Rhythm Pharmaceuticals Enters into a Non-dilutive Revenue Interest Financing Agreement with HealthCare Royalty for up to $100 Million

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Extends Cash Runway into 2H 2024

BOSTON, June 16, 2022 (GLOBE NEWSWIRE) -- Rhythm Pharmaceuticals, Inc. (Nasdaq: RYTM) ("Rhythm"), a commercial-stage biopharmaceutical company committed to transforming the care of people living with rare genetic diseases of obesity, today announced that it has entered into a Revenue Interest Financing Agreement (the "Agreement"), with HealthCare Royalty Partners ("HealthCare Royalty") for a total investment amount of up to $100 million. Rhythm intends to use the proceeds from the Agreement and its cash on hand to support global commercialization efforts for IMCIVREE® (setmelanotide) and ongoing clinical development.

Under the terms of the Agreement, Rhythm will receive an initial investment amount of $37.5 million from HealthCare Royalty, as a result of the approval of IMCIVREE by the U.S. Food and Drug Administration ("FDA") for the treatment of obesity and control of hunger in adult and pediatric patients 6 years old and older with Bardet-Biedl syndrome ("BBS"). Rhythm will receive an additional investment amount of $37.5 million following European Commission marketing authorization for IMCIVREE for BBS, which is anticipated in the second half of 2022. The final investment amount of $25 million will be payable upon Rhythm's achievement of certain agreed sales milestones in 2023.

In exchange for the total investment amount received by Rhythm, HealthCare Royalty will receive a tiered royalty based on global net product sales generated by IMCIVREE. This royalty will begin in the low double digits and decrease to the low single digits upon the achievement of certain annual revenue thresholds. The total royalty payable by Rhythm to HealthCare Royalty is capped between 185 percent and 250 percent of the amount paid to Rhythm, dependent on the aggregate royalty paid between 2028 and 2032. Based on the total funding under this Agreement, together with Rhythm's current cash balance, Rhythm anticipates that it will be able to fund its operating expenses and capital expenditure requirements into the second half of 2024, regardless of whether the sales milestone relating to the third tranche is achieved.

"This Agreement with HealthCare Royalty, a premier investment firm, underscores the significant opportunity for IMCIVREE as the first-ever treatment to address the unmet needs of hyperphagia and severe obesity in people living with BBS," said David Meeker, M.D., Chair, President and Chief Executive Officer of Rhythm. "We are excited to announce this transaction concurrently with U.S. approval for IMCIVREE in BBS, as it provides meaningful non-dilutive capital as we initiate our launch. The added financial flexibility will also support investment in our broad clinical development program for setmelanotide, with the goal of delivering our precision medicine to many more people suffering from hyperphagia and severe obesity caused by rare melanocortin-4 receptor (MC4R) pathway diseases."

"Our investment reflects our confidence in Rhythm and IMCIVREE's commercial prospects in BBS, as well as its potential for expansion into additional indications," said Clarke Futch, Chairman and Chief Executive Officer of HealthCare Royalty. "Our extensive due diligence indicates that the BBS community is well established and that Rhythm has identified health care providers and patients who are eager to initiate therapy with IMCIVREE. We are also excited to collaborate with Rhythm to support further clinical development of setmelanotide in additional indications with substantial medical and commercial opportunity."

Morgan Stanley & Co. LLC acted as Sole Structuring Agent and Latham & Watkins LLP acted as legal advisor to Rhythm on the transaction. Morgan, Lewis & Bockius LLP acted as legal advisor to HealthCare Royalty.

About Rhythm Pharmaceuticals
Rhythm is a commercial-stage biopharmaceutical company committed transforming the lives of patients and their families living with hyperphagia and severe obesity caused by rare melanocortin-4 receptor (MC4R) pathway diseases. Rhythm's precision medicine, IMCIVREE (setmelanotide), is approved by the U.S. Food and Drug Administration (FDA) for chronic weight management in adult and pediatric patients 6 years of age and older with monogenic or syndromic obesity due to POMC, PCSK1 or LEPR deficiency confirmed by genetic testing, or patients with a clinical diagnosis of Bardet-Biedl syndrome (BBS). The European Commission (EC) and Great Britain's Medicines & Healthcare Products Regulatory Agency (MHRA) have authorized IMCIVREE for the treatment of obesity and the control of hunger associated with genetically confirmed loss-of-function biallelic POMC, including PCSK1, deficiency or biallelic LEPR deficiency in adults and children 6 years of age and above. IMCIVREE is the first-ever FDA-approved and EC- and MHRA-authorized therapy for patients with these rare genetic diseases of obesity. The Company submitted a Type II variation application to the European Medicines Agency seeking regulatory approval and authorization for setmelanotide to treat obesity and control of hunger in adult and pediatric patients 6 years of age and older with BBS in the European Union. Additionally, Rhythm is advancing a broad clinical development program for setmelanotide in other rare genetic diseases of obesity and is leveraging the Rhythm Engine and the largest known obesity DNA database -- now with approximately 45,000 sequencing samples -- to improve the understanding, diagnosis and care of people living with severe obesity due to certain genetic deficiencies. Rhythm's headquarters is in Boston, MA.

