Radius Health Business Update

April 22, 2021

- Growth of 14% for new U.S. TYMLOS® patients in Q1, 2021 vs. Q4, 2020
- Q1, 2021 TYMLOS net revenue impacted by seasonality and distribution channel destocking
- April, 2021 month-to-date new patient adds indicate significant patient growth
- Three pivotal studies: all remain on track for 2H, 2021 readouts: elacestrant (EMERALD), abaloparatide (ATOM & wearABLe)
- Bioequivalence (TD) and human factor studies (ATOM & wearABLe): studies completed and successful outcomes achieved
- RAD011 June Type C FDA meeting confirmed; Prader Willi Syndrome (PWS) protocol discussion
- PWSA Conference, June 23: RAD011 abstract accepted, oral presentation on previous Phase 2 data
- Lifecycle for RAD011: additional target orphan indications – beyond PWS – being analyzed

BOSTON, April 22, 2021 (GLOBE NEWSWIRE) -- Radius Health, Inc. (“Radius” or the “Company”) (Nasdaq: RDUS), provided the following business update. The Company’s first quarter 2021 earnings will take place on Friday, May 7 at 8:30am EST.

ABALOPARATIDE ASSET

TYMLOS

Patient growth increased by 14% in Q1, 2021 vs. Q4, 2020. For the first quarter, patient adds were strong in January, weakened in the short and weather impacted month of February, and rebounded in March. To date for the month of April, the new patient numbers appear robust.

Within the first quarter, there were seasonally driven headwinds for the net revenue totals. These are consistent with previous years, although Q1 2020 – as a comparator – was an unusual quarter given the underlying patient and HCP activity-based volatility resulting from COVID-19. We also experienced reasonable destocking within our distribution channel for the quarter. We expect net revenues will normalize throughout the balance of 2021.

Male Indication (ATOM Study)

Completed several human factors studies designed to evaluate the usability of the current commercial TYMLOS product. These formative human factors studies included both men and women, and the results were positive. We anticipate that the results will be included in an sNDA submission to add the male population to the label.

TD (wearABLe Study) Sterile Product and Human Factor Studies

Study completed to assess commercial sterile patch pharmacokinetic performance compared to the initial Phase 3 product. The results of the study were positive and passed the strict FDA bioequivalence criteria. This will enable a transition of all remaining patients in our wearABLe Phase 3 study from the current product to the sterile commercial product.

Final human factors studies were also completed, and the results were positive. This enables us to proceed to summative studies and would be an integral component in an anticipated abaloparatide-TD NDA submission.

ELACESTRANT ASSET

Pivotal data readout remains on track for 2H 2021. We continue to work closely with our partner, the Menarini Group, on execution, implementation, and progression of the program.

RAD011 ASSET

FDA Type C meeting is scheduled to take place in June, 2021. This meeting will review and discuss our proposed Phase 3 protocol for PWS. A recent advisory board meeting provided us with additional insights and considerations for the proposed pivotal trial.

Beyond PWS, the Company is critically assessing additional orphan indications that might be applicable for the RAD011 molecule. Several disease specific opportunities will be considered for clinical advancement over the course of the next 12 months.

The upcoming PWSA/USA Virtual Medical and Scientific Meeting will take place on June 23 and 24. The Company’s abstract “Preliminary results from a randomized, placebo-controlled Phase 2 trial using synthetic cannabidiol (CBD) oral solution in 7 individuals with Prader Willi Syndrome,” has been accepted. Results will be presented during an oral presentation.

About Radius

Radius is a commercialized 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 Phase 3 wearABLe study is the first pivotal study to evaluate treatment using a novel non-injectable delivery of an anabolic therapy. 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 Elacestrant (RAD1901) and EMERALD Phase 3 Study

Elacestrant is a selective estrogen receptor degrader (SERD), out-licensed to Menarini Group, which is being evaluated for potential use as a once daily oral treatment in patients with ER+/ HER2- advanced breast cancer. Studies completed to date indicate that the compound has the potential for use as a single agent or in combination with other therapies for the treatment of breast cancer. The EMERALD Phase 3 trial is a randomized, open label, active-controlled study evaluating elacestrant as second- or third-line monotherapy in ER+/HER2- advanced/metastatic breast cancer patients. The study has enrolled 466 patients who have received prior treatment with one or two lines of endocrine therapy, including a cyclin-dependent kinase (CDK) 4/6 inhibitor. Patients in the study were randomized to receive either elacestrant or the investigator’s choice of an approved hormonal agent. The primary endpoint of the study is progression-free survival (PFS) in the overall patient population and in patients with estrogen receptor 1 gene (ESR1) mutations. Secondary endpoints include evaluation of overall survival (OS), objective response rate (ORR), and duration of response (DOR).

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 regarding continued commercialization of TYMLOS in the U.S.; our expectations with respect to our net revenues; our expectations regarding our clinical trials or studies, including our wearABLe and ATOM Phase 3 clinical trials and the EMERALD Phase 3 clinical trial; the progress in the development of our product candidates, including the abaloparatide transdermal system, RAD011 and elacestrant (RAD1901); our expectations regarding our regulatory submissions; and the potential clinical uses and therapeutic and other benefits of our product candidates, including the abaloparatide transdermal system and elacestrant.

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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