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Safety and Effectiveness of ^{177}Lu-Satoreotide Tetraxetan in Patients with Progressive Neuroendocrine Tumors (NETs): Interim Analysis of a Phase I/II Study

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BACKGROUND: ^{177}Lu-satoreotide tetraxetan is a novel SSTR antagonist, associated with higher tumor uptake compared to SSTR agonists. We report safety and effectiveness data of an ongoing phase I/II study (NCT02592707) investigating ^{177}Lu-satoreotide tetraxetan in progressive NETs, in which kidney (maximum 23 Gy) and bone marrow (maximum 1.5 Gy) dosimetry is used to guide administered activity.

METHODS: The study started on 6 Mar 2017 and enrolled 40 patients with unresectable/metastatic NETs; it is conducted in two parts. Part A comprises 15 patients who completed 3 cycles of ^{177}Lu-satoreotide tetraxetan at a fixed administered activity of 4.5 GBq/cycle and a peptide mass of 300 µg/cycle. Part B enrolled 25 patients who completed 1-5 cycles at different administered activities (4.5 or 6.0 GBq/cycle) and peptide masses (300, 700, or 1,300 _g/cycle).

RESULTS: As of 1 Apr 2021, median cumulative activity of ^{177}Lu-satoreotide tetraxetan was 13.0 GBq over 3 cycles. Most common grade 3/4 treatment-related adverse events (TRAEs) were lymphopenia, thrombocytopenia, and neutropenia

(Table). No grade 3/4 nephrotoxicity was observed. Serious hematological TRAEs were myelodysplastic syndrome (n=1) (part A), grade 4 thrombocytopenia (n=1), and acute myeloid leukemia (n=1) (part B). Disease control rate (DCR) was 94.7% (95% CI, 82.3-99.4), and objective response rate 21.1% (95% CI, 9.6-37.3). Median PFS has not been reached. No association between peptide mass of ^{177}Lu-satoreotide tetraxetan/cycle (300 to 1,300 µg) and increased toxicity was observed.

CONCLUSION: These preliminary data, reporting an acceptable safety profile and a high DCR, are promising and support a potential role for ^{177}Lu-satoreotide tetraxetan in treating advanced NETs.

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Grade ≥3 TRAEs

Number of patients (%)	Part A (N=15)	Part B (N=25)	Total (N=40)
Total	*5 (33.3)*	*10 (40.0)*	*15 (37.5)*
Lymphopenia	2 (13.3)	5 (20.0)	7 (17.5)
Thrombocytopenia	2 (13.3)	3 (12.0)	5 (12.5)
Neutropenia	0	3 (12.0)	3 (7.5)
Anemia	1 (6.7)	0	1 (2.5)
Acute myeloid leukemia	0	1 (4.0)	1 (2.5)
Myelodysplastic syndrome	1 (6.7)	0	1 (2.5)
Presyncope	1 (6.7)	0	1 (2.5)
Musculoskeletal pain	0	1 (4.0)	1 (2.5)