

ITM and Grand Pharma Enter into a Commercialization Agreement for Targeted Radiopharmaceuticals in the Greater China Area

- Grand Pharma has licensed the development, manufacturing and commercialization rights of ITM's Targeted Radionuclide Therapeutic candidates ITM-11 (n.c.a. ¹⁷⁷Lu-edotreotide) and ITM-41 (n.c.a. ¹⁷⁷Lu-zoledronate) as well as diagnostic TOCscan® (⁶⁸Ga-edotreotide) for the treatment and diagnosis of cancer patients in Greater China
- ITM to receive a significant upfront payment as well as potential regulatory and commercial milestone payments totaling up to approximately EUR 520 M in addition to tiered royalties

Garching / Munich and Hong Kong, December 27, 2021 - [ITM Isotope Technologies Munich SE \(ITM\)](#), a leading radiopharmaceutical biotech company, and [Grand Pharmaceutical Group Limited \(GP\)](#) a diversified global pharmaceutical company listed in Hong Kong, today announced that they have entered into an exclusive licensing agreement for GP to develop, manufacture and commercialize ITM's oncological radiopharmaceutical candidates, ITM-11 ([n.c.a. ¹⁷⁷Lu-edotreotide](#)) and ITM-41 ([n.c.a. ¹⁷⁷Lu-zoledronate](#)) as well as the diagnostic TOCscan® ([⁶⁸Ga-edotreotide](#)) in the territory of mainland China, Hong Kong, Macau and Taiwan.

Under the terms of the agreement, ITM grants GP an exclusive license for the named products in the licensed territory and will support the supply of the pharmaceutical materials needed to conduct clinical and commercial activities. GP will be responsible for clinical development, regulatory activities and commercialization of these products in the licensed geographies. ITM is eligible for a significant upfront payment as well as potential aggregate regulatory and commercial milestone payments totalling up to approximately EUR 520 million in addition to tiered royalties.

"In line with our isotope production collaboration with CIRC and the formation of our Shanghai subsidiary (WFOE) in 2021, ITM continues to strengthen its global footprint in Asian regions. This agreement with GP creates a strong partnership that supports the development and future commercial launch of our targeted radiopharmaceutical products with a recognized leader in Asia," commented Steffen Schuster, Chief Executive Officer of ITM. *"We look forward to working with GP to develop and provide our radiopharmaceuticals in a region with a growing patient population in need of precision oncology treatments."*

"We value our strategic partnership with ITM as we focus on bringing improved precision oncology treatments to Greater China," said Frank Zhou, Chief Executive Officer of GP. *"By combining our resources, expertise and patient-centric approach we are confident in our ability to develop, distribute and commercialize innovative and high quality radiopharmaceutical products."*

ITM-11 (n.c.a. ¹⁷⁷Lu-edotreotide) is ITM's most advanced Targeted Radionuclide Therapy being developed for the treatment of gastroenteropancreatic neuroendocrine tumors (GEP-NETs) and is currently undergoing two phase III clinical trials, COMPETE for patients with grade 1 and grade 2 GEP-NETs and COMPOSE for grade 2 and grade 3 GEP-NETs. ITM-11 has already demonstrated a favorable safety and efficacy profile in phase II clinical evaluation in GEP-NET patients. ITM-41 (n.c.a. ¹⁷⁷Lu-zoledronate) is in preclinical development for in the treatment of osteosarcoma and bone metastases. TOCscan® (⁶⁸Ga-edotreotide) is ITM's radiopharmaceutical for the diagnosis and staging of neuroendocrine tumors (NETs).

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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 entities such as receptors which are expressed on the 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 highly precise localization potentially enables targeted treatment with minimal impact to healthy surrounding tissue.

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

ITM-11 (n.c.a. ¹⁷⁷Lu-edotreotide) is ITM's therapeutic radiopharmaceutical candidate being investigated in the phase III clinical trials COMPETE and COMPOSE. ITM-11 consists of the medical radioisotope no-carrier-added lutetium-177 (n.c.a. ¹⁷⁷Lu) linked to the targeting molecule edotreotide, a synthetic form of the peptide hormone somatostatin that targets receptors that are highly expressed by the tumor. ITM-11 is internalized into the tumor cells and decays, releasing medical radiation (ionizing β -radiation) destroying tumor tissue.

About ITM-41 (n.c.a. ¹⁷⁷Lu-zoledronate)

ITM-41 (n.c.a. ¹⁷⁷Lu-zoledronate) is a targeted radiopharmaceutical candidate being investigated for the treatment of osteosarcoma or osteoblastic bone metastases. ITM-41 consists of two molecular components: the medical radioisotope no-carrier-added lutetium-177 (n.c.a. ¹⁷⁷Lu), and the novel bisphosphonate derivate zoledronate. ITM-41 binds to the bone mineral hydroxyapatite, accumulating in bone with malignant bone disease and may demonstrate potential therapeutic benefit.

About TOCscan® (⁶⁸Ga-edotreotide)

TOCscan® (⁶⁸Ga-edotreotide) is ITM's ready-to-use radiopharmaceutical for diagnosis and staging of neuroendocrine tumors (NETs). TOCscan® contains the targeting molecule edotreotide, a somatostatin analogue, labeled with the medical radioisotope Gallium-68 (⁶⁸Ga). TOCscan® is used for PET or PET/CT molecular imaging of neuroendocrine tumors (NETs). In addition to diagnosis and staging of NETs, ⁶⁸Ga-edotreotide imaging is used for therapy planning and dosimetry in preparation for ¹⁷⁷Lu-edotreotide or ⁹⁰Y (Yttrium-90) DOTA therapy. Administered by injection, TOCscan® provides high-quality PET imaging, low radiation exposure and quick procedures with short imaging time. TOCscan® is authorized for use in Austria, France and Germany.

ITM Isotope Technologies Munich SE

ITM, a radiopharmaceutical biotech company, is dedicated to providing the most precise cancer radiotherapeutics and diagnostics to meet the needs of patients, clinicians and our partners through excellence in development, production and global supply. With patient benefit as the driving principle for all we do, ITM is advancing a broad pipeline, including two phase III studies, combining its high-quality radioisotopes with targeting molecules to develop precision oncology treatments. ITM is leveraging its leadership and nearly two decades of radiopharma expertise combined with its worldwide network to enable nuclear medicine to reach its full potential for helping patients live longer and better.

For more information please visit: www.itm-radiopharma.com.

About Grand Pharmaceutical Group Limited:

Grand Pharmaceutical Group Limited (GP) is a diversified global pharmaceutical enterprise sticking to core values and principles of patients-centered, market-oriented and innovation-driven, GP has extensive capabilities in R&D, manufacturing and sales of pharmaceutical products, advanced medical devices, specialized pharmaceutical ingredients, bio-technology products, and nutritional products. Its core product portfolio covers several major therapeutic areas including cerebro-cardiovascular emergency, respiratory and Ear, Nose & Throat (the "ENT") as well as ophthalmic treatments and selective internal radiation therapy for tumor treatment. With the strategy of "global expansion and

dual-cycle operation”, GP has formed a new pattern of domestic and international cycles that synergize with each other. GP is devoted to health and dedicated to science through R&D and M&A activities. GP is accomplishing its promises to physicians and patients and trying our best to make meaningful contributions to our society.

For further information, please refer to GP’s website at <http://www.grandpharm.com/>

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