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SBI Holdings, Inc.

SBI Pharmaceuticals Co., Ltd.

**SBI Pharmaceuticals Obtains Manufacture and Marketing Approval for Orally-administered *in vivo* Diagnostic Agent “ALAGLIO®” for Malignant Glioma**  
**— Japan’s First Orally-administered Fluorescence Diagnostic Agent for Use in the Surgical Resection of Brain Tumor**

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., which is engaged in research and development of pharmaceuticals, health foods and cosmetics using 5-aminolevulinic acid (“5-ALA”), has obtained approval from the Ministry of Health, Labour and Welfare for manufacture and marketing of an *in vivo* diagnostic agent that is used during the surgical resection of malignant glioma, a type of brain tumor.

SBI Pharmaceuticals and Nobelpharma Co., Ltd. (Head office: Tokyo; President: Jin Shiomura; “Nobelpharma”), a manufacturer of prescription drugs, had jointly developed the said diagnostic agent, whose ingredient is “5-aminolevulinic acid hydrochloride,” and applied for its approval. This time, SBI Pharmaceuticals has obtained approval for the agent, with “ALAGLIO® Internal Medicine 1.5g” as its brand name.

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). In Japan, SBI Pharmaceuticals and Nobelpharma have jointly developed the agent based on a license agreement between photonamic GmbH & Co. KG, a subsidiary of medac, and SBI Pharmaceuticals.

In a clinical study in Japan, conducted in association with the application for approval of the said diagnostic agent, the efficacy and safety of the agent were verified by orally administering it to subjects, two to four hours before surgical resection of tumors. It allows doctors to easily discriminate tumors from normal tissues by making them glow red when a special light is applied to the affected area during an operation.

SBI Pharmaceuticals believes that since the manufacturing and marketing of ALAGLIO® have been approved in Japan, this product will contribute to improving tumor resection rates in the surgical resection of brain tumor, and become useful as a new treatment option that can reduce the physical burden placed on patients both during and after operations.

The agent became the first pharmaceutical agent for SBI Pharmaceuticals, and we continue research and development of pharmaceuticals using “5-aminolevulinic acid hydrochloride” in many various fields.

## References

### ■ 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 <http://www.sbipharma.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.

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