



## **A.P. Pharma Files First Investigational New Drug Application for APF112 Formulation Using Biochronomer System**

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Lead Product for Post-Surgical Pain Cleared to Commence Phase I Clinical Trials

REDWOOD CITY, Calif.--(BW HealthWire)--Dec. 20, 2001-- A.P. Pharma Inc. (Nasdaq: APPA), a specialty pharmaceutical company, today announced that it has received clearance from the U.S. Food and Drug Administration (FDA) to begin Phase I clinical trials of APF 112, the company's lead product candidate for the treatment of post-surgical pain.

The company will begin its Phase I clinical trials in the next four weeks and anticipates that it will commence a Phase II clinical trial in the second half of 2002, subject to acceptance of the clinical protocol.

APF 112 is designed to provide 24 to 36 hours of localized post-surgical pain relief utilizing the company's proprietary Biochronomer(TM) drug delivery system, minimizing the need for opiates. Currently, opiates are used in the majority of post-surgical procedures as a means of pain management, with unpleasant side effects including nausea, constipation and disorientation.

APF 112 incorporates mepivacaine, an amide-type local anesthetic, which has been used extensively in clinical practice for several years. As an aqueous solution, it is effective in relieving pain for short periods only. In numerous animal studies, APF 112 using the bioerodible Biochronomer system has demonstrated prolonged duration of anesthetic effect.

"Our lead product focuses on the area of post-surgical pain, an underserved market estimated to be \$500 million annually," said Michael O'Connell, A.P. Pharma's president and chief executive officer. "In addition to our plans to commence Phase I clinical trials on our lead product, we are also preparing for the filing of an IND for A.P. Pharma's second clinical candidate in the second half of 2002."

### **About the Biochronomer System**

The Biochronomer polymer system is a family of bioerodible polymers specifically designed for drug delivery. The entire family of polymers is a versatile delivery platform, which can deliver drugs over a wide range of time periods. The first generation of this family has been designed for the short-term release of pharmaceutically active materials. This generation of polymers, frequently referred to as the "semi-solid" form of the polymer, has been the internal focus of the company for a variety of commercial applications.

### **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 targeted areas of application for the Company's drug delivery technology include pain management, inflammation, anti-adhesion and protein delivery applications. The Company's product development programs are funded by royalties from topical products currently marketed by pharmaceutical partners and proceeds from the divestiture of its cosmeceutical product lines. For further information visit the Company's Website at [www.appharma.com](http://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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