Context Therapeutics Announces First Patient Dosed in the Phase 1 Clinical Trial of CTIM-76

January 14, 2025

CTIM-76 Phase 1 trial focused on CLDN6-positive gynecologic and testicular cancers

Trial marks key milestone in driving pipeline progress

PHILADELPHIA, Jan. 14, 2025 (GLOBE NEWSWIRE) -- Context Therapeutics Inc. (“Context” or the “Company”) (Nasdaq: CNTX), a biopharmaceutical company advancing T cell engagers for solid tumors, today announced that the first patient has been dosed in its Phase 1 clinical trial evaluating CTIM-76, a Claudin 6 (“CLDN6”) x CD3 T cell engaging bispecific antibody. The Phase 1 dose escalation and expansion trial is enrolling patients with CLDN6-positive gynecologic and testicular cancers. The Company anticipates sharing initial data for the CTIM-76 Phase 1 trial in the first half of 2026.

“Dosing of the first patient in the CTIM-76 Phase 1 trial represents a key advancement of our clinical pipeline,” said Martin Lehr, CEO of Context. “We recently presented at the 39th Annual Meeting of the Society for Immunotherapy of Cancer (SITC), supporting the selection of this first-in-human dose and highlighting the potential of CTIM-76 to treat CLDN6-positive cancers.”

“We look forward to advancing CTIM-76 toward target dose levels in 2025," commented Claudio Dansky Ullmann, M.D., Chief Medical Officer of Context.

The Phase 1 clinical trial is an open-label, dose escalation and expansion study to evaluate the safety and efficacy of CTIM-76 in subjects with CLDN6-positive advanced or metastatic ovarian, endometrial, and testicular cancer. 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 study is expected to enroll up to 70 patients.

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 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 (CLDN6) x CD3 bispecific antibody, CT-95, a Mesothelin x CD3 bispecific antibody, and CT-202, a Nectin-4 x CD3 bispecific antibody. 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 have initial data in the first half of 2026 for CTIM-76, (ii) our expectation to advance CTIM-76 toward target dose levels in 2025, (iii) our expectation to enroll up to 70 patients in our Phase 1 clinical trial evaluating CTIM-76, (iv) the potential benefits, characteristics, safety and side effect profile of our product candidates, (v) the likelihood data will support future development of our product candidates, and (vi) 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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