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Randomized Embolization Trial for Neuroendocrine Tumors (RETNET): First Safety Report

Michael Soulen[1]; Rony Avritscher[2]; Ghassan El-Haddad[3]; Nicholas Fidelman[4]; Ricardo Garcia-Monaco[5]; Sarah White[6]; E. Paul Wileyto[1]

[1]University of Pennsylvania; [2]MD Anderson Cancer Center; [3]Moffit Cancer Center; [4]University of California San Francisco; [5]Hospital Italiano; [6]Medical College of Wisconsin

BACKGROUND: Embolotherapy of progressive or symptomatic neuroendocrine tumor (NET) liver metastases is standard of care in international guidelines, without recommendation regarding embolization technique. RETNET (NCT02724540) is a prospective randomized controlled trial comparing bland, cTACE, and DEB-TACE. Interim safety analyses are planned following accrual of 10 and 30 subjects in each arm. The first safety review is reported here.

METHODS: Society of Interventional Radiology (SIR) QI guidelines for embolization and TACE set the performance threshold for major complications at 8%, and for any complications 15%. For RETNET, a 20% incidence of serious adverse events as defined by the SIR (D = unplanned increase in level of care; E = permanent adverse sequelae; F = death) would be grounds for closing an arm. This provides a probability of halting of 62% at the first safety review if the true event rate is 20%. Blinded review was performed by an independent DSMB consisting of three senior interventional oncologists at non-participating institutions after a minimum of 10 subjects in each arm had one-month follow-up after their first embolization cycle.

RESULTS: Two subjects in the bland arm had SIR Category D events (pain; unrelated pancreatitis 6 months post-embo). The subject with pain required re-hospitalization and withdrew from the study. Two subjects in the cTACE arm had SIR Category D events (unrelated renal infection, hyponatremia), none resulted in study discontinuation. 4 subjects in the DEB arm had

Category D (hyponatremia, carcinoid crisis, both requiring ICU admission) or E (hepatobiliary necrosis; biloma) events, two of which resulted in study discontinuation.

CONCLUSION: 4/10 NET subjects embolized with DEB had serious adverse events, two permanent and two resulting in study discontinuation. Based on the trial stopping rule, the DSMB closed the DEB arm.