



A.P. Pharma Announces FDA Acceptance of APF530 New Drug Application for Chemotherapy-Induced Nausea and Vomiting

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REDWOOD CITY, Calif.--(BUSINESS WIRE)--Jul. 20, 2009-- A.P. Pharma, Inc. (Nasdaq:APPA), a specialty pharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the New Drug Application (NDA) for [APF530](#) for the potential treatment of chemotherapy-induced nausea and vomiting (CINV). APF530 is a long-acting formulation of granisetron that utilizes the Company's proprietary Biochronomer™ drug delivery system. Based on the Prescription Drug User Fee Act (PDUFA), the FDA has issued an action date of March 18, 2010.

"The acceptance of the APF530 NDA represents another important step towards providing physicians and patients with a potential new long-acting therapeutic agent to combat chemotherapy-induced nausea and vomiting," said Ronald J. Prentki, A.P. Pharma's President and Chief Executive Officer. "Our team recognizes the important role APF530 could play in cancer care, and we are dedicated to working with the FDA as it reviews our NDA submission."

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 APF530

A.P. Pharma's lead product candidate, APF530, is being developed for the prevention of both acute and delayed onset chemotherapy-induced nausea and vomiting (CINV). APF530 contains the 5-HT₃ antagonist, granisetron, formulated in our proprietary Biochronomer™ drug delivery system, which allows therapeutic drug levels to be maintained for five days with a single subcutaneous injection. Injections and oral tablets containing granisetron are approved for the prevention of acute onset CINV, but not for delayed onset CINV. Granisetron was selected because it is widely prescribed by physicians based on a well-established record of safety and efficacy. In September 2008, A.P. Pharma reported positive top-line results from its pivotal Phase 3 study. In this multi-center, randomized trial that enrolled 1,395 cancer patients, APF530 was shown to be equally as effective as (statistically non-inferior to) palonosetron (Aloxi®) in the prevention of both acute onset and delayed onset CINV. The NDA for APF530 was submitted in May 2009 and the FDA set a Prescription Drug User Fee Act (PDUFA) date of March 18, 2010. Palonosetron is the only injectable 5-HT₃ antagonist FDA-approved for the prevention of delayed onset CINV. APF530 was also generally well-tolerated in this study.

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 anti-emetic, 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 anti-emetic. 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 A.P. Pharma

A.P. Pharma is a specialty pharmaceutical company developing products using its proprietary Biochronomer™ polymer-based drug delivery technology. The Company's primary focus is on its lead product candidate, APF530, which has completed a pivotal Phase 3 clinical trial for the prevention of CINV. The NDA for APF530 was submitted in May 2009 and the FDA set a Prescription Drug User Fee Act (PDUFA) date of March 18, 2010. 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. 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 timely development, approval, launch and acceptance of new products, satisfactory completion of clinical studies, establishment of new corporate alliances, progress in research and development programs 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.

Source: A.P. Pharma, Inc.

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