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Symbio Pharmaceuticals Limited
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(Securities Code: 4582)

Initiation of Collaborative Research with Keio University on TREAKISYM® for Systemic Lupus Erythematosus

TOKYO, Japan, May 10, 2018 -- Symbio Pharmaceuticals Limited (Headquarters: Tokyo, "Symbio") announced today that it has entered into a joint research agreement with Keio University (Principal Investigator: Professor Takeuchi, Department of Rheumatology and Collagen Diseases) to conduct a preclinical study on the therapeutic effect of TREAKISYM® on systemic lupus erythematosus (SLE).

SLE, which affects an estimated 60,000 to 100,000 patients in Japan, is an intractable autoimmune disease that can affect many parts of the body. Currently, treatment options for SLE are limited, and steroids are mainly used. If treatment with steroids is ineffective, the immunosuppressive drug cyclophosphamide is used as the standard treatment. However, treatment with cyclophosphamide is associated with side effects such as hair loss and myelosuppression, and there is an urgent need to develop effective treatments with reduced side effects.

TREAKISYM® is already used as a first choice treatment for many patients with malignant lymphoma, and is superior in terms of side effects (such as less hair loss). TREAKISYM® is anticipated to have clinical efficacy in autoimmune diseases. Its anti-inflammatory effect has already been confirmed in basic studies with human cells by inducing the production of interleukin-10, which suppresses inflammation. SLE has a high level of unmet medical needs among autoimmune diseases. The Company is currently planning a clinical trial of TREAKISYM® oral for patients with SLE and will conduct a preclinical study for this purpose.

In addition to expanding the indications for malignant lymphoma, Symbio is developing a TREAKISYM® platform including products for use in the treatment of autoimmune diseases. The joint research with Keio University is part of this business strategy. Symbio will continue to explore the potential of TREAKISYM® oral and liquid formulations to maximize business value and bring benefits to patients.

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About TREAKISYM®

TREAKISYM® (non-proprietary name: bendamustine hydrochloride), a cytotoxic anti-cancer drug first used in Germany in the 1970s, is now widely used in more than 50 countries with indications for low-grade non-Hodgkin's lymphoma, mantle cell lymphoma, and chronic lymphocytic leukemia.

Bendamustine is a unique compound having chemical properties of both an alkylating agent³ and a metabolic antagonist⁴, and a mode of action different from other anti-cancer drugs. It is expected that bendamustine, given its unique properties, could be effective for the treatment of solid tumors as well as malignant lymphoma. A number of clinical studies of bendamustine injectables have been conducted outside of Japan to explore this potential, with clinical efficacy reported for certain solid tumors, including breast cancer, small-cell lung cancer, and soft tissue sarcoma. Furthermore, clinical studies of oral bendamustine for multiple myeloma, low-grade non-Hodgkin's lymphoma, and chronic lymphocytic leukemia have indicated favorable results with respect to both safety and tolerability³ of oral formulation.

- TREAKISYM® Intravenous Infusion 100 mg was approved in October, 2010 for manufacturing and marketing for the indication of relapsed/refractory low-grade B-cell non-Hodgkin's lymphoma and mantle cell lymphoma in Japan.
- TREAKISYM® was approved for the additional indication of chronic lymphocytic leukemia in Japan in August, 2016.
- TREAKISYM® Intravenous Infusion 25 mg, a standard low-dose product, was approved for manufacturing and marketing in Japan in September, 2016.
- TREAKISYM® was approved for the additional indication of first-line treatment of low-grade B-cell non-Hodgkin's lymphoma and mantle cell lymphoma in Japan in December, 2016.

TREAKISYM® has been marketed through Eisai Co., Ltd. since December, 2010.

1. An alkylating agent is a type of cytotoxic anti-cancer drug. Alkylating agents inhibit DNA replication by attaching alkyl group sites to the DNA chain.
2. A metabolic antagonist is a type of cytotoxic anti-cancer drug. Metabolic antagonists prevent DNA replication and the growth and division of tumor cells by interfering with the utilization of substances produced in the metabolic process.

About Systemic Lupus Erythematosus (SLE)

SLE is an autoimmune disease characterized by systemic inflammatory lesions triggered by immune complexes, such as DNA bound to antibodies that recognize and bind to DNA (anti-DNA antibodies) deposited in various organs and tissues. Although its symptoms can be controlled through treatment, the disease is chronic with remissions and exacerbations. The cause of SLE is thought to be a combination of genetic as well as environmental factors, such as infection, sex hormones, ultraviolet light, or drugs.

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 SymBio incorporated its wholly-owned subsidiary in the U.S., SymBio Pharma USA, Inc. (Headquarters: Menlo Park, California, President: Mr. Fuminori Yoshida). SymBio'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.