LINKER-MM3 (NCT05730036) **PHASE 3 ENROLLING**

Study of investigational linvoseltamab versus the combination of EPd in patients with **relapsed or refractory multiple myeloma**

Primary Objective: compare progression-free survival per ICR of linvoseltamab monotherapy versus the combination of elