Radius Announces Results from the wearABLe Trial Evaluating Abaloparatide Transdermal System in Postmenopausal Women with Osteoporosis

December 8, 2021

- The wearABLe study did not demonstrate non-inferiority of abalo-TDS to TYMLOS®
- Lumbar spine BMD at 12 months vs. baseline for abalo-TDS was +7.1% vs. TYMLOS +10.9%
- Both abalo-TDS and TYMLOS 12-month results are considered clinically meaningful
- Abalo-TDS was well tolerated with no significant safety signals identified
- Trial data and technical details to be fully analyzed and then utilized as a basis for future plans

BOSTON, Dec. 08, 2021 (GLOBE NEWSWIRE) -- Radius Health, Inc. ("Radius" or the "Company") (NASDAQ: RDUS), today announced phase 3 topline results from the wearABLe study evaluating the non-inferiority (NI) of abaloparatide transdermal system (abalo-TDS) compared to abaloparatide subcutaneous injection (TYMLOS) in postmenopausal women with osteoporosis.

The wearABLe study did not meet its primary endpoint of NI for abalo-TDS 300 micrograms (ug) vs. TYMLOS 80 ug in the percent change from baseline in lumbar spine (LS) bone mineral density (BMD) at 12 months based on a NI margin of 2.0%.

PRIMARY ENDPOINT

- Abalo-TDS group demonstrated an increase of 7.1% (95% CI: 6.2, 8.0) vs. baseline
- TYMLOS group demonstrated an increase of 10.9% (95% CI: 9.9, 11.8) vs. baseline
- Treatment difference: -3.7% (95% CI: -5.0, -2.4)

SECONDARY ENDPOINTS

Percent change in total hip and femoral neck BMD at 12 months vs. baseline:

- Abalo-TDS group: total hip and femoral neck BMD increased by an avg. of 2.0% and 1.9%
- TYMLOS group: total hip and femoral neck BMD increased by an avg. of 3.7% and 3.4%

SAFETY RESULTS

- Incidence of severe or serious treatment-emergent adverse events (TEAEs): similar in both groups
- More subjects in the abalo-TDS group reported TEAEs related to the application site as compared to the TYMLOS group
- Fewer subjects in the abalo-TDS group had TEAEs leading to study drug withdrawal, interruption, or discontinuation than in the TYMLOS group

DATA FROM PREVIOUS TYMLOS REGISTRATIONAL STUDY (ACTIVE, BA058-05-003)

- TYMLOS group LS BMD increase at 12 months vs. baseline: 9.1%
- Teriparatide group LS BMD increase at 12 months vs. baseline: 7.9%

The wearABLe study data and technical details are to be analyzed and utilized as a basis for future abalo-TDS plans.

Bruce Mitlak, MD, Chief Medical Officer, commented, "We are pleased to see a clinically meaningful increase in lumbar spine and hip bone mineral density versus baseline for patients receiving the transdermal system. Despite missing the non-inferiority margin, the transdermal system demonstrated a clear bone building benefit to patients and was well tolerated with less than 10% of patients experiencing TEAEs leading to discontinuation." Dr. Mitlak continued, "TYMLOS is an outstanding molecule –it exceeded our efficacy expectations in this trial and with the recently completed ATOM study in men with osteoporosis, we remain highly committed to meeting the needs of our patients."

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 the Abaloparatide Transdermal System and wearABLe Phase 3 Study
The abaloparatide transdermal system was developed in a collaboration between Radius and Kindeva Drug Delivery ("Kindeva") (formerly 3M Drug Delivery Systems) with the application of Kindeva's innovative microstructured transdermal system technology. The Phase 3 wearABLe study is the first pivotal study to evaluate treatment using a novel non-injectable delivery of an anabolic therapy. The wearABLe study is a pivotal, randomized, open label, active-controlled, bone mineral density non-inferiority bridging study that will evaluate the efficacy and safety of abaloparatide transdermal system versus TYMLOS (abaloparatide) injection in approximately 500 patients with postmenopausal osteoporosis at high risk for fracture. The primary endpoint of the study is the percentage change in lumbar spine BMD at 12 months.

About the ACTIVE Phase 3 Study
The ACTIVE pivotal Phase 3 fracture prevention trial, Study BA058-05-003, was a randomized, double-blind, placebo-controlled trial in 2,463 postmenopausal osteoporotic women randomized to receive daily doses of one of the following for 18 months: 80 ug of abaloparatide; a matching placebo; or the approved dose of 20 ug of teriparatide. Study medication was self-administered daily by subcutaneous injection for a maximum of 18 months. The primary efficacy endpoint was the number of patients treated with abaloparatide-SC with incident vertebral fractures at the end of treatment as compared to those who received placebo. The pre-specified secondary efficacy parameters included, among other endpoints, reduction in the incidence of non-vertebral fractures; changes in BMD of the spine, hip, and femoral neck from baseline to end of treatment as assessed by DXA and as compared to teriparatide; and the number of hypercalcemic events in abaloparatide-SC treated patients when compared to teriparatide at end of treatment.

Forward-Looking Statements
This press release may contain 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 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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