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News release

European Commission Approves Crysvita® (burosumab) for Infants with X-linked Hypophosphataemia in the European Union

- *Approval expands the approved indication for Crysvita to include infants from 1 month to 1 year of age, enabling earlier intervention in a rare, progressive disease that can impact skeletal development from infancy.*
- *Approval applies across the European Union and European Economic Area, expanding access to treatment for the youngest patients living with XLH.*

Galashiels and Marlow, United Kingdom, July 21st, 2026 — Kyowa Kirin EMEA, a wholly owned subsidiary of Kyowa Kirin Co., Ltd. (TSE:4151), today announced that the European Commission (EC) has approved an expansion of the indication for Crysvita® (burosumab) for the treatment of X-linked hypophosphataemia (XLH), to include infants from 1 month to 1 year of age across the European Union and European Economic Area.

The approval represents an important step forward for infants living with XLH, a rare, progressive genetic disease that can affect skeletal development from an early age. Earlier diagnosis and treatment are considered important in XLH given the potential impact of the disease on skeletal development during infancy and childhood.

XLH is a rare, progressive, lifelong genetic disease characterised by phosphate wasting that can impair bone mineralisation from an early age, leading to skeletal deformities, impaired growth and other serious complications. Clinical manifestations of XLH can emerge during infancy and early childhood, with progressive effects on skeletal development and physical function. Expanding access to treatment in this younger population reflects the importance of early disease management and intervention.

"For families affected by XLH, the impact of the disease can begin in the earliest months of a child's life," said Myriam Hakim, Regional Franchise Head, Kyowa Kirin EMEA. "This approval means healthcare professionals can now consider treatment with burosumab from as young as one month of age, creating an opportunity to address the disease earlier than ever before. It represents an important step forward for infants living with XLH and the families who care for them."

The EC decision follows the positive opinion adopted by the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) in April 2026.

The approval is supported by data from BUR-CL207 (NCT04188964), a Phase 1/2, open-label, multicentre study evaluating the safety, tolerability, pharmacokinetics and efficacy of burosumab in paediatric patients from birth to one year of age with XLH. The safety profile observed in infants was consistent with the established safety profile of burosumab.

"XLH is a progressive disorder in which manifestations can begin during infancy, affecting skeletal development from the earliest stages of life. The approval of a treatment option for infants is an important milestone, as it enables the initiation of evidence-based therapy earlier in the disease course, with the goal of limiting disease progression and improving long-term patient outcomes," said Prof. Agnès Linglart, AP-HP and Paris Saclay University.

The approval also qualifies Crysvita for a two-year extension of orphan market exclusivity in the European Union for XLH, extending regulatory protection from February 2028 until February 2030.[1]

END.

KKI/INT/CYS/0831
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About CRYSVITA® (burosumab)
Burosumab is a recombinant human monoclonal antibody that binds to the protein fibroblast growth factor 23 (FGF23). This has the impact of inhibiting the action of FGF23, allowing phosphate regulation in the body to be restored.[2]

Following the latest approval, burosumab is authorised in the European Union for the treatment of XLH in infants from 1 month to 1 year of age with hypophosphataemia, children and adolescents aged 1 to 17 years with radiographic evidence of bone disease, and adults.

In 2018, the European Commission granted a conditional marketing authorisation for burosumab for the treatment of XLH with radiographic evidence of bone disease in children one year of age and older and in adolescents with growing skeletons.[2] Following this, the European Commission granted burosumab a conditional marketing authorisation in 2020, for the treatment of adolescents regardless of growth status and adults with XLH.[3] The licence was then converted from a conditional to a full standard marketing authorisation in 2022.[2]

Burosumab is now reimbursed in several European countries for both paediatric and adult XLH populations, including France, Germany, Italy, Spain and the UK.

Burosumab received European Commission approval in tumour induced osteomalacia (TIO) in August 2022 and is indicated for the treatment of FGF23-related hypophosphatemia in TIO associated with phosphaturic mesenchymal tumours that cannot be curatively resected or localised in children and adolescents aged 1 to 17 years and in adults.[4]

About X-linked Hypophosphataemia (XLH)
XLH is caused by a genetic mutation which leads to overexpression of the protein FGF23, a protein involved in the regulation of phosphate concentration in the blood. In XLH, FGF23 is produced in excess leading to depletion of phosphate in the blood, known as hypophosphataemia.[5]

Individuals living with the disease may display a multitude of symptoms including short stature, limb deformities, bone and joint pain, oral abscesses, and hearing loss.[6] To manage this wide variety of symptoms, the disease is managed through multi-disciplinary teams.[7]

About Kyowa Kirin
Kyowa Kirin aims to discover novel medicines with life-changing value. As a Japan-based global specialty pharmaceutical company, we have invested in drug discovery and biotechnology innovation for more than 75 years and are currently working to engineer the next generation of antibodies and cell and gene therapies with the potential to help patients affected by severe and rare diseases. A shared commitment to our values, to sustainable growth, and to making people smile unites us across our four regions—Japan, Asia Pacific, North America, and EMEA/International.

You can learn more about the business of Kyowa Kirin EMEA at:
https://kyowakirininternational.com/

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