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

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BACKGROUND: Telotristat ethyl (TE), an inhibitor of tryptophan hydroxylase, is indicated for carcinoid syndrome (CS) diarrhea. Patients receiving TE in clinical trials reported meaningful reductions in bowel movements that led to improvements in treatment satisfaction. This registry was established to evaluate satisfaction with TE in a larger, longitudinal, real-world cohort of patients.

METHODS: This observational, noninterventional registry is currently enrolling patients with CS who are initiating treatment with TE. The specialty pharmacy invites participants. 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 SSA use, work productivity, and health resource utilization. We describe the demographics and clinical characteristics of patients at the time of this interim analysis, and report patient satisfaction with CS-related symptom control at 6 months for patients with available data.

RESULTS: Patient demographics for those enrolled in the registry align with the known epidemiology of CS (Table). Satisfaction with previous treatment

for overall CS-related symptom control, CS diarrhea, and CS flushing was low, with at least half of patients expressing dissatisfaction (Table). Patients reported satisfaction with overall (70%, n=16), diarrhea-related (78%, n=18), and flushing-related (50%, n=10) symptom control at Month 6. Number of bowel movements were "much" or "great deal" improved in 64% (n=15) of patients 6 months after initiating TE.

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

Table 1:

Baseline Demographic Characteristics and Burden of CS-related Symptoms in RELAX

Variable	Baseline (N = 56)
Age, mean (SD) years	62.0 (11.5)
Sex, female, n (%)	34 (60.7)
Race or ethnicity, white or Caucasian, n (%)	47 (83.9)
SSA use for CS in past 1 month, short-acting SSA rescue medication, n (%)	13 (23.2)
SSA use for CS in past 1 month, long-acting SSA injection, n (%)	55 (98.2)
Baseline satisfaction with CS symptom control, mean score on scale of 1-5 (SD)	2.7 (1.4)
Baseline satisfaction with CS diarrhea control, mean score on scale of 1-5 (SD)	2.5 (1.4)
Baseline satisfaction with CS flushing control, mean score on scale of 1-5 (SD)	3.0 (1.4)

SD, standard deviation; SSA, somatostatin analog; CS, carcinoid syndrome.