PRESS RELEASE

ImCheck Reports Durable Responses and Early Overall Survival Signal with ICT01 in First-line AML at ASH 2025

- Updated clinical data presented at ASH show robust efficacy, rapid onset of remission, high incidence of MRD[1]-negativity, and an encouraging survival signal with ICT01 in combination with azacitidine and venetoclax (Aza-Ven) in newly diagnosed unfit AML patients
- ICT01 has received Orphan Drug Designation from the FDA and EMA; dose selection has been endorsed by FDA as ICT01 advances toward late-stage development

Marseille, France, December 7, 2025, 5:30 pm ET/ 11:30 pm CET – ImCheck Therapeutics today announced updated results from its Phase I/II EVICTION study evaluating ICT01, a first-in-class γ9δ2 T-cell activator, in combination with azacitidine and venetoclax in newly diagnosed AML patients ineligible for intensive chemotherapy. The data were presented by Dr. Sylvain Garciaz (Institut Paoli-Calmettes, Marseille, France) in an oral session at the 67th ASH Annual Meeting, taking place December 6-9, in Orlando, Florida. The data presentation follows ImCheck's recently announced agreement to be acquired by Ipsen, pending transaction close.

The ASH 2025 dataset builds on the promising efficacy signals previously shared at ASCO[2] 2025, highlighting rapid, deep, and durable responses with a favorable safety profile and encouraging early overall survival. Notably, responses were strongest at the 10mg ICT01 dose, which has now been endorsed by the FDA for further development. In 2025, ICT01 also received Orphan Drug Designation from both the FDA[3] and EMA[4].

"ICT01 continues to demonstrate rapid and durable responses across AML subtypes. The updated ASH data further strengthens our confidence in ICT01's ability, when added to Aza-Ven, to deliver deep, lasting remissions that have the potential to translate into meaningful overall survival improvement for patients" said Stephan Braun, MD, PhD, Chief Medical Officer of ImCheck Therapeutics. *"We see an early onset of complete remissions, consistently strong efficacy at the selected dose across molecular subtypes, and signs of durable responses even in adverse-risk patients. These findings together with the encouraging early survival signal create a compelling case as we advance toward late-stage development."*

Key Highlights:

- Patient population: At the data cut-off on October 6, 2025, 57 patients aged 51 to 87 had been enrolled. Of these, 41 received 10 mg ICT01 and 16 received 75 mg ICT01, each in combination with Aza-Ven.
- Rapid responses: More than 90% of patients treated with ICT01 (10 mg) achieved CRc[4] as their best response already by end of Cycle 2.

1 MRD: Minimal residual disease. A patient who tests "MRD negative" after treatment for leukemia has less than one leukemia cell per 1 thousand bone marrow cells
[2] ASCO: American Society of Clinical Oncology
[3] FDA: U.S. Food and Drug Administration
[4] EMA: European Medicines Agency

- Broad molecular activity: The 10 mg dose selected for future studies produced higher CR/CRc rates across molecular subtypes, including favorable-, intermediate-, and adverse-risk AML (e.g., TP53-mutated) versus the 75 mg dose.
- Durability emerging: At a median follow-up of 10.8 months median DoR[5] was not yet reached for the 10 mg ICT01 dose.
- Early survival signal: A 12-month OS[6] rate of 62% was observed, which is numerically higher than the ~54% reported for the Aza-Ven regimen in recent Phase 3 trials.
- Favorable benefit–risk profile: Safety of the novel triplet regimen ICT01-Aza-Ven remains well manageable, with a 30-day mortality rate of 4%, and no deaths attributed to ICT01.
- Regulatory momentum: ICT01 received Orphan Drug Designation from both FDA and EMA. The 10 mg ICT01 dose has been endorsed by FDA for further clinical development of the triplet regimen.

"ImCheck has in hand the alignment of strong clinical activity, a favorable safety profile, Orphan Drug Designations on both sides of the Atlantic, and now a clear regulatory-endorsed dose for ICT01 for accelerated late-stage development," added Pierre d'Epenoux, Chief Executive Officer of ImCheck Therapeutics. *"These results arrive at a transformative moment for ImCheck, following the announced acquisition agreement with Ipsen. We remain deeply grateful to the patients, investigators, and our team for bringing ICT01 to this important inflection point."*

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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

[5] DoR: Duration of response
[6] OS: Overall survival

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. As announced on October 22, Ipsen (Euronext: IPN; ADR: IPSEY) and ImCheck have entered into a definitive share purchase agreement in which Ipsen will acquire all issued and outstanding shares of ImCheck, with the transaction close anticipated by the end of Q1 2026.

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)6 62 12 53 39
imcheck@atcg-partners.com