

September 25th, 2024
SBI Pharmaceuticals Co., Ltd.

**SBI Pharma to succeed Marketing Authorization of “Alabel[®] Oral 1.5g”
from Nobelpharma**

SBI Pharmaceuticals Co., Ltd. (Head office: Minato-ku, Tokyo; Representative Director & President: Yoshitaka Kitao; hereinafter “SBI Pharma”), a subsidiary company of SBI Holdings, Inc. which conducts research and development pharmaceuticals, etc., utilizing 5-aminolevulinic acid(*) will succeed marketing authorization of “Alabel[®] Oral 1.5g,” photodynamic diagnostic agent for malignant glioma, in Japan from Nobelpharma Co., Ltd. (Head office: Chuo-ku, Tokyo; Representative Director: Jin Shiomura; hereinafter “Nobelpharma”) as of October 1st, 2024.

SBI Pharma and Nobelpharma have jointly conducted the clinical trial for obtaining the marketing authorization of Alabel in March 2013 of which Nobelpharma became marketing authorization holder based on a license from photonamic GmbH & Co. KG (Head office: Pinneberg, Germany, CEO: Ulrich Kosciessa, Ph.D.; hereinafter “photonamic”). Now SBI Pharma will succeed the marketing authorization of Alabel based on a license agreement with photonamic GmbH & Co. KG, a subsidiary company of SBI Holdings, Inc. After the transfer, SBI Pharma will promote the proper use and sales as a Marketing Authorization Holder and a Seller.

With this succession of marketing authorization, SBI Pharma will be the sole Marketing Authorization Holder of intraoperative diagnostic drugs using 5-ALA in Japan, including “ALAGLIO[®] Divided Granules 1.5g” and “ALAGLIO[®] Oral 1.5g” (Distributor: Nippon Kayaku Co., Ltd.), which are intraoperative diagnostic drugs for bladder cancer whose usage was recently changed.

SBI Pharma strives to contribute to everyone’s health and prosperity, by delivering Alabel to patients and healthcare professionals involved in the treatment of cancers.

■Alabel[®] Oral 1.5g

Alabel is the diagnostic drug used in photodynamic diagnosis (PDD) during surgical resection

of malignant glioma, and it is already marketed in over 45 countries worldwide including EU countries and the United States, etc.

In Japan, SBI Pharma and Nobelpharma have conducted the clinical trial as joint business. By the trial, the safety and efficacy of distinguishing tumor lesion from normal tissue by dissolving Alabel in water and administer orally 3 hours (range: 2-4 hours) prior to to induction of anesthesia during malignant glioma surgery and making the tumor glow red by the irradiating with a specific wavelength of light were confirmed.

■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.

* 5-aminolevulinic acid is an amino acid produced in the mitochondria of the body. When 5-aminolevulinic acid is taken up by cancer cells, its main metabolic product, protoporphyrin IX, accumulates. By utilizing the property of protoporphyrin IX emitting fluorescence when irradiated with excitation light, it has been put to practical use as an intraoperative cancer diagnostic agent by visualizing cancer, and further development is ongoing.

For further information, please contact:

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