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Titan Pharmaceuticals Receives FDA Clearance To Begin Clinical Study Of Parkinson's Disease Treatment

First trial site qualified to start screening study patients

SOUTH SAN FRANCISCO, Calif., Aug. 24, 2017 /PRNewswire/ --Titan Pharmaceuticals, Inc. (NASDAQ: TTNP) announced today 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.

"While oral formulations of ropinirole have greatly benefitted those suffering from Parkinson's disease, many patients develop serious motor complications and dyskinesias after several years, due to the peak-trough fluctuations of medication in the blood," said Kate Beebe, PhD, executive vice president and chief development officer at Titan. "Our ropinirole implant is designed to provide continuous, non-fluctuating therapeutic levels of medication for up to three months, potentially offering patients and clinicians a more effective treatment option. We thank the FDA for their timely review and comments on the IND and clinical protocol."

About Titan Pharmaceuticals

Titan Pharmaceuticals Inc. (NASDAQ: TTNP), based in South San Francisco, CA, is developing proprietary therapeutics primarily for the treatment of serious medical disorders. The company's lead product is Probuphine®, a novel and long-acting formulation of buprenorphine and the first and only commercialized treatment of opioid dependence approved by the U.S. Food and Drug Administration to provide continuous, around-the-clock blood levels of buprenorphine for six months following a single procedure. Probuphine employs Titan's proprietary drug delivery system ProNeura™, which is capable of delivering sustained, consistent levels of medication for three months or longer. Titan has granted commercial rights in the U.S. and Canada for Probuphine to Braeburn Pharmaceuticals. The ProNeura technology has the potential to be used in developing products for treating other chronic conditions such as Parkinson's disease and hypothyroidism, where maintaining consistent, around-the-clock blood levels of medication may benefit the patient and improve medical outcomes. For more information about Titan, please visit www.titanpharm.com.

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