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Titan Pharmaceuticals and Braeburn Pharmaceuticals Announce FDA Advisory Committee Recommends Approval of Probuphine, First 6-Month Implant to Treat Opioid Addiction

SOUTH SAN FRANCISCO, Calif. and PRINCETON, N.J., Jan. 12, 2016 /PRNewswire/ -- Titan Pharmaceuticals, Inc. (NASDAQ: TTNP) and partner Braeburn Pharmaceuticals today announced that the Psychopharmacologic Drugs Advisory Committee (PDAC) of the U.S. Food and Drug Administration (FDA) voted 12 to 5 in favor of approving Probuphine, the first long-acting, subdermal buprenorphine implant for the maintenance treatment of opioid addiction, in stable patients receiving 8mg or less per day of buprenorphine. The Committee's vote followed presentation and discussion of data regarding Probuphine's efficacy, safety, and risk-benefit profile. The New Drug Application (NDA) for Probuphine was resubmitted to the FDA in August 2015, and accepted by the FDA in September 2015. A target agency action date has been set for February 27, 2016.

At the meeting, Braeburn presented efficacy data from the most recent clinical trial confirming the effectiveness of Probuphine as a six-month maintenance treatment for opioid dependence in the population studied. Multiple sensitivity analyses were also presented by both Braeburn and the FDA to evaluate the robustness of the results, which consistently favored Probuphine. Braeburn also presented summary safety findings with a focus on the Probuphine insertion and removal procedures. Braeburn's proposed Risk Evaluation and Mitigation Strategy (REMS) was presented jointly by Braeburn and the FDA.

"Medication offers the best chance for people with opioid addiction to sustain recovery, but as evidenced by the moving comments from patients, physicians and advocates at today's meeting, the few, current options are not enough to address the tremendous needs of the vast population dealing with this complex disease," said Braeburn Pharmaceuticals President and CEO Behshad Sheldon. "Our vision is to bring change to this underserved population. We are fully committed to making a lasting impact on the way this disease is treated."

"New treatment options for the millions of patients and their families suffering from opioid addiction are desperately needed, and we appreciate the Committee's comprehensive review of Probuphine," said Titan Pharmaceuticals President and CEO Sunil Bhonsle. "Probuphine has the potential to be the first marketed product to provide maintenance treatment of opioid addiction continuously for six months following a single procedure. As a subdermal implant, Probuphine could increase patient compliance, decrease the risk of diversion and improve patients' quality of life. We look forward to the Agency completing its

review of the NDA."

An open public hearing was included as part of today's Advisory Committee Meeting, and demonstrated the public's intense desire for new treatment options like Probuphine, to become available for people with opioid addiction. For over an hour, patients, advocates, physicians and clinical trial investigators spoke urging the Committee to recommend approval of Probuphine. In addition to these remarks, several letters were read, including one from mental health and addiction activist Rep. Patrick J. Kennedy, who stated, "Adding Probuphine to the short list of approved products to treat addiction is a first step in meeting the goals of government officials, while offering patients a long-term option for treatment. The active agent, buprenorphine, is already the go-to choice for providers and patients alike. The ability to now deliver the medication in a safer way for individuals, their families and society is truly a breakthrough."

The FDA is not obligated to follow the recommendations of its Advisory Committee, but will consider the Committee's guidance as it completes its review of the Probuphine NDA.

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. 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 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 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 has 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 Braeburn Pharmaceuticals
Braeburn Pharmaceuticals, an Apple Tree Partners company, is a pill-free pharmaceutical company delivering precision medicine in neuroscience. In September 2015 the Food and Drug Administration (FDA) accepted for review Braeburn's New Drug Application for its lead

candidate, Probuphine®, a six-month buprenorphine implant for treatment of opioid addiction. The Agency set February 27, 2016 as the target date for action.

Long-acting therapeutic treatment options can be essential to improving patient outcomes and facilitating recovery in these conditions, which are often complicated by stigma and present significant public health challenges. Braeburn's investigational product pipeline consists of long-acting implantable and injectable therapies for serious neurological and psychiatric disorders, including opioid addiction, pain, and schizophrenia. Candidates include: Probuphine®, a six-month buprenorphine implant for treatment of opioid addiction; CAM2038, weekly and monthly subcutaneous injection depot formulations of buprenorphine for treatment of opioid addiction and pain; a risperidone six-month implant for treatment of schizophrenia; and a novel molecule, ATI-9242, for treatment of schizophrenia. More information on Braeburn, can be found at www.braeburnpharmaceuticals.com.

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. 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.

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 the Company's development program and any other statements that are not historical facts. Such statements involve risks and uncertainties, including, but not limited to, those risks and uncertainties relating to difficulties or delays in development, testing, regulatory approval, production and marketing of the Company's drug candidates, adverse side effects or inadequate therapeutic efficacy of the Company's drug candidates that could slow or prevent product development or commercialization, the uncertainty of patent protection for the Company's intellectual property or trade secrets. Such statements are based on management's current expectations, but actual results may differ materially due to various factors, including those risks and uncertainties mentioned or referred to in this press release.

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