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First-In-Human, Multicenter Study of SENTI-202, a CD33/FLT3 Selective Off-the-Shelf Logic Gated CAR NK Cell Therapy in Hematologic Malignancies including AML: Clinical Data

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SENTI BIO

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Disclosure Information

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Stephen Strickland, MD

I have the following relevant financial relationships to disclose:

Employee of: HCA Healthcare

In addition, payments were made to Sarah Cannon Research Institute, SCRI for my work, no personal compensation was received from any of these companies.

Consultant for: AbbVie, Caribou, Genentech, Kura Oncology, Novartis, SentiBio, Sobi, Sumitomo, Syros, Terns within the past 24 months

Speaker's Bureau for: GSK

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Stockholder in: None

Honoraria from: None

Acute Myeloid Leukemia (AML) Is an Aggressive Leukemia with Poor Prognosis

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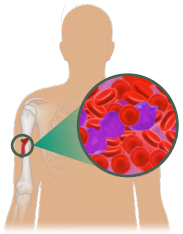
AML Estimated Disease Burden

- **20,800 newly diagnosed AML patients in US every year[1]**
  - **~60% patients experience relapse or death within 12 months[2]**

Relapsed/Refractory AML Patient Outcomes



Median survival of 5.3 months[3]

5-year survival rate is 12.6%[3]

- **Current standard of care responses[4,5]**
  - **CR rate ~15-25%**
  - **CR/CRh rate ~20-33%**

Effective Anti-AML Therapies Need To:

1. Target heterogenous clones / leukemia stem cells (LSCs)[6]
   - To achieve deep / MRD negative CR
   - Leading to durable remissions / longer survival[4,6]
2. Selectively kill AML blasts & LSCs, and spare HSCs
   - To support normal blood cell count recovery
   - Leading to improved prognosis / longer survival[7]

CR: complete remission; CRh: complete remission with partial hematologic recovery; MRD: measurable residual disease; HSC: hematopoietic stem cell

[1]SEER 2024; [2]Tenold Frontiers in Oncology 2021; [3]Brandwein AJBR 2020; [4]Dohner Blood 2022; [5]USPI Idhifa, Xospata, Tibsovo; [6]Zeijlemaker Leukemia 2019; [7]Innes Blood 2018

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SENTI-202 is a First-in-Class Off-the-Shelf Logic Gated Selective CD33 OR FLT3 NOT EMCN CAR NK Cell Therapy for Blood Cancers

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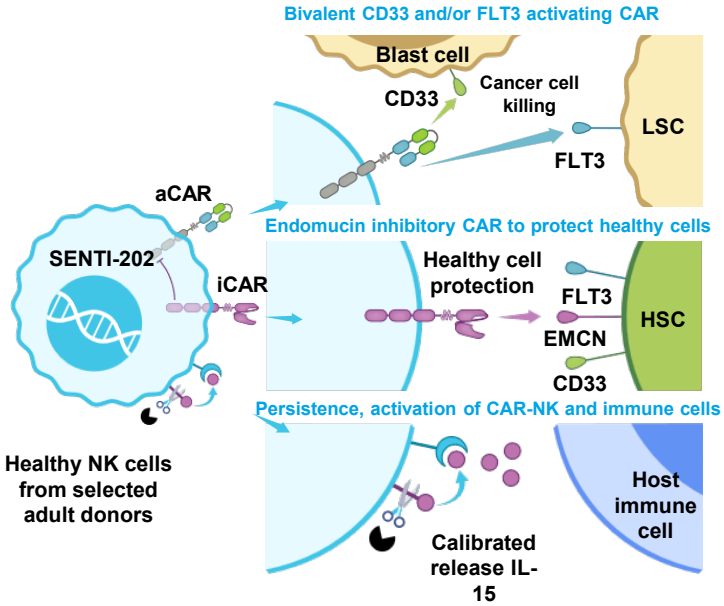

SENTI-202 Gene Circuit Design

- **OR Logic Gate "Kills"** leukemia blasts and LSCs via CD33 OR FLT3 activating CAR (aCAR)
  - CD33 and/or FLT3 expressed in ~95% of AML patients with CD33 being predominantly expressed on bulk blasts and FLT3 on LSCs
- **NOT Logic Gate "Protects"** healthy HSC/HSPCs from 'off-tumor, on-target' effects
  - Protection of HSC/HSPCs via NOT Endomucin (EMCN) inhibitory CAR (iCAR) even when they express CD33 and/or FLT3
  - EMCN found predominantly on healthy HSC/HSPC surface, rarely on AML blasts
- **Calibrated release IL-15 "Enhances"** SENTI-202 and host immune cell activity and persistence

