October 1, 2009

Titan Announces Award of NIH Grant for Probuphine(R) Clinical Development

SOUTH SAN FRANCISCO, Calif.-- Titan Pharmaceuticals, Inc (Pink Sheets:TTNP) today announced that the National Institutes of Health (NIH) has awarded a Research and Research Infrastructure Grand Opportunities grant to the company through the American Reinvestment and Recovery Act of 2009 (ARRA). The two year grant for Probuphine clinical development is expected to provide approximately $7.6 million, with the first year award of approximately $ 5.6 million now made available to Titan by the NIH. This grant will be administered by the National Institute on Drug Abuse (NIDA). These funds will directly support a substantial part of the second Phase 3 clinical study to confirm the safety and efficacy of Probuphine for the treatment of opioid addiction. Probuphine is an innovative, long-term, implantable formulation of buprenorphine that is designed to provide a constant, low level of drug for six months following a single treatment. It has the potential to address the key issues of treatment non-compliance and illicit diversion often reported with the currently available sublingual pill formulation.

Probuphine has been shown to be safe and effective in the three Phase 3 studies that have been completed to date, specifically:

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--  A six-month, double-blind, placebo-controlled safety and efficacy trial,
--  A six-month, open-label re-treatment safety trial, and
--  A pharmacokinetic safety study.
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Data from these studies have been presented at the International Society of Addiction Medicine 2008 Annual Meeting in Cape Town, South Africa, and the American Society of Addiction Medicine 2009 Annual Meeting in New Orleans, LA.

"Seeking new and better medications for treating addiction is an important part of NIDA's mission," says Dr. Nora Volkow, NIDA director. "If successful, this study will broaden the options for treating opioid dependence and give physicians and their patients meaningful information on comparative risks and benefits."

"This collaboration with NIDA will enable us to conduct the second, registration-directed, placebo-controlled trial of Probuphine as required by the FDA and significantly accelerate completion of the Phase 3 development program. We appreciate the support and guidance of our investigators which was instrumental in the success of this grant application, and we look forward to working closely with the NIDA Clinical Trial Network (CTN) in conducting this important study with the first patient expected to be enrolled in Q1 2010," said Dr. Katherine L. Beebe, Principal Investigator of the NIH study, and Senior Vice President of Clinical Development and Medical Affairs at Titan.

The pivotal Phase 3 study will be a three arm, six-month, randomized, active- and placebo-

controlled trial of Probuphine in recently diagnosed patients with opioid addiction. The active control will be the sublingual formulation of buprenorphine, Suboxone. Approximately 250 subjects will be enrolled across 20-25 experienced and qualified clinical sites, including many that are part of NIDA's Clinical Trial Network.

"We are very pleased to be awarded this NIH grant, and appreciate the support of NIDA in the development of Probuphine," said Sunil Bhonsle, President of Titan. "This substantial award recognizes the importance of developing effective treatments 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.

Probuphine Development Program

Probuphine represents an innovative technology that offers a number of potential advantages over existing therapies and may improve treatment outcome. Specifically, as an implantable delivery system, it significantly improves treatment compliance, reduces the risk of diversion, and also greatly lowers overall patient exposure to buprenorphine plasma levels over an extended treatment period compared to the currently-marketed, sublingual formulation. The first pivotal study in this Phase 3 program enrolled 163 subjects and consistently demonstrated across a number of outcome measures that Probuphine is a safe and effective treatment for opioid addiction. In this initial study, the FDA-required primary efficacy endpoint and key secondary endpoint were successfully met. Additional Phase 3 studies completed include a six-month open-label retreatment trial in 62 subjects demonstrating the safety of Probuphine for up to one year and a nine-subject pharmacokinetic study comparing relative bioavailability of Probuphine and sublingual tablets. Further discussions with the Food and Drug Administration (FDA) to confirm the final requirements of the Probuphine development program are also planned prior to commencing the next Phase 3 study.

The prosecution of the method of use patent application for Probuphine continues and on September 4 2009 Titan provided a complete response to the US Patent and Trademark Office (USPTO) addressing all the comments in the non-final office action letter issued by the USPTO in early summer.

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.

Source: Titan Pharmaceuticals, Inc