



A.P. Pharma Resubmits New Drug Application for APF530, a Product Candidate for the Prevention of Chemotherapy-Induced Nausea and Vomiting

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REDWOOD CITY, Calif.--(BUSINESS WIRE)--Sep. 28, 2012-- [A.P. Pharma, Inc.](#) (OTCBB: APPA), a specialty pharmaceutical company, today announced that it has resubmitted its New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for its lead product candidate, APF530, for the prevention of acute- and delayed-onset chemotherapy-induced nausea and vomiting (CINV). A.P. Pharma expects confirmation of acceptance from the FDA and a Prescription Drug User Fee Act (PDUFA) goal date within the next few weeks. The Company anticipates a six-month review by FDA.

"The resubmission of the APF530 NDA is a pivotal milestone for A.P. Pharma and brings this important therapeutic option one step closer to cancer patients suffering from CINV," said John B. Whelan, A.P. Pharma's president and chief executive officer. "Now that we have resubmitted the NDA, our focus will shift to pre-marketing and pre-commercialization activities in anticipation of potential FDA approval of APF530."

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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