Prospective observational study in patients with locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) treated with lanreotide depot/autogel in a US community oncology setting: interim analysis

Andrew Scott Paulson, MD[1,2]; Beloo Mirakhur, MD[3]; David Ray, PharmD, MBA[3]; Eric Hui-Tseng Liu, MD, FACS[2,4]; Allen L. Cohn, MD[2,4]; David P. Cosgrove, MD[2,5]; Donald A. Richards, MD, PhD[2,6]; Richard S. Siegel, MD[2,7]; Yunfei Wang, PhD[8]; Sharan Aranha, BDS, MHA[8]; Yolanda Caddick, RN[8]; Amy Scales[8]; Kathy Allen[3]; Sonia Pulgar, MPH[3]

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BACKGROUND

- Neuroendocrine tumors (NETs) are a rare and serious form of cancer arising from cells throughout the endocrine system.[1]
- Somatostatin analogs are recommended to control hormone-related symptoms associated with NETs and as a first-line option for the treatment of unresectable, metastatic gastroenteropancreatic (GEP) NETs in the National Comprehensive Care Network (NCCN) treatment guidelines.[1]
- While clinical trials provide valuable objective information on the efficacy and safety of therapeutic agents, patients enrolled in clinical trials are often highly selected and may not accurately reflect or completely represent the majority of patients who receive treatment in the community setting.
- Lanreotide depot/autogel was recently indicated for the treatment of patients with GEP-NETs, creating a need to understand real-world effectiveness of lanreotide depot/autogel in this population.
  - In the phase 3 CLARINET study, estimated rates of progression-free survival at 24 months were 65.1% (95% confidence interval (CI): 54.0, 74.1) in lanreotide-treated patients and 33.0% (95% CI: 23.0, 43.3) in placebo-treated patients.[2]
- The aim of this study is to provide real-world insights into the experience of patients receiving lanreotide depot/autogel for the treatment of locally advanced or metastatic well-differentiated GEP-NETs in the community setting.

OBJECTIVES

- Primary objective: estimate the probability of progression-free survival for patients with locally advanced, metastatic GEP-NETs being treated with lanreotide depot/autogel in a community setting
- Secondary objectives/endpoints:
  - Overall survival
  - Adverse events (AEs)
  - Change in flushing and diarrhea
  - Patient satisfaction with treatment (Treatment Satisfaction Questionnaire for Medication [TSQM-9])

METHODS

- This is a prospective, non-interventional study of GEP-NET patients treated with lanreotide depot/autogel for a 24-month observation period from initiation of treatment (NCT02730104).
- This pre-planned interim analysis describes the experience of the first 50 patients (total planned sample is 100 patients) who have had 1 year of follow-up on lanreotide depot/autogel or an event (ie, death or disease progression).

Inclusion criteria

1. Male or female ≥18 years of age.
2. Histologically confirmed locally advanced or metastatic, well-differentiated NET of the small bowel, stomach, colon/rectum, or pancreas (low or intermediate grade; ie, G1 or G2).
   a. NETs of unknown primary origin may be included if lung can be excluded as the primary origin and there is suspicion of GEP-NET origin.
3. Treatment with lanreotide depot/autogel (SSA-naïve patients and patients with prior treatment with octreotide LAR are permitted).
4. Eastern Cooperative Oncology Group (ECOG) performance status of 0–2.

Exclusion criteria

1. Poorly differentiated or high grade (ie, G3) GEP-NETs or tumors with unknown grading.
2. Patients who have previously initiated treatment with lanreotide depot/autogel prior to the start of the study cannot have progressed between lanreotide initiation and study entry.

Clinically defined disease progression

- Defined as at least 1 of the following:
  - Tumor growth (radiographic progression)
  - New sites of metastatic disease
  - Worsening clinical symptoms
  - Tumor-related death

AND

- In addition, one of the following:
  - Treatment modification (dose increase, regimen change)
  - Treatment discontinuation
  - Additional or other NET therapeutic intervention

Statistical considerations

- Outcomes included clinically defined progression-free survival (defined above) and overall survival, as well as changes in flushing and diarrhea, and satisfaction (using the TSQM-9).
- For time-to-event endpoints (clinically defined progression-free survival and overall survival), Kaplan-Meier curves were constructed and Kaplan-Meier estimates were calculated along with 95% CIs.

