



For Immediate Release
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APR announces today successful Phase III clinical trial results for PRO-513, its product candidate for the treatment of migraine headaches licensed in 2005 to the Montgomery (Alabama) based ProEthic Pharmaceuticals, Inc.

In an eight month randomized, double-blind, placebo-controlled trial that enrolled 690 adult patients, PRO-513, a proprietary formulation of diclofenac potassium powder for oral solution originally developed by APR Applied Pharma Research s.a. (APR) and assigned to ProEthic Pharmaceuticals, Inc. (ProEthic) for North America, reached all of its primary endpoints by achieving statistical superiority to placebo in pain relief (p greater than 0.001) and the associated symptoms of nausea ($p=0.002$), photophobia or sensitivity to light (p less than 0.001) and phonophobia, or sensitivity to sound (p less than 0.001) at two hours for all conditions. PRO-513 was well tolerated in the study, with no safety issues reported.

"These trial results are a significant achievement for ProEthic and a critical step forward in our efforts to improve the treatment options available to the 30 million Americans who experience migraine headaches," said Carl Whatley, Chairman and CEO of ProEthic. "These results add to the extensive body of clinical data demonstrating PRO-513's potential advantages over current treatments in safety and efficacy, as well as its ability to offer the more rapid form pain relief sought by migraine sufferers and their physicians. We are thrilled at the performance by our clinical team in successfully completing this study and look forward to working with the FDA on the approval for this product candidate."

Richard B. Lipton, MD, Professor and Vice Chair of Neurology at the Albert Einstein College of Medicine and Director of the Montefiore Headache Center and study principal investigator, said, "The results are good news for migraine sufferers. Diclofenac, in this new formulation, rapidly relieved the pain of migraine and the associated symptoms, including nausea, sensitivity to light and sensitivity to sound."

"These trial results represent additional clear evidence of the APR's capacity to create new significant value on well established, sometimes heavily genericized, drugs" said Paolo Galfetti, CEO of APR Applied Pharma Research s.a. "our ability to leverage on our platform drug delivery systems, on our know how and deep knowledge of the development and regulatory systems are key for the successful identification, development and licensing of promising candidates and projects".



Under the terms of the Agreement between APR and ProEthic, these US Phase III trials can be also used by APR to seek regulatory approvals in all the countries outside US and Canada. "These trials represent a great valuable asset for APR in its attempts to relieve migraine sufferers outside US" continued Paolo Galfetti, CEO of APR.

Technology Platform

PRO-513 utilizes patented Dynamic Buffering Technology (DBT) originally developed by APR and assigned to ProEthic for the North American markets, which enhances the absorption of its active ingredient, diclofenac potassium. By utilizing potassium bicarbonate as a localized buffer, DBT 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(R).

About Migraines and PRO-513 Development History

Migraine headaches affect an estimated 30 million people in the United States and disproportionately affect women 3 to 1. According to a recent peer reviewed publication authored by leading migraine researchers, more than 70 percent of patients indicated that they were less than completely satisfied with their current treatment. Over 85 percent complained that pain relief took too long and 25 percent decided to stop seeking treating all together. In 2005, ProEthic obtained exclusive U.S. and Canadian marketing rights for PRO-513 from APR. The product candidate is currently marketed by Novartis Pharma AG, under the trademarks Voltfast(R) or Catafast(R) in Switzerland, Italy, Egypt and Portugal under license from APR. Novartis has also recently received marketing approval in a dozen additional countries outside of North America and expects to receive over two dozen additional approvals during 2007.

About APR Applied Pharma Research s.a.

APR is a Swiss drug delivery and drug development company focused on oral and topical drug delivery systems. Founded in 1990, the privately held company, focuses its efforts on the development of its own selected drug candidates (developed using APR proprietary technologies) as well as on the development under contract of third party pharmaceutical products and medical devices. For more information, please visit the APR web site at: www.apr.ch or contact Paolo Galfetti, CEO of APR at paolo.galfetti@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.