

## Bonsity<sup>™</sup> (teriparatide) – New drug approval

- On October 7, 2019, [Pfenex announced](#) the FDA approval of [Bonsity \(teriparatide\)](#), for the following indications:
  - Treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Bonsity reduces the risk of vertebral and nonvertebral fractures
  - To increase bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy
  - Treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy (daily dosage equivalent to 5 mg or greater of [prednisone](#)) at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.
- The efficacy of Bonsity was demonstrated by using the clinical studies for [Forteo<sup>®</sup> \(teriparatide\)](#).
  - In addition, Pfenex is asking the FDA to designate Bonsity as therapeutically equivalent ([A-rated](#)) to Forteo.
  - Pfenex is conducting a comparative human factors study between Bonsity and Forteo. Pfenex anticipates submitting the final study report to the FDA as early as the second half of October 2019.
- Bonsity carries a boxed warning for potential risk of osteosarcoma.
- Warnings and precautions of Bonsity include treatment duration beyond two years, bone metastases and skeletal malignancies, metabolic bone diseases, hypercalcemia and hypercalcemic disorders, urolithiasis or pre-existing hypercalciuria, orthostatic hypotension, and drug interactions.
- The most common adverse reactions (> 10%) with Bonsity use were arthralgia, pain, and nausea.
- The recommended dose of Bonsity for all indications is 20 mcg subcutaneously once a day into the thigh or abdominal wall.
  - Patients and caregivers who administer Bonsity should receive appropriate training and instruction on the proper use of the Bonsity delivery device from a qualified health professional.
  - The safety and efficacy of teriparatide have not been evaluated beyond 2 years of treatment. Consequently, use of Bonsity for more than 2 years during a patient's lifetime is not recommended.
- Alvogen's launch plans for Pfenex's Bonsity are pending based on the FDA review of therapeutic equivalence to Forteo. Bonsity will be available as a solution in a single-patient-use pen containing 620 mcg/2.48 mL (28 daily doses of 20 mcg).