

ITM Announces Operational Readiness for NOVA Facility, the World's Largest Lutetium-177 Production Site

- Receipt of Radioactive Material Handling License (RAM License) for production of n.c.a. Lutetium-177
- Progress demonstrates company's ability to rapidly increase GMP manufacturing capabilities to further supply growing demand for radiopharmaceuticals

Garching / Munich, January 4, 2024 – [ITM Isotope Technologies Munich SE \(ITM\)](#), a leading radiopharmaceutical biotech company, today announced the receipt of the Radioactive Material Handling License (RAM License) for the company's [NOVA facility](#), the world's largest Lutetium-177 production site. Lutetium-177 is an innovative medical radioisotope frequently used in Radiopharmaceutical Therapy (RPT) for the treatment of cancer. Having obtained the RAM License together with other regulatory approvals required, ITM has achieved operational readiness. The RAM License has been granted by the Bavarian Environment Agency (LfU), the relevant regulatory body, in line with the highest quality standards.

*"Our rapid progress in commissioning the NOVA site, only eight months after opening the facility, demonstrates our team's focus and ability to deliver on our corporate objectives," said **Steffen Schuster, CEO of ITM**. "This is a critical achievement that brings us one step closer to full-scale manufacturing at NOVA. Along with solidifying our position as the world's largest manufacturer of n.c.a. Lutetium-177, NOVA will allow us to provide cancer patients with high-quality medical radioisotopes needed for precision oncology diagnostics and treatments."*

The RAM License grants ITM the approval to start "hot commissioning", meaning the start of radioactive operations on-site with the purpose of qualifying and validating all systems, a mandatory process needed to obtain the pharmaceutical manufacturing authorization. The fit-out of NOVA has been completed, with all major production, safety and quality control systems installed. In addition, ITM has initiated quality control and waste management operations.

NOVA will be instrumental to ITM's ability to meet the rapidly increasing global demand for radiopharmaceuticals used for cancer treatment by allowing ITM to significantly expand its capacity to supply clinics, pharmaceutical partners, and its own radiopharmaceutical pipeline. Based on its size and production scale, NOVA could potentially serve up to several hundred thousand patients worldwide per year.

This facility covers an area of approximately 7,000 m² and operates at an industry 4.0 technical level, featuring a high degree of automation in production processes and internal logistics. The facility offers clean rooms, laboratories and offices that can be used by up to 200 employees for radiopharmaceutical manufacturing meeting the highest level of quality standards.

About Radiopharmaceutical Therapy (RPT)

Radiopharmaceutical Therapy (RPT) applies very small amounts of radioactive compounds to diagnose and treat various solid tumor indications. Injected in vivo, radiopharmaceuticals accumulate directly in the affected organ or tumor, largely sparing surrounding healthy tissue. The high specificity of radiopharmaceutical diagnostics and therapeutics has the potential to detect and target even the smallest tissue changes such as tumor metastases. Due to these properties and its safety profile, Radiopharmaceutical Therapy is already being used for the treatment of various cancers including neuroendocrine tumors (NETs) and certain metastatic prostate tumors.

About ITM Isotope Technologies Munich SE

ITM, a leading radiopharmaceutical biotech company, is dedicated to providing a new generation of radiomolecular precision therapeutics and diagnostics for hard-to-treat tumors. We aim to meet the needs of cancer patients, clinicians and our partners through excellence in development, production and global supply. With improved patient benefit as the driving principle for all we do, ITM advances a broad precision oncology pipeline, including two phase III studies, combining the company's high-quality radioisotopes with a range of targeting molecules. By leveraging our nearly two decades of pioneering radiopharma expertise, central industry position and established global network, ITM strives to provide patients with more effective targeted treatment to improve clinical outcome and quality of life.

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