

16 January 2014

SBI Holdings, Inc.

SBI Pharmaceuticals Co., Ltd.

Announcement of the First Successful Surgical Removal of Bladder Cancer in the Middle East Using 5-Aminolevulinic Acid as an Intraoperative Diagnostic Drug at a Medical Center of Arabian Gulf University in Bahrain

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. We are pleased to inform you that King Abdulla Medical City (“KAMC”), a medical center of Arabian Gulf University (“AGU”), a medical university established in Bahrain by the six Gulf states^{*1} and one of the research partners of SBI Pharmaceuticals in Bahrain, succeeded in surgically removing bladder cancer using 5-ALA as an intraoperative diagnostic drug. In addition, a medical light source device developed by SBI Pharmaceuticals for diagnosis was used during the surgery.

Dr. Ziad Al-Naieb from KAMC performed the first successful surgery to remove the bladder cancer in the Middle East with approval from Bahraini regulators. AGU and SBI Pharmaceuticals held a joint press conference in Bahrain, announcing the details of the surgery.

In Gulf Cooperation Council (GCC) countries in the Middle East including Bahrain, bladder cancer is the fourth most common cancer in men and the eighth most common in women. Dr. Al-Naieb stated his determination to promote an orally administered *in vivo* diagnostic drug using 5-ALA^{*2} used in photodynamic diagnosis (PDD), which aims to help doctors visualize the tumor tissue, as well as a medical light source device used during the surgical removal of the bladder cancer in other GCC countries.

Mr. Shigeki Sumi, Ambassador of Japan to the Kingdom of Bahrain, was present at the joint press conference held in Bahrain. We believe that the successful surgical removal of the bladder cancer performed by KAMC’s Dr. Al-Naieb is highly significant as it will contribute greatly to advancing medicine in Bahrain while facilitating partnership between Japan and Bahrain in the field of medicine. From hereafter, by leveraging AGU’s network, we will strive to accelerate the spread of an intraoperative diagnostic drug using 5-ALA and medical devices of SBI Pharmaceuticals in the six Gulf states.

The development of an intraoperative diagnostic drug for bladder cancer used successfully in Bahrain has been granted orphan drug^{*3} designation in Japan and progress has been made in doctor-led clinical trials at five universities mainly Kochi University.



The SBI Group will continue research and development on pharmaceuticals using 5-ALA for delivery to patients suffering from a wide range of medical conditions.

*1: Saudi Arabia, UAE, Kuwait, Oman, Qatar, and Bahrain

*2: Intraoperative diagnostic drug using 5-ALA

The purpose of an intraoperative diagnostic drug using 5-ALA is to improve tumor resection rates. Orally administering 5-ALA several hours before the surgical resection of tumors allows doctors to completely discriminate tumors from normal tissues by making them glow red when a special light is applied to the affected area during an operation. In Japan, SBI Pharmaceuticals has been selling “ALAGLIO® Internal Medicine 1.5g,” an *in vivo* diagnostic agent for malignant glioma, a type of brain tumor, based on approval from the Ministry of Health, Labour and Welfare.

*3: Orphan drugs are pharmaceutical agents used to treat serious disorders having significant medical needs.

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