English translation

February 10, 2015

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SymBio's Long Range Plan: FY2015 to FY2017

I. Long Range Plan for the next three years

(1) Overview of FY 2014 business results as of the date of the Long Range Plan

Progress in the Company's business for FY 2014 (from January 1, 2014 to December 31, 2014) is as follows.

1. Domestic

[SyB L-0501, generic name: bendamustine hydrochloride; trade name: TREAKISYM®]

The Company markets the anti-cancer agent TREAKISYM® in Japan through its business partner, Eisai Co., Ltd. ("Eisai"), for the indications of refractory/relapsed low-grade non-Hodgkin's lymphoma and mantle cell lymphoma. Net sales (NHI price basis) increased as expected, with an increase of 102% year-on-year.

Aiming to maximize the product value of TREAKISYM®, the Company continues to pursue three additional indications.

Firstly, as for the indications of frontline low-grade non-Hodgkin's lymphoma and mantle cell lymphoma, the Company completed the Phase II clinical trial in February, 2014 and is currently preparing the application for approval. In the EU, Astellas Pharma Europe Ltd. has already completed the application process for regulatory approval. Considering this approval progress in Europe, the Company plans to file for approval in Japan;

Secondly, as for the indication of chronic lymphocytic leukemia, the patient enrollment for Phase II clinical trial was completed in October, 2014. TREAKISYM® has been designated as an orphan drug (pharmaceutical for treatment of rare diseases) for the

indication of chronic lymphocytic leukemia in June, 2012.
Lastly, as for the additional indication of refractory/relapsed intermediate/high-grade non-Hodgkin's lymphoma, the Company's development approach is being considered.

[SyB L-1101 (intravenous formulation) and SyB C-1101 (oral formulation), generic name: rigosertib]

The domestic phase I clinical trial of anticancer agent SyB L-1101 (intravenous formulation) for the indication of refractory/relapsed higher risk myelodysplastic syndrome (MDS), which is a hematological malignancy, is underway.
In February, 2014, Onconova Therapeutics, Inc. ("Onconova"), the U.S. Licensor, announced results from its Phase 3 ONTIME trial of IV rigosertib conducted at clinical trial sites in Europe and the U.S. Although treatment with IV rigosertib plus best supportive care (BSC) did not demonstrate a statistically significant improvement in median overall survival when compared to BSC only, post-hoc analysis demonstrated a statistically significant increase in median overall survival in the subset of patients who had progressed on or failed previous treatment with hypomethylating agents (HMAs) (i.e., had not responded to HMAs), thus demonstrating potential activity of rigosertib in these MDS patients
Onconova continues discussions with the U.S. and European regulatory agencies regarding the possibility of approval based on top-line results of the Phase III ONTIME trial. These discussions have consequently led Onconova to focus its development efforts on the unmet medical need of patients who do not respond to treatment with the current standard of care, hypomethylating agents ("Primary HMA Failure"). Onconova announced its future development plan for Primary HMA Failures.
The Company will continue with its development of IV rigosertib in Japan based on Onconova's development plan in the US and Europe.
Patient enrollment for the Phase I clinical trial of SyB C-1101 (oral formulation, or "Oral rigosertib") in lower risk MDS was completed in August, 2014.

2. Overseas

In June, 2014, SyB L-0501 was approved by the Ministry of Food and Drug Safety (MFDS) in South Korea for the indication of refractory/relapsed low-grade non-Hodgkin's lymphoma. In addition to the earlier approval of chronic lymphocytic leukemia and multiple myeloma, Eisai Korea Inc. (Eisai Korea), a Korean subsidiary of Eisai, promotes the product for these three indications. The Company's overseas sales continue to grow steadily as planned and have increased by 2.2 times compared to budget, in particular because the Company received a purchase order from Eisai Korea in connection with

their change of packaging facility in FY 2014, and recognized the related sales revenue which had been originally expected in FY 2015.

