

Titan Pharmaceuticals Announces Positive Results From Phase III Clinical Trial of Probuphine for the Treatment of Opioid Addiction

Titan Pharmaceuticals, Inc. (AMEX:TTP) today announced positive, statistically significant results from its randomized, double-blind, placebo controlled, multi-center Phase III clinical trial of Probuphine(R). Probuphine is Titan's novel, subcutaneous implant formulation designed using its ProNeura technology to deliver six months of buprenorphine. Buprenorphine is currently marketed as a sublingual formulation for the treatment of opioid addiction.

Probuphine showed a clinically and statistically significant difference over placebo in illicit opioid use over 16 weeks as measured by urine testing performed three times per week ($p=0.0361$) - this was the primary endpoint acceptable to the U.S. Food and Drug Administration (FDA). Additionally, Probuphine achieved statistical significance in the Phase III trial's key secondary endpoint, the difference in illicit opioid use from weeks 17-24 ($p=0.0004$). Moreover, Probuphine treatment showed a statistically significant difference in illicit opioid use versus placebo over the full six-month (weeks 1-24) period ($p=0.0117$).

"We are extremely pleased by these positive results and the potential of Probuphine to be an important advance in the treatment of opioid addiction," said Marc Rubin, M.D., President and CEO of Titan. "Even as buprenorphine, with estimated sales of half a billion dollars in worldwide sales, is fast becoming the gold standard for opioid addiction treatment, there are growing concerns about compliance with and abuse of the currently available treatment options and a critical need for safe, effective treatment options. These data show that our proprietary subcutaneous implant can safely deliver Probuphine over six months. We look forward to completing this development program and forging strategic alliances to commercialize Probuphine worldwide."

Additional secondary efficacy analyses, including the mean percentage of urines negative for illicit opioids over treatment weeks 1-16, 17-24, and the complete six-month period also statistically favored Probuphine over placebo. Another important indicator of treatment effectiveness, patient retention, was approximately 66 percent for Probuphine compared to 31 percent for placebo. Probuphine was also well tolerated throughout the six-month trial.

"These data are very promising and I believe that the success of Probuphine should have a very significant impact on our ability to effectively treat opioid addiction," said Walter Ling, M.D., Professor of Psychiatry and Director of the Integrated Substance Abuse Programs at the David Geffen School of Medicine at UCLA, and a principal investigator in this trial. "As a clinician, I am concerned by the growing problem of opioid addiction, especially prescription opioid abuse, and the challenge of effectively treating our patients with a safe, abuse-resistant and diversion-resistant treatment. These data could translate into a dramatic change in our treatment possibilities."

Worldwide, it is estimated that there are 6 million opioid addicts. Approximately one-half of this potential patient population is addicted to illicit opioids, such as heroin, and the other half to prescription drugs, such as oxycontin, methadone, and codeine. Until recently, the only approved medication assisted therapies for opioid addiction had been available at only a limited number of authorized facilities in the U.S. As of 2000, U.S. physicians can be certified to prescribe less restricted opioid addiction medications in an office setting, which has greatly expanded patient access to opioid addiction pharmaceutical therapies. Despite these advances, this remains a highly underserved market with only about 750,000 people globally receiving medicinal treatment for opioid addiction.

Details Regarding the Phase III Trial of Probuphine for the Treatment of Opioid Addiction

This trial is a randomized, double-blind, placebo controlled, multi-center Phase III clinical study of Probuphine for the potential treatment of opioid addiction. A total of 163 patients were enrolled at 18 sites into two arms - Probuphine and placebo - for 24 weeks of treatment. Patients were randomized 2:1 (Probuphine to placebo). In both the Probuphine and placebo arms, approximately 60 percent of patients were addicted to heroin and 40 percent were addicted to prescription opioids.

