# TYMLOS Label and Business Update

September 22, 2021

- TYMLOS® label: significant update to the Mechanism of Action (MOA) section
- Label change aligns with strategic focus on postmenopausal women at high risk of fracture
- Danielle Holtschlag joins as Head of Sales, bringing 20 years of experience to the team
- Added ~3,000 new TYMLOS patients throughout July and August, up 13% year-over-year

BOSTON, Sept. 22, 2021 (GLOBE NEWSWIRE) -- Radius Health, Inc. (“Radius” or the “Company”) (NASDAQ: RDUS), provided a business update.

Effective September 20, 2021, the following sentence was added to the MOA section of the TYMLOS (abaloparatide) label: “Once-daily administration of abaloparatide stimulates new bone formation on trabecular and cortical bone surfaces by stimulation of osteoblastic activity.” This addition is based on the findings from the Company’s histomorphometry study (BA058-05-020) that was published in the Journal of Bone & Mineral Research (JBMR) in April 2021.

Dr. Bruce Mitlak, the Company’s Chief Medical Officer, commented “This is an important addition to the TYMLOS label as it highlights to our patients and prescribers the bone building MOA of the molecule.” Dr. Mitlak continued “The histomorphometry study provides the first histologic evidence in humans that abaloparatide stimulates new bone formation, in other words, builds new bone.”

Growing the abaloparatide franchise’s commercial business is a major focus of the Company. To that end, Radius has added Danielle Holtschlag as the new Head of Sales. Danielle has over 20 years of commercial leadership experience including 7+ years at Genzyme where she created an inside out sales approach. This effort balances centralized sales coverage with regional representation. Danielle will report directly to Kelly Martin, CEO of Radius.

Sal Grausso will take on a new role leading the Company’s Patient Access Group (PAG). In this role, Sal and his team will focus on the completeness of the TYMLOS patient journey including patient support and product access. PAG will also lay groundwork for patient support and market access for the RAD011 franchise.

Throughout July and August, Radius added 3,002 new TYMLOS patients, up 13% compared to 2,664 new patients added during the same period in 2020.

**About Radius**
Radius is a commercial biopharmaceutical company committed to serving patients with unmet medical needs in endocrinology and other therapeutic areas. Radius’ lead product, TYMLOS® (abaloparatide) injection, was approved by the U.S. Food and Drug Administration for the treatment of postmenopausal women with osteoporosis at high risk for fracture. The Radius clinical pipeline includes investigational abaloparatide injection for potential use in the treatment of men with osteoporosis; an investigational abaloparatide transdermal system for potential use in the treatment of postmenopausal women with osteoporosis; the investigational drug, elacestrant (RAD1901), for potential use in the treatment of hormone-receptor positive breast cancer out-licensed to Menarini Group; and the investigational drug RAD011, a synthetic cannabidiol oral solution with potential utilization in multiple endocrine and metabolic orphan diseases, initially targeting Prader-Willi syndrome.

**About TYMLOS (abaloparatide) injection**
TYMLOS (abaloparatide) 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.

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

**Contraindications:** TYMLOS is contraindicated in patients with a history of systemic hypersensitivity to abaloparatide or to any component of the product formulation. Reactions have included anaphylaxis, dyspnea and urticaria.

**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 pre-existing 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 pre-existing 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.

Please see Full Prescribing Information, including Boxed Warning available at TymlosPI.com.

**About RAD011**
Investigational drug RAD011 is a pharmaceutical-grade synthetic cannabidiol oral solution, manufactured utilizing traditional pharmaceutical manufacturing processes. The product has purity specifications that meet standardized regulatory and quality control requirements and, compared to the process of developing a plant-derived product, the synthetic manufacturing process usually enables increased consistency and greater precision in the product supply. RAD011 has been assessed in over 150 patients across multiple indications and has potential utilization in multiple endocrine and metabolic orphan diseases. Radius is initially targeting Prader-Willi syndrome (PWS) and anticipates initiating a seamless pivotal Phase 2/3 study for patients with PWS in the fourth quarter of 2021 or first quarter of 2022.

**Investor & Media Relations Contact:**
Ethan Holdaway
Email: investor-relations@radiuspharm.com
Phone: (617) 583-2017

Source: Radius Health Inc.