T-3:
Pilot Study: Yttrium-90 DOTA-TOC Intra-arterial (IA) Peptide Receptor Radionuclide Therapy (PRRT) for Neuroendocrine Tumor Regimen for Metastatic Disease

Thomas Hope[1]; *Nicholas Fidelman[1]; Salma Jivan[1]; Erik K. Nakakura[2]; Emily Bergsland[3]*

[1]UCSF School of Medicine; [2]University of California San Francisco; [3]UCSF Helen Diller Family Comprehensive Cancer Center

BACKGROUND: This is a prospective, pilot, single center, open-label study in patients with metastatic neuroendocrine tumor. Study participants will receive a one-time administration of 90Y-DOTA-TOC via the hepatic artery.

METHODS: All participants will receive a single administration of intra-arterial 90Y-DOTA-TOC.
Participants in the correlative sub-study will receive 68Ga-DOTA-TOC concurrent with the 90Y-DOTA-TOC dose, and undergo additional imaging and assessment. There will be a sub-study involving 10 patients from the main study who will undergo additionally correlative imaging to compare IA vs IV administration (intra-arterial 68Ga-DOTA-TOC administration and subsequent PET imaging).

RESULTS: Primary Outcome Measures:
Overall Response Rate (ORR) [Time Frame: Over the duration of the study, which is estimated to be approximately 36 months] Based on change in size of hepatic lesions three and six months after treatment with IA 90Y-DOTA-TOC using RECIST criteria.
Incidence of Treatment-Related Adverse Events [Safety] [Time Frame: Over the

duration of the study, which is estimated to be approximately 36 months] Based on laboratory evaluation and CTCAE 4.0 criteria.

Secondary Outcome Measures:
Change in SUVmax between pre-treatment IV 68Ga-DOTA-TOC PET and treatment IA 68Ga-DOTA-TOC. [Time Frame: Over the duration of the study, which is estimated to be approximately 36 months]

Data from patients in the imaging correlate sub-study only:
Correlation between uptake on IA 68Ga-DOTA-TOC PET/CT compared to 24-hour post-treatment IA 90Y-DOTA-TOC PET/MRI. [Time Frame: Over the duration of the study, which is estimated to be approximately 36 months]

CONCLUSION: The primary goals are to evaluate possible liver, bone marrow and kidney toxicity after hepatic arterial injection and evaluate imaging tumor response to 90Y-DOTA-TOC hepatic arterial injection three months after treatment.