



APPLIED PHARMA RESEARCH S.A.

## PRESS RELEASE

### For Immediate Release:

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**FDA has approved Cambia™, Potassium Diclofenac Powder for Oral Solution for the treatment of acute migraine attacks with or without aura, originally developed by APR Applied Pharma Research SA (APR) using the patented Dynamic Buffering Technology (DBT).**

Cambia™, formerly known also with its development code “PRO-513”, is an innovative product now ready to enter the \$ 4.1 billion US migraine market. Cambia™ has unique features in the treatment of moderate to severe migraine attacks by combining a fast pain relief profile (statistically significant relief of migraine pain between 15 and 30 minutes after intake) and a more favorable safety profile than triptans in a very convenient and portable packaging. Clinical studies also demonstrated Cambia’s™ efficacy in treating the associated symptoms of migraine such as nausea, photophobia and phonophobia. APR’s patented Dynamic Buffering Technology is the “engine” that boosts Cambia™ to unique performances for a diclofenac based product in the treatment of migraine.

This unique combination makes Cambia™ an ideal first line therapy product to treat migraine attacks, finally giving an answer to one of the most common unmet need in the migraine therapy: speed in providing pain relief. A recent publication by experts in the migraine therapies pointed out that more than 70% of the migraine patients are not completely satisfied with current treatments. Of these patients, over 85% cited slow onset of pain relief as the main cause of dissatisfaction.

“APR core business is the delivery of innovative, well differentiated products with improved efficacy, safety and/or delivery format”, said Paolo Galfetti, CEO of APR. “We are heavily investing in the development of our business in the US and we are confident that Cambia™ is just the first of many APR products to be introduced into the US market. We have recently established a subsidiary in the US, and plan to expand our presence in the US, specifically to increase our focus on this vision”.

The North American rights on Cambia™ as well as on the Dynamic Buffering Technology were licensed and assigned by APR to Kowa Pharmaceutical America Inc. (“KPA”), formerly known as ProEthic Pharmaceuticals Inc., in 2005. ProEthic and KPA were responsible for local development and registration.

APR and KPA are now actively working together to secure a marketing partner for Cambia™ in the US as soon as possible and to ideally secure a launch in the US before year end.

### **About APR Applied Pharma Research s.a. (“APR”)**

APR is an independent, vertically integrated Research & Development Healthcare company headquartered in Switzerland. The 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. Leveraging on its own technology platforms, R&D know-how, 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 third parties for distribution and marketing. R&D activities are carried out directly or under contract. APR has signed licensing agreements with pharmaceutical companies in more than 100 countries worldwide and its sales are almost totally achieved abroad.

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