PRESS RELEASE

ImCheck Reports High Remission Rates in AML Patients with ICT01 Combination Therapy at ASCO 2025

- **ICT01 in combination with azacitidine and venetoclax (Aza-Ven) achieves unprecedented high remission rates overall and across molecular subtypes** in newly diagnosed AML patients
- **Favorable safety profile**, with Grade ≥3 adverse events consistent with expected Aza-Ven hematological toxicity and AML-related effects
- **ICT01 10 mg is the proposed dose** for further clinical development
- **Oral presentation at ASCO 2025:** Monday, June 2, 2025, 5:12 p.m.- 5:24 p.m. CDT, Room S100a

Marseille, France, May 22, 2025, 5:00 pm ET/11:00 pm CET – ImCheck Therapeutics today announced the publication of its abstract for an upcoming oral presentation at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, Illinois. The presentation will feature updated data from the ongoing Phase I/II EVICTION study. The study evaluates ICT01, a novel γ9δ2 T-cell activator, administered in combination with azacitidine and venetoclax (Aza-Ven) in patients with newly diagnosed acute myeloid leukemia (AML) who are unfit for intensive chemotherapy. The updated interim results demonstrate a 96% composite complete remission (CRc) rate, including 74% complete remissions (CR), with responses observed across molecular subtypes. Notably, high response rates were achieved in patients with adverse- or intermediate-risk mutations, a population typically less responsive to Aza-Ven. In addition, the preliminary 9-month overall survival rate for patients treated with 10 mg of ICT01 was 83%, underscoring the strong clinical potential of the novel triple combination. The oral presentation will be held 5:12 p.m.- 5:24 p.m. CDT, on Monday, June 2, during Session "Hematologic Malignancies—Leukemia, Myelodysplastic Syndromes, and Allotransplant" (Room S100a).

"The updated data reinforce ICT01's potential to meaningfully enhance the therapeutic effects of Aza-Ven in AML by harnessing the unique biology of γ9δ2 T cells," said Stephan Braun, MD, PhD, Chief Medical Officer of ImCheck Therapeutics. *"The depth and consistency of responses observed with ICT01, combined with its manageable safety profile, provide a strong foundation as we advance toward a randomized study."*

Key Highlights:

- **Patient population**: At the data cut-off on January 20, 2025, 45 patients aged 51 to 87 were enrolled. A total of 29 patients received 10 mg of ICT01 and 16 patients received 75 mg of ICT01, each in combination with Aza-Ven; of these, 39 patients were evaluable for efficacy.
- **Clear signs of immune activation**: ICT01 at the 10 mg dose provided optimal activation of γ9δ2 T cells and a downstream immune cascade, supporting its role in enhancing Aza-Ven efficacy, and confirming it as the proposed dose for further clinical development.

- Strong efficacy for ICT01 with Aza-Ven: Treatment with ICT01 at the proposed dose in combination with Aza-Ven resulted in high rates of CRc (96%) and CR (74%).
- Encouraging efficacy in difficult-to-treat AML patients: Among evaluable patients, the majority had adverse- or intermediate-risk genetic aberrations, which are typically associated with limited clinical benefit from Aza-Ven. Specifically, the CR and CRc rates in patients with *TP53*-mutated AML were 60% and 83%, respectively.
- Early survival trends: At a median follow-up time of 8.5 months, high response rates were associated with a longer duration of response and an improved 9-month overall survival. While these time-to-event data are encouraging, they remain preliminary because the majority of patients are still on treatment.
- Favorable safety profile: The combination treatment was clinically well manageable, with a low 30-day mortality rate of 4% (all deaths unrelated to ICT01) and a low rate of infectious complications. The most frequent adverse events of Grade ≥3 were febrile neutropenia, neutropenia, thrombocytopenia, and sepsis, reported as unrelated to ICT01 and consistent with the known hematological toxicity of Aza-Ven.

