



December 21, 2014

## Radius Announces Positive Phase 3 Top-Line Results for Its Investigational Drug Abaloparatide-SC in Postmenopausal Women With Severe Osteoporosis

*Study Meets Primary Endpoint of Reducing the Percentage of Patients with Incident Vertebral Fracture and Also Meets Important Secondary Endpoints: Adverse Events Consistent with Previous Clinical Experience*

*Radius Remains on Track for Completion of the Ongoing 6-Month ACTIVEExtend Study and NDA Submission in the Second Half of 2015*

*Radius' Investigational Drug Abaloparatide Transdermal Program Achieves Key Milestone in its Development as a Post-Approval Line Extension*

*Company to Host Conference Call Tomorrow (Monday, December 22, 2014) at 8:00 a.m. ET*

WALTHAM, Mass., Dec. 21, 2014 (GLOBE NEWSWIRE) -- Radius Health, Inc. (Nasdaq:RDUS) today announced positive top-line 18-month fracture results from the Company's Phase 3 clinical trial (ACTIVE) evaluating the investigational drug abaloparatide-SC for potential use in the reduction of fractures in postmenopausal osteoporosis.

On the primary endpoint, the investigational drug abaloparatide-SC (n=690, fracture rate 0.72%) achieved a statistically significant 83% reduction of incident vertebral fractures as compared to the placebo-treated group (n=711, fracture rate 4.36%) (p < 0.0001). The ACTIVE trial included an open-label teriparatide [rDNA origin] injection treatment group (n=717, fracture rate 0.98%) that showed a statistically significant 78% reduction of incident vertebral fractures as compared to the placebo-treated group (p < 0.0001). On the secondary endpoints as compared to placebo, abaloparatide-SC achieved a statistically significant fracture-rate reduction of 43% in the adjudicated non-vertebral fracture subset of patients; a statistically significant reduction of 41% in the adjudicated clinical fracture group, which includes both vertebral and non-vertebral fractures; and a statistically significant difference in the time to first incident non-vertebral fracture in both the adjudicated non-vertebral fracture and the clinical fracture subset of patients.

Comparative analyses of abaloparatide-SC versus teriparatide have been completed on the following BMD secondary endpoints:

	Percent Change In Bone Mineral Density (BMD) From Baseline								
	Lumbar Spine			Total Hip			Femoral Neck		
	6 mo	12 mo	18 mo	6 mo	12 mo	18 mo	6 mo	12 mo	18 mo
Placebo	0.60	0.45	0.63	0.31	0.09	-0.10	-0.13	-0.41	-0.43
abaloparatide-SC	6.58**	9.77**	11.20*	2.32**	3.41**	4.18**	1.72**	2.65**	3.60**
teriparatide	5.25*	8.28*	10.49*	1.44*	2.29*	3.26*	0.87*	1.54*	2.66*

\*\* p < 0.0001 vs placebo and teriparatide

\* p < 0.0001 vs placebo

The ACTIVE trial also evaluated several potential safety measures, including blood calcium levels, orthostatic hypotension, nausea, dizziness, and injection-site reactions. Top-line results from the ACTIVE study on these parameters are consistent with results in prior studies. Among the most frequently reported adverse events, the following incidence rates were reported:

- back pain: placebo (10.0%), abaloparatide (8.6%), teriparatide (7.2%)
- arthralgia: placebo (9.8%), abaloparatide (8.5%), teriparatide (8.6%)
- upper respiratory infection: placebo (8.9%), abaloparatide (9.0%), teriparatide (9.8%)
- hypercalciuria: placebo (8.9%), abaloparatide (10.9%), teriparatide (12.5%)
- dizziness: placebo (6.1%), abaloparatide (10.0%), teriparatide (7.3%)

The rates for hypercalcemia in the ACTIVE trial were: 1.2% for patients in the placebo arm, 6.0% for patients in the abaloparatide arm, and 10.8% for patients in the teriparatide arm.

