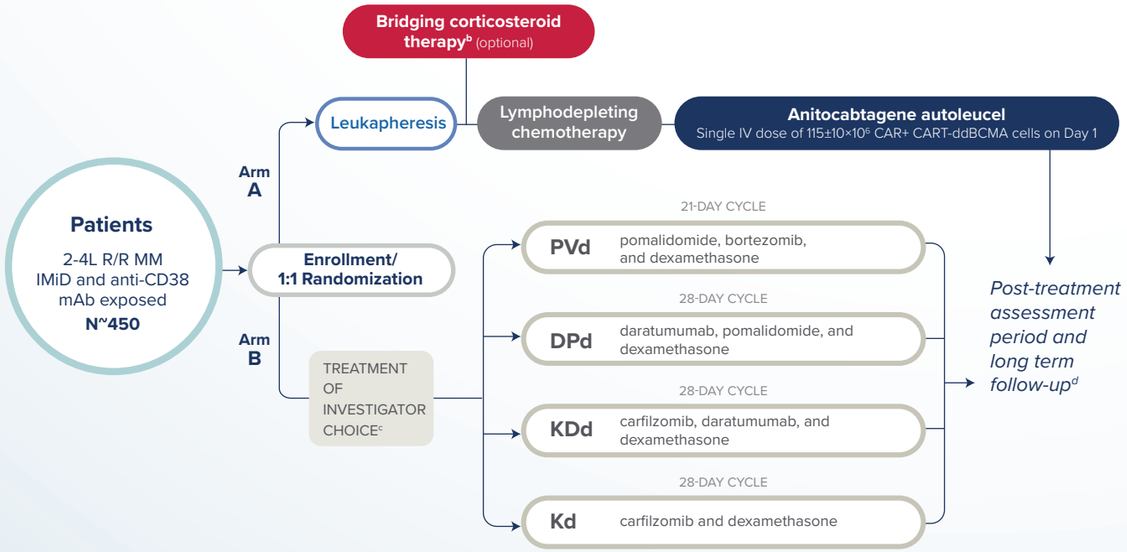
ClinicalTrials.gov Identifier: NCT06413498

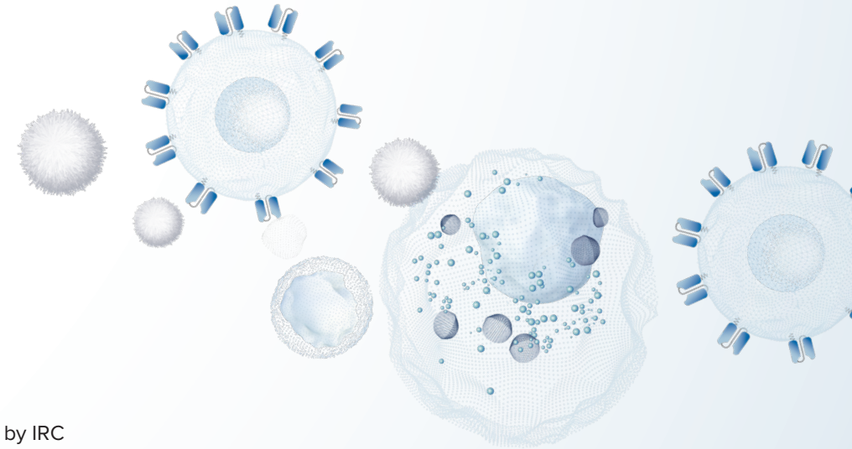
iMMagine-3: A Phase 3, Randomized, Open-Label Study to Compare the Efficacy and Safety of Anitocabtagene Autoleucel Versus Standard of Care Therapy in Participants With Relapsed/Refractory Multiple Myeloma

Study Design[1,2]



[a]Bridging therapy, if used, will be with the selected standard-of-care regimen per investigator discretion. [b]Cycles will continue until unacceptable toxicity, progression per IMWG criteria, or participant withdrawal of consent, whichever occurs first. [c]All participants who will receive anitocabtagene autoleucel will be followed in the post-treatment follow-up period and will transition to a separate long-term follow-up study.

