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SBI Holdings, Inc.

SBI Pharmaceuticals Co., Ltd.

## **Announcement of Decision to Grant a Patent in Japan for Method of Detecting Bladder Cancer through Oral Administration of 5-Aminolevulinic Acid**

SBI Pharmaceuticals Co., Ltd. (Head office: Minato-ku, Tokyo; Representative Director and CEO: Yoshitaka Kitao; “SBI Pharmaceuticals”), a subsidiary of SBI Holdings, Inc. (SBIH), engages in research and development of pharmaceuticals, health foods and cosmetics using 5-aminolevulinic acid (“5-ALA”)<sup>\*1</sup>. We are pleased to announce that we have been received a decision to grant a patent<sup>\*2</sup> for a method of detecting bladder cancer through oral administration of 5-ALA.

Surgical removal of bladder cancer requires improvement of tumor resection rates by discriminating tumors from normal tissues. We applied for a patent for a technique to orally administer 5-ALA several hours before the surgical resection of tumors to allow doctors to easily discriminate tumors from normal tissues by making them glow red when a special light is applied to the affected area during an operation.

[Patent application number] 2010-509075

[Name of invention] Method of detecting bladder cancer

[Patent applicant] SBI Pharmaceuticals Co., Ltd., Kochi University

The development of an intraoperative diagnostic drug for bladder cancer was granted orphan drug<sup>\*3</sup> designation in Japan and progress has been made in doctor-led clinical trials at five universities mainly Kochi University.

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: Decision to grant a patent: A decision as to whether or not to grant a patent is made in an examination conducted by the Japan Patent Office examiner for inventions that are deemed worthy of granting a patent right.

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

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