Onconova Therapeutics Announces Issuance of a New U.S. Patent for Rigosertib

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- Granted claims cover both oral and injectable formulations of Rigosertib
- Newly issued US patent 10,098,862 extends protection for Rigosertib into 2037
- Equivalent coverage is being sought worldwide and, if granted, will expand intellectual property protection for Rigosertib in additional countries

NEWTOWN, Pa., Oct. 17, 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 that the United States Patent and Trademark Office issued a new patent protecting the company's lead product candidate, Rigosertib. U.S. patent 10,098,862 "Formulations with enhanced stability and bioavailability for administration of (E)-2, 6-Dialkoxystyryl 4-Substituted Benzyl Sulfones" describes novel compositions directed towards improving stability and enhancing bioavailability of Rigosertib. The issued patent claims novel formulations for oral and parenteral administration and oral dosing regimens of Rigosertib for the treatment of cancer and proliferative disorders.

"Rigosertib is well protected by issued US and foreign patents as well as by Orphan Designation in the U.S., Europe, and Japan. We remain focused on our broader IP strategy that provides additional barriers to entry and expanded geographical coverage for our lead product candidate, which is in advanced clinical trials for unmet medical needs of patients with Myelodysplastic Syndromes," commented, Ramesh Kumar, Chief Executive Officer of Onconova. "Ensuring multi-faceted intellectual property protection around Rigosertib helps enhance the potential value of this innovative program."

U.S. patent 10,098,862 complements and adds to coverage provided by previously issued Composition of Matter patent U.S. 7,598,232 and its international counterpart patents and patent applications, including Rigosertib drug combination patents. While previous patents cover compositions, methods, formulations and other aspects of utility, the new patent provides additional coverage related to an oral dosing regimen of Rigosertib. The novel formulation patent was filed in 2017 as a PCT application globally and as National Phase applications in the U.S. and in Non-PCT countries including Taiwan and various countries in Latin America.

The named inventor of the patented technology is Dr. Manoj Maniar, Senior Vice President of Product Development for Onconova. The patent was filed by and is assigned to the Company.

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 nine 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," "is being sought," 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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