

March 25, 2020  
SymBio Pharmaceuticals Limited  
Fuminori Yoshida  
Representative Director  
President and Chief Executive Officer  
(Securities Code: 4582)

## **Onconova Announces Completion of Enrollment of Phase 3 INSPIRE Trial for IV Rigosertib**

TOKYO, Japan, March 25, 2020 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "SymBio") today announced that its U.S. licensor for Rigosertib, Onconova Therapeutics, Inc. (Headquarters: Newtown, PA, "Onconova"), announced on March 24, 2020 (EST) that it has completed the planned enrollment of 360 patients in the INSPIRE trial, Onconova's Phase 3 study of IV rigosertib for the treatment of higher risk (HR) Myelodysplastic Syndromes (MDS).

Patients with HR MDS, following progression or failure of patients to respond to previous treatment with a hypomethylating agent (HMA), have limited treatment options and there is a tremendous unmet medical need. In collaboration with Onconova, SymBio has participated in the international study and conducted the clinical trial in Japan. 48 of the 360 patients were enrolled in Japan. Onconova anticipates reporting topline survival data in the second half of 2020 and presenting the results at a medical meeting later this year.

For Onconova's full press release, please visit Onconova's website:

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

Fuminori Yoshida, President and Chief Executive Officer of SymBio, stated: "Completion of the planned enrollment in the clinical trial in second line HR MDS is an important milestone. We look forward to the topline data in which the experimental agent rigosertib can prolong the survival of the patients."

In addition to the development of IV rigosertib, SymBio plans to participate in the international study of oral rigosertib plus azacitidine in first-line and refractory HR MDS patients, for which Onconova is currently designing the protocol.

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

MDS are conditions that can occur the blood-forming cells in the bone marrow become dysfunctional and thus produce an inadequate number of circulating blood cells. 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 11,000 in Japan at male-female ratio of 2:1 and majority of the patients are elderly.

### **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., 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.