Lutetium 177Lu-Edotreotide Versus Best Standard of Care in Well-differentiated Aggressive Grade-2 and Grade-3 GastroEnteroPancreatic NeuroEndocrine Tumors (GEP-NETs) - COMPOSE (COMPOSE)

ClinicalTrials.gov Identifier: NCT04919226

Recruitment Status : Recruiting
First Posted : June 9, 2021
Last Update Posted : April 8, 2024

See **Contacts and Locations**

View this study on the modernized ClinicalTrials.gov

Sponsor:
ITM Solucin GmbH

Information provided by (Responsible Party):
ITM Solucin GmbH

Study Details | **Tabular View** | **No Results Posted** | Disclaimer

How to Read a Study Record

Study Description

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Brief Summary:

The purpose of the study is to evaluate the efficacy, safety & patient-reported outcomes of peptide receptor radionuclide therapy (PRRT) with 177Lu-Edotreotide as 1st or 2nd line of treatment compared to best standard of care in patients with well-differentiated aggressive grade 2 and grade 3, somatostatin receptor-positive (SSTR+), neuroendocrine tumours of gastroenteric or pancreatic origin.

Condition or disease	Intervention/treatment	Phase
Neuroendocrine Tumors	Drug: 177Lu-Edotreotide (Peptide Receptor Radionuclide Therapy) PRRT Drug: CAPTEM (Capecitabine and Temozolomide) Other: Amino-Acid Solution Drug: Everolimus Drug: FOLFOX (Folinic acid + Fluorouracil + Oxaliplatin)	Phase 3

Study Design

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Study Type :	Interventional (Clinical Trial)
Estimated Enrollment :	202 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	None (Open Label)
Primary Purpose:	Treatment
Official Title:	A Prospective, Randomised, Controlled, Open-label, Multicentre Study to Evaluate Efficacy, Safety and Patient-Reported Outcomes of Peptide Receptor Radionuclide Therapy (PRRT) With 177Lu-Edotreotide Compared to Best Standard of Care in Patients With Well-differentiated Aggressive Grade 2 and Grade 3, Somatostatin Receptor-Positive (SSTR+), Neuroendocrine Tumours of GastroEnteric or Pancreatic Origin
Actual Study Start Date :	December 21, 2021
Estimated Primary Completion Date :	June 2027
Estimated Study Completion Date :	September 2027

Resource links provided by the National Library of Medicine NIH NLM

Genetic and Rare Diseases Information Center resources:

Neuroendocrine Tumor Gastro-enteropancreatic Neuroendocrine Tumor Neuroepithelioma

U.S. FDA Resources

Arms and Interventions

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Arm	Intervention/treatment
Experimental: Peptide Receptor Radionuclide Therapy (PRRT) Arm	Drug: 177Lu-Edotreotide (Peptide Receptor Radionuclide Therapy) PRRT Peptide Receptor Radionuclide Therapy (PRRT) using 177Lu-edotreotide with a defined number of cycles will be administered. Other Name: 177Lu-DOTATOC 177Lu-Edo Other: Amino-Acid Solution The Amino-Acid Solution (AAS) to be used in this study will contain a mixture of lysine and arginine diluted in an electrolyte solution. Other Name: Arginine-Lysine Solution
Active Comparator: CAPTEM(Capecitabine-Temozolomide), Everolimus, FOLFOX(Folinic acid + Fluorouracil + Oxaliplatin)	Drug: CAPTEM (Capecitabine and Temozolomide) Best standard of care treatment (investigator's choice [from the protocol comparator list]) according to individual risk-benefit assessment, institutional protocols, the local Prescribing Information, local regulations, or the local guidelines. Drug: Everolimus Best standard of care treatment (investigator's choice [from the protocol comparator list]) according to individual risk-benefit assessment, institutional protocols, the local Prescribing Information, local regulations, or the local guidelines. Drug: FOLFOX (Folinic acid + Fluorouracil + Oxaliplatin)

Arm	Intervention/treatment
	Best standard of care treatment (investigator's choice [from the protocol comparator list]) according to individual risk-benefit assessment, institutional protocols, the local Prescribing Information, local regulations, or the local guidelines.

