

## ImCheck Provides Updated ICT01 and Pembrolizumab Combination Data from the Phase I/IIa EVICTION Trial at AACR Annual Meeting 2022

- Continued positive safety data across a range of ICT01 doses in 69 cancer patients and updated efficacy data from 22 evaluable patients treated with ICT01 plus pembrolizumab
- Clinical responses achieved with low doses of ICT01 in combination with pembrolizumab in solid tumor patients who previously failed checkpoint-inhibitor therapy support the complementary mechanisms of action with potential for anti-tumor activity in this difficult to treat patient population
- Patient with checkpoint-inhibitor refractory metastatic melanoma achieved a complete response of a brain metastasis and a partial response of liver metastases with effects ongoing at 11 months

Marseille, France, April 8, 2022 – [ImCheck Therapeutics](https://www.imchecktherapeutics.com) provided newly updated patient response data from its ongoing EVICTION Phase I/IIa clinical trial of its lead candidate ICT01 in a poster presentation at the American Association for Cancer Research (AACR) Annual Meeting 2022. In efficacy evaluable patients (n=22) treated with the combination of low dose ICT01 plus pembrolizumab who previously failed at least one prior checkpoint inhibitor (CPI) regimen, 36% showed disease control by RECIST1.1 criteria. A previously reported metastatic melanoma patient with a brain metastasis, which would typically be unresponsive to standard of care treatments, achieved a complete response of the brain metastasis observed at week 27 of treatment with response ongoing at week 44.

*“We continue to observe a robust safety and tolerability profile for ICT01 in the EVICTION trial while gaining important data on its immune remodeling activity on the tumor microenvironment in specific advanced solid tumor indications, which will inform the next stage of our development program,”* commented [Paul Frohna](#), MD, PhD, Chief Medical Officer at ImCheck Therapeutics. *“The clinical results describing ICT01’s ability to induce activation and migration of circulating  $\gamma\delta$  T cells, CD8 T cells, and NK cells that leads to increased tumor infiltration by  $\gamma\delta$ , CD3 and CD8 T cells indicates it can safely coordinate broad anti-tumor immune responses in a group of patients who have previously failed multiple courses of therapy.”*

Dr. Stéphane Champiat, EVICTION lead study investigator at the Gustave Roussy Cancer Center, Paris, France, will present the poster titled, *“ICT01, an anti-butyrophilin 3A targeted mAb activating  $\gamma\delta$  T cells, induces immune remodeling of the tumor microenvironment and clinical responses in combination with pembrolizumab in patients with advanced solid tumors who failed prior checkpoint inhibitor therapy: EVICTION Trial”*, on April 12, from 9:00am - 12:30pm CDT.

[Pierre d’Epenoux](#), Chief Executive Officer of ImCheck Therapeutics added: *“The positive results to date and the steady progress we have achieved with the EVICTION trial demonstrates the potential of ICT01 and ImCheck’s ability to execute an ambitious international study. We remain on target with our timelines and have started enrollment in the Phase 2a portion of the study with ICT01 as a monotherapy in patients with ovarian cancer or head and neck squamous cell cancer. Our goal is to further establish the therapeutic value and highly differentiated aspects of our approach.”*

The poster will be made available on ImCheck’s website.

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### 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. Part 2 of the trial is a Phase II cohort expansion study in selected indications as both monotherapy and in combination. First indications selected for this Phase II are ovarian cancer and Head and Neck Squamous Cell Carcinoma (HNSCC). More information on the EVICTION trial can be found at [clinicaltrials.gov](https://clinicaltrials.gov/NCT04243499) (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 the AACR, EMSO and SITC conferences, 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,  $IFN\gamma$  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  $\gamma\delta$  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](#)

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