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Prana provides updates on clinical trials of PBT2

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Singapore: Prana Biotechnology, listed with the ASX, has reported progress in the phase II clinical trials with its lead development asset PBT2. PBT2 has a unique therapeutic action that can benefit people suffering neurodegenerative disease because of its specialized ability to prevent the toxic relationship between disease proteins and biological metals in the brain.

"There is mounting evidence that compounds that can restore metal homeostasis in the neuron can stop and even reverse cognitive decline associated with neurodegenerative diseases. We think Prana's PBT2 could be such a compound," said senior biotech analyst Dr George Zavoico of New York-based MLV Equity Research.

The Alzheimer's disease trial, IMAGINE, is a randomized, double-blind, placebo controlled trial is enrolling 40 patients with prodromal or mild Alzheimer's disease in five sites in Melbourne, Australia. Brain imaging is being used to measure PBT2's effect on amyloid deposits in the brain (using PiB-PET scanning) and effects on increasing brain activity (FDG PET). Cognition effects are being measured by the Neuropsychological Test Battery (NTB).

"The results of the IMAGINE trial will be closely watched by the Alzheimer's community, given the recent failure of several late-stage therapeutic candidates. We believe that PBT2's mechanism of action explains the clinical benefits that the drug has already shown, and we anticipate positive results from this trial," said Mr Geoffrey Kempler, chief executive officer of Prana. The trial has received funding from the Alzheimer's Drug Discovery Foundation (ADDF).

Dr Howard Fillit, ADDF's executive director, commented, "PBT2 stands out as one of the few orally available agents with clinical trial evidence of cognitive benefit for Alzheimer's patients. Success in this trial will demonstrate target engagement by PBT2 in the brain of people with Alzheimer's disease, and accelerate the clinical development of PBT2 to patients."

The Huntington Disease trial, Reach2HD, is a six-month trial in 100 patients with early to mid-stage Huntington disease. An

IND was opened to conduct the trial across sites in the US and Australia.

Dr 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 favorable signals from the PBT2 trial in Alzheimer's disease are particularly promising."

Only one drug is marketed for Huntington disease and that is only for the relief of the severe motor or chorea symptoms. There are no approved treatments for the significant cognitive and behavioural components of the disease, which typically manifest before motor problems. "The trial objective is to demonstrate safety, motor and behavioral benefits and the same cognitive benefits for Huntington's patients that it has already demonstrated in Alzheimer's patients treated with PBT2," said Mr Kempler.