



Press Release

ORPHELIA Pharma and K.S. KIM (SK-Pharma) sign a license agreement for the distribution of Kigabeq® in the territory of the Russian federation

Paris and Tel Aviv – November 16th 2021 – ORPHELIA Pharma and K.S. KIM INTERNATIONAL (SK-PHARMA) LTD announce today the execution of an exclusive distribution and marketing agreement for Kigabeq® (vigabatrin) in the territory of the Russian Federation.

Kigabeq®, the first pediatric form of vigabatrin developed by ORPHELIA Pharma, is notably indicated in the treatment of infantile spasms (West syndrome). Kigabeq® is approved in the European Union, where this medicine, intended exclusively for children, benefits from a centralized marketing authorization (Pediatric Use Marketing authorization, PUMA).

"We are delighted to sign this agreement with K.S. KIM, which is based on the value of Kigabeq® in paediatrics", says Hugues BIENAYME, Founder and CEO of ORPHELIA Pharma, "With their strong footstep in the distribution of orphan medicines in the Russian territory, K.S. KIM is an excellent partner for Kigabeq®."

"With Kigabeq®, the only pediatric presentation of vigabatrin, K.S. KIM is expanding its portfolio of drugs intended for rare and serious pathologies in children" adds Dr. Shlomo Sadoun, CEO of K.S. KIM, "Kigabeq® is a drug which address unmet medical needs for young patients affected by severe and resistant epilepsies. Our ultimate objective is to register Kigabeq® as an orphan drug in Russia, nevertheless we will start distributing it immediately as an unlicensed medicine augmenting unmet needs".

"Our objective is to make Kigabeq® available as widely as possible, so that all children affected by infantile spasms can benefit." concludes Gilles ALBERICI, President of ORPHELIA Pharma, "Thanks to this agreement with K.S. KIM, we are very confident that Russian children suffering from infantile spasms will have access to Kigabeq® as quickly as possible."

About Kigabeq®

Kigabeq® is the first pediatric formulation of vigabatrin, an essential anti-epileptic drug. Presented as soluble and scored tablets of 100 mg and 500 mg for oral or nasogastric administration, Kigabeq® is notably indicated for the treatment of infantile spasms (West syndrome), an extremely serious epileptic encephalopathy of the infant. Kigabeq® was developed exclusively for children and has been granted European Pediatric Marketing Authorization (PUMA).

About infantile spasms

West syndrome, or infantile spasms, is an extremely serious epileptic encephalopathy in infants that combines epileptic spasms, psychomotor deterioration and a hypsarrhythmic type electroencephalogram. It is a rare disease, with an estimated incidence of 5 per 10,000 births. It can occur in an infant with previously normal development or with a pre-existing delay; in all cases,



infantile spasms severely hamper the psychomotor development. Pharmacological treatment should be started quickly to allow the spasms to stop and to improve the prognosis.

About K.S. KIM (SK-Pharma)

K.S. Kim International Ltd. operates as part of the SK-Pharma group of companies. The main areas of focus are the registration, commercialization and marketing of pharmaceutical specialty and orphan drugs, by utilizing data driven decision and distributive marketing strategies. The group is operating in 15 countries with a main focus on the Israeli and Russian markets.

For further information, please go to <https://sk-pharma.com>

About ORPHELIA Pharma

ORPHELIA Pharma is a biopharmaceutical company based in Paris and Lyon that develops and markets drugs for the treatment of pediatric and orphan diseases.

ORPHELIA's mission is to provide patients with essential hospital products in the fields of epilepsy and oncology, with formulations that are suited to the pediatric population. With 2 products approved in the European Union and one project in late-stage clinical development, ORPHELIA Pharma recently sets up regional agreements in the EU, the USA and China and conducts research projects through academic and industrial partnerships.

For further information, please go to www.orphelia-pharma.eu

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