A.P. Pharma Establishes Timetable to Re-Initiate Clinical Program for APF112; Company provides regulatory update on progress towards Phase II clinical studies

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REDWOOD CITY, Calif.--(BUSINESS WIRE)--Dec. 3, 2002--A.P. Pharma, Inc. (NASDAQ:APPA) today reported that Company executives have met with U.S. Food and Drug Administration (FDA) officials to review the Company's proposals to proceed with the clinical development of its lead proprietary product, APF112. The action plans agreed to at the meeting will be implemented immediately and, assuming that the preclinical testing proceeds as planned, the company expects to submit a new Phase II protocol for APF112 to the FDA by the middle of 2003.

APF112 is a development-stage Biochronomer(TM)-based product containing mepivacaine that is designed to provide 24 to 36 hours of pain relief following certain surgical procedures. The Phase II protocol was withdrawn in August 2002 following concerns raised by the FDA on observations of irritation in both active and control animal groups.

A number of key decisions reached at the meeting include:

- The initial clinical target for APF112 will be pain relief following abdominal surgery. Clinical trials will study the potential benefit of APF112 introduced at the site of a surgical wound at the time of surgery. The Company believes that this indication will provide a more direct regulatory pathway compared with the original clinical target of pain relief following arthroscopic knee surgery. More than 6.5 million abdominal surgeries are performed annually in the U.S.
- The preclinical studies proposed at the meeting will be initiated immediately. They have been designed so that the measurement and resolution of any irritation that may occur will be observed for an extended time beyond the intended therapeutic period.
- The formulation of APF112 will be modified to minimize irritation. Recent animal testing suggests that modified formulations result in a minimal inflammatory response.

"We are very encouraged by our recent discussions with the FDA and the comprehensive and expeditious way in which the Agency reviewed our submission," said Michael O'Connell, President and CEO of A.P. Pharma. "We are now proceeding with the implementation of the action plans and the initiation of the preclinical studies," he added.

About APF112 and the Biochronomer System

APF112 is an injectable gel specifically designed to provide 24 to 36 hours of pain relief at the surgical site. Multiple clinical opportunities for such a product have been identified, especially in patients who undergo a surgical procedure and are discharged on a same day basis. Optimal pain management therapy is not achieved in these patients and the use of a long acting formulation of mepivacaine is anticipated to provide a significant improvement in pain management in this patient population. The active ingredient, mepivacaine, is an off-patent drug currently used for short-term, localized pain relief. Additional potential benefits of APF112 include minimizing the use of morphine-like opioids, which can have serious side effects.

A.P. Pharma's patented Biochronomer system is specifically designed for delivering medical therapies. The Company's bioerodible polymers are simple to synthesize, and are reproducible, scalable and stable at room temperature. Drug delivery can be varied from hours to days, weeks or months, and the polymer's mechanical properties can be adjusted to produce materials ranging from injectables, to strands or rods, wafers or films and microspheres.

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 targeted areas of application for the Company's drug delivery technology include pain management, inflammation, oncology and ophthalmology applications. The Company's product development programs are funded by royalties from topical products currently marketed by pharmaceutical partners and by proceeds from the divestiture of its cosmeceutical product lines as well as 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.

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