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Improvement in Carcinoid Syndrome-Related Symptoms with Telotristat Ethyl in Patients with 2 or Less Bowel Movements per Day

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BACKGROUND: In the Phase 3 TELECAST randomized, controlled trial (N=76), telotristat ethyl (TE), a tryptophan hydroxylase inhibitor, was well tolerated and efficacious in patients with carcinoid syndrome (CS). The aim of this analysis was to assess the efficacy and safety of TE in those patients enrolled in TELECAST with ≤2 bowel movements (BMs)/day at baseline.

METHODS: Data on BM frequency, flushing episodes, stool form, nausea, and abdominal pain were collected in electronic diaries over the 12-week double-blind (DB) treatment period. The percent change from baseline at Week 12 for TE groups (250 mg three-times daily [tid] and 500 mg tid) versus placebo were described with nonparametric tests.

RESULTS: A total of 28 (placebo, n=9; TE 250 mg tid, n=10; TE 500 mg tid, n=9) out of 76 patients (37%) in the TELECAST study had ≤2 BMs/day at baseline and were included in the analyses. At the end of the DB treatment period, patients treated with TE 250 mg tid exhibited reductions in flushing by 63.3%, fewer BMs (-12.7%), and less abdominal pain (-78.1%). At the end of the DB period, the incidences of constipation were 20% for the 250mg tid group and 11% for the 500 mg tid group, respectively. Constipation was not reported as a serious adverse event, and TE was not discontinued in any of the cases. Moreover, concomitant medications that induce constipation were present in 87% of the constipation events.