

PATIENT CASE STUDY #2:

SYMPTOMATIC CARCINOID MIDGUT NET



Lauren* is a 45-year-old paralegal who has been married for 25 years.

*Patient portrayed is an actor, and represents a hypothetical case.



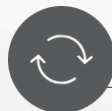
Testing and Workup, Tumor Characteristics

- Gallium-68 somatostatin-receptor (SSR) imaging showed evidence of strong uptake, indicating mass in the ileum (primary tumor) with numerous liver metastases
- CgA[†]: 150 ng/mL
- 5-HIAA[‡]: 18 mg/24 hr
- Biopsy reveals Ki-67 6%, moderately differentiated histology



Treatment Consideration

- Referred patient to surgeon for resection of primary tumor
- Somatuline[®] Depot (lanreotide) first-line (1L) as monotherapy
- Somatostatin analog, or SSA, therapy for patients with midgut neuroendocrine tumors (NETs) that are unresectable and well- or moderately-differentiated are a proven 1L option^{1,2}



Disease Progression

- Treatment for 5 years before evidence of progression
- Repeat Gallium-68 SSR imaging identified new and enlarging liver metastases with evidence of strong SSR expression
- Decision to consider combination therapy based on discussion with the tumor board, including input from surgery and nuclear medicine

[†]CgA=chromogranin A.

[‡]5-HIAA=5-hydroxyindoleacetic acid.

INDICATIONS

SOMATULINE[®] DEPOT (lanreotide) is a somatostatin analog indicated for:

- the treatment of adult patients with unresectable, well- or moderately-differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression-free survival; and
- the treatment of adults with carcinoid syndrome; when used, it reduces the frequency of short-acting somatostatin analog rescue therapy.

IMPORTANT SAFETY INFORMATION

Contraindications

- SOMATULINE DEPOT is contraindicated in patients with hypersensitivity to lanreotide. Allergic reactions (including angioedema and anaphylaxis) have been reported following administration of lanreotide.

Please see full Important Safety Information throughout; click here for full Prescribing Information and Patient Information.



Somatuline[®] Depot
(lanreotide) Injection 120 mg

PATIENT CASE STUDY #2:

PRACTICE POINTERS



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Dr. Strosberg is a paid consultant of Ipsen Biopharmaceuticals, Inc.

- In patients with disease recurrence, combination therapy falls within the NCCN Clinical Practice Guidelines In Oncology (NCCN Guidelines[®]) for neuroendocrine and adrenal tumors.³ Usually, progression on scan serves as a trigger to consider another treatment option, but symptom progression could be a trigger as well
- For this particular patient, consider liver-directed therapy:
 - Transarterial embolization is a reasonable option that falls within the NCCN Guidelines^{®3}
 - Selection of other treatments may depend on factors such as SSR expression; consider the details of the case, discuss with your tumor board, and consider patient preferences before prescribing combination therapy
- When coordinating combination therapy:
 - Consider factors such as true disease progression and/or strong SSR expression
- Maintaining treatment with SSA should be considered for management of symptomatic patients

“Consider consulting an experienced NETs physician or tumor board as part of a referral for combination therapy”

–Dr. Jonathan Strosberg

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions

- **Cholelithiasis and Gallbladder Sludge**
 - SOMATULINE DEPOT may reduce gallbladder motility and lead to gallstone formation.
 - Periodic monitoring may be needed.
 - If complications of cholelithiasis are suspected, discontinue SOMATULINE DEPOT and treat appropriately.
- **Hypoglycemia or Hyperglycemia**
 - Patients treated with SOMATULINE DEPOT may experience hypoglycemia or hyperglycemia.
 - Blood glucose levels should be monitored when SOMATULINE DEPOT treatment is initiated, or when the dose is altered, and antidiabetic treatment should be adjusted accordingly.

Please see full Important Safety Information throughout; click here for the full [Prescribing Information](#) and [Patient Information](#).



Somatuline[®] Depot
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IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

- **Cardiovascular Abnormalities**

- SOMATULINE DEPOT may decrease heart rate.
- In patients without underlying cardiac disease, SOMATULINE DEPOT may lead to a decrease in heart rate without necessarily reaching the threshold of bradycardia.
- In patients suffering from cardiac disorders prior to treatment, sinus bradycardia may occur. Care should be taken when initiating treatment in patients with bradycardia.

Most Common Adverse Reactions

- **GEP-NETs:** Adverse reactions in >10% of patients who received SOMATULINE DEPOT were abdominal pain (34%), musculoskeletal pain (19%), vomiting (19%), headache (16%), injection site reaction (15%), hyperglycemia (14%), hypertension (14%), and cholelithiasis (14%).
- **Carcinoid Syndrome:** Adverse reactions occurring in the carcinoid syndrome trial were generally similar to those in the GEP-NET trial. Adverse reactions in $\geq 5\%$ of patients who received SOMATULINE DEPOT and at least 5% greater than placebo were headache (12%), dizziness (7%) and muscle spasm (5%).

Drug Interactions: SOMATULINE DEPOT may decrease the absorption of cyclosporine (dosage adjustment may be needed); increase the absorption of bromocriptine; and require dosage adjustment for bradycardia-inducing drugs (e.g., beta-blockers).

Special Populations

- **Lactation:** Advise women not to breastfeed during treatment and for 6 months after the last dose.

To report **SUSPECTED ADVERSE REACTIONS**, contact Ipsen Biopharmaceuticals, Inc. at 1-855-463-5127 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please click here for the full [Prescribing Information](#) and [Patient Information](#).

“Ensure you refer to a center with an experienced nuclear medicine department”

–Dr. Jonathan Strosberg

References: 1. Somatuline Depot (lanreotide) Injection [Prescribing Information]. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc.; April 2019. 2. Kos-kudła B, Ćwikła J, Ruchała M, et al. Current treatment options for gastroenteropancreatic neuroendocrine tumors with a focus on the role of lanreotide. *Contemp Oncol (Pozn)*. 2017;21(2):115-122. 3. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Neuroendocrine and Adrenal Tumors V.3.2018. © National Comprehensive Cancer Network, Inc. 2018. All rights reserved. Accessed September 11, 2018. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use, or application and disclaims any responsibility for their application or use in any way. 4. Strosberg J, El-Haddad G, Wolin E, et al. Phase 3 trial of (177) lu-dotatate for midgut neuroendocrine tumors. *N Engl J Med*. 2017;376(2):125-135. 5. Barone R, Pauwels S, De Camps J, et al. Metabolic effects of amino acid solutions infused for renal protection during therapy with radiolabelled somatostatin analogues. *Nephrol Dial Transplant*. 2004;19(9):2275-2281.