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An Exploratory Patient Centric Analysis of the ELECT Trial: A Phase 3 Study of Efficacy and Safety of Lanreotide Autogel/ Depot (LAN) Treatment for Patients (pts) with Carcinoid Syndrome (CS)

Luc Duchateau¹; Benedicte Lescauwae²; Koenraad Blot²; Nilani Liyanage³; David Ray⁴; Susan Pitman Lowenthal⁴; Stephan Braun³; Beloo Mirakhur⁴

¹Ghent University; ²Xintera Ltd; ³Ipsen Innovation; ⁴Ipsen Biopharmaceuticals

BACKGROUND: In ELECT, LAN 120mg every 4 weeks significantly reduced octreotide rescue therapy use for symptomatic CS control vs placebo (PBO). This patient centric analysis explores the treatment effect on patient benefit during this trial.

METHODS: The analysis used all patient-reported outcomes collected during the double-blind phase of ELECT: daily diarrhea and flushing symptoms, octreotide rescue use and EORTC QLQ-C30 and QLQ-GINET.21 questionnaires at baseline and week 12. We applied principal component (PC) analysis on the baseline data to identify independent variable clusters, identified summary measures that were highly correlated to these PCs, derived minimum clinical important differences (MCID) and performed a responder analysis.

RESULTS: The 3 largest PCs captured 42.9% of the variation among the baseline variables. The C30 summary score (C30-SS), diarrhea burden (BD) and flushing burden (BF) were highly correlated with PC1, PC2 and PC3, respectively. LAN pts had a higher response rate for the C30-SS score (RR 2.42; P=0.023), BD (RR 2.42; P=0.002) and BF (RR 1.28; P=0.43) compared to PBO pts. LAN pts had a significantly higher probability of being a responder in at least one of the 3 domains of C30-SS, BD or BF as compared to PBO pts (RR 1.55; P=0.014).

CONCLUSION: This analysis found significantly higher response rates in the BD and QoL domains among LAN carcinoid syndrome pts, which adds to the previously reported significant reduction in rescue medication use.