PRESS RELEASE

ITM OBTAINS EXCLUSIVE WORLDWIDE LICENSE FROM DEBIOPHARM FOR CA IX-TARGETED PEPTIDE-BASED RADIOPHARMACEUTICAL PROGRAMS TARGETING SOLID TUMORS

- *ITM gains exclusive global development and commercialization rights to Debiopharm's first-in-class, peptide-based theranostic pair which combines therapeutic compound, Debio 0228 ([^{177}Lu]Lu-DPI-4452) and diagnostic imaging agent, Debio 0328 ([^{68}Ga]Ga-DPI-4452) to target Carbonic Anhydrase IX (CA IX)*
- *Debiopharm to receive upfront, development and regulatory milestone payments of approximately €300 million, as well as commercial milestones and low double-digit royalties on potential future sales*
- *Debio 0228/0328 is currently being evaluated in the phase 1/2 GaLuCi™ clinical trial as a theranostic pair for Clear Cell Renal Cell Carcinoma (ccRCC), Pancreatic Ductal Adenocarcinoma (PDAC) and Colorectal Cancer (CRC)*
- *ITM aims to rapidly advance the program through clinical evaluation in-line with strategy to expand radiopharmaceutical pipeline*

Garching / Munich, Germany, and Lausanne, Switzerland – September 12th, 2024 – ITM Isotope Technologies Munich SE (ITM), a leading radiopharmaceutical biotech company and Debiopharm (www.debiopharm.com), a Swiss-based, global biopharmaceutical company, aiming to establish tomorrow's standard-of-care to cure cancer and infectious diseases, today announced that the companies entered an agreement under which ITM gains the exclusive global license for the clinical and commercial development of the peptide-based, theranostic pair ITM-91/ITM-94D, formerly Debio 0228/0328, targeting the Carbonic Anhydrase IX (CA IX) surface protein. CA IX plays a key role in the tumor microenvironment, promoting tumor growth, survival, invasion and metastasis. ITM-91 (Debio 0228) ([^{177}Lu]Lu-DPI-4452) is a Lutetium-177-labeled radioligand therapeutic compound and ITM-94D (Debio 0328) ([^{68}Ga]Ga-DPI-4452) is a Gallium-68-labeled imaging agent. The theranostic pair is being investigated in the phase 1/2 GaLuCi™ (NCT05706129) clinical trial in patients living with locally advanced ccRCC, PDAC and CRC. Further terms and financial details have not been disclosed.

"Obtaining this clinical-stage theranostic pairing significantly bolsters our radiopharmaceutical pipeline and reinforces our commitment to delivering life-changing diagnostic and therapeutic agents to patients. Adding a clinical stage theranostic pair that targets the critical CA IX protein aligns seamlessly with our mission to expand access to innovative radiopharmaceuticals on a global scale," said **Dr. Andrew Cavey, CEO of ITM**. *"We see great potential for CA IX-targeted radiopharmaceutical therapies. We look forward to advancing the GaLuCi™ trial and to building the optimal clinical strategy for this molecule."*

"Curing patients is our mission. Through this agreement with ITM, we hope to bring breakthrough solutions to patients living with hard-to-treat cancer types. We're extremely pleased that the trial

data generated to-date for our imaging radiotracer have provided high-quality images with high tumor uptake and excellent tumor-to-background ratios. Debio 0328's outstanding potential as a stand-alone imaging agent has also boosted our confidence for the upcoming evaluation of Debio 0228, the therapeutic agent. As development continues, we are grateful to be able to rely on ITM's radiopharmaceutical expertise to advance research for patients," said **Bertrand Ducrey, CEO of Debiopharm**.

Debiopharm is a drug development expert with an evolving radioligand therapy pipeline and strong pre-clinical and clinical competence in this field. Their unique business model allows Debiopharm to continuously bridge the gap between innovative discoveries and leading pharmaceutical companies for commercialization. As the globally leading manufacturer of n.c.a. Lutetium-177 and with a broad pipeline of radiopharmaceutical diagnostic and therapeutic candidates, ITM will use its production capabilities and clinical expertise to advance this theranostic pair.

"Patients with advanced renal cancer often have a long and difficult journey, with recurrence after surgery not infrequent and limited treatment options following immune-oncology or tyrosine kinase inhibitor therapy. I have high hopes for trials like GaLuCi™ will finally shift the odds defining both a new PET/CT scan and targeted treatment option," said **Prof. Michael Hofman, Peter MacCallum Cancer of Melbourne and investigator of the Phase 1/2 GaLuCi™ study**.

"Theranostic approaches are a very exciting treatment modality for patients with hard-to-treat malignancies due to their potential to target specific surface proteins, often regardless of tumor origin. This technique has been shown to improve outcomes for patients with advanced-staged prostate cancer and we are hoping to bring it to the forefront of treatment for kidney cancer," added **Darren R. Feldman, MD, Medical Oncologist, Genitourinary Oncology Service at Memorial Sloan Kettering Cancer Center and investigator of the Phase 1/2 GaLuCi™ study**.

About ITM-91/ ITM-94D (Debio 0228/0328)
ITM-91/ ITM-94D (Debio 0228/0328) is an investigational theranostic pair originally discovered by 3B Pharmaceuticals GmbH and now exclusively licensed to ITM. ITM-94D (Debio 0328) ([^{68}Ga]Ga-DPI-4452) is a PET imaging agent that may be used independently and is designed to identify patients whose cancers overexpress CA IX. Once identified, these patients may be treated with the lutetium-labelled radioligand, ITM-91 (Debio 0228) ([^{177}Lu]Lu-DPI-4452), which is designed to deliver targeted radiation to the tumor with the aim to destroy it from the inside.

About the GaLuCi™ trial
The GaLuCi™ trial is the first-in-human, multicenter, non-randomized phase 1/2 clinical trial assessing safety and tolerability, imaging characteristics, and the efficacy of the theranostic pair ITM-91/ ITM-94D (Debio 0228/0328) in patients with unresectable, locally advanced, or metastatic solid tumors. This theranostic trial is being carried out in three stages. The ongoing Part A is evaluating the safety and performance of the imaging agent in detecting CA IX-expressing solid tumors. Part B will assess escalating doses of the therapeutic agent, ITM-91 (Debio 0228) in patients, whose tumors show high uptake of imaging tracer. Finally, based on the recommended dose from Part B, Part C of the study will further assess the safety and preliminary efficacy of ITM-91 (Debio 0228) in ccRCC, PDAC and CRC.

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

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
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