



27 August 2013 SBI Holdings, Inc. SBI Pharmaceuticals Co., Ltd.

## Announcement—the new drug "ALAGLIO® Internal Medicine 1.5g", an Orally-administered in vivo Diagnostic for Malignant Glioma, is Listed on the NHI Drug Price List

We are pleased to inform you that SBI Pharmaceuticals Co., Ltd. (Head office: Minato-ku, Tokyo; Representative Director and CEO: Yoshitaka Kitao; "SBI Pharmaceuticals"), a subsidiary of SBI Holdings, Inc., engaged in research and development of pharmaceuticals, health foods and cosmetics using 5-aminolevulinicacid (5-ALA) (\*), announces that the *in vivo* diagnostic drug ALAGLIO® Internal Medicine 1.5 g (generic name: 5-aminolevulinic acid hydrochloride), for which manufacture and marketing approval was obtained in March this year, has been added to the National Health Insurance (NHI) drug price list as of today. The drug is used during surgical resection of malignant glioma. The release date and distribution method in Japan have yet to be determined.

This diagnostic drug, an orally-administered *in vivo* diagnostic drug used in photodynamic diagnosis (PDD) whose aim is to help doctors visualize the tumor tissue during surgical resection of malignant glioma, is already sold in over 20 European countries including Germany and the U.K., by medac GmbH of Germany, a business partner of SBI Pharmaceuticals, with approval from the European Medicines Agency (EMA).

The product is the first drug of SBI Pharmaceuticals, and we will continue research and development on pharmaceuticals using 5-aminolevulinic acid hydrochloride for delivery to patients suffering from a wide range of medical conditions.

## < Product Outline >

Brand name: ALAGLIO® Internal Medicine 1.5g
Generic name: 5-aminolevulinic acid hydrochloride

Efficacy and effectiveness: Visualize tumor tissue during surgical resection of malignant

glioma

Dose and administration: The recommended dose for adult patients is 20 mg per kilogram

of 5-aminolevulinic acid hydrochloride administered orally (after dissolving in water) three hours (range: two to four hours) before

the patient is anaesthetized for surgery

Date of approval for 25 March 2013

manufacturing and marketing:

Date of NHI drug price listing: 27 August 2013

Manufactured and distributed by: SBI Pharmaceuticals Co., Ltd.

NHI drug price: JPY 87,867.30





\* 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

For further information, please contact:

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