



Context Therapeutics® and Jefferson Health Announce First Patient Dosed in Phase 2 Trial of ONA-XR in Advanced Endometrial Cancer

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-- Trial Will Evaluate Progesterone Receptor ONA-XR in Combination with Antiestrogen to Determine Potential of Complete Hormone Blockade on Endometrial Cancer Outcomes --

PHILADELPHIA, PA—May 12, 2021—Context Therapeutics, a women's oncology company developing advanced small molecule and immunotherapy treatments to transform care for hormone-driven breast and gynecological cancers, and the Sidney Kimmel Cancer Center – Jefferson Health, today announced the first patient has been dosed in the Phase 2 ONWARD 221 trial in patients with metastatic endometrial cancer.

The trial, sponsored by Jefferson Health, is a clinical collaboration between Context and Jefferson Health's Sidney Kimmel Cancer Center (SKCC) to evaluate the effect of the addition of progesterone receptor (PR) antagonist onapristone extended release (ONA-XR) to the antiestrogen, anastrozole, on outcomes for patients with metastatic endometrial cancer who have failed prior therapy. ONA-XR is an orally-administered full antagonist of the PR, a key unchecked mechanism in women's cancers. ONA-XR is currently being evaluated in ongoing Phase 2 clinical trials in hormone-driven breast, ovarian and endometrial cancers.

"The majority of endometrial cancer patients have hormone-driven cancer. Both estrogen and progesterone drive progression in those patients, and antiestrogens, most often anastrozole, have proven, albeit limited, activity," said Russell Schilder, MD, Co-Principal Investigator and Director of the Gynecologic Medical Oncology Program at SKCC. "We will evaluate whether combining anastrozole with ONA-XR will achieve more complete hormone blockade compared with anastrozole alone, which may lead to better outcomes for patients."

The trial will enroll up to 25 patients who express the ER and/or PR biomarker (ER+ &/or PR+) and who have received prior chemotherapy treatment. The primary endpoint will be overall response rate (ORR), which is the proportion of patients who have either a complete or partial response. Secondary endpoints will include duration of response, clinical benefit rate and progression-free survival (PFS). In addition, the trial will evaluate the safety and pharmacological profile, as well as biomarker analyses to explore predictive factors of response to complete hormone blockade to inform additional ongoing Phase 2 trials of ONA-XR and a planned future Phase 3 trial.

"Context is humbled by the support and enthusiasm of Dr. Schilder and his colleagues at SKCC, one of the premier gynecologic oncology programs in the country based right here in Philadelphia," said Martin Lehr, CEO of Context Therapeutics. "Patients with advanced endometrial cancer currently have limited therapeutic options. Recent preclinical and Phase 1 data give us reason to believe ONA-XR can make a powerful addition to the current standard of care in hormone-driven endometrial cancer. Together, we look forward to exploring the potential of this combination to improve the lives of patients with this devastating disease."

For more information on the trial, visit <https://clinicaltrials.gov/ct2/show/NCT04719273> or <https://sidneykimmeltcancercenter.jeffersonhealth.org/research.html#trials-listing?trial=15031>.

About Endometrial Cancer

Endometrial cancer is the most common gynecologic malignancy in the United States with an incidence that continues to increase each year. More than 60,000 women were diagnosed with endometrial cancer in 2018 and this disease contributes to more than 10,000 deaths annually. Unopposed estrogen production and obesity are the most common risk factors for the development of endometrial cancer. The majority of patients with recurrent endometrial cancer have limited therapeutic options and the development of second-line therapies that result in improved response is an unmet clinical need.

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., 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.

About the Sidney Kimmel Cancer Center – Jefferson Health

The National Cancer Institute (NCI)-designated Sidney Kimmel Cancer Center – Jefferson Health (SKCC) is a nationally recognized center for

practice-changing discovery and comprehensive cancer treatment, offering a depth and breadth of experience in all aspects of cancer from the laboratory to the clinic. Our mission is to improve the lives of cancer patients and their families through compassion, innovation, and breakthrough discoveries. For more information, visit sidneykimmeltcancercenter.jeffersonhealth.org.

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