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Titan Pharmaceuticals Announces Presentation of Probuphine Phase 3 Data at American Society of Addiction Medicine Annual Conference

SOUTH SAN FRANCISCO, CA -- (Marketwired) -- 04/15/16 -- [Titan Pharmaceuticals, Inc.](#) (NASDAQ: TTNP) announced today the presentation of data from the last Phase 3 study of Probuphine®, a six month subdermal buprenorphine implant for the long-term maintenance treatment of opioid addiction, at a poster session during the [47th Annual American Society of Addiction Medicine \(ASAM\) Annual Conference](#). The data indicates that participants who were clinically stable on sublingual buprenorphine at a dose of 8mg or less per day maintained stability when transferred to Probuphine, and that they were more likely to sustain abstinence from illicit opioids throughout the six months than participants who remained on sublingual buprenorphine. The Probuphine New Drug Application (NDA) is currently under review by the FDA with an action date of May 27, 2016.

"This was the first head-to-head comparison study of Probuphine and sublingual buprenorphine, demonstrating the efficacy of a long-acting six month buprenorphine implant," said co-lead investigator and an author of the presentation Richard N. Rosenthal, M.D., Professor of Psychiatry and Medical Director of Addiction Psychiatry at the Icahn School of Medicine at Mount Sinai. "The study results show that participants in the implant group sustained clinical stability over the course of six months. The implant group was also more likely to remain free from illicit opioids at 85.7% compared to 71.9% of those maintained on sublingual buprenorphine. If approved, Probuphine could help expand access to medication to treat opioid use disorders, providing people with a new option."

The poster titled, "A Randomized Trial of Probuphine Implants in Adults Stabilized on Sublingual Buprenorphine," presented data from the double-blind, double-dummy study, which was designed to determine the efficacy and safety of Probuphine as a maintenance treatment for opioid addiction. The primary endpoint was a non-inferiority comparison of the Probuphine and the sublingual buprenorphine treatment arms. As previously reported, the study met its primary endpoint as well as all secondary endpoints, and the treatment was well tolerated by the study subjects. Further details are included in the poster presentation, which was co-authored by Michelle R. Lofwall, M.D., University of Kentucky College of Medicine, Center on Drug and Alcohol Research in Lexington, Kentucky; Sonnie Kim, Ph.D., Braeburn Pharmaceuticals; Katherine L. Beebe, Ph.D., Titan Pharmaceuticals; Michael Chen, Ph.D., TCM Groups, Inc.; and Frank J. Vocci, Ph.D., Friends Research Institute.

"We are very pleased to be presenting these important data for the first time at the ASAM meeting and will continue to work closely with our partner, Braeburn Pharmaceuticals, on a broad medical communications strategy for Probuphine, if approved by the FDA," said Kate

Beebe, Ph.D., Executive Vice President and Chief Development Officer of Titan Pharmaceuticals.

Probuphine was developed using Titan's proprietary platform technology, ProNeura™, a non-biodegradable drug delivery implant designed to provide continuous, long-term steady state levels of medication in the blood. In January 2016, the FDA reviewed the Probuphine NDA at a meeting of the Psychopharmacologic Drugs Advisory Committee (PDAC), and following a discussion of the data presented, the committee voted 12-5 in favor of approval of Probuphine. If approved by the FDA, Probuphine would be the first marketed product to provide maintenance treatment of opioid addiction continuously for six months following a single procedure.

About the ProNeura Long-term Drug Delivery Platform

ProNeura is Titan's proprietary, long-term drug delivery platform utilized in the development of products for the treatment of select chronic conditions that may benefit from the delivery of continuous, non-fluctuating levels of certain medications over an extended period of six months to a year. ProNeura consists of a small, solid rod made from a mixture of ethylene-vinyl acetate ("EVA") and a drug substance. The resulting product is a solid matrix that is placed subdermally, normally in the inner part of the upper arm, during a simple office procedure, and is removed in a similar manner at the end of treatment. The drug substance is released continuously through the process of dissolution, resulting in a stable, non-fluctuating blood level similar to that seen with intravenous administration. These long-term, linear-release characteristics are medically desirable to avoid the peak and trough swings from oral dosing that pose problems in the current treatments for many diseases, especially diseases of the central nervous system. Titan has issued patents as well as patent applications covering the use of the ProNeura long-term drug delivery platform for the formulation of specific products for the treatment of certain chronic diseases, such as opioid addiction, Parkinson's disease, and others.

About Titan Pharmaceuticals

Titan Pharmaceuticals Inc. (NASDAQ: TTNP), based in South San Francisco, CA, is a specialty pharmaceutical company developing proprietary therapeutics primarily for the treatment of serious medical disorders. The company's lead product candidate 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 U.S. and Canadian commercial rights for Probuphine to Braeburn Pharmaceuticals. If approved, Probuphine would be 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, where maintaining consistent blood levels of a therapeutic agent 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.

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