Radius Health, Inc.: Progress Since May 2020

October 21, 2020

- *Completed enrollment in 3 pivotal clinical trials; multiple data read outs in Q4 2021*
- *Released meaningful abaloparatide histomorphometry data at recent ASBMR meeting*
- *Completed two business development transactions with existing oncology assets*
- *Repositioned commercial effort to focus on high risk/fracture patient segment*
- *Increased current operating leverage by re-engineering components of infrastructure*

WALTHAM, Mass., Oct. 21, 2020 (GLOBE NEWSWIRE) -- Radius Health, Inc. (“Radius” or the “Company”) (Nasdaq: RDUS) provided a general business update on progress made since May 2020. The Company will provide further updates during its third quarter earnings call and at subsequent investor conferences. The key areas of activity included as part of its update are outlined below.

Clinical and Regulatory:

- Patient enrollment completed for 3 Pivotal Phase III trials:
  - ATOM study evaluating abaloparatide injection for potential use in osteoporotic men with high risk of fracture
  - wearABLe study evaluating the effects on bone mineral density of abaloparatide delivered via a novel transdermal system
  - EMERALD study for use of elacestrant to treat ER+/HER2- advanced or metastatic breast cancer in men and postmenopausal women
- Japan: Pivotal Phase III trial of abaloparatide injection to treat both men and postmenopausal women
  - Execution success by Radius partner, Teijin Pharma
  - Achieved primary endpoint: for osteoporotic patients with high risk for fractures
  - NDA submitted
- Europe
  - Seeking guidance and clarity regarding possible regulatory re-submission
- Histomorphometry Phase 2 Study data
  - Presented at American Society for Bone and Mineral Research (ASBMR) in September
  - Study assessed the early effect of abaloparatide at the tissue level and demonstrated significant increases in bone formation after three months in postmenopausal women with osteoporosis

Business Development

- Completed transaction with Menarini Group for Elacestrant, an oral SERD
  - Menarini licenses global development and commercial rights
  - Received $30 million as an upfront payment and up to $320 million in additional milestones along with tiered low to mid-teen royalties
  - Phase 3 development costs to be fully reimbursed by Menarini Group
- Completed transaction with Ellipses Pharma for RAD 140, an oral SARM
  - Ellipses responsible for all clinical development and advancement
  - Receive low double-digit percentage of future economics received by Ellipses

US TYMLOS Commercial Business

- Re-engineering internal operations
  - Combined market access with sales and marketing under one umbrella
  - Reduced sales territories from 159 to 109 and sales regions from 19 to 13
  - Adjusted incentive compensation plan to incentivize growth in PMO patients at high risk for fracture
- Performance Measurement
  - Net new patients on TYMLOS per month vs. 3 month trailing moving average
  - Total patients and duration of patients on TYMLOS vs. 3 month moving average
  - No longer focused on anabolic market share as Radius/TYMLOS business driver
- Transparency of TYMLOS performance metrics for the marketplace
  - Communicate Radius net new patients each month, commencing November 2020

- Communicate total Radius patients quarterly, starting with Q1, 2021 results
- Share avg. Radius patient months on therapy quarterly, starting Q2, 2021 results

Increasing Current Operating Leverage:

- Real estate goal: reduce from ~ 60,000 to ~ 12,000 sq. ft. actioning a hybrid work model
- Reduced silos at the senior level: consolidated commercial; integrated human resources, information technology, compliance, legal, QA, supply chain and real estate
- Total FTE headcount reduced from ~ 400 in 2019 to 315 as of Oct. 1, 2020, an absolute reduction of more than 20 %
- Capital allocation: adjusting abaloparatide planned clinical programs to focus on growth through patient segmentation and utilizing existing data with precision of message (s)
- Net new patient numbers for Radius: September and October demonstrating growth from mid-year COVID-19 slow down

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 a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.

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 ≥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 the TYMLOS prescribing information, including Boxed Warning, please visit www.tymlospi.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: 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; success of any collaboration, partnership, license or similar agreements; achievement of milestones; receipt of royalties or other future contingent payments; ability to implement pricing increases. 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.