Outcome Measures

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Primary Outcome Measures :

1. Progression-Free Survival [Time Frame: Every 12 weeks from randomization until disease progression or death whichever occurs earlier, during the time necessary to observe 148 Progression Free Survival (PFS) events.]

   PFS (Progression-Free Survival), defined as the time from randomization until documented RECIST v1.1 (Response evaluation criteria in solid tumors) progression.

Secondary Outcome Measures :

1. Overall Survival [Time Frame: Up to 2 years after disease progression]

   OS (Overall Survival), defined as the time from randomization until death;

Eligibility Criteria

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Information from the National Library of Medicine NIH NLM

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:

- Patients aged ≥ 18 years.
- Histologically confirmed diagnosis of unresectable, well-differentiated GastroEnteroPancreatic NeuroEndocrine Tumors (GEP-NETs). measurable site of disease per RECIST v1.1 (Response evaluation criteria in solid tumors) using contrast computed tomography (CT) / magnetic resonance imaging (MRI).
- Somatostatin receptor-positive (SSTR+) disease.

Exclusion Criteria:

- Known hypersensitivity to Lutetium 177Lu, edotreotide, DOTA (dodecane tetraacetic acid), any of the comparators, or any excipient or derivative (e.g. rapamycin).
- Prior (Peptide Receptor Radionuclide Therapy) PRRT.
- Any major surgery within 4 weeks prior to randomization in the trial.
- Therapy with an investigational compound and/or medical device within 30 days or 7 half-life periods (whichever is longer) prior to randomization.
- Other known malignancies.
- Serious non-malignant disease.
- Renal, hepatic, cardiovascular, or hematological organ dysfunction, potentially interfering with the safety of the trial treatments.
- Pregnant or breastfeeding women.
- Patients not able to declare meaningful informed consent on their own or any other vulnerable population to that.

Contacts and Locations

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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): ***NCT04919226***

Contacts

Contact: Nicolas Schneider, Dr info-solucin@itm-radiopharma.com

Contact: Amanda Rotger, Dr info-solucin@itm-radiopharma.com

Locations

▸ Show 41 study locations

Sponsors and Collaborators

ITM Solucin GmbH

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Responsible Party:	ITM Solucin GmbH
ClinicalTrials.gov Identifier:	NCT04919226 History of Changes
Other Study ID Numbers:	DP-1111-02CT
First Posted:	June 9, 2021 Key Record Dates
Last Update Posted:	April 8, 2024
Last Verified:	April 2024

Studies a U.S. FDA-regulated Drug Product:	Yes
Studies a U.S. FDA-regulated Device Product:	No
Product Manufactured in and Exported from the U.S.:	No

Keywords provided by ITM Solucin GmbH:

GastroEnteroPancreatic

non-functional and functional GastroEnteroPancreatic NeuroEndocrine Tumors (GEP-NET)

Additional relevant MeSH terms:

Neuroendocrine Tumors	Edotreotide
Neoplasms	Edotreotide lutetium LU-177
Neuroectodermal Tumors	Antimetabolites, Antineoplastic
Neoplasms, Germ Cell and Embryonal	Antimetabolites
Neoplasms by Histologic Type	Molecular Mechanisms of Pharmacological Action
Neoplasms, Nerve Tissue	Antineoplastic Agents
Leucovorin	Immunosuppressive Agents
Folic Acid	Immunologic Factors
Capecitabine	Physiological Effects of Drugs
Fluorouracil	MTOR Inhibitors
Oxaliplatin	Protein Kinase Inhibitors
Everolimus	Enzyme Inhibitors
Temozolomide	Antineoplastic Agents, Alkylating
Pharmaceutical Solutions	Alkylating Agents
Levoleucovorin	Antidotes