Committee considered that this could constitute a clinically relevant advantage.
>
> A positive opinion for containing 5,7-dichloro-2-dimethylaminomethyl-8-hydroxyquinoline hydrochloride, for treatment of Huntington's disease, was adopted by consensus."

Prana's Chairman and CEO, Geoffrey Kempler, said "The Minutes support our strategy to gain Orphan disease status for PBT2 to treat Huntington Disease and I am optimistic that the European Commission will review the recommendation and grant approval for Orphan drug designation for PBT2 in the near future".

*the extract refers to PBT2's chemical name.

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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 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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