3. Fundraising

The Company passed a resolution on November 14, 2014, to issue a 2nd unsecured bond with convertible bond-type stock acquisition rights (total issue price: 500 million yen) with Oak Capital Corporation as the allottee, and the 34th warrant (total issue price: 10,363 thousand yen, total issue price of stock when issued through the exercise of stock acquisition rights: 1,000 million yen). Accordingly, Oak Capital Corporation completed payment of 510,363 thousand yen to the Company on December 1, 2014. With regard to the 2nd unsecured bond with convertible bond-type stock acquisition rights, all stock acquisition rights have been exercised and all bonds converted to the Company's common stock in December, 2014.

4. Business results

As a result of the above, net sales totaled 1,955,027 thousand yen for the fiscal year ended December 31, 2014, primarily reflecting product sales of SyB L-0501 in Japan and overseas markets. Net domestic sales of TREAKISYM® showed a year-on-year increase of 12.9%. While net overseas sales increased by 3.6 times compared to the previous fiscal year mainly due to the recognition of sales from the fulfillment of early purchase orders in South Korea, milestone revenue showed a year-on-year decrease of 85.0%. In total, net sales increased by 27.6% compared to the previous fiscal year.
Selling, general and administrative expenses totaled 1,829,918 thousand yen (a year-on-year decrease of 8.4%), including research and development ("R&D") expenses of 774,103 thousand yen (a year-on-year decrease of 26.5%) primarily due to expenses associated with clinical trials for SyB L-0501, SyB L-1101 and SyB C-1101, and other selling, general and administrative expenses of 1,055,815 thousand yen (a year-on-year increase of 11.6 %).
As a result, operating loss of 1,303,279 thousand yen was recognized for the fiscal year ended December 31, 2014 (operating loss of 1,680,528 thousand yen for the previous fiscal year). In addition, the Company recorded non-operating expenses totaling 22,288 thousand yen primarily comprising commission fees and stock issuance costs, and non-operating income totaling 215,251 thousand yen primarily due to foreign exchange gains. This resulted in an ordinary loss of 1,110,316 thousand yen (ordinary loss of 1,601,424 thousand yen for the previous fiscal year) and net loss of 1,115,877 thousand yen (net loss of 1,605,224 thousand yen for the previous fiscal year).

(2) SymBio's Long Range Plan – Summary and Background

SymBio is the first "specialty pharma" in Japan to specialize in the following three areas: oncology, hematology and autoimmune disease. Although strong demand exists in these therapeutic areas, development remains challenging due to the need for a high degree of specialization. Because major pharmaceutical companies are reluctant to develop drugs for smaller indications and patient numbers in these areas due to questionable returns versus the amount of investment required, oncology, hematology and autoimmune disease are regarded as the "undeserved therapeutic areas" in terms of development in Japan and Asia.

The Company sees business opportunities in these "undeserved therapeutic areas" despite the relatively small market potential, focusing on new drug candidates having high unmet medical needs instead of pursuing new "blockbuster" drugs (where sales often surpass 100 billion yen). Capturing high revenues through the development and sale of drugs in these therapeutic areas is at the core of business development in the Company.

One significant aspect of the Company's business model is the lack of its own research and manufacturing facilities, outsourcing and overseeing the clinical development of quality that drug candidates that it has in-licensed from pharmaceutical companies in the US and/or Europe. This enables the Company to avoid a large capital investment and to conduct effective business operations with low fixed costs. Also, by focusing on later stage drug candidates that have been tested for efficacy and safety in clinical trials, the development period is shortened, thus lowering the overall development cost and risk.

The Company is building a strong pipeline portfolio and aiming for an early return to profitability through these efforts.

SymBio's Long Range Plan is as follows:

- Maximize the value of our main product, TREAKISYM®, for which manufacturing and marketing approval has been granted in refractory/relapsed low-grade non-Hodgkin's lymphoma and mantle cell lymphoma, and aggressively pursue the expansion of indications (life cycle management).
- Develop the anticancer agent SyB L-1101 (intravenous formulation) /C-1101 (oral formulation) (generic name; rigosertib) as therapy for MDS. Development decisions regarding the development of rigosertib for solid tumors will be made after considering the status and data of development overseas.
- Proactively negotiate with the aim of in-licensing new drug candidates during FY2015 while continuously searching for and evaluating other new drug candidates.
- Increase selling, general and administrative expenses, mainly research and development costs, in order to in-license and begin the development of new drug

candidates, and undertake clinical trials with the aim of launching SyB L-1101/C-1101.

