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Titan Pharmaceuticals Provides Update on Confirmatory Phase 3 Study of Probuphine

SOUTH SAN FRANCISCO, CA -- (MARKET WIRE) -- 06/30/11 -- Titan Pharmaceuticals, Inc. (OTCBB: TTNP) today provided an update on its recent communications with the U.S. Food and Drug Administration (FDA) regarding the Statistical Analysis Plan (SAP) for the company's confirmatory Phase 3 study of Probuphine™ for patients with opioid dependence.

Based upon its ongoing dialogue with the FDA and to maintain the trial's clinical integrity, Titan will conduct primary efficacy analyses comparing the Probuphine and placebo arms using the trial's protocol-specified primary endpoint of the cumulative distribution function of the percent negative urine samples, as well as an additional analysis of this urine toxicology that will incorporate patients' self-reports of illicit opioid use, as requested by the FDA. Specifically, this additional analysis comparing the Probuphine and placebo arms incorporates patients' self-reported data to ensure that within the assessment time period, the number of positive urine test results correspond to at least the number of days of opioid use reported by the patient. Titan has retrospectively conducted this same type of analysis on the cumulative distribution function of the percent negative urines incorporating patient self-report data from its first controlled Phase 3 study (PRO-805) of Probuphine in patients with opioid dependence, with the findings fully supporting the previously reported positive results. The FDA has indicated that it will put primary emphasis on this additional efficacy analysis when reviewing any New Drug Application for the approval of Probuphine.

With this clarity around the trial's Statistical Analysis Plan, Titan will now commence the unblinding and analysis of the data from its Phase 3 confirmatory clinical trial and expects to report top-line results in July 2011.

The Phase 3 confirmatory clinical trial is a randomized, placebo and active controlled, multi-center study conducted at 20 sites in the U.S. treating approximately 285 patients, aged 18 to 55 years across three dosing arms: Probuphine, Titan's innovative, subcutaneous implant formulation that delivers a steady dose of the marketed drug buprenorphine over six months following a single treatment; SUBOXONE®, the approved and widely-used sublingual formulation of buprenorphine; and placebo. Patients in the trial were treated for 24 weeks and the Probuphine and placebo dosing arms were double-blinded, while the SUBOXONE arm was open-label. Titan's first placebo controlled Phase 3 clinical trial of Probuphine was completed in 2008 with positive findings published in the Journal of the American Medical Association (JAMA) in October 2010.

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.

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