



Press release

Granting of the marketing authorization for Kigabeq®

Paris and Lyon, October 1st, 2018 – ORPHELIA Pharma, a French biopharmaceutical company dedicated to the development and marketing of pediatric drugs in the fields of oncology and neurology, announces today that the European Commission has granted Kigabeq® a European marketing authorization.

Kigabeq® is the first pediatric formulation of vigabatrin, an essential antiepileptic drug and will be available as scored soluble tablets of 100 mg and 500 mg strengths. Kigabeq® is expected to be used as first-line treatment for infantile spasms, an extremely severe early childhood encephalopathic epilepsy. Kigabeq® has been developed exclusively for children and will be granted a PUMA (Paediatric Use Marketing Authorization).

« This approval is a key milestone for ORPHELIA Pharma as Kigabeq® represents the first in a series of pediatric-focused products we plan to launch. We believe it addresses important pediatric needs and will meaningfully improve the lives of children » comments Hugues Bienaymé, Founder and General Manager. « We can now focus on launching Kigabeq® in France and building relationships with distribution partners to commercialize Kigabeq® throughout Europe ».

« This Marketing Authorization comes at the right time for ORPHELIA Pharma and the company will now structure itself upon this first medicine in which we have great expectations » says Gilles Alberici, President. « Our vision is to develop and bring new pediatric drugs with age-adapted formulations to the market for the treatment of life-threatening orphan indications. Today's milestone is a first step on this exciting journey ».

About infantile spasms

Infantile spasms, or West Syndrome, is an early childhood epileptic encephalopathy which combines axial spasms in cluster, a marked psychomotor delay and an hypsarythmic electroencephalogram. It is a rare disease with an estimated incidence of around 5 per 10,000

living births. It affects infants who were previously normal or children with impaired cognitive development. Children with infantile spasms must be treated rapidly for spasms cessation and to improve prognosis.

About ORPHELIA Pharma

Based in Paris and Lyon, ORPHELIA Pharma SAS is a French biopharmaceutical company dedicated to the development and marketing of oncology and neurology pediatric drugs. Its mission is to significantly improve essential medicines administered to children through the development of efficient, reliable and safe drugs with child-friendly formulations. ORPHELIA Pharma also leads innovative R&D projects through academic and industrial partnerships. Key investors include *initiative* OCTALFA (lead investor) and Pierre Fabre Medicament.