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Investigational Drug Abaloparatide Reduces the Incidence of Fractures in Postmenopausal Women With Osteoporosis

Radius Health announces positive Phase 3 data from the ACTIVExtend trial presented at the American Society for Bone and Mineral Research (ASBMR) 2015 Annual Meeting

First six months of top-line data from ACTIVExtend show that treatment with investigational drug abaloparatide-SC followed by alendronate provides important clinical benefit with reductions in new vertebral, non-vertebral and clinical osteoporotic fractures

WALTHAM, Mass., Oct. 12, 2015 (GLOBE NEWSWIRE) -- Radius Health, Inc. (Nasdaq:RDUS) announced positive top-line data from the first six months of the ACTIVExtend trial that showed women who were previously treated with 18 months of abaloparatide (ABL) subcutaneous (SC) injection experienced no new vertebral fractures and an increased bone mineral density (BMD) during the first six months of treatment on alendronate (ALN). These data were presented today at a plenary oral session during the American Society for Bone and Mineral Research (ASBMR) 2015 Annual Meeting.

The first six months of the Phase 3 ACTIVExtend trial were conducted in 1,139 subjects enrolled in the ACTIVE trial, who completed 18 months of treatment with either ABL-SC or placebo. Patients in the ACTIVE study were offered up to 24 additional months of treatment with ALN at a dose of 70 mg per week.

"There is a significant need for additional treatment options for women with postmenopausal osteoporosis who are at risk of experiencing a fracture," said Dr. Felicia Cosman, Lead Investigator of the ACTIVExtend trial, osteoporosis specialist and 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. "Abaloparatide was designed to have a unique mechanism of action with the goal of stimulating bone formation, increasing bone mineral density, restoring bone microarchitecture and augmenting bone strength. Impressive results on bone density and fracture risk were seen throughout the skeleton after the first six months of the ACTIVExtend trial, when women were given alendronate after 18 months of abaloparatide treatment. This therapeutic sequence could have the potential to help a broad range of osteoporosis patients."

Over a 25 month period, women in the ABL-SC/ALN treatment group on average achieved a 12.8 percent increase in BMD at the lumbar spine, a 5.5 percent increase in BMD at the total hip and a 4.5 percent increase in BMD at the femoral neck. In this treatment group, 20.4 percent of patients achieved a 6 percent increase or greater in BMD at all three sites (lumbar spine, total hip and femoral neck).

The adverse events reported during the ALN treatment period were consistent with previous clinical experience. The most common adverse events included arthralgia, dyspepsia, upper respiratory infection, urinary tract infection and bone pain.

"These data build on the positive top-line results from the previously presented ACTIVE trial, which supports the potential use of abaloparatide in women with postmenopausal osteoporosis," said Robert E. Ward, President and Chief Executive Officer at Radius Health. "Osteoporosis is often undiagnosed and is a major public health concern worldwide. We are focusing on providing patients with options for managing this undertreated disease, and we look forward to advancing our U.S. and European regulatory submissions for abaloparatide."

About ACTIVExtend

ACTIVExtend is an extension study evaluating 24 months of standard-of-care osteoporosis management in women who were at risk for experiencing a fracture, following completion of 18 months of ABL-SC or placebo treatment in the Phase 3 ACTIVE trial.

About Osteoporosis

Osteoporosis affects many postmenopausal women since the production of estrogen, a hormone in women that protects bones, decreases sharply when women reach menopause, resulting in bone loss and increasing the risk for a fracture. Approximately one in two women over age 50 will break a bone because of osteoporosis.

The World Health Organization has officially declared osteoporosis a public health crisis. Osteoporosis is a silent disease, often displaying no signs or symptoms until a broken bone occurs. When a woman experiences a fracture, it can often have devastating consequences and make it hard to complete daily activities, such as driving, climbing stairs, or even walking.

These fractures are common and place an enormous medical and personal burden on postmenopausal women. Over 200 million people worldwide suffer from osteoporosis, and two million osteoporosis related fractures occur annually in the United States.

The majority of osteoporosis patients remain undiagnosed and undertreated, and there is an unmet medical need for treatment of incident non-vertebral fractures which currently represent 73 percent of all fractures.

