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compose

Phase III Clinical Trial

Patient Information

A clinical trial investigating Targeted Radionuclide Therapy in advanced neuroendocrine tumors

Introduction

Dear patient,

This brochure will provide you with a comprehensive overview of a new treatment option for advanced neuroendocrine tumors (NETs) being investigated in a phase III clinical trial called COMPOSE. The information outlined in this brochure does not replace a consultation with your doctor. If you are interested in participating in this clinical trial, you must still arrange for a consultation with your physician.

The purpose of COMPOSE is to evaluate the efficacy, safety and impact on the quality of life of Targeted Radionuclide Therapy with a radiopharmaceutical, n.c.a. Lutetium-177-Edotreotide*, in patients with specific advanced Grade 2 and Grade 3 NETs of gastroenteric** or pancreatic origin (GEP-NETs). This includes patients with advanced or progressive GEP-NET which cannot be surgically removed and might have spread to other parts of the body (metastatic).

If you are interested in participating in this study, please reach out to your attending physician who will provide you with detailed information and determine whether you meet the eligibility criteria to enter the study.

Sincerely,
Your COMPOSE Team

* n.c.a. Lutetium-177-Edotreotide: no-carrier-added (n.c.a.) Lutetium-177 is a synthetically produced low-energy Lutetium isotope emitting beta radiation, used as a precursor in Targeted Radionuclide Therapy. Combined with a targeting molecule and within a maximum radius of 1.7 mm, the medical radioisotope releases a small amount of radioactivity to the tumor tissue which can destroy the tumor cells. A highly precise localization can result in the healthy tissue surrounding the targeted tumor being minimally affected. The special property of no-carrier-added (n.c.a.) Lutetium-177 is its high purity.

** The gastroenteric tract includes the stomach and bowel

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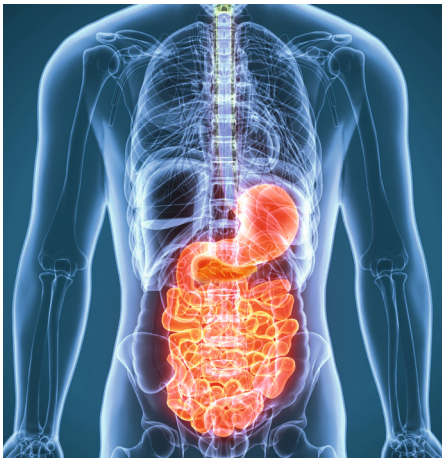
1. Neuroendocrine tumors (NETs)

Neuroendocrine tumors (NETs) are a rare form of cancer with just five to six new cases per 100,000 individuals diagnosed each year.* NETs originate in neuroendocrine cells and often develop slowly over several years. Neuroendocrine cells are part of both the endocrine and the nervous system and can be found throughout the body. These cells release neurotransmitters, cell messengers or hormones into the blood, which control how the body works. This means that they play a key role in the interaction between the nervous and the endocrine systems.

NETs frequently originate in the gastroenteropancreatic tract and are referred to as gastroenteropancreatic neuroendocrine tumors (GEP-NETs). GEP-NETs can be found throughout the digestive system or related parts of the body. Although a rare disease, the number of newly diagnosed patients is continuously rising.** GEP-NETs are often asymptomatic and challenging to diagnose. Therefore, they are often diagnosed at a late stage with metastases and with limited possibility of surgical removal. GEP-NETs appear predominantly in patients aged 50-60 years with women being approximately 2.5 times more likely to be affected than men.* In some cases, GEP-NETs can secrete various hormones and are then referred to as functioning GEP-NETs.



Neuroendocrine tumors of gastroenteric or pancreatic origin

Surgery is the main treatment for NETs and often the only course of treatment needed. However,

* Oronsky et al., Dec 2017, Neoplasia Vol. 19, pp. 991-1002
** Dasari et al., JAMA Oncol 2017

NETs can spread to other parts of the body, or your clinician may not be able to completely remove the cancer by surgery alone. If this happens, other treatment options such as chemotherapy or targeted therapeutics are available.

