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RESORTTRUST GROUP

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Cancer Intelligence Care Systems, Inc. (Consolidated Subsidiary of Resorttrust, Inc.) and Edogawa Hospital Enter Agreement to Conduct Specified Clinical Research ～Provision of Technology for BNCT Equipment in Research Targeting FDG-PET Positive Superficial Tumors～

Resorttrust, Inc. (“the Company”) announces that its consolidated subsidiary, Cancer Intelligence Care Systems, Inc. (“CICS”; President, Tetsuya Furukawa; headquarters, Koto-ku, Tokyo), has entered into an agreement to collaborate in investigator-initiated specified clinical research* (“the Research”) targeting superficial tumors. CICS will cooperate in the Research, which is to be conducted at Edogawa Hospital (Edogawa-ku, Tokyo), by providing technology related to a neutron irradiation device for boron neutron capture therapy (BNCT).

*1About clinical research

The term “clinical trials,” as defined by the Clinical Trials Act, “refers to research to clarify the efficacy or safety of pharmaceuticals by the use of such pharmaceuticals in humans” (excluding those falling under clinical trials and other research specified by an Ordinance of the Ministry of Health, Labour and Welfare).

The term “specified clinical research” refers to clinical research that is conducted under the auspices of a pharmaceutical marketing authorization holder or its special related party (i.e., subsidiary) (limited to clinical research that uses pharmaceuticals manufactured and sold or intended to be manufactured and sold by the said manufacturer or distributor) or clinical research that uses drugs not yet approved of or that are off label.

*Reference: Ministry of Health, Labour and Welfare “About Clinical Trials Act”

The purpose of the research is to evaluate the safety and efficacy of BNCT in the treatment of tumors with uptake of FDG (a glucose-like compound). The usefulness of FDG-PET as a preliminary indicator of efficacy for BNCT will also be studied.

Patients who have been diagnosed with malignant tumors situated within 6cm of the skin surface*2 and who have at least one tumor that has FDG uptake will be eligible.

Edogawa Hospital is equipped with a neutron irradiation device that CICS has installed and is developing at National Cancer Center Hospital. In the Research, this device will be used in combination with boron compounds for BNCT developed by STELLA PHARMA CORPORATION (Chuo-ku, Osaka).

CICS supports the intent of the Research and will provide technology related to CICS’s neutron irradiation device for BNCT. The impact this project has on the Company’s consolidated business performance will be immaterial.

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. It is thought that FBPA-PET will be useful in predicting the efficacy of BNCT before commencing therapy. However, one of the challenges faced is the limited number of facilities which can administer FBPA-PET, as it is not covered by health insurance.

Meanwhile, FDG-based FDG-PET is already ubiquitous in cancer diagnosis, and has the advantage of being available at many facilities. FDG-PET examines the presence, absence, and extent of spread of cancer by visualizing the distribution of glucose uptake in cancer cells, based on the principle that cancer cells require more glucose compared to normal cells.

It is thought that FDG-PET may be a viable alternative to FBPA-PET, due to data that suggests that in cancer cells, FDG accumulation is significantly related to FBPA accumulation. If FDG-PET administered as part of routine treatment is able to predict the efficacy of BNCT, it can be expected that more patients may be eligible for BNCT.

*2 BNCT therapy is only effective to a depth of within 6-7cm of the skin surface.

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.

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.