

ImCheck to Present New Positive Data on ICT01 Monotherapy in Hematological Cancers at ESMO 2023

Interim data from Phase I dose escalation portion of EVICTION Phase I/IIa trial show strong safety profile and encouraging clinical activity for ICT01 monotherapy in relapsed/refractory hematological malignancies

Marseille, France, October 16, 2023 – [ImCheck Therapeutics](#) announced today that updated data from its ongoing Phase I/IIa clinical trial EVICTION will be presented at the European Society for Medical Oncology (ESMO) Congress in an oral session on October 22nd in Madrid. The presentation ([8220](#)) entitled: “Activation of $\gamma\delta 2$ T Cells by ICT01 as a Novel Immunotherapeutic Approach for Relapsed/Refractory Hematologic Cancers (EVICTION Study)” will provide safety and patient response results from the Phase I dose escalation portion of the EVICTION trial of ImCheck’s lead antibody, ICT01, administered as a monotherapy to relapsed/refractory patients with hematological cancers, primarily Acute Myeloid Leukemia (AML).

“The positive safety profile, consistent with previous data in solid tumor patients, together with the promising clinical activity underscores the potential of ICT01 in hematological malignancies. These results in last-line patients further support the initiation of the ongoing Phase IIa cohort expansion study of ICT01 in combination with standard of care in first-line AML patients,” commented **Sylvain Garciaz, M.D., Ph.D.**, member of the Department of Hematology, Institut Paoli-Calmettes, investigator in the EVICTION study, and presenter of the data at ESMO 2023.

“We continue to generate highly encouraging clinical signals in both solid and hematological tumors. We remain focused on rapidly advancing ICT01 into late-stage clinical evaluation in combination settings as a unique clinical approach to boost the anti-tumor immune response in cancer patients,” commented [Pierre d’Epenoux](#), Chief Executive Officer of ImCheck Therapeutics.

EVICTION is an open-label Phase I/IIa trial assessing ICT01, a humanized anti-BTN3A monoclonal antibody that selectively activates $\gamma\delta 2$ T cells, as a monotherapy in solid and hematological tumors, and as a combination therapy with pembrolizumab in solid tumors. The Phase 1 dose escalation study in relapsed/refractory hematological cancers included 26 patients who failed all available standard of care, 24 of which had acute myeloid leukemia, 1 with diffuse large B-cell lymphoma and 1 with follicular lymphoma. ICT01 was administered at doses ranging from 200 μ g to 75 mg every 21 days and primary endpoints consisted of the incidence of treatment-adverse events (AE) and the disease control rate (DCR) defined as the sum of complete response (CR), CR with incomplete recovery (CRi), partial response (PR) and stable disease (SD). Secondary endpoints included circulating $\gamma\delta 2$ T cell measurements as well as pharmacokinetic and pharmacodynamic analyses. The reported data did not reveal any dose-limiting toxicities and demonstrated a DCR of 30% among the 10 evaluable patients at week 8. Notably, ICT01 treatment safely induced the activation and migration of $\gamma\delta 2$ T cells from the blood within hours of dosing, suggesting effective target engagement.

Based on these results, the company has started evaluating ICT01 in combination with Venetoclax/azacitidine in a Phase IIa expansion cohort in first-line AML patients.

Details of the presentation are:

Abstract title: "Activation of $\gamma\delta 2$ T Cells by ICT01 as a Novel Immunotherapeutic Approach for Relapsed/Refractory Hematologic Cancers (EVICTION Study)"

Session title: Proffered paper sessions – Haematological malignancies

Abstract number: 8220

Authors: Sylvain Garciaz (presenter), Stéphane Champiat, Pierre Peterlin, Katrien Lemmens, Aude De Gassart, Patrick Brune, Emmanuel Valentin, Céline Leparquier, Marina Iché, Daniel Olive, Norbert Vey, Paul Frohna

Date/Time: Sunday October 22nd, 2023, 4:30 PM - 6:00 PM CET

Location: Toledo Auditorium - Hall 3

The ESMO presentation will be available starting October 22, 2023, at 4:30 pm CET on ImCheck's corporate website.

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 the Phase II monotherapy expansion cohorts are relapsed/refractory ovarian cancer and metastatic castrate-resistant prostate cancer. More information on the EVICTION trial can be found at [clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT04243499) (NCT04243499). A second clinical trial, 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.

Co-founder of the Marseille Immunopole cluster, 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/>

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