Context Therapeutics® Reports Third Quarter 2022 Operating and Financial Results

November 9, 2022

Company reports preliminary ONA-XR data from two ongoing Phase 2 trials

ONA-XR demonstrates preliminary 4-month PFS rate of 77.7% in ongoing Phase 2 trial evaluating the combination of ONA-XR and the antiestrogen anastrozole in PR+ recurrent endometrial cancer

ONA-XR continues to exhibit favorable safety and tolerability profile

Cash and cash equivalents of $39 million as of September 30, 2022, expected to provide runway into Q1 2024

PHILADELPHIA, Nov. 09, 2022 (GLOBE NEWSWIRE) -- Context Therapeutics Inc. (“Context” or the “Company”) (Nasdaq: CNTX), a women’s oncology company developing novel treatments for breast and gynecologic cancers, today reported on recent and upcoming business highlights and announced its financial results for the third quarter ended September 30, 2022.

“We are pleased with the continued strengthening of onapristone extended release’s (“ONA-XR”) clinical profile. The preliminary Phase 2 findings for ONA-XR in combination with anastrozole in progesterone receptor-positive (PR+) recurrent endometrial cancer highlight a 4-month progression free survival (PFS) rate of 77.7%, and favorable safety and tolerability, representing a meaningful improvement over the single activity of either agent alone. Additionally, we are pleased to announce that we initiated the Phase 1b portion of our Phase 1b/2 ELONA breast cancer clinical trial to evaluate ONA-XR in combination with elacestrant. These achievements underscore our commitment to creating new standards of care in the women’s oncology field,” said Martin Lehr, CEO of Context Therapeutics.

“Looking ahead, we plan to complete enrollment of the Phase 2 PR+ recurrent endometrial cancer trial and evaluate a potential registrational path. We will also continue to assess ONA-XR across multiple ongoing clinical trials, including an initial Phase 2 data readout in second- or third-line advanced or metastatic ER+,PR+,HER2- breast cancer in December 2022,” Lehr added. “Separately, we anticipate nominating a development candidate for our Claudin 6 bispecific antibody program in December. Our expected cash runway into Q1 2024 gives us the financial flexibility to execute on the advancement of our pipeline targeting female cancers.”

ONA-XR Clinical Update

- **PR+ Endometrial Cancer:** In an ongoing Phase 2 trial in collaboration with Jefferson Health investigating ONA-XR 50mg BID in combination with anastrozole 1mg QD in women with PR+ endometrial adenocarcinoma who have failed front-line therapy with a platinum/taxane-based chemotherapy regimen, we note the following as of September 30, 2022:
    - The trial has enrolled 12 of 25 planned patients.
    - The preliminary 4-month PFS rate was 77.7%, based on nine evaluable patients.
    - Three patients received treatment for greater than 12 months.
    - Overall, seven patients remain in the trial.
    - There have been no treatment-related serious adverse events reported.
- **PR+ Granulosa Cell Tumor (GCT) of Ovary:** In an ongoing Phase 2 basket trial in collaboration with Memorial Sloan Kettering Cancer Center investigating ONA-XR 50mg BID as a single agent or in combination with anastrozole 1 mg QD in women with PR+ recurrent gynecologic cancers, we note the following as of September 30, 2022:
    - Cohort 1, which treats patients with PR+ recurrent granulosa cell tumors with ONA-XR as a single agent, completed accrual to stage 1 and has shown a 12-month PFS rate of 20.1% and a Clinical Benefit Rate (stable disease) of 35.7%. Two patients continued on active treatment for greater than 18 months. One patient remains on trial.
    - Cohort 4, which treats patients with PR+ recurrent granulosa cell tumors with ONA-XR in combination with anastrozole, enrolled 14 patients in stage 1 and will expand to stage 2 when greater than or equal to one response is observed. Seven patients remain on trial.
    - There have been no treatment-related serious adverse events reported.
- **SMILE trial:** Enrollment continues in an ongoing Phase 2 trial in collaboration with Wisconsin Oncology Network evaluating the combination of ONA-XR with fulvestrant in patients with second- or third-line advanced or metastatic ER+,PR+,HER2- breast cancer (the “SMILE” trial). Initial clinical data are expected in December 2022.
- **ELONA trial:** In August 2022, Context entered into a clinical trial and supply agreement with The Menarini Group (“Menarini”) to evaluate the combination of ONA-XR with Menarini’s oral selective estrogen degrader, elacestrant, in patients with second- or third-line advanced or metastatic ER+,PR+,HER2- breast cancer (the “ELONA” trial). We initiated the ELONA trial in November 2022 and Phase 1b data is expected in Q4 2023.

