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Theranostic Trial of Well Differentiated Neuroendocrine Tumors (NETs) with 68Ga-OPS201 and 177Lu-OPS201

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BACKGROUND: Radiolabeled somatostatin receptor 2 (sstr2) antagonists have shown higher tumor uptake than agonists in preclinical models. We performed a phase I study to evaluate the safety and dosimetry of the sstr2 antagonists 68Ga-OPS201 and 177Lu-OPS201 (68Ga/177Lu-DOTA-JR11) in patients (pts) with metastatic well differentiated NETs (NCT02609737).

METHODS: Pts with RECIST disease progression underwent a 68Ga-OPS202 PET/CT to confirm in-vivo binding of the sstr2 antagonists and if positive, underwent treatment with 3 doses of 177Lu-OPS201. The first dose of 50 mCi 177Lu-OPS201was used to calculate tumor and normal organ radiation doses. Dosimetry was then calculated to administer 177Lu-OPS201 in divided doses for the 2nd and 3rd fractions, 8-10 weeks apart.

RESULTS: 19 pts enrolled (1 lung, 7 small bowel, 8 pancreatic, 1 gastric, 1 rectal, 1 kidney). Average age was 55 y (22-73 y), 52% female; mean number of prior treatments was 3. All pts received 1 therapeutic dose of 177Lu-OPS201, 7 pts received 2 doses. With the exception of the kidneys and bladder, no organ demonstrated uptake of 68Ga-OPS201 above background. Tumor radiation doses ranged from 0.15 Gy/mCi to 0.48 Gy/mCi. Subacute hematologic toxicity after cycle 1 was mild-moderate (G3 2/19 leukopenia that reversed before

cycle 2). 4/7 (57%) pts that received the second dose of 177Lu-OPS201had G4 hematological toxicities, which occurred 4-6 weeks after administration. G 3/4 toxicities in the four pts have resolved to G2 or lower; none of these pts demonstrated fever, infection, bleeding, or renal toxicity. Substantial efficacy was observed: 1 patient achieved a CR (1/19, 5%), 32% PR (6/19), 47% SD (9/19) and 16% POD (3/19). Median PFS has not yet been reached.

CONCLUSION: In this trial of treated NETs, preliminary data are promising for the use of 68Ga-OPS201/177Lu-OPS201 as a theranostic combination for imaging and therapy. Additional studies are planned to determine an optimal therapeutic dose and schedule.