APPLICANT/ COORDINATING INVESTIGATOR	ITM Solucin GmbH/ Prof. Dr. Wolfgang Weber Technische Universität München
CONDITION	Well-differentiated neuroendocrine tumours of gastroenteric or pancreatic origin (GEP-NET), with positive SSTR expression
OBJECTIVE(S)	**Primary objective** progression-free survival (PFS) **Secondary objectives** 1. overall survival (OS)
INTERVENTION(S)	- Slow intravenous infusion/injection (IV) of ^{177}Lu-edotreotide, - A maximum of four cycles of 7.5 ± 0.7 GBq ^{177}Lu-edotreotide
KEY EXCLUSION CRITERIA	A patient will be excluded from participation in the trial if one or more of the following criteria are met: 1. Known hypersensitivity to edotreotide or everolimus 2. Known hypersensitivity to DOTA, lutetium-177, or any excipient of edotreotide or everolimus or any other Rapamycin derivative 3. Prior exposure to any peptide receptor radionuclide therapy (PRRT) 4. Prior therapy with mTor inhibitors 5. Prior EFR (extended field radiation) to GEP-NET lesions within 90 days before randomisation or radioembolisation therapy 6. Therapy with an investigational compound and/or medical device within 30 days prior to randomisation 7. Indication for surgical lesion removal with curative potential 8. Planned alternative therapy (for the period of study participation) 9. Serious non-malignant disease 10. Clinically relevant renal, hepatic, cardiovascular, or haematological organ dysfunction, potentially interfering with the safety of the study treatments 11. Pregnant or breast-feeding women. 12. Subjects not able to declare meaningful informed consent on their own (e.g. with legal guardian for mental disorders) or any other vulnerable population to that sense (e.g. persons institutionalised, incarcerated etc.).
KEY INCLUSION CRITERIA	All patients must meet all of the following criteria: 1. Histologically confirmed diagnosis of well-differentiated neuro-endocrine tumour of non-functional gastroenteric origin (GE-NET) or both functional or non-functional pancreatic origin (P-NET) 2. Measurable disease per RECIST 1.1Somatostatin receptor positive (SSTR^{+}) disease 3. Progressive disease based on RECIST 1.1. criteria as eviden-ced by two morphological imaging examinations made with the same imaging method (either CT or MRI)
OUTCOME(S)	To demonstrate the efficacy of PRRT with 177Lu-edotreotide to prolong median progression-free survival (mPFS) in patients with inoperable, progressive, SSTR+ GEP-NET, compared to everolimus.
STUDY TYPE	This will be a prospective, randomised, controlled, open-label, multi-centre phase III study to evaluate the efficacy and safety of 177Lu-edotreotide in comparison to molecular targeted therapy with everolimus in patients with inoperable, progressive, somatostatin receptor-positive (SSTR+), neuroendocrine tumours of gastroenteric or pancreatic origin (GEP-NET).
SAMPLE SIZE	300
TRIAL DURATION	PFS will be assessed individually per patient from date of randomization until the date of first documented progression, assessed up to 30 months.