RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Crysvita (burosumab-twza) Injection
Clinical Update

Clinical update: FDA Approval of Crysvita (burosumab) for the Treatment of Tumor-Induced Osteomalacia (TIO).
FDA approval date: June 18, 2020

Crysvita is designed to bind to and thereby inhibit the biological activity of fibroblast growth factor 23 (FGF23). FGF23 is hormone that reduces serum levels of phosphorus and active vitamin D by regulating phosphate excretion and active vitamin D production by the kidney. Crysvita is a recombinant fully human monoclonal IgG1 antibody, discovered by Kyowa Kirin against FGF23. By blocking excess FGF23 in patients with TIO and X-linked hypophosphatemia (XLH), crysvita is intended to increase phosphate reabsorption from the kidney and increase the production of active vitamin D, which enhances intestinal absorption of phosphate and calcium.
Crysvita is approved by U.S. FDA for treatment of adult and pediatric six months of age and older suffering from XLH and FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized in adults and pediatric patients 2 years of age and older.

FDA approved crysvita for TIO on the basis of data obtained from two single-arm Phase 2 studies, a 144-week study in 14 adult patients conducted by Ultragenyx in the United States and an 88-week study in 13 adult patients conducted by Kyowa Kirin in Japan and South Korea.
In both studies, crysvita was associated with increases in serum phosphorus and serum 1,25-dihydroxyvitamin D levels. Increased phosphate levels led to improvements in osteomalacia. Additionally, whole body bone scans demonstrated reduced tracer uptake with long-term treatment suggesting healing of bone lesions. Most common adverse reactions (>10%) observed in TIO patients are: tooth abscess, muscle spasms, dizziness, constipation, injection site reaction, rash, and headache.
FDA has granted crysvita, Priority Review designation for the supplemental BLA for TIO.

This document is designed to be an informational resource to facilitate discussion and should be used neither as a basis for clinical decision-making or treatment nor as a substitute for reading original literature. RxAdvance makes every effort to ensure that the information provided is up-to-date, accurate, and complete, but no guarantee is made to that effect. If this information is provided to clients or vendors, it is subject to any contractual confidentiality provisions. Third-party disclosures are in violation of confidentiality provisions.

© RxAdvance Corporation. Confidential and Proprietary.

This document is designed to be an informational resource to facilitate discussion and should be used neither as a basis for clinical decision-making or treatment nor as a substitute for reading original literature. RxAdvance makes every effort to ensure that the information provided is up-to-date, accurate, and complete, but no guarantee is made to that effect. If this information is provided to clients or vendors, it is subject to any contractual confidentiality provisions. Third-party disclosures are in violation of confidentiality provisions.

© RxAdvance Corporation. Confidential and Proprietary.