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Radius Health Receives FDA Fast Track Designation for Elacestrant (RAD1901)

- Radius plans to initiate Phase 2 clinical study of elacestrant as a third-line therapy for women with ER+ and HER2- breast cancer early in 2018 -

- Phase 2 Study is a potentially pivotal trial for accelerated approval -

WALTHAM, Mass., Oct. 18, 2017 (GLOBE NEWSWIRE) -- Radius Health, Inc. ("Radius" or the "Company") (Nasdaq:RDUS), today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for elacestrant, an investigational oral selective estrogen receptor down-regulator/degrader (SERD) as a treatment of women with ER+ and HER2- advanced or metastatic breast cancer. Fast Track designation is a process designed to facilitate the development and expedite the review of new therapies to treat serious conditions and fill unmet medical needs.

"It is estimated that about 1 in 8 women will develop invasive breast cancer over the course of their lifetime," said Jesper Høiland, President and Chief Executive Officer of Radius Health. "If approved, elacestrant could offer a hormonal therapy alternative and potentially delay the use of chemotherapy in patients with estrogen receptor positive breast cancer. Early results of our Phase 1 trial show an encouraging efficacy and safety profile. We look forward to working closely with the FDA as we rapidly advance the development of elacestrant."

The elacestrant clinical development program is currently ongoing with two Phase I studies in patients with ER+, HER2- advanced or metastatic breast cancer who have been heavily pre-treated (median of three prior lines of therapy) and have evaluable disease.

"The Company will provide updates on both Phase 1 studies and present two preclinical posters at the 2017 San Antonio Breast Cancer Symposium in December," said Gary Hattersley, PhD, Chief Scientific Officer. "The FDA has indicated that, depending on the Phase 2 study results, the single-arm Phase 2 trial could be considered a pivotal study with a confirmatory study on-going at the time of NDA submission. We expect to enroll the first patient in the Phase 2 study in early 2018."

For more information on ongoing clinical trials of elacestrant, visit 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-driven and/or hormone-resistant breast cancer, and vasomotor symptoms in postmenopausal women; and 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.

About Elacestrant (RAD1901)

Elacestrant is a selective estrogen receptor down-regulator/degrader (SERD), which at high doses is being evaluated for potential use as an oral non-steroidal treatment for hormone-driven or hormone-resistant breast cancer. Elacestrant is currently being investigated for potential use in postmenopausal women with estrogen receptor positive 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.

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 timing of providing updates on our ongoing studies of elacestrant and timing of initiating a Phase 2 study of elacestrant; the progress of abaloparatide-SC in the regulatory process with the EMA, and the potential clinical uses and therapeutic and other benefits of our product candidates, including elacestrant, abaloparatide-TD 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 most recent Quarterly Report on Form 10-Q 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.

Investor & Media Relations contact:

Alex Fudukidis
Email: alex.fudukidis@russopartnersllc.com
Phone: 646-942-5632