Onconova Therapeutics Announces License Agreement with Pint Pharma to Commercialize Rigosertib for Treatment of Myelodysplastic Syndromes in Latin America

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• Pint Pharma to Make Upfront Investment in Onconova
• Onconova also Eligible to Receive up to $42.75 Million in Regulatory and Sales Milestones

NEWTOWN, Pa., March 05, 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 they have entered into a license agreement with Pint Pharma GmbH to commercialize rigosertib, a novel and targeted anti-cancer compound currently in a Phase 3 study for the treatment of MDS, a group of rare hematologic malignancies. Pint Pharma is a European-based pharmaceutical company focused on the development, registration and commercialization of specialty-based treatments for the Latin American market.

Under the terms of the agreement, Onconova has granted to Pint Pharma an exclusive license to commercialize rigosertib in Latin America. In exchange for these rights, Pint will make investment totaling up to $2.5 million by purchasing shares at a premium to market. In addition, Pint Pharma will make additional regulatory, development and sales-based milestone payments to Onconova of up to $42.75 million and pay double digit tiered royalties on net sales in Latin America. Onconova will supply the finished product for sale in the licensed territories. Pint Pharma will also support Onconova's clinical trial initiatives in the territory.

“Following the recently announced promising interim analysis of our Phase 3 INSPIRE trial, we remain dedicated to advancing IV rigosertib towards commercialization in order to address the needs of MDS patients who fail hypomethylating agents (HMAs). Since HMAs are used globally, we are seeking regional partnerships to help prepare for the commercialization of rigosertib worldwide. We are delighted to partner with Pint Pharma, which has a wide footprint in South and Central America, and view this license agreement as further validation of the potential of rigosertib for the treatment of MDS. We also look forward to working with the clinicians and experts at Pint Pharma to advance clinical trials for IV and oral rigosertib in important centers in their territory,” said Dr. Ramesh Kumar, President and CEO of Onconova Therapeutics, Inc.

“We are excited about the opportunity to provide this therapy to patients in our region; we hope that rigosertib will become a reality in clinical oncological practice and deliver a new option to patients and specialists,” said David Munoz, Chief Executive Officer of Pint Pharma. “Rigosertib is highly complementary to our comprehensive hematology oncology portfolio, and will further strengthen our mission to enable the Latin American population with life-altering conditions to live better lives by providing early and efficient access to innovative technologies.”

Rigosertib is currently being evaluated in a Phase 3 INSPIRE clinical trial in patients who have failed or relapsed after receiving current therapeutic options, with top-line data expected in 2019. Rigosertib is also being evaluated in an expanded Phase 2 combination study with Azacitidine in MDS patients. Onconova recently signed a research collaboration agreement with the National Cancer Institute to study rigosertib in rare pediatric diseases. Rigosertib has been granted orphan drug designation for MDS in the United States and Europe. Onconova is partnered with SymBio Pharmaceuticals, Tokyo, for commercialization of rigosertib in Japan and Korea.

About Pint Pharma

PINT PHARMA INTERNATIONAL SA is a company registered under Swiss laws, having its registered office at Route de Chenaux 9, 1091 Bourg-en-Levaux, Switzerland, and is devoted to the development, registration, and commercialization of specialty based treatments. Pint Pharma benefits from leaders with extensive experience in the pharmaceutical sector and who are based strategically throughout Latin America and Europe. Pint Pharma has a long track record of developing strong relationships with global pharmaceutical and healthcare companies. Pint Pharma strives to be the first Pan-Latin American provider of innovative and high value-added treatments within Rare Diseases, Specialty Care, and Oncology.

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 **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 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

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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 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 Onconova Therapeutics, Inc.'s expectations regarding the INSPIRE Trial and the transactions contemplated by the licensing agreement. 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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