endpoints included disease control rate (DCR), progression-free survival (PFS) and safety.

**Results** Between Aug 5, 2019, and Jun 19, 2020, we enrolled 29 patients, 25 patients were available evaluated, ORR and DCR was 36% (9/25) and 92% (23/25), respectively. 25 of 29 patients were still receiving the treatment, the median PFS was not yet achieved. Compared with those without reactive cutaneous capillary endothelial proliferation (RCCEP), patients with RCCEP had higher ORR (60% vs. 28.6%). Treatment-related adverse events (AEs) occurred in 69.0% of patients (all Grade), and the most common were RCCEP (37.9%), pneumonitis (6.9%), and chest congestion (6.9%). Treatment-related grade 3 to 4 adverse events occurred in 10.3% of patients.

**Conclusions** In patients with previously treated advanced NSCLC, camrelizumab demonstrated improved ORR and DCR, compared with historical data of the 2nd line chemotherapy, with a manageable safety profile. While patients with RCCEP derived greater benefit from camrelizumab. Further studies are needed in large sample size trials.

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**OUTCOMES OF PATIENTS WITH METASTATIC RENAL CELL CARCINOMA WITH INTERMEDIATE- OR POOR-RISK SYMPTOMATIC DISEASE WHO RECEIVED THEIR FIRST CYCLE OF NIVOLUMAB AND IPILUMIMAB WHILE BEING HOSPITALIZED**

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**Background** Nivolumab plus ipilimumab (nivo/ipi) is an approved therapy for patients with metastatic renal cell carcinoma (mRCC) who have intermediate- or poor-risk disease.\(^1\) Clinical factors that guide the selection of this regimen for patients with mRCC are urgently needed.

**Methods** We retrospectively analyzed medical records of patients with mRCC who were hospitalized because of cancer-related symptoms and received their first cycle of nivo/ipi in the inpatient setting. Clinical parameters including demographics, histology, clinical history, response and survival were collected. The 4-month survival probability, progression-free survival (PFS) and overall survival (OS) were calculated using Kaplan-Meier methods.

**Results** Between November 2017 and June 2020, 21 patients were identified that fit the search: 19 patients (91%) had poor-risk disease based on the International metastatic Renal Cell Carcinoma Database Consortium (IMDC) risk score; 17 patients (81%) had ≥4 risk factors; 9 patients (43%) had sarcomatoid features on histology. Shortness of breath (28%) and abdominal pain (19%) were the two most common reasons for hospitalization. Partial response was achieved in 14% (3/21) of patients. Median PFS for all patients was 1.7 months (95% CI 0 - 3.9); median OS for all patients was 1.7 months (95% CI 0 - 4.2); the 4-month survival probability was 36% (95% CI 25% - 47%) (figure 1).

**Conclusions** In this retrospective study, patients with mRCC who have intermediate- or poor-risk disease and are hospitalized for cancer-related symptoms derive little clinical benefit from nivo/ipi when started in the inpatient setting. Alternative more effective systemic therapies should be considered for these patients.

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**Ethics Approval** This study was approved by the Institutional Review Board of MD Anderson Cancer Center, approval number PA16-0736.

**Consent** N/A

**REFERENCE**


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cancer immunotherapy, and the association between tumor infiltration and positive prognosis.\textsuperscript{1, 2} ImCheck Therapeutics is developing ICT01, an anti-human butyrophilin-3A (BTN3A/CD277) mAb specifically activating $\gamma$9$\delta$2 T-cells in a phosphoantigen (pAg)-independent manner. ICT01 is currently in a Phase 1/2a study in solid and hematologic tumors (NCT04234499). IL-2 has been shown to expand $\gamma$9$\delta$2 T-cells in vitro and in non-human primates in presence of pAgs.\textsuperscript{3, 4, 5}

We wanted to characterize the proliferative effects of combining ICT01 with IL-2 on $\gamma$9$\delta$2 T-cells as an approach to potentiate $\gamma$9$\delta$2 T-cell mediated cancer immunotherapy.

**Methods** $\gamma$9$\delta$2 T-cell activation and expansion was assessed in vitro in human PBMCs treated with ICT01+IL-2, and in vivo, in the blood of immunocompromised NCG mice engrafted with $20 \times 10^6$ human PBMCs and treated with ICT01 (single IV dose, 5 mg/kg on Day 1) ±IL-2 (0.3 MIU/kg IP on Day 1–4). A dose-ranging ICT01 (single IV dose, 1 or $5 \mathrm{mg/kg}$ on Day 1)+IL-2 combination (1 MIU SC QD on Days 1–5) study was conducted in cynomolgus monkeys.

