



28 March 2014 SBI Holdings, Inc. SBI Pharmaceuticals Co., Ltd.

Notice Regarding Start of Clinical Studies on Type 2 Diabetes by Using 5-ALA at the Bahrain Defense Force Royal Medical Service Hospital

SBI Pharmaceuticals Co., Ltd. (Head office: Minato-ku, Tokyo; Representative Director and CEO: Yoshitaka Kitao; "SBI Pharmaceuticals") is a subsidiary of SBI Holdings, Inc. engaged in research and development of pharmaceuticals, health foods and cosmetics using 5-aminolevulinic acid (5-ALA) (*1). It has been engaging in the 5-aminolevulinic acid ("5-ALA") business in Bahrain since April 2012. SBI Pharmaceuticals together with the Bahrain Defense Force Royal Medical Service Hospital has been preparing to start clinical studies on type 2 diabetes (*2) by using 5-ALA. We are pleased to inform you that SBI Pharmaceuticals has received approval from the National Health Regulatory Authority ("NHRA") in Bahrain to conduct clinical studies on type 2 diabetes at the Bahrain Defense Force Royal Medical Service Hospital and will start the clinical studies.

SBI Pharmaceuticals will confirm the safety and effectiveness of a combination drug of 5-ALA + Fe for type 2 diabetes patients at the Bahrain Defense Force Royal Medical Service Hospital. This hospital will conduct the clinical studies using the combination drug of 5-ALA + Fe provided by SBI Pharmaceuticals. The clinical studies will be conducted carefully while making periodic reports to the NHRA.

SBI Pharmaceuticals will continue to work closely with the government of Bahrain in accommodating the needs of the country and advancing the business. Simultaneously, we will endeavor to help people around the world stay healthy by further identifying the various possibilities of 5-ALA through pursuing R&D jointly with our partners inside and outside Japan.

(*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) Diabetes can be largely categorized into two groups: type 1 and type 2. Type 1 diabetes is caused by the congenital inability to produce insulin whereas type 2 diabetes is caused by acquired factors including lifestyle-related behaviours. In type 2 diabetes, reduced insulin secretion and reduced insulin sensitivity (a decline in insulin function) cause a rise in blood sugar levels.

For further information, please contact:

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