

ImCheck Provides Promising Updated Patient Response Data from the Phase I/IIa EVICTION Trial with ICT01 at SITC Meeting 2021

- Oral presentation includes positive safety data across a wide range of ICT01 doses and efficacy data from patients receiving ICT01 plus pembrolizumab confirming durable clinical responses at low ICT01 doses
- One patient with checkpoint-inhibitor refractory metastatic melanoma achieved a complete response of a brain metastasis and a partial response of liver metastases at six months
- Company to present a collaboration poster with Neoleukin on the preclinical combination of ICT01 plus NL201, a novel IL-2/IL-15 agonist, which safely induces activation, proliferation and anti-tumor activity of $\gamma\delta 2$ T cells

Marseille, France, November 12, 2021 – [ImCheck Therapeutics](https://www.imchecktherapeutics.com) provided updated patient response data from its ongoing EVICTION Phase I/IIa clinical trial of its lead candidate ICT01 in an oral presentation at the Society for Immunotherapy of Cancer (SITC) Meeting 2021. In efficacy evaluable patients (n=8) treated with the combination of low dose ICT01 plus pembrolizumab who previously failed at least one prior checkpoint inhibitor regimen, 62% showed disease control by RECIST1.1 criteria. Two patients demonstrated a preliminary positive durable response at 24 and 32 weeks. In one metastatic melanoma patient with a brain metastasis, which would typically be unresponsive to standard of care treatments, a complete response of the brain metastasis was observed at week 27 of treatment. ImCheck is presenting these updates in addition to two posters covering ICT01 at SITC. The conference is taking place in Washington, D.C. and virtually, from November 10 - 14, 2021.

“These latest data from the EVICTION trial support our confidence that ICT01 has significant potential to provide meaningful therapeutic effects, particularly in patients with advanced, metastatic solid tumors that did not respond to prior checkpoint inhibitor therapy,” commented [Paul Frohna, MD, PhD, Chief Medical Officer at ImCheck Therapeutics](#). *“Although the brain metastasis response needs replication in more patients, this provides a highly valuable, clinical development opportunity in a group of patients with high unmet medical need that we intend to explore further.”*

In the oral presentation today, titled *“Clinical Activity of ICT01, an anti-BTN3A-Targeted, $\gamma\delta 2$ -Activating mAb, Alone and in Combination with Pembrolizumab in Patients with Advanced/Refractory Solid Tumors: EVICTION Trial”*, Prof. Martin Wermke, Early Clinical Trial Unit, University Hospital Carl Gustav Carus, Dresden, Germany, presented results demonstrating ICT01 plus pembrolizumab induced anti-tumor responses in patients with a range of solid tumors. Five of eight patients (bladder cancer, metastatic melanoma, non-small cell lung cancer (n=3)) achieved disease control at 8 weeks and beyond according to RECIST1.1, including two partial responses at week 16 and beyond.

In the poster presentation titled, *“ICT01, an anti-BTN3A monoclonal antibody, and NL-201, an alpha-independent IL-2/IL-15 agonist, combine to elicit a potent anti-tumor response by synergistically stimulating $\gamma\delta 2$ T cell activation and proliferation”*, a preclinical study of ICT01 plus NL-201 treatment suggests favorable results from the synergistic activity of both candidates through enhanced $\gamma\delta 2$ T cell activation, expansion and anti-tumor activity in comparison with monotherapy. The synergistic effect of this combined treatment makes a strong case for further investigation of this therapeutic approach.

The second poster, “Correlation of Baseline Circulating $\gamma\delta$ T Cells Counts and Pharmacodynamic Activity of ICT01 in Cancer Patients: Preliminary Results from EVICTION and a Novel Patient Enrichment Strategy”, evaluated the relationship between the baseline number of circulating $\gamma\delta$ T cells in patients and their response to ICT01 as an enrichment strategy that is being implemented in the monotherapy expansion arms of the EVICTION trial.

[Pierre d’Epenoux](#), Chief Executive Officer of ImCheck Therapeutics added: “*These new clinical data and the preclinical combination data provide a deeper understanding of ICT01 and enable us to expand our pipeline-in-a-product strategy into additional indications and combinations. We are building momentum in the EVICTION trial including the start of enrollment in the Phase 2a portion of the study with monotherapy in patients with ovarian or head and neck squamous cell cancer using the baseline number of circulating $\gamma\delta$ T cells as a patient enrichment strategy as described in our second SITC poster.*”

All posters presented in the poster hall will be made available as virtual ePosters throughout the SITC 36th Annual Meeting.

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 relapsed or refractory 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 patients, Group B includes acute myeloid leukemia, acute lymphocytic leukemia, follicular lymphoma, and diffuse large B cell lymphoma patients, and Group C includes bladder, head and neck squamous cell carcinoma, melanoma, and non-small cell lung cancer patients. Basket trials are a clinical trial design that allows new drugs to be tested rapidly in a range of indications, providing initial data on multiple parameters that can contribute to an accelerated development timeline. More information on the EVICTION trial can be found at clinicaltrials.gov (NCT04243499).

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 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 $\gamma\delta$ T cells.

As demonstrated in EVICTION data presented at AACR, 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), while also activating the tumor-resident $\gamma\delta$ T cells to directly kill malignant cells, which is accompanied by secretion of two key inflammatory cytokines, IFN γ and TNF α , 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 $\gamma\delta$ 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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