

## ImCheck Presents Initial Patient Data from the EVICTION-2 Clinical Trial at SITC Annual Meeting

Low-dose ICT01 plus low-dose IL-2 safely and significantly increase the number of activated  $\gamma\delta 2$  T cells, CD8 T cells, and Natural Killer cells in patients with solid tumors

Marseille, France, November 11, 2022 – [ImCheck Therapeutics](https://www.imchecktherapeutics.com) presented today the first patient data from EVICTION-2, a Phase I/II clinical trial evaluating the combination of ImCheck's lead program, ICT01, a  $\gamma\delta 2$  T cell-activating monoclonal antibody targeting BTN3A, combined with low-dose (LD) IL-2, to selectively expand the number of  $\gamma\delta 2$  T cells in relapsed/refractory patients with solid tumors. In a poster presentation at the Society for Immunotherapy of Cancer (SITC) 37<sup>th</sup> Annual Meeting being held in Boston, ImCheck researchers and academic collaborators showed data of the combination's ability to safely and reproducibly induce  $\gamma\delta 2$  T cell activation, expansion, and migration out of the circulation, which was accompanied by similar effects on CD8 T cells and Natural Killer cells (NKs).

In 6 out of 6 evaluable relapsed/refractory ovarian and colorectal cancer patients who had failed >5 lines of treatment, ICT01 (1 or 5 mg IV Day 1 of each cycle) plus LD IL-2 (1 or 2 MIU/m<sup>2</sup> SC Days 1-5 of first 3 cycles) increased  $\gamma\delta 2$  T cells 2 to 9 times above baseline during each of the first three 21-day cycles. The combination also demonstrated the activation, mobilization, and proliferation of CD8 T cells and NKs, with slightly more modest effects on granulocytes, in most patients at lower ICT01 doses than shown in previously presented data of ICT01 monotherapy in a similar patient population (EVICTION trial). The safety profile for the combination exhibited no dose-limiting toxicities in the first 3 dose cohorts and tolerability remained consistent without any new or increased adverse reactions.

*"The data presented today provide initial clinical evidence that ICT01 plus LD IL-2 can significantly increase the number of  $\gamma\delta 2$  T cells and other important immune cell populations that could generate a stronger anti-tumor immune response in heavily pre-treated solid tumor patients," commented [Paul Frohna](#), MD, PhD, Chief Medical Officer at ImCheck Therapeutics. "The combination's safety profile is a positive outcome and is firmly in line with the results for ICT01 monotherapy and in combination with pembrolizumab that we have seen from over 100 cancer patients who have participated in the ongoing EVICTION trial."*

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### About the EVICTION-2 Trial

EVICTION-2 is a first-in-human, dose escalation (Part 1) and cohort expansion (Part 2) clinical trial evaluating ICT01 in combination with low dose subcutaneous IL-2. The trial's objective is to demonstrate the combination's ability to selectively expand the number of  $\gamma\delta 2$  T cells in patients with solid tumors (prostate, pancreatic, ovarian, or colorectal cancer). 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  $\gamma\delta 2$  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.,  $\gamma\delta$  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 past AACR, EMSO and SITC conferences, 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  $\gamma\delta 2$  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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