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Lanreotide Autogel (LAN) 120 mg Every 14 Days in Progressive Midgut Neuroendocrine Tumors (NETs): CLARINET FORTE Study



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BACKGROUND: The efficacy and safety of increasing LAN 120 mg dosing from every 28 (q28) days (standard) to q14 days to treat progressive pancreatic or midgut NETs was assessed; midgut NET results are reported here.

METHODS: A prospective, single-arm, open-label, exploratory, international phase II study (NCT02651987). Planned recruitment for this cohort was 50 patients with metastatic or locally advanced, unresectable, G1/2 midgut NETs (Ki67 index $\leq 20\%$) and centrally assessed progression in the past 2 years on the standard LAN regimen for ≥ 24 weeks. LAN 120 mg q14 days was administered for 96 weeks (or until centrally assessed progressive disease, unacceptable toxicity, or death) or longer if < 25 events occurred.

RESULTS: Patients (N=51) had a median (95% CI) in-study treatment duration of 10.1 (7.0; 12.9) months, and progression-free survival (PFS; primary endpoint) of 8.3 (5.6; 11.1) months. Median (95% CI) PFS in patients with Ki67 $\leq 10\%$ (N=47) and $> 10\%$, (N=4), respectively (post-hoc analysis) was 8.6 (5.6; 13.8) and 5.5 (2.6; not calculable) months.

Disease control rate (DCR; complete response, partial response, stable disease; 95% CI): Week 24, 58.8% (44.2; 72.4); Week 48, 33.3% (20.8; 47.9). DCR in patients with Ki67 \leq 10% and >10%, respectively (post-hoc analysis): Week 24, 59.6% (44.3; 73.6) and 50.0% (6.8; 93.2); Week 48, 36.2% (22.7; 51.5) and 0%. Treatment-related treatment-emergent AEs (TEAEs) occurred in 51.0% of patients. The most common (\geq 10%) class of treatment-related TEAEs were gastrointestinal disorders (37.3%) and general disorders/administration-site conditions (13.7%). Of note, each of the following treatment-related TEAEs were reported in 2.0% of patients (all N=1): bile stones, steatorrhea, and hyperglycemia.

CONCLUSION: LAN 120 mg q14 days in progressive midgut NETs provided encouraging PFS and DCR efficacy results, with an acceptable safety profile.

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