Tumor stage and grade play an important role in the treatment of NETs. The stage refers to the state of development of the tumor, i.e. whether the tumor has just emerged, whether it is advanced, or whether it has already spread to other parts in the body (metastasized). The tumor grade gives information on how quickly the tumor is expected to grow and spread by comparing the abnormal tumor cells with normal, healthy cells under the microscope. In technical terms, this is indicated by the Ki-67 value. Cells of a low-grade tumor (low Ki-67 index), also described as "well-differentiated", often grow and spread slowly. Cells of a high-grade "poorly differentiated" tumor (high Ki-67 index) grow rapidly. This study examines advanced, well-differentiated G2 and G3 GEP-NETs (Ki-67 index of 15 to 55) for which there is still an unmet high medical need for treatment.

Current standard of care therapies for the treatment of G2 and G3 NETs in the pancreas and small bowel include for example combination chemotherapy with capecitabine and temozolomide (CAPTEM) or with folinic acid, fluoruracil and oxaliplatin (FOLFOX) as well as the targeted therapeutic/immunosuppressive agent, everolimus, an mTOR inhibitor that affects the division and growth of cancer cells by blocking the enzyme mTOR. The above-mentioned therapy options are used as comparator treatments in the COMPOSE study. Other standard treatments include a special form of Targeted Radionuclide Therapy with Lutetium-177-Oxodotreotide and the targeted therapy sunitinib, a multitargeted tyrosine kinase inhibitor.

In addition to standard therapies, new treatment approaches are being investigated in clinical trials to improve patient care.

2. What are clinical trials and why participate as a patient?

Clinical trials play an important role in the development of new treatment opportunities. Patients can decide to participate in such trials voluntarily. In order to guarantee the safety of participating patients, clinical trials are subject to strict quality control guidelines.

For a clinical trial to be approved by a health authority such as the European Medicines Agency (EMA) or the U.S. Food and Drug Administration (FDA), a new therapy has to establish its safety through a preclinical evaluation. This means that the potential treatment is tested for possible dangerous side effects in a controlled manner before it is ever tested in patients. After the drug is deemed safe by the EMA or FDA, it receives permission to enter clinical testing. Clinical trials are divided into three phases that investigate and evaluate the efficacy and safety of the substance in an increasing number of patients.

Phase	Number of participants*	Purpose
I	20–100 healthy volunteers or people with the disease or condition	Identifying a safe dose for use in humans and determining whether the drug is safe enough to proceed with efficacy checks.
II	Up to several hundred patients with the disease or condition	Testing the drug on patients to assess efficacy and side effects at the dose selected for use in humans providing additional safety data. These studies are not large enough to show whether a drug will be beneficial.
III	300 – 3,000 patients with the disease or condition	Testing the drug on patients to assess adverse reactions and efficacy of the selected dose, often in comparison with the current standard of care treatment.
IV	Thousands of patients with the disease or condition	Postmarketing surveillance – observing the drug's long-term efficacy and safety.

Source: https://www.fda.gov/patients/drug-development-process/step-3-clinical-research

*For clinical trials that focus on rare diseases number of participants can be lower.

The drug-development process normally progresses throughout four phases over the course of many years. If the drug successfully passes through the clinical phases (I, II and III) it is typically approved by the national regulatory authority for use in the general population.

The COMPOSE clinical trial is investigating a new treatment option for GEP-NETs. COMPOSE is a phase III study, which means that the Targeted Radionuclide Therapy option being tested in the trial has already proven itself in the prior phases outlined on page eight.

> The main objective of the phase III clinical trial COMPOSE is to determine whether Targeted Radionuclide Therapy displays greater efficacy in a subgroup of patients with specific advanced Grade 2 and Grade 3 GEP-NETs than therapy with either CAPTEM or everolimus or FOLFOX, current standard of care therapies.

