May 26, 2016

Titan Pharmaceuticals Announces FDA Approval of Probuphine(R) for the Treatment of Opioid Dependence

Buprenorphine Implant Is First Product for Six-Month, Long-Term Maintenance Treatment of Opioid Dependence; Titan to Receive $15 Million Milestone Payment

SOUTH SAN FRANCISCO, CA -- (Marketwired) -- 05/26/16 -- Titan Pharmaceuticals, Inc. (NASDAQ: TTNP) today announced that the U.S. Food and Drug Administration has approved Probuphine® (buprenorphine) implant, the first product for the long-term maintenance treatment of opioid dependence in clinically stable patients on 8 mg or less a day of oral buprenorphine. The Probuphine subdermal implant, which utilizes Titan's proprietary ProNeura™ technology, delivers buprenorphine continuously for up to six months. The product is expected to be commercially available this summer and is recommended for use as part of a complete treatment program including counseling and psychosocial support.

"The approval of Probuphine marks a major milestone for Titan and we look forward to supporting our partner Braeburn Pharmaceuticals during the product launch this summer," said Titan President and CEO Sunil Bhonsle. "At a time when the government is supporting the expansion of access to opioid addiction treatments, the launch of Probuphine will provide the medical community with a novel, long-term treatment alternative that can provide benefits to many patients suffering from this disease."

"As a clinician who has treated hundreds of patients for opioid addiction, including as a clinical investigator in the Probuphine studies, I am very encouraged by the prospects of this new treatment," said Dr. Genie Bailey, Associate Clinical Professor of Psychiatry, Brown University and Director of Research, Stanley Street Treatment & Resources, Fall River, Massachusetts. "It's extremely important that patients maintain their addiction treatment once they've stabilized on daily dosing of buprenorphine. Probuphine's method of continuously delivering buprenorphine provides for long-term maintenance and offers the potential for enhanced patient compliance and a better quality of life."

Buprenorphine is the most commonly prescribed medication for the treatment of opioid dependence. Until today, it has only been available in daily dosed sublingual (oral) formulations. Probuphine offers the potential to address issues associated with oral buprenorphine such as poor compliance, misuse, diversion and accidental pediatric exposure. Each Probuphine implant contains 80 mg of buprenorphine hydrochloride. Four flexible Probuphine implants, each about the size of a small matchstick, are inserted by a certified healthcare provider just under the skin of the inside of the patient's upper arm

through a simple in-office procedure and are removed in a similar manner at the end of treatment.

"As a family medicine doctor with a specialty in addiction medicine, and as a Probuphine clinical investigator, I have seen the benefits of Probuphine firsthand. Probuphine's ability to provide around-the-clock, stable levels of buprenorphine for six months significantly benefits patients and clinicians by assisting with compliance and by decreasing the possibility of abuse or diversion. The hands-on training program for qualified health care providers enhances the ease and safety of both the implant insertion and removal process," said Dr. Matthew A. Torrington, FASAM, ABAM, Senior Master Trainer: Probuphine REMS program and a clinical research physician at UCLA.

The product label emphasizes safety considerations associated with the insertion and removal procedures for Probuphine. Details describing the risks and complications associated with the insertion and removal procedures, as well as rare but serious complications that may result from improperly inserting the implants are included in the Probuphine Prescribing Information. Because of these risks, only certified healthcare providers may insert or remove Probuphine implants. Probuphine will only be available through a restricted distribution program (REMS) that includes required training for provider certification. Please see below in the 'Indication and Important Safety Information' section for additional details.

"We believe Probuphine will be an important tool in fighting the serious and complex disease of opioid addiction, and on behalf of Titan, I especially want to thank the patients, clinical investigation teams, NIDA, the FDA, and our partner Braeburn Pharmaceuticals for the exceptional effort that resulted in this approval," said Kate Beebe, Ph.D., Titan's executive vice president and chief development officer.

Titan granted exclusive commercialization rights to Probuphine in the U.S. and Canada to Braeburn in 2012 and is currently exploring licensing opportunities outside of the U.S. Under the Braeburn license, Titan will receive a $15 million milestone payment for the FDA approval as well as double-digit tiered royalties, and is eligible for sales milestones of up to $165 million.

"The Titan Board of Directors commends all those who have worked so hard over the years to make approval of Probuphine a reality," said Marc Rubin, M.D., Titan's executive chairman. "Our goal is to continue adding value to the company by building a strong pipeline of ProNeura-based product candidates. We are now well positioned to devote increasing resources to our Parkinson's disease and hypothyroidism programs and will continue to evaluate additional opportunities for ProNeura."

Conference Call

Titan plans to host a conference call on Tuesday, May 31 in the afternoon at 4:15pm ET/1:15pm PT. Participating on the call will be Sunil Bhonsle, president and CEO; Marc Rubin, M.D., executive chairman; Kate Beebe, Ph.D., executive vice president and chief development officer; and Behshad Sheldon, president and CEO of Braeburn Pharmaceuticals. The live webcast of the call may be accessed by visiting the Titan website at www.titanpharm.com. The call can also be accessed by dialing *888-806-6202*, Participant Code: 7721843 five minutes prior to the start time. A replay of the call will be available on the Titan website approximately two hours after completion of the call and will be archived

for two weeks.

