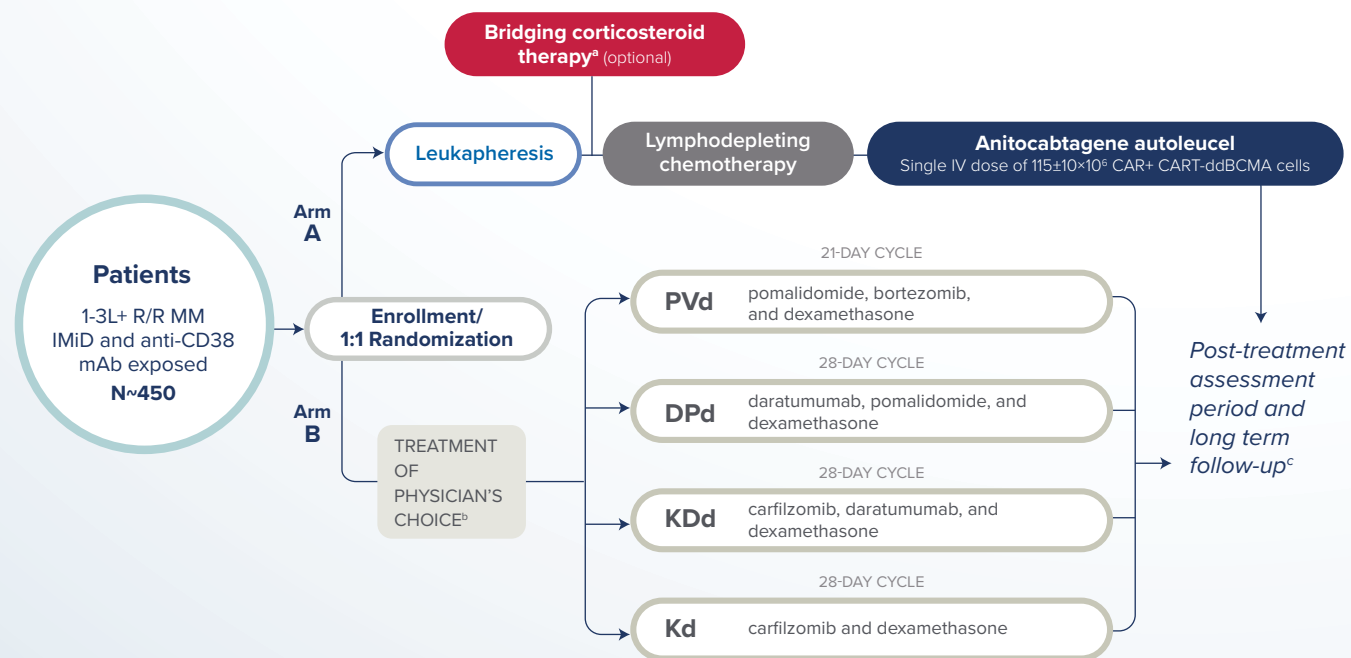


# iMMagine-3: A Phase 3, Randomized, Open-Label Study to Compare the Efficacy and Safety of Anitocabtagene Autoleucel Versus Standard of Care Therapy in Participants With Relapsed/Refractory Multiple Myeloma

## Study Design<sup>1,2</sup>



<sup>a</sup>Bridging therapy, if used, will be with the selected standard-of-care regimen per investigator discretion. <sup>b</sup>Cycles will continue until unacceptable toxicity, progression per IMWG criteria, or participant withdrawal of consent, whichever occurs first. <sup>c</sup>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.

