



ONCONOVA
THERAPEUTICS

Onconova Therapeutics Announces the Initial Dosing of the First Patient in the U.S. Phase 1 Clinical Trial of ON 123300

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Phase 1 study to evaluate ON 123300 in advanced cancer patients including HR+ HER 2- metastatic breast cancer patients resistant to approved CDK 4/6 inhibitors

NEWTOWN, Pa., May 21, 2021 (GLOBE NEWSWIRE) -- **Onconova Therapeutics, Inc. (NASDAQ: ONTX)**, a clinical-stage biopharmaceutical company focused on discovering and developing novel products for patients with cancer, today announced that the first patient has been dosed in the U.S. Phase 1 clinical trial of ON 123300, the Company's proprietary, novel multi-kinase inhibitor. The trial is expected to include three U.S. sites that will enroll patients with advanced cancer including, but not limited to, HR+ HER 2- metastatic breast cancer patients who are refractory to, or progressing on, currently approved CDK 4/6 inhibitors.

The Phase 1 trial is designed to assess the safety, tolerability, and pharmacokinetics of ON 123300 administered orally as monotherapy at increasing doses starting at 40 mg daily for consecutive 28-day cycles. Following completion of the dose-escalation phase of the trial and once the recommended Phase 2 dose (RP2D) is established, additional patients with HR+ HER 2- metastatic breast cancer with at least one prior line of therapy, which are expected to include approved CDK 4/6 inhibitors, will be enrolled into the trial with the intent to identify signals of efficacy. Additional cancer indications are also under consideration for study, and will be chosen based on preclinical and developing data.

"We are excited to begin dosing patients in this Phase 1 study and are pleased to be advancing ON 123300's clinical development in the United States," said Steven M. Fruchtman, M.D., President and Chief Executive Officer of Onconova Therapeutics. "Our goal is to provide an innovative treatment option for patients with advanced breast cancer who have become resistant to the commercial CDK 4/6 inhibitors, and other refractory solid tumors driven by the overexpression of tyrosine kinases targeted by ON 123300. Notably, ON 123300's ability to target multiple kinase pathways that are overexpressed in cancer may allow for single-agent efficacy and better tolerability compared to existing treatment regimens."

Dr. Fruchtman added, "We are also pleased by the progress our partner HanX Biopharmaceuticals is making with their ongoing Phase 1 trial with ON 123300 in China. While the administration schedule differs between these two Phase 1 trials, the maximum tolerated dose has not yet been reached in the first two dose-escalation cohorts of this trial, which is a promising sign for ON 123300's safety profile. Collectively, we expect these two complementary Phase 1 studies to provide important insights that will inform the design of subsequent trials."

For more information on the U.S. Phase 1 clinical trial of ON 123300 see ClinicalTrials.gov identifier: [NCT04739293](https://clinicaltrials.gov/ct2/show/study/NCT04739293).

About Onconova Therapeutics, Inc.

Onconova Therapeutics is a clinical-stage biopharmaceutical company focused on discovering and developing novel products for patients with cancer. The Company has proprietary targeted anti-cancer agents designed to disrupt specific cellular pathways that are important for cancer cell proliferation.

Onconova's novel, proprietary multi-kinase inhibitor ON 123300 is being evaluated in two separate and complementary Phase 1 dose-escalation and expansion studies. These trials are currently underway in the United States and China.

Onconova's product candidate rigosertib is being studied in an investigator-initiated study program, including in a dose-escalation and expansion Phase 1 investigator-initiated study targeting patients with KRAS+ non-small cell lung cancer with oral rigosertib in combination with nivolumab. In addition, Onconova continues to conduct preclinical work investigating rigosertib in COVID-19.

For more information, please visit www.onconova.com.

Forward-Looking Statements

Some of the statements in this release are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995, and involve risks and uncertainties. These statements relate to Onconova's expectations regarding the registered direct offering, its patents and clinical development plans including patient enrollment timelines and indications for its product candidates. Onconova has attempted to identify forward-looking statements by terminology including "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately" or other words that convey uncertainty of future events or outcomes. Although Onconova believes that the expectations reflected in such forward-looking statements are reasonable as of the date made, expectations may prove to have been materially different from the results expressed or implied by such forward-looking statements. These statements are only predictions and involve known and unknown risks, uncertainties, and other factors, including the success and timing of Onconova's clinical trials and regulatory agency and institutional review board approvals of protocols, Onconova's ability to continue as a going concern, the need for additional financing, Onconova's collaborations, market conditions and those discussed under the heading "Risk Factors" in Onconova's most recent Annual Report on Form 10-K and quarterly reports on Form 10-Q. Any forward-looking statements contained in this release speak only as of its date. Onconova undertakes no obligation to update any forward-looking statements contained in this release to reflect events or circumstances occurring after its date or to reflect the occurrence of unanticipated events.

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