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Titan Pharmaceuticals Receives Official Minutes From FDA Meeting on Probuphine New Drug Application

SOUTH SAN FRANCISCO, CA -- (Marketwired) -- 12/23/13 -- Titan Pharmaceuticals, Inc. (OTCBB: TTNP) today announced the receipt of the official minutes (the "Minutes") from a Type C meeting with the U.S. Food and Drug Administration (FDA) on November 19, 2013 to discuss the Complete Response Letter (CRL) to its New Drug Application (NDA) for Probuphine®, an investigational subdermal implant for the maintenance treatment of opioid dependence in adult patients. Per the Minutes, the FDA emphasized its commitment to working with Titan and its partner, Braeburn Pharmaceuticals, to pursue a reasonable path to approval, and all parties agreed that seeking an indication in individuals stabilized on 8 mg/day or less of sublingual buprenorphine (SL BPN) may be a suitable approval pathway for Probuphine. Titan and Braeburn proposed the revised indication following a review of the FDA's comments on the briefing material and to address one of the primary concerns in the CRL regarding dose adequacy among the original study population (newly inducted patients maintained at 12-16 mg SL BPN/day). The FDA maintained the need for clinical data in this patient population as a requirement for approval, stipulating that the study "*need not be large*," "*be adequate and well-controlled,*" and "*must support labeling for the duration of treatment (6 months).*" Titan and Braeburn are working with experts in the field to develop a clinical study design for submission to the FDA within the next few weeks.

"We appreciate the FDA's close consideration of our proposal addressing the CRL and its continued support to advance the Probuphine program," said Sunil Bhonsle, president of Titan Pharmaceuticals. "While our path forward includes an additional clinical study, we are encouraged by the FDA's noted willingness to work closely and iteratively with us on all aspects of the CRL to ensure a mutually feasible and expeditious path to approval. We will provide updates to our shareholders on an as needed basis."

The plan forward for additional items outlined in the April 2013 CRL was also summarized in the Minutes.

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 confirmatory study of 287 patients (published in the journal *Addiction*).

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

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 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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