Crysvita® (burosumab-twza) – New indication

- On June 18, 2020, the FDA announced the approval of Kyowa Kirin and Ultragenyx's and Crysvita (burosumab-twza), for the treatment of fibroblast growth factor 23 (FGF23)-related hypophosphatemia in tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized in adult and pediatric patients 2 years of age and older.

- Crysvita is also approved for the treatment of X-linked hypophosphatemia (XLH) in adult and pediatric patients 6 months of age and older.

- FGF23 regulates levels of phosphate, an electrolyte that plays important roles in bone maintenance, energy production by cells and nerve function. When there is not enough phosphate in the body, bones begin to soften and weaken, causing osteomalacia (marked softening of bones).

    — There are an estimated 500 to 1,000 people in the U.S. with TIO, and approximately half of all cases are believed to be inoperable.

- Crysvita is the first FDA approved therapy for this condition.

- The approval of Crysvita for the new indication was based on two, single-arm, open label studies enrolling a total of 27 patients with TIO. The first study enrolled 14 adult patients with a confirmed diagnosis of FGF23-related hypophosphatemia produced by an underlying tumor that was not amenable to surgical excision or could not be located. The second study enrolled 13 adult patients with a confirmed diagnosis of TIO. In both studies, patients received Crysvita every 4 weeks.

    — In the first study, Crysvita increased mean (standard deviation [SD]) serum phosphorus levels from 1.60 (0.47) mg/dL at baseline to 2.64 (0.76) mg/dL averaged across the midpoint of dose intervals through week 24 with 50% of patients achieving a mean serum phosphorus level above the lower limit of normal (LLN) averaged across the midpoint of dose intervals through week 24.
    — In the second study, Crysvita increased mean (SD) serum phosphorus levels from 1.62 (0.49) mg/dL at baseline to 2.63 (0.87) mg/dL averaged across the midpoint of dose intervals through week 24 with 69% of patients achieving a mean serum phosphorus level above the LLN averaged across the midpoint on dose interval through week 24.
    — The results of bone scans for patients in the first study also suggested healing of the bone lesions related to osteomalacia.

- The most common adverse reactions (> 10%) with Crysvita use in TIO patients were tooth abscess, muscle spasms, dizziness, constipation, injection site reaction, rash, and headache.

- The recommended starting dose of Crysvita for the treatment of TIO in pediatric patients is 0.4 mg/kg of body weight rounded to the nearest 10 mg every 2 weeks. The dose may be increased up to 2 mg/kg (not to exceed 180 mg), administered every 2 weeks.

- The recommended starting dose of Crysvita for the treatment of TIO in adults is 0.5 mg/kg body weight administered every 4 weeks, rounded to the nearest 10 mg, up to a maximum dose of 2 mg/kg (not to exceed 180 mg), administered every 2 weeks.

- Crysvita is administered by subcutaneous injection and should be administered by a healthcare provider.

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- Refer to the Crysvita drug label for dosing in XLH.