



Press release

ORPHELIA Pharma and Ethypharm sign a licensing agreement for the development and marketing of Kigabeq® in China

Saint-Cloud and Paris – January 19, 2021 - Ethypharm and ORPHELIA Pharma announce today the signature of an exclusive agreement for the development, registration and marketing in the People's Republic of China of Kigabeq® (vigabatrin) indicated for the first-line treatment of infantile spasms (West syndrome).

Kigabeq®, the first paediatric form of vigabatrin developed by ORPHELIA Pharma, is approved and marketed in Europe, where this medicine, intended exclusively for children, has been granted a Paediatric Use Marketing Authorisation (PUMA). Kigabeq® is indicated for the first-line treatment of infantile spasms (West's syndrome), a severe epileptic encephalopathy in infants.

There is a significant unmet medical need in China for patients suffering from this rare and devastating form of epilepsy. By entering into this agreement, Ethypharm and ORPHELIA Pharma are committed to providing appropriate treatment for Chinese children suffering from this rare disease.

As part of this agreement, ORPHELIA Pharma grants Ethypharm exclusive rights to Kigabeq® in the People's Republic of China. After registration, Ethypharm will be responsible for the distribution and sale of Kigabeq® in China.

"Our objective is to make Kigabeq® available in many territories. After Europe and China, new agreements will be signed to enable the marketing of this formulation of vigabatrin, which is particularly suitable for children," comments Hugues BIENAYMÉ, founder and Managing Director of ORPHELIA Pharma.

"We are very pleased to establish this partnership with ORPHELIA Pharma. This collaboration brings an effective solution to young Chinese patients. The upcoming commercialisation of Kigabeq® is fully in line with our strategy to strengthen our rare disease franchise in China" said Bertrand DELUARD, President and CEO of Ethypharm.

Through this partnership, Ethypharm is strengthening its ambition to become a key player in the field of rare diseases in China. Operating successfully for more than 20 years in an ever-changing Chinese environment, Ethypharm has a fully integrated subsidiary located in Shanghai. "Our subsidiary is a partner of choice for companies wishing to make their existing internationally-marketed orphan drugs or drugs for rare diseases available to Chinese patients," says François LIOT, General manager of Shanghai Ethypharm.

"I am delighted to sign this agreement with Ethypharm, which is based on the value of Kigabeq® in paediatrics. Thanks to the in-depth knowledge that the Ethypharm Group is developing in China, we are very confident that Chinese children suffering from infantile spasms will have access to Kigabeq® as quickly as possible," adds Gilles ALBERICI, Chairman of ORPHELIA Pharma.



About Kigabeq®

Kigabeq® is the first paediatric formulation of vigabatrin, an essential anti-epileptic drug. Kigabeq® is available in 100 mg and 500 mg soluble and scored tablets for oral or (naso)gastric administration and is indicated for the first-line treatment of childhood spasms (West's syndrome), a severe epileptic encephalopathy in infants. Kigabeq® has been developed exclusively for children and has been granted Paediatric Use Marketing Authorisation (PUMA).

About infantile spasms

West's syndrome, or infantile spasms, is a severe epileptic encephalopathy of the infant that combines epileptic spasms, a psychomotor deterioration and an hypsarrhythmic electroencephalogram tracing. It is a rare disease, with an estimated incidence of 5 per 10,000 births. It can occur in infants with previously normal development or with a pre-existing delay; in all cases, infantile spasms have a strong impact on the psychomotor development. Pharmacological treatment must be started quickly to allow the spasms to stop and improve the prognosis.

About the Ethypharm Group

Ethypharm is a European pharmaceutical company focused on two therapeutic areas: the Central Nervous System and Critical Care. Ethypharm markets its drugs directly in Europe and China, and with partners in North America and the Middle East where its drugs are in high demand. The Group employs more than 1,500 people, mainly in Europe and China.

Ethypharm works closely with authorities and healthcare professionals to ensure the appropriate use of and access to its medicines, by as many people as possible.

About ORPHELIA Pharma

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

Our mission is to provide patients with essential hospital products in the fields of epilepsy and oncology with formulations adapted to the paediatric population. Our first product, Kigabeq®, received European marketing authorisation in September 2018 and is being launched in several countries. Our second product, Ivozall®, obtained European marketing authorisation in November 2019 for the treatment of acute lymphoblastic leukaemia. ORPHELIA Pharma conducts research projects through academic and industrial collaborations. For more information, please visit www.orphelia-pharma.eu

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