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Titan Pharmaceuticals Announces Submission of FDA Meeting Request Regarding Probuphine

SOUTH SAN FRANCISCO, CA -- (Marketwired) -- 09/04/13 -- [Titan Pharmaceuticals, Inc.](#) (OTCBB: TTNP) today announced the submission of a Type B meeting request to the U.S. Food and Drug Administration (FDA) to discuss [Probuphine®](#), the company's investigational subdermal implant designed to deliver continuous, blood levels of buprenorphine for six months following a single treatment.

The goal of this meeting is to understand more fully the issues raised in the April 2013 [Complete Response Letter](#) (CRL) to the New Drug Application (NDA) for Probuphine for the maintenance treatment of opioid dependence in adults, review and discuss the available data from the Probuphine studies conducted to date and gain further clarity regarding the regulatory path forward for Probuphine. In accordance with FDA guidance that establishes performance goals for meeting requests, Titan expects to learn within 21 days whether the meeting request will be granted and, if the meeting is granted, expects to have a meeting scheduled within 60 days.

Titan and its partner, Braeburn Pharmaceuticals, which has licensed the exclusive rights to commercialize Probuphine in the U.S. and Canada, continue to work closely with regulatory counsel and a team of expert advisors to systematically evaluate the options available to address the concerns identified by the FDA in the CRL.

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.

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 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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