September 2, 2024

FOR IMMEDIATE RELEASE

Company name Resorttrust, Inc.
Representative Ariyoshi Fushimi, President
Code 4681, Prime of Tokyo Stock Exchange and Premier of Nagoya Stock Exchanges

Cancer Intelligence Care Systems, Inc. (Consolidated Subsidiary of Resorttrust, Inc.), National Cancer Center Japan, Sumitomo Heavy Industries, Ltd., and STELLA PHARMA CORPORATION Conclude an Agreement for a Boron Neutron Capture Therapy (BNCT) Clinical Trial

Cancer Intelligence Care Systems, Inc. ("CICS," President: Tetsuya Furukawa; headquarters: Koto-ku, Tokyo), a consolidated subsidiary of Resorttrust, Inc., has concluded an agreement (the "Agreement") with the National Cancer Center Japan ("NCC;" Chuo-ku, Tokyo), Sumitomo Heavy Industries, Ltd. ("Sumitomo Heavy Industries;" Shinagawa-ku, Tokyo), and STELLA PHARMA CORPORATION ("STELLA PHARMA;" Chuo-ku, Osaka), with regard to a Phase I/II basket study[*1] (the "Clinical Trial") for boron neutron capture therapy ("BNCT") covering patients for whom standard therapy[*2] is difficult to implement and who have unresectable recurrent solid malignant thoracic tumors[*3].

The purpose of the Clinical Trial is to evaluate the safety and efficacy of BNCT using CICS's neutron irradiation device (CICS-1) and STELLA PHARMA's boron compound (SPM-011), and to conduct an exploratory evaluation[*4] of the safety of the drug "FBPA," synthesized by Sumitomo Heavy Industries' FBPA synthesizing device (MPS200FBPA), as well as the utility of "FBPA-PET scan" to determine the suitability of BNCT. The Clinical Trial will cover patients with unresectable recurrent solid malignancies of the thoracic region for whom standard radiation therapy and drug therapy are difficult to implement.

BNCT is a type of therapy that selectively kills cancer cells based on the principle that a boron compound known as BPA is specifically taken up by cancer cells. Currently, FBPA-PET is undergoing development. FBPA-PET uses a drug known as FBPA (a drug that contains BPA and is used in PET scans) to determine how much of the BPA required to target cancer cells has accumulated in the cancer cells.Under the Clinical Trial, FBPA-PET scans will be performed on all subjects prior to BNCT.

The Clinical Trial will be the world's first BNCT study to cover multiple types of cancer. Multiple thoracic solid malignancies can be targeted to share the same normal tissue around the lesion where the neutrons are irradiated, and it is expected that the development period will be shortened compared to clinical trials for individual cancer types. Also expected is that the use of a FBPA-PET scan to determine the suitability of BNCT prior to the procedure will enable consideration of the optimal treatment for each patient.

When solid malignancies of the thoracic region are initially treated with standard therapy, drug therapy is the only option with recurrence, and there is no local treatment available. Under these circumstances, the Company will continue to develop BNCT so that it can meet medical needs to treat diseases for which no cure has been found.

The Agreement's contract period will extend until October 31, 2028. The impact this project has on the Company's consolidated business performance will be immaterial.

The Resorttrust Group entered the medical business in 1994, beginning its membership-based medical club. For cancer screening, the Group introduced positron emission tomography (PET), which at the time was used for research conducted at Yamanakako Clinic. In addition to greatly contributing to the spread of PET in Japan, 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.

Based on the brand identity of “Together for a Wonderful Life” the Resorttrust Group has as its slogan “contributing to the age of 100-year life spans (wellbeing).” Furthermore, reflecting the Group’s hope to create a society where cancer claims no precious lives, it has engaged in cancer screening and treatment. Through our initiatives with BNCT, together with helping to create a more affluent, happy time, we hope to bring new light to cancer treatment.

*1 Basket study: A study to evaluate the efficacy and safety of a single treatment for multiple diseases, etc.

*2 Standard therapy: Based on scientific evidence, this is demonstrated to be the “optimal treatment” currently available and is the generally recommended treatment for most patients.

*3 Solid malignant thoracic tumors: Esophageal cancer, non-small cell lung cancer, breast cancer, malignant soft tissue sarcoma arising in the thoracic region, malignant pleural mesothelioma, etc.

*4 Exploratory evaluation: The conduct of various evaluations for the next stage of testing, etc.; a preliminary step in a confirmatory evaluation to test a hypothesis.

*5 FBPA-PET: A PET scan using FBPA (2-fluoro-4-boronophenylalanine) to measure selective boron accumulation within the target tumor of L-4boronophenylalanine (BPA), a boron compound used in BNCT

About BNCT

Boron neutron capture therapy (BNCT), a form of radiotherapy, is a new method of treating cancer.

When patients receive a boron agent, a boron compound (^{10}B) accumulates in their cancer cells. The area of the tumor is then exposed to an external source of extremely low-energy neutron radiation, which while having little effect on the human body, causes the boron (^{10}B) to capture neutrons, resulting in a reaction that causes the release of alpha rays and ^{7}Li nuclei. BNCT is therefore a medical treatment that leverages radiation to selectively kill cancer cells.

In addition, in principle, as treatment is completed with a single neutron irradiation, expectations are for this to be a treatment that causes little damage to the body.

About the CICS neutron capture therapy device

This 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.