Radius Health, Inc. Announces Acquisition of Orphan Disease Program

January 6, 2021

- RAD011 is a pivotal-trial ready synthetic cannabidiol oral solution with potential utilization in multiple endocrine and metabolic orphan diseases
- Prader-Willi syndrome (“PWS”) will be the initial indication, which has been granted Orphan Drug and Fast Track Designation by the FDA
- Acquisition and associated PWS trial costs to be funded from existing operations
- Management to host conference call and webcast this morning at 8:15 a.m. ET

BOSTON, Jan. 06, 2021 (GLOBE NEWSWIRE) -- Radius Health, Inc. (“Radius” or the “Company”) (Nasdaq: RDUS) today announced a definitive agreement to acquire the global development and commercialization rights to Benuvia Therapeutics Inc.’s (“Benuvia”) synthetic cannabidiol oral solution (“RAD011”). The Company plans to initiate a pivotal Phase 2/3 study for patients with Prader-Willi syndrome (“PWS”) in the second half of 2021 pending regulatory discussion with the U.S. Food and Drug Administration (“FDA”).

Under the terms of the agreement, Radius acquired RAD011 for $12.5 million, with an additional $15 million to be paid contingent on the successful conclusion of PWS development milestones. For the next three indications, any or all of which can be pursued at Radius’ discretion, the Company may pay up to $45 million in development milestones. In addition, Radius may pay sales-based milestone payments and a tiered, high single-digit effective royalty.

The Company has financed the acquisition through cash on hand and the utilization of $15 million from an existing debt facility, resulting in no equity dilution to Radius shareholders. On an operating basis, the Company believes the combination of a rationalized cost structure and expected ongoing growth in TYMLOS® net revenue will fully fund the development of RAD011 through the top line readout in 2023 with minimal impact on near term cashflow generation. As part of this transaction, the Company expects to take a one-time charge of up to $16 million in the fourth quarter of 2020.

“This acquisition advances our business across several dimensions. It increases the optionality to the Company’s value proposition, leverages our endocrine expertise and adds a late-stage pivotal trial-ready orphan disease product to the existing Phase 3 programs for abaloparatide and elacestrant,” said Radius Chief Executive Officer, Kelly Martin. “RAD011 has the potential for broad clinical applicability. We intend to use PWS as the anchor indication and will further investigate additional orphan disease opportunities in due course.”

“Benuvia is excited to partner with the leadership of Radius Health to progress the late-stage development and commercialization of our synthetic cannabidiol oral solution for the treatment of rare and underserved diseases. We look forward to supporting Radius through our U.S. based contract manufacturing business, Benuvia Manufacturing, which has significant chemistry and formulation capabilities, including manufacturing our FDA-approved cannabinoid drug, SYNDROS®,” said Todd C. Davis, executive chairman of Benuvia.

Disease Highlights

PWS is an orphan disease with major endocrine and behavioral manifestations and no FDA-approved therapies for the treatment of hyperphagia. Caregivers of these patients often prioritize hyperphagia, the most common genetic cause of life-threatening childhood obesity, and anxiety as the most important symptoms for treatment of the disease. From existing literature and previous clinical trial data generated, cannabidiol has a multifactorial mechanism of action showing clear biological activity against both of these symptoms.

Lynne M. Bird, M.D., medical director of Rady Children's Hospital multidisciplinary Prader-Willi Syndrome Clinic, said, “Currently, there is no treatment for Prader-Willi syndrome. For many patients with the disorder, ameliorating some of the most difficult symptoms, such as insatiable appetite and anxiety, would be life-changing for them and their families.”

Theresa Strong, Ph.D., director of research programs for the Foundation for Prader-Willi Research, said, "With a focus on individuals with PWS and their caregivers, our mission is to accelerate research and support the development of therapies that will eliminate the challenges of PWS." Dr. Strong added, "We have played an active and instrumental role with pharmaceutical companies through the engagement of the PWS community, support of innovative research programs, and creation of PWS research tools and clinical trial endpoints."

