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SBI Holdings, Inc.

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SBI Pharmaceuticals Submits a Phase-2 Clinical Trial CTA to MHRA for a Drug to Treat Cancer Chemotherapy-induced Anemia

SBI Pharmaceuticals Co., Ltd., (Head office: Minato-ku, Tokyo; Representative Director and CEO: Yoshitaka Kitao; hereinafter “SBI Pharmaceuticals”), a subsidiary of SBI Holdings, Inc., which researches and develops pharmaceuticals, health foods, and cosmetics using 5-aminolevulinic acid (5-ALA) (*1) has submitted a clinical trial application (CTA) to the Medicines and Healthcare products Regulatory Agency of the U.K. to conduct a phase-2 clinical trial on a formulation including 5-ALA for treating anemia caused by cancer chemotherapy (hereinafter the “Formulation”) (*2).

Cancer chemotherapy-induced anemia is one of the side effects of cancer chemotherapy drugs, and 43.2% (*3) of patients under treatment using such drugs are said to have symptoms of anemia. Currently, erythrocyte transfusions and erythropoietin preparations are used to treat anemia caused by cancer chemotherapy. However, their prescription is limited, because they have side effects depending on dosage. As a result, a definitive treatment for cancer chemotherapy-induced anemia has not been established, and there is a pressing need to develop a treatment. Formulations including 5-ALA are expected to improve symptoms of anemia by activating the hematopoietic capability.

In the U.K., SBI Pharmaceuticals completed the phase-1 clinical trial of the Formulation this May, and accordingly the safety of the Formulation in healthy subjects has been confirmed. Hereafter, as soon as the CTA is accepted by the Medicines and Healthcare products Regulatory Agency, SBI Pharmaceuticals plans to start the phase-2 clinical trial. The clinical trial will study the efficacy of the Formulation in the actual patients and lead to a more comprehensive follow-up clinical trial.

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

(*1) 5-aminolevulinic acid (5-ALA): An amino acid created in mitochondria. It is an important substance that serves as protein material related to energy production in the form of hemes and cytochromes, and its productivity is known to decrease with age. 5-ALA is contained in shochu distillation remnants, red wine and food such as radish sprouts. It is also known as a material forming chloroplasts in plants.

(*2) Anemia caused by cancer chemotherapy means: symptoms of anemia arising from a decline in erythrocyte production capability, mainly caused by bone marrow suppression attendant upon cancer treatment using chemotherapy. While chemotherapy destroys cancer cells, at the same time it damages normal cells. In particular, bone marrow that produces blood is readily affected by chemotherapy, resulting in various symptoms, including anemia.

(*3) Source of data: Wu Y, Aravind S, Ranganathan G, Martin A, Nalysnyk L. *Clin Ther.* 2009;31:2416-2432.

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