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Titan Initiates Confirmatory Phase 3 Study of Probuphine(R) in the Treatment of Opioid Addiction

SOUTH SAN FRANCISCO, Calif., March 30 /PRNewswire-FirstCall/ -- Titan Pharmaceuticals, Inc. (Pink Sheets: TTNP) today announced the initiation of a randomized, placebo and active controlled, multi-center Phase 3 clinical study of Probuphine in the treatment of opioid addiction. This confirmatory Phase 3 study will be conducted at approximately 23 sites in the United States and randomize approximately 250 patients into three arms: Probuphine (100 patients), Suboxone® (100 patients) and placebo (50 patients). The Probuphine and placebo arms will be double blinded, while the Suboxone arm will be open-label. This study is designed to confirm the safety and effectiveness of treatment with Probuphine versus placebo in reducing use of illicit opioids over the 24 week treatment period, and also to perform a non-inferiority comparison of Probuphine with Suboxone which is the widely used sublingual formulation of buprenorphine, an approved drug for the treatment of opioid addiction.

Following a Principal Investigator training meeting in early March, about a third of the sites have now been initiated and have commenced patient recruitment, with the remaining sites on schedule to be initiated in the next several weeks. We are targeting completion of patient enrollment by the end of 2010 and study completion by early Q3 2011, with results being available soon thereafter. This study is part of a registration directed program intended to obtain marketing approval of Probuphine for the treatment of opioid addiction in the United States and Europe.

"We are very pleased by the progress being made towards completion of the Probuphine Phase 3 clinical development program with the initiation of this confirmatory safety and efficacy study, and by the tremendous support for Probuphine provided by our investigators and the National Institute on Drug Abuse," said Dr. Katherine L. Beebe, Senior Vice President, Clinical Development and Medical Affairs and Principal Investigator of the study. "The study sites represent a mix of academic centers, VA medical centers and private outpatient treatment centers which today typically provide the majority of buprenorphine therapy for patients with opioid addiction," added Dr. Beebe.

Probuphine is designed to deliver six months of continuous, therapeutic levels of buprenorphine, and has the potential to reduce limitations currently associated with daily oral buprenorphine therapy, including poor compliance, variable blood levels, morning withdrawal symptoms before each daily dose, and misdirection of drug.

The safety and effectiveness of treatment with Probuphine has been initially established in the three Phase 3 studies conducted to date, specifically, a 163 patient placebo controlled study which demonstrated clinically meaningful and statistically significant treatment with

Probuphine over a 24 week period, an open label 24 week retreatment study in 62 patients who had successfully completed six months of treatment in the controlled study, and a relative bioavailability study in nine patients treated with Suboxone and then switched to Probuphine treatment for 60 days.

The National Institutes of Health (NIH) has supported this confirmatory study by awarding the company a two year $7.6 million Research and Research Infrastructure Grand Opportunities grant through the American Reinvestment and Recovery Act of 2009 (ARRA), with the first year award of approximately $5.6 million now available to Titan. This grant covers a little over half the cost of the study and it will be administered by the National Institute on Drug Abuse (NIDA).

The World Health Organization estimates that 2.8 million individuals in the U.S. andEurope are addicted to illicit opiates 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 less than 20% of this population are currently receiving pharmacological treatment.

"We are pleased to initiate this important confirmatory Phase 3 clinical study of Probuphine in the treatment of opioid addiction," stated Sunil Bhonsle, President of Titan.

"We appreciate the support of NIDA and all the clinical investigators in the development of Probuphine for treating opioid addiction, an ever increasing problem in the United States and elsewhere in the world," added Marc Rubin MD, Executive Chairman of Titan.

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 a sublingual tablet formulation under the brand names Suboxone® (buprenorphine HCl/nalaxone HCl dehydrate) and Subutex® (buprenorphine HCl).

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.

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 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 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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