Advancements in the Treatment of Myelodysplastic Syndromes and RAS-Mutated Lung Cancers to be Presented by Key Opinion Leaders on Thursday, February 7, 2019, in New York City

January 31, 2019

- Invitation-only breakfast event sponsored by Onconova Therapeutics will also be webcast, beginning at 8:00 a.m. EST

NEWTOWN, Pa., Jan. 31, 2019 (GLOBE NEWSWIRE) -- Onconova Therapeutics, Inc. (Nasdaq: ONTX), a Phase 3 stage biopharmaceutical company focused on discovering and developing novel products to treat cancer, with a primary focus on Myelodysplastic Syndromes (MDS), today announced it will host a KOL breakfast for security analysts and institutional investors on Thursday, February 7, 2019, in New York City.

The event will include presentations by Lewis Silverman, MD, Associate Professor of Medicine and Director of the Translational Research Center for the Myelodysplastic Syndrome in the Division of Hematology/Oncology/Tisch Cancer Institute and Rajwanth Veluswamy, MD, MSCR, Assistant Professor of Medicine, Thoracic Oncology, Tisch Cancer Institute, Institute for Translational Epidemiology, Icahn School of Medicine, Mount Sinai Health System. In addition, Steven Fruchtman, MD, President and Chief Executive Officer of Onconova, will present a Company overview and detailed information from the Company's Phase 2 rigosertib trial and the Company's clinical strategy and near-term milestones.

Presentations will begin at 8:00 a.m. Eastern Standard Time. A live and archived audio and slide webcast of the event will be available on Onconova's Corporate Events and Presentations page. Following the presentations, all speakers will be available for questions. This on-site event is open to analysts and institutional investors only. Kindly RSVP in advance if you would like to attend in person, as space is limited. To request a spot, please send an email to ir@onconova.us.

"We are excited to host this important educational event on recent advances in the treatment of myelodysplastic syndromes and other RAS-mutated cancers, and honored that two prominent research leaders in their field, Dr. Lewis Silverman, a recognized expert in MDS, and Dr. Rajwanth Veluswamy, a prominent researcher and clinician in lung cancer, have agreed to speak," said Steven M. Fruchtman, MD, President and Chief Executive Officer of Onconova. "In addition to the presentations by Drs. Silverman and Veluswamy, we will be discussing our Phase 2 oral rigosertib data, which were recently presented at the American Society of Hematology (ASH) annual meeting in December. We will also discuss future plans and near-term milestones, including pivotal Phase 3 data with IV rigosertib in high-risk MDS patients."

Key findings from the Phase 2 trial data presented at ASH include:

- Overall response rate (ORR) of 90% reported in this multi-institutional Phase 2 study in hypomethylating agent (HMA) naïve patients, including Complete Remission (CR) rate of 34%
- Median duration of response for the HMA naïve patients was 12.2 months
- Acceptable safety profile when oral rigosertib is combined with the FDA-approved dose of azacitidine

KOL Event Presentation Highlights

- *Participating Key Opinion Leaders*
    - Lewis R. Silverman, MD, is an Associate Professor of Medicine and Director of the Myelodysplastic Syndrome and Myeloproliferative Disease Program, Mount Sinai School of Medicine, in New York City. He served as Principal Investigator of the randomized Phase 3 trial of azacitidine vs. Supportive Care, which served as the basis for approval of azacitidine by the FDA for MDS in the United States. Dr. Silverman is a pioneer in developing treatments for patients with Higher-risk MDS and has served as a Principal Investigator on Onconova's rigosertib clinical trial program for treatment of Higher-risk MDS patients.
    - Rajwanth R. Veluswamy, MD, MSCR, is an Assistant Professor of Medicine, Hematology and Medical Oncology, and a board-certified medical oncologist who specializes in the treatment of lung cancer and other thoracic malignancies. He completed both a clinical fellowship in Hematology and Medical Oncology and a General Medicine research fellowship at the Icahn School of Medicine at Mount Sinai. Prior to this, he completed residency in Internal Medicine at Methodist Dallas Medical Center, and a research internship at MD Anderson Cancer Center in Houston.
- *New developments in the treatment of MDS and the rigosertib clinical trial program*
- *New approaches for the treatment of RAS-mutated lung cancers*
- *Phase 2 efficacy and safety results of oral rigosertib in combination with azacitidine (Vidaza®) in high-risk MDS patients, as reported at the 2018 annual meeting of the American Society of Hematology*

- *Onconova's rigosertib clinical program – the broadest in myelodysplastic syndromes*

About Onconova Therapeutics, Inc.

