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

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BACKGROUND: CLARINET FORTE assessed the efficacy and safety of increasing LAN 120 mg dosing frequency to every 14 (q14) days from q28 days (standard) in patients with a progressive panNET (reported here) or midgut NET.

METHODS: In this prospective, single-arm, open-label, exploratory, international phase II study (NCT02651987), LAN 120 mg q14 days was administered for 48 weeks (or until centrally assessed progressive disease, unacceptable toxicity, or death), or longer if <25 events occurred. Planned recruitment was 50 patients with a metastatic or locally advanced, unresectable, G1/2 panNET (Ki67 index ≤20%) and centrally assessed progression within the past 2 years while on the standard LAN regimen for ≥24 weeks.

RESULTS: The panNET cohort included 48 patients (median [95% CI] in-study treatment duration, 7.1 [6.4; 9.7] months). Overall median (95% CI) progression-free survival was 5.6 (5.5; 8.3) months (primary endpoint); 8.0 (5.6; 8.3) months in patients with Ki67 ≤10% (N=43), and 2.8 (2.8; 2.9) months in patients with Ki67 >10% (N=5) (post hoc analysis).

Disease control rate (DCR; complete response, partial response, stable disease; 95% CI): Week 24, 43.8% (29.5; 58.8); Week 48, 22.9% (12.0; 37.3). DCR in patients with Ki67 ≤10% and >10%, respectively (post hoc analysis): Week 24, 48.8% (33.3; 64.5) and 0% (0; 0); Week 48, 25.6% (13.5; 41.2) and not applicable. Treatment-related treatment-emergent adverse events (TEAEs) occurred in 37.5% of patients; gastrointestinal disorders (25.0%) were the most common (≥10%) class of treatment-related TEAEs. Of note, 2.1% of patients (N=1) experienced a treatment-related TEAE of hyperglycemia; no patients experienced a treatment-related TEAE of bile stones or steatorrhea.

CONCLUSION: LAN 120 mg q14 days in progressive panNETs produced no new safety signals; patients with Ki67 ≤10% appear to benefit most from the increased dose.

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