About Abaloparatide
Radius Health's investigational drug abaloparatide is a synthetic peptide analog of human parathyroid hormone-related protein (hPTHrP), a naturally occurring bone-building hormone that has the potential to increase bone mineral density by stimulating new bone formation. Abaloparatide-SC is currently completing Phase 3 development for potential use as a daily self-administered injection for the treatment of patients with postmenopausal osteoporosis, who are at an increased risk for a fracture. Radius is also developing the investigational drug abaloparatide-transdermal for potential use as a short wear-time transdermal patch designed to administer abaloparatide without the need for subcutaneous injection based on 3M's patented Microstructured Transdermal System technology.

About Radius Health
Through cutting-edge science, Radius Health discovers, develops and plans to deliver innovative therapies for the large and underserved osteoporosis patient population, as well as other serious endocrine-mediated diseases including metastatic breast cancer. The Company's lead investigational drug product candidate, abaloparatide, is in development, in both injection (Abaloparatide-SC) and transdermal (Abaloparatide-TD) methods of administration, for the potential prevention of fractures in postmenopausal women who are at risk of fracture from osteoporosis. The Radius clinical portfolio also includes an investigational drug, RAD1901, for the treatment of hormone driven, or hormone resistant, metastatic breast cancer and vasomotor symptoms. 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 statements regarding expectations for abaloparatide, including without limitation, expectations regarding the clinical significance of data from our Phase 3 ACTIVExtend study, the mechanism of action of abaloparatide, regulatory submissions seeking approval of abaloparatide-SC, the potential therapeutic benefits of abaloparatide-SC for patients, and the incidence of and adequacy of treatments for osteoporosis.

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: our dependence on the success of abaloparatide-SC, and our inability to ensure that abaloparatide-SC will obtain regulatory approval in the timeframe anticipated or at all or be successfully commercialized; we have no product revenues; our need for additional funding, which may not be available; we are not currently profitable and may never become profitable; restrictions imposed on our business by our credit facility, and risks related to default on our obligations under our credit facility; risks related to raising additional capital; our limited operating history; quarterly fluctuation in our financial results; risks related to clinical trials, including having most of our products in early stage 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; product candidates for which we obtain marketing approval, if any, could be subject to restrictions or withdrawal from the market and we may be subject to penalties; failure to achieve market acceptance of our product candidates; risks related to the use of our limited resources on particular product candidates and not others; delays in enrollment of patients in our clinical trials, which could delay or prevent regulatory approvals; the dependence of our drug development program upon third-parties who are outside our control; 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; our reliance on third parties to formulate and manufacture our product candidates; failure to establish additional collaborations; our lack of experience selling, marketing and distributing products and our lack of internal capability to do so; failure to compete successfully against other drug companies; developments by competitors may render our products or technologies obsolete or non-competitive; risks related to the fact that our drugs may sell for inadequate prices or patients may be unable to obtain adequate reimbursement; effects of product liability lawsuits on commercialization of our products; failure to comply with obligations of our intellectual property licenses; failure to protect our intellectual property or failure to secure necessary intellectual property related to abaloparatide-SC, abaloparatide-TD, RAD-1901 and/or RAD-140; our or our licensors' inability to obtain and maintain patent protection for technology and products; risks related to our compliance with patent application requirements; failure to protect the confidentiality of our trade secrets; risks related to our infringement of third parties' rights; risks related to employees' disclosure of former employers' trade secrets; risks associated with intellectual property litigation, including expending substantial resources and distracting personnel from their normal responsibilities; risks associated with healthcare reform; our failure to comply with healthcare laws and regulations; our exposure to claims associated with the use of hazardous materials and chemicals; inability to successfully manage our growth; risks relating to business combinations and acquisitions; our reliance on key executive officers and advisors; our inability to hire additional qualified personnel; volatility in the price of our common

stock; capital appreciation is the only source of gain for our common stock; risks related to increased costs and compliance initiatives associated with operating as a public company; our directors, executive officers and principal stockholders have substantial control over us and could delay or prevent a change in control; future sales of our common stock could depress the price of our common stock; inaccurate or unfavorable information about us could cause the price of our common stock to decline; provisions in our charter documents and Delaware law could discourage takeover attempts; and our ability to use our net operating loss carry forwards and certain other tax attributes may be limited.

These and other important factors discussed under the caption "Risk Factors" in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 10, 2015, and our most recent quarterly and other reports filed 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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