Onconova Therapeutics, Inc. is a Phase 3-stage biopharmaceutical company focused on discovering and developing novel small molecule drug candidates to treat cancer, with a primary focus on Myelodysplastic Syndromes (MDS). Rigosertib, Onconova's lead candidate, is a proprietary Phase 3 small molecule agent, which the Company believes blocks cellular signaling by targeting RAS effector pathways. Using a proprietary chemistry platform, Onconova has created a pipeline of targeted agents designed to work against specific cellular pathways that are important in cancer cells. Onconova has three product candidates in the clinical stage and several pre-clinical programs. 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. For more information, please visit http://www.onconova.com.

About Rigosertib

Rigosertib is a small molecule that is reported to block cellular signaling by targeting RAS effector pathways (Divikar, 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 clinic with oral and IV rigosertib. This includes single agent IV rigosertib in 2nd line high-risk MDS patients (pivotal Phase 3 INSPIRE trial) and oral rigosertib plus azacitidine in 1st line high-risk MDS patients (Phase 2).

About IV Rigosertib
The intravenous form of rigosertib has been employed in Phase 1, 2, and 3 clinical trials involving more than 800 patients, and is currently being evaluated in a randomized Phase 3 international INSPIRE trial for patients with higher-risk MDS, after failure of hypomethylating agent, or HMA, therapy.

About the INSPIRE Phase 3 Clinical Trial

The **IN**ternational **S**tudy of **P**hase 3 **I**V **R**igos**E**rtib, or **INSPIRE**, was finalized following guidance received from the U.S. Food and Drug Administration and European Medicines Agency and derives from the findings of the ONTIME Phase 3 trial. INSPIRE is a multi-center, randomized controlled study to assess the efficacy and safety of IV rigosertib in HR-MDS patients who had progressed on, failed to respond to, or relapsed after previous treatment with an HMA within the first 9 months or nine cycles over the course of one year after initiation of HMA treatment. This time frame optimizes the opportunity to respond to treatment with an HMA prior to declaring treatment failure, as per NCCN Guidelines. Following interim analysis in early 2018, the independent Data Monitoring Committee recommended that the trial continue with an expansion in enrollment to 360 patients based on a pre-planned sample size re-estimation. Patients are randomized at a 2:1 ratio into two treatment arms: IV rigosertib plus Best Supportive Care versus Physician's Choice plus Best Supportive Care. The primary endpoint of INSPIRE is overall survival. Full details of the INSPIRE trial, such as inclusion and exclusion criteria, as well as secondary endpoints, can be found on clinicaltrials.gov (NCT02562443).

About Oral Rigosertib

The oral form of rigosertib was developed to provide more convenient dosing for use where the duration of treatment may extend to multiple years. This dosage form may also support many combination therapy modalities. To date, 368 patients have been treated with the oral formulation of rigosertib. Initial studies with single-agent oral rigosertib were conducted in hematological malignancies, lower-risk MDS, and solid tumors. Combination therapy of oral rigosertib with azacitidine and chemoradiotherapy has also been explored. Currently, oral rigosertib is being developed as a combination therapy together with azacitidine for patients with higher-risk MDS who require HMA therapy. A Phase 1/2 trial of the combination therapy has been fully enrolled, and the preliminary results were presented in 2016. This novel combination is the subject of an issued U.S. patent with earliest expiration in 2028.

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, the need for additional financing, the success and timing of Onconova's clinical trials and regulatory approval of protocols, 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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