

# Study of investigational livoseltamab in patients with relapsed or refractory multiple myeloma



Primary Objective: evaluate the safety and tolerability, and anti-tumor activity of livoseltamab in combination with other cancer treatments



PATIENTS WITH RELAPSED OR REFRACTORY (R/R) MM (N~317)

OPEN LABEL INTERVENTION

**Livoseltamab (IV)**

Q2W or Q3W depending on cohort



Cohorts:

1	2	3	4	5	6	7	8	9
Daratumumab (IV or SC)	Carfilzomib (IV)	Lenalidomide (PO)	Bortezomib (IV or SC)	Pomalidomide (PO)	Isatuximab (IV)	Fianlimab (IV)	Cemiplimab (IV)	Nirogacestat (PO)

## Primary Endpoints

Safety, tolerability, and DLT

## Secondary Endpoints

Objective response<sup>a</sup>  
Duration of response<sup>a</sup>  
Progression-free survival<sup>a</sup>  
MRD-negative status<sup>a</sup>

Pharmacokinetics  
Immunogenicity  
Overall survival



### FIND OUT MORE

Scan here to find out more about this study at <https://clinicaltrials.gov/ct2/show/NCT05137054>

This information is intended for investigators interested in open clinical trials.

Livoseltamab and fianlimab are investigational agents and have not been evaluated by any regulatory authority.

<sup>a</sup>Using the International Myeloma Working Group (IMWG) response criteria.

DLT, dose-limiting toxicity; IV, intravenous; MM, multiple myeloma; MRD, minimal residual disease; N, number of patients; PO, by mouth; Q2W, administered every 2 weeks; Q3W, administered every 3 weeks; SC, subcutaneous.

# LINVOSELTAMAB

## An Investigational BCMAxCD3 Bispecific Antibody

Designed to bridge BCMA on MM cells with CD3 on T cells to facilitate local T-cell activation and cytotoxicity<sup>1</sup>

### SELECTED INCLUSION CRITERIA<sup>a</sup>



ECOG PS 0 or 1



Measurable disease as defined in the protocol according to IMWG response assessment criteria



Adequate creatinine clearance, hematologic function, and hepatic function



Life expectancy  $\geq 6$  months



Treatment with at least 3 lines of therapy, or at least 2 lines of therapy and either prior exposure to at least 1 anti-CD38 antibody, 1 IMiD and 1 PI, or double-refractory to 1 PI and 1 IMiD, or the combination of 1 PI and 1 IMiD<sup>b</sup>

### SELECTED EXCLUSION CRITERIA<sup>a</sup>



Diagnosis of plasma cell leukemia, amyloidosis, Waldenström macroglobulinemia, or POEMS syndrome



Known MM brain lesions or meningeal involvement



Treatment with any systemic anti-cancer therapy within 5 half-lives or within 21 days prior to first administration of study drug



History of allogeneic stem cell transplantation, or autologous stem cell transplantation within 12 weeks of the start of study treatment



Prior treatment with BCMA-directed immunotherapies excluding antibody-drug conjugates



History of PML, neurodegenerative condition, CNS movement disorder, or seizures<sup>c</sup>



Live or attenuated vaccination within 28 days prior to first study drug regimen administration with a vector that has replicative potential



Cardiac ejection fraction <40%



For more information, visit [www.clinicaltrials.gov](https://www.clinicaltrials.gov) or please call 844 REGN-MID.  
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<sup>a</sup>Inclusion/exclusion criteria include a summary of selected criteria. Please review the complete study design on [clinicaltrials.gov](https://www.clinicaltrials.gov) for complete details and cohort-specific criteria. <sup>b</sup>Protocol defines cohort-specific criteria. <sup>c</sup>Within 12-months prior to study drug.

BCMA, B cell maturation antigen; CD, cluster of differentiation; CNS, central nervous system; ECOG PS, Eastern Cooperative Oncology Group performance status; IMiD, immunomodulatory drug; IMWG, International Myeloma Working Group; MM, multiple myeloma; PI, protease inhibitor; PML, progressive multifocal leukoencephalopathy; POEMS, polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, and skin changes.

Current per [clinicaltrials.gov](https://www.clinicaltrials.gov) as of September 6, 2023.

1. DiLillo DJ et al. *Blood Adv*. 2021;5(5):1291-04.

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