A.P. Pharma Provides Regulatory Update on APF530 NDA

April 25, 2011

- NDA Resubmission Targeted for the First Half of 2012 -

REDWOOD CITY, Calif., Apr 25, 2011 (BUSINESS WIRE) -- A.P. Pharma, Inc. (OTCQB: APPA), a specialty pharmaceutical company, today provided an update on its lead product candidate, APF530, for the prevention of chemotherapy-induced nausea and vomiting (CINV).

Company management and consultants met with the U.S. Food and Drug Administration (FDA) on March 31, 2011 to discuss certain aspects of the Complete Response Letter issued by the FDA for the APF530 New Drug Application (NDA). This meeting followed an earlier meeting held with the FDA in February 2011 to discuss clinical and clinical pharmacology issues raised in the Complete Response Letter.

"A.P. Pharma has had two productive meetings with the FDA, which have helped clarify the work needed to resubmit the APF530 NDA," said John Whelan, A.P. Pharma's president and chief executive officer. "Based on our discussions with the FDA and our assessment of the work remaining, we expect to resubmit the APF530 NDA during the first half of 2012."

At the March meeting, the Company presented information concerning the product dosing system for APF530 and the characterization and manufacture of APF530. The primary topics discussed with the FDA are described below:

- The Company proposed replacing its former, two-syringe dosing system with a new, single-syringe system it has developed over the past year. The Company believes that the new system offers significant safety and convenience advantages over the old system. The FDA acknowledged that the single-syringe design would be an improvement, suggested certain labeling enhancements, and requested additional, non-clinical, human factors studies be conducted prior to resubmission.
- The FDA agreed to the Company's plan to switch to terminal sterilization of the filled product syringes.
- The Company presented additional characterization data, analytical data and revised specifications for APF530 and its constituent materials. Previously, the FDA suggested a bioavailability study would be necessary to compare materials manufactured at two separate manufacturing sites. Based on the discussions with the FDA, the Company does not see a need for a bioavailability study at this time.
- The FDA clarified which assays will be required for controlling the manufacture and quality of APF530. The Company plans to make and analyze additional lots of APF530 prior to resubmission.
- Based on the February meeting with the FDA, the Company plans to conduct a clinical study that will serve as both a thorough QT study and a metabolism study. The FDA agreed that these studies could be combined into a single study conducted in healthy volunteers.
- Also at the February meeting, the FDA indicated that the revised presentation format for the pivotal Phase 3 clinical data was acceptable for resubmission and did not request any additional efficacy studies.

The Company is currently targeting resubmission of the APF530 NDA for the first half of 2012. The FDA's review will likely take a minimum of six months. The Company has not yet received written minutes for the March meeting from the FDA, and the FDA will make its final decision once it reviews the full APF530 NDA resubmission.

About APF530

A.P. Pharma's lead product, APF530, prevents both acute-onset and delayed-onset chemotherapy-induced nausea and vomiting. APF530 contains the 5-HT_3 antagonist, granisetron, formulated in the Company's proprietary Biochronomer(TM) drug delivery system, which allows therapeutic drug levels to be maintained for five days with a single subcutaneous injection. Granisetron was selected because it is widely prescribed by physicians based on a well-established record of safety and efficacy.

About A.P. Pharma

A.P. Pharma is a specialty pharmaceutical company developing products using its proprietary Biochronomer(TM) polymer-based drug delivery technology. The Company's primary focus is on its lead product, APF530, for the prevention of CINV. A.P. Pharma received a Complete Response Letter on the APF530 NDA and is targeting the resubmission of the NDA for the first half of 2012. The Company has additional clinical and preclinical stage programs in the area of pain management, all of which utilize its bioerodible injectable and implantable delivery systems. Further work on these programs has been deferred while the Company focuses on the approval of APF530. For further information, please visit the Company's web site at www.appharma.com.

Forward-looking Statements

This news release contains "forward-looking statements" as defined by the Private Securities Litigation Reform Act of 1995. These forward-looking statements involve risks and uncertainties, including uncertainties associated with capital resources and liquidity, timely development and regulatory approval of product candidates, satisfactory completion of clinical studies, progress in research and development programs, launch and acceptance of new products 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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