

Press release

Renhe Group and APR Applied Pharma Research announce a license agreement for the distribution in the Chinese market of an innovative solution to treat migraine

Beijing (China) and Balerna (Switzerland) 19 January, 2017– APR Applied Pharma Research s.a. (“APR”), the Swiss, independent developer of science driven, patent protected healthcare products, and Renhe Group, a Chinese leading pharmaceutical company, today are proud to announce the start of a partnership for the promotion, distribution and marketing of APR’s patented Diclofenac powder for oral solution for migraine treatment, in China, Hong Kong, Macao and Taiwan.

Migraine prevalence in China is rapidly growing due to the increasing population of patients affected in combination with the swift change of the society towards a modern industrialized country lifestyle, thus making the anti-migraine drugs market potential attractive.

The current market size for specific anti-migraine preparations is still very limited in China, accounting for around 1 mio USD, as disease awareness amongst patients and doctors is scarce and differentiated diagnosis is still very limited; however, its growth rate is significant (+117%) as underdiagnoses reduces. Moreover, the main drugs available specific for migraine therapy are standard triptans (either branded or generics), thus leaving unaddressed the need of a fast effective and tolerable treatment.

APR’s unique and exclusive formulation of Diclofenac, based on the APR’s patented Dynamic Buffering Technology (“DBT”), is particularly suitable for the management of migraine, by securing faster pain relief, rapid onset of action and sustained pain-free, thus reducing recurrence of migraine attacks associated with a favourable side-effect profile and projecting this product to be the first NSAID specifically approved for migraine in China, thus replicating the same success story APR was able to achieve in the USA.

“With this agreement, Renhe Group aims to seize this market opportunity by fulfilling the need for a specific fast acting and tolerable migraine treatment. At the same time, this innovative and proven solution perfectly matches the current increasing demand for Western-type therapies in China. We are confident that adding this drug to our portfolio will help us to successfully position Renhe Group as reference company in the migraine market.”- states Mr Chunyu Li, Renhe Group General Manager.

*“We are proud of this new agreement, which allows us to enter dynamic markets with the highest population rate worldwide, like China, Macao and Hong Kong. We believe this partnership will offer great business opportunities to an European based company like APR as well as to our local partner Renhe Group- said **Paolo Galfetti**, Chief Executive Officer of APR -APR’s Diclofenac drugs, including DBT based ones, are currently marketed and promoted in several countries all over the world, thanks to a wide network of partners, such as Novartis AG and Depomed.*

Approximately 100 million doses of APR's Diclofenac DBT are sold every year, confirming the distinctive and exclusive competitive advantage of APR's formulation over conventional preparations."

About Diclofenac Powder for Oral Solution

APR's Diclofenac powder for oral Solution is based on APR's patented Dynamic Buffering Technology (DBT): this exclusive technology includes a unique blend of Diclofenac and bicarbonate that creates a suitable microenvironment at gastrointestinal level, avoiding precipitation of acid Diclofenac in the gastric environment and, thus, allowing a fast absorption, without affecting overall tolerability and safety of the drug product. Pharmacokinetic data support its positive results in terms of an immediate and ready absorption in the gastro-intestinal tract, hence achieving a faster onset of action.

As shown in clinical trials on migraine patients^(1,2,3,4), APR's Diclofenac powder for oral solution consistently provides a rapid relief from multiple migraine symptoms (nausea, photophobia, phonophobia) in 2 hours by starting to work in just 15 minutes - at achievement of peak plasma levels-as well as a pain-free response lasting up to 24 hours, by targeting effectively inflammation. On the other hand, it comes in a convenient water-soluble formulation and has a favorable and tolerable side-effect profile, similar to placebo.

Moreover, Diclofenac powder for oral solution has been recently established as "effective" (Level A) for the therapy of acute migraine attacks by the AHS (America Headache Society), following an evidence-based assessment via a systematic review of Class I studies (www.apr.ch/news/new-patent-for-aprs-diclofenac-formulation-in-canada).

1. Diener HC, Montagna P, Gács G, et al. Efficacy and tolerability of diclofenac potassium sachets in migraine: a randomized, double-blind, cross-over study in comparison with diclofenac potassium tablets and placebo. *Cephalalgia*. 2006;26(5):537-547. 2. Lipton RB, Grosberg B, Singer RP, et al. Efficacy and tolerability of a new powdered formulation of diclofenac potassium for oral solution for the acute treatment of migraine: results from the International Migraine Pain Assessment Clinical Trial (IMPACT). *Cephalalgia*. 2010;30(11):1336-1345. 3. Headache Classification Committee of the International Headache Society (IHS). The International Classification of Headache Disorders, 3rd edition (beta version). *Cephalalgia*. 2013;33(9):629-808. 4. Marmura MJ, Silberstein SD, Schwedt TJ. The acute treatment of migraine in adults: the American Headache Society evidence assessment of migraine pharmacotherapies. *Headache*. 2015;55(1):3-20.

About APR – APPLIED PHARMA RESEARCH

APR is a Swiss, independent developer of science driven, patent protected healthcare products. The Company identifies, develops and licenses, value added products designed to address patient or consumer needs in niche or rare therapeutic areas on a global basis. In particular, APR's business model is currently focused on two pillars: (i) internally developed and financed (alone or together with co-development partners) proprietary, value added products to be licensed to healthcare companies for their commercialization, and (ii) support to third party projects by offering added



value R&D services under contract and fee for service arrangements. APR has a balanced pipeline of revenue generating branded products marketed in all major markets, combined with a compelling pipeline of products at different stages of development. APR has entered into licensing and partnership agreements with pharmaceutical companies in over 70 countries, with international sales on a worldwide basis.

For press releases and other company information, please visit: www.apr.ch

About Renhe

RenHe pharmaceutical Bioengineering Co. Ltd., established in 2008, is a GSP certified pharmaceutical sales organization with a distribution network cross the nation. The company main focus is on chemical compounds for prescription drugs and traditional Chinese products for OTC market. The company now has regional office in Beijing, Shanghai, and Hangzhou with total revenue over 200 million RMB in 2015

For press releases and other company information, please visit: www.renhe.com

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