



ITM and ANSTO Announce Extension of Licensing Agreement for the Production and Supply of the Medical Radioisotope n.c.a. Lutetium-177

Garching / Munich, Germany and Lucas Heights / Sydney, Australia, December 21, 2021 – [ITM Isotope Technologies Munich SE](#), a leading radiopharmaceutical biotech company, and the [Australian Nuclear Science and Technology Organisation](#) (ANSTO), a public research organization and international leader in the field of nuclear science and technology, today announced the extension of their partnership by entering into a further long-term licensing agreement. Under the terms of the agreement, ANSTO will continue producing n.c.a. ¹⁷⁷Lu for the Australian and New Zealand markets by utilizing ITM's unique production technology, continuing to address the needs of patients, clinicians and partners alike. ITM retains all intellectual property rights to the medical radioisotope. Further details of the agreement were not disclosed.

N.c.a. ¹⁷⁷Lu is used as a radiopharmaceutical precursor in Targeted Radionuclide Therapy, a novel treatment regimen in precision oncology. Due to the rise of Targeted Radionuclide Therapy, the global demand for medical radioisotopes is growing significantly. The agreement between ITM and ANSTO directly addresses this demand and further solidifies ITM's established global network, which ensures clinics and patients around the world have reliable, timely access to high value medical radioisotopes.

"One of our goals as a leading radiopharmaceutical company with long-standing expertise in the production and distribution of high-grade medical radioisotopes is to serve patients around the world. We continue delivering on this promise by extending our agreement with ANSTO for Australia and New Zealand," commented Steffen Schuster, Chief Executive Officer of ITM. *"By sharing our technical know-how with ANSTO, we further ensure quality and supply, especially as the need for medical radioisotopes continues to grow."*

"We deeply value the opportunity to extend our partnership with ITM as we combine their technical know-how with our renowned facilities and infrastructure to meet the needs of patients," added Mr. Shaun Jenkinson, Chief Executive Officer of ANSTO. *"Targeted Radionuclide Therapy is a growing treatment approach in our region, and it is important for Australia to have local manufacturing capabilities to support the demand from local patients in our region. Our international collaboration with ITM enables us to continue supplying no-carrier-added Lutetium-177 as successfully as we have over the past ten years."*

ITM's highly pure version of the beta-emitting radioisotope, Lutetium-177, can be linked to a variety of tumor-specific targeting molecules for precise treatment of various cancer indications and has already demonstrated significant anti-tumor effects. ITM is further exploring the potential of the medical radioisotope in late-stage clinical trials for indications with high unmet medical need in its wide-reaching pipeline of targeted radiopharmaceuticals, including two phase III trials.

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About Targeted Radionuclide Therapy

Targeted Radionuclide Therapy is an emerging class of cancer therapeutics, which seeks to deliver radiation directly to the tumor while minimizing radiation exposure to normal tissue. Targeted radiopharmaceuticals are created by linking a therapeutic radioisotope to a targeting molecule (e.g., peptide, antibody, small molecule) that can precisely recognize tumor cells and bind to tumor-specific characteristics, like receptors on the tumor cell surface. As a result, the radioisotope accumulates at the tumor site and decays, releasing a small amount of ionizing radiation, thereby destroying the tumor. The highly precise localization enables targeted treatment with minimal impact to healthy surrounding tissue.

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

No carrier-added Lutetium-177 (n.c.a. ¹⁷⁷Lu) chloride, is a radiopharmaceutical precursor used in Targeted Radionuclide Therapy for the treatment of various diseases, like cancer. When labeled with a tumor-specific targeting molecule (e. g. peptide or antibody), the targeted radiopharmaceutical binds to a tumor-specific receptor, according to the lock and key principle. N.c.a. ¹⁷⁷Lu has a half-life of 6.647 days and provides the highest specific activity of more than 3,000 GBq/mg at Activity Reference Time (ART). Optimal preconditions for efficient radiolabeling of biomolecules over its entire shelf-life of 9 days after production are ensured. N.c.a. ¹⁷⁷Lu exhibits an extraordinary level of radionuclidic purity and does not contain metastable Lutetium-177m circumventing cost intensive clinical disposal management.

ITM Isotope Technologies Munich SE

ITM, a radiopharmaceutical biotech company, is dedicated to providing the most precise cancer radiotherapeutics and diagnostics to meet the needs of patients, clinicians and our partners through excellence in development, production and global supply. With patient benefit as the driving principle for all we do, ITM is advancing a broad pipeline combining its high-quality radioisotopes with targeting molecules to develop precision oncology treatments. ITM is leveraging its leadership and nearly two decades of radiopharma expertise combined with its worldwide network to enable nuclear medicine to reach its full potential for helping patients live longer and better. For more information please visit: www.itm-radiopharma.com.

ANSTO

ANSTO leverages great science to deliver big outcomes. We partner with a broad range of industry partners to apply new technologies to provide real-world benefits. Our work improves human health, saves lives, builds our industries and protects the environment. ANSTO is the home of Australia's most significant landmark and national infrastructure for research. Thousands of scientists from industry and academia benefit from gaining access to state-of-the-art instruments every year. For more information visit www.ansto.gov.au

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