γ9δ2 T-cell activation with ICT01 and Aza-Ven induces high rates of CR in newly diagnosed AML: preliminary results of the Phase 1/2 study EVICTION

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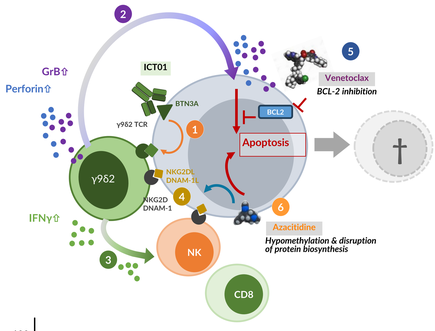
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ImCheck therapeutics

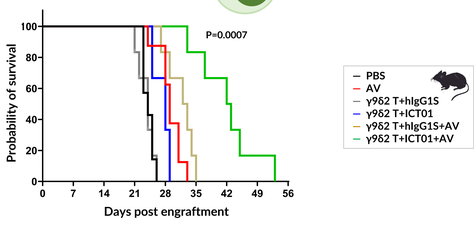
Introduction

- γ9δ2 T cells are known to drive graft-versus-leukemia efficacy.
- ICT01 is an anti-BTN3A mAb that selectively activates γ9δ2 T cells & triggers cytotoxicity (Panel **A**)
- ICT01-activated γ9δ2 T cells promote anti-leukemic cytotoxicity and immunomodulation
- ICT01-Ven-Aza showed synergistic anti-leukemic efficacy *in vivo* (MOLM-14 mouse model; Panel **B**)
- ICT01 monotherapy was safe, tolerable at 0.7–75 mg ICT01 & modestly effective in R/R phase1 patients

A



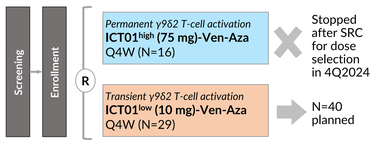
B



Methods

Dose-optimizing, efficacy-estimating Phase 1 cohorts
Pts with newly diagnosed AML ineligible for intensive chemo/HSCT

Exclusion of patients with:
- Eligible for intensive chemo/HSCT
- t(15;17), t(8;21), inv(16), or t(16;16)
- Prior MPN, PV, CML or AML with tBCR-ABL1
- Prior Ven exposure
- Systemic corticosteroids in last 28 days
- Active auto-immune disease

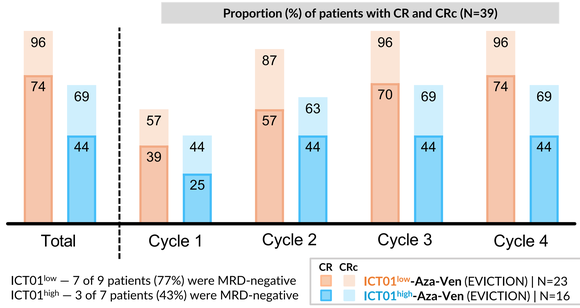


- **Interim analysis:** ICT01^{high} stopped based on pharmacodynamic findings following SRC meeting
- **Safety Population (N=45)**: all patients that received at least one dose
- **Efficacy Population (N=39)**: evaluable for efficacy with informative disease/bone marrow assessments
  - Primary Endpoint: ***CR rate*** per European LeukemiaNet 2022 criteria
  - Secondary Endpoints: CRc, OS, EFS, safety, pharmacokinetics, pharmacodynamics (MRD is explored)

Abbreviations: **CR**, complete response; **CRc**, composite CR (CR+CRi+CRh); **CRh**, CR with partial hematological recovery; **CRi**, CR with incomplete hematological recovery; **EFS**, event-free survival; **HSCT**, hematopoietic stem cell transplantation; **SRC**, Safety Review Committee (meeting); **Ven-Aza**, venetoclax-azacitidine.

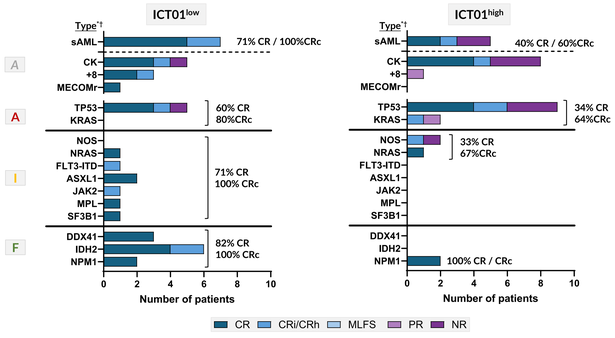
Results

Clinical Efficacy of ICT01-Ven-Aza



ICT01^{low} — 7 of 9 patients (77%) were MRD-negative
ICT01^{high} — 3 of 7 patients (43%) were MRD-negative

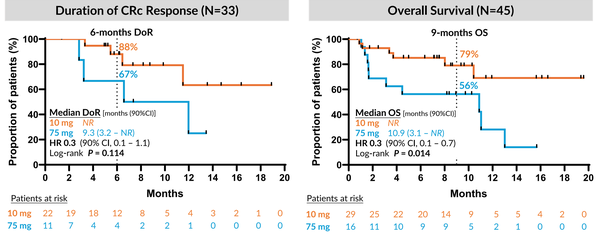
Clinical Efficacy by Molecular Subtypes



*Secondary AML includes therapy related and prior MDS | †Multiple entries possible due to multiple aberrations | #Refined ELN 2024 per Lachowiez et al. Blood 2024:144(26):2788–92.

Abbreviations: **A/I/F**, adverse/intermediate/favorable risk category; **CR**, complete response; **CRc**, composite CR (CR+CRh+CRi); **CRh**, CR with partial hematological recovery; **CRi**, CR with incomplete hematological recovery; **MLFS**, morphologic leukemia-free state; **NR**, non-response reported; **PR**, partial remission; **sAML**, secondary AML; **Ven-Aza**, venetoclax-azacitidine.

Preliminary Response Duration & OS



Abbreviations: **CI**, confidence interval; **DoR**, duration of response; **HR**, hazard ratio; **NR**, not reached; **OS**, overall survival.

Conclusions

- ICT01^{low}-Ven-Aza generated **very high response rates across molecular AML subtypes** and is clinically well manageable
- ICT01 activates γ9δ2 T cells in the presence of Ven-Aza, and **the RP2D is 10 mg Q4W** (ICT01^{low})
- ICT01-mediated γ9δ2 T cell activation may emerge as the **first immunotherapeutic option for newly diagnosed AML patients ineligible for induction chemotherapy**

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