

[Home](#) [Investors](#) [Radius Announces Positive Topline Data From...](#)

Radius Announces Positive Topline Data From Phase 2 Study of Abaloparatide (BA058) for Postmenopausal Osteoporosis Using Two Delivery Systems

January 09, 2014

Proof of Concept Demonstrated for Abaloparatide Transdermal Short Wear-Time Patch; Phase 2 Results for Abaloparatide Subcutaneous Injection Arm Consistent With Prior Phase 2 Data; Both Studies Continue to Support Potential of Abaloparatide to Be Best-in-Class Bone-Building Therapy

CAMBRIDGE, MA--(Marketwired - Jan 9, 2014) - Radius Health, Inc. ("Radius"), a late-stage biopharmaceutical company focused on developing novel therapeutics for osteoporosis and other serious endocrine-mediated diseases, today announced topline results from a Phase 2 study of BA058, or abaloparatide¹, the company's novel synthetic peptide analog of PTHrP (human parathyroid hormone-related protein, a naturally occurring bone-building hormone) in development for the treatment of osteoporosis.

The Phase 2 trial compared abaloparatide delivered via self-administered subcutaneous injection ("Abaloparatide SC") with administration via a short wear-time transdermal patch ("Abaloparatide TD") based on 3M's patented Microstructured Transdermal System technology. The Abaloparatide TD program is part of Radius' commitment to better meet patient needs through the development of this novel, patient-friendly, injection-free, short wear-time skin patch.

Abaloparatide SC is currently in a Phase 3 pivotal clinical study, which has enrolled 2,463 women with severe postmenopausal osteoporosis, designed to compare Abaloparatide SC daily injection to placebo and teriparatide as an active comparator for the prevention of new vertebral fractures over 18 months of treatment with topline results expected late in the fourth quarter of 2014. More than 1,100 patients have completed the treatment portion of the Phase 3 Abaloparatide SC pivotal study.

"These results expand on and highlight the impressive bone-building efficacy and well-documented safety data reported in the previous Abaloparatide SC Phase 2 study," said Robert Ward, President and CEO of Radius. "The prospect of following Abaloparatide SC, currently in Phase 3 development, with a patient-friendly, short wear-time transdermal patch, will allow us to better meet the needs of osteoporotic women looking for an injection-free delivery option. We are encouraged by these study results, which reinforce the clinical promise of Abaloparatide SC and the continued development of Abaloparatide TD as a line extension."

Trial Design:

A total of 250 healthy postmenopausal women with osteoporosis were enrolled in this randomized, placebo-controlled, Phase 2 study designed to evaluate the efficacy and tolerability of abaloparatide administered via a novel, short wear-time transdermal patch delivery system compared to subcutaneous injection delivery of abaloparatide. At baseline, the mean age of the randomized patients was 66.2 years, and the mean t-score [bone mineral density ("BMD")] compared with what is normally expected in a healthy young woman] for spine and total hip were -2.33 and -1.47, respectively. Thirty-nine percent of randomized patients had a history of fracture. The study was designed to assess changes in lumbar spine BMD as well as hip and forearm BMD; safety; tolerability; pharmacokinetic parameters; and serum markers of bone metabolism. Patients were randomized to receive either Abaloparatide TD (50 µg, 100 µg, or 150 µg), transdermal placebo, or Abaloparatide SC (80 µg – the same dose being studied in the ongoing Phase 3 study) once daily for six months. The transdermal patches were applied to the skin and removed after five minutes.

Summary Results:

Each of the three doses of Abaloparatide TD patch at the six-month endpoint demonstrated a statistically significant lumbar spine BMD increase from baseline versus placebo, with the 150 µg dose showing the greatest gains (2.95% increase, p value less than 0.0001) versus placebo (0.04% increase). Both the 100 µg and 150 µg doses demonstrated a statistically significant increase in total hip BMD compared to baseline, with the 150 µg dose again showing the greatest gain (1.49% increase, p=0.0018) versus placebo (0.02% decrease). Consistent with a previous Phase 2 study of Abaloparatide SC, patients who received the 80 µg dose of Abaloparatide SC demonstrated consistent increases in BMD in both lumbar spine (5.80% increase from baseline) and hip (2.74% increase from baseline). All doses of Abaloparatide TD and Abaloparatide SC were well tolerated, and there were no treatment-related serious adverse events reported in the study, consistent with the safety data from the prior Phase 2 study of Abaloparatide SC. The Microstructured Transdermal System also demonstrated a favorable local skin tolerance profile across the three dosing groups.

Radius plans to submit the full results of this Phase 2 study for presentation at a future scientific meeting following completion of ongoing analysis.

