October 22, 2015
SBI Holdings, Inc.
SBI Pharmaceuticals Co., Ltd.

Registration of a U. S. Patent on a Method for Treating Diabetes Containing 5-ALA as an Active Ingredient

SBI Pharmaceuticals Co., Ltd. (Head office: Minato-ku, Tokyo; Representative Director and CEO: Yoshitaka Kitao; "SBI Pharmaceuticals"), a subsidiary of SBI Holdings, Inc., engages in research and development of pharmaceuticals, health foods and cosmetics using 5-aminolevulinic acid ("5-ALA")[*1]. We are pleased to inform you that a U. S. Patent was registered on a method for treating diabetes containing 5-ALA as an active ingredient. As announced in the press release on January 14, 2015, we already obtained this corresponding patent in Japan.

Patent number:	US 9,095,165 B2
Title of invention:	Prophylactic/ameliorating agent for adult diseases comprising 5-aminolevulinic acid, derivative of 5-aminolevulinic acid, or salt of 5-aminolevulinic acid or the derivative of 5-aminolevulinic acid as active ingredient
Claims	A method for treating an adult disease, comprising administering a composition consisting essentially of 5-aminolevulinic acid (ALA), its ester derivative or acyl derivative, or a salt thereof to a subject in need thereof, wherein the adult disease is diabetes
Assignee:	SBI Pharmaceuticals Co., Ltd.
Filing date:	October 27, 2009

SBI Pharmaceuticals has been presently developing business in the Middle East, especially Bahrain, where the ratio of diabetes (including IGT (*2)) is extremely high at 24.6% (*3). The Department of Diabetes at Bahrain Defense Force Royal Medical Service Hospital has been conducting clinical studies on type 2 diabetes by using a high dose of 5-ALA, and a food intervention trial was completed in July. Since the safety and efficacy of high dose of 5-ALA was already confirmed in this trial, the result of the trial will be announced in Bahrain in November. In addition, preparations are currently underway to conduct similar clinical studies in collaboration with the Arabian Gulf University Hospital and Royal College of Surgeons in Ireland - Medical University of Bahrain.

SBI Pharmaceuticals also published research papers on the results of clinical studies conducted jointly with Hiroshima University (Higashikawa F et al. *Nutrition* 2013 Jul–Aug; 29(7-8): 1030–6), University of Hawaii (Rodriguez, BL et al. *Clin. Trans. Sci. 2012* Aug; 5(4): 314–20), and the Institute of Medical Science, the University of Tokyo (Yamashita N et al. *Functional Foods in Health and Disease 2014*; 4(9) 415–428).

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

*1: 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 and red wine. It is also known as a material forming chloroplasts in plants.

*2: Impaired Glucose Tolerance

*3: (Source) International Diabetes Federation, Diabetes Atlas 6th Edition

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