# Context Therapeutics® Highlights 2023 Corporate Priorities and Pipeline Milestones

January 4, 2023

*CTIM-76 nominated as Claudin 6 x CD3 bispecific antibody clinical candidate*

*Encouraging endometrial and breast cancer data in ongoing ONA-XR Phase 2 trials, with additional data updates expected in 2023*

*ELONA breast cancer trial open and enrolled first patient*

PHILADELPHIA, Jan. 04, 2023 (GLOBE NEWSWIRE) -- Context Therapeutics Inc. (“Context” or the “Company”) (Nasdaq: CNTX), a clinical-stage biopharmaceutical company developing novel treatments for solid tumors, with a primary focus on female cancers, today provided 2022 year-end updates and corporate guidance for 2023.

"I am proud of the substantial progress the Context team made in 2022. We achieved key corporate milestones including nominating CTIM-76 as our Claudin 6 (CLDN6) bispecific antibody clinical candidate and delivering preliminary data in clinical trials of onapristone extended release (ONA-XR), our highly potent and selective progesterone receptor antagonist," said Martin Lehr, CEO of Context. "In 2023, we will continue to advance ONA-XR across the endometrial (OATH) and breast (SMILE and ELONA) cancer clinical trials. We expect to provide a clinical data update from the ongoing OATH Phase 2 trial in mid-2023, as well as a Phase 2 data update and Phase 1b data from the SMILE and ELONA breast cancer trials, respectively, in Q4 2023. In addition, we look forward to rapidly advancing CTIM-76 toward IND submission in Q1 2024."

**Key Highlights**

- **CTIM-76 nominated as CLDN6 x CD3 bispecific antibody clinical candidate**
  - During Q4 2022, Context presented preclinical data introducing CTIM-76 as a differentiated, potent, and selective CLDN6-directed immunotherapy. CLDN6 is an emerging, potentially high-value oncology target that is expressed in a broad range of cancers and CLDN6 expression is associated with a poor prognosis and diminished survival in cancer patients. The Company estimates that there are approximately 62,000 patients in the United States with CLDN6-positive metastatic cancers, including lung, ovarian, endometrial, gastric, and testicular cancers. Currently, there are no FDA-approved treatments targeting CLDN6. In cell-based assays, CTIM-76 was found to be over 1,000 times more selective for CLDN6 versus CLDN9, a structurally similar protein that unlike CLDN6 is associated with potential off-target side effects. Further, CTIM-76 was also found to be approximately 28 times more potent than a competing approach utilizing a bispecific T-cell engager (BiTE) format. These data were presented during a R&D webinar hosted by Context in December 2022. IND-enabling studies are scheduled for 2023 with an IND filing to support human clinical trials expected in Q1 2024.
- **ONA-XR ongoing Phase 2 trials show encouraging endometrial and breast cancer data**
  - **Endometrial cancer (OATH trial)**: Metastatic endometrial cancer is an aggressive cancer of the uterus that results in approximately 13,000 deaths per year in the United States. Current treatments are limited, with combination platinum and taxane chemotherapy being the standard of care. Clinician and patient feedback indicates a high unmet need for a novel therapeutic that provides chemotherapy-like efficacy but with fewer side effects. Initial data from a Phase 2 investigator-led clinical trial found that the combination of ONA-XR with anastrozole in progesterone receptor-positive (PR+) metastatic endometrial cancer demonstrated a 4-month progression free survival (PFS) rate of 77%, a 12-month PFS rate of 33%, and favorable safety and tolerability in patients who had failed at least one prior chemotherapy in the metastatic setting. Preliminary results suggest that ONA-XR exhibits a favorable efficacy and tolerability profile relative to chemotherapy, the standard of care, which in a similar treatment setting demonstrated a 3.8-month median PFS in the KEYNOTE-775 Phase 3 trial[1]. In the KEYNOTE-775 trial, chemotherapy demonstrated a limited durability of effect as only 4% of patients treated with chemotherapy were progression free at 12 months, and chemotherapy resulted in significant toxicity with 72.9% of patients exhibiting a Grade 3 or higher adverse event. Initial clinical results from the endometrial trial were presented in Context's Q3 2022 earnings release and additional data are expected in mid-2023.
  - **Breast cancer (SMILE trial)**: Metastatic breast cancer results in approximately 43,250 deaths per year in the United States. Primary treatment in the metastatic setting is antiestrogen plus CDK4/6 inhibitor combination therapy. CDK4/6 resistance is a clinical challenge due to the activation of resistance mechanisms that limit the utility of current standard-of-care treatments, including fulvestrant, after prior CDK4/6 inhibitor exposure. Initial data from a Phase 2 investigator-led clinical trial found that the combination of ONA-XR with fulvestrant in estrogen receptor-positive (ER+), HER2- locally advanced or metastatic breast cancer demonstrated a 4-month PFS rate of 44%, and favorable safety and tolerability in patients who had failed prior CDK4/6 inhibitor therapy in the metastatic setting. Preliminary results suggest that ONA-XR in combination with fulvestrant exhibits a favorable efficacy and tolerability profile relative to fulvestrant alone, which in a similar treatment setting to the SMILE trial, fulvestrant demonstrated

