



Press Release

CSC Pharmaceuticals announces the launch of the innovative migraine and pain treatment developed by APR Applied Pharma Research

Balerna, 3rd April - APR Applied Pharma Research's patented formulation of Diclofenac 50 mg powder oral solution for migraine treatment and other pain areas is now available in Russia, promoted and commercialized with the brand Dialrapid by the leading pharmaceutical company CSC Pharmaceuticals.

Estimates indicate that migraine prevalence in Russia is quite high, affecting almost 30 million of adult population, while around 2% of them suffer from chronic migraine with clinical manifestations for more than ten days per month. Chronic headache is quite common as well, accounting for 10% of the adult population.

Currently available NSAID and analgesics formulations, which together with triptans are commonly used as therapy for migraine and severe headache, leave unaddressed the need for a fast effective and tolerable treatment. Moreover, this need leads often patients and physicians to still rely on traditional formulation such as injections, with clear practical downsides. This formulation indeed showed a positive growth rate (+20%) within the total market of NSAIDs equal to almost 300 mio €.

APR's exclusive water-soluble in sachet form of Diclofenac, based on the company patented Dynamic Buffering Technology (DBT), is particularly suitable for the management of migraine as well as severe headache and other acute conditions, as it secures significantly faster pain relief and rapid onset of action than NSAIDs conventional preparations, associated with a favorable side-effect profile.

The unique advantages of this powder formulation have been formally acknowledged by the International Headache Society, which strongly recommends it as a first line treatment for migraine attacks, as well as by the Russian local guidelines for migraine therapy.

To support the launch of Dialrapid and its awareness among physicians dealing with migraine, CSC is carrying out a comprehensive set of activities, which span from the participation to main congresses with lectures by top-notch Russian KOLs, to educational programs on a regional basis in cooperation with headache and pain centers, digital tools and the promotion to pharmacists.

"We are proud to make this unique and innovative formulation of Diclofenac available for healthcare professionals and patients in Russia. We believe that APR's patented in sachet form can be the right answer to the demand of more effective and specific treatment for severe headache and migraine, as it offers the fastest pain relief action combined with excellent tolerability and a convenient water-soluble formulation. We are confident that we can make this drug the gold standard therapy for headache, thus becoming the reference company in this market." said Mr. Sergey Beloborodov, General Director of CSC Pharmaceuticals.

"We are very pleased to see our patented product on the Russian market. Actually, this launch allows us to further spread the Diclofenac products and our DBT technology on a worldwide basis as it follows the remarkable success in the USA and the future distribution in the promising Asian markets, China and Malaysia to name a few, where the product is being registered. We are confident that, thanks to the partnership with CSC, Russia could contribute to the proven track record of success of APR's Diclofenac formulation." said Paolo Galfetti, CEO of APR.



About APR's 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 acute pain 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).

1. Diener HC, Montagna P, Gács G, et al. Efficacy and tolerability of diclofenac potassium sachets in migraine: a randomized, doubleblind, 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 s.a.

APR is a Swiss independent pharma company focused on development and global commercialization of innovative, research-driven products designed to address unmet needs in specialized therapeutic areas and rare diseases. APR combine pharmaceutical development expertise with proprietary drug delivery technologies to realize solutions that meaningfully improve the lives of people with rare diseases and empower families through novel approaches to disease management. A diverse and balanced portfolio of revenue-generating products in all major markets is complemented by a robust pipeline of innovative products at different stages of development for the treatment of recessive metabolic disorders, as well as rare dermatological and ocular diseases. Products are directly commercialized by APR through inhouse sales and marketing teams in strategically important countries across Europe and a growing worldwide network of commercial partners. For more information about the company, please visit the website: www.apr.ch.



About CSC Pharmaceuticals

CSC today is a dynamically developing pharmaceutical company of full cycle, based on advanced technology of the pharmaceutical industry. We have built our name and reputation that is supported at a high level and we continue to develop. CSC has been on the market for 30 years, millions of people have already been helped thanks to our products, and millions still to help. We implement and promote modern high-quality pharmaceutical products. Our products contribute to improve the health and quality of patients' life. CSC shares a strong sense of responsibility for business and takes work with the maximum responsibility in all the areas.

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