Sarepta and Catalent Expand Strategic Manufacturing Partnership With Commercial Supply Agreement for Duchenne Muscular Dystrophy Gene Therapy Candidate

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SOMERSET, N.J. & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jan. 5, 2023-- Catalent, Inc. (NYSE:CTLT), the leader in enabling the development and supply of better treatments for patients worldwide, and Sarepta Therapeutics, Inc. (NASDAQ:SRPT), the leader in precision genetic medicine for rare diseases, today announced the signing of a commercial supply agreement for Catalent to manufacture delandistrogene moxeparvovec (SRP-9001), Sarepta's most advanced gene therapy candidate for the treatment of Duchenne muscular dystrophy (DMD). The agreement also structures how Catalent may support multiple gene therapy candidates in Sarepta's pipeline for limb-girdle muscular dystrophy (LGMD).

In November 2022, Sarepta announced that the U.S. Food and Drug Administration (FDA) had accepted its biologics license application (BLA) seeking accelerated approval of delandistrogene moxeparvovec. Under the terms of this expanded agreement, Catalent will be Sarepta's primary commercial manufacturing partner for this therapy.

"Sarepta is working as quickly as possible to advance new genetic medicines to treat progressive neuromuscular diseases like Duchenne and LGMD. We are excited to strengthen and expand our relationship with Catalent to meet anticipated demand for SRP-9001 and develop commercially scalable processes for additional gene therapy programs in our pipeline," said Doug Ingram, Sarepta's President and Chief Executive Officer. "We appreciate the years of dedication and collaboration that Catalent has provided in supporting our clinical trials for SRP-9001, and we look forward to continuing our work together through this expanded partnership."

"Our partnership with the Sarepta team spans nearly a decade across multiple programs and modalities, and we look forward to working together to manufacture these potentially life-changing and life-saving products for patients diagnosed with DMD and LGMD," said Alessandro Maselli, Catalent's President and Chief Executive Officer. "We look forward to leveraging our deep expertise in gene therapy development, manufacturing, and commercialization to support these programs as they advance toward potential regulatory approval."

Catalent's gene therapy network includes state-of-the-art facilities that currently house 10 cGMP gene therapy manufacturing suites, with another 8 suites under construction, each capable of accommodating multiple bioreactors up to 2,000-liter scale. For gene therapy development, customers can leverage the company's UpTempo Virtuoso ℠ adeno-associated virus (AAV) platform, a scalable, GMP-ready process for viral vector manufacturing that can reduce a typical 18-month development timeline for drug product by half. Catalent is also the only contract development and manufacturing organization (CDMO) with a facility approved by the FDA for commercial manufacturing of an AAV gene therapy.

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Notes for Editors

About Catalent

Catalent is the global leader in enabling pharma, biotech, and consumer health partners to optimize product development, launch, and full life-cycle supply for patients around the world. With broad and deep scale and expertise in development sciences, delivery technologies, and multi-modality manufacturing, Catalent is a preferred industry partner for personalized medicines, consumer health brand extensions, and blockbuster drugs.

Catalent helps accelerate over 1,000 partner programs and launch over 150 new products every year. Its flexible manufacturing platforms at over 50 global sites supply around 80 billion doses of nearly 8,000 products annually. Catalent's expert workforce of approximately 18,000 includes more than 3,000 scientists and technicians.

Headquartered in Somerset, New Jersey, the company generated nearly $5 billion in revenue in its 2022 fiscal year. For more information, www.catalent.com.

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 Twitter, LinkedIn, Instagram and Facebook.