SENTI-202 is designed to selectively kill both AML blasts and LSCs while protecting healthy HSC/HSPCs using its novel CD33 OR FLT3 NOT EMCN logic gated gene circuit

LSC: Leukemia stem cell; HSC: hematopoietic stem cell; HSPC: hematopoietic stem and progenitor cell

SENTI-202 Scalable Manufacturing Process

Off-the-Shelf Allogeneic CAR-NK

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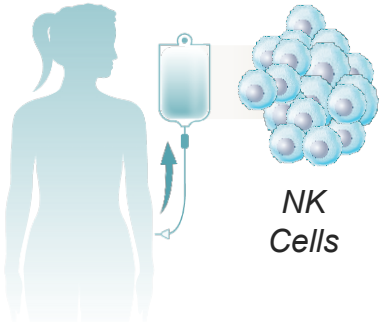
Scalable Process

1

Isolate from selected donors



NK Cells

Selected Donor

2

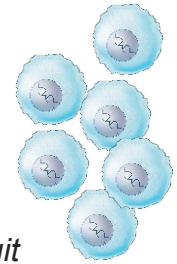
Engineer

Gene Circuit Engineered CAR-NK cells

Gene Circuit delivered through single transduction step

3

Expand



4

Cryopreserve and Store

Final product harvested and cryopreserved

NK cells isolated from peripheral blood of selected donors

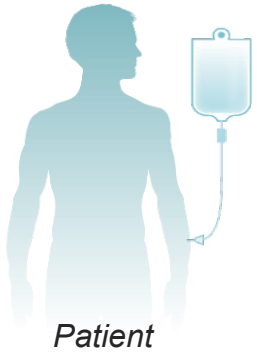
NK cells efficiently engineered with Gene Circuits

High post-thaw potency

SENTI-202

1

Thaw and Infuse Off-the-Shelf



Patient

Easy to thaw vials

Outpatient use potential

SENTI-202 Phase 1 Trial (SENTI-202-101) Design

A multicenter, multinational, open-label study (NCT06325748)

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Key Eligibility Criteria

- ≥18 and <75 years
- ECOG 0-1
- R/R CD33 and/or FLT3 expressing heme malignancies
  - CD33+ by local assessment
- R/R AML (1-3 prior Rx)
- R/R MDS with increased blasts[1](1-2 prior Rx)
- Must have received targeted agents if applicable mutations

Study Design

"3+3"

Dose finding followed by AML, MDS and other expansion cohorts at RP2D

Study Dosing

2 Dose Levels and

2 Schedules

Opening dose cohort was anticipated to be biologically active

Study Objectives

- Primary objective- safety and determination of MTD/RP2D
- DLT definition includes:
  - ≥ G3 non-hematologic toxicities
  - Prolonged G4 neutropenia/ thrombocytopenia not due to underlying disease
- Other key objectives
  - Efficacy based on ELN 2022 criteria (AML)
  - MRD assessed per local standard of care
  - Pharmacokinetics (PK)
  - Pharmacodynamics (PDn) using CyTOF on serial BM samples

ECOG: European Cooperative Oncology Group; RP2D: recommended phase 2 dose; MTD: Maximum tolerated dose; DLT: dose limiting toxicity; G: Grade by CTCAE v5.0 and other applicable Grading systems; ELN: European LeukemiaNet; CyTOF: Cytometry by Time-of-Flight; BM: bone marrow
[1]Per WHO 2022 Classification;

SENTI-202 Phase 1 Trial (SENTI-202-101) Dosing Schema- Preliminary RP2D Identified

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SENTI-202 Dose Levels

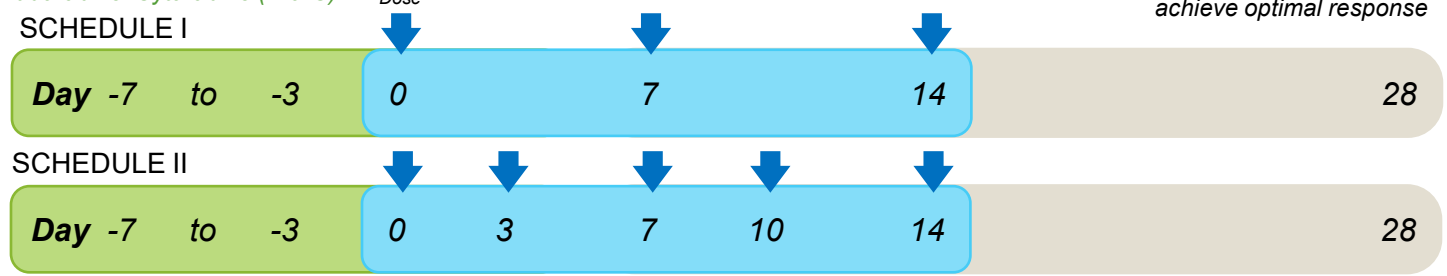
Dose Level	CAR+ NK Cells/Dose
1	1 x 10^9
2	1.5 x 10^9

