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

If your patient with an SSTR+ GEP-NET has progressed on an SSA,[1-3]

NOW IS THE TIME TO START LUTATHERA

Take earlier action: Enhance your patient's standard of care with LUTATHERA immediately after SSA progression[2]

Not an actual patient.

GEP-NET, gastroenteropancreatic neuroendocrine tumor; SSA, somatostatin analogue; SSTR+, somatostatin receptor-positive.

INDICATION

LUTATHERA® (lutetium Lu 177 dotatate) is indicated for the treatment of adult and pediatric patients aged 12 years and older with somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

- **Radiation Exposure:** Treatment with LUTATHERA contributes to a patient's overall long-term cumulative radiation exposure and is associated with an increased risk for cancer. Radiation can be detected in the urine for up to 30 days following LUTATHERA administration. Minimize radiation exposure to patients, medical personnel, and household contacts during and after treatment with LUTATHERA consistent with institutional good radiation safety practices, patient management procedures, Nuclear Regulatory Commission patient release guidance, and instructions to the patient for follow-up radiation protection at home.

Please see additional Important Safety Information throughout and full Prescribing Information.

NOVARTIS

Patients in NETTER-1 were required to meet certain overall fitness and organ function criteria[2]

Patient characteristics and health status[2,4]

Diagnosis

- Patients with midgut NETs that had metastasized or were locally advanced, that were inoperable, and that had progressed during treatment with long-acting octreotide
- Tumor with well-differentiated histologic features (Ki-67 index ≤20%)
- Patients must have progressive disease based on RECIST v1.1, while receiving an uninterrupted fixed dose of long-acting octreotide (20–30 mg/3-4 weeks)
- Confirmed presence of SSTRs on all lesions (tumor uptake ≥ normal liver uptake)

Blood Test Results

- Hemoglobin level ≥8.0 g/dL
- Serum albumin ≤3.0 g/dL unless prothrombin time was within the normal range
- Platelet count ≥75,000/mm^3

Kidney

- CrCL ≥50 mL/min
- Serum creatinine level ≤150 µmol/L

Immune System

- White blood cell count ≥2000/mm^3

Liver

- Total bilirubin level ≤3× ULN

Karnofsky Performance Score

- Karnofsky performance score ≥60

Excluded due to previous treatment[2,4]

- Treatment with >30 mg long-acting octreotide within 12 weeks before randomization
- PRRT at any time before randomization
- Any surgery, liver-directed transarterial therapy, or chemotherapy within 12 weeks before randomization
- Prior external radiation therapy to >25% of the bone marrow

CrCL, creatinine clearance; NETs, neuroendocrine tumors; PRRT, peptide receptor radionuclide therapy; RECIST, Response Evaluation Criteria in Solid Tumors; SSTR, somatostatin receptor; ULN, upper limit of normal.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

- **Myelosuppression:** In the NETTER-1 clinical trial, myelosuppression occurred more frequently in patients receiving LUTATHERA with long-acting octreotide compared with patients receiving high-dose long-acting octreotide (all grades/grade 3/4): anemia (81%/0 vs 54%/1%), thrombocytopenia (53%/1% vs 17%/0), and neutropenia (26%/3% vs 11%/0). In NETTER-1, platelet nadir occurred at a median of 5.1 months following the first dose. Of the 59 patients who developed thrombocytopenia, 68% had platelet recovery to baseline or normal levels. The median time to platelet recovery was 2 months. Fifteen of the 19 patients in whom platelet recovery was not documented had post-nadir platelet counts. Among these 15 patients, 5 improved to grade 1, 9 to grade 2, and 1 to grade 3. Monitor blood cell counts. Withhold dose, reduce dose, or permanently discontinue LUTATHERA based on the severity of myelosuppression.

