Vertex and Lonza to Build Dedicated Manufacturing Facility for Type 1 Diabetes (T1D) Cell Therapies

June 26, 2023

- Following positive Phase 1/2 results in Vertex's VX-880 program, Vertex and Lonza announce strategic manufacturing collaboration -
- Dedicated large-scale facility will support commercial production of Vertex’s T1D cell therapy portfolio -
- Approximately 300 new jobs anticipated at Lonza Portsmouth, New Hampshire Site -

BOSTON & BASEL, Switzerland--(BUSINESS WIRE)--Jun. 26, 2023--Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) and Lonza (SIX: LONN) today announced a strategic collaboration to support the manufacture of Vertex's portfolio of investigational stem cell-derived, fully differentiated insulin-producing islet cell therapies for people with T1D, currently focusing on the VX-880 and VX-264 programs that are currently in clinical trials.

Vertex's first clinical program, VX-880, has already demonstrated clinical proof-of-concept. In new data released last week, all six patients treated with VX-880 engrafted islet cells, produced endogenous insulin (C-peptide), and had improved glycemic control, while reducing or eliminating insulin use. Patients with greater than 90 days of follow-up had elimination of severe hypoglycemic events in the evaluation period.

Vertex's second approach, VX-264, utilizes the same fully differentiated insulin-producing islet cells as in VX-880 and is being studied in a Phase 1/2 clinical trial. In VX-264, the cells are encapsulated in a proprietary device designed to shield the cells from the body's immune system, thereby eliminating the need for immunosuppression. In a third approach, Vertex's hypoimmune program, the same cells are edited to cloak them from the immune system; this program continues to progress in preclinical development.

Under the terms of the collaboration, Vertex and Lonza will partner in the process development and scale-up for the manufacturing of the product portfolio and co-invest to build a dedicated new facility in Portsmouth, New Hampshire. Operated by Lonza, the facility will span more than 130,000 square feet and is anticipated to create up to 300 new jobs at peak capacity. Construction is scheduled to begin later this year.

The dedicated facility will complement Lonza's global cell and gene technologies manufacturing network, which supports customers in developing, de-risking, commercializing and scaling their emerging therapies. Lonza’s scientific, regulatory and manufacturing expertise, its focus on operational excellence, and first-hand experience supporting the commercialization of marketed cell therapy products is expected to accelerate the development and commercialization of Vertex’s potentially transformative therapies.

"Vertex’s allogeneic, fully differentiated, insulin-producing islet cells and the results from the Phase 1/2 VX-880 program represent a scientific breakthrough that offers the potential to transform the treatment of T1D," said Reshma Kewalramani, M.D., Chief Executive Officer and President of Vertex. “Establishing this strategic partnership with Lonza, a world-class manufacturing organization, is a critical milestone in this journey and underscores our long-term commitment to patients with T1D."

"Lonza has a strong history and established reputation for applying cutting-edge development and manufacturing expertise to enable the progression of exceptional scientific innovations like those developed by Vertex," said Pierre-Alain Ruffieux, Chief Executive Officer of Lonza. “Vertex has made impressive progress with its T1D cell therapy program, and we are proud to be the company’s partner of choice in supporting its ambition to transform the treatment landscape for this disease."

About Vertex

Vertex is a global biotechnology company that invests in scientific innovation to create transformative medicines for people with serious diseases. The company has multiple approved medicines that treat the underlying cause of cystic fibrosis (CF) — a rare, life-threatening genetic disease — and has several ongoing clinical and research programs in CF. Beyond CF, Vertex has a robust clinical pipeline of investigational small molecule, mRNA, cell and genetic therapies (including gene editing) in other serious diseases where it has deep insight into causal human biology, including sickle cell disease, beta thalassemia, APOL1-mediated kidney disease, acute and neuropathic pain, type 1 diabetes and alpha-1 antitrypsin deficiency.