Multi-Dose Cycle

Lymphodepletion
Fludarabine/ Cytarabine (Ara-C)

SENTI-202
Dose Schedule

Efficacy Assessment
Multiple cycles allowed to achieve optimal response



Opening Dose Cohort was Anticipated to be Biologically Active
Schedule I Dose Level 1, N = 3
No DLTs

Schedule I Dose Level 2, N = 3
No DLTs
Identified as preliminary RP2D based on totality of clinical data

Schedule II Dose Level 1, N = 3
No DLTs

Study Enrolled a High-Risk R/R AML Population with Multiple Baseline Adverse Characteristics

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Baseline Characteristics	Dose Level 1		Dose Level 2	All Patients N = 9
	Schedule I N = 3	Schedule II N = 3	Schedule I N = 3	
Age, yr, median (range)	64 (26,72)	41 (36, 67)	**63 (51, 69)**	63 (26, 72)
Male, n (%)	1 (33)	2 (67)	**3 (100)**	6 (67)
AML, n (%)	3 (100)	3 (100)	**3 (100)**	9 (100)
Years from AML diagnosis, median (range)	2.84 (0.5, 6.2)	0.49 (0.3, 0.8)	**0.94 (0.5, 1.0)**	0.75 (0.3, 6.2)
Adverse risk by ELN 2022, n (%)	2 (67)	2 (67)	**3 (100)**	7 (78)
Baseline bone marrow blasts, %, median (range)	20 (15, 69)	30 (18, 31)	**45 (10, 93)**	30 (10, 93)
Baseline platelet count < 50 x 10^9/L , n (%)	0 (0)	2 (67)	**2 (67)**	4 (44)

preliminary RP2D

- Median of <1 yr from diagnosis to trial entry across all patients and in preliminary RP2D cohort
- Majority of patients (all in preliminary RP2D cohort) with adverse risk genetics by ELN 2022 criteria

Data from an open clinical database of an ongoing study as of 7 Apr 2025

Study Subjects had Received Multiple Prior Therapies

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Prior Therapy	Dose Level 1		Dose Level 2	All Patients N = 9
	Schedule I N = 3	Schedule II N = 3	Schedule I N = 3	
Number of prior lines, median (range)	1 (1,1)	2 (1, 2)	**2 (2, 3)**	2 (1,3)
Chemotherapy, n(%)	3 (100)	3 (100)	**3 (100)**	9 (100)
Fludarabine and/or Ara-C, n (%)	3 (100)	3 (100)	**3 (100)**	9 (100)
Anthracycline, n (%)	3 (100)	2 (67)	**3 (100)**	8 (89)
Venetoclax, n (%)	1 (33)	3 (100)	**3 (100)**	7 (78)
Hypo-methylating Agents, n (%)	2 (67)	3 (100)	**3 (100)**	8 (89)
FLT3/IDH2 targeted therapy, n (%)	1 (33)	1 (33)	**1 (33)**	3 (33)
Bone marrow transplant, n (%)	1 (33)	0 (0)	**1 (33)**	2 (22)
Primary refractory*, n (%)	1 (33)	2 (67)	**2 (67)**	5 (56)

preliminary RP2D

- Median of 2 lines before study entry overall and in preliminary RP2D cohort
- All patients with previous chemotherapy exposure including fludarabine and/or cytarabine (4 received both) and majority with previous venetoclax exposure

Data from an open clinical database of an ongoing study as of 7 Apr 2025; * Primary refractory defined as failure to achieve cCR or cCR lasting <3 mo with front-line therapy

Patients Received a Median of 2 Cycles of SENTI-202 Therapy

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Exposure	Dose Level 1		Dose Level 2	All Patients N = 9
	Schedule I N = 3	Schedule II N = 3	Schedule I N = 3	
Number of SENTI-202 treatment cycles, median (range)	2 (1, 2)	2 (1, 2)	**2 (1, 2)**	2 (1, 2)
Subjects continuing treatment as of data-cut, n (%)	0	2 (67)	**0**	2 (22)
Subjects discontinuing treatment, n (%)	3 (100)	1 (33)	**3 (100)**	7 (78)
Adverse Event	0	0	**0**	0
Achieved Optimal Response (cCR)	2 (67)	0	**2 (67)**	4 (44)
Disease Progression/ Stable Disease	1 (33)	1 (33)	**1 (33)**	3 (33)

