

March 29, 2012  
SymBio Pharmaceuticals Limited  
Fuminori Yoshida  
Representative Director  
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Clinical Trial Notification Accepted for SymBio's Japan Phase 1 Trial  
of *Rigosertib* (SyB L-1101) in Refractory/Relapsed MDS

TOKYO, Japan, March 29, 2012 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, President & CEO: Fuminori Yoshida, "SymBio") announced that clinical trial notification (CTN) has been accepted for its Phase 1 clinical trial using *rigosertib* (SyB L-1101) in refractory and relapsed myelodysplastic syndrome (MDS) patients.

Onconova Therapeutics, Inc., a U.S.-based biopharmaceutical company which has licensed *rigosertib* to SymBio, is conducting late-stage clinical trials with *rigosertib* (ON 01910.Na) in the U.S., Europe and India in hematological cancers and solid tumors. A pivotal Phase III trial in refractory/relapsed MDS patients was initiated under a Special Protocol Assessment from the U.S. FDA and is underway at more than 50 centers in the U.S. and Europe. The U.S. FDA has granted orphan drug designation for the use of *rigosertib* in MDS and pancreatic cancer. In addition to the intravenous product in advanced-stage development and with the successful completion of two Phase I trials, an oral formulation of *rigosertib* is being developed for frontline MDS in Phase II trials and other indications. To date, more than 500 cancer patients have been treated with *rigosertib* in Phase I, II and III clinical trials conducted in the U.S., EU and India.

As well as this first trial for the treatment of refractory and relapsed MDS patients, SymBio is planning to initiate a Phase I clinical trial for the treatment of frontline MDS using the oral form of *rigosertib* (SyB C-1101) based on promising results generated in U.S. Phase II clinical trials.

Patients with MDS often require frequent blood transfusions due to the development of severe anemia (decrease in number of red blood cells), with approximately one third of patients progressing to acute myelogenous leukemia (AML). MDS remains an underserved therapeutic area with few available treatment options for patients, hence SymBio is moving *rigosertib* through clinical development as nimbly as possible.

**[Please read the following for additional information on MDS, *Rigosertib*, and Onconova ]**

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Note to Editors

### **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 with treatment being more difficult in the elderly population.

### **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 500 patients with solid tumors and hematological cancers, including MDS and AML. MDS and AML are blood disorders widely recognized as being 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). The 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 patent for ON 01910.Na has been issued in the U.S. with international patent coverage.

### **About Onconova Therapeutics<sup>®</sup>, 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 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<sup>®</sup>), 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>.

### **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 oncology, hematology and autoimmune diseases. 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, Korea and Taiwan. For additional information, please visit our homepage at <http://www.symbiopharma.com>.