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# Mayo Clinic Proceedings Publishes Positive Results from the ACTIVExtend Clinical Trial of Abaloparatide-SC in Postmenopausal Women With Osteoporosis

*— Results from interim analysis of the ACTIVExtend study of postmenopausal women with osteoporosis treated for 18 months with investigational drug abaloparatide-SC in the ACTIVE trial who were transitioned to alendronate in ACTIVExtend show statistically significant reductions at six months in the incidence of new vertebral, nonvertebral, and major osteoporotic fractures when compared with placebo treated patients who were also transitioned to alendronate —*

WALTHAM, Mass., Feb. 01, 2017 (GLOBE NEWSWIRE) -- Radius Health, Inc. (Nasdaq:RDUS), a science-driven biopharmaceutical company that is committed to developing innovative therapeutics in the areas of osteoporosis, oncology and other endocrine diseases, today announced that positive results from a planned 6-month interim analysis of the ACTIVExtend clinical trial were published in the *Mayo Clinic Proceedings*. The results of ACTIVExtend following 6 months of alendronate treatment show that patients previously treated with daily abaloparatide-SC for 18 months in the ACTIVE trial who were transitioned to alendronate had significantly greater reduction of 87% in the incidence of new vertebral fractures ($p < 0.001$), of 52% in nonvertebral fractures ($p = 0.02$) and 58% in major osteoporotic fractures ($p<0.01$) compared to the previous placebo treated patients who were also transitioned to alendronate. Bone mineral density at the spine, femoral neck and hip increased significantly in the abaloparatide-treated patients after transitioning to alendronate ($p<0.0001$).

The initial separation of incidence of nonvertebral fractures on the Kaplan-Meier curve during ACTIVE for the abaloparatide-SC treated patients versus placebo continued into the first six months of alendronate treatment during ACTIVExtend, and the early separation in the incidence of major osteoporotic fracture continued to diverge over time. The only treatment-emergent AE that occurred in more than 4% of patients was arthralgia, and the incidence was similar between both groups.

Abaloparatide-SC is an investigational treatment for postmenopausal women with osteoporosis and its safety and efficacy have not been established. A New Drug Application for abaloparatide is currently under review by the U.S. Food & Drug Administration.

"Results from the landmark ACTIVE and ACTIVExtend trial showed statistically significant reductions in the incidence of new vertebral, nonvertebral, and major osteoporotic fractures versus placebo in postmenopausal women with osteoporosis," said Dr. Felicia Cosman, MD, lead author of the paper and osteoporosis specialist, Medical Director of the Clinical Research Center at Helen Hayes Hospital, Senior Clinical Director of the National Osteoporosis Foundation and Professor of Medicine at Columbia University and North American Editor in Chief of the Osteoporosis International Journal. "Our findings indicate that there is a persistent effect of abaloparatide after transition to alendronate. Even though both the abaloparatide and placebo groups were on alendronate for 6 months, there was a significant reduction in fractures in the group that had been on abaloparatide. Approximately two million osteoporotic fractures occur annually in the U.S., and the risk of a subsequent fracture is substantially increased in the first few years after a fracture. These findings suggest that early treatment with a bone-building anabolic such as abaloparatide-SC, if approved, followed by maintenance with an antiresorptive agent could be an attractive treatment strategy for postmenopausal women with osteoporosis."

"We are pleased to have these initial findings from ACTIVExtend published in the Mayo Clinic Proceedings and are encouraged by the totality of clinical trial data collected which show that abaloparatide-SC, if approved, could have a significant impact in improving outcomes for women with postmenopausal osteoporosis," said Dr. Lorraine A. Fitzpatrick, Chief Medical Officer of Radius. "We look forward to presenting additional analyses at future scientific meetings.

**About Postmenopausal Osteoporosis**
Osteoporosis is a silent disease, often displaying no signs or symptoms until a fracture occurs, leaving the majority of patients undiagnosed and untreated, representing a high unmet medical need. Osteoporotic fractures create a significant healthcare burden. An estimated two million osteoporotic fractures occur annually in the U.S., and this number is projected to grow to three million by 2025.

