A.P. Pharma Announces Positive Phase 3 Results with APF530 in the Prevention of CINV

September 30, 2008

Company on Track to Submit NDA in the Fourth Quarter of 2008 Conference Call Begins Today at 9:00 A.M. Eastern Time

REDWOOD CITY, Calif.--(BUSINESS WIRE)--

A.P. Pharma, Inc. (NASDAQ:APPA), a specialty pharmaceutical company, announced today positive results from its pivotal Phase 3 study comparing the efficacy of APF530 (the Company's proprietary, sustained release formulation of granisetron) with Aloxi(R) for the prevention of chemotherapy induced nausea and vomiting (CINV). Patients in the study were classified into moderately or highly emetogenic chemotherapy levels according to the Hesketh algorithm, which assigns emetogenic levels based on the chemotherapy agent, drug dosage and combinations employed. The Phase 3 trial included 1,395 patients treated at 103 centers in the United States, Poland and India. The results announced today represent top-line data; full data from the trial will be subject to further review and analysis.

The goals of the trial were to demonstrate the safety and efficacy of APF530 in the treatment of CINV following the administration of highly or moderately emetogenic chemotherapy, and to establish an effective dose for APF530, creating a data package suitable for inclusion in the New Drug Application (NDA) the company plans to submit to the U.S. Food and Drug Administration (FDA) during the fourth quarter of 2008. In the trial 5mg and 10mg doses of granisetron were evaluated, and based on the results the 10mg dose appears to provide greater efficacy with a side effect profile similar to the 5mg dose. As such, the APF530 10mg dose will be the proposed therapeutic dose included in the NDA. The NDA will be submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, whereby the company can rely on the significant clinical data for safety and efficacy of APF530's active ingredient, granisetron.

The trial was structured to compare the two APF530 doses with Aloxi in four different assessments: acute and delayed onset CINV following both moderately and highly emetogenic chemotherapy. The 10mg dose of APF530 achieved complete response (CR) rates that were numerically higher than Aloxi across all four assessments. The results met the primary endpoint of "non-inferiority" (comparability) for three assessments, including moderately emetogenic (acute and delayed onset) and highly emetogenic (acute onset), but did not achieve the primary endpoint of superiority for the highly emetogenic delayed onset assessment. CR was defined as the absence of emetic episodes or use of anti-emetic rescue medications during a specified period of time. The time periods studied for CINV onset were acute (0 to 24 hours after chemotherapy) and delayed (24 to 120 hours after chemotherapy).

The results summarized below are the primary endpoints from the study, with such data being drawn from the first cycle of four cycles of treatment available to the patients:

Complete Response by Treatment - Cycle 1

	Treatment Group		
Emetogenicity Level	APF530 (5mg)	APF530 (10mg)	Aloxi
Moderately emetogenic	(n=214)	(n=212)	(n=208)
-- Acute onset	74.8%	76.9%	75.0%
-- Delayed onset	51.4%	59.0%	57.7%
Highly emetogenic	(n=229)	(n=240)	(n=238)
-- Acute onset	77.7%	81.3%	80.7%
-- Delayed onset	64.6%	68.3%	66.4%

Complete Response by Treatment - Cycle 1

	Statistics vs. Aloxi (Confidence Interval)	
Emetogenicity Level	5mg	10mg
Moderately emetogenic		
-- Acute onset	NI (-9.8, 9.3)	NI (-7.5, 11.4)

-- Delayed onset	I (-17.1, 4.6)	NI (-9.5, 12.1)
Highly emetogenic		
-- Acute onset	NI (-12.1, 6.1)	NI (-8.2, 9.3)
-- Delayed onset	NS (-12.4, 8.8)	NS (-8.3, 12.2)

(NI) Non-inferior efficacy was established using a modified Bonferroni step down procedure. AP530 non-inferior to Aloxi (i.e. lower bound of adjusted 95% CI for AP530), Aloxi difference excludes less than or equal to negative 15%. The Confidence Intervals shown for the moderately emetogenic and highly emetogenic levels are 97.5% and 98.3%, respectively. (NS) No significant difference. (I) Inferior efficacy.

Secondary evaluations such as number and timing of emetic episodes, degree of nausea, and use of rescue medications are consistent with the Complete Response comparisons of both doses of APF530 to Aloxi.

Commenting on the results, Ronald Prentki, A.P. Pharma's President and CEO, stated, "We are highly encouraged with the results of our Phase 3 trial and are working diligently to get our product approved for marketing as soon as possible. In the meantime, we will be carefully evaluating the best way to maximize the value of this asset for our shareholders. I would like to thank the clinical investigators and patients who participated in the study, and our employees who worked so hard over the past two years to complete the Phase 3 program, which is critical to the future of A.P. Pharma."

Mr. Prentki added, "CINV remains a significant medical problem. According to our market research there are more than 6 million cycles of chemotherapy administered each year in the U.S. We believe this equates to an annual market opportunity in excess of $1 billion. Importantly, virtually all patients who experience acute onset nausea and vomiting will also experience delayed onset nausea and vomiting. There is currently only one 5HT3 antagonist, Aloxi, that addresses both acute and delayed segments. We are delighted to have the second product to potentially address this use. We believe that the positive results announced today from one of the largest randomized clinical trials ever conducted in CINV, together with physicians' historical positive experience with our active ingredient, granisetron, will allow APF530 to play a major role in serving cancer patients."

