

# Titan Reports Completion of Patient Enrollment in Phase 3 Study of Probuphine™

# Symposium on Probuphine in October at The 2010 International Society of Addiction Medicine Conference

SOUTH SAN FRANCISCO, Calif., Sept. 22 /PRNewswire-FirstCall/ -- Titan Pharmaceuticals, Inc. (OTC Bulletin Board: TTNP) today announced that patient enrollment is now complete in the confirmatory, Phase 3 clinical study of Probuphine for the treatment of opioid addiction. This placebo and active controlled Phase 3 study is being conducted at 20 sites in the United States and the results are expected in the second quarter of 2011, about three months ahead of the original schedule. 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 encouraged by the excellent response to recruitment for this trial. Thanks to the ongoing dedication of the Probuphine Consortium of clinical investigators and their staff, we expect to report the results of this important trial significantly ahead of schedule, in the second quarter of next year," said Dr. Katherine L. Beebe, Senior Vice President, Clinical Development and Medical Affairs and Principal Investigator of the study.

This study is partially supported by a two-year\$7.6 million, Research and Research Infrastructure Grand Opportunities grant through the American Reinvestment and Recovery Act of 2009 (ARRA), and the second year allocation of approximately \$2 million has recently been approved by the National Institutes of Health (NIH). The grant is administered by the National Institute on Drug Abuse (NIDA).

Initial safety and effectiveness of treatment for opioid addiction with Probuphine has been demonstrated in a series of clinical studies. Probuphine also has the potential to reduce limitations currently associated with daily oral buprenorphine therapy, including poor compliance, withdrawal and craving symptoms associated with variable blood levels and diversion and non-medical use of the drug. Results of the Probuphine development program to date will be presented during a symposium titled "Buprenorphine Implant for the Long-Term Treatment of Opioid Dependence," on October 6, 2010 in Milan, Italy at the 2010 International Society of Addiction Medicine (ISAM) conference. The 90-minute symposium is co-chaired by Dr. Beebe of Titan and Dr. Ivan Montoya of NIDA, Division of Pharmacotherapies and Medical Consequences of Drug Abuse (DPMCDA), and will cover all aspects of the Probuphine development program from early non-clinical studies to pharmacokinetic and clinical studies demonstrating the safety and effectiveness of Probuphine. Further information about the scientific program may be found on the ISAM

website at <a href="http://www.isam2010.medicina.unimib.it/scientific">http://www.isam2010.medicina.unimib.it/scientific</a> program/day6/

The World Health Organization estimates that 2.8 million individuals in the U.S. and Europe 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.

## **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. 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.

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 <a href="http://www.recovery.gov/">www.hhs.gov/recovery</a>. To track all federal funds provided through the recovery act, visit <a href="http://www.recovery.gov/">http://www.recovery.gov/</a>.

### **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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