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Radius Health Presents Positive Data for the ACTIVExtend BMD Responder Analysis for TYMLOS™ (abaloparatide) Injection at ENDO 2018 Annual Meeting

WALTHAM, Mass., March 17, 2018 (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 results from "Response Rates for Hip, Femoral Neck, and Lumbar Spine Bone Mineral Density (BMD) in Patients Treated with Abaloparatide Followed by Alendronate — Results from Phase 3 ACTIVExtend" at ENDO 2018, the Endocrine Society's 100th Annual Meeting and Expo in Chicago.

In ACTIVExtend, patients who had completed 18 months of TYMLOS (abaloparatide) injection or placebo in the ACTIVE Phase 3 trial were transitioned to receive 24 additional months of open-label alendronate, a bisphosphonate. BMD was measured at the lumbar spine, total hip, and femoral neck from the beginning of ACTIVE to the end of ACTIVExtend. A responder was defined as a patient with BMD increases at all three sites.

BMD response rates increased in both the abaloparatide followed by alendronate group and the placebo followed by alendronate group from ACTIVE baseline through the 43 months of ACTIVExtend. In addition, there were significantly greater BMD response rates in the abaloparatide followed by alendronate group vs. the placebo followed by alendronate group at all three sites combined for BMD increases of more than 0 percent, 3 percent, and 6 percent at 43 months and at each anatomic site for BMD increases of more than 3 percent and 6 percent at each visit and at 43 months.

"We are extremely pleased to share our new responder analysis from the 43-month data relating to BMD," said Chad Deal, MD, lead author and Head of the Center for Osteoporosis and Metabolic Bone Disease and Vice Chair Quality and Outcomes, Department of Rheumatology, Cleveland Clinic. "These findings support the belief that sequential treatment with abaloparatide followed by alendronate may result in consistent gains in bone mass."

At the 43-month timepoint, 60.7 percent (n=307/506) of abaloparatide followed by alendronate patients experienced BMD increases of more than 3 percent at all three sites ($p<0.0001$) compared with 24 percent (n=121/505) of patients who received placebo followed by alendronate. Increases of more than 6 percent at all three sites were experienced by 33.2 percent (n=168/506) of abaloparatide followed by alendronate patients compared with 4 percent (n=20/505) of patients who received placebo followed by alendronate ($p<0.0001$).

"It's encouraging to see that the results from the ACTIVExtend Responder Analysis are consistent with the significant BMD response with TYMLOS versus placebo observed in ACTIVE," said Lorie Fitzpatrick, MD, Chief Medical Officer, Radius Health.

Separately, ACTIVExtend BMD findings in risk subgroups are being presented at ENDO 2018 today at 1:00 p.m. CT in the poster presentation titled: "Fracture and Bone Mineral Density Response by Baseline Risk in Patients Treated with Abaloparatide Followed by Alendronate — Results from Phase 3 ACTIVExtend" (Leder).

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 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 ACTIVE and ACTIVExtend

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. ACTIVExtend, an extension of ACTIVE, enrolled patients who had completed 18 months of abaloparatide-SC or placebo in ACTIVE to receive up to 24 additional months of open-label alendronate. The results of the first six months of ACTIVExtend were published in the *Mayo Clinic Proceedings* in February of 2017.

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. Radius' Marketing Authorisation Application (MAA) for abaloparatide-SC for the treatment of women with postmenopausal osteoporosis was validated and is currently undergoing regulatory review by the European Medicines Agency (EMA).

Radius also is developing abaloparatide patch based on 3M's patented Microstructured Transdermal System technology for potential use as a treatment for postmenopausal women with osteoporosis.

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. Radius' Marketing Authorisation Application (MAA) for abaloparatide-SC for the treatment of postmenopausal women with osteoporosis is under regulatory review in Europe. 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 progress of abaloparatide-SC in the regulatory process with the EMA, 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 and any collaboration agreements 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 period ending December 31, 2017 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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