Garching / Munich, April 10, 2021

# ITM Presents Design for Ongoing Phase III COMPETE Trial with n.c.a. $^{177}$Lu-Edotreotide at AACR Annual Meeting 2021

**First pivotal study to compare Peptide Receptor Radionuclide Therapy (PRRT) in patients with Grade 1 and 2 gastroenteropancreatic neuroendocrine tumors (GEP-NETs) with approved standard of care**

ITM AG today announced the presentation of a trial-in-progress poster highlighting its ongoing Phase III trial COMPETE with n.c.a. $^{177}$Lu-Edotreotide in patients with gastroenteropancreatic neuroendocrine tumors (GEP-NETs) at the virtual American Association for Cancer Research (AACR) Annual Meeting 2021. The poster will be presented in video format as part of the Phase III trials in progress poster session by Mona M. Wahba, MD, Deputy Chief Medical Officer at ITM. It will be available following the e-poster website launch on April 10, 2021, at 8:30 am ET / 2:30 pm CET and remain available for viewing through June 21, 2021.

*"GEP-NETs are often diagnosed at an advanced stage in patients who have a high unmet medical need. N.c.a. $^{177}$Lu-Edotreotide has already shown very promising signs of efficacy and safety in this patient population in a Phase II study and we look forward to building on these results in COMPETE, with the goal of improving the treatment options that are available for these patients," stated Philip E. Harris, PhD, Chief Medical Officer at ITM. "The AACR Annual Meeting is one of the key oncology conferences in our industry and we welcome the opportunity to present our lead program as well as to discuss the potential benefits of targeted radiopharmaceuticals such as n.c.a. $^{177}$Lu-Edotreotide with the global scientific community."*

The presented COMPETE trial (NCT03049189) is a prospective, randomized, controlled, open-label, multi-center Phase III study to evaluate the efficacy and safety of n.c.a. $^{177}$Lu-Edotreotide PRRT compared to mTOR inhibitor everolimus in patients with inoperable, progressive, somatostatin receptor-positive (SSTR+) GEP-NETs. The study is currently recruiting patients in 14 countries. As part of the study, 300 patients with progressive SSTR+ Grade 1 and 2 GEP-NETs are being randomized, of which 200 receive up to 4 cycles of n.c.a. $^{177}$Lu-Edotreotide (7.5 GBq/cycle) every 3 months or until diagnosis of progression, while 100 patients receive 10 mg everolimus daily for 24 months, or until diagnosis of progression. The overall study duration per patient will be 30 months. Primary objective of the study is to demonstrate prolonged progression free survival (PFS) in patients in the n.c.a. $^{177}$Lu-Edotreotide arm vs. everolimus, while secondary objectives include safety, objective response rates and overall survival after 5 years follow-up.

The initiation of the Phase III study was based on the successful completion of a Phase II study that evaluated the efficacy and safety of n.c.a. $^{177}$Lu-Edotreotide ($^{177}$Lu-DOTATOC) in 56 patients with metastasized and progressive NETs (50% gastroenteral, 26.8% pancreatic, 23.2% other primary sites). The results demonstrated the promising efficacy and safety that ITM's lead candidate can provide in this advanced patient population, achieving a median PFS (mPFS) of 17.4 months and an overall survival of 34.2 months, respectively, with a mPFS of 34.5 months for GEP-NETs. Objective response rates (Complete/Partial Responses) were 54.2% in GEP-NETs, with complete response rates of 25%, of which 78% were maintained throughout the follow-up period. In addition, no serious adverse events were observed. These results indicate that n.c.a. $^{177}$Lu-Edotreotide has a major potential to induce

objective tumor responses and sustained disease control in progressive neuroendocrine tumors. The observed safety profile suggests a particularly favorable therapeutic index, including in patients with impaired bone marrow or renal function, reflecting the low uptake of n.c.a. $^{177}$Lu-Edotreotide by normal organs. The ongoing Phase III COMPETE study will now aim to confirm and further build on these results.

**Presentation information**

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| **Title:** | COMPETE Phase III Trial – Peptide Receptor Radionuclide Therapy (PRRT) with $^{177}$Lu-Edotreotide vs. Everolimus in Progressive GEP-NET |
| **Abstract No:** | 5201 |
| **Session:** | Phase III Clinical Trials in Progress |
| **Presenter:** | Mona M. Wahba, MD<br>*Mona M. Wahba is available for questions and discussions via the chat box function of the AACR poster section and will respond within 24 hours. Meetings can also be requested using the AACR system.* |

The poster will also be made available on the company's website under the event section.

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**ITM Isotopen Technologien München**

ITM, a radiopharmaceutical biotech company founded in 2004, 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 combining its superior radioisotopes with targeting molecules to create 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.ag.

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