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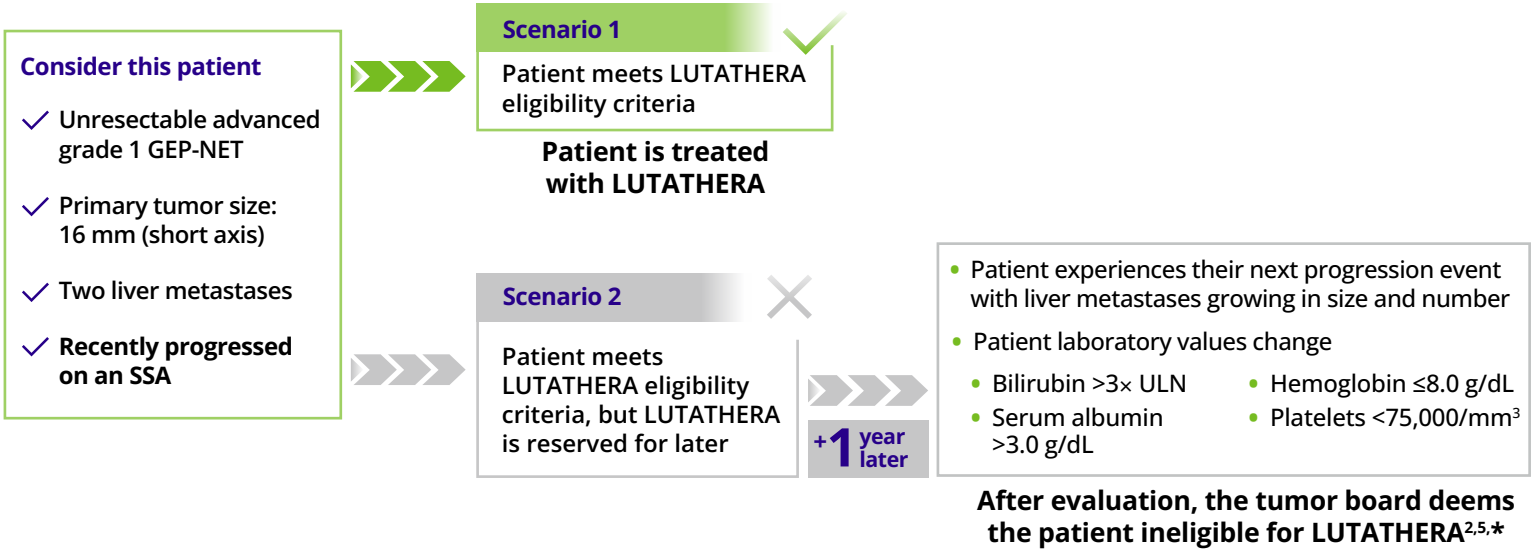
Don't wait—start eligible patients on LUTATHERA immediately after SSA progression[1-3]

Consider your patient's health status before reserving LUTATHERA for later

- When evaluating the results as seen in NETTER-1, it is important to consider the relative fitness of the patients in the trial, including their immune and organ function[2]
- If a patient's health status changes between progression events, they may no longer be eligible to receive LUTATHERA[2,5]

Hypothetical treatment scenarios[2,4,5]



How are you monitoring your patients for progression?

Most GEP-NETs have nonspecific symptoms. Guidelines recommend routine anatomic imaging at regular intervals (every 3–12 months) based on patient's clinical status[5,6]

*Based on recommendations from the NANETS/SNMMI Consensus Guidelines for the administration of ^{177}Lu-DOTATATE.[5]

NANETS, North American Neuroendocrine Tumor Society; SNMMI, Society of Nuclear Medicine and Molecular Imaging.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

- **Secondary Myelodysplastic Syndrome and Leukemia:** In NETTER-1, with a median follow-up time of 76 months in the main study, myelodysplastic syndrome (MDS) was reported in 2.3% of patients receiving LUTATHERA with long-acting octreotide compared with no patients receiving high-dose long-acting octreotide. In ERASMUS, a phase 2 clinical study, 16 patients (2.0%) developed MDS and 4 (0.5%) developed acute leukemia. The median time to onset was 29 months (range, 9-45 months) for MDS and 55 months (range, 32-125 months) for acute leukemia.

