



Context Therapeutics Announces CTIM-76 Receives FDA Fast Track Designation for the Treatment of Platinum-Resistant Ovarian Cancer

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Fast Track Designation highlights potential of CTIM-76 to address unmet need for patients with PROC

CTIM-76 Phase 1a trial ongoing, with interim data expected in June 2026

PHILADELPHIA, April 02, 2026 (GLOBE NEWSWIRE) -- Context Therapeutics Inc. ("Context" or the "Company") (Nasdaq: CNTX), a clinical-stage biopharmaceutical company advancing T cell engaging ("TCE") bispecific antibodies for solid tumors, today announced that the U.S. Food and Drug Administration ("FDA") has granted Fast Track Designation to CTIM-76, a CLDN6 x CD3 T cell engaging bispecific antibody, for the treatment of platinum-resistant ovarian cancer ("PROC") in patients that have received all standard of care therapies.

Context is currently evaluating CTIM-76 in a Phase 1 clinical trial designed to evaluate the safety and efficacy of CTIM-76 in subjects with CLDN6-positive advanced or metastatic ovarian, endometrial and testicular 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.

"We are pleased to receive Fast Track Designation for CTIM-76, which underscores its potential to improve the lives of patients with platinum-resistant ovarian cancer," said Karen Chagin, M.D., Chief Medical Officer of Context. "This designation is an important step forward in our goal to quickly and efficiently advance CTIM-76 through clinical development and we look forward to sharing interim data for this program in June 2026."

The FDA's Fast Track Designation program is designed to expedite the development and review timelines of drugs that demonstrate the potential to treat serious conditions, aiming to deliver therapeutics to patients more quickly in areas of unmet need.

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. More information about the CTIM-76 clinical trial (NCT06515613) can be found on <https://clinicaltrials.gov/>.

About Context Therapeutics®

Context Therapeutics Inc. (Nasdaq: CNTX) is a biopharmaceutical company advancing T cell engaging ("TCE") bispecific antibodies for solid tumors. Context's goal is to build 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) the Company's expectation to provide Phase 1a interim data for CTIM-76 in June 2026, (ii) the potential benefits, characteristics, safety and side effect profile of the Company's product candidates, (iii) the likelihood data will support future development, and (iv) the likelihood of obtaining regulatory approval of the Company's 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 the Company therefore cannot assure the reader that its 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 the Company's filings with the U.S. Securities and Exchange Commission, including the section titled "Risk Factors" contained therein. Except as otherwise required by law, the Company disclaims 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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