"We are on track for NDA submission in the second half of 2015 and encouraged by the consistency of our Phase 3 results with those from our two Phase 2 studies," said Robert E. Ward, Radius President and Chief Executive Officer. "These results reinforce the emerging profile of abaloparatide, and we eagerly await the first six-month results from the ongoing ACTIVEExtend trial expected in the second quarter of 2015."

Radius remains blinded at the site and patient-identification level for the Phase 3 ACTIVE study participants who have enrolled in the extension study, ACTIVEExtend (Study BA058-05-005, see [ClinicalTrials.gov](#)). Nordic Biosciences, Radius' CRO collaborator, reports that 91% of eligible patients from the ACTIVE study have enrolled. Upon completion of the full 24 months of treatment exposure, the combined data set from ACTIVE and ACTIVEExtend will be unblinded for data analysis.

The results from the ACTIVE trial and from its extension study, together with the entire data set from the abaloparatide development program, are subject to regulatory review. Health authorities are the final arbiter of comparative claims against an active comparator that is an approved drug product with approved labeling. Once the health authorities complete their review, we will be in a position to discuss those comparative claims.

**Update On Development Program For The Investigational Drug Abaloparatide-TD:** Radius is pleased to report that it has made significant progress towards the development of an optimized, short-wear-time transdermal patch, for its investigational drug abaloparatide-TD based on 3M Drug Delivery Systems' sMTS platform. Together with 3M Drug Delivery Systems, Radius evaluated a number of new TD patch configurations with the goal of selecting a configuration that may be capable of demonstrating therapeutic comparability to abaloparatide-SC injection. In preliminary, non-human primate pharmacokinetic studies, prototype A7 achieved a desirable pharmacokinetic profile, with comparable AUC and Cmax relative to the investigational abaloparatide-SC program. We believe that these results support continued clinical development toward future global regulatory submissions as a potential post-approval line extension of the investigational drug abaloparatide-SC.

#### **Trial Design:**

The ACTIVE pivotal Phase 3 fracture prevention trial for the investigational drug abaloparatide, Study BA058-05-003 (see [ClinicalTrials.gov](#)), was a randomized, double-blind, placebo-controlled trial in postmenopausal osteoporotic women randomized to receive daily doses of one of the following for 18 months: 80 micrograms ( $\mu\text{g}$ ) of abaloparatide; a matching placebo; or the approved dose of 20  $\mu\text{g}$  of teriparatide. Treatment with abaloparatide at a dose of 80  $\mu\text{g}$  or placebo remained blinded to all parties throughout the study. Teriparatide comes as a proprietary prefilled drug and device combination that cannot be repackaged. Therefore, its identity could not be blinded to treating physicians and patients once use began. Study medication was self-administered daily by subcutaneous injection for a maximum of 18 months. All enrolled patients also received calcium and vitamin D supplementation from the time of enrollment until the end of the treatment period. It was recommended to patients that they also continue these supplements through the one-month follow-up period.

The trial completed enrollment in March 2013 with 2,463 patients at 28 medical centers in 10 countries in the United States, Europe, Latin America, and Asia. The study enrolled otherwise healthy ambulatory women aged 50 to 85 (inclusive) who had been postmenopausal for at least five years, met the study entry criteria, and had provided written informed consent. The women enrolled in the study had to have a BMD t-score  $\leq 2.5$  and  $> -5.0$  at the lumbar spine or hip (femoral neck) by dual-energy X-ray absorptiometry, or DXA, and radiological evidence of two or more mild or one or more moderate lumbar or thoracic vertebral fractures, or history of low trauma forearm, humerus, sacral, pelvic, hip, femoral or tibial fracture within the past five years. Postmenopausal women older than 65 who met the above fracture criteria but had a t-score of  $\leq 2.0$  and  $> -5.0$  could also be enrolled. Women older than 65 who did not meet the fracture criteria could also be enrolled if their t-score was  $\leq -3.0$  and  $> -5.0$ . All patients were to be in good general health as determined by medical history, physical examination (including vital signs), and clinical laboratory testing. Radius believes this study population contained a patient population reflective of the type of severe osteoporosis patients that specialists would be expected to treat in their practices.

