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SBI Holdings, Inc.

SBI Pharmaceuticals Co., Ltd.

Oxford University

Conclusion of Agreement on Joint Research between the University of Oxford in the United Kingdom and SBI Pharmaceuticals

— Planning to start a phase II clinical trial to assess the effectiveness of 5-ALA in preventing a reduction in cardiac output after heart bypass surgery —

SBI Pharmaceuticals and the University of Oxford in the United Kingdom have signed an agreement for joint research to start a phase II clinical trial to assess the effectiveness of 5-aminolevulinic acid (“5-ALA”) (*1) in preventing a reduction in cardiac output (*2) after heart bypass surgery.

SBI Pharmaceuticals Co., Ltd. (Head office: Minato-ku, Tokyo; Representative Director and CEO: Yoshitaka Kitao; “SBI Pharmaceuticals”) is a subsidiary of SBI Holdings, Inc. (Head office: Minato-ku, Tokyo; Representative Director and CEO: Yoshitaka Kitao; “SBIH”) engaging in research and development of pharmaceuticals, health foods and cosmetics using 5-ALA.

SBI Pharmaceuticals and Professor Houman Ashrafian, Associate Professor of Medicine and Head of Experimental Therapeutics, Radcliffe Department of Medicine, University of Oxford, will discuss the details of a phase II clinical trial. The two parties will jointly submit a test plan to the Medicines and Healthcare products Regulatory Agency (“MHRA”) by the end of the fiscal year and start an investigator-led phase II clinical trial after obtaining approval from the MHRA.

Professor. Ashrafian at the University of Oxford has shown the effectiveness of 5-ALA in preventing cardiac ischemia–reperfusion injury (*3) in preclinical models. Prof Ashrafian presented a proposal to SBI Pharmaceuticals for a clinical trial to assess whether 5-ALA would be effective in preventing ischemia–reperfusion injury related to heart bypass surgery using a pump,. The proposal resulted in the conclusion of an agreement for joint research to implement an investigator-led phase II clinical trial in the United Kingdom.

In heart bypass surgeries using a pump, approximately 30% (*4) of patients experience a low cardiac output state after surgery and require treatment for decreased cardiac output.

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 heme and cytochromes, and its productivity is known to decrease with age. 5-ALA is contained in food such as shochu distillation remnants and red wine. It is also known as a material forming chloroplasts in plants.

*2: The cardiac output is the volume of blood pumped per stroke.

*3: Ischemia–reperfusion injury is a phenomenon that occurs when blood is resupplied to organs and tissues where blood no longer flows. The injury is caused when reperfusion of blood produces toxic materials including active oxygen.

*4: Source: European Journal of Cardio-Thoracic Surgery (2014) 1–9

For further information, please contact:

SBI Pharmaceuticals Co., Ltd.: Corporate Planning Dept., Tel: +81 3 6229 0095