INDICATIONS AND USAGE

PROBUPHINE contains buprenorphine, a partial opioid agonist. PROBUPHINE is indicated for the maintenance treatment of opioid dependence in patients who have achieved and sustained prolonged clinical stability on low-to-moderate doses of a transmucosal buprenorphine-containing product (i.e., doses of no more than 8 mg per day of Subutex or Suboxone sublingual tablet or generic equivalent).

PROBUPHINE should be used as part of a complete treatment program to include counseling and psychosocial support.

PROBUPHINE is not appropriate for new entrants to treatment and patients who have not achieved and sustained prolonged clinical stability, while being maintained on buprenorphine 8 mg per day or less of a Subutex or Suboxone sublingual tablet or generic equivalent.

WARNING: IMPLANT MIGRATION, PROTRUSION, EXPULSION and NERVE DAMAGE ASSOCIATED WITH INSERTION and REMOVAL

Risk Associated with Insertion and Removal

Insertion and removal of PROBUPHINE are associated with the risk of implant migration, protrusion, expulsion resulting from the procedure. Rare but serious complications including nerve damage and migration resulting in embolism and death may result from improper insertion of drug implants inserted in the upper arm. Additional complications may include local migration, protrusion and expulsion. Incomplete insertions or infections may lead to protrusion or expulsion.

Because of the risks associated with insertion and removal, PROBUPHINE is available only through a restricted program called the PROBUPHINE REMS Program. All Healthcare Providers must successfully complete a live training program on the insertion and removal procedures and become certified, prior to performing insertions or prescribing PROBUPHINE implants. Patients must be monitored to ensure that PROBUPHINE is removed by a healthcare provider certified to perform insertions.

CONTRAINDICATIONS

- Hypersensitivity to buprenorphine or any other ingredients in PROBUPHINE (e.g., EVA).

WARNINGS AND PRECAUTIONS

- Serious Complications from Insertion and Removal: Rare but serious complications including nerve damage and migration resulting in embolism and death may result from improper insertion of drug implants inserted in the upper arm. Additional complications may include local migration, protrusion and expulsion. Incomplete insertions or infections may lead to protrusion or expulsion. All Healthcare Providers must successfully complete a live training program on the insertion and removal procedures and become certified in the PROBUPHINE REMS program, prior to performing insertions or prescribing PROBUPHINE implants.

- Addiction, Abuse and Misuse: Buprenorphine can be abused in a manner similar to other opioids. Monitor patients for conditions indicative of diversion or progression of opioid dependence and addictive behaviors.

- Respiratory and CNS Depression: Significant respiratory depression and death have occurred in association with buprenorphine particularly when taken by the intravenous (IV) route in combination with benzodiazepines or other CNS depressants (including alcohol). Consider dose reduction of CNS depressants when used concomitantly.

- Neonatal Opioid Withdrawal Syndrome: Neonatal opioid withdrawal syndrome(NOWS) is an expected and treatable outcome of prolonged use of opioids during pregnancy.

- Adrenal Insufficiency: If diagnosed, treat with physiologic replacement of corticosteroids, and wean patient off of the opioid.

- Unintentional Pediatric Exposure: In the event an implant protrudes or comes out, keep the implant away from children. Buprenorphine can cause severe, possibly fatal, respiratory depression in children.

- Risk of Opioid Withdrawal with Abrupt Discontinuation: If treatment is temporarily interrupted or discontinued, monitor patients for withdrawal and treat appropriately.

- Risk of Hepatitis, Hepatic Events: Monitor liver function tests prior to initiation and during treatment.

- Risk of Withdrawal in Patients Dependent on Full Agonist Opioids: Verify that patient is clinically stable on transmucosal buprenorphine and not dependent on full agonists before inserting PROBUPHINE.

- Treatment of Emergent Acute Pain: Treat pain with a non-opioid analgesic whenever possible. If opioid therapy is required, monitor patients closely because higher doses may be required for analgesic effect.

- Most common side effects of PROBUPHINE include: headache, insomnia, rhinorrhea, upper respiratory tract infection, nausea, anxiety, back pain, depression, constipation, and vomiting.

Please read the full prescribing information, including boxed warning and Medication Guide, which you can access at www.probuphine.com

To report SUSPECTED ADVERSE REACTIONS, contact Braeburn at 1-844- 859-6341 or FDA at *1-800-FDA-1088* or www.fda.gov/medwatch

About Opioid Addiction

According to recent estimates, there are 2.5 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 (MAT). In 2015, the U.S. Health and Human Services Department announced it would move to expand access to medication-assisted-treatment even further by revising regulations that cap the number of patients who can be treated with buprenorphine products by physicians. The HHS revision to the regulation will be developed to provide a balance between expanding the supply of buprenorphine-based treatment, encouraging use of evidence-based MAT, and minimizing the risk of drug diversion. Sales of buprenorphine drug products for treatment of opioid addiction in 2014 were approximately $1.75 billion in the United States.

About Probuphine®
Probuphine is a 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 dependence, 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 have previously 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
Titan Pharmaceuticals Inc. (NASDAQ: 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 three months or longer. Titan has granted U.S. and Canadian commercial rights for Probuphine to Braeburn Pharmaceuticals. Probuphine will 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
(650) 989-2215
skilmer@titanpharm.com

Media:
Susan Thomas
(650) 989-2216
sthomas@titanpharm.com

Source: Titan Pharmaceuticals, Inc.