Looking for more information? Below you can find additional resources on the background and processes behind clinical trials:

www.centerwatch.com/clinical-trials/overview

www.clinicaltrials.gov/ct2/about-studies/learn

For further information about ongoing studies please visit the following websites or reach out to your attending physician or a patient organization near you.

www.clinicaltrials.gov

www.clinicaltrialsregister.eu

3. Targeted Radionuclide Therapy in COMPOSE

3.1 What is Targeted Radionuclide Therapy?

In contrast to radiotherapy, where radiation is applied from outside the body, Targeted Radionuclide Therapy is defined by the injection of a radiopharmaceutical into the body which precisely recognizes tumor cells. Over the past decades, biomedical investigations on various tumor characteristics and tumor-binding molecules have contributed to the evolution of radiation therapy towards precision oncology and the development of Targeted Radionuclide Therapy.

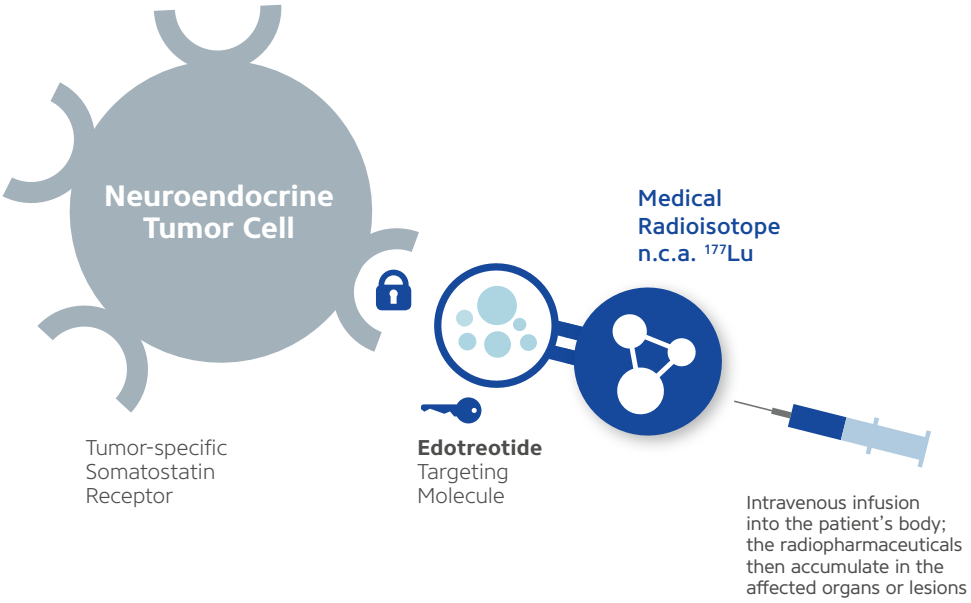
Targeted Radionuclide Therapy uses radiopharmaceuticals consisting of a medical radioisotope and a tumor-specific targeting molecule. In this study, the radiopharmaceutical being used is n.c.a. Lutetium-177-Edotreotide. It consists of two parts: the medical radioisotope, no-carrier-added (n.c.a.) Lutetium-177 which is used to destroy the tumor cells by emission of a very small amount of radiation, and the targeting molecule Edotreotide, a synthetic form of the peptide hormone somatostatin that targets neuroendocrine tumor-specific receptors.

3.2 How does Targeted Radionuclide Therapy work?

Healthy neuroendocrine cells have somatostatin receptors on their surface. The neurotransmitter somatostatin regulates the endocrine system within normal body functions by binding to these receptors according to the lock-and-key principle. Targeted Radionuclide Therapy uses this same principle to treat NETs. The therapy is based on the fact that neuroendocrine tumor cells often express an increased number of somatostatin receptors on their surface, displaying a unique tumor characteristic that differs from that of

healthy neuroendocrine cells.* Just like the naturally produced hormone, somatostatin, Edotreotide binds to these receptors and places the medical radioactivity directly onto the diseased neuroendocrine cells so that the therapeutic radioisotope accumulates at the tumor site. The radioisotope is internalized into the tumor cells and decays, releasing medical radiation with a maximum radius of 1.7 mm and destroying the tumor. The highly precise localization can result in the healthy tissue surrounding the targeted tumor being minimally affected. The radiopharmaceutical is produced in a laboratory under Good Manufacturing Practice (GMP) and underlying strict certified international guidelines.

