

Long-Term Safety/Tolerability of Lanreotide Autogel/Depot (LAN) in Neuroendocrine Tumors (NETs) Patients with Carcinoid Syndrome (CS): The ELECT Long-Term Open-label Extension

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Background: The ELECT study demonstrated that LAN treatment for CS in NET patients reduced rescue medication use vs placebo (PBO) during a 16-wk double-blind (DB) phase, and sustained symptomatic control during a 32-wk initial open-label (IOL) phase. Here we present final results of a long-term open-label extension (LTOLE).

Methods: Adult patients with NETs and a history of CS with/without prior somatostatin analog use were randomized to DB LAN 120mg or PBO every 4 wks for 16 wks, followed by an initial 32 wk IOL phase on LAN. Patients could then enter a LTOLE on LAN for up to 2 yrs (at sites where LAN was not already approved for symptom control). The LTOLE focused only on safety assessments.

Results: Of the 115 patients who took part in the DB phase (LAN, n=59; PBO, n=56) and 101 who then entered the IOL, 57 also entered the LTOLE on LAN. The overall adverse event (AE) profile of LAN is summarized in Table 1. The duration (median [IQR]) of LAN treatment for the 57 patients who entered the LTOLE was 109.6 (64.0–134.6) wks during this phase alone. During the LTOLE, the most common AEs reported by patients were abdominal pain (n=14 [25%]), fatigue (n=9 [16%]), diarrhea, hyperglycemia and back pain (each n=8 [14%]). The treatment related AEs most frequently reported by patients were cholelithiasis (n=4 [7%]), hyperglycemia and fatigue (both n=2 [4%]). Few patients (n=2[4%]) reported serious AEs considered treatment-related (hyperglycemia and glucose intolerance) but none led to study withdrawal.

Conclusion: These results on long-term use are consistent with the established safety/tolerability of LAN and extend the evidence base supporting the use of LAN 120mg in patients with NETs. (NCT00774930; EudraCT 2010-019066-92).

Table 1: AE profile of LAN during the ELECT LTOLE

	LTOLE LAN (n=57)
Treatment exposure, weeks (median[IQR])	109.6 (64.0–134.6)
Any AE, n (%)	48 (84)
Severe	18 (32)
Treatment-related AEs, n (%)	13 (23)
Severe	2(4)
Serious AEs, n (%)	15 (26)
Treatment-related	2 (4)
AEs with death as outcome	5 (9)*
AEs leading to discontinuation, n (%)	5 (9)*

None treatment-related