

FOR IMMEDIATE RELEASE

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Cancer Treatment Device (BNCT System) Being Developed by Resorttrust Group is Designated as an “Orphan Medical Device for Rare Diseases”

On December 22, the CICS-1 neutron irradiation device (“the Device”) being developed for practical application by Cancer Intelligence Care Systems, Inc. (“CICS”; President, Tetsuya Furukawa; headquarters, Koto-ku, Tokyo), a consolidated subsidiary of Resorttrust, Inc., was designated as an “orphan medical device for rare diseases” by Japan’s Ministry of Health, Labour and Welfare. The device is used in boron neutron capture therapy for the treatment of cutaneous angiosarcoma.

CICS has been conducting clinical trials on the Device used to administer boron neutron capture therapy (“BNCT”), a form of radiotherapy, since 2019 at the National Cancer Center Hospital (“NCCH”; Director, Dr. Kazuaki Shimada; Chuo-ku, Tokyo).

The latest designation of the device will open fresh avenues of support, such as subsidies to help fund development costs and guidance or advance on how to go about seeking approval for manufacturing and marketing. Since the government prioritizes the review of manufacturing and marketing approval, we can expect the device to be made promptly available to people working in the medical field.

The support system was first established in 1993 for the purpose of accelerating research and development into medical devices and pharmaceuticals meeting certain criteria, such as the existence of a strong medical need and a total number of less than 50,000 eligible patients in Japan. The Device is just the 33rd designation of an “orphan medical device for rare diseases” and the first in two years, which illustrates the extremely rare nature of this designation compared to the more than 500 “orphan drugs” designations to date.

The targeted cutaneous angiosarcoma is a malignant soft tissue tumor that occurs in vascular endothelial cells in blood vessels. It is an extremely rare cancer in Japan, with only roughly 300 patients diagnosed in Japan each year. The cancer can be treated through surgery, drug treatments and radiation therapy, but the burden on the patient is heavy and an effective standard treatment has so far not been established, so a new treatment method was required.

BNCT treatment, which uses boron and neutron reactions to selectively destroy cancer cells, has been designated as a promising treatment for unresectable cutaneous angiosarcoma. A patient can, in principle, be treated with a single neutron beam irradiation, which is considered to reduce the burden on patients and contribute to better quality of life (QOL).

In 1994, the Resorttrust Group introduced positron emission tomography (PET) in cancer screening, which resulted in a significant expansion of the use of that technology. We subsequently expanded our business to include treatments by conducting research activities with university hospitals and supporting the operation of advanced immunotherapy facilities for the treatment of cancer.

This latest designation will provide strong impetus for preparing and achieving our goal of introducing the Device for practical application in 2026 and help fulfil the Resorttrust Group’s medical business commitment to “contributing to healthy longevity and well-being in the age of 100-year life” and “create a society where cancer claims no precious

lives.” The impact of this matter on the consolidated results of the Company in the current financial year will be insignificant.

Designation System for Orphan Drugs, Orphan Medical Devices for Rare Diseases and Regenerative Medicine Products for the Treatment of Rare Diseases (Ministry of Health, Labour and Welfare) (Japanese only)

<https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000068484.html>

About CICS-1

CICS-1 is an accelerator-based neutron capture therapy device developed by CICS, Inc. The device produces neutrons by bombarding a lithium target with protons accelerated by a Radio Frequency Quadrupole (RFQ) linear accelerator. CICS-1 is notable for the low level of contamination of fast neutrons, which are detrimental to the human body. The neutrons produced have a low energy level of 800keV or less, facilitating the miniaturization of the moderator used to slow the neutrons down to around 10keV, a level suitable for BNCT.



CICS-1 at the National Cancer Center Hospital.

About BNCT

Boron neutron capture therapy (BNCT) is a form of radiotherapy for treating cancer that uses the $^{10}\text{B}(\text{n},\alpha)^7\text{Li}$ nuclear reaction generated through the capture of neutrons by boron (^{10}B). A specific boron (^{10}B) compound is administered into the body and selectively absorbed by cancer cells, which are then exposed to an external source of extremely low-energy neutron radiation. The boron (^{10}B) nuclei capture neutrons and cause a $^{10}\text{B}(\text{n},\alpha)^7\text{Li}$ nuclear reaction that emits alpha (α) rays and Li nuclei. These particles have short ranges of approximately $9\mu\text{m}$ and $4\mu\text{m}$ respectively and are roughly the size of a single cell. Given their range, the particles dissipate all of their energy within the cancel cell itself, enabling them to selectively destroy cancel cells without affecting the surrounding normal cells.

