

# Onconova Therapeutics Promotes Dr. Steven M. Fruchtman to Chief Executive Officer

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- Executive succession plan maintains momentum of recent significant advances
- Onconova well-positioned to deliver key milestones in 2019 for both intravenous and oral rigosertib, as well as other pipeline products

NEWTOWN, Pa., Jan. 15, 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 the appointment of Dr. Steven Fruchtman as Chief Executive Officer and a member of the Board of Directors, effective immediately. Dr. Fruchtman has served as President of Onconova since June 2018, and originally joined the Company in January 2015 as Chief Medical Officer. Previously, he held senior leadership positions in pharmaceutical and biotechnology companies and academia. Dr. Fruchtman is a board certified hematologist, who specialized in bone marrow diseases and stem cell transplantation. Dr. Fruchtman replaces Dr. Ramesh Kumar, who will transition to an advisory role for the Company.

"Steve is the right leader for Onconova at this time. He has been instrumental to the Company's progress thus far and his proven track record in drug development will continue to serve the Company well as it advances the Phase 3-stage rigosertib programs toward approval and commercialization. The Board thanks Ramesh for his leadership and contributions to Onconova, and for positioning Onconova to reach critical upcoming milestones. We view Steve, and the recently expanded executive team that he has assembled, as poised to achieve clinical progress and business development objectives," said Michael Hoffman, Chairman of the Onconova Board of Directors.

Dr. Fruchtman has extensive industry experience in clinical research in MDS, hematologic malignancies, and solid tumors. He served with increasing leadership responsibilities at Ortho Biotech, Novartis, and biotechnology companies leading to successful clinical trial completion and regulatory approvals for a number of new chemical entities in various malignancies. Prior to his transition to industry, Steve served as the Director of the Myeloproliferative Disorder Program at The Mount Sinai Hospital in New York City, a Center of Excellence, and established the Stem Cell Transplant Program there. His commitment to the areas of hematology/oncology and myeloproliferative disorders is exemplified by his service as an external reviewer for prestigious journals such as the *New England Journal of Medicine, Mayo Clinic Proceedings, Experimental Hematology*, and others. He received his Bachelor of Arts with Honors from Cornell University, and his M.D. from New York Medical College. He was recently named to the Board of The Bone Marrow Foundation. Dr. Fruchtman commented, "I am very grateful to the Board for this honor. I thank Ramesh for his mentorship during my tenure as President and Chief Medical Officer. My colleagues at Onconova and I are focused on achieving our milestones. The global INSPIRE trial for rigosertib in MDS has the potential to offer a novel treatment option for these patients. We are very excited about the anticipated full enrollment of the INSPIRE trial in the second half of 2019, the advancement to Phase 3 of the oral rigosertib combination trial, and the studies of rigosertib in pediatric RASopathies and other unmet medical needs. I firmly believe that rigosertib has the potential to support multiple indications in different areas of oncology. In addition, our innovative CDK 4/6 inhibitor, ON 123300, is in advanced pre-IND stage, and is expected to enter the clinic during the first half of the year. This vision presents opportunities to enhance the value of the Company in the coming years."

## 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 IV Rigosertib**

Intravenous 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 **IV R**igosErtib, 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 Higher Risk-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 study 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 combination therapy modalities. To date, more than 400 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, chemotherapy or radiotherapy 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. The results of an expanded Phase 2 trial of oral rigosertib combination therapy with azacitidine were presented at the 2018 ASH Annual Meeting. Patents covering oral and injectable rigosertib have been issued in the US, and are expected to provide coverage until at least 2037.

### **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 executive team, rigosertib and the INSPIRE Trial, ON 123300 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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