ITM Receives Complete Response Letter for ^{177}Lu-edotreotide (ITM-11)

- No clinical safety or efficacy issues identified and no additional clinical or nonclinical data requested
- The Complete Response Letter for the ongoing ITM-11 New Drug Application (NDA) cites Chemistry, Manufacturing and Controls (CMC) and third-party commercial facility inspection-related items

Garching / Munich, Germany and Princeton, New Jersey, August 10, 2026 – ITM Isotope Technologies Munich SE (ITM), a leading radiopharmaceutical biotech company, today announced that it received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) on August 7, 2026, regarding its New Drug Application (NDA) for ^{177}Lu-edotreotide (ITM-11), an investigational agent for the treatment of gastroenteropancreatic neuroendocrine tumors (GEP-NETs).

The CRL stated that the FDA is unable to approve the NDA in its present form and cited CMC- and third-party commercial facility-related items that must be addressed before the application can be approved.

The FDA did not identify any concerns regarding the clinical or nonclinical data package or safety profile of ITM-11. ITM is reviewing the agency's feedback and assessing the appropriate next steps with the relevant external parties.

The Company remains confident in the potential of ITM-11 and is reviewing the FDA's feedback to determine the most appropriate path forward. The Company intends to resubmit to complete the review of the NDA.

"Our confidence in ITM-11's therapeutic potential has not wavered, and we are committed to working closely with the FDA and our partners to address the items outlined in the CRL," said **Dr. Andrew Cavey, chief executive officer of ITM.** "Our pivotal COMPETE trial data package stands, and our goal remains unchanged as we work toward bringing ITM-11 to patients living with advanced GEP-NETs."

About the COMPETE Trial

The COMPETE trial (NCT03049189) evaluated ^{177}Lu-edotreotide (ITM-11), a proprietary, synthetic, targeted radiotherapeutic investigational agent compared to everolimus, a targeted molecular therapy, in patients with inoperable, progressive Grade 1 or Grade 2 gastroenteropancreatic neuroendocrine tumors (GEP-NETs). This trial met its primary endpoint, with ^{177}Lu-edotreotide demonstrating clinically and statistically significant

improvement in progression-free survival (PFS) compared to everolimus. ^{177}Lu-edotreotide is an investigational product and is not approved by any regulatory authority for the safety and/or efficacy of any intended use. It is also being evaluated in COMPOSE, a Phase 3 study in patients with well-differentiated, aggressive Grade 2 or Grade 3, somatostatin receptor (SSTR)-positive GEP-NETs.

About ITM Isotope Technologies Munich SE

ITM, a leading radiopharmaceutical biotech company, is dedicated to providing a new generation of radiopharmaceutical 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 of medical radioisotopes. With improved patient benefit as the driving principle for all we do, ITM advances a broad precision oncology pipeline, including multiple Phase 3 studies, combining the company's high-quality radioisotopes with a range of targeting molecules. By leveraging our 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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