

ImCheck Presents at SITC First Clinical Demonstration of Gamma Delta T Cell Activation and Tumor Infiltration with Positive Safety for ICT01

Preliminary EVICTION Phase I/IIa trial data shows butyrophilin-targeted mAb ICT01's dose-dependent and specific activation of $\gamma\delta$ T cells

Marseille, France, November 11, 2020 – [ImCheck Therapeutics](#) presented preliminary results from its ongoing EVICTION Phase I/IIa clinical trial evaluating ICT01, a first-in-class gamma delta ($\gamma\delta$) T cell-activating monoclonal antibody, in patients with advanced, relapsed/refractory cancers. The data from the first cohort of six solid tumor cancer patients treated with ICT01 monotherapy demonstrated dose-dependent and specific $\gamma\delta$ T cell activation and trafficking out of the circulation without dose-limiting toxicities or related serious adverse events.

In addition, a limited immunohistochemistry (IHC) analysis in one melanoma patient provided a first demonstration in humans of infiltration of $\gamma\delta$ T cells into the tumor including increases over baseline in $\gamma\delta$ T cell density and CD3+/pan- $\gamma\delta$ TCR+ cell density in the tumor after the 2nd dose of ICT01. The IHC analysis also showed increases in the number of activated CD3, CD4 and CD8 T cells in this patient's tumor, indicating that ICT01 may activate a range of immune cells with the potential of generating a more complete anti-tumor immune response.

[These results are being presented at the 2020 Society for Immunotherapy of Cancer \(SITC\) Annual Meeting in a virtual poster session.](#)

Based on recommendation from an independent Safety Review Committee, the EVICTION trial has continued enrollment. The second cohort of patients with solid tumors receiving ICT01 as monotherapy has been enrolled and the Safety Review Committee unanimously approved further dose escalation. The trial is also currently recruiting patients with hematologic malignancies for ICT01 monotherapy, and a group of patients with solid tumors who will receive ICT01 in combination with pembrolizumab.

*"The data presented at SITC are in line with ImCheck's preclinical results showing that targeting *BTN3A* with ICT01 specifically and dose-dependently activates $\gamma\delta$ T cells against tumor cells. The preliminary immunohistochemistry analysis also shows that ICT01 activates a range of immune cells, which is very exciting," commented **Aurélien Marabelle, MD, PhD, Immuno-Oncologist at the Gustave Roussy Cancer Centre, Villejuif, France and Principal Investigator for EVICTION.** "We look forward to the trial continuation and further insight on ICT01's mechanism of action through biomarker and sequential tumor biopsies."*

*"As a first-in-class, immune-activating antibody, we are encouraged to see rapid and potent dose-dependent activity of ICT01 without safety concerns in the patients treated to date. 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," said **Paul Frohna, MD, PhD, Chief Medical Officer at ImCheck Therapeutics.** "We remain on target to report on the topline results from the dose escalation part of the trial in 2021."*

ImCheck is presenting three additional ICT01 posters at the SITC 2020 Annual Meeting:

- ["Enhancement of anti-tumor immunity by ICT01: a novel \$\gamma\delta\$ T cell-activating antibody targeting Butyrophilin-3A \(BTN3A\)";](#)
- ["Characterization of Butyrophilin 3A Expression Across Multiple Tumor Types to Support Target Patient Population Selection in the EVICTION Study with ICT01, an Anti-BTN3A Monoclonal Antibody that Selectively Activates \$V\gamma 9V\delta 2\$ T Cells";](#)
- ["ICT01, an anti-BTN3A mAb that activates \$V\gamma 9V\delta 2\$ T cells, plus interleukin-2: a potent and promising combination for cancer immunotherapy";](#)

All posters are available on ImCheck's website under the following link: <https://cutt.ly/UgXN7Fn>

The company is also presenting preclinical data on ICT03, its earlier-stage pipeline program targeting BTN2A1, another butyrophilin implicated in the activation of $\gamma\delta$ T cells.

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 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 appears essential for the activation of the anti-tumor immune response of $\gamma\delta$ T cells.

ICT01 selectively activates circulating $\gamma\delta$ T cells that leads to migration of $\gamma\delta$ T cells out of the circulation and into target tissue (e.g., tumors or infection site), while also activating the tumor-resident $\gamma\delta$ 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 pembrolizumab, an approved anti-PD-1 inhibitor. 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 immunotherapeutic antibodies positioned at the crossroads of two high-potential immunological fields: $\gamma\delta$ T cells and butyrophilins (BTN), a novel super-family of checkpoint molecules.

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 clinical results as compared to the first-generation of immune checkpoint inhibitors and when used in combination to overcome the resistance to this group of agents. In addition, preclinical experiments with ImCheck's antagonist antibodies are being evaluated as potential treatments for autoimmune diseases.

Co-founder of the Marseille Immunopole cluster, ImCheck benefits from the continued support from scientific founder Prof. Daniel Olive (INSERM, CNRS, Institut Paoli Calmettes, Aix-Marseille Université), a worldwide leader in $\gamma\delta$ T cells and BTN research, and from the commitment of leading US and European investors.

For further information on ImCheck: <http://www.imchecktherapeutics.com> and [@ImCheckThx](#)

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