Radius Health & Menarini Group Provide Elacestrant Update

September 24, 2020

- *Target enrollment milestone reached in the Phase 3 EMERALD study*
- *Life cycle planning advancing in parallel with current Phase 3 monotherapy program*

WALTHAM, Mass. and FLORENCE, Italy, Sept. 24, 2020 (GLOBE NEWSWIRE) -- Radius Health, Inc. (“Radius” or the “Company”) (Nasdaq: RDUS) and the Menarini Group today announced an update on the elacestrant Phase 3 EMERALD trial.

EMERALD Phase 3 Study

The target enrollment milestone has been reached in the Phase 3 EMERALD clinical trial of elacestrant. Elacestrant is an oral Selective Estrogen Receptor Degrader (SERD) that is being studied in postmenopausal women and men with ER+/HER2- advanced or metastatic breast cancer. The study reached its enrollment goal of 466 patients overall, including 220 (47%) with tumors harboring an ESR1 mutation as detected in circulating tumor DNA by the Guardant Health Guardant360 liquid biopsy test.

Patients will be followed until the required number of events to assess progression-free survival - the primary endpoint of the study- is reached at which time the primary analysis will be performed. It is anticipated that this analysis will take place in the second half of 2021.

An independent data monitoring committee (IDMC) has been continuously monitoring the safety and efficacy of patients enrolled in the EMERALD trial. After enrollment of 70% of planned patients, the committee formally reviewed results of a futility analysis. In completing their review, the IDMC recommended that the trial continues to advance in an unmodified manner.

“We are thrilled about the continued progress for the program. Elacestrant continues to be the most advanced oral SERD in Phase 3 development and given that, we aim on being first to deliver Phase 3 data in the class, and upon clinical success, a regulatory submission,” said Elcin Barker Ergun, Chief Executive Officer of the Menarini Group.

Commenting further, Barker Ergun added that “the Menarini/Radius partnership has been a tremendous success to date and the completion of patient enrollment in the EMERALD trial brings us one step closer to bringing an oral SERD to women and men with advanced breast cancer.”

Dr. Maureen Conlan, Oncology Therapeutic Area Head for Radius, commented “Completing the enrollment of the EMERALD trial, despite the challenges of the COVID-19 pandemic, has been a great achievement. I am grateful to our team as well as the study investigators and patients for their efforts to date in supporting and participating in this trial.”

In summarizing on recent progress, Dr. Charles Morris, Chief Medical Officer for Radius added “This is an exciting milestone for Radius and our partner, the Menarini Group, with regard to the elacestrant program. We look forward to seeing additional advancement of the program including activities related to various life cycle management opportunities for the compound.”

About Menarini Group

Menarini Group is a leading international pharmaceutical company with a presence in 140 countries, including a direct presence in over 70 countries. Its global platform extends throughout Europe, U.S., Central America, Africa, the Middle East and Asia Pacific, and generates over $4.2 billion in annual sales. Menarini is committed to oncology, with an already commercialized product in the US and several new investigational drugs in development for the treatment of a variety of tumors. For over 130 years, Menarini has also been investing in the development, production and distribution of pharmaceuticals to serve patients and physicians around the world with a full portfolio of products covering a number of different therapeutic areas.

About Radius

Radius is a science-driven fully integrated biopharmaceutical company that is committed to developing and commercializing innovative endocrine therapeutics. For more information, please visit www.radiuspharm.com

About elacestrant (RAD1901) and EMERALD Phase 3 Study

Elacestrant is a selective estrogen receptor degrader (SERD), out-licensed to Menarini Group, which is being evaluated for potential use as a once daily oral treatment in patients with ER+/ HER2- advanced breast cancer. 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. The EMERALD Phase 3 trial is a randomized, open label, active-controlled study evaluating elacestrant as second- or third-line monotherapy in ER+/HER2- advanced/metastatic breast cancer patients. The study has enrolled 466 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 were randomized to receive either elacestrant or the investigator’s choice of an approved hormonal agent. The primary endpoint of the study is progression-free survival (PFS) in the overall patient population and in patients with estrogen receptor 1 gene (ESR1) mutations. Secondary endpoints include evaluation of overall survival (OS), objective response rate (ORR), and duration of response (DOR).

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.

These forward-looking statements are based on management's current expectations. These statements involve known and unknown risks and

uncertainties that may cause our actual results, performance or achievements to be materially different from any expressed or implied by the forward-looking statements. These risks include, but are not limited to, risks related to elacestrant's development and, if approved, commercialization, including the impact of the COVID-19 pandemic thereon. 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, 2019 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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Source: Radius Health Inc.

Source: Menarini Group