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NETTER-1 was designed to evaluate the efficacy and safety of LUTATHERA after SSA progression[1,2]

NETTER-1 was a phase 3, randomized, open-label, multicenter study in well-differentiated, grade 1/2 advanced GEP-NETs after SSA progression[1,2]

Select Inclusion Criteria[1-3]

- ✓ SSTR+ metastatic, inoperable, or locally advanced midgut GEP-NETs that had progressed during SSA treatment
- ✓ Well-differentiated grade 1 or 2 tumors
- ✓ Ki-67 index ≤20%
- ✓ Karnofsky Performance Score ≥60

Stratification Factors[2]

- **SSTR uptake:** grade 2, 3, or 4
- **Time receiving constant dose of octreotide:** ≤6 months vs >6 months

Randomization[1,2]
1:1
(N=229)

LUTATHERA + 30 mg octreotide LAR (n=116)[1,2]

LUTATHERA: 4 cycles, 7.4 GBq (200 mCi) every 8 weeks (+/-1 week), maximum cumulative dose 29.6 GBq
Octreotide LAR: 30 mg 4 to 24 hours after each LUTATHERA dose and then every 4 weeks after completion of treatment with LUTATHERA until disease progression or until Week 76 of the study

60 mg octreotide LAR (n=113)[1,2]
Octreotide LAR: 60 mg every 4 weeks

Primary end point[2]

- PFS (independent central review by radiologists unaware of the treatment according to RECIST v1.1), defined as time from randomization to documented disease progression or death from any cause[1,2]

Secondary end points[1,2]

- Objective response rate (ORR)
- Duration of response
- Overall survival (OS)
- Safety

Additional information

- Patients in both arms could receive short-acting octreotide for symptom management; however, short-acting octreotide was withheld for at least 24 hours before each dose of LUTATHERA[1]
- **Final Analysis:** After centrally confirmed disease progression, discontinuation of the study treatment without confirmed progression, or completion of the 18-month treatment period, patients entered long-term follow-up. In total, 200 (87%) of 231 patients entered long-term follow-up, including 101 (86%) of 117 patients in the LUTATHERA arm and 99 (87%) of 114 patients in the 60-mg octreotide LAR arm.* Median duration of follow-up was 76.3 months (range, 0.4-95.0 months) in the LUTATHERA arm and 76.5 months (range, 0.1-92.3 months) in the 60-mg octreotide arm[7]

*Included 2 patients randomized after the primary PFS analysis data cutoff (July 24, 2015).[7]
GBq, gigabecquerel; LAR, long-acting release; mCi, millicurie; PFS, progression-free survival.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

- **Renal Toxicity:** In ERASMUS, 8 patients (<1%) developed renal failure 3 to 36 months following LUTATHERA. Two of these patients had underlying renal impairment or risk factors for renal failure (eg, diabetes or hypertension) and required dialysis.

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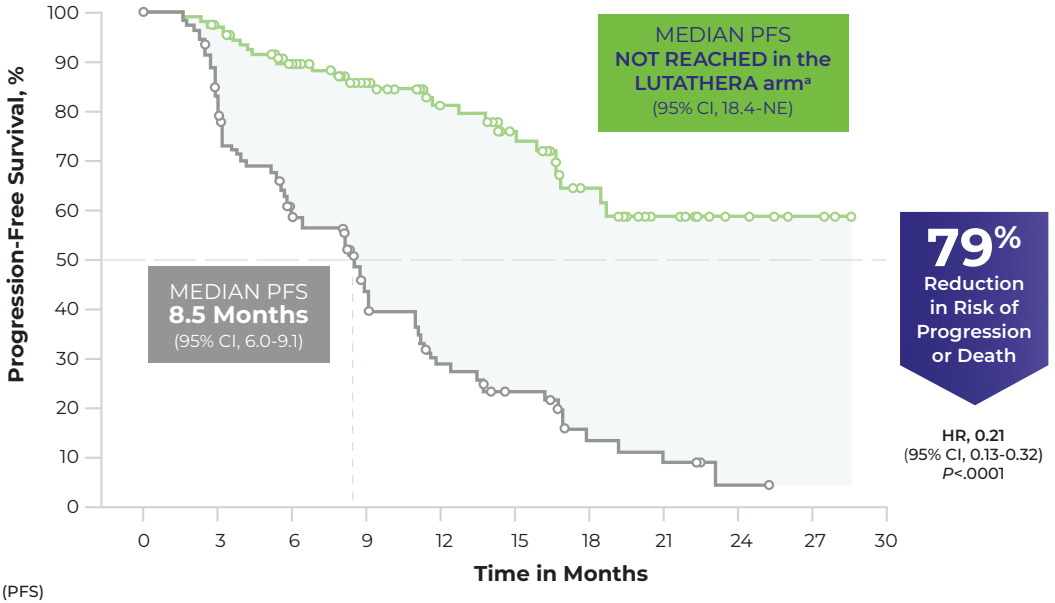
There's no need to wait

