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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, 6 July 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 Li Peilung, 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.



July 6, 2012 SBI Holdings, Inc.

(TOKYO: 8473 / Hong Kong: 6488)

SBI Pharmaceuticals Co., Ltd.

## Notice on application for marketing approval of in vivo diagnostic agent for malignant glioma in Japan

SBI Pharmaceuticals Co., Ltd. (head office: Minato-ku, Tokyo; Representative Director and CEO: Yoshitaka Kitao; "SBI Pharmaceuticals") ,affiliate company of SBI Holdings, Inc. ,is engaged in research and development of cosmetics, health foods and drugs using 5-aminolevulinic acid (5-ALA). SBI Pharmaceuticals and Nobelpharma Co., Ltd. (head office: Tokyo; President: Jin Shiomura; "Nobelpharma") have collaborated on commercialization of an in vivo diagnostic agent (active pharmaceutical ingredient: aminolevulinic acid hydrochloride; "the ALA diagnostic agent") for the surgical resection of malignant glioma, a type of brain tumor. We would like to announce that it submitted a new drug application (NDA) to the Ministry of Health, Labor and Welfare in Japan for the ALA diagnostic agent on July 5, 2012. This ALA diagnostic agent was also granted an orphan drug (drug used for treating rare diseases) designation in September of 2010.

The agent has already been marketed in more than 20 European countries including Germany and the U.K., by Medac GmbH, a business partner of SBI Pharmaceuticals, with approval from the European Medicines Agency (EMA). SBI Pharmaceuticals and Nobelpharma have conducted a clinical study of the ALA diagnostic agent as part of their collaboration in Japan under a license agreement between Medac GmbH and SBI Pharmaceuticals.

In a clinical study in Japan, the efficacy and safety of the ALA diagnostic agent was verified by orally administering it several hours before the surgical resection of tumors. It allows doctors to completely discriminate tumors from normal tissues by making them glow red when a special light is applied to the affected area during operation. SBI Pharmaceuticals and Nobelpharma believe the results of this clinical study will help improve tumor resection rates and outcomes in Japan while also reducing the physical burden placed on patients both during and after operations.

## ■ SBI Pharmaceuticals

SBI Pharmaceuticals Co., Ltd. is a joint venture company founded by SBI Holdings, Inc. and COSMO Oil Co., Ltd. in 2008 for the research, development and sale of products containing 5-ALA (5-aminolevulinic acid). The purpose of SBI Pharmaceuticals Co., Ltd. is to provide 5-ALA-based products in the field of medicine, health foods and cosmetics. SBI

Pharmaceuticals Co., Ltd. is committed to enriching people's lives by creating innovative products that utilize 5-ALA. For

details of SBI Pharmaceuticals Co., Ltd., please visit <a href="http://www.sbipharma.co.jp/">http://www.sbipharma.co.jp/</a>.

Nobelpharma Co., Ltd.

Nobelpharma Co., Ltd. was founded in 2003 with the mission to contribute to medical services through providing

pharmaceutical products for important unmet needs. The company has already received the marketing approval of 5 new

drugs and delivered them to patients in need of them. All of these drugs have been used for the treatment that is less

satisfied with existing drugs ever. Continuously, the company is devoting itself to research and development of

pharmaceuticals for critical unmet needs, such as orphan drugs, drugs for off-label use, and drugs for inveterate diseases.

For more information about Nobelpharma Co., Ltd., please go to the company's website: http://www.nobelpharma.co.jp

■ 5-aminolevulinic acid (5-ALA)

5-ALA is a type of natural amino acid that has survived the last 3,600 million years and is contained even in food products

such as red wine and radish sprouts. It is known to get involved in production of chlorophyll, which is essential for

photosynthesis in plants, and in production of vitamin B12, blood constituents and intracellular energy in animals. 5-ALA

is well known as an extremely important and essential ingredient for any species. It is used in a wide range of applications

from intraoperative diagnosis of brain tumors and cancer screening in the medical field, anemia prophylaxis in the health

foods field, to care for pimples and rough skin in the cosmetics field.

■ Glioma

Glioma is a tumor that arises from the glial cells of the brain, many of them malignant tumors with poor prognosis.

Gliomas account for about 30% of all primary brain tumors, classified into several types according to the form of cells

composing tumors. Astrocytomas, the most common gliomas, are broadly grouped by malignancy into four grades (Grade

I-IV). In particular, Grade IV, called glioblastoma, represents the most malignant tumors with extremely poor prognosis.

The treatment for gliomas is typically done by surgical operations (craniotomies), but complete tumor removal is so

difficult that postoperative radiotherapy and chemotherapy are applied in many cases.

For further information, please contact:

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