Context Therapeutics Doses First Patient in Phase 1 Clinical Trial of CT-95

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CT-95 is a mesothelin x CD3 T cell engaging bispecific antibody

CT-95 is Context's second T cell engaging bispecific antibody to enter the clinic in 2025

PHILADELPHIA, April 09, 2025 (GLOBE NEWSWIRE) -- Context Therapeutics Inc. ("Context" or "Company") (Nasdaq: CNTX), a biopharmaceutical company advancing T cell engagers for solid tumors, today announced that the first patient has been dosed in the Phase 1 clinical trial of CT-95, a mesothelin ("MSLN") x CD3 T cell engaging ("TCE") bispecific antibody designed to target mesothelin-expressing cancers. The Company anticipates sharing initial data for the CT-95 Phase 1 trial in mid-2026.

This milestone marks Context's second active clinical trial, following the dosing of the first patient in the CTIM-76 trial earlier this year. CTIM-76 is a Claudin 6 ("CLDN6") x CD3 TCE bispecific antibody currently being evaluated in CLDN6-positive tumors, including ovarian, endometrial, and testicular cancers.

MSLN is a membrane protein overexpressed in an estimated 30% of all cancers with limited expression in normal tissues. CT-95 is being developed as a therapy for advanced cancers associated with MSLN expression, including pancreatic, ovarian, mesothelioma, and other solid tumors.

"Dosing of the first patient in our CT-95 Phase 1 clinical trial represents another step forward in our mission to develop next generation precision immunotherapies for solid tumors," said Martin Lehr, CEO of Context. "With both CT-95 and CTIM-76 now dosed in initial patients, we are advancing our clinical pipeline and expanding our leadership in T cell engaging bispecific antibody therapies."

The Phase 1 clinical trial of CT-95 (NCT06756035) is an open-label, dose escalation and expansion study to evaluate the safety and efficacy of CT-95 in subjects with MSLN-expressing advanced solid tumors, including ovarian, pancreatic, lung, and mesothelioma cancers. The dose escalation and dose expansion portions of the trial are expected to evaluate safety, tolerability, and pharmacokinetics, as well as anti-tumor activity by overall response rate, duration of response, and disease control rate. The dose escalation portion of the study is expected to enroll up to 30 patients.

About CT-95
CT-95 is a MSLN x CD3 bispecific antibody that is intended to redirect T-cell-mediated lysis toward malignant cells expressing MSLN. MSLN is a membrane protein overexpressed in approximately 30% of cancers. One challenge in developing MSLN-targeted therapies has been the presence of MSLN fragments, also referred to as shed MSLN, found in both blood and the tumor microenvironment that can serve as a decoy or sink for MSLN-targeting antibodies. CT-95 is a fully humanized bispecific T cell engager that has a moderate affinity but high avidity for membrane-bound MSLN, that is intended to minimize the impact of the shed MSLN.

About Context Therapeutics®
Context Therapeutics Inc. (Nasdaq: CNTX) is a biopharmaceutical company advancing T cell engaging ("TCE") bispecific antibodies for solid tumors. Context is building an innovative portfolio of TCE bispecific therapeutics, including CTIM-76, a Claudin 6 x CD3 TCE, CT-95, a Mesothelin x CD3 TCE, and CT-202, a Nectin-4 x CD3 TCE. 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 share initial data in mid-2026 for CT-95, (ii) our expectation to enroll up to 30 patients in the dose escalation portion of the Phase 1 clinical trial evaluating CT-95, (iii) the potential benefits, characteristics, safety and side effect profile of our product candidates, (iv) the likelihood data will support future development, and (v) the likelihood of obtaining regulatory approval for our product candidates. 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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