Radius Investigational Drug Elacestrant (RAD1901) Continues to Show Promise in Advanced ER+ / HER2- Breast Cancer at the 2017 San Antonio Breast Cancer Symposium

- Elacestrant 400mg single agent Objective Response Rate (ORR) was 27.3% in heavily pre-treated patients with advanced ER+ breast cancer at the pre-determined study cutoff date of October 30, 2017.

- Median PFS was 5.4 months and Clinical Benefit Rate at 24 weeks was 47.4%.

- 38% of study patients previously received fulvestrant; 40% received palbociclib or other CDK 4/6 inhibitor; 50% had an ESR1 mutation.

- 10 of the 40 patients remain on treatment as of the cutoff date.

- Investor Webcast today at 8:00 pm CT

WALTHAM, Mass., Dec. 07, 2017 (GLOBE NEWSWIRE) -- Radius Health, Inc. (Nasdaq:RDUS) today provided an update on data from the Phase 1 005 clinical study of elacestrant (RAD1901), an oral selective estrogen receptor degrader (SERD), in patients with estrogen receptor positive (ER+) breast cancer. The data were presented at a Spotlight Presentation (Abstract 1410) during the 2017 San Antonio Breast Cancer Symposium (SABCS). Elacestrant recently received Fast Track designation from the U.S. Food and Drug Administration.

There are 40 patients that have been treated at the 400 mg dose in the elacestrant Phase I dose escalation and expansion cohorts. All study participants are heavily pretreated ER+, HER2-negative, advanced breast cancer patients that have received a median of three prior lines of systemic therapy and have evaluable advanced or metastatic disease. Of the enrolled patients, 22 patients met the RECIST measurable disease criteria at baseline and there were 6 confirmed partial responses in this group. Elacestrant was well-tolerated with the most common adverse events being low grade nausea, dyspepsia and vomiting.

"It is quite encouraging to see the clinical activity with elacestrant in the heavily pretreated advanced patient population, and further therapeutic development is warranted for patients with hormone receptor positive breast cancer", commented Dr. Aditya Bardia, Director of Precision Medicine and attending physician at Center for Breast Cancer, Massachusetts General Hospital Cancer Center, Harvard Medical School, Boston, MA.

Radius plans to initiate a Phase 2 clinical study of elacestrant monotherapy, a potentially pivotal study, for women with advanced or metastatic ER+/HER2- breast cancer early in 2018.

"Patients cycle through and generally do not repeat treatment regimens, limiting treatment options as their disease advances. We are pleased about the potential to offer patients who have progressed or relapsed during their current standard of care with a new treatment option," said Gary Hattersley, PhD, Chief Scientific Officer. "Radius is committed to developing and to providing breast cancer patients with the next generation of hormonal treatment options, as a single agent and in combination, across all lines of therapy."

An update on data from the elacestrant FES PET 106 Phase I clinical study in the EU was presented yesterday and demonstrated that elacestrant reduces 18F-FES uptake in patients with advanced ER+ breast cancer who progressed on prior endocrine therapy. The reduction in FES uptake supports elacestrant dose selection for further clinical development and was similar in patients harboring mutant or wildtype ESR-1. Three preclinical poster presentations further highlighting and demonstrating elacestrant activity, as a single agent and in combination with other targeted therapies, will be presented tomorrow morning at SABCS.

Following a strategic review, Radius has decided to discontinue further evaluation of elacestrant for vasomotor symptoms and will focus instead on the continued clinical development of the compound as a potential treatment option in breast cancer.
In conjunction with today's elacestrant Spotlight presentation at SABCS, Radius will host a conference call and live webcast at 8:00 p.m. CT today to discuss the results of the Phase I program as of the cutoff date of October 30, 2017 and provide a company update.

The live webcast titled "Oncology Program Update from San Antonio Breast Cancer Symposium — 2017" will be available at https://edge.media-server.com/m6/p/vcgfk3pd or by visiting the Investors section of Radius' website at http://ir.radiuspharm.com/events.cfm.

Conference call information:

Domestic Dial-in Number: (866) 323-7965
International Dial-in Number: (346) 406-0961
Conference ID: 9089206

A replay of the webcast will be available on the company's website, www.radiuspharm.com in the Investor section under Events and Presentations for 7 days following the live webcast.

About Elacestrant (RAD1901)
Elacestrant is a selective estrogen receptor degrader (SERD), which is being evaluated for potential use as a once daily oral treatment for hormone-receptor positive breast cancer. Elacestrant is currently being investigated for potential use in women with advanced estrogen receptor positive, HER2 negative, breast cancer, the most common form of the disease. Studies completed to date indicate that the compound has the potential for use as a single agent or in combination with other therapies for the treatment of breast cancer.

Additional information on the clinical trial program of elacestrant (RAD1901) is available on www.clinicaltrials.gov.

About Radius
Radius is a science-driven fully integrated biopharmaceutical company that is committed to developing and commercializing innovative therapeutics in the areas of osteoporosis, oncology and endocrine diseases. Radius' lead product, TYMLOS (abaloparatide) injection, was approved by the U.S. Food and Drug Administration for the treatment of postmenopausal women with osteoporosis at high risk for fracture. Radius’ Marketing Authorisation Application (MAA) for abaloparatide-SC for the treatment of postmenopausal women with osteoporosis is under regulatory review in Europe. The Radius clinical pipeline includes an investigational abaloparatide transdermal patch for potential use in osteoporosis; the investigational drug elacestrant (RAD1901) for potential use in hormone-receptor positive breast cancer; and the investigational drug RAD140, a non-steroidal, selective androgen receptor modulator (SARM) under investigation for potential use in hormone-receptor positive breast 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 the progress of abaloparatide-SC in the regulatory process with the EMA, the progress in the development of our product candidates, including abaloparatide-TD, elacestrant (RAD1901) and RAD140, and the potential clinical uses and therapeutic and other benefits of our product candidates, including abaloparatide-TD, elacestrant 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: we expect to need to raise additional funding, which may not be available; risks related to raising additional capital; our limited operating history; quarterly fluctuation in our financial results; our dependence on the success of TYMLOS, and our inability to ensure that TYMLOS will obtain regulatory approval outside the U.S. or be successfully commercialized in any market in which it is approved, including as a result of risk related to coverage, pricing and reimbursement; risks related to competitive products and any collaboration agreements failing to be successful; risks related to clinical trials, including our reliance on third parties to conduct key portions of our 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 or during commercialization, if approved; risks related to manufacturing, supply and distribution; and the risk of litigation or other challenges regarding our intellectual property rights. These and other important risks and uncertainties discussed in our filings with the Securities and Exchange Commission, or SEC, including under the caption "Risk Factors" in our Quarterly
Report on Form 10-Q for the period ending June 30, 2017 and subsequent filings 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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