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## **FOR IMMEDIATE RELEASE**

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## **Radius' Investigational Bone Anabolic Agent, BA058, Increased Bone Mineral Density (BMD) at Key Fracture Sites in Phase 2 Clinical Trial in Postmenopausal Osteoporosis**

—Novel PTHrP Analog Meets Primary Endpoints—

*CAMBRIDGE, Mass., August 5, 2009*— Radius Health (“Radius”) today announced topline Phase 2 data demonstrating that in women with osteoporosis, BA058—the company’s novel PTHrP (parathyroid hormone-related protein) analog—significantly increased bone mineral density (BMD) at the lumbar spine and femoral neck (a common fracture site located in the hip joint) after six months of therapy. The gains in lumbar spine and femoral neck BMD were further increased in a subset of patients that elected to continue therapy for a total of 12 months of treatment, and at both time points, the changes were greater than those seen with Forteo® (teriparatide), the reference drug used in this dose-finding study.

The objective of the 221-patient Phase 2 clinical trial was to assess safety and evaluate the effect of three doses of BA058 on bone formation markers and on lumbar spine and femoral neck BMD over six months relative to placebo. The study also included a Forteo® reference arm. Forteo®, a form of parathyroid hormone, is the only anabolic (bone-building) agent approved for marketing by the U.S. Food and Drug Administration for the treatment of osteoporosis in women and men at high risk of fracture.

BA058 significantly increased mean lumbar spine BMD by 6.7 percent compared with 1.6 percent for placebo and significantly boosted mean femoral neck BMD by 3.1 percent compared with 0.8 percent for placebo at six months for the highest dose tested. By comparison, the mean percent change in the Forteo® group for lumbar spine BMD was 5.5 percent, and for femoral neck BMD was 1.1 percent. In the 12-month treatment period, patients receiving the highest dose of BA058 increased lumbar spine BMD by 12.9 percent at 12 months compared with 8.6 percent in the Forteo® group and boosted femoral neck BMD by 4.1 percent compared with 2.2 percent for the Forteo® group.

BA058 was generally safe and well tolerated in this study, with adverse events similar between the BA058 and placebo/Forteo® groups. In addition, the occurrence of hypercalcemia was half that of Forteo® in the highest dose of BA058 tested. Radius will submit additional detailed results from the Phase 2 study for presentation at an upcoming medical meeting.

“The results of this study affirm BA058’s safety and bone-building activity and support its promise as a next-generation anabolic treatment for osteoporosis,” said C. Richard Lyttle, PhD, President and CEO of Radius.

“We are especially encouraged by BA058’s superior efficacy in building new bone rapidly, particularly at the

femoral neck, since hip fractures are one of the most serious complications of osteoporosis and an area in which currently available osteoporosis treatments are weak.”

“These data are consistent with the clinical hypothesis for BA058—greater gains in BMD at the critical anatomic sites with less resorptive effect and less hypercalcemia compared to PTH and its analogs,” said Louis O’Dea, MD, Chief Medical Officer of Radius. “The greater and faster accrual of BMD with BA058 may allow for shorter durations of treatment and a more rapid reduction in fracture risk in the severe osteoporotic postmenopausal population, which would be a significant advance in the treatment of this debilitating disease.”

### **About the Phase 2 Clinical Trial**

The Phase 2 randomized, placebo- and comparator-controlled, parallel-group, dose-finding study was conducted in the U.S., Argentina, United Kingdom and India and was designed to evaluate the safety and efficacy of BA058 in the treatment of otherwise healthy postmenopausal women with osteoporosis. A total of 221 patients were enrolled and treated in the initial six-month period, and 55 patients continued into a subsequent additional six-month treatment period. Patients were on average 65 years old (54-84) and had an average lumbar spine BMD T-score of -2.93. All patients underwent four weeks of pretreatment with standard regional supplementation requirements for osteoporosis of not less than 400 IU per day of Vitamin D and not less than 500 mg per day of calcium, which continued throughout the study. Treatment was randomized to Forteo® or one of three doses of BA058 (20 µg, 40 µg, or 80 µg), or matching placebo. The study's co-primary endpoints were change from baseline in lumbar spine BMD and changes in anabolic bone markers. BMD is a measurement of mineralized bone tissue used to diagnose osteoporosis and to help determine a patient's fracture risk, as well as response to treatment.

### **About PTHrP and PTH**

In bone metabolism, PTHrP (parathyroid hormone-related protein) and its analogs are critical peptides for promoting new bone formation. Though they act through the same receptor, PTHrP and its analogs play a distinct biological role from the PTH (parathyroid hormone) peptide by activating different signaling responses—PTH regulates calcium homeostasis and bone resorption by acting primarily on target cells in bone and kidney, whereas PTHrP and its analogs regulate cell proliferation and differentiation in developing tissues and appear to play an important role in regulating bone remodeling in adults. While both peptides have demonstrated the ability to increase bone mineral density and bone strength in humans, PTHrP and its analogs do not stimulate adverse bone resorption and hypercalcemia to the same extent as PTH, highlighting differing therapeutic effects of the two peptide types on calcium and bone metabolism.

### **About BA058**

BA058 is Radius’ novel analog of hPTHrP (human parathyroid hormone-related protein). In Phase I and II studies, BA058 has demonstrated the potential to widen the anabolic window for bone therapeutics by stimulating bone formation with limited effect on bone resorption and less risk of hypercalcemia. In addition, BA058 in a prefilled cartridge presentation for self-injection has demonstrated long-term stability at room temperature without loss of functionality or impairment of safety and tolerability, an important convenience advantage for patients that would eliminate the refrigeration requirement of daily-injected Forteo®. Sales of PTH analogs are projected to surpass bisphosphonate sales and reach \$2.3 billion by 2018, driven by robust efficacy data in reducing fractures.

### **About Osteoporosis**

Osteoporosis is a leading cause of morbidity and mortality in elderly people worldwide. In the U.S. alone, more than 44 million men and women have osteoporosis or low bone-mineral density. A 50-year-old woman in the U.S. has a 40 percent lifetime risk of osteoporotic fracture. Twenty percent of hip-fracture patients enter long-term care, and half of this group never returns to living independently.

### **About Radius ([www.RADIUSPHARM.COM](http://www.radiuspharm.com))**

Radius is a leading company in the discovery and development of a new generation of drug therapies for osteoporosis and women’s health. Radius has raised \$106.5 million in private equity financing since its establishment in 2003 and is based in Cambridge, Massachusetts.

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