XERMELO® Patient Registry: A Real-World Evidence Study Evaluating Patient-Reported Outcomes with XERMELO

TAP TO GO BACK TO KIOSK MENU

Vijay N. Joish[1], Mark A. Price[2], Steven Schwartz[3], Shanna Jackson[1], Lee Bennett[2], Christina Darden[2], Eshetu Tesfaye[1], Quintellia Mobley[3], Karie Arnold[1], Suman Wason[1], Pablo Lapuerta[1]

[1]Lexicon Pharmaceuticals, Inc., The Woodlands, TX, USA; [2]RTI Health Solutions, Research Triangle Park, NC, USA; [3]Envoy Health, Flint, MI, USA.

Full ePoster

Table

Figure 1

Figure 2

Reference

1. Anthony L et al. *Clin Ther*. 2017;39(11):2158-68.

Disclosures

VNJ, SJ, ET, KA, SW, PL are employees of Lexicon Pharmaceuticals, Inc. MAP, LB, CD are employees of RTI Health Solutions who received funding from Lexicon Pharmaceuticals, Inc. for this research. S. Schwartz, QM are employees of Envoy Health who received funding from Lexicon Pharmaceuticals, Inc. for this research.

Acknowledgements

Jeff Frimpter, MPH, provided content development support for this ePoster, funded by Lexicon Pharmaceuticals, Inc.

Background

- Telotristat ethyl (TE, XERMELO®) is an inhibitor of tryptophan hydroxylase and the only oral treatment indicated for patients with carcinoid syndrome (CS) diarrhea
- Patients receiving TE in clinical trials reported meaningful reductions in number of bowel movements that led to improvements in treatment satisfaction[1]

This registry was established to evaluate satisfaction with CS symptom control before and during treatment with TE in a large, longitudinal, real-world cohort of patients

Methods

- This observational, noninterventional registry is currently enrolling patients with CS who are initiating treatment with TE
- Participants are invited through the specialty pharmacy
- Online surveys are conducted at baseline and every 6 months to a maximum of 3 years
- Baseline assessments evaluate satisfaction related to the current standard of care and other demographic and clinical characteristics
- Six-month outcomes include:
  - Patient satisfaction and global impression of change for CS-related symptom control
  - Rescue medication and long-acting somatostatin analog (SSA) use
  - Work productivity
  - Health resource utilization
- This interim report presents demographics and clinical characteristics for patients with available data at the time of this analysis, including satisfaction with CS-related symptom control at baseline before initiation of TE, and after 6 months of TE therapy
- At the time of data analysis, the 6-month response rate was 75% and 9% of patients had discontinued TE
  - 14 patients did not respond to the 6-month survey
  - 5 patients were no longer taking TE and not eligible to receive the 6-month survey

Results

- Demographics of RELAX registry participants aligned with the known epidemiology of CS (Table)
- At baseline, few patients (12.5%) had history of surgery in the previous 6 months to help their CS, most (71.4%) of which were to remove or reduce the size or number of tumors
- At baseline, most patients (75.0%) had not received additional treatment for their CS in the previous 6 months. The majority of those who reported additional CS treatment 6 months before baseline had received chemotherapy (7.1%), radiation (5.4%), embolization (5.4%), or radionucleotide therapy (3.6%)
- Satisfaction with previous treatment for overall CS-related symptom control or for CS diarrhea was low, with at least half of patients expressing dissatisfaction (Figure 1)
- After 6 months of TE treatment, patients reported satisfaction with overall (70%, n=16/23), diarrhea-related (78%, n=18/23), and flushing-related (50%, n=10/20) symptom control
- Number of bowel movements was reported as being better in 83% (n=19/23) of patients 6 months after initiating TE (Figure 2)

Click image to enlarge

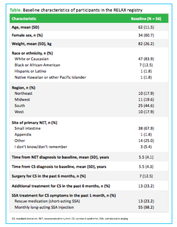
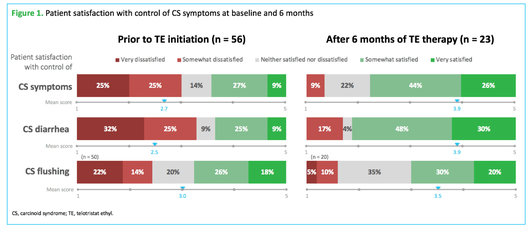
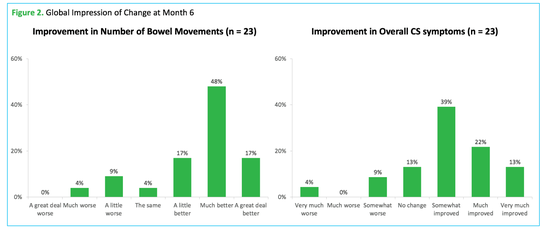


