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Efficacy and Safety of Lanreotide Depot vs Placebo in Patients with Neuroendocrine Tumor and a History of Carcinoid Syndrome and Prior Octreotide Therapy

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Background: In the ELECT double-blind study, treatment with lanreotide depot, a long-acting somatostatin analog (SSA), significantly reduced the need for short-acting octreotide rescue medication for symptomatic control of carcinoid syndrome (CS) in patients with gastroenteropancreatic neuroendocrine tumors (GEP-NETs) compared with placebo. This subanalysis assessed the efficacy and safety of lanreotide depot in patients with prior octreotide use.

Methods: Adults with histopathologically-confirmed GEP-NET or NET of unknown location with liver metastases and a history of CS (flushing and/or diarrhea) were included. Patients SSA-naïve or responsive to conventional doses of octreotide LAR (≤30 mg q4W) or short-acting octreotide (≤600 µg daily) were

randomized to receive lanreotide depot 120 mg (SC q4W) or placebo. Efficacy assessment included complete treatment success, defined as 0 days of rescue short-acting octreotide between weeks 12-15 during double-blind.

Results: 64 patients (n=33 lanreotide; n=31 placebo) were previously treated with octreotide LAR (n=56), short-acting octreotide (n=24), or both (n=6). Patient mean age was 58.8 years, 45% were male, and 84% had been diagnosed ≥1 year before the study. Among the lanreotide-treated patients, 52% experienced complete treatment success vs 26% of placebo patients (RR = 1.996 [95% CI: 1.009, 3.950], *P*=0.0471). As expected, the mean daily frequency of diarrhea and/or flushing events was similar between treatment groups because both received SSAs (lanreotide and/or octreotide rescue). Most treatment-emergent adverse events were mild or moderate in severity (Table). One patient receiving lanreotide experienced serious TEAEs (small intestinal obstruction and urinary infection).

Conclusions: The relative chance for achieving complete treatment success was 2 times greater with lanreotide treatment than placebo in patients with GEP-NETs who were previously treated with octreotide for CS. Transition to lanreotide depot 120 mg was well-tolerated with no new safety signals detected.

Table: Treatment-emergent adverse events (TEAEs) in patients previously treated with octreotide

	Lanreotide depot (n=33)	Placebo (n=31)
Any TEAEs	19 (58%)	22 (71%)
Severity of TEAEs		
Severe	2 (6%)	0
Moderate	10 (30%)	10 (32%)
Mild	7 (21%)	12 (39%)
5 most common TEAEs occurring in either treatment group		
Headache	6 (18%)	2 (7%)
Abdominal pain	4 (12%)	5 (16%)
Nausea	3 (9%)	5 (16%)
Fatigue	2 (6.1%)	4 (13%)
Dyspnea	0	4 (13%)