Context Therapeutics and Lonza Enter Manufacturing Agreement for Bispecific Antibody Targeting Claudin 6-Positive Cancers

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Lonza to support the development and manufacturing of CTIM-76, Context's CLDN6 x CD3 bispecific antibody clinical candidate

The bispecific antibody-based therapy is being developed to redirect T-cell mediated lysis toward malignant cells expressing CLDN6

PHILADELPHIA and BASEL, Switzerland, Jan. 09, 2023 (GLOBE NEWSWIRE) -- Context Therapeutics Inc. ("Context" or the "Company") (Nasdaq: CNTX), a clinical-stage biopharmaceutical company advancing medicines for solid tumors, and Lonza, a global development and manufacturing partner to the pharma, biotech, and nutrition industries, today announced that the companies are collaborating to manufacture CTIM-76, Context's clinical development candidate. CTIM-76 is a Claudin 6 (CLDN6) x CD3 T-cell engaging bispecific antibody targeting CLDN6 positive tumors.

Under the terms of the agreement, Lonza will provide manufacturability assessment, gene and cell line construction, and process development. The drug substance will be manufactured at Lonza's Slough (UK) site, and the drug product will be manufactured at the Stein and Visp (CH) sites. Context will leverage Lonza's expertise in developing and manufacturing complex proteins, as well as the extensive regulatory competence and manufacturing network.

Martin Lehr, CEO, Context, commented: "Bispecific antibody drug candidates targeting cancer signaling pathways pose unique challenges related to their development and manufacturing. We are delighted to entrust Lonza with manufacturing Context's clinical development candidate, CTIM-76, to target CLDN6-positive tumors. We believe this collaboration will provide us with high-quality drug substance and drug product for clinical development and beyond."

Jennifer Cannon, Executive Vice President, Global Head of Mammalian Biologics, Lonza, added: "With the biopharmaceutical sector shifting towards more complex protein formats, it is crucial to ensure manufacturability and scalability of these novel therapies. Context has an exciting portfolio, including its CTIM-76 bispecific antibody product, that can benefit from our expertise and experience in supporting the manufacturing of complex therapeutics."

About Claudin 6 and CTIM-76

Claudin 6 (CLDN6) is differentially expressed on cancer cells with no or very low expression in normal, healthy tissue. CLDN6-enriched cancers include ovarian, endometrial, testicular, and gastric, among others. With the potential to reach a large patient population and selective expression on cancer cells, CLDN6 has emerged as an important drug target.

CTIM-76 is a CLDN6 and CD3 bispecific antibody currently in preclinical development that is capable of binding to tumor cells expressing CLDN6 and stimulating intra-tumoral T cells by the CD3 arm that is designed to be activated only upon tumor engagement while silent elsewhere. CLDN6 is expressed on multiple solid tumors such as ovarian cancer, sarcoma, testicular cancer, endometrial cancer, and gastric cancer. Preclinical studies of CTIM-76 show it effectively maintains a strong tumor binding property and anti-tumor activity attributable to a synergistic effect of both CLDN6 antibody and CD3 antibody while avoiding systemic immunotoxicity commonly seen with CD3 antibodies as a drug class. CTIM-76 has the potential for convenient dosing and scalable manufacturing to address the significant number of patients who are potentially eligible for CTIM-76 therapy.

About Context Therapeutics®
Context Therapeutics Inc. (Nasdaq: CNTX) is a clinical-stage biopharmaceutical company committed to advancing medicines for solid tumors, with a primary focus on female cancers. The Company's pipeline includes small molecule and bispecific antibody drug candidates that target cancer signaling pathways. Context is developing CTIM-76, a selective Claudin 6 (CLDN6) x CD3 bispecific antibody for CLDN6 positive tumors, currently in preclinical development. Additionally, the company is advancing onapristone extended release (ONA-XR), a novel, first-in-class, potent, and selective progesterone receptor antagonist, currently in three Phase 2 clinical trials and one Phase 1b/2 clinical trial in hormone-driven breast, ovarian, and endometrial cancers. Context is headquartered in Philadelphia.

For more information, please visit **www.contexttherapeutics.com** or follow the Company on **Twitter** and **LinkedIn**.

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 unparalleled breadth of offerings 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 more than 17,000 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 3 billion with a CORE EBITDA of CHF 987 million in H1 2022. Find out more at **www.lonza.com**.

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Forward-looking Statements
This press release contains “forward-looking statements” that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. Any statements, other than statements of historical fact, included in this press release regarding strategy, future operations, prospects, plans and objectives of management, including words such as "may," "will," "expect," "anticipate," "plan," "intend," and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are forward-looking statements. These include, without limitation, statements regarding (i) the selectivity, dosing convenience, potency, binding, scalable manufacturing, and safety profile of CTIM-76, (ii) the potential benefits of the agreement, including the ability of Lonza to perform as expected and to provide Context with the necessary drug substance and drug product, (iii) the potential benefits of our product candidates, and (iv) the likelihood data will support future development. Forward-looking statements in this release involve substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by the forward-looking statements, and we, therefore cannot assure you that our plans, intentions, expectations or strategies will be attained or achieved. Other factors that may cause actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in our filings with the U.S. Securities and Exchange Commission, including the section titled “Risk Factors” contained therein. Except as otherwise required by law, we disclaim any intention or obligation to update or revise any forward-looking statements, which speak only as of the date they were made, whether as a result of new information, future events or circumstances or otherwise.