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compose

Phase III Clinical Trial

n.c.a. ^{177}Lu-edotreotide vs. Best Standard of Care in Well-differentiated Aggressive G2 & G3 GEP-NETs

A Prospective, Randomized, **C**ontrolled, **O**pen-label, **M**ulticenter Trial to Evaluate Efficacy, Safety and **P**atient-reported **O**utcomes of Peptide Receptor Radionuclide Therapy (PRRT) with Lutetium (^{177}Lu) Edotreotide compared to Best **S**tandard of Care in Patients with Well-differentiated Aggressive Grade 2 and Grade 3, Somatostatin Receptor-positive (SSTR^{+}), Neuroendocrine Tumors of Gastro**E**nteric or Pancreatic Origin (COMPOSE).

COMPOSE is an international, prospective, randomized, controlled, open-label, multicenter phase III clinical study

to evaluate the efficacy, safety and impact on quality of life of Targeted Radionuclide Therapy (Peptide Receptor Radionuclide Therapy / PRRT) with no-carrier-added lutetium-177-edotreotide (n.c.a. ^{177}Lu-edotreotide) compared to a standard therapy with either CAPTEM or everolimus or FOLFOX, in patients with well-differentiated advanced Grade 2 and Grade 3, somatostatin receptor-positive (SSTR$^+$) neuroendocrine tumors of gastroenteric or pancreatic origin (G2 and G3 GEP-NETs).

The study is being conducted predominantly in Europe, North America, India and Australia, in approximately 10 countries and 40 sites.

INVESTIGATIONAL MEDICINAL TREATMENT

n.c.a. ^{177}Lu-edotreotide is an octreotide-derived somatostatin analogue containing the chelator DOTA, radiolabeled with no-carrier-added lutetium-177 (n.c.a. ^{177}Lu), a highly pure therapeutic radioisotope, emitting β- and ɣ-radiation.

ACTIVE COMPARATOR TREATMENT

Standard therapy with either CAPTEM or everolimus or FOLFOX.

PRIMARY OBJECTIVE

To demonstrate the efficacy of Targeted Radionuclide Therapy with n.c.a. ^{177}Lu-edotreotide in the treatment of advanced Grade 2 (G2; Ki-67 between 15 and 20, both inclusive) and Grade 3 (G3; Ki-67 above 20 up to 55, inclusive) SSTR$^+$ GEP-NETs compared to best standard of care treatment with either CAPTEM or everolimus or FOLFOX.

KEY SECONDARY OBJECTIVES

To further demonstrate the efficacy of Targeted Radionuclide Therapy with ^{177}Lu-edotreotide, safety and impact on quality of life.

TREATMENT ARMS

In total, 202 patients with advanced Grade 2 and Grade 3 GEP-NETs will be randomized 1:1 to receive either:

- **Targeted Radionuclide Therapy with n.c.a. ^{177}Lu-edotreotide consisting of six cycles (7.5 GBq n.c.a. ^{177}Lu-edotreotide per cycle), administered as i.v. infusion (101 patients). A nephroprotective Amino-Acid Solution (AAS) will be given as an infusion, starting 30-60 minutes before each cycle, and lasting 4-6 hours.**
- **Either CAPTEM or everolimus or FOLFOX, administered orally as a tablet or as i.v. infusion until diagnosis of progression or EOS (101 patients)**

The appropriate standard therapy will be determined by the study doctor based on the individual benefit-risk assessment and according to local prescribing information and guidelines. The overall time in the study depends on multiple factors including the individual variability of treatment response and tumor progression.

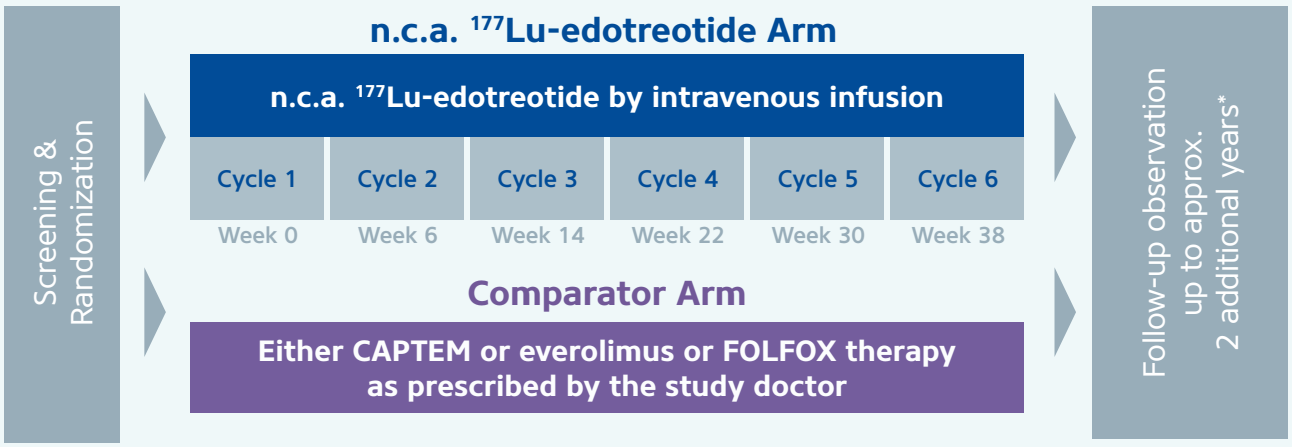
MAIN INCLUSION CRITERIA

- Patients aged ≥ 18 years
- Somatostatin receptor-positive (SSTR+) disease
- Histologically confirmed diagnosis of unresectable, well-differentiated 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)

MAIN EXCLUSION CRITERIA

- Known hypersensitivity to lutetium ^{177}Lu, 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 (e.g. with legal guardian for mental disorders) or any other vulnerable population to that sense (e.g. persons institutionalized, incarcerated etc.)

TREATMENT AND ASSESSMENTS



** Treatment response, tumor progression, survival data, information on further antineoplastic treatments and secondary malignancies*

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Please refer to this study by its ClinicalTrials.gov identifier: NCT04919226
This information is intended for investigators and interested healthcare professionals only.
The distribution to potential or included patients is not permitted.

SPONSOR

ITM Solucin GmbH
Lichtenbergstrasse 1
85748 Garching/Munich, Germany
Email: info-solucin@itm-radiopharma.com

CONTACT (CROs)

PSI CRO AG
Baarerstrasse 113 a
6300 Zug, Switzerland
Email: contact@psi-cro.com

PSI

Cmed (Clinical Research Services)
Ashurst, Broadlands Business Campus
Langhurstwood Road Horsham
West Sussex, RH12 4QP, UK
Email: info@cmedresearch.com

Cmed
A Technology-Led CRO

About the ITM Group

ITM, a radiopharmaceutical biotech company, is dedicated to providing the most precise cancer radiotherapeutics and diagnostics to meet the needs of patients, clinicians and our partners through excellence in development, production and global supply. With patient benefit as the driving principle for all we do, ITM is advancing a broad pipeline combining its superior radioisotopes with targeting molecules to create precision oncology treatments. ITM is leveraging its leadership and nearly two decades of radiopharma expertise combined with its worldwide network to enable nuclear medicine to reach its full potential for helping patients live longer and better.

Your contact:

Phone: +49 89 329 8986-6000
Email: info@itm-radiopharma.com
Web: www.itm-radiopharma.com

ITM Isotope Technologies Munich SE
Lichtenbergstrasse 1
85748 Garching/Munich, Germany

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