



Learn about LUTATHERA and how to talk to your doctor about when it may fit into your NET treatment plan.

NET, neuroendocrine tumor.



#### What is LUTATHERA?

LUTATHERA® (lutetium Lu 177 dotatate) is a prescription medicine used to treat adults and children aged 12 years and older with a type of cancer known as gastroenteropancreatic neuroendocrine tumors (GEP-NETs) that are positive for the hormone receptor somatostatin, including GEP-NETs in the foregut, midgut, and hindgut.

#### **IMPORTANT SAFETY INFORMATION**

What are some important things to know about the safety of LUTATHERA?

LUTATHERA is associated with some serious safety considerations and, in some cases, these may require your health care provider to adjust or stop your treatment. You should always follow your health care provider's instructions. Safety considerations include:

 Radiation exposure: Treatment with LUTATHERA will expose you to radiation, which can contribute to your long-term radiation exposure. Overall radiation exposure is associated with an increased risk for cancer.



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## Why should I consider LUTATHERA now?

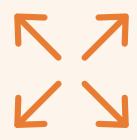
## Living with NETs means living with the risk of ongoing progression

Gastroenteropancreatic neuroendocrine tumors (GEP-NETs) are a disease that grows and progresses over time. Most are slow growing, but NETs are not all alike. It's important to understand your cancer when deciding on treatment options.



#### Some NETs can grow and spread quickly

- Your doctor can check how fast your cancer is growing by testing for a protein called Ki-67. A higher Ki-67 index means the cancer is higher grade, and is growing and spreading more quickly
- Ask your doctor about your Ki-67 index and how to slow down cancer growth as early as possible



#### NETs can progress even while on treatment

- Standard treatment with somatostatin analogues (SSAs) can help control symptoms but may not be enough on its own to slow progression
- Regular scans and follow-ups can help you know when you need another treatment. It's important to make a plan with your doctor about monitoring for progression and what the next step could be

#### **IMPORTANT SAFETY INFORMATION (continued)**

What are some important things to know about the safety of LUTATHERA? (continued)

• Radiation exposure (continued): The radiation will be detectable in your urine for up to 30 days following administration of the drug. It is important to minimize radiation exposure to household contacts consistent with good radiation safety practices as advised by your health care provider.





# Why should I consider LUTATHERA now? (continued)

## LUTATHERA early can help slow NET progression for longer



#### **LUTATHERA** delivers targeted radiation to NETs

- Most GEP-NETs have proteins called somatostatin receptors (SSTRs) on the surface of their cells
- As a peptide receptor radionuclide therapy (PRRT), LUTATHERA finds and attacks SSTR-positive (SSTR+) NETs



## LUTATHERA was proven to slow progression for longer

• In people with recently diagnosed, faster-growing NETs (Ki-67,10%–55% [grade 2 or 3])

Learn more on page 5 >

In people with NETs that progressed on an SSA

Learn more on page 7 >

## More than 15,000 people have received LUTATHERA for GEP-NETs in the United States

#### **IMPORTANT SAFETY INFORMATION (continued)**

What are some important things to know about the safety of LUTATHERA? (continued)

• Bone marrow problems: Treatment with LUTATHERA increases the risk of myelosuppression, a condition in which bone marrow activity is decreased, resulting in a drop in blood cell counts. You may experience blood-related side effects such as low red blood cells (anemia), low numbers of cells that are responsible for blood clotting (thrombocytopenia), and low numbers of white blood cells (neutropenia).





# I was recently diagnosed with GEP-NETs Can LUTATHERA be my first treatment?

Know your NETs: Understand what your recently diagnosed cancer looks like
Go over these questions with your doctor and see if LUTATHERA is an option from the start.





Has my cancer spread to my lymph nodes or other organs?



Is my cancer well differentiated?



Is my tumor functional (producing hormones) or nonfunctional?



Does my cancer have somatostatin receptors (SSTR+ NETs)?



Is my cancer faster growing (Ki-67, 10% or more [grade 2 or 3])?

If these apply to your cancer, LUTATHERA could be the right first treatment for you

#### **IMPORTANT SAFETY INFORMATION (continued)**

What are some important things to know about the safety of LUTATHERA? (continued)

• Bone marrow problems (continued): Speak with your health care provider if you experience any signs or symptoms of infection, fever, chills, dizziness, shortness of breath, or increased bleeding or bruising. Your health care provider may need to adjust or stop your treatment accordingly.





# In people who were recently diagnosed LUTATHERA slowed NET progression for longer

LUTATHERA was studied in 226 people who were recently diagnosed with SSTR+ GEP-NETs that were faster growing (Ki-67, 10%–55% [grade 2 or 3]): 151 received LUTATHERA and a longacting SSA; 75 received a long-acting, high-dose SSA alone.



