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Titan Pharmaceuticals Announces Positive Top Line Results in Confirmatory Phase 3 Trial of Probuphine

Second Probuphine Pivotal Trial Shows Statistically Significant Decrease in Opioid Use for Patients Suffering From Opioid Addiction

SOUTH SAN FRANCISCO, CA -- (MARKET WIRE) -- 07/11/11 -- Titan Pharmaceuticals, Inc. (OTCBB: TTNP) today announced 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. The study results were clinically meaningful and statistically significant as demonstrated by two primary analyses, which both confirmed the efficacy of Probuphine compared to placebo ($p < 0.0001$ for the trial's protocol defined primary endpoint based on the percentages of urine samples tested negative for illicit opioid use over the 24-week treatment period and $p < 0.0001$ for the additional primary efficacy analysis of the urine toxicology with patient self-reported opioid use incorporated). Probuphine also met a key trial objective by demonstrating non-inferiority to treatment with the approved drug SUBOXONE® (12-16 mg /day). The trial further demonstrated that Probuphine was well tolerated, with an overall safety profile similar to that seen in previous studies. Titan expects that additional study findings will be reported in the coming weeks followed by a management conference call, as appropriate, and study results will be presented at scientific meetings later this year. Titan plans to request a meeting with the U.S. Food and Drug Administration (FDA) for this fall to review the Probuphine development program and plan for filing a New Drug Application.

"While buprenorphine has made a dramatic impact in the clinical treatment of opioid addiction, there is still a concern among physicians about compliance and diversion and the potential for abuse with the sublingual formulations of the drug," 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 study. "Probuphine has again shown the potential to alleviate those concerns while providing patients with a consistent and effective dose of buprenorphine. These findings are extremely important to the clinical community as opioid addiction is an undeniable -- and growing -- healthcare issue and there is a critical need for safe and effective treatments that offer patients relief without serious concerns of diversion and potential for abuse."

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.

"We are highly encouraged by these compelling findings, which confirm the positive results from our previously reported, placebo-controlled study, and believe that Probuphine represents an important medical advance in the effective treatment of patients suffering from opioid addiction," said Katherine L. Beebe, Ph.D., Principal Investigator for the study and Executive Vice President and Chief Development Officer of Titan. "We look forward to continuing our ongoing dialogue with regulatory authorities to efficiently advance Probuphine toward approval and also to progressing discussions with potential commercialization business partners."

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 trial results are provided below:

- The study demonstrated the superiority of Probuphine over placebo on the Cumulative Distribution Function of the percentages of opioid-negative urines over the 24-week treatment period ($p < 0.0001$) and this result was confirmatory and consistent with the first placebo-controlled trial published in the Journal of the American Medical Association (JAMA) in October 2010.

- The second, FDA requested primary efficacy analysis also demonstrated the superiority of Probuphine over placebo on the Cumulative Distribution Function of the percentages of opioid-negative urines incorporating patient self reported opioid use over the 24-week treatment period ($p < 0.0001$).

- Probuphine was shown to be non-inferior to Suboxone in its ability to significantly reduce illicit opioid use over the six-month trial (proportion of negative urine samples = 31% for Probuphine, 33% for Suboxone, [95% Confidence Interval of the mean difference between Probuphine and Suboxone, -10.8, 5.9], using a pre-specified non-inferiority margin of -15%), with the same rates of trial completion (64% for Probuphine; 64% for Suboxone), and a similar safety profile.

- Retention in the trial for Probuphine patients (64% completed the study) was superior to placebo patients (26% completed) ($p < 0.0002$).

- Consistent with the first controlled trial, the rates of adverse events were low and similar between treatment groups.

- The in-office procedures to administer and remove Probuphine and placebo implants were also shown to be well tolerated.

"The executive management and the board of directors are very pleased with the results of this study and would like to thank all the clinical investigators, their staff and the patients for their participation in the trial and ongoing support for the development of Probuphine," said Marc Rubin, M.D., Executive Chairman of Titan. "Just as important has been the support

received from the National Institute on Drug Abuse (NIDA), especially the $7.6 million Research and Research Infrastructure Grand Opportunities grant through the American Reinvestment and Recovery Act. These positive results should bring Probuphine another step closer to being a meaningful therapeutic alternative to patients with the disease of opioid addiction."

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.

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 the Research and Research Infrastructure Grand Opportunities Program
The purpose of the Research and Research Infrastructure Grand Opportunities program is to support high impact ideas and large-scale research projects that accelerate critical breakthroughs, early and applied research on cutting-edge technologies, and new approaches to improve the synergy and interactions among multi and interdisciplinary research teams. This initiative is being offered to help fulfill the goals of the American Recovery and Reinvestment Act (ARRA) to help stimulate the economy through support of biomedical and behavioral research. The ARRA will provide economic stimulus to the nation while furthering the NIH mission to uncover new knowledge that will lead to better health for everyone. For more information on ARRA funding, visit http://grants.nih.gov/recovery. To track the progress of Health and Human Services activities funded through the recovery act, visit www.hhs.gov/recovery. To track all federal funds provided through the recovery act, visit http://www.recovery.gov

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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