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Titan Pharmaceuticals Announces Enrollment Reaches Halfway Mark in Phase 3 Study of Probuphine for Opioid Dependence

SOUTH SAN FRANCISCO, CA -- (Marketwired) -- 09/23/14 -- Titan Pharmaceuticals, Inc. (OTCBB: TTNP) today announced that patient enrollment in the Phase 3 study of Probuphine®, the company's investigational subdermal implant for the maintenance treatment of opioid dependence, has reached the halfway mark. Titan's partner, Braeburn Pharmaceuticals, is sponsoring the study and expects it to be fully enrolled before the end of this year, with study completion on schedule by the middle of 2015. The study is designed to support resubmission of the New Drug Application for Probuphine with the U.S. Food and Drug Administration, which is expected later in 2015.

This study currently includes 21 clinical research sites and is expected to enroll approximately 180 patients. As of September 22, all 21 sites are actively recruiting subjects, and there are already 94 subjects randomized in the study.

"We are encouraged by the speed with which stable opioid-dependent patients are enrolling in this trial," said Behshad Sheldon, president and CEO of Braeburn Pharmaceuticals. "We believe the pace of enrollment reflects the great need for new long-term maintenance treatment options for those suffering from opioid dependence. We look forward to working with our clinical investigators to complete this study expeditiously, and if ultimately approved by the FDA, the opportunity to provide physicians and their patients a unique treatment alternative."

Probuphine was developed using ProNeura™, Titan's proprietary continuous drug delivery system. If approved, Probuphine would be the only treatment available that can deliver around-the-clock blood levels of buprenorphine for six months following a single treatment. Probuphine was designed to facilitate patient compliance and improve retention in treatment.

The clinical study is a randomized, double-blind, double-dummy design that is enrolling patients in 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 either to receive four Probuphine implants, or to continue the daily sublingual buprenorphine therapy. Under the double-blind, double-dummy 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 will be treated for six months, and the primary analysis will be a non-inferiority comparison of responders in the two arms.

"We are very pleased with the progress Braeburn is making with enrollment in this study, which was designed to address key questions posed by the FDA in its complete response letter last year," said Kate Glassman Beebe, Ph.D., Titan's executive vice president and chief development officer. "We believe the study design represents a well-controlled evaluation of Probuphine compared with the current standard of care in stable maintenance patients. We will continue to assist Braeburn with this clinical trial, and we look forward to further progress throughout the year."

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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