Poster C-18

Heloisa P. Soares | Heloisa.Soares@hci.utah.edu

Patient characteristics and treatment patterns with [^{177}Lu]Lu-DOTA-TATE (^{177}Lu-DOTATATE) in the US: A real-world assessment

Heloisa P. Soares,[1] Anteneh Tesfaye,[2] Samuel Crawford,[2] Jennifer Nguyen,[2] Barinder Kang,[2] Antonio Nakasato,[2] Jasjit K. Multani,[3] Elizabeth J. Wang,[3] Jeetvan Patel[2]

[1]Huntsman Cancer Institute, Salt Lake City, UT, USA; [2]Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA; [3]IQVIA, King of Prussia, PA, USA

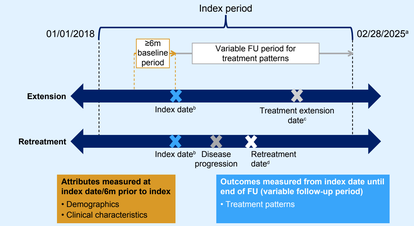
INTRODUCTION

- Gastroenteropancreatic neuroendocrine tumors (GEP-NETs), comprising neuroendocrine tumors of the gastrointestinal tract and pancreas, represent the most frequent subtype of NETs with varying survival rates depending on stage and grade[1,2]
- Somatostatin receptors (SSTRs) are expressed in most GEP-NETs; ^{177}Lu-DOTATATE, a radiolabeled somatostatin analog (SSA) administered every 8 weeks for a total of 4 cycles, has recently been approved in the US as first-line (1L) treatment of SSTR-positive GEP-NETs in adults after Phase III trials demonstrated significantly improved outcomes with ^{177}Lu-DOTATATE versus standard of care[3–7]
- The aim of this study was to describe patient characteristics and treatment patterns of ^{177}Lu-DOTATATE in patients with GEP-NETs in the real-world setting in the US

METHODS

- This was a descriptive, retrospective cohort study of patients treated with ^{177}Lu-DOTATATE using data from the open-source IQVIA Longitudinal Prescription and Patient Centric Medical Claims databases
- The study population comprised adults with evidence of ^{177}Lu-DOTATATE treatment from January 1, 2018 to February 28, 2025 and ≥6 months of continuous data prior to the index date (^{177}Lu-DOTATATE treatment initiation) and were followed up until the last medical or pharmacy claim or date of death (**Figure 1**)
- The primary outcome measure was assessment of ^{177}Lu-DOTATATE treatment patterns, including number of treatment cycles, treatment discontinuation, treatment switching/addition of other systemic therapies, treatment extension, and retreatment:
  - ^{177}Lu-DOTATATE treatment extension is defined as:
    - Receipt of >4 cycles of ^{177}Lu-DOTATATE, with no evidence of other systemic therapies for GEP-NET between the fourth and fifth cycle of ^{177}Lu-DOTATATE
  - ^{177}Lu-DOTATATE retreatment is defined as:
    - Restarting treatment with ^{177}Lu-DOTATATE following a progression event among patients who received ≥1 cycle of ^{177}Lu-DOTATATE
    - A proxy for disease progression was defined as a switch to another systemic therapy and meeting ≥1 of the additional criteria within 30 days of switch: new initiation of pain/anti-diarrhea/anti-emetic medications, or hospitalization event

Figure 1. Study Design



[a]In the open-source medical or pharmacy claims data between January 1, 2018 and February 28, 2025; [b]Date of ^{177}Lu-DOTATATE initiation; [c]Date of fifth dose of ^{177}Lu-DOTATATE; [d]Date of ^{177}Lu-DOTATATE restart.
FU, follow-up; m, month.

RESULTS

Patient Characteristics

- A total of 3410 patients were included in the study population (**Figure 2**); mean (SD) follow-up was 759 (599) days
- Mean age was 64.9 years and the proportion of males and females was balanced (**Table 1**)
- Common comorbidities included hypertension (38.4%), liver, gallbladder and pancreatic disease (29.0%), and diabetes (24.4%)
- Patients had liver (67.0%), bone (26.5%) GI (16.5%), lymph node (19.7%), lung (4.6%), and brain (1.1%) metastases
- Prior systemic treatments were received by 67.6% of patients, primarily SSAs

