1331P Tumour growth rate (TGR) when using lanreotide Autogel® (LAN) before, during and after peptide receptor radionuclide therapy (PRRT) in advanced neuroendocrine tumours (NETs)

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Background: ^{177}Lu-DOTATATE is licensed for gastroenteropancreatic (GEP-)NETs. PRELUDE is an international retrospective study (NCT02788578) to describe LAN use with ^{177}Lu-PRRT (LAN–PRRT) in advanced NETs. Here we report effectiveness results, including a post hoc TGR analysis to complement RECIST-based progression measures.

Methods: Analysis of patients (pts) receiving LAN with ^{177}Lu-DOTATATE/DOTATOC followed by LAN only. Key inclusion criteria: metastatic/locally advanced, grade 1/2, somatostatin receptor-positive GEP-/lung NET, progressive disease (PD) within 12 mo and within 6 mo before LAN–PRRT start (assessed locally), $\geq$1 LAN injection 8 wks before LAN–PRRT start, continuous LAN use during LAN–PRRT, cumulative PRRT activity $\geq$500 mCi. Primary endpoint: progression-free survival (PFS) rate at end of last LAN–PRRT cycle (RECIST v1.1, central review). Key secondary endpoints: PFS rate at last available follow-up (RECIST v1.1 central review), best overall response (OR; RECIST v1.1 central review). Post hoc analysis: TGR (% variation of tumour volume/mo) calculated from sum of longest diameter of target lesions between two MRI/CT scans during: prebaseline/baseline (within 12 mo and within 6 mo before baseline), baseline/end of last LAN–PRRT cycle (within 6 mo before baseline and end of last LAN–PRRT cycle), and end of last LAN–PRRT cycle/last available follow-up visit.

Results: Enrolment terminated early (insufficient recruitment): 40 pts (GEP n = 39; lung n = 1) (full analysis set: GEP n = 23, lung n = 1). LAN exposure and effectiveness results in GEP-NETs are shown in the table. Waterfall plots of prebaseline/baseline TGR showed individual progressions and regressions, with a mean of 0 [–1.4; 1.5].

Table: 1331P

	Patients with GEP-NETs (n = 23)
Median (range) LAN exposure, mo Overall Prior to LAN–PRRT During LAN–PRRT During LAN only follow-up	37.0 (16.7–90.0) 10.5 (0.7–61.7) 14.2 (7.0–24.0) 12.6 (6.1–32.5)
PFS rate [95% CI] at end of last LAN–PRRT cycle	91.7% [53.9; 98.8]
PFS rate [95% CI] at last available follow-up (up to 12 mo post-treatment)	95.0% [69.5; 99.3]
Best OR [95% CI] RECIST v1.1	Partial response (PR): 34.8% [18.8; 55.1] Stable disease: 60.9% [40.8; 77.8] PD: 4.3% [0.8; 21.0]
Mean [95% CI] TGR: Prebaseline/baseline Baseline/end of last LAN–PRRT cycle End of last LAN–PRRT cycle/last available follow-up visit	0.0% [−1.4; 1.5] −1.6% [−2.7; −0.4] −0.2% [−1.3; 0.9]

Conclusions: Effectiveness data were encouraging in this small selected population. TGR suggested tumour regression during LAN–PRRT. Despite low baseline TGR, 35% pts had RECIST PR on central assessment.

Clinical trial identification: PRELUDE: NCT02788578.

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