Context Therapeutics® and Wisconsin Oncology Network Announce First Patient Dosed in Phase 2 Trial of ONA-XR in Metastatic Breast Cancer

October 27, 2021

Trial Will Evaluate Progesterone Receptor ONA-XR in Combination with Estrogen Receptor Antagonist to Determine Potential of Complete Hormone Blockade on Metastatic Breast Cancer Outcomes

PHILADELPHIA, Oct. 27, 2021 (GLOBE NEWSWIRE) -- Context Therapeutics Inc. (Nasdaq: CNTX), a women's oncology company developing advanced small molecule and immunotherapy treatments to transform care for hormone-driven breast and gynecological cancers, and Wisconsin Oncology Network (WON), today announced the first patient has been dosed in the Phase 2 Trial of OnapriStone in CoMbInation with FuLvestrant for Patients with ER-positive, and HER2-negative Metastatic Breast Cancer after Progression on Endocrine therapy and CDK 4/6 Inhibitors (The SMILE Study).

The single-arm trial conducted by the WON will evaluate the effect of progesterone receptor (PR) antagonist onapristone extended release (ONA-XR) in combination with Faslodex (fulvestrant) for women and men with ER+, PR+, HER2-negative metastatic breast cancer after treatment failure of CDK4/6 inhibitor and/or PIK3α inhibitors. Estrogen and progesterone drive progression in many breast cancer patients, but resistance after endocrine therapy is a clinical challenge given the broad use of antiestrogens. ONA-XR is an investigational, orally-administered full antagonist of PR, a key unchecked mechanism in women's cancers, and this clinical trial will evaluate the potential of ONA-XR and fulvestrant to address this resistance and improve patient outcomes. ONA-XR is currently being evaluated in ongoing Phase 2 clinical trials in hormone-driven breast, ovarian and endometrial cancers.

The trial will enroll up to 39 patients with ER+, PR+, HER2- metastatic breast cancer who have progressed on aromatase inhibitor and CDK4/6 inhibitor combination therapy. The primary endpoint will be the overall response rate (ORR), which is the proportion of patients with a complete or partial tumor response. Secondary endpoints will include duration of tumor response, progression-free survival (PFS), disease control rate, time to response and incidence of adverse events.

"Context is honored to have WON Co-Principal Investigators Sailaja Kamaraju, MD, MS, Associate Professor at the Medical College of Wisconsin, Milwaukee and Kari Wisinski, MD, Professor, Interim Chief of the Division of Hematology, Medical Oncology and Palliative Care for the Department of Medicine at UW-Madison to spearhead this important research collaboration and explore this combination as a potential additional treatment option for patients living with this devastating disease," said Martin Lehr, CEO of Context Therapeutics. "We hope this study will provide a robust picture of how ONA-XR works in advanced ER+, PR+, HER2- breast cancer and inform the design of a future Phase 3 trial."

Additional information about the trial, which is recruiting patients, can be found on clinicaltrials.gov using the identifier NCT04738292.

About Onapristone Extended Release
ONA-XR (onapristone extended release) is a potent and specific antagonist of the progesterone receptor (PR) that is orally administered. Currently, there are no approved therapies that selectively target PR+ cancers. Preliminary preclinical and clinical data suggest that ONA-XR has anticancer activity by inhibiting progesterone receptor binding to chromatin, downregulating cancer stem cell mobilization and blocking immune evasion. ONA-XR is currently being evaluated in three Phase 2 clinical trials and one Phase 1b/2 clinical trial in PR+ breast, ovarian and endometrial cancers, as well as in two Phase 0 biomarker pharmacodynamic trials in breast cancer. ONA-XR is an investigational drug that has not been approved for marketing by any regulatory authority.

About Wisconsin Oncology Network
The Wisconsin Oncology Network (WON) is a regional network of 19 sites that allows community health centers to enroll patients in select cancer clinical trials that are open at the University of Wisconsin Carbone Cancer Center. Non-UW sites account for nearly 40% of accrual to WON clinical trials. To date, more than 2,200 patients have participated in WON studies, leading to multiple publications and scientific presentations.

About Context Therapeutics®
Context Therapeutics Inc. (Nasdaq: CNTX), is a women's oncology company developing advanced small molecule and immunotherapy treatments to transform care for hormone-driven breast and gynecological cancers. The company's robust clinical program for lead candidate onapristone extended release (ONA-XR) comprises three Phase 2 clinical trials and one Phase 1b/2 clinical trial in hormone-driven breast, ovarian and endometrial cancer, as well as two Phase 0 biomarker pharmacodynamic trials in breast cancer. ONA-XR is a novel, first-in-class small molecule under development as a complete antagonist of the progesterone receptor, a key unchecked mechanism in hormone-driven women's cancers. Context is headquartered in Philadelphia, PA. For more information, visit www.contexttherapeutics.com.

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 design, timing, scope and results of our clinical trials, (ii) anticipated timing of disclosure of results of our clinical trials, (iii) the potential benefits of the product candidates, (iv) the likelihood data will support future development, and (v) 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 SEC, 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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