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Safety of ^{177}Lu DOTATATE in Patients with Advanced Neuroendocrine Tumors: Data from a US Expanded Access Program

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BACKGROUND: The NETTER-1 study showed that peptide receptor radionuclide therapy (PRRT) with ^{177}Lu-DOTATATE significantly increases progression-free survival in patients with somatostatin-receptor-positive advanced midgut neuroendocrine tumors (NETs) compared with high-dose octreotide long-acting repeatable, and had a tolerable safety profile. The safety profile of ^{177}Lu-DOTATATE was analyzed using data from a US expanded access program (NCT02705313).

METHODS: Patients had inoperable, histologically proven, somatostatin-receptor-positive, locally advanced or metastatic bronchial or gastroenteropancreatic NETs that progressed after somatostatin analog therapy. Exclusion criteria were: surgery, radiotherapy or chemotherapy (within 12 weeks); treatment with an interferon, mTOR inhibitor, or other systemic therapy (within 4 weeks); ongoing octreotide therapy that could not be interrupted; impaired renal function; or serious coexisting conditions. Patients who received ≥1 cycle of ^{177}Lu-DOTATATE between July 5, 2016 and December 21, 2018 were included. Data were collected from the first cycle until October 7, 2019.

RESULTS: 299 patients (mean age, 60.8 years; 38.5% men) received a mean ^{177}Lu-DOTATATE cumulative dose of 552 mCi (20.4 GBq) over a mean of 2.8 cycles. Over a mean follow-up of 131 days, 48.8% of patients reported treatment-related adverse events (TRAEs), with a maximum severity of grade 1, 2 and 3 for 26.8% (n=80), 18.1% (n=54) and 4.0% (n=12) of patients, respectively, with no grade 4–5 TRAEs. Common any grade TRAEs were nausea (31.1%), vomiting (13.7%), fatigue (9.4%) and thrombocytopenia (6.0%). Prevalent grade 3 TRAEs were lymphocytopenia (1.0%) and thrombocytopenia (0.7%). Serious TRAEs occurred in 1.0% of patients. AEs led to dose modification in 1.7% of patients, dose delay in 6.4% and discontinuation in 1.3%.

CONCLUSION: In US patients with advanced NETs in the expanded access program, ^{177}Lu-DOTATATE treatment showed few TRAEs, consistent with the safety profile in NETTER-1.

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