

Quality of Life (QoL) with Lanreotide Autogel/Depot (LAN) vs. Placebo in Patients with Enteropancreatic Neuroendocrine Tumors: Results From the CLARINET Core Study

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Background: QoL in patients with gastroenteropancreatic NETs can be affected by symptom burden, but also by treatment efficacy and safety. To better evaluate this, the EORTC developed a NET-specific QoL questionnaire (QLQ-GI.NET21) to be used in combination with its more generic questionnaire, EORTC QLQ-C30. Here, we examine the impact of LAN vs. placebo on QoL in patients in the CLARINET core study.

Methods: The CLARINET core study was a 96-week randomized double-blind phase III trial. Patients with metastatic well/moderately differentiated non-functioning enteropancreatic NETs were randomized to LAN 120 mg (n=101) or placebo (n=103) every 28 days, administered by deep subcutaneous injection (NCT00353496). The primary endpoint was progression-free survival (PFS). QoL, a secondary endpoint, was assessed at each study visit using the EORTC QLQ-C30 and the EORTC QLQ-GI.NET21. Safety was a key secondary endpoint.

Results: LAN significantly prolonged PFS vs. placebo (stratified log rank, $p < 0.001$; hazard ratio 0.47 [95% CI: 0.30, 0.73]). Treatment-related AEs occurred in 50% of patients in the LAN group vs. 28% in the placebo group. Gastrointestinal disorders were the most common treatment-related AEs (37% vs. 19%). QLQ-C30 global health status and QLQ-GI.NET21 endocrine and gastrointestinal subscale scores were similar in the two treatment groups at baseline and throughout treatment, though inter-individual variation was high (Table). Results for other subscale scores of the QLQ-C30 and QLQ-GI.NET21 questionnaires were also similar between LAN and placebo.

Conclusions: Overall, patients receiving LAN 120 mg had a significantly improved PFS and a good safety/tolerability profile that did not compromise patients' QoL vs. placebo. Further analyses are ongoing to evaluate QoL based on patient characteristics and treatment response.

Table. Effect of LAN on patients' QoL

Mean (SD)	Baseline	Week 48	Week 96	Last post-baseline value available
QLQ-C30 Global health status/QoL				
LAN	70.2 (19.9) [n=98]	70.9 (17.3) [n=71]	66.4 (22.1) [n=57]	64.5 (23.2) [n=98]
Placebo	73.6 (19.6) [n=99]	72.0 (14.9) [n=59]	70.1 (22.2) [n=34]	67.0 (22.4) [n=102]
QLQ-GI.NET21 Endocrine symptoms				
LAN	10.9 (15.0) [n=98]	11.0 (15.5) [n=71]	11.1 (15.1) [n=56]	11.7 (14.9) [n=97]
Placebo	12.0 (16.9) [n=98]	13.2 (18.0) [n=58]	11.8 (11.3) [n=34]	13.9 (19.0) [n=102]
QLQ-GI.NET21 GI symptoms				
LAN	17.1 (16.4) [n=98]	19.9 (17.6) [n=71]	15.3 (13.8) [n=56]	18.2 (16.5) [n=97]
Placebo	18.3 (18.0) [n=98]	16.0 (14.3) [n=58]	17.5 (17.4) [n=34]	19.8 (18.5) [n=102]

Data are transformed scores (range, 0–100). Higher transformed score represents better QoL for global health status and higher level of symptomatology/problems for endocrine and GI symptoms.