

ImCheck Presents Positive Safety and Efficacy Data from the Completed Phase 1 Dose Escalation Cohort of ICT01 plus Pembrolizumab in the EVICTION Trial at ESMO Congress 2022

- Broad antitumor immune responses and demonstration of durable disease control from solid tumor patients who previously failed one or more checkpoint-inhibitor regimen, across a range of ICT01 doses in combination with pembrolizumab
- ICT01 demonstrated a favorable and consistent safety and tolerability profile without dose-limiting toxicities in combination, in line with monotherapy results

Marseille, France, September 10, 2022 – [ImCheck Therapeutics](#) today presented promising updated safety and patient response data from the completed dose escalation combination cohort of its ongoing EVICTION clinical trial during an oral session at the European Society for Medical Oncology (ESMO) Congress currently being held in Paris, France. EVICTION is an open-label Phase I/IIa study evaluating ImCheck's lead antibody ICT01 as a monotherapy in both solid tumor and hematological cancers, and in combination with pembrolizumab in solid tumors.

Results from the Phase I dose-escalation, combination cohorts (n=40 across 6 dose levels) demonstrated that treatment with ICT01 plus pembrolizumab induced disease control in 42% of melanoma (5/12), 22% of non-small-cell lung carcinoma (4/18), 22% of bladder cancer (2/9) patients and in 1 head and neck squamous cell carcinoma (HNSCC) patient, (1/1) as determined by RECIST1.1 criteria. All patients treated had previously failed at least one checkpoint inhibitor (CPI) regimen, which underscores the potential of ICT01 combination therapy as a novel option for relapsed/refractory patients post-CPI treatment, which remains a significant unmet medical need. Two partial responses were achieved in melanoma patients who reached follow-up beyond 6 and 16 months, with the latter patient also achieving a durable complete regression of a brain metastasis from 6 months onward. The broad antitumor response data suggest that higher baseline circulating $\gamma\delta 2$ T cell levels correlate with better treatment outcomes. This supports the planned patient enrichment strategy utilizing lower baseline $\gamma\delta 2$ T cell counts, as compared to ICT01 monotherapy, for eligibility in the upcoming Phase IIa combination groups of patients with CPI-refractory melanoma, chemotherapy-resistant bladder cancer, or CPI-refractory HNSCC.

"The data presented today demonstrate that the complementary mechanisms of action for ICT01 and pembrolizumab alter the tumor microenvironment to generate clinical responses against multiple CPI-resistant solid tumors," commented [Paul Frohna](#), MD, PhD, Chief Medical Officer at ImCheck Therapeutics. *"It is encouraging to see a continued good safety profile for ICT01 in the combination setting in addition to robust activation of $\gamma\delta 2$ T cells that promote tumor infiltration of CD8 and NK cells, which can be fully unleashed to attack the cancerous cells by concomitant PD-1 blockade."*

[Pierre d'Epenoux](#), Chief Executive Officer of ImCheck Therapeutics added: *“With these positive data, we further substantiate the potential of ICT01 as a novel, differentiated therapeutic approach for a broad population of cancer patients. We feel confident that we have achieved our goals for the first part of the EVICTION trial, both in monotherapy with cohort expansion already underway and in combination with pembrolizumab. We eagerly anticipate exciting clinical efficacy results from the Phase IIa next year.”*

The oral presentation, titled *“The Combination of ICT01, a γ 9 δ 2 T cell-activating mAb, plus Pembrolizumab Induces a Broad Antitumor Immune Response and Disease Control in Patients with CPI-Failure Melanoma, NSCLC and Bladder Cancer: EVICTION Trial”*, was given by Dr. Stéphane Champiat, lead study investigator of the EVICTION trial at the Gustave Roussy Cancer Center, Paris, France. The data was presented during the investigational immunotherapy session from 14:45 to 16:15 CEST on Saturday September 10, 2022.

