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Patient-Reported Symptom Experiences Following Participation in a Study of Telotristat Etiprate for Patients with Carcinoid Tumor and Octreotide-Refractory Diarrhea

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Background: Telotristat etiprate (LX1606), an oral serotonin synthesis inhibitor, was recently evaluated in a randomized, placebo-controlled, dose-escalation study in patients with carcinoid tumors and octreotide-refractory diarrhea. The objective of this current study was to characterize the symptom experiences of patients participating in that trial.

Methods: Consenting patients participated in semi-structured, one-on-one, qualitative interviews focused on eliciting symptoms they had experienced in association with their carcinoid diagnosis and their recollection of any changes in symptoms they experienced while participating in the dose-escalation study. After the interviews, patients completed the EORTC-QLQ-C30 and GI.NET-21 questionnaires assessing their current symptoms.

Results: Patient interview results are reported. Among 23 patients who previously participated in the 4-week dose-escalation study, 11 consented to participate in the current study (treatment with LX1606 n=9; placebo n=2). The median time from completion of the dose-escalation study to the interview was 31 months. Four of the 11 patients were receiving LX1606 as part of a follow-up, open-label study at the time of their interview. Common symptoms reported by patients included: diarrhea (100%), abdominal pain (100%), flushing (82%), and fatigue/tiredness (82%); >50% of patients also reported sleep interruptions, irregular heartbeat, and abdominal cramping, which was described by participants as distinct from abdominal pain. Nine of 11 patients recalled symptom changes during their participation in the dose-escalation study; all recalled improvements most commonly in diarrhea (82%), abdominal pain (45%), flushing (36%), and abdominal cramping (36%); no patients recalled symptom worsening. Results are summarized in Table 1.

Conclusions: Diarrhea, abdominal pain, flushing, and fatigue were the most common symptoms reported by the interviewed carcinoid patients. Several patients who were interviewed about their experience during the LX1606 study recalled improvements in these and other symptoms during study participation.

Table 1: Most common patient-reported symptoms associated with carcinoid disease, and reported changes during LX1606 study

Symptom	N (%) Reported Symptoms	N (%) Recalling Improvement in Symptom during Participation in LX1606 Study.
Diarrhea	11 (100%)	9 (82%)
Abdominal pain	11 (100%)	5 (45%)
Flushing	9 (82%)	4 (36%)
Fatigue/tiredness	9 (82%)	2 (18%)
Sleep interruptions	8 (73%)	0 (0%)
Irregular heartbeat	7 (63%)	1 (9%)
Abdominal cramping	6 (55%)	4 (36%)
Wheezing	5 (45%)	0 (0%)
Feeling sick	5 (45%)	0 (0%)
Breathing difficulty	4 (36%)	0 (0%)
Gas	4 (36%)	3 (27%)
Blood in stool	3 (27%)	0 (0%)
Hot flashes/night sweats	3 (27%)	1 (9%) each
Dehydration	3 (27%)	2 (18%)
Lack of appetite	3 (27%)	2 (18%)