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Public University Corporation Fukushima Medical University
National University Corporation Hokkaido University
Sumitomo Heavy Industries, Ltd.

Notice of Establishment of Gallium-68 Production System Produced by Cyclotron and Achievement of Gallium-68 Labeled PSMA-11[*1]

【Summary】
Public University Corporation Fukushima Medical University (the “University”, President: Seiichi Takenoshita, and Professor, Advanced Clinical Research Center: Tohru Shiga) hereby announced that the University, National University Corporation Hokkaido University (Professor, Central Institute of Isotope Science: Yuji Kuge), and Sumitomo Heavy Industries, Ltd. (President and CEO: Shinji Shimomura) achieved establishment of Gallium-68 production system produced by cyclotron and production of Gallium-68 labelled PSMA-11 under the support of “Research on Development of New Medical Devices” from Japan Agency for Medical Research and Development, AMED.

From now on, the University will proceed with the preparations for investigator initiated clinical trial for Phase I regarding Ga-68 PSMA-11, which is produced by Pharmaceuticals and Medical Devices Agency (hereinafter referred to as the “PMDA”), along with the review by the PMDA for quality and safety of Ga-68 PSMA-11 synthesis used production system by Sumitomo Heavy Industries, Ltd.

【Significance of the development】

Prostate cancer is well known as one of the most prevalent cancers in Japan. Although Prostate-Specific Antigen (PSA), a tumor marker in the blood, is being tested as a screening method for prostate cancer, it is difficult to determine the focus of tumor lesion and the presence or absence of tumor metastasis. Computed Tomography (CT), Magnetic Resonance Imaging (MRI), Bone Scintigraphy, etc. are being used to determine the spread of primary lesion and the presence or absence of distant metastasis, however all of them have not obtained sufficient accuracy, and more accurate diagnostic method has been desired.

In recent years, as a diagnostic imaging technology that surpasses these prostate cancer detection methods, research and development on Ga-68 labelled PSMA PET is underway in Europe and the United States. It has been reported that accurate grasp of the spread of primary lesion helps reduce patients’ burden during examinations, and accurate therapeutic intervention with proper staging (stage of cancer progression). It is expected to lead to an improvement in prognosis and QOL of patients. The US Food and Drug Administration (FDA) has already approved as a radiopharmaceutical in December 2020, and early approval for pharmaceutical affairs in Japan is expected.

Since Ga-68 is a positron emission radioisotope with a half-life of approx. 68 minutes, it is being actively used for clinical practice and basic research and development mainly in Europe and the United States as a labeled nuclide for PET diagnosis. A $^{68}Ge/^{68}Ga$ generator, which is a simple manufacturing device, is generally used as a supply source for Ga-68, however there is no generator manufacturing base in Japan, and it is necessary to import everything. Due to the increase in demand for Ga-68 on a global scale, it is raised as a concern that it will take time for domestic supply.

We are able to obtain a larger amount of Ga-68 than a $^{68}Ge/^{68}Ga$ generator by manufacturing Ga-68 with a cyclotron since Japan has a large number of cyclotrons in the world. Therefore, the University thought that it is an urgent task to establish a Ga-68 manufacturing method using a cyclotron, and have been working on this AMED task.

From now on, the University will promote the safety assessment through human clinical research, and contribute to the progress of prostate cancer diagnosis in Japan.

*1 Ga-68 labeled PSMA-11: A radio labeled compound that binds to prostate specific membrane antigens. It is known that a large amount of PSMA is expressed in prostate cancer tissue, and by administering Ga-68 labeled PSMA-11, it is expected that non-invasive detection of prostate cancer tissue and the presence or absence of metastasis can be confirmed. This drug has already received regulatory approval from U.S. Food and Drug Administration (FDA) in December 2020, and early regulatory approval is expected in Japan as well.

*2 PET Diagnosis: A method of imaging and inspecting organs using a “PET camera” from outside the body by injecting a test drug that emits positrons, and the drug moves inside the body and gathers in various places such as disease and organs. By selecting this test drug according to the purpose of the test, it is possible to diagnose the brain, heart, and cancer, etc.

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