Onconova Therapeutics Announces Plan for Expanding Rigosertib Clinical Trials for Patients with Myelodysplastic Syndromes (MDS) to South America with Pint Pharma

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- Pint Pharma to facilitate expansion of Phase 3 INSPIRE trial to Argentina, Chile, and Brazil in preparation for future studies of oral rigosertib

NEWTOWN, Pa., Aug. 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 that its commercial partner, Pint Pharma GmbH, will assist in expanding access to clinical trials studying rigosertib, a novel and targeted anti-cancer compound currently in a Phase 3 study for the treatment of MDS, to several selected sites across South America. Pint Pharma is a European-based pharmaceutical company focused on the development, registration and commercialization of specialty-based treatments for the Latin American market and has successfully participated in clinical trials for hematological cancers.

"This assistance will help make rigosertib available to cancer patients on a fifth continent, following our ongoing clinical trials in North America, Europe, Asia and Australia. We are delighted to partner with Pint Pharma, which has a wide footprint in South and Central America, with first-hand experience in running clinical trials for malignant hematological disorders," said Dr. Ramesh Kumar, CEO of Onconova Therapeutics, Inc.

"We are excited to start helping Onconova open new clinical sites in Latin America. We are hopeful that Onconova will be able to start recruiting patients as soon as possible to continue the development of IV and Oral Rigosertib," said David Munoz, Chief Executive Officer of Pint Pharma. He added, "Rigosertib is highly complementary to our comprehensive hematology oncology portfolio, and will further strengthen our mission to enable the Latin American population with life-threatening conditions to live better lives by providing early and efficient access to innovative technologies."

Dr. Steven Fruchtman, President and Chief Medical Officer of Onconova, is working closely with Dr. Valnei Canutti, General Manager, Brazil, and Chief Medical Officer of Pint. Dr. Fruchtman commented, "Completion of the INSPIRE Trial and expanding the potential utility of rigosertib for cancer patients are our core objectives and we are delighted that our commercial partner will assist us in recruiting patients in the INSPIRE trial. There is a great medical need and interest to conduct studies in patients with higher risk MDS in this geographical region."

Dr. Canutti added, "We are looking forward to working with Dr. Fruchtman on this important initiative. My prior experience in MDS and our connections with Key Opinion Leaders across this continent will be greatly helpful as we collaborate with Onconova."

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).

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.

General Contact

Mark Guerin
Onconova Therapeutics, Inc.
267-759-3680
http://www.onconova.com/contact/

Pint Pharma GmbH
Wipplingerstrasse 34 Top 112 – 119
Vienna (Austria)
Central line: +43 1 259 47 35
www.pint-pharma.com
Alejandra Pedraza
Head of Business & Corporate Development
Office: +43 1 259 47 35 66
Email: alejandra.pedraza@pint-pharma.com


Primary Logo

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