A.P. Pharma Announces Pipeline Expansion

November 12, 2013

– First program moving into development is a long-acting anesthetic for post-surgical pain –

– Planned post marketing study for Sustol with goal of label expansion in delayed onset CINV in patients receiving HEC regimens –

REDWOOD CITY, Calif.--(BUSINESS WIRE)--Nov. 12, 2013-- A.P. Pharma, Inc. (OTCBB: APPA.OB), a specialty pharmaceutical company, today reported it has initiated a program to expand its pipeline of sustained release products, including a new program targeting the relief of post-surgical pain. The company also announced it will pursue a post-approval expansion of its leading drug program for the treatment of chemotherapy-induced nausea and vomiting (CINV) with the goal of demonstrating the utility of its lead agent, Sustol™(formerly known as APF530) in the treatment of delayed onset CINV in patients receiving highly emetogenic chemotherapy (HEC) agents. Currently there is no approved 5-HT3 receptor antagonist for the treatment of delayed HEC.

“AP Pharma continues to make significant progress toward resubmission of the NDA for Sustol targeted for the end of the first quarter 2014,” said Dr. Barry Quart, CEO of A.P. Pharma. “Our plan to initiate a new clinical trial to further expand the potential label is an indicator of our high level of confidence in this product and is part of a broader plan to build a CINV franchise. With the anticipated FDA approval of our lead product, it will be much more efficient to develop and register other drugs utilizing the same proprietary, Biochronomer™, sustained-release technology. We are very excited to move our most advanced program for post-surgical pain relief into full-scale development. This product candidate has the potential to significantly reduce the need for opiates post-surgery and reduce the length of hospital stay post-surgery.”

Post-surgical Pain Program

A.P. Pharma’s pain relief program utilizes the company’s polymer-based Biochronomer drug delivery platform to continuously release anesthetic agents directly at the source of pain over a period of several days. The company is targeting a prolonged period of anesthetic release such that therapeutic concentrations of active drug are achieved rapidly and maintained for at least 72 hours. The potential benefit of A.P. Pharma’s prolonged release profile is to achieve rapid pain relief, maintaining higher levels of active drug at the site of the pain over time to potentially provide greater relief from pain, and to maintain pain relief for up to 5 days following surgery. The current market leader, Exparel®, reduced mean pain intensity only during the first 24 hours following study drug administration; between 24 and 72 hours after study drug administration, there was minimal to no difference between EXPAREL and placebo treatments.

In animal models, the company has demonstrated continuous release of the pain-relieving agent bupivacaine for more than seven days and release of the agent ropivacaine for greater than five days. Bupivacaine and ropivacaine are well established anesthetic agents that provide short term pain relief. Based on the superior profile of ropivacaine, the company is focusing its development efforts on this anesthetic agent.

A.P. Pharma expects to move its pain program into human clinical trials in 2014. The Company will pursue approval utilizing the Food and Drug Administration’s 505(b)(2) approval process, which provides for much faster and less costly development than traditional drug approval. In 2012 approximately 24.8 million procedures were performed that were associated with post-operative pain.

Expansion of CINV Opportunity

A.P. Pharma is currently pursuing the approval of Sustol for the treatment of acute and delayed CINV in patients administered moderately emetogenic chemotherapy (MEC) agents and for the treatment of acute CINV in HEC. Currently, there is no long-acting 5-HT3 receptor antagonist approved for the treatment of delayed HEC. However, published results of large clinical trials shows that approximately 35 percent of patients receiving HEC agents experience breakthrough CINV in the delayed phase with the currently available standard three-drug regimen, leaving a significant unmet medical need for better therapy.

With the goal of addressing this significant unmet medical need and to further differentiate Sustol from all other 5-HT3 antagonists, A.P. Pharma plans to initiate a clinical study in 2014 designed to establish the utility of Sustol in the treatment of delayed onset CINV in patients receiving HEC regimens. The randomized two-arm study will compare approximately 500 HEC administered patients receiving Sustol plus the NK-1 inhibitor fosaprepitant to a similar number of HEC administered patients receiving ondansetron plus fosaprepitant. The company expects this study to complete following the resubmission and resulting PDUFA date for Sustol. If the study is successful, the company will seek to expand the Sustol label (if approved) to incorporate delayed HEC treatment on a post-approval basis.

In another example of the utility of the company’s Biochronomer platform, the company has demonstrated in animal models the simultaneous and prolonged release of three drugs commonly administered individually for the treatment of CINV. In this study, the company combined granisetron, dexamethasone and an NK-1 inhibitor to achieve desired pharmacokinetic levels of these drugs over a period of five days. The company is evaluating this three-drug combination as a potential lifecycle extension to its lead program for the treatment of CINV.

About Sustol (formerly known as APF530)

A.P. Pharma's lead product candidate, Sustol, is being developed for the prevention of both acute- and delayed-onset chemotherapy-induced nausea

and vomiting (CINV). One of the most debilitating side effects of cancer chemotherapy, CINV is a leading cause of premature discontinuation of treatment. There is only one injectable 5-HT3 antagonist approved for the prevention of delayed-onset CINV in patients receiving MEC; none are approved for delayed-onset CINV in patients receiving HEC. Sustol contains the 5-HT3 antagonist granisetron formulated in the Company's proprietary Biochronomer™ drug delivery system, which allows therapeutic drug levels to be maintained for five days with a single subcutaneous injection. Currently available intravenous and oral formulations of granisetron are approved only for the prevention of acute-onset CINV. Granisetron was selected for Sustol because it is widely prescribed by physicians based on a well-established record of safety and efficacy.

About A.P. Pharma

A.P. Pharma is a specialty pharmaceutical company developing products using its proprietary Biochronomer™ polymer-based drug delivery platform. This drug delivery platform is designed to improve the therapeutic profile of injectable pharmaceuticals by converting them from products that must be injected once or twice per day to products that need to be injected only once every one or two weeks. The Company's lead product, Sustol, is being developed for the prevention of both acute- and delayed-onset chemotherapy-induced nausea and vomiting. For further information, please visit the Company's web site at www.appharma.com.

Forward Looking Statements

This news release contains "forward-looking statements" as defined by the Private Securities Litigation Reform Act of 1995. These forward-looking statements involve risks and uncertainties, including uncertainties associated with the potential approval of APF530 and the potential timing for such approval, if approved at all, as well as risks relating to qualifying for listing on the NASDAQ Capital Market, capital resources and liquidity, satisfactory completion of clinical studies, progress in research and development programs, launch and acceptance of new products and other risks and uncertainties identified in the Company's filings with the Securities and Exchange Commission. We caution investors that forward-looking statements reflect our analysis only on their stated date. We do not intend to update them except as required by law.

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