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Symbio Pharmaceuticals Limited
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(Securities Code: 4582)

Initiation in Japan of the Phase I Clinical Trial of Single-Agent Oral Rigosertib in Higher-Risk Myelodysplastic Syndromes

TOKYO, Japan, June 30, 2017 -- Symbio Pharmaceuticals Limited (Headquarters: Tokyo, "Symbio,") announced today that Symbio initiated a Phase 1 study in Japan for single-agent oral rigosertib in patients with higher-risk myelodysplastic syndromes (MDS).

This is due to the resumption of supply of clinical trial materials from Onconova Therapeutics, Inc. (Headquarters: Newtown, PA, "Onconova"), the licensor for oral rigosertib, following completion of a change of manufacturing sites. The purpose of this Japanese Phase 1 study is to confirm the safety of high-dose oral rigosertib which was added to the ongoing overseas Phase 2 study in untreated or relapsed/refractory patients with higher-risk MDS after failure of hypomethylating agent therapy.

Symbio will immediately recommence 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. In logical parallel to initiating this Phase 1 study, Symbio has ceased the currently suspended Phase 1 combination study for oral rigosertib/azacitidine.

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, in which Symbio has been taking part since December 2015.

Symbio obtained the licensing rights for rigosertib from Onconova in July, 2011 and retains the development rights for Japan and Korea.

The initiation of 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.

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.