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Radius Announces Publication of Additional Positive Results from the Phase 3 ACTIVE Trial of Abaloparatide-SC in JBMR

Results show consistency of Abaloparatide-SC responses across a wide range of patient subgroups

WALTHAM, Mass., Sept. 18, 2016 (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 endocrine diseases, today announced that additional positive results from the Phase 3 ACTIVE (**A**baloparatide **C**omparator **T**rial **I**n **V**ertebral **E**ndpoints) trial were published in the *Journal of Bone and Mineral Research (JBMR)*.

In the article "Effects of Abaloparatide-SC on Fracture and Bone Mineral Density in Subgroups of Postmenopausal Women with Osteoporosis and Varying Baseline Risk Factors" JBMR 2016 Sept 9 [Epub ahead of print] patients in the ACTIVE trial were stratified into prespecified subgroups of baseline risk factors, inclusive of BMD, prior fracture history and age, to determine the consistency of the response for abaloparatide-SC versus placebo. http://onlinelibrary.wiley.com/doi/10.1002/jbmr.2991/epdf

"Results from the Phase 3 ACTIVE trial show that abaloparatide-SC may provide substantial benefit for a broad range of postmenopausal women with osteoporosis irrespective of their baseline risk factors, including age and prior fracture history," said Dr. Felicia Cosman, M.D., osteoporosis specialist and Medical Director of the Clinical Research Center at Helen Hayes Hospital, Senior Clinical Director of the National Osteoporosis Foundation, Professor of Medicine at Columbia University, consultant to Radius and lead author of the paper. "These data are important for the large number of postmenopausal women who may be at risk of a fracture and show that anabolic therapy could provide more consistent, potent and early benefits and may be the most efficient way for these patients to achieve ultimate bone mineral density goals."

"We are pleased to have these findings published in *JBMR*, as well as the opportunity to present additional scientific information about abaloparatide-SC as part of the American Society of Bone and Mineral Research 2016 Annual Meeting," said Dr. Lorraine A. Fitzpatrick, Chief Medical Officer of Radius. "Approximately two million osteoporotic fractures occur annually in the U.S., which create physical and psychological burdens for those affected by diminishing their independence and quality of life. Radius Health is committed to pursuing new therapeutic options which have the potential to improve outcomes for these patients."

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

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. 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

The Phase 3 ACTIVE (**A**baloparatide **C**omparator **T**rial **I**n **V**ertebral **E**ndpoints) 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.

About Abaloparatide

Abaloparatide 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 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 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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