LUTATHERA delivered superior PFS results for patients after SSA progression[1]

LUTATHERA + SSA prolonged PFS in patients with grade 1/2 advanced GEP-NETs vs high-dose SSA alone[1-3]

Statistically Significant Improvement in PFS (Primary End Point)[1]



No. at Risk (PFS)

LUTATHERA + 30 mg octreotide LAR	116	102	84	66	48	38	22	13	6	3	0
60 mg octreotide LAR	113	84	57	35	21	14	6	4	1	0	0

LUTATHERA + 30 mg octreotide LAR — 60 mg octreotide LAR

	LUTATHERA + 30 mg octreotide LAR (n=116)	60 mg octreotide LAR (n=113)
Events, n (%)	27 (23%)	78 (69%)
Progressive disease, n (%)	15 (13%)	61 (54%)
Deaths, n (%)	12 (10%)	17 (15%)

Primary PFS analysis

- PFS (as assessed by independent central review according to RECIST v1.1 by radiologists unaware of the treatment), defined as the time from randomization to documented disease progression or death from any cause[2,4]
- The primary PFS analysis data cutoff was July 24, 2015. Median duration of follow-up was 14 months[2]

[a]At primary analysis detailed in Prescribing Information for LUTATHERA.[1]

HR, hazard ratio; NE, not evaluable.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

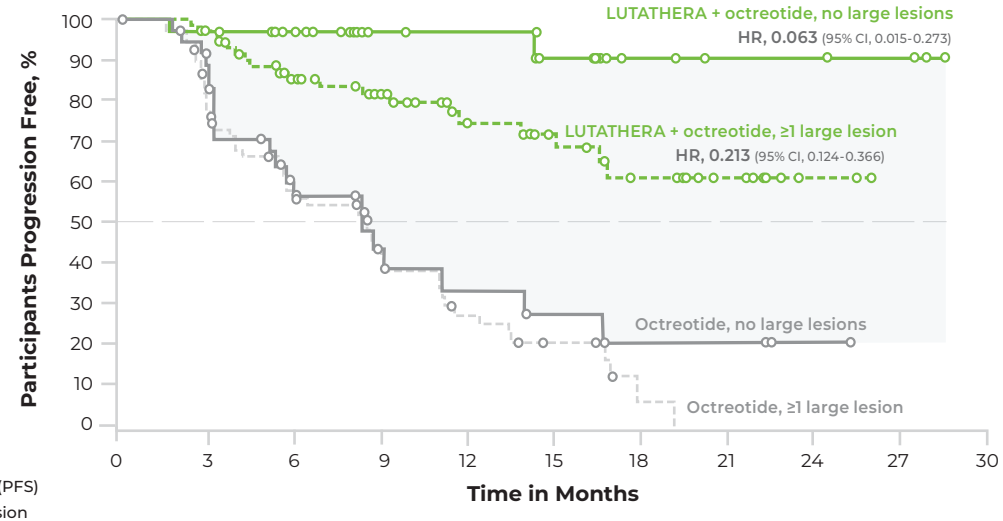
- **Renal Toxicity (continued):** Administer the recommended amino acid solution before, during, and after LUTATHERA to decrease the reabsorption of lutetium Lu 177 dotatate through the proximal tubules and decrease the radiation dose to the kidneys.

