

December 9, 2019
SymBio Pharmaceuticals Limited
Fuminori Yoshida
Representative Director
President and Chief Executive Officer
(Securities Code: 4582)

Onconova Announces Collaboration with Inceptua for Pre-approval Access to Anti-cancer Drug Rigosertib

TOKYO, Japan, December 9, 2019 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "SymBio") today announced that its U.S. licensor for Rigosertib, Onconova Therapeutics, Inc., (Headquarters: Newtown, PA, "Onconova"), announced on December 6, 2019 (EST) that Onconova has entered into a collaboration with Inceptua Medicines Access (a business unit of the Inceptua Group) (Head office: Luxembourg, "Inceptua") to make available intravenous rigosertib via a Pre-approval Access Program in selected countries around the world.

Patients with high-risk MDS who are refractory to HMAs have limited treatment options, and there is an extremely high unmet medical need for patients who respond inadequately to existing therapies. In collaboration with Onconova, SymBio has been conducting the global Phase 3 INSPIRE Trial designed to assess the efficacy and safety of intravenous rigosertib, and steadily advancing the enrollment of patients in Japan.

The rigosertib Pre-approval Access Program is expected to launch in the first half of 2020 and will allow Inceptua to supply intravenous rigosertib within designated countries, primarily and initially in selected countries in Europe, in response to physician requests for patients with high-risk MDS who have exhausted all available treatment options, and are not eligible for or have no access to the INSPIRE Trial.

For more information, please see Onconova's website:

investor.onconova.com/press-releases

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 is 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. 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 approximately 11,000 in Japan at male to female ratio of 2 to 1. The 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 licensed the development and commercialization 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 Onconova's website at: 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.