ITM Receives U.S. FDA Fast Track Designation for ITM-94 as a Diagnostic Agent for Clear Cell Renal Cell Carcinoma

- ITM-94 forms a theranostic pair with therapeutic candidate ITM-91, targeting carbonic anhydrase IX (CAIX) in clear cell renal cell carcinoma

Garching / Munich, Germany, November 17, 2025 – ITM Isotope Technologies Munich SE (ITM), a leading radiopharmaceutical biotech company, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to ITM-94 ([^{68}Ga]Ga-DPI-4452) as a diagnostic agent for the detection of clear cell renal cell carcinoma (ccRCC). The Fast Track designation was granted based on the potential of ITM-94 as a more effective, non-invasive diagnostic agent designed to improve outcomes for people living with ccRCC, a condition with high unmet medical need[1].

"The FDA's Fast Track designation is a validation of ITM-94's potential to aid in the non-invasive diagnosis of renal cell carcinoma," said **Dr. Celine Wilke, chief medical officer of ITM**. "We have seen promising data in our ongoing clinical trial that suggest ITM-94 could change how clinicians diagnose and stage patients across the broader ccRCC disease landscape, with potential utility in supporting clinical decision-making for indeterminate renal masses as well. This news highlights the innovation within our pipeline and the important role an effective diagnostic can play in cancer treatment."

ITM-94 is a gallium-68-radiolabeled PET imaging agent and, together with radiotherapeutic compound ITM-91 ([^{177}Lu]Lu-DPI-4452), comprise a first-in-class, peptide-based theranostic pair. The theranostic pair targets carbonic anhydrase IX (CAIX), a cell surface protein that plays a key role in the tumor microenvironment, promoting tumor growth, survival, invasion and metastasis. ITM-94 is currently being evaluated in Part D of the ongoing Phase 1/2 clinical trial for its effectiveness to accurately detect ccRCC in patients with indeterminate renal masses (IDRM) when compared to CT/MRI imaging, with histopathological confirmation of diagnosis. Secondary endpoints include assessments of the imaging agent's sensitivity, specificity and Positive Predictive Value (PPV) and Negative Predictive Value (NPV) compared to histology.

FDA Fast Track designation is designed to facilitate the development and expedite the review of new diagnostics and therapies that are intended to treat serious or life-threatening conditions and have the potential to address an unmet medical need. Programs granted this designation are eligible for more frequent communications with the FDA during clinical development and for accelerated approval and/or priority review over standard reviews if relevant criteria are met.

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[1] Hofman, M. S., B. Tran, D. R. Feldman, A. Pokorska-Bocci, S. Pichereau, J. Wessen, M. B. Haskali, R. B. Sparks, O. Vlasyuk, and I. Galetic. 2024. '[First-in-Human Safety, Imaging, and Dosimetry of a Carbonic Anhydrase IX-Targeting Peptide, [(68)Ga]Ga-DPI-4452, in Patients with Clear Cell Renal Cell Carcinoma]', *J Nucl Med*, 65: 740-3.

About the Phase 1/2 ITM-91/ITM-94 Trial

The multi-part clinical trial (NCT05706129) is designed to assess the safety and tolerability, imaging characteristics, and efficacy of the theranostic pair ITM-91/ITM-94 in patients with unresectable, locally advanced or metastatic solid tumors. In the first-in-human part of the trial (Part A), ITM-94 has demonstrated exceptional tumor imaging characteristics, with a high tumor-to-background ratio and a favorable tolerability profile in patients with confirmed ccRCC[1]. Part B is currently assessing increasing doses of the therapeutic agent, ITM-91, in ccRCC patients whose tumors show CAIX expression as evidenced by uptake of the imaging tracer, ITM-94. Based on the recommended dose and treatment schedule obtained from Part B, expansion Part C of the trial will evaluate the safety and preliminary efficacy of ITM-91 in patients with ccRCC, and potentially other CAIX-expressing tumor types. Part D is evaluating the effectiveness of ITM-94 in classifying indeterminate renal masses, such as ccRCC.

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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