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Titan Pharmaceuticals Provides Update On Parkinson's Disease Clinical Development Program

SAN FRANCISCO, July 2, 2018 /PRNewswire/ -- Titan Pharmaceuticals, Inc. (NASDAQ: TTNP), a company developing proprietary therapeutics for the treatment of select chronic diseases utilizing its ProNeura™ long-term, continuous drug delivery technology, announced today that the independent Data Safety Monitoring Board ("DSMB") for the company's Phase 1/2 trial of its ropinirole implant intended for the treatment of the signs and symptoms of idiopathic Parkinson's disease has completed a review of the data from the first cohort of patients and recommended that the trial continue with enrollment of the second cohort of patients.

"We appreciate the DSMB's recommendation to continue the study and evaluate the pharmacokinetic profile, safety and tolerability of our ropinirole implant, however, we have decided to temporarily postpone enrollment of the second cohort of patients in this study," said Titan's President and CEO, Sunil Bhonsle. "Our overriding priority over the next few months is to focus our resources on driving the commercial success of Probuphine implant, the first product to provide maintenance treatment of opioid addiction continuously for six months following a single procedure. Nevertheless, we remain very committed to adding value for our stockholders based on achievements with Probuphine and our other ProNeura-based products, such as our ropinirole implant. To that end, we intend to resume enrolling patients in this Phase 1/2 trial as resources allow."

Ropinirole is a dopamine agonist currently available in daily or more frequently dosed oral formulations for the treatment of Parkinson's disease symptoms and restless leg syndrome. It is commonly used in conjunction with L-dopa to help control serious motor complications and dyskinesias that frequently occur in patients after several years of L-dopa treatment. Clinical studies have shown that these side effects are associated with fluctuating medication levels that occur with oral formulations. Titan's ropinirole implant, which was developed utilizing its ProNeura drug delivery technology, is designed for the long-term, continuous delivery of ropinirole HCL for the treatment of signs and symptoms of Parkinson's

disease. Continuous delivery of ropinirole could potentially minimize the serious motor complications experienced by some patients on oral daily dosed formulations of the medication.

Probuphine® (buprenorphine) implant

Indication & Important Safety Information

INDICATIONS AND USAGE

PROBUPHINE implant 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 equivalent 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.

IMPORTANT SAFETY INFORMATION

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.

PROBUPHINE is contraindicated in patients with a history of hypersensitivity to buprenorphine or any other ingredients in PROBUPHINE (e.g., EVA).

SUMMARY OF WARNINGS AND PRECAUTIONS

- **Respiratory and CNS Depression:** Life-threatening respiratory depression and death have occurred in association with buprenorphine particularly when taken by the intravenous (IV) route. PROBUPHINE should be administered with caution to patients taking taking benzodiazepines, CNS depressants (including alcohol) or other drugs that act on the CNS at onset of treatment. Warn patients of the potential danger of self-administration of benzodiazepines or other CNS depressants while under treatment with PROBUPHINE.
  Use in caution in patients with compromised respiratory function (e.g. COPD, cor pulmonale, decreased respiratory reserve, hypoxia, hypercapnia or preexisting respiratory depression).
- **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 doses 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.
- **Impairment of Ability to Drive and Operate Machinery:** PROBUPHINE may impair the mental or physical abilities required for the performance of potentially dangerous tasks such as driving a car or operating machinery.
- **Other systemic effects:** PROBUPHINE may cause orthostatic hypotension in ambulatory patients.
- **Effects in Acute Abdominal Conditions:** As with other opioids, buprenorphine may obscure the diagnosis or clinical course of patients with acute abdominal conditions.
- **Infection at Implant Site:** Infection may occur at the site of the insertion or removal. Excessive palpation may increase an opportunity for infection. Improper removal carries risk of implant-site infection.
- **General Precautions:** PROBUPHINE should also be administered with caution in patients with a history of keloid formation, connective tissue disease, e.g., scleroderma or history of recurrent MRSA infections.

Adverse events commonly associated with PROBUPHINE administration (>10% of subjects) were implant-site pain, pruritis, and erythema, as well as non-implant-site related events (≥5%) of headache, depression, constipation, nausea, vomiting, back pain, toothache, and oropharyngeal pain.

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

Please see FULL PRESCRIBING INFORMATION including BOXED WARNING and MEDICATION GUIDE.

About Titan Pharmaceuticals

Titan Pharmaceuticals, Inc. (NASDAQ:TTNP), based in South San Francisco, CA, is developing proprietary therapeutics primarily for the treatment of select chronic diseases. The company's lead product 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. Approved by the U.S. Food and Drug Administration in May 2016, Probuphine is 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 where maintaining consistent, around-the-clock blood levels of medication may benefit the patient and improve medical outcomes. For more information about Titan, please visit www.titanpharm.com.

Forward-Looking Statements

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 commercialization of Probuphine, the regulatory approval process, the development, testing, production and marketing of our drug candidates, patent, our ability to obtain financing on acceptable terms, 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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