A.P. Pharma Presents APF530 Phase 3 Data at Annual Meeting of the American Society of Clinical Oncology

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REDWOOD CITY, Calif. & ORLANDO, Fla.--(BUSINESS WIRE)--Jun. 1, 2009-- A.P. Pharma, Inc. (Nasdaq:APPA), a specialty pharmaceutical company, today announced additional findings from the Company's Phase 3 study of APF530 for the prevention of chemotherapy-induced nausea and vomiting (CINV). The new data were included in a poster presentation during the 45th Annual Meeting of the American Society of Clinical Oncology (ASCO). APF530 is a long-acting formulation of granisetron that utilizes the Company's proprietary Biochronomer™ drug delivery system. The Company filed a new drug application (NDA) for APF530 in May 2009.

APF530 Data Presented

Preliminary data from the 1,395 patient, multi-center, randomized Phase 3 study were announced in September 2008. The results demonstrated that complete response (CR) rates for APF530 10 mg dose were non-inferior to palonosetron (Aloxi®) during acute CINV (0 to 24 hours) following moderate or highly emetogenic chemotherapy and also during delayed CINV (24 to 120 hours) following moderately emetogenic chemotherapy. In addition, the CR rate observed for APF530 in delayed CINV following highly emetogenic chemotherapy was comparable to palonosetron. APF530 was generally well tolerated, with a side effect profile consistent with previous human use of granisetron and consisting primarily of constipation and headaches. Both the rate and severity of systemic side effects were similar between the APF530 and palonosetron arms of the study.

Below is a summary of the additional data presented in today's session:

- CR rates for APF530 10 mg dose were generally higher in treatment experienced patients when compared to treatment naïve patients. Additionally, in all instances, CR rates for APF530 in treatment experienced patients were numerically higher than those observed for palonosetron. Based on previous clinical studies, many physicians believe that the risk of CINV increases with each additional cycle of chemotherapy. These new data may suggest potential utility for APF530 in treating patients who have received prior chemotherapy.
- Of the highly emetogenic chemotherapy regimens, those containing cisplatin are considered to be the most troublesome due to their ability to cause significant delayed CINV. The CR rates for patients receiving cisplatin based regimens were numerically higher for APF530 10 mg when compared to palonosetron in both acute and delayed CINV. Specifically, in acute CINV, APF530 had an 81.1% CR rate versus 75.5% for palonosetron, and 66.0% versus 60.4%, respectively, in delayed CINV.
- A pharmacokinetic analysis, conducted in a sub-group of patients, confirmed that a single APF530 10 mg dose successfully maintained blood levels of granisetron for the entire five day period.

Commenting on the results, Nash Gabrail, M.D., of the Gabrail Cancer Center and an investigator in the Phase 3 study stated "Delayed onset nausea and vomiting remains a major problem in the treatment of cancer, which can affect not only the patient's quality of life but also his or her ability to continue receiving potentially lifesaving chemotherapy. I believe physicians will welcome APF530 as a possible new addition to the treatment armamentarium for this serious unmet need."

A copy of the poster is available in the investor relations section of the Company's website, at www.appharma.com.

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. An NDA for APF530 was submitted in May 2009. 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 our proprietary Biochronomer™ polymer-based drug delivery technology. Our primary focus is on our lead product candidate, APF530, which has completed a pivotal Phase 3 clinical trial for the prevention of CINV. An NDA for APF530 was submitted in May 2009. 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.

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