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# Titan Pharmaceuticals Announces Agreement in Principle on Path Forward for Probuphine Clinical Study

SOUTH SAN FRANCISCO, CA -- (Marketwired) -- 03/03/14 -- Titan Pharmaceuticals, Inc. (OTCBB: TTNP) today announced that the company and its partner, Braeburn Pharmaceuticals, have agreed in principle with the U.S. Food and Drug Administration (FDA) on the design of a clinical study in support of the New Drug Application (NDA) for Probuphine®, the company's investigational subdermal implant for the maintenance treatment of opioid dependence. The proposed clinical study will be a randomized, double blind and double dummy design that will provide information for a non-inferiority comparison of a six-month treatment with a dose of four Probuphine implants to treatment with 8mg or less of an approved daily dosed sublingual formulation of buprenorphine. Details of the study, including size and the data analysis plan, will be established following the FDA's review of a complete study protocol, which Braeburn expects to submit within the next two weeks.

"We are pleased that there is general agreement on the clinical study," said Dr. Kate Glassman-Beebe, executive vice president and chief development officer. "This study design provides the best opportunity for an unbiased comparison of treatment with Probuphine to the current standard of care practice, while making sure all patients will receive active treatment for the disease."

Titan and Braeburn submitted a detailed clinical study synopsis to the FDA several weeks ago, following discussions with the FDA in November 2013 regarding the Complete Response Letter issued to the Probuphine NDA. These discussions and feedback from the FDA led to the study design described above.

***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***
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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