Please see additional Important Safety Information throughout and full Prescribing Information.

PFS results for patients with and without a large lesion

Results are based on a post hoc analysis of the key primary end point and are observational in nature; as such, they were not powered to show statistical significance.[8]

PFS by Target Lesion Size (Post Hoc Subgroup Analysis)[8]



No. at Risk (PFS)

No large lesion

LUTATHERA + 30 mg octreotide LAR	37	32	28	17	16	12	6	4	4	3	0
60 mg octreotide LAR	39	30	16	9	6	4	3	3	1	0	0

	LUTATHERA + 30 mg octreotide LAR (n=37)	60 mg octreotide LAR (n=39)
Events, n (%)	2 (5.4%)	21 (53.8%)
Median PFS, months	NR	8.31

≥1 large lesion

LUTATHERA + 30 mg octreotide LAR	79	68	52	44	27	22	14	9	2	0	0
60 mg octreotide LAR	74	51	34	21	12	7	1	0	0	0	0

	LUTATHERA + 30 mg octreotide LAR (n=79)	60 mg octreotide LAR (n=74)
Events, n (%)	19 (24.1%)	49 (66.2%)
Median PFS, months	NR	8.54

Post hoc: Study design and limitations[8]

These data are from a post hoc, subgroup analysis of the NETTER-1 study and are not included in the Prescribing Information for LUTATHERA. Patients were stratified into 2 subgroups based on the presence or absence of at least 1 target lesion >30 mm in diameter at any body site on CT or MRI at baseline. The approximate size threshold has been described in previous literature as distinguishing "large" tumors from smaller ones in animal studies of PRRT. PFS curves were generated for each treatment arm, stratified by the presence or absence of a large target tumor, and the log-rank test was used for within–treatment arm comparisons of PFS. A limitation of this study is that central readers did not specify the patients with extreme tumor burden (>90%) and, therefore, no specific safety analysis in that subgroup was possible.

CT, computed tomography; MRI, magnetic resonance imaging; NR, not reached.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

- **Renal Toxicity (continued):** Advise patients to hydrate and to urinate frequently before, on the day of, and on the day after administration of LUTATHERA. Monitor serum creatinine and calculated creatinine clearance.

Please see additional Important Safety Information throughout and full Prescribing Information.

LUTATHERA has an established safety profile[1,7]

The most common grade 3/4 adverse reactions with a higher incidence in the LUTATHERA arm were lymphopenia (44%), increased GGT (20%), vomiting (7%), nausea (5%), increased AST (5%), increased ALT (4%), hyperglycemia (4%), and hypokalemia (4%)[1]

No new safety signals were reported in the 5-year, long-term follow-up for NETTER-1[7,*]

Adverse Events	During the long-term follow-up, only serious adverse events (SAEs) deemed related to treatment with LUTATHERA and AEs of special interest (hematotoxicity, cardiovascular events, and nephrotoxicity, regardless of causality) in the LUTATHERA arm were reported[7]
Grade ≥3 Treatment-Related SAEs During the Entire Study	7 (6%) of 111 patients treated in the LUTATHERA arm[7]
Incidence of Treatment-Related SAEs During the Long-Term Follow-Up Period	**3 (3%) of 111 patients treated with LUTATHERA[7]** — 2 (1.8%) patients experienced at least 1 grade ≥3 SAE (1 grade 5 MDS event)[7] — 1 (0.9%) patient experienced an SAE leading to study discontinuation[7]
MDS or Acute Leukemia	**No new cases were reported during long-term follow-up[7]** — MDS incidence from the Prescribing Information for LUTATHERA: In NETTER-1, with a median follow-up time of 76 months in the main study, MDS was reported in 2.3% of patients receiving LUTATHERA with long-acting octreotide compared with no patients receiving high-dose, long-acting octreotide[1,7] — In ERASMUS, 16 patients (2.0%) developed MDS and 4 (0.5%) developed acute leukemia. The median time to onset was 29 months (range, 9-45 months) for MDS and 55 months (range, 32-125 months) for acute leukemia[1,a]
Diffuse Large B-Cell Lymphoma	One patient developed diffuse large B-cell lymphoma during long-term follow-up that was deemed unrelated to treatment with LUTATHERA[7]
Nephrotoxicity of Grade ≥3, Regardless of Causality	Reported in 6 (5%) of 111 patients in the LUTATHERA arm and 4 (4%) of 112 patients in the control arm during the study[7]

