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Titan Pharmaceuticals Receives Complete Response Letter From the FDA for Probuphine New Drug Application

SOUTH SAN FRANCISCO, CA -- (Marketwired) -- 04/30/13 -- Titan Pharmaceuticals, Inc. (OTCBB: TTNP) announced that the U.S. Food and Drug Administration (FDA) has issued this evening a Complete Response Letter (CRL) to its New Drug Application (NDA) for Probuphine®, the company's investigational subdermal implant for the maintenance treatment of opioid dependence in adult patients.

"Titan and our partner, Braeburn Pharmaceuticals, are extremely surprised and disappointed with the FDA's response. Probuphine is a diversion-resistant formulation that is consistent with the recently-issued FDA guidance supporting diversion- and abuse-resistant products, and the NDA was designated Priority Review by the FDA. We believe Probuphine has demonstrated both safety and efficacy in accordance with primary endpoints that were pre-agreed with the FDA and, moreover, the safety, efficacy and overall approval of Probuphine was strongly supported by the Psychopharmacologic Drugs Advisory Committee," said Marc Rubin, M.D., executive chairman of Titan Pharmaceuticals. "Given the nationally-recognized, growing and devastating opioid dependence epidemic, there is critical need for new safe and effective treatments that reduce the likelihood of abuse, diversion and accidental pediatric exposure, and Titan and Braeburn remain committed to making Probuphine available for patients that need it."

The CRL states that the FDA cannot approve the application in its present form. The FDA has requested additional data supporting the efficacy of Probuphine, including:

- The ability of Probuphine to provide opioid blockade of relevant doses of agonists
- The effect of higher doses of Probuphine, ideally doses more closely approximating the blood plasma levels associated with sublingual doses of buprenorphine of 12 to 16 mg / day
- Human factors testing of the training associated with Probuphine's insertion and removal

The CRL also included recommendations regarding product labeling and the implementation of the Risk Evaluation and Mitigation Strategy (REMS).

Titan and Braeburn Pharmaceuticals, which has licensed the commercialization rights for Probuphine in the U.S. and Canada, are committed to addressing the concerns raised by the FDA in the CRL. Titan will discuss with the FDA the scope of the CRL comments to obtain clarification and determine next steps.

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 and persistent, 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 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 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 designed to evaluate efficacy versus placebo, and non-inferiority with a currently marketed sublingual formulation of buprenorphine. Results of the confirmatory study were announced in July 2011.

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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