



ONCONOVA THERAPEUTICS

Onconova Therapeutics Announces Promotion for Steven M. Fruchtman, M.D.

June 21, 2018

- New Role as the President involves leadership of the entire product portfolio
- Promotion reflects progress of Rigosertib to key data milestones

NEWTOWN, Pa., June 21, 2018 (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 promotion of Dr. Steven M. Fruchtman. In his new role as President, Dr. Fruchtman will have oversight over the entire product portfolio, as well as a key role in all other areas of the Company. He will continue to maintain the responsibilities of Chief Medical Officer until a replacement is hired to assume that role. Dr. Fruchtman will continue to report to Dr. Ramesh Kumar, co-founder and Chief Executive Officer of the Company.

Dr. Fruchtman joined Onconova as Chief Medical Officer (CMO) and Senior Vice President, Research and Development, in January 2015. He is a board certified hematologist with extensive industry experience in clinical research for myelodysplastic syndromes, hematologic malignancies and solid tumors. Prior to his transition to industry, Dr. Fruchtman served as the Director of the Myeloproliferative Disorder Program at Mt. Sinai Hospital in New York City and established the Stem Cell Transplant Program there. He has served with increasing responsibilities at Ortho Biotech, Novartis, and biotechnology companies Allos, Spectrum, and Syndax, leading to Health Authority approvals for a number of new chemical entities in various malignancies. His commitment to the areas of hematology/oncology and myeloproliferative disorders is exemplified by his service as an external reviewer for the *New England Journal of Medicine*, *Mayo Clinic Proceedings*, *Experimental Hematology*, *European Journal of Haematology*, *Leukemia*, and his role as a member of the editorial board of *The Mount Sinai Journal of Medicine*. Dr. Fruchtman is an author of more than 170 lectures, presentations, books, and chapters. 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 located in NYC.

"Steve has an enviable track record of successful development and approval of several new drugs for the unmet needs of cancer patients. His background as a practicing hematologist/oncologist, combined with his research and development acumen and experience, position him very well to lead the development of our innovative late stage portfolio of small molecule products for MDS and other cancers," said Dr. Kumar.

"I am honored by this promotion and to be entrusted with increased responsibility," said Dr. Fruchtman. "We have made significant progress on the INSPIRE TRIAL in higher-risk MDS since announcing the results of a pre-planned interim analysis in January. We are also advancing the design of a pivotal combination trial of oral rigosertib and azacitidine by optimizing the dosage. These trials have set a solid foundation in the studies of rigosertib in patients with MDS. While focused on advancing Rigosertib towards regulatory approval for MDS, we also recognize the many additional opportunities and avenues open to us. In the era of genomic medicine, we plan to investigate other indications where mutated and overexpressed pathways could be targeted by our novel compounds. These are exciting times for Onconova."

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

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 **INTERNATIONAL Study of Phase III IV Rigosertib**, 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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