



## **ORPHELIA Pharma and Gustave Roussy announce issuance of European Patent covering Kimozo<sup>®</sup>, the first oral liquid formulation of temozolomide**

**Paris and Lyon, on June 16, 2021** – ORPHELIA Pharma, a French biopharmaceutical company dedicated to the development and marketing of pediatric and orphan drugs and Gustave Roussy, the leading cancer center in Europe, announce today that the European Patent Office has issued Patent EP3613436, which is directed to Kimozo<sup>®</sup>, the first pediatric, ready-to-use and taste-masked oral suspension of temozolomide. Kimozo<sup>®</sup> results from the collaboration between the pharmacists and clinicians from Gustave Roussy and ORPHELIA Pharma.

*“Temozolomide is an essential oncology drug used to treat relapsed or refractory neuroblastoma, a disease that unfortunately affects very young children. We are working in close collaboration with European clinicians and our goal is to make this pediatric form of temozolomide available as early as 2021 through early access programs”*; commented Jeremy Bastid, Chief Development Officer of ORPHELIA Pharma.

*“We have developed a hospital compounded liquid preparation of temozolomide in 2015 to address the needs of young patients treated at our center”,* explain Maxime Annereau, pharmacist and Samuel Abbou, pediatric oncologist at Gustave Roussy, both at the origin of this project. *“This hospital formulation was suitable for children but did not exhibit the physico-chemical and stability properties compatible with an industrialized product. This product was therefore not available to all patients. Three years of research and development between Gustave Roussy and ORPHELIA Pharma were necessary in order to achieve the targeted specifications: a highly concentrated, taste-masked and stable formulation”.*

*“Our research efforts led to the development of Kimozo<sup>®</sup>, the first drinkable formulation of temozolomide. The innovation is based on the discovery of a key excipient involved in the stability and the control of the rheological properties of the suspension, an invention that has been patented”,* concludes Jeremy Bastid.

The grant of Patent EP3613436 entitled “oral suspension of temozolomide” and co-owned by ORPHELIA Pharma and Gustave Roussy has been published in the European Patent Bulletin. Based on the filing date of the application, the patent protection is expected to last until 2038.

### **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. Our 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. Our first product, Kigabeq<sup>®</sup>, which was approved during the latter part of 2018 for the treatment of West Syndrome in particular, has been launched in several European countries. Our second product, Ivozall<sup>®</sup>, obtained a European marketing authorization at the end of 2019 for the treatment of acute lymphoblastic leukemia. ORPHELIA Pharma also conducts research projects through academic and industrial partnerships.

For further information, please go to [www.orphelia-pharma.eu](http://www.orphelia-pharma.eu)

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### **About Gustave Roussy**

Classed as the leading European Cancer Centre and the fifth on the world stage, Gustave Roussy is a center with comprehensive expertise and is devoted entirely to patients suffering with cancer. It is a source of diagnostic and therapeutic advances. It caters for almost 50,000 patients per year and its approach is one that integrates research, patient care and teaching. It is specialized in the treatment of rare cancers and complex tumors and it treats all cancers in patients of any age. Its care is personalized and combines the most advanced medical methods with an appreciation of the patient's human requirements. In addition to the quality of treatment offered, the physical, psychological and social aspects of the patient's life are respected. 3,200 health professionals work on its two campuses: Villejuif and Chevilly-Larue. Gustave Roussy brings together the skills which are essential for the highest quality research in oncology: a quarter of patients treated are included in clinical trials.

For further information: [www.gustaveroussy.fr/en](http://www.gustaveroussy.fr/en)

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### **About Kimozo®**

Kimozo® (also known as ORP-005 or Ped-TMZ) is a ready-to-use and taste-masked oral suspension of temozolomide that is currently under development to address the needs of children. Kimozo® is an investigational medicinal product not yet approved for marketing.