

## European Medicines Agency Accepts Titan Pharmaceuticals' Marketing Authorization Application For Probuphine®

# Acceptance marks beginning of regulatory review process for opioid use disorder treatment with Probuphine in Europe

SOUTH SAN FRANCISCO, Calif., Nov. 27, 2017 /PRNewswire/ -- Titan Pharmaceuticals, Inc. (NASDAQ: TTNP), a company developing proprietary therapeutics for the treatment of select chronic diseases utilizing its ProNeura<sup>™</sup> long-term, continuous drug delivery technology, today announced that the European Medicines Agency has accepted for review its Marketing Authorization Application for Probuphine<sup>®</sup>. The acceptance marks the beginning of the EMA's regulatory review process for Probuphine for substitution treatment for opioid drug dependence, within a framework of medical, social and psychological treatment.



"The acceptance of the MAA for Probuphine is an important step toward bringing Probuphine to a wide population of patients suffering from opioid use disorder in Europe, the second largest market for buprenorphine-based products worldwide. We look forward to working with the EMA, and key stake-holders in Europe, throughout the regulatory review and approval process," said Kate Beebe, PhD, Titan's executive vice president and chief development officer.

Probuphine, a subdermal implant utilizing ProNeura, is available in the U.S. as the only sixmonth treatment for opioid dependence that delivers buprenorphine continuously.

In October 2017, Titan received a notice of allowance from the European Patent Office for a patent covering methods of use claims for treating opioid dependence with a subdermal implant containing buprenorphine. Upon issuance, this patent is expected to provide protection for Probuphine in Europe into 2023.

#### **About Titan Pharmaceuticals**

Titan Pharmaceuticals, Inc. (NASDAQ: TTNP), based in South San Francisco, CA, is developing proprietary therapeutics primarily for the treatment of serious medical disorders. The company's lead product is Probuphine<sup>®</sup>, 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<sup>™</sup>, which is capable of delivering sustained, consistent levels of medication for three months or longer. Titan has granted commercial rights in the U.S. and Canada for Probuphine to Braeburn Pharmaceuticals. 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-theclock 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 and hypothyroidism, 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 <u>www.titanpharm.com</u>.

#### 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 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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