A.P. Pharma Expects Data from APF530 Pivotal Trial in Second Half of 2007

September 28, 2006

REDWOOD CITY, Calif., Sep 28, 2006 (BUSINESS WIRE) -- A.P. Pharma, Inc. (NASDAQ:APPA), a specialty pharmaceutical company, today announced that it expects to have initial data from its Phase 3 clinical trial with APF530 in the second half of 2007, and plans to file a New Drug Application (NDA) with the U.S. Food and Drug Administration before the end of 2007. Previously, the Company expected to have initial data from the Phase 3 trial in the first quarter of 2007. The revised timing is due to a slower-than-expected start in getting IRB approvals and clinical sites prepared to begin enrolling patients, and in recruiting patients during the summer months. The revised timeline assumes that there is only a modest improvement in the current patient enrollment rate. Based on the normal experience in this type of trial, the Company anticipates an acceleration in patient enrollment as the study progresses. The Company noted that over fifty percent of the planned 80 clinical sites for this complex double blind study are now open for enrollment. All of these sites have received IRB approval, all necessary materials and study drug and have completed site initiation visits and training. The remainder of the planned clinical sites are finalizing preparations prior to enrolling their first patients. Even though the logistical requirements of this trial are somewhat complex, the enrollment process continues to move forward. Enrollment is particularly strong at certain sites, where a number of patients have received multiple cycles of treatment. The Company stated that it is undertaking a variety of measures to accelerate enrollment rates.

A qualitative and quantitative market assessment conducted by an independent research company has confirmed the significance of the market potential for APF530 at its targeted profile. By achieving the clinical end points of the Phase 3 trial in the management of acute and especially delayed onset nausea and vomiting, which is the head-to-head trial against Aloxi, APF530 has the potential to have significant adoption rates in many oncology practices. Over 90% of the physicians reporting in the survey indicated that they would use APF530 at least some of the time with highly emetogenic chemotherapy, and over 80% of physicians reporting would use it some of the time with moderately emetogenic chemotherapy.

As part of its strategy for the regional licensing of APF530 and funding a portion of the APF530 development costs, the Company continues to pursue opportunities for partnering the development of APF530 prior to completion of the Phase 3 trials. Additionally, in order to support ongoing business requirements, the Company is exploring other general corporate financing avenues.

About APF530 and the Phase 3 Program

APF530, which contains the 5HT(3) antagonist anti-nausea drug granisetron formulated with the Company's proprietary Biochronomer(TM) bioerodible drug delivery system, is being developed for the prevention of acute and delayed chemotherapy-induced nausea and vomiting (CINV) in patients undergoing either moderately or highly emetogenic chemotherapy for cancer. No other 5HT(3) antagonist is currently approved for the prevention of both acute and delayed CINV for both moderately and highly emetogenic chemotherapy.

The APF530 Phase 3 pivotal trial protocol includes a total of approximately 1,350 patients, with approximately 675 patients receiving moderately emetogenic chemotherapy agents in one group and approximately 675 patients receiving highly emetogenic chemotherapeutic agents in another group. In each group there will initially be three arms of approximately 225 patients each; two arms will be treated with APF530, high and low dose form and a third arm will be treated with the currently approved dose of palonosetron (brand name ALOXI(R)). The study's primary endpoint is to establish the efficacy of APF530 for the prevention of acute onset (first 24 hours) and delayed onset (4-5 days) CINV in patients receiving either moderately or highly emetogenic chemotherapy.

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. Initial target areas of application for the Company's drug delivery technology include anti-nausea, pain management, anti-inflammation and DNA/RNAI applications. For further information visit the Company's web site at www.appharma.com.

Forward-looking Statements

Except for historical information, this news release contains certain forward-looking statements that involve risks and uncertainties including, among others, uncertainty associated with timely development, approval, launch and acceptance of new products, satisfactory completion of clinical studies, establishment of new corporate alliances and progress in research and development programs. Other risks and uncertainties associated with the Company's business and prospects are identified in the Company's filings with the Securities and Exchange Commission. The Company does not intend to revise these forward-looking statements to reflect events or circumstances occurring in the future.

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