



Rhythm Pharmaceuticals Reports Second Quarter 2022 Financial Results and Business Update

August 2, 2022

- Received FDA approval for IMCIVREE[®] (setmelanotide) as the first-ever therapy for patients with Bardet-Biedl syndrome --*
- U.S. launch off to a strong start with more than 50 IMCIVREE prescriptions written for patients with BBS in first six weeks since FDA approval --*
- EMA's CHMP recommended expansion of IMCIVREE marketing authorization to include treatment of obesity and control of hunger in patients with genetically confirmed BBS; EC approval anticipated in the fourth quarter of 2022 --*
- Announced positive interim results from Phase 2 trial in hypothalamic obesity and plans to initiate Phase 3 trial in early 2023 --*
- Entered into non-dilutive revenue interest financing agreement with Healthcare Royalty Partners for up to \$100 million, extending cash runway into second half of 2024 --*
- Management to host conference call today at 8:00 a.m. ET --*

BOSTON, Aug. 02, 2022 (GLOBE NEWSWIRE) -- Rhythm Pharmaceuticals, Inc. (Nasdaq: RYTM) today reported financial results and provided a business update for the second quarter ended June 30, 2022.

"Rhythm is executing on our global mission to transform the lives of patients and families living with hyperphagia and severe obesity caused by rare MC4R pathway diseases," said David Meeker, M.D., Chair, President and Chief Executive Officer of Rhythm. "Our commercial launch of IMCIVREE[®] (setmelanotide) in Bardet-Biedl syndrome (BBS) is off to a strong start, and we continue to make meaningful progress towards securing market access in Europe, for both our initial indications and, more recently, BBS."

Dr. Meeker added, "We are highly encouraged by the interim data from our Phase 2 trial evaluating setmelanotide in hypothalamic obesity and the potential role it may play in transforming how this disease is treated. We look forward to reviewing these data with the U.S. Food and Drug Administration (FDA) and seeking input on a pivotal Phase 3 trial, which we plan to initiate in the first half of 2023. We are excited to add a potential Phase 3 trial in hypothalamic obesity to our broad setmelanotide clinical development program, which also includes the ongoing Phase 3 EMANATE trial, Phase 2 DAYBREAK trial, Phase 3 switch study evaluating a weekly formulation of setmelanotide and our Phase 3 pediatrics trial, which has completed enrollment."

Second Quarter and Recent Business Highlights:

Regulatory and Commercial Updates:

Bardet-Biedl Syndrome:

- Today, Rhythm announced that more than 35 physicians have written more than 50 prescriptions for IMCIVREE for patients with BBS in the first six weeks since IMCIVREE was approved by the FDA on June 16, 2022 for chronic weight management in adult and pediatric patients 6 years of age and older with obesity due to BBS.
- In July 2022, Rhythm announced that the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending to expand the current indication for IMCIVREE to include the treatment of obesity and control of hunger in adult and pediatric patients 6 years of age and older with genetically confirmed BBS.
- In July 2022, Rhythm announced that the French National Agency for Medicines and Health Products Safety (ANSM) and Haute Autorité de santé (HAS) granted post-marketing authorization AP1 (autorisation d'accès précoce -- early access authorization) for setmelanotide for the treatment of obesity and control of hunger in patients with genetically confirmed BBS. AP1 allows for early access to innovative therapies in France prior to regulatory approval when a positive benefit/risk ratio is recognized and when no other therapeutic alternatives are available.

POMC and LEPR Deficiency Obesities:

- In July 2022, Rhythm announced that the National Institute for Health and Care Excellence (NICE) issued guidance recommending IMCIVREE as an option for treating obesity and controlling hunger caused by POMC, PCSK1 or LEPR deficiency in people 6 years of age or older. With this recommendation under the Highly Specialised Technologies (HST) pathway, IMCIVREE will be funded and available for use within 90 days in the National Health Service.

- In June 2022, Rhythm launched IMCIVREE in Germany for patients with POMC, PCSK1 or LEPR deficiency obesity. IMCIVREE is the first precision medicine designed to induce weight loss and control of hunger that has received a lifestyle exemption from the German Federal Joint Committee (G-BA).
- Also in June 2022, Rhythm announced that the European Commission (EC) authorized a variation for IMCIVREE that allows for dosing in patients aged 6 years or older with POMC or LEPR deficiency who have mild, moderate or severe renal impairment.

