Radius Health Provides Business Update

August 25, 2020

- TYMLOS® patent extended to 2031, adding approximately 3½ years to the TYMLOS-SC patent life
- Enrollment completed for ATOM Phase 3 study assessing the efficacy and safety of abaloparatide-SC in males with osteoporosis

WALTHAM, Mass., Aug. 25, 2020 (GLOBE NEWSWIRE) -- Radius Health, Inc. (“Radius” or the “Company”) (Nasdaq: RDUS) today announced a business update including the extension of the patent for TYMLOS® as well as the completion of enrollment for its Phase 3 study, which is assessing the safety and efficacy of abaloparatide-SC in men with osteoporosis.

Intellectual Property

On July 30, 2020, the United States Patent and Trademark Office extended the term of Radius’s FDA Orange book listed US Patent 7,803,770 directed to methods of treating osteoporosis by 1,303 days. As a result, the term of US Patent 7,803,770 has been extended until April 28, 2031.

Radius recently requested the extension under 35 U.S.C 156, which compensated for the term loss during the regulatory review process.

“We are pleased that the US Patent Office has extended the term of US patent 7,803,770, which protects TYMLOS by an additional three and a half years,” stated James Harrington, Radius’ newly appointed Chief of Intellectual Property. “The patent extension was obtained in record time and is a testament to the outstanding work of our regulatory and IP teams.”

Abaloparatide-SC Phase 3 Study

Patient enrollment in the Phase 3 ATOM study of TYMLOS (abaloparatide-SC) assessing the efficacy and safety of abaloparatide-SC in men with osteoporosis at high risk for fracture, is now complete. The study enrolled a total of 228 patients in four countries.

“We are excited to have completed patient enrollment in the first of our three ongoing Phase 3 clinical trials,” said Dr. Charles Morris, Chief Medical Officer. “Our team has done a great job reaching this milestone despite the challenges of the global pandemic. We are on track for top-line data in the second half of 2021.”

Commenting further, Dr. Morris added, “We would like to thank our investigators and their patients for helping us advance this study. Male osteoporosis is an important health issue for many older men and greater understanding, diagnosis, and treatment of osteoporosis in these men is an important goal. We look forward to understanding whether TYMLOS can be a new therapeutic option for these patients.”

Kelly Martin, Chief Executive Officer, commented on the Company’s overall recent advancements summarizing that, “In the last eight weeks, we have made a number of internal organizational adjustments, completed the elacestrant transaction with the Menarini Group, extended the patent life of TYMLOS by approximately 3½ years, and completed the enrollment in the ATOM Phase 3 men with osteoporosis study. We look forward to providing additional updates as and when appropriate.”

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-SC in approximately 225 men with osteoporosis. The primary endpoint is change in lumbar spine BMD at 12 months compared with placebo, and if successful, will form the basis of a supplemental NDA seeking to expand the use of TYMLOS to treat men with osteoporosis at high risk for fracture.

About Radius
Radius is a science-driven fully integrated biopharmaceutical company that is committed to developing and commercializing innovative endocrine therapeutics. 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.

These forward-looking statements are based on management's current expectations. These statements involve known and unknown risks and uncertainties that may cause our actual results, performance or achievements to be materially different from any expressed or implied by the forward-looking statements. These risks include, but are not limited to, the following: the adverse impact the COVID-19 pandemic may have on our business; availability of additional capital; uncertainty regarding the results of regulatory submissions and oversight; success of our commercial operations; success of our clinical trials and preclinical studies; risks related to manufacturing, supply and distribution; the risk of litigation or other challenges regarding our intellectual property rights; success of any collaboration or partnership agreements. 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, 2019 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. 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.

Investor Relations Contact:
Elhan Webb, CFA
Email: ewebb@radiuspharm.com
Phone: 617-551-4011

Source: Radius Health Inc.