January 7, 2019
SymBio Pharmaceuticals Limited
Fuminori Yoshida
Representative Director
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(Securities Code: 4582)

Onconova Announces Submission of Special Protocol Assessment (SPA) to FDA for Phase 3 Trial of Oral Rigosertib

TOKYO, Japan, January 7, 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 January 2, 2019 (EST) that Onconova has submitted a Special Protocol Assessment request to the U.S. Food and Drug Administration (FDA) for a Phase 3 study of oral rigosertib combination therapy with azacitidine for the treatment of adult patients with treatment-naïve higher risk Myelodysplastic Syndromes (MDS).

The FDA's SPA process fosters dialogue between the FDA and clinical trial sponsors before studies commence, in an attempt to reach potential agreement with the agency on the design and size of clinical trials, to determine if they adequately address the scientific and regulatory requirements for a study to ultimately support marketing approval.

Onconova expects its dialogue with the FDA on this SPA submission to conclude in H1 2019 and to be followed by the proposed Phase 3 program with the primary endpoint of overall response rate (ORR), a composite of complete remission (CR), and partial remission (PR) based on the IWG Response Criteria.

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

Based on the favorable Phase 2 trial results presented at the American Society of Hematology ("ASH") in December 2018, SymBio plans to participate with respect to Japan in an Onconova initiated international Phase 3 clinical trial for oral rigosertib in combination with azacytidine in HMA naïve HR-MDS patients, after the conclusion of the dialogue between Onconova and the U.S. FDA.

SymBio's press release on the Phase 2 trial results presented at ASH 2018:
https://www.symbiopharma.com/news_e/20181204e.pdf

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 and higher-risk MDS. The number of drug-treated MDS patients is estimated to be 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 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.