Context Therapeutics Submits IND Application to Evaluate CTIM-76 in Claudin 6-Positive Cancers

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Important Regulatory Milestone Supports Next Phase of CTIM-76 Development

PHILADELPHIA, April 01, 2024 (GLOBE NEWSWIRE) -- Context Therapeutics Inc. (“Context” or the “Company”) (Nasdaq: CNTX), a biopharmaceutical company advancing medicines for solid tumors, today announced that on March 28, 2024, the Company submitted an Investigational New Drug (IND) application to the U.S. Food and Drug Administration to begin a first-in-human clinical study of CTIM-76. The IND supports the initiation of a Phase 1 dose escalation and expansion clinical trial of CTIM-76 in patients with Claudin 6 (CLDN6)-positive gynecologic and testicular cancers.

“Our IND submission for CTIM-76 is a significant milestone for Context,” said Martin Lehr, CEO of Context. “In 2021, we set an aggressive timeline to advance CTIM-76 into the clinic and we prioritized this program as we believe it is a potentially best-in-class CLDN6-targeting therapy that is highly selective for CLDN6. The IND application includes extensive manufacturing, preclinical, and toxicology data to support a first-in-human trial. I am incredibly proud of the entire Context team who worked tirelessly to complete this IND submission. We are excited to continue advancing the development of CTIM-76 and remain focused on preparing for the initiation of the Phase 1 clinical trial so that we can make CTIM-76 available to physicians and their patients as soon as possible.”

About CTIM-76
CTIM-76 is a CLDN6 x CD3 T cell engaging bispecific antibody. CLDN6 is enriched in a wide range of solid tumors, including ovarian, endometrial, lung, gastric, and testicular. Preclinical research suggests the potential for convenient dosing with low immunogenicity risk 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 biopharmaceutical company advancing medicines for solid tumors. Context is developing CTIM-76, a selective CLDN6 x CD3 bispecific antibody for CLDN6-positive tumors, currently in preclinical development. CLDN6 is a tight junction membrane protein target expressed in multiple solid tumors, including ovarian, endometrial, testicular, and lung, and absent from or expressed at low levels in healthy adult tissues. Context is headquartered in Philadelphia. For more information, please visit www.contexttherapeutics.com or follow the Company on X (formerly Twitter) and LinkedIn.

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,” “look forward,” “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) our expectation to initiate a Phase 1 trial for CTIM-76 and the indications to be part of such trials, (ii) our expectation regarding the trial design of any CTIM-76 trial, (iii) our belief regarding the quality of the data included in our IND for CTIM-76, (iv) our expectation to receive IND clearance from the FDA for CTIM-76, (v) the potential benefits, characteristics, safety and side effect profile of CTIM-76, (vi) the ability of CTIM-76 to have benefits, characteristics, and a side effect profile that is differentiated and/or better than third party product candidates, (vii) the likelihood data will support future development of CTIM-76, and (viii) the likelihood of obtaining regulatory approval for CTIM-76. 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.

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