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SBI Pharmaceuticals Co., Ltd.
Chugai Pharmaceutical Co., Ltd.

“ALAGLIO® Divided Granules 1.5g,” a Photodynamic Diagnostic Agent Obtained Manufacture and Marketing Approval

TOKYO, September 27, 2017 -- [SBI Pharmaceuticals Co., Ltd.](#), (Head office: Minato-ku, Tokyo; Representative Director & President: Yoshitaka Kitao; “SBI Pharma”), a subsidiary of SBI Holdings, Inc., engaged in the research and development of medicines using 5-ALA (5-Aminolevulinic acid) (*1) and [Chugai Pharmaceutical Co., Ltd.](#) (Head office: Chuo-ku, Tokyo; Chairman & CEO: Osamu Nagayama; “Chugai”) hereby announce that the manufacture and marketing approval of a photodynamic diagnostic agent, “ALAGLIO® Divided Granules 1.5g” (Generic name: Aminolevulinic acid hydrochloride; “this Agent”) has been obtained from the Ministry of Health, Labour and Welfare for the indication of diagnostic agent to visualize non-muscle invasive bladder cancer at the operation of its transurethral resection.

This Agent is the world-first orally administered formulation for photodynamic diagnosis (PDD) for the purpose of visualizing the non-muscle invasive bladder cancer (*3) at the operation of the transurethral resection of the bladder tumor (TURBT) (*2) and designated as an orphan drug. The Phase II/III clinical trials of this Agent were conducted at 5 medical institutions with the central role of Kochi University as Investigator-Initiated Clinical Trials of Clinical Research Promotion Program supported by the Center for Clinical Trials, Japan Medical Association. (The results of the follow-up Phase III clinical trials conducted at the same medical institutions were shown on [the news of SBI Pharma dated April 24, 2017.](#))

This Agent is dissolved in water and orally administered to the patient 3 hours (Range: 2-4 hours) before the insertion of a cystoscope to the bladder, and then blue light is irradiated inside the bladder. This procedure emits red fluorescence at the site of tumor lesion and elevates the visibility of the lesion. This is thought to make it easy to distinguish even minute cancer and flat cancer that cannot easily be visible by the conventional method with white light source only. Resecting tumor lesion as much as possible at the initial treatment of the non-invasive bladder cancer is expected to be clinically useful to prevent progression and recurrence of bladder cancer after the operation.

Chugai has been granted the exclusive marketing rights on this Agent in Japan by SBI Pharma, which obtained the manufacture and marketing approval of this Agent. (Please refer to [the news dated March 13, 2017.](#))

SBI Pharma and Chugai join and further strengthen the efforts to speed up the availability of ALAGLIO® Divided Granules 1.5g, a new therapeutic option, for patients fighting against the bladder cancer and healthcare professionals.

(*1) 5-aminolevulinic acid (5-ALA): An amino acid produced in mitochondria. It is an important substance that serves as a functional molecule 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 lees, red wine and Asian ginseng. It is also known as a material forming chloroplasts in plants.

(*2) Transurethral resection of the bladder tumor (TURBT): TURBT is an abbreviation of Transurethral Resection of the Bladder Tumor. A method to insert a surgical endoscope (cystoscope) from the urethra without laparotomy, and resect the tumor while preserving the bladder function.

(*3) Non-muscle invasive bladder cancer: The bladder cancer of a relatively early stage, without invading muscular layer of urinary bladder. It accounts for about 70% of all types of the bladder cancer*. The initial treatment for this type of cancer is primarily TURBT, aiming at the preservation of the bladder function. However, TURBT with a conventional white light source only results in the recurrence with the ratio of 31 - 78% within 5 years after the operation**.

* Guideline for the Diagnosis and Treatment of the Bladder Cancer 2015 (Edited by The Japanese Urological Association) Igakutosho-shuppan Ltd.; p25

** Sylvester RJ, et al. (2006) Eur Urol; 49:466-77

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