PRESS RELEASE

ImCheck Presented Updated Positive Data from Phase I/IIa EVICTION-2 Trial of ICT01 in Combination with Low-dose IL-2 at SITC 2023

Interim data from EVICTION-2 study confirms safety and tolerability profile and broad anti-tumor immune response that is durable across multiple treatment cycles

Marseille, France, November 3, 2023, 7 pm CET – ImCheck Therapeutics presented today updated data from its ongoing Phase I/IIa EVICTION-2 clinical trial at the Society for Immunotherapy of Cancer 38th annual meeting in San Diego, USA. The poster presentation entitled "*ICT01 plus Low Dose SC IL-2 Produces a Robust Anti-Tumor Immune Activation in Advanced Cancer Patients (EVICTION-2 Study)*" provided data from the Phase I/IIa study assessing ICT01, a humanized anti-BTN3A monoclonal antibody that selectively activates γ9δ2 T cells, in combination with low-dose IL-2 in patients with advanced solid tumors.

"*The data show a clear increase in γ9δ2 T cell counts as well as activation and mobilization of CD8 T cells and NK cells, indicating ICT01 in combination with low dose IL-2 can generate a broad immune response. The immune cell expansion and the positive safety and tolerability profile observed support the advance of the study toward the proof of concept stage in part 2*," commented **Johann S. de Bono, PhD, Regius Professor of Cancer Research at The Institute of Cancer Research, The University of London, investigator in the EVICTION-2 study, and presenter of the data at SITC 2023.**

"*The effect of ICT01 with low dose IL-2 on anti-tumor immunity suggests the combination regimen holds promise, notably for the treatment of patients with low circulating γ9δ2 T cells and, together with the results from the EVICTION study, underlines the strong immunotherapeutic potential of ICT01 in oncology*," commented **Pierre d'Epenoux, Chief Executive Officer of ImCheck Therapeutics**.

EVICTION-2 is a two-part, open-label, Phase I/IIa trial assessing the safety, tolerability, pharmacodynamics and anti-tumor effects of ICT01 in combination with low dose IL-2 in advanced-stage solid tumor patients. In the dose escalation Part 1 of the study, patients receive intravenous ICT01 administered on the first day of every 21-day cycle in combination with daily subcutaneous IL-2 on days 1-5 of cycles 1-3. The primary endpoint measured the incidence and severity of treatment-related adverse events and secondary outcomes included γ9δ2 T cell numbers and analysis of the disease control rate in order to select the best regimen(s) for testing in Part 2 of the trial where it will be combined with pembrolizumab. As reported in the poster, 19 patients have completed at least 1 cycle and no dose-limiting toxicities were observed. Reported treatment-related adverse events were mainly mild to moderate and correlated with the profile of ICT01 and IL-2 monotherapy. All cohorts demonstrated an elevation in γ9δ2 T cell counts that peaked at day 8-15. Further immunological observations included the activation, mobilization and proliferation of CD8 T cells and NK cells. Notably, the broad anti-tumor immune response induced by the combination regimen was durable across multiple treatment cycles.

Details of the presentation are:
Abstract title: "ICT01 plus Low Dose SC IL-2 Produces a Robust Anti-Tumor Immune Activation in Advanced Cancer Patients (EVICTION-2 Study)"
Session title: Clinical Trials in Progress
Abstract number: 715

Authors: Johann de Bono, Stéphane Champiat, Francois-Xavier Danlos, Martin Wermke, Volker Kunzmann, Aude De Gassart, Emmanuel Valentin, Marina Iché, Maelle Mairesse, Patrick Brune, Katrien Lemmens, Daniel Olive, Paul Frohna
Date/Time: Friday November 3rd, 2023, 12:00–1:30 pm and 5:10–6:40 pm PT
Location: Ground Level - Exhibit Halls A and B1 - San Diego Convention Center

The SITC poster is available on ImCheck's corporate website.

***

About the EVICTION 2 Trial

EVICTION-2 is a first-in-human, dose escalation (Part 1) and cohort expansion (Part 2) clinical trial evaluating ICT01 in combination with low dose subcutaneous IL-2. The trial's objective is to demonstrate the combination's ability to safely and selectively expand the number of γ9δ2 T cells in patients with solid tumors (prostate, pancreatic, ovarian, or colorectal cancer) that produces a more robust antitumor immune response and improved patient outcomes.

For more information, please refer to https://clinicaltrials.gov and reference NCT05307874.

About ICT01

ICT01 is a humanized, anti-BTN3A (also known as CD277) monoclonal antibody that selectively 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., γδ 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 γ9δ2 T cells.

As demonstrated in EVICTION data presented at past AACR, EMSO and SITC conferences, ICT01 selectively activates circulating γ9δ2 T cells that leads to migration of γ9δ2 T cells out of the circulation and into target tissue (e.g., tumors), while also activating the tumor-resident γ9δ2 Tcells to directly kill malignant cells, which is accompanied by secretion of two key inflammatory cytokines, IFNγ and TNFα, 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 γ9δ2 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