*Cutoff date for final analysis was January 18, 2021.[7]

[a] ERASMUS study design: Retrospective safety data are available from 1214 patients in ERASMUS, an international, single-institution, single-arm, open-label trial of patients with SSTR-positive tumors (neuroendocrine and other primaries). The median duration of follow-up was >4 years.[1]

AEs, adverse events; ALT, alanine aminotransferase; AST, aspartate aminotransferase; GGT, gamma-glutamyl transferase; MDS, myelodysplastic syndrome.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

- **Renal Toxicity (continued):** Withhold dose, reduce dose, or permanently discontinue LUTATHERA based on the severity of renal toxicity. Patients with baseline renal impairment may be at increased risk of toxicity due to increased radiation exposure; perform more frequent assessments of renal function in patients with baseline mild or moderate impairment. LUTATHERA has not been studied in patients with baseline severe renal impairment (creatinine clearance <30 mL/min) or those with end-stage renal disease.

Please see additional Important Safety Information throughout and full Prescribing Information.

Important Safety Information

INDICATION

LUTATHERA® (lutetium Lu 177 dotatate) is indicated for the treatment of adult and pediatric patients aged 12 years and older with somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

- **Radiation Exposure:** Treatment with LUTATHERA contributes to a patient's overall long-term cumulative radiation exposure and is associated with an increased risk for cancer. Radiation can be detected in the urine for up to 30 days following LUTATHERA administration. Minimize radiation exposure to patients, medical personnel, and household contacts during and after treatment with LUTATHERA consistent with institutional good radiation safety practices, patient management procedures, Nuclear Regulatory Commission patient release guidance, and instructions to the patient for follow-up radiation protection at home.
- **Myelosuppression:** In the NETTER-1 clinical trial, myelosuppression occurred more frequently in patients receiving LUTATHERA with long-acting octreotide compared with patients receiving high-dose long-acting octreotide (all grades/grade 3/4): anemia (81%/0 vs 54%/1%), thrombocytopenia (53%/1% vs 17%/0), and neutropenia (26%/3% vs 11%/0). In NETTER-1, platelet nadir occurred at a median of 5.1 months following the first dose. Of the 59 patients who developed thrombocytopenia, 68% had platelet recovery to baseline or normal levels. The median time to platelet recovery was 2 months. Fifteen of the 19 patients in whom platelet recovery was not documented had post-nadir platelet counts. Among these 15 patients, 5 improved to grade 1, 9 to grade 2, and 1 to grade 3. Monitor blood cell counts. Withhold dose, reduce dose, or permanently discontinue LUTATHERA based on the severity of myelosuppression.
- **Secondary Myelodysplastic Syndrome and Leukemia:** In NETTER-1, with a median follow-up time of 76 months in the main study, myelodysplastic syndrome (MDS) was reported in 2.3% of patients receiving LUTATHERA with long-acting octreotide compared with no patients receiving high-dose long-acting octreotide. In ERASMUS, a phase 2 clinical study, 16 patients (2.0%) developed MDS and 4 (0.5%) developed acute leukemia. The median time to onset was 29 months (range, 9-45 months) for MDS and 55 months (range, 32-125 months) for acute leukemia.
- **Renal Toxicity:** In ERASMUS, 8 patients (<1%) developed renal failure 3 to 36 months following LUTATHERA. Two of these patients had underlying renal impairment or risk factors for renal failure (eg, diabetes or hypertension) and required dialysis. Administer the recommended amino acid solution before, during, and after LUTATHERA to decrease the reabsorption of lutetium Lu 177 dotatate through the proximal tubules and decrease the radiation dose to the kidneys. Advise patients to hydrate and to urinate frequently before, on the day of, and on the day after administration of LUTATHERA. Monitor serum creatinine and calculated creatinine clearance. Withhold dose, reduce dose, or permanently discontinue LUTATHERA based on the severity of renal toxicity. Patients with baseline renal impairment may be at increased risk of toxicity due to increased radiation exposure; perform more frequent assessments of renal function in patients with baseline mild or moderate impairment. LUTATHERA has not been studied in patients with baseline severe renal impairment (creatinine clearance <30 mL/min) or those with end-stage renal disease.
- **Hepatotoxicity:** In ERASMUS, 2 patients (<1%) were reported to have hepatic tumor hemorrhage, edema, or necrosis, with 1 patient experiencing intrahepatic congestion and cholestasis. Patients with hepatic metastasis may be at increased risk of hepatotoxicity due to radiation exposure. Monitor transaminases, bilirubin, serum albumin, and the international normalized ratio during treatment. Withhold dose, reduce dose, or permanently discontinue LUTATHERA based on the severity of hepatotoxicity.
- **Hypersensitivity Reactions:** Hypersensitivity reactions, including angioedema, occurred in patients treated with LUTATHERA. Monitor patients closely for signs and symptoms of hypersensitivity reactions, including anaphylaxis, during and following LUTATHERA administration for a minimum of 2 hours in a setting in which cardiopulmonary resuscitation medication and equipment are available. Discontinue the infusion upon the first observation of any signs or symptoms consistent with a severe hypersensitivity reaction and initiate appropriate therapy. Premedicate patients with a history of grade 1/2 hypersensitivity reactions to LUTATHERA before subsequent doses. Permanently discontinue LUTATHERA in patients who experience grade 3/4 hypersensitivity reactions.

