Trial record **1 of 1** for: COMPETE AND NET

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

This study is currently recruiting participants.

See **Contacts and Locations**

Verified October 2017 by ITM Solucin GmbH

Sponsor:
ITM Solucin GmbH

ClinicalTrials.gov Identifier:
NCT03049189

First Posted: February 9, 2017
Last Update Posted: October 13, 2017

Collaborator:
ABX CRO

Information provided by (Responsible Party):
ITM Solucin GmbH

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

Purpose

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	Intervention	Phase
Neuroendocrine Tumors	Drug: 177Lu-edotreotide PRRT Drug: Everolimus Other: Amino-Acid Solution	Phase 3

Study Type: Interventional

Study Design: 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**)

Resource links provided by NLM:

MedlinePlus related topics: Carcinoid Tumors

Drug Information available for: Sirolimus Everolimus Temsirolimus

Genetic and Rare Diseases Information Center resources: Carcinoid Tumor Neuroepithelioma

U.S. FDA Resources

Further study details as provided by ITM Solucin GmbH:

Primary Outcome Measures:

- progression-free survival (PFS) [Time Frame: 12 weeks +/- 14 days, up to 24 months]

PFS will be assessed individually per patient from date of randomization until the date of first documented progression, assessed up to 24 months, primary outcome will be measured by CT/MRI every 12 weeks +/- 14 days

Secondary Outcome Measures:

- overall survival (OS) [Time Frame: every 3 months for a period of at least 24 months]

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

Estimated Enrollment:	300
Actual Study Start Date:	February 2, 2017
Estimated Study Completion Date:	May 2021
Estimated Primary Completion Date:	December 2020 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: 177Lu-edotreotide PRRT 177Lu-edotreotide (177Lu-DOTATOC) A maximum of four cycles of 7.5 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 ®)	Drug: Everolimus Everolimus will be adminstered as a standard dosis of 10 mg daily which may

Doses: 10 mg/d Route of administration: Oral Duration of treatment: Continuous daily treatment until diagnosis of progression or End of Study (EOS)	be reduced where required for acceptable tolerability. Other Name: Afinitor

Eligibility

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, Senior)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Histologically and clinically 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
- Radiological disease progression, defined as progressive disease per RECIST 1.1. criteria

Exclusion Criteria:

- Known hypersensitivity to edotreotide or everolimus
- Known hypersensitivity to DOTA, lutetium-177, or any excipient of edotreotide or everolimus
- Prior exposure to any peptide receptor radionuclide therapy (PRRT)
- Prior therapy with mTor inhibitors
- Prior EFR (extended field radiation) to GEP-NET lesions 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
- Renal, hepatic, cardiovascular, or haematological organ dysfunction, potentially interfering with the safety of the study treatments
- Pregnant or breast-feeding.

Contacts and Locations

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***

Contacts

Contact: Konstantin Zhernosekov, Dr info@itm-solucin.de

Contact: Ulrike Schorr-Neufing, Dr info@abx-cro.com

Locations

Australia, New South Wales

Royal North Shore Hospital — **Recruiting**
Saint Leonards, New South Wales, Australia, 2065

Australia, Victoria

Olivia Newton-John Cancer & Wellness Centre, Austin Hospital — **Not yet recr**
Heidelberg, Victoria, Australia, 3084

Peter MacCallum Cancer Centre — **Recruiting**
Melbourne, Victoria, Australia, 3000

Austria

Allgemeines Krankenhaus Wien — **Not yet recr**
Wien, Austria, 1090

France

Hospices civils de Lyon Bron, France, 69677	**Not yet recr**
HP Hôpital Beaujon Clichy, France, 92110	**Not yet recr**
Institut de Recherche en Cancérologie de Montpellier (IRCM) Montpellier, France, 34298	**Not yet recr**
CHU de Nantes - Hôtel Dieu Nantes, France, 44093	**Not yet recr**

Germany

Zentralklinik Bad Berka GmbH Bad Berka, Germany, 99437	**Not yet recr**
Charité - Universitätsmedizin Berlin Berlin, Germany, 10117	**Not yet recr**
Universitätsklinikum Bonn Bonn, Germany, 53127	**Not yet recr**
Universitätsklinikum des Saarlandes Homburg, Germany, 66421	**Not yet recr**
Philipps Universität Marburg Marburg, Germany, 35043	**Not yet recr**
LMU - Klinikum der Universität München, Campus Großhadern Munich, Germany, 81377	**Not yet recr**
Universitätsklinikum Würzburg Wurzburg, Germany, 97080	**Not yet recr**

Italy

Istituto Scientifico Romagnolo per lo Studio e la Cura dei Tumori (IRST) Srl Meldola, Italy, 47014	**Not yet recr**
European Institute of Oncology (EIO) Milano, Italy, 20141	**Not yet recr**

Netherlands

Academic Medical Center, University of Amsterdam Amsterdam, Netherlands, 1100DD	**Not yet recr**

Poland

MSC Memorial Cancer Centre	**Not yet recr**

Gliwice, Poland, 44-100

Jagiellonian University — **Not yet recr**
Krakow, Poland, 31-501

Medical University of Warsaw — **Not yet recr**
Warsaw, Poland, 02-097

South Africa

University of Pretoria & Steve Biko Academic Hospital — **Recruiting**
Pretoria, South Africa, 0001

Switzerland

Universitätsspital Basel — **Recruiting**
Basel, Switzerland, 4031

Inselspital, Universitätsspital Bern — **Not yet recr**
Bern, Switzerland, 3010

United Kingdom

Clatterbridge Cancer Centre NHS Foundation Trust — **Not yet recr**
Liverpool, United Kingdom, L7 8XP

Royal Free NHS Foundation Trust — **Not yet recr**
London, United Kingdom, NW3 2QG

Sponsors and Collaborators

ITM Solucin GmbH

ABX CRO

More Information

Responsible Party:	ITM Solucin GmbH
ClinicalTrials.gov Identifier:	NCT03049189 History of Changes
Other Study ID Numbers:	ITM-LET-01
First Submitted:	January 13, 2017
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Last Verified:	October 2017

Studies a U.S. FDA-regulated Drug Product:	No
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	Edotreotide
Carcinoid Tumor	Antineoplastic Agents
Neuroectodermal Tumors	Immunosuppressive Agents
Neoplasms, Germ Cell and Embryonal	Immunologic Factors
Neoplasms by Histologic Type	Physiological Effects of Drugs
Neoplasms	Anti-Bacterial Agents
Neoplasms, Nerve Tissue	Anti-Infective Agents
Adenocarcinoma	Antibiotics, Antineoplastic
Carcinoma	Antifungal Agents
Neoplasms, Glandular and Epithelial	Radiopharmaceuticals
Pharmaceutical Solutions	Molecular Mechanisms of Pharmacological Action
Everolimus	
Sirolimus	Gastrointestinal Agents
Octreotide	Antineoplastic Agents, Hormonal