

April 24, 2017
SBI Pharmaceuticals Co., Ltd.

**Positive Data of Phase III Clinical Trial in Patients of
Non-Muscle Invasive Bladder Cancer were Presented at the
105th Annual Meeting of the Japanese Urological Association**

SBI Pharmaceuticals Co., Ltd., (Head office: Minato-ku, Tokyo; Representative Director & President: Yoshitaka Kitao; "SBI Pharmaceuticals"), a subsidiary of SBI Holdings, Inc., engaged in research and development of pharmaceuticals, health foods and cosmetics using 5-aminolevulinic acid ("5-ALA")^{*1}, hereby announces that the resection of bladder cancer by using aminolevulinic acid hydrochloride (SPP-005) (hereinafter "this Agent"), currently being applied for marketing approval (the method to visualize cancer cells by red fluorescence excited by emission of blue light after administration of this Agent) showed higher sensitivity than the conventional method by using white light only (hereinafter "Conventional method") in the patients of non-muscle invasive bladder cancer^{*2} in its Phase III clinical trial. The data of the trial were presented at the 105th annual meeting of the Japanese Urological Association (held in Kagoshima during April 21 to 24) and are summarized as follows:

This Agent is the world-first orally administered formulation for photodynamic diagnosis (PDD) for the purpose of visualizing tumor tissue at the operation of the transurethral resection of bladder tumor (TURBT)^{*3}, a resection method of bladder cancer therapy. Phase III clinical trial using this Agent was conducted by enrolling 61 cases consisting of the incipient cases and the recurrences after TURBT of the definite and suspicious patients of non-muscle invasive bladder cancer to examine diagnosability of bladder cancer by the fluorescence cystoscope after oral administration of 20mg/kg of this Agent in comparison with the Conventional method with white light. As a result of the analysis on 511 specimens (tumor positive 181 and negative 330) obtained from 60 cases of the targeted group, the diagnosis by using this Agent showed 79.6% in the primary evaluation point of sensitivity, higher than 54.1% by Conventional method. Furthermore this Agent could detect 46 specimens (25.4%) which could not be detected by Conventional method, and showed significantly high sensitivity.

The phase III clinical trial using this Agent was conducted at the respective medical institutions of Kochi University, Nara Medical University, Hamamatsu University School of Medicine, Yamaguchi University and Saitama Medical University International Medical Center.

SBI Pharmaceuticals continues to further strengthen the effort to speed the availability of this Agent as a new therapeutic option, for patients fighting against bladder cancer and healthcare professionals.

(*1): 5-aminolevulinic acid (5-ALA)

An amino acid created 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): Non-muscle invasive bladder cancer

Non-muscle invasive bladder cancer is the bladder cancer of a relatively early stage, without invading muscular layer of urinary bladder and accounts for 70-80% of all types of bladder cancer.

(*3): Transurethral resection of bladder tumor (TURBT)

TURBT is a method to insert a surgical endoscope from the urethra without laparotomy, and resect the tumor while preserving the bladder function.

For further information, please contact:

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