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## Phase I trial of molecularly targeted, radiolabeled somatostatin analog in children and young adults with recurrent or progressive solid tumors.

**Sub-category:** [Pediatric Solid Tumors](#)

**Category:** Pediatric Cancer

**Meeting:** [2008 ASCO Annual Meeting](#)

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**Abstract No:** 10029

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**Abstract:** **Background:** Somatostatin receptors are highly expressed in several pediatric solid tumors, including neuroblastoma, medulloblastoma and neuroendocrine tumors. We hypothesize that molecularly targeted somatostatin analog,  $^{90}\text{Y}$ -DOTA-tyr<sup>3</sup>-Octreotide which binds with high affinity to somatostatin receptor type 2 (sst2), will be an effective therapy for pediatric malignancies that express sst2. **Methods:** A Phase I, dose/toxicity trial of  $^{90}\text{Y}$ -DOTA-tyr<sup>3</sup>-Octreotide was conducted at 30 (cohort 1), 40 (cohort 2), and 50 (cohort 3) mCi/m<sup>2</sup> with concomitant Aminosyn II infusion. Subjects received 3 cycles of treatment, 6 weeks apart. Eligibility criteria included: recurrent or progressive malignancy with at least one Octreoscan positive lesion; age 2-25 yrs; bone marrow cellularity >40%; GFR >80 ml/min/m<sup>2</sup>; no radiation therapy for 3 months; no chemotherapy for 30 days. Escalation was based on 3/3 or 4/6 subjects with no dose limiting toxicity. Additionally, subjects were limited to <21 Gy calculated radiation dose to kidneys, including any previous external beam radiotherapy received prior to  $^{90}\text{Y}$ -DOTA-tyr<sup>3</sup>-Octreotide dosing. **Results:** Twelve subjects completed 3 cycles (5, 3 and 4 subjects in cohorts 1, 2, 3, respectively). Diagnoses included gastrinoma (3), foregut carcinoid (3), neuroblastoma (2), paraganglioma (2), MEN1lb, and anaplastic astrocytoma. Five subjects (38%) had a PR (>50% decrease in target lesion); four subjects had a positive response (>25%<50% decrease in target lesion); three subjects had stable disease for > 4 months; seven subjects remain alive without progression 2 months to 3.5 years after completion of therapy. Four subjects withdrew from the study after one cycle and had progressive disease within 6 weeks. No dose limiting toxicities were observed; specifically, no Grade III or greater renal or hematologic toxicity was observed. **Conclusions:** Based on intent to treat, 53% of children and young adults with recurrent, sst2 positive tumor had a positive response to  $^{90}\text{Y}$ -DOTA-tyr<sup>3</sup>-Octreotide. PR was obtained in at least one subject at each dose level. No dose limiting toxicities were observed with 50 mCi/m<sup>2</sup>, the recommended dose for Phase II studies.

### [Abstract Disclosures](#)

### Associated Presentation(s):

- Phase I trial of molecularly targeted, radiolabeled somatostatin analog in children and young adults with recurrent or progressive solid tumors.**

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