Conclusions Altogether, our data revealed multiple effects of IL-7 in these patients, highlighting a complex set of in vivo mechanisms. In the future, knowledge of these effects may help in choosing the best agents to use in combination with IL-7 and/or the best patients to benefit from IL-7 as part of their therapeutic approach.

**Trial Registration** NCT01881867

**Ethics Approval** The study was last approved by Fred Hutchinson Cancer Research Center Institutional Review Board, IR file 8037, on January 23, 2020

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Abstract 270 Figure 1

a. Waterfall plot indicating maximum change in baseline tumor measurement following treatment. Crosshatch indicates patient failed therapy and do not have tumor measurements available due to early clinical progression or progression due to new lesions without RECIST measurable changes (N=2). b. Swimmer’s plot of PFS following therapy. Triangles indicated confirmed PR, targets indicate unconfirmed PR and squares indicate SD.

Conclusions Combination therapy with ipilimumab plus nivolumab in thyroid cancer resulted in an ORR of 12% with two partial responses in seventeen treated patients.

**Trial Registration** NCT02834013

**Ethics Approval** The study was approved by the NCI Adult Central Institutional Review Board, approval number 02834013.

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Abstract 264

**Correlation of Virus-Specific CD8+ T Cells to Clinical Response Following Treatment with Pexa-Vec and Cemiplimab in Patients with Advanced Renal Cell Carcinoma**

**Background** To better understand the immune stimulatory mechanisms of Oncolytic virus (OV), we evaluated the circulating OV-specific T cell response in patients during the course of OV therapy. Patients with histologically confirmed advanced clear cell renal cell carcinoma, who were naïve or refractory to prior systemic treatment and who had no prior treatment with immune checkpoint inhibitors, were treated with 4 weekly intravenous infusions of Pexa-Vec at 1 × 10⁹ plaque forming units starting at Day -7 plus Cemiplimab (350 mg every 3 weeks) from Day 1. Radiographic assessments per RECIST 1.1 were performed centrally every 9 weeks from Day 1. Quantifying OV-specific CD8+ T cells during the course of treatment may help us determine which patients are likely to respond to OV therapy and which patients may benefit from additional treatments or combinations of treatments.

**Methods** We evaluated the OV-specific CD8+ T cell response measured by intracellular cytokine staining (ICS) from day -5 through day 77 in 8 patients with advanced RCC. The median number of CD8+ T cells was 268,812 cells/mL at day -5 and 26,075 cells/mL at day 0. We saw a mean increase of 27,803% from day -5 to day 77. The most common factors contributing to the increase in CD8+ T cells were the number of TGF-β and IL-6 (27,803% and 20,694% increase, respectively) from day -5 to day 77. We also observed a significant increase in the number of circulating OV-specific CD8+ T cells from day -5 to day 77, with a peak increase of 27,803%.

**Results** During the course of treatment, we observed an increase in the number of circulating OV-specific CD8+ T cells from day -5 to day 77. The median number of CD8+ T cells was 268,812 cells/mL at day -5 and 26,075 cells/mL at day 0. The most common factors contributing to the increase in CD8+ T cells were the number of TGF-β and IL-6 (27,803% and 20,694% increase, respectively) from day -5 to day 77. We also observed a significant increase in the number of circulating OV-specific CD8+ T cells from day -5 to day 77, with a peak increase of 27,803%.