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Titan Pharmaceuticals Announces First Patient Enrollment in Clinical Study of Probuphine for Opioid Dependence

Study Completion Expected in Mid-2015 Followed by Potential Resubmission of Probuphine New Drug Application

SOUTH SAN FRANCISCO, CA -- (Marketwired) -- 07/21/14 -- Titan Pharmaceuticals, Inc. (OTCBB: TTNP) today announced enrollment of the first patients in the Phase 3 clinical study to support resubmission of the New Drug Application (NDA) for Probuphine®, the company's investigational subdermal implant for the maintenance treatment of opioid dependence. The study, which is expected to be completed by the middle of 2015, is designed to address key questions posed by the U.S. Food and Drug Administration (FDA) in its complete response letter last year after review of the original NDA. Titan's partner Braeburn Pharmaceuticals is sponsoring the trial and anticipates resubmission of the NDA to the FDA in late 2015.

"With more than 2 million people in the U.S. suffering from opioid dependence, there is a strong need for new treatments. 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," said Kate Glassman-Beebe, PhD., Titan's executive vice president and chief development officer.

Investigator training was conducted by Braeburn in June to review clinical study procedures, including special training for implant insertion and removal. Fifteen sites have obtained Institutional Review Board (IRB) approval, and Braeburn expects an additional six sites to be operational within the next few weeks. Fourteen sites are currently screening patients for randomization into the study and five patients have already been enrolled.

"We believe the fast pace with which a number of sites received IRB approval following our recent investigator training indicates the addiction community's support and need for novel treatments like Probuphine. Braeburn is committed to continue working with our clinical investigators to identify appropriate study patients and expedite enrollment in this study," said Behshad Sheldon, president and CEO of Braeburn Pharmaceuticals.

The clinical study is a randomized, double-blind, double-dummy design that is expected to enroll approximately 180 patients into two parallel treatment arms. The study population is clinically stable patients who are receiving maintenance treatment with an FDA-approved sublingual formulation containing buprenorphine at a daily dose of 8mg or less. Patients are being randomized to either receive four Probuphine implants, or to continue the daily sublingual buprenorphine therapy. To enable the double-blind design, those receiving Probuphine implants are required to take daily placebo sublingual pills, while those

continuing on their stable dose of sublingual buprenorphine pills are required to be treated with four placebo implants. The patients are expected to be treated for six months, and the primary analysis will be a non-inferiority comparison of responders in the two arms.

Probuphine is designed to deliver continuous, around the clock blood levels of buprenorphine for six months following a single insertion procedure, and to simplify patient compliance and improve retention. It was developed using ProNeura™, Titan's continuous drug delivery system. Titan also has in development a ProNeura technology-based product for the treatment of Parkinson's disease and the company anticipates filing an investigational new drug application for that program in 2015.

About Opioid Dependence

According to recent estimates, there are 2.2 million people with opioid dependence in the U.S. Approximately 20 percent of this population is addicted to illicit opioids, such as heroin, and the other 80 percent to prescription opioids, such as oxycodone, hydrocodone, methadone, hydromorphone and codeine. Before the year 2000, medication-assisted therapies for opioid dependence had been sanctioned to a limited number of facilities in the U.S. The Drug Addiction Treatment Act of 2000 (DATA 2000) allowed medical office-based treatment of opioid dependence and greatly expanded patient access to medication-assisted treatments. As a result, an estimated 1.2 million people in the U.S. sought treatment for opioid dependence in 2011.

About Probuphine

Probuphine is an investigational subdermal implant designed to deliver continuous, around the clock blood levels of buprenorphine for six months following a single treatment, and to simplify patient compliance and retention. Buprenorphine, an approved agent for the treatment of opioid dependence, is currently available in the form of daily dosed sublingual tablets and film formulations, with reported 2012 sales of $1.5 billion in the United States.

Probuphine was developed using ProNeura™, Titan's continuous drug delivery system that consists of a small, solid implant made from a mixture of ethylene-vinyl acetate (EVA) and a drug substance. The resulting construct is a solid matrix that is placed subdermally, normally in the upper arm in a simple office procedure, and removed in a similar manner at the end of the treatment period. The drug substance is released slowly and continuously through the process of dissolution resulting in a steady rate of release.

The efficacy and safety of Probuphine has been studied in several clinical trials, including a 163-patient, placebo-controlled study over a 24-week period (published in the *Journal of the American Medical Association (JAMA)*), and a follow on study of 287 patients (published in the journal *Addiction*).

About Titan Pharmaceuticals

Titan Pharmaceuticals Inc. (OTCBB: 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 six months or longer. Titan has granted North American 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 dopamine agonist 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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