* Papotti et al., 2002, Virchows Archiv 440(5): 461-75



3.3 Study design

COMPOSE is an international, prospective, randomized, controlled, open label, multicenter phase III study. This means that during the study, new data will be collected (prospective). Patients participating in the COMPOSE trial will be randomly assigned by computer to one of two groups to receive either the investigational treatment with n.c.a. Lutetium-177-Edotreotide or a current standard of care treatment with either CAPTEM or everolimus or FOLFOX (randomized). Results in patients receiving the investigational treatment will be compared to a control group receiving the standard therapy with either CAPTEM or everolimus or FOLFOX (controlled). Both patients and physicians will know which drug is being administered (open-label). The study will be conducted at multiple sites (multicenter) across different countries simultaneously.

3.4 Study objectives

The trial will evaluate the efficacy, safety and impact on quality of life of the targeted radiopharmaceutical n.c.a Lutetium-177-Edotreotide compared to a standard therapy with either CAPTEM or everolimus or FOLFOX in patients with advanced G2 and G3 GEP-NETs.

3.5 Trial therapy

Targeted Radionuclide Therapy also known as Peptide Receptor Radionuclide Therapy (PRRT) is the GEP-NETs treatment option being investigated in this trial. It is not to be confused with traditional radiation therapy, where radiation is applied from outside the body. In contrast to external radiotherapy, Targeted Radionuclide Therapy is defined by the injection of a radiopharmaceutical into the body which precisely recognizes tumor cells.

4. Key facts about COMPOSE

COMPOSE is led as an international, prospective, randomized, controlled, open-label, multicenter phase III clinical trial.

Investigational medicinal product

Targeted Radionuclide Therapy with n.c.a. Lutetium-177-Edotreotide

Comparator treatment

Standard therapy with either CAPTEM or everolimus or FOLFOX

Study objectives

Evaluate efficacy, safety and impact on quality of life

Indication

Patients with specific advanced Grade 2 and Grade 3 neuroendocrine tumors of gastroenteric or pancreatic origin (G2 and G3 GEP-NETs) which cannot be surgically removed and might have spread to other parts of the body (metastatic).

Clinical trial procedure

202 patients with advanced Grade 2 and Grade 3 GEP-NETs will be randomized 1:1 by a computerized system. Neither you nor your doctor will be able to choose which group you will be assigned to. You are equally as likely to receive Targeted Radionuclide Therapy with n.c.a. Lutetium-177-Edotreotide as you are to receive a standard therapy with CAPTEM, everolimus or FOLFOX.

- 101 patients will receive Targeted Radionuclide Therapy with n.c.a. Lutetium-177-Edotreotide with six cycles, administered as an infusion (second infusion at six weeks, then subsequent infusions at two-month intervals).

To protect the kidneys, 30-60 minutes before each cycle with Targeted Radionuclide Therapy, an Amino-Acid Solution (AAS) will be given as an infusion over 4-6 hours.

- 101 patients will receive either CAPTEM or everolimus or FOLFOX. The appropriate standard therapy will be 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 (treatment and follow-up observation) will be approximately four 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. You may withdraw your consent to treatment at any time; however, follow-up procedures and information will continue to be collected unless you withdraw from the study completely. You are free to withdraw from the study at any time. If you withdraw, your regular medical care will continue unchanged.

Participating countries

Approximately 40 specialist centers across 10 countries (Australia, France, Germany, India, Italy, Netherlands, Spain, Sweden, UK and USA).

Participating sites

An up-to-date list of participating sites can be found at:

[LINK]

5. Key COMPOSE participation features

- Only standard of care treatments in the comparator arm, no placebo (medication without active ingredient)
- Participation of patients with and without prior GEP-NET treatment possible (study treatment options offered first-line and second-line)
- Special kidney protection will be provided during Targeted Radionuclide Therapy
- Treatment costs will be covered
- Should travel be necessary expenses will be covered*

*Based on travel distance & country and according to sponsorship regulations

6. Who can participate in COMPOSE?

Before you can be admitted into the trial, you will be given detailed information about the trial and your doctor will evaluate initial information on your condition. The following list outlines the basic entry conditions for COMPOSE. Please contact your doctor to check if you meet these requirements.

