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SymBio Pharmaceuticals Limited
Fuminori Yoshida
Representative Director
President and Chief Executive Officer
(Securities Code: 4582)

SymBio Begins Preparation for Own Sales Organization for the Anti-Cancer Agent TREAKISYM®

TOKYO, Japan, October 16, 2018 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, Japan; "SymBio") today announced that SymBio has made its decision to initiate preparation to establish its own sales organization for the sale of the anti-cancer agent TREAKISYM® (bendamustine HCl) in Japan, looking towards the expiration of its business alliance agreement with Eisai Co., Ltd. (Headquarters: Tokyo, Japan; "Eisai") for the development and sale of TREAKISYM®. The business alliance agreement, entered into in August 2008, will expire in December 2020.

While TREAKISYM® is currently sold in Japan through SymBio's sales partner, Eisai, SymBio has carefully examined all options, including potential alliances, to determine how best to achieve the key management objectives of attaining profitability in fiscal year 2021, and maintaining sustainable growth thereafter. Considering the importance of understanding patient needs and responding to the market with greater precision and speed, SymBio has determined that conveying the value of the product through information provided by in-house sales and marketing experts will benefit patients, and that building its own sales organization is the right choice to maximize the business value of TREAKISYM®.

Looking toward 2021, SymBio will develop a sales organization highly specialized for hematology-related diseases and will achieve high productivity by selling rigosertib for myelodysplastic syndromes (MDS) (both IV and oral rigosertib formulations currently under development) in addition to TREAKISYM®, thereby increasing value for shareholders.

Statement from Fuminori Yoshida, President and CEO of SymBio: "With the positioning of TREAKISYM® and rituximab combination therapy (BR therapy) established in July of this year as the standard therapy for malignant lymphoma, the addition of new indications including relapsed/refractory diffuse large B-cell lymphoma (r/ r DLBCL), and a number of new therapies under development in combination with a bendamustine regimen by pharmaceutical companies globally, we are optimistic that the intrinsic value of TREAKISYM® will continue to grow. It is a great strength of SymBio that BR therapy has become the backbone for the treatment of malignant lymphoma, and we

will fully take advantage of this strength in building our own sales organization and expanding our business. We are aiming to achieve sales of JPY 10 billion on a NHI drug price basis at the earliest possible stage and realize the vision of SymBio's founding to become a Specialty Pharma."

The financial forecast for 2018 and the mid-range business plan released by SymBio on February 7, 2018, are prepared on the basis that SymBio will have its own sales organization in place for 2021 and remain unchanged.

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TREAKISYM® Business Strategy Developments

Since its founding in 2005, SymBio has actively promoted strategies of product life cycle management to maximize the business value of TREAKISYM®.

1. After obtaining marketing approval for relapsed/refractory low-grade B-cell non-Hodgkin's lymphoma (low-grade NHL) and mantle cell lymphoma (MCL) in October 2010, SymBio obtained approval for (i) chronic lymphocytic leukemia (CLL) as an additional indication in August 2016, (ii) TREAKISYM® Intravenous Infusion 25 mg in September 2016, and (iii) 1st line low-grade NHL and MCL as additional indications in December 2016. In August 2017, SymBio also initiated a phase III clinical trial for the indication of relapsed/refractory diffuse large B-cell lymphoma (r/r DLBCL), which has the largest number of malignant lymphoma patients.

2. For TREAKISYM® oral formulation, SymBio is currently conducting a phase I clinical study for advanced solid tumors in addition to joint research with Keio University for systemic lupus erythematosus (SLE), an autoimmune disease with high unmet medical need.

3. In July 2018, TREAKISYM® was approved for use in combination with other new anti-CD20 antibodies in addition to rituximab. As a result, TREAKISYM® and obinutuzumab (GAZYVA®, with marketing authorization held by Chugai Pharmaceutical Co., Ltd.) combination therapy is now available for CD20 positive follicular lymphoma (FL), a typical histologic type of low-grade NHL.

In addition, in September 2018, SymBio filed a partial change application for the use of TREAKISYM® as a pretreatment to regenerative medical products. Novartis Pharma K.K. (headquarters: Tokyo) filed for the marketing approval of Kymriah™, the first chimeric antigen receptor T-cell (CAR-T) therapy in Japan, on April 23, 2018. After both approvals are obtained, TREAKISYM® can be used as a pretreatment to Kymriah™.

4. In September 2017, SymBio signed an exclusive license agreement with Eagle Pharmaceuticals, Inc. for the development and commercialization in Japan of Eagle's ready-to-dilute ("RTD") and rapid infusion ("RI") injection bendamustine HCl products, patent protected liquid formulations that will extend the product life of TREAKISYM® through 2031.

In fiscal 2021, SymBio plans to launch the RTD liquid formulation and obtain approval for r/r DLBCL, and by delivering the value of TREAKISYM® to healthcare providers with precision and speed through its own sales organization, SymBio will continue to evolve its business to further benefit patients.

Development Status of Rigosertib

Since entering into an exclusive licensing agreement with Onconova Therapeutics, Inc. (Onconova) in July 2011 for the development and commercialization of rigosertib in Japan, SymBio has been actively developing rigosertib (both IV and oral formulations) for myelodysplastic syndromes (MDS), for which there is high medical need.

1) For rigosertib IV, SymBio leads clinical development in Japan as part of an international phase III clinical trial conducted by Onconova for patients with high-risk myelodysplastic syndrome (MDS) who have failed to respond to hypomethylating agents, relapsed after treatment, or were intolerant of hypomethylating agents. The trial in Japan began in December 2015, and 37 patients have been enrolled as of the end of September 2018.

2) With respect to rigosertib oral, Onconova is conducting a phase I/II clinical trial in the United States targeting high-risk MDS for 1st line treatment (in combination with azacytidine) and a phase II clinical trial targeting transfusion-dependent low-risk MDS. In June 2017, SymBio commenced a phase I clinical trial in Japan to confirm tolerability and safety, and the trial has progressed steadily since the first patient enrollment in October 2017.

TREAKISYM® is currently used by hematologists at approximately 900 healthcare institutions across Japan, with the top 400 institutions accounting for approximately 90% of sales. It is anticipated that, as with TREAKISYM®, rigosertib will be used by hematologists of these 400 institutions.

Current status of the SymBio pipeline

Drug	Indication	Phase 1	Phase 2	Phase 3	NDA	MA
SyB L-0501 TREAKISYM®	r/r Low-grade NHL/MCL	Approved October 2010				
	CLL	Approved August 2016				
	1st line Low-grade NHL/MCL	Approved December 2016				
	r/r DLBCL	P3 initiated August 2017				
	RTD (Ready-to-Dilute) Injection (liquid formulation)	NDA under preparation				
	RI (Rapid Infusion) Injection (liquid formulation)	Clinical trial under preparation				
SyB C-0501 TREAKISYM® ORAL	Advanced solid tumors	P1 initiated January 2018				
SyB C-0501 TREAKISYM® ORAL	SLE	Pre-clinical study ongoing				
SyB L-1101 RIGOSERTIB IV	Post-HMA Higher Risk MDS	Global P3 (INSPIRE study)				
SyB C-1101 RIGOSERTIB ORAL	1. 1st line Higher Risk MDS* 2. Transfusion dependent Lower Risk MDS *monotherapy to be followed by combination therapy with azacitidine	P1 initiated June 2017				

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., called 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.