

News release

Kyowa Kirin Launches Crysvita[®] Prefilled Syringe Formulation in Japan

Tokyo, Japan, November 19th, 2025 -- Kyowa Kirin Co., Ltd. (TSE: 4151; President and COO: Abdul Mullick) today announced the market launch in Japan of a new prefilled syringe formulation of Crysvita[®] [generic name: burosumab (genetical recombination)] on November 19.

Crysvita[®] was first approved in September 2019 in Japan as a vial formulation for the treatment of FGF23-related hypophosphatemic rickets and osteomalacia* in September 2019, and it became available for self-injection in December 2020 in Japan. However, patients and healthcare professionals had been seeking a dosage form that was both more convenient and offered enhanced safety during preparation and administration. In June 2025 in Japan, Crysvita[®] has been approved as a ready-to-use pre-filled syringe containing the drug solution. This new formulation eliminates the need for manual preparation, making self-administration easier for patients and families, and is expected to reduce the overall treatment burden compared to the conventional vial. For healthcare professionals, the simplified process is anticipated to improve administration efficiency and reduce workload in clinical practice.

Crysvita[®] is a recombinant fully human monoclonal IgG1 antibody, discovered by Kyowa Kirin, and is the only drug that directly targets fibroblast growth factor 23 (FGF23), a “phosphaturic” hormone. FGF23 reduces serum levels of phosphorus by regulating phosphate excretion and vitamin D activation in the kidney. Crysvita[®] has been developed to treat FGF23-related hypophosphatemic diseases, such as X-linked hypophosphatemia (XLH) and tumor-induced osteomalacia (TIO).

The Kyowa Kirin Group companies strive to contribute to the health and well-being of people around the world by creating new value through the pursuit of advances in life sciences and technologies.

*** About FGF23-related Hypophosphatemic Rickets and Osteomalacia**

FGF23-related hypophosphatemic rickets and osteomalacia is an inclusive term for diseases caused by excessive actions of FGF23, which leads to impaired phosphate reabsorption in the renal proximal tubules. In Japan, the disease corresponds to vitamin D resistant rickets and osteomalacia (Intractable Diseases) and primary

hypophosphataemic rickets and vitamin D resistant osteomalacia (Specific Pediatric Chronic Diseases). The term also encompasses diseases, such as X-linked hypophosphatemia (XLH), tumor-induced osteomalacia (TIO) and epidermal nevus syndrome (ENS). These diseases are rare and characterized by skeletal disorders associated with renal phosphate wasting.