



November 7, 2019

FOR IMMEDIATE RELEASE

Company name	Resorttrust, Inc.
Representative	Ariyoshi Fushimi, President
Code	4681, First Section of the Tokyo and Nagoya Stock Exchanges

Commencement of Clinical Trial by Cancer Intelligence Care Systems, Inc. (Consolidated Subsidiary of Resorttrust, Inc.) of Boron Neutron Capture Therapy (BNCT) for Malignant Melanoma and Angiosarcoma

Cancer Intelligence Care Systems, Inc. (“CICS,” President: Tetsuya Furukawa, headquarters: Koto-ku, Tokyo), a consolidated subsidiary of Resorttrust, Inc. (“the Company”), and STELLA PHARMA CORPORATION (“STELLA PHARMA,” President: Tomoyuki Asano; headquarters: Chuo-ku, Osaka; a consolidated subsidiary of STELLA CHEMIFA CORPORATION) will commence a Phase I clinical trial (“the Trial”) of Boron Neutron Capture Therapy (“BNCT”) for malignant melanoma and angiosarcoma, using the CICS-1 accelerator-based neutron capture therapy device with lithium targets developed by CICS, and the SPM-011 boron compound for use in BNCT developed by STELLA PHARMA, beginning in November 2019. The Trial will be conducted in the National Cancer Center Hospital (“the Hospital,” Director: Toshirou Nishida; Chuo-ku, Tokyo) of the National Cancer Center Japan (“NCC,” President: Hitoshi Nakagama; Chuo-ku, Tokyo).

BNCT is a method of cancer treatment in which a specially formulated compound of boron (^{10}B) is injected intravenously and after the compound selectively accumulates into cancer cells, patients are exposed to external neutron radiation, causing the boron and neutrons to react, producing alpha rays and Li nuclei that selectively destroy cancer cells. This treatment method was first conducted in the U.S. in 1951 using neutron source from a nuclear reactor, and clinical research began in Japan in 1968.

CICS concluded a joint research agreement with NCC, and an accelerator-based neutron capture therapy device was installed (using an accelerator supplied by a U.S. subsidiary of Hitachi, Ltd.) when the Hospital’s clinical building was completed in 2014. Since then, non-clinical tests have been carried out until now.

The Trial aims to evaluate the safety and tolerability of BNCT using the CICS-1 accelerator-based neutron capture therapy device and the SPM-011 boron compound.

Please see the attached sheet for details. The Trial will have no material impact on the Company’s consolidated results for this fiscal year.

The Company entered the medical business in 1994, and achieved a world’s first with the introduction of Positron Emission Tomography (PET), which was used for research at the time, for cancer screening at HIMEDIC Yamanakako. This success contributed greatly to the popularization of PET in Japan, and was used in the creation of cancer screening guidelines by the Japanese Society of Nuclear Medicine. In addition, it has helped to promote research activities with university hospitals in fields such as image diagnosis and preemptive medicine. Today, the Resorttrust Group is not only involved in screening but is also expanding treatment solutions, supporting the operation of facilities providing advanced cancer immunotherapy and radiotherapy.

The implementation of the therapy that will be used in the Trial, BNCT, at hospitals was once considered impractical, due to the fact that neutron sources were previously limited to nuclear reactors. However, by making the accelerator function as a neutron source, it became possible to install a therapy device in hospitals.

The Resorttrust Group will strive to establish BNCT as a method of cancer treatment in the future in the context of its aspiration to “create a society where cancer claims no precious lives” – an aspiration that has guided its involvement in cancer screening and treatment.

The Resorttrust Group hopes to bring new light to cancer treatment through the development of new technologies.



