

## Assessing Treatment Benefit of Telotristat Etiprate in Patients with Carcinoid Syndrome: Patient Exit Interviews

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**Background:** Telotristat etiprate (TE), an oral tryptophan hydroxylase inhibitor, is intended to treat carcinoid syndrome (CS) by reducing serotonin production. TE was evaluated in TELESTAR, a phase 3 study; the primary endpoint showed significant reductions in bowel movement (BM) frequency for 2 TE dosages + standard of care (SOC) vs. SOC. TELESTAR

patients had CS inadequately controlled on somatostatin analog therapy with  $\geq 4$  BMs per day. They were interviewed about baseline symptoms and clinical trial experiences.

**Materials and Methods:** Participating sites were asked to invite all TELESTAR patients (consent obtained prior to randomization) to phone interviews scheduled between Weeks 12 and 14. Patients and interviewers remained blinded to treatment assignment. Interview data were summarized with standard qualitative analysis methods.

**Results:** All interview participants (N=35) reported diarrhea and/or excessive BMs at baseline. Diarrhea (n=17), followed by BM frequency (n=9), and urgency (n=5) were identified as the most bothersome and important symptoms to treat. BM frequency negatively affected emotional, social, physical, and occupational well-being. When probed, most participants reported that a reduction of  $\geq 30\%$  would be considered meaningful.

Improvements in CS symptoms were reported by 69% of participants. Among these, 88% reported reductions in BM frequency and 79% reported improvements in stool consistency. 95% who reported reductions in BM frequency noted that it was meaningful, describing a better ability to enjoy life, leave the house, and participate in social and other activities.

Among the 33 participants answering a question about treatment satisfaction, 55% reported being somewhat or very satisfied with TE in relieving CS symptoms. Reports of “very satisfied” were 0% (0/9) on placebo (SOC) and 50% (12/24) on TE, with similar results in the 2 TE dosage groups.

**Conclusions:** Diarrhea and BM frequency were identified as the most impactful CS symptoms. The primary endpoint of TELESTAR is very meaningful to patients.