



March 30, 2018

Radius Health Initiates Phase 3 Clinical Trial of Abaloparatide Injection for the Treatment of Male Osteoporosis

Bridging study will evaluate change in spine bone mineral density (BMD) at 12 months compared with placebo

WALTHAM, Mass., March 30, 2018 (GLOBE NEWSWIRE) -- Radius Health, Inc. (Nasdaq:RDUS) announced today that the company has initiated the Phase 3 ATOM (Abaloparatide Treatment for Osteoporosis in Males) study of abaloparatide injection for the treatment of osteoporosis in men.

"Approximately 20 percent of men over the age of 50 years will sustain an osteoporotic-related fracture in their lifetime attributed to multiple risk factors. If successful, this study will serve as the basis of a supplemental New Drug Application (sNDA) seeking to expand the use of abaloparatide to treat men with osteoporosis at high risk for fracture," said Gary Hattersley, PhD, Chief Scientific Officer of Radius Health. "The study will also include specialized high-resolution imaging to examine the effect of abaloparatide on bone structure, such as the hip, in a subset of the study participants."

The primary endpoint of the male osteoporosis study is change in lumbar spine bone mineral density (BMD) at 12 months compared with placebo. The randomized, double-blind, placebo-controlled trial will enroll approximately 225 men with osteoporosis.

"Radius' strategy is to continue to expand the abaloparatide label and innovate on the mechanism of delivery, via our investigational abaloparatide patch, to position the Company as the market leader in osteoporosis," said Jesper Høiland, President and Chief Executive Officer. "As males represent approximately 10 percent of the total treated osteoporotic patient population, it is important to explore new treatment options for this group of patients."

Abaloparatide, marketed as TYMLOS™ in the United States, was approved in April 2017 by the US Food and Drug Administration (FDA) for the treatment of postmenopausal women with osteoporosis at high risk for fracture.

IMPORTANT SAFETY INFORMATION

WARNING: RISK OF OSTEOSARCOMA

- Abaloparatide caused a dose-dependent increase in the incidence of osteosarcoma (a malignant bone tumor) in male and female rats. The effect was observed at systemic exposures to abaloparatide ranging from 4 to 28 times the exposure in humans receiving the 80 mcg dose. It is unknown if TYMLOS will cause osteosarcoma in humans.
- The use of TYMLOS is not recommended in patients at increased risk of osteosarcoma including those with Paget's disease of bone or unexplained elevations of alkaline phosphatase, open epiphyses, bone metastases or skeletal malignancies, hereditary disorders predisposing to osteosarcoma, or prior external beam or implant radiation therapy involving the skeleton.
- Cumulative use of TYMLOS and parathyroid hormone analogs (e.g., teriparatide) for more than 2 years during a patient's lifetime is not recommended.

Orthostatic Hypotension: Orthostatic hypotension may occur with TYMLOS, typically within 4 hours of injection. Associated symptoms may include dizziness, palpitations, tachycardia or nausea, and may resolve by having the patient lie down. For the first several doses, TYMLOS should be administered where the patient can sit or lie down if necessary.

Hypercalcemia: TYMLOS may cause hypercalcemia. TYMLOS is not recommended in patients with pre-existing hypercalcemia or in patients who have an underlying hypercalcemic disorder, such as primary hyperparathyroidism, because of the possibility of exacerbating hypercalcemia.

Hypercalciuria and Urolithiasis: TYMLOS may cause hypercalciuria. It is unknown whether TYMLOS may exacerbate urolithiasis in patients with active or a history of urolithiasis. If active urolithiasis or pre-existing hypercalciuria is suspected,

measurement of urinary calcium excretion should be considered.

Adverse Reactions: The most common adverse reactions (incidence $\geq 2\%$) are hypercalciuria, dizziness, nausea, headache, palpitations, fatigue, upper abdominal pain and vertigo.

INDICATIONS AND USAGE

TYMLOS is indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, TYMLOS reduces the risk of vertebral fractures and nonvertebral fractures.

Limitations of Use

Because of the unknown relevance of the rodent osteosarcoma findings to humans, cumulative use of TYMLOS and parathyroid hormone analogs (e.g., teriparatide) for more than 2 years during a patient's lifetime is not recommended.

For the TYMLOS prescribing information, including Boxed Warning, please visit www.tymlospi.com.

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. Radius also is developing abaloparatide patch based on 3M's patented Microstructured Transdermal System technology for potential use as a treatment for postmenopausal women with osteoporosis.

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 the incidence of male osteoporotic-related fractures, expected enrollment in the male osteoporosis study, our efforts to expand the abaloparatide label, including our plans to file an sNDA to seek to expand the use of abaloparatide to treat men with osteoporosis at high risk for fracture, our efforts to position ourselves as the market leader in osteoporosis, 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 period 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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