



Pivotal Phase III trial of abaloparatide-SC in Japanese women and men with osteoporosis achieves primary endpoint

May 27, 2020

Radius partner Teijin Pharma has submitted a New Drug Application for abaloparatide-SC for treatment of osteoporosis in Japan

WALTHAM, Mass., May 27, 2020 (GLOBE NEWSWIRE) -- Radius Health, Inc. ("Radius" or the "Company") (Nasdaq: RDUS), today announced that its partner, Teijin Pharma Limited, has submitted a New Drug Application for abaloparatide-SC in Japan for the treatment of osteoporosis in patients who are at high risk for fractures.

The application is based on the positive results of the Phase III clinical study of abaloparatide-SC in Japan which included osteoporosis patients at high risk for fracture. The study achieved its efficacy endpoint with a significant increase in lumbar spine bone mineral density at 18 months and showed an acceptable safety profile. Detailed results of this trial are planned to be presented at a global medical conference in the second half of this year.

"We are pleased that our partner Teijin has achieved this significant milestone toward the potential introduction of abaloparatide as a new treatment option for osteoporosis patients," stated Kelly Martin, CEO of Radius. "Japan represents the largest anabolic market in the world. This is a critically important step in expanding our osteoporosis business globally."

"Under the Teijin Group's current medium-term management plan, we are contributing to sustainability by developing solutions for a demographic change and increased health consciousness," said Ichiro Watanabe, president of Teijin Pharma Limited. "Launching abaloparatide will be a key factor in our implementation of this plan, so we hope to obtain approval and begin marketing to improve patients' quality of life (QOL) as soon as possible."

It is estimated that there are 13 million patients¹ with osteoporosis in Japan. Fractures associated with osteoporosis can restrict patients' activities of daily living and reduce their quality of life dramatically. Therapies – such as abaloparatide-SC, that increase bone mass and decrease risk for subsequent fractures, will provide a meaningful treatment option for physicians and their patients.

The market for osteoporosis drugs in Japan reached USD 3 billion in 2019. Under its license and development agreement with Teijin, Radius is entitled to receive milestone payments upon achievement of certain regulatory and sales milestones and a fixed double-digit royalty based on net sales of abaloparatide-SC in Japan during the royalty term.

About Radius

Radius is a science-driven fully integrated biopharmaceutical company that is committed to developing and commercializing innovative endocrine therapeutics. 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 the investigational use of abaloparatide injection for the treatment of men with osteoporosis, 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.

About the Teijin Group

Teijin (TSE: 3401) is a technology-driven global group offering advanced solutions in the fields of environmental value; safety, security and disaster mitigation; and demographic change and increased health consciousness. Originally established as Japan's first rayon manufacturer in 1918, Teijin has evolved into a unique enterprise encompassing three core business domains: high-performance materials including aramid, carbon fibers and composites, and also resin and plastic processing, films, polyester fibers and products converting; healthcare including pharmaceuticals and home healthcare equipment for bone/joint, respiratory and cardiovascular/metabolic diseases, nursing care and pre-symptomatic healthcare; and IT including B2B solutions for medical, corporate and public systems as well as packaged software and B2C online services for digital entertainment. Deeply committed to its stakeholders, as expressed in the brand statement "Human Chemistry, Human Solutions", Teijin aims to be a company that supports the society of the future. The group comprises more than 170 companies and employs some 20,000 people across 20 countries worldwide. Teijin posted consolidated sales of JPY 853.7 billion (USD 8.0 billion) and total assets of JPY 1,004.2 billion (USD 9.4 billion) in the fiscal year that ended on March 31, 2020. Please visit www.teijin.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 Teijin's expected timing for reporting detailed results from its Phase 3 clinical trial of abaloparatide-SC and for obtaining approval and commercializing abaloparatide-SC in Japan; the potential market opportunity for abaloparatide-SC in Japan, including the potential achievement of regulatory and sales milestones related to abaloparatide-SC in Japan; and the potential clinical uses and therapeutic and other benefits of abaloparatide-SC, 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: Teijin's inability to ensure that abaloparatide-SC will obtain regulatory approval in Japan or be successfully commercialized, if

approved, including as a result of risks related to coverage, pricing and reimbursement, manufacturing, supply and distribution, and potential adverse impacts on Teijin's business from the ongoing COVID-19 pandemic; risks related to competitive products in Japan; risks of litigation or other challenges regarding intellectual property rights in Japan; risks that adverse side effects of abaloparatide-SC will be identified during commercialization, if approved, or during development activities. 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.

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¹ Guidelines for Prevention and Treatment of Osteoporosis 2015



Source: Radius Health Inc.