



A.P. Pharma Ready to Initiate Phase II Studies With APF112; Company Plans to Initiate Phase II Clinical Trials in September

August 26, 2003

REDWOOD CITY, Calif.--(BUSINESS WIRE)--Aug. 26, 2003--A.P. Pharma, Inc. (Nasdaq: APPA) today announced it intends to initiate a Phase II study for its post-surgical pain product, APF112, in the next month. In July, the Company submitted a comprehensive data package to the U.S. Food and Drug Administration (FDA) which included a proposed Phase II protocol. Following a review with FDA officials, the Company was given clearance to initiate the proposed clinical study. The Company intends to initiate Phase II trials with APF112 in September 2003 for the treatment of pain in patients following repair of inguinal hernia.

APF112 incorporates mepivacaine, a local anesthetic with analgesic properties, which has been used extensively in clinical practice for several years and provides good but short-term pain relief following surgery. In animal studies, APF112, which incorporates the Company's Biochronomer(TM) bioerodible drug delivery system, has demonstrated prolonged analgesic effect. APF112 is designed to provide 24-36 hours of post-surgical pain relief and to minimize the use of morphine-like drugs (opioids), which are used extensively in post-surgical pain management. Opioids are associated with a wide range of side effects, such as nausea, sedation, dizziness, constipation, vomiting, urinary retention, and in some situations life-threatening respiratory depression.

The APF112 Phase II trial will be conducted in two parts involving a total of approximately 100 patients. The first part will be an open label safety assessment. The second part is a blinded study comparing two doses of APF112 with current standard treatments for post-surgical pain. The end point for the trial will include a visual analog score of pain intensity, the standard means of measuring pain, and patient reduction in opioid-type pain medication.

"We are pleased to be moving into Phase II clinical trials with APF112," said A.P. Pharma President and CEO Michael O'Connell. "In preparing for this trial, we presented a comprehensive package to the FDA that included the results of studies designed to demonstrate the biocompatibility of the polymer, and extensive preclinical safety studies using the enhanced APF112 formulation for the treatment of post-surgical pain.

"Our plan is to complete the patient studies by the end of this year, and seek to enter a corporate partnership in conjunction with initiating pivotal studies in 2004," added Mr. O'Connell.

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 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, by 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.

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SOURCE: A.P. Pharma, Inc.