

## ImCheck Achieves the Primary Objectives of Phase I of the EVICTION-2 Trial of ICT01 in Combination with Low Dose IL-2, Data Presented at AACR 2023

- ICT01 in combination with low dose IL-2 safely induced substantial  $\gamma$ 9 $\delta$ 2 T cell expansion across multiple dosing cycles for all dose cohorts of patients with advanced solid tumors
- Activation of expanded innate and adaptive antitumor immune responses also observed across all dose cohorts

Marseille, France, April 18, 2023 – [ImCheck Therapeutics](#) announced today data from its ongoing Phase I/IIa clinical trial EVICTION-2 at the American Association for Cancer Research (AACR) Annual Meeting 2023 in a poster presentation ([CT179](#)) titled: “First-in-Human Study of ICT01, an Anti-BTN3A Activating Monoclonal Antibody in Combination with Low Dose IL-2 in Patients with Advanced Solid Tumors (EVICTION-2 Study)”. As described in the poster, ImCheck’s lead antibody ICT01, administered at doses ranging from 1 to 75 mg, combined with low-dose subcutaneous IL-2 (1 MIU/m<sup>2</sup>) safely induced multi-cycle expansion of  $\gamma$ 9 $\delta$ 2 T cells in 11/11 evaluable patients with no dose limiting toxicities and no new safety events observed. The combination also generated innate and adaptive immune stimulation characterized by the activation, mobilization, and expansion of CD8 T cells, NKs and granulocytes. Taken together, these data demonstrate achievement of the primary objectives of Phase I of the study, support that this combination could be a novel approach to maximize  $\gamma$ 9 $\delta$ 2 T cell-mediated antitumor efficacy, and set the foundation for the Phase IIa portion of EVICTION-2.

“In addition to a good safety profile and broad immune expansion and stimulation, we observed an increase in PD-1 and PD-L1 expression on various immune cell populations, suggesting checkpoint inhibitor therapy may significantly enhance clinical response to this combination. We plan to test this in Phase IIa of EVICTION-2 by adding pembrolizumab to the combination regimen,” commented [Paul Frohna](#), MD, PhD, Chief Medical Officer at ImCheck Therapeutics.

Details of the poster presentation are:

**Abstract title:** “First-in-Human Study of ICT01, an Anti-BTN3A Activating Monoclonal Antibody in Combination with Low Dose IL-2 in Patients with Advanced Solid Tumors (EVICTION-2 Study)”

**Session title:** First-in-Human Phase I Clinical Trials 2

**Abstract number:** CT179

**Authors:** Johann de Bono, Stéphane Champiat, Francois-Xavier Danlos, Martin Wermke, Volker Kunzmann, Aude De Gassart, Emmanuel Valentin, Marina Iché, Maelle Mairesse, Patrick Brune, Katrien Lemmens, Aurélien Marabelle, Daniel Olive, Paul Frohna

**Date/Time:** Tuesday Apr 18, 2023, 9:00 AM - 12:30 PM Eastern Time

**Location:** Poster Section 45

**Poster Board Number:** 11

The AACR poster will be available starting April 18, 2021, at 12:30 pm US Eastern Time / 18:30 CEST on ImCheck’s corporate website.

\*\*\*

### About the EVICTION 2 Trial

EVICTION-2 is a Phase I/IIa, open-label, multi-center trial designed to characterize ImCheck's lead program, ICT01, a  $\gamma 9\delta 2$  T cell-activating monoclonal antibody targeting BTN3A, combined with low dose subcutaneous (LDSC) IL-2 in patients with advanced, relapsed/refractory solid tumors. The Phase I dose escalation assesses the safety of the combination regimen and the expansion of  $\gamma 9\delta 2$  T cells across three cycles of combination treatment, followed by ICT01 alone for the remaining cycles of treatment to identify the dosing regimen(s) to test in Phase IIa. Phase I has enrolled relapsed/refractory patients suffering from colorectal, ovarian, pancreatic or prostate cancer who had failed at least two lines of systemic therapy or had failed first line therapy and were not eligible for the standard second line of treatment. Phase IIa will include the use of pembrolizumab in combination with ICT01/LDSC IL-2 in an indication to be determined. For more information, please refer to <https://clinicaltrials.gov> and reference NCT05307874.

### About ICT01

ICT01 is a humanized, anti-BTN3A (also known as CD277) monoclonal antibody that selectively activates  $\gamma 9\delta 2$  T cells, which are part of the innate immune system that is responsible for immunosurveillance of malignancy and infections. The three 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  $\gamma 9\delta 2$  T cells.

As demonstrated in EVICTION data presented at past AACR, EMSO and SITC conferences, ICT01 selectively activates circulating  $\gamma 9\delta 2$  T cells that leads to migration of  $\gamma 9\delta 2$  T cells out of the circulation and into target tissue (e.g., tumors), while also activating the tumor-resident  $\gamma 9\delta 2$  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 its 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 and infectious diseases.

Co-founder of the Marseille Immunopole cluster, ImCheck benefits from support from Prof. Daniel Olive (INSERM, CNRS, Institut Paoli Calmettes, Aix-Marseille University), a worldwide leader in  $\gamma 9\delta 2$  T cells and butyrophilins research, as well as 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)

Press contacts:

US and EU

Trophic Communications

Gretchen Schweitzer

+49 (0) 172 861 8540

[imcheck@trophic.eu](mailto:imcheck@trophic.eu)

France

ATCG PARTNERS

Céline Voisin

+33 (0)9 81 87 46 72 / +33 (0)6 62 12 53 39

[imcheck@atcg-partners.com](mailto:imcheck@atcg-partners.com)