

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: ¹⁷⁷Lu-DOTATATE is licensed for gastroenteropancreatic (GEP-)NETs. PRELUDE is an international retrospective study (NCT02788578) to describe LAN use with ¹⁷⁷Lu-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 ¹⁷⁷Lu-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), ≥ 1 LAN injection 8 wks before LAN-PRRT start, continuous LAN use during LAN-PRRT, cumulative PRRT activity ≥ 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 | 0.0% [–1.4; 1.5] –1.6% [–2.7; –0.4] –0.2% [–1.3; 0.9] | | | |
| Baseline/end of last LAN-PRRT cycle | | | | |
| End of last LAN-PRRT cycle/last available follow-up visit | | | | |

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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