



A.P. Pharma Announces PDUFA Action Date for APF530 New Drug Application Resubmission

October 16, 2012

REDWOOD CITY, Calif.--(BUSINESS WIRE)--Oct. 16, 2012-- [A.P. Pharma, Inc.](#) (OTCBB: APPA), a specialty pharmaceutical company, announced today that the U.S. Food and Drug Administration (FDA) has accepted the Company's resubmission of its New Drug Application (NDA) for APF530. The FDA has set a Prescription Drug User Fee Act (PDUFA) action date of March 27, 2013. APF530 is a long-acting formulation of granisetron and is being developed for the prevention of acute- and delayed-onset chemotherapy-induced nausea and vomiting (CINV).

"The acceptance of our New Drug Application for APF530 represents an important step towards providing physicians and patients with a potential new long-acting therapeutic agent to combat the debilitating side effects of nausea and vomiting associated with many chemotherapy treatments," said John B. Whelan, A.P. Pharma's president and chief executive officer. "We will continue working with the FDA as it reviews our NDA submission, recognizing the important role APF530 could play in reducing chemotherapy treatment side effects for cancer patients."

A.P. Pharma's NDA for APF530, which was resubmitted to the FDA on September 27, 2012, seeks approval to market and sell APF530 in the United States for the prevention of acute- and delayed-onset CINV. The NDA was submitted under section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, whereby the Company can rely upon the FDA's prior safety and efficacy findings for APF530's active ingredient, granisetron.

About CINV

Prevention and control of nausea and vomiting, or emesis, are very important in the treatment of cancer patients. The majority of patients receiving chemotherapy will experience some degree of emesis if not prevented with an antiemetic, typically administered just prior to chemotherapy.

Chemotherapy treatments can be classified as moderately emetogenic, meaning that 30% to 90% of patients experience CINV, or highly emetogenic, meaning that more than 90% of patients experience CINV, if they do not receive an antiemetic. Acute-onset CINV occurs within the first 24 hours following chemotherapy treatment. Delayed-onset CINV occurs more than 24 hours after treatment and may persist for several days. Prevention of CINV is important because the distress caused by CINV can severely disrupt patient quality of life and can lead some patients to delay or discontinue chemotherapy.

About APF530

A.P. Pharma's lead product, APF530, is in development for the prevention of both acute-onset and delayed-onset chemotherapy-induced nausea and vomiting (CINV). APF530 contains the 5-HT₃ antagonist, granisetron, formulated in the Company's proprietary Biochronomer™ drug delivery system, which allows therapeutic drug levels to be maintained for five days with a single subcutaneous injection. Intravenous and oral formulations containing granisetron are approved for the prevention of acute-onset CINV, but not delayed-onset CINV. 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™ polymer-based drug delivery platform. This drug delivery platform is designed to improve the therapeutic profile of injectable pharmaceuticals by converting them from products that must be injected once or twice per day to products that need to be injected only once every one or two weeks. The Company's lead product, APF530, is being developed for the prevention of both acute- and delayed-onset chemotherapy-induced nausea and vomiting. 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 the potential approval of APF530 and the potential timing for such approval, if approved at all, as well as risks relating to capital resources and liquidity, 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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