Clinical Highlights

The efficacy and safety of Benuvia’s synthetic cannabidiol oral solution has been assessed in over 150 patients across multiple indications. Existing data demonstrates that safety and tolerability have been favorable. In the PWS indication, efficacy data from an abbreviated Phase 2 trial with RAD011 is directionally supportive of reducing both hyperphagia as well as demonstrating a reduction in weight. The reduced appetite and associated weight reduction are further supported by additional RAD011 trials as well as published data from other botanical cannabidiol products.

Radius plans to promptly request a meeting with the FDA to discuss the initiation of a pivotal Phase 2/3 study for the treatment of patients with PWS. The study design will be informed by learnings from previous clinical studies that have been conducted in the PWS patient population. RAD011 was granted Fast Track Designation in 2017 and Orphan Drug Designation in August 2020 for the treatment of hyperphagia behavior and weight loss in patients with PWS. In addition to seven years orphan regulatory exclusivity for the PWS indication, there is an extensive global patent portfolio which will provide protection for the novel formulations through 2035 and, if granted, novel methods of manufacturing through 2040. Top line data could be available in approximately two years from a trial initiation in the second half of 2021.

J.P. Morgan Securities LLC served as an advisor and Ropes & Gray LLP served as legal counsel to the Company on this transaction.

Conference Call & Webcast (with Slides)

Radius will host a conference call and webcast this morning, Wednesday, January 6, 2021 at 8:15 a.m. Eastern Time. Management will review the transaction and be available to address Q&A. Interested participants and investors may access the conference call by dialing (866) 323-7965 (U.S./Canada) or (346) 406-0961 (international); conference ID: 9156145. A live webcast presentation can also be accessed via the Investors section of the Radius' corporate web site at: http://www.radiuspharm.com.

For those unable to participate in the conference call or webcast, a replay will be available on Wednesday, January 6, 2021 at 11:15 a.m. Eastern Time and will be archived on the Company's website for 90 days. To access the replay, dial (855) 859-2056 for U.S. or (404) 537-3406 for International, using conference ID number 9156145.

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 anxiety, habitual skin picking, oppositional defiance and cognitive rigidity. There are currently no approved therapies to treat this disorder's hyperphagia, anxiety, or metabolic aspects. In the U.S., PWS occurs in approximately one out of every 15,000 births.

About Cannabidiol

Cannabinoids can be classified into three groups: phytocannabinoids (Cannabis plant-derived), endocannabinoids (produced by body), or synthetic cannabinoids (pharmaceutically manufactured). The two most commonly researched cannabinoids are tetrahydrocannabinol (THC), the most potent psychoactive cannabinoid, and cannabidiol (CBD), which is not psychoactive. Within PWS, cannabidiol targets signaling pathways and receptors that regulate the physical symptoms of hyperphagia and anxiety. This multifactorial mechanism of action positions cannabidiol to interact beyond CB1 and CB2 receptors, including the body's endocannabinoid system and inhibition of anandamide reuptake, activation of PPAR- γ, and agonism of 5HT-1A, which regulate food intake, metabolism, weight control, and anxiety. Cannabidiol may also improve other complications associated with PWS, including behavioral disorders.

About Radius

Radius is a science-driven fully integrated biopharmaceutical company that is committed to developing and commercializing innovative endocrine therapeutics. For more information, please visit www.radiuspharm.com.

About Benuvia

Benuvia Therapeutics Inc. is focused on financing and developing low-risk assets with high clinical value to improve the quality of life for patients with rare and underserved diseases. Benuvia markets SYNDROS® our FDA-approved cannabinoid drug and through our affiliate, Benuvia Manufacturing, we operate a state-of-the-art Research & Development and cGMP manufacturing facility. Benuvia's highly experienced team identifies, acquires and develops high-potential assets at key inflection points, with the ultimate goal of engaging premier partners for final development and commercialization. This enables superior risk adjusted returns for our biopharmaceutical investors. For more information, please visit www.benuvia.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, including those related to Radius' ability to absorb program costs, cost and revenue projections, the financial impact of the acquisition. These forward-looking statements are based on management's current expectations, and expected trial submission and completion timelines. 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.

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