Onconova Therapeutics Announces License and Collaborative Development Agreement with HanX Biopharmaceuticals for ON 123300, a Dual Inhibitor of CDK4/6 + ARK5

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- HanX to commercialize in Greater China: Onconova retains rights in rest of the world
- HanX will fund studies towards Investigational New Drug (IND) applications in both the US and China
- Agreement includes licensing fee, customary milestone payments and royalties on sales

NEWTOWN, Pa., Dec. 19, 2017 (GLOBE NEWSWIRE) -- Onconova Therapeutics, Inc. (Nasdaq:ONTX), a Phase 3-stage biopharmaceutical company focused on discovering and developing small molecule drug candidates to treat cancer, with a focus on Myelodysplastic Syndromes (MDS), today announced the signing of a license and collaboration agreement with HanX Biopharmaceuticals, Inc., a company focused on development of novel oncology products, for the further development, registration and commercialization of ON 123300 in China. ON 123300 is a first-in-class dual inhibitor of CDK4/6 + ARK5, which is currently in advanced pre-clinical development. This compound has the potential to overcome the limitations of current generation CDK 4/6 inhibitors.

Under the terms of the agreement, Onconova will receive an upfront payment, regulatory and commercial milestone payments, as well as royalties on Chinese sales. The key feature of the collaboration is that HanX will provide all funding required for Chinese IND enabling studies performed for Chinese Food and Drug Administration IND approval. The Companies also intend for these studies to comply with US Food and Drug Administration (FDA) standards. Accordingly, such studies may be used by Onconova for an IND filing with the FDA. Both Companies will oversee the IND enabling studies. Onconova will maintain global rights outside of China.

“This collaboration provides an innovative way forward for our promising pipeline molecule. We are excited to advance ON 123300 towards a US IND as we seek to create a new standard of care with the potential to overcome the limitations of current generation compounds that require a combination treatment for therapeutic use. We believe that ON 123300 also has the potential to act as a single agent, due to the unique targeting of ARK 5, as well as CDK 4 and 6, making it potentially suitable for indications that may not be responsive to the current generation of CDK4/6 inhibitors, such as Palbociclib,” commented Ramesh Kumar, President and CEO of Onconova. “CDK inhibitors have emerged as one of the most promising and targeted large market cancer therapies. We remain focused on our later stage rigosertib clinical development programs in MDS with near term milestones, and look forward to a close collaboration with HanX as we leverage their strong expertise in drug development and commercialization.”

Faming Zhang, Ph.D., founder and Chief Executive Officer of HanX, commented, “HanX is a specialty pharmaceutical company focused on oncology, with an emerging pipeline of targeted agents including a proprietary PD-1 checkpoint antibody soon entering Phase 1 trials. We are pleased to be working with Onconova, which shares our commitment to developing innovative therapeutics in oncology. We look forward to working together to accelerate the development of ON 123300 for patients suffering from many types of cancer, including breast cancer, in both China and globally. As we launch our internally developed programs, such as a novel PD-1 program and other kinase inhibitors, we are excited by the potential synergies between our pipeline of checkpoint product candidates and CDK inhibitors.”

Onconova recently presented promising pre-clinical data on in vitro metabolism and bioavailability for ON 123300 at the American Association of Pharmaceutical Scientists Annual Meeting and Exposition. The data showed improved understanding of the metabolism of ON 123300 and the identification of metabolites, as well as a two to three-fold increase in bioavailability as a result of the Company’s formulation development efforts.

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. The advanced clinical trial with the Company’s lead compound, rigosertib, is aimed at what the Company believes are unmet medical needs of patients with MDS. For more information, please visit http://www.onconova.com.

About HanX

HanX is an oncology specialty company with an innovative pipeline targeting PD1, VEGFR, OX40 in clinical and pre-clinical stages. The company has a strong management team with cross-border experience and advisors with expertise in drug discovery, regulatory, and GMP manufacturing.

About CDK Inhibitors:

A key feature of cancer cells is their ability to rapidly multiply. CDK inhibitors are thought to disrupt this process by blocking the activity of enzymes known as CDKs. In particular, CDK4 and CDK6 are considered potential anticancer drug targets, due to their role regulating cell cycle progression at the G1 restriction point. CDK inhibitors have the potential to treat one of the most common types of breast cancer known as hormone receptor-positive metastatic breast cancer, in which the cancer cells express hormone receptors.

ON 123300 was found to be as active as Palbociclib (Pfizer's Ibrance®) in a preclinical Rb + ve xenograft model. Moreover, the molecule may have the potential advantage of reduced neutropenia when compared to Palbociclib. Both compounds decreased RBC and platelet counts, however in this model system, Palbociclib had a more prominent and statistically significant (P≤0.05) inhibitory effect on neutrophil counts when compared to ON 123300 (30.70 ± 3.55 vs. 45.10 ± 2.04).

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 future events, clinical development and the potential of Onconova's product candidates, Onconova's anticipated milestones and future expectations and plans and prospects for its product candidates. 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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