



PRESS RELEASE

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Title:

APR Applied Pharma Research s.a. (“APR”) announces a New Drug Application has been initiated for its Immediate Release Diclofenac-K 50mg Sachet for Migraine by its United States licensee ProEthic Pharmaceuticals, Inc

Balerna (Switzerland). A new success for APR Immediate Release Technology. After the launch of APR Immediate Release Diclofenac-K 50mg Sachet for Migraine by Novartis Pharma AG, under the trademarks Voltfast® or Catafast® in Switzerland, Italy, Egypt, Mexico, Hong Kong, Taiwan and the plan to launch the product in a dozen additional countries where Novartis Pharma AG has recently obtained the marketing approval, Pro-Ethic Pharmaceuticals Inc, the US licensee of APR, has announced yesterday the filing of APR Immediate Release Diclofenac-K 50mg Sachet for Migraine, as its lead product candidate for the treatment of migraine headaches, as a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) with the provisional name PRO-513.

Earlier this year, ProEthic announced that all co-primary endpoints of the U.S. Phase III IMPACT trial for PRO-513 were successfully achieved. These endpoints included pain relief and the symptoms associated with migraine, including photophobia (sensitivity to light), phonophobia (sensitivity to sound) and nausea. PRO-513, a proprietary formulation of diclofenac potassium powder for oral solution, achieved statistical superiority to placebo in pain relief and nausea, photophobia and phonophobia at two hours for all conditions. In addition, results demonstrated that PRO-513 began to relieve the pain of migraine for patients within 30 minutes and that its benefits persisted up to 24 hours. PRO-513 was well tolerated in the eight month, randomized, double-blind, placebo-controlled trial.

“The filing of a NDA for our top IR Diclofenac preparation is a confirmation that we did not make just another Diclofenac , APR has developed a new drug based on Diclofenac with unique efficacy and safety profiles for the treatment of Migraine and Acute Pain in general” said Paolo Galfetti, CEO of APR Applied Pharma Reserach SA. “Our patented Immediate Release (IR) technology enhances the absorption of its active ingredient, diclofenac potassium by utilizing potassium bicarbonate as a localized buffer, IR enables diclofenac to enter the bloodstream more quickly, resulting in a faster rate of drug absorption and increased peak plasma concentrations while not increasing the total amount of drug exposure for the patient compared to currently marketed reference drug, Cataflam®. We have developed a full range of dosages (50mg, 25mg and 12,5mg) and oral forms (Sachet, Oral Solution, Film Coated Tablets) of IR Diclofenac , targeting all the range of acute pain , migraine and post-operative pain. It’s not common these days to have available a full range of truly innovative products in this field and we are confident we will complete our worldwide licensing effort soon by finding other companies willing to market these preparations in their target territories.”

Carl Whatley, Chairman and CEO of ProEthic Pharmaceuticals, stated, “The filing of an NDA for PRO-513 represents an important milestone for ProEthic; and our drug development team deserves the highest of praise for executing the filing in such an accelerated fashion. Our team successfully advanced PRO-513 from an Investigational New Drug to an NDA filing in approximately 18 months, an impressive achievement for an organization of any size. If approved, we believe PRO-513 could meet the recognized and growing demand by patients and physicians alike for new options to treat



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migraines. We look forward to working with the FDA during the registration process and remain committed to advancing the standard of care for the 30 million migraine sufferers in the U.S.”

About APR Applied Pharma Research

APR Applied Pharma Research SA is a privately owned internationally oriented Drug Delivery company with registered offices in Switzerland. It is focused in the research & development of innovative and patented drug delivery systems as well as innovative pharmaceutical products primarily for oral and topical administration. The APR products and technologies are licensed to third parties for distribution and marketing activities. 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. Interview Contact: Paolo Galfetti, CEO Telephone: +41.91.6957020 Email: paolo.galfetti@apr.ch Website: www.apr.ch

About ProEthic Pharmaceuticals, Inc.

ProEthic is an emerging specialty pharmaceutical company enhancing treatment strategies initially in the areas of pain and migraine. Founded in 2001, the privately held company focuses its efforts on the acquisition, development, licensing, and marketing of pharmaceutical products. ProEthic also markets niche generic prescription pharmaceutical products through Midlothian Laboratories LLC, a wholly owned subsidiary. For more information, please visit the ProEthic website at: www.proethic.com

Contacts:

Paolo Galfetti; CEO

APR Applied Pharma Research s.a., www.apr.ch

Via Corti 5, CH - 6828 Balerna, Switzerland

T: +41 91 6957020

Lauren Vinson; Director of Public Relations

ProEthic Pharmaceuticals, Inc.

Phone: (334) 288-1288

Email: lvinson@proethic.com