itm SOLUCIN

Phase III Clinical Trial

Efficacy and Safety of n.c.a. ^{177}Lu-Edotreotide (Solucin®) PRRT in GEP-NET Patients vs. Everolimus

A prospective, randomized, controlled, open-label, multicenter phase III study to evaluate efficacy and safety of Peptide Receptor Radionuclide Therapy (PRRT) with ^{177}Lu-Edotreotide compared to targeted molecular therapy with Everolimus in patients with inoperable, progressive, somatostatin receptor-positive ($SSTR^+$), neuroendocrine tumors of gastroenteric or pancreatic origin (GEP-NET).

STUDY DESIGN

The phase III clinical trial COMPETE is led as an international, prospective, randomized, controlled, open-label, multicenter phase III study to evaluate efficacy and safety of PRRT with n.c.a. ^{177}Lu-Edotreotide (Solucin®) compared to targeted molecular therapy with Everolimus in patients with inoperable, progressive, somatostatin receptor-positive (SSTR$^+$) neuroendocrine tumors of gastroenteric or pancreatic origin (GEP-NET). The trial will be conducted worldwide in min. 11 countries and approx. 40 sites.

IMP: N.C.A. ^{177}LU-EDOTREOTIDE (SOLUCIN®)

n.c.a. ^{177}Lu-Edotreotide is an octreotide-derived somatostatin analogue containing the chelator DOTA, radiolabeled with n.c.a. Lutetium-177, a radio-lanthanide, emitting β- and ɣ-radiation.

PRIMARY OBJECTIVE

To demonstrate the efficacy of PRRT with ^{177}Lu-Edotreotide to prolong median progression-free survival (mPFS) in patients with inoperable, progressive, SSTR$^+$ GEP-NET, compared to Everolimus.

KEY SECONDARY OBJECTIVES

To demonstrate the prolongation of duration of disease control (DDC), measured from the time of initial diagnosis of response (SD, PR or CR) until diagnosis of progression, with ^{177}Lu-Edotreotide compared to Everolimus.
To show an increase in objective response rates (ORR), defined as the proportion of patients achieving partial response (PR) or complete response (CR) as best outcome, with ^{177}Lu-Edotreotide compared to Everolimus.

INCLUSION CRITERIA

- Histologically confirmed diagnosis of well-differentiated neuroendocrine tumor of non-functional gastroenteric origin (GE-NET) or both functional or non-functional pancreatic origin (P-NET)
- Measurable disease per RECIST 1.1
- Somatostatin receptor positive (SSTR$^+$) disease
- Radiological disease progression, defined as progressive disease per RECIST 1.1. criteria

EXCLUSION CRITERIA

- Known hypersensitivity to Edotreotide or Everolimus
- Known hypersensitivity to DOTA, ^{177}Lu, or any excipient of Edotreotide or Everolimus
- Prior exposure to any Peptide Receptor Radionuclide Therapy (PRRT)
- Prior therapy with mTor inhibitors