The study measured progression-free survival (PFS). PFS is the amount of time cancer doesn't grow or spread during and after treatment. Median PFS is the length of time when half of the people treated have not yet progressed. It's about slowing progression.

## LUTATHERA works with SSA to give people more time without progression



Median PFS

Results with LUTATHERA + SSA compared with **8.5 months** for people taking SSA alone

Half of the people taking LUTATHERA + SSA did not have their cancer progress at 22.8 months compared with 8.5 months for people taking SSA alone.

#### **IMPORTANT SAFETY INFORMATION (continued)**

What are some important things to know about the safety of LUTATHERA? (continued)

 Secondary bone marrow and blood cancers: Other serious conditions that you may develop as a direct result of treatment with LUTATHERA include blood and bone marrow disorders known as secondary myelodysplastic syndrome and cancer known as acute leukemia. Your health care provider will routinely check your blood cell counts and tell you if they are too low or too high.





# I am currently on an SSA Can LUTATHERA be my next step?

Know your NETs: Understand what your cancer looks like after SSA progression Go over these questions with your doctor and see if LUTATHERA is an option after progressing on an SSA.



- Is my cancer slower growing (Ki-67, 0%–20% [grade 1 or 2])?
- Is my cancer progressing while on SSA treatment?
- Has my cancer spread to my lymph nodes or other organs?
- Has my doctor confirmed that my cancer has somatostatin receptors (SSTR+ NETs)?

If these apply to your cancer, LUTATHERA could be the **right next step** for you

#### **IMPORTANT SAFETY INFORMATION (continued)**

What are some important things to know about the safety of LUTATHERA? (continued)

• **Kidney problems:** Treatment with LUTATHERA will expose your kidneys to radiation and may impair their ability to work as normal. You may be at an increased risk for kidney problems after LUTATHERA treatment if you already have kidney impairment before treatment. In some cases, patients have experienced kidney failure after treatment with LUTATHERA.





# In people with NETs that progressed on an SSA LUTATHERA slowed NET progression for longer

**LUTATHERA** was studied in 229 people who already tried SSA treatment for SSTR+ GEP-NETs that were slower growing (Ki-67, 0%–20% [grade 1 or 2]): 116 received LUTATHERA and a long-acting SSA; 113 received a long-acting, high-dose SSA alone.



The study measured PFS. PFS is the amount of time cancer doesn't grow or spread during and after treatment. It's about slowing progression.

# LUTATHERA works with SSA to give people more time without progression



People taking LUTATHERA + SSA were
79% less likely to have their cancer progress
compared with people taking SSA alone

#### IMPORTANT SAFETY INFORMATION (continued)

What are some important things to know about the safety of LUTATHERA? (continued)

• Kidney problems (continued): Your health care provider will provide you with an amino acid solution before, during, and after LUTATHERA to help protect your kidneys. You should stay well hydrated before, on the day of, and on the day after your treatment. You should urinate frequently before, on the day of, and on the day after administration of LUTATHERA. Your doctor will monitor your kidney function and may withhold, reduce, or stop your LUTATHERA treatment accordingly.





## What should I know about treatment with LUTATHERA?

#### LUTATHERA will be given at your nearest treatment center

Because LUTATHERA uses radiation, your doctor will send you to a treatment center with a care team that is trained to give LUTATHERA.

Find the closest treatment center for LUTATHERA by using the treatment site locator >

You can also ask your doctor if there are specific treatment centers they have worked with before.





LUTATHERA is given as 1 infusion, every 8 weeks, for 4 doses

A long-acting SSA is also given as an intramuscular (IM) injection 4 to 24 hours after each dose of LUTATHERA. After your last dose of LUTATHERA, you may continue receiving a long-acting SSA every 4 weeks.\*

\*You may continue to receive a long-acting SSA every 4 weeks for 18 months after starting treatment with LUTATHERA or until your cancer progresses.

#### **IMPORTANT SAFETY INFORMATION (continued)**

What are some important things to know about the safety of LUTATHERA? (continued)

• Liver problems: In clinical studies of LUTATHERA, less than 1% of patients were reported to have tumor bleeding (hemorrhage), swelling (edema), or tissue damage (necrosis) to the liver. If you have tumors in your liver, you may be more likely to experience these side effects.





