April 30, 2014

Titan Pharmaceuticals Provides Overview of Upcoming Clinical Study of Probuphine Following Clear Guidance From the FDA

Study of Approximately 180 Opioid Dependent Patients Expected to Begin Enrollment by Mid-Year 2014

SOUTH SAN FRANCISCO, CA -- (Marketwired) -- 04/30/14 -- Titan Pharmaceuticals, Inc. (OTCBB: TTNP) announced today that the U.S. Food and Drug Administration (FDA) has provided clear guidance on the full clinical study protocol of Probuphine®, the company's investigational subdermal implant for the maintenance treatment of opioid dependence. The study, which was submitted for FDA review in mid-March by Titan's partner, Braeburn Pharmaceuticals, is expected to begin enrollment by mid-year, and study completion is anticipated by the middle of 2015.

"The responsiveness and insightful guidance from the FDA has been very helpful in establishing the path forward for the Probuphine program," said Behshad Sheldon, Braeburn's president and CEO. "We have revised the final study protocol to incorporate the FDA's guidance, and preparations are under way to qualify investigator sites, obtain Institutional Review Board (IRB) approval and train the clinicians in study procedures. We look forward to working closely with Titan on preparations for the clinical study and to ultimately bringing this important treatment option to patients with opioid addiction."

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 will be clinically stable patients who are receiving maintenance treatment with an approved sublingual formulation containing buprenorphine at a daily dose of 8mg or less. Patients will be randomized to receive either four Probuphine implants, or to continue the daily sublingual buprenorphine therapy. To enable the double blind design, those receiving Probuphine implants will also be required to take daily placebo sublingual pills, while those continuing on their stable dose of sublingual buprenorphine pills will be 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. Updates on the progress of the study will be provided periodically.

"This clinical study will provide a well-controlled evaluation of Probuphine compared with the current standard of care in stable, maintenance patients, while allowing all participants to receive active treatment," said Kate Glassman-Beebe, Ph.D., Titan's executive vice president and chief development officer. "We appreciate the collaborative process that has resulted in this robust study design and we are encouraged by the interactions with potential investigators regarding clinical study conduct. We will continue to support our partner,

Braeburn, with the study and remain optimistic about the resubmission of the Probuphine NDA next year."

About Opioid Dependence

According to recent estimates, there are approximately 2.7 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 approximately $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 at 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*).

ProNeura™ Technology

Probuphine is the first product to utilize Titan's proprietary, long-term drug delivery technology, ProNeura, which has the potential to be used in developing products for the treatment of other chronic conditions. In July 2012, Titan announced that it had successfully completed preclinical investigation into the feasibility of a long-term, around-the-clock, non-fluctuating dopamine agonist treatment for Parkinson's disease, where maintaining stable, around-the-clock blood levels of dopamine agonists may benefit the patient and improve medical outcomes. Titan has been issued patents covering certain dopamine agonist implants in Europe, Japan, Australia, Canada, South Korea, Mexico, New Zealand, South Africa, and Hong Kong, while prosecution of patent applications continues in the U.S., Israel, India and China.

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.

CONTACT:
Titan Pharmaceuticals, Inc.
Sunil Bhonsle
650-244-4990
President

Media
Susan Thomas
619-540-9195
stcommunications@aol.com

Source: Titan Pharmaceuticals, Inc.