Key findings include:

- For the primary endpoint, treatment with Probuphine resulted in a clinically and statistically significant difference in opioid-negative urine samples compared to placebo treatment over weeks 1-16 as measured by the cumulative distribution function of negative urines, an analysis agreed upon with the FDA ($p=0.0361$)
- Analysis of the trial's key secondary endpoint also showed positive results:
 - Treatment with Probuphine resulted in a statistically significant difference in opioid-negative urine samples compared to placebo treatment over weeks 17-24 as measured by the cumulative distribution function of negative urines ($p=0.0004$)
 - Analysis of an additional secondary endpoint showed that treatment with Probuphine resulted in a statistically significant difference in illicit opioid use as measured by mean percentage of urine samples free of illicit opioids for weeks 1-16 ($p=0.0253$) and weeks 17-24 ($p=0.0006$)
 - Probuphine also demonstrated a difference in opioid-negative urine samples compared to placebo as measured by the cumulative distribution function of negative urines over the full duration of weeks 1-24 ($p=0.0117$)
 - Probuphine was well-tolerated and demonstrated an acceptable safety profile

"It's clear from these study findings that Probuphine had an extremely positive effect on patients dealing with opioid addiction," said Paul Casadonte, M.D., Associate Clinical Professor of Psychiatry, at the New York University School of Medicine, and Director of Drug Treatment Programs at the NY VAMC, and a principal investigator in this trial. "Patients appeared to do very well and were very satisfied with the treatment. I think this treatment, with its novel formulation and delivery, could lead to a greater level of compliance and eliminate buprenorphine abuse - both of which will allow patients to more effectively treat their addiction and lead more productive day-to-day lives."

Dr. Rubin added, "These data are very exciting for Titan. We are also very enthusiastic about moving forward with Probuphine for the potential treatment of chronic pain. For many of the same reasons that Probuphine offers potential advantages for opioid addiction, it is a promising candidate for the potential treatment of chronic pain, which represents a significant unmet need and an even larger market than opioid addiction. Buprenorphine is currently approved for the treatment of chronic pain in Europe, primarily utilizing a patch formulation. Probuphine's long-term delivery and stable blood levels of drug may provide certain advantages in potential treatment of chronic pain. We look forward to further discussing the significant opportunities for Titan and Probuphine on our conference call on Tuesday."

Conference Call Details

Titan management will host a live call and webcast tomorrow, Tuesday, July 29, 2008 at 10:30 a.m. (EDT) to discuss these Phase III results. The live webcast may be accessed by visiting the investor relations section of the Company's website at www.titanpharm.com. The call can also be accessed by dialing 1-866-203-2528 (domestic) or 1-617-213-8847 (international) five minutes prior to the start time and providing the passcode 86329355. A replay of the call will be available on the Titan website approximately two hours after completion of the call and will be archived for two weeks.

About Probuphine

Probuphine is designed to provide continuous, long-term therapeutic levels of the drug buprenorphine, an approved agent for the treatment of opioid addiction. Buprenorphine is sold mainly in the form of a sublingually delivered tablet under the brand names Suboxone(R) (buprenorphine HCl/naloxone HCl dehydrate) and Subutex(R) (buprenorphine HCl). Estimated US sales in 2007 approach \$350 million. Since its U.S. approval in 2002, the number of doctors certified to prescribe buprenorphine has grown to approximately 13,000.

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 Titan

Titan Pharmaceuticals, Inc. (AMEX: TTP) is focused on the late-stage development and commercialization of innovative treatments for central nervous system disorders. In addition to Probuphine, which is Titan's first product in clinical testing to utilize its proprietary ProNeura long term drug delivery technology, the Company is planning to develop its ProNeura sustained drug delivery technology for other potential treatment applications in which conventional treatment is limited by variability in blood drug levels and poor patient compliance. ProNeura technology was developed to address the need for a simple, practical method to achieve continuous long-term drug delivery, and potentially can provide controlled drug release on an outpatient basis over extended periods of up to 6--12 months. For more information, 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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