Onconova Therapeutics Announces Exclusive License Agreement with Knight Therapeutics for Rigosertib in Canada

November 21, 2019

- **Knight receives exclusive license to commercialize rigosertib in Canada**
- **Onconova eligible to receive up to CAD 33.95 million in clinical, regulatory, and sales-based milestones and tiered double-digit royalties**

NEWTOWN, Pa., Nov. 21, 2019 (GLOBE NEWSWIRE) -- Onconova Therapeutics, Inc. (NASDAQ: ONTX) ("**Onconova**"), a Phase 3-stage biopharmaceutical company discovering and developing novel products to treat cancer, with a focus on myelodysplastic syndromes (MDS), today announced they have entered into a Distribution, License and Supply Agreement with Knight Therapeutics Inc. ("**Knight"),** a Canadian-based specialty pharmaceutical company focused on acquiring, in-licensing, selling and marketing innovative prescription and over-the-counter pharmaceutical products, whereby Knight shall have the exclusive rights to commercialize rigosertib in Canada. In addition, Onconova may be entitled to receive clinical, regulatory and sales-based milestone payments up to CAD 33.95 million and tiered double-digit royalties on net sales.

"We are pleased to add Knight to our roster of global partners for rigosertib," said Dr. Steven Fruchtman, President and Chief Executive Officer of Onconova. "We are eager to work with Knight's team, which has successfully partnered with a number of biotechnology companies to commercialize innovative medicines in Canada."

"Patients with high-risk MDS have limited treatment options after first-line hypomethylating agents such as azacitidine fail," said Jonathan Ross Goodman, Chief Executive Officer of Knight. "If approved, rigosertib would address this unmet need and we look forward to the results of the ongoing phase III INSPIRE trial of IV rigosertib."

About Myelodysplastic Syndromes

MDS is a group of blood disorders that affect bone marrow function, whereby the bone marrow cells appear dysplastic and their capacity to produce cells is defective. As a result, patients with MDS have low blood cell counts and require frequent blood transfusions. In approximately one-third of patients, higher-risk MDS can progress to acute myelogenous leukemia (AML).

The Leukemia and Lymphoma Society of Canada estimates that there are between 1,800 and 5,900 new cases of MDS diagnosed in Canada each year. MDS is typically diagnosed in older individuals, and most patients diagnosed with the disease are over the age of 60. Approximately 23% of cases can be classified as having high risk or very high risk MDS as per the revised International Prognostic Scoring System (IPSS-R)[1].

About Rigosertib

Rigosertib, Onconova's lead candidate, is a proprietary Phase 3 small molecule. A key publication in a preclinical model demonstrated rigosertib's ability to block cellular signaling by targeting RAS effector pathways (Divakar, S.K., et al., 2016: "A Small Molecule RAS-Mimetic Disrupts RAS Association with Effector Proteins to Block Signaling." Cell 165, 643). Onconova is currently in the clinical development stage with oral and IV rigosertib, including clinical trials studying single agent IV rigosertib in second-line higher-risk MDS patients (pivotal Phase 3 INSPIRE trial) and oral rigosertib plus azacitidine in first-line and refractory higher-risk MDS patients (Phase 2). Patents covering oral and injectable rigosertib have been issued in the US and are expected to provide coverage until at least 2037.

About the INSPIRE Phase 3 Clinical Trial

The clinical trial **IN**ternational **S**tudy of **P**hase 3 **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 global, multi-center, randomized, controlled study to assess the efficacy and safety of IV rigosertib in higher-risk MDS (HR-MDS) patients who had progressed on, failed to respond to, or relapsed after previous treatment with a hypomethylating agent (HMA) within 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. 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. The trial continued beyond the pre-specified interim analysis and is nearing its conclusion. 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 Onconova Therapeutics, Inc.

Onconova Therapeutics, Inc. is a Phase 3-stage biopharmaceutical company discovering and developing novel small molecule drug candidates to treat cancer, with a focus on Myelodysplastic Syndromes (MDS). 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. 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. Onconova has conducted trials with two other research compounds and has a pre-clinical program with a CDK4/6 and Ark5 inhibitor, ON 123300.

For more information, please visit http://www.onconova.com.

About Knight Therapeutics Inc.

Knight Therapeutics, Inc., headquartered in Montreal, Canada, is a specialty pharmaceutical company focused on acquiring or in-licensing innovative pharmaceutical products for the Canadian and select international markets. Knight Therapeutics Inc.'s shares trade on TSX under the symbol GUD. For more information about Knight Therapeutics Inc., please visit the company's web site at www.gudknight.com.

Onconova 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 products, its collaboration with Knight, 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.

1. Greenberg PL, Tuechler H, Schanz J, et al. Revised international prognostic scoring system for myelodysplastic syndromes. *Blood*. 2012;120(12):2454–2465.

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