December 1, 2011

Titan Pharmaceuticals Confirms Regulatory Guidance for Probuphine

Company Receives Final Meeting Minutes From the U.S. Food & Drug Administration

SOUTH SAN FRANCISCO, CA -- (MARKET WIRE) -- 12/01/11 -- Titan Pharmaceuticals, Inc. (OTCBB: TTNP) today announced that final minutes of its Pre-New Drug Application meeting regarding Probuphine™, an innovative subcutaneous implant formulation of the marketed drug buprenorphine, have been received from the U.S. Food and Drug Administration (FDA) and confirm the previously announced regulatory path for the program. Titan's Phase 3 clinical program completed to date, along with its ongoing open-label safety study of re-treatment with Probuphine, expected to be completed by the end of 2011, are acceptable to the FDA to support submission of a New Drug Application (NDA) via the 505(b)(2) pathway. The meeting minutes also confirm that no additional clinical efficacy or safety studies are required to support the submission and provide clear guidance on the submission requirements for an NDA to be considered for Priority Review.

The minutes provide additional guidance on the integrated analyses and presentation of clinical data in the NDA. While the overall manufacturing process and controls were acceptable to the FDA, final determination will be made during the standard FDA review, including onsite inspections.

The FDA also confirmed that Titan should include information in the NDA on the full characterization of Probuphine and the components of the product, ethylene-vinyl acetate (EVA) and buprenorphine HCl, along with information on product stability. Titan has already completed the majority of this analytical testing and plans to complete the remainder in the next few months.

"We were very pleased to receive the meeting minutes in a timely manner and truly appreciate the guidance provided by the FDA," said Sunil Bhonsle, president of Titan. "The Titan team has been working with a number of contract companies to finalize the remaining activities and complete the required testing expeditiously, including the preparation of the NDA. We believe all of this work will be completed mid-year 2012 and we look forward to providing you with periodic updates as appropriate."

About Probuphine
Probuphine is designed to deliver six months of continuous round-the-clock, long-term therapeutic levels of the drug buprenorphine following a single subcutaneous treatment. Buprenorphine, an approved agent for the treatment of opioid addiction, is currently available mainly in the form of sublingual tablet and film formulations. The safety and effectiveness of treatment with Probuphine has been demonstrated in several late-stage and Phase 3 studies

conducted to date, including a 163-patient placebo-controlled study which demonstrated clinically meaningful and statistically significant treatment with Probuphine over a 24-week period and was published in the Journal of the American Medical Association (JAMA) and a confirmatory study of 287 patients that showed statistically significant efficacy versus placebo and non-inferiority with a currently marketed sublingual formulation of buprenorphine.

Probuphine was developed using ProNeura™, Titan's continuous drug delivery system that consists of a small, solid rod made from a mixture of ethylene-vinyl acetate (EVA) and a drug substance. The resulting product is a solid matrix that is placed subcutaneously, normally in the upper arm in a simple office procedure, and is removed in a similar manner at the end of the treatment period. The drug substance is released slowly, at continuous levels, through the process of diffusion. This results in a constant rate of release similar to intravenous administration.

About Titan Pharmaceuticals
For information concerning Titan Pharmaceuticals, Inc., please visit the company's website at www.titanpharm.com.

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, and the Company's ability to obtain additional financing. 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.

CONTACT:
Titan Pharmaceuticals, Inc.
Sunil Bhonsle
650-244-4990
President

Pure Communications
Dan Budwick
973-271-6085
dan@purecommunicationsinc.com

Source: Titan Pharmaceuticals, Inc.