

June 23rd, 2026

SBI Pharmaceuticals Co., Ltd.

Notice of Orphan Drug Designation for Ovarian Cancer

SBI Pharmaceuticals Co., Ltd., (Head office: Minato-ku, Tokyo; Representative Director & President: Yoshitaka Kitao), a subsidiary of SBI Holdings, Inc., engaged in the research and development of pharmaceuticals and medical devices regarding 5-aminolevulinic acid (5-ALA) (*1), announces that the Ministry of Health, Labour and Welfare (MHLW) has granted Orphan Drug Designation (*2) for 5-aminolevulinic acid hydrochloride (hereinafter, “the drug”) for the planned indication of visualization of peritoneal dissemination in debulking surgery for ovarian cancer.

Ovarian cancer ranks as the ninth most common cancer among women with annual incidence of approx. 13,000 in Japan and is reported to be the leading cause of death among gynecologic malignancies (*3). Improving treatment outcomes, particularly in advanced ovarian cancer, remains a critical challenge. In the treatment of advanced ovarian cancer, complete tumor resection through surgery is considered one of the most important prognostic factors. We are currently conducting a Phase III clinical trial (ASTROPIC study; jRCT2021250012) in Japan, in collaboration with Nippon Kayaku Co., Ltd. (Head Office: Chiyoda-ku, Tokyo; President: Shigeyuki Kawamura), the authorized distributor, to develop the drug for use in the visualization of peritoneal dissemination in debulking surgery for ovarian cancer (*4).

In the United States, the drug has been granted orphan drug designation by the U.S. Food and Drug Administration (FDA) for ovarian cancer, fallopian tube cancer, and primary peritoneal cancer. In Europe, it has been granted orphan drug designation by the European Commission (EC) for ovarian cancer. In addition, in the United States, a Phase III clinical trial has been conducted to evaluate the visualization of peritoneal dissemination in patients with ovarian cancer.

SBI Pharmaceuticals remains committed to advancing research and development to support healthier and more fulfilling lives. The company continues to strive to make the drug a valuable tool for both patients and healthcare professionals involved in the treatment of ovarian cancer.

- *1 5-ALA is an amino acid produced in the mitochondria of the body. When taken up by cancer cells, its major metabolite, protoporphyrin IX, accumulates. Upon exposure to excitation light, protoporphyrin IX emits fluorescence from the cancer cells. This property has led to the practical use of 5-ALA hydrochloride as an intraoperative diagnostic agent for non-muscle invasive bladder cancer and malignant glioma (brand name: ALAGLIO[®], LABEL[®]).
- *2 Orphan drugs are designated by the Minister of Health, Labour and Welfare after consultation with the opinion of the Pharmaceutical Affairs and Food Sanitation Council based on Article 77-2 of the Pharmaceuticals and Medical Devices Act, as they meet the conditions such as the number of eligible patients in Japan is less than 50,000 and that there is a particularly high medical need for such products. For designation as an orphan drug, the product must meet criteria concerning the number of target patients, medical necessity, and feasibility of development.
- *3 Source: National Cancer Center Japan
- *4 Press release "[Notice of Initiation and First Patient Enrollment in Phase III Study in Patients with Ovarian, Fallopian Tube, or Peritoneal Cancer \(ASTROPIC study\)](#)"

For further information:

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