Radius Health Presents Analysis from Phase 3 ACTIVE Trial and Data from Preclinical Studies for TYMLOS® (abaloparatide) Injection at ENDO 2019 Annual Meeting

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-Post-hoc analysis suggests abaloparatide may be useful in the treatment of women with postmenopausal osteoporosis and concurrent osteoarthritis, at high risk for fracture-

-Preclinical studies provide explanations for the net bone gain observed in the Phase 3 ACTIVE trial in abaloparatide-treated patients-

WALTHAM, Mass., March 23, 2019 (GLOBE NEWSWIRE) -- Radius Health, Inc. (Nasdaq: RDUS), a science-driven fully integrated biopharmaceutical company that is committed to developing and commercializing innovative endocrine therapeutics in the areas of osteoporosis and oncology, today presented a post-hoc analysis of Phase 3 data from different patient populations included in the ACTIVE trial, and results from preclinical studies of abaloparatide and its effect on the development and growth of osteoclasts and on bone resorption during an oral session at ENDO 2019, the Endocrine Society's Annual Meeting and Expo in New Orleans, LA.

The first oral presentation titled "The Effect of Abaloparatide on Bone Mineral Density and Fracture Incidence in Postmenopausal Women with Osteoporosis and Osteoarthritis," showed that in a subpopulation of postmenopausal women from the ACTIVE study who also had osteoarthritis (OA), abaloparatide was associated with significant reduction in new vertebral fractures as well as significant improvements in bone mineral density (BMD), versus placebo.

The relationship between OA and osteoporosis is unclear but increased risk of fragility fracture has been associated with OA despite those patients having higher than average BMD. Of the 2,463 women enrolled in the Phase 3 ACTIVE trial, 888 patients with ongoing OA were identified. The most common sites of OA were at the spine (n=348, 39.2 percent) and knee (n=338, 38.1 percent). At 18 months, significant increases ($P<0.0001$) in BMD from baseline were observed for abaloparatide versus placebo at the total hip (mean change 3.17 percent versus -0.35 percent), femoral neck (2.81 percent versus -0.36 percent), and lumbar spine (8.78 percent versus 0.86 percent); which was consistent with the overall ACTIVE population results.

"Many patients with osteoporosis also have osteoarthritis. This post-hoc analysis of the pivotal ACTIVE clinical trial provides important information regarding the effects of abaloparatide in this patient population," said John P. Bilezikian, M.D., Chief, Emeritus, of the Division of Endocrinology and Director, Emeritus, of the Metabolic Bone Diseases Program at the Vagelos College of Physicians and Surgeons, Columbia University Medical Center. "Results from this analysis suggest abaloparatide may be useful as a therapy of postmenopausal women with osteoporosis who also have osteoarthritis and are at high risk for fracture."

The second oral presentation titled "Different Effects of Abaloparatide and hPTH(1-34) on Osteoclastogenesis and Bone Resorption" used data from preclinical studies of abaloparatide. The analysis provides mechanistic explanations for the net bone gain observed in the ACTIVE trial, indicating that increased bone mass is, at least partly, the consequence of reduced osteoclast (bone resorption) activity.

"We're pleased to share this new analysis in women who have postmenopausal osteoporosis and osteoarthritis, as well as data from preclinical studies that may explain the increased bone mass observed in abaloparatide-treated patients," said Bruce Mitlak, M.D., Vice President of Clinical Development at Radius Health. "We are committed to providing information about abaloparatide to help inform treatment decisions for healthcare professionals managing women with postmenopausal osteoporosis."

Separately, Radius Health will present a poster titled: "Effect of Abaloparatide on Bone Mineral Density and Fracture Incidence in a Subset of Younger Postmenopausal Women with Osteoporosis at High Risk for Fracture Representative of Covered Commercial Insurance Enrollees."

About Postmenopausal Osteoporosis
Osteoporosis is a silent disease, often displaying no signs or symptoms until a fracture occurs, leaving a majority of patients undiagnosed and undertreated. Osteoporotic fractures create a significant healthcare burden, and represent a significant unmet medical need. The majority (71 percent) of osteoporosis-related fractures in the U.S. among those 50 and older occur in women.

The National Osteoporosis Foundation (NOF) has estimated that nearly 8.2 million women in the U.S. over the age of 50 have osteoporosis, and nearly one in two women over the age of 50 will have a fragility fracture (or low-impact fracture that is often the result of a fall from standing height or lower) in her remaining lifetime.

The annual incidence of osteoporotic fractures is higher than that of stroke, heart attack and breast cancer combined; osteoporotic fractures also account for more hospitalizations and associated costs than cardiovascular disease and breast cancer.

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 a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. Radius also is developing abaloparatide-patch based on 3M Company's patented Microstructured Transdermal System technology for potential use as a treatment for postmenopausal women with osteoporosis.

About ACTIVE
The Phase 3 ACTIVE (Abaloparatide Comparator Trial In Vertebral Endpoints) trial was a randomized, double-blind, placebo-controlled, comparative, multicenter, 18-month international study in 2,463 postmenopausal women with osteoporosis designed to evaluate the efficacy and safety of abaloparatide-SC 80 mcg to reduce the risk of vertebral and nonvertebral fractures. The results of ACTIVE were published in the *Journal of the American Medical Association* in August of 2016.

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 therapeutics in the areas of osteoporosis and oncology. 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 an investigational abaloparatide patch for potential use in osteoporosis; the investigational drug elacestrant (RAD1901) for potential use in hormone-receptor positive breast cancer; and the investigational drug RAD140, a non-steroidal, selective androgen receptor modulator (SARM) under investigation for potential use in hormone-receptor positive breast cancer. 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 without limitation statements regarding the incidence of osteoporotic fractures and the health burden associated with osteoporosis; and the potential clinical uses and therapeutic and other benefits of our product candidates, including abaloparatide-patch, elacestrant and RAD140.

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: we expect to need to raise additional funding, which may not be available; risks related to raising additional capital; our limited operating history; 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 agreements and any collaborations failing to be successful; risks related to clinical trials, including our reliance on third parties to conduct key portions of our clinical trials and uncertainty that results 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, 2018 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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