The National Osteoporosis Foundation (NOF) has estimated that 10 million people in the U.S., composed of eight million women and two million men, already have osteoporosis, and another approximately 44 million people have low bone mass placing them at increased risk for osteoporosis.

The debilitating effects of osteoporosis have substantial costs. When left untreated, osteoporosis leads to fractures which can have both physical and emotional consequences on a patient including pain and disability, inability to fully perform routine work or daily activities, and in some cases, result in death.

**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 the investigational drug abaloparatide-SC 80 mcg to reduce the risk of vertebral and nonvertebral fractures. Miller PD et al, "Effect of Abaloparatide vs. Placebo on New Vertebral Fractures in Postmenopausal Women With Osteoporosis, A Randomized Clinical Trial" Journal of the American Medical Association 2016 Aug 16;316(7):722-733. 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.

**About Abaloparatide**

Abaloparatide-SC is an investigational therapy for the potential treatment of postmenopausal women with osteoporosis. Abaloparatide is a novel peptide that engages the parathyroid hormone receptor (PTH1 receptor) and was selected for clinical development based on its favorable bone building activity.

Abaloparatide-SC has completed Phase 3 development for potential use as a daily self-administered injection (abaloparatide-SC). In the fourth quarter of 2015, Radius' Marketing Authorisation Application (MAA) for abaloparatide-SC for the treatment of patients with postmenopausal osteoporosis was validated and is currently undergoing regulatory review by the European Medicines Agency (EMA). Radius submitted a New Drug Application (NDA) for abaloparatide-SC to the US Food and Drug Administration (FDA) at the end of the first quarter of 2016, which has been accepted for filing with a PDUFA date of March 30, 2017. Radius also is developing abaloparatide-transdermal (abaloparatide-TD) 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 biopharmaceutical company that is committed to developing innovative therapeutics in the areas of osteoporosis, oncology and endocrine diseases. Radius' lead product candidate, the investigational drug abaloparatide for subcutaneous injection, has completed Phase 3 development for potential use in the treatment of postmenopausal women with osteoporosis. Radius' Marketing Authorisation Application (MAA) for abaloparatide-SC for the treatment of postmenopausal women with osteoporosis is under regulatory review by the EMA in Europe and a New Drug Application (NDA) has been accepted for filing by the FDA with a PDUFA date of March 30, 2017. The Radius clinical pipeline also includes an investigational abaloparatide transdermal patch for potential use in postmenopausal women with osteoporosis and the investigational drug RAD1901 for potential use in hormone-driven and/or hormone-resistant breast cancer, and vasomotor symptoms in postmenopausal women. Radius' preclinical pipeline includes RAD140, a non-steroidal, selective androgen receptor modulator (SARM) under investigation for potential use in 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 expectations for abaloparatide-SC, including without limitation, expectations regarding the clinical significance of clinical trial data for abaloparatide-SC, the potential medical benefit of treatment with abaloparatide-SC for postmenopausal women with osteoporosis, the progress of abaloparatide-SC in the regulatory process with the FDA and the EMA, the potential indications for abaloparatide-SC, the incidence of osteoporotic fractures and the health burden associated with osteoporosis, and the potential clinical uses for the abaloparatide transdermal patch, RAD1901 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: the risk that the results of clinical trials of abaloparatide-SC will not meet regulatory requirements for approval or that regulatory authorities may require additional data or further studies; our dependence on the success of abaloparatide-SC, and our inability to ensure that abaloparatide-SC will obtain regulatory approval or be successfully commercialized; the risk that results of clinical trials of abaloparatide-SC and of our other product candidates may not support product claims, even if approved; failure to achieve market acceptance of abaloparatide-SC, if approved; the availability of coverage and reimbursement for abaloparatide-SC, if approved; the risk that a regulatory or government official will determine that third-

parties with a financial interest in the outcome of the Phase 3 study of abaloparatide-SC affected the reliability of the data from the study; failure to establish an effective process for distribution of abaloparatide-SC; and the other important factors discussed under the caption "Risk Factors" in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on February 25, 2016, and in our other reports filed with the SEC, that 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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