



STELLA PHARMA

News Release

May 19, 2020

Stella Pharma Corporation

STELLA PHARMA will launch Steboronine[®], the World's First BNCT Drug, on May 20, 2020

Tokyo, Japan, May 19, 2020 – STELLA PHARMA CORPORATION (Head office: Chuo-ku, Osaka City; President: Tomoyuki Asano) is pleased to announce that Steboronine[®] intravenous drip bag 9000 mg/300 mL (Generic name: Borofalan [¹⁰B]; "Steboronine[®]"), a boron drug for boron neutron capture therapy ("BNCT"¹), has been listed on the National Health Insurance Drug Price List, as published in the Official Gazette today (May 19,2020). We are also pleased to announce that the product will be available for sale on May 20.

The Ministry of Health, Labour and Welfare ("MHLW") in Japan designated Steboronin[®] as a product subject to the "SAKIGAKE Designation System."

Stella Pharma received approval on March 25, 2020, to manufacture and sell Steboronin[®] for the treatment of locally unresectable recurrent or unresectable advanced head and neck cancer.

Product Outline

Product Name	Steboronine [®] intravenous drip bag 9000 mg/300 mL
Generic Name	Borofalan [¹⁰ B]
Indications	Locally unresectable recurrent or unresectable advanced head and neck cancer
Dosage & Administration	For adult patients, Borofalan [¹⁰ B] is administered intravenous infusion at approximately 500 mg/kg. In particular, for the first two (2) hours, the amount of Borofalan [¹⁰ B] per hour is adjusted for 200 mg/kg (i.e. total amount for 2 hours: 400 mg/kg). After that 2 hours, neutron irradiation to the cancer lesion begins, and at the

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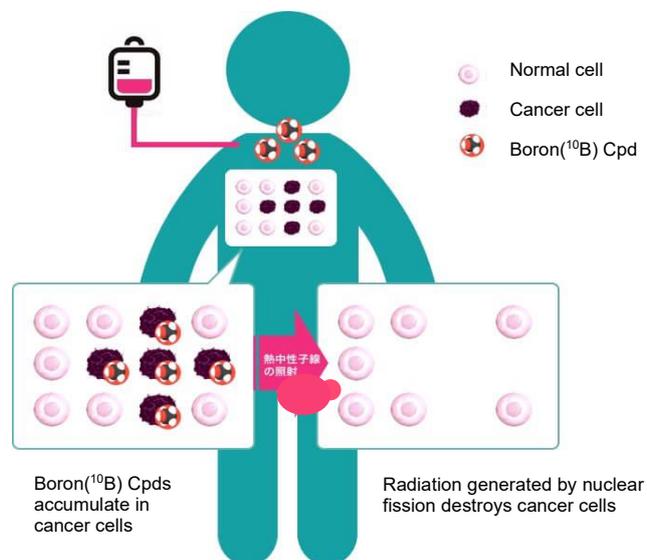
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	same time, Borofalan [¹⁰ B] is administered at 100 mg/kg for one (1) hour until the neutron irradiation is completed.
NHI Price	JPY 444,215 (per 300mL bag)
Date of manufacturing and marketing approval in Japan	March 25, 2020
NHI Drug Price Standard Listing Date	May 20, 2020
Launch Date	May 20, 2020
Manufactured by	Stella Pharma Corporation
Product Photography	

MORE

¹ Boron neutron capture therapy

Boron-neutron capture therapy (BNCT) is a type of radiotherapy and a new way to treat cancer. Boron [¹⁰B] accumulates in cancer cells when the ¹⁰B compound is administered to patients, and a neutron beam is then irradiated to the cancerous area from outside the body. The irradiated neutron-beam is very low-energy and has little effect on the human body. When the neutrons collide with the boron [¹⁰B] in the cancer cells, nuclear fission occurs so as to generate radiation (alpha-rays and ⁷Li-nuclei). BNCT is a treatment in which the radiation destroys cancer cells only.



We have been working on BNCT clinical trials since 2012, the first in the world.

About Stella Pharma Corporation

We are committed to implementing our corporate mission of “shedding new light on medical practice globally to save every irreplaceable life” as a principle of corporate philosophy.

As the only company in the world equipped with the technology required for drug development of BNCT, we are working on the practical application of this technology and promoting various development projects with the goal of contributing to society through the development of drugs.

Click here to read the press release issued on March 25 regarding Steboronine[®] marketing and manufacturing approval:

https://stella-pharma.co.jp/cp-bin/wordpress5/wp-content/uploads/2020/03/Press-release_Steboronine-approvalENG.pdf

Precaution

The information contained in this document is intended to disclose management information and is not for advertising or promotional purposes.

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