RESULTS

- Among the 50 patients with 1 year of follow-up, median age was 65 years, 84% were Caucasians, and 96% had ECOG performance status of 0 or 1 (**Table 1**).
  - There were 36% of patients who had octreotide LAR experience prior to the study.

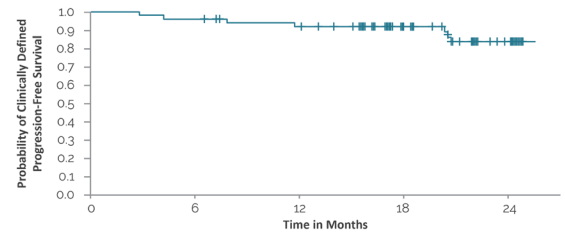
Table 1. Demographics and baseline characteristics

	Patients (N=50)
Age, mean (SD)	64.2 (10.5)
Sex, n (%)	
Female	29 (58.0)
Male	21 (42.0)
Race, n (%)	
Caucasian	42 (84.0)
Asian	2 (4.0)
Black	2 (4.0)
Hispanic	1 (2.0)
Other	3 (6.0)
ECOG Performance Status, n (%)	
0	27 (54.0)
1	21 (42.0)
2	1 (2.0)
Pending	1 (2.0)
Grade, n (%)	
1	39 (78.0)
2	11 (22.0)
Prior Chemotherapy, n (%)*	
Yes	9 (18.0)
No	51 (82.0)
Flushing at Screening, n (%)	
N-Present	36 (72.0)
P-Mild	7 (14.0)
P-Moderate	3 (6.0)
Diarrhea at Screening, n (%)	
N-Present	31 (62.0)
P-Mild	10 (20.0)
P-Moderate	8 (16.0)

*Excludes treatment with lanreotide depot/autogel and octreotide LAR.
ECOG, Eastern Cooperative Oncology Group; N-, not; P-, present; SD, standard deviation

- The probability of clinically defined progression-free survival at 12 months was 92% (**Figure 1**).

Figure 1. Probability of progression-free survival

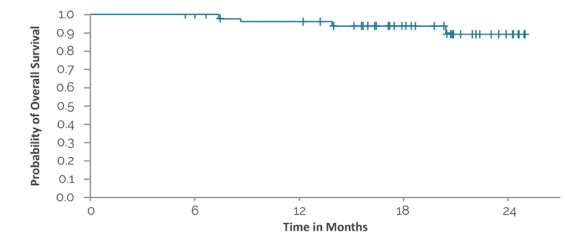


Summary of Clinically Defined Progression-Free Survival					
Total Patients	Deaths or PD (%)	Months			
		6	12	18	24
50	6 (12)				
Patients at Risk		48	43	26	8
% Estimated Survival (95% CI)		96.0 (84.9, 99.0)	91.7 (79.4, 96.8)	91.7 (79.4, 96.8)	82.8 (63.5, 92.4)

CI, confidence interval; PD, progressive disease.

- The probability of overall survival at 12 months was 96% (**Figure 2**).

Figure 2. Probability of overall survival



Summary of Overall Survival					
Total Patients	Deaths or PD (%)	Months			
		6	12	18	24
50	4 (8)				
Patients at Risk		49	44	26	8
% Estimated Survival (95% CI)		100	95.7 (83.9, 98.9)	93.4 (80.9, 97.8)	89.0 (71.6, 96.0)

CI, confidence interval.

- Largely, flushing and diarrhea remained stable at 1-year, and at 1 year follow-up on treatment, >80% of patients were at least somewhat satisfied with the drug (**Tables 2** and **3**).

Table 2. Change in flushing and diarrhea at 12 months of follow-up

	Better	Stable	Worse
Flushing, n (%)	2 (10.5)	17 (89.5)	0
Diarrhea, n (%)	2 (11.1)	15 (83.3)	1 (5.6)

For flushing, n=19 patients. For diarrhea, n=18 patients.

