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Abstract CT014: 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 FREE

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Abstract

Relapsed/refractory (R/R) AML is associated with poor outcomes. Preclinical studies have shown that SENTI-202, a first-in-class CAR NK cell therapy, selectively kills AML blasts and leukemia stem cells (LSCs) while sparing hematopoietic stem & progenitor cells (HSPCs) via its Logic Gated CAR design (Kaveri, 2024). Here, we report interim clinical trial data in patients with R/R AML who received SENTI-202. Interim correlative results are submitted as a separate abstract. SENTI-202-101 is an ongoing multicenter Phase 1 dose finding study in adult patients (pt) with R/R hematologic malignancies including AML (NCT06325748). 2 SENTI-202 Dose Levels (DLs): 1e9 & 1.5e9 CAR NK cells/dose & 2 Schedules: 3 or 5 doses/ 28-day Cycle (I on Days 0, 7, 14; & II on Days 0, 3, 7, 10, 14, respectively), following lymphodepletion (LD) with fludarabine and cytarabine are being evaluated. Adverse events (AEs) including dose limiting toxicities (DLT) are graded per CTCAEv5 or ASTCT criteria. Efficacy is assessed by investigator per ELN 2022 and measurable residual disease (MRD) is assessed locally. Pharmacokinetics (PK) is assessed at multiple timepoints by ddPCR detection of transgene in peripheral blood (PB) and cytometry by time of flight (CyTOF) is conducted on serial bone marrow (BM) samples. As of 6 Jan 2025, 6 R/R AML pts with a median age 63.5 years (range 26, 72) were treated across both DLs in Schedule I with median 4.5 (3, 6) SENTI-202 doses. At baseline, the median time from diagnosis was 0.95yr (0.5, 6.2), with a median of 1.5 (1, 3) prior lines & median BM blasts 41.82% (8.9, 92.5). SENTI-202 was well tolerated with no DLTs. Grade (G) 3-4 AEs in > 1 pt were febrile neutropenia and decreased platelet count (3 pts each), all unrelated to SENTI-202 except 1 pt with decreased platelets; and all related to LD. SENTI-202 related AEs in > 1 pt were G1-2 pyrexia reported as CRS (3 pts). There were no G5 AEs or SENTI-202 related SAEs. 4 of 6 response evaluable pts achieved composite complete remission (cCR) across both DLs (3 CRs,

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1 CRh currently receiving a 2nd cycle). 3/3 CRs were MRD-. All responses are ongoing at time of data cut with longest follow up of 5+ months & 2 pts receiving post treatment BM transplant. SENTI-202 transgene was detected in PB up to Day 15 in all 5 patients with PK data. Preliminary CyTOF analyses of BM showed a decrease in LSCs & maintenance/expansion of HSPCs in responders. Interim clinical data from ongoing Phase 1 trial reveals a well-tolerated safety profile for SENTI-202 administered after LD. 4/6 patients achieved cCR with all 3 CR patients being MRD- as assessed locally and responses ongoing. Preliminary PK profile is consistent with allogeneic NK cell therapies and CyTOF analyses reveal LSC killing & HSPC protection consistent with SENTI-202 Logic Gated Gene Circuit design. Dose finding is ongoing & additional data from pts in Schedule II will be reported.

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