



April 28, 2017

FDA Approves Radius Health's TYMLOS™ (abaloparatide), a Bone Building Agent for the Treatment of Postmenopausal Women with Osteoporosis at High Risk for Fracture

TYMLOS is the first new anabolic (bone building) agent for postmenopausal women with osteoporosis in the United States in nearly 15 years

US Commercial Launch in May

Approval Based on Results at 18 months from the Landmark ACTIVE Trial and the first six months of ACTIVEExtend Trial

Nearly One in Two Women in the US Will Experience an Osteoporosis-Related Fracture in Her Lifetime

Webcast scheduled for Monday, May 1, 2017 at 7:30 a.m. ET

WALTHAM, Mass., April 28, 2017 (GLOBE NEWSWIRE) -- Radius Health, Inc. (Nasdaq:RDUS), a science-driven fully integrated biopharmaceutical company that is committed to developing innovative therapeutics in the areas of osteoporosis, oncology and endocrine diseases, today announced that the US Food and Drug Administration (FDA) has approved TYMLOS (abaloparatide) injection 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. In postmenopausal women with osteoporosis, TYMLOS reduces the risk of vertebral and nonvertebral fractures.

"Today's FDA approval of TYMLOS is an important milestone for Radius, and marks our transition to a fully integrated commercial biopharmaceutical company. I am highly confident that we have the people, strategies and resources to maximize the potential of the TYMLOS franchise and deliver sustainable high performance," said Robert Ward, President and Chief Executive Officer of Radius Health. "We believe that an osteoporotic fracture can be a life-altering event for a woman and her family. Osteoporosis in postmenopausal women represents a significant disease burden for which diagnosis and treatment should be healthcare priorities."

Clinical Data

The FDA's approval of TYMLOS was based on results at 18 months from the landmark ACTIVE trial and first six months of ACTIVEExtend trial that demonstrated consistent significant and rapid reductions in the risk of vertebral and nonvertebral fractures regardless of age, years since menopause, presence or absence of prior fracture (vertebral or nonvertebral) and bone mineral density (BMD) at baseline. In human clinical studies, TYMLOS has been shown to decrease the incidence of new vertebral and nonvertebral fractures, to increase bone mineral density (BMD), and to increase a marker of bone formation. In addition, the anabolic effect of TYMLOS was demonstrated in animal studies by increases in BMD and bone mineral content that correlated with increases in bone strength at vertebral and/or nonvertebral sites.

The results from the ACTIVE trial were published in the Journal of the American Medical Association in August of 2016, and the results of the first six months of ACTIVEExtend were published in the Mayo Clinic Proceedings in February 2017.

Specifically, in the ACTIVE trial, TYMLOS demonstrated significant reductions in the relative risk of new vertebral and nonvertebral fractures compared to placebo in the ACTIVE trial of:

- | **86% in new vertebral fractures**
- | **43% in nonvertebral fractures**

The absolute risk reductions were 3.6% and 2.0%, respectively.

"Today's TYMLOS approval by the FDA is exciting since it provides physicians a new treatment option for postmenopausal women with osteoporosis which could help to rapidly, consistently and significantly increase bone mineral density and reduce their risk of fractures," said John Bilezikian, M.D., Professor of Medicine and Pharmacology at the College of

Physicians & Surgeons, Columbia University, Chief, Emeritus, of the of the Division of Endocrinology and Director of the Metabolic Bone Diseases Program at Columbia University Medical Center. "Fragility fractures should be viewed as sentinel events which require urgent evaluation and treatment because after that first fragility fracture, patients are at greater risk for subsequent fractures. The FDA's approval of *TYMLOS* represents an important step in our ability to treat this serious and complex disease and, in the process, address this urgent public health crisis."

WEBCAST

In connection with the FDA approval of *TYMLOS* announced today, Radius will host a live audio webcast at 7:30 a.m. ET on Monday, May 1, 2017.

Please note, Radius now also plans to report First Quarter 2017 Financial Results on Monday, May 1, 2017 and will review these results and provide a company update on the webcast.

Webcast Information:

Date: Monday, May 1, 2017

Time: 7:30 a.m. ET

Live webcast: <http://edge.media-server.com/m/p/z5woyvf3>

For those unable to participate in the webcast, a replay of the webcast will be available until May 15, 2017 at 11:59 p.m. ET on the company's website, www.radiuspharm.com.

