Menarini Group and Radius Health Announce Global License Agreement for the Development and Commercialization of Elacestrant

- *Menarini licenses global development and commercialization rights of elacestrant, an oral SERD currently in late stage Phase 3 development*
- *Elacestrant further strengthens Menarini's global oncology portfolio, recently bolstered by the acquisition of Stemline Therapeutics in the U.S.*
- *Radius will receive $30M as an upfront payment and up to $320M in additional milestones along with tiered low to mid-teen percentage royalties*

WALTHAM, Mass. – Florence, Italy, July 23, 2020 – The Menarini Group and Radius Health, Inc. (Nasdaq: RDUS) announced today that the companies have entered into an exclusive global license agreement for development and commercialization of elacestrant.

Elacestrant is an oral SERD, a selective estrogen receptor degrader, currently being evaluated in the EMERALD Phase 3 study as hormonal treatment for postmenopausal women and men with advanced ER+/HER2- breast cancer.

Under the agreement, Menarini Group will be responsible for worldwide commercialization of elacestrant, after the completion of EMERALD Phase 3 study and, assuming positive results, successful registration of elacestrant.

Elcin Barker Ergun, Chief Executive Officer of Menarini Group, commented: "Elacestrant is a perfect addition to our global oncology portfolio following our recent acquisition of Stemline Therapeutics and entering the US biopharmaceuticals market. Oral SERDs can potentially lead to new treatment paradigms in breast cancer and we look forward to advancing elacestrant's development to provide novel options that can help patients."

Kelly Martin, Chief Executive Officer of Radius commented, "Menarini will be a terrific global partner on this program and, given their recent investment and expansion in the oncology space, we are extremely pleased to have completed this transaction with them." Martin further commented that "this transaction is a significant step for Radius and provides us with flexibility in moving forward."

As part of the agreement, Radius will receive an upfront payment of $30 million and up to $320 million in additional payments based on the successful achievement of future development and sales milestones. Menarini Group will make tiered, low to mid-teen percentage royalty payments to Radius Health on global net sales.

Radius will continue to be responsible for the conduct and completion of the Phase 3 EMERALD study through NDA filing. Costs associated with this activity will be reimbursed by Menarini Group.

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. 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 the investigational use of abaloparatide injection for the treatment of men with osteoporosis, an investigational abaloparatide-patch for potential use in osteoporosis; the investigational drug elacestrant (RAD1901) for potential use in hormone-receptor positive breast cancer out-licensed to Menarini Group; 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.

About Elacestrant (RAD1901)
Elacestrant is a selective estrogen receptor degrader (SERD), which is being evaluated for potential use as a once daily oral treatment in patients with advanced estrogen receptor positive, HER2 negative (HER2-), breast cancer, the most common form of the disease. Fulvestrant is the only SERD that has been approved and marketed in this indication and has generated over $1 billion worldwide revenues. Unlike fulvestrant, which is administered as an intramuscular injection, elacestrant, if approved, has the potential to improve the patient experience with oral dosing. In addition, preclinical data have shown elacestrant to have greater antitumor activity than fulvestrant in in vivo models suggesting the potential for improved efficacy in patients. In a Phase 1 study with a heavily pre-treated population (n=50), elacestrant had an acceptable safety profile with the most commonly reported adverse events being low grade nausea and dyspepsia, and demonstrated single-agent activity with a 19.4% objective response rate (ORR) and 4.5 months progression-free survival (PFS). Encouraging activity was seen in patients whose tumors harbored ESR1 mutations as well as in patients whose disease had progressed after prior treatment with fulvestrant or CDK4/6 inhibitors.

Studies completed to date indicate that elacestrant has the potential for use as a single agent or in combination with other therapies for the treatment of breast cancer.

About EMERALD Phase 3 Study

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- 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). Top-line data from the EMERALD study is expected to be reported in the second half of 2021.

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 market opportunity for elacestrant, including the potential achievement of development and sales milestones related to elacestrant; our expectations regarding the completion of, and timing of results from, the EMERALD study; our expectations regarding an NDA filing in the U.S. and other regulatory filings globally for elacestrant; our expectations regarding our license agreement with Menarini for elacestrant; and the potential clinical uses and therapeutic and other benefits of elacestrant, abaloparatide-SC, abaloparatide-patch, 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: Our inability to ensure the timing of results from the EMERALD trial or that its primary endpoint will be met; Menarini's inability to ensure that elacestrant will obtain regulatory approval or be successfully commercialized, if approved, including as a result of risks related to coverage, pricing and reimbursement, manufacturing, supply and distribution, and potential adverse impacts on the EMERALD trial or Menarini's business from the ongoing COVID-19 pandemic; risks related to competitive products; risks of litigation or other challenges regarding intellectual property rights; risks that adverse side effects of elacestrant will be identified during commercialization, if approved, or during development activities. 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.

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