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ASIA EDITION

Titan Pharmaceuticals receives FDA clearance to begin clinical study of Parkinson's Disease treatment

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First trial site qualified to start screening study patients.

Titan Pharmaceuticals (a US based pharmaceutical company) announced that the U.S. Food and Drug Administration (FDA) has cleared the Investigational New Drug (IND) application for its ropinirole implant intended for treatment of the signs and symptoms of Parkinson's disease. The Phase 1/2 clinical study in patients will commence shortly.

"New treatments that offer continuous delivery of medication providing non-pulsatile stimulation of dopamine receptors in the brain appear to have some advantages over oral formulations," said Dr. Aaron Ellenbogen of the Michigan Institute of Neurological Disorders, and the principal investigator at the first trial site, near Detroit, Michigan. "The ProNeura implants with ropinirole could potentially offer an important treatment option for continuous drug delivery that overcomes the fluctuating drug levels associated with oral administration of ropinirole, and we look forward to conducting this study."

The ropinirole implant, developed utilizing Titan's ProNeura technology, is designed for the long-term, continuous delivery of ropinirole HCL for the treatment of signs and symptoms of Parkinson's disease, including stiffness, tremors, muscle spasms, and poor muscle control. Ropinirole is a dopamine agonist currently available in daily or more frequently dosed oral formulations for the treatment of Parkinson's disease symptoms and restless leg syndrome.

The trial is an open-label, sequential, dose escalation study that will enroll approximately 20 subjects with idiopathic Parkinson's disease across three or more U.S. research sites. The primary objectives are to characterize the pharmacokinetic profile of the ropinirole implants, to evaluate their safety and tolerability, and to explore potential signals of efficacy using established disease-specific assessment scales. Patients on a stable dose of L-dopa plus oral ropinirole will have their oral ropinirole switched to ropinirole implants for three months of treatment.