6.1 Main inclusion criteria

Inclusion criteria that need to be fulfilled before being considered for participation in this study include:

- your GEP-NET started in the gastrointestinal tract or pancreas
- your GEP-NET is growing rapidly and classified as a well-differentiated G2 or G3 tumor (Ki-67 index of 15 to 55)
- your tumor has spread to other parts of the body (metastatic) and cannot be removed completely by surgery
- your tumor has somatostatin receptors on its surface (somatostatin receptor positive)
- you have not received previous treatment for GEP-NET, or you have received a prior therapy (including somatostatin analogues) and your GEP-NET has progressed in the past four months
- you are at least 18 years old
- you are willing to use highly effective* contraception during treatment and afterwards** if there is any possibility that you or your partner could become pregnant

*Methods of effective contraception as required by the study protocol will be explained by your study doctor.

**6 months for CAPTEM; 8 weeks for everolimus; 6 months for FOLFOX; 66 days for Targeted Radionuclide Therapy

6.2 Main exclusion criteria

Exclusion criteria that would prohibit participation include:

Cancer related conditions

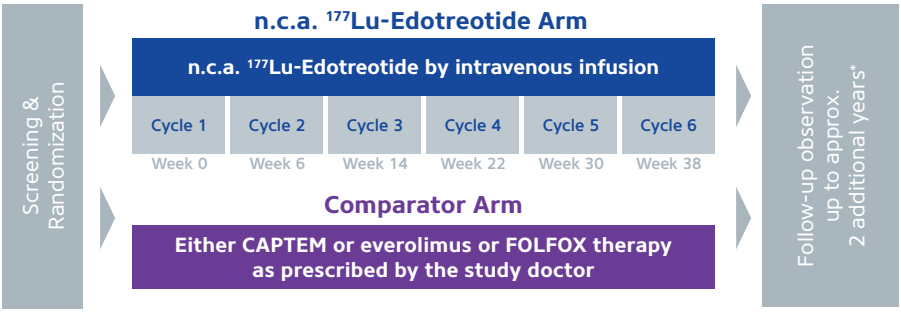
- your GEP-NET has spread to the brain
- you have had another form of malignancy within the previous five years (except for non-invasive skin cancer and non-invasive carcinoma of the cervix)
- you have had treatment for your GEP-NET (other than symptom control with somatostatin analogues) in the past month
- you still have moderate or serious side effects from previous GEP-NET treatment
- you have had any Targeted Radionuclide Therapy in the past

Medical conditions

- you have serious medical conditions or mental health problems that could affect your participation and that are evaluated by the study doctor
- you have had an investigational treatment in the past month
- you are sensitive to treatment or any treatment component used in this trial
- you have spontaneous urinary incontinence

7. COMPOSE treatment & assessments

The following graphic shows how and at what intervals n.c.a. Lutetium-177-Edotreotide and the comparator treatments (CAPTEM, everolimus or FOLFOX) are administered. You will also receive a chronological overview of the accompanying examinations.



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

COMPOSE treatment and assessment plan

The following pages outline:

- which examinations are performed before and during the COMPOSE clinical trial
- how treatment with n.c.a. Lutetium-177-Edotreotide Targeted Radionuclide Therapy works
- how standard therapy with the comparator treatments works
- how often hospital visits are required during the COMPOSE clinical trial
- how n.c.a. Lutetium-177-Edotreotide might affect you on a day-to-day basis

7.1 Pre-treatment & follow-up tests

You will be closely monitored during the study. Therefore, it is very important that your trial team knows everything about your current health status. This includes any symptoms you experience and all medications you are taking, especially if you are taking a somatostatin analogue e.g. lanreotide and octreotide.

Your trial team will conduct tests to ensure that you are ready for treatment.