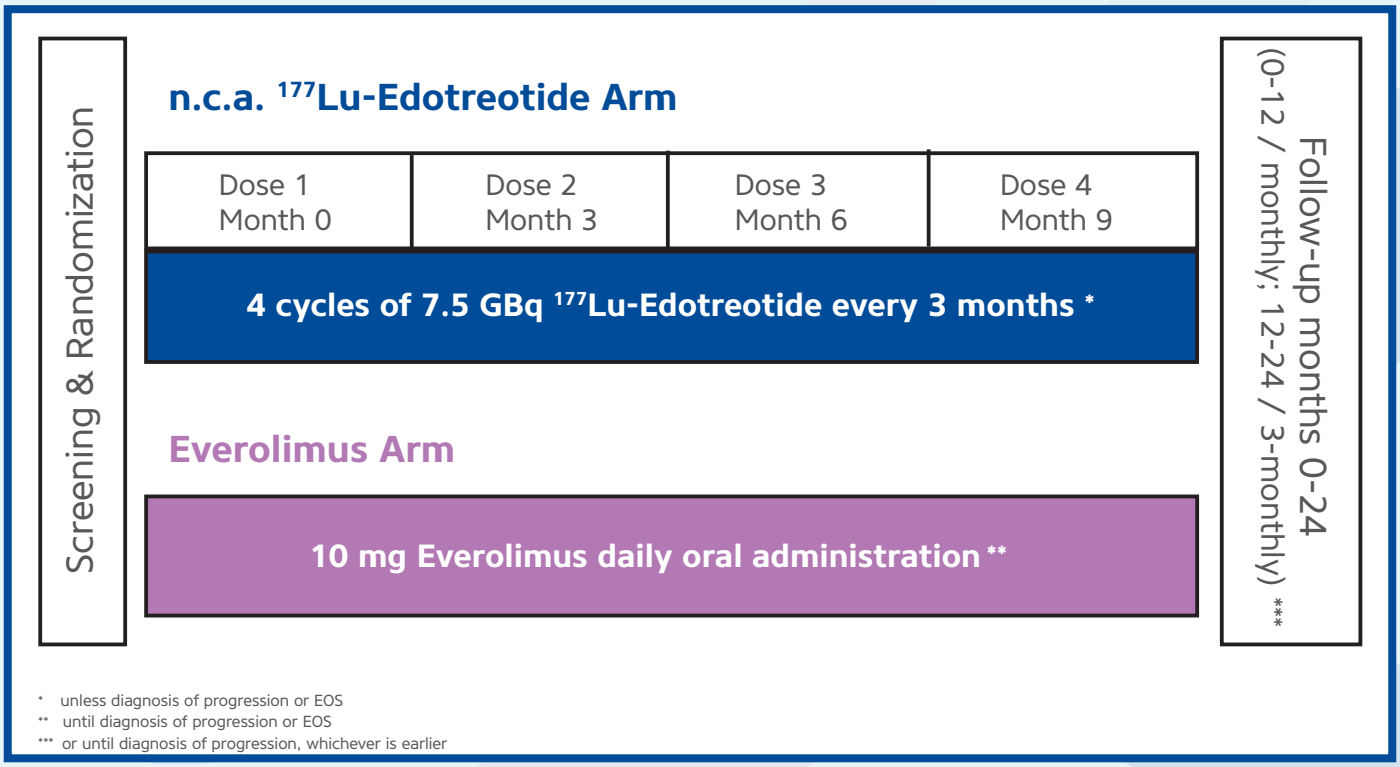
- Prior EFR (external field radiation) to GEP-NET lesions or radioembolization therapy
- Prior therapy with chemotherapy, immunotherapy, interferon, chemo-embolisation, bland embolisation, cyclosporine-A within 4 weeks before randomisation
- Therapy with an investigational compound and/or medical device within 30 days prior to randomization
- Indication for surgical lesion removal with curative potential
- Planned alternative therapy (for the period of study participation)
- Serious non-malignant disease
- Renal, hepatic, cardiovascular, or haematological organ dysfunction, potentially interfering with the safety of the study treatments
- Pregnant or breast-feeding women

TREATMENT ARMS

In total, 300 GEP-NET patients will be randomized 2:1 to receive either

- PRRT with n.c.a. ^{177}Lu-Edotreotide consisting of a maximum of four cycles (7.5 GBq ^{177}Lu-Edotreotide each), administered as i.v. infusion at 3-monthly intervals for 9 months, or unless diagnosis of progression or EOS (200 patients), or
- 10 mg Everolimus daily, administered orally as a tablet until diagnosis of progression or EOS (100 patients)

TREATMENT AND ASSESSMENTS (24 MONTHS)



* unless diagnosis of progression or EOS
** until diagnosis of progression or EOS
*** or until diagnosis of progression, whichever is earlier

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COMPETE. Phase III clinical trial.
Efficacy and safety of Solucin® (^{177}Lu-Edotreotide) PRRT in GEP-NET Patients vs. Everolimus.
Please refer to this study by its ClinicalTrials.gov identifier: NCT03049189

This information is intended for investigators and interested healthcare professionals only.
The distribution to potential or included patients is not permitted.

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About ITM Group

ITM Isotopen Technologien München AG is a privately held group of companies dedicated to the development, production and global supply of innovative diagnostic and therapeutic radionuclides and radiopharmaceuticals.

ITM's main objectives are to significantly improve outcomes and quality-of-life for cancer patients while at the same time reducing side-effects and improving health economics through a new generation of targeted radionuclide therapies in precision oncology.

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