ITM Receives FDA Fast Track Designation for Radionuclide Therapy Candidate ITM-11 (n.c.a. ^{177}Lu-edotreotide) in Neuroendocrine Tumors (GEP-NETs)

Garching / Munich, October 27, 2022 – ITM Isotope Technologies Munich SE (ITM), a leading radiopharmaceutical biotech company, today announced that the U.S. Food and Drug Administration (FDA) has granted the company Fast Track designation for ITM-11 (n.c.a. ^{177}Lu-edotreotide), an investigational radiopharmaceutical for the treatment of gastroenteropancreatic neuroendocrine tumors (GEP-NETs). ITM-11 is being evaluated as a Targeted Radionuclide Therapy in two phase III clinical trials, COMPETE and COMPOSE.

The FDA Fast Track is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and address an unmet medical need. The purpose is to bring new and promising medicines to patients sooner. The Fast Track designation enables ITM to have more frequent interactions with the FDA to discuss the ITM-11 development path. It also allows rolling review of the new drug application (NDA) for ITM-11, when submitted. The rolling submission will allow ITM to submit completed sections of an application for review by FDA, rather than wait until all sections are completed.

"We are dedicated to helping people living with hard-to-treat cancers through our research and development of innovative treatments. Receiving Fast Track designation provides us the opportunity to work closely with the FDA to optimize and accelerate the final stages of development for ITM-11, bringing our radiotherapeutic to GEP-NET patients as fast as possible," commented **Steffen Schuster, CEO of ITM.**

GEP-NETs are rare types of tumors originating in the pancreas or other parts of the gastrointestinal tract. Due to their heterogeneity and unique characteristics, early diagnosis is difficult, increasing the likelihood of metastatic disease and severely limiting treatment options. ITM is developing ITM-11 to provide patients with a new, targeted treatment approach to these difficult-to-treat tumors with the goal to improve clinical outcome and quality of life.

COMPETE (NCT03049189) and COMPOSE (NCT04919226) are international, prospective, randomized, controlled, open-label, multi-center phase III clinical studies to evaluate the efficacy and safety, of ITM-11 compared to standard therapy in patients with inoperable, progressive, grade 1 and 2 (COMPETE) and aggressive grade 2 and 3 (COMPOSE), somatostatin receptor-positive (SSTR+) neuroendocrine tumors of gastroenteric or pancreatic origin (GEP-NETs). The primary endpoint of the studies is progression-free survival (PFS), and secondary outcome measures include overall survival (OS). Patient recruitment for COMPETE was completed with 300 randomized patients in April 2022.

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About ITM-11 (n.c.a. ^{177}Lu-edotreotide)

ITM-11, ITM's therapeutic radiopharmaceutical candidate being investigated in the phase III clinical studies COMPETE and COMPOSE, consists of two components: the medical radioisotope non-carrier-added lutetium-177 (n.c.a. ^{177}Lu) and the targeting molecule edotreotide, a synthetic form of the peptide hormone somatostatin that targets neuroendocrine tumor-specific receptors. Edotreotide

binds to these receptors and places the medical radioisotope n.c.a. lutetium-177 directly onto the diseased neuroendocrine cells so that it accumulates at the tumor site. N.c.a. lutetium-177 is internalized into the tumor cells and decays, releasing medical radiation (ionizing beta-radiation) with a maximum radius of 1.7 mm and destroying tumor tissue.

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 tumor tissue. The precise localization enables targeted treatment with potentially minimal impact to healthy surrounding tissue.

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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