Table. Baseline characteristics of participants in the RELAX registry

Characteristic	Baseline (N = 56)
Age, mean (SD)	62 (11.5)
Female sex, n (%)	34 (60.7)
Weight, mean (SD), kg	82 (26.2)
Race or ethnicity, n (%)	
White or Caucasian	47 (83.9)
Black or African American	7 (12.5)
Hispanic or Latino	1 (1.8)
Native Hawaiian or other Pacific Islander	1 (1.8)
Region, n (%)	
Northeast	10 (17.9)
Midwest	11 (19.6)
South	25 (44.6)
West	10 (17.9)
Site of primary NET, n (%)	
Small intestine	38 (67.9)
Appendix	1 (1.8)
Other	14 (25.0)
I don't know/don't remember	3 (5.4)
Time from NET diagnosis to baseline, mean (SD), years	5.9 (4.1)
Time from CS diagnosis to baseline, mean (SD), years	5.5 (4.3)
Surgery for CS in the past 6 months, n (%)	7 (12.5)
Additional treatment for CS in the past 6 months, n (%)	14 (25.0)
SSA treatment for CS symptoms in the past 1 month, n (%)	
Rescue medication (short-acting SSA)	13 (23.2)
Monthly long-acting SSA injection	55 (98.2)

CS, carcinoid syndrome; NET, neuroendocrine tumor; SD, standard deviation; SSA, somatostatin analog





Conclusions

- Baseline findings from the RELAX registry highlight the substantial unmet need in patients with CS diarrhea on long-acting SSA therapy
- Initial results indicate high satisfaction related to CS-related symptom control and reductions in number of bowel movements after TE initiation among patients with available 6-month data at the time of this interim analysis

Presented at the NANETS Annual Multidisciplinary NET Disease Symposium, October 4-6, 2018, Seattle, WA

Lexicon pharmaceuticals
Precision Science. Pioneering Medicine.

XERMELO® Patient Registry: A Real-World Evidence Study Evaluating Patient-Reported Outcomes with XERMELO

TAP TO GO BACK TO KIOSK MENU

Vijay N. Joish[1], Mark A. Price[2], Steven Schwartz[3], Shanna Jackson[1], Lee Bennett[2], Christina Darden[2], Eshetu Tesfaye[1], Quintellia Mobley[3], Karie Arnold[1], Suman Wason[1], Pablo Lapuerta[1]

[1]Lexicon Pharmaceuticals, Inc., The Woodlands, TX, USA; [2]RTI Health Solutions, Research Triangle Park, NC, USA; [3]Envoy Health, Flint, MI, USA.

Full ePoster

Table

Figure 1

Figure 2

Table. Baseline characteristics of participants in the RELAX registry

Characteristic	Baseline (N = 56)
Age, mean (SD)	62 (11.5)
Female sex, n (%)	34 (60.7)
Weight, mean (SD), kg	82 (26.2)
Race or ethnicity, n (%)	
White or Caucasian	47 (83.9)
Black or African-American	7 (12.5)
Hispanic or Latino	1 (1.8)
Native Hawaiian or other Pacific Islander	1 (1.8)
Region, n (%)	
Northeast	10 (17.9)
Midwest	11 (19.6)
South	25 (44.6)
West	10 (17.9)
Site of primary NET, n (%)	
Small intestine	38 (67.9)
Appendix	1 (1.8)
Other	14 (25.0)
I don’t know/don’t remember	3 (5.4)
Time from NET diagnosis to baseline, mean (SD), years	5.5 (4.1)
Time from CS diagnosis to baseline, mean (SD), years	5.5 (4.3)
Surgery for CS in the past 6 months, n (%)	7 (12.5)
Additional treatment for CS in the past 6 months, n (%)	13 (23.2)
SSA treatment for CS symptoms in the past 1 month, n (%)	
Rescue medication (short-acting SSA)	13 (23.2)
Monthly long-acting SSA injection	55 (98.2)

SD, standard deviation; NET, neuroendocrine tumor; CS, carcinoid syndrome; SSA, somatostatin analog

Lexicon pharmaceuticals
Precision Science. Pioneering Medicine.

XERMELO® Patient Registry: A Real-World Evidence Study Evaluating Patient-Reported Outcomes with XERMELO