- Proactively develop and commercialize drugs for Asian markets that are expected to experience rapid growth (China, Hong Kong, Taiwan, South Korea and Singapore).

(3) Business Status, Outlook and Other Assumptions

○ SyB L-0501 (generic name: bendamustine hydrochloride; trade name: TREAKISYM®)

- Domestic sales of TREAKISYM® began through Eisai, our business partner, with the drug's launch in December, 2010, for refractory/relapsed low-grade non-Hodgkin's lymphoma and mantle cell lymphoma. Sales have been increasing steadily and market share has reached a high point.
- Going forward, in order to further increase sales, the Company aims to strengthen its marketing arrangement for TREAKISYM® with Eisai, achieve product differentiation from targeted competing drugs, and will endeavor to obtain early approval for additional indications.
- Regarding clinical trials for additional indications, the Phase II clinical trial for frontline low-grade non-Hodgkin's lymphoma and mantle cell lymphoma has been completed. Taking into account the possibility of approval of this indication in Europe, the Company will continue to prepare for the filing of marketing approval in Japan. The Company has completed patient enrollment in its Phase II clinical trial for chronic lymphocytic leukemia, and will prepare for filing of marketing approval in Japan upon completion of the trial.
- Regarding the additional indication of refractory/relapsed intermediate/high-grade non-Hodgkin's lymphoma, the Phase II clinical trial generated positive data and the Company will continue to pursue approval of this indication.

○ SyB L-1101 (intravenous formulation) and SyB C-1101 (oral formulation); generic name: rigosertib

- With regard to SyB L-1101 (intravenous formulation), patient enrollment of the Phase I clinical trial for the target indication of refractory/relapsed higher risk MDS was completed in January, 2015. The Company will reassess its domestic development plan, taking into account Onconova's development plan in the U.S. and Europe.
- Regarding SyB C-1101 (oral formulation), the Company will continue to advance the development of rigosertib for higher risk MDS (in combination with azacitidine) and transfusion-dependent lower risk MDS. As for development relating to solid tumor, determination will be made after consideration of overseas development status and data.

○ Expansion to other Asian markets

- SyB L-0501 has been approved and is being marketed in Singapore, Hong Kong, South Korea and Taiwan, with sales growing at a steady rate. Sales in these markets are being generated through local partners. In order to maximize sales in Asian markets, the Company will work toward further strengthening its business alliances.
- With regard to SyB L-1101/C-1101, the Company owns the exclusive right to develop and market the drug in South Korea as well as Japan, and will continue to pursue approval in this market.

○ New drug candidates

- The Company will continue current negotiations with several companies with the aim of in-licensing during FY2015.

II. Earnings Forecast and Performance Target

(Unit: millions of yen)

Fiscal year	Net sales	Operating income (loss)	Ordinary income (loss)	Net income (loss)
FY 2014 (Actual)	1,955	(1,303)	(1,110)	(1,115)
FY 2015 (Forecast)	1,870	(2,452)	(2,481)	(2,485)
FY 2016 (Target)	2,919 to 2,148	(2,390) to (3,005)	(2,419) to (3,034)	(2,422) to (3,038)
FY 2017 (Target)	3,754 to 2,160	(2,525) to (3,492)	(2,554) to (3,521)	(2,557) to (3,524)

Assumptions and Numerical Basis for Projections and Performance Targets

○ With regard to sales, TREAKISYM® makes up the majority of product sales. The performance target for drug sales assumes that new drugs (additional indications) are approved as assumed in the business plan, and figures are derived after detailed analysis and discussions on market size projections, competitive positioning vis-à-vis existing therapies, market dominance, and sales performance after the commencement of sales. Furthermore, milestone revenue is estimated based on the Company's development plan.

