Efficacy and Safety of 177Lu-edotreotide PRRT in GEP-NET Patients (COMPETE)

ClinicalTrials.gov Identifier: NCT03049189

Recruitment Status : Active, not recruiting
First Posted : February 9, 2017
Last Update Posted : November 30, 2023

View this study on the modernized ClinicalTrials.gov

Sponsor:
ITM Solucin GmbH

Collaborators:
ABX CRO
PSI CRO

Information provided by (Responsible Party):
ITM Solucin GmbH

Study Details | Tabular View | No Results Posted | Disclaimer | How to Read a Study Record

Study Description

Go to

Brief Summary:

The purpose of the study is to evaluate efficacy and safety of Peptide Receptor Radionuclide Therapy (PRRT) with 177Lu-Edotreotide compared to targeted molecular therapy with Everolimus in patients with inoperable, progressive, somatostatin receptor-positive (SSTR+), neuroendocrine tumours of gastroenteric or pancreatic origin (GEP-NET).

Condition or disease	Intervention/treatment	Phase
Neuroendocrine Tumors	Drug: 177Lu-edotreotide PRRT Drug: Everolimus Other: Amino-Acid Solution	Phase 3

Study Design

Go to

Study Type :	Interventional (Clinical Trial)
Actual Enrollment :	309 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	None (Open Label)
Primary Purpose:	Treatment
Official Title:	A Prospective, Randomised, Controlled, Open-label, Multicentre Phase III Study to Evaluate Efficacy and Safety of Peptide Receptor Radionuclide Therapy (PRRT) With 177Lu-Edotreotide Compared to Targeted Molecular Therapy With Everolimus in Patients With Inoperable, Progressive, Somatostatin Receptor-positive (SSTR+), Neuroendocrine Tumours of Gastroenteric or Pancreatic Origin (GEP-NET)
Actual Study Start Date :	February 2, 2017
Estimated Primary Completion Date :	December 2024
Estimated Study Completion Date :	December 2029

Resource links provided by the National Library of Medicine NIH NLM

Drug Information available for: Everolimus

Genetic and Rare Diseases Information Center resources:
Neuroendocrine Tumor Gastro-enteropancreatic Neuroendocrine Tumor
Neuroepithelioma

U.S. FDA Resources

Arms and Interventions

Go to

Arm	Intervention/treatment
Experimental: 177Lu-edotreotide PRRT 177Lu-edotreotide (177Lu-DOTATOC) A maximum of four cycles of 7.5 ± 0.7 GBq (gigabequerel) 177Lu-edotreotide, each. Route of administration: Slow intravenous infusion/injection (i.v.) Duration of treatment: 4 cycles, 90 days apart (total duration: 270 days/9 months)	Drug: 177Lu-edotreotide PRRT PRRT using 177Lu-edotreotide will be performed 3-monthly. A maximum of four cycles will be administered. Other Names: • 177Lu-DOTATOC • 177Lu-Edo Other: Amino-Acid Solution The Amino-Acid Solution (AAS) to be used in this study will contain a mixture of 25 g lysine and 25 g arginine diluted in 2000 mL of electrolyte solution, infused over 4 - 6 h, starting 30 - 60 min before PRRT Other Name: Arginine-Lysine Solution
Active Comparator: Everolimus Everolimus (Afinitor ®) Doses: 10 mg/d Route of administration: Oral Duration of treatment: Continuous daily treatment until diagnosis of progression or End of Study (EOS)	Drug: Everolimus Everolimus will be adminstered as a standard dosis of 10 mg daily which may be reduced where required for acceptable tolerability. Other Name: Afinitor

Outcome Measures

Go to

Primary Outcome Measures :

1. progression-free survival (PFS) [Time Frame: 12 weeks +/- 14 days, up to 30 months]

   PFS will be assessed individually per patient from date of randomization until the date of first documented progression, assessed up to 30 months, primary outcome will be measured by CT/MRI every 12 weeks +/- 14 days

Secondary Outcome Measures :

1. overall survival (OS) [Time Frame: every 3 months for a period of at least 30 months]

   OS as secondary outcome measure will be assessed per patient from date of randomization until the date of death, whichever came first

Eligibility Criteria

Go to

Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:	18 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- 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)
- Measurable disease per RECIST 1.1
- Somatostatin receptor positive (SSTR+) disease
- Progressive disease based on RECIST 1.1. criteria as evidenced by two morphological imaging examinations made with the same imaging method (either CT or MRI)

Exclusion Criteria:

- Known hypersensitivity to edotreotide or everolimus
- Known hypersensitivity to DOTA, lutetium-177, or any excipient of edotreotide or everolimus or any other Rapamycin derivative
- Prior exposure to any peptide receptor radionuclide therapy (PRRT)
- Prior therapy with mTor inhibitors
- Prior EFR (external field radiation) to GEP-NET lesions within 90 days before randomisation or radioembolisation therapy
- Therapy with an investigational compound and/or medical device within 30 days prior to randomisation

- Indication for surgical lesion removal with curative potential
- Planned alternative therapy (for the period of study participation)
- Serious non-malignant disease
- Clinically relevant renal, hepatic, cardiovascular, or haematological organ dysfunction, potentially interfering with the safety of the study treatments
- Pregnant or breast-feeding women
- 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.).

Contacts and Locations

Go to

Information from the National Library of Medicine NIH NLM

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT03049189***

Locations

Show 52 study locations

Sponsors and Collaborators

ITM Solucin GmbH

ABX CRO

PSI CRO

More Information

Go to

Responsible Party:	ITM Solucin GmbH
ClinicalTrials.gov Identifier:	NCT03049189 History of Changes
Other Study ID Numbers:	ITM-LET-01
First Posted:	February 9, 2017 Key Record Dates
Last Update Posted:	November 30, 2023
Last Verified:	November 2023

Studies a U.S. FDA-regulated Drug Product:	Yes
Studies a U.S. FDA-regulated Device Product:	No

Keywords provided by ITM Solucin GmbH:

non-functional and functional P-NET

non-functional GE-NET

Additional relevant MeSH terms:

Neuroendocrine Tumors

Neuroectodermal Tumors

Neoplasms, Germ Cell and Embryonal

Neoplasms by Histologic Type

Neoplasms

Neoplasms, Nerve Tissue

Everolimus

Pharmaceutical Solutions

Edotreotide

Edotreotide lutetium LU-177

MTOR Inhibitors

Protein Kinase Inhibitors

Enzyme Inhibitors

Molecular Mechanisms of Pharmacological Action

Immunosuppressive Agents

Immunologic Factors

Physiological Effects of Drugs

Antineoplastic Agents

Radiopharmaceuticals