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Titan Pharmaceuticals Announces Completion of Enrollment in Phase 3 Study of Probuphine for Opioid Dependence

Braeburn Expands Portfolio for Opioid Addiction Treatment, Potentially Adding up to $50 Million to Future Titan Royalties

SOUTH SAN FRANCISCO, CA -- (Marketwired) -- 11/20/14 -- Titan Pharmaceuticals, Inc. (OTCBB: TTNP) today announced completion of enrollment in the ongoing Phase 3 study of Probuphine®, the company's investigational subdermal implant for the maintenance treatment of opioid dependence. Study completion is expected to be on schedule by the middle of 2015, paving the way for resubmission of the New Drug Application (NDA) for Probuphine with the U.S. Food and Drug Administration (FDA) later in the year.

The study, which is being sponsored and managed by Braeburn Pharmaceuticals, has randomized 178 patients across 21 centers. With a low screening failure rate and high patient interest, Braeburn successfully enrolled the entire study in a little over four months.

"We have been very pleased with the progress in recruitment and enrollment of the Phase 3 study of Probuphine and are looking forward to supporting Braeburn to complete the trial and resubmit the NDA," said Kate Glassman Beebe, Ph.D., Titan's executive vice president and chief development officer. "We believe the design is robust and that the study will provide a well-controlled evaluation of Probuphine compared with the current standard of care in stable, maintenance patients."

The Probuphine clinical study in progress is a randomized, double-blind, double-dummy design that has enrolled 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 have been randomized either to receive four Probuphine implants or to continue the daily sublingual buprenorphine therapy. 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.

Separately, Braeburn announced today that it has obtained new exclusive marketing rights to subcutaneous buprenorphine injection products for the treatment of opioid addiction and pain in North America. These products developed by Camurus as weekly and monthly injection depot formulations expand Braeburn's portfolio of products in development for the treatment of opioid dependence. These new products are expected to enter into Phase 3 development in 2015, following discussions with regulatory authorities. Under a 2013 amendment to the license agreement between Titan and Braeburn, Titan is entitled to a low single-digit royalty on sales of certain such products, if approved for commercialization, up to a maximum of $50 million.

"With enrollment in the Phase 3 trial of Probuphine complete, we are eager to conclude the study and resubmit the NDA," said Behshad Sheldon, president and CEO of Braeburn Pharmaceuticals. "Braeburn is committed to providing a broad range of treatments for opioid dependence and views Probuphine as a critically needed alternative for the treatment of opioid dependence. With its unique capability to deliver steady state levels of buprenorphine for six months, Probuphine is the only implantable option in our portfolio and is well suited for the long-term maintenance treatment of patients suffering from opioid dependence. These new depot formulations complement Probuphine, and, if approved, will enable Braeburn to offer multiple long-acting buprenorphine alternatives to daily oral formulations that can be selected based on patient need and treatment stage."

"We're very pleased to see the commitment of Braeburn to the field of opioid addiction treatment and believe that Probuphine, which is capable of delivering a stable dose of buprenorphine for six months following a single treatment, has the potential to be the first long-term maintenance treatment with the opportunity to increase patient compliance and retention, and minimize diversion and abuse," said Titan President Sunil Bhonsle.

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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