



Context Therapeutics and The Menarini Group Announce Clinical Trial Collaboration and Supply Agreement to Evaluate ONA-XR and Elacestrant Combination

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Preclinical data support the potential of ONA-XR plus estrogen receptor degraders in endocrine resistant disease models

Context to initiate Phase 1b/2 clinical trial in Q4 2022

PHILADELPHIA and FLORENCE, Italy, Aug. 02, 2022 (GLOBE NEWSWIRE) -- Context Therapeutics Inc. ("Context" or the "Company") (Nasdaq: CNTX), a women's oncology company developing small molecule and immunotherapy treatments for breast and gynecological cancers, and The Menarini Group ("Menarini") today announced a clinical trial collaboration and supply agreement for Menarini's oral selective estrogen receptor degrader (SERD), elacestrant.

This agreement will support the upcoming Phase 1b/2 ELONA clinical proof-of-concept trial evaluating onapristone extended release (ONA-XR), an oral progesterone receptor (PR) antagonist, in combination with elacestrant in estrogen receptor positive (ER+), PR+ HER2- metastatic breast cancer (mBC) patients who have previously been treated with a CDK4/6 inhibitor. Context will sponsor the clinical trial and Menarini will supply elacestrant at no cost.

According to the American Cancer Society, breast cancer is the second most common cancer among women occurring in 1 in 8 women (13%) over the course of a woman's lifetime, with ~280,000 new cases of invasive breast cancer and 51,400 cases of non-invasive breast cancer expected in 2022. Elacestrant is the [first oral SERD to demonstrate](#) a statistically significant and clinically meaningful improvement in progression-free survival (PFS) versus standard-of-care (SOC) endocrine therapy in a Phase 3 trial in patients with ER+, HER2- mBC, with 30% reduction in the risk of progression or death in all patients. Data also showed that 22% of patients were alive and progression-free at 12 months after elacestrant treatment initiation vs. 9% with SOC in the overall population. Therefore, elacestrant may become the new backbone endocrine therapy for ER+, HER2- mBC.

Preliminary data from preclinical studies suggest that a dual ER and PR blockade may be associated with enhanced tumor control. The ELONA clinical trial will be evaluating this important hypothesis.

"We are grateful to Menarini for their collaboration as we explore the therapeutic potential of adding ONA-XR, our oral PR antagonist, to elacestrant," said Tarek Sahnoun, MBBCh, Ph.D., Context's Chief Medical Officer. "We hope that this combination will further improve the clinical outcome in patients with ER+, PR+, HER2- mBC."

"ONA-XR's ability to restore hormone sensitivity and its tolerability profile positions it well for combination with elacestrant," said Nassir Habboubi, M.D., Menarini's Global Head of R&D.

Context anticipates initiating the Phase 1b/2 clinical trial in the fourth quarter of 2022. The two companies will form a joint committee to review results.

About Menarini Group

The Menarini Group is a leading international pharmaceutical and diagnostics company, with a turnover of over \$4 billion and over 17,000 employees. Menarini is focused on therapeutic areas with high unmet needs with products for oncology, cardiology, pneumology, gastroenterology, infectious diseases, diabetology, inflammation, and analgesia. With 18 production sites and 9 Research and Development centers, Menarini's products are available in 140 countries worldwide. For further information, please visit www.menarini.com.

About ONA-XR

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. 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. 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 timing to initiate, enroll, and obtain initial data for our clinical trials, (ii) the 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 the 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

Media Contact:

Gina Cestari

6 Degrees

917-797-7904

gcestari@6degreespr.com

Investor Relations Contact:

Laine Yonker

Edison Group

lyonker@edisongroup.com

Menarini Group

Media Contact:

Valeria Speroni Cardi

pressoffice@menarini.com