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SBI Pharmaceuticals Co., Ltd.

**Publication on UroToday of Results from Domestic Phase III Study
(SPP2C102) Aimed at Administration Modification of ALAGLIO® Divided
Granules 1.5g and ALAGLIO® Oral 1.5g**

SBI Pharmaceuticals Co., Ltd. (Head office: Minato-ku, Tokyo; Representative Director & President: Yoshitaka Kitao; hereinafter "SBI Pharma"), a subsidiary of SBI Holdings, Inc., engaged in the research and development of medical devices and pharmaceuticals utilizing 5-aminolevulinic acid (*1) has announced that the results of a domestic Phase III study (*2) conducted to modify the usage of "ALAGLIO® Divided Granules 1.5g" and "ALAGLIO® Oral 1.5g" (SPP2C102) were presented at the Annual Meeting of the European Association of Urology (EAU) held in Madrid, Spain in March 2025. Furthermore, the results were also published in UroToday, a leading media publication on the latest clinical developments in the field of urology and GU oncology (*3).

Media	UroToday
Title	EAU 2025: Diagnostic Accuracy and Efficacy of Photodynamic Diagnosis 4 -8 Hours After 5-Aminolevulinic Acid Hydrochloride Administration for Non-Muscle Invasive Bladder Cancer: An Exploratory Analysis of the Phase III SPP2C102 Trial
URL	https://www.urotoday.com/conference-highlights/eau-2025/eau-2025-bladder-cancer/159176-eau-2025-diagnostic-accuracy-and-efficacy-of-photodynamic-diagnosis-4-8-hours-after-5-aminolevulinic-acid-hydrochloride-administration-for-non-muscle-invasive-bladder-cancer-an-exploratory-analysis-of-the-phase-iii-spp2c102-trial.html

*1 5-aminolevulinic acid is an amino acid produced in the mitochondria of the body. When 5-aminolevulinic acid is taken up by cancer cells, its main metabolic product, protoporphyrin IX, accumulates. By utilizing the property of protoporphyrin IX emitting fluorescence when irradiated with excitation light, it has been put to practical use as an intraoperative cancer diagnostic agent by visualizing cancer, and further development is ongoing.

*2 A summary of the results of the SPP2C102 study is also available on the jRCT clinical research submission and release system (jRCT number: JRCT2061210055).

<https://jrct.mhlw.go.jp/latest-detail/jRCT2061210055>

- *3 GU oncology is the field of medical research on cancers of the genitourinary and genitourinary system. Specifically, it focuses on the diagnosis, treatment, and prevention of prostate, bladder, kidney, and testicular cancers; GU stands for “genitourinary” and covers a broad area that includes both urology and genitourinary medicine. Research in this area plays an important role in improving the quality of life of our patients.

For further information, please contact:

SBI Pharmaceuticals Co., Ltd.: e-mail: info_ala@sbigroup.co.jp