- Median of 2 cycles across dose cohorts
- Majority of patients discontinued SENTI-202 after achieving cCR with none discontinuing due to adverse event

preliminary RP2D

Data from an open clinical database of an ongoing study as of 7 Apr 2025; cCR: composite CR includes CR, CRh, CRi

Preliminary Safety Data Indicate that SENTI-202 is Well Tolerated

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Any Grade 3-4* AEs Regardless of Relationship	Dose Level 1		Dose Level 2	All Patients N = 9
	Schedule I N = 3	Schedule II N = 3	Schedule I N = 3	
Any Grade ≥ 3 AEs	3 (100)	3 (100)	**3 (100) ^**	9 (100)
Febrile Neutropenia	1 (33)	1 (33)	**2 (67) ^**	4 (44)
Platelet Count Decreased	2 (67)	0	**2 (67) ^**	4 (44)
Anemia	1 (33)	1 (33)	**0**	2 (22)
Abdominal Pain	1 (33)	1 (33)	**0**	2 (22)

**No Grade 5 AEs, ^ 1 patient with G3 febrile neutropenia and G4 platelet count decreased assessed as possibly related to SENTI-202*

preliminary RP2D

SENTI-202 was well tolerated

- In general, G3-4 AEs on study were hematologic, unrelated to SENTI-202 and consistent with R/R AML patients receiving LD
- No single type of SAE reported in > 1 patient
- No significant difference in AE profile across dose cohorts

AEs: treatment emergent adverse events includes adverse events with onset after SENTI-202 dosing and within 30 days of last dose of study treatment; Grading per CTCAE v5.0
Data from an open clinical database of an ongoing study as of 7 Apr 2025

SENTI-202 Related AEIs Were Low Grade and Manageable with Standard of Care

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Patient # (Dose Cohort)	Event Term (Grade)	Onset from SENTI-202 Dose (days)	Duration (days)
001-0004, (1)	Chills, G1	0	1
	Pyrexia, G1	0	1
008-005, (1)	Pyrexia, G1	0	5
	Hypotension, G1	3	1
102-007, (prelim. RP2D)	Pyrexia, G1	1	1
	Hypoxia, G2	1	1

- 3 pts experienced G1 pyrexia with either hypotension or hypoxia in 1 each, typically within 1 day of SENTI-202 dosing that were reported as Cytokine Release Syndrome (CRS)
  - Events resolved rapidly with standard of care; None were serious
- Likely represent delayed infusion reactions described with NK cell therapies
- No other AEIs or DLTs reported on study

AEIs: AEs of Interest; Grading per ASTCT criteria
Data from an open clinical database of an ongoing study as of 7 Apr 2025

Responses Observed Across All Dose Cohorts

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Best Overall Response on Study, n (%)	Dose Level 1		Dose Level 2	All Patients N = 7*
	Schedule I N = 3	Schedule II N = 1*	Schedule I N = 3	
Overall Response Rate (ORR)	2 (67)	1 (100)	**2 (67)**	5 (71)
composite CR Rate (cCR)^	2 (67)	0	**2 (67)**	4 (57)
Negative MRD Status in cCR Patients	2/2 (100)	N/A	**2/2 (100)**	4/4 (100)
Response Category, n(%)				
CR	2 (100)	0	**1 (33)**	3 (43)
CRh	0	0	**1 (33)**	1 (14)
MLFS	0	1 (100)	**0**	1 (14)
SD	0	0	**1 (33)**	1 (14)
PD	1 (33)	0	**0**	1 (14)

**Two patients continuing into second Cycle after achieving SD with blast reduction from 31% to 13% and 5% to 3% respectively are excluded from best overall response assessment; ^CR + CRh + CRi*

preliminary RP2D

AML Response

- 5 of 7 patients overall achieved ORR
- 2/3 and 4/7 patients achieved cCR respectively in preliminary RP2D cohort and across all patients
- 4/4 cCR patients were MRD-
- All cCR responses are ongoing as of data-cut with median duration of response not reached

