



STELLA PHARMA

News Release

October 15, 2019

STELLA PHARMA CORPORATION

NOTICE OF APPLICATION FOR MARKETING

APPROVAL OF THE ^{Boron} ^{Neutron} ^{Capture} ^{Therapy} **BNCT** DRUG

STELLA PHARMA CORPORATION (Head office: Chuo-ku, Osaka City; President: Tomoyuki Asano) has recently filed for approval to manufacture and sell a boron agent for boron neutron capture therapy (BNCT [Supplement*1]) (Code No.: SPM-011; generic name: borofalan [¹⁰B]; hereinafter referred to as the “drug”).

The drug is the first product developed since our founding. We developed this drug through an industry-academia-government collaboration with support from Osaka Prefectural University (location: Sakai City Naka-ku; President: Masahiro Tatsumisago) and the Japan Agency for Medical Research and Development (location: Chiyoda-ku, Tokyo; President: Makoto Suematsu), using the boron isotope enrichment technology (Supplement*2) that our parent company, STELLA CHEMIFA CORPORATION (head office: Chuo-ku, Osaka City; Chairperson and Representative Director: Junko Fukada), holds as proprietary technology. In April 2017, the product was designated by the Ministry of Health, Labour and Welfare as a product subject to the "SAKIGAKE Designation System."

This application was based on the results of a Japanese phase II study (Supplementary⁴) in patients with head and neck cancer (Supplement*3) (locally unresectable recurrent head and neck cancer and unresectable advanced head and neck non-squamous cell cancer). The drug has not yet been approved in any country or region, and this application is the first to be approved in Japan.

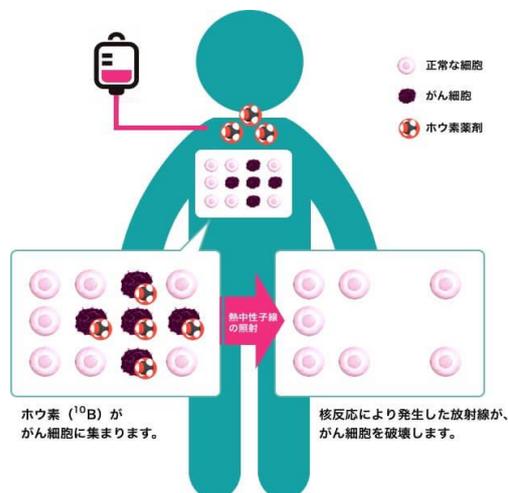
Thanks to the support of various parties during development of BNCT, we are able to take a significant step towards the marketing authorization of the drug for BNCT. We will continue to work with all stakeholders to bring new hope to people suffering from cancer through the earliest practical use of BNCT.

MORE

SUPPLEMENT INFORMATION

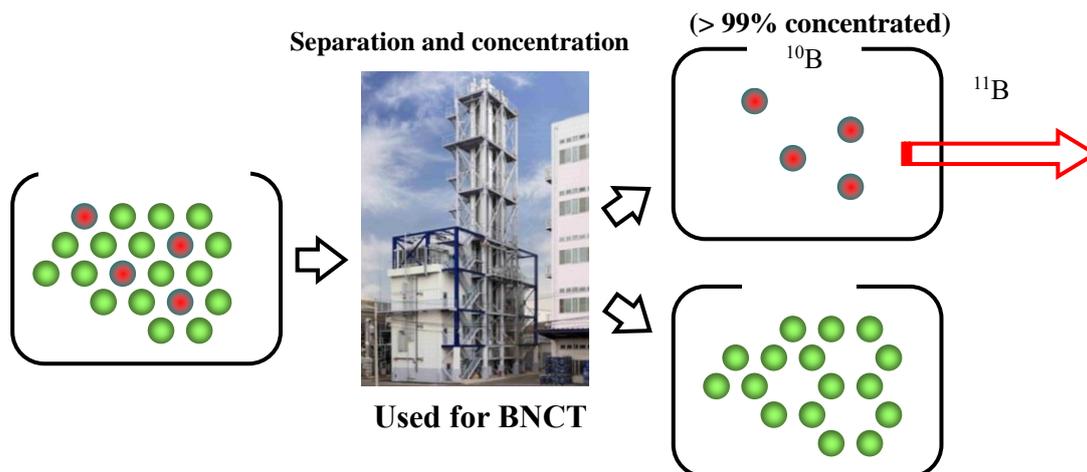
※1 About boron neutron capture therapy

Boron-neutron capture therapy (Boron Neutron Capture Therapy; BNCT) is a type of radiotherapy and a new way to treat cancer. Boron (^{10}B) accumulates in cancer cells when a ^{10}B compound is administered to the patients. A neutron beam is then 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 neutron collides with the boron (^{10}B) in cancer cells, nuclear fission occurs to generate radiation (alpha rays and ^7Li -nuclei). BNCT is a treatment in which the radiation destroys cancer cells only.



※2 Isotope enrichment technology for boron

Naturally-occurring boron contains ^{10}B with a mass of 10 and ^{11}B with a mass of 11. ^{10}B comprises only about 20% thereof. Nuclear fission by the neutrons used in the BNCT to destroy cancer cells is caused only by ^{10}B , but not by ^{11}B . Boron isotope enrichment technology is indispensable for BNCT. In Japan, boron isotope enrichment technology to separate and concentrate only ^{10}B at high concentrations is owned only by STELLA CHEMIFA CORPORATION.



MORE

※3 Head and Neck Cancer

Head and neck cancer is a group of cancers developed below the brain, ranging from the face to the collarbone, that occur in many different parts of the body depending on the cause, treatment, and prognosis. In addition, the head and neck areas contain organs necessary for everyday activities (such as the nose, mouth, ears, jaw, and throat), and therefore the establishment of treatment methods that can preserve these functions is required.

※4 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 a tumor response (response rate) 90 days after BNCT. This study was conducted in collaboration with Sumitomo Heavy Industries Ltd. (head office: Shinagawa-ku, Tokyo; President: Shinji Shimomura), which developed an accelerator for BNCT at two facilities in Japan.

STELLA PHARMA CORPORATION - Company Info

Stella Pharma is committed to implementing its corporate mission to “shed new light on medical practice worldwide to save every irreplaceable life” as a principle of our corporate philosophy. 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 the corporation. We have decided to contribute to a prosperous society through the development of innovative pharmaceuticals and new treatment options for cancer patients.

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

- ◆ This development is supported by the Japan Agency for Medical Research and Development (AMED)'s Research Outcome Optimization Support Program (AMED • A-STEP) for outsourced development (target name: boron drugs used in boron neutron capture therapy).

Precaution

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

#####