About *TYMLOS* (abaloparatide)

TYMLOS (abaloparatide) 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' Marketing Authorisation Application (MAA) for abaloparatide-SC for the treatment of women with postmenopausal osteoporosis was validated and is currently undergoing regulatory review by the European Medicines Agency (EMA).

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

About *ACTIVE* and *ACTIVE*Extend

The Phase 3 *ACTIVE* (Abaloparatide Comparator Trial In Vertebral Endpoints) trial was a randomized, double-blind, placebo-controlled, comparative, multicenter, 18 month international study in 2,463 postmenopausal women with osteoporosis designed to evaluate the efficacy and safety of abaloparatide-SC 80 mcg to reduce the risk of vertebral and nonvertebral fractures. The results of *ACTIVE* were published in the Journal of the American Medical Association in August of 2016. *ACTIVE*Extend, an extension of *ACTIVE*, enrolled patients who had completed 18 months of abaloparatide-SC or placebo in *ACTIVE* to receive up to 24 additional months of open-label alendronate. The results of the first six months of *ACTIVE*Extend were published in the Mayo Clinic Proceedings in February of 2017.

About "Together with *TYMLOS*" Program

TYMLOS will be available in the United States in June. For eligible patients, Radius Health will offer the "Together with *TYMLOS*" support program. For more information please visit www.togetherwithTYMLOS.com or call 1-866-TYMLOS4 (1-866-896-5674) between 8 am and 8 pm EST, Monday through Friday.

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 complete TYMLOS prescribing information, including Boxed Warning, please visit www.tymlos.com

About Osteoporosis

Osteoporosis is a silent disease, often displaying no signs or symptoms until a fracture occurs, leaving the majority of patients undiagnosed and untreated, representing a high unmet medical need. Osteoporotic fractures create a significant healthcare burden. An estimated two million osteoporotic fractures occur annually in the United States, and this number is projected to grow to three million by 2025.

The National Osteoporosis Foundation (NOF) has estimated that eight million women already have osteoporosis, and another approximately 44 million may have low bone mass placing them at increased risk for osteoporosis.

The annual incidence of osteoporotic fractures is higher than that of stroke, heart attack and breast cancer combined; osteoporotic fractures also account for more hospitalizations and associated costs than cardiovascular disease and breast cancer.

About Radius

Radius is a science-driven fully integrated biopharmaceutical company that is committed to developing and commercializing innovative therapeutics in the areas of osteoporosis, oncology and endocrine diseases. 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 in April 2017. Radius' Marketing Authorisation Application (MAA) for abaloparatide-SC for the treatment of postmenopausal women with osteoporosis is under regulatory review in Europe. The Radius clinical pipeline includes an investigational abaloparatide transdermal patch for potential use in postmenopausal women with osteoporosis and the investigational drug elacestrant (RAD1901) for potential use in hormone-driven and/or hormone-resistant breast cancer, and vasomotor symptoms in postmenopausal women. Radius' RAD140, a non-steroidal, selective androgen receptor modulator (SARM), is 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 expectations for TYMLOS (abaloparatide) including without limitation, expectations regarding the clinical significance of clinical trial data for TYMLOS, the expected timing for the U.S. commercial launch and availability of TYMLOS, our ability to maximize the potential of the TYMLOS franchise and deliver sustainable high performance, the potential medical benefit of treatment with TYMLOS for postmenopausal women with osteoporosis, the progress of abaloparatide-SC in the regulatory process with the EMA, the incidence of osteoporotic fractures and the health burden associated with osteoporosis, and the potential clinical uses for the abaloparatide transdermal patch, elacestrant (RAD1901) 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:; our dependence on the success of TYMLOS; risks related to competitive products; risks related to our ability to successfully commercialize TYMLOS, including the failure to achieve market acceptance of TYMLOS in the U.S. or in any market where it may be approved; the availability of coverage and risks related to pricing and reimbursement for TYMLOS; risks related to manufacturing and supply; risks related to intellectual property; risks related to establishing and maintaining an effective process for distribution of TYMLOS; the risk that the results of clinical trials of TYMLOS will not meet ex-U.S. regulatory requirements for approval or that ex-U.S. regulatory authorities may require additional data or further studies, including our inability to ensure that abaloparatide-SC will obtain regulatory approval in Europe; and the other important factors discussed under the caption "Risk Factors" in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on February 24, 2017, and in our other reports filed with the SEC, that 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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