Tymlos™ (abaloparatide) – New drug approval

- On April 28, 2017, Radius Health announced the FDA approval of Tymlos (abaloparatide) injection for the 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, Tymlos reduces the risk of vertebral fractures and nonvertebral fractures.
    - Because of the unknown relevance of the rodent osteosarcoma findings to humans, cumulative use of Tymlos and parathyroid hormone analogs [eg, Forteo® (teriparatide)] for more than 2 years during a patient's lifetime is not recommended.

- Tymlos is an analog of human parathyroid hormone related peptide, PTHrP(1-34). In animal studies, Tymlos had an anabolic effect on bone, demonstrated by increases in bone mineral density and bone mineral content that correlated with increases in bone strength at vertebral and/or nonvertebral sites.

- The efficacy of Tymlos was evaluated in a clinical study of 2,463 postmenopausal women randomized to Tymlos or placebo. The primary endpoint was the incidence of new vertebral fractures at 18 months. The incidence of nonvertebral fractures was also measured at 18 months.
    - Tymlos resulted in a significant reduction in the incidence of new vertebral fractures vs. placebo at 18 months [0.6% vs. 4.2%, respectively; relative risk = 0.14 (95% CI: 0.05, 0.39, $p < 0.001$)].
    - Tymlos resulted in a significant reduction in the incidence of nonvertebral fractures at the end of 18 months of treatment plus 1 month of follow-up where no drug was administered [2.7% vs. 4.7%, respectively; hazard ratio = 0.57 (95% CI: 0.32, 1.00, $p = 0.49$)].

- Tymlos carries a boxed warning for risk of osteosarcoma.

- Warnings and precautions of Tymlos include orthostatic hypotension, hypercalcemia, and hypercalciuria and urolithiasis.

- The most common adverse reactions (≥ 2%) with Tymlos use were hypercalciuria, dizziness, nausea, headache, palpitations, fatigue, upper abdominal pain, and vertigo.

- The recommended dosage of Tymlos is 80 mcg subcutaneously once daily.
    - The first few doses of Tymlos should be administered where the patient can sit or lie down if necessary, in case symptoms of orthostatic hypotension occur.
    - Patients should receive supplemental calcium and vitamin D if dietary intake is inadequate.

- Radius Health plans to launch Tymlos in June 2017. Tymlos will be available as a 3120 mcg/1.56 mL (2000 mcg/mL) single-patient-use prefilled pen. The prefilled pen delivers 30 doses of Tymlos, each containing 80 mcg of abaloparatide.