"Patients with newly diagnosed AML, particularly those with high-risk genetic features, continue to face limited therapeutic options. Our results suggest that ICT01's ability to engage γ9δ2 T cells could offer a powerful new option for a population typically underserved by current therapies," added Pierre d'Epenoux, Chief Executive Officer of ImCheck Therapeutics. *"Based on this compelling validation of our novel approach and the momentum we are building as an organization, we will accelerate clinical development of ICT01 in patients with AML, myelodysplastic syndrome, and select solid tumor indications. We are grateful for the patients' participation in our study and the support from the investigators, the ImCheck team and our investors."*

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About the medical need in AML

Acute myeloid leukemia (AML) remains a significant clinical challenge, particularly for older or unfit patients who cannot tolerate intensive chemotherapy. While the combination of venetoclax and azacitidine has become the standard non-intensive regimen, it is not curative and relapse rates remain high. Most patients are not eligible for stem cell transplantation, often due to age, comorbidities, or insufficient response, and face limited treatment options and poor overall survival. Despite AML's known sensitivity to immune-mediated control, current immunotherapies targeting PD-1, TIM-3, or CD47 have not delivered meaningful clinical benefit. This underscores the urgent need for novel immuno-oncology approaches. Recently, γ9δ2 T cells, with their cytotoxic activity and unique dual role in both innate and adaptive immunity, have emerged as promising immune modulators. Their association with reduced relapse and prolonged survival, particularly in the post-transplant setting, suggests that enhancing their anti-leukemic potential could offer a meaningful new treatment option for high-risk AML patients.

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 (Phase I) is designed to characterize the preliminary safety, tolerability, and pharmacodynamic activity of increasing

doses of ICT01 as monotherapy (Group A: solid tumors; Group B: hematologic tumors) and in combination with pembrolizumab (Group C: solid tumors). Part 2 comprises randomized dose-optimizing and efficacy estimating expansion cohorts of monotherapy (Group D: ovarian cancer; Group E: prostate cancer) and combination treatment of patients with AML (Group F), melanoma (Group G), urothelial cell carcinoma (Group H), or head-and-neck squamous cell carcinoma (Group I). More information on the EVICTION study can be found at clinicaltrials.gov (NCT04243499).

About ICT01

ICT01 is a humanized, anti-BTN3A (also known as CD277) monoclonal antibody that selectively activates γ9δ2 T cells, which are responsible for immunosurveillance of malignancy and infections. The three isoforms of BTN3A targeted by ICT01 are overexpressed on many solid tumors (e.g., melanoma, urothelial cell, colorectal, ovarian, pancreatic, and lung cancer) and hematologic malignancies (e.g., leukemia and lymphomas) 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 by data presented at past AACR, ASCO, ASH, ESMO and SITC conferences, ICT01 selectively activates circulating γ9δ2 T cells leading to migration of γ9δ2 T cells out of the circulation and into the tumor tissue and triggers a downstream immunological cascade through secretion of pro-inflammatory cytokines, including but not limited to IFNγ and TNFα, further augmenting the anti-tumor immune response. Anti-tumor activity and efficacy of ICT01 have been shown in patients across several cancer indications.

About IMCHECK THERAPEUTICS

ImCheck Therapeutics is developing a new generation of immunotherapeutic antibodies targeting butyrophilins, a novel superfamily of immunomodulators. By unlocking the power of γ9δ2 T cells, ImCheck's innovative approach has the potential to transform treatments across oncology, autoimmune, and infectious diseases.

The lead clinical-stage program, ICT01, has been advancing to late-stage trials, demonstrating a unique mechanism of action that modulates both innate and adaptive immunity. These "first-in-class" activating antibodies may deliver superior clinical outcomes compared to first-generation immunotherapy approaches, in particular in rationale combinations with immune checkpoint inhibitors and immunomodulatory anti-cancer drugs. Additionally, ImCheck's pipeline compounds are progressing toward clinical development for autoimmune and infectious diseases.

The company benefits from the pioneering research of Prof. Daniel Olive (INSERM, CNRS, Institut Paoli Calmettes, Aix-Marseille University), a global leader in γ9δ2 T cells and butyrophilins, as well as the expertise of a seasoned management team and the commitment of leading U.S. and European investors.

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

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