



ONCONOVA THERAPEUTICS

Onconova Therapeutics Announces the Initiation of a Phase 1/2a Study of Rigosertib plus Nivolumab for the Treatment of KRAS+ Lung Adenocarcinoma

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NEWTOWN, Pa., June 22, 2020 (GLOBE NEWSWIRE) -- Onconova Therapeutics, Inc. (NASDAQ: ONTX), a Phase 3-stage biopharmaceutical company focused on discovering and developing novel products to treat cancer, with an initial focus on myelodysplastic syndromes (MDS) today announced an investigator-initiated Phase 1/2a trial of oral rigosertib plus nivolumab in advanced metastatic KRAS mutated (KRAS+) lung adenocarcinoma has begun enrolling patients.

"Over half of non-small cell lung cancers are classified as lung adenocarcinomas; of these, the largest subset has a KRAS mutation as the predominant genetic driver," said Dr. Steven Fruchtman, President and CEO, Onconova Therapeutics. "Despite discovering the KRAS mutation over 30 years ago, little progress has been made in KRAS+ directed treatments. The work under Dr. Rajwanth Veluswamy's leadership at the Icahn School of Medicine is an important step towards determining if rigosertib, as a RAS-mimetic, can change that."

The investigator-initiated trial is an open-label, dose-escalating Phase 1 study followed by a Phase 2a dose-expansion phase to study the combination of oral rigosertib and nivolumab in metastatic KRAS+ lung adenocarcinoma patients who have progressed on standard frontline treatment. The study will assess safety and efficacy. Additional details are available on www.clinicaltrials.gov (NCT04263090).

"The novel combination of rigosertib with an anti-PD-1 antibody targets two of the most important oncogenic pathways in cancer biology," said Dr. Rajwanth Veluswamy, Assistant Professor, Medicine, Hematology and Medical Oncology, Icahn School of Medicine at Mount Sinai. "This study will evaluate the safety and tolerability of this combination in KRAS mutated NSCLC in which patients have failed frontline immunotherapy. The study will explore efficacy of the combination in this common lung cancer subset and will also determine if rigosertib may restore sensitivity to the PD-1 blockade."

About Rigosertib

Rigosertib, Onconova's lead candidate, is a proprietary Phase 3 small molecule. A key publication in a preclinical model reported rigosertib's ability to block cellular signaling by targeting RAS effector pathways (Divakar, S.K., et al., 2016: "A Small Molecule RAS-Mimetic Disrupts RAS Association with Effector Proteins to Block Signaling." Cell 165, 643). Onconova is currently in the clinical development stage with oral and IV rigosertib, including clinical trials studying single agent IV rigosertib in second-line higher-risk MDS patients (pivotal Phase 3 INSPIRE trial) and oral rigosertib plus azacitidine in HMA naive and refractory higher-risk MDS patients (Phase 2). Patents covering oral and injectable rigosertib have been issued in the US and are expected to provide coverage until at least 2037.

About Onconova Therapeutics, Inc.

Onconova Therapeutics, Inc. is a Phase 3-stage biopharmaceutical company focused on discovering and developing novel drugs to treat cancer, with an initial focus on myelodysplastic syndromes (MDS). Onconova has a pipeline of proprietary targeted agents designed to work against specific cellular pathways that are important in cancer cells. Advanced clinical trials with the Company's lead compound, rigosertib, are aimed at what the Company believes are unmet medical needs of patients with MDS. Onconova has conducted trials with two other research compounds and has a pre-clinical program with a CDK4/6 and ARK5 inhibitor, ON 123300.

For more information, please visit <https://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 expectations regarding the INSPIRE Trial and Onconova's other development plans. 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 Onconova's ability to continue as a going concern, maintain its Nasdaq listing, the need for additional financing, the success and timing of Onconova's clinical trials and regulatory approval of protocols, our collaborations including the effective termination of the HanX license and securities purchase agreements and plans for partnering certain territories, 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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