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Lanreotide Depot/Autogel for Symptomatic Control of Carcinoid Syndrome (CS) in Patients With Neuroendocrine Tumors (NETs) Previously Responsive to Octreotide: Subanalysis of Patient-Reported Symptoms From the Phase 3 ELECT Study

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BACKGROUND: In ELECT, lanreotide significantly reduced the need for short-acting octreotide rescue therapy for symptomatic CS control in NET patients vs placebo (primary result). We present flushing and diarrhea symptom data and biochemical response for patients with or without prior octreotide use from ELECT.

METHODS: Adults with histopathologically-confirmed NETs and stable CS (no tumor progression or treatment-refractory symptoms) who were octreotide-naïve or responsive to octreotide long-acting release (≤ 30 mg q4W) or short-acting octreotide (≤ 600 μ g daily) were randomized (stratified by previous SSA therapy and region) to lanreotide 120 mg (SC q4W) or placebo for 16 weeks. Patients administered SC octreotide if needed and recorded daily symptom frequency and severity using Interactive Voice/Web Response System for 1 month pre-randomization and throughout the study. 24-hr urinary 5-HIAA and plasma CgA were assessed at baseline and Week 12.

RESULTS: Of 115 patients randomized, 51 were octreotide-naive (de novo) and 64 received prior octreotide. Mean percentage of days with moderate/severe diarrhea and/or flushing was lower in lanreotide vs placebo patients in de novo and prior octreotide groups; least squares mean difference (lanreotide-placebo) was significant in the de novo group (Table 1). By Week 12, 5-HIAA and CgA levels among patients with elevated baseline (>upper limit of normal) dropped by $\geq 50\%$ in 33.3% and 27.8% of de novo lanreotide patients and 30.0% and 22.2% of prior octreotide lanreotide patients; 5-HIAA and CgA reductions $\geq 50\%$ were seen in 25.0% and 30.0% of de novo placebo patients and in 14.3% and 7.7% of prior octreotide placebo patients. Treatment-emergent AEs occurred in 44.0% of lanreotide and 46.2% of placebo de novo patients and in 60.6% of lanreotide and 71.0% of placebo prior octreotide patients.

CONCLUSION: Patients showed improvement in CS symptoms with lanreotide treatment, regardless of prior octreotide use. Transition from octreotide to lanreotide was generally well tolerated.

Table 1:
Mean Percentage of Days With Moderate/Severe Diarrhea and/or Flushing (ANCOVA, ITT Population).

	De novo (n=51)	Prior octreotide (n=64)
Lanreotide (least squares mean [95% CI])	4.4 (0.0, 16.4)	33.0 (24.8, 41.3)
Placebo (least squares mean [95% CI])	19.0 (7.1, 30.9)	43.9 (35.3, 52.4)
Lanreotide-Placebo (least squares mean [95% CI])	-14.6 (-26.0, -3.1)	-10.9 (-22.8, 1.1)
P-value	0.0140	0.0746

De novo lanreotide group n=26, de novo placebo group n=25. Prior octreotide lanreotide group n=33, prior octreotide placebo group n=31.