LINKER-MM1 (NCT03761108) **PHASE 1/2**

Study of investigational linvoseltamab in patients with **relapsed or refractory multiple myeloma**

Primary Objective: evaluate the safety and efficacy, and identify the recommended phase 2 dose, of linvoseltamab in patients with relapsed or refractory (R/R) multiple myeloma

PATIENTS WITH R/R MM (N≈309)

OPEN LABEL INTERVENTION

Phase 1	Phase 2
Dose escalation: Linvoseltamab (IV)	**Dose expansion: Linvoseltamab (IV)**

Primary Endpoints

Phase 1: Safety, tolerability and DLT

Phase 2: Overall response rate[a,b]

Secondary Endpoints

Phase 1/2: Objective response rate[a]
Duration of response[a]
Progression-free survival[a]
MRD-negative status[a]
Overall survival[a]
Pharmacokinetics
Immunogenicity
Phase 2: HRQoL, Safety, and tolerability

FIND OUT MORE

Scan here to find out more about this study at https://clinicaltrials.gov/ct2/show/NCT03761108

This information is intended for investigators interested in open clinical trials.
Linvoseltamab is an investigational agent and has not been evaluated by any regulatory authority.

[a]Using the International Myeloma Working Group (IMWG) response criteria. [b]Based on Blinded Independent Central Review (BICR) in phase 2 portion. [c]Based on investigator assessment.
DLT, dose-limiting toxicity; HRQoL, health-related quality of life; IV, intravenous; MM, multiple myeloma; MRD, minimal residual disease;
N, number of patients.

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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[1]

SELECTED INCLUSION CRITERIA[a]

- 0 or 1 — ECOG PS 0 or 1
- Measurable disease according to IMWG consensus criteria
- P1 — **Phase 1:** Progression on or after at least 3 lines of therapy, or intolerance to therapy, including a PI, an IMiD, and an anti-CD38 antibody, OR progression on or after an anti-CD38 antibody[b] and have disease that is double refractory[c] to a PI and an IMiD, or intolerance to therapy
- P2 — **Phase 2:** Progression on or after at least 3 prior lines of therapy including a PI, IMiD, and anti-CD38 antibody. Patients must be triple-refractory, defined as being refractory[d] to prior treatment with at least one anti-CD38 antibody, PI, and IMiD

SELECTED EXCLUSION CRITERIA[a]

- Diagnosis of plasma cell leukemia, primary light-chain amyloidosis, Waldenström macroglobulinemia, or POEMS syndrome
- Known MM brain lesions or meningeal involvement
- Cardiac ejection fraction <40%
- Prior treatment with BCMA-directed immunotherapies excluding BCMA antibody-drug conjugates[e]
- History of allogeneic stem cell transplantation, or autologous stem cell transplantation within 12 weeks of the start of study drug regimen

For more information, visit www.clinicaltrials.gov or please call 844 REGN-MID.
NCT03761108
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[a]Inclusion/exclusion criteria include a summary of selected criteria. Please review the complete study design on clinicaltrials.gov for complete details. [b]The anti-CD38 antibody may have been administered alone or in combination with another agent such as a PI; [c]Defined as lack of response or relapse within 60 days of last treatment; [d]Defined as progression during treatment or within 60 days after completion of therapy, or <25% response to therapy; [e]Includes BCMA bispecific antibodies, bispecific T Cell engagers, and CAR T Cells.

BCMA, B cell maturation antigen; CD, cluster of differentiation; ECOG PS, Eastern Cooperative Oncology Group performance status; IMiD, immunomodulatory imide drug; IMWG, International Myeloma Working Group; MM, multiple myeloma; PI, proteosome inhibitor; POEMS, polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, and skin changes.

Current per clinicaltrials.gov as of April 5, 2023.

1. DiLillo DJ et al. *Blood Adv.* 2021;5(5):1291–04.
LNVO-EM-0001 October 2023.

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