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SBI Holdings, Inc.

SBI Pharmaceuticals Co., Ltd.

Presentation of Research Paper on 5-ALA by Kochi University to *PLoS ONE*, a U.S. Scientific Journal

— Findings of 5-Aminolevulinic Acid (5-ALA) in Protecting against Cisplatin-Induced Acute Kidney Injury (AKI) —

The SBI Group is engaged in research and development of pharmaceuticals, health foods and cosmetics using 5-aminolevulinic acid ("5-ALA") at SBI Pharmaceuticals Co., Ltd. (Head office: Minato-ku, Tokyo; Representative Director and CEO: Yoshitaka Kitao; "SBI Pharmaceuticals"), a subsidiary of SBI Holdings, Inc. (SBIH). We are pleased to inform you that Professor Yoshio Terada, Department of Endocrinology, Metabolism and Nephrology, Kochi Medical School, Kochi University, and Professor Taro Shuin, Department of Urology, Kochi Medical School, Kochi University, who conduct cooperative research with SBI Pharmaceuticals, published a research paper "5-Aminolevulinic Acid Protects against Cisplatin-Induced Nephrotoxicity without Compromising the Anticancer Efficiency of Cisplatin in Rats In Vitro and In Vivo" in ***PLoS ONE***, a U.S. scientific journal, as follows.

Journal carrying the paper:	***PLoS ONE***
Title:	5-Aminolevulinic Acid Protects against Cisplatin-Induced Nephrotoxicity without Compromising the Anticancer Efficiency of Cisplatin in Rats In Vitro and In Vivo
Summary:	Nephrotoxicity is a frequent and major limitation in Cisplatin (CDDP; a type of anticancer agent)-based chemotherapy. The aim of this study is to evaluate the protective role of 5-aminolevulinic acid (5-ALA) in CDDP-induced acute kidney injury (AKI). CDDP, when used alone, increased Cr (creatinine) and BUN (blood urea nitrogen) in rat renal tissues. However, application of 5-ALA significantly reduced these changes. In addition, 5-ALA ameliorated CDDP-induced morphological renal damage. An evaluation of the protective role of 5-ALA at the protein and gene levels in renal tubular cells in addition to renal tissues confirmed that 5-ALA treatments increased Heme Oxigenase (HO)-1 expression. Furthermore, an evaluation of the size of transplanted bladder carcinoma to the rat skin confirmed that 5-ALA does not change the anticancer effects of CDDP. These pieces of data suggested that 5-ALA has the potential to prevent CDDP nephrotoxicity without compromising its anticancer efficacy.

Based on the results of the study, the researchers confirmed that 5-ALA + Fe have the potential to prevent CDDP (a type of anticancer agent) nephrotoxicity. 5-ALA + Fe treatment is believed to block CDDP-induced oxidative stress. Therefore, 5-ALA + Fe treatment is believed to be effective for treating acute kidney injury (AKI) induced by other anticancer agents, sensitizers, and antibacterial agents, expanding the scope of the future 5-ALA study.

SBI Pharmaceuticals will continue to explore various possibilities of utilizing 5-ALA and conduct R&D on it, hoping to contribute to the health of as many people as possible in the world.

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