

September 25, 2024
Nobelpharma Co., Ltd.

Marketing Approval for “Alabel® Oral 1.5 g” Succeeded by SBI Pharma

Nobelpharma Co., Ltd. (Headquarters: Chuo-ku, Tokyo, Managing Director & CEO: Jin Shiomura) (“Nobelpharma”) announced today that its “Alabel® Oral 1.5 g,” photodynamic diagnostic agent for malignant glioma, (“Alabel”) will be succeeded by SBI Pharmaceuticals Co., Ltd. (Headquarters: Minato-ku, Tokyo, Representative Director & President: Yoshitaka Kitao) (“SBI Pharma”), a subsidiary of SBI Holdings, Inc. as of October 1, 2024.

Nobelpharma received the marketing approval for Alabel on March 2013 in Japan after the clinical trial conducted by Nobelpharma and SBI Pharma as their joint project. This time Nobelpharma has reached an agreement with photonamic GmbH & Co. KG (Headquarters: Pinneberg, Germany, CEO: Ulrich Kosciessa) (“photonamic”), a subsidiary of SBI Holdings, Inc., to transfer the marketing approval from Nobelpharma to SBI Pharma.

■ Alabel® Oral 1.5 g

Alabel is a drug used for photodynamic diagnosis (generic name: aminolevulinic acid hydrochloride) during surgical removal of malignant glioma, a type of brain tumor, and has been globally marketed by photonamic through its partner companies in over 45 countries including European countries and the USA.

In Japan, the clinical trial jointly conducted by SBI Pharma and Nobelpharma confirmed the efficacy and safety of Alabel to be resolved in water and administered orally 3 hours (range: 2 – 4 hours) prior to anesthesia induction, making tumor sites glow red under the light of a specific wavelength and easily distinguishable from normal tissues in a surgery to remove malignant glioma.

■ Glioma

Gliomas are tumors of the glial tissues in the brain and are mostly malignant with unfavorable prognosis, accounting for about 30% of primary brain tumors. Gliomas fall into several categories based on shapes of the cells forming the tumors. The most common category is astroglioma, which are broadly graded according to the malignancy into 4 phases (Grade I – IV). In particular, Grade IV is a tumor of highest grade called glioblastoma having extremely poor prognosis. A surgical approach (craniotomy procedure) is normally taken as a standard management for glioma, however, it is difficult

to surgically remove entire tumors and requires post-operative radiotherapy and/or chemotherapy in many cases.

Nobelpharama is committed to continue contributing to society by providing critical but neglected pharmaceuticals and medical devices.

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