Radius Announces Update on TYMLOS® (abaloparatide) Label

December 23, 2021

- FDA approved the removal of the boxed warning from the TYMLOS label, effective December 22, 2021
- The boxed warning had referred to the potential risk of osteosarcoma
- Action follows review of long-term post-marketing data for TYMLOS and PTH class of drugs

BOSTON, Dec. 23, 2021 (GLOBE NEWSWIRE) -- Radius Health, Inc. (“Radius” or the “Company”) (NASDAQ: RDUS) today announced that the U.S. Food and Drug Administration (FDA) has approved updates to the TYMLOS label, including the removal of the boxed warning regarding the risk of osteosarcoma.

The removal of the boxed warning comes after a thorough regulatory review of long-term post-marketing data in TYMLOS and the parathyroid hormone (PTH) class of drugs. Additional labeling revisions include updates to the Warnings and Precautions section about the risk of osteosarcoma (see Important Safety Information below).

Bruce Mitlak, M.D., the Chief Medical Officer of Radius, commented, “This is an important update to the TYMLOS label. Achieving this result was made possible by FDA analysis of a significant amount of data that had been generated over many years.” Dr. Mitlak continued, “This action and subsequent label change will provide both physicians and their patients with valuable information regarding individual treatment decisions.”

“This was a tremendous effort by the Radius team in working with the FDA to obtain approval to remove the boxed warning regarding the risk of osteosarcoma,” added Chhaya Shah, Senior Vice President, who leads the clinical and regulatory activities for abaloparatide. Shah continued, “We remain focused on exploring additional label adjustment opportunities for TYMLOS and, in that regard, maintain an ongoing dialogue with the FDA around additional data.”

About Radius
Radius Health is a global biopharmaceutical company focused on addressing unmet medical needs in the areas of bone health, neuroscience, and oncology. Our team works collaboratively and relentlessly to advance our therapies; all with the goal of improving the lives of patients, their families, and their caregivers. The Radius portfolio consists of commercial and clinical development assets, including early to late-stage drug candidates. Find out more at www.radiuspharm.com.

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

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.

Risk of Osteosarcoma: It is unknown whether TYMLOS will cause osteosarcoma in humans. Osteosarcoma has been reported in patients treated with a PTH-analog in the post marketing setting; however, an increased risk of osteosarcoma has not been observed in observational studies in humans. There are limited data assessing the risk of osteosarcoma beyond 2 years of TYMLOS use. Avoid use of TYMLOS for patients at an increased baseline risk for osteosarcoma including patients with open epiphysis (pediatric and young adult patients); metabolic bone diseases other than osteoporosis, including Paget’s disease of the bone; bone metastases or a history of skeletal malignancies; prior external beam or implant radiation therapy involving the skeleton; or hereditary disorders predisposing to osteosarcoma.

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.

Pregnancy and Lactation: TYMLOS is not indicated for use in females of reproductive potential.

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

Please see Full Prescribing Information available at TymlosPI.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 without

limitation statements regarding future opportunities to further adjust the TYMLOS label.

These forward-looking statements are based on management's current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: the adverse impact the ongoing COVID-19 pandemic is having and is expected to continue to have on our business, financial condition and results of operations, including our commercial operations and sales, clinical trials, preclinical studies, and employees; quarterly fluctuation in our financial results; our dependence on the success of TYMLOS, and our inability to ensure that TYMLOS will obtain regulatory approval outside the U.S. or be successfully commercialized in any market in which it is approved, including as a result of risk related to coverage, pricing and reimbursement; risks related to competitive products; risks related to our ability to successfully enter into collaboration, partnership, license or similar agreements; risks related to clinical trials, including our reliance on third parties to conduct key portions of our clinical trials and uncertainty that the results of those trials will support our product candidate claims; the risk that adverse side effects will be identified during the development of our product candidates or during commercialization, if approved; risks related to manufacturing, supply and distribution; and the risk of litigation or other challenges regarding our intellectual property rights. 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, 2020 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. Any such forward-looking statements represent management's estimates as of the date of 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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