SymBio Pharmaceuticals Limited

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SymBio Pharmaceuticals Limited
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Onconova Presents Phase 2 Data for Oral rigosertib at 2013 American Society of Clinical Oncology Annual Meeting

- Oral rigosertib (ON 01910.Na) in Transfusion-Dependent Lower Risk MDS -

TOKYO, Japan, June 3, 2013 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "SymBio") announces that Onconova Therapeutics, Inc. (Headquarters: Newtown, PA and Pennington, NJ, "Onconova") presented favorable data from its US Phase 2 ONTARGET trial in transfusion-dependent lower risk myelodysplastic syndrome (MDS) patients treated with oral rigosertib (ON 01910.Na) at the 2013 American Society of Clinical Oncology (ASCO) Annual Meeting (ASCO Abstract #7031) in Chicago, IL on June 1, 2013. This Phase 2 study follows the positive findings of a Phase I dose escalation study in MDS patients treated with orally-administered rigosertib. SymBio signed a license agreement with Onconova in July, 2011, for the exclusive right to develop and commercialize both the intravenous and oral forms of rigosertib in Japan and Korea.

Azra Raza, MD, Director, MDS Center, Columbia University Medical Center, New York, NY presented interim results in 43 patients enrolled in the ONTARGET study. ONTARGET is a randomized, two-arm study of oral rigosertib (560 mg bid) administered either intermittently (two out of three weeks) or continuously. Transfusion-dependent patients must have received at least four units of red blood cells (RBC) transfusions over eight weeks before randomization and can receive transfusions and erythrocyte stimulating agents (ESAs) while on study.

In the ONTARGET study, 13 of the 26 (50%) evaluable patients in the intermittent dosing arm and 2 of the 8 (25%) evaluable patients in the continuous dosing arm achieved transfusion independence, defined as no RBC transfusions for at least eight consecutive weeks. Onset of transfusion independence ranged from 1 -24 weeks following the initiation of rigosertib dosing, and the duration of transfusion independence ranged from eight to greater than 48 weeks. None of the responders had a del5q karyotype. Transfusion independence was durable and two patients continue to benefit from therapy more than nine months after starting rigosertib. Eleven of the 13 transfusion-independent patients in the intermittent dosing arm received one or more injections of ESAs during the time of oral rigosertib administration, and the patterns of hemoglobin responses observed in a few patients suggest a possible synergy between oral rigosertib and ESAs.

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Evaluation of safety indicated that oral rigosertib was generally well tolerated with the most frequently observed side effects being urologic in nature. In the continuous dosing arm of the study, grade 2+ urinary side effects were observed in five of the first nine patients. Accordingly, the protocol was amended to allow all patients to be treated with intermittent dosing. The most frequent urinary adverse events in the intermittent dosing arm were grade 2+ urinary urgency/frequency (38% of patients), grade 2+ dysuria (15%), and hematuria (15%). Other grade 2+ adverse events included intermittent neutropenia (1 grade 3/1 grade 4). Median onset of Gr2+ urinary Adverse Events in the intermittent dosing arm was 28 weeks compared with 12 weeks in the continuous dosing arm. Median duration of treatment in the intermittent dosing arm has not yet been reached (greater than 48 weeks compared with 24 weeks in the continuous dosing arm). Renal function was unaffected and gastrointestinal adverse events were infrequently observed.

Rigosertib is being developed in both oral and intravenous forms. Onconova is conducting late-stage clinical trials with rigosertib in the U.S., Europe and India for the treatment of MDS and solid tumors. Onconova recently announced reaching the enrollment goal in its randomized, controlled ONTIME Phase 3 trial for intravenous rigosertib in adult patients with myelodysplastic syndromes whose disease has failed azacitidine or decitabine therapy. Rigosertib is also being evaluated in a Phase 3 trial for first-line treatment in combination with gemcitabine for patients with metastatic pancreatic cancer who had not previously received any chemotherapy.
In Japan, two Phase 1 trials are underway by SymBio Pharmaceuticals, Onconova's licensee for Japan Korea, in relapsed or refractory high-risk MDS patients using the IV formulation of the drug (SyB L-1101), and in frontline low-risk MDS patients using the oral formulation of rigosertib (SyB C-1101). SymBio is striving to ensure that this much-needed drug is made available to MDS patients in Japan as soon as possible.

[Please see the following for further information on MDS, rigosertib, and Onconova]

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Note to Editors

About Myelodysplastic Syndrome (MDS)

MDS represents a group of diverse myeloid (bone marrow) stem cell disorders that gradually affect the ability of bone marrow to produce normal red blood cells, white blood cells, and platelets. Blood stem cells fail to mature into healthy blood cells, and the immature blood cells, called blasts, do not function normally and either die in the bone marrow or enter the blood. A higher percent of blasts is linked to a higher likelihood of developing leukemia and poorer overall prognosis. The risk of MDS increases with age and the disease commonly affects the elderly.

About rigosertib

Rigosertib is an inhibitor of two important cellular signaling pathways, phosphoinositide 3-kinase, or PI3K, and polo-like kinase, or PLK, both of which are frequently activated in cancer cells. Rigosertib is being developed in both oral and intravenous forms as a treatment for hematological diseases and solid tumors. Onconova recently announced reaching the enrollment goal in its randomized, controlled ONTIME Phase 3 Trial for intravenous rigosertib in adult patients with myelodysplastic syndromes whose disease has failed azacitidine or decitabine therapy. Rigosertib is also being evaluated in a Phase 3 trial for first-line treatment in combination with gemcitabine for patients with metastatic pancreatic cancer who had not previously received any chemotherapy. The oral form of rigosertib is currently being studied in Phase 2 trials in patients with transfusion-dependent lower risk myelodysplastic syndromes and in patients with head and neck cancer. Rigosertib has been granted orphan drug status for MDS in both the United States and Europe, as well as orphan drug status for pancreatic cancer in the United States. Rigosertib is being developed in partnership with Baxter International (commercialization rights in Europe) and SymBio Pharmaceuticals (Japan and Korea). Onconova has retained all other territories for commercialization.

About Onconova Therapeutics, Inc.

Onconova Therapeutics 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 proprietary chemical library and are designed to work against specific cellular pathways that promote cancer while causing minimal damage to normal cells. In addition to rigosertib, the Company’s most advanced product candidate, two other candidates are in clinical trials, and several candidates are in pre-clinical stages. For more information, please visit http://www.onconova.com.

About SymBio Pharmaceuticals Limited

SymBio Pharmaceuticals Limited, based in Tokyo, Japan, was established in March, 2005 by Fuminori Yoshida, who previously served concurrently as Corporate VP of Amgen Inc. and founding President of Amgen Japan. The company’s underlying corporate mission is to “deliver hope to patients in need” as

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it aspires to be a leading specialty pharma in Asia Pacific dedicated to addressing underserved medical needs in the areas of oncology, hematology and autoimmune. The company's lead drug candidate, bendamustine hydrochloride, has been successfully developed and launched in Japan for refractory/relapsed indolent non-Hodgkin's lymphoma (NHL) and mantle cell lymphoma. SymBio is also actively developing bendamustine in frontline indolent NHL, refractory/relapsed aggressive NHL and multiple myeloma in Japan. The product has been launched in Hong Kong, Singapore and Korea, with market approval recently granted in Taiwan. For additional information, please visit our homepage at http://www.symbiopharma.com.