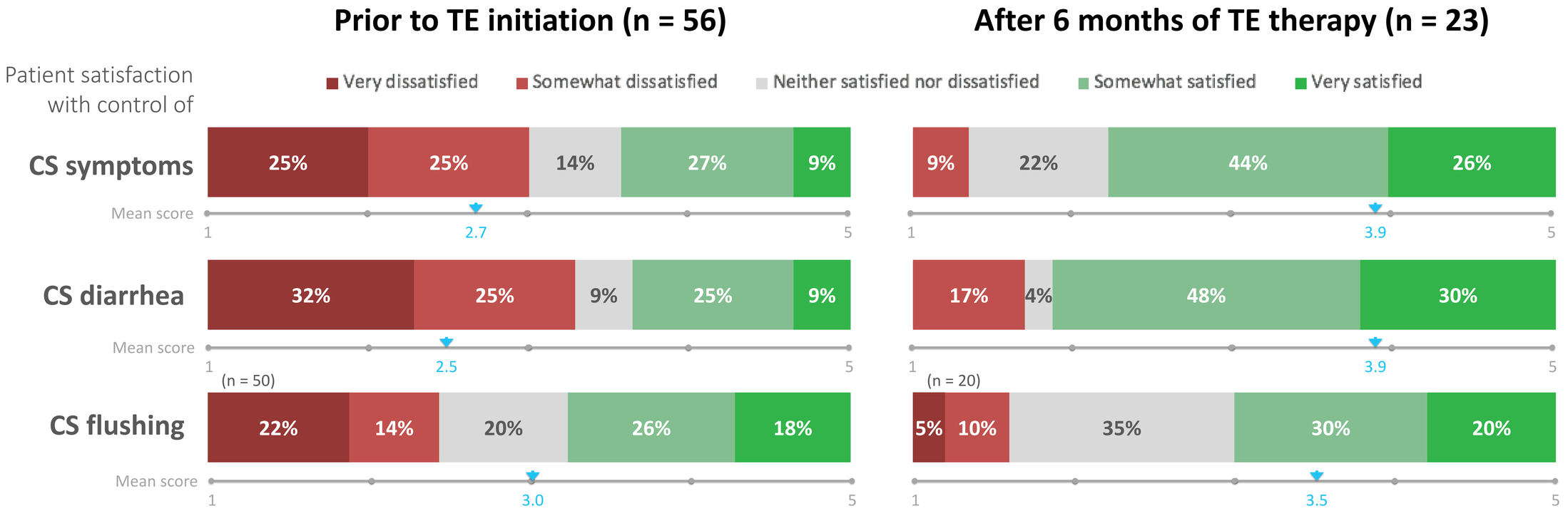
TAP TO GO BACK TO KIOSK MENU

Vijay N. Joish[1], Mark A. Price[2], Steven Schwartz[3], Shanna Jackson[1], Lee Bennett[2], Christina Darden[2], Eshetu Tesfaye[1], Quintellia Mobley[3], Karie Arnold[1], Suman Wason[1], Pablo Lapuerta[1]

[1]Lexicon Pharmaceuticals, Inc., The Woodlands, TX, USA; [2]RTI Health Solutions, Research Triangle Park, NC, USA; [3]Envoy Health, Flint, MI, USA.

Full ePoster
Table
Figure 1
Figure 2

Figure 1. Patient satisfaction with control of CS symptoms at baseline and after 6 months



CS, carcinoid syndrome; TE, telotristat ethyl.

Lexicon pharmaceuticals
Precision Science. Pioneering Medicine.

XERMELO® Patient Registry: A Real-World Evidence Study Evaluating Patient-Reported Outcomes with XERMELO