Catalent Forward Looking Statements

This release contains both historical and forward-looking statements. All statements other than statements of historical fact, are, or may be deemed to be, forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements generally can be identified by the use of statements that include phrases such as "believe," "expect," "anticipate," "intend," "estimate," "plan," "project," "foresee," "likely," "may," "will," "would," or other words or phrases with similar meanings. Similarly, statements that describe Catalent's objectives, plans, or goals are, or may be, forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could vary materially from Catalent's expectations and projections. Some of the factors that could cause actual results to differ include, but are not limited to, the following: the current or future effects of the COVID-19 pandemic or any global health developments on Catalent's and its customers' or suppliers' businesses; participation in a highly competitive market and increased competition that may adversely affect Catalent's business; demand for its offerings, which depends in part on its customers' research and development and the clinical and market success of their products; product and

other liability risks that could adversely affect Catalent's results of operations, financial condition, liquidity and cash flows; failure to comply with existing and future regulatory requirements; failure to provide quality offerings to customers could have an adverse effect on Catalent's business and subject it to regulatory actions and costly litigation; problems providing the highly exacting and complex services or support required; global economic, political and regulatory risks to Catalent's operations; inability to enhance existing or introduce new technology or service offerings in a timely manner; inadequate patents, copyrights, trademarks and other forms of intellectual property protections; fluctuations in the costs, availability, and suitability of the components of the products Catalent manufactures, including active pharmaceutical ingredients, excipients, purchased components and raw materials; changes in market access or healthcare reimbursement in the United States or internationally; fluctuations in the exchange rates of the U.S. dollar against other currencies; adverse tax legislative or regulatory initiatives or challenges or adjustments to Catalent's tax positions; loss of key personnel; risks generally associated with information systems; inability to complete any future acquisition or other transaction that may complement or expand its business or divest non-strategic businesses or assets and difficulties in successfully integrating acquired businesses and realizing anticipated benefits of such acquisitions; risks associated with timely and successfully completing, and correctly anticipating the future demand predicted for, capital expansion projects at existing facilities, offerings and customers' products that may infringe on the intellectual property rights of third parties; environmental, health and safety laws and regulations, which could increase costs and restrict operations; labor and employment laws and regulations or labor difficulties, which could increase costs or result in operational disruptions; additional cash contributions required to satisfy Catalent's existing pension plan obligations; substantial leverage that may limit its ability to raise additional capital to fund operations and react to changes in the economy or in the industry; and exposure to interest-rate risk to the extent of its variable-rate debt preventing it from meeting its obligations under its indebtedness. For a more detailed discussion of these and other factors, see the information under the caption "Risk Factors" in Catalent's Annual Report on Form 10-K for the fiscal year ended June 30, 2022, filed August 29, 2022. All forward-looking statements speak only as of the date of this release or as of the date they are made, and Catalent does not undertake to update any forward-looking statement as a result of new information or future events or developments except to the extent required by law.

Sarepta Forward Looking Statement

This press release contains "forward-looking statements." Any statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "will," "intends," "potential," "possible" and similar expressions are intended to identify forward-looking statements. These forward-looking statements include statements regarding the parties' obligations and responsibilities under the agreement, meeting anticipated demand for SRP-9001, the potential approval of SRP-9001 and developing commercially scalable processes for additional gene therapy programs in Sarepta's pipeline.

These forward-looking statements involve risks and uncertainties, many of which are beyond Sarepta's control. Known risk factors include, among others: the expected benefits and opportunities related to the agreement may not be realized or may take longer to realize than expected; Sarepta may not be able to execute on its business plans and goals, including meeting its expected or planned regulatory milestones and timelines, clinical development plans, and bringing its product candidates to market, due to a variety of reasons, many of which may be outside of Sarepta's control, including possible limitations of company financial and other resources, manufacturing limitations that may not be anticipated or resolved for in a timely manner, regulatory, court or agency decisions, such as decisions by the United States Patent and Trademark Office with respect to patents that cover Sarepta's product candidates; the COVID-19 pandemic; and those risks identified under the heading "Risk Factors" in Sarepta's most recent Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) as well as other SEC filings made by Sarepta which you are encouraged to review.

Any of the foregoing risks could materially and adversely affect Sarepta'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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