

## ImCheck Presents Preliminary Patient Response Data from the Phase I/IIa EVICTION Trial with ICT01 at ESMO Congress 2021

- First EVICTION data from checkpoint inhibitor-refractory solid tumor patients treated in the first two dose-escalation cohorts of ICT01 with pembrolizumab show disease control by RECIST1.1
- Expanded data on ICT01's ability to activate  $\gamma\delta 2$  T cells, NK cells and CD8+ T cells via cytokine release, leading to tumor infiltration and remodeling of the tumor immune microenvironment

Marseille, France, September 17, 2021 – [ImCheck Therapeutics](#) today presented data at the ESMO Congress 2021 from its ongoing EVICTION Phase I/IIa clinical trial with its lead antibody ICT01 showing anti-tumor immune responses, resulting in increased tumor infiltration and disease control in patients with a variety of relapsed/refractory solid tumors. The presentation includes the first data from the trial's combination cohort of ICT01 plus pembrolizumab in patients who progressed on at least one prior checkpoint inhibitor regimen. Five of the six enrolled patients in the first two dose cohorts were evaluable for efficacy at week eight or beyond. Three of four patients receiving 2 mg ICT01 plus 200 mg pembrolizumab every three weeks (cohort two) achieved disease control: two patients (bladder cancer, metastatic melanoma) showed partial responses and one patient (non-small cell lung cancer) showed stable disease at week 16 or beyond, according to RECIST1.1. Although preliminary, these data provide the first demonstration of clinical responses that are consistent with the observed coordinated antitumor immune response of the innate ( $\gamma\delta 2$  T cells) and adaptive (CD8 T cells) immune systems following ICT01 treatment.

The data were included in an oral presentation ([9580](#)) by Aurélien Marabelle, MD, PhD, Lead Investigator for EVICTION, titled: *"Coordinated Activation of Antitumor Responses of  $\gamma\delta 2$  and CD8 T Cells by Targeting BTN3A with ICT01 in Patients with Solid Tumors: EVICTION Trial,"* on September 17, 2021, from 1:50 - 2:00 pm CET in the Proffered Paper session - Investigational Immunotherapy.

*"These data are exciting as they demonstrate for the first time tumor responses in patients treated with ICT01, which continues to support the previously observed immune system activation and good safety profile,"* commented Aurélien Marabelle, MD, PhD, Immuno-Oncologist at Gustave Roussy, Villejuif, France and Lead Investigator for EVICTION. *"Patients in this study are heavily pre-treated, including prior checkpoint inhibitor therapy, and at the stage they join the EVICTION trial have no available standard-of-care treatment options. These preliminary signs of disease control are encouraging and, therefore, we are looking forward to additional data readouts from the EVICTION trial."*

*"Our anti-BTN3A antibody, ICT01, has already shown promising anti-tumor immune activation and responses so we are cautiously optimistic when reporting today's preliminary signs of disease control in three patients, including a reduction in tumor burden of up to [~]50% in two of those patients,"* said Paul Frohna, MD, PhD, Chief Medical Officer at ImCheck Therapeutics. *"We remain on target to present additional EVICTION trial data later this year. On behalf of all of us at ImCheck, I want to thank the patients and their families, and the investigators and their clinical study teams for contributing to our study."*

The ongoing EVICTION trial is evaluating ICT01 in patients with advanced relapsed/refractory solid and hematologic cancers who have no remaining standard of care treatment options. The

presentation today covers results from a dose escalation cohort of evaluable patients with solid tumors (n=32) receiving ICT01 monotherapy and two dose cohorts of evaluable patients with solid tumors (n=6) who previously failed at least one checkpoint inhibitor regimen that were treated with ICT01 in combination with pembrolizumab.

The data from patients with solid tumors treated with ICT01 monotherapy demonstrated a dose-dependent target occupancy of ICT01 binding to BTN3A on T cells that induced a dose-dependent migration of  $\gamma\delta$  T cells out of the circulation. Increases in serum TNF $\alpha$  and IFN $\gamma$  were observed within minutes to hours at doses  $\geq 2$  mg ICT01 that appear to positively correlate with ICT01 dose, the baseline  $\gamma\delta$  T cell counts, and the activation and migration of NK and CD8+ T cells from the circulation. Tumor biopsies showed infiltration of  $\gamma\delta$ , CD3+ and CD8+ T cells in patients with immune desert at baseline demonstrating the ability to remodel the tumor immune microenvironment across a range of tumor phenotypes. Across the two cohorts treated with a combination of ICT01 and pembrolizumab, preliminary signs of tumor regression were observed at 2 mg ICT01 in two patients. These data may reflect the contribution of ICT01-activated  $\gamma\delta$  T cells to remodel the tumor immune microenvironment and increase tumor infiltration of CD8+ T cells, which can be activated by an anti-PD-1 agent like pembrolizumab.

Following multiple safety reviews by the independent Safety Review Committee, the EVICTION trial is continuing further dose escalation in the hematologic monotherapy and combination therapy arms of the study. Part 2 for the monotherapy expansion cohorts is expected to begin enrolling second- and third-line treated patients with ovarian (Group D) or head and neck squamous cell carcinomas (Group E) in Q4 2021. In addition to good preliminary safety, tolerability and immune response data, new results presented at this conference indicate for the first time a beneficial clinical response with signs of tumor shrinkage.

The ESMO presentation slides will be available on ImCheck's corporate website directly following the presentation.

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### 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. More information on the EVICTION trial can be found at [clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT04243499) (NCT04243499).

### About ICT01

ICT01 is a humanized, anti-BTN3A (also known as CD277) monoclonal antibody that selectively activates  $\gamma\delta$  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.,  $\gamma\delta$  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  $\gamma\delta 2$  T cells.

As demonstrated in EVICTION data presented at AACR, ICT01 selectively activates circulating  $\gamma\delta 2$  T cells that leads to migration of  $\gamma\delta 2$  T cells out of the circulation and into target tissue (e.g., tumors), while also activating the tumor-resident  $\gamma\delta 2$  T cells to directly kill malignant cells, which is accompanied by secretion of two key inflammatory cytokines, IFN $\gamma$  and TNF $\alpha$ , 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 on ImCheck: <http://www.imchecktherapeutics.com> and [@ImCheckThx](https://twitter.com/ImCheckThx)

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