



26 September 2013 SBI Holdings, Inc. SBI Pharmaceuticals Co., Ltd.

New Launch of "ALAGLIO® Internal Medicine 1.5g," an Orally-administered in vivo Diagnostic Agent for Malignant Glioma

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-aminolevulinic acid (5-ALA) (*), announces that today the *in vivo* diagnostic agent for use in the surgical resection of malignant glioma, ALAGLIO® Internal Medicine 1.5g (generic name: 5-aminolevulinic acid hydrochloride), for which manufacture and marketing approval was obtained in March this year, has been newly launched.

This diagnostic agent, an orally-administered *in vivo* diagnostic agent 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 pharmaceutical agent 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:

NHI drug price: JPY 87,867.30 (Date of NHI drug price listing:27 August 2013)

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

^{* 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:

SBI Holdings, Inc.: Corporate Communications Dept., Tel: +81 3 6229 0126

SBI Pharmaceuticals Co., Ltd.: Division of Drug Development, Tel: +81 3 6229 0095