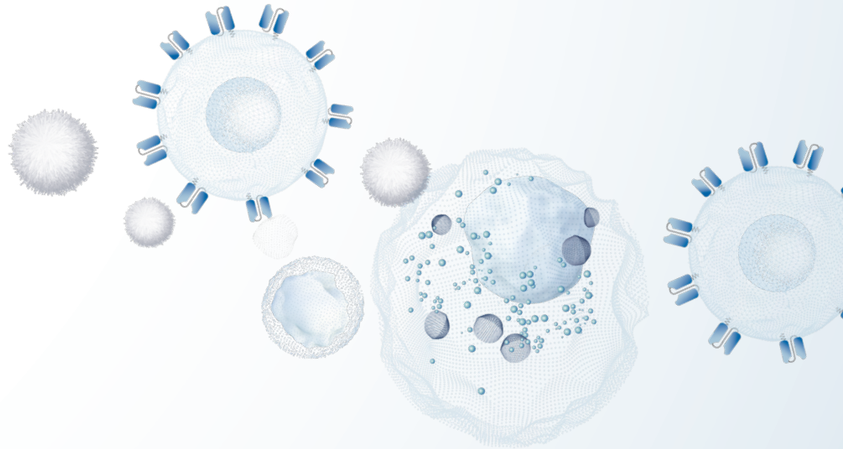
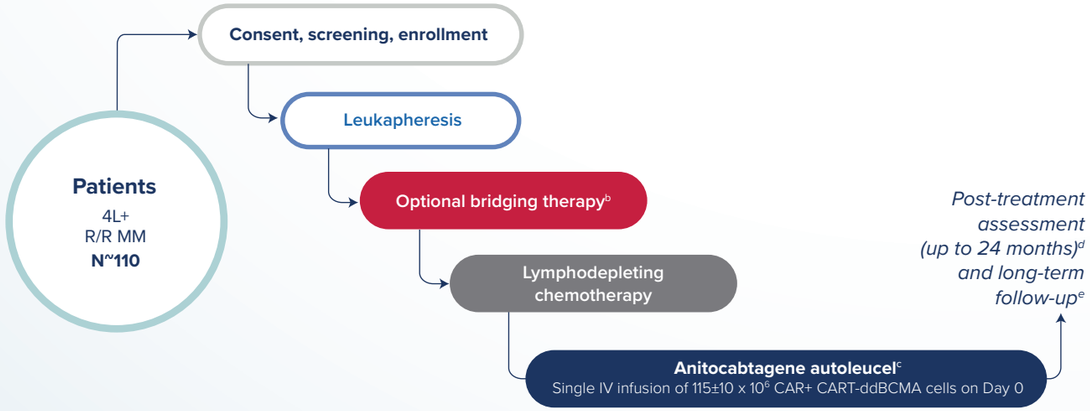
ClinicalTrials.gov Identifier: NCT05396885

iMMagine-1: A Phase 2, Multicenter Study Evaluating the Safety and Efficacy of Anitocabtagene Autoleucel (CART-ddBCMA) in Participants With Relapsed or Refractory Multiple Myeloma[a]



Study Design[1,2]



[a]In collaboration with Arcellx. [b]If necessary, bridging therapy is allowed to control growth of MM disease while CART-ddBCMA is being manufactured. [c]CART-ddBCMA drug product (anitocabtagene autoleucel) consists of autologous T cells that have been genetically modified ex vivo to express a D-domain Chimeric Antigen Receptor (CAR), followed by a cluster of differentiation 8 (CD8) hinge and transmembrane region that is fused to the intracellular signaling domains for 4-1BB and CD3ξ, that specifically recognizes B-cell maturation antigen (BCMA). The active substance of CART-ddBCMA is CAR+ CD3+ T cells that have undergone ex vivo T-cell activation, gene transfer by replication-deficient lentiviral vector, and expansion. [d]Following a single infusion of CART-ddBCMA, both safety and efficacy data will be assessed. Efficacy will be assessed monthly for the first 6 months, then quarterly up to study completion, or upon patient relapse. [e]Long-term safety data will be collected under a separate long-term follow-up study for up to 15 years per health authority guidelines.

