Sarepta Therapeutics Reports Preliminary* Fourth Quarter and Full-Year 2024 Net Product Revenue

1/13/25

– ***Preliminary total net product revenue of $638.2 million for the fourth quarter and $1.79 billion for full-year 2024, exceeding full-year guidance by over $100 million***

– ***Preliminary ELEVIDYS net product revenue totaled $384.2 million for the fourth quarter, exceeding guidance by over $60 million, and $820.8 million for full-year 2024***

– ***Preliminary RNA-based PMO net product revenue for the fourth quarter and full-year of 2024 totaled $254.0 million and $967.2 million, respectively***

– ***Preliminary year-end 2024 cash, cash equivalents, restricted cash and investments balance of approximately $1.5 billion***

– ***Reiterates 2025 full-year total net product revenue guidance of $2.9 to $3.1 billion***

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jan. 13, 2025-- Sarepta Therapeutics, Inc. (NASDAQ:SRPT), the leader in precision genetic medicine for rare diseases, today reported preliminary* fourth quarter and full-year 2024 net product revenue and cash on hand as of December 31, 2024, as part of its presentation today at the 43rd Annual J.P. Morgan Healthcare Conference in San Francisco, Calif.

Financial Update* (preliminary and unaudited):

- Total net product revenue of $638.2 million for the fourth quarter and $1.79 billion for full-year 2024, exceeding full-year guidance by over $100 million. Sarepta's net product revenue does not include collaboration, contract manufacturing or royalty revenue.
- Fourth quarter and full-year 2024 net product revenue for ELEVIDYS totaled $384.2 million and $820.8 million, respectively. Sarepta's net product revenue does not include collaboration, contract manufacturing or royalty revenue.
- Fourth quarter and full-year 2024 net product revenue for Sarepta's RNA-based PMOs totaled $254.0 million and $967.2 million, respectively. Sarepta's net product revenue does not include collaboration, contract manufacturing or royalty revenue.
- As of December 31, 2024, the Company had preliminary cash, cash equivalents, restricted cash and investments of approximately $1.5 billion.
- The Company reiterates 2025 full-year total net product revenue guidance of $2.9 to $3.1 billion.

"2024 marked the most significant year to date for Sarepta and for the patients we serve. And consistent with our long track record of execution, we ended 2024 and enter 2025 with exceptionally strong performance," said Doug Ingram, president and chief executive officer, Sarepta Therapeutics. "In the fourth quarter, we grew total net product revenue by 75% year-over-year and grew ELEVIDYS by a very robust 112% over the prior sequential quarter, overachieving our guidance by more than $60 million. Our 2024 total net product revenue grew some 56% over 2023. And we were pleased to see that even in the face of a strong ELEVIDYS launch, our PMO franchise continued to perform and grow year-over-year."

*These preliminary selected financial results are unaudited and subject to adjustment. Sarepta will report its final and complete fourth quarter and full-year 2024 financial results in late February 2025. The Company has not completed its financial closing procedures for the quarter or year-ended December 31, 2024, and its actual results could be materially different from these preliminary financial results.

About ELEVIDYS (delandistrogene moxeparvovec-rokl)

ELEVIDYS (delandistrogene moxeparvovec-rokl) is a single-dose, adeno-associated virus (AAV)-based gene transfer therapy for intravenous infusion designed to address the underlying genetic cause of Duchenne muscular dystrophy – mutations or changes in the *DMD* gene that result in the lack of dystrophin protein – through the delivery of a transgene that codes for the targeted production of ELEVIDYS micro-dystrophin in skeletal muscle.

ELEVIDYS is indicated for the treatment of Duchenne muscular dystrophy (DMD) in individuals at least 4 years of age.

- For patients who are ambulatory and have a confirmed mutation in the *DMD* gene
- For patients who are non-ambulatory and have a confirmed mutation in the *DMD* gene.

The DMD indication in non-ambulatory patients is approved under accelerated approval based on expression of ELEVIDYS micro-dystrophin (noted hereafter as "micro-dystrophin") in skeletal muscle. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

IMPORTANT SAFETY INFORMATION

CONTRAINDICATION: ELEVIDYS is contraindicated in patients with any deletion in exon 8 and/or exon 9 in the *DMD* gene.

WARNINGS AND PRECAUTIONS:

Infusion-related Reactions:

- Infusion-related reactions, including hypersensitivity reactions and anaphylaxis, have occurred during or up to several hours following ELEVIDYS administration. Closely monitor patients during administration and for at least 3 hours after the end of infusion. If symptoms of infusion-related reactions occur, slow, or stop the infusion and give appropriate treatment. Once symptoms resolve, the infusion may be restarted at a lower rate.
- ELEVIDYS should be administered in a setting where treatment for infusion-related reactions is immediately available.
- Discontinue infusion for anaphylaxis.

