Swiss Drug Delivery Firm Licenses Fast-Acting Diclofenac Products to U.S. Based ProEthic Pharmaceuticals

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MONTGOMERY, Ala. & BALERNA, Switzerland--(BUSINESS WIRE)--Sept. 13, 2005--Applied Pharma Research (APR), a Swiss-based R&D firm that specializes in enhancing drug delivery, and ProEthic Pharmaceuticals Inc., announced today that APR has granted an exclusive license to ProEthic to develop and market two fast-acting formulations of diclofenac potassium in the U.S. and Canada.

Diclofenac potassium, commonly referred to as an "NSAID" (non-steroidal anti-inflammatory drug), was originally marketed by Novartis in the 1990's for the treatment of rheumatoid and osteoarthritis, dysmenorrhea and mild to moderate pain.

ProEthic will develop and market two formulations in the U.S. as 505(b)2 applications. The first, designed to treat migraine headaches, contains 50 mg of diclofenac potassium in a powder formulation and incorporates a unique, patent-pending Immediate Release Technology ("IRT") developed by APR. Shown to enhance the pharmacokinetics of diclofenac, IRT uses potassium bicarbonate to create a dynamic buffering environment in the gastrointestinal tract that helps facilitate a more rapid and consistent absorption of diclofenac. As a result, the drug delivery occurs more quickly with a higher peak blood concentration of diclofenac. The new formulation will offer migraine patients exceptionally fast relief with symptomatic improvement beginning in seven to eight minutes after the initial dose. Peak blood levels occur within 12 to15 minutes after dosing. ProEthic has scheduled a Pre-IND for October 19 and anticipates filing an IND by year-end. The product is currently marketed in Europe by Novartis under the trademark Voltfast®.

The second formulation will provide fast, effective relief to patients experiencing mild to moderate pain. The patent-pending Immediate Release Technology ("IRT") will deliver a 30 percent higher plasma level and a time-to-onset that is roughly 30 percent faster than the reference listed drug. ProEthic has completed a Pre-IND and plans to file the IND in the fourth quarter of 2005. Two clinical trials are planned and will commence in January, 2006. The NDA submission is planned for the fourth quarter of 2006 with an anticipated approval in late 2007. The product is currently marketed in Europe by Spirig Pharma SA, under the trademark Inflammac® Rapid.

"We are extremely excited about the potential of both of these products and the unique advantages they will bring to the treatment of pain and migraine headaches," said Carl Whatley, Chairman and CEO of ProEthic. "The 28 million Americans who suffer from these horrendous headaches will soon have another option that is not only safe and effective, but very fast."

As part of the agreement, ProEthic will pay APR an upfront fee, consisting of cash and stock, in exchange for the exclusive license to both diclofenac products. ProEthic also will pay APR milestone payments for key clinical and regulatory achievements and royalties on product sales. ProEthic will have sole responsibility for clinical development and commercialization of the drug.

Source: ProEthic Pharmaceuticals Inc.