



## Rhythm Pharmaceuticals Announces Promotions within its Executive Leadership Team

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BOSTON, Feb. 23, 2022 (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 promotions of Joe Shulman to Chief Technical Officer, Patrick Kleyn, Ph.D., to Senior Vice President and Head of Translational Research and Development, and Elisabeth Crönert-Bendell, M.D., to Senior Vice President and Head of Strategy.

"We are pleased to announce the promotions of three exceptionally talented and influential leaders on Rhythm's executive leadership team," said David Meeker, M.D., Chair, President and Chief Executive Officer of Rhythm. "Joe, Patrick and Elisabeth continue to play vital roles in our efforts to build a global organization, deliver IMCIVREE® (setmelanotide) to patients and families and execute on our mission of transforming the care of rare genetic diseases of obesity."

Mr. Shulman joined Rhythm in 2020 as Senior Vice President of Technical Operations. He previously served as Senior Vice President of Technical Operations at Ra Pharmaceuticals, acquired by UCB, where he oversaw all aspects of CMC development and strategy as a member of the executive leadership team. Prior to that, he was Senior Vice President of Global Technical Operations at Novilion Therapeutics, and earlier in his career, Mr. Shulman held similar roles at Ziopharm Oncology and Dyax Corp. He holds an M.B.A. from Boston University and earned a B.S. in chemical engineering from Miami University of Ohio.

Dr. Kleyn joined Rhythm's Translational Research and Development team in 2018 and has recently been serving as its interim head. He has 30 years of experience across industry and academia and brings a deep understanding of both genetics and management. Dr. Kleyn previously held leadership positions including Chief Scientific Officer and Chief Executive Officer at several biotechnology and pharmaceutical companies. He earned a Ph.D. in molecular genetics from the University College London in the UK.

Dr. Crönert-Bendell joined Rhythm in 2021 and has been serving as Vice President and Head of International Strategy, playing a leading role in global expansion. A neurologist by training, she has led clinical development programs, medical affairs organizations, sales and marketing teams, and served as the global product lead for multiple companies including Kyowa Kirin and Sanofi Genzyme. Prior to that, she worked in Strategic Consulting at Monitor. Dr. Crönert-Bendell holds an M.B.A. from INSEAD and earned an M.D. from the Université Paris-Est.

### 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. Rhythm'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 in July and September 2021, respectively, by the European Commission (EC) and Great Britain's Medicines & Healthcare Products Regulatory Agency (MHRA) 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 supplemental New Drug Application (sNDA) to the FDA, which was accepted for filing in November 2021 and assigned a Prescription Drug User Fee Act (PDUFA) goal date of March 16, 2022, and submitted a Type II variation application to the European Medicines Agency in October 2021 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 or Alström syndrome in both the United States and 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.

### 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, confirmed by genetic testing demonstrating variants in *POMC*, *PCSK1*, or *LEPR* genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS).

In the EU and Great Britain, 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](http://www.fda.gov/medwatch).

See [Full Prescribing Information](#), [EU SmPC](#) and [MHRA SmPC](#) 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, including with respect to our ongoing DAYBREAK and Phase 3 weekly switch trials and planned EMANATE, VENTURE and Phase 3 de novo trials, our expectations surrounding potential regulatory submissions, approvals and timing thereof, our business strategy and plans, including regarding commercialization of setmelanotide, and our participation in upcoming events and presentations. 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 quarterly period ended September 30, 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.

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