a 1.9-month median PFS in the EMERALD Phase 3 trial[2]. The initial clinical results of the SMILE trial were presented in December 2022 at the San Antonio Breast Cancer Symposium and additional data are expected in Q4 2023.

- **ELONA Phase 1b/2 breast cancer trial open and enrolled first patient**: In January 2023, Context enrolled the first patient in the ELONA study, an open-label, Phase 1b/2 breast cancer clinical trial being conducted in partnership with The Menarini Group ("Menarini"). The ELONA study is designed to explore the efficacy of ONA-XR in combination with elacestrant, Menarini's selective estrogen receptor degrader, in patients with locally advanced or metastatic breast cancer who have received prior treatment with a CDK4/6 inhibitor. In Menarini's recently completed EMERALD Phase 3 trial, elacestrant demonstrated a 0.9-month PFS improvement versus the standard-of-care fulvestrant (2.8 vs 1.9 months) in a similar treatment population and as a result may become the standard-of-care antiestrogen treatment[2]. Compared to elacestrant alone, Context believes that the combination of ONA-XR plus elacestrant may more completely inhibit progesterone and estrogen hormone signaling that is required for breast cancer growth and metastasis. Such a combination would potentially improve outcomes in patients without adding significant toxicity.

**Cash Guidance**

The Company had cash and cash equivalents of $39.4 million as of September 30, 2022. The Company expects its current level of cash and cash equivalents will enable the Company to fund its operations into Q1 2024.

**About Context Therapeutics®**
Context Therapeutics Inc. (Nasdaq: CNTX) is a clinical-stage biopharmaceutical company committed to advancing medicines for solid tumors, with a primary focus on female cancers. The Company's pipeline includes small molecule and bispecific antibody drug candidates that target cancer signaling pathways. Context is developing CTIM-76, a selective Claudin 6 (CLDN6) x CD3 bispecific antibody for CLDN6 positive tumors, currently in preclinical development. Context is also developing onapristone extended release (ONA-XR), a novel, first-in-class potent and selective progesterone receptor antagonist, currently in three Phase 2 clinical trials and one Phase 1b/2 clinical trial in hormone-driven breast, ovarian, and endometrial cancers. Context is headquartered in Philadelphia. For more information, please visit www.contexttherapeutics.com or follow the Company on Twitter and LinkedIn.

**References**

[1] Makker V, et al.; KEYNOTE-775 Investigators. Lenvatinib plus Pembrolizumab for Advanced Endometrial Cancer. N Engl J Med. 2022 Feb 3;386(5):437-448.

[2] Bidard FC, et al; EMERALD Investigators. Elacestrant Versus Standard Endocrine Therapy for Estrogen Receptor-Positive, Human Epidermal Growth Factor Receptor 2-Negative Advanced Breast Cancer: Results From the Randomized Phase III EMERALD Trial. J Clin Oncol. 2022 Oct 1;40(28):3246-3256.

**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," "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 expectation to provide a clinical data update from the OATH trial in mid-2023, as well as a Phase 2 data update from the SMILE trial and Phase 1b data for the ELONA trial in the fourth quarter of 2023, (ii) the expectation to have an IND submission for CTIM-76 in the first quarter of 2024, (iii) the selectivity, potency, and safety profile of CTIM-76, (iv) the timing, enrollment and results of our clinical trials, (v) the potential benefits and side effect profile of our product candidates, (vi) the likelihood data will support future development, and (vii) the likelihood of obtaining regulatory approval of 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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