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## **SBI HOLDINGS, INC.**

(Incorporated in Japan with limited liability)

(Stock code: 6488)

### **OVERSEAS REGULATORY ANNOUNCEMENT**

This announcement is made pursuant to Rule 13.09(2) of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited.

Please refer to the attached copy of the Announcement.

On behalf of the Board

**SBI Holdings, Inc.**

**Yoshitaka Kitao**

*Representative Director,*

*President & Chief Executive Officer*

Japan, 30 October 2012

*As of the date of this announcement, the executive Directors are Mr Yoshitaka Kitao, Mr Taro Izuchi, Mr Takashi Nakagawa, Mr Tomoya Asakura, Mr Shumpei Morita, Mr Noriaki Maruyama and Mr Peilung Li, the non-executive Directors are Mr Yasutaro Sawada, Mr Hiroyoshi Kido, Mr Noriyoshi Kimura, Mr Hiroshi Tasaka and Mr Takashi Okita and the independent non-executive Directors are Mr Masaki Yoshida, Mr Kiyoshi Nagano, Mr Keiji Watanabe, Mr Akihiro Tamaki and Mr Masanao Marumono.*

October 30, 2012  
SBI Holdings, Inc.  
(TOKYO: 8473 / Hong Kong: 6488)

## **SBI Pharmaceuticals Submits a Phase-1 Clinical Trial CTA to MHRA for a Drug to Treat Cancer Chemotherapy-induced Anemia**

SBI Pharmaceuticals Co., Ltd., (Head office: Minato-ku, Tokyo; Representative Director and CEO: Yoshitaka Kitao), a subsidiary of SBI Holdings, Inc., which researches and develops pharmaceuticals, health foods, and cosmetics using 5-aminolevulinic acid (5-ALA) (\*1) has submitted a clinical trial application (CTA) to the Medicines and Healthcare products Regulatory Agency of the U.K. to conduct a phase-1 clinical trial on a formulation including 5-ALA for treating anemia caused by cancer chemotherapy (\*2).

Cancer chemotherapy-induced anemia is one of the side effects of cancer chemotherapy drugs, and 43.2% (\*3) of patients under treatment using such drugs are said to have symptoms of anemia. Currently, erythrocyte transfusions and erythropoietin preparations are used to treat anemia caused by cancer chemotherapy. However, their prescription is limited, because they have side effects depending on dosage. As a result, a definitive treatment for cancer chemotherapy-induced anemia has not been established, and there is a pressing need to develop a treatment.

Formulations including 5-ALA are expected to improve symptoms of anemia by activating the hematopoietic capability.

As soon as the CTA is accepted by the Medicines and Healthcare products Regulatory Agency, SBI Pharmaceuticals plans to start a clinical trial in the U.K. by the end of this year. The clinical trial will study the safety of the formulation in healthy subjects and lead to a more comprehensive follow-up clinical trial.

SBI Pharmaceuticals will continue to pursue various potential applications of 5-ALA, and focus on research and development to provide pharmaceuticals that satisfy the unmet medical needs of as many people as possible around the world.

(\*1) 5-aminolevulinic acid (5-ALA): An amino acid created in mitochondria. It is an important substance that serves as protein material related to energy production in the form of hemes and cytochromes, and its productivity is known to decrease with age. 5-ALA is contained in shochu distillation remnants, red wine and food such as radish sprouts. It is also known as a material forming chloroplasts in plants.

(\*2) Anemia caused by cancer chemotherapy means: symptoms of anemia arising from a decline in erythrocyte production capability, mainly caused by bone marrow suppression attendant upon cancer treatment using chemotherapy. While chemotherapy destroys cancer cells, at the same time it damages normal cells. In particular, bone marrow that produces blood is readily affected by chemotherapy, resulting in various symptoms, including anemia.

(\*3) Source of data: Wu Y, Aravind S, Ranganathan G, Martin A, Nalysnyk L. *Clin Ther.* 2009;31:2416-2432.

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