



A.P. Pharma Reports All Clinical Endpoints Achieved in APF530 Phase 2 Trial; Conference Call to Begin at 11:00 A.M. Eastern Time Tuesday, October 4, 2005

September 29, 2005

REDWOOD CITY, Calif.--(BUSINESS WIRE)--Sept. 29, 2005--A.P. Pharma, Inc. (NASDAQ:APPA), a specialty pharmaceutical company, today reported results from its APF530 Phase 2 clinical trial. All clinical endpoints were achieved and results support advancement of APF530 into pivotal clinical trials. The primary endpoints included an evaluation of safety, pharmacokinetics and tolerability. In addition, efficacy endpoints were evaluated relating to emetic events and the use of rescue medication.

The overall results of this Phase 2 study compare very favorably with published results of other anti-emetic products, and support APF530 advancing into pivotal clinical trials, planned to be initiated in the fourth quarter of 2005, subject to ratification by the FDA. The company believes that there are sufficient data from this study to select the appropriate doses for pivotal studies.

APF530, which contains the anti-nausea drug granisetron formulated with the Company's proprietary Biochronomer(TM) bioerodible drug delivery system, is being developed for the prevention of both acute and delayed chemotherapy-induced nausea and vomiting (CINV). Preliminary data from this trial were discussed during the Company's most recent conference call on August 8, 2005.

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 in order to prevent CINV during this period. The Phase 2 study was an open-label, dose-ascending trial in patients undergoing chemotherapy for cancer. Patients in the study received an injection of APF530 containing one of three doses of granisetron: 5, 10 or 15 milligrams.

A total of 45 patients received one of the three doses. There were no serious clinical adverse events attributed to the drug and injections of APF530 were well tolerated. Overall, the safety profile of APF530 in this study was excellent.

The pharmacokinetic evaluation of granisetron in all three dose groups has now been completed. This involved the measurement of granisetron in plasma of patients undergoing chemotherapy over a seven-day period. The results clearly indicate dose proportionality on the pharmacokinetic parameters assessed, including time to maximum levels and overall systemic exposure.

The plasma profile of granisetron shows that peak values were obtained over the first 24 hours with measurable sustained levels over the next five days. No effect of age or gender on the pharmacokinetics of granisetron was observed following release from our unique APF530 formulation. Moreover, it is evident that the release of granisetron from the formulation following a single subcutaneous dose provides for sustained plasma levels over the time course of both the acute and delayed phases of the condition.

The pharmacokinetic profile of granisetron in patients undergoing chemotherapy is notably different from that in healthy individuals. At an equivalent dose of granisetron, the plasma levels of granisetron are considerably higher and more sustained in patients undergoing chemotherapy when compared with healthy individuals.

The results of this pharmacokinetic evaluation support a single injection of APF530 given 30 minutes before the initiation of chemotherapy. These results also suggest that APF530 could be given weekly in patients who are being given multiple cycles of chemotherapy at such an interval.

The efficacy of the formulation was determined by monitoring the number of emetic episodes, the use of rescue medication and the degree of nausea on a daily basis over the seven days following chemotherapy administration. By convention, the first 24 hours following chemotherapy are considered to be the "acute" phase and the subsequent days are considered the "delayed" phase. It should be noted that this study included only patients who received either moderate or highly emetogenic chemotherapy regimens.

Over the acute phase, more than 90 percent of both the 5 and 10 mg groups were complete responders, and slightly less than 80 percent were complete responders at the 15 mg dose. In the delayed phase, the percentage of complete responders was just over 90% in the 5 mg group, over 80% in the 10 mg group and just less than 70% in the 15 mg dose group. This appears to be in line with results from other products in the 5HT3 antagonist class that appear to have a slightly lower response at higher doses. "Complete response" was defined as no emetic episodes and no use of rescue medication.

It is also noteworthy in a subset of patients who were administered a highly emetogenic chemotherapy regimen that the overall percentage of complete responders was approximately 80 percent in both the acute and delayed phases of CINV. This result indicates that APF530 may find broader applicability in the complete range of chemotherapy treatments beyond the moderately emetogenic regimen.

Conference Call Information

Management will be hosting an investment community conference call beginning at 11:00 a.m. Eastern Time (8:00 a.m. Pacific Time) on Tuesday, October 4 to discuss this announcement and to answer questions.

To participate in the live call by telephone, please dial (888) 803-8275 from the U.S. or (706) 634-1287 from outside the U.S. A telephone replay will be

available for 48 hours by dialing (800) 642-1687 from the U.S. or (706) 645-9291 from outside the U.S., and entering reservation number 9996953.

Individuals interested in listening to the conference call via the Internet may do so by visiting www.appharma.com. A replay will be available on the Company's Web site for 30 days.

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 ophthalmic applications. The Company's product development programs are funded by the sale of common stock in June 2004, royalties from topical products currently marketed by pharmaceutical partners, proceeds from the divestitures of its cosmeceutical and analytical standards product lines and by fees it receives from collaborative partners. 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, 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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