Radius Health Business Update

July 27, 2021

- Added 5,000+ new TYMLOS patients in Q2, 2021, up 40+% vs. Q2, 2020 and 3% vs. Q1, 2021
- ATOM and wearABLe abaloparatide Phase 3 trial readouts remain on track for 2H, 2021
- EU abaloparatide regulatory resubmission remains on schedule for Q4, 2021
- Prader-Willi Syndrome (PWS) pivotal Phase 2/3 study to be initiated in Q4, 2021 or Q1, 2022
- Q2, 2021 earnings results scheduled for August 5, 2021

BOSTON, July 27, 2021 (GLOBE NEWSWIRE) -- Radius Health, Inc. (“Radius” or the “Company”) (NASDAQ: RDUS), provided a business update today on the Company’s progress.

Abaloparatide

New patient adds for the U.S. TYMLOS business continue to grow. New TYMLOS patients in Q2, 2021 were up over 40% vs. the same period in 2020. New patients are defined as those patients who have been prescribed TYMLOS and subsequently filled their first prescription.

The Company’s focus on fracture patients and corresponding healthcare providers – as the primary patient target for TYMLOS – is deepening. To date in 2021, 80+% of our top 50 TYMLOS prescribers are fracture / bone health focused, a trend we see accelerating.

From a U.S. regulatory point of view, both pivotal studies, ATOM (Osteoporotic Men at High Risk of Fracture) and wearABLe (Transdermal System) are on track for topline readouts in 2H, 2021. Pending the wearABLe trial results and FDA approval, the Company intends to price the Transdermal System at a premium to TYMLOS.

On the European regulatory front, Radius completed scientific consultations with several EU member states in Q1, 2021, submitted a letter of intent to resubmit, completed a dossier review with the EMA, and is on track refile in Q4, 2021.

RAD011

The Company received clarity from the FDA following the Type C meeting in June. Radius plans to move forward with a seamless Phase 2/3 pivotal trial for PWS. RAD011 had previously been granted Orphan Drug and Fast Track Designation by the FDA.

Based on current plans, the pivotal trial will initiate in Q4, 2021 or Q1, 2022, with anticipated topline readout in the second half of 2024.

There are approximately 22,000 to 24,000 PWS patients in the U.S. To date, there are no approved therapies to treat the hyperphagia experienced with the disease. The Company is committed to working closely with caregivers, advocacy groups, and regulators – globally – to safely advance RAD011 for this orphan disease.

Radius’ goal: through the pivotal trial and subsequent data readout, demonstrate efficacy and safety for FDA approval, and to help patients living with PWS.

About Radius
Radius is a commercial biopharmaceutical company committed to serving patients with unmet medical needs in endocrinology and other therapeutic areas. 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 investigational abaloparatide injection for potential use in the treatment of men with osteoporosis; an investigational abaloparatide transdermal system for potential use in the treatment of postmenopausal women with osteoporosis; the investigational drug, elacestrant (RAD1901), for potential use in the treatment of hormone-receptor positive breast cancer out-licensed to Menarini Group; and the investigational drug RAD011, a synthetic cannabidiol oral solution with potential utilization in multiple endocrine and metabolic orphan diseases, initially targeting Prader-Willi syndrome.

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 injection in 228 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 the Abaloparatide Transdermal System and wearABLe Phase 3 Study
The abaloparatide transdermal system was developed in a collaboration between Radius and Kindeva Drug Delivery (“Kindeva”) (formerly 3M Drug Delivery Systems) with the application of Kindeva’s innovative microstructured transdermal system technology. The wearABLe study is a pivotal, randomized, open label, active-controlled, bone mineral density (“BMD”) non-inferiority bridging study that will evaluate the efficacy and safety of abaloparatide transdermal system versus TYMLOS (abaloparatide) injection in approximately 500 patients with postmenopausal osteoporosis at high risk for fracture. The primary endpoint of the study is the percentage change in lumbar spine BMD at 12 months.

About Prader-Willi Syndrome

PWS, an orphan disease, is a complex genetic disorder with clinical manifestations on the endocrine and neurological systems. Clinical signs of PWS develop throughout childhood, with hyperphagia and anxiety ranked as the key clinical features seeking medical attention by caregivers of individuals with PWS. Hyperphagia is a relentless, insatiable, pathological drive to eat that requires caregivers to strictly manage access to food through the locking of cabinets and refrigerators. PWS is recognized as the leading genetic cause of life-threatening obesity in children. As life-threatening hyperphagia persists into adulthood, metabolic syndrome expressed through obesity and diabetes can develop and contribute to morbidity and mortality. In addition to food-related behaviors, the behavioral symptoms commonly observed in PWS include high irritability, habitual skin picking, oppositional defiance and cognitive rigidity. There are currently no approved therapies to treat this disorder's hyperphagia, irritability, or metabolic aspects. In the U.S., PWS occurs in approximately one out of every 15,000 births.

About RAD011
Investigational drug RAD011 is a pharmaceutical-grade synthetic cannabidiol oral solution, manufactured utilizing traditional pharmaceutical manufacturing processes. The product has purity specifications that meet standardized regulatory and quality control requirements and, compared to the process of developing a plant-derived product, the synthetic manufacturing process usually enables increased consistency and greater precision in the product supply. RAD011 has been assessed in over 150 patients across multiple indications and has potential utilization in multiple endocrine and metabolic orphan diseases. Radius is initially targeting Prader-Willi syndrome (PWS) and anticipates initiating a seamless pivotal Phase 2/3 study for patients with PWS in the fourth quarter of 2021 or first quarter of 2022.

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 our expectations with respect to the continued commercialization of TYMLOS in the U.S.; pricing of abaloparatide-TD; our clinical trials, studies and other regulatory initiatives, including our wearABLe and ATOM Phase 3 clinical trials of abaloparatide, our planned seamless Phase 2/3 trial for RAD011, and the resubmission of our MAA application in the EU; and our goals for the development of our product candidates, including RAD011.

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: the adverse impact the ongoing COVID-19 pandemic is having and is expected to continue to have on our business, financial condition and results of operations, including our commercial operations and sales, clinical trials, preclinical studies, and employees; quarterly fluctuation in our financial results; our dependence on the success of TYMLOS, and our inability to ensure that TYMLOS will obtain regulatory approval outside the U.S. or be successfully commercialized in any market in which it is approved, including as a result of risk related to coverage, pricing and reimbursement; risks related to competitive products; risks related to our ability to successfully enter into collaboration, partnership, license or similar agreements; risks related to clinical trials, including our reliance on third parties to conduct key portions of our clinical trials and uncertainty that the results of those trials will support our product candidate claims; the risk that adverse side effects will be identified during the development of our product candidates or during commercialization, if approved; risks related to manufacturing, supply and distribution; and the risk of litigation or other challenges regarding our intellectual property rights. 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, 2020 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. Any such forward-looking statements represent management's estimates as of the date of 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 & Media Relations Contact:
Ethan Holdaway
Email: investor-relations@radiuspharm.com
Phone: (617) 583-2017

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