

Clinical Data with ImCheck's ICT01 to be Presented at AACR: Positive Results Observed on Safety, Activation of Gamma 9 Delta 2 T Cells and Anti-tumor Immune Response

- ICT01 activates $\gamma 9\delta 2$ T cells that rapidly migrate out of the circulation and secrete IFN γ and TNF α leading to an expanded immune system activation
- Increased densities of activated and proliferating $\gamma\delta$, CD3+ and CD8+ T cells were observed in tumor biopsies post ICT01 treatment

Marseille, France, April 9, 2021 – [ImCheck Therapeutics](#) announced today that data from its ongoing EVICTION Phase I/IIa clinical trial will be presented at the American Association for Cancer Research (AACR) Annual Meeting 2021 in an oral presentation ([CT034](#)) by Aurélien Marabelle, MD, PhD, Lead Investigator for EVICTION, titled: “Activation of the anti-tumor immune response of $\gamma 9\delta 2$ T cells in patients with solid or hematologic malignancies with ICT01, a first-in-class, monoclonal antibody targeting Butyrophilin 3A: The EVICTION study”, on April 11, 2021 from 4:50 – 5:00 PM US ET in the CTMS03 - Clinical Trials with Novel Immuno-oncology Strategies session.

ICT01 is a first-in-class, anti-BTN3A monoclonal antibody that activates $\gamma 9\delta 2$ T cells, a subset of tumor infiltrating lymphocytes that have potent cytotoxic effects on solid and hematologic cancer cells and can activate other immune cells against the cancer. To the company's knowledge, the data that will be presented is the first demonstration of an activating antibody safely and dose-dependently engaging $\gamma 9\delta 2$ T cells that also coordinate an anti-tumor immune response from the innate and adaptive immune systems.

The ongoing EVICTION trial is evaluating ICT01 in patients with advanced, relapsed/refractory solid and hematologic cancers with no remaining standard of care. The abstract published today covers results from four cohorts of patients with solid tumors (n=20) and one cohort of patients with hematologic cancer (n=3) and demonstrated that ICT01 monotherapy, at doses from 20 μ g to 20 mg, achieved safe and potent activation of the anti-tumor immune responses of $\gamma 9\delta 2$ T cells.

Across the cohorts treated, more than 95% of $\gamma 9\delta 2$ T cells migrated out of the circulation at all four ICT01 doses. Levels of IFN γ and TNF α increased in a generally dose-dependent manner, which correlated with baseline $\gamma 9\delta 2$ T cell counts, and activation and migration of NK and CD8+ T cells from the circulation at doses \geq 7 mg. The second ICT01 administration induced similar cell activation and trafficking. Immunohistochemical staining showed a significant increase in $\gamma\delta$, CD3 and CD8 T cells in several tumor biopsies post ICT01 treatment, indicating that ICT01, via tumor-infiltrating activated $\gamma 9\delta 2$ T cells, induces a broad anti-tumor immune response within the tumor microenvironment.

“These new data from increasing doses of ICT01 indicate that ICT01 safely and dose-dependently activates $\gamma 9\delta 2$ T cells that induce an expanded immune system activation within the blood and tumor, which supports our proposed mechanism of action,” commented Aurélien Marabelle, MD, PhD, Immuno-Oncologist at Gustave Roussy, Villejuif, France and Lead Investigator for EVICTION, who will present the data at the AACR. “We look forward to completing Part 1 and initiating Part 2 where we will test the efficacy of ICT01 in target patient populations.”

“As a first-in-class, immune system-activating mAb, we are encouraged to see rapid and potent dose-dependent activity of ICT01 without any safety concerns in the patients treated to date. We are now more than halfway through patient recruitment for Part 1 of the trial and we remain on target to report on the topline results in 2021,” said [Paul Frohna](#), MD, PhD, Chief Medical Officer at ImCheck

Therapeutics. *“We are thankful for the efforts of the EVICTION investigators and their study teams, and their patients’ willingness to participate in our trial despite the ongoing pandemic.”*

Following multiple safety reviews by the independent Safety Review Committee, the EVICTION trial has continued to dose escalation in all arms of the study.

The AACR presentation slides will be available starting April 11, 2021 at 5:00 pm US Eastern Time / 23:00 CET on ImCheck’s corporate website.

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 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, Group B includes AML, ALL, follicular lymphoma, and diffuse large B cell lymphoma, and Group C includes bladder, HNSCC, melanoma, and NSCLC. Basket trials represent a clinical trial design that allows new drugs to be tested rapidly in a range of indications, providing initial results 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 $\gamma\delta 2$ T cells, which are part of the innate immune system that is responsible for immunosurveillance for malignancy and infection. The 3 isoforms of BTN3A targeted by ICT01 are expressed on the surface of innate (e.g., $\gamma\delta$ T cells and NK cells) and adaptive immune cells (T cells and B cells) and are overexpressed on a number of solid tumors (e.g., bladder, colorectal, melanoma, ovarian, pancreatic, lung) and hematologic cancers (e.g., leukemia & lymphoma). BTN3A is essential for the activation of the anti-tumor immune response of $\gamma\delta 2$ T cells.

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 or infection site), 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 expand 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, preclinical experiments with ImCheck’s antagonist antibodies have shown their potential as treatments for a wide 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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