



ORPHELIA Pharma Selects Tanner Pharma Group to Initiate Named Patient Program for KIMOZO® (temozolomide) in European Countries

Paris (France) and Charlotte, N.C. (USA), on April 18th, 2023 – [ORPHELIA Pharma](#), a French biopharmaceutical company dedicated to the development and marketing of pediatric and orphan medicines, and [Tanner Pharma Group](#), a global provider of integrated specialty access solutions, have signed an exclusive agreement to manage the supply and distribution of Ped-TMZ, also known as KIMOZO® (temozolomide 40 mg/ml, oral suspension), to meet the special demands which may come from European physicians for this unapproved pediatric form of temozolomide.

Temozolomide is an anti-cancer drug approved as capsules or IV formulation in Europe for certain brain tumors. It is also used in treatment protocols for other rare cancer indications that mainly affect very young children, including refractory or relapsed neuroblastoma. In young children, an oral suspension of temozolomide is age-appropriate to ensure correct medication administration.

Under the terms of the agreement, Tanner Pharma will provide access to KIMOZO® via a named patient program in European countries, in particular these countries where KIMOZO® has already been used as investigational medication in the context of the now fully enrolled clinical trial TEMOkids sponsored by ORPHELIA Pharma. A named patient program is a mechanism through which physicians can legally and ethically prescribe investigational or approved drugs for patients prior to their commercial availability. The access to unapproved drugs is strictly regulated and adherence to national regulations is mandatory.

Tanner Pharma will manage all elements of the supply including healthcare practitioner enquiry management, national regulatory oversight, liaison with national authorities, and logistics. The agreement currently covers all European territories but France.

Hugues Bienaymé, General Manager of ORPHELIA Pharma, said:

“KIMOZO® is currently available in France through an early access program, and ORPHELIA has already received requests from physicians from other countries. To meet these demands, ORPHELIA Pharma will use the services of Tanner Pharma, a world-leading pharmaceutical services provider with extensive experience in enabling access to innovative therapies when no other treatment options exist. With this agreement, our ambition is to make KIMOZO® available to children in need of a ready-to-use drinkable suspension of temozolomide, anywhere in Europe and with no delay, in strict adherence with local regulations.”

Rob Keel, Executive Vice President at Tanner Pharma, said:

“We are pleased to be partnering with ORPHELIA Pharma on this impactful program to help children with neuroblastoma and other malignancies. ORPHELIA Pharma has done extensive research to develop a product to address a critical unmet need for pediatric patients. We look forward to supporting physicians and enabling access to this innovative treatment.”

Healthcare professionals can obtain details about the products by contacting: kimozo@tannerpharma.com



About KIMOZO® 40 mg/ml

KIMOZO® 40 mg/ml is a liquid, taste-masked and ready-to-use drinkable formulation of temozolomide developed in collaboration between the pharmacists and clinicians of Gustave Roussy hospital and the development team of ORPHELIA Pharma. KIMOZO® is being developed for the treatment of refractory and relapsed neuroblastoma, a childhood cancer of dismal prognosis.

KIMOZO® has been granted Early Access Authorization (Autorisation d'Accès Précoce) for the treatment of refractory and relapsed neuroblastoma as monotherapy or in combination with a specific DNA inhibitor topoisomerase I (irinotecan or topotecan) in patients aged 1 to 6 years and patients over 6 years of age unable to swallow temozolomide in capsule form, by the French authorities in March 2022.

The formulation of KIMOZO® has been covered by a patent application in Europe and in the US.

About ORPHELIA Pharma

ORPHELIA Pharma is a pharmaceutical company based in Paris and Lyon that develops and markets drugs for the treatment of pediatric and orphan diseases. ORPHELIA Pharma's mission is to provide patients with essential products in the fields of neurology and oncology, in formulations adapted to the pediatric population. With two drugs approved in the European Union and one product in late-stage clinical development, ORPHELIA Pharma has recently established regional agreements in the European Union, the USA and China and conducts research projects through academic and industrial partnerships. For further information, please visit www.orphelia-pharma.eu.

About Tanner Pharma

Tanner Pharma Group is a specialist pharmaceutical services provider based in Charlotte, USA with offices in Europe and Latin America. Over the past 20 years, Tanner has developed a portfolio of service offerings focused on improving global access to medicines. Through its TannerMAP division, Tanner Pharma supports manufacturers by providing ethical, controlled and compliant access to their innovative medicines in countries where they are not commercially accessible. For more information, visit www.tannerpharma.com.

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