Data from an open clinical database of an ongoing study as of 7 Apr 2025

Rapid Bone-Marrow Blast Reduction Observed Across All Dose Cohorts

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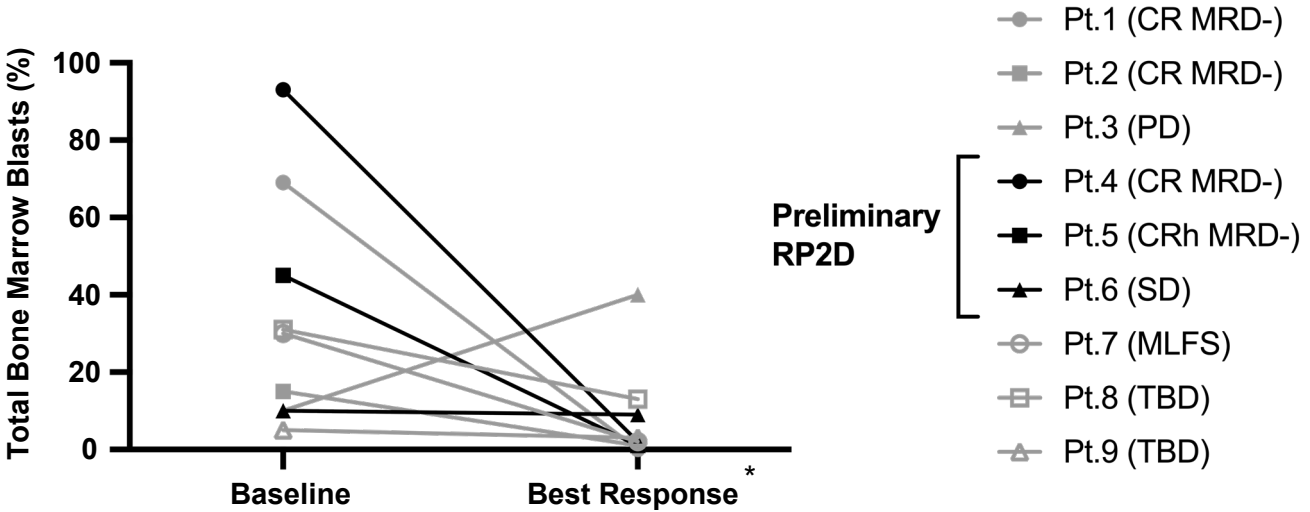

* End of cycle 1 for patients 8 and 9

Blast reduction noted in majority of patients across all dose cohorts

Data from an open clinical database of an ongoing study as of 7 Apr 2025

Early Deep Responses Noted Across Dose Levels with Durability 8+ months

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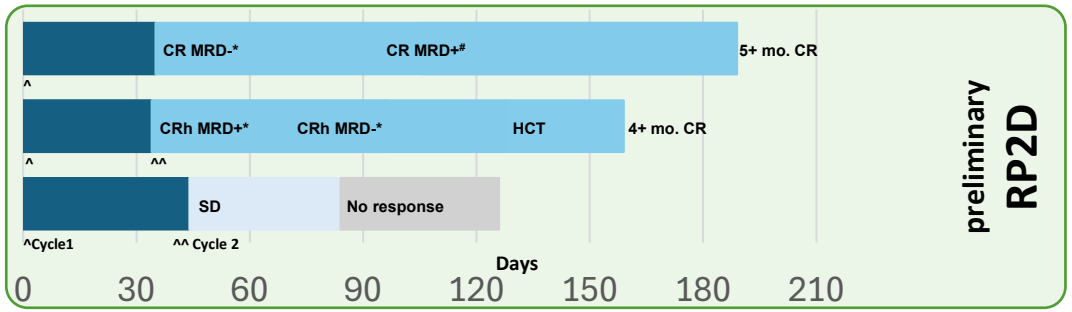
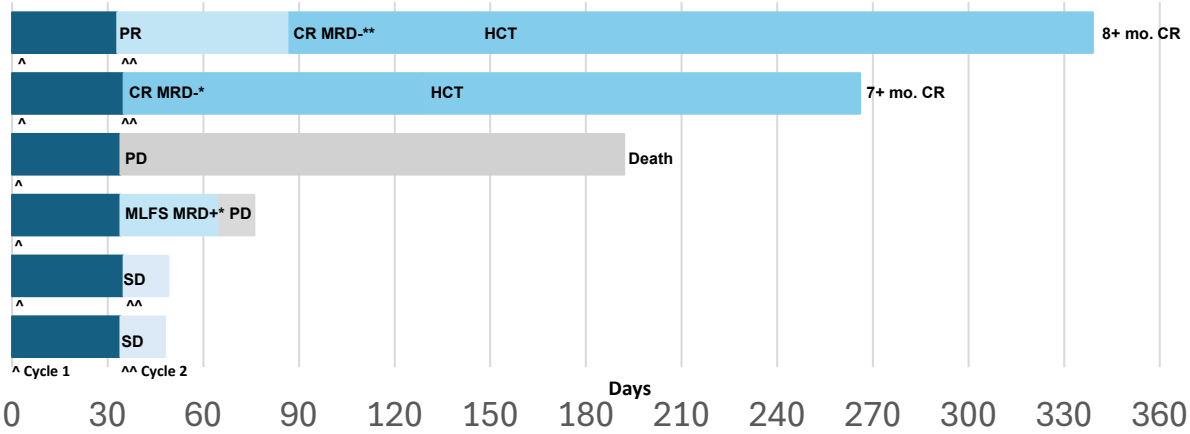
Pt	I⁰ Ref	Adv. Risk	FA Exp	FA Ref
Pt4	Yes	Yes	Yes-both	Yes-both
Pt5	No	Yes	Yes-both	No
Pt6	Yes	Yes	Yes	Yes

