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Feasibility and Safety of Integrated CapTemY90 for Liver-Dominant G2 NETS

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BACKGROUND: Grade 2 neuroendocrine tumors (NET) have an intermediate proliferative rate and progress more aggressively than low-grade NETs, with median TTP around 12 months. The combination of capecitabine and temozolomide (CapTem) has been shown to achieve response rates of 61%. Capecitabine is synergistic with radiation and often used concurrently in other malignancies. We investigated the safety and tolerability of combining CapTem with Y90 radioembolization for progressive Grade 2 NETs with liver-dominant metastases.

METHODS: 20 patients with liver dominant G2 NET were treated with capecitabine 600 mg/m2 twice daily for 14 days and temozolomide 150-200 mg/m2 in two divided doses on Days 10-14, with 14 days between cycles. Simulation angiography and MAA scan for Y90 planning were performed during the first cycle of chemotherapy. During the second cycle, Y90 radioembolization with resin microspheres was performed to one lobe on Day 7. The other lobe was treated if needed on Day 7 of the 3rd or 4th cycle. CapTem was continued monthly. Clinical and laboratory toxicities were assessed monthly. Imaging was performed 3 months after the first radioembolization, then every 3 months.

RESULTS: There were no unexpected AE's. 6/20 patients required CapTem dose reduction for thrombocytopenia. >50% reduction in CgA was observed in 18/20 patients, mean 70%. Mean TTP was 35 mo [95% CI 28-42 mo; mean TTP in liver was 41 mo [95% CI 37-46 mo]; medians not reached.

CONCLUSION: Integrated CapTem with radioembolization is feasible and safe. Duration of disease control exceeds expectations for grade 2 NETs, supporting a multicenter Phase 2 efficacy study.