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Radius Health Provides Update on Appeal of CHMP Opinion for Abaloparatide-SC

WALTHAM, Mass., July 24, 2018 (GLOBE NEWSWIRE) -- Radius Health, Inc. (Nasdaq:RDUS), a science-driven fully integrated biopharmaceutical company that is committed to developing and commercializing innovative endocrine therapeutics in the areas of osteoporosis and oncology, today announced that after an oral explanation following a re-examination procedure, the Committee for Medicinal Products for Human Use (CHMP), the scientific committee of the European Medicines Agency (EMA), has communicated a negative trend vote for the Company's marketing authorization application (MAA) for abaloparatide-SC for the treatment of osteoporosis in postmenopausal women at increased risk for fracture. A negative trend vote means that it is likely that the CHMP will maintain its negative opinion for the MAA at its formal final vote, which it has indicated will occur prior to the end of its meeting this week.

"We are disappointed with this assessment on behalf of the estimated 22 million women in Europe who are diagnosed with osteoporosis. No new anabolic bone-building agent has been approved in Europe for the treatment of this debilitating disease in almost 10 years," said Jesper Høiland, President and Chief Executive Officer of Radius Health. "We remain confident in abaloparatide-SC and focused on the commercialization of TYMLOS[®] in the U.S., the largest market in revenues for anabolics globally, and continue our efforts to make abaloparatide-SC available in Japan through our collaboration with Teijin Limited, as well as in other markets through partnership agreements."

TYMLOS (abaloparatide) injection was approved by the U.S. Food and Drug Administration in April 2017, for the treatment of postmenopausal women with osteoporosis at high risk for fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. Since then, over 10,000 patients have been treated with TYMLOS in the U.S.

About Radius

Radius is a science-driven fully integrated biopharmaceutical company that is committed to developing and commercializing innovative endocrine therapeutics in the areas of osteoporosis 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 an investigational abaloparatide patch for potential use in osteoporosis; the investigational drug elacestrant (RAD1901) for potential use in hormone-receptor positive breast cancer; 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.

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 a final CHMP vote on our MAA; our expectations regarding commercialization of TYMLOS in the U.S.; our efforts to make abaloparatide available in other markets and our entry into potential collaborations related thereto; and the potential clinical uses and therapeutic and other benefits of our product candidates, including abaloparatide-patch, elacestrant 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: we expect to need to raise additional funding, which may not be available; risks related to raising additional capital; our limited operating history; 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 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 Annual Report on Form 10-K for the year ending December 31, 2017 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.

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