# What should I know about treatment with LUTATHERA? (continued)

#### **Potential side effects**

The most common and most serious side effects of LUTATHERA include:

- Decreased blood cell counts
   Nausea
- Increased liver enzymes
   Increased blood glucose
- Vomiting
   Decreased blood potassium levels

There are other possible side effects of LUTATHERA. Talk to your care team if you experience any side effects. You are encouraged to report negative side effects of prescription drugs to the US Food and Drug Administration (FDA). Visit <a href="www.fda.gov/medwatch">www.fda.gov/medwatch</a>, or call <a href="1-800-FDA-1088">1-800-FDA-1088</a>.

#### **Guidance for radiation safety**

Radiation will be present in your body, blood, and urine right after treatment. You and your loved ones will need to follow guidance to help reduce radiation exposure to those around you.

The treatment centers will provide instructions once you start treatment.

#### **IMPORTANT SAFETY INFORMATION (continued)**

What are some important things to know about the safety of LUTATHERA? (continued)

• Liver problems (continued): Tell your health care provider right away if you have any of these signs and symptoms of liver problems: yellowing of the skin or the whites of the eyes (jaundice), unusual darkening of the urine, unusual tiredness, right upper stomach area (abdomen) pain, confusion, and/or swelling of the stomach area (abdomen). Your health care provider will monitor your liver using blood tests and may need to withhold, reduce, or stop your LUTATHERA treatment accordingly.





## Understanding targeted radiation with LUTATHERA

LUTATHERA is a targeted radiation treatment that works inside your body.



After each infusion, your care team will tell you when you can leave the treatment center

You will have to wait until the amount of radiation in your body decreases before you can leave the treatment center. After each infusion, your care team will monitor the radiation in your body and tell you when it is safe to leave.



#### The radiation travels no more than 2.2 millimeters

Beta radiation from LUTATHERA spreads no more than 2.2 millimeters (about 1/10 of an inch) in your tissue. **This** is similar to the thickness of a nickel coin.



The amount of radiation exposure to those around you is less than a chest x-ray

In a clinical trial, the average total exposure to caregivers in the 5 days after a treatment was **less than the exposure from 1 chest x-ray.** 



Radiation from LUTATHERA does not stay in your body long

Within 2 days, most of the radiation will leave your body. Within 14 days, more than 99% of the radiation will be gone.

# IMPORTANT SAFETY INFORMATION (continued) What are some important things to know about the safety of LUTATHERA? (continued)

 Allergic reactions: Allergic reactions have occurred in people who were treated with LUTATHERA. Notify your health care provider if you develop symptoms of an allergic reaction. Seek emergency help right away for any serious allergic reactions. Symptoms may include trouble breathing or swallowing; raised bumps (hives); rash or itching; and swelling of the face, lips, tongue, throat, or arms.





### Hear from other people with GEP-NETs

Advocacy and support groups can provide information you and your caregivers may find helpful. They can connect you with doctors who are experts at treating NETs, and with a community of people like you who are living with NETs. You may even find other people who have been treated with LUTATHERA and can ask about their experience.



**Carcinoid Cancer** Foundation (CCF)

www.carcinoid.org



The Neuroendocrine Cancer **Awareness Network (NCAN)** 

1-866-850-9555 info@netcancerawareness.org www.netcancerawareness.org



**Learn** · Advocate · Connect **A Neuroendocrine Tumor Society (LACNETS)** 

info@lacnets.org www.lacnets.org



**The Healing NET Foundation** 

1-615-369-6463 info@thehealingnet.org www.thehealingnet.org



**Neuroendocrine Tumor Research Foundation (NETRF)** 

1-617-946-1780 info@netrf.org www.netrf.org



NorCal CarciNET Strength in Community

Northern California CarciNET Community (NorCal CarciNET)

info@norcalcarcinet.org

www.norcalcarcinet.org

Provided for informational purposes only. This is not intended to be a recommendation or endorsement of any organization.





### Questions for your doctor

There are many things to consider when deciding on a treatment for your NETs. The questions below can help you talk to your doctor about your treatment plan and LUTATHERA.

### **About GEP-NETs and progression**

- How am I being monitored for progression?
- Is my cancer fast growing? What is my Ki-67 index?

### **Considering LUTATHERA**

- When is the right time to add LUTATHERA to my treatment plan?
- How can LUTATHERA slow down progression of my cancer?
- What are the next steps if LUTATHERA is right for me?
- How can I find out where to get treatment with LUTATHERA?

#### **Treatment with LUTATHERA**

- How is LUTATHERA administered? How often?
- Are there any steps I need to take at home while being treated with LUTATHERA?
- What things do I need to consider when planning travel to and from treatment?