BCMA, B-cell maturation antigen; CAR, chimeric antigen receptor; IMiD, immunomodulatory drug; mAb, monoclonal antibody; IMWG, International Myeloma Working Group; MM, multiple myeloma; R/R relapsed or refractory.



Endpoints[1,2]

Primary Endpoint

- PFS, per IMWG criteria as assessed by IRC

Secondary Endpoints

- CR/sCR rate, per IMWG criteria as determined by IRC
- Overall MRD negativity (minimum, 10^{-5})
- OS
- ORR
- MRD-negative CR/sCR and MRD-negative VGPR+
- Sustained MRD negativity
- DOR
- Time to progression
- Time to next treatment
- TEAEs
- Anti-anitocel CAR antibodies
- Replication-competent lentivirus+
- EORTC-QLQ-C30 score
- EORTC-QLQ-MY20 score
- EQ-5D-5L score
- HCRU

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DOR, duration of response; CD38, cluster of differentiation 38; CR, complete response; EORTC-QLQ-C30, European Organization for Research and Treatment of Cancer quality of life questionnaire; EORTC-QLQ-MY20, European Organization for Research and Treatment of Cancer quality of life multiple myeloma questionnaire; EQ-5D-5L, European quality of life 5-dimension 5-level scale; HCRU, healthcare resource utilization; IRC, independent review committee; IV, intravenous; MRD, measurable residual disease; ORR, overall response rate; OS, overall survival; PR, partial response; sCR, stringent complete response; TEAE, treatment-emergent adverse event; 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
- ECOG PS of 0 or 1
- Documented evidence of progressive disease, per IMWG within 12 months of the last dose of the last regimen
- Measurable disease at screening per IMWG criteria
  - Serum M protein of ≥0.5 g/dL or urine M protein of ≥200 mg/24 hours; or
  - Light chain MM without measurable disease in the serum or urine: serum free light chain of ≥10 mg/dL and abnormal serum free light chain ratio
- Received 1 to 3 prior lines of therapy, including an IMiD and anti-CD38 mAb
  - Minimum of 2 consecutive cycles required
  - IMiD and anti-CD38 mAb do not need to be from the same regimen
- Eligible to receive PVd, DPd, KDd, or Kd, as determined by investigator

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

DPd, daratumumab, pomalidomide, and dexamethasone; ECOG PS, Eastern Cooperative Oncology Group performance status; IMiD, immunomodulatory drug; IMWG, International Myeloma Working Group; Kd, carfilzomib and dexamethasone; KDd, carfilzomib, daratumumab, and dexamethasone; mAb, monoclonal antibody; MM, multiple myeloma; PVd, pomalidomide, bortezomib, and dexamethasone.

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

Key Exclusion Criteria

- Any of the following prior therapies:
  - BCMA-directed therapy
  - T-cell engager therapy
  - CAR T-cell therapy or other genetically modified T-cell therapy
  - Auto-SCT within 12 weeks before randomization
  - Allo-SCT
  - High-dose systemic steroid therapy, or other immunosuppressive therapy within 14 days of randomization
- Active or prior history of CNS or meningeal involvement of MM
- Cardiac atrial or ventricular MM involvement
- History of or active plasma cell leukemia, Waldenström macroglobulinemia, POEMS syndrome, or amyloidosis
- Active malignancy (other than MM) requiring ongoing treatment within the last 24 months
- Myelodysplastic syndrome (even without ongoing treatment) is not permitted
- Contraindication to fludarabine or cyclophosphamide
- History of severe hypersensitivity reaction to dimethyl sulfoxide
- Life expectancy <12 weeks

Allo, allogenic; auto, autologous; BCMA, B-cell maturation antigen; CAR, chimeric antigen receptor; CNS, central nervous system; MM, multiple myeloma; POEMS, polyneuropathy, organomegaly, endocrinopathy, M-protein, and skin changes; SCT, stem cell transplant.

References

1. Clinicaltrials.gov website. Accessed June 18, 2024. https://www.clinicaltrials.gov/study/NCT06413498
2. Martin T, et al. EHA Library. 2024;421490: Abstract PB2724.

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