# ITM and Debiopharm Announce First Patient Imaged in New Study Arm of Phase 1/2 Trial Evaluating ITM-94 as Diagnostic Agent for Clear Cell Renal Cell Carcinoma (ccRCC)

- New study arm (Part D) is part of the broad clinical development plan of the ITM-91/ITM-94 theranostic program in patients with Carbonic Anhydrase IX (CAIX)-expressing tumors
- Part D builds on promising imaging data demonstrated in Part A of the study for ITM-94, a Gallium-68 ($^{68}$Ga)-labeled PET imaging candidate, as a diagnostic agent for early-stage clear cell renal cell carcinoma (ccRCC)
- Together with ITM-91, a Lutetium-177 ($^{177}$Lu)-labeled radiotherapeutic candidate, ITM-94 is a theranostic pair, which ITM licensed exclusively from Debiopharm for clinical and commercial development in September 2024

**Garching / Munich, Germany, and Lausanne, Switzerland - June 23, 2025** – ITM Isotope Technologies Munich SE (ITM), a leading radiopharmaceutical biotech company and Debiopharm, a Swiss-based, global biopharmaceutical company aiming to establish tomorrow's standard-of-care to cure cancer and infectious diseases, today announced that the first patient was imaged in a new study arm of a five-part, Phase 1/2 clinical trial (formerly GaLuCi™) (NCT05706129) evaluating the theranostic pair ITM-94/ITM-91 for identification and treatment of patients who have unresectable, locally advanced or metastatic solid tumors. As a new component of a broad clinical development plan for ITM-91/ITM-94, Part D of the trial will evaluate the effectiveness of ITM-94 in classifying indeterminate renal mass as either ccRCC or non-cancerous.

ITM-91/ITM-94 is a first-in-class, peptide-based theranostic pair combining the radiotherapeutic compound ITM-91 (Debio 0228) ([$^{177}$Lu]Lu-DPI-4452), with the diagnostic agent ITM-94 (Debio 0328) ([$^{68}$Ga]Ga-DPI-4452) to target Carbonic Anhydrase IX (CAIX). CAIX is a cell surface protein that plays a key role in the tumor microenvironment, promoting tumor growth, survival, invasion and metastasis. In September 2024, ITM gained the exclusive worldwide license from Debiopharm for the development and commercial rights of ITM-91/ITM-94. The initiation of this study arm represents a significant advancement for ITM and Debiopharm following their licensing agreement.

In the now initiated Part D of the trial, ITM-94 is being evaluated for its effectiveness to accurately classify an indeterminate renal mass as ccRCC or non-cancerous, when compared to CT/MRI imaging and histopathology. Secondary endpoints include sensitivity, specificity, and the positive and predictive value of ITM-94 PET/CT imaging compared to histopathology. This study arm is expected to enroll approximately 36 patients at around 15 clinical sites across the EU, US and Australia.

"*The early results from the Gallium-68 CAIX PET/CT diagnostic are remarkable to date. I believe ITM-94 has the potential to change the way urologists and oncologists diagnose and stage patients with clear cell renal cell carcinoma, improving accuracy and reducing the need for biopsies. I have not seen a tracer with a similar profile since the PSMA PET/CT was established*," *added* **Prof. Michael Hofman, Director, Prostate Cancer Theranostics and Imaging Centre of Excellence (ProSTIC), Peter MacCallum Cancer Centre, Melbourne, Australia.**

"*Clear cell renal cell carcinoma is the most common form of kidney cancer, with more than 90% of cases overexpressing the CAIX encoding gene. As survival rates are highly dependent on the stage of progression, rapid and precise diagnosis is essential to provide patients with the best possible treatment options and therapeutic outcomes. ITM-94 has already demonstrated potential exceptional imaging qualities, including high tumor-to-background ratios and detecting lesions not visible by CT scan with a potential favorable safety profile. We look forward to exploring the full potential of the theranostic pair ITM-91/ITM-94 across this trial to characterize and treat CAIX expressing cancer cells, advancing the efficacy of targeted radiopharmaceutical therapies*," said **Dr. Celine Wilke, Chief Medical Officer of ITM**.

"*With high-quality imaging and high tumor uptake, ITM-94 has already demonstrated potentially significant diagnostic capabilities in solid tumors. The data gathered in Part D of the trial will be instrumental to the further validation of this theranostic pair. We highly value our partnership with ITM, which will continue to advance the rapid progression of these novel radio-diagnostics and -therapeutics through the clinic*," said **Angela Zubel, Chief Development Officer, Research & Development at Debiopharm**.

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

The five-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 Part A of the trial, ITM-94 demonstrated exceptional tumor imaging characteristics, with a high tumor-to-background ratio and a favorable tolerability profile in patients with confirmed ccRCC, with results published in the Journal of Nuclear Medicine. Part B, which is ongoing, is assessing escalating doses of the therapeutic agent, ITM-91, in patients whose tumors show high uptake of the imaging tracer. Based on the recommended dose from Part B, Part C of the trial will assess the safety and preliminary efficacy of ITM-91 in patients with ccRCC, pancreatic ductal adenocarcinoma, colorectal cancer, urothelial carcinoma and potentially other tumor types. In addition to the newly initiated Part D, Part E will assess ITM-94 uptake in other tumors. ITM will assume full sponsorship of the program from Debiopharm once the transfer is completed.

**About ITM-91/ITM-94** (Debio 0228/ 0328)

ITM-91/ITM-94 is an investigational theranostic pair originally discovered by 3B Pharmaceuticals GmbH and now exclusively licensed to ITM. ITM-94 ([$^{68}$Ga]Ga-DPI-4452) is a PET imaging agent that may be used independently and is designed to identify patients whose cancers overexpress CAIX. Once identified, these patients may be treated with the lutetium-labelled radioligand, ITM-91 ([$^{177}$Lu]Lu-DPI-4452), which delivers targeted radiation to the tumor with the aim to destroy it from the inside.

**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. 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

**Debiopharm's commitment to patients**

Debiopharm aims to develop innovative therapies that target high unmet medical needs in oncology and bacterial infections. Bridging the gap between disruptive discovery products and real-world patient reach, we identify high-potential compounds and technologies for in-licensing, clinically demonstrate their safety and efficacy, and then select large pharmaceutical commercialization partners to maximize patient access globally. For more information, please visit www.debiopharm.com We are on X. Follow us @DebiopharmNews at http://twitter.com/DebiopharmNews or on LinkedIn

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