The tests may include:

- a physical examination
- blood tests and a urine test
- a pregnancy test
- a recording of the electrical signals in your heart (ECG)
- computed tomography (CT) scans or magnetic resonance imaging (MRI)
- radioactive scans

In order for the doctors to identify the tumor grade, the trial team will ask to use a sample of your tumor taken at the time of your diagnosis. You will need to have a biopsy if a suitable sample is unavailable.

You will need to complete a quality of life (QoL) questionnaire before the treatment can start and at set times during the trial. The questionnaire will assess how you have been feeling and what side effects, if any, you have been experiencing.

7.2 Treatment cycles with n.c.a. Lutetium-177-Edotreotide

If you are assigned to the treatment with n.c.a. Lutetium-177-Edotreotide, you will have an appointment at the clinic for each of the six treatment cycles, and an additional appointment two to three weeks before each cycle for pre-testing (e.g. blood sampling) to check your health status for the next cycle. You will receive Targeted Radionuclide Therapy with n.c.a. Lutetium-177-Edotreotide under closely supervised conditions. A short hospital stay (one to three days) might be required for treatment depending on local regulations and your trial doctor. The second infusion will be given six weeks after the first, each subsequent infusion at eight week intervals for six doses of treatment in total. About four weeks after the fifth and sixth infusion, you will also need to go to the hospital for additional safety tests (e.g., physical examination, vital signs, blood sampling).

YOUR INFUSION

Your trial team will conduct tests to check your health status. Before every treatment infusion, you will be given an amino acid solution as an infusion to protect your kidneys. The amino acid infusion will continue during and after you receive n.c.a. Lutetium-177-Edotreotide and will last 4–6 hours. During this time, n.c.a. Lutetium-177-Edotreotide will be administered for 10–20 minutes.

AFTER YOUR TREATMENT

After each treatment, you may be able to leave after several hours or you may need to stay in the hospital according to local regulations. Your trial team will explain how n.c.a. Lutetium-177-Edotreotide might affect you on a day-to-day basis, the precautions you need to take at home and for how long you will need to adhere to them.

AFTER YOUR INFUSION

Directly after your infusion, another blood sample is taken, vital signs are measured, and an ECG is performed.

7.3 Standard therapy with CAPTEM, everolimus or FOLFOX

The comparator treatments CAPTEM, everolimus or FOLFOX used in this study, are some of the current standard of care treatments. If you are allocated to the 'best standard of care' group, you will receive treatment with one of these drugs based on the prior decision of your study doctor. This decision cannot be changed after randomization. Your study doctor will provide you with either CAPTEM or everolimus or FOLFOX, as she or he would do if you were not part of the study. The administration and frequency of the standard therapy assigned to you will be determined by your physician based on your individual benefit-risk assessment and will follow local prescribing information and guidelines. This continues for as long as it is helping you and the side effects are tolerable. If you are assigned to a standard of care treatment and your disease worsens on that treatment, your doctor might decide to offer you Targeted Radionuclide Therapy outside this study, if this is to be considered appropriate and beneficial for you.

Below you can find a short overview of the three "best standard of care" medications you could receive within this study. Your study team will provide you with more information.

CAPTEM is a chemotherapy that combines the two orally or intravenous administered active ingredients capecitabine and temozolomide. CAPTEM inhibits the cell division of tumor cells.

Everolimus is an orally administered immunosuppressive cancer therapy that affects the division and growth of cancer cells by blocking the enzyme mTOR.

FOLFOX is a chemotherapy that contains the active ingredients folinic acid, fluorouracil and oxaliplatin. FOLFOX is given by intravenous infusion and affects the DNA synthesis and tumor cell division.

7.4 Hospital visits during the COMPOSE clinical trial

During treatment, you will be closely monitored and will see the trial team at regular intervals for blood tests and a physical examination.

After completion of the course of treatment and if you have not experienced a tumor progression, you will have a CT scan or an MRI scan every three months to assess your tumor.

If you have experienced a tumor progression you will be contacted by the trial team to collect limited information including details of any new anti-cancer drugs you have started taking and whether you have had any serious adverse reactions since you completed the study.

