

## Onconova and SymBio Complete License Agreement for *Rigosertib*, a Phase III Stage Multi-Kinase Inhibitor for Cancer

NEWTOWN, Pa. and TOKYO, Japan, July 8, 2011

Onconova Therapeutics, Inc., and SymBio Pharmaceuticals Limited announced today that they will collaborate to develop and commercialize *rigosertib* in Japan and Korea. Onconova is conducting late-stage clinical trials with *rigosertib* (ON 01910.Na) in the U.S., Europe and India for the treatment of Myelodysplastic Syndromes (MDS) and solid tumors. A pivotal trial in the refractory/relapsed MDS clinical program is underway in the U.S. and Europe. The U.S. FDA has granted orphan drug designation for the use of *rigosertib* in MDS, and has agreed to a Special Protocol Assessment (SPA) for the phase III trial design.

In addition to the intravenous product in advanced-stage development, an oral formulation of *rigosertib* is being developed for frontline MDS and other indications. The clinical program in solid tumors is also advancing with the initiation of a Phase II/III combination trial in pancreatic cancer and Phase II single agent trial in ovarian cancer.

Under the terms of the agreement, SymBio has an exclusive license for Japan and Korea and will develop and commercialize *rigosertib* in these countries. Onconova will receive an upfront payment and development milestones tied to the progress of *rigosertib*, as well as sales milestone payments plus royalties on net sales. The two companies will enter into an agreement for the supply of development stage and commercial product.

*Rigosertib*, a novel styryl benzyl sulfone, is a patent protected multi-kinase inhibitor with a unique mode of action. Currently there is no approved therapy for MDS patients who fail frontline treatment with hypomethylating agents, and there is an urgent need to develop a new class of drugs to treat refractory/relapsed and frontline MDS patients.

“This is the first commercial transaction for our lead product *rigosertib*, and we are delighted that SymBio is our partner in Japan and Korea,” said Dr. Ramesh Kumar, President and CEO of Onconova. “The broad reach of *rigosertib* across blood cancers as well as solid tumors, and the ability to address previously intractable indications with single agent and combination therapies, will provide multiple opportunities to serve the unmet medical needs of patients worldwide.”

“Following our development agreement for MDS with the Leukemia and Lymphoma Society announced last year, the SymBio collaboration provides additional validation for the commercial potential of our lead product.” Mr. Michael Hoffman, Chairman of the Board of Directors of Onconova added, “We are looking forward to working with SymBio and other partners to bring *rigosertib* to market expeditiously.”

“We are very excited about collaborating with Onconova to develop this new class of agent for MDS, a

hard-to-treat cancer,” said Mr. Fuminori Yoshida, President and CEO of SymBio. “Due to the paucity of effective therapies to treat MDS patients, especially those who are refractory or have relapsed, we are fully committed to bringing this much-needed cancer drug to market as nimbly as possible in order to improve the lives of patients in Japan and Korea. *Rigosertib* is an excellent strategic fit for SymBio, and the addition of *rigosertib* to our pipeline will further strengthen SymBio’s presence in the oncology space as we capitalize on the synergy between *bendamustine* and *rigosertib*.”

#### About Myelodysplastic Syndromes (MDS)

MDS represent a group of diverse myeloid (bone marrow) stem cell disorders with a poor prognosis that gradually affect the ability of bone marrow to produce normal red blood cells, white blood cells, and platelets. Blood stem cells fail to mature into healthy blood cells, and the immature blood cells, called blasts, do not function normally and either die in the bone marrow or enter the blood. A higher percent of blasts is linked to a higher likelihood of developing leukemia and a poorer prognosis. The risk of MDS increases with age and the disease commonly affects the elderly.

#### About *Rigosertib*

*Rigosertib* (ON 01910.Na) is a small molecule inhibitor of critical pathways important in the growth and proliferation of cancer cells. Extensive Phase I and Phase II studies with *rigosertib* have been conducted in patients with solid tumors and hematological cancers, including MDS, pancreatic and ovarian cancers. Based on data from clinical studies that explored various dose regimens of *rigosertib*, administered alone or in combination with other chemotherapeutic agents in patients with myelodysplastic syndromes (MDS) or with advanced solid tumors, *rigosertib* is overall well tolerated. In phase I and II clinical trials in patients who have a limited number of approved treatments for their diseases, *rigosertib* has demonstrated significant bone marrow blast count improvement (at least 50% blast reduction) in 53% of MDS patients and greater than 50% reduction in CA 19-9 marker in about 36% of patients with pancreatic cancer. The most frequent drug-related adverse events (in at least 10% of patients) in the MDS population were fatigue, dysuria, abdominal pain, nausea and diarrhea. In patients with advanced solid tumors, the most frequent drug related adverse events (in greater than 10% of patients) were anorexia, diarrhea, vomiting, nausea, and fatigue. The majority of these drug-related adverse events were Grade 1 or 2 in severity (NCI CTCAE). The Phase III ONTIME and Phase II/III ONTRAC studies of *rigosertib* are designed to further investigate these results and address the unmet medical needs for MDS and pancreatic cancer patients. A U.S. Patent covering *rigosertib* has been issued and European and other international patents are expected to issue shortly.

#### About Onconova Therapeutics, Inc.

Onconova, based in Newtown, PA and Pennington, NJ, and founded in 1998, discovers and develops novel small molecule therapeutics targeting signal transduction, cell-cycle, and DNA repair pathways. Onconova has a novel discovery platform focusing on non-ATP competitive kinase inhibitors, and the

company is also exploring a new immunoconjugate technology (comprising potent active compounds and proprietary linkers) for arming monoclonal antibodies for cancer therapy. These products, technologies, and candidates are derived internally from a proprietary library of new chemical entities. In addition to *rigosertib*, Onconova is also developing Ex-RAD<sup>®</sup> (ON 01210.Na) as a novel radiation protection drug (oral and injection) in collaboration with the U.S. Department of Defense to protect against radiation injury of tissue and whole body. For additional information, please visit <http://www.onconova.com>.

JSB Partners and Dechert, LLP, advised Onconova for this transaction.

#### About SymBio Pharmaceuticals Limited

SymBio Pharmaceuticals Limited, based in Tokyo, Japan, was established in March, 2005 by Fuminori Yoshida, who previously served concurrently as Corporate VP of Amgen Ltd. and founding President of Amgen Japan. The company's underlying corporate mission is "delivering hope to patients in need" as it aspires to be a leading specialty pharmaceutical company in Asia Pacific dedicated to addressing underserved medical needs in the areas of oncology, hematology and autoimmune disease. The first drug candidate SymBio in-licensed, *bendamustine*, has been developed for refractory/relapsed indolent non-Hodgkin's lymphoma (NHL) and mantle cell lymphoma, and successfully launched in Japan. SymBio is actively developing *bendamustine* in frontline indolent NHL, aggressive NHL and multiple myeloma in Japan. The product has also been launched in Hong Kong and Singapore, with Korea and Taiwan to follow by year end. For additional information, please visit <http://www.symbiopharma.com>.

Latham & Watkins LLP, advised SymBio for this transaction.

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