

March 18, 2011
SBI ALA promo Co., Ltd.

Announcement of publication of ALA research in *International Immunopharmacology*

SBI ALA promo Co., Ltd. (head office: Minato-ku, Tokyo; Representative Director and CEO: Yoshitaka Kitao; “SBI ALA promo”), a subsidiary of SBI Holdings, Inc., that conducts the research and development of cosmetics, health foods and medicines containing 5-aminolevulinic acid (ALA) is pleased to announce that its research paper on the diagnosis and treatment of malignant glioma with ALA (5-aminolevulinic acid) has been published in the *International Immunopharmacology*, March 2011. An international academic journal commonly referred in the fields of immunology and pharmacology around the world. It should be noted that the novel research results are presented in this academic journal.

Name of journal: *International Immunopharmacology* Volume 11, Issue 3, March 2011, Pages 358-365

Title: Novel development of 5-aminolevulinic acid (ALA) in cancer diagnoses and therapy

Abstract: This paper provides a review of the significance of biological responses of heme metabolism and discusses the mechanism of selective accumulation of protoporphyrin (PpIX) in tumor tissues. In addition, to improve the therapeutic effect of ALA-assisted photodynamic therapy (PDT), the paper proposes the use of PDT in combination with thermotherapy or immunotherapy aimed at improving the microenvironment surrounding tumors in the post-operative period and inducing anti-tumor immune responses.

This orally active *in vivo* diagnostic product for the diagnosis and also treatment of malignant glioma (“the ALA diagnostic agent”) is currently being in a Phase III clinical study in collaboration with Nobelpharma Co., Ltd. In light of the fact that there are significant medical needs despite the limited number of patients with malignant glioma in Japan, the Ministry of Health, Labor and Welfare has granted orphan drug designation to the agent in order to encourage its development.

SBI ALA promo 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.