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Efficacy Update on the First Real- World Experience of Peptide Receptor Radionuclide Therapy (PRRT) in Neuroendocrine Tumors (NET) Since US FDA Approval

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BACKGROUND: Real-world data on 177Lu-DOTATATE in the US is lacking. We recently reported the first real-world experience of PRRT in NET (Konda et al, E-Abstract ASCO 2019). Here, we present updated efficacy data after a median follow-up of 10.2 months.

METHODS: We reviewed medical records of patients who began PRRT between 03/14/18-10/01/18 at the Ohio State University. 177Lu-DOTATATE was administered at 200mCi over 20-30min every 8 weeks for 4 doses. Arginine-lysine 25gm/25gm in 1L saline and intravenous palanosetron 0.25mg were infused over 4hrs, starting 30min pre-treatment. Clinical evaluation occurred 2 weeks before and after each PRRT dose, and radiographic assessment using contrast CT/ MRI was performed following 2 and 4 doses. Patients who received ≥2 PRRT doses were considered evaluable for efficacy.

RESULTS: 46 patients received ≥2 PRRT doses and 42/46 were evaluable for response (RECIST v1.1). 50% were female and median age was 63 (range: 39-84) years. 33/42 (79%) completed 4 doses, 1/42 (2%) had 3 doses (on active therapy at this time), and 8/42 (19%) discontinued treatment after 2 or 3 doses.

Treatment discontinuation was due to toxicities (4/8), progressive disease (PD; 1/8), or patient/physician preference unrelated to toxicities (3/8). Primary site was GI (62%), pancreas (12%), lung (10%), unknown (10%), GI and pancreas (5%), and ampullary (2%). 31% had grade 1 (G1), 56% G2, 7% G3 (2/42; Ki 67:25% and 40%), and 7% unknown grade. 9% were systemic therapy naïve, 55% received ≥1 prior systemic therapies (excluding somatostatin analogs), and 43% had ≥1 prior liver-directed therapies. Median follow-up from first PRRT to last clinic visit/death was 10.2 months. Objective response rate (partial response) was 17% (7/42; table). 76% (32/42) had stable disease, and 5% (2/42) had PD.

CONCLUSION: 177Lu-DOTATATE is an effective treatment in advanced NET, and our results are consistent with the NETTER 1 data.

Table 1. Characteristics of patients with objective response

Patient #	Primary site	Ki 67	Prior systemic/liver-directed therapies
1	Small intestine	1%	Octreotide LAR, Lanreotide
2	Small intestine	Unknown	Bortezomib on clinical trial, Everolimus, Octreotide LAR, Transarterial chemoembolization (TACE)
3	Lung	15-29%	Capecitabine/Temozolomide (CAPTEM), Everolimus
4	Small intestine	2%	Pertuzumab, Bevacizumab, Octreotide LAR on clinical trial
5	Small intestine	5%	Octreotide LAR, TACE
6	Lung	7%	CAPTEM, Octreotide LAR, TACE
7	Small intestine	5%	Octreotide LAR
Median OS (months)	Not reached	55.3	0.026 (0.38, 0.21-0.68)
Sirolimus	mTOR inhibitor	-31.50/-91.20	0.01/0.03