



STELLA PHARMA

## News Release

March 25, 2020

STELLA PHARMA CORPORATION

### **STELLA PHARMA Receives Marketing and Manufacturing Approval in Japan for “Steboronine® Intravenous Drip Bag 9000mg/300mL” ~ World’s First BNCT Drug ~**

STELLA PHARMA CORPORATION (Head office: Chuo-ku, Osaka City, President: Tomoyuki Asano) hereby announces that its drug for Boron Neutron Capture Therapy (BNCT [Note \*1]) Steboronine® intravenous drip bag 9000mg/300mL (Generic name: Borofalan [<sup>10</sup>B]; hereinafter referred to as Steboronine®) was approved today by the Ministry of Health, Labour and Welfare of Japan for the treatment of locally unresectable recurrent or unresectable advanced head and neck cancer.

Head and neck cancer is a group of cancers that develop below the brain, ranging from the cranial base to the collarbone (such as the ear, nose, mouth, jaw and throat areas). The head and neck areas contain organs necessary for everyday activities, and therefore there is a need for the establishment of treatment that can both control the cancer and preserve such functions after the treatment. BNCT is a treatment in which the radiation destroys <sup>10</sup>B-loaded cancer cells only, and is therefore expected to control the cancer while having less impact on peripheral normal tissues and their functions.

STELLA PHARMA CORPORATION conducted a Japanese phase II study (Note \*2) with head and neck cancer patients in collaboration with Sumitomo Heavy Industries Ltd. (Head office: Shinagawa-ku, Tokyo; President: Shinji Shimomura), and filed for approval to manufacture and sell Steboronine® based on the phase II results in October 2019. Steboronine® was approved today by the Ministry of Health, Labour and Welfare of Japan as the world’s first boron drug for BNCT. Sumitomo Heavy Industries Ltd. obtained medical device approval for manufacturing and sales of an accelerator-based BNCT system on March 11, 2020 from the Ministry of Health, Labour and Welfare of Japan (Note \*3).

STELLA PHARMA CORPORATION has been developing Steboronine® through industry-academia-government collaboration with support from Osaka Prefectural University (Location: Sakai City Naka-ku; President: Masahiro Tatsumisago), the Japan Science and Technology Agency, and the Japan Agency for Medical Research and Development, using the boron isotope enrichment technology

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(Note \*4), established by our parent company STELLA CHEMIFA CORPORATION (Head office: Chuo-ku, Osaka City; Representative Director, President and Chief Executive Officer: Aki Hashimoto). In April 2017, the product was designated as a product subject to the “SAKIGAKE Designation System” by the Ministry of Health, Labour and Welfare.

STELLA PHARMA CORPORATION will continue to work toward having Steboronine® listed in the National Health Insurance drug price list and toward further development to expand the drug’s indications. STELLA PHARMA CORPORATION will continue to contribute to global medical care through the development of innovative pharmaceuticals and new treatment options for patients.

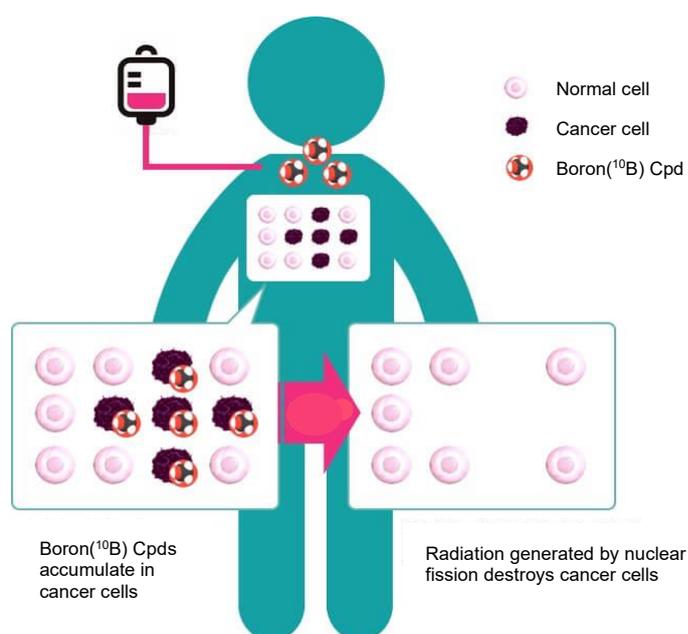
### Product Outline

Product Name	Steboronine® intravenous drip bag 9000mg/300mL
Generic Name	Borofalan [ <sup>10</sup> B]
Indications	Locally unresectable recurrent or unresectable advanced head and neck cancer
Dosage & Administration	For adult patients, administer Steboronine® intravenously at 200 mg/kg/h as Borofalan( <sup>10</sup> B) for 2 hours, followed by neutron irradiation to the cancer lesion with continuous infusion at 100 mg/kg/h.

