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

## Initiation of Patient Enrollment in Japan for the Global Randomized Phase 3 Trial of

IV Rigosertib for Higher-risk Myelodysplastic Syndromes (MDS)

TOKYO, Japan, July 19, 2016 - SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "SymBio") announced today that the first patient has been enrolled in Japan for the global randomized Phase 3 trial of the novel, RAS pathway targeted anti-cancer drug IV rigosertib in relapsed/refractory patients with higher-risk myelodysplastic syndromes (MDS) after failure of hypomethylating agent therapy.

SymBio is participating in the global randomized Phase 3 trial for IV rigosertib ("04-30" or "INSPIRE" trial) conducted by SymBio's U.S. partner, Onconova Therapeutics, Inc. (Headquarters: Newtown, PA). SymBio completed a Phase 1 clinical trial of IV rigosertib in Japan in October, 2015. Patients are currently being enrolled in the INSPIRE trial at more than 90 sites in the U.S., Europe and Japan.

The INSPIRE trial is designed to enroll 225 patients, including more than 20 patients expected to be enrolled in Japan, corresponding to approximately 10% of the total.

Following completion of the INSPIRE trail, SymBio is planning to submit new drug applications in Japan concurrently with submission in the U.S.

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

This event will not impact the Company's current financial forecast.





[Contact]

**Investor Relations** 

Tel: +81 (0)3 5472 1125

## 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). There are an estimated 11,000 MDS patients in Japan alone, with the number of cases 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 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 in the pre-clinical stage of development. For more information, please visit <a href="http://www.onconova.com">http://www.onconova.com</a>.

## 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.