Pt	I⁰ Ref	Adv. Risk	FA Exp	FA Ref
Pt1	No	Yes	Yes	No
Pt2	No	No	Yes	No
Pt3	Yes	Yes	Yes	Yes
Pt7	Yes	No	Yes-both	Yes-both
Pt8	Yes	Yes	Yes	Yes
Pt9	Unk	Yes	Yes-both	Unk



*MRD by multi-parametric flow (sensitivity ≤ $1/10^{-4}$),

**MRD by NGS (sensitivity ≤ $1/10^{-2}$)



I⁰ Ref: Primary refractory defined as failure to achieve cCR or cCR lasting <3 mo with front-line therapy; Adv. Risk: Adverse Risk genetics by ELN 2022; FA Exp: fludarabine and/or Ara-C Exposed, both indicates exposed to both agents; FA Ref: Fludarabine and/or Ara-C refractory (failure to achieve cCR or cCR lasting < 3 mo), both indicates refractory to both agents; #Patient had detectable IDH2 mutation by NGS while in morphologic remission and started on venetoclax/enasidenib; Data from an open clinical database of an ongoing study as of 7 Apr 2025

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CyTOF Bone Marrow Data Reveals SENTI-202 Treatment Results in Decreased LSCs in Responders

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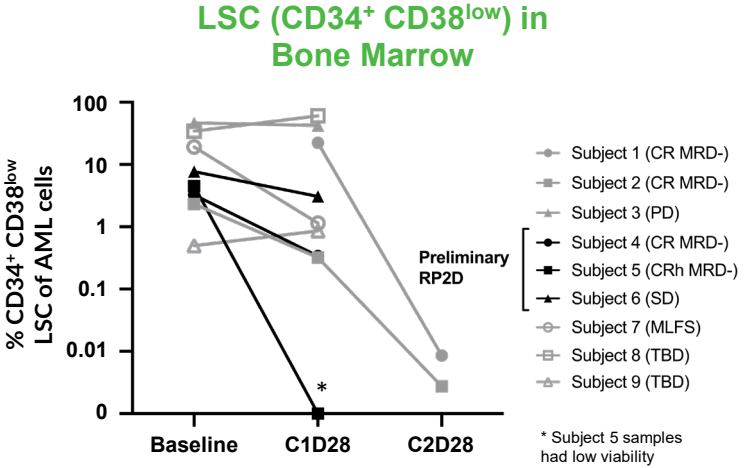
LSCs in bone marrow at baseline are largely non-cycling when analyzed by Ki67 and IdU



- CyTOF measured 49 different proteins in serial bone marrow derived mononuclear cells samples from baseline and end of each Cycle
- At baseline, majority of leukemia stem cells (LSCs) were in G0 phase and not expected to be susceptible to chemotherapy
- With SENTI-202 treatment, LSCs decreased > 10-fold in all patients who achieved cCR

IdU: 5-Iodo-2'-Deoxyuridine; Data from an open clinical database of an ongoing study as of 7 Apr 2025

Rapid Normalization of Peripheral Blood Cell Count along with Protection of BM HSPCs in Patients who Achieved cCR

