

# **Efficacy of Lanreotide Depot/Autogel for Symptomatic Control of Carcinoid Syndrome (CS) in Neuroendocrine Tumor Patients: Follow-up Analysis of the ELECT Prospective, Randomized, Double-blind and Open-label Phases**

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**Background:** In ELECT, lanreotide significantly reduced rescue medication use for symptomatic control of CS in Neuroendocrine tumor (NET) patients vs PBO in the 16-week double-blind (DB) phase. Patient-reported symptoms during DB and initial open-label (IOL) treatment are presented.

**Methods:** Adults with NETs and CS history, with/without prior somatostatin analog (SSA) use, were randomized to DB Lanreotide (LAN) 120 mg or PBO every 4weeks for 16weeks, followed by a 32-week IOL phase on lanreotide. Each patient recorded daily the frequency and severity of diarrhea and flushing by Interactive Voice (Web) Response System for 1 month pre-randomization until study end. Analysis of covariance models incorporated baseline symptoms, prior SSA, and country. Given high variability of urinary 5HIAA, values were log-transformed.

**Results:** Of 115 patients randomized (n=59 LAN, n=56 PBO), 56 LAN- and 45 PBO-treated patients switched to LAN, continued in IOL (LAN-LAN and PBO-LAN). During DB phase, least square (LS) mean percentage of days with moderate/severe diarrhea and/or flushing were significantly lower for LAN (23.4%) vs placebo (35.8%) (LS mean difference [95% CI] -12.4 [-20.73, -4.07]; p=0.004) Among LAN-LAN patients in IOL, composite (frequency x severity) diarrhea scores improved significantly from DB to IOL and were not significantly different for flushing or diarrhea and flushing (Table 1). Composite symptom scores improved significantly from DB to IOL for PBO-LAN patients. Mean (95% CI) differences in changes from baseline in urinary 5HIAA between DB week12 and IOL week48 were -14.75µmol/d (-27.02, 56.51) for LAN-LAN and 73.96µmol/d (-11.77, 159.7) for PBO-LAN. Adverse event frequency during IOL by DB group (LAN, PBO) was 70% vs 71%. The safety profiles observed during IOL and DB were similar.

**Conclusion:** Lanreotide improved control of diarrhea and flushing in carcinoid patients during initial 16weeks of treatment, and was sustained for an additional 32weeks through week48 of this phase 3 study.

**Table 1:** Mean differences in composite symptom scores from DB to IOL phases

	LAN-LAN n=56	PBO-LAN n=45
Diarrhea	0.7 [0.22,1.20] (p=0.005)	1.1 [0.49,1.65] (p=0.0005)
Flushing	-0.2 [-1.25,0.80] (p=NS)	1.1 [0.19,1.93] (p=0.02)
Diarrhea and flushing	0.5 [-0.69,1.67] (p=NS)	2.1 [0.91,3.35] (p=0.001)

NS, non-significant