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Probuphine(R) Receives FDA Priority Review Designation for Adult Patients With Opioid Dependence

PDUFA Date Set for April 30, 2013

SOUTH SAN FRANCISCO, CA -- (Marketwire) -- 01/02/13 -- Titan Pharmaceuticals, Inc. (OTCBB: TTNP) today announced that the New Drug Application (NDA) for Probuphine® has been accepted for review and granted Priority Review designation by the U.S. Food and Drug Administration (FDA). Probuphine is a novel, subdermal implant and the first long-acting product designed to deliver six months of the drug buprenorphine hydrochloride following a single treatment. Titan submitted the NDA for the maintenance treatment of opioid dependence in adult patients in October 2012 under Section 505(b)(2) of the Food, Drug and Cosmetic Act and referenced the approved sublingual tablet formulations of buprenorphine.

Priority designation is given to therapies that offer potential major advances in treatment, including improved safety, or provide a treatment where no adequate therapy exists. Based upon the Prescription Drug User Fee Act (PDUFA), the FDA has set a target date of April 30, 2013 for FDA action on the NDA.

"This is an important milestone for Probuphine and the Priority Review designation further underscores the critical need for new treatments for opioid dependence," said Katherine Beebe, Ph.D., executive vice president and chief development officer at Titan. "With more than two million people addicted to opioids in the U.S. alone, there is a need for safe and effective treatments that also reduce the risk of abuse or accidental use. Probuphine has demonstrated clinically meaningful and statistically significant treatment benefits across several clinical trials and we look forward to supporting the NDA review process and, potentially, offering a new treatment option to patients and physicians."

Last month, Titan announced the signing of a license agreement with Braeburn Pharmaceuticals Sprl, wholly owned by Apple Tree Partners IV, L.P., a partnership affiliated with Apple Tree Partners. The license grants Braeburn exclusive commercialization rights in the United States and Canada to the investigational product Probuphine and, has provided Titan a $15.75 million upfront payment and entitles the company to up to $215 million in milestone payments plus tiered double digit royalties on Probuphine sales. The milestone payment from Braeburn in the event of FDA approval of Probuphine for the treatment of opioid dependence will be $50 million since the NDA has received Priority Review designation.

About Opioid Addiction
It is estimated that there are 2.3 million opioid addicts in the U.S. Approximately 20 percent

of this potential patient population is addicted to illicit opioids, such as heroin, and the other 80 percent to prescription drugs, such as oxycontin, methadone, and codeine. Until recently, medication-assisted therapies for opioid addiction had been sanctioned to a limited number of facilities in the U.S. Today, physicians can be certified to prescribe certain opioid addiction medications in an office setting, which has greatly expanded patient access to opioid addiction pharmaceutical therapies. As a result, it is estimated that there are approximately 750,000 people in the U.S. receiving medicinal treatment for opioid addiction.

About Probuphine®
Probuphine is an investigational subcutaneous implant capable of delivering continuous and persistent, around the clock blood levels of buprenorphine for six months following a single treatment, enhancing 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 2011 sales of $1.3 billion in the United States. Probuphine was developed using ProNeura™, Titan's continuous drug delivery system that consists of a small, solid rod made from a mixture of ethylene-vinyl acetate (EVA) and a drug substance. The resulting construct is a solid matrix that is placed subcutaneously, 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, at continuous levels, through the process of diffusion. This results in a constant rate of release similar to intravenous administration.

The efficacy and safety of Probuphine has been studied in several clinical trials, including a 163-patient, placebo-controlled study that demonstrated clinically meaningful and statistically significant treatment benefits with Probuphine over a 24-week period (published in the Journal of the American Medical Association (JAMA)), and a confirmatory study of 287 patients that showed statistically significant improvement in efficacy versus placebo, and non-inferiority with a currently marketed sublingual formulation of buprenorphine. Results of the confirmatory study were announced in July 2011. Probuphine was well-tolerated in all clinical studies, including in two open label safety studies that provided treatment with Probuphine for an additional six months to patients who completed the six-month controlled study.

About Titan Pharmaceuticals
For information concerning Titan Pharmaceuticals, Inc., please visit the company's website at www.titanpharm.com.

Safe Harbor Statement
The 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 the Company's development program and any other statements that are not historical facts. Such statements involve risks and uncertainties, including, but not limited to, those risks and uncertainties relating to difficulties or delays in development, testing, regulatory approval, production and marketing of the Company's drug candidates, adverse side effects or inadequate therapeutic efficacy of the Company's drug candidates that could slow or prevent product development or commercialization, the uncertainty of patent protection for the Company's intellectual property or trade secrets. Such statements are based on management's current expectations, but actual results may differ materially due to various

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