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Efficacy and Safety of [^{177}Lu]Lu-DOTA-TATE in Patients With Advanced Pancreatic Neuroendocrine Tumours (panNETs): Data From the NETTER-R International, Retrospective Registry

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BACKGROUND: Peptide receptor radionuclide therapy with [^{177}Lu]Lu-DOTA-TATE (177Lu-DOTATATE) is used for the treatment of adults with somatostatin receptor (SSTR)-positive gastroenteropancreatic neuroendocrine tumours. Additional efficacy and safety of 177Lu-DOTATATE in patients with pancreatic neuroendocrine tumours (panNETs) are presented here.

METHODS: NETTER-R is a retrospective registry of patients with unresectable/metastatic, well-differentiated, SSTR-positive, progressive panNETs treated with ≥1 administration of 177Lu-DOTATATE. The primary endpoint was progression-free survival (PFS) by RECIST v1.1. Secondary endpoints included overall survival (OS), safety and tumour response.

RESULTS: A total of 110 patients were identified. 70.0% of patients received all four cycles of 177Lu-DOTATATE. Cumulative activity was 29.6 GBq ±10% (26.6-32.6 GBq) in 65.5% of patients. Twelve patients received 1-4 additional cycles of 177Lu-DOTATATE after the initial treatment. By RECIST v1.1, evaluable in

62 patients, median PFS was 24.8 months (95% confidence interval [CI] 17.5-34.5) and objective response rate was 40.3% (95% CI 28.1-53.6); all responses were partial. With a median follow up of 24.5 months (range 2.0-123.4), median OS in 110 patients was 41.4 months (95% CI 28.6-50.2). PFS (hazard ratio [HR] 3.672; p=0.0009) and OS (HR 3.360; p<0.0001) were improved in patients who had not previously received chemotherapy compared with those that had. 71.8% of patients (n=79/110) had ≥1 treatment-emergent adverse event (TEAE). The most frequent TEAEs were nausea (28.2%) and fatigue (22.7%), predominantly grade 1/2. No TEAEs led to treatment discontinuation. Grade 3 anaemia, lymphopenia and thrombocytopenia occurred in 0.9%, 5.4% and 0.9% of patients, respectively. Renal TEAEs occurred in six patients (5.5%; grade 1: n=1, grade 2: n=2, grade 3: n=3). All renal grade ≥3 events were transient and did not lead to treatment modification. No acute leukaemia or myelodysplastic syndrome was reported.

CONCLUSION: These results reinforce 177Lu-DOTATATE as a treatment option in patients with advanced, SSTR-positive panNETs.

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