Radius Health Initiates Phase 3 wearABLe Study of Abaloparatide-Patch in Postmenopausal Osteoporosis Patients at High Risk for Fracture

August 5, 2019

- Abaloparatide-Patch patient assessment study results demonstrated high patient acceptability and self-administration accuracy over a 29-day period
- Levels of PINP, a biomarker for bone formation, after one month in patient assessment study were consistent with results in Phase 3 ACTIVE study of TYMLOS® (abaloparatide) injection
- Abaloparatide-Patch SPA agreement with FDA includes a non-inferiority margin of 2% for the difference in percentage change in lumbar spine BMD at 12 months (i.e. preserves ~77% of the historical effect of TYMLOS)

WALTHAM, Mass., Aug. 05, 2019 (GLOBE NEWSWIRE) -- Radius Health, Inc. (“Radius” or the “Company”) (Nasdaq: RDUS) today announced the randomization of the first patient in the Phase 3 wearABLe clinical trial studying the safety and efficacy of abaloparatide-transdermal patch (abaloparatide-patch) in the treatment of postmenopausal patients with osteoporosis at high risk for fracture. Prior to initiating the study, the Company achieved a Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA) for the acceptability of the overall protocol design. An SPA agreement provides a concurrence with the FDA that the study can be considered adequate and well-controlled in support of a marketing application.

Abaloparatide-patch was developed in a collaboration between Radius and 3M Company with the application of 3M’s innovative microstructured transdermal patch technology. The Phase 3 wearABLe abaloparatide-patch study is the first pivotal study to evaluate treatment of a novel non-injectable delivery of an anabolic therapy.

“The initiation of our Phase 3 wearABLe study of abaloparatide-patch is a major accomplishment toward our goal of increasing treatment options for postmenopausal osteoporosis patients at high risk for fracture by expanding the use of anabolic bone building therapies,” said Jesper Hoeiland, President & Chief Executive Officer of Radius. “We are excited about the encouraging results from our patient assessment study and about receiving an SPA agreement from the FDA, which provides us with a clearly defined and further de-risked development and regulatory pathway for our pivotal program.”

“We are excited to reach this critical milestone in our successful strategic partnership with Radius, utilizing our innovative microstructured transdermal patch delivery technology in a potentially transformative treatment option for osteoporosis,” said Aaron Mann, President and General Manager, Drug Delivery Systems, 3M Company. “We are driven to develop patient-friendly delivery systems that enable our partners to bring their therapies to populations in need.”

The wearABLe Phase 3 study is a pivotal, randomized, open label, active-controlled, bone mineral density (“BMD”) non-inferiority bridging study that will evaluate the efficacy and safety of abaloparatide-patch versus TYMLOS (abaloparatide injection) in approximately 470 patients with postmenopausal osteoporosis at high risk of fracture. The primary endpoint of the study is the percentage of change in lumbar spine BMD at 12 months. Non-inferiority of abaloparatide-patch to abaloparatide injection will be concluded if the lower bound of the 2-sided 95% confidence interval for the estimated treatment difference (abaloparatide-patch minus abaloparatide injection) in the percentage change from baseline in lumbar spine BMD at 12 months is above -2.0%. A non-inferiority margin of 2% preserves ~77% of the historical effect of TYMLOS based on the data from the Phase 3 ACTIVE Study which showed placebo-adjusted increase in lumbar spine BMD of 9.1% (95% CI: 8.6%, 9.6%) at 12 months.

The wearABLe Phase 3 study is currently open for enrollment at multiple clinical sites. Radius plans to complete patient recruitment in this study by the end of 2019.

In July 2019, Radius obtained preliminary results from the abaloparatide-patch patient assessment study which evaluated self-administration of abaloparatide-patch over 29 days in 22 postmenopausal women with low bone density. The patients were observed at a study site on the first, 15th and 29th day of the study. Top-line study results showed that patients were able to follow the instructions for use (IFU) and applied the patches with a 99.7% success rate. The data also measured patient acceptability and indicated changes in patient PINP (procollagen type I propeptide) levels. The mean subject acceptability score on a 5-point scale was ≥ 4.5 at each site visit. An exploratory assessment of PINP levels, a biomarker that indicates bone formation, compared the PINP results at one month in this study with the one-month results in the Phase 3 ACTIVE study of TYMLOS (abaloparatide injection). The PINP levels and baseline increase at one month in this study were consistent with those values seen with abaloparatide injection at one month in the ACTIVE trial. At baseline, the median PINP level was 50.5 ng/ml, increasing to a median value of 100.1 ng/ml at day 29. The median PINP values observed with abaloparatide injection in the ACTIVE study were 50.6 ng/ml at baseline and 100.5 ng/ml at one month.

Webcast and Conference Call

In connection with today’s announcement, Radius will host a conference call and live audio webcast at 5:00 p.m. ET today, August 5, 2019.

Conference Call Information:
Date: August 5, 2019
Time: 5:00 p.m. ET
Domestic Dial-in Number: (866) 323-7965
International Dial-in Number: (346) 406-0961
Conference ID: 5489050
Live webcast: https://edge.media-server.com/mmc/p/scqm3f4x

For those unable to participate in the conference call or webcast, a replay will be available from August 5, 2019 at 8:00 p.m. ET and will be archived on the Company's website for 90 days. To access the replay (855) 859-2056 for U.S. or (404) 537-3406 for International, using conference ID number 5489050.

A live audio webcast of the call can be accessed from the Investors section of the Company's website, www.radiuspharm.com. The full text of the announcement will also be available on the Company's website.

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.

Important Safety Information

TYMLOS may cause serious side effects including possible bone cancer (osteosarcoma). During animal drug testing, TYMLOS caused some rats to develop a bone cancer called osteosarcoma. It is not known if people who take TYMLOS will have a higher chance of getting osteosarcoma.

It is not recommended that people use TYMLOS for more than 2 years during their lifetime.

TYMLOS can cause serious side effects including: Decrease in blood pressure when you change positions. Some people may feel dizzy, have a faster heartbeat, or feel lightheaded soon after the TYMLOS injection is given. These symptoms generally go away within a few hours; Increased blood calcium (hypercalcemia). TYMLOS can cause some people to have a higher blood calcium level than normal. Tell your healthcare provider if you have nausea, vomiting, constipation, low energy, or muscle weakness. These may be signs there is too much calcium in your blood; Increased urine calcium (hypercalciuria). TYMLOS can cause some people to have higher levels of calcium in their urine than normal. Increased calcium may also cause you to develop kidney stones (urolithiasis) in your kidneys, bladder or urinary tract.

The most common side effects of TYMLOS include dizziness, nausea, headache, fast heartbeat, feeling very tired (fatigue), upper stomach pain, and vertigo.

About Radius Health

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 the potential benefits of the SPA agreement for abaloparatide-patch and results from the patient assessment study of abaloparatide-patch; our expectations for our Phase 3 study of abaloparatide-patch, including the timing for recruitment; and the potential clinical uses and therapeutic and other benefits of our product candidates, including abaloparatide-patch, elacestrant and RAD140, and our expectations regarding our clinical trials.

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; risks related to our ability to successfully enter into collaboration agreements and any executed 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 abaloparatide-patch or our other product candidate claims; the risk that adverse side effects will be identified during the development of abaloparatide-patch or our other 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, 2018 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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Source: Radius Health Inc.