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JAMA Publishes Positive Phase 3 Data for Abaloparatide in Postmenopausal Women With Osteoporosis

Results from Phase 3 ACTIVE trial show abaloparatide significantly reduced the incidence of new vertebral fractures and nonvertebral fractures in postmenopausal women with osteoporosis at 18 months when compared with placebo

WALTHAM, Mass., Aug. 16, 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 other endocrine diseases, today announced that positive results from the Phase 3 ACTIVE (Abaloparatide Comparator Trial In Vertebral Endpoints) trial were published in the *Journal of the American Medical Association (JAMA)*. This landmark trial enrolled 2,463 patients to evaluate the safety and efficacy of investigational drug abaloparatide for the treatment of postmenopausal women with osteoporosis. The ACTIVE results showed that patients treated with daily abaloparatide for 18 months had a significantly greater reduction in the incidence of new vertebral fractures ($p < 0.001$) and nonvertebral fractures ($p = 0.049$) compared to placebo.

"The landmark ACTIVE trial results are important and further validate abaloparatide's potential to consistently, substantially and rapidly reduce both new vertebral and nonvertebral fractures in postmenopausal women with osteoporosis," said Dr. Paul Miller, Medical Director at the Colorado Center for Bone Research and lead author of the paper. "Approximately two million osteoporotic fractures occur annually in the U.S., which create physical and psychological burdens for affected women by diminishing their independence and quality of life. There is a great unmet medical need for therapies which could provide more consistent potent and early benefits to patients."

"We are honored to have these findings published in *JAMA*, and are encouraged by the totality of data collected to date which demonstrate that abaloparatide, 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 scientific information about abaloparatide as part of the [American Society for Bone Mineral Research \(ASBMR\) Annual Meeting](#) in Atlanta, Georgia September 16-19, 2016."

Abaloparatide 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.

Access the online JAMA manuscript: <http://jama.jamanetwork.com/article.aspx?doi=10.1001/jama.2016.11136>

Attachments accompanying this release are available at:

<http://www.globenewswire.com/NewsRoom/AttachmentNg/5c505534-2d72-4096-8270-62ad86966e54>

<http://www.globenewswire.com/NewsRoom/AttachmentNg/87b6b29d-7897-4ec7-a23b-0fc480ca72b2>

<http://www.globenewswire.com/NewsRoom/AttachmentNg/ec83330c-3e30-4940-bd8c-669eb275ae71>

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 high 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 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.

About Abaloparatide

Abaloparatide is an investigational therapy for the potential treatment of women with postmenopausal osteoporosis who are at an increased risk for a fracture. Abaloparatide is a novel synthetic 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 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 reduction of fracture risk in postmenopausal women with osteoporosis. Radius' Marketing Authorisation Application (MAA) for abaloparatide-SC for the treatment of postmenopausal women with osteoporosis is under regulatory review 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 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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