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Titan Pharmaceuticals Receives FDA Communication On Ropinirole Implant Investigational New Drug Application

SOUTH SAN FRANCISCO, Calif., Feb. 27, 2017 /PRNewswire/ -- Titan Pharmaceuticals, Inc. (NASDAQ: TTNP), a company developing proprietary therapeutics for the treatment of select chronic diseases utilizing its ProNeura™ long-term, continuous drug delivery platform, today announced that the U.S. Food & Drug Administration (FDA) has completed its initial review of the ropinirole implant Investigational New Drug Application (IND) and has requested that Titan hold the initiation of the clinical study pending submission of the requested information and the agency's 30-day review.

In a telephone communication with Titan, the FDA indicated that it will require final release test data on the ropinirole implant and the applicator used to insert the implant before clearing the IND. Additionally, the FDA is requesting that Titan identify a participating Principal Investigator for the study. Titan expects to have final test data on the implant and the applicator within the next several weeks, and is in the process of qualifying the participating clinical sites. The FDA informed Titan that its written comments on the IND will be sent within the next 30 days.

"We understand the FDA's diligence and respect its request for additional information," said Titan Executive Vice President and Chief Development Officer Kate Beebe, Ph.D. "We are working quickly to provide the FDA with the additional information required, and are hopeful that we will be able to commence the clinical study toward the end of the second quarter."

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 for the long-term maintenance treatment of opioid dependence. 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.

Approved by the U.S. Food and Drug Administration in May 2016, Probuphine is the first and only commercialized treatment of opioid dependence to provide continuous, around-the-clock blood levels of buprenorphine for six months following a single procedure. 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.

This press release may contain "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. Such statements include, but are not limited to, any statements relating to our product development programs and any other statements that are not historical facts. Such statements involve risks and uncertainties that could negatively affect our business, operating results, financial condition and stock price. Factors that could cause actual results to differ materially from management's current expectations include those risks and uncertainties relating to the regulatory approval process, the development, testing, production and marketing of our drug candidates, patent and intellectual property matters and strategic agreements and relationships. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as required by law.

Contact:
Titan Pharmaceuticals, Inc.
Sunil Bhonsle, President and CEO
(650) 244-4990

Investors:
Stephen Kilmer
(650) 989-2215
skilmer@titanpharm.com

Media:
Susan Thomas
(650) 989-2216
sthomas@titanpharm.com

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