4L, fourth line; CAR, chimeric antigen receptor; IV, intravenous; MM, mulitple myeloma; R/R, relapsed or refractory.

Endpoints[1,2]

Primary Endpoint

- ORR[f]

Secondary Endpoints

- sCR or CR rate[f]
- ORR in patients limited to 3 prior LOT[f]
- DOR
- VGPR and PR rate
- Time to initial response
- PFS
- OS
- Safety profile
- PK
- HRQoL
- Anti-CART-ddBCMA antibodies
- MRD negativity
- Time to progression

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[f]Per IMWG criteria as assessed by IRC.

DOR, duration of response; CR, complete response; HRQoL, health-related quality of life; IMWG, International Myeloma Working Group; IRC, independent review committee; LOT, line of therapy; MRD, minimal residual disease; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PK, pharmacokinetics; PR, partial response; sCR, stringent complete response; VGPR, very good partial response.

The safety and efficacy of these investigational agents and/or uses have not been established. There is no guarantee that they will become commercially available.

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Key Eligibility Criteria[1,2,a]

Key Inclusion Criteria

- ≥18 years of age
- Relapsed or refractory MM with ≥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
  - Note: Induction treatment with or without hematopoietic stem cell transplant and with or without maintenance is considered a single regimen
- Documented measurable disease including at least one or more of the following criteria:
  - 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)
- Life expectancy >12 weeks
- Male and female participants of childbearing potential must agree to use highly effective methods of birth control through 12 months after the dose of study treatment
- Willing to comply with and able to tolerate study procedures, including consent to participate in separate long-term safety follow-up lasting up to 15 years per FDA guidance
- Subject's leukapheresis product from non-mobilized cells is received and accepted for cell processing by manufacturing site.
  - NOTE: Leukapheresis will be performed only after all other eligibility criteria are confirmed

[a]Other protocol defined Inclusion/Exclusion criteria may apply.

AEs, adverse events; CD, cluster of differentiation; ECOG PS, Eastern Cooperative Oncology Group performance status; FDA, The Food and Drug Administration; IMiD®, immunomodulatory drug; IMWG, International Myeloma Working Group; PD, progressive disease; PI, proteasome inhibitor.

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Key Eligibility Criteria[1,2,a] (cont'd)

Key Exclusion Criteria

- Plasma cell leukemia or history of plasma cell leukemia
- Any of the following prior therapies:
  - Systemic treatment for MM 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[b]
- History of allergy or hypersensitivity to study drug components
- Contraindication to fludarabine or cyclophosphamide
- Active malignancy not related to myeloma that has required therapy in the last 3 years or is not in complete remission[c]
- Active hepatitis B or C infection at the time of screening,[d] or HIV seropositive
- Severe or uncontrolled intercurrent illness or laboratory abnormalities[e]
- 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

[a]Other protocol defined Inclusion/Exclusion criteria may apply. [b]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. [c]Exceptions to this criterion include successfully treated nonmetastatic basal cell or squamous cell skin carcinoma, or prostate cancer that does not require therapy. [d]Subjects with history of treated hepatitis B or C and have nondetectable viral DNA are eligible. [e]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.

BCMA, B-cell maturation antigen; CHF, congestive heart failure; CNS, central nervous system; DNA, deoxyribonucleic acid; DVT, deep vein thrombosis; HIV, human immunodeficiency virus; MI, myocardial infarction; MM, multiple myeloma; PE, pulmonary embolism.

References

1. Clinicaltrials.gov website. Accessed July 8, 2024. https://www.clinicaltrials.gov/study/NCT05396885
2. Data on file. Gilead Sciences, Inc.; 2022.

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