Context Therapeutics® Amends Cash Guidance, Extends Runway into Q1 2024

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Company to focus resources on advancing ONA-XR ELONA Phase 1b/2 clinical trial and on advancing CLDN6xCD3 bispecific antibody toward IND

PHILADELPHIA, Sept. 27, 2022 (GLOBE NEWSWIRE) -- Context Therapeutics Inc. (“Context” or the “Company”) (Nasdaq: CNTX), a women’s oncology company developing novel treatments for breast and gynecological cancers, today announced updated cash guidance to extend its runway into Q1 2024.

The company plans to defer noncritical R&D activities, reduce future overhead and infrastructure expenditures, and prioritize its onapristone extended release (ONA-XR) ELONA Phase 1b/2 clinical trial and Claudin 6 (CLDN6) program.

“Context has been fortunate to collaborate with two tremendous organizations – The Menarini Group and Integral Molecular. We believe these collaborations have broadened the therapeutic potential for ONA-XR through the ELONA trial and accelerated the development of a new treatment modality to address CLDN6 positive tumors,” said Martin Lehr, CEO of Context Therapeutics. “In light of the challenging current investment climate for biotechnology, we are streamlining the organization’s resources with the intent to take the Company through the execution of the Phase 1b portion of the ELONA trial and the advancement of our CLDN6xCD3 bispecific antibody program to an Investigational New Drug Application (IND).”

The ELONA Phase 1b/2 clinical trial is evaluating ONA-XR, an oral progesterone receptor (PR) antagonist, in combination with Menarini’s elacestrant in estrogen receptor positive (ER+), PR+, HER2- metastatic breast cancer (mBCa) patients who have previously been treated with a CDK4/6 inhibitor. An IND amendment filed specifically for this trial was submitted to the U.S. Food and Drug Administration in September 2022. The Company remains on track to initiate the ELONA clinical trial in Q4 2022 and to report Phase 1b data in Q4 2023. Context retains worldwide rights for ONA-XR, other than the rights it out-licensed for Greater China.

Context anticipates the nomination of a CLDN6xCD3 bispecific monoclonal antibody (BsMAb) development candidate from the organization’s research collaboration with Integral Molecular in Q4 2022. An IND submission is planned in Q1 2024. Context retains worldwide rights to certain CLDN6 antibody patents in the field of bispecific antibodies.

In addition, Context will continue to provide access to ONA-XR through the Company’s ongoing Investigator-Sponsored Trials (ISTs) and anticipates sharing preliminary data from its Phase 2 clinical trials in granulosa cell tumors and endometrial cancer in November 2022, and from its Phase 2 clinical trial in breast cancer in December 2022.

“We’re fortunate to have ISTs that can continue to explore the potential of ONA-XR while we focus on derisking and moving our near-term priority programs forward,” said Lehr. “We’re thinking long-term; Context is committed to improving the lives of women with cancer and we believe that these thoughtful and future-focused changes best position us to be nimble during the current market challenges. We continue to concentrate on fully realizing the value of our collaborations and pipeline.”

About Context Therapeutics®
Context Therapeutics Inc. (Nasdaq: CNTX) is a clinical-stage biopharmaceutical company committed to advancing medicines for female cancers. The Company’s pipeline includes small molecule and bispecific antibody drug candidates that target cancer signaling pathways. Onapristone extended release (ONA-XR), a novel, first-in-class potent and selective progesterone receptor antagonist, is currently in three Phase 2 clinical trials and one Phase 1/2 clinical trial in hormone-driven breast, ovarian, and endometrial cancers. Context and The Menarini Group have also entered a Clinical Trial Collaboration and Supply Agreement for a Phase 1b/2 clinical proof-of-concept trial evaluating ONA-XR in combination with Menarini’s oral selective estrogen receptor degrader (SERD), elacestrant. Context is also developing a selective Claudin 6 (CLDN6) x CD3 bispecific antibody for CLDN6 positive tumors, currently in preclinical development. Context is headquartered in Philadelphia. For more information, please visit www.contexttherapeutics.com or follow the Company on 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," "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) having sufficient cash to fund our operations into the first quarter 2024, (ii) the expectation to report preliminary data from certain of our currently ongoing clinical trials in November and December 2022, (iii) the expectation to select a development candidate for our CLDN6xCD3 program in the fourth quarter of 2022, (iv) the expectation to initiate the combination study of ONA-XR and elacestrant in the fourth quarter of 2022 and to report Phase 1b data in the fourth quarter of 2023, (v) the intent to streamline the organization’s resources to take the Company through the execution of the Phase 1b portion of the ELONA trial and the advancement of our CLDN6xCD3 bispecific program to an IND, (vi) the expectation to have an IND submission for our CLDN6xCD3 bispecific in the first quarter of 2024, (vii) the results of our clinical trials, (viii) the potential benefits of the product candidates, (ix) the likelihood data will support future development, and (x) 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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