



October 25, 2019 SymBio Pharmaceuticals Limited Fuminori Yoshida Representative Director President and Chief Executive Officer (Securities Code: 4582)

Onconova Provides Update on the Global Phase 3 INSPIRE Trial of Rigosertib in Myelodysplastic Syndromes and on Future Clinical Trial Plans

TOKYO, Japan, October 25, 2019 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "SymBio") announced today that on October 24, 2019 (EST), its U.S. licensor for Rigosertib, Onconova Therapeutics, Inc. (Headquarters: Newtown, PA, "Onconova"), provided an update on the global Phase 3 INSPIRE study of IV rigosertib and on Onconova's future clinical trial plans.

For Onconova's full press release, please visit Onconova's website at: investor.onconova.com/press-releases

According to Onconova's announcement, Onconova is approaching enrollment of 90 percent of the required 360 randomized patients for the global Phase 3 INSPIRE Trial and Onconova continues to anticipate reporting top-line data in the first half of 2020. The INSPIRE Trial is a global, multicenter, randomized, controlled study to assess the efficacy and safety of IV rigosertib in higher-risk myelodysplastic syndromes ("HR-MDS") patients who had progressed on, failed to respond to, or relapsed after previous treatment with a hypomethylating agent ("HMA-refractory").

Regarding the development of oral rigosertib, as a result of Onconova's consultations with the FDA on SPA (Special Protocol Assessment), Onconova plans to conduct a randomized Phase 2 trial with a control arm of single agent azacitidine for the continued development of oral rigosertib plus azacitidine in first-line HR-MDS patients.

In collaboration with Onconova and as part of the global Phase 3 INSPIRE Trial, SymBio is conducting the trial in Japan and proceeding with planned enrollment. Treatment options are limited for HR-MDS patients who are HMA-refractory and there is an extremely high medical need.

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 people.

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.