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FDA Accepts IND Application for Radius Health's Investigational Drug RAD1901 Being Developed for Potential Use in Metastatic Breast Cancer

WALTHAM, Mass., Dec. 19, 2014 (GLOBE NEWSWIRE) -- Radius Health, Inc. (Nasdaq:RDUS) announced today that the U.S. Food and Drug Administration (FDA) has accepted the Company's Investigational New Drug (IND) application for its investigational drug RAD1901, a tissue-selective estrogen receptor degrader (SERD) being developed for potential use in metastatic breast cancer.

The Phase 1 study that is the subject of the IND is a multicenter, open-label, two-part, dose-escalation study of the investigational drug RAD1901 in postmenopausal women with advanced estrogen receptor positive and HER2-negative breast cancer, that is designed to determine the recommended phase 2 dose and include a preliminary evaluation of the potential anti-tumor effect of RAD1901. The details of the planned Phase 1 study of RAD1901 in breast cancer metastases will be posted on www.clinicaltrials.gov.

We also are continuing discussions with the European Organization for the Research and Treatment of Cancer (EORTC) to develop a protocol for the initiation of a European Phase1 trial. We anticipate initiation of the European trial following regulatory review and upon institutional review board approval.

About The Investigational Drug RAD1901

Radius is developing the investigational agent RAD1901 as a potential treatment for estrogen positive (ER+) cancers, like breast, ovarian or endometrial cancer. Currently we are focusing our clinical research activities in breast cancer. The National Cancer Institute estimates that approximately 70% of breast cancers are ER+ and may grow in response to exposure to estrogen. Endocrine therapy is intended to block the estrogen signal or reduce the production of estrogen. More information about breast cancer and endocrine therapy may be found on the National Cancer Institute website http://www.cancer.gov/cancertopics/factsheet/Therapy/hormone-therapy-breast.

RAD1901 is an investigational, non-steroidal small molecule that is designed to selectively bind and degrade the ER. RAD1901 has demonstrated potent anti-tumor activity in xenograft models of ER+ breast cancer in preclinical testing and complete suppression of the FES-PET signal after six days of dosing in a maximum tolerated dose clinical study. In preclinical models thus far, RAD1901 has shown good tissue selectivity, does not appear to stimulate the uterine endometrium, and appears to protect against bone loss in an ovariectomy-induced osteopenia rat model. In addition, we believe that RAD1901 also has the ability to cross the blood-brain barrier. In vitro, treatment of human breast cancer cell lines with the investigational drug RAD1901 resulted in degradation of the ER and inhibition of both basal and estradiol-stimulated proliferation.

A recent poster presented at the San Antonio Breast Cancer Symposium (SABCS) included preclinical data indicating that increasing doses of RAD1901 potently induced tumor regression. Tamoxifen and fulvestrant were the comparator drugs in this study. The poster also included data from the Phase 1 study in which 18F-estradiol positron emission tomography (FES-PET) was used to provide a pharmacodynamic assessment of estrogen receptor engagement/turnover. Following 6-days of daily treatment with the investigational drug RAD1901 at 200mg and 500mg doses, a complete suppression of FES-PET signal was observed, with standardized uptake values (SUV) comparable to background tissues. To date, the maximum tolerated dose of RAD1901 has not been determined.

The potential clinical significance, if any, of the data presented in the poster is currently unknown and will be evaluated further as the development program for the investigational drug RAD1901 continues.

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 (BA058) 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. 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 statements regarding the potential clinical significance of the data presented in the poster presentation at SABCS, the ability of RAD1901 to cross the blood-brain barrier, and the timing of the initiation of clinical trials of RAD1901.

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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