January 18, 2018
SymBio Pharmaceuticals Limited
Fuminori Yoshida
Representative Director
President and Chief Executive Officer
(Securities Code: 4582)

Onconova Announces Plans for the Global Randomized Phase 3 Trial of IV Rigosertib after Promising Interim Analysis

TOKYO, Japan, January 18, 2017 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "SymBio,") announced today that its U.S. partner, Onconova Therapeutics, Inc. (Headquarters: Newtown, PA, "Onconova") announced on January 17, 2018 (EST) that it is moving forward with the Global Randomized Phase 3 trial for the RAS pathway targeted anti-cancer drug IV rigosertib in patients with higher-risk myelodysplastic syndromes (MDS) who had progressed on, failed, or relapsed after prior hypomethylating agent (HMA) therapy (the "INSPIRE" trial) with a one-time increase in enrollment following the interim analysis.

Based on the interim analysis, the independent Data Monitoring Committee (DMC) has recommended that the INSPIRE trial continue with enrollment increased from the current 225 patients to reach a total enrollment of 360 patients. The expanded study enrollment criteria will be identical to the original study. For Onconova's full press release, please visit Onconova's website at: http://investor.onconova.com/press-releases

Patients with high-risk MDS who are refractory to HMAs have limited treatment options and there is extremely high unmet medical need for patients who respond inadequately to existing therapies. Based on the DMC's recommendation, SymBio will continue in collaboration with Onconova to move forward with the trial with an increase in the total enrollment of patients in Japan.

The financial impact of this event will be reflected in the Company's current financial forecast to be released on Febraury 7th, 2018.

About the Data Monitoring Committee (DMC)

The DMC is a committee of clinical research experts with expertise to conduct an independent review of the results of the interim analysis and to provide a recommendation to the sponsor on the appropriateness of continuing the trial and on any needed changes to the trail.

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 rights to develop and commercialize rigosertib in Japan and Korea from Onconova in July 2011.

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 with main therapeutic focus in oncology, hematology and pain management.