

**The PROBEAT-RT Proton Beam Therapy System Incorporating  
Real-time Tumor-tracking is Approved for Commercial Manufacturing  
and Sales under Japan's Pharmaceutical Affairs Law**

*Treatments to begin using the world's first spot scanning proton beam therapy system  
equipped with Real-time Tumor-tracking capability*

**Sapporo, Japan, October 23, 2014** --- Hokkaido University and Hitachi, Ltd. (TSE:6501) today announced that the approval under Japan's Pharmaceutical Affairs Law has been granted to Hitachi for the manufacture and sales of the PROBEAT-RT, a proton beam therapy treatment system combining spot scanning irradiation and Real-time Tumor-tracking Radiation Therapy. Hokkaido University and Hitachi had been jointly developing this system after the project was awarded a grant in 2010 under the Funding Program for World-Leading Innovative R&D on Science and Technology (the "FIRST Program"), a national project sponsored by the Japanese government. Treatments using this new method are scheduled to begin within fiscal year 2014 at Hokkaido University. The approval for the manufacture and sales of this system is the first of its type in the world and marks the start of irradiation treatments by a single system utilizing both Real-time Tumor-tracking and spot scanning irradiation.

Proton beam therapy (PBT) is an advanced type of cancer radiotherapy. Protons, the atomic nuclei of hydrogen, are accelerated to high speed and their energy is concentrated onto tumors. The superb characteristics of proton beams allow patients to maintain their normal lifestyles during treatment as it is painless and impact to the body's normal functions are minimized. PBT has thus been expected as a cutting-edge therapy for treating cancer whilst maintaining patients' quality of life (QOL). As these characteristics enable precise dose concentration, PBT can be easily applied to stationary targets such as brain tumors. Treatment however, of tumors in the torso such as those in the lung or liver which move due to respiration, require special care - and thus the combination of PBT with real-time tracking to target moving tumors has been highly anticipated.

The PROBEAT-RT Proton Beam Therapy System brings together Real-time Tumor-tracking technique developed by Hokkaido University with Hitachi's Spot Scanning Technology. After spot scanning irradiation was approved under Japan's Pharmaceutical Law in March 2014, Real-time Tumor-tracking was incorporated into the PROBEAT-RT system enabling the precise irradiation of targets in motion – for example, due to respiration, achieving high dose delivery while significantly minimizing exposure to normal tissue and organs.

The FIRST Program is a major research support structure established as part of a Japanese government initiative to promote science and technology. At a meeting of the Council for Science and Technology Policy in March 2010, out of a total of 565 applications from across Japan, 30 "Core Researchers and Projects" were awarded grants based on their notable potential in the advancement of Japanese science and technology. Hokkaido University's "Advanced Radiation Therapy Project Real-time Tumor-tracking with Molecular Imaging Technique" project was awarded a FIRST grant following an application by Professor Hiroki Shirato of the Department of Radiation Medicine, Graduate School of Medicine\*. This was the only application accepted in the field of radiation therapy. The proposed system has gained worldwide attention as a potential driving force behind the advancement of radiation treatment and cancer therapy.

The goal of the "Advanced Radiation Therapy Project Real-time Tumor-tracking with Molecular Imaging Technique" is to develop a treatment system that can dramatically reduce the irradiation of normal tissue, in a compact, low-cost system that demonstrates international competitiveness. This goal is achieved by combining the Real-time Tumor-tracking Radiation Therapy developed by Hokkaido University through X-ray therapy with Hitachi's Spot Scanning proton beam irradiation technology, which was delivered for the first time ever to a general hospital. In this way, Hokkaido University and Hitachi will offer a proton beam therapy system that can accurately irradiate a tumor that moves due to respiration, for example in the lung or liver.

The PROBEAT-RT Proton Beam Therapy System is a compact, low-cost proton beam cancer treatment system developed jointly by Hokkaido University and Hitachi. By merging Hitachi's technologies with the expertise that Hokkaido University has developed through radiation treatment, and by using only spot scanning irradiation as the irradiation method, it became possible to reduce the size of the gantry, the irradiation nozzle, and the accelerator. Hokkaido University began treatments using the compact system from March, 2014. Approval of this system allows us not only to bring to market a compact, proton beam therapy system with spot scanning, but one enhanced with Real-time Tumor-tracking. This additional, high precision capability can treat patients with tumors in motion due to respiration and thus achieves the goal stated in the "Advanced Radiation Therapy Project Real-time Tumor-tracking with Molecular Imaging Technique."

Hokkaido University and Hitachi will combine their respective outstanding technologies, knowledge and experience in the medical and engineering fields, to contribute to cutting-edge radiation therapy and cancer treatments that maintain excellent QOL for patients through the development of this Proton Beam Therapy System.

\* In parallel with development of the proton beam cancer treatment system, a component of the "Advanced Radiation Therapy Project Real-time Tumor-tracking with Molecular Imaging Technique," Kyoto University Professor Masahiro Hiraoka, who collaborated in the proposal for this national project, developed a tracking-image X-ray therapy system that tracks and irradiates tumors, as part of his activities in the X-ray therapy field.

### **Overview of Real-time Tumor-tracking Radiation Therapy**

In "Real-time Tumor-tracking Radiation Therapy," gold markers are inserted in the proximity of the tumor, and a computed tomography (CT) system is used to identify the marker positions in relation to the tumor core. Using an X-ray fluoroscopy system from two directions, this technology automatically pinpoints the gold markers positions on a fluoroscopy image using pattern recognition, and repeatedly calculates the spatial position at regular intervals. The treatment beam only irradiates the targeted tumor when the gold markers are located within a few millimeters of the planned positions. As this operation is performed at high speed, it is possible to irradiate tumors with a high degree of accuracy, even when they move within the body, for example due to the patient's respiration. Compared to conventional methods that irradiate the entire area in which the tumor might migrate, this system reduces the irradiation volume by 50-75 percent, allowing a dramatic reduction in the irradiation of normal tissue.

### **Overview of spot scanning Irradiation Technology**

Rather than scattering proton beams as in the case of conventional proton beam therapy, Hitachi's Spot Scanning irradiation technology uses a constant, narrow beam, repeatedly turning this beam on and off at high speed as it progressively changes location. In this way, the beams can be targeted with high precision according to the shape of the tumors, even if those shapes are extremely complex, thus minimizing the impact on normal tissue.

**About Hitachi, Ltd.**

Hitachi, Ltd. (TSE: 6501), headquartered in Tokyo, Japan, delivers innovations that answer society's challenges with our talented team and proven experience in global markets. The company's consolidated revenues for fiscal 2013 (ended March 31, 2014) totaled 9,616 billion yen (\$93.4 billion). Hitachi is focusing more than ever on the Social Innovation Business, which includes infrastructure systems, information & telecommunication systems, power systems, construction machinery, high functional materials & components, automotive systems, healthcare and others. For more information on Hitachi, please visit the company's website at <http://www.hitachi.com>.

**About Hokkaido University**

Hokkaido University started out in 1876 as the Sapporo Agricultural College, the first modern academic institution in Japan. Over many generations, today we enroll approximately 18,000 students, including many international students from more than 85 countries. In order to meet the demands of society and to move ahead as a National University Corporation, Hokkaido University needs to formulate a long term goal for developing the basis of knowledge creation, knowledge dissemination and knowledge application in the new century, while re-realizing our basic philosophies and recognizing our accountability to society.

For more information on Hokkaido University, please visit university's website at <http://www.oia.hokudai.ac.jp/>.

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Information contained in this news release is current as of the date of the press announcement, but may be subject to change without prior notice.

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