

December 4, 2018  
SymBio Pharmaceuticals Limited  
Fuminori Yoshida  
Representative Director  
President and Chief Executive Officer  
(Securities Code: 4582)

## Onconova Presents Results from Phase 2 Trial of Oral Rigosertib in Myelodysplastic Syndromes (MDS) at the ASH 2018 Meeting

TOKYO, Japan, December 4, 2018 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "SymBio") today announced that its U.S. licensor for rigosertib, Onconova Therapeutics, Inc., (Headquarters: Newtown, PA, "Onconova") announced the presentation of the efficacy and safety results of oral rigosertib in combination with azacitidine (Vidaza®) in patients with HR-MDS reported at an oral presentation during the 60<sup>th</sup> American Society of Hematology (ASH) Annual Meeting & Exposition in San Diego, California on December 1<sup>st</sup>, 2018.

Oral Presentation: Phase 2 Expansion Study of Oral Rigosertib Combined with Azacitidine treatment in Patients with Higher-Risk (HR) Myelodysplastic Syndromes (MDS): Efficacy and Safety Results in HMA Treatment Naïve & Relapsed (Rel)/Refractory (Ref) Patients

Summary of the oral presentation:

“Patients received either 840 mg or 1,120 mg of oral rigosertib daily divided into two doses, in combination with a standard dose of injectable azacitidine. The overall response rate (ORR) in 29 HMA naïve patients, was 90%; including 10 patients (34%) with Complete Remission (CR). Among the 26 evaluable HMA-failed patients, the ORR was 54% including 8% CR or partial remission. Other than genitourinary adverse events, the adverse event profile was similar to those described for azacitidine alone in this patient population. A Safety Optimization Strategy was implemented for the higher dose cohort of 1,120 mg of oral rigosertib, resulting in mitigation of the target genitourinary adverse events. In conclusion, oral rigosertib in combination with azacitidine was well tolerated in HMA naïve and HMA failed HR-MDS patients. The combination produced an encouraging rate of overall response and complete remission in both groups. Based on the results of this study, a pivotal Phase 3 trial in HMA naïve HR-MDS patients is planned.”

For more information, please see Onconova’s website:

<https://investor.onconova.com/press-releases>

Statement from Fuminori Yoshida, President and CEO of SymBio: “Based on the favorable trial results presented at the American Society of Hematology, SymBio plans to participate with respect to Japan in an Onconova initiated international Phase 3 clinical trial for oral rigosertib in combination with azacitidine in HMA naïve HR-MDS patients.”

### **About myelodysplastic syndromes (MDS)**

MDS patients often require frequent blood transfusions due to the development of severe anemia (decrease in the number of red blood cells), with a high rate of progression to acute myelogenous leukemia (AML). The number of MDS cases are expected to increase as the population ages. MDS and AML are widely recognized as two blood disorders that are difficult to manage given the limited therapeutic options available for patients, particularly for patients who have a drug-resistant form of the disease. A high unmet medical need clearly exists for the establishment of new effective therapies to treat both lower-risk and higher-risk MDS. The number of drug-treated MDS patients is estimated to be about 7,700 in Japan (CancerMPact 2016).

### **About Rigosertib**

Rigosertib is a small molecule inhibitor that has a new mechanism of action: it inhibits the activation of Ras as an oncogene-related product, thereby blocking the action of multikinases, including PI3K, and inhibits cellular signaling in cancer cells necessary for their survival and proliferation, thus killing cancer cells.

SymBio obtained the development and commercialization licensing rights for Rigosertib from Onconova in July, 2011 for Japan and Korea.

### **About Onconova Therapeutics, Inc.**

Onconova Therapeutics, Inc. is a clinical-stage biopharmaceutical company focused on discovering and developing novel products to treat cancer. Onconova's clinical and pre-clinical stage drug development candidates are derived from its extensive chemical library and are designed to work against specific cellular pathways that are important in cancer cells, while causing minimal damage to normal cells. In addition to Rigosertib, Onconova's most advanced drug candidate under development, two other drug candidates are in clinical trials and several other compounds are in the pre-clinical stage of development. For more information, please visit <http://www.onconova.com>.

### **About SymBio Pharmaceuticals Limited**

SymBio Pharmaceuticals Limited was established in March, 2005 by Fuminori Yoshida who previously served concurrently as Corporate VP of Amgen Inc. and founding President of Amgen Japan. In May, 2016 the Company incorporated its wholly-owned subsidiary in the U.S., called SymBio Pharma USA, Inc. (Headquarters: Menlo Park, California, President: Mr. Fuminori Yoshida). The Company's underlying corporate mission is to "deliver hope to patients in need" as it aspires to be a leading global specialty biopharmaceutical company dedicated to addressing underserved medical needs with main therapeutic focus in oncology, hematology and pain management.