A.P. Pharma Reports Preliminary Clinical Data Results from Studies Using APF112 AND APF530; Conference Call to Begin Today at 12:00 Noon ET/9:00 a.m. PT

August 12, 2004

REDWOOD CITY, Calif.--(BUSINESS WIRE)--Aug. 12, 2004--A.P. Pharma, Inc. (Nasdaq:APPA), a specialty pharmaceutical company, today reported preliminary top-line results from the second part of the Phase 2 trial using APF112, and also reported initial Phase 1 data for APF530. APF112 is being tested for the treatment of pain following surgical inguinal hernia repair, and APF530 is being tested for the treatment of chemotherapy-induced nausea and vomiting.

APF112

- Safety and tolerability of APF112 as evaluated in both parts of this study (Part 1 reported March 12, 2004) were very good.

- Initial open-label study (Part 1) included a pharmacokinetic evaluation that showed measurable blood levels of mepivacaine over a three-day period.

- Blinded study (Part 2) with two doses of APF112 (150 mg and 300 mg of mepivacaine) compared with standard of care (infiltration with bupivacaine) was completed in 90 patients; top-line data was analyzed in 79 patients.

- No significant difference was shown between the two doses of APF112 and standard of care (bupivacaine) in terms of pain scores as well as amount of rescue pain medication used.

- Mean Visual Analog Scale (VAS) pain scores in the standard of care group (bupivacaine) were unusually low at approximately 3, compared with historical published data of approximately 5, within the first 24 hours post surgery.

APF530

- First dosing in six healthy human volunteers showed sustained blood levels over four days following administration.

- APF530 was well tolerated in all subjects with no unanticipated side effects.

- Further dosing with higher levels in two cohorts of six volunteers each should begin following approval by U.K. regulatory authorities in the near term. The Company notes that a change in procedures for clinical trial authorization implemented mid 2004 has led to an unexpected regulatory review delay.

- U.S. regulatory submission still planned for end of the year to allow the start of Phase 2 clinical studies.

"APF112 preliminary Phase 2 clinical results came as a surprise and a disappointment, and we intend to further analyze and evaluate the data to determine potential alternatives and next steps with that program," said Paul Goddard, Ph.D., A.P. Pharma Chairman. "We are, however, encouraged by some of the preliminary results and also by the initial data from the APF530 study, and we remain committed to the development and commercialization of bioerodible injectable and implantable delivery systems utilizing our Biochronomer(TM) polymer-based drug delivery technologies."

Preliminary Results - APF112

APF112 contains the local anesthetic mepivacaine and is designed to provide pain relief for a sustained period of time following surgery. The APF112 Phase 2 study for the treatment of pain following inguinal hernia procedures was designed in two parts. Part one of the Phase 2 study was a 10-patient open-label study completed in early 2004. In that study mepivacaine was sustained in blood levels for up to 72 hours, wound healing in all patients was observed to be normal and no adverse events were reported. In addition, both patients and physicians reported good to very good quality of pain control. Based on these results, the second part of the study was initiated.

The second part of the Phase 2 trial was a 90-patient blinded study comparing two doses of APF112 with bupivacaine, the current standard of treatment for post-surgical pain. Although the primary endpoints for the study were the evaluation of safety and tolerability, additional efficacy endpoints included a visual analog score (VAS) of pain intensity, the standard means of measuring pain, and reduction in use of opioid-type rescue pain medication such as Vicodin. Analysis of preliminary top-line clinical data from the second part of the study indicates that safety, tolerability and wound healing aspects of APF112 were very good in these patients. However, there was no meaningful trend or significant difference in clinical efficacy data between the two selected formulations of APF112 and bupivacaine. The pain scores following bupivacaine infiltration, as assessed by the VAS scale, appear to be significantly lower in this study when compared with other previously published studies in similar hernia trials for reasons that we do not yet understand. Based on published data, VAS scores for the standard of care in similar inguinal hernia studies ranged from 4.5 to 6.7, whereas in this study the mean score for the bupivacaine arm was 2.9 within the first 24 hours post surgery.

The Company and its consultants are continuing to analyze and evaluate the results of the trial, and are currently considering a variety of alternatives regarding the future of the APF112 clinical program including higher dosing levels, alternative surgical procedures and variations in current polymeric formulations.

Preliminary Results - APF530

APF530 contains the anti-emetic granisetron and is designed to provide three to five days of continuous relief from chemotherapy-induced nausea and vomiting (CINV) following a single subcutaneous injection. The polymer formulation in APF530 is the same as that included in the APF112 Phase 2 studies, which demonstrated a very good safety profile. A Phase 1 open-label clinical study with APF530 was initiated in the U.K. and analysis of preliminary data from the first arm (lowest dose) of the study indicates that pharmacokinetic measurements demonstrated measurable blood levels of granisetron over a four-day period.

These preliminary data are consistent with pre-clinical dose ranging studies and the Company therefore anticipates achieving potentially therapeutic blood levels as the remaining human dose ranging studies are completed. These initial clinical data, together with other pre-clinical and safety data, have been submitted to the U.K. regulatory authorities (MHRA) in compliance with new regulatory procedures initiated in mid 2004 in order to complete the study. These new regulatory procedures have led to an unexpected delay but the Company still plans to make a regulatory submission to the U.S. Food and Drug Administration (FDA) around the end of the year seeking permission to allow the start of Phase 2 clinical studies with APF530.

Current treatment for CINV involves the intravenous injection of the drug prior to chemotherapy to treat nausea and vomiting over 24 hours. Additionally, oral drug treatment is generally taken twice a day for three to four days in an attempt to treat delayed nausea and vomiting. It is the Company's goal to treat both the acute and delayed nausea and vomiting associated with chemotherapy following a single, small-volume subcutaneous administration of APF530.

Conference Call

Management will be hosting an investment community conference call beginning at 12:00 noon Eastern Time/9:00 a.m. Pacific Time today to discuss this announcement as well as 2004 second quarter financial results and to 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 from outside the U.S., and entering reservation number 9289034.

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.

Please note: In light of today's conference call A.P. Pharma will not be holding its previously scheduled conference call to discuss 2004 second quarter results. That call was to be held Monday, August 16 at 11:00 a.m. Eastern Time/8:00 a.m. Pacific Time.

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(TM). Initial target areas of application for the Company's drug delivery technology include pain management, anti-nausea, inflammation, oncology and ophthalmology applications. The Company's product development programs are funded by the sale of common stock, royalties from topical products currently marketed by pharmaceutical partners, proceeds from the divestitures of its cosmeceutical and analytical standards product lines and by fees it receives from collaborative partners. For further information visit the Company's web site at www.appharma.com.

Forward-looking Statements

Except for historical information, this news release contains certain forward-looking statements that involve risks and uncertainties including, among others, uncertainty associated with timely development, approval, launch and acceptance of new products, establishment of new corporate alliances and progress in research and development programs. Other risks and uncertainties associated with the Company's business and prospects are identified in the Company's filings with the Securities and Exchange Commission. The Company does not undertake to revise these forward-looking statements to reflect events or circumstances occurring in the future.

CONTACT: A.P. Pharma, Inc.
Gordon Sangster, 650-366-2626
or

Investor Relations Contacts:
Lippert/Heilshorn & Associates
Zachary Bryant (zbryant@lhai.com)
Jody Cain (jcain@lhai.com)
Bruce Voss (bvoss@lhai.com)
310-691-7100

SOURCE: A.P. Pharma, Inc.