

# Titan Pharmaceuticals Announces Date of FDA Advisory Committee Review of Probuphine(R) for the Treatment of Opioid Dependence

# Psychopharmacologic Drugs Advisory Committee Meeting Scheduled for March 21, 2013

SOUTH SAN FRANCISCO, CA -- (Marketwire) -- 02/27/13 -- <u>Titan Pharmaceuticals, Inc.</u> (OTCBB: TTNP) today announced that the Psychopharmacologic Drugs Advisory Committee (PDAC) of the U.S. Food and Drug Administration (FDA) is scheduled to review the Company's New Drug Application (NDA) for Probuphine® for the maintenance treatment of adult patients with opioid dependence on March 21, 2013.

Titan submitted the NDA for the maintenance treatment of opioid dependence in adult patients in October 2012 under Section 505(b)(2) of the Food, Drug and Cosmetic Act and referenced the approved sublingual tablet formulations of buprenorphine. On January 2, 2013, Titan announced that the FDA had accepted the Probuphine NDA for review and granted Priority Review designation. The target PDUFA date for the FDA to complete its review of the Probuphine NDA is April 30, 2013.

More information on FDA Advisory Committee meetings is available <u>here</u> on the FDA website.

## About Probuphine®

Probuphine is an investigational subdermal implant capable of delivering continuous and persistent, around the clock blood levels of buprenorphine for six months following a single treatment, simplifying patient compliance and retention. Buprenorphine, an approved agent for the treatment of opioid dependence, is currently available in the form of daily dosed sublingual tablets and film formulations, with reported 2011 sales of \$1.3 billion in the United States.

Probuphine was developed using ProNeura<sup>™</sup>, 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 a simple office procedure, and removed in a similar manner at the end of the treatment period. The drug substance is released slowly and continuously through the process of dissolution resulting in a steady rate of release similar to intravenous administration.

The efficacy and safety of Probuphine has been studied in several clinical trials, including a

163-patient, placebo-controlled study that demonstrated clinically meaningful and statistically significant treatment benefits with Probuphine over a 24-week period (<u>published</u> in the Journal of the American Medical Association (JAMA)), and a confirmatory study of 287 patients that showed statistically significant improvement in efficacy versus placebo, and non-inferiority with a currently marketed sublingual formulation of buprenorphine. Results of the confirmatory study were <u>announced</u> in July 2011. Probuphine was well-tolerated in all clinical studies, including in two open label safety studies that provided treatment with Probuphine for an additional six months to patients who completed the six-month controlled study.

### About Titan Pharmaceuticals

For information concerning Titan Pharmaceuticals, Inc., please visit the company's website at <u>www.titanpharm.com</u>.

### 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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