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Radius Presents Abaloparatide Transdermal Patch Development Program at American Society for Bone and Mineral Research (ASBMR) 2016 Annual Meeting

-Second Generation Transdermal Patch Achieves Pharmacokinetic Objectives—

WALTHAM, Mass., Sept. 19, 2016 (GLOBE NEWSWIRE) -- Radius Health Inc. (Nasdaq:RDUS) a science-driven biopharmaceutical company committed to developing innovative therapeutics in the areas of osteoporosis, oncology and endocrine diseases today gave an oral presentation at the Late-Breaking Abstract Session titled "Clinical Development of an Optimized Abaloparatide Transdermal Patch" at the American Society for Bone and Mineral Research (ASBMR) 2016 Annual Meeting, at the Georgia World Congress Center in Atlanta, Georgia.

"This is the first successful application of formulation technology to enable alterations in the pharmacokinetic profile of transdermally delivered abaloparatide in post menopausal women," said Dr. Gary Hattersley, Chief Scientific Officer of Radius Health. "We believe the results from these pilot pharmacokinetic studies place us firmly on the path to establishing comparable drug exposure to subcutaneous abaloparatide."

Radius presented results from the pilot pharmacokinetic studies of the second generation transdermal patch in postmenopausal women demonstrating the targeted changes in the time to peak concentration (T_{max}); half life (T_{1/2}) and area under the curve (AUC). These results establish the basis for selection of the transdermal patch formulation for bioequivalence studies.

The presentation included a report on the overall safety profile of the first generation transdermal patch in the completed six month Phase 2 bone mineral density study where there was a similar incidence of treatment emergent adverse events across the subcutaneous and transdermal dose groups. As previously reported, the first generation transdermal patch demonstrated a unique and pulsatile pharmacokinetic profile and resulted in dose proportionate increases in bone mineral density when patients self administered the patch over the six month duration of the study.

Radius initiated a second generation program to apply formulation technology in developing multiple transdermal patch alternatives that were screened in a nonhuman primate model for changes in the pharmacokinetic profile. These primate studies identified second generation transdermal patches with the potential to achieve bioequivalence to the subcutaneous administration of abaloparatide. The pilot pharmacokinetic studies were initiated to replicate these findings after single dose administration in the postmenopausal subjects.

The pilot pharmacokinetic studies establish a basis for Radius to select an optimized second generation transdermal patch and to design a formal bioequivalence study. Final selection of the optimized patch will include an evaluation of manufacturing, stability, and other considerations as required to meet regulatory requirements.

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 (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.

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-TD, including without limitation, expectations regarding the significance of clinical trial data from the pilot pharmacokinetic studies of abaloparatide-TD for the conduct of a formal bioequivalence study and demonstration of comparable drug exposure to abaloparatide-SC, the potential medical benefit of treatment with abaloparatide 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 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.

Investor Relations Contact:

Barbara Ryan

Email: bryan@radiuspharm.com

Phone: 203-274-2825

Media Contact:

Lori Gorski

Email: Lgorski@radiuspharm.com

Phone: 617-551-4096