About the EVICTION Trial

EVICTION is a first-in-human, dose escalation (Part 1) and cohort expansion (Part 2) clinical trial of ICT01 in patients with various advanced relapsed or refractory solid or hematologic cancers that have exhausted standard of care treatment options. Part 1 is a basket trial designed to characterize the preliminary safety, tolerability, and pharmacodynamic activity of ICT01 as monotherapy (Group A: solid tumors; Group B: hematologic tumors) and in combination with pembrolizumab (Group C: solid tumors). Group A includes bladder, breast, colorectal, gastric, melanoma, ovarian, prostate, and pancreatic cancer patients, Group B includes acute myeloid leukemia, acute lymphocytic leukemia, follicular lymphoma, and diffuse large B cell lymphoma patients, and Group C includes bladder, head and neck squamous cell carcinoma, melanoma, and non-small cell lung cancer patients. Basket trials are a clinical trial design that allows new drugs to be tested rapidly in a range of indications, providing initial data on multiple parameters that can contribute to an accelerated development timeline. Part 2 of the trial is a Phase II cohort expansion study in selected indications as both monotherapy and in combination. First indications selected for the Phase II monotherapy expansion cohorts are relapsed/refractory ovarian cancer and metastatic castrate-resistant prostate cancer. More information on the EVICTION trial can be found at [clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT04243499) (NCT04243499). A second clinical trial, EVICTION-2, evaluating the combination of ICT01 plus low dose subcutaneous IL-2 to selectively expand the number of γ 9 δ 2 T cells in patients with solid tumors (prostate, pancreatic, ovarian, or colorectal cancer) is also ongoing (NCT05307874).

About ICT01

ICT01 is a humanized, anti-BTN3A (also known as CD277) monoclonal antibody that selectively activates γ 9 δ 2 T cells, which are part of the innate immune system that is responsible for immunosurveillance of malignancy and infections. The 3 isoforms of BTN3A targeted by ICT01 are overexpressed on a number of solid tumors (e.g., bladder, colorectal, melanoma, ovarian, pancreatic, lung) and hematologic cancers (e.g., leukemia & lymphoma) and also expressed on the surface of innate (e.g., γ δ T cells and NK cells)

and adaptive immune cells (T cells and B cells). BTN3A is essential for the activation of the anti-tumor immune response of $\gamma\delta$ T cells.

As demonstrated in EVICTION data presented at past AACR, EMSO and SITC conferences, ICT01 selectively activates circulating $\gamma\delta$ T cells that leads to migration of $\gamma\delta$ T cells out of the circulation and into target tissue (e.g., tumors), while also activating the tumor-resident $\gamma\delta$ T cells to directly kill malignant cells, which is accompanied by secretion of two key inflammatory cytokines, IFN γ and TNF α , that contribute to the expansion of the anti-tumor immune response. ICT01 has been shown to have anti-tumor activity against a range of cancers in *in vitro* and *in vivo* tumor models.

About IMCHECK THERAPEUTICS

ImCheck Therapeutics is designing and developing a new generation of immunotherapeutic antibodies targeting butyrophilins, a novel super-family of immunomodulators.

As demonstrated by lead clinical-stage program ICT01, which has a mechanism of action to simultaneously modulate innate and adaptive immunity, ImCheck's "first-in-class" activating antibodies may be able to produce superior clinical results as compared to the first-generation of immune checkpoint inhibitors and, when used in combination, to overcome resistance to this group of agents. In addition, ImCheck's antagonist antibodies are being evaluated as potential treatments for a range of autoimmune diseases.

Co-founder of the Marseille Immunopole cluster, ImCheck benefits from support from Prof. Daniel Olive (INSERM, CNRS, Institut Paoli Calmettes, Aix-Marseille Université), a worldwide leader in $\gamma\delta$ T cells and butyrophilins research; from the experience of an expert management team; and from the commitment of leading US and European investors.

For further information: <https://www.imchecktherapeutics.com/> and [@ImCheckThx](https://twitter.com/ImCheckThx)

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