Context Therapeutics® Announces Positive Data from ONA-XR in Early Breast Cancer at 2021 San Antonio Breast Cancer Symposium

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Data demonstrated ONA-XR decreased proliferation in tumors with high PR+ at baseline in early breast cancer

Two additional metastatic breast cancer clinical trials in progress also presented

PHILADELPHIA, Dec. 09, 2021 (GLOBE NEWSWIRE) -- Context Therapeutics Inc. (Nasdaq: CNTX), a women's oncology company developing small molecule and immunotherapy treatments for breast and gynecological cancers, today announced that data from the window-of-opportunity clinical trial of onapristone extended release (ONA-XR) in postmenopausal patients with progesterone receptor positive (PR+) early breast cancer demonstrated ONA-XR significantly increased suppression of tumor cell proliferation. The data were presented today during the 2021 San Antonio Breast Cancer Symposium (SABCS).

The Phase 0 open-label, single-arm, multicenter ONAWA (SOLTI-1802) trial conducted by Spanish cancer research group SOLTI, enrolled 10 patients with ER+/PR+/HER2- negative tumors and levels of the cell proliferation marker "Ki67" above 10% to evaluate ONA-XR by the rate of Complete Cell Cycle Arrest (CCCR) determined by Ki-67 (≤2.7%) when administered for three weeks prior to surgery (Abstract #511). Secondary endpoints of the trial included safety and correlating biological activity with immunohistochemistry (IHC) of tumor expression (ER, PR, Ser294-PgR, CD24, CD44, ALDH1, Ki-67), estradiol, and progesterone blood levels, and gene expression profile (NanoString nCounter® Breast 360TM panel). While no patients achieved a CCCR, tumor Ki-67 expression decreased in six patients, remained stable in one patient, and increased in three patients. Mean percentage decrease of Ki67 for tumors with baseline PR expression ≥90% (N=4) and <90% (N=6) was -25.23% and 2.54%, respectively, indicating a trend towards enhance response for patients with high levels of PR expression at baseline. In addition, a shift towards more endocrine-sensitive disease was detected, implying an increased chance of the tumor responding to anti-estrogen therapy when used in combination with ONA-XR. Six patients reported adverse events (AEs), of which most were grade 1 or 2 including post-procedural pain, dry mouth, and an increase of gamma-glutamyl transferase (GGT). One patient experienced Grade 3 reversible GGT and aspartate aminotransferase (AST).

"The data from the ONAWA trial signal the potential of ONA-XR to help inhibit tumor proliferation and shift tumors to a more endocrine treatment-sensitive phenotype during treatment prior to surgery in postmenopausal women with operable breast cancer and improve overall prognosis for these patients," said co-principal investigator Meritxell Bellet, M.D., Ph.D., medical oncologist at Vall d'Hebron University Hospital in Barcelona and an executive board member of SOLTI. "These results support further evaluation of ONA-XR in the treatment of early breast cancer."

"ONA-XR is being evaluated in four investigator-sponsored clinical trials in hormone-driven breast, ovarian and endometrial cancers. This readout is the first for the novel PR antagonist, and the results are encouraging early evidence of the potential of ONA-XR to offer a new therapeutic option for hormone-dependent cancers," said Martin Lehr, CEO of Context Therapeutics. "We look forward to data updates from three other ONA-XR trials in 2022."

The design of two additional clinical trials evaluating ONA-XR in metastatic breast cancer (MBC) were also presented in trials-in-progress posters during SABCS: The SMILE Study, a Phase 2 trial evaluating ONA-XR in combination with fulvestrant for patients with ER+ and HER2- metastatic breast cancer after progression on endocrine therapy and CDK4/6 inhibitors that is being conducted in collaboration with the Wisconsin Oncology Network (Abstract #311); and Memorial Sloan Kettering Cancer Center's Phase 1b trial designed to define the safety, tolerability and recommended Phase 2 dose of ONA-XR in combination with letrozole and palbociclib, in addition to investigating the circulating tumor DNA-guided response of this triplet therapy regimen in high-risk patients (Abstract #1538).

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 Context Therapeutics®
Context Therapeutics Inc. (Nasdaq: CNTX), is a women's oncology company developing small molecule and immunotherapy treatments to transform care for 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 potent and specific 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 results of our clinical trials, (ii) the potential benefits of the product

candidates, (iii) the likelihood data will support future development, and (iv) 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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