

You are cordially invited to join a presentation on:

# **Incorporating an Anabolic Agent Into Practice**

# Presented by

Alex Hertzman, MD

### **Date & Location**

Wednesday, April 10, 2019 6:30 PM Eastern At Cooper's Hawk Restaurant 7490 Bales Street Liberty Township, Ohio 45069

# **Program Objectives**

- Examine a patient profile that may be appropriate for TYMLOS (abaloparatide)
- Recognize that prior (and especially recent) fractures contribute to an increased risk for future fractures
- Review efficacy and safety data for TYMLOS, including data from its pivotal clinical trial and extension study

## **RSVP Information**

Please contact Julie Gillespie at 937-407-2000 or by email at jgillespie@radiuspharm.com to register.

## **IMPORTANT SAFETY INFORMATION**

#### WARNING: RISK OF OSTEOSARCOMA

- Abaloparatide caused a dose-dependent increase in the incidence of osteosarcoma (a malignant bone tumor) in male and female rats. The effect was observed at systemic exposures to abaloparatide ranging from 4 to 28 times the exposure in humans receiving the 80 mcg dose. It is unknown if TYMLOS will cause osteosarcoma in humans.
- The use of TYMLOS is not recommended in patients at increased risk of osteosarcoma including those with Paget's disease of bone or unexplained elevations of alkaline phosphatase, open epiphyses, bone metastases or skeletal malignancies, hereditary disorders predisposing to osteosarcoma, or prior external beam or implant radiation therapy involving the skeleton.

IMPORTANT SAFETY INFORMATION CONTINUED ON NEXT PAGE





# **IMPORTANT SAFETY INFORMATION (CONT.)**

• Cumulative use of TYMLOS and parathyroid hormone analogs (e.g., teriparatide) for more than 2 years during a patient's lifetime is not recommended.

**Orthostatic Hypotension:** Orthostatic hypotension may occur with TYMLOS, typically within 4 hours of injection. Associated symptoms may include dizziness, palpitations, tachycardia or nausea, and may resolve by having the patient lie down. For the first several doses, TYMLOS should be administered where the patient can sit or lie down if necessary.

**Hypercalcemia:** TYMLOS may cause hypercalcemia. TYMLOS is not recommended in patients with preexisting hypercalcemia or in patients who have an underlying hypercalcemic disorder, such as primary hyperparathyroidism, because of the possibility of exacerbating hypercalcemia.

**Hypercalciuria and Urolithiasis:** TYMLOS may cause hypercalciuria. It is unknown whether TYMLOS may exacerbate urolithiasis in patients with active or a history of urolithiasis. If active urolithiasis or preexisting hypercalciuria is suspected, measurement of urinary calcium excretion should be considered.

**Adverse Reactions:** The most common adverse reactions (incidence ≥2%) are hypercalciuria, dizziness, nausea, headache, palpitations, fatigue, upper abdominal pain, and vertigo.

## **INDICATIONS AND USAGE**

TYMLOS is indicated 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.

## Limitations of Use

Because of the unknown relevance of the rodent osteosarcoma findings to humans, cumulative use of TYMLOS and parathyroid hormone analogs (e.g., teriparatide) for more than 2 years during a patient's lifetime is not recommended.

#### Please see the accompanying Full Prescribing Information, including Boxed Warning.

This program is sponsored by Radius Health.

This invitation is nontransferable.

Attendance at this program is limited to health care professionals (HCPs) involved in the care or treatment of patients with osteoporosis. Further, the following specialties are excluded from participation: Adolescence, Pediatrics, Dentistry, Psychiatry, and Veterinary Services. Guests or spouses who are not HCPs involved in the care or treatment of patients with osteoporosis may not attend. No CME credits are offered for this program. This program may include the provision of a modest meal. Radius Health does not offer such a meal to HCPs whose institutions prohibit such hospitality, nor does Radius Health offer a meal where federal or state laws (e.g., Vermont, Minnesota and New Jersey) limit an HCP's ability to accept such a meal. Accordingly, please consult your legal or ethics advisor regarding any applicable limitation before attending this program. If you are licensed to practice in a state where meals are either prohibited and/or restricted and you accept a meal, you understand that you will be required to reimburse Radius Health for the cost of this meal. Please note that Radius Health is required to report the value of a provided meal pursuant to applicable federal and/or state laws.

