

PRESS RELEASE

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APR and Fidia have received IND approval from FDA for a new NSAID Matrix Patch product

Balerna, Switzerland, and Abano Terme (PD) Italy, November 17th, 2008 – Applied Pharma Research sa (APR), and Fidia Farmaceutici SpA (Fidia) today announced that the U.S. Food and Drug Administration (FDA) has accepted the Investigational New Drug (IND) application for the development of a 140mg Diclofenac Sodium Matrix Patch for the topical treatment of acute pain due to minor strains, sprains and contusions.

The Diclofenac Sodium Matrix Patch uses a proprietary technology able to deliver the active ingredient directly to the affected area, thus providing sustained pain relief without the systemic exposure and GI side effects typical of oral NSAIDs or the cardiovascular risks associated with the Cox-2 inhibitors. The proprietary co-developed Matrix Patch technology has several advantages over conventional marketed hydrogel plasters, such as higher adhesive properties, elasticity (long and crosswise), minimal thinness, a superior high tech look as well as ease of use

APR and Fidia are co-developing the product under a joint global partnership. In the United States, APR and Fidia intend to submit a 505(b)(2) NDA referencing the Flector[®] patch (diclofenac epolamine 1.3%) that was recently introduced into the market. The completion of the clinical development and filing of the dossier with the FDA is expected during Q1/2010.

“We are very pleased about the comments received by the FDA on the diclofenac patch IND” says Paolo Galfetti, CEO of APR “We have now a well defined path to registration that will help us to quickly reach and participate to the fast growing topical NSAIDs market in the US”

As Antonio Germani, Fidia’s CEO, stated "Receiving FDA’s positive consideration for our next generation diclofenac sodium Matrix Patch is a further accomplishment for our team and another key milestone in our worldwide leadership in the joint care field."

A parallel development program is being carried out in Europe with three pivotal studies being conducted in ankle sprains (once-a-day application for 7 days), lateral epicondylitis and osteoarthritis (BID application for 14 days). The registration application will be a decentralized procedure using France as the reference country. Filing is also expected in Q1/2010. The Diclofenac Sodium Matrix Patch is already approved and marketed in Italy since 2005 by a major multinational company under license from APR/Fidia and has already been licensed in select European markets to a France-based multinational company. It is available for licensing in North America and other international markets.

Topical NSAIDs products, and particularly patches, have been a well established and accepted delivery form for this class of anti-inflammatory agents for several years in Europe and Japan. In the United States, the first NSAID patch was successfully introduced in January of 2008 and is expected to generate more than US\$ 150 million in sales in its first year of commercialization and peak sales in excess of US\$ 500 million. Sales of NSAIDs/Cox-2 inhibitors in the United States exceed US\$ 6 billion annually and the topical segment is expected to grow to account for more than 20% of that total by the year 2012.

“Although the APR/Fidia diclofenac patch was introduced in Italy 6 years after Flector[®]” says Antonio Germani, CEO of Fidia “the two products have now similar volume of sales and account for approximately



26% of the patch segment, i.e., 60% of the total Flector® sales. We are confident the product will have the same successful acceptance among doctors and consumers in the United States.”

About APR Applied Pharma Research s.a.

APR Applied Pharma Research s.a. (APR) is an international Drug Research & Development company headquartered in Switzerland that develops Rx, medical devices and OTC products using its own proprietary technologies and out-licenses them at late stage of development for distribution and marketing. APR also provides contract product development services based on its technologies. Leveraging on its own technology platforms, R&D know-how and marketing and regulatory systems, APR is committed to create new sustainable value on its own as well as on third party products and projects. The APR products and technologies are licensed to R&D activities are carried out directly or under contract. APR has signed licensing agreements with pharmaceutical companies in about 35 countries worldwide and its sales are almost totally achieved abroad.

About Fidia Farmaceutici S.p.A.

Fidia Farmaceutici S.p.A. is a fully integrated, Italian pharmaceutical company that operates worldwide, to develop and market innovative medicinal products, medical devices, nutritional supplements and biomaterials, mainly based on proprietary technology and know-how since 1946. Fidia distributes its products worldwide, through an established network of over 80 international partners, and has acquired a long-standing experience in the U.S. and Canada markets with its injectable and topical products based on hyaluronic acid and its derivatives for the treatment of movement-related pathologies. Fidia is now including highly sophisticated finished products among the company's strategic assets, with integrated industrial projects and high-quality standards, thanks to its facilities and state-of-the-art equipment for the production of oral, topical, and injectable forms. Manufacturing for third parties has also become a core business for Fidia, which complies with the strictest international guidelines for the manufacturing of pharmaceuticals.

Contacts:

Applied Pharma Research - www.apr.ch

Paolo Galfetti; CEO
T: +41 91 6957020
paolo.galfetti@apr.ch

Aldo Donati
APR Applied Pharma Research USA, LLC
T: (704) 641-1586
aldo.donati@apr.ch

Fidia Farmaceutici SpA – www.fidiapharma.com

Antonio Germani, CEO
T:+39 049 8232 770
agermani@fidiapharma.it