Clinical Development Updates:

- Today, Rhythm announced it completed enrollment in the Phase 3, open-label trial evaluating one year of setmelanotide therapy in pediatric patients with MC4R pathway deficiencies between the ages of 2 and 6 years old.
- In July 2022, Rhythm announced positive interim results from the Phase 2 study in patients with hypothalamic obesity. All 11 evaluable patients achieved the primary endpoint of at least 5% reduction in body mass index (BMI) ($P < 0.0001$) at 16 weeks on therapy, with a mean change in BMI of -17.2% and a mean change in hunger score of -2.7. Consistent with prior clinical experience in other rare MC4R pathway diseases, setmelanotide was observed to be generally well tolerated.
- In June 2022 at the Endocrine Society Annual Meeting & Expo (ENDO), Rhythm and its collaborators presented new data from the Company's long-term extension (LTE) trial, which show continued BMI and weight reductions in patients with BBS or POMC or LEPR deficiency obesity (biallelic) receiving between 18 months and three years of setmelanotide therapy. Also at ENDO, Rhythm presented initial data from the LTE trial demonstrating continued BMI and weight reductions in patients with SH2B1 or SRC1 deficiency obesity, or with POMC or LEPR insufficiency obesity (heterozygous).

Corporate:

- In June 2022, Rhythm entered into a non-dilutive Revenue Interest Financing Agreement (RIFA) with HealthCare Royalty Partners for a total investment amount of up to \$100 million. In exchange for the total investment amount received by Rhythm, HealthCare Royalty Partners will receive a tiered royalty based on global net product sales generated by IMCIVREE.

Key Upcoming Milestones:

In the second half of 2022, Rhythm expects to:

- Complete regulatory review by the European Commission and, pending approval, make IMCIVREE commercially available in Europe for the treatment of obesity and control of hunger in adult and pediatric patients 6 years old and older with genetically confirmed BBS.
- Launch IMCIVREE in the U.K. and Italy for patients with POMC, PCSK1 or LEPR deficiencies.
- Present full data from the 18 patients enrolled in the Phase 2 clinical trial evaluating setmelanotide for the treatment of hypothalamic obesity at a medical meeting.

Second Quarter 2022 Financial Results:

- **Cash Position:** As of June 30, 2022, cash, cash equivalents and short-term investments were approximately \$235.6 million, as compared to \$294.9 million as of December 31, 2021, primarily due to operating activities in the first half of 2022. This amount was partially offset by the initial investment of \$37.5 million from HealthCare Royalty, which Rhythm received following FDA approval of IMCIVREE for use in patients with BBS.
- **Revenue:** Product net revenues relating to sales of IMCIVREE were \$2.3 million for the second quarter of 2022, as compared to \$0.3 million for the second quarter of 2021.
- **License Revenue:** License revenue relating to the Company's out-license arrangement with RareStone was \$6.8 million for the second quarter of 2022. There were no comparable transactions in the prior year.
- **R&D Expenses:** R&D expenses were \$31.5 million in the second quarter of 2022, as compared to \$25.1 million in the second quarter of 2021. The year-over-year increase was due to an increase of \$4.6 million in clinical trial costs associated with new and planned clinical trials, including the Phase 2 DAYBREAK and Phase 3 EMANATE trials, Phase 3 pediatrics trial, QTc study and Phase 2 hypothalamic obesity trial, and increased enrollment in the long-term extension trial. These increases were partially offset by reduced activity and winding down of the Phase 3 BBS and Phase 2 Basket trials, and the GO-ID study. In addition, there was an increase of \$0.7 million for gene sequencing costs, an increase of \$1.3 million in compensation and benefits due to the hiring of additional full-time employees in order to support the growth of Rhythm's research and development programs and regulatory affairs operations, and \$1.0 million associated with support for regulatory filing and clinical supply material. These increases were partially offset by a decrease of \$1.2 million in costs associated with medical affairs.
- **S,G&A Expenses:** S,G&A expenses were \$22.3 million for the second quarter of 2022, as compared to \$15.5 million for the second quarter of 2021. The year-over-year increase was primarily due to an increase of \$5.0 million related to increased costs associated with commercial operations, sales and marketing activities for IMCIVREE in connection with preparing for the U.S approval and commercial launch in BBS, an increase of \$1.0 million due to increased compensation and benefits related costs associated with additional headcount to support expanding business operations and global commercial operations, and an increase of \$1.0 million due to increased costs associated with office support and insurance costs for Rhythm's expanding workforce.
- **Net Loss:** Net loss was (\$45.0) million for the second quarter of 2022, or a net loss per basic and diluted share of (\$0.89), as compared to a net loss of (\$35.4) million for the second quarter of 2021, or a net loss per basic and diluted share of (\$0.70).

