Radius Announces Positive Phase 3 Topline Results for TYMLOS® (abaloparatide) Subcutaneous Injection in Males with Osteoporosis

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- ATOM study met the primary endpoint of change in lumbar spine bone mineral density at 12 months (p-value < 0.0001)
- Study also met secondary endpoints relating to bone mineral density changes in lumbar spine at 6 months as well as at hip and femoral neck at 12 months
- Safety profile was consistent with results in previously reported trials with abaloparatide
- Plan to submit supplemental new drug application (sNDA) in Q1, 2022

BOSTON, Oct. 18, 2021 (GLOBE NEWSWIRE) -- Radius Health, Inc. (“Radius” or the “Company”) (NASDAQ: RDUS), today announced positive topline results from the ATOM study evaluating abaloparatide 80mcg subcutaneous (SC) for use in males with osteoporosis.

The ATOM study met its primary endpoint – the percentage change in lumbar spine (LS) bone mineral density (BMD) compared to placebo – demonstrating statistical significance after 12 months (p-value < 0.0001). Study participants receiving abaloparatide-SC experienced an average increase in LS BMD of 8.5% compared to patients receiving the placebo experiencing an average increase of 1.2%.

The study also met secondary endpoints, which measured the percentage change compared to placebo for lumbar spine BMD at 6 months, total hip BMD at 12 months, and femoral neck BMD at 12 months.

The safety profile of abaloparatide in the ATOM study was consistent with results in previously reported trials.

Chhaya Shah, Senior Vice President, who leads the clinical and regulatory activities for abaloparatide, commented, “The team did a phenomenal job working through all of the complexities encountered as a result of the Covid-19 virus, in completing the study and delivering positive results.” Shah added further, “We remain on track for an sNDA submission in the first quarter of 2022.”

Bruce Mitlak MD, the Chief Medical Officer of Radius, added, “Osteoporosis in men is underdiagnosed and therefore, often undertreated. The study results are highly encouraging as they demonstrated a significant effect of abaloparatide in increasing lumbar spine BMD as well as the key secondary endpoint of hip BMD and are an important step towards making abaloparatide available for treating men with osteoporosis.”

The Company will complete a full evaluation of the ATOM data and work with investigators to present detailed results at a future medical meeting.

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.

About TYMLOS (abaloparatide) injection
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 defined as history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.

About ATOM Phase 3 Study
The ATOM Phase 3 study is a randomized, double-blind, placebo-controlled study to assess efficacy and safety of abaloparatide injection in 228 men with osteoporosis. The primary endpoint is change in lumbar spine BMD at 12 months compared with placebo, and it is expected to form the basis of a supplemental NDA seeking to expand the use of TYMLOS to treat men with osteoporosis at high risk for fracture. More information can be found on www.clinicaltrials.gov, NCT03512262.

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 our sNDA submission based on the ATOM Phase 3 study results.

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.

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