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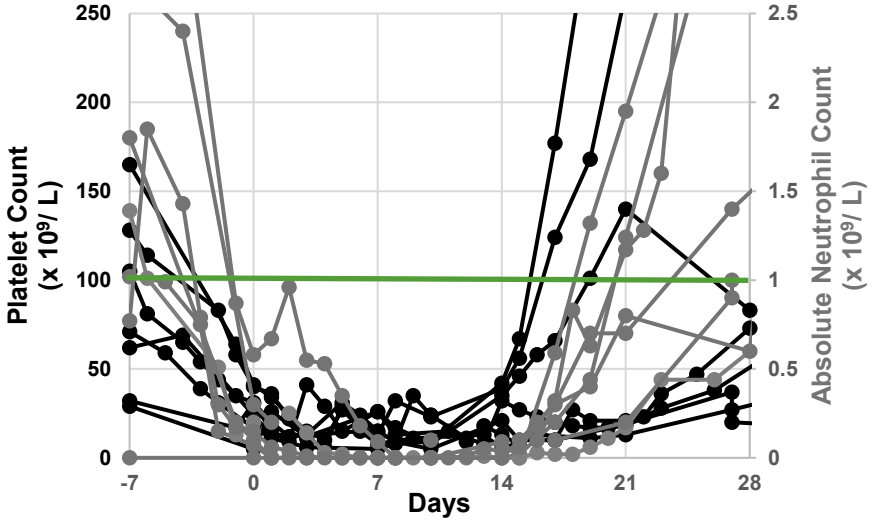
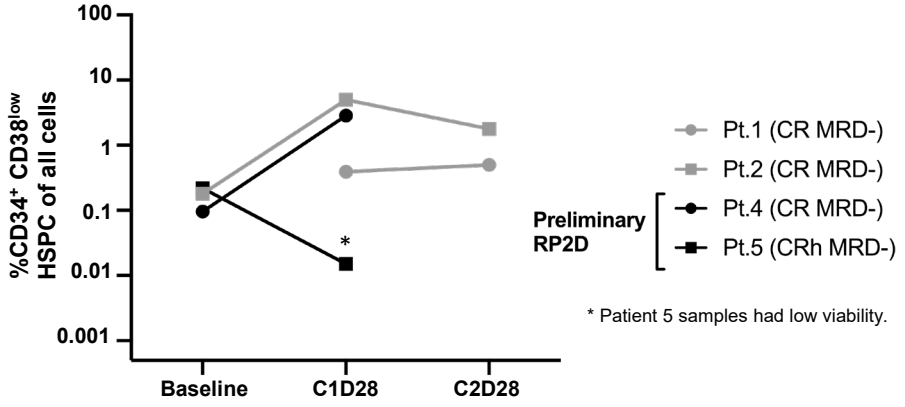
Peripheral Blood Cell Counts



HSPC (CD34⁺ CD38^{low}) in Bone Marrow (BM)



Rapid blood cell count recovery in periphery in patients who achieved cCR

- Median of 21 days for neutrophil count ≥ 0.5 and 1 x10^9/ L, and 28/35 days to platelet count ≥ 50 and 100 x10^9/ L
- CyTOF analyses revealed HSPCs were maintained or increased in bone marrow of patients who achieved cCR consistent with SENTI-202 Logic Gate mechanism of action

Data from an open clinical database of an ongoing study as of 7 Apr 2025

Senti-202 Is Detected in Periphery of All Treated Patients Consistent with Allo-NK Profile

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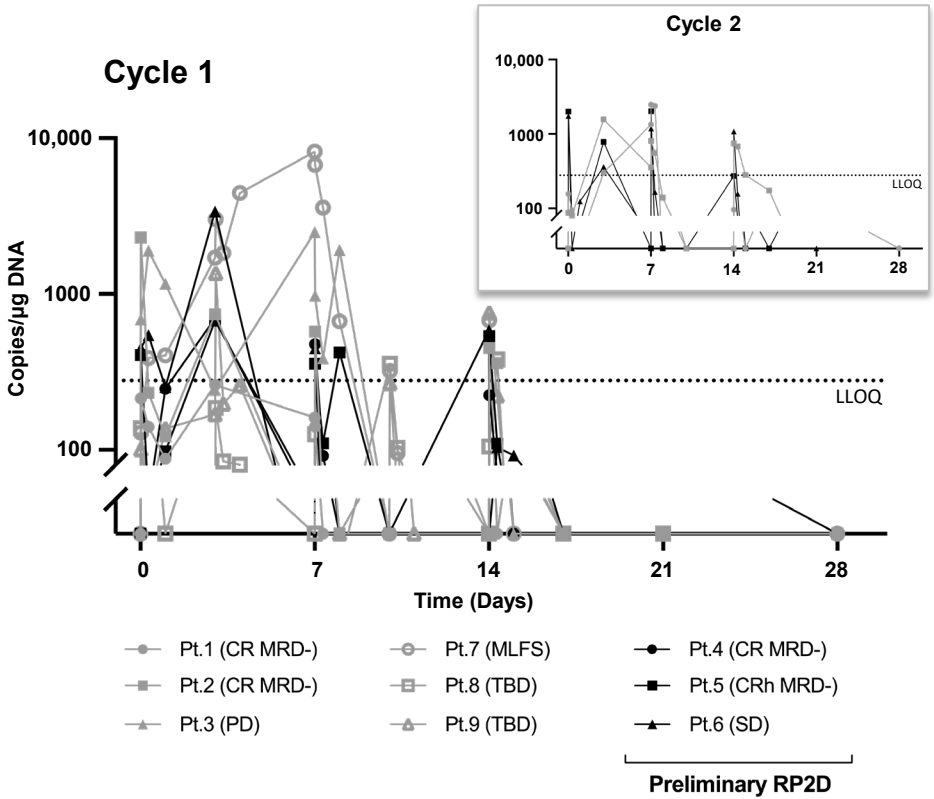

