Menarini Group and Radius Health Announce Positive Phase 3 Topline Results from the EMERALD Trial Evaluating Elacestrant in Breast Cancer

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- Study met both primary endpoints in patients with ER+/HER2- advanced or mBC
- Elacestrant becomes the first oral SERD with positive topline results in pivotal study as a monotherapy versus SoC for the treatment of ER+/HER2- advanced or mBC
- Elacestrant extended PFS in the overall population and the ESR1 mutation subgroup
- Plans for regulatory submissions in both the United States and Europe in 2022
- Data planned to be presented at the San Antonio Breast Cancer Symposium in December, 2021

FLORENCE, Italy and BOSTON, Oct. 20, 2021 (GLOBE NEWSWIRE) -- the Menarini Group ("Menarini") and Radius Health, Inc. ("Radius") (NASDAQ: RDUS) (collectively, the "Companies") today announced positive topline results from the EMERALD study.

The study was designed to evaluate elacestrant as a monotherapy versus the standard of care (SoC) for the treatment of ER+/HER2- advanced or metastatic breast cancer (mBC). There were two primary endpoints: progression-free survival (PFS) in the overall population and PFS in patients with tumors harboring estrogen receptor 1 (ESR1) mutations.

EMERALD met both primary endpoints, showing statistically significant PFS in the overall population and ESR1 mutation subgroup. The safety profile of elacestrant exhibited in EMERALD was similar to that of the previous clinical trial. Given these results, Menarini and Radius plan on proceeding with regulatory submissions in both the United States and European Union in 2022. In 2018, elacestrant received fast track designation from the FDA.

"We are extremely excited as elacestrant is the first oral SERD to show positive topline results in a pivotal trial as a monotherapy vs SoC for the treatment of ER+HER2-advanced or mBC," commented Elcin Barker Ergun, Chief Executive Officer of the Menarini Group. "The results pave the way towards our working with the regulators to bring elacestrant to patients with ER+/HER2- advanced or metastatic breast cancer, which remains a huge unmet medical need. Notably, the topline results were also positive for the ESR1 mutation sub segment, an important driver of resistance to endocrine therapy in ER+/HER2- mBC patients. We intend to share the data at the San Antonio Breast Cancer Symposium in December."

Elacestrant is a selective estrogen receptor degrader (SERD). It was being investigated in the Phase 3 EMERALD trial as a potential once daily, oral treatment, in patients with ER+/ HER2- mBC. Overall, 466 patients were enrolled in the study, including 220 (47%) with tumors harboring an Estrogen Receptor 1 (ESR1) mutation. ESR1 mutations are important drivers for the development of resistance to endocrine therapy in ER+/ HER2- mBC patients.

"Advanced /metastatic ER+/HER2- BC pre-treated with endocrine therapy remains an area of high unmet medical need. Additional therapeutic options for this patient population are urgently needed," said Dr. Aditya Bardia, MD, MPH of the MGH, Associate Professor at the Medicine Department at Harvard Medical School, and Principal Investigator for the EMERALD trial. "The trial results being statistically significant demonstrate a clinically meaningful improvement of PFS in the elacestrant group versus endocrine standard of care in patients previously treated with endocrine therapies and CDK 4/6 inhibitors. The results provide a significant advancement for patients suffering from this devastating disease. It was also important to see the positive data for those patients with ESR1 mutations, known to confer additional resistance to standard endocrine therapy."

Kelly Martin, Radius' Chief Executive Officer, added, "Completing the EMERALD trial was a tremendous effort given the myriad of Covid related obstacles across the globe. Our collective teams did an outstanding job delivering the results of the trial in a high-quality and, ultimately, successful manner." Martin continued, "The Menarini Group and its leadership team are terrific partners. All of us at Radius look forward to supporting them through U.S. NDA submission."

A full evaluation of the data is ongoing. Current plans are to have those results presented at the upcoming San Antonio Breast Cancer Symposium in December, 2021 and to publish them in a peer-reviewed journal.

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 prior to EMERALD 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).

About Menarini
The Menarini Group is a leading international pharmaceutical and diagnostics company, with a turnover of $4.2 billion and over 17,000 employees. Menarini is focused on therapeutic areas with high unmet needs with products for cardiology, oncology, pneumology, gastroenterology, infectious diseases, diabetology, inflammation, and analgesia. With 18 production sites and 10 Research and Development centers, Menarini's products are available in 140 countries worldwide. For further information, please visit www.menarini.com.

About Radius

Radius is a global biopharmaceutical company focused on addressing unmet medical needs in the areas of bone health, orphan diseases, and oncology. 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 investigational abaloparatide injection for potential use in the treatment of men with osteoporosis; an investigational abaloparatide transdermal system for potential use in the treatment of postmenopausal women with osteoporosis; the investigational drug, elacestrant (RAD1901), for potential use in the treatment of hormone-receptor positive breast cancer out-licensed to Menarini Group; and the investigational drug RAD011, a synthetic cannabidiol oral solution with potential utilization in multiple endocrine and metabolic orphan diseases, initially targeting Prader-Willi syndrome.

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 expected timing of announcement and publication of the EMERALD Phase 3 topline results and regulatory submissions in the United States and European Union.

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: the adverse impact the ongoing COVID-19 pandemic is having and is expected to continue to have on our business, financial condition and results of operations, including our commercial operations and sales, clinical trials, preclinical studies, and employees; 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; risks related to our ability to successfully enter into collaboration, partnership, license or similar agreements; risks related to clinical trials, including our reliance on third parties to conduct key portions of our clinical trials and uncertainty that the results of those trials 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 Annual Report on Form 10-K for the year ending December 31, 2020 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 Contacts:

Menarini:
Valeria Speroni Cardi
Email: pressoffice@menarini.com

Radius:
Ethan Holdaway
Email: investor-relations@radiuspharm.com
Phone: (617) 583-2017

Source: Radius Health Inc.

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