



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

Launch of the Photodynamic Diagnostic Agent “ALAGLIO® Divided Granules 1.5g”

- Contributing to the Initial Treatment of Non-Muscle Invasive Bladder Cancer through the Visualization of Tumor Lesions -

TOKYO, December 18, 2017 -- [Chugai Pharmaceutical Co., Ltd.](#) (Head office: Tokyo; Chairman & CEO: Osamu Nagayama; “Chugai”) announced that it will launch the photodynamic diagnostic agent, “ALAGLIO® Divided Granules 1.5g” (“this Agent”) on December 19th. This Agent was developed by [SBI Pharmaceuticals Co., Ltd.](#), (Head office: 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) and received a manufacturing and marketing approval on September 27th, 2017 for the indication of “visualization of non-muscle invasive bladder cancer during transurethral resection” and was listed on the National Health Insurance reimbursement price list on November 22nd.

This Agent for photodynamic diagnosis (PDD) works because the site of the tumor lesion emits red fluorescence when the metabolite of the Agent, protoporphyrin IX, is irradiated with blue light. ALAGLIO® is an orphan drug and the first in the world to be approved for this indication. Combining PDD to the transurethral resection of bladder tumors (TURBT) is expected to facilitate the detection of non-muscle invasive bladder cancer and be clinically useful in preventing post-TURBT progression and recurrence.

Chugai and SBI Pharma are dedicated to providing information to ensure that “ALAGLIO® Divided Granules 1.5g” is used appropriately and can make an even greater contribution to the treatment of patients with bladder cancer.

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.

Transurethral resection of the bladder tumor (TURBT):

A method to insert a surgical endoscope (cystoscope) from the urethra without laparotomy, and resect the tumor while preserving the bladder function.

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**.

* Edited by The Japanese Urological Association; Guideline for the Diagnosis and Treatment of the Bladder Cancer 2015 (Igakutosho-shuppan Ltd.); 25

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

Drug Information

Brand name: ALAGLIO® Divided Granules 1.5g

Generic name: Aminolevulinic acid hydrochloride

Indications: Diagnostic agent to visualize non-muscle invasive bladder cancer at the operation of its transurethral resection

Dosage and administration: The recommended dose for adult patients is 20mg of 5-aminolevulinic acid hydrochloride per kg body weight, dissolved in water and orally administered to the patient 3 hours (range: 2 – 4 hours) before the insertion of a cystoscope to the bladder

Storage: Protection from light, Store at room temperature

Date of approval: September 27, 2017

Date of NHI reimbursement price listing: November 22, 2017

Date of launch: December 19, 2017

Drug price: JPY 74,873.70/ one 1.5g packet

Trademarks used or mentioned in this release are protected by law.

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