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Bruce Power and IsoGen set first critical milestone for exclusive irradiation service provided to ITM for its production of no-carrier-added Lutetium-177

Validation, testing and training will start on a mock-up isotope production system in fall 2020

ITM Medical Isotopes GmbH, a subsidiary of the biotechnology and radiopharmaceutical group of companies ITM Isotopen Technologien München AG (ITM), announced today that Bruce Power, an electricity company, and IsoGen, a joint venture between the two nuclear energy companies Framatome and Kinectrics, have set the first critical milestone for a reliable and consistent irradiation service which will be provided to ITM exclusively for 15 years. Thereby a dedicated mockup of the isotope production system was developed for validation, testing and training which will start in fall 2020.

The medical radioisotope Lutetium-177 (¹⁷⁷Lu) will be obtained by irradiating Ytterbium-176 at the Bruce Power Reactors, as contractually stipulated in an exclusive agreement between Bruce Power, IsoGen and ITM Medical Isotopes GmbH. Bruce Power Reactors are uniquely positioned to fulfil the necessary requirements to reach ITM's high standards validated in a successful feasibility study September last year. The construction of the isotope production system at Bruce Power by IsoGen is currently planned to start in January 2021 once the mock-up has been fully tested. The mock-up is currently in the final phase of engineering, evaluation, and design and will allow validation and training before deploying the isotope production system to Bruce Power's units.

The intermediate material to be generated at Bruce Power over 15 years will be processed by ITM via its unique manufacturing methodology to the highly pure form of ¹⁷⁷Lu, no-carrier-added (n.c.a.) ¹⁷⁷Lu (EndolucinBeta®), at ITM's global network of radiopharmaceutical production facilities. N.c.a. ¹⁷⁷Lu is supplied by ITM to clinics worldwide and is used as a therapeutic radiopharmaceutical precursor for Targeted Radionuclide Therapy of cancers such as neuroendocrine tumors, prostate cancer, Non-Hodgkin's lymphoma, bone metastases and several further indications.

Steffen Schuster, CEO of ITM commented: "Seeing the great progress in the development of the isotope production system by Bruce Power and IsoGen, we are confident that this partnership secures another high-quality source of Lutetium-177 for ITM which further increases scalability of our production ensuring a steady supply of n.c.a. Lutetium-177 on a global scale. Our clinical and industry partner's demand for the radiopharmaceutical precursor no-carrier-added Lutetium-177 is constantly growing and as a company we are dedicated to providing our highly pure radioisotope for Targeted Radionuclide Therapy to cancer patients worldwide."

About n.c.a. Lutetium-177 / EndolucinBeta®

EndolucinBeta®, no carrier-added (n.c.a.) Lutetium-177 (¹⁷⁷Lu) chloride, is a radiopharmaceutical precursor used in Targeted Radionuclide Therapy for the treatment of various diseases, like cancer. When labeled with a disease-specific carrier molecule (e.g. peptide or antibody), the targeted radiopharmaceutical binds to a tumor specific receptor, according to the lock and key principle. EndolucinBeta® has a half-life of 6.647 days. No-carrier-added Lutetium-177 provides the highest specific activity of more than 3,000 GBq/mg at Activity Reference Time (ART), whereas the day of calibration can be flexibly selected by the customer. Optimal preconditions for efficient radiolabeling of biomolecules over its entire shelf-life of 9 days after production are ensured. EndolucinBeta® exhibits an extraordinary level of radionuclidic purity. EndolucinBeta® does not contain metastable Lutetium-177m. Thus, there is no need for cost intensive clinical disposal management and EndolucinBeta® can therefore be used globally — also in regions facing strict radiation protection regulations.

About ITM Isotopen Technologien München

ITM Isotopen Technologien München AG is a privately owned biotechnology and radiopharmaceutical group of companies dedicated to the development, production and global supply of targeted diagnostic and therapeutic radiopharmaceuticals and radioisotopes for use in cancer treatment. Since its foundation in 2004, ITM and its subsidiaries have established GMP manufacturing and a robust global supply network of a novel, first-in-class medical radioisotopes and generator platform for a new generation of targeted cancer diagnostics and therapies. Furthermore, ITM is developing a proprietary portfolio and growing pipeline of targeted treatments in various stages of clinical development, which address a range of cancers such as neuroendocrine tumors, glioblastoma, osteosarcoma and bone metastases, as well as folate receptor α positive tumors like lung, ovarian or breast cancer. ITM's main objectives, together with its scientific, medical and industrial collaboration partners worldwide, are to significantly improve treatment outcomes and quality of life for cancer patients while at the same time reducing side effects and improving health economics through a new generation of Targeted Radionuclide Therapies in Precision Oncology. For more information please visit: www.itm.ag

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