APF530 was generally well tolerated, with a side effect profile consistent with previous human use of granisetron and only one serious adverse event reported as possibly attributed to APF530. In Cycle 1 the data showed a low incidence of patients discontinuing therapy due to any adverse events (related or unrelated to study drugs): 0.5%, 0.9% and 0.9% in the moderately emetogenic patient group, and 2.0%, 3.5% and 1.2% in the highly emetogenic patient group for APF530 5mg, APF530 10mg and Aloxi, respectively. Further, although the safety data has not yet been fully analyzed, of the patients completing the first cycle, 1,043 went on to receive a total of 2,374 additional doses of APF530 in Cycles 2 to 4. Of these patients only 2, or 0.2%, discontinued therapy due to treatment related adverse events. As expected, some APF530-treated patients experienced injection-site reactions, but of these more than 90% were mild in severity and none were severe.

As discussed previously, the CR rate for the APF530 10mg dose in delayed onset highly emetogenic patients was numerically better than Aloxi, although this difference did not achieve statistical significance. Prentki observed, "Aloxi is not approved for this indication, so we do not believe APF530 will be disadvantaged from either a regulatory or market positioning standpoint. We believe that patients clearly benefited from APF530 in the delayed onset setting following highly emetogenic chemotherapy, with the CR rates higher than those seen in the moderately emetogenic patients studied in this trial and higher than previous studies conducted with combinations of other agents in this setting. Further analysis of the highly emetogenic chemotherapy data may provide additional insights on how to approach this patient population."

John Barr, Ph.D., A.P. Pharma's Senior Vice President of Research and Development, stated, "Importantly, these data with APF530 underscore the value of our Biochronomer(TM) drug delivery technology to improve the effectiveness of a drug. In the case of granisetron, we have extended efficacy from 24 hours under its current formulation, to up to five days in a Biochronomer formulation. We are very encouraged that this demonstrates its viability as a platform technology."

Results released by A.P. Pharma are top-line data and the company is therefore unable to provide the level of detail and analysis that will be possible once the final safety and efficacy data become available and all additional sub-group analyses are completed. The company plans to release this data at a future date through publication in a scientific journal, or presentation at an appropriate medical conference.

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 30-90% 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 significant 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 and the Phase 3 Trial

A.P. Pharma's lead product, APF530, is being developed for the prevention of both acute and delayed onset CINV in patients receiving either moderately or highly emetogenic chemotherapy. APF530 is delivered by a single subcutaneous injection and contains the 5HT3 antagonist granisetron. 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 a potent drug and the applicable granisetron U.S. patent expired on December 29, 2007.

The pivotal Phase 3 clinical trial, initiated in May 2006, is a multi-center, randomized, observer-blind, actively-controlled, double-dummy, parallel group study that compared the efficacy of APF530 with Aloxi. During 2006 and the first half of 2007, all patient enrollments were within the U.S.; beginning in the second half of 2007, enrollments were broadened to include sites in India and Poland. The trial enrolled and treated 1,395 patients stratified in two groups, one receiving moderately and the other receiving highly emetogenic chemotherapeutic agents. In each group, the patients were randomized to receive in the first chemotherapy treatment cycle either APF530 high dose (10mg), APF530 low dose (5mg) or the currently approved dose of Aloxi. Standardized doses of a corticosteroid were employed in this trial, the doses used depended on the emetogenic level of chemotherapy calculated

according to the Hesketh algorithm. In subsequent treatment cycles (up to three additional cycles), the patients were re-randomized to either of the two APF530 doses.

Conference Call Information

The Company will host an investment-community conference call today beginning at 9:00 a.m. Eastern time (6:00 a.m. Pacific time) to discuss the results of the of the Phase 3 trial and answer questions.

To participate in the live call by telephone, please dial (888) 803-8275 from the U.S., or (706) 634-1287 from outside the U.S. A telephone replay will be available for 48 hours by dialing (800) 642-1687 from the U.S., or (706) 645-9291 for international callers, and entering reservation number 66813306.

Individuals interested in listening to the conference call via the Internet may do so by visiting www.appharma.com. A replay will be available on the Company's Web site for 30 days.

About A.P. Pharma

A.P. Pharma is a specialty pharmaceutical company focused on the development of ethical (prescription) pharmaceuticals utilizing its proprietary polymer-based drug delivery systems. The Company's primary focus is the development and commercialization of its bioerodible injectable and implantable systems under the trade name Biochronomer. Initial target areas of application for the Company's drug delivery technology include anti-nausea, pain management, anti-inflammation and DNA/RNAi applications. For further information 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 Reform Act of 1995. These forward-looking statements, including statements regarding the Phase 3 trial data for APF530 and the planned filing of its NDA, involve risks and uncertainties, including uncertainties associated with timely development, approval, launch and acceptance of new products, satisfactory completion of clinical studies, 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.