**Results** In PBMCs cultures in vitro, ICT01 selectively activated $\gamma$9$\delta$2 T-cells and IL-2 significantly enhanced ICT01-mediated $\gamma$9$\delta$2 T-cell proliferation, this compartment reaching $>50\%$ of T-cells after 8 days of treatment versus $\sim10\%$ with ICT01 alone. This was confirmed in vivo in mice models. Flow cytometry analysis of mice blood revealed a 5.5-fold increase in human $\gamma$9$\delta$2 T-cell number in the combination groups compared to ICT01 or IL-2 alone treated animals, with $\gamma$9$\delta$2 T-cell frequency reaching $\sim35\%$ of the CD3+$\gamma$9$\delta$2 T-cell compartment. In Cynomolgus, a specific expansion of $\gamma$9$\delta$2 T-cells in several organs in ICT01+IL-2 treated monkeys. There was no evidence for a systemic cytokine release syndrome at any time point. Adverse effects with variable severity were observed, most of them being reversible and commonly associated with IL-2 alone, and not reported in the IND-enabling GLP toxicity study with ICT01 monotherapy at doses up to 100 mg/kg.

**Conclusions** These results demonstrate the ability of ICT01+IL-2 combination to trigger profound $\gamma$9$\delta$2 T-cell activation and expansion, suggesting that the clinical combination of ICT01 with a lymphoproliferative cytokine (e.g., IL-2) may be a novel therapeutic approach for cancer patients.

**Ethics Approval** Pseudonymized samples isolated from healthy volunteers: whole blood by ImCheck Therapeutics under the agreement n° 7173 between ImCheck Therapeutic SAS and EFS PACA (Etablissement Français du Sang Provence-Alpes-Côte d’Azur)

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**Background** Outcomes for recurrent or metastatic (R/M) head and neck squamous cell carcinoma (HNSCC) are dismal and responses to anti-PD-1 appear best in tumors with PD-1+ T cells in proximity to PD-L1+ cells, suggesting that improved outcome is associated with a pre-existing anti-cancer immune response. Based on this, we hypothesize that vaccines which prime and/or expand T cells to a spectrum of antigens overexpressed by HNSCC combined with T cell agonists, like anti-GITR, that provide costimulatory signals will improve the anti-PD-1 response rates. We have developed a cancer vaccine, DPV-001, that contains more than 300 proteins for genes overexpressed by HNSCC, encapsulated in a CLEC9A-targeted microvesicle and containing TLR/NOD agonists and DAMPs. Recently, we reported that combining anti-GITR + vaccine + anti-PD-1 augmented therapeutic efficacy in a preclinical model and now plan a phase 1b trial of this combination in patients with advanced HNSCC.

**Methods** Sera from patients receiving DPV-001 as adjuvant therapy for definitively treated NSCLC, were analyzed for IgG responses to human proteins by MAP bead arrays and results compared to TCGA gene expression data sets for HNSCC. HNSCC cell lines were evaluated by RNASeq and peptides were eluted from HLA, analyzed by mass spectroscopy and correlated against MAP bead arrays and TCGA data sets. Tumor-reactive T cells from a vaccinated patient were enriched and expanded, and used in cytokine release assay (CRA) against autologous NSCLC and partially HLA matched allogeneic HNSCC cell lines.

**Results** Patients receiving DPV-001 (N=13) made 147 IgG responses to at least 70 proteins for genes overexpressed by HNSCC. Preliminary evaluation of the HNSCC peptidome against the results of MAP bead arrays and TCGA data sets. Tumor-reactive T cells from a vaccinated patient were enriched and expanded, and used in cytokine release assay (CRA) against autologous NSCLC and partially HLA matched allogeneic HNSCC cell lines.

**Conclusions** Recent observations from our lab and others have correlated IgG Ab responses with T cell responses to epitopes of the same protein. Based on the data summarized above, we hypothesize that we have induced T cell responses against a broad spectrum of shared cancer antigens that are common among adenocarcinomas and squamous cell cancers. Our planned clinical trial will vaccinate and boost the induced responses by costimulation with anti-GITR and then sequence in delayed anti-PD-1 to relieve checkpoint inhibition. MAP