Year to Date 2022 Financial Results:

- **Revenue:** Product revenues relating to sales of IMCIVREE were \$3.8 million for the six months ended June 30, 2022, as compared to \$0.3 million for the six months ended June 30, 2021.
- **License Revenue:** License revenue relating to the Company's out-license arrangement with RareStone was \$6.8 million for the six months ended June 30, 2022. There were no comparable transactions in the prior year.
- **R&D Expenses:** R&D expenses were \$64.0 million for the six months ended June 30, 2022, as compared to \$45.0 million for the six months ended June 30, 2021. This increase was primarily due to an increase of \$14.0 million in clinical trial costs associated with new and planned clinical trials, including Phase 2 DAYBREAK and Phase 3 EMANATE trials, Phase 3 pediatrics trial, QTc study, Phase 2 hypothalamic obesity study, and increased enrollment in the long-term extension study. These increases were partially offset by reduced activity due to the completion and winding down of BBS, Phase 2 basket, renal and GO-ID studies. Additional increases during the period included; an increase of \$4.2 million due to increased purchases of clinical supply material; an increase of \$1.5 million in compensation and benefits due to the hiring of additional full-time employees in order to support the growth of R&D programs and expansion of regulatory affairs operations; an increase of \$1.2 million due to gene sequencing costs; and an increase of \$1.0 million in development milestones earned by Camurus, related to development milestone achieved related to the weekly formulation. These increases were partially offset by a decrease of \$3.2 million in costs associated with medical affairs.
- **S,G&A Expenses:** S,G&A expenses were \$43.8 million for the six months ended June 30, 2022, as compared to \$30.0 million for the six months ended June 30, 2021. The increase was primarily due to an increase of \$7.3 million related to increased costs associated with commercial operations, sales and marketing activities for IMCIVREE in connection with preparing for the U.S approval for BBS obtained in June 2022; an increase of \$4.4 million due to increased compensation and benefits related costs associated with additional headcount to support expansion of business operations and build out of commercial operations in the United States and internationally; and an increase of \$2.0 million due to increased costs associated with information technology, international office space, sponsorships and travel related expenses for our expanding workforce.
- **Other income, net:** Other income decreased by \$100.1 million in the six months ended June 30, 2022 as compared to the six months ended June 30, 2021 primarily due to the sale of the priority review voucher (PRV) in February 2021. The sale of the PRV in the prior year was a non-recurring transaction.
- **Provision for income taxes:** There is no provision for income taxes for the six months ended June 30, 2022, as Rhythm projects to generate operating losses during the year. The Company recorded a provision for income taxes of \$17.0 million as a result of the sale of its PRV during the six months ended June 30, 2021.
- **Net (loss) income:** Net loss was (\$97.7) million for the six months ended June 30, 2022, or a net loss per basic and diluted share of (\$1.94), as compared to a net income of \$8.4 million for the six months ended June 30, 2021, or a net income per basic and diluted share of \$0.17.

Financial Guidance: Based on its current operating plans, Rhythm expects that its existing cash and cash equivalents and short-term investments as of June 30, 2022 will be sufficient to fund operations into 2024, and that such existing cash and cash equivalents and short term investments, together with the second investment tranche under the RIFA with HealthCare Royalty Partners expected in the second half of 2022, will be sufficient to fund its operating expenses and capital expenditure requirements into at least the second half of 2024.

Conference Call Information

Rhythm Pharmaceuticals will host a live conference call and webcast at 8:00 a.m. ET today to review its second quarter 2022 financial results and recent business activities. Participants may register for the conference call [here](#). While not required, it is recommended that participants join the call ten minutes prior to the scheduled start.

A live webcast of the call will also be available under "Events and Presentations" in the Investor Relations section of the Rhythm Pharmaceuticals website at <http://ir.rhythmtx.com/>. The archived webcast will be available on Rhythm Pharmaceuticals' website approximately two hours after the conference call and will be available for 30 days following the call.

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. Rhythm received a positive Committee for Medicinal Products for Human Use (CHMP) opinion on its 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 and a decision from the EC is expected in the fourth quarter of 2022. 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 Setmelanotide

Setmelanotide is a melanocortin-4 receptor (MC4R) agonist. The MC4R is part of the key biological pathway that regulates hunger, caloric intake and energy expenditure. Variants in genes may impair the function of the MC4R pathway, potentially leading to hyperphagia and early-onset, severe obesity. Rhythm is developing setmelanotide as a targeted therapy to potentially restore the function of an impaired MC4R pathway and, in so doing, potentially reduce hunger and weight in patients with rare genetic diseases of obesity.

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.

