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Titan Reports Patient Enrollment in Phase III Study of Probuphine® is Ahead of Schedule

SOUTH SAN FRANCISCO, Calif., Aug. 3 /PRNewswire-FirstCall/ -- Titan Pharmaceuticals, Inc. (OTC Bulletin Board: TTNP) today announced that patient enrollment is more than 60% complete in the confirmatory Phase 3 clinical study of Probuphine for the treatment of opioid addiction, and the study is expected to complete enrollment by early fourth quarter of this year, which is almost three months ahead of schedule. This placebo and active controlled Phase 3 study is being conducted at 21 sites in the United States and will randomize approximately 250 patients to be treated for six months as follows: Probuphine (100 patients), Suboxone® (100 patients) and placebo (50 patients). With full enrollment in the study by early fourth quarter of this year, the results are expected to be available by late second quarter of 2011. 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.

As previously announced, the National Institutes of Health (NIH) has awarded 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) which covers approximately half of the cost of this study, with the first year award of approximately $5.6 million available to Titan through September 2010. This grant is administered by the National Institute on Drug Abuse (NIDA).

"We are extremely pleased with the rapid progress being made towards completion of this confirmatory safety and efficacy study," said Dr. Katherine L. Beebe, Senior Vice President, Clinical Development and Medical Affairs, Titan Pharmaceuticals, and Principal Investigator of the study. "Thanks to the support for Probuphine by NIDA/NIH and the hard work of our investigators and their staff we are able to quickly advance the Probuphine Phase III clinical development program," she added.

Probuphine has the potential to reduce limitations currently associated with daily oral buprenorphine therapy, including poor compliance, morning withdrawal symptoms associated with variable blood levels 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 9 patients treated with Suboxone and then switched to Probuphine treatment for 60 days.

"These clinical sites have done an excellent job at recruiting and enrolling patients in our

study, and we look forward to completing this confirmatory study in the second quarter of next year," said Sunil Bhonsle, President of Titan Pharmaceuticals.

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 about twenty percent of this population are currently receiving pharmacological treatment.

"We are very encouraged with the progress of this important clinical study and believe that this is indicative of Probuphine's potential to serve unmet needs in the opioid addiction community for treatment alternatives," said Dr. Marc Rubin, Executive Chairman of Titan Pharmaceuticals.

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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