



A.P. Pharma Revises Target Date for APF530 NDA

December 18, 2008

REDWOOD CITY, Calif.--(BUSINESS WIRE)--Dec. 18, 2008--A.P. Pharma, Inc. (NASDAQ:APPA), a specialty pharmaceutical company, today provided an update on the timing for the submission of the New Drug Application (NDA) for APF530, the company's lead product, which is being developed for the treatment of chemotherapy-induced nausea and vomiting (CINV).

Together with its regulatory consultants, the company recently completed a comprehensive review of the APF530 NDA, which is currently under development. Among the results from this assessment was a recommendation that the company conduct and include in the NDA additional sterility testing and analyses of the transfer and delivery system used in administering the product to patients. The company accepted this recommendation. The additional testing is being completed with the objective of submitting a comprehensive sterility assurance package to FDA and does not reflect any particular issues with either the transfer system or any specific concerns regarding the sterility of the product. The company has determined that with the incorporation of this additional work, the target NDA filing date would need to be adjusted from late December 2008 to the end of February 2009.

The company does not expect this delay to significantly impact the timeline for approval, which is still projected for the first quarter of 2010.

Commenting on the NDA submission, Ronald Prentki, A.P., Pharma's President and Chief Executive Officer stated, "Despite this modest deferral in the targeted filing date, I am pleased with the status of the work on the NDA submission package. Given the strength of the Phase 3 data and the additions we have made to key sections of the NDA, we believe the result will be a more complete and high quality filing, which we are confident will have a clear path forward to submission and approval. Completing and filing the APF530 NDA remains our highest priority, closely followed by establishing a commercialization partnership."

About CINV

Prevention and control of nausea and vomiting, or emesis, are very important in the treatment of cancer patients. The majority of patients receiving chemotherapy will experience some degree of emesis if not prevented with an anti-emetic, typically administered just prior to chemotherapy.

Chemotherapy treatments can be classified as moderately emetogenic, meaning that 30% to 90% of patients experience CINV, or highly emetogenic, meaning that more than 90% of patients experience CINV, if they do not receive an anti-emetic. Acute onset CINV occurs within the first 24 hours following chemotherapy treatment. Delayed onset CINV occurs more than 24 hours after treatment and may persist for several days. Prevention of CINV is significant because the distress caused by CINV can severely disrupt patient quality of life and can lead some patients to delay or discontinue chemotherapy.

About APF530 and the Phase 3 Trial

A.P. Pharma's lead product, APF530, is being developed for the prevention of both acute and delayed onset CINV. APF530 is delivered by a single subcutaneous injection and contains the 5HT₃ antagonist granisetron. Injections and oral tablets containing granisetron are approved for the prevention of acute onset CINV, but not for delayed onset CINV. Granisetron was selected because it is a potent drug and the applicable granisetron U.S. patent expired on December 29, 2007.

The pivotal Phase 3 clinical trial, initiated in May 2006, was a multi-center, randomized, observer-blind, actively-controlled, double-dummy, parallel group study that compared the efficacy of APF530 with Aloxi. In the trial patients were stratified in two groups, one receiving moderately and the other receiving highly emetogenic chemotherapeutic agents. In each group, the patients were randomized to receive in the first chemotherapy treatment cycle either APF530 high dose (10mg), APF530 low dose (5mg) or the currently approved dose of Aloxi. Standardized doses of a corticosteroid were employed in this trial, the doses used depended on the emetogenic level of chemotherapy calculated according to the Hesketh algorithm. In subsequent treatment cycles (up to three additional cycles), the patients were re-randomized to either of the two APF530 doses. In June of 2008 the company completed full enrollment and treatment of 1,395 patients in the trial. Preliminary top-line data from the trial was announced in September 2008.

About A.P. Pharma

A.P. Pharma is a specialty pharmaceutical company focused on the development of ethical (prescription) pharmaceuticals utilizing its proprietary polymer-based drug delivery systems. The company's primary focus is the development and commercialization of its bioerodible injectable and implantable systems under the trade name Biochronomer(TM). Initial target areas of application for the company's drug delivery technology include anti-nausea, where its lead product APF530 is being developed to prevent CINV, pain management, anti-inflammation and DNA/RNAi applications. For further information visit the company's web site at www.apppharma.com.

Forward-looking Statements

This news release contains "forward-looking statements" as defined by the Private Securities Reform Act of 1995. These forward-looking statements involve risks and uncertainties, including uncertainties associated with timely development, approval, launch and acceptance of new products, establishment of new corporate alliances, 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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