LINKER-MM4 (NCT05828511) **PHASE 1/2 ENROLLING**

Study of investigational linvoseltamab for previously untreated patients with **symptomatic multiple myeloma**

Primary Objective: evaluate the safety, tolerability, and preliminary antitumor activity, and identify the recommended dosing schedule of linvoseltamab in patients with NDMM

PATIENTS WITH TREATMENT-NAIVE NDMM (N≈132)

OPEN LABEL INTERVENTION

Phase 1

Linvoseltamab (IV) dose escalation (part A) and dose expansion (part B)[a]

Phase 2

Transplant eligible: selected linvoseltamab (IV) regimen for a fixed duration of treatment
Transplant ineligible: selected linvoseltamab (IV) regimen until disease progression

Primary Endpoints

Safety and tolerability
Phase 1: DLT

Phase 1: Recommended Phase 2 dose
Phase 2: VGPR[b]
Phase 2: MRD-negative status

Key Secondary Endpoints

Pharmacokinetics
Soluble BCMA concentration

Phase 1: ORR[b], DOR[b], PFS[b], MRD-negative status
Phase 2: OS, TTR[b]

FIND OUT MORE
Scan here to find out more about this study at https://clinicaltrials.gov/ct2/show/NCT05828511

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]Phase 1 part B will be randomized 1:1. All other participants will be non-randomized. [b]Using the International Myeloma Working Group (IMWG) response criteria.
BCMA, B-cell maturation antigen; DLT, dose-limiting toxicity; DOR, duration of response; IV, intravenous; MM, multiple myeloma; MRD, minimal residual disease; N, number of patients; NDMM, newly diagnosed multiple myeloma; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; Q2W, administered every 2 weeks; SCT, stem cell transplant; SOC, standard of care; TTR, time to response; VGPR, very good partial response.

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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]

- ECOG PS ≤2
- Confirmed diagnosis of symptomatic MM that is response-evaluable according to IMWG criteria
- No prior therapy for MM, with the exception of prior emergent or palliative radiation and up to 1 month of single-agent corticosteroids
- Adequate bone marrow reserves and hepatic, renal, and cardiac function
- **Transplant eligible:** age <70 with adequate hepatic, renal, pulmonary, and cardiac function

SELECTED EXCLUSION CRITERIA[a]

- Receiving any concurrent investigational agent with known or suspected activity against MM, or agents targeting the APRIL/TACI/BCMA axis
- Known CNS involvement with MM, neurocognitive conditions, CNS movement disorder, or history of seizure within 12 months prior to study enrollment
- Rapidly progressive symptomatic disease urgently requiring chemotherapy treatment
- Diagnosis of non-secretory MM, active plasma cell leukemia, primary light-chain amyloidosis, Waldenström macroglobulinemia, or known POEMS syndrome

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 complete study design on clinicaltrials.gov for complete details.

APRIL, A proliferation-inducing ligand; BCMA, B-cell maturation antigen; CD, cluster of differentiation; CNS, central nervous system; ECOG PS, Eastern Cooperative Oncology Group performance status; IMWG, International Myeloma Working Group; MM, multiple myeloma; POEMS, polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, and skin changes; TACI, transmembrane activator and calcium modulator and cyclophilin ligand interactor.

Current per clinicaltrials.gov as of January 25, 2024.

1. DiLillo DJ et al. *Blood Adv.* 2021;5(5):1291–04.
Linvoseltamab-EM-0011 v2.0 February 2024.

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