C-13

Tumor Growth Rate (TGR) to Monitor Growth/Predict Response to Lanreotide Autogel Use Before, During and After PRRT in Advanced GEP-NETS: Data from the PRELUDE Study

Lisa Bodei[1]; Raj Srirajaskanthan[2]; Chiara Maria Grana[3]; Sergio Baldari[4]; Tahir Shah[5]; Angela Lamarca[6]; Frédéric Courbon[7]; Klemens Scheidhauer[8]; Eric Baudin[9]; Gustave Roussy Xuan-Mai[9]; Truong Thanh[9]; Aude Houchard[9]; Vikas Prasad[10]

[1]Memorial Sloan Kettering Cancer Center; [2]Kings College Hospital; [3]IRCCS European Institute of Oncology; [4]University of Messina; [5]Queen Elizabeth Hospital Birmingham; [6]The Christie NHS Foundation Trust; [7]IUCT-Oncopole; [8]Technical University Muenchen, Klinikum r.d. Isar; [9]Ipsen; [10]Universitätsklinikum Ulm

BACKGROUND: 177Lu-DOTATATE is licensed for gastroenteropancreatic neuroendocrine tumors (GEP-NETs). PRELUDE (NCT02788578) is the first international multicenter retrospective study with central radiology reading to describe lanreotide autogel (LAN) with and after 177Lu–peptide receptor radionuclide therapy (PRRT; LAN–PRRT) in advanced NETs. We report effectiveness data and post hoc analyses of TGR as a growth measure/predictive factor of LAN–PRRT response.

METHODS: PRELUDE was a retrospective, non-comparative study that analyzed the medical records of patients receiving LAN and 177Lu-DOTATATE/TOC then LAN only. Patients had metastatic/locally advanced G1/2 somatostatin receptor-positive GEP/lung NET; progressive disease on two scans 6 and 12 months before LAN–PRRT; ≥1 LAN injection 8 weeks before LAN–PRRT; continuous LAN during

LAN–PRRT; cumulative PRRT activity ≥500 mCi. Primary endpoint: progression-free survival (PFS) rate at end of last LAN–PRRT cycle (RECIST1.1 central review). Key secondary endpoint: objective response rate (ORR; RECIST1.1 central review). TGR (%/months from CT/MRI) was assessed post hoc: prebaseline/baseline (T1), baseline/end of last LAN–PRRT cycle (T2), end of last LAN–PRRT cycle/last follow-up (T3). TGR cut-offs predicting ORR for end of last PRRT/last follow-up were derived from ROC curves.

RESULTS: Overall, there were 24/40 enrolled patients in full analysis set (FAS; GEP-NET n=23, lung-NET n=1). In the GEP-NET FAS, median LAN exposure was 37 months. PFS rate and ORR: 91.7% [95% CI 53.9;98.8] and 27.3% [13.2;48.2] at last LAN–PRRT cycle; 95.0% [69.5;99.3] and 36.8% [19.1;59.0] at last follow up. Mean [95% CI] TGR: 0.0% [–1.4;1.5] (T1), –1.6% [–2.7;–0.4] (T2), –0.2% [–1.3;0.9] (T3). Based on the Youden index, optimal T1 TGR cut-offs to predict ORR for end of last PRRT/last follow-up derived from ROC curves: 1.18%/0.33% (sensitivity: 0.75/0.83; specificity: 0.80/0.83; area under curve [95%CI]: 0.75 [0.5013;0.9987]/0.82 [0.6108;1.000]).

CONCLUSION: TGR suggested tumor regression during LAN–PRRT. Objective response at the end/within 12 months after LAN–PRRT was more likely if baseline TGR was ≤1.18%/≤0.33%.