

November 30, 2010
SBI Holdings, Inc.
SBI ALApromo Co., Ltd.
Nobelpharma Co., Ltd.

Announcement of orphan drug designation granted to orally active *in vivo* diagnostic agent for malignant glioma

SBI ALApromo Co., Ltd. (head office: Minato-ku, Tokyo; Representative Director and CEO: Yoshitaka Kitao; “SBI ALApromo”), a subsidiary of SBI Holdings, Inc., that conducts the research and development of cosmetics, health foods and medicines containing 5-aminolevulinic acid (ALA)^{*1} and Nobelpharma Co., Ltd. (head office: Tokyo; president: Jin Shiomura; “Nobelpharma”)^{*2} are pleased to announce that the Ministry of Health, Labor and Welfare has granted orphan designation to an *in vivo* diagnostic agent for use during the surgical resection of malignant glioma^{*3} (active pharmaceutical ingredient: 5-aminolevulinic acid hydrochloride; “the ALA diagnostic agent”) which is currently under clinical development.

As a result of this orphan drug designation, the ALA diagnostic agent has been recognized as medically necessary and will be entitled to various preferential treatments in the development and commercialization of the agent, including preferential clinical trial consultations, priority review or extension of the re-examination period. This designation can also lead to a shorter development period and further support the efforts of SBI ALApromo and Nobelpharma to contribute to higher tumor resection rates, improved outcomes and reduction of patients’ physical burden in the intra- and post-operative periods in Japan.

SBI ALApromo and Nobelpharma will continue with further efforts to provide clinical practice as early as possible with access to the ALA diagnostic agent as a novel option for individuals suffering from malignant glioma.

Glossary:

***1: 5-aminolevulinic acid (ALA)**

"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. "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.

***2: Nobelpharma Co., Ltd.**

Nobelpharma Co., Ltd. was founded in 2003 with the mission to develop pharmaceutical products for important unmet needs and deliver them to patients in need of them.

The company is contributing to medical care by devoting itself to research and development of pharmaceuticals for critical unmet needs, such as orphan drugs, drugs for off-label use, and drugs for children, and supplying them where they are needed. For more information about Nobelpharma Co., Ltd., please go to the company's website: <http://www.nobelpharma.co.jp>

***3: 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.

***4: Orphan Drug**

Orphan drugs are pharmaceutical agents used to treat serious disorders having significant medical needs, but deemed unprofitable due to the limited number of target patients (50,000 or less in Japan). For the purpose of encouraging development from the humanitarian standpoint, preferential treatments, including preferential clinical trial consultations, priority review, and extension of the re-examination period, are granted by the Ministry of Health, Labour and Welfare and Pharmaceuticals and Medical Devices Agency. Together with the medical devices for the treatment of rare diseases, 251 product items have been designated "orphan" since FY1993 (7 items in FY2009).

November 30, 2010
SBI Holdings, Inc.
SBI ALApromo Co., Ltd.
Nobelpharma Co., Ltd.

Announcement of orphan drug designation granted to orally active *in vivo* diagnostic agent for malignant glioma

SBI ALApromo Co., Ltd. (head office: Minato-ku, Tokyo; Representative Director and CEO: Yoshitaka Kitao; “SBI ALApromo”), a subsidiary of SBI Holdings, Inc., that conducts the research and development of cosmetics, health foods and medicines containing 5-aminolevulinic acid (ALA)^{*1} and Nobelpharma Co., Ltd. (head office: Tokyo; president: Jin Shiomura; “Nobelpharma”)^{*2} are pleased to announce that the Ministry of Health, Labor and Welfare has granted orphan designation to an *in vivo* diagnostic agent for use during the surgical resection of malignant glioma^{*3} (active pharmaceutical ingredient: 5-aminolevulinic acid hydrochloride; “the ALA diagnostic agent”) which is currently under clinical development.

As a result of this orphan drug designation, the ALA diagnostic agent has been recognized as medically necessary and will be entitled to various preferential treatments in the development and commercialization of the agent, including preferential clinical trial consultations, priority review or extension of the re-examination period. This designation can also lead to a shorter development period and further support the efforts of SBI ALApromo and Nobelpharma to contribute to higher tumor resection rates, improved outcomes and reduction of patients’ physical burden in the intra- and post-operative periods in Japan.

SBI ALApromo and Nobelpharma will continue with further efforts to provide clinical practice as early as possible with access to the ALA diagnostic agent as a novel option for individuals suffering from malignant glioma.

Glossary:

***1: 5-aminolevulinic acid (ALA)**

"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. "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.

***2: Nobelpharma Co., Ltd.**

Nobelpharma Co., Ltd. was founded in 2003 with the mission to develop pharmaceutical products for important unmet needs and deliver them to patients in need of them.

The company is contributing to medical care by devoting itself to research and development of pharmaceuticals for critical unmet needs, such as orphan drugs, drugs for off-label use, and drugs for children, and supplying them where they are needed. For more information about Nobelpharma Co., Ltd., please go to the company's website: <http://www.nobelpharma.co.jp>

***3: 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.

***4: Orphan Drug**

Orphan drugs are pharmaceutical agents used to treat serious disorders having significant medical needs, but deemed unprofitable due to the limited number of target patients (50,000 or less in Japan). For the purpose of encouraging development from the humanitarian standpoint, preferential treatments, including preferential clinical trial consultations, priority review, and extension of the re-examination period, are granted by the Ministry of Health, Labour and Welfare and Pharmaceuticals and Medical Devices Agency. Together with the medical devices for the treatment of rare diseases, 251 product items have been designated "orphan" since FY1993 (7 items in FY2009).