



A.P. Pharma Receives FDA Complete Response Letter for APF530

March 19, 2010

- Company to host conference call at 9:00 a.m. ET on Friday, March 19, 2010 -

REDWOOD CITY, Calif., Mar 19, 2010 (BUSINESS WIRE) -- A.P. Pharma, Inc. (Nasdaq:APPA), a specialty pharmaceutical company, today announced that it received a Complete Response Letter from the U.S. Food and Drug Administration (FDA or Agency) regarding its New Drug Application (NDA) for APF530 in the prevention of both acute and delayed onset chemotherapy-induced nausea and vomiting (CINV). APF530 is a long-acting formulation of granisetron utilizing the Company's proprietary Biochronomer(TM) drug delivery system. A conference call has been scheduled for Friday, March 19, 2010 at 9:00 a.m. Eastern Time.

A Complete Response Letter is issued by the FDA's Center for Drug Evaluation and Research when the review of a file is completed and questions remain that preclude the approval of the NDA in its current form. The primary points raised in the FDA Complete Response Letter are discussed below:

Dosing System

- The FDA expressed concerns relating to A.P. Pharma's two-syringe administration system, including potential issues with the transfer of material from one syringe to the other syringe prior to patient administration, certain components used in the dosing system and the potential risk of improper administration of the drug product.

Chemistry, Manufacturing and Control

- The FDA has completed inspections of A.P. Pharma and several of its contract manufacturing facilities. The Agency identified certain deficiencies during these inspections, and satisfactory resolution of these deficiencies will be required for approval.
- During the NDA review, the FDA asked that the Company determine if terminal sterilization with gamma irradiation is a feasible approach to enhance the assurance of sterility. A.P. Pharma has subsequently demonstrated that terminal sterilization is feasible, and the FDA has requested the Company change to terminal sterilization prior to approval.
- The FDA requested clarification and revision of certain analytical specifications proposed in the Company's NDA.

Clinical

- The FDA did not request additional clinical efficacy studies, although the Agency has asked for the re-presentation and re-analysis of select existing Phase 3 clinical trial data.
- The FDA requested the Company perform two studies relating to bioavailability and metabolism. A.P. Pharma believes these studies should be of short duration in normal volunteers.
- The FDA did not accept the Company's request to waive the requirement for a thorough QT study. A.P. Pharma believes this study should be of short duration in normal volunteers. The Company plans to discuss the design and timing of the study with the FDA.

Some of the FDA's points were addressed in recent NDA amendments by A.P. Pharma that the Agency did not review prior to issuing the Complete Response Letter. The Company believes that these amendments may address some of the issues raised in the Complete Response Letter. The FDA has indicated that A.P. Pharma may incorporate applicable sections of these amendments by specific reference in its resubmission. The Company will be contacting the FDA to request an End-of-Review meeting to discuss the Complete Response Letter. A.P. Pharma is committed to expeditiously resolving the remaining issues required for FDA approval; however, based on the anticipated time needed to prepare a resubmission, the Company does not anticipate the commercial launch of APF530 in 2010.

Conference Call and Webcast Details

A.P. Pharma's management will host a conference call on Friday, March 19, 2010 at 9:00 a.m. Eastern Time (6:00 a.m. Pacific Time) and interested investors may participate in the conference call by dialing (888) 732-6202 (domestic) or (719) 457-1017 (international) and use passcode 844199. In addition, the live conference call is being webcast and can be accessed on the "Calendar of Events" page of the "News & Events" section of the Company's website at www.appharma.com. A replay of the webcast will be available approximately two hours after the call and will be available

through April 2, 2010.

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 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. 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(R)) in the prevention of both acute onset and delayed onset CINV. 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. A.P. Pharma received a Complete Response Letter on the APF530 NDA in March 2010 and intends to respond to the issues in the Complete Response Letter in as timely and expeditious a manner as possible.

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(TM) polymer-based drug delivery technology. The Company's primary focus is on its lead product candidate, APF530, for the prevention of chemotherapy-induced nausea and vomiting (CINV). A.P. Pharma received a Complete Response Letter on the APF530 NDA in March 2010 and is in the process of preparing a resubmission responsive to the deficiencies listed in the Complete Response Letter. 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, visit the Company's web site at www.appharma.com.

A.P. Pharma's 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.

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