7.5 How can n.c.a. Lutetium-177-Edotreotide therapy affect you?

Medical administration of radionuclide therapies such as n.c.a. Lutetium-177-Edotreotide is guided by national radiation safety regulations, which differ between countries. Excretion limits acceptable for hospital discharge will be defined by your doctor in compliance with local regulations. As you will be emitting small quantities of the radioactive substance over a seven day period following the Targeted Radionuclide Therapy, you will be given precautions and recommendations to follow by the study team, such as:

- Good hydration is recommended - drink more fluids (water) than you usually do
- Subjects should urinate as often as possible and observe rigorous hygiene in order to avoid risk of contamination of others (sitting down to urinate; using toilet paper after urinating; flushing the toilet twice; washing hands thoroughly and having a towel that only you use)

8. Possible side effects

The trial team will be monitoring your health during treatment and afterwards. You will be given a phone number to call if you are worried about anything. The trial team will tell you about possible side effects of your treatment before you start the trial. The most frequently reported side effects for all four treatment options are summarized below, without claiming to be complete. For more information, please refer to the package leaflet of the respective drug, which will be given to you by the study team, or ask your attending physician. Should you suffer from any side effect, your study doctor may, depending on the severity of the side effects, give you medication to treat this side effect, prescribe a break from medication, or consider stopping the study in consultation with you.

Potential risks caused by n.c.a. Lutetium-177-Edotreotide may arise from radiation exposure and somatostatin-related side effects. Some side effects may continue after treatment is over, as it takes time for healthy cells to recover from the effects of Targeted Radionuclide Therapy. Please consult your doctor should you feel sick or experience any other symptoms.

Possible side effects of Targeted Radionuclide Therapy with n.c.a. Lutetium-177-Edotreotide include among others:

- Reduction of blood cells, which can lead to an increased risk of bleeding, faster exhaustion, shortness of breath and infections
- sickness, vomiting and abdominal pain during drug administration
- fatigue, changes in appetite afterwards
- constipation
- diarrhoea
- dizziness

Possible very common side effects of CAPTEM include among others:

- abdominal pain
- rash, dry or itchy skin
- hair loss
- tiredness
- loss of appetite
- difficulty speaking
- headache
- vomiting, nausea, diarrhea, constipation

Possible very common side effects of FOLFOX include among others:

- ischemic heart abnormalities
- fever
- nausea, vomiting, diarrhea, malaise, weakness
- inflammation of rectum or anus
- delayed wound healing
- inflammation of lining of the mouth or esophagus, sore lips or mouth ulcers
- increase in uric acid in the blood
- blood disorders including low red or white blood cells, low platelets
- loss of appetite
- nose bleeds
- infections
- hair loss
- toxic skin reactions, allergies/ allergic reactions
- dry cough, difficulty breathing or crackles

Possible very common side effects of everolimus include among others:

- increased temperature, chills (signs of infection), fever
- coughing, difficulty breathing, wheezing
- high level of sugar in the blood (hyperglycemia)
- loss of appetite
- disturbed taste (dysgeusia)
- headache
- nose bleeds (epistaxis)
- mouth ulcers
- upset stomach including feeling sick (nausea) or diarrhea
- skin rash
- itching (pruritus)
- feeling weak or tired
- tiredness, breathlessness, dizziness, pale skind, signs of low red blood cells (anemia)
- swelling of arms, hands, feet, ankles or other part of the body (signs of edema)
- weight loss
- high level of lipids (fats) in the blood (hypercholesterolemia)

Interested in participating in COMPOSE?

If you are interested in participating in the study, reach out to your attending doctor who can provide you with detailed information and determine whether you meet the eligibility criteria to enter the study.

compose

Efficacy, safety and quality of life of n.c.a. Lutetium-177-Edotreotide PRRT vs. CAPTEM, everolimus or FOLFOX in patients with GEP-NETs.

Patient organizations:
For national and international registered NET patient organizations or cancer groups please see:

International Neuroendocrine Cancer Alliance (INCA)
www.incalliance.org

Further information:

[LINK]

www.clinicaltrials.gov

www.clinicaltrialsregister.eu

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V 1.0 AUS 03/2021