Table 3. Summary of the worst score of satisfaction (TSQM-9) over the study period

	Extremely Dissatisfied n (%)	Very Dissatisfied n (%)	Dissatisfied n (%)	Somewhat Satisfied n (%)	Satisfied n (%)	Very Satisfied n (%)	Extremely Satisfied n (%)	Total N
How satisfied or dissatisfied are you with the ability of the medication to prevent or treat your condition?	1 (2.4)	1 (2.4)	4 (9.8)	12 (29.3)	6 (14.6)	10 (24.4)	7 (17.1)	41
How satisfied or dissatisfied are you with the way the medication relieves your symptoms?	1 (2.4)	1 (2.4)	3 (7.3)	13 (31.7)	9 (22.0)	7 (17.1)	7 (17.1)	41
How satisfied or dissatisfied are you with the amount of time it takes the medication to start working?	1 (2.4)	1 (2.4)	2 (4.9)	7 (17.1)	16 (39.0)	6 (14.6)	8 (19.5)	41
How easy or difficult is it to use the medication in its current form?	0	1 (2.4)	4 (9.8)	11 (26.8)	6 (14.6)	8 (19.5)	11 (26.8)	41
How easy or difficult is it to plan when you will use the medication each time?	0	0	2 (4.9)	4 (9.8)	14 (34.1)	8 (19.5)	13 (31.7)	41
How convenient or inconvenient is it to take the medication as instructed?	1 (2.4)	1 (2.4)	4 (9.8)	6 (14.6)	10 (24.4)	4 (9.8)	15 (36.6)	41
Taking all things into account, how satisfied or dissatisfied are you with this medication?	0	0	4 (9.8)	9 (22.0)	10 (24.4)	9 (22.0)	9 (22.0)	41

All patients answered all questions (ie, no missing data).

- The top reasons for discontinuation were disease progression (10%) and AEs (4%).
- The main AEs reported thus far were nausea (6%), fatigue (4%), and abdominal pain (4%).
- The most common AEs leading to discontinuation included hypoglycemia (2%) and pneumonitis (2%).

LIMITATIONS

- This study captures a convenience sample from the US Oncology patient population, which potentially may limit its generalizability to other populations.
- The 12-month duration of this interim analysis may lack the long-term follow-up needed to identify progressive events in an indolent disease such as GEP-NETs.

CONCLUSION

- This interim analysis provides the first prospectively collected real-world outcomes of patients treated with lanreotide depot/autogel for GEP-NETs.
- Interim results suggest lanreotide depot/autogel is effective in disease control and most patients are satisfied with their treatment.

References

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Conflicts of interest

ASP: member of advisory board for Ipsen, Advanced Accelerator Applications, Eisai, Taiho, and BMS. **ALC:** consultant/advisor for Ipsen. **SP:** employee of Ipsen; stock ownership in Ipsen and Johnson & Johnson; research funding from Ipsen. **BM, DR,** and **KA:** employee of Ipsen. **DAR, DC, YC, AS, SA,** and **YW:** nothing to disclose.

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Grade, n (%)	
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Prior Chemotherapy, n (%)*	
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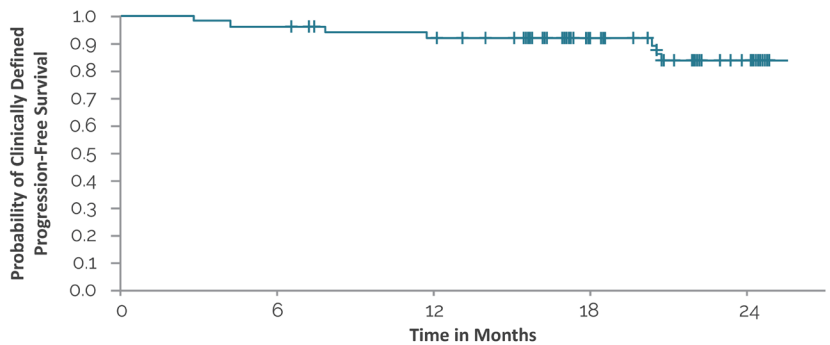
- The probability of clinically defined progression-free survival at 12 months was 92% (**Figure 1**).

