



A.P. Pharma Initiates APF530 Phase 3 Clinical Trial; IRB Approval Received

April 27, 2006

REDWOOD CITY, Calif.--(BUSINESS WIRE)--April 27, 2006--A.P. Pharma, Inc. (NASDAQ:APPA), a specialty pharmaceutical company, today reported that the protocol for the Phase 3 clinical trial for APF530 has been finalized in cooperation with U.S. Food & Drug Administration (FDA) officials. Additionally, the company has received approval for the Phase 3 protocol for APF530 from the governing IRB that is responsible for overseeing the study. IRB approval of the protocol is the final step before initiation of the pivotal study.

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.

"We are extremely pleased to finalize the APF530 protocol without any significant changes following productive interactions with FDA officials, and to have received the governing IRB approval necessary to initiate many of the clinical sites. A total of 80 U.S. sites are expected to participate in this study and the recruitment of investigators is underway," stated Michael O'Connell, A.P. Pharma's president and chief executive officer. "We anticipate dosing patients in the coming weeks, and our goal is to complete patient enrollment by the end of this year. In tandem with this progress, we are actively seeking potential partners to assist in the development and commercialization of APF530."

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.

In September 2005 the Company reported success in meeting the APF530 Phase 2 study endpoints, which included an evaluation of safety, tolerability and pharmacokinetics. In addition, efficacy endpoints were evaluated relating to emetic events and the use of rescue medication. Analysis of the open-label efficacy data from the Phase 2 patient groups receiving either moderately or highly emetogenic chemotherapy indicated that the percentage of complete responders in the moderately emetogenic group was 90% in the acute phase and 78% in the delayed phase. In the group receiving highly emetogenic chemotherapy, the percentage of complete responders was 81% in the acute phase and 80% in the delayed phase. "Complete response" was defined as no emetic episodes and no use of rescue medication.

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 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 undertake to revise these forward-looking statements to reflect events or circumstances occurring in the future.

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