



ImCheck Achieves Initial Positive Independent Safety Review and Initiates Next Stage of Phase I/IIa EVICTION Trial for ICT01 Company Receives FDA Approval for US IND

Marseille, France, September 10, 2020 – [ImCheck Therapeutics](#) announced today that the independent Safety Review Committee for the [EVICTION](#) Phase I/II clinical trial for its lead antibody ICT01 ([NCT04243499](#)) unanimously approved dose escalation in the solid tumor indications and the start of enrollment in the two other arms of the study: treatment with ICT01 in patients with hematologic malignancies as monotherapy and in solid tumor patients in combination with pembrolizumab. The first patients in the second cohort have now been treated.

ImCheck's Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) cleared in August of this year, allowing for U.S. patient inclusion in EVICTION. The first U.S. sites will include the MD Anderson Cancer Center, Yale University Cancer Center and the University of Washington/Seattle Cancer Care Alliance.

"ICT01 is a first-in-class activating antibody designed to target cancer cells directly through cytotoxic activity and indirectly through the activation of other immune cells. Approval from the independent safety review committee is therefore an important achievement, enabling us to move ahead with the second phase of the study and remain on track with our planned timeline," said [Paul Frohna](#), MD, PhD, Chief Medical Officer at ImCheck Therapeutics. "We are excited to expand the trial to include patients with hematologic cancers and to test ICT01 in combination with pembrolizumab. Our focus is now on achieving our patient enrollment goals, confirming pharmacodynamic activity and demonstrating clinical proof of mechanism."

EVICTION is an open-label basket study assessing the safety, tolerability and activity of ICT01 as monotherapy in patients with advanced solid or hematologic malignancies, and in combination with pembrolizumab in patients with solid tumors. The first cohort enrolled six patients treated at four different starting doses of ICT01 as monotherapy, followed by intra-patient dose-escalation. No dose-limiting toxicities or related serious adverse events were reported. ICT01 is a gamma9 delta2 ($\gamma 9\delta 2$) T cell-activating monoclonal antibody (mAb) targeting Butyrophilin 3A (BTN3A), a member of the [butyrophilin superfamily](#) of immunomodulators.

"ICT01 is the first of a series of novel agents targeting butyrophilins that we are developing at ImCheck. The outstanding ground work in early development coupled with strong relationships with the clinical centers has enabled us to move rapidly through the first stage of the Phase I study, treat the first patients in the second cohort and open the IND in the U.S.," said [Pierre d'Epenoux](#), Chief Executive Officer at ImCheck Therapeutics. "All of us at ImCheck thank the patients, investigators and the sites for continuing to support EVICTION during these difficult times due to the COVID-19 crisis."

About ICT01

ICT01 is a humanized, monoclonal antibody that activates $\gamma 9\delta 2$ T cells, which are part of the innate immune system that is responsible for immunosurveillance for malignancy and infection, by targeting all three isoforms of BTN3A (also known as CD277). BTN3A is expressed on the surface of innate and adaptive immune cells (T cells, B cells and NK cells) and is overexpressed

on a number of solid tumors (e.g., bladder, breast, colon, gastric, melanoma, ovarian and prostate) and hematologic cancers (e.g., leukemia & lymphoma). BTN3A appears 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. ICT01 has been shown to have anti-tumor activity against a range of cancers in *in vitro* and *in vivo* tumor models.

About the EVICTION Trial

EVICTION is a first-in-human, dose escalation (Part 1) and cohort expansion (Part 2) study of ICT01 monotherapy in patients with relapsed or refractory solid or hematologic cancers that have exhausted standard of care treatment options. A third group of cancer patients will test ICT01 in combination with an anti-PD-1 inhibitor (immune checkpoint inhibitor, pembrolizumab). More information on the EVICTION trial can be found at clinicaltrials.gov.

The study is being managed in Europe by ILife Consulting (a Paris-based CRO) in collaboration with Precision for Medicine (the CRO managing US sites). Precision for Medicine is also providing central lab capabilities for biomarker sample handling and flow cytometry. HaliDx (Marseille), a leader in Immuno-oncology testing with Immunoscore® and related assays, will be responsible for analyzing tumor biopsies as part of the precision medicine-guided analysis of baseline and on-treatment samples.

About IMCHECK THERAPEUTICS

ImCheck Therapeutics is designing and developing a new generation of immunotherapy antibodies positioned at the crossroads of two high-potential immunological fields: $\gamma\delta 2$ T cells and a novel super-family of immunomodulators, butyrophilins.

Due to their mechanism of action, and notably their ability to simultaneously modulate innate and adaptive immunity, ImCheck's "first-in-class" activating antibodies may be able to produce superior anti-cancer efficacy as compared to the first-generation of immune checkpoint inhibitors and, when used in combination, overcome the resistance to this class of agents. Activated $\gamma\delta 2$ T cells also have therapeutic potential in infectious diseases (e.g., bacteria and viruses), while antagonist antibodies have potential as 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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