SymBio Pharmaceuticals Limited

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SymBio Pharmaceuticals Limited
Fuminori Yoshida
Representative Director
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Onconova Presents Phase I Data for Oral Rigosertib at the 53rd American Society of Hematology Annual Meeting

- Oral Rigosertib (ON 01910.Na) Advancing to Phase II -

TOKYO, Japan, December 13, 2011 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "SymBio") announces that Onconova Therapeutics®, Inc. (Headquarters: Newtown, PA and Pennington, NJ, "Onconova") presented positive data from its US Phase I trial in myelodysplastic syndrome (MDS) patients treated with oral rigosertib (ON 01910.Na) at the 53rd American Society of Hematology (ASH) Annual Meeting and Exposition in San Diego, CA on December 12, 2011. SymBio signed a license agreement with Onconova in July, 2011, for the exclusive right to develop and commercialize both the intravenous and oral forms of rigosertib in Japan and Korea.

An oral dosage form of rigosertib has completed a Phase I dose escalation trial with 33 MDS patients in the U.S. The rigosertib capsule formulation was well tolerated and pharmacodynamically relevant doses were achieved in MDS patients with encouraging signs of clinical activity observed, including two cases of bone marrow responses in higher-risk patients refractory to hypomethylating agents, reduced need for red cell transfusions in low-risk, transfusion-dependent patients, and transition to transfusion independence in some patients. Based on these results, Phase II studies will be conducted using oral rigosertib in Low or Intermediate-1 risk, transfusion-dependent MDS patients.

Onconova is conducting late-stage clinical trials with rigosertib, a patent protected multi-kinase inhibitor with a unique mode of action, in the U.S., Europe and India for the treatment of MDS and solid tumors. A pivotal Phase III trial in the refractory/relapsed MDS clinical program is underway in the U.S. and Europe..

SymBio is now preparing to initiate a Phase I clinical trial in Japan and Korea for the treatment of refractory/relapsed MDS patients using the intravenous form (SyB L-1101) of rigosertib, with the treatment of frontline MDS using the oral form (SyB C-1101) to follow based on results generated in US Phase II clinical trials.

[Please see the following for further information on Onconova]

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Note to Editors

About Myelodysplastic Syndrome (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 Sodium

Rigosertib sodium is a small molecule inhibitor of critical pathways important in the growth and survival of cancer cells. Extensive Phase I and Phase II studies with rigosertib have been conducted at leading institutions in the U.S. and abroad in more than 450 patients with solid tumors and hematological cancers, including MDS and AML. MDS and AML are blood disorders widely recognized as difficult to manage with limited therapeutic options available for patients, especially those with drug-resistant disease. Onconova's multi-site Phase III ONTIME trial in MDS patients is under a Special Protocol Assessment (SPA) from the U.S. FDA and is being supported by an award from the Therapeutics Acceleration Program (TAP) of the Leukemia and Lymphoma Society (LLS). FDA has granted Orphan Drug Designation for the use of rigosertib in MDS. The clinical program in solid tumors is also advancing with initiation of the Phase II/III combination ONTRAC trial (ON 01910.Na TRial in Patients with Advanced Pancreatic Cancer) and Phase II single agent trial in ovarian cancer. A U.S. patent covering ON 01910.Na is issued with international patent coverage.

About Onconova Therapeutics®, Inc.

Onconova Therapeutics, based in Newtown, PA and Pennington, NJ, discovers and develops novel small molecule therapeutics directed against targets involved in signal transduction, cell-cycle, and DNA repair. These candidates are derived from a proprietary new chemical entities and non-ATP competitive chemotypes. In addition to rigosertib sodium (ON 01910.Na), Onconova is developing two other products in clinical trials: ON 01210.Na (Ex-RAD®), an injectable and oral radioprotectant, and ON 013105 for refractory lymphomas. The oncology preclinical pipeline at Onconova includes inhibitors of Plk2, ALK, CDK, JAK, and Bcr-Abl pathways and a novel immunoconjugate platform for arming therapeutic antibodies. For additional information, please visit Onconova's homepage at http://www.onconova.com.

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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 Inc. and founding President of Amgen Japan. The company's underlying corporate mission is to "deliver hope to patients in need" as it aspires to be a leading specialty Pharma in Asia Pacific dedicated to addressing underserved medical needs in the areas of oncology, hematology and autoimmune. The company's lead drug candidate, bendamustine hydrochloride, has been successfully developed and launched in Japan for refractory/relapsed indolent non-Hodgkin's lymphoma (NHL) and mantle cell lymphoma. SymBio is also actively developing bendamustine in frontline indolent NHL, refractory/relapsed aggressive NHL and multiple myeloma in Japan. The product has been launched in Hong Kong, Singapore and Korea, with market approval recently granted in Taiwan. For additional information, please visit our homepage at http://www.symbiopharma.com.