### SUPPLEMENTARY INFORMATION

#### \*1 Boron neutron capture therapy

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



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**\*2 Japanese phase II study**

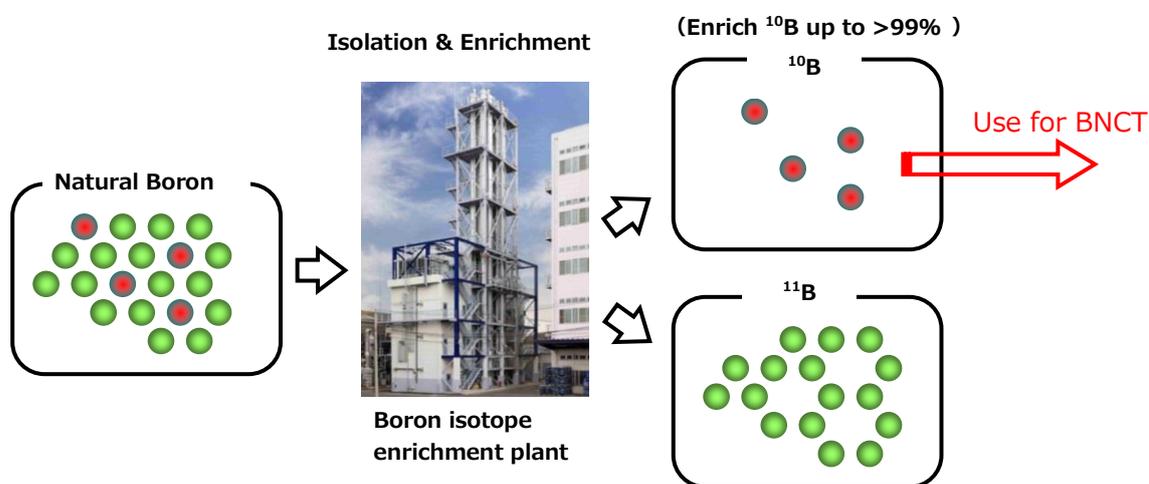
A Japanese phase II study was conducted in 21 patients with locally unresectable recurrent squamous cell carcinoma of the head and neck or unresectable non-squamous cell carcinoma of the head and neck with the primary endpoint of tumor response (response rate) based on RECIST (Response Evaluation Criteria in Solid Tumors) v 1. 1. Overall response rate (95% CI) at 90 days after neutron irradiation was 71.4 (47.8-88.7) %. No dead or discontinued cases were observed during the primary endpoint evaluation period (90 days after neutron irradiation).

**\*3 Medical devices for BNCT in combination with Steboronine®**

- BNCT System NeuCure™ (Approval No. : 30200BZX00084000)
- BNCT dose calculation program NeuCure™ Dose Engine (Approval No. 30200BZX00083000)

**\*4 Isotope enrichment technology for boron**

Naturally occurring boron contains  $^{10}\text{B}$  with a mass of 10 and  $^{11}\text{B}$  with a mass of 11.  $^{10}\text{B}$  contains only about 20%. Nuclear fission by neutrons used in the BNCT to destroy cancer cells is caused only by  $^{10}\text{B}$ , but not by  $^{11}\text{B}$ . Boron isotope enrichment technology is indispensable for BNCT. In Japan, STELLA CHEMIFA CORPORATION is the sole owner of boron isotope enrichment technology for separating and concentrating only  $^{10}\text{B}$  at high concentrations.



**STELLA PHARMA CORPORATION - Company Info**

STELLA PHARMA CORPORATION is committed to implementing its own corporate mission of “we shed new light on medical practice world-wide to save every irreplaceable life” as a principle of its corporate philosophy. In order to realize this corporate philosophy, we have been working to deliver BNCT to the market as a new treatment for incurable cancer since the founding of our

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company. We have decided to contribute to the prosperity and health of society through the development of innovative pharmaceuticals and new treatment options for cancer patients.

For more information, please refer to the STELLA PHARMA website at <https://stella-pharma.co.jp/en/>

**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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