August 13, 2013

# Titan Pharmaceuticals Announces Publication of Phase 3 Probuphine Data in Addiction

SOUTH SAN FRANCISCO, CA -- (Marketwired) -- 08/13/13 -- Titan Pharmaceuticals, Inc. (OTCBB: TTNP) today announced that data from its previously completed and announced Phase 3 placebo- and active drug-controlled confirmatory clinical study of Probuphine®, evaluating the safety and efficacy of its subdermal implant for the maintenance treatment of opioid dependence in adult patients, were published online in the journal *Addiction*. The paper is expected to appear in a future print issue of the journal.

Key Probuphine findings outlined in the publication include:

- Probuphine results were statistically significant for the trial's protocol defined primary endpoint based on the percentages of urine samples that were negative for illicit opioid use, and incorporating patient self-reported opioid use over the 24-week treatment period ($p < 0.0001$)
- Patients receiving the Probuphine implant had a higher study completion rate relative to placebo (64 percent vs. 26 percent ($p < 0.0001$)
- Patients receiving the Probuphine implant had lower clinician-rated ($p < 0.0001$) and patient-rated ($p < 0.0001$) withdrawal, lower patient-rated ($p < 0.0001$) craving and better patients' ($p = 0.031$) and clinicians' ($p = 0.022$) global ratings of improvement
- Patients in the Probuphine arm and the SUBOXONE® arms had similar results for the mean number of urines that tested negative for illicit opioids (Probuphine: 36 percent SUBOXONE: 35 percent)

This study of 287 patients was funded by a grant from the National Institute on Drug Abuse (NIDA) and by Titan Pharmaceuticals.

In April 2013, Titan received a Complete Response Letter (CRL) to the New Drug Application (NDA) for Probuphine, requesting, among other things, additional data supporting efficacy and safety of the product and the clinical benefit to patients. Titan and its commercialization partner in the U.S. and Canada, Braeburn Pharmaceuticals, are working closely with regulatory counsel and a team of expert advisors to systematically evaluate the options available to address the issues in the CRL and remain committed to advancing Probuphine.

***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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