Figure 2. Patient attrition

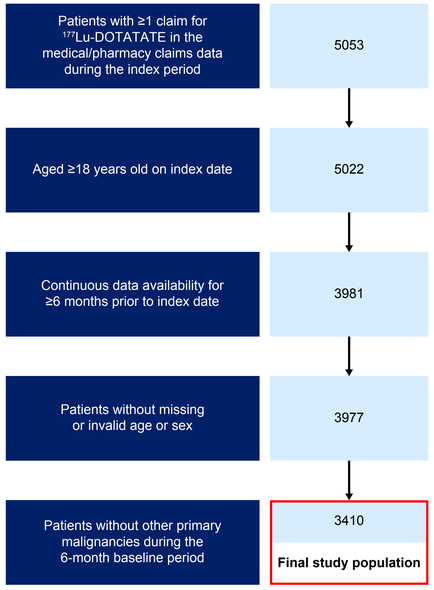


Table 1. Patient characteristics

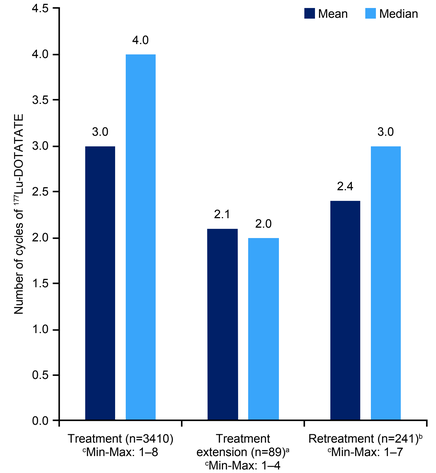
Characteristic	Overall cohort (N=3410)
Age, years, mean (SD)	64.9 (12.3)
Males, n (%)	1748 (51.3)
Race,[a] n (%)	
White	935 (51.0)
Black	102 (5.6)
Hispanic	72 (3.9)
Asian (other)	32 (1.8)
Comorbidities in > 20% of patients, n (%)	
Hypertension	1309 (38.4)
Liver/gallbladder/pancreatic disease	989 (29.0)
Diabetes	831 (24.4)
Dyslipidemia	681 (20.0)
Metastatic sites, n (%)	
Liver	2284 (67.0)
Bone	903 (26.5)
Lymph node only	672 (19.7)
GI	563 (16.5)
Respiratory system	157 (4.6)
Brain	39 (1.1)
Reproductive system	14 (0.4)
Skin	4 (0.1)
Kidney	3 (0.1)
Prior systemic treatments, n (%)	
SSAs (lanreotide, octreotide)	2117 (62.1)
Chemotherapy	257 (7.5)
Targeted therapy (everolimus, sunitinib)	210 (6.2)
Immunotherapy (pembrolizumab)	7 (0.2)
Patients with documented GEP-NET diagnosis, n (%)	2310 (67.7)
Time from diagnosis to ^{177}Lu-DOTATATE initiation, days, mean (SD)	729 (615)

[a]Among 1832 patients with linkage to the Consumer Attributes (Cx) database.
GEP-NET, gastroenteropancreatic neuroendocrine tumor; GI, gastrointestinal; SSAs, somatostatin analogs; SD, standard deviation

Treatment Patterns

- In the overall cohort, the median (range) number of ^{177}Lu-DOTATATE treatment cycles was 4.0 (1–8) with 1747 (51.2%) patients receiving ≥4 cycles of therapy (**Figure 3**)
- Overall, 1000 (29.3%) patients who received <4 cycles of treatment during follow-up discontinued ^{177}Lu-DOTATATE at a median (range) time of 16.0 (8.0–41.0) weeks (**Table 2**)
- Among patients who discontinued ^{177}Lu-DOTATATE, 200 (5.9%) patients switched treatment; mostly switching to chemotherapy and targeted treatment (**Table 2**)
- Overall, few patients received add-on therapy to ^{177}Lu-DOTATATE (n=52; 1.5%) (**Table 2**)
- ^{177}Lu-DOTATATE treatment extension was observed in 89 (2.6%) patients with a median (range) of 2 (1–4) additional cycles; 241 (7.1%) patients restarted ^{177}Lu-DOTATATE treatment after disease progression with a median (range) of 3 (1–7) cycles (**Figure 3**)

Figure 3. Number of ^{177}Lu-DOTATATE treatment cycles*



*In patients from index date until death or end of follow up; [a]Patients with >4 cycles of ^{177}Lu-DOTATATE and no evidence of other systemic therapies for GEP-NET between the fourth and fifth cycle of ^{177}Lu-DOTATATE; [b]Restart of ^{177}Lu-DOTATATE following a progression event among patients who received ≥1 dose of ^{177}Lu-DOTATATE; [c]Range (min-max) of median value.
GEP-NET, gastroenteropancreatic neuroendocrine tumor; Max, maximum; Min, minimum.

