Onconova Announces Four Presentations from Rigosertib Clinical Trials in Myelodysplastic Syndromes (MDS) at the 2018 ASH Annual Meeting & Exposition

November 5, 2018

- Oral presentation on Saturday will feature efficacy and safety data from Expanded Phase 2 trial of rigosertib in combination with Azacitidine
- Three Poster presentations to feature pharmacokinetics, dose optimization, and biomarker studies

NEWTOWN, Pa., Nov. 05, 2018 (GLOBE NEWSWIRE) -- Onconova Therapeutics, Inc. (NASDAQ:ONTX), a Phase 3 clinical-stage biopharmaceutical company focused on discovering and developing novel products to treat cancer, today announced that four abstracts relating to the Company's lead product candidate, rigosertib, were accepted for presentation at the 60th American Society of Hematology (ASH) Annual Meeting & Exposition in San Diego, California, which takes place December 1-4, 2018.

ORAL PRESENTATION:

Phase 2 Expansion Study of Oral Rigosertib Combined with Azacitidine (AZA) in Patients (Pts) with Higher-Risk (HR) Myelodysplastic Syndromes (MDS): Efficacy and Safety Results in HMA Treatment Naïve & Relapsed (Rel)/Refractory (Ref) Patients

Session Name: 637. Myelodysplastic Syndromes – Clinical Studies: Novel Therapeutics I

Date: Saturday, December 1, 2018

Session Time: 4:00 – 5:30 PM

Presentation Time: ORAL SESSION 4:15 PM PST

Room: Manchester Grand Hyatt San Diego, Grand Hall A

Presenter: Shyamala C. Navada, MD, Division of Hematology/Oncology, Icahn School of Medicine at Mount Sinai, New York, NY

POSTER PRESENTATIONS:

1) ***Truncation Products of Stromal Cell Derived Factor-1 (CXCL12) Quantified By Mass Spectrometry in Patients with Myelodysplastic Syndrome (MDS) or Acute Myeloid Leukemia (AML) Treated with Rigosertib in a Phase I-II Study***

Session Name: 604. Molecular Pharmacology and Drug Resistance in Myeloid Diseases: Poster I

Date: Saturday, December 1, 2018

Presentation Time: 6:15 - 8:15 PM

Location: San Diego Convention Center, Hall GH

Presenter: John Roboz, PhD, Icahn School of Medicine at Mount Sinai, New York, NY

2) Evaluation of Underlying Cause of Genitourinary (GU) Adverse Events (AEs) in Patients with Myelodysplastic Syndromes upon Oral Administration of Rigosertib: Safety and Pharmacokinetic Analysis of Rigosertib across Three Clinical Trials

Session Name: 637. Myelodysplastic Syndromes – Clinical Studies: Poster II

Date: Sunday, December 2, 2018

Presentation Time: 6:00 - 8:00 PM

Location: San Diego Convention Center, Hall GH

Presenter: Manoj Maniar, PhD, Onconova Therapeutics, Inc., Newtown, PA

3) ***Amelioration of Rigosertib Treatment Related Genitourinary (GU) Adverse Events (AEs) in Patients with Myelodysplastic Syndromes: Implementation of Novel Dosing Regimen Derived through Pharmacokinetic Modeling in Phase 2 Study of Oral Rigosertib in Combination with Azacitidine***

Session Name: 637. Myelodysplastic Syndromes – Clinical Studies: Poster III

Date: Monday, December 3, 2018

Presentation Time: 6:00 - 8:00 PM

Location*:* San Diego Convention Center, Hall GH

Presenter: David Taft, PhD, Arnold & Marie Schwartz College of Pharmacy and Health Sciences, Long Island University, Brooklyn, NY

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 is reported to block 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 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 INSPIRE

The **IN**ternational **S**tudy of **P**hase III **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. 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 9 cycles over the course of one year after initiation and with progression or failure to respond to 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 where the duration of treatment may extend for years in lower risk MDS patients. 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.

General Contact

Mark Guerin
Onconova Therapeutics, Inc.
267-759-3680
http://www.onconova.com/contact/