A.P. Pharma Announces Submission of APF530 Pivotal Trial Protocol for FDA Review; Phase 3 Trial to Compare APF530 With Palonosetron

January 24, 2006

REDWOOD CITY, Calif.--(BUSINESS WIRE)--Jan. 24, 2006--A.P. Pharma, Inc. (NASDAQ: APPA), a specialty pharmaceutical company, today announced it has submitted a protocol to the U.S. Food and Drug Administration (FDA) for a single pivotal Phase 3 clinical trial with the Company's lead product candidate APF530. The proposed trial will compare the safety and efficacy of APF530 with palonosetron (brand name ALOXI(R)) for the treatment of acute and delayed chemotherapy-induced nausea and vomiting (CINV) in patients receiving either moderately or highly emetogenic chemotherapy.

The Phase 3 protocol is based on collaborative and directional discussions with FDA officials during a recent end of Phase 2 meeting, while chemistry, manufacturing and controls (CMC) matters were agreed upon in writing. A.P. Pharma is undertaking activities to prepare for initiation of the Phase 3 trial following protocol review by the FDA, with enrollment planned to commence at the beginning of April 2006. Enrollment of patients is expected to be completed within nine months of initiation in up to 100 sites across the U.S.

The proposed Phase 3 pivotal trial protocol design includes approximately 1,200 patients comprised of two groups, including roughly equal numbers of those receiving either moderately or highly emetogenic chemotherapeutic agents. In each group, three sets of approximately 200 patients will be treated with APF530 containing 5 milligrams or 10 milligrams of granisetron, compared with the currently approved dose of palonosetron. 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. No other 5HT3 antagonist is currently approved for the prevention of both acute and delayed CINV for both moderately and highly emetogenic chemotherapy.

A.P. Pharma's decision to move into a Phase 3 clinical trial with APF530 is based on the positive safety and efficacy data from the open label Phase 2 study of APF530, in which all clinical endpoints were achieved, including an evaluation of safety, pharmacokinetics, tolerability and efficacy. There were no serious clinical adverse events attributed to the formulation and injections of APF530 were well tolerated. In that Phase 2 study, high response rates were observed in patients receiving either moderately or highly emetogenic chemotherapy.

Currently ongoing are additional toxicology studies, including 90 day repeat doses studies in rats and dogs to further assess the overall safety of the Biochronomer(TM) system, with and without granisetron. It is anticipated that these additional studies will be completed in the first quarter of this year.

The Company affirms plans to submit a New Drug Application (NDA) for APF530 with the FDA under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, if the pivotal trial of APF530 successfully meets its endpoints.

APF530 contains the anti-nausea drug granisetron formulated with the Company's proprietary Biochronomer bioerodible drug delivery system. Following a single subcutaneous injection prior to the initiation of chemotherapy, APF530 is designed to provide therapeutic plasma levels of granisetron for four to five days to prevent CINV during this period.

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, 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, timely development, approval, launch and acceptance of new products, 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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