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## Lutetium 177-DOTATATE Therapy in Progressive Metastatic Well-Differentiated G1/G2 Neuroendocrine Tumors: Review of the University of Kentucky's Post-FDA Approval PRRT Program



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**BACKGROUND:** The US FDA approved peptide receptor radionuclide therapy (PRRT) using <sup>177</sup>Lu-DOTATATE in January 2018. Clinical experience/data, although deficient, are emerging.

**METHODS:** We retrospectively reviewed patient medical records who began PRRT 5/2018-6/2019 at the University of Kentucky. <sup>177</sup>Lu-DOTATATE was administered at dose 200mCi over 30 minutes every 8 weeks for 4 doses. An amino acid solution containing Arginine HCL 2.5%/Lysine HCL 2.5% in one-liter NS, infused over 4 hours, 30 minutes prior to radiotherapy treatment, was given with 16mg ondansetron ODT.

**RESULTS:** Twenty-nine patients received at least 1 of 4 doses, 19/29 completed dose 2, 8/29 completed dose 3, and 1/29 completed all 4 doses. 5/29 (17%) were deceased after dose 1. Currently five patients are not due for dose 2, ten for dose 3, and seven for dose 4. 8/19 were evaluable for radiological responses via NM Tumor Total Body Scan (Luta-Scan). Categorically, 14/29 (48%) had GI NET, 8/29 (28%) pNET (pancreatic), 4/29 (14%) tNET (thoracic), and 3/29 (10%) uNET (unknown primary). Furthermore, 28% had G1 disease, 41% G2, and 31% (9/29) were uncategorized (lacking Ki-67). 17/29 (59%) had received 2 prior non-somatostatin analog systemic therapies and 41% had 1 prior liver-directed therapy. Follow-up after dose 4 was 21 days. Clinical/Luta-Scan response was 63% (5/8) for those completing at least 3 PRRT doses. 14/19 (74%) had

stable disease and 1/19 had Luta-Scan progression. Grade 1/2 adverse events (AEs) included fatigue, nausea, edema, and thrombocytopenia. Grade 3/4 AEs prompting treatment discontinuation included generalized weakness (1/29) and thrombocytopenia (1/29). All AE Grade 3/4 patients had baseline progressive disease and  $\geq 3$  prior lines of treatment.

**CONCLUSION:** Our PRRT experience with  $^{177}\text{Lu}$ -DOTATATE has been well-tolerated and effective in the ongoing treatment of progressive metastatic well-differentiated G1/G2 NET. Our results, although limited and ongoing, include a broader spectrum of patients than NETTER-1 and include interim Luta-Scan response data.