

ITM Obtains Manufacturing License in the U.S.

- License will support ITM's efforts in preparing for the commercialization of its diagnostic and therapeutic radiopharmaceutical pipeline across the U.S.

Garching / Munich and Princeton, NJ, February 1, 2024 – [ITM Isotope Technologies Munich SE \(ITM\)](#), a leading radiopharmaceutical biotech company, today announced that the company has obtained a wholesale license issued by the New Jersey Department of Health (NJDOH) in order to operate as a virtual manufacturer. Obtaining the wholesale license is a pivotal requirement for ITM's business activities in the United States. This milestone enables the company to distribute its radiopharmaceutical products, thereby facilitating patient access to ITM's radiopharmaceuticals upon their approval by the U.S. Food and Drug Administration (FDA).

ITM [opened its U.S. headquarters](#) in Princeton, New Jersey in April 2023. Upon opening its new offices, the company prepared for potential market registration of its targeted radiopharmaceutical pipeline product candidates and filed for obtaining the wholesale license. After an inspection from regulatory bodies that found no deficiencies, the wholesale license was issued to ITM on January 16, 2024.

"Obtaining the wholesale license is a crucial step in expanding our U.S. business as we prepare for the future launch of both our diagnostic and therapeutic radiopharmaceutical products in this important geography," commented **Steffen Schuster, CEO of ITM**. *"With this license and our U.S. team in place, we are on the right path to growing our capabilities in serving the healthcare community, our partners, and most importantly, patients on a global scale."*

About Radiopharmaceutical Therapy (RPT)

Radiopharmaceutical Therapy (RPT) 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 such as Lutetium-177 or Actinium-225 to a targeting molecule (e.g., peptide, antibody, small molecule) that can precisely recognize tumor cells and bind to tumor-specific characteristics, such as 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, with the goal of destroying tumor tissue. The precise localization enables targeted treatment with potentially minimal impact to healthy surrounding tissue.

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. www.itm-radiopharma.com

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