SymBio Pharmaceuticals Limited

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SymBio Pharmaceuticals Limited
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Representative Director
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Onconova Announces Results from Phase 3 ONTIME Study of Rigosertib in Higher Risk Myelodysplastic Syndromes (MDS)

Rigosertib vs. Best Supportive Care did not meet the primary endpoint of statistically significant improvement in median overall survival-

-Post-hoc analysis demonstrates statistically significant improvement in median overall survival in patients who had progressed on or failed prior treatment with hypomethylating agents-

-Additional analysis of data will be discussed with regulatory authorities and presented at the 2014 ASCO Annual Meeting-

TOKYO, Japan, February 20, 2014 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "SymBio") announces that Onconova Therapeutics, Inc. (Headquarters: Newtown, PA, "Onconova") has released the results from the Phase 3 randomized ONTIME trial of intravenous (IV) rigosertib (ON 01910.na) in patients with myelodysplastic syndromes (MDS) who had progressed on, failed or relapsed after prior therapy with hypomethylating agents (HMAs).

The ONTIME trial is a Phase 3, multi-center, randomized, controlled study to assess efficacy and safety of rigosertib IV plus best supportive care (BSC) compared to BSC alone in higher risk MDS patients with excess blasts (5% to 30% bone marrow blasts), who have failed with HMAs. Regarding the detail of this trial result, please visit Onconova's website http://www.onconova.com for more information.

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. Other than the ONTIME trial with the IV form of rigosertib, the oral form of rigosertib is currently being studied in Phase 2 trials in patients with transfusion-dependent lower risk MDS, in patients with head and neck cancer, and also in a Phase 1/2 trial in frontline MDS.

In Japan, two Phase 1 trials are currently underway by SymBio Pharmaceuticals in higher risk MDS patients who have failed prior therapy with HMAs using the intravenous formulation of the drug (SyB

L-1101) and also in transfusion-dependent lower risk MDS patients using the oral formulation of rigosertib (SyB C-1101). Based on the result of the ONTIME trial, we will review our development plan in higher risk MDS following our discussions with Onconova. Meanwhile, SymBio will continue an on-going Ph1 study in Japan. SymBio will conduct further trials with oral rigosertib in transfusion-dependent lower risk MDS and also frontline higher risk MDS. With these trials, SymBio is striving to ensure that this much-needed drug is made available to MDS patients in Japan as soon as possible.

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

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About Rigosertib

Rigosertib is a small molecule 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. Recently, it was shown that rigosertib inhibits these pathways by interacting with the Ras Binding Domain (RBD) of several signaling molecules. Due to the dual effect of inhibiting PI3K and PLK pathways, rigosertib has shown activity in a variety of cancers including solid tumors and hematological malignancies. Clinical trials with IV and oral formulations of rigosertib have been conducted at leading institutions in the US and abroad. To date, more than 1,100 patients with solid tumors or hematological diseases have been enrolled in clinical trials with rigosertib. Rigosertib has been granted orphan drug status for MDS in the US, Europe and Japan. 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 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, 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.