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Prana completes phase II trial with PBT2

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Singapore: Prana Biotechnology announced the successful completion of Reach2HD, a phase II clinical trial in patients with early to mid-stage Huntington disease. The company expects to announce the results arising from the trial in October. Reach2HD is a randomized, double-blind, placebo-controlled Phase 2 trial testing the safety and efficacy of PBT2, the company's lead compound under development for both Huntington disease and Alzheimer's disease.

"We have been extremely pleased with the conduct of the trial, at all levels including recruitment and patient retention," said Dr Ray Dorsey, principal investigator of the Reach2HD study and director of the Huntington Study Group Coordination Center.

Reach2HD had planned to recruit 100 patients with Huntington disease in nine months. In fact, 109 participants were enrolled in the trial within that period. "The strong rate of recruitment reflects support for the Reach2HD trial within the Huntington disease clinical research community," said Dr Dorsey. Of the 109 enrolled, 104 patients completed the trial, reflecting a retention rate of over 95 percent.

A Data Safety Monitoring Board met on five occasions throughout the trial and on each occasion recommended that no changes or modifications to the study protocol be made based on their review of the safety data.

The primary outcome of the trial is safety and tolerability. The trial also includes a number of secondary outcome measures from the cognitive, motor and behavioral domains affected in Huntington disease. A positive result of Reach2HD will identify signals of therapeutic benefit in one or more of the domains measured, which will inform the design of the next clinical trial.

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Mr Geoffrey Kempler, Prana's chairman and CEO, said, "Assuming we achieve the positive results we are hoping for in Reach2HD, we plan to meet with the US regulator, the Food and Drug Administration, and other regulatory agencies to discuss the next steps in the clinical development of PBT2 for the treatment of Huntington disease."

"We plan to discuss the design of the next trial and agree on a set of clinical outcomes that, when achieved, will allow us to submit a New Drug Application for approval to start to market PBT2 for Huntington disease," he added.

Huntington disease is a complex and severely debilitating genetic, neurodegenerative disease, for which there is no cure. The disease often affects young adults and, whilst associated with severe physical movement symptoms, progressively impacts the mind and emotions as well. The disease causes incapacitation and death about 15-25 years after onset. The disease affects over 30,000 people in the US and 70,000 worldwide.

The Huntington Study Group (HSG) collaborated with Prana to coordinate the Reach2HD trial across 20 sites in the USA and Australia.