Important Safety Information (continued)

WARNINGS AND PRECAUTIONS (continued)

- **Neuroendocrine Hormonal Crisis:** Neuroendocrine hormonal crises, manifesting with flushing, diarrhea, bronchospasm, and hypotension, occurred in <1% of patients in ERASMUS and typically occurred during or within 24 hours following the initial LUTATHERA dose. Two (<1%) patients were reported to have hypercalcemia. Monitor patients for flushing, diarrhea, hypotension, bronchoconstriction, or other signs and symptoms of tumor-related hormonal release. Administer intravenous somatostatin analogues, fluids, corticosteroids, and electrolytes as indicated.
- **Embryo-Fetal Toxicity:** LUTATHERA can cause fetal harm when administered to a pregnant woman. Verify the pregnancy status of females of reproductive potential prior to initiating LUTATHERA. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with LUTATHERA and for 7 months after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with LUTATHERA and for 4 months after the last dose.
- **Risk of Infertility:** LUTATHERA may cause infertility in males and females. Radiation absorbed by testes and ovaries from the recommended cumulative LUTATHERA dose falls within the range in which temporary or permanent infertility can be expected following external beam radiotherapy.

ADVERSE REACTIONS

The most common grade 3/4 adverse reactions (≥4% with a higher incidence in the LUTATHERA arm) observed in NETTER-1 were lymphopenia (44%), increased gamma-glutamyl transferase (20%), vomiting (7%), nausea (5%), increased aspartate aminotransferase (5%), increased alanine aminotransferase (4%), hyperglycemia (4%), and hypokalemia (4%).

In ERASMUS, the following serious adverse reactions have been observed with a median follow-up time of >4 years after treatment with LUTATHERA: myelodysplastic syndrome (2%), acute leukemia (1%), renal failure (2%), hypotension (1%), cardiac failure (2%), myocardial infarction (1%), and neuroendocrine hormonal crisis (1%). Patients should be counseled and monitored in accordance with the LUTATHERA Prescribing Information.

Adverse reactions observed in pediatric patients were similar to those observed in adults treated with LUTATHERA.

DRUG INTERACTIONS

Discontinue long-acting somatostatin analogues at least 4 weeks and short-acting octreotide at least 24 hours prior to each LUTATHERA dose.

SPECIFIC POPULATIONS

Lactation: Advise patients not to breastfeed during LUTATHERA treatment.

