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
Press Release

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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.

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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 T cells 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/

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