

## C-8

# Lanreotide Autogel/Depot (LAN) in Patients with Advanced Bronchopulmonary (BP) Neuroendocrine Tumors (NETs): Results From the Phase 3 SPINET Study

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**BACKGROUND:** Well-differentiated BP-NETs (typical [TC] and atypical carcinoids [AC]) account for ~25% of NETs. SPINET evaluated LAN in advanced somatostatin receptor (SSTR)-positive TCs and ACs.

**METHODS:** SPINET (NCT02683941) was a phase 3, randomized (2 LAN:1 PBO, stratified by TC vs AC), double-blind (DB) study of LAN (120 mg/28 days), with optional open-label LAN treatment (OL\_LAN). Enrollment was stopped due to slow accrual; ongoing patients without centrally assessed progression in the DB phase could transition to open-label LAN. The primary endpoint was adapted: centrally assessed (RECIST 1.1) PFS during the DB/OL-LAN phases in patients

randomized to LAN. Secondary endpoints included PFS, objective response rate (ORR) [central], and time to treatment failure (TTF) in each treatment arm during DB phase, and safety.

**RESULTS:** Seventy-seven patients were randomized and treated (LAN, n=51; PBO, n=26; [OL\_LAN, n=40]). Mean (SD) age was 66.2 (12.5) years; 42 patients (54.5%) were male, 45 (58.4%) and 32 (41.6%) had TC and AC respectively, all (Octreoscan) patients had a Krenning score  $\geq 2$ , 6 (7.8%) had received prior chemotherapy, and 71 (92.2%) had hepatic tumor load  $\leq 25\%$ . Median (95% CI) PFS in the LAN randomized group was 16.6 (12.8-21.9) months (TC 21.9 [12.8-not calculable (NC)]; AC 14.1 [5.6-16.6]). Key secondary endpoints are shown in the Table. In the DB phase, PFS for LAN and PBO, respectively, was 21.9 (13.8-NC) vs 13.9 (13.4-NC) months in TC and 13.8 (5.6-16.6) vs 11.0 (2.8-16.9) in AC.

**Secondary endpoints.**

	DB LAN (n=51)	DB PBO (n=26)	LAN vs PBO: HR [95% CI]
PFS (TC and AC), median (95% CI), months	16.6 (11.3-21.9)	13.6 (8.3-NC)	0.90 [0.46-1.88] (p = 0.769)
ORR, % (95% CI)	14.0 (5.8-26.7)	0 (0.0-13.7)	-
TTF, median (95% CI), months	13.3 (5.6-14.1)	9.8 (5.4-13.6)	0.86 [0.50-1.50]
Treatment-emergent adverse events, n (%) <sup>a</sup>	DB LAN (n=51)	DB PBO (n=26)	OL-LAN (n=40)
Any	49 (96.1)	25 (96.2)	26 (65.0)
Treatment-related	38 (74.5)	14 (53.8)	13 (32.5)
Grade 3/4/5	13 (25.5)/1 (2.0)/1 (2.0)	8 (30.8)/0/0	3 (7.5)/0/0
Serious treatment-related adverse events	2 (3.9)	1 (3.8)	0

<sup>a</sup>Excludes death/progression (part of PFS assessment)

**CONCLUSION:** SPINET, the largest prospective study to date with a somatostatin analog in SSTR-positive BP\_NETs, suggests LAN 120 mg could be an appropriate treatment option, especially for TC. This study is funded by Ipsen.

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