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SymBio Pharmaceuticals Limited
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# SYMBIO INITIATES JAPANESE PHASE I TRIAL OF RIGOSERTIB (SYB L-1101) IN RELAPSED/REFRACTORY MDS

TOKYO, Japan, June 29, 2012 -- SymBio Pharmaceuticals Limited (JASDAQ: 4582) announced today that it commenced enrollment in a Phase I clinical trial using intravenous *rigosertib* (SyB L-1101) in relapsed/refractory (r/r) myelodysplastic syndrome (MDS) patients in Japan.

Under the terms of the license agreement concluded with Onconova Therapeutics, Inc. in July, 2011, SymBio has an exclusive license to develop and commercialize *rigosertib* in Japan and Korea.

*Rigosertib* is a patent protected multi-kinase inhibitor with a unique mechanism of action. Patients with MDS often require frequent blood transfusions due to the development of severe anemia (decrease in number of red blood cells), with a high rate of progression to acute myelogenous leukemia (AML). There are an estimated 9,000 MDS patients in Japan alone. Currently there is no approved drug for MDS patients who fail frontline treatment with hypomethylating agents, and there is an urgent need to develop new therapies to treat r/r and frontline MDS patients.

Onconova is conducting advanced clinical trials with *rigosertib* in the US and EU for the treatment of MDS and solid tumors. A pivotal Phase III trial for the treatment of r/r MDS is underway in more than 70 US/EU centers. The US FDA has granted orphan drug designation for the use of *rigosertib* in MDS, and has agreed to a Special Protocol Assessment (SPA) for the r/r MDS Phase III trial design. Other ongoing advanced trials in low-risk transfusion dependent MDS (employing oral *rigosertib*) and in metastatic pancreatic cancer (employing a rationally designed combination therapy incorporating *rigosertib*) are also underway in the US and India.

[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 progressively 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 AML and a poorer prognosis. 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. The risk of MDS increases with age and treatment is more difficult in elderly populations.

#### About Rigosertib

Rigosertib (ON 01910.Na) 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 US and abroad in more than 500 patients with solid tumors and hematological cancers, including MDS and AML. An ongoing multi-site Phase III trial, called ONTIME (ON 01910.Na Trial In Myelodysplastic SyndromE), is being conducted in MDS patients by Onconova under a SPA from the US FDA. The ONTIME trial is being supported by an award from the Therapeutics Acceleration Program of The Leukemia & 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 the Phase II/III combination ONTRAC trial (ON 01910.Na TRial in Patients with Advanced Pancreatic Cancer). Onconova has also initiated a Phase II trial, ONTARGET (Oral ON 01910.Na in TrAnsfusion-RequirinG patients with myElodysplasTic syndrome), studying a transfusion-dependent low-risk MDS patient population with the oral formulation of rigosertib. A patent for rigosertib has been issued in the US, with corresponding 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 at targets involved in signal transduction, cell-cycle, and DNA repair. These product candidates are proprietary new chemical entities derived from non-ATP competitive chemotypes. In addition to *rigosertib* (ON 01910.Na). Onconova is developing two other product candidates 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, 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 pharmaceutical company 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 relapsed/refractory indolent non-Hodgkin's lymphoma (NHL) and mantle cell lymphoma (MCL). SymBio is also actively developing bendamustine in frontline indolent NHL and relapsed/refractory multiple myeloma (MM) in Japan. As well as Japan, bendamustine has been launched in Hong Kong, Singapore, Korea and Taiwan. For additional information, please visit our homepage at http://www.symbiopharma.com.