"These Phase 2 results provide first proof of concept of a transdermal delivery system for abaloparatide -- demonstrating a consistent dose effect with increasing doses of Abaloparatide TD, with a statistically significant dosing trend for changes in both spine and hip BMD," said Paul Miller, MD, Distinguished Clinical Professor of Medicine at the University of Colorado Health Sciences Center, Medical Director at the Colorado Center for Bone Research, and an investigator in the study. "We are pleased by these efficacy results and favorable safety profile for Abaloparatide TD and would welcome a novel new treatment option that surpasses current standard of care."

About Abaloparatide

Abaloparatide (BA058) is a novel synthetic peptide analog of human parathyroid hormone-related protein (hPTHrP), a naturally occurring bone-building hormone, that increases bone mineral density by stimulating new bone formation. Unlike parathyroid hormone (PTH), hPTHrP is critical in the formation of the skeleton, is involved in the regulation of bone formation and is able to rebuild bone with lower associated risk of inducing the presence of too much calcium in the blood, known as hypercalcemia, as a side effect. Abaloparatide SC is in Phase 3 development as a daily self-administered injection for the treatment of patients with postmenopausal osteoporosis at high risk of fracture. Topline results from an ongoing Phase 3 pivotal trial comparing Abaloparatide SC daily

injection to placebo and an active comparator for the prevention of new vertebral fractures are expected at the end of 2014. Radius is also developing Abaloparatide TD, a short wear-time transdermal patch designed to administer abaloparatide without the need for subcutaneous injection, based on 3M's patented Microstructured Transdermal System technology.

About Radius Health

Radius Health, Inc. is a science-driven biopharmaceutical company developing novel differentiated therapeutics for patients with advanced osteoporosis as well as other serious endocrine-mediated diseases. The company's lead development candidate is abaloparatide (BA058) for subcutaneous injection, currently in Phase 3 development for the reduction of fracture risk in postmenopausal women with severe osteoporosis. The Radius clinical portfolio also includes an abaloparatide transdermal patch for osteoporosis and RAD1901 for estrogen-driven breast cancer brain metastases. www.radiuspharm.com

About 3M Drug Delivery Systems

3M Drug Delivery Systems partners with pharmaceutical and biotech companies to develop and manufacture pharmaceutical products using 3M's inhalation, transdermal or microneedle drug delivery technology. 3M offers a full range of feasibility, development and manufacturing capabilities to help bring products to market. Regulatory expertise, quality assurance, operations, marketed product support and other in-house resources are available for each step of the development and commercialization process. For more information, please visit www.3M.com/dds or call 1-800-643-8086.

About 3M

3M captures the spark of new ideas and transforms them into thousands of ingenious products. Our culture of creative collaboration inspires a never-ending stream of powerful technologies that make life better. 3M is the innovation company that never stops inventing. With \$30 billion in sales, 3M employs 88,000 people worldwide and has operations in more than 70 countries. For more information, visit www.3M.com or follow @3MNews on Twitter.

3M is a trademark of 3M Company.

Safe Harbor for Forward-Looking Statements

Any statements made in this press release relating to future financial or business performance, conditions, plans, prospects, trends, or strategies and other financial and business matters, including without limitation, the prospects for Abaloparatide SC and Abaloparatide TD, clinical development plans and regulatory filings are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In addition, when or if used in this press release, the words "may," "could," "should," "anticipate," "believe," "estimate," "expect," "intend," "plan," "predict" and similar expressions and their variants, as they relate to Radius or its management, may identify forward-looking statements. Radius cautions that these forward-looking statements are subject to numerous assumptions, risks, and uncertainties, which change over time. Important factors that may cause actual results to differ materially from the results discussed in the forward-looking statements or historical experience include risks and uncertainties, including the failure by Radius to secure and maintain relationships with collaborators; risks relating to clinical trials; risks relating to the commercialization, if any, of Radius' proposed product candidates (such as marketing, regulatory, patent, product liability, supply, competition, and other risks); dependence on the efforts of third parties; dependence on intellectual property; and risks that Radius may lack the financial resources and access to capital to fund our operations. Further information on the factors and risks that could affect Radius' business, financial conditions and results of operations are contained in Radius' filings with the U.S. Securities and Exchange Commission, which are available at www.sec.gov. The forward-looking statements represent Radius' estimate as of the date hereof only, and Radius specifically disclaims any duty or obligation to update forward-looking statements.

¹ Abaloparatide is Radius' lead development candidate. Abaloparatide delivered via self-administered subcutaneous injection is currently in Phase 3 development for the reduction of fracture risk in postmenopausal women with severe osteoporosis. Abaloparatide delivered via transdermal patch is in Phase 2 development. Abaloparatide was previously referred to as BA058.

Contact:

Heather Savelle or Chris Erdman
MacDougall Biomedical Communications
781-235-3060
Nick Harvey
CFO
Radius Health
617-551-4700

Privacy Policy

Copyright © 2014 Radius Pharmaceutical