



PRESS RELEASE

ImCheck to Present Promising ICT01 Data from the EVICTION Study at ASCO 2024

Interim data from Phase I/II EVICTION study shows favorable safety profile and promising efficacy for ICT01 in combination with pembrolizumab in refractory melanoma patients

Marseille, France, May 30, 2024, 11 am CET – [ImCheck Therapeutics](#) announced today that updated data from its ongoing Phase I/II study EVICTION will be presented in a poster session at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting being held in Chicago. The poster will provide new data from the study assessing ICT01, a humanized anti-BTN3A monoclonal antibody that selectively activates γ 9 δ 2 T cells, in combination with checkpoint inhibitor (CPI) pembrolizumab. The results, specifically in patients with CPI-refractory melanoma, support the therapeutic potential of the ICT01-pembrolizumab combination.

“Our objective with the EVICTION study is to validate ICT01’s promise as an innovative therapy and inform the next steps of its clinical development. The data presented at ASCO further define ICT01’s therapeutic potential, in particular in combination with pembrolizumab, where we see promising data in CPI-refractory patients. ImCheck intends to further investigate this combination regimen in refractory solid tumors, where patients have limited treatment options,” commented [Pierre d’Epenoux](#), Chief Executive Officer of ImCheck Therapeutics.

Data from EVICTION presented at ASCO will include full safety data from all cohorts and preliminary efficacy data from ongoing assessments performed every 8 weeks in patients with metastatic melanoma. ICT01-pembrolizumab combination treatment showed a clinically manageable safety profile with generally mild and clinically manageable first-dose Grade 1/2 infusion-related reactions (38%) and cytokine release syndrome (19%) as the most common adverse events across all doses and indications. In the CPI-refractory melanoma group, 21 patients were evaluable at week 16 with 3 partial responses and a disease control rate of 42%. In addition, biomarker analyses revealed clinical response was associated with baseline BTN3A tumoral expression, sustained elevation of IFN γ levels, and tumor microenvironment remodeling. Based on these findings, biomarker-driven patient selection will be further investigated as a potential enrichment strategy.

Details of the poster presentation are:

Abstract title: “EVICTION study: ICT01, an anti-Butyrophilin 3A monoclonal antibody activating γ 9 δ 2 T cells in combination with pembrolizumab in checkpoint inhibitor refractory melanoma.”

Session title: Melanoma/Skin Cancers

Abstract number: 9534

Poster board: 318

Presenter: Dr Stephane Champiat, Gustave Roussy

Authors: Stephane Champiat, Martin Wermke, Cecile Vicier, Johann S. De Bono, Emiliano Calvo, Jorge Ramón, Evan Thomas Hall, Elena Garralda, Vladimir Galvao, Emanuela Romano, Antoine Italiano, Esmá Saada, Benoit You, Aude De Gassart, Maelle Mairesse, Emmanuel Valentin, Patrick Brune, Daniel Olive, Katrien Lemmens, Paul Frohna

Date/Time: Saturday June 1st, 2024, 1:30–4:30 pm CST

Location: Hall A - McCormick Place



The ASCO poster will be available on ImCheck's corporate website after the presentation has been completed.

About the EVICTION Study

EVICTION is a first-in-human, dose escalation (Part 1) and cohort expansion (Part 2) clinical study 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 the Phase II monotherapy expansion cohorts are relapsed/refractory ovarian cancer and metastatic castrate-resistant prostate cancer. More information on the EVICTION study can be found at clinicaltrials.gov (NCT04243499). A second clinical study, EVICTION-2, evaluating the combination of ICT01 plus low dose subcutaneous IL-2 to selectively expand the number of $\gamma\delta 2$ T cells in patients with solid tumors (prostate, pancreatic, ovarian, or colorectal cancer) is also ongoing (NCT05307874).

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 of malignancy and infections. The three 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 $\gamma\delta 2$ T cells.

As demonstrated in EVICTION data presented at past AACR, EMSO and SITC conferences, 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), 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 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 its 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 and infectious diseases.

ImCheck benefits from support from Prof. Daniel Olive (INSERM, CNRS, Institut Paoli Calmettes, Aix-Marseille University), a worldwide leader in $\gamma\delta 2$ T cells and butyrophilins research, as well as from the experience of an expert management team and from the commitment of leading US and European investors.

For further information: <https://www.imchecktherapeutics.com/>

Press contacts:

US and EU

Trophic Communications

Gretchen Schweitzer

+49 (0) 172 861 8540

imcheck@trophic.eu

France

ATCG PARTNERS

Céline Voisin

+33 (0)9 81 87 46 72 / +33 (0)6 62 12 53 39

imcheck@atcg-partners.com