Radius Health Business Update

June 2, 2021

- TYMLOS® new patient adds in April: modest growth vs. previous 4-month trailing averages
- ~67% of new patients in April were initiated by a fracture focused bone health account
- Meaningful FDA guidance on generic peptide requirements published on May 19, 2021
- Anticipate abaloparatide depot formulation technical development work to commence 2H, 2021
- RAD011 Type C meeting with the FDA on Prader Willi Syndrome ("PWS") the week of June 14

BOSTON, June 02, 2021 (GLOBE NEWSWIRE) -- Radius Health, Inc. ("Radius" or the "Company") (NASDAQ: RDUS), provided a business update covering continued progress for the Company. Additional business updates will be provided as progress is achieved.

ABALOPARATIDE ASSET

U.S. TYMLOS Commercial Performance:

- TYMLOS added ~1,650 new patients in April; 1% growth vs. trailing 4-month average
- New patients: defined as those who have been prescribed TYMLOS and received their first dose
- ~67% of new patients in April were initiated by a fracture focused bone health account
- Added 45 new fracture / bone health focused prescribers during the month of April

Life Cycle:

- ATOM (Male) Phase 3 pivotal study on schedule for readout: 2H, 2021
- wearABLe (Transdermal System) Phase 3 pivotal study on schedule for readout: 2H, 2021
- Anticipate abaloparatide depot formulation technical development work to commence 2H, 2021

Geographic Footprint:

- Europe: re-submission expected for abaloparatide SC to EMA in 2H, 2021
- Canada: abaloparatide SC submission – by our partner – expected in January, 2022
- Japan: 'planning discussions' with PMDA, a precursor to potential abaloparatide-TD agreement with Teijin
- Rest of world: multiple discussions ongoing with variety of counterparties

Intellectual Property Portfolio Advancement:

- Three U.S. patents are presently listed in the Orange Book for TYMLOS: U.S. Patent No. 7,803,770 which expires on April 28, 2031 and U.S. Patent Nos. 8,148,333 and 8,748,382 which each expire on October 30, 2027
- A fourth U.S. patent, U.S. Patent No. 10,996,208 directed to certain methods of analyzing abaloparatide to detect and quantify presence of beta Asp10, was issued on May 4, 2021 and will be added to the Orange book listing shortly; this patent expires on April 30, 2038
- A new Japanese patent covering the abaloparatide transdermal system and its use in treating osteoporosis was granted in April, 2021 and will expire October 8, 2036

FDA Guidance on Synthetic Peptides:

On May 19, 2021 the FDA published updated guidance and requirements for synthetic peptides and what would be required in any generic filings and advancement. Radius views this new guidance as meaningful in assessing the probability of a generic synthetic peptide being filed and gaining market entry.

In sum, the Company views these newly communicated FDA requirements as making it significantly more challenging to advance and develop a generic version of abaloparatide.

The key components of the new FDA guidelines include:

- Recombinantly sourced peptides cannot be approved in an ANDA and must be submitted in a 505(b)(2) NDA
- Explicit references to the potential for significant consequences if anti-drug antibodies cross-react against endogenous peptides
- New impurities must be within the FDA's threshold; if greater, must be submitted as a 505(b)(2)
- Explicit expectation: ANDA with new impurity must evaluate immunogenicity risks prior to filing

RAD011 ASSET

- FDA Type C meeting for PWS will take place the week of June 14
- Written minutes from the FDA meeting expected by the end of July
- Post FDA discussion, expectation is to initiate a pivotal PWS trial before year end
- Additional orphan indications being assessed in parallel – decisions and clarity in 2H, 2021
- Multiple Advisory Board meetings completed: U.S., UK, EU for PWS plus a Psychiatry meeting
- Internal team formed: clinical, pharm. science, regulatory, bio-stats, CMC, global franchise
- External team established: manufacturing & supply chain, development, regulatory, advocacy

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).

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 pivotal Phase 2/3 study for patients with PWS in the second half of 2021 pending regulatory discussion with the U.S. Food and Drug Administration (FDA).

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 regarding our clinical trials, studies and other regulatory initiatives, including our wearABLe and ATOM Phase 3 clinical trials; and the progress in 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

Source: Radius Health Inc.