A.P. Pharma Announces Positive APF530 Patient-Satisfaction Data from Phase 3 Study in Patients with Chemotherapy-Induced Nausea and Vomiting

June 29, 2012

- Poster at the Multinational Association of Supportive Care in Cancer and the International Society of Oral Oncology International Symposium -

REDWOOD CITY, Calif.--(BUSINESS WIRE)--Jun. 29, 2012-- A.P. Pharma, Inc. (OTCBB: APPA.OB), a specialty pharmaceutical company, today announced additional data from the Company's Phase 3 study of APF530 for the prevention of chemotherapy-induced nausea and vomiting (CINV). The findings from the analysis of this subset of data indicate that APF530 offered comparable nausea control and patient satisfaction to palonosetron (Aloxi®) over a 5-day period. The Company presented the study results today at a poster presentation during the Multinational Association of Supportive Care in Cancer and the International Society of Oral Oncology (MASCC/ISOO) International Symposium in New York. As previously reported, the Phase 3 study showed APF530 was comparable to palonosetron in preventing both acute- and delayed-onset CINV in patients receiving either moderately emetogenic chemotherapy (MEC) or highly emetogenic chemotherapy (HEC).

"Delayed-onset nausea and vomiting remains a major issue associated with many cancer treatment options, which can affect a patient's quality of life as well as his or her ability to sustain the recommended potentially lifesaving chemotherapy regimen," said Rebecca A. Clark-Snow, RN, BSN, OCN, clinical nurse coordinator and chair of the MASCC Antiemetic Study Group. "In particular, patients who have experienced nausea and vomiting during previous chemotherapy treatments are more susceptible to experiencing a recurrence during subsequent therapy. These data indicate that APF530 has the potential to be a promising therapy option for physicians and patients."

Study Results

The study found patient satisfaction between patients administered APF530 and palonosetron to prevent CINV following MEC or HEC were comparable, with no statistically significant differences. The severity of nausea experienced by patients in the study was also comparable with no statistically significant differences. These findings held for subgroups of patients regardless of whether, or not, they had previously received chemotherapy treatment. The study also showed that for each day of a 5-day period there were no statistically significant differences between APF530 and palonosetron in patient satisfaction and severity of nausea.

"These data indicate that APF530 has the potential to provide both comparable antiemetic effects and patient satisfaction results to palonosetron," said John Whelan, A.P. Pharma's president and chief executive officer. "Our continued analysis of the Phase 3 study further demonstrates the potential role APF530 could play as a new therapeutic agent in cancer care."

Study Design

A.P. Pharma's pivotal Phase 3 clinical trial was a multicenter, randomized, observer-blind, actively-controlled, double-dummy, parallel group study that compared the efficacy of APF530 with palonosetron. The trial stratified patients into two groups, one receiving moderately and the other receiving highly emetogenic chemotherapeutic agents in accordance with the Hesketh algorithm, which assigns emetogenic levels based on the chemotherapy agent, drug dosage and combinations employed. In each group, the patients were randomized to receive in the first chemotherapy treatment cycle either APF530 high dose (10 mg granisetron), APF530 low dose (5 mg granisetron) or the currently approved dose of palonosetron. Patients used a daily diary to record severity of nausea, vomiting/retching episodes, use of rescue medication, and satisfaction with nausea/vomiting control over a 5-day period following chemotherapy.

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 technology. The Company's primary focus is on its lead product, APF530, for the prevention of CINV. A.P. Pharma received a Complete Response Letter on the APF530 NDA and is targeting the resubmission of the NDA in mid-2012. The Company has additional research and development programs that utilize its bioerodible, injectable and implantable delivery systems. For further information, please visit the Company's web site at http://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 capital resources and liquidity, timely development and regulatory approval of product candidates, 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.

Source: A.P. Pharma, Inc.

Investor Relations Contact:
Michael Rice
Office Phone: 646-597-6979
Email: mrice@lifesciadvisors.com
and
Corporate Contact:
A.P. Pharma, Inc.
John B. Whelan, President and Chief Executive Officer
Office Phone: 650-366-2626