Prolia® (denosumab) – FDA drug safety communication

- On November 22, 2022, the FDA announced they are investigating the risk of severe hypocalcemia with serious outcomes, including hospitalization and death, in patients with advanced kidney disease on dialysis treated with Prolia (denosumab).

- The FDA's review of interim results from an ongoing safety study of Prolia suggests an increased risk of hypocalcemia, or low calcium levels in the blood, in patients with advanced kidney disease. Preliminary results from a separate internal FDA study further investigating hypocalcemia in dialysis patients treated with Prolia show a substantial risk with serious outcomes, including hospitalization and death.

- Because of the frequency and seriousness of these risks, the FDA is alerting healthcare professionals and patients about them, and the FDA is continuing to evaluate this potential safety issue with Prolia use in patients with advanced kidney disease, particularly those on dialysis.

    — The FDA will communicate their final conclusions and recommendations when they have completed the review or have more information to share.

- Prolia is approved for: treatment of postmenopausal women with osteoporosis at high risk for fracture; increase bone mass in men with osteoporosis; treatment of glucocorticoid-induced osteoporosis; treatment of bone loss in men receiving androgen deprivation therapy for prostate cancer; and treatment of bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer.

- Patients should not stop Prolia treatment without first consulting with their healthcare professional, as stopping may worsen your bone condition.

    — Patients should tell their healthcare professional if they experience any symptoms of low blood calcium levels such as unusual tingling or numbness in the hands, arms, legs, or feet; painful muscle spasms or cramps; voice box or lung spasms causing difficulty breathing; vomiting; seizures; or irregular heart rhythm.

- Healthcare professionals should consider the risks of hypocalcemia with the use of Prolia in patients on dialysis. When Prolia is used in these patients, adequate calcium and vitamin D supplementation and frequent blood calcium monitoring, possibly more often than is already being conducted, may help decrease the likelihood or severity of these risks. Patients on dialysis should be advised to immediately seek help if they experience symptoms of hypocalcemia.