

ITM Provides n.c.a. Lutetium-177 as Long-Term Supplier for Recently Approved Novel Radiotherapeutic in Metastatic Prostate Cancer

ITM to supply Advanced Accelerator Applications on an industrial scale with its high-quality n.c.a. lutetium-177 as core component of the newly approved radiotherapeutic, Pluvicto™

Garching / Munich, Germany – March 25, 2022 – [ITM Isotope Technologies Munich SE \(ITM\)](#), a leading radiopharmaceutical biotech company, supports Advanced Accelerator Applications, a Novartis company, as a long-term supplier for the medical radioisotope component of the newly U.S. Food and Drug Administration (FDA) approved radiotherapeutic, Pluvicto™ (lutetium Lu 177 vipivotide tetraxetan) for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor pathway inhibition and taxane-based chemotherapy. ITM will now supply its medical radioisotope n.c.a. ¹⁷⁷Lu (EndolucinBeta®), a core component of the newly approved radiotherapeutic, for the commercial phase based on a [supply agreement](#) entered in 2020, supporting the scalability and security-of-supply for patients worldwide.

“As a long-standing supplier of n.c.a. lutetium-177 for Pluvicto, we share in the excitement of this approval,” commented Steffen Schuster, Chief Executive Officer of ITM. *“At ITM, we strive to provide high-quality radioisotopes not only for our own pipeline, but also for our partners in an effort to bring improved precision oncology treatments to patients on the widest scale possible. We congratulate Advanced Accelerator Applications on its notable achievement and are proud to have contributed clinical supply for the development of this new therapeutic.”*

ITM has established an industrial scale production of high-quality n.c.a. ¹⁷⁷Lu which is intended to be used to damage tumor tissue by emitting a small amount of ionizing beta radiation at short distances thereby minimizing damage to surrounding healthy tissue. ITM’s n.c.a. ¹⁷⁷Lu is designed to have an extraordinarily high level of purity which cuts storage and logistic costs otherwise associated with handling contaminated waste and enables its global use in areas adhering to strict radiation protection rules and regulations. ITM holds a U.S. DMF with the FDA for n.c.a. ¹⁷⁷Lu and has marketing authorization in the EU (brand name EndolucinBeta®).

ITM is a global leader in the production and supply of high-quality medical radioisotopes used as radiopharmaceutical precursors for precise diagnosis and targeted treatment of cancer and has established a wide-reaching international supply network. Furthermore, ITM is developing a proprietary broad pipeline of Targeted Radionuclide Therapies and Diagnostics for various cancer indications which includes its lead candidate, ITM-11 for the treatment of gastroenteropancreatic neuroendocrine tumors (GEP-NETs), currently being investigated in two phase III clinical trials.

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 entities such as receptors which are expressed on the cell surface. As a result, the radioisotope accumulates at the tumor site and decays, releasing a small amount of ionizing radiation, thereby destroying tumor tissue. The highly precise localization potentially enables targeted treatment with minimal impact to healthy surrounding tissue.

About 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, including two phase III studies, 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.

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