Radius Health Provides Updates on its Oncology Programs and Announces Scientific Presentations at 2018 San Antonio Breast Cancer Symposium (SABCS)

November 30, 2018

- Phase 3 elacestrant study has opened for enrollment
- Fast Track designation from the FDA for the Phase 3 study population
- Elacestrant pre-clinical data demonstrates further evidence of anti-tumor activity in breast cancer models with resistance to CDK 4/6 inhibitors and ESR1 mutations
- RAD140 Phase 1 study continues to enroll patients with further evaluation of the maximum tolerated dose

WALTHAM, Mass., Nov. 30, 2018 (GLOBE NEWSWIRE) -- Radius Health, Inc. (“Radius” or the “Company”) (Nasdaq: RDUS) today announced updates from its oncology pipeline and its scientific presentations on elacestrant and RAD140 at the upcoming 2018 San Antonio Breast Cancer Symposium.

The Company’s Phase 3 EMERALD study has been initiated and is now open for enrollment. The trial is a randomized, open label, active-controlled study evaluating elacestrant as second- or third-line monotherapy in advanced/metastatic ER-positive (ER+)/HER2-negative (HER2-) breast cancer patients. Depending on the results, this single trial is intended to support applications for marketing approvals for elacestrant as a second- and third-line monotherapy in the U.S., European Union, and other markets.

The U.S. Food and Drug Administration recently granted Fast Track designation for the investigation of elacestrant for hormonal treatment for men and postmenopausal women with advanced ER+/HER2- breast cancer who have received at least 1 prior line of endocrine therapy, including prior cyclin-dependent kinase (CDK) 4/6 inhibitor therapy in combination with fulvestrant or an aromatase inhibitor. Fast Track is a process designed to facilitate the development and expedite the review of new therapies to treat serious conditions and fill unmet medical needs.

“Elacestrant’s clinical profile to date is very encouraging and has the potential to provide breast cancer patients with an effective oral hormonal therapy option following treatment after a CDK 4/6 inhibitor,” said Charles Morris, M.D., Chief Medical Officer of Radius. “This is the first study to prospectively evaluate treatment benefit for second- and third-line breast cancer patients following CDK 4/6 inhibitor therapy as well as prospectively compare outcomes in patients whose tumors harbor ESR1 mutations.”

The Company’s Phase 1 dose escalation study of RAD140 in HR+ breast cancer patients is ongoing and enrollment is expected to remain active through the first quarter of 2019. Radius has identified a provisional maximum tolerated dose (MTD) and an additional cohort has been opened to further confirm tolerability, pharmacokinetics, and on-treatment pharmacodynamics effects of RAD140 at that dose.

Radius Health will be presenting the following abstracts at SABCS:

Abstract #1055, “A phase 1, first-in-human, multi-part study of RAD140, an oral nonsteroidal selective androgen receptor modulator, in postmenopausal women with hormone receptor positive breast cancer”

Session Title: Endocrine Therapy - AR
Session Date: Wednesday, 12/5/2018
Session Time: 5:00 PM - 7:00 PM

Abstract #769, “Selective androgen receptor modulator RAD140 inhibits the growth of endocrine-resistant breast cancer models with defined genetic backgrounds”

Session Title: Treatment: Advanced Endocrine Therapy
Session Date: Friday, 12/7/2018
Session Time: 7:30 AM - 9:00 AM

Abstract #771, “Elacestrant (RAD1901) demonstrates anti-tumor activity in models resistant to CDK4/6 inhibitors”

Program Number: P4-13-03
Session Title: Treatment: Advanced Endocrine Therapy
Session Date: Friday, 12/7/2018
Session Time: 7:30 AM - 9:00 AM

Abstract #511, “Anti-tumor activity of elacestrant (RAD1901) in models harboring ESR1 mutations resistant to standard of care therapies”

Program Number: P6-20-08
Session Title: Treatment: Novel Targets and Targeted Agents
Session Date: Saturday, 12/8/2018
Session Time: 7:30 AM - 9:00 AM

About Elacestrant and EMERALD Phase 3 Study

Elacestrant is an investigational oral selective estrogen receptor degrader (SERD). In a Phase 1 study with a heavily pre-treated population (n=40), elacestrant was well-tolerated with the most commonly reported adverse events being low grade nausea and dyspepsia, and demonstrated a single

agent activity with a 27.3% objective response rate (ORR) and 5.4 months progression-free survival (PFS) as of the study cut-off date (October 30, 2017).

The EMERALD Phase 3 trial is a randomized, open label, active-controlled study evaluating elacestrant as second- or third-line monotherapy in advanced/metastatic ER-positive (ER+)/HER2-negative (HER2-) breast cancer patients. The study will enroll approximately 460 patients who have received prior treatment with one or two lines of endocrine therapy, including a cyclin-dependent kinase (CDK) 4/6 inhibitor. Patients in the study will be randomized to receive either elacestrant or the investigator's choice of an approved hormonal agent. The primary endpoint of the study will be progression-free survival (PFS) in the overall patient population and in patients with estrogen receptor 1 gene (ESR1) mutations. Secondary endpoints will include evaluation of overall survival (OS), objective response rate (ORR), and duration of response (DOR).

About RAD140

RAD140 is an oral Selective Androgen Receptor Modulator (SARM) being evaluated for the treatment of AR+/ER+ metastatic breast cancer. AR is expressed in approximately 90% ER+ Breast cancer patients.

About Radius Health

Radius is a science-driven fully integrated biopharmaceutical company that is committed to developing and commercializing innovative endocrine therapeutics in the areas of osteoporosis and oncology. 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. The Radius clinical pipeline includes an investigational abaloparatide 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 potential clinical uses and therapeutic and other benefits of our product candidates, including abaloparatide-patch, elacestrant and RAD140, and our expectations regarding our clinical trials.

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 Annual Report on Form 10-K for the year ending December 31, 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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