



## **A.P. Pharma Receives Additional Patent for 5-FU Microsponge Formulation; Patent Covering Carac Formulation Extended to 2021**

September 17, 2003

REDWOOD CITY, Calif.--(BUSINESS WIRE)--Sept. 17, 2003--A.P. Pharma, Inc. (Nasdaq:APPA) today announced that the Company has received a notice of allowance from the U.S. Patent and Trademark Office (USPTO) extending patent coverage to 2021 for the use of its Microsponge(R) delivery system in its formulation containing 5-fluorouracil. The Company receives royalties on this formulation from marketing partner Dermik Laboratories Inc., an Aventis company, on sales of Carac(TM) in the U.S. for the life of the patents.

Carac is a once-a-day topical prescription product for the treatment of actinic keratoses (AK), a common precancerous skin condition caused by over-exposure to the sun. The product has a number of advantages over existing topical therapies, including less irritation with shorter duration of therapy and reduced dosage frequency. Since its launch in April 2001, Carac has captured approximately 25% of the U.S. topical market for AK.

In 1999 the Company received a notice of allowance from the USPTO extending patent coverage to 2016 for use of its Microsponge technology with tretinoin, which is marketed as Retin-A Micro(R) by Ortho Neutrogena, a Johnson & Johnson company. Retin-A Micro is a leading prescription treatment for mild to moderate acne. Retin-A Micro was launched in the U.S. in 1997 and in Canada in 2001. A lower dose formulation of Retin-A Micro was introduced in the U.S. in 2002 after receiving U.S. marketing approval.

A.P. Pharma's royalty income last year totaled more than \$4 million and to date this year has grown by 18%. This additional patent now extends royalty income from Carac sales to 2021. Combined with patents on Retin-A Micro, which last until 2016, A.P. Pharma's royalty income from these two product lines is expected to continue to grow both through increased U.S. sales and introductions in additional markets. Royalty income is key in the Company's strategy to support product development programs incorporating its site-specific Biochronomer(TM) drug delivery systems.

### **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](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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