Radius Health, Inc. Provides Abaloparatide Business Update

February 12, 2021

- 17% growth in January 2021 for new TYMLOS® patients vs. previous 4 month trailing average
- Histomorphometry study published: Journal of Bone & Mineral Research in January 2021
- Cardiovascular safety study published: Journal of Clinical Endocrinology & Metabolism in November 2020
- Japan: with our partner – Teijin – the regulatory timelines remain on schedule
- Canada: with our recently announced partner – Paladin Labs – regulatory activity on schedule
- Abaloparatide wearABLe study (Transdermal System) and the ATOM study (Osteoporotic Men at High Risk of Fracture) remain on schedule

BOSTON, Feb. 12, 2021 (GLOBE NEWSWIRE) -- Radius Health, Inc. ("Radius" or the "Company") (Nasdaq: RDUS) provided a business update on the abaloparatide global business. Progress was made, and continues to be made, across the following areas.

New Patient Growth: TYMLOS in the U.S. market

"Our focus on postmenopausal osteoporotic-related fracture patients continues to gain traction," commented Sal Grausso, Chief Commercial Officer for the Company. Grausso added that "We are making progress adjusting our sales and marketing efforts to focus on these fragility fracture patients. We expect continued new patient growth with our U.S. TYMLOS business."

Radius added 1,692 new patients in the month of January. This represents a 17% increase from the previous four-month trailing average. New patients are defined as those patients who have been prescribed TYMLOS and subsequently filled their first prescription.

Abaloparatide Publications: adding to the underlying data of the molecule

"Recently published data continues to reinforce the depth, breadth and overall quality of the abaloparatide molecule," commented Bruce Mitlak, MD, the Company's Chief Medical Officer, focusing on continued progress of the abaloparatide molecule and other bone and endocrine areas of interest. Two publications warrant being highlighted:

- **"Early Effects of Abaloparatide on Bone Formation and Resorption Indices in Postmenopausal Women with Osteoporosis"**
  Dempster et al, JBMR January 2021
  In an open-label, single-arm study conducted over 90 days in 23 postmenopausal women with osteoporosis:

  - Abaloparatide demonstrated increases in bone formation across all four bone envelopes (cancellous, endocortical, intracortical, and periosteal envelopes) in iliac bone biopsies
  - Increases in the bone formation were associated with stimulation of both modeling-based and remodeling-based formation
  - Histomorphometric changes are correlated with the serum biomarker response to abaloparatide, which is associated with increases in bone mass at cortical and trabecular sites

- **"Cardiovascular Safety of Abaloparatide in Postmenopausal Women with Osteoporosis: Analysis From the ACTIVE Phase 3 Trial"**
  Cosman et al, JCEM November 2020
  In a post-hoc analysis:

  - Treatment with abaloparatide and teriparatide resulted in a transient increase in heart rate and a small decrease in one-hour post dose blood pressure, however, these changes were not associated with an increase in serious cardiac adverse events evaluated in ACTIVE, major adverse cardiac events (MACE), or heart failure (HF)
  - Time to first incidence of MACE + HF was longer with abaloparatide and teriparatide vs. placebo

Expanding Abaloparatide

"We continue to make progress on expanding, strengthening and broadening the abaloparatide molecule," commented Chhaya Shah, the Company's Chief Business Officer and head of clinical, regulatory and supply chain for the asset.

Shah added that, "There is currently ongoing regulatory activity in the U.S., Japan, Canada and the E.U. Simultaneously, we are focused on completing both the ATOM study for male osteoporotic patients at high risk of fracture plus the wearABLe study."

About TYMLOS® (abaloparatide) Injection

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 defined as history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.

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.

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.

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.

For the TYMLOS prescribing information, including Boxed Warning, please visit www.tymlospi.com.

About Radius

Radius is a science-driven fully integrated biopharmaceutical company that is committed to developing and commercializing innovative endocrine and other therapeutics. For more information, please visit www.radiuspharm.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including those related to the Company's U.S. and *ex*-U.S. regulatory initiatives and timelines, and growth of the TYMLOS business. These forward-looking statements are based on management's current expectations, and involve known and unknown risks and uncertainties that may cause our actual results, performance or achievements to be materially different from any expressed or implied by the forward-looking statements. These risks include, but are not limited to, the following: uncertainty regarding the results of regulatory submissions and oversight; success of our commercial operations; success of our clinical trials and preclinical studies; and success of any collaboration, partnership, license or similar agreements. These and other important risks and uncertainties discussed in our filings with the Securities and Exchange Commission, or SEC, including under the caption "Risk Factors" in our Annual Report on Form 10-K for the year ending December 31, 2019 and subsequent filings with the SEC, could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

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