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Onconova Therapeutics Announces Establishment of Collaborative Research and Clinical Programs Evaluating Rigosertib in Pediatric "RASopathies"

- ***Company to highlight approaches for studying rigosertib in multiple rare diseases associated with RAS gene at upcoming scientific conference***
- ***Collaboration with National Cancer Institute (NCI) for evaluation of rigosertib in pediatric rare disease***
- ***Onconova to host KOL breakfast symposium for investors on October 11th, 2017***

NEWTOWN, Pa., July 25, 2017 (GLOBE NEWSWIRE) -- Onconova Therapeutics, Inc. (NASDAQ:ONTX), 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), today announced the establishment of a collaborative, multi-institutional research and clinical program to evaluate rigosertib in pediatric RASopathies, a group of rare syndromes, which, together, are among the most common genetic conditions in the world, according to the RASopathies.Net. The program will generate supportive non-clinical data and obtain early clinical experience in the pediatric setting with rigosertib, Onconova's lead clinical candidate.

Rigosertib in currently being evaluated in a global Phase 3 trial (INSPIRE) for MDS patients after failure of therapy with Hypomethylating Agents (HMAs). A Phase 2 trial of oral Rigosertib combined with Azacitidine is aimed at patients with MDS and AML.

The RASopathies are developmental syndromes usually caused by mutations that alter the RAS subfamily and mitogen-activated protein kinases that control signal transduction. Together, the RASopathies represent a group of neurodevelopmental syndromes affecting more than 1 in 1000 individuals, according to RASopathies.Net.

Reflecting Onconova's focus on MDS and Myeloproliferative Neoplasms (MPNs), the Company will initially prioritize Juvenile Myelomonocytic Leukemia (JMML), a pediatric, typically germline, disease that shares characteristics of adult MDS and MPNs. JMML is a well-described RASopathy affecting children, which is incurable without an allogenic hematopoietic stem cell transplant. In addition, Onconova will collaborate with the National Cancer Institute on a broad clinical trial for pediatric patients with RASopathies.

"We are advancing research into one of the most important pediatric genetic syndromes, as we work together with families, clinicians and scientists to foster collaborative research efforts. Our program is based on mechanistic rationale, clinical activity in adult marrow diseases and sound safety data. By leveraging our focus in MDS and MPNs, we expect to further advance approaches to studying rigosertib in a variety of RAS associated diseases," said Steven Fruchtman, M.D., Onconova's Chief Medical Officer.

Dr. Fruchtman will present findings highlighting approaches for studying rigosertib in RAS associated diseases on Sunday, July 30th, at the 5th International RASopathies Symposium, organized by RASopathies.Net and held at the Renaissance Hotel in Orlando, Florida.

A copy of the presentation, "Strategies to RASopathies and JMML," can be accessed by visiting "Scientific Presentations" in the Investors section of Onconova's website.

Onconova is also hosting a Key Opinion Leader Breakfast Symposium for investors in New York City on Wednesday, October 11, 2017, to further highlight RASopathies. Dr. Elliot Steigholtz from the University of California San Francisco, and Dr. Bruce Gelb from Mount Sinai, along with Dr. Fruchtman, will present on novel approaches in this evolving area. The Company will disclose further details regarding the Symposium in the coming months.

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, while causing minimal damage to normal 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 the randomized Phase 3 international INSPIRE trial for patients with higher-risk MDS, after failure of hypomethylating agent, or HMA, therapy. This formulation is intended for patients with advanced disease, provides long duration of exposure, and ensures dosing under a controlled setting.

About INSPIRE

The **IN**ternational **S**tudy of **P**hase III **I**V **R**igos**E**rtib, or INSPIRE, is based on 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. The trial will enroll approximately 225 patients 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 and an interim analysis is anticipated. 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 also supports 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 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 US 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 future events or Onconova Therapeutics, Inc.'s future operations, clinical development of Onconova's product candidates and presentation of data with respect thereto, regulatory approvals, expectations regarding the sufficiency of Onconova's cash and other resources to fund operating expenses and capital expenditures, Onconova's anticipated milestones and future expectations and plans and prospects. 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. 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. 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 and current plans and future needs to scale back operations if adequate financing is not obtained, 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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