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Radius Health Initiates Phase 1 Clinical Trial of RAD140 for the Treatment of Hormone Receptor Positive Breast Cancer

Study will evaluate safety, dose and tumor response in postmenopausal women with metastatic disease

WALTHAM, Mass., Sept. 29, 2017 (GLOBE NEWSWIRE) -- Radius Health, Inc. (Nasdaq:RDUS) announced today that the first patient has been enrolled in the company's Phase 1 study of RAD140, a nonsteroidal selective androgen receptor modulator (SARM) undergoing clinical evaluation for the treatment of hormone receptor positive breast cancer. The clinical trial is designed to evaluate the safety and maximum tolerated dose of RAD140 in approximately 40 patients.

"The RAD140 mechanism of action is differentiated from both selective estrogen receptor modulators (SERMs) and selective estrogen receptor degraders (SERDs). We expect RAD140 to play a broad role in endocrine resistance, including a genetically defined population, in patients with tumors that are resistant to treatment with the current standard of care," said Gary Hattersley, PhD, Chief Scientific Officer of Radius Health.

"RAD140 has significant potential to complement future applications of elacestrant (RAD1901) by targeting distinct mechanisms of endocrine resistance," commented Jesper Høiland, President and CEO of Radius. "We will provide additional details in peer-reviewed publications and plan to report results from the trial at upcoming scientific conferences."

The Phase 1 clinical trial is a safety and dose-ranging study in approximately 40 patients with progressive metastatic or locally advanced or metastatic breast cancer. In Part A of the trial, postmenopausal women with metastatic hormone receptor positive breast cancer will receive escalating doses of RAD140 by oral administration over a period of 28 days. Primary safety outcomes include rate of dose-limiting toxicities, adverse events related to treatment, and tolerability as measured by dose interruptions or adjustments. In addition, pharmacokinetics, pharmacodynamics and tumor response will also be evaluated.

About RAD140
RAD140 is an internally discovered nonsteroidal selective androgen receptor modulator, or SARM, which is under investigation for potential use in hormone receptor positive breast cancer. The androgen receptor, or AR, is highly expressed in hormone receptor positive breast cancers. An investigational new drug application, or IND, submitted to the FDA for RAD140 has been accepted.

Emerging clinical data suggest that androgen receptor positivity is associated with favorable clinical outcome in breast cancer. RAD140 selectively targets the AR receptor and has shown significant preclinical activity in endocrine resistant models as a single agent and in combination with standard of care.

About Hormone Receptor Positive Breast Cancer
Approximately 70 percent of breast cancers are hormone receptor positive, expressing either estrogen receptors or progesterone receptors. Although some hormone receptor positive breast cancers respond to hormone therapies that lower hormone levels or block hormone receptors, these cancers often develop resistance to therapy.

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. The Radius clinical pipeline includes an investigational abaloparatide transdermal patch for potential use in osteoporosis and the investigational drug elacestrant (RAD1901) for potential use in hormone-driven and/or hormone-resistant breast cancer, and vasomotor symptoms in postmenopausal women. Radius' RAD140, a nonsteroidal, selective androgen receptor modulator (SARM), is 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. 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 therapeutic potential of RAD140, including the significance of RAD140 preclinical data and the potential of RAD140 to complement elacestrant (RAD1901); and the potential clinical uses for abaloparatide-TD and elacestrant (RAD1901). Forward-looking statements contained herein are based on management's expectations and estimates as of the date of this announcement. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause actual results, performance or achievements to be materially different from future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: that we may need to raise additional funding, which may not be available; risks related to raising additional capital; our limited operating history; fluctuations in our quarterly 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. 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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