PRESS RELEASE

Commencement of Clinical Trial of Boron Neutron Capture Therapy (BNCT) for Malignant Melanoma and Angiosarcoma

November 7, 2019

Cancer Intelligence Care Systems, Inc.
STELLA PHARMA CORPORATION
National Cancer Center Japan

Cancer Intelligence Care Systems, Inc. ("CICS;" President: Tetsuya Furukawa; headquarters: Koto-ku, Tokyo; consolidated subsidiary of Resorttrust, Inc.) and STELLA PHARMA CORPORATION ("STELLA PHARMA;" President: Tomoyuki Asano; headquarters: Chuo-ku, Osaka; a consolidated subsidiary of STELLA CHEMIFA CORPORATION) will commence a Phase I clinical trial ("the Trial") of Boron Neutron Capture Therapy ("BNCT") for malignant melanoma and angiosarcoma, using the CICS-1 accelerator-based neutron capture therapy device with lithium targets developed by CICS, and the SPM-011 boron compound for use in BNCT developed by STELLA PHARMA, beginning in November 2019. The Trial will be conducted in the National Cancer Center Hospital ("the Hospital;" Director: Toshiro Nishida; Chuo-ku, Tokyo) of the National Cancer Center Japan ("NCC;" President: Hitoshi Nakagama; Chuo-ku, Tokyo).

BNCT is a method of cancer treatment in which a specially formulated compound of boron (^{10}B) is injected intravenously and after the compound selectively accumulates into cancer cells, patients are exposed to external neutron radiation, causing the boron and neutrons to react, producing alpha rays and Li nuclei that selectively destroy cancer cells. This treatment method was first conducted in the U.S. in 1951 using neutron source from a nuclear reactor, and clinical research began in Japan in 1968.

CICS concluded a joint research agreement with NCC, and an accelerator-based neutron capture therapy device was installed when the Hospital's clinical building was completed in 2014. Since then, non-clinical tests have been carried out until now.

The Trial aims to evaluate the safety and tolerability of BNCT using the CICS-1 accelerator-based neutron capture therapy device and the SPM-011 boron compound.

Overview of the Trial

Participants

The Trial is designed for patients suffering from malignant melanoma or angiosarcoma, both of which are forms of skin cancer. Patients who have been diagnosed histopathologically with tumors originating on the skin and no lymph node metastasis or distant metastasis will be considered for the Trial.

Malignant melanoma and angiosarcoma are currently treated using surgery, pharmacotherapy or radiotherapy, depending on the symptoms and prognosis of the disease. Surgical removal of the cancer is generally preferred. However, extensive surgical excision can deteriorate the patient's quality of life seriously, and research today aims at establishing more effective treatments with fewer side-effects, which reduce patient burden.

About BNCT

Boron Neutron Capture Therapy (BNCT) is a form of radiotherapy. It utilizes a nuclear reaction – $^{10}\text{B}(n,\alpha)^7\text{Li}$ – that occurs through boron (^{10}B) neutron capture reaction. Cancer cells selectively accumulate a specially formulated compound of boron (^{10}B), and then the tumor is exposed to external, low-energy neutron radiation. This causes the boron (^{10}B) to capture neutrons and causes a nuclear reaction – $^{10}\text{B}(n,\alpha)^7\text{Li}$ – releasing alpha rays and Li nuclei. The ranges of these particles are short, with about $9\mu\text{m}$ and $4\mu\text{m}$ respectively, about the size of a single cell. Due to their short ranges, the particles lose most energy within the cancer cell itself, selectively killing the cancer cells without affecting the surrounding normal cells.

About SPM-011

SPM-011 is a boron compound (generic name: borofalan (^{10}B)) created by STELLA PHARMA CORPORATION for use in BNCT. In previous clinical research, problems with the compound's instability had become apparent, but SPM-011 resolves these issues through innovations in the solubilizing agent. SPM-011 also uses ^{10}B at a concentration of more than 99%, thanks to the ^{10}B concentration technology, unique in Japan, owned by STELLA CHEMIFA CORPORATION, the parent company of STELLA PHARMA.

About CICS-1

CICS-1 is an accelerator-based neutron capture therapy device developed by CICS. It produces neutrons by bombarding a lithium target with protons which are 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.