



Rhythm Pharmaceuticals Announces Senior Leadership Additions

July 29, 2021

-- Pamela Cramer appointed Chief Human Resources Officer --

-- Linda Shapiro Manning, M.D., Ph.D., appointed Senior Vice President, Clinical --

BOSTON, July 29, 2021 (GLOBE NEWSWIRE) -- Rhythm Pharmaceuticals, Inc. (Nasdaq: RYTM), a commercial-stage biopharmaceutical company committed to transforming the care of people living with rare genetic diseases of obesity, today announced the appointments of Pamela Cramer as Chief Human Resources Officer and Linda Shapiro Manning, M.D., Ph.D., as Senior Vice President, Clinical.

"We are excited to welcome Pam and Linda to the Rhythm team at a transformational time for the company, as we work to deliver IMCIVREE™ (setmelanotide) to patients with certain rare genetic diseases of obesity in the United States and Europe and expand our reach with a multi-faceted, global clinical development strategy," said David Meeker, M.D., Rhythm Chairman, Chief Executive Officer and President. "Pam brings deep talent management and organizational development experience and a strong track record as an effective business partner, and Linda comes with significant clinical experience in obesity, both as a practicing physician and clinical development leader in industry. We are thrilled both senior leaders chose to join us and look forward to their contributions as we execute on our mission."

Ms. Cramer joined Rhythm as Chief Human Resources Officer, effective July 26. She brings 20 years of leadership experience in organizational effectiveness, talent development and human resources (HR) transformation with globally diverse life sciences and financial services companies. She joins Rhythm from Foundation Medicine, where she most recently served as Head of People Solutions and was responsible for leading HR delivery for its more than 1700 employees. Prior to that, Ms. Cramer held senior HR positions at Cambridge Associates, PAREXEL International and Epsilon Data Management. Earlier in her career, Ms. Cramer served in a wide range of positions at Bank of America Merrill Lynch and General Electric, where she began her career as a graduate of the Human Resources Leadership Program. She holds an M.B.A. from Georgetown University.

Dr. Shapiro joined Rhythm earlier in July, bringing more than 20 years of experience in obesity medicine. For the past ten years, she has worked in the biopharmaceutical industry, with clinical development and medical affairs roles at Applied Therapeutics, Boehringer Ingelheim, Merck and Novo Nordisk. In these roles, she led clinical development for assets in type 2 diabetes and cardiometabolic conditions and, at Novo Nordisk, she served as head of medical science and international medical director for the company's GLP-1 and obesity global development programs. Prior to joining industry, Dr. Shapiro practiced medicine in Colorado, obtaining certification and specializing in obesity medicine. She holds a Ph.D. and completed a post-doctoral research fellowship in kinesiology and applied physiology from the University of Colorado, an M.D. from Tulane University School of Medicine, and a bachelor's degree in exercise science from the University of Southern California.

About Rhythm Pharmaceuticals

Rhythm is a commercial-stage biopharmaceutical company committed to transforming the treatment paradigm for people living with rare genetic diseases of obesity. The Company's precision medicine, IMCIVREE (setmelanotide), was approved in November 2020 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 obesity due to POMC, PCSK1 or LEPR deficiency confirmed by genetic testing and by the European Commission (EC) in July 2021 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-authorized therapy for these rare genetic diseases of obesity. Rhythm is advancing a broad clinical development program for setmelanotide in other rare genetic diseases of obesity. The Company is leveraging the Rhythm Engine and the largest known obesity DNA database – now with approximately 37,500 sequencing samples – to improve the understanding, diagnosis and care of people living with severe obesity due to certain genetic deficiencies. The company is based in Boston, MA.

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 obesity due to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency. The condition must be confirmed by genetic testing demonstrating variants in *POMC*, *PCSK1*, or *LEPR* genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VOUS).

In the EU, IMCIVREE is indicated 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 should be prescribed and supervised by a physician with expertise in obesity with underlying genetic etiology.

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, including obesity associated with other genetic syndromes and general (polygenic) obesity.

Important Safety Information

WARNINGS AND PRECAUTIONS

Disturbance in Sexual Arousal: Sexual adverse reactions may occur in patients treated with IMCIVREE. Spontaneous penile erections in males and sexual adverse reactions in females occurred in clinical studies with IMCIVREE. Instruct patients who have an erection lasting longer than 4 hours to seek emergency medical attention.

Depression and Suicidal Ideation: Some drugs that target the central nervous system, such as IMCIVREE, may cause depression or suicidal ideation. Monitor patients for new onset or worsening of depression. Consider discontinuing IMCIVREE if patients experience suicidal thoughts or behaviors.

Skin Pigmentation and Darkening of Pre-Existing Nevi: IMCIVREE may cause generalized increased skin pigmentation and darkening of pre-existing nevi due to its pharmacologic effect. This effect is reversible upon discontinuation of the drug. Perform a full body skin examination prior to initiation and periodically during treatment with IMCIVREE to monitor pre-existing and new skin 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.

ADVERSE REACTIONS

- The most common adverse reactions (incidence $\geq 23\%$) were injection site reactions, skin hyperpigmentation, nausea, headache, diarrhea, abdominal pain, back pain, fatigue, vomiting, depression, upper respiratory tract infection, and spontaneous penile erection.

USE IN SPECIFIC POPULATIONS

Discontinue IMCIVREE when pregnancy is recognized unless the benefits of therapy outweigh the potential risks to the fetus.

Treatment with IMCIVREE is not recommended for use while breastfeeding.

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

See [Full Prescribing Information](#) for IMCIVREE.

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, and management changes. 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, the impact of our management transition, 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 quarterly period ended March 31, 2021 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.

Corporate Contact:

David Connolly
Head of Investor Relations and Corporate Communications
Rhythm Pharmaceuticals, Inc.
857-264-4280
dconnolly@rhythmtx.com

Investor Contact:

Hannah Deresiewicz
Stern Investor Relations, Inc.
212-362-1200
hannah.deresiewicz@sternir.com

Media Contact:

Adam Daley
Berry & Company Public Relations
212-253-8881
adaley@berrypr.com

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Source: Rhythm Pharmaceuticals, Inc.

Linda Shapiro Manning Headshot



Linda Shapiro Manning, M.D., Ph.D., Senior Vice President, Clinical

Pamela Carter Headshot



Pamela Cramer, Chief Human Resources Officer