Rhythm's Type II variation application to the European Medicines Agency (EMA) for the treatment of obesity and control of hyperphagia in adult and pediatric patients 6 years of age and older with BBS is under review. The Company is also continuing to advance the most comprehensive clinical research program ever initiated in MC4R pathway diseases, including the pivotal Phase 3 EMANATE clinical trial evaluating setmelanotide in four independent sub-studies in patients with obesity due to POMC insufficiency caused by heterozygous variants in the *POMC* or *PCSK1* genes, LEPR insufficiency caused by heterozygous variants in the *LEPR* gene, SRC1 deficiency caused by a variant in the *NCOA1* gene, and SH2B1 deficiency caused by a variant in the *SH2B1* gene or 16p11.2 deletion encompassing the *SH2B1* gene. The Phase 2 DAYBREAK trial is evaluating setmelanotide in patients with severe obesity and hyperphagia caused by rare variants associated with 10 prioritized MC4R-relevant genes. Rhythm has also initiated a Phase 3 pediatric trial and a Phase 3 trial evaluating a weekly formulation of setmelanotide.

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 pigmented 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 $\geq 20\%$) 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, including the anticipated timing for initiation of clinical trials and release of clinical trial data and our expectations surrounding potential regulatory submissions, approvals and timing thereof, including in the United States and Europe, our business strategy and plans, including regarding commercialization of setmelanotide, sales of our lead product candidate IMCIVREE, our participation in upcoming events and presentations, and the sufficiency of our cash, cash equivalents and short-term investments to fund our operations. 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 June 30, 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.

Rhythm Pharmaceuticals, Inc.
Condensed Consolidated Statements of Operations and Comprehensive (Loss) Income
(in thousands, except share and per share data)
(Unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2022	2021	2022	2021
Product revenue, net	\$ 2,312	\$ 274	\$ 3,810	\$ 309
License revenue	6,754	—	6,754	—
Costs and expenses:				
Cost of sales	378	137	608	141
Research and development	31,456	25,104	63,966	45,015
Selling, general, and administrative	22,328	15,465	43,777	29,983
Total costs and expenses	<u>54,162</u>	<u>40,706</u>	<u>108,351</u>	<u>75,139</u>
Loss from operations	(45,096)	(40,432)	(97,787)	(74,830)
Other income:				
Other income	—	—	—	100,000
Interest income, net	95	21	22	175
Total other income, net	<u>95</u>	<u>21</u>	<u>22</u>	<u>100,175</u>
(Loss) income before taxes	(45,001)	(40,411)	(97,765)	25,345
(Benefit from) provision for income taxes	—	(5,022)	—	16,984
Net (loss) income	\$ (45,001)	\$ (35,389)	\$ (97,765)	\$ 8,361
Net (loss) income per share				
Basic	\$ (0.89)	\$ (0.70)	\$ (1.94)	\$ 0.17
Diluted	\$ (0.89)	\$ (0.70)	\$ (1.94)	\$ 0.17
Weighted-average common shares outstanding				
Basic	50,398,003	50,209,484	50,362,512	48,931,127
Diluted	50,398,003	50,209,484	50,362,512	49,644,704
Other comprehensive (loss) income:				
Net (loss) income	\$ (45,001)	\$ (35,389)	\$ (97,765)	\$ 8,361
Unrealized (loss) income on marketable securities and other long-term assets	(277)	79	(905)	(28)
Comprehensive (loss) income	\$ (45,278)	\$ (35,310)	\$ (98,670)	\$ 8,333

Rhythm Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except share and per share data)

(Unaudited)

	<u>June 30, 2022</u>	<u>December 31, 2021</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 113,207	\$\$ 59,248
Short-term investments	122,389	235,607
Accounts receivable, net	1,707	1,025
Prepaid expenses and other current assets	12,029	12,507
Total current assets	249,332	308,387
Property and equipment, net	2,559	2,813
Right-of-use asset	1,359	1,522
Intangible assets, net	8,311	4,658
Restricted cash	328	328
Other long-term assets	15,786	11,815
Total assets	\$ 277,675	\$\$ 329,523
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 6,012	\$\$ 5,737
Accrued expenses and other current liabilities	35,605	30,084
Deferred revenue	2,309	7,000
Lease liability	644	606
Total current liabilities	44,570	43,427
Long-term liabilities:		
Deferred royalty obligation	34,273	—
Lease liability	1,614	1,945
Derivative liability	1,590	—
Total liabilities	82,047	45,372
Stockholders' equity:		
Preferred Stock, \$0.001 par value: 10,000,000 shares authorized; no shares issued and outstanding at June 30, 2022 and December 31, 2021	—	—
Common stock, \$0.001 par value: 120,000,000 shares authorized; 50,454,170 and 50,283,574 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	50	50
Additional paid-in capital	823,188	813,041
Accumulated other comprehensive loss	(906)	(1)
Accumulated deficit	(626,704)	(528,939)
Total stockholders' equity	195,628	284,151
Total liabilities and stockholders' equity	\$ 277,675	\$\$ 329,523

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