CAR T-Cell Therapy Study

KITE-222

KT-US-486-0201

KITE-222 (Anti-CLL-1 CAR T) in Adult Participants With Relapsed/Refractory De Novo or Secondary Acute Myeloid Leukemia

NOW ENROLLING

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Study Design[1,2]

Phase 1

R/R de novo or secondary AML (n≈40)

- Cohort 1: KITE-222 $2x10^7$ (<50 kg) to $3x10^7$ (≥50 kg)
- Cohort 2: KITE-222 $7x10^7$ (<50 kg) to $1x10^8$ (≥50 kg)
- Cohort 3: KITE-222 $2x10^8$ (<50 kg) to $3x10^8$ (≥50 kg)

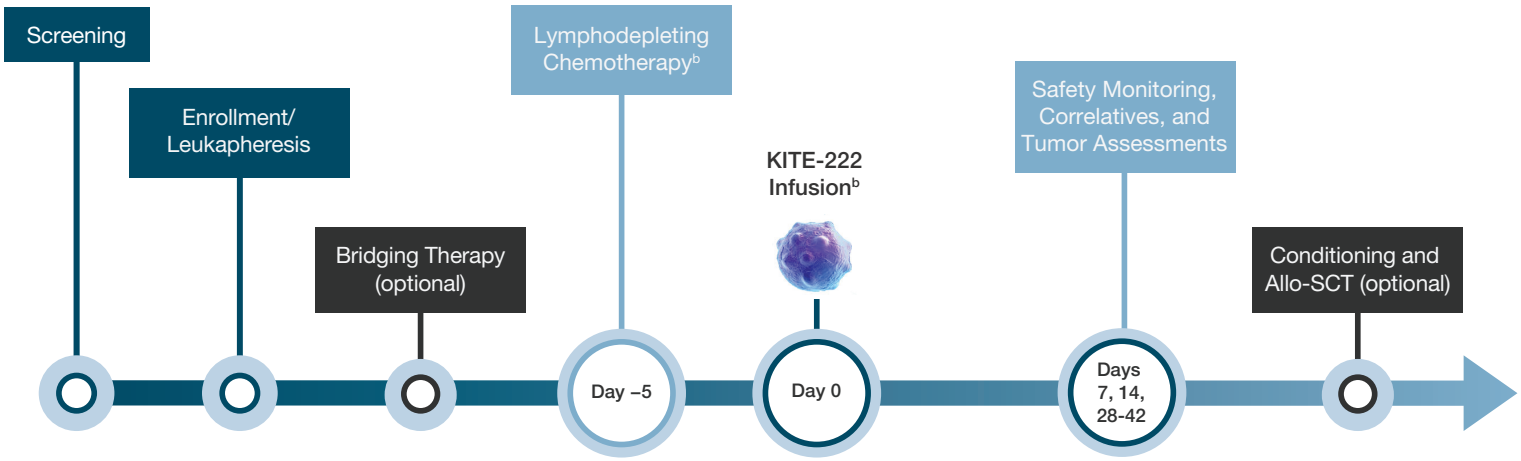
Primary End Point

- Percent of patients experiencing DLTs

Key Secondary End Points

- Safety
- Percent of patients experiencing clinically significant changes in laboratory parameters
- Time to neutrophil and platelet recovery
- CCR rate (CR + CRMRD-negative + CRi) per investigator assessment[a]
- ORR (CR + CRMRD- + CRi + MLFS + PR) per investigator assessment[a]
- RFS
- Allo-SCT rate
- EFS
- OS
- 30- and 60-day MR
- PK/PD
- Incidence of anti-KITE-222 antibodies

Treatment Schema[1,2]



[a]ELN 2017 classification.
[b]KITE-222 treatment consists of lymphodepleting chemotherapy with cyclophosphamide and fludarabine on day –5, followed by a single target starting dose of CAR T cells on day 0.

The safety and efficacy of these investigational agents and/or uses have not been established. There is no guarantee that the investigational therapies or uses will be commercialized. Visit ClinicalTrials.gov for more information on trial inclusion and exclusion criteria. ClinicalTrials.gov: NCT04789408.

Eligibility Criteria[1,2]

Key Inclusion Criteria

- Age ≥18 years
- R/R de novo or secondary AML
- Morphological disease in bone marrow and/or peripheral blood within 28 days of enrollment
- Prior exposure to relevant agent class for patients with AML characterized by a mutation targeted by an approved therapy
- Institutional criteria for allo-SCT fitness must be met: patients must have an identified stem-cell donor readily available for potential allo-SCT after therapy with KITE-222
- ECOG PS of 0 or 1
- Adequate hematologic status
- Adequate renal, hepatic, pulmonary, and cardiac function

Key Exclusion Criteria

- Diagnosis of APL
- Auto-SCT within 6 weeks before enrollment
- DLI within 28 days before enrollment
- GVHD treatment within 4 weeks before enrollment
- Acute GVHD grade II-IV by Mount Sinai Acute GVHD International Consortium criteria
- Active CNS disease involvement
- Requirement or possible requirement for urgent therapy due to ongoing or impending oncologic emergency (eg, leukostasis or TLS)
- History of CLL-1–directed therapy or genetically modified T-cell therapy
- History of malignancy other than melanoma skin cancer or carcinoma in situ unless disease-free for ≥3 years after last definitive therapy
- History of severe hypersensitivity reaction to aminoglycosides
- History of concomitant genetic syndrome associated with bone marrow failure
- Genetic syndrome that increases risk of allo-SCT, including Down syndrome
- History of cardiovascular disease within 12 months before enrollment
- History of symptomatic DVT or pulmonary embolism within 6 months before enrollment or history of upper-extremity line–related DVT within 3 months of conditioning chemotherapy
- Presence or suspicion of a fungal, bacterial, viral, or other infection that is uncontrolled or requiring antimicrobials for management
- Live vaccine ≤4 weeks before enrollment

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References: 1. ClinicalTrials.gov. Accessed October 14, 2021. https://clinicaltrials.gov/ct2/show/NCT04789408. **2.** Data on file. Kite Pharma, Inc; 2021.

allo-SCT, allogeneic stem cell transplant; AML, acute myeloid leukemia; APL, acute promyelocytic leukemia; auto-SCT, autologous stem cell transplant; CAR T, chimeric antigen receptor; CCR, composite complete remission; CLL-1, C-type lectin-like molecule-1; CNS, central nervous system; CR, complete response; CRi, complete response with incomplete hematologic recovery; CRMRD, complete response without measurable residual disease; DLI, donor lymphocyte infusion; DLT, dose-limiting toxicity; DVT, deep vein thrombosis; ECOG PS, Eastern Cooperative Oncology Group performance status; EFS, event-free survival; ELN, European Leukemia Net; GVHD, graft-vs-host disease; MLFS, morphologic leukemia-free state; MR, mortality rate; ORR, overall remission rate; OS, overall survival; PD, pharmacodynamics; PK, pharmacokinetics; PR, partial remission; R/R, relapsed/refractory; RFS, relapse-free survival; TLS, tumor lysis syndrome.

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