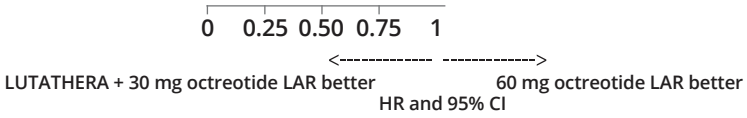
Please see full Prescribing Information.

References: 1. Lutathera. Prescribing information. Novartis Pharmaceuticals Corp. **2.** Strosberg J, El-Haddad G, Wolin E, et al; for the NETTER-1 trial investigators. Phase 3 trial of ^{177}Lu-dotatate for midgut neuroendocrine tumors. *N Engl J Med*. 2017;376(2):125-135. **3.** Strosberg J, El-Haddad G, Wolin E, et al; for the NETTER-1 trial investigators. Phase 3 trial of ^{177}Lu-dotatate for midgut neuroendocrine tumors. *N Engl J Med*. 2017;376(2)(suppl):125-135. **4.** Strosberg J, El-Haddad G, Wolin E, et al; for the NETTER-1 trial investigators. Phase 3 trial of ^{177}Lu-dotatate for midgut neuroendocrine tumors. *N Engl J Med*. 2017;376(2)(protocol):125-135. **5.** Hope TA, Abbott A, Colucci K, et al. NANETS/SNMMI procedure standard for somatostatin receptor-based peptide receptor radionuclide therapy with ^{177}Lu-DOTATATE. *J Nucl Med.* 2019;60(7):937-943. **6.** Singh S, Granberg D, Wolin E, et al. Patient-reported burden of a neuroendocrine tumor (NET) diagnosis: results from the first global survey of patients with NETs. *J Glob Oncol.* 2016;3(1):43-53. **7.** Strosberg JR, Caplin ME, Kunz PL, et al; NETTER-1 investigators. ^{177}Lu-dotatate plus long-acting octreotide versus high-dose long-acting octreotide in patients with midgut neuroendocrine tumours (NETTER-1): final overall survival and long-term safety results from an open-label, randomised, controlled, phase 3 trial. *Lancet Oncol*. 2021;22(12):1752-1763. **8.** Strosberg J, Kunz PL, Hendifar A, et al. Impact of liver tumour burden, alkaline phosphatase elevation, and target lesion size on treatment outcomes with ^{177}Lu-dotatate: an analysis of the NETTER-1 study. *Eur J Nucl Med Mol Imaging.* 2020;47(10):2372-2382.

The right time for *LUTATHERA* is right after SSA progression[1-3]

Post Hoc Subgroup Analysis of PFS in Patients With and Without a Large Lesion Treated With LUTATHERA + SSA vs SSA Alone[8]

	Hazard ratio (95% CI)	LUTATHERA + 30 mg octreotide LAR Median PFS, months	60 mg octreotide LAR Median PFS, months
Baseline large tumor[a,b]			
Presence of ≥1 large tumor (>30 mm diameter) (n=153)	0.21 (0.12-0.37)	NR	8.5
Absence of large tumor (all ≤30 mm diameter) (n=76)	0.06 (0.02-0.27)	NR	8.3



Analysis not powered to demonstrate a benefit between subgroups. Results should be interpreted with caution.

Results are based on a post hoc analysis of the key primary end point and are observational in nature; as such, they were not powered to show statistical significance.[8]

[a]Patients were stratified into 2 subgroups based on the presence or absence of at least 1 target lesion >30 mm in diameter at any body site on CT or MRI at baseline. The approximate size threshold has been described in previous literature as distinguishing "large" tumors from smaller ones in animal studies of PRRT.[8]

[b]Among patients treated with LUTATHERA + 30 mg octreotide LAR, 128 large tumors (>30 mm in diameter) were identified, of which 89 (70%) were liver tumors. In patients treated with 60 mg octreotide, 134 large tumors were identified; 93 (69%) were liver tumors.[8]

Ready to START LUTATHERA?

Visit www.LUTATHERA-hcp.com for more information and to find a treatment center

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

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NOVARTIS

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injection, for intravenous use

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