As set forth in the ACTIVE protocol, the primary efficacy endpoint was the number of patients treated with abaloparatide-SC with incident vertebral fractures at the end of treatment as compared to those who received placebo. The pre-specified secondary efficacy parameters included, among other endpoints, reduction in the incidence of non-vertebral fractures; changes in BMD of the spine, hip, and femoral neck from baseline to end of treatment as assessed by DXA and as compared to teriparatide; and the number of hypercalcemic events in abaloparatide-SC treated patients when compared to teriparatide at end of treatment.

Safety evaluations performed in the ACTIVE trial included physical examinations, vital signs, 12-lead electrocardiograms, or ECGs, clinical laboratory tests and monitoring, and recording of adverse events. Specific safety assessments included pre-dose and post-dose (four hours) determination of serum calcium, determination of creatinine clearance, post-dose ECG assessments at selected visits, and assessments of postural hypotension (60 minutes post-dose) at selected clinic visits.

Each of the patients in the abaloparatide 80 µg and placebo groups in the Phase 3 ACTIVE trial were eligible to continue in an extension study (ACTIVEExtend), in which they are receiving an approved alendronate therapy for osteoporosis management. Key endpoints for the abaloparatide-SC development program are the reduction in incident vertebral and non-vertebral fractures at up to 24 months in all randomized patients, including abaloparatide-treated and placebo-treated patients, all of whom are treated with alendronate in ACTIVEExtend.

### **About the Investigational Drug Abaloparatide**

Radius' investigational drug abaloparatide is a synthetic peptide analog of human parathyroid hormone-related protein (hPTHrP), a naturally occurring bone-building hormone that we believe has the potential to increase bone mineral density by stimulating new bone formation. Abaloparatide-SC is an investigational drug currently in Phase 3 development for potential use as a daily self-administered injection for the treatment of patients with postmenopausal osteoporosis at high risk of fracture. Radius also is developing the investigational drug abaloparatide-TD 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.

### **Conference Call Information:**

**Date:** Monday, December 22, 2014

**Time:** 8:00 a.m. ET

**Domestic Dial-in Number:** 1-877-705-6003

**International Dial-in Number:** 1-201-493-6725

**Live webcast:** <http://public.viavid.com/player/index.php?id=112424>

For those unable to participate in the conference call or webcast, a replay will be available beginning December 22, 2014, at approximately 10:00 a.m. ET until January 3, 2015. To access the replay, dial 1-877-870-5176 or 1-858-384-5517. The replay passcode is 13598238.

A live audio webcast of the call also will be available on the Investors section of the Company's website, [www.radiuspharm.com](http://www.radiuspharm.com). A webcast replay will be available until January 3, 2015 on the Radius website, [www.radiuspharm.com](http://www.radiuspharm.com). The full text of the announcement also will be available on the Company's website.

### **About Radius Health**

Radius is a science-driven biopharmaceutical company developing new therapeutics for patients with advanced osteoporosis as well as other serious endocrine-mediated diseases including hormone responsive cancers. Radius' lead development candidate is the investigational drug abaloparatide for subcutaneous injection, currently in Phase 3 development for potential use in the reduction of fracture risk in postmenopausal women with severe osteoporosis. The Radius clinical portfolio also includes an investigational abaloparatide transdermal patch for potential use in osteoporosis and the investigational drug RAD1901 for potential use in hormone-driven, or hormone-resistant, metastatic breast cancer, including breast cancer brain metastases.

### **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 the expectations regarding abaloparatide, including without limitation, expectations regarding the clinical significance and regulatory review of top-line data from our Phase 3 ACTIVE study and from our extension study, the submission of an NDA for abaloparatide-SC, the timing of the completion of the ACTIVEExtend study, the timing of regulatory submissions applying for approval of abaloparatide-SC and the clinical development of abaloparatide-TD.

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: 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;

our dependence on the success of abaloparatide-SC, and our inability to ensure that abaloparatide-SC will obtain regulatory approval or be successfully commercialized; 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 carryforwards and certain other tax attributes may be limited. These and other important factors discussed under the caption "Risk Factors" in our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission, or SEC, on November 10, 2014, and our 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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