Onconova Therapeutics Announces Enrollment in Second Cohort of Phase 1 Study with ON 123300 in China

April 1, 2021

Corporate Partner HanX Biopharmaceuticals enrolled third patient in 80 mg group

NEWTOWN, Pa., April 01, 2021 (GLOBE NEWSWIRE) -- **Onconova Therapeutics, Inc. (NASDAQ: ONTX)**, a clinical-stage biopharmaceutical company focused on discovering and developing novel products for patients with cancer, announces that its corporate partner HanX Biopharmaceuticals has enrolled three patients in the second dosing cohort of its Phase 1 study with ON 123300 in HR+ HER2- metastatic breast cancer and other advanced relapsed/refractory cancers in China.

The HanX trial has enrolled six patients to date in two cohorts and may continue to enroll patients with advanced relapsed/refractory cancer at increasing doses with three to six patients per dose until the recommended Phase 2 dose is identified. To date, patients have been dosed at the 40 mg and 80 mg dosage levels. HanX recently opened a third site, in Shanghai, for the conduct of the study.

“We are encouraged that the HanX Phase 1 study is proceeding as planned, and look forward to the identification of a recommended Phase 2 dose to move into later-stage trials. The third cohort in this trial with 120 mg of ON 123300 is expected to begin enrollment next; depending on the incidence of dose limiting toxicities, if any, at the 80 mg cohort,” said Steven M. Fruchtman, M.D., President and Chief Executive Officer of Onconova Therapeutics. “The HanX study trial design calls for dosing on days 1-21 of each 28-day cycle, compared with our planned Phase 1 study in the U.S. that will assess the safety, tolerability and pharmacokinetics of ON 123300 administered orally as monotherapy at increasing doses starting at 40 mg daily for continuous 28-day cycles. We are preparing to begin our U.S. study in the second quarter of 2021.”

“ON 123300 is a multi-kinase inhibitor in addition to targeting CDK 4/6, which we believe presents an innovative approach to treating advanced cancers including HR+ HER2- metastatic breast cancer that is, or has become, resistant to commercial CDK 4/6 inhibitors. Beyond metastatic breast cancer, we believe ON 123300 may present an innovative approach to treating other cancers including mantle cell lymphoma, multiple myeloma, advanced colorectal cancer, hepatocellular carcinoma and inoperable glioblastoma,” concluded Dr. Fruchtman.

In December 2017, Onconova entered into an agreement with HanX Biopharmaceuticals for the development, registration, and commercialization of ON 123300 in Greater China. The agreement included a licensing fee, future potential milestone payments, and royalties on sales. Onconova retains rights to ON 123300 in the rest of the world outside of Greater China.

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 planned to begin a dose-escalation and expansion Phase 1 trial in the U.S. in 2Q21, and a dose-escalation and expansion Phase 1 trial is currently underway in China.

Onconova’s product candidate oral rigosertib is currently in a dose-escalation and expansion Phase 1 investigator-initiated study targeting patients with KRAS+ lung adenocarcinoma 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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