August 16, 2011

Titan Pharmaceuticals Provides Additional Positive Results in Confirmatory Phase 3 Trial of Probuphine

Results to Be Discussed on Conference Call Today at 8:00 a.m. PT/11:00 a.m. ET; Data to Be Presented in Plenary Session at ISAM 2011 in September

SOUTH SAN FRANCISCO, CA -- (MARKET WIRE) -- 08/16/11 -- Titan Pharmaceuticals, Inc. (OTCBB: TTNP) today announced additional positive results from its Phase 3 placebo- and active drug-controlled confirmatory clinical study of Probuphine™, evaluating the safety and efficacy of its investigational drug in treating patients with opioid dependence. Probuphine was found to be well tolerated and Probuphine treatment resulted in a significant improvement in the global severity of opioid dependence ($p = 0.0003$) and overall patient improvement ($p = 0.0002$) versus placebo, as assessed by clinicians. The additional data analyses also confirm Probuphine's non-inferiority to the approved drug SUBOXONE®. These findings build upon the clinically meaningful and statistically significant top line data announced by Titan in July 2011, which confirmed the efficacy of Probuphine compared to placebo for two primary endpoints ($p < 0.0001$ for both). Titan has been invited to present these findings during a plenary session on September 10 and in a poster presentation on September 8 at the 13th annual meeting of the International Society of Addiction Medicine (ISAM) in Oslo, Norway.

"As a clinician, I can say that the advent and introduction of buprenorphine has absolutely changed and improved the landscape of opioid dependence treatment. However, there are also real concerns and increasing worry about medication compliance and diversion within the current treatment setting," said Walter Ling, M.D., Professor of Psychiatry and Director, Integrated Substance Abuse Programs at the David Geffen School of Medicine at UCLA and a lead investigator in the Probuphine Phase 3 study. "Probuphine represents a new, different and potentially improved method of delivering buprenorphine to patients -- one that could lessen or eliminate physicians' concerns about medication compliance and diversion."

Probuphine is an innovative, subcutaneous implant formulation that delivers a steady, round-the-clock dose of the marketed drug buprenorphine over six months following a single treatment. Probuphine, designed using Titan's proprietary ProNeura™ technology, has been developed to reduce the risk of diversion and abuse while assuring compliance to treatment and potentially improved medical outcomes.

"In my opinion, Probuphine combines the right medication with the right delivery system. We all know that people with opioid addiction may have difficulty taking effective medications reliably," said Dr. Richard N. Rosenthal, Chairman of Psychiatry at St. Luke's-Roosevelt

Hospital Center, a teaching hospital of Columbia University, and past president of the American Academy of Addiction Psychiatry. "These Phase 3 trial results confirm that this medication strategy has specific promise in our national battle against opioid dependence, in that it is both efficacious and reduces the potential risk to patients from missed doses and to the public through intentional or unintentional diversion."

The Phase 3 clinical trial was a randomized, placebo and active-controlled, multi-center study conducted at 20 sites in the U.S. that treated 287 patients, aged 18 to 60 years across three dosing arms: Probuphine (114 patients), the approved and widely-used sublingual formulation of buprenorphine, Suboxone, (119 patients) and placebo implants (54 patients). Patients were treated for up to 24 weeks and the Probuphine and placebo dosing arms were double-blinded, while the Suboxone arm was open-label. Highlights of the additional trial analyses announced today include:

- Probuphine demonstrated a statistical and clinical superiority over placebo on the Cumulative Distribution Function of the percentages of urine samples negative for opioids over the trial's weeks 1-16 ($p < 0.0001$) and weeks 17-24 ($p = 0.0002$) -- this is consistent with the findings of Titan's first Phase 3 trial of Probuphine, which was published in the Journal of the American Medical Association (JAMA) in October 2010.
- Probuphine also demonstrated statistical and clinical superiority over placebo for the 24-week treatment period in the mean percentages of urine samples negative for illicit opioids (least square mean of 36% for Probuphine versus 14% for placebo, $p < 0.0001$).
- Probuphine treatment resulted in significant improvement in clinician-rated global severity of opioid dependence ($p = 0.0003$) and clinician-rated global improvement in opioid dependence ($p = 0.0002$) versus placebo at the end of the 24-week treatment period.
- Consistent with the previously reported non-inferiority of Probuphine to Suboxone in the Cumulative Distribution Function of the percentages of urine samples negative for opioids over 24 weeks of treatment, additional data analyses confirm that there were no differences in the mean percentage of negative urine results (36% for Probuphine versus 35% for Suboxone).
- There were also no treatment differences observed between Probuphine and Suboxone in clinician-rated global severity ($p = 0.7831$) and clinician-rated global improvement ($p = 0.9881$).
- Probuphine was well tolerated -- the majority of adverse events were mild to moderate in severity and unrelated to the study treatment.
- The most common adverse events seen were:

	Probuphine	Placebo	Suboxone
Headache	13.2%	9.3%	16%
Upper Respiratory Tract Infection	8.8%	7.4%	9.2%
Depression	8.8%	3.7%	2.5%
Insomnia	7.9%	14.8%	13.4%
Sore Throat	7.0%	1.9%	3.4%

Nausea	6.1%	1.9%	6.7%
Vomiting	6.1%	1.9%	4.2%

"We believe Probuphine represents an important step forward in the treatment of opioid dependence and are looking forward to sharing additional findings with the scientific and clinical community at the ISAM annual meeting next month and at future medical conferences and in peer-reviewed publications. We are also planning to review the program at a pre-NDA meeting with the FDA this fall," said Katherine L. Beebe, Ph.D., Principal Investigator for the study and Executive Vice President and Chief Development Officer of Titan. "Another near-term priority is to establish a strategic commercialization partnership and, ultimately, to deliver a safe and effective treatment option for patients with opioid dependence."

The World Health Organization estimates that between 4.6 and 5.2 million individuals in the U.S. and Europe use illicit opioids such as heroin, and more than 2.0 million individuals in the U.S. alone are addicted to prescription opioid medications. It is estimated that more than 1.0 million people in the U.S. and Europe currently receive pharmacological treatment for opioid addiction.

Conference Call
Titan management will host a live call and webcast on Tuesday, August 16, 2011 at 8:00 a.m. PT (11:00 a.m. ET) to discuss the results of this positive Phase 3 clinical trial of Probuphine in patients with opioid dependence, as well as the Company's second quarter 2011 results. Joining the Titan management team for the call will be Dr. Ling and Dr. Rosenthal.

The live webcast of the call may be accessed by visiting our website at www.titanpharm.com. The call can also be accessed by dialing 1-888-206-4836, participant code: 6514332 five minutes prior to the start time. A replay of the call will be available on our website approximately two hours after completion of the call and will be archived for two weeks.

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.

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