Context Therapeutics Announces FDA Clearance of IND Application for a Phase 1 Clinical Trial of CTIM-76

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CTIM-76 Phase 1 clinical trial to focus on CLDN6-positive gynecologic and testicular cancers

Company expects to enroll first patient in mid-2024

PHILADELPHIA, May 02, 2024 (GLOBE NEWSWIRE) -- Context Therapeutics Inc. (“Context” or the “Company”) (Nasdaq: CNTX), a biopharmaceutical company advancing medicines for solid tumors, today announced that the U.S. Food and Drug Administration (“FDA”) has cleared its Investigational New Drug (“IND”) application for CTIM-76, a Claudin 6 (“CLDN6”) x CD3 T cell engaging bispecific antibody. The IND supports the initiation of a Phase 1 dose escalation and expansion clinical trial of CTIM-76 in patients with CLDN6-positive gynecologic and testicular cancers. The Company anticipates the enrollment of the first patient in the dose escalation portion of its clinical trial in mid-2024.

“The FDA’s clearance of our IND marks an important achievement for Context, allowing us to proceed with the Phase 1 clinical program for this potentially best-in-class CLDN6-targeting therapy,” said Martin Lehr, CEO of Context. “We look forward to the expected dosing of the first patient with CTIM-76 in the coming months, and we believe the Company is well-positioned to achieve key program milestones.”

The Phase 1 clinical trial is expected to be 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 medicines for solid tumors. Context’s clinical stage product candidate, CTIM-76, is a selective CLDN6 x CD3 bispecific antibody for CLDN6-positive tumors. 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 enroll the first patient in a Phase 1 clinical trial for CTIM-76 in mid-2024, (ii) our expectation regarding the trial design, treatment indications, and patient size of our Phase 1 CTIM-76 trial, (iii) our belief that we can achieve key program milestones, (iv) the potential benefits, characteristics, safety and side effect profile of CTIM-76, (v) the ability of CTIM-76 to have benefits, characteristics, manufacturability, and a side effect profile that is differentiated and/or better than third party product candidates, (vi) the likelihood data will support future development of CTIM-76, and (vii) 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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