- PK profile consistent with allogeneic NK cell therapy
  - Modest peripheral expansion in first 14 days consistent with NK biology and safety of SENTI-202
  - Clearance >14 days from periphery
- No significant difference in exposure across patients who achieved cCR or not
- No significant difference in exposure across Dose Cohorts
- No significant difference in exposure between Cycle 1 and 2

Interim PK data as of 7 Apr 2025; value of 1 assigned for timepoints with non-measurable transgene, LLOQ estimated using equivalent DNA loading and is the lower limit of quantitation

Dosing and Safety Conclusions- SENTI-202 Well Tolerated in R/R AML Patients

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- SENTI-202 is a First-In-Class Off-the-Shelf Logic Gated selective CD33 OR FLT3 NOT EMCN CAR NK cell therapy
  - Designed to selectively kill both AML blasts and LSCs while protecting healthy HSPCs with a novel OR/NOT logic gated gene circuit
- SENTI-202-101 trial enrolled heavily treated R/R AML patients with poor prognosis
- SENTI-202 is well tolerated
  - Most frequent Grade 3+ AEs were hematologic and consistent with R/R AML patients receiving LD
  - MTD not reached and preliminary RP2D identified as 1.5B cells/ dose x 3 weekly doses/ 28 days

Efficacy Conclusions- Promising Preliminary Efficacy Noted with SENTI-202 in R/R AML Patients

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- Efficacy
  - 5/7 ORR and 4/7 cCR across all patients including 2/3 cCR in preliminary RP2D cohort
  - 4/4 cCR MRD- as assessed per local standard of care
  - All cCR patients maintaining morphologic remission with longest follow up of 8+ mo
- PK
  - SENTI-202 detected in all treated patients, consistent with other allogeneic CAR NK cell therapy PK profiles and its well-tolerated safety profile
- CyTOF analyses of BM
  - SENTI-202 treatment decreased LSC frequencies and maintained (or increased) healthy HSPC frequencies in patients achieving cCR consistent with SENTI-202 Logic Gated gene circuit design

Also at AACR…

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- First-In-Human, Multicenter Study of SENTI-202, a CD33/FLT3 Selective Off-the-Shelf Logic Gated CAR NK Cell Therapy in Hematologic Malignancies including AML: Correlative Data (#10977)

  Session: PO.CT01.02 - First-in-Human Phase I Clinical Trials 2

  Location: Section 48, #9

  Time: 4/29/2025 9:00:00 - 12:00:00 PM

- SENTI-202 CD33 OR FLT3 NOT EMCN Logic-Gated Gene Circuit Components Selectively Target AML while Protecting Human HSC/HPCs from Off-Tumor Toxicity in a Humanized Mouse Model (#6833)

  Session: PO.IM01.17 - Novel In Vivo, In Vitro, and In Silico Models

  Location: Section 38, #18;

  Time: 4/30/2025 9:00:00 - 12:00:00 PM

Acknowledgements

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- **We deeply appreciate our Patients and their caregivers**
- Clinical and research staff at all participating Institutions
  - **United States:**
    - SCRI at TriStar Centennial, Nashville, TN
    - Colorado Blood Cancer Institute, Denver CO
    - Methodist Physician Practices, PLLC, San Antonio
    - The University of Texas M.D. Anderson Cancer Center, Houston, TX
    - UCLA Department of Medicine, Los Angeles, CA
  - **Australia:**
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