## Endpoints<sup>1,2</sup>

### Primary Endpoint

- PFS, per IMWG criteria as assessed by IRC

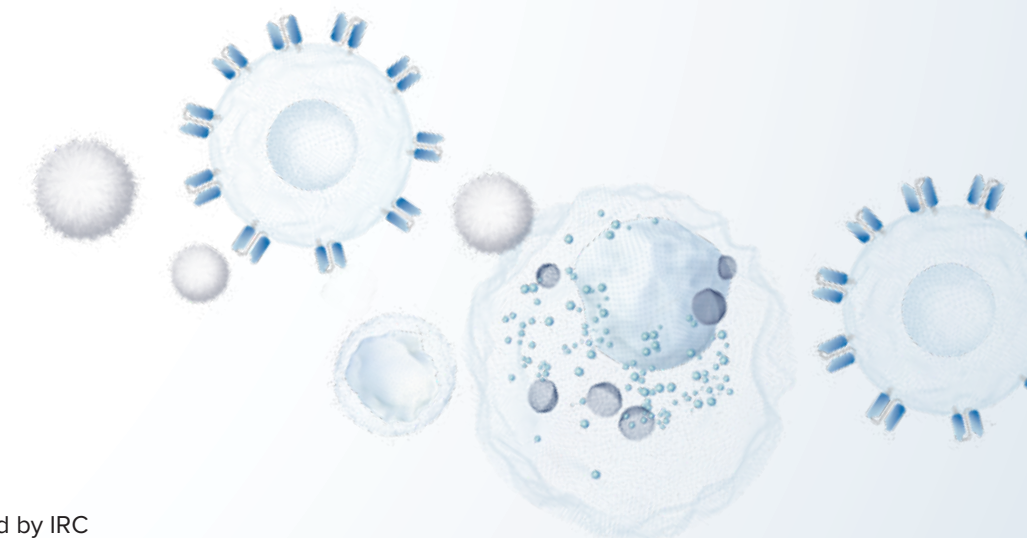
### Secondary Endpoints

- CR/sCR rate, per IMWG criteria as determined by IRC
- Overall MRD negativity (minimum, 10<sup>-5</sup>)
- OS
- ORR
- MRD-negative CR/sCR and MRD-negative VGPR+
- Sustained MRD negativity
- Duration of response
- 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

*Continued on next page*

BCMA, B-cell maturation antigen; CAR, chimeric antigen receptor; CD38, cluster of differentiation 38; CR, complete response; DPd, daratumumab, pomalidomide, and dexamethasone; 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; HRQOL, health-related quality of life; IMiD, immunomodulatory drug; IMWG, International Myeloma Working Group; IRC, independent review committee; IV, intravenous; Kd, carfilzomib and dexamethasone; KDd, carfilzomib, daratumumab, and dexamethasone; mAb, monoclonal antibody; MRD, measurable residual disease; ORR, overall response rate; OS, overall survival; PD, pharmacodynamics; PFS, progression-free survival; PFS2, time to second progression; PK, pharmacokinetics; PR, partial response; PVd, pomalidomide, bortezomib, and dexamethasone; RRM, relapsed or refractory multiple myeloma; sCR, stringent complete response; TEAE, treatment-emergent adverse event; VGPR, very good partial response.

**The safety and efficacy of these investigational agents have not been established, and they have not received marketing authorization in this setting. There is no guarantee that these investigational agents and/or uses will receive Health Authority approval and/or become commercially available.**



## Key Eligibility Criteria<sup>1,2,a</sup>

### Key Inclusion Criteria

- Age  $\geq$ 18 years
- 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 2016 IMWG criteria
  - Serum M protein of  $\geq$ 0.5 g/dL or urine M protein of  $\geq$ 200 mg/24 hours; or
  - Light chain MM without measurable disease in the serum or urine: serum free light chain of  $\geq$ 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

<sup>a</sup>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; mAb, monoclonal antibody; MM, multiple myeloma; PVd, pomalidomide, bortezomib, and dexamethasone; Kd, carfilzomib and dexamethasone; KDd, carfilzomib, daratumumab, and dexamethasone.

## Key Eligibility Criteria (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<sup>b</sup>
- 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

AE, adverse event; allo, allogenic; auto, autologous; BCMA, B-cell maturation antigen; CAR, chimeric antigen receptor; CHF, congestive heart failure; CNS, central nervous system; DVT, deep vein thrombosis; MI, myocardial infarction; MM, multiple myeloma; PD, progressive disease; PE, pulmonary embolism; POEMS, polyneuropathy, organomegaly, endocrinopathy, M-protein, and skin changes; SCT, stem cell transplant.

### References

1. Clinicaltrials.gov website. Accessed May 20, 2024. <https://www.clinicaltrials.gov/study/NCT06413498>

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