CAR T-Cell Therapy Study

iMMagine-1

NCT05396885

A Phase 2, Multicenter Study Evaluating the Safety and Efficacy of Anitocabtagene Autoleucel (CART-ddBCMA) in Participants with Relapsed or Refractory Multiple Myeloma

NOW ENROLLING

Contact:
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Study Design

Phase 2

R/R multiple myeloma, 4L+

N≈110

Experimental arm: single IV dose of anitocabtagene autoleucel (115±10 × 10^6 CAR+ CART-ddBCMA cells)

Anitocabtagene autoleucel (CART-ddBCMA) is an autologous BCMA-directed CAR T-cell therapy using a novel, synthetic binding domain, called a D-Domain.

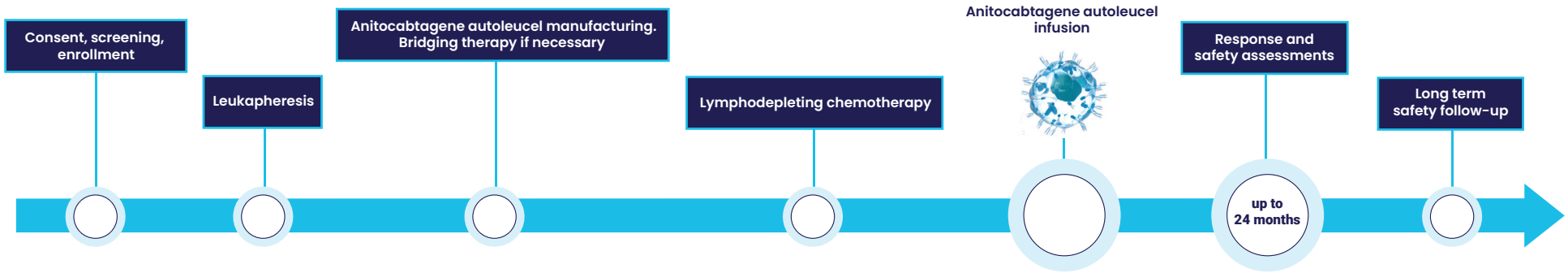
Primary Outcome Measures

- ORR, per IMWG criteria as assessed by IRC

Secondary Outcome Measures

- sCR or CR rate, per IMWG criteria as assessed by IRC
- ORR in patients limited to 3 prior LOT, per IMWG criteria as assessed by IRC
- Duration of response
- VGPR and PR rate
- Time to initial response
- PFS
- OS
- Safety profile of anitocabtagene autoleucel
- PK of anitocabtagene autoleucel
- HRQoL
- Anti-CART-ddBCMA antibodies
- MRD negativity
- Time to progression

Treatment Schema



The safety and efficacy of these investigational agents or investigational uses of marketed products have not been established. These uses have not been approved by the US Food and Drug Administration or other regulatory authorities. There is no guarantee that these therapies or uses will be commercialized.
Please visit ClinicalTrials.gov for more information on trial eligibility criteria and other study details. ClinicalTrials.gov Identifier: NCT05396885.

4L, fourth line; BCMA, B cell maturation antigen; CAR, chimeric antigen receptor; HRQoL, health related quality of life; IMWG, International Myeloma Working Group; IRC, independent review committee; IV, intravenous; LOT, line of therapy; MRD, minimal residual disease; ORR, overall response rate; OS, overall survival; PFS, progression-free survival; PK, pharmacokinetics; PR, partial response; R/R, relapsed or refractory; sCR, stringent complete response; VGPR, very good partial response

Eligibility Criteria

Key Inclusion Criteria

- 18 Years and older
- Relapsed or refractory multiple myeloma:
  - ≥3 prior regimens of systemic therapy including a PI, iMiD®, and anti-CD38 antibody
  - Refractory to last line of therapy
  - For each line, 2 consecutive cycles are required unless best response after 1 cycle was PD

Note: IMWG criteria define refractory disease as disease progression on or within 60 days of a therapy.

- Documented measurable disease
  - Serum M-protein ≥1 g/dL
  - Urine M-protein ≥200 mg/24 hours
  - Involved serum free light chain ≥10 mg/dL with abnormal κ/λ ratio (ie, >4:1 or <1:2)
- ECOG PS 0-1
- Adequate bone marrow, renal, hepatic, pulmonary, and cardiac function
- Resolution of AEs from any prior systemic anticancer therapy, radiotherapy, or surgery to grade 1 or baseline (except grade 2 alopecia and grade 2 sensory neuropathy)

Key Exclusion Criteria

- Plasma cell leukemia or history of plasma cell leukemia
- Any of the following prior therapies:
  - Systemic treatment for multiple myeloma or high-dose systemic steroid therapy within the 14 days prior to leukapheresis
  - Gene therapy or gene-modified cellular immune therapy
  - BCMA-directed therapy
  - Autologous stem cell transplant within 3 months prior to leukapheresis
  - Allogeneic stem cell transplant
- Solitary plasmacytomas without evidence of other measurable disease
- Active CNS involvement by malignancy or any sign of active or prior CNS pathology[a]
- Active malignancy not related to myeloma that has required therapy in the last 3 years or is not in complete remission[b]
- Active hepatitis B or C infection at the time of screening,[c] or HIV seropositive
- Severe or uncontrolled intercurrent illness or laboratory abnormalities[d]
- Any significant medical condition, laboratory abnormality, or psychiatric illness that would prevent the subject from participating in study (or full access to medical records) as written including follow-up, the interpretation of data, or place the subject at unacceptable risk
- Any vaccine ≤6 weeks before leukapheresis and/or anticipation of the need for such a vaccine during subject's participation in the study

Nearest Trial Site:

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PI at Nearest Trial Site:

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PI's Contact Information:

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Note: Other protocol-defined inclusion or exclusion criteria may apply.

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Reference: ClinicalTrials.gov. Accessed October 3, 2023. https://www.clinicaltrials.gov/study/NCT05396885

[a]Including but not limited to history of epilepsy, seizure, paresis, aphasia, stroke, subarachnoid hemorrhage or CNS bleed, severe brain injury, dementia, cerebellar disease, Parkinson's disease, organic brain syndrome or psychosis. [b]Exceptions to this criterion include successfully treated nonmetastatic basal cell or squamous cell skin carcinoma, or prostate cancer that does not require therapy. [c]Subjects with history of treated hepatitis B or C and have nondetectable viral DNA are eligible. [d]Including but not limited to active infection, symptomatic CHF, other cardiac disease (unstable angina, arrhythmia, or MI within 6 months prior to screening), significant pulmonary dysfunction, uncontrolled thromboembolic events or recent severe hemorrhage within 1 year, PE within 12 months or DVT within 3 months of enrollment, autoimmune disease requiring immunosuppressive therapy within the last 24 months.

AEs, adverse event; BCMA, B cell maturation antigen; CHF, congestive heart failure; CNS, central nervous system; DVT, deep vein thrombosis; ECOG PS, Eastern Cooperative Oncology Group performance status; HIV, human immunodeficiency virus; HSCT, hematopoietic stem cell transplant; IMiD®, immunomodulatory drugs; IMWG, International Myeloma Working Group; MI, myocardial infarction; PD, progressive disease; PE, pulmonary embolism; PI, proteasome inhibitor

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