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SymBio Pharmaceuticals Limited
Fuminori Yoshida
Representative Director
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(Securities Code: 4582)

Onconova Announces Over 75 Percent of Planned Enrollment Achieved in Phase 3 INSPIRE Study of Rigosertib

TOKYO, Japan, April 1, 2019 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "SymBio") today announced that its U.S. licensor for Rigosertib, Onconova Therapeutics, Inc. (Headquarters: Newtown, PA, "Onconova"), announced on March 25, 2019 (EST) that it has surpassed the 75 percent enrollment milestone in its Phase 3 study of IV rigosertib for the potential treatment of higher risk Myelodysplastic Syndromes (MDS), a study known as INSPIRE.

Onconova expects full enrollment of 360 patients to be completed in second half of 2019.
For Onconova's full press release, please visit Onconova's website:
https://investor.onconova.com/press-releases

The INSPIRE study is a Phase 3 international study designed to assess the efficacy and safety of single agent intravenous (IV) rigosertib to treat second line higher risk MDS patients who have progressed on, relapsed or failed to respond to previous treatment with hypomethylating agent (HMA) therapy.

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.
In collaboration with Onconova, SymBio has been steadily advancing the enrollment of patients in Japan.

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.