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Lanreotide Depot/Autogel Before, During, and After Peptide Receptor Radionuclide Therapy in Advanced Neuroendocrine Tumors: Data from the PRELUDE Study

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BACKGROUND: ^{177}Lu-DOTATATE, a peptide receptor radionuclide therapy (PRRT) licensed for gastroenteropancreatic (GEP) neuroendocrine tumors (NETs), has been used with somatostatin analogs such as lanreotide depot (LAN). PRELUDE is the first retrospective study to describe use of LAN with PRRT (LAN–PRRT) in advanced NETs.

METHODS: PRELUDE (NCT02788578) was an international, retrospective, non-comparative analysis of medical records of patients receiving LAN with ^{177}Lu-DOTATATE/DOTATOC, and up to 12 months follow-up with LAN only. Key inclusion criteria: metastatic/locally advanced, grade 1/2, somatostatin receptor positive GEP- or lung-NET; progressive disease (PD) in the year prior to LAN–PRRT start; ≥1 LAN injection 8 weeks before the first LAN–PRRT cycle; continuous LAN use during LAN–PRRT; and cumulative PRRT activity ≥500 mCi. Primary endpoint: progression-free survival (PFS) rate at the end of the last LAN–PRRT

cycle (RECISTv1.1, centrally assessed). Secondary endpoints included best overall response (OR), objective response rate (ORR) (both RECISTv1.1, centrally assessed), change from baseline in diarrhea and flushing. Safety included incidence of nephro-, hemato- and hepatotoxicity; vomiting during infusion.

RESULTS: Enrollment was terminated early (insufficient recruitment). Of 40 patients enrolled, 39 had GEP-NET (including: ileum 33.3%, unknown origin 25.6%, right colon 20.5%, pancreas 10.3%); one had lung-NET (full analysis set [FAS]: GEP-NET n=23, lung-NET n=1). Most patients with GEP-NET had Ki67>2–≤20% (53.1%), global overall Krenning score (centrally assessed) grade 4 (70.4%), received 4 (17/23 patients) LAN–PRRT cycles, and 120 mg LAN (18/23) last dose before PRRT (enrolled population). LAN exposure and effectiveness data (FAS) are shown in Table 1. Most patients with GEP-NET had stable/improved diarrhea (15/15) and flushing (13/14) at the end of the last LAN–PRRT cycle (FAS). Few toxicities reported; no safety issues identified.

CONCLUSION: Effectiveness data were encouraging in this selected population. In clinical practice, LAN use is considered before, during, and after PRRT.

Table 1:

Parameter	Patients with GEP-NETs (n=23; FAS)
Median (range) LAN overall exposure, months	37.0 (16.7–90.0)
Median (range) LAN exposure during LAN only follow-up, months	12.6 (6.1–32.5)
PFS rate [95% CI] at end of last LAN–PRRT cycle*	91.7% [53.9; 98.8]
Best OR [95% CI]* partial response	34.8% [18.8; 55.1]
Best OR [95% CI]* stable disease	60.9% [40.8; 77.8]
Best OR [95% CI]* progressive disease	4.3% [0.8; 21.0]
ORR at time of last LAN–PRRT cycle [95% CI]*	27.3% [13.2; 48.2]

*RECISTv1.1, centrally assessed. CI, confidence interval; FAS, full analysis set; GEP-NETs, gastroenteropancreatic neuroendocrine tumors; LAN, lanreotide depot; PFS, progression-free survival; PRRT, peptide receptor radionuclide therapy; OR, overall response; ORR, objective response rate.