The observations from the ongoing clinical trials noted above are based on information available as of September 30, 2022. These trials are still actively enrolling patients, and these preliminary clinical findings may materially fluctuate on a month-to-month basis as the trials progress and may

not be representative of results after all patients complete the respective trial and all data is collected and analyzed. Further, this data is subject to continuing audit and verification procedures that will not be complete until the conclusion of the respective trial and therefore the interim data is subject to change.

Claudin 6 Update

- Our Claudin 6 bispecific antibody program remains on track with a development candidate nomination expected in December 2022.
- We anticipate an Investigational New Drug Application submission for this program in Q1 2024.

Third Quarter 2022 Financial Results

- **Cash Position:** Cash, cash equivalents, and restricted cash were $39.4 million at September 30, 2022, compared to $49.7 million at December 31, 2021.
- **R&D Expense:** Research and development (R&D) expenses were $2.1 million for third quarter 2022, as compared to $0.7 million for the same period in 2021. The increase in R&D expenses was primarily driven by increased ONA-XR contract manufacturing and clinical costs and an increase in salaries and related benefits due to a higher employee headcount.
- **G&A Expense:** General and administrative (G&A) expenses were $2.0 million for third quarter 2022, as compared to $0.8 million for the same period in 2021. The increase in G&A expenses was primarily driven by increased compensation and share-based compensation due to a higher employee headcount and changes to compensation arrangements, higher insurance costs, and other costs associated with operating as a public company.
- **Net Loss:** Context reported a net loss of $3.9 million for third quarter 2022, as compared to $1.4 million for the same period in 2021.

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 initial clinical data for the SMILE trial in December 2022 and Phase 1b data for the ELONA trial in the fourth quarter of 2023, (iii) the expectation to select a development candidate for our CLDN6xCD3 program in December 2022, (iv) the expectation to have an IND submission for our CLDN6xCD3 bispecific in the first quarter of 2024, (v) the results of our clinical trials, (vi) the potential benefits of our product candidates, (vii) the likelihood data will support future development, and (viii) 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.

Context Therapeutics Inc.
Condensed Statements of Operations
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating Expenses:				
Acquired in-process research and development	$ -	$ -	$ 500,000	$ 3,087,832
Research and development	2,077,566	739,598	4,946,304	2,511,438
General and administrative	1,970,521	828,464	6,052,556	1,834,645
Loss from operations	(4,048,087)	(1,568,062)	(11,498,860)	(7,433,915)
Other income	193,777	125,270	219,702	68,910

Net loss	$ (3,854,310)	$ (1,442,792)	$ (11,279,158)	$ (7,365,005)
Net loss per common share, basic and diluted	($0.24)	($4.00)	($0.71)	($20.74)
Weighted average shares outstanding, basic and diluted	15,966,053	361,067	15,966,053	355,087

Context Therapeutics Inc.
Condensed Balance Sheets Data
(Unaudited)

	September 30, 2022	December 31, 2021
Cash, cash equivalents and restricted cash	$ 39,427,118	$ 49,685,586
Other assets	2,655,903	1,620,164
Total assets	$ 42,083,021	$ 51,305,750
Total liabilities	$ 4,011,511	$ 3,033,415
Total stockholders' equity	38,071,510	48,272,335
Total liabilities and stockholders' equity	$ 42,083,021	$ 51,305,750

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