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 +353 (0)61 533 400.
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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