Figure 1. Probability of progression-free survival

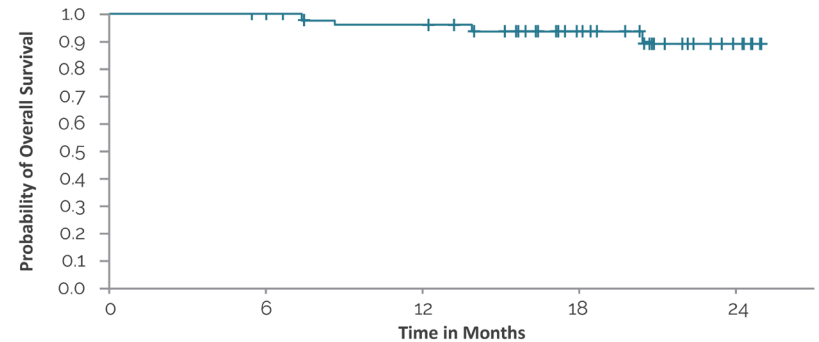


Summary of Clinically Defined Progression-Free Survival					
Total Patients	**Deaths or PD (%)**	**Months**			
50	6 (12)	**6**	**12**	**18**	**24**
Patients at Risk		48	43	26	8
% Estimated Survival (95% CI)		96.0 (84.9, 99.0)	91.7 (79.4, 96.8)	91.7 (79.4, 96.8)	82.8 (63.5, 92.4)

CI, confidence interval; PD, progressive disease.

- The probability of overall survival at 12 months was 96% (**Figure 2**).

Figure 2. Probability of overall survival



Summary of Overall Survival					
Total Patients	**Deaths or PD (%)**	**Months**			
50	4 (8)	**6**	**12**	**18**	**24**
Patients at Risk		49	44	26	8
% Estimated Survival (95% CI)		100	95.7 (83.9, 98.9)	93.4 (80.9, 97.8)	89.0 (71.6, 96.0)

CI, confidence interval

- Largely, flushing and diarrhea remained stable at 1-year, and at 1 year follow-up on treatment, >80% of patients were at least somewhat satisfied with the drug (**Tables 2** and **3**).

Table 2. Change in flushing and diarrhea at 12 months of follow-up

	Better	Stable	Worse
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Table 3. Summary of the worst score of satisfaction (TSQM-9) over the study period

	Extremely Dissatisfied n (%)	Very Dissatisfied n (%)	Dissatisfied n (%)	Somewhat Satisfied n (%)	Satisfied n (%)	Very Satisfied n (%)	Extremely Satisfied n (%)	Total N
How satisfied or dissatisfied are you with the ability of the medication to prevent or treat your condition?	1 (2.4)	1 (2.4)	4 (9.8)	12 (29.3)	6 (14.6)	10 (24.4)	7 (17.1)	41
How satisfied or dissatisfied are you with the way the medication relieves your symptoms?	1 (2.4)	1 (2.4)	3 (7.3)	13 (31.7)	9 (22.0)	7 (17.1)	7 (17.1)	41
How satisfied or dissatisfied are you with the amount of time it takes the medication to start working?	1 (2.4)	1 (2.4)	2 (4.9)	7 (17.1)	16 (39.0)	6 (14.6)	8 (19.5)	41
How easy or difficult is it to use the medication in its current form?	0	1 (2.4)	4 (9.8)	11 (26.8)	6 (14.6)	8 (19.5)	11 (26.8)	41
How easy or difficult is it to plan when you will use the medication each time?	0	0	2 (4.9)	4 (9.8)	14 (34.1)	8 (19.5)	13 (31.7)	41
How convenient or inconvenient is it to take the medication as instructed?	1 (2.4)	1 (2.4)	4 (9.8)	6 (14.6)	10 (24.4)	4 (9.8)	15 (36.6)	41
Taking all things into account, how satisfied or dissatisfied are you with this medication?	0	0	4 (9.8)	9 (22.0)	10 (24.4)	9 (22.0)	9 (22.0)	41

All patients answered all questions (ie, no missing data).

- The top reasons for discontinuation were disease progression (10%) and AEs (4%).
- The main AEs reported thus far were nausea (6%), fatigue (4%), and abdominal pain (4%).
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Conflicts of interest

ASP: member of advisory board for Ipsen, Advanced Accelerator Applications, Eisai, Taiho, and BMS. **ALC:** consultant/advisor for Ipsen. **SP:** employee of Ipsen; stock ownership in Ipsen and Johnson & Johnson; research funding from Ipsen. **BM, DR,** and **KA:** employee of Ipsen. **DAR, DC, YC, AS, SA,** and **YW:** nothing to disclose.

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