FDA has Approved Intraoperative Imaging Agent for Malignant Glioma, One of Brain Tumors, Developed by photonamic

photonamic GmbH & Co. KG (Head office: Wedel, Germany; “photonamic”) is a subsidiary company of SBI Holdings, Inc. (Head office: Minato-ku, Tokyo; Representative Director, President and CEO: Yoshitaka Kitao) and is dedicated to pharmaceutical development business for which uses 5-Amino Levulinic Acid (“5-ALA”)* as the main component in Europe.

photonamic hereby announces that the drug (“the Drug”) is an intraoperative imaging agent for the resection of malignant glioma, a type of brain tumors, and which has been approved by the US Food and Drug Administration (FDA).

The Drug is an oral administration diagnostic drug for photodynamic diagnosis (“PDD”), which visualizes tumor tissues for resection of malignant glioma. The efficacy and the safety of the Drug were proven with the method of which a patient orally administers the Drug 2 to 4 hours prior to the resection and irradiate with light of a defined wavelength in order to distinguish tumor tissues and normal tissues.

The Drug has already been approved as “Gliolan” by European Medicines Agency (EMA) in 2007 and is distributed through photonamic’s partner companies in more than 25 countries including Germany and the UK. In addition, SBI Pharmaceuticals, a group company of SBI Holdings, Inc., is also dedicated to the 5-ALA related business and has been distributing the Drug as “ALAGLIO Oral 1.5g” since 2013 in Japan.

photonamic has been and will keep delivering the Drugs and expanding its business with partners all over the world.

The SBI Group will also continue to pursue various potential applications of 5-ALA, and focus on research and development to provide drug products that satisfy the unmet medical needs of as many people as possible around the world.

(*) 5-aminolevulinic acid (5-ALA)
An amino acid produced in mitochondria. It is an important substance that serves as a functional molecule related to energy production in the form of heme and cytochromes, and its productivity is known to decrease with age. 5-ALA is contained in food such as shochu lees, red wine and Asian ginseng. It is also known as a material forming chloroplasts in plants.

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