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SymBio Pharmaceuticals Limited
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(Securities Code: 4582)

Initiation of Patient Enrollment in the Phase 1 Clinical Trial of Single-Agent Oral Rigosertib in Higher-Risk Myelodysplastic Syndromes

TOKYO, Japan, October 10, 2017 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "SymBio,") announced today that the first patient has been enrolled in the Phase 1 clinical trial of single-agent oral rigosertib in higher-risk myelodysplastic syndromes (MDS), which began on June 30, 2017.

The purpose of this Japanese Phase 1 study is to confirm the safety of high-dose oral rigosertib which was added to the overseas Phase 2 study in untreated or relapsed/refractory patients with higher-risk MDS after failure of hypomethylating agent therapy, currently being conducted by Onconova Therapeutics, Inc. (Headquarters: Newtown, PA, "Onconova"), the licensor for oral rigosertib. SymBio will promptly conduct an oral rigosertib/azacitidine combination trial in Japan after demonstrating the safety of high-dose oral rigosertib, and intends to participate in the global Phase 3 study in untreated higher-risk MDS patients that Onconova is now planning.

The enrollment of patients is presently underway in the global randomized Phase 3 INSPIRE trial for IV rigosertib in relapsed/refractory patients with higher-risk MDS. With regard to oral rigosertib, SymBio will advance the development for the indication of untreated higher-risk MDS in combination with azacitidine. SymBio intends to make a high-priority effort to obtain approvals for both IV and oral rigosertib for the two indications – relapsed/refractory higher-risk MDS and untreated higher-risk MDS respectively, for which there has long been a need for superior drug, at the earliest possible time.

The first patient enrollment in this Phase 1 study will not impact SymBio's current financial forecast for FY2017.

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 MDS and higher-risk MDS. The number of drug-treated MDS patients is estimated at 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 licensing rights for rigosertib from Onconova in July, 2011 and retains the development rights for Japan and Korea.

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.