LINKER-MM2 (NCT05137054) **PHASE 1 ENROLLING**

Study of investigational linvoseltamab in combination with other cancer treatments for patients with **relapsed or refractory multiple myeloma**

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

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

OPEN LABEL INTERVENTION

Linvoseltamab (IV)

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 rate[a]
- Duration of response[a]
- Progression-free survival[a]
- MRD-negative status[a]
- 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.
Linvoseltamab ± fianlimab or cemiplimab are investigational agents and have not been evaluated by any regulatory authority.
Please see cemiplimab prescribing information in your country.

[a]According to IMWG response criteria.
DLT, dose-limiting toxicity; IMWG, International Myeloma Working Group; 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.

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LINVOSELTAMAB

An Investigational BCMAxCD3 Bispecific Antibody

Designed to simultaneously engage BCMA on MM cells with CD3 on T cells[1]

SELECTED INCLUSION CRITERIA[a,b]

- ECOG PS 0 or 1
- Measurable disease as defined in the protocol according to IMWG consensus criteria
- Adequate creatinine clearance, hematologic function, and hepatic function
- Life expectancy ≥6 months
- Progression after 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[b]

SELECTED EXCLUSION CRITERIA[a,b]

- Diagnosis of plasma cell leukemia, primary light-chain amyloidosis, Waldenström macroglobulinemia, or POEMS syndrome
- Known MM brain lesions or meningeal involvement
- Treatment with any systemic anti-myeloma 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[c]
- 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 or please call [+353 (0)61 533 400 or 844 REGN-MID].
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[a]Inclusion/exclusion criteria include a summary of selected criteria. Please review the full study design on clinicaltrials.gov for complete details and cohort-specific criteria. [b]Protocol defines cohort-specific criteria. [c]Within 12-months prior to treatment with 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, proteasome inhibitor; PML, progressive multifocal leukoencephalopathy; POEMS, polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, and skin changes.

Current per clinicaltrials.gov as of January 24, 2024.

1. DiLillo DJ et al. *Blood Adv*. 2021;5(5):1291-04.
LNVO-EM-0002 v2.0 February 2024.

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