Founded in 1989 in Cambridge, Mass., Vertex's global headquarters is now located in Boston's Innovation District and its international headquarters is in London. Additionally, the company has research and development sites and commercial offices in North America, Europe, Australia and Latin America. Vertex is consistently recognized as one of the industry’s top places to work, including 13 consecutive years on Science magazine's Top Employers list and one of Fortune's 100 Best Companies to Work For. For company updates and to learn more about Vertex's history of innovation, visit www.vrtx.com or follow us on Facebook, Twitter, LinkedIn, YouTube and Instagram.

(VRTX-GEN)

About Lonza

Lonza is a preferred global partner to the pharmaceutical, biotech and nutrition markets. We work to enable a healthier world by supporting our customers to deliver new and innovative medicines that help treat a wide range of diseases. We achieve this by combining technological insight with world-class manufacturing, scientific expertise and process excellence. Our business is structured to meet our customers’ complex needs across four divisions: Biologics, Small Molecules, Cell & Gene and Capsules & Health Ingredients. Our unparalleled breadth of offerings across divisions enables our customers to commercialize their discoveries and innovations in the healthcare industry.

Founded in 1897 in the Swiss Alps, today, Lonza operates across five continents. With approximately 17,500 full-time employees, we comprise high-performing teams and individual talent who make a meaningful difference to our own business, as well as to the communities in which we
operate. The company generated sales of CHF 6.2 billion with a CORE EBITDA of CHF 2.0 billion in Full-Year 2022. Find out more at www.lonza.com

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**Vertex Special Note Regarding Forward-Looking Statements**

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements by Reshma Kewalramani, M.D. and Pierre-Alain Ruffieux in this press release, our plans to build a manufacturing facility with our collaborators to support clinical and commercial production of Vertex’s investigational T1D cell therapy portfolio, anticipated benefits of the collaboration with Lonza, including potential acceleration of the development and commercialization of Vertex’s therapies, expectations for the new manufacturing facility, including the creation of up to 300 new jobs, plans and expectations for our T1D programs, including study designs and potential benefits of our products, and anticipated investments in the facility and construction timelines. While Vertex believes the forward-looking statements contained in this press release are accurate, these forward-looking statements represent the company’s beliefs only as of the date of this press release and there are a number of risks and uncertainties that could cause actual events or results to differ materially from those expressed or implied by such forward-looking statements. Those risks and uncertainties include, among other things, that construction of the manufacturing facility may be delayed, that data from a limited number of patients may not be indicative of final clinical trial results, that data from the company’s development programs, including its programs with its collaborators, may not support registration or further development of its compounds due to safety and/or efficacy, or other reasons, that internal or external factors could delay, divert, or change our plans and objectives with respect to our research and development programs, and other risks listed under the heading “Risk Factors” in Vertex’s most recent annual report and subsequent quarterly reports filed with the Securities and Exchange Commission (SEC) and available through the company’s website at www.vrtx.com and on the SEC’s website at www.sec.gov. You should not place undue reliance on these statements or the scientific data presented. Vertex disclaims any obligation to update the information contained in this press release as new information becomes available.

**Additional Information and Disclaimer**

Lonza Group Ltd has its headquarters in Basel, Switzerland, and is listed on the SIX Swiss Exchange. It has a secondary listing on the Singapore Exchange Securities Trading Limited (“SGX-ST”). Lonza Group Ltd is not subject to the SGX-ST’s continuing listing requirements but remains subject to Rules 217 and 751 of the SGX-ST Listing Manual.

Certain matters discussed in this news release may constitute forward-looking statements. These statements are based on current expectations and estimates of Lonza Group Ltd, although Lonza Group Ltd can give no assurance that these expectations and estimates will be achieved. Investors are cautioned that all forward-looking statements involve risks and uncertainty and are qualified in their entirety. The actual results may differ materially in the future from the forward-looking statements included in this news release due to various factors. Furthermore, except as otherwise required by law, Lonza Group Ltd disclaims any intention or obligation to update the statements contained in this news release.

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Source: Vertex Pharmaceuticals Incorporated