

January 28, 2013  
SymBio Pharmaceuticals Limited  
Fuminori Yoshida  
Representative Director  
President and Chief Executive Officer

SymBio Completes Phase II Trial of  
Antiemetic Transdermal Patch (SyB D-0701) in RINV

TOKYO, Japan, January 28, 2013 -- SymBio Pharmaceuticals Limited (JASDAQ: 4582) today announced the completion of the Phase II clinical trial of its antiemetic transdermal patch (SyB D-0701) for the treatment of radiation-induced nausea and vomiting (RINV).

SyB D-0701 is a sustained-release transdermal patch containing granisetron, a commercially available 5-HT<sub>3</sub> antagonist designed to continuously deliver the active agent through the skin for over five days. Radiation therapy, which is categorized into total body irradiation and conventional fractionation, is widely used to treat cancer in combination with various anticancer agent(s) and surgery. Patients often experience treatment related radiation-induced nausea and vomiting (RINV) that can last from a few days to several weeks.

The Phase II trial was a randomized double-blind comparative study consisting of 189 patients who received local radiation therapy. Two patch sizes, 40cm<sup>2</sup> (high dose) and 25cm<sup>2</sup> (low dose), were examined to determine dose response of SyB D-0701 versus placebo to reduce RINV. Statistically significant efficacy was not observed with either the 25cm<sup>2</sup> or 40cm<sup>2</sup> patch in the trial, however, with the 40cm<sup>2</sup> patch, a higher control rate of RINV versus placebo was observed. Further development of SyB D-0701, pending the results of additional in-depth analyses of Phase II trial results, is being considered.

**[Please see the following for further information on Glossary and SymBio ]**

[Contact]

Hiroki Maekawa

Board Director, Corporate Officer, Chief Financial Officer

Tel: +081(0)3 5472 1125

## **Glossary**

<sup>1</sup>**Local radiation therapy:** high energy radiation that is focused on tumors to destroy cancer cells and suppress cancer cell growth.

<sup>2</sup>**Randomized double-blind comparative study:** an experimental trial in which neither the subjects of the experiment nor the persons administering the experiment know the critical aspects of the experiment; a double-blind procedure is used to guard against both experimenter bias and placebo effects.

<sup>3</sup>**Placebo:** any substance known not to have any pharmacological effect (produces no meaningful changes in an organism, either chemical or biological, etc.) that is made to appear like an active ('real') drug

<sup>4</sup>**Dose response:** a response pattern over a range of drug doses. Doses lower than the threshold produce no response, while those in excess of the threshold exert no additional efficacy response.

## **About Symbio Pharmaceuticals Limited**

Symbio Pharmaceuticals Ltd, established in March, 2005, by Fuminori Yoshida who previously served concurrently as Corporate VP of Amgen Ltd. and founding President of Amgen Japan (currently Takeda Bio), aspires to be a leading commercial stage specialty pharmaceutical company in Asia Pacific dedicated to addressing underserved medical needs with a main focus in the areas of oncology, hematology and autoimmune disease. The company's underlying corporate mission is "delivering hope to patients in need." Symbio's lead drug candidate, TREAKISYM® (bendamustine hydrochloride), has been successfully developed and launched in Japan for refractory/relapsed indolent non-Hodgkin's lymphoma (NHL) and mantle cell lymphoma. The company is also actively developing bendamustine in several Phase II trials in Japan: frontline indolent NHL, refractory/relapsed aggressive NHL (Phase II completed), and refractory/relapsed multiple myeloma. The product has been launched in Hong Kong, Singapore, Korea and Taiwan. For additional information, please visit our homepage at <http://www.symbiopharma.com>.