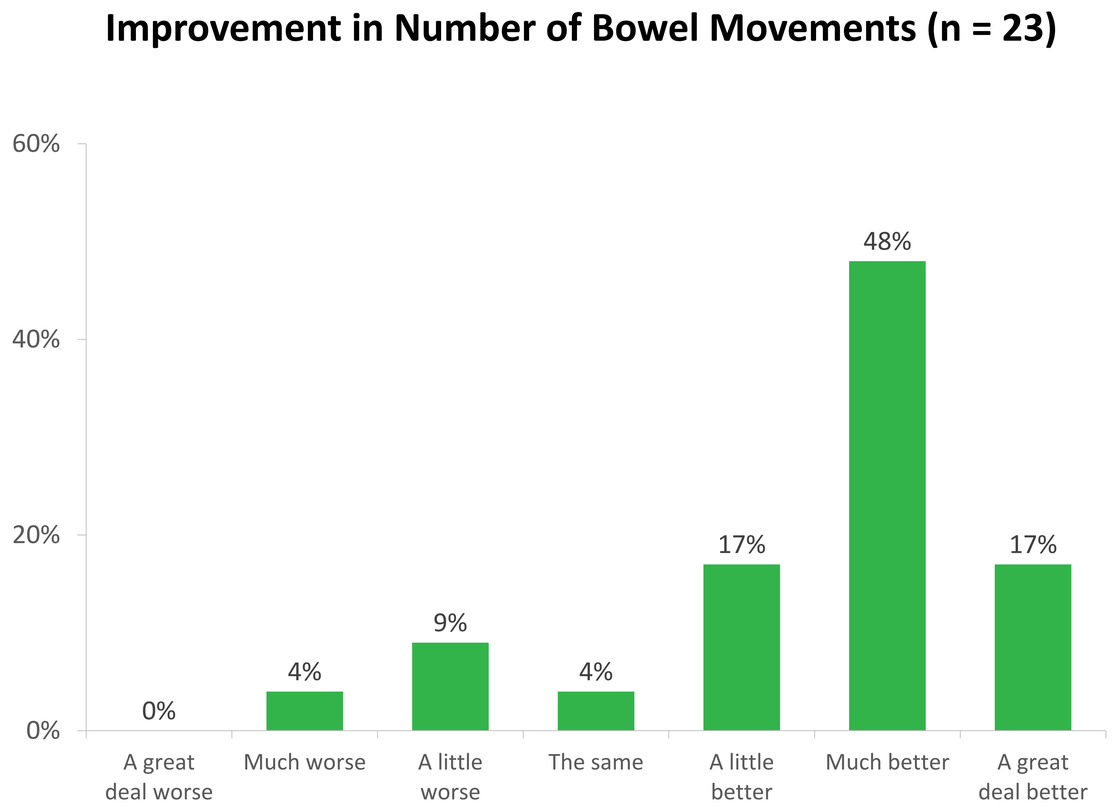
TAP TO GO BACK TO KIOSK MENU

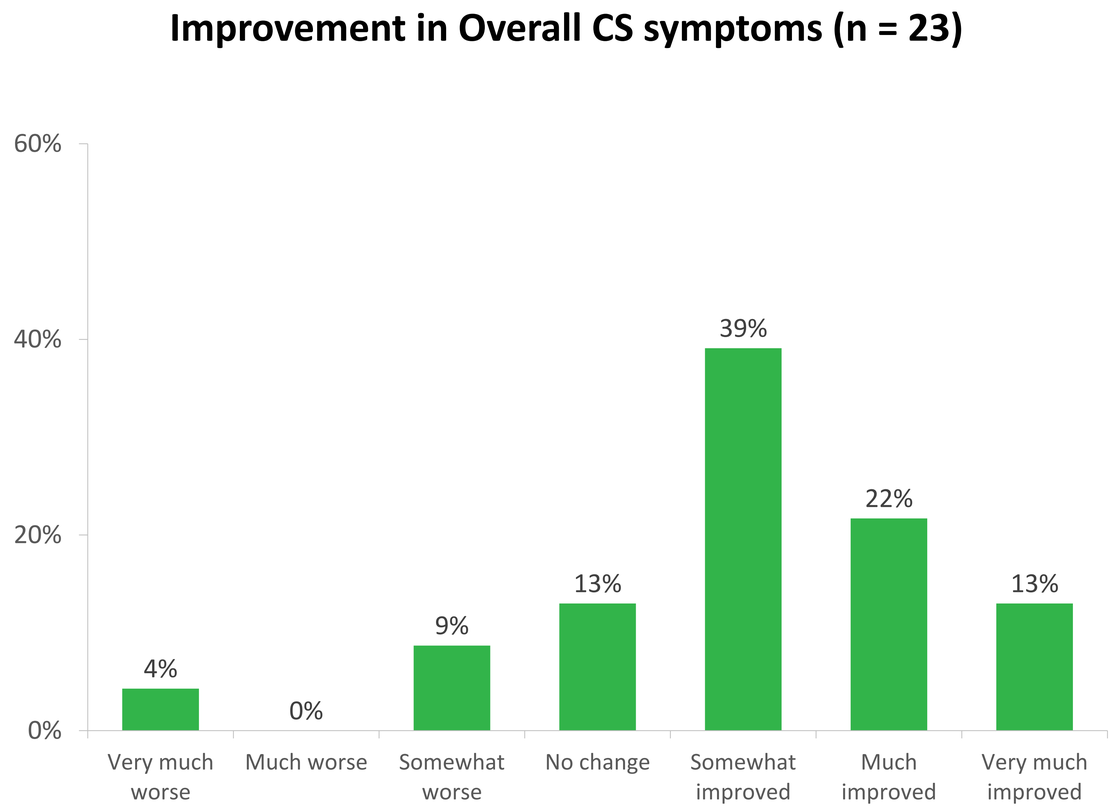
Vijay N. Joish[1], Mark A. Price[2], Steven Schwartz[3], Shanna Jackson[1], Lee Bennett[2], Christina Darden[2], Eshetu Tesfaye[1], Quintellia Mobley[3], Karie Arnold[1], Suman Wason[1], Pablo Lapuerta[1]

[1]Lexicon Pharmaceuticals, Inc., The Woodlands, TX, USA; [2]RTI Health Solutions, Research Triangle Park, NC, USA; [3]Envoy Health, Flint, MI, USA.

Full ePoster
Table
Figure 1
Figure 2

Figure 2. Global Impression of Change at Month 6





Lexicon pharmaceuticals
Precision Science. Pioneering Medicine.