Context Therapeutics Highlights Clinical Responses from the Phase 2 OATH Clinical Trial Evaluating ONA-XR for the Treatment of Endometrial Cancer

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ONA-XR initial data signals positive clinical activity and confirmed tumor shrinkage

ONA-XR continues to be safe and well-tolerated

PHILADELPHIA, Feb. 06, 2023 (GLOBE NEWSWIRE) -- Context Therapeutics Inc. (“Context” or the “Company”) (Nasdaq: CNTX), a company developing novel treatments for solid tumors, with a primary focus on female cancers, today announced that two patients have achieved a confirmed partial response (PR) among the first 12 patients (9 evaluable) enrolled in the Phase 2 OATH clinical trial evaluating the potential of Context’s oral progesterone receptor antagonist onapristone extended release (ONA-XR) in combination with anastrozole (ANA) to treat hormone receptor positive (HR+) metastatic endometrial cancer (EC).

“Data from the ongoing Phase 2 OATH clinical trial supports the potential for ONA-XR plus ANA combination therapy to serve as an effective therapeutic option in metastatic EC. We are encouraged by these findings and look forward to continued enrollment in the trial,” said Martin Lehr, CEO of Context Therapeutics.

Metastatic EC is an aggressive cancer of the uterus that is the fourth leading cause of cancer-related mortality in women and results in approximately 13,000 deaths per year in the United States. Current treatments are limited, with platinum plus taxane combination chemotherapy being the standard of care for first line metastatic disease. After first-line therapy, patients are typically treated with additional toxic infusion therapies, including chemotherapy or Lenvima® (lenvatinib) plus Keytruda® (pembrolizumab) combination therapy. Clinician and patient feedback indicates a high unmet need for a novel orally administered therapeutic that provides toxic therapy-like efficacy but with fewer debilitating side effects. Grade 3 or higher adverse events (AE) with standard EC therapies include diarrhea, nausea, vomiting, and hypertension.

Preliminary data from the ongoing Phase 2 OATH clinical trial evaluating the combination of ONA-XR with ANA in HR+ EC found that ONA-XR plus ANA demonstrated a 4-month progression free survival (PFS) rate of 77% and an overall response rate (ORR) of 22%. These results suggest that ONA-XR plus ANA exhibits favorable efficacy and tolerability relative to historical data that evaluated physician’s choice of chemotherapy (doxorubicin or paclitaxel) versus Lenvima plus Keytruda combination therapy in a similar treatment setting of metastatic EC.[1]

Preliminary Comparison of OATH Trial versus Historical Studies

	ONA-XR + ANA*	**Chemotherapy**	**Lenvima + Keytruda**
Trial	OATH (ongoing)	KEYNOTE-775[1]	KEYNOTE-775
Patients (n)	12 (9 evaluable)	416	411
Lines of Prior Chemotherapy, n (%)			
1	8 (67)	277 (67)	324 (79)
≥2	4 (33)	139 (33)	87 (21)
4-month PFS rate, n (%)	7 (77)	174 (42)**	278 (67)**
ORR, n (%)	2 (22)	61 (14)	131 (32)
Drug-related Discontinuation Rate, n (%)	0 (0)	31 (8)	134 (33)
Side Effects	Mainly Grade 1 or Grade 2 AE	73% experienced Grade 3 or higher AE	89% experienced Grade 3 or higher AE

*Data cut off as of September 30, 2022, preliminary raw data; **Context estimates

Updated data regarding the Phase 2 OATH trial is expected to be provided in Q2 2023.

About ONA-XR
ONA-XR (onapristone extended release) is an oral, twice-a-day, selective progesterone receptor (PR) antagonist designed to block both ligand-dependent and ligand-independent activity of PR. 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 PR binding to chromatin, downregulating cancer stem cell mobilization, and blocking immune evasion. In addition to the Phase 2 OATH clinical trial evaluating the combination of ONA-XR and anastrozole to treat endometrial cancer, ONA-XR is also being studied in other Phase 2 clinical trials, including two breast cancer trials in combination with selective estrogen receptor degraders (SERD). The Phase 1b/2 ELONA trial is evaluating the combination of ONA-XR plus the recently approved orally administered SERD ORSERDU ™ (elacestrant) and the Phase 2 SMILE trial is evaluating the combination of ONA-XR with the injectable SERD fulvestrant. 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 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 advancing 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.

Reference

[1] Makker et al., 2022. Lenvatinib plus Pembrolizumab for Advanced Endometrial Cancer. The New England Journal of Medicine, 386 (2022), pp. 437 448, 10.1056/NEJMoa2108330

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) preliminary results which may not be indicative of any final results, which may not be replicated in subsequent or confirmatory trials, or which may not be predictive of results in later stage or large scale clinical trials or trials in other potential indications, (ii) the expectation to timely provide updated data for the Phase 2 OATH trial, (iii) the potential benefits of ONA-XR in combination with other products, including anastrozole and ORSERDU, (iv) the timing, enrollment and results of our clinical trials, (v) the potential benefits, treatment potential, and side effect profile of our product candidates and other approved products, (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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