Table 2. Treatment patterns in the overall cohort

	Overall cohort (N=3410)
Patients who completed 4 cycles of ^{177}Lu-DOTATATE, n (%)	**1649 (48.4)**
Patients who discontinued ^{177}Lu-DOTATATE,[a] n (%)	**1000 (29.3)**
Cycles before discontinuation, number, median (range)	2.0 (1–3)
Time to discontinuation, weeks, median (range)	16.0 (8.0–41.0)
Patients who switched to other therapies,[b] n (%)	**200 (5.9)**
Chemotherapy	108 (54.0)
Targeted therapy	69 (34.5)
SSA	9 (4.5)
Chemotherapy + SSA	6 (3.0)
Immunotherapy	4 (2.0)
Chemotherapy + immunotherapy	3 (1.5)
Chemotherapy + SSA + immunotherapy	1 (0.5)
Cycles before treatment switch, number, median (range)	2 (1–3)
Time to switch, weeks, median (range)	56.6 (9.0–317.1)
Patients with addition of other therapies, n (%)	**52 (1.5)**
SSA	45 (86.5)
Chemotherapy	3 (5.8)
Targeted therapy	3 (5.8)
Immunotherapy	1 (1.9)
Patients with ^{177}Lu-DOTATATE treatment extension,[c] n (%)	**89 (2.6)**
Patients with ^{177}Lu-DOTATATE retreatment,[d] n (%)	**241 (7.1)**

[a]A gap of >90 days between the date of administration plus the duration of benefit [8 weeks; 56 days] and the next claim for ^{177}Lu-DOTATATE; [b]Any new treatment for GEP-NET other than ^{177}Lu-DOTATATE or octreotide after the date of ^{177}Lu-DOTATATE discontinuation; [c]Patients with >4 cycles of ^{177}Lu-DOTATATE and no evidence of other systemic therapies for GEP-NET between the fourth and fifth cycle of ^{177}Lu-DOTATATE; [d]Restart of ^{177}Lu-DOTATATE following a progression event among patients who received ≥1 dose of ^{177}Lu-DOTATATE.
GEP-NET, gastroenteropancreatic neuroendocrine tumor; SSA, somatostatin analog.

LIMITATIONS

- Limitations of this study reflect the limitations of claims-based data, meaning that best proxies were required to define treatment extension and retreatment from the data
  - From the claims-based data, signs of progression included both a switch to a new systemic therapy and the initiation of treatments to manage symptoms of progression; a sensitivity analysis is ongoing where these criteria are relaxed

CONCLUSIONS

- There is high patient adherence to ^{177}Lu-DOTATATE, with most patients receiving 4 cycles of treatment at 8-week intervals, consistent with the label indication
- There is a growing body of evidence on use of more than 4 cycles of ^{177}Lu-DOTATATE in clinical practice. Treatment extension (receiving ^{177}Lu-DOTATATE beyond 4 cycles) or retreatment (receiving ^{177}Lu-DOTATATE following progression) are both occurring in current clinical practice
- Long term follow-up of these patients will be conducted to understand impact on patient outcomes
- This study demonstrates how ^{177}Lu-DOTATATE is a cornerstone for the treatment of NET in clinical practice

Scan to obtain:
• Poster

https://medicalcongressposters.com/Default.aspx?doc=bb2dc

This study is sponsored by Novartis Pharmaceuticals Corporation.
Poster presented at North American Neuroendocrine Tumor Society (NANETS) Multidisciplinary NET Medical Symposium, October 23-25 2025, Austin, TX

References

1. Oronsky B, *et al.* "Nothing but NET: a review of neuroendocrine tumors and carcinomas." *Neoplasia*, vol 19, 2017, pp. 991–1002.
2. Poleé IN, *et al.* "Long-term survival in patients with gastroenteropancreatic neuroendocrine neoplasms: A population-based study." *Eur J Cancer*, vol 172, 2022, pp. 252–263.
3. Cives M, Strosberg JR. "Gastroenteropancreatic neuroendocrine tumors." *CA Cancer J Clin*, vol 68, 2018, pp. 471–487.
4. Del Rivero J, *et al.* "Systemic therapy for tumor control in metastatic well-differentiated gastroenteropancreatic neuroendocrine Tumors: ASCO Guideline." *J Clin Oncol*, vol 41, 2023, pp. 5049–5067.
5. Strosberg J, *et al.* "Phase 3 trial of ^{177}Lu-Dotatate for midgut neuroendocrine tumors." *N Engl J Med*, vol 376, 2017, pp. 125–135.
6. Singh S, *et al.* "[^{177}Lu]Lu-DOTA-TATE plus long-acting octreotide versus high-dose long-acting octreotide for the treatment of newly diagnosed, advanced grade 2-3, well-differentiated, gastroenteropancreatic neuroendocrine tumours (NETTER-2): an open-label, randomised, phase 3 study." *Lancet*, vol 403, 2024, pp. 2807–2817.
7. Novartis. Lutathera® Prescribing Information. Available at: https://www.novartis.com/us-en/sites/novartis_us/files/lutathera.pdf. Accessed September 2025.

Acknowledgments

This study was sponsored by Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA. Medical writing support was provided by Lara-Mari Burgess, MD (Nucleus Global) and was funded by Novartis Pharmaceuticals Corporation. This poster was developed in accordance with Good Publication Practice (GPP 2022) guidelines. Authors had full control of the content and made the final decisions on all aspects of this publication.

Disclosures

HPS: Consulting/Advisory Role: Bristol Myers Squibb, Curium Pharma, Exelixis, Ipsen, Novartis; **Honoraria:** TM Isotope Technologies Munich SE