#### **IMPORTANT SAFETY INFORMATION (continued)**

What are some important things to know about the safety of LUTATHERA? (continued)

- Hormonal gland problems (carcinoid crisis): During your treatment you may experience certain symptoms that are related to hormones released from your cancer. These symptoms may include flushing, diarrhea, difficulty breathing (bronchospasm), and low blood pressure (hypotension), and may occur during or within the 24 hours after your first LUTATHERA treatment. Your health care provider will monitor you closely. Speak with your health care provider if you experience any of these signs or symptoms.
- Pregnancy warning: Tell your health care provider if you are pregnant. LUTATHERA can harm your unborn baby. Females should use an effective method of birth control during treatment and for 7 months after the last dose of LUTATHERA. Males with female partners should use an effective method of birth control during treatment with LUTATHERA and for 4 months after the last dose.
- **Breastfeeding warning:** You should not breastfeed during treatment with LUTATHERA and for 2.5 months after your last dose of LUTATHERA.
- **Fertility problems:** Treatment with LUTATHERA may cause infertility. This is because radiation absorbed by your testes or ovaries over the treatment period falls within the range of exposure in which temporary or permanent infertility may occur.

#### What are the most common side effects of LUTATHERA?

The most common and most serious side effects of LUTATHERA include decreased blood cell counts, increased liver enzymes, vomiting, nausea, increased blood glucose, and decreased blood potassium levels.

Talk to your doctor if you experience any of these side effects. There are other possible side effects of LUTATHERA. For more information and to learn more about LUTATHERA, talk to your doctor or health care provider.

Adverse reactions observed in children aged 12 years and older were similar to those observed in adults treated with LUTATHERA.





Is RIGHT NOW the RIGHT TIME for LUTATHERA?

Ask when LUTATHERA could fit into your NET treatment plan



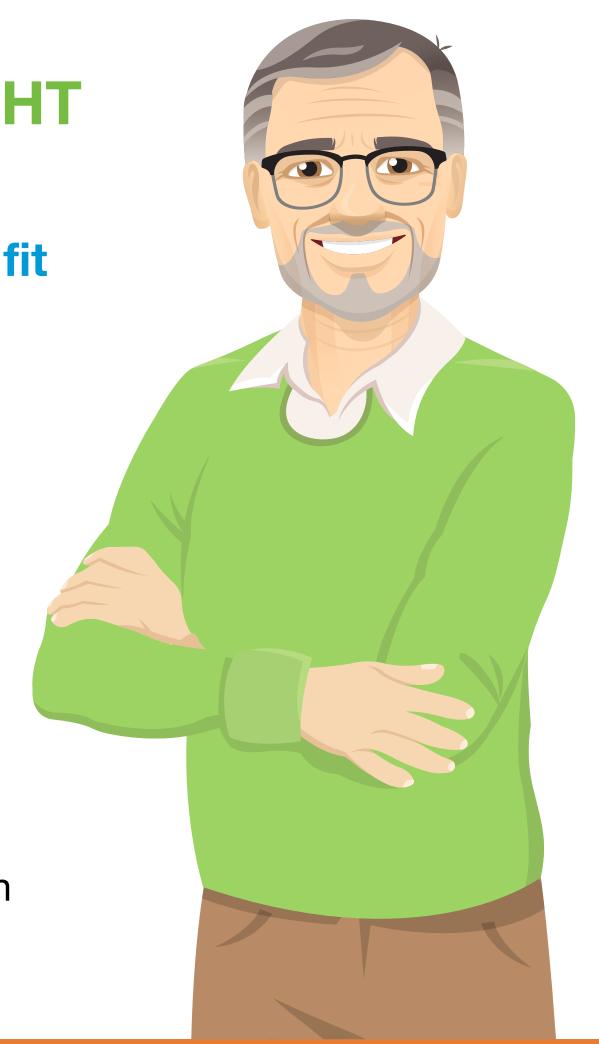
Right from the start

if you are recently diagnosed and have faster-growing tumors (Ki-67, 10% or more)



As your next step

if you are on SSA treatment and are experiencing progression



#### Learn more about LUTATHERA

Visit www.LUTATHERA.com for more information and resources

### IMPORTANT SAFETY INFORMATION (continued)

What other medicines may interact with LUTATHERA?

Tell your health care provider if you are taking any other medications. You should stop taking your long-acting somatostatin analogue at least 4 weeks before LUTATHERA treatment. You may continue taking short-acting somatostatin analogues up to 24 hours before your LUTATHERA treatment.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit <a href="https://www.fda.gov/medwatch">www.fda.gov/medwatch</a>, or call <a href="https://www.fda.gov/medwatch">1-800-FDA-1088</a>.

Please see additional Important Safety Information throughout the brochure and full <u>Prescribing Information</u> for LUTATHERA.



LUTATHERA® (lutetium Lu 177 dotatate) injection, for intravenous use