Acute Serious Liver Injury:

- Acute serious liver injury has been observed with ELEVIDYS, and administration may result in elevations of liver enzymes (such as GGT, GLDH, ALT, AST) or total bilirubin, typically seen within 8 weeks.
- Patients with preexisting liver impairment, chronic hepatic condition, or acute liver disease (e.g., acute hepatic viral infection) may be at higher risk of acute serious liver injury. Postpone ELEVIDYS administration in patients with acute liver disease until resolved or controlled.
- Prior to ELEVIDYS administration, perform liver enzyme test and monitor liver function (clinical exam, GGT, and total bilirubin) weekly for the first 3 months following ELEVIDYS infusion. Continue monitoring if clinically indicated, until results are unremarkable (normal clinical exam, GGT, and total bilirubin levels return to near baseline levels).
- Systemic corticosteroid treatment is recommended for patients before and after ELEVIDYS infusion. Adjust corticosteroid regimen when indicated. If acute serious liver injury is suspected, consultation with a specialist is recommended.

Immune-mediated Myositis:

- In clinical trials, immune-mediated myositis has been observed approximately 1 month following ELEVIDYS infusion in patients with deletion mutations involving exon 8 and/or exon 9 in the *DMD* gene. Symptoms of severe muscle weakness, including dysphagia, dyspnea, and hypophonia, were observed.
- Limited data are available for ELEVIDYS treatment in patients with mutations in the *DMD* gene in exons 1 to 17 and/or exons 59 to 71. Patients with deletions in these regions may be at risk for a severe immune-mediated myositis reaction.
- Advise patients to contact a physician immediately if they experience any unexplained increased muscle pain, tenderness, or weakness, including dysphagia, dyspnea, or hypophonia, as these may be symptoms of myositis. Consider additional immunomodulatory treatment (immunosuppressants [e.g., calcineurin-inhibitor] in addition to corticosteroids) based on patient's clinical presentation and medical history if these symptoms occur.

Myocarditis:

- Acute serious myocarditis and troponin-I elevations have been observed following ELEVIDYS infusion in clinical trials.
- If a patient experiences myocarditis, those with pre-existing left ventricle ejection fraction (LVEF) impairment may be at higher risk of adverse outcomes. Monitor troponin-I before ELEVIDYS infusion and weekly for the first month following infusion and continue monitoring if clinically indicated. More frequent monitoring may be warranted in the presence of cardiac symptoms, such as chest pain or shortness of breath.
- Advise patients to contact a physician immediately if they experience cardiac symptoms.

Preexisting Immunity against AAVrh74:

- In AAV-vector based gene therapies, preexisting anti-AAV antibodies may impede transgene expression at desired therapeutic levels. Following treatment with ELEVIDYS, all patients developed anti-AAVrh74 antibodies.
- Perform baseline testing for presence of anti-AAVrh74 total binding antibodies prior to ELEVIDYS administration.
- ELEVIDYS administration is not recommended in patients with elevated anti-AAVrh74 total binding antibody titers greater than or equal to 1:400.

Adverse Reactions:

- The most common adverse reactions (incidence ≥5%) reported in clinical studies were vomiting, nausea, liver injury, pyrexia, and thrombocytopenia.

Report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088. You may also report side effects to Sarepta Therapeutics at 1-888-SAREPTA (1-888-727-3782).

For further information, please see the full Prescribing Information.

About Sarepta Therapeutics

Sarepta is on an urgent mission: engineer precision genetic medicine for rare diseases that devastate lives and cut futures short. We hold leadership positions in Duchenne muscular dystrophy (DMD) and limb-girdle muscular dystrophies (LGMDs), and we currently have more than 40 programs in various stages of development. Our vast pipeline is driven by our multi-platform Precision Genetic Medicine Engine in gene therapy, RNA and gene

editing. For more information, please visit www.sarepta.com or follow us on LinkedIn, X, Instagram and Facebook.

Internet Posting of Information

We routinely post information that may be important to investors in the 'For Investors' section of our website at www.sarepta.com. We encourage investors and potential investors to consult our website regularly for important information about us.

Forward-Looking Statements

This press release contains "forward-looking statements." Any statements that are not statements of historical fact may be deemed to be forward-looking statements. Words such as "believe," "anticipate," "plan," "expect," "will," "may," "intend," "prepare," "look," "potential," "possible" and similar expressions are intended to identify forward-looking statements. These forward-looking statements include statements relating to our expected financial results.

These forward-looking statements involve risks and uncertainties, many of which are beyond Sarepta's control. Actual results could materially differ from those stated or implied by these forward-looking statements as a result of such risks and uncertainties. Known risk factors include the following: the estimates and judgments we make, or the assumptions on which we rely, in preparing our consolidated financial statements could prove inaccurate; our revenues and operating results could fluctuate significantly, which may adversely affect our stock price; and those risks identified under the heading "Risk Factors" in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2024 as well as other SEC filings made by the Company which you are encouraged to review.

Any of the foregoing risks could materially and adversely affect the Company's business, results of operations and the trading price of Sarepta's common stock. For a detailed description of risks and uncertainties Sarepta faces, you are encouraged to review the SEC filings made by Sarepta. We caution investors not to place considerable reliance on the forward-looking statements contained in this press release. Sarepta does not undertake any obligation to publicly update its forward-looking statements based on events or circumstances after the date hereof, except as required by law.

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