

January 14, 2021
SBI Holdings, Inc.
SBI Pharmaceuticals. Co., Ltd.

Notice Regarding Case Reports on Treatment with 5-Aminolevulinic Acid Phosphate for Patients with New Coronavirus Infection (COVID-19)

SBI Pharmaceuticals Co., Ltd., (Head office: Minato-ku, Tokyo; Representative Director & President: Yoshitaka Kitao; “SBI Pharmaceuticals”), a subsidiary of SBI Holdings, Inc., engaged in research and development of pharmaceuticals, health foods and cosmetics using 5-aminolevulinic acid (“5-ALA”)*1, hereby announces that SBI Pharmaceuticals and Showakai Medical Corporation Hanzomon Gastrointestinal Clinic (Clinic Director: Kazutoshi Kaketani, MD/PhD; “Hanzomon Gastrointestinal Clinic”) has created case reports on treatment with 5-aminolevulinic acid phosphate for patients with new coronavirus infection (COVID-19), and uploaded the reports on the pre-print depository of “Open Science Framework (OSF)”. The case reports have been submitted to Case Reports in Infectious Diseases and are now under critical review.

-About case reports-

Site Name : Open Science Framework (OSF) <https://osf.io/>

Title : Safety, Tolerability, and Efficacy of 5-Aminolevulinic Acid Phosphate, an Inducer of Heme Oxygenase 1, in Combination with Sodium Ferrous Citrate for the Treatment of COVID-19 Patients

Author : Kazutoshi Kaketani, M.D., Ph.D., Hanzomon Gastrointestinal Clinic, and Motowo Nakajima, Ph.D., SBI Pharmaceuticals Co. Ltd.

URL : <https://osf.io/azxsm/>

Abstract : The COVID-19 pandemic is the greatest life-threatening disaster currently facing the worldwide population. Patients infected with SARS-CoV-2 suffer from sore throat, dry cough, high fever, fatigue, and headache. In addition, patients often lose their sense of smell and taste in the early stage of the disease. Some patients, especially those with concomitant diseases such as chronic obstructive pulmonary disease (COPD), diabetes, hypertension, and cardiovascular problems, quickly develop severe pneumonia with low arterial oxygen saturation

by pulse oximetry (SpO₂) and multiorgan failure, resulting in sudden death. All of these symptoms are caused by deadly inflammation that occurs in various organs all over the body. Various types of inflammation caused by RNA virus infection have been known to be manageable by induction of heme oxygenase-1 (HO-1) in local tissues, and HO-1 is also known to be a key enzyme for the suppression of RNA viral replication. Therefore, in addition to standard medical care for pneumonic viral infection, we have attempted to treat COVID-19 patients using a highly effective HO-1 inducer, 5-aminolevulinic acid phosphate, in combination with sodium ferrous citrate (5-ALA phosphate with SFC), a supplement formulation registered in Japan as a food with functional claims. Six patients with typical symptoms of COVID-19 and some suspected COPD associated with heavy smoking were received oral administration of multiple doses of 5-ALA phosphate with SFC at the maximum tolerated dose (MTD) for 3 to 7 days followed by treatment with a lower dose of 5-ALA phosphate with SFC for 2 to 3 weeks. The recovery time of each individual patient was significantly shorter than reported for patients who received only standard care for coronavirus infection. These results confirm the safety, tolerability, and efficacy of 5-ALA phosphate with SFC as a therapeutic supplement for patients with acute-phase COVID-19.

This press release is for the purpose of introducing the paper. It does not support the efficacy and safety of 5-aminolevulinic acid phosphate and SFC against the new coronavirus infection (COVID-19). In addition, we do not recommend the purchase or intake of products handled by our group.

(*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, red wine and Asian ginseng. It is also known as a material forming chloroplasts in plants.

(*2) 5-Aminolevulinic acid phosphate has been added to the Ministry of Health, Labor and Welfare's "List of Ingredients Determined as Non-drug if Not Described with Pharmaceutical Efficacy is claimed." It is not a pharmaceutical ingredient.



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