Onconova Therapeutics Announces Initiation of a Phase 1 Clinical Trial of ON 123300 in China by Partner HanX Biopharmaceuticals

September 21, 2020

Company remains on track to file a US IND in Q4 2020, with commencement of a US Phase 1 study targeted for Q1 2021

NEWTOWN, Pa., Sept. 21, 2020 (GLOBE NEWSWIRE) -- Onconova Therapeutics, Inc. (NASDAQ: ONTX) a biopharmaceutical company focused on discovering and developing novel products to treat cancer, today announced the initiation of a Phase 1 clinical trial in China for ON 123300 by its partner, HanX Biopharmaceuticals.

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

ON 123300 is a novel small molecule, and a dual inhibitor of CDK4/6 and ARK5, a key enzyme controlling cellular energy homeostasis. Inhibition of ARK5 by ON 123300 results in the collapse of oncogene-altered energy metabolism, leading to programmed cell death. Differentiated from health authority approved CDK4/6 inhibitors, ON 123300 exhibits single agent toxicity against various cancers in preclinical studies including breast cancer, colon cancer, mantle cell lymphoma and multiple myeloma.

“As a proprietary first-in-class anti-cancer agent, ON 123300 is reported to have a unique dual mechanism of action that could improve upon the clinical efficacy of approved CDK4/6 inhibitors and may impact on the development of metastatic disease, while potentially mitigating the commonly observed side effects based on animal studies already conducted,” said Steven M. Fruchtman, M.D., President and Chief Executive Officer. “We look forward to filing our US IND by the end of this year and beginning a US Phase 1 study in refractory solid tumors in the first quarter of next year.”

About Onconova Therapeutics, Inc.
Onconova Therapeutics is a biopharmaceutical company focused on discovering and developing novel products to treat cancer. Using a proprietary chemistry platform, the Company has created a pipeline of targeted anti-cancer agents designed to disrupt specific cellular pathways that are important for cancer cell proliferation. Onconova’s RAS pathway inhibitor, oral rigosertib, is currently in a Phase 1/2 investigator-initiated study (IIS) targeting patients with KRAS+ lung adenocarcinoma in combination with nivolumab. Preclinical work with rigosertib in COVID-19 is underway as well. Onconova is in preclinical development with its novel, proprietary, CDK4/6 + ARK5 inhibitor, ON 123300.

For more information, please visit https://www.onconova.com.

About HanX Biopharmaceuticals, Inc.
HanX is an oncology specialty company with an innovative pipeline targeting PD1, VEGFR, OX40 in clinical and pre-clinical stages. The company has a strong management team with cross-border experience and advisors with expertise in drug discovery, regulatory, and GMP manufacturing.

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 expectations regarding its clinical development plans and patents. 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 approval of protocols, Onconova’s ability to continue as a going concern, the need for additional financing, our collaborations, 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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