Aim: To study the safety and effectiveness of peptide receptor radionuclide therapy (PRRT) with $^{177}$Lu-DOTATATE in patients with somatostatin receptor-expressing neuroendocrine tumors (NET).

Background: At this time, the only approved systemic therapies for NET in the United States are streptozocin, everolimus, and sunitinib for pancreatic NET. PRRT with radio-labeled somatostatin analogues is a novel method of treatment in patients with inoperable and/or metastatic neuroendocrine tumors expressing high levels of somatostatin receptors. We are reporting the first U.S. experience on $^{177}$Lu-DOTATATE PRRT under FDA approved IND, at our institution.

Methods: $^{177}$Lu-DOTA Octreotate (200 mCi (7.4GBq) per cycle) was administered to 39 patients diagnosed with disseminated NET. Co-infusion of 15% Clinisol was used as a kidney radioprotectant.

Results: Response to treatment (PR+MR) and stable disease (SD) were seen in 29.4% and 47% of evaluable patients, respectively. PR was significantly associated with the lower burden of disease in the liver. No significant acute toxicity was observed during or immediately following the treatment. Hematological and hepatic toxicity grade III was seen in 12.9% and 9.67%, respectively. Also, a significantly longer PFS was seen in patients who completed all four cycles of treatment vs. those who received one cycle. An impressive improvement of Karnofsky performance status and also overall quality of life was seen after $^{177}$Lu-DOTATATE therapy.

Conclusion: The first U.S. experience with $^{177}$Lu-DOTATATE PRRT suggests that this agent is an effective and a rather safe method of treatment for patients with progressive, disseminated neuroendocrine tumors. Our preliminary results confirm the information published by other investigators in Europe and Australia.