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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INTRODUCTION

The symptoms of carcinoid syndrome (CS), diarrhea and flushing in particular, have a significant negative impact on patient quality of life. 1, 2, 3 The objective of this post hoc analysis was to examine patient-reported symptom data from the 16-week double-blind (DB) phase and open-label phase of the ELECT study. 2, 3 Also included are post hoc analyses of biochemical responses (urinary 5-HIAA and SSAs) as well as safety data during the IOL phase.

METHODS

In the 16-week primary ELECT study, lanreotide depot/autogel (SC 120 mg every 4 weeks) was randomized 1:1 to receive SC lanreotide depot/autogel or placebo every 4 weeks in the DB phase, and of those, 101 continued in the IOL phase, including: 2, 3

- LAN–Placebo (n=56) (LAN DB/LAN IOL)
- PBO–PBO (n=45) (PBO DB/PBO IOL)

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Patient characteristics and 5-HIAA changes between the DB and IOL phases were analyzed using paired t-tests. 2, 3

Symptoms of CS consisted of diarrhea and flushing. Inpatients with a histopathologically-confirmed NET or NET of intermediate malignancy (NETs) and a modified Carcinoid 3 disease activity index score 3 or greater were eligible to enter the study. 2, 3

RESULTS

The adjusted square LS (least squares) mean percentage of days with moderate/severe diarrhea (4.5% vs 24.6%, P=0.016), moderate/severe flushing (8.4% vs 21.7%, P=0.004), and severe diarrhea and/or flushing (15.6% vs 24.6%, P=0.016) were significantly lower for patients treated with lanreotide depot/autogel compared with placebo in week 48, relative to week 24, which remained comparable at week 52 and all 4 patients with CS were treated with lanreotide depot/autogel for a total of 5 years.

DISCUSSION/CONCLUSIONS

Additional post hoc analyses found rapid decreases in urinary 5-HIAA levels at week 12 (P=0.012), week 24 (P=0.004), and week 48 (P=0.004) in patients treated with lanreotide depot/autogel compared with placebo in the DB phase. 2, 3

REFERENCES


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Figure 3. Mean (CI) difference in daily composite symptom scores for diarrhea, flushing, and diarrhea and/or flushing among all patients (LAN DB/LAN IOL vs PBO DB/PBO IOL) for all phases of the ELECT study (P-values are based on paired t-tests) (Figure 3)

Figure 4. Mean composite symptoms score difference (LS mean (SE) percentage of days with moderate/severe diarrhea, moderate/severe flushing, and severe diarrhea and/or flushing) between the DB and IOL phases (P-values are based on ANCOVA model adjusted for prior SSA use, region, and baseline values) (Figure 4)