Background Immune checkpoint inhibitors (ICI) are standard-of-care in the treatment of several types of cancer; however, an unmet medical need exists for early-line combination therapies that are able to provide higher response rates, more durable responses, and manageable long-term safety. Lifileucel (LN-144) and LN-145, adoptive cell therapies using tumor-infiltrating lymphocytes (TIL), have demonstrated encouraging efficacy with acceptable safety in patients with advanced cancer that has failed ICI.1,2 To improve efficacy and safety of early-line treatment options, we explored a combination of TIL and pembrolizumab in patients with ICI-naïve melanoma, head and neck squamous cell carcinoma (HNSCC), and cervical cancer. Methods IOV-COM-202 (NCT03645928) and C-145-04 (NCT03108495) are ongoing Phase 2 multicenter, multicohort, prospective, open-label studies evaluating TIL cell therapy in ICI-naïve patients with solid tumors. We report efficacy and safety from IOV-COM-202 (Cohort 1A: lifileucel and pembrolizumab in ICI-naïve melanoma, head and neck squamous cell carcinoma (HNSCC), and cervical cancer. Conclusions The observed efficacy, including ORR and CR rate, and acceptable safety profile are encouraging and warrant continued investigation of the combination of TIL and pembrolizumab in early-line treatment of patients with advanced cancer. Enrollment is ongoing; updated data will be presented.

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*One patient in COM-202 Cohort 2A who did not have post-dose tumor response assessment was excluded.

Abstracts
Ethics Approval The IOV-COM-202 study was approved by Advarra Institutional Review Board, approval number Pro00035064; the C-145-04 was approved by WIRB Copernicus Group, approval number 7-1425772-1. All study participants provided written consent via signature of the IRB-approved informed consent form.

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