A phase III clinical trial investigating a new treatment option for advanced neuroendocrine tumors of gastroenteric or pancreatic origin (GEP-NETs)

Information flyer for adults with gastroenteropancreatic neuroendocrine tumors

Investigational treatment

Targeted Radionuclide Therapy with n.c.a. Lutetium-177-Edotreotide, consisting of the highly pure medical radioisotope, no-carrier-added (n.c.a.) Lutetium-177, used to destroy tumor cells, and the molecule Edotreotide, which targets neuroendocrine tumor-specific receptors and delivers the medical radioisotope to the tumor site.

What is Targeted Radionuclide Therapy?

In contrast to external radiotherapy, where radiation is applied from outside the body, Targeted Radionuclide Therapy is defined by the infusion of a radiopharmaceutical into the body which precisely recognizes and destroys tumor cells while healthy surrounding tissue is minimally affected.

Comparator treatment

Standard therapy with either CAPTEM (chemotherapy) or everolimus (immunosuppressive cancer therapy) or FOLFOX (chemotherapy), determined by the doctor based on individual benefit-risk assessment and according to institutional protocols, local prescribing information, local regulations or local guidelines.

Study objectives

Evaluate efficacy, safety and impact on quality of life

Who can participate? – Main inclusion criteria

- You are at least 18 years old
- Your GEP-NET started in the gastrointestinal tract or pancreas
- Your GEP-NET has somatostatin receptors on its surface ($SSTR^+$)
- Your GEP-NET has spread to other parts of the body (metastatic) and cannot be removed completely by surgery

Please contact your doctor to learn more about the inclusion and exclusion criteria and to check if you meet all requirements.

Your doctor will evaluate initial information on your condition and will decide if you can be included in the study.

Study design

COMPOSE is an international, prospective (new data to be collected), randomized (patients randomly assigned by a computerized system to the investigational or standard therapy group), controlled (investigational group compared to control group), open label (patients and physicians know which drug is administered), multicenter phase III trial to evaluate efficacy, safety and impact on quality of life of the Targeted Radionuclide Therapy n.c.a. Lutetium-177-Edotreotide compared to best standard therapy in patients with well-differentiated advanced Grade 2 and Grade 3 somatostatin receptor positive ($SSTR^+$) neuroendocrine tumors of gastroenteric or pancreatic origin (G2 & G3 GEP-NETs).

Clinical trial procedure

202 patients with specific advanced G2 and G3 GEP-NETs will be randomized 1:1 by a computerized system. You are equally as likely to receive Targeted Radionuclide Therapy as you are to receive one of the comparator treatments. Neither you nor your doctor will be able to choose which group you will be assigned to.

- 101 patients are planned to receive 6 cycles of n.c.a. Lutetium-177-Edotreotide, administered as an infusion. To protect the kidneys, 30-60 minutes before each n.c.a. Lutetium-177-Edotreotide cycle, an Amino-Acid Solution (AAS) will be given as an infusion over 4-6 hours.
- 101 patients are planned to receive a standard therapy with either CAPTEM, or everolimus or FOLFOX, determined by your doctor based on your individual benefit-risk assessment and according to local prescribing information and guidelines.

Study duration

The average trial duration for each patient will be approximately 4 years but may vary on an individual patient basis. The overall time in the trial depends on multiple factors including the individual variability of treatment response and tumor progression.

Further Information

If you are interested in COMPOSE, please contact one of the participating trial locations for further details. A list of participating sites and more information about GEP-NETs and the COMPOSE trial can be found below:

Participating sites	COMPOSE Website	Clinical trial registry	Clinical trial registry	International NET patient organization
[LINK]	[LINK]	www.clinicaltrials.gov	www.clinicaltrialsregister.eu	www.incalliance.org

The study has been evaluated favourably by the responsible ethics committee and has been approved by the responsible authority.

Study Sponsor:
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