About HealthCare Royalty
HealthCare Royalty purchases royalties and uses debt-like structures to invest in commercial or near-commercial stage life science assets. HealthCare Royalty has $6.0 billion in cumulative capital commitments with offices in Stamford (CT), San Francisco, Boston and London. For more information, visit www.healthcareroyalty.com. HEALTHCARE ROYALTY PARTNERS® is a registered trademark of HealthCare Royalty Management, LLC in the U.S. and a trademark in other countries.

IMCIVREE® (setmelanotide) Indication

In the United States, IMCIVREE is indicated for chronic weight management in adult and pediatric patients 6 years of age and older with monogenic or syndromic obesity due to:

- Pro-opiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency as determined by an FDA-approved test demonstrating variants in *POMC*, *PCSK1*, or *LEPR* genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS)
- Bardet-Biedl syndrome (BBS)

Limitations of Use
IMCIVREE is not indicated for the treatment of patients with the following conditions as IMCIVREE would not be expected to be effective:

- Obesity due to suspected POMC, PCSK1, or LEPR deficiency with *POMC*, *PCSK1*, or *LEPR* variants classified as benign or likely benign
- Other types of obesity not related to POMC, PCSK1, or LEPR deficiency, or BBS, including obesity associated with other genetic syndromes and general (polygenic) obesity

WARNINGS AND PRECAUTIONS

Disturbance in Sexual Arousal: Spontaneous penile erections in males and sexual adverse reactions in females have occurred. Inform patients that these events may occur and instruct patients who have an erection lasting longer than 4 hours to seek emergency medical attention.

Depression and Suicidal Ideation: Depression and suicidal ideation have occurred. Monitor patients for new onset or worsening depression or suicidal thoughts or behaviors. Consider discontinuing IMCIVREE if patients experience suicidal thoughts or behaviors, or clinically significant or persistent depression symptoms occur.

Skin Pigmentation and Darkening of Pre-existing Nevi: Generalized increased skin pigmentation and darkening of pre-existing nevi have occurred. Perform a full body skin examination prior to initiation and periodically during treatment to monitor pre-existing and new pigmentary lesions.

Risk of Serious Adverse Reactions Due to Benzyl Alcohol Preservative in Neonates and Low Birth Weight Infants: IMCIVREE is not approved for use in neonates or infants. Serious and fatal adverse reactions including “gasping syndrome” can occur in neonates and low birth weight infants treated with benzyl alcohol-preserved drugs.

ADVERSE REACTIONS

- The most common adverse reactions (incidence ≥20%) included skin hyperpigmentation, injection site reactions, nausea, headache, diarrhea, abdominal pain, vomiting, depression, and spontaneous penile erection.

USE IN SPECIFIC POPULATIONS
Treatment with IMCIVREE is not recommended when breastfeeding. Discontinue IMCIVREE when pregnancy is recognized unless the benefits of therapy outweigh the potential risks to the fetus.

To report SUSPECTED ADVERSE REACTIONS, contact Rhythm Pharmaceuticals at 833-789-6337 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see the full Prescribing Information for additional Important Safety Information.

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 the potential, safety, efficacy, and regulatory and clinical progress of setmelanotide, our expectations surrounding potential regulatory submissions, approvals and timing thereof, our business strategy and plans, including regarding commercialization of setmelanotide, anticipated benefits of and activities under our financing agreement with HealthCare Royalty, our use of proceeds from the transaction with HealthCare Royalty and our business strategy and plans. Statements using word such as “expect”, “anticipate”, “believe”, “may”, “will” and similar terms are also forward-looking statements. Such statements are subject to numerous risks and uncertainties, including, but not limited to, our ability to enroll patients in clinical trials, the design and outcome of clinical trials, the impact of competition, the ability to achieve or obtain necessary regulatory approvals, risks associated with data analysis and reporting, our liquidity and expenses, the impact of the COVID-19 pandemic on our business and operations, including our preclinical studies, clinical trials and commercialization prospects, and general economic conditions, and the other important factors discussed under the caption “Risk Factors” in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2022 and our other filings with the Securities and Exchange Commission. Except as required by law, we undertake no obligations to make any revisions to the forward-looking statements contained in this release or to update them to reflect events or circumstances occurring after the date of this release, whether as a result of new information, future developments or otherwise.

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