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Titan Pharmaceuticals Announces Resubmission of the New Drug Application for Probuphine for the Maintenance Treatment of Opioid Addiction

SOUTH SAN FRANCISCO, CA -- (Marketwired) -- 08/31/15 -- [Titan Pharmaceuticals, Inc.](#) (OTCQB: TTNP), a specialty pharmaceutical company developing proprietary therapeutics for the treatment of select chronic diseases utilizing its ProNeura™ long-term drug delivery technology, today announced the resubmission by Braeburn Pharmaceuticals of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for Probuphine®, Titan's subdermal implant containing buprenorphine HCl for the maintenance treatment of opioid addiction. Probuphine is designed to deliver continuous, non-fluctuating levels of buprenorphine for six months following a single treatment.

"We are extremely pleased by the Braeburn and Titan teams' expeditious preparation of this NDA following the positive results of the final Phase 3 trial," said Kate Glassman Beebe, PhD, Titan's executive vice president and chief development officer. "We expect a six-month review cycle, and if approved, Probuphine would be the first marketed product to provide maintenance treatment of opioid addiction continuously for six months following a single procedure. Probuphine has the potential to increase patient compliance and decrease the risk of diversion, and could become an essential tool in the treatment of opioid addiction."

About Probuphine®

Probuphine is an investigational subdermal implant designed to deliver buprenorphine continuously for six months following a single treatment, and to promote patient compliance and retention. Buprenorphine, which is the active ingredient in multiple FDA-approved drug products for the treatment of opioid addiction, is currently available in tablet and film formulations that require self-administration by patients on a daily basis.

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 an outpatient office procedure, and removed in a similar manner at the end of the treatment period.

The efficacy and safety of Probuphine has been studied in several clinical trials, including the recently completed double blind, double dummy final Phase 3 study, which provided positive results (announced June 2015) in the comparison of maintenance treatment with Probuphine to maintenance treatment with daily sublingual buprenorphine in stable patients

receiving a daily dose of 8mg or less of buprenorphine; the previously reported 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 Opioid Addiction

According to recent estimates, there are 2.2 million people with opioid addiction 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. Sales of buprenorphine drug products for treatment of opioid addiction in 2014 were approximately \$1.75 billion in the United States.

About Titan Pharmaceuticals

Titan Pharmaceuticals Inc. (OTCQB: TTNP), based in South San Francisco, CA, is a specialty pharmaceutical company developing proprietary therapeutics primarily for the treatment of serious medical disorders. The company's lead product candidate is Probuphine®, a novel and long-acting formulation of buprenorphine for the long-term maintenance treatment of opioid dependence. Probuphine employs Titan's proprietary drug delivery system ProNeura™, which is capable of delivering sustained, consistent levels of medication for six months or longer. Titan has granted U.S. and Canadian commercial rights for Probuphine to Braeburn Pharmaceuticals. If approved, Probuphine would be the first and only commercialized treatment of opioid dependence to provide continuous, around-the-clock blood levels of buprenorphine for six months following a single procedure. The ProNeura technology has the potential to be used in developing products for treating other chronic conditions, such as Parkinson's disease, where maintaining consistent blood levels of a therapeutic agent may benefit the patient and improve medical outcomes. For more information about Titan, please visit www.titanpharm.com.

This 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.

CONTACT:

Titan Pharmaceuticals, Inc.:
Sunil Bhonsle
President
(650) 244-4990

Investors:
Stephen Kilmer
(647) 872-4849
skilmer@titanpharm.com

Media:
Susan Thomas
(619) 540-9195
stthomas@titanpharm.com

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