○ Cost of sales is estimated based on the provisions of existing license agreements.

○ Selling and general administrative expenses mainly consist of research and development ("R&D") expenses or other selling expenses and general administrative expenses.

- Research and development expenses are estimated based on "III. Other reference information – Status of Development Portfolio and Performance Targets". With regard to TREAKISYM®, since the business alliance agreement with Eisai provides that R&D expenses shall be split equally between the two parties, half of the estimated expenses are assumed. Milestone payments are estimated in accordance with provisions in the existing contract. In-licensing and development costs for one or two new drug candidates are estimated based on the current status of negotiations.
- Other selling and general administrative expenses mainly consist of expenses incurred from TREAKISYM® marketing, new business development, production & distribution and administrative operations. With regard to TREAKISYM®, since the business alliance agreement with Eisai provides that marketing expenses shall be split equally between the two parties, half of the estimated expenses are assumed, similar to the R&D expenses.

○ With respect to the additional indication of refractory/relapsed intermediate/high-grade

non-Hodgkin’s lymphoma, no related sales and expenses are assumed.

○ As stated in “I. (3) Business Status, Outlook and Other Assumptions,” application for approval for the indication fist-line low-grade non-Hodgkin's lymphoma is dependent upon the outcome of approval in Europe. Therefore, numerical assumptions were made based on two scenarios (approval obtained in Europe / approval not obtained in Europe) and presented as the maximum and minimum figures.

III. Other Reference Information

Status of Development Portfolio and Performance Targets

Development code Therapeutic category	Indication	Preclinical study	Phase I clinical trial	Phase II clinical trial	File for Marketing Approval	Marketing Approval
SyB L-0501 Anticancer drug	Refractory/relapsed low-grade non-Hodgkin's lymphoma; mantle cell lymphoma	Marketing Approval (October, 2010)				
	Frontline low-grade non-Hodgkin's lymphoma; mantle cell lymphoma					
	Chronic lymphocytic leukemia					
	Refractory/relapsed intermediate/high-grade non-Hodgkin's lymphoma	Phase II completed				
SyB L-1101 Anticancer drug (Intravenous formulation)	Refractory/relapsed higher risk MDS (myelodysplastic syndrome)	To be determined based on Onconova's development plan				
SyB C-1101 Anticancer drug (Oral formulation)	Higher risk MDS (in combination with azacitidine)	Participation in global clinical trials to be considered				
	Transfusion-dependent lower risk MDS	Participation in global clinical trials to be considered				

Note 1. : The development plan
: Completed as of December 31, 2014 (FY 2014)
: FY 2015 target
: FY 2016 target
: FY 2017 target

2. With regard to SyB C-1101, upon completion of the Phase I clinical trial for the target indication of higher risk MDS currently underway in Japan, the Company plans to carry out development for the indications of higher risk MDS (in combination with azacitidine) and transfusion-dependent lower risk MDS. The Company will consider its participation in global clinical trials for such development.

Portfolio summary and issues for achieving plans are set out below.

○ **SyB L-0501 (generic name: bendamustine hydrochloride; trade name: TREAKISYM®)**

Summary:

- Bendamustine hydrochloride was used in Germany for many years as an anticancer drug for non-Hodgkin's lymphoma, multiple myeloma and chronic lymphocytic leukemia (trade name: Ribomustin).
- From 2000, the efficacy and safety of this drug has been re-evaluated and it is now approved and sold in 69 countries around the world. In December,2005, the Company obtained the exclusive rights of development and marketing from the licensor, Astellas Deutschland GmbH, a German subsidiary of Astellas Pharma Inc., to develop and sell the drug in Japan, China (incl. Hong Kong), South Korea, Taiwan and Singapore, and has obtained approval in all licensed territories with the exception of China. Going forward, the Company will continue to collaborate closely with local business partners to maximize sales.
- In Japan, manufacturing and marketing approval was obtained in October, 2010, for refractory/relapsed low-grade non-Hodgkin's lymphoma and mantle cell lymphoma, and sales initiated through Eisai, a business alliance, in December, 2010. Since its launch in Japan, his TREAKISYM® has been administered to over 9,500 patients (estimated by the Company) by the end of FY 2014.
- In order to expand the value of TREAKISYM®, the Company is working on development for other indications such as frontline low-grade non-Hodgkin's lymphoma, mantle cell lymphoma and chronic lymphocytic leukemia. The Company's future development plan for the additional indication of refractory/relapsed intermediate/high-grade non-Hodgkin's lymphoma is under consideration.

Issues and Specific Measures:

- Promotion of Indication Expansion

As for fist-line low-grade non-Hodgkin's lymphoma and mantle cell lymphoma, patient enrollment for the Phase II clinical trial has been completed. Since application for approval in Japan is closely linked to approval of the indication in Europe, as soon as such European approval is confirmed, the Company will proceed with the domestic application process.

As for chronic lymphocytic leukemia, patient enrollment has also been completed and the Company will complete the clinical trial as soon as possible followed by preparations to file for marketing approval in Japan.

Regarding the additional indication of refractory/relapsed intermediate/high-grade

non-Hodgkin's lymphoma, the Phase II clinical trial has shown positive results and the Company will continue to make its best efforts in obtaining approval.

Sales and expenses related to this indication are not reflected in this Long Range Plan.

- Maximizing Sales

In Japan, our most significant market, sales of TREAKISYM® are generated through Eisai, our business partner. In order to further promote market penetration, the efficacy and safety of the drug supported by positive data in clinical trials needs to be more widely understood so that it is more often prescribed. To that end, the Company will work closely with Eisai and plan strategies vis-à-vis competing therapies, and aggressively develop marketing strategies such as future collaborations with Eisai on academic conferences and study groups.

○ **SyB L-1101 (intravenous formulation) /C-1101 (oral formulation) (the generic name: rigosertib)**

Summary:

- SyB L-1101/C-1101 is an anticancer drug which functions as a unique multi-kinase inhibitor. Since obtaining exclusive rights to develop and commercialize the in Japan and South Korea from Onconova in July, 2011, the Company has been actively developing this drug. The Company has obtained rights for both the intravenous and oral formulations.
- With regard to development of this drug, currently, Onconova is pursuing development in the U.S. and Europe for the indications of myelodysplastic syndromes ("MDS"), head and neck cancer, ovarian cancer, etc. With regard to the intravenous formulation for refractory/relapsed higher risk MDS, Onconova announced its future development plan for Primary HMA Failure based on the results of its Phase III ONTIME trial. With regard to the oral formulation, the Phase II clinical trial for the indication of transfusion-dependent lower risk MDS is underway, and the Phase I/II clinical trial for the target indication of higher risk MDS (in combination with azacitidine) is also underway.
- Onconova is proceeding with its Phase II clinical trial for the indication of head and neck cancer, and the Company will wait for data generated from the clinical trial to determine whether or not to proceed with domestic development.
- Currently, the Company is conducting a Phase I clinical trials using the intravenous formulation for the target indication of refractory/relapsed higher risk MDS, and the oral formulation higher risk MDS.

Issues and Specific Measures:

- Promotion of Indication Expansion

  With regard to the intravenous formulation, the Company will determine its domestic development plan based on the results of the Phase III clinical trial in refractory/relapsed higher risk MDS which was carried out by Onconova in the U.S. and Europe. Patient enrollment in Phase I clinical trial was completed in January, 2015, with the final process for completion of the trial now underway.

  With regard to the oral formulation, domestic clinical trials will be conducted after taking into consideration two trials: frontline higher risk MDS in combination with azacitidine), and transfusion-dependent lower risk MDS which are currently underway in Europe and the U.S. With regard to solid tumors (head and neck cancer, etc.), the overseas development status/data will be evaluated.

- Use of Overseas Data

  In order to reduce costs and shorten development timelines, the future development of drug candidates in the Company's pipeline will include the participation in global clinical trials whenever possible. The Company will thoroughly review clinical data generated from overseas clinical trials to ensure the quality of domestic marketing approval applications.