Tymlos® (abaloparatide) – New indication

- On December 20, 2022, Radius Health announced the FDA approval of Tymlos (abaloparatide), to increase bone density in men with osteoporosis at high risk for fracture (defined as a history of osteoporotic fracture or multiple risk factors for fracture), or patients who have failed or are intolerant to other available osteoporosis therapy.

- Tymlos is also approved for the for the treatment of postmenopausal women with osteoporosis at high risk for fracture (defined as a history of osteoporotic fracture or multiple risk factors for fracture), or patients who have failed or are intolerant to other available osteoporosis therapy.

- The approval of Tymlos for the new indication was based on Study 019, a randomized, double-blind, placebo-controlled study in 228 men aged 42 to 85 years with osteoporosis. Patients were randomized to receive Tymlos or placebo. The primary endpoint was the percent change from baseline in lumbar spine bone mineral density (BMD) at 12 months.

    — The mean percent change in BMD from baseline to 12 months was 8.5% with Tymlos vs. 1.2% with placebo (treatment difference 7.3, 99% CI: 5.1, 9.6; $p < 0.0001$).

- The most common adverse reactions (≥ 2%) with Tymlos use for osteoporosis in men were injection site erythema, dizziness, arthralgia, injection site pain, injection site swelling, injection site pain, contusion, nausea, diarrhea, abdominal distension, abdominal pain, and bone pain.

- The recommended dosage of Tymlos in all patients is 80 mcg administered subcutaneously once daily.

    — Patients should receive supplemental calcium and vitamin D if dietary intake is inadequate.
    — The safety and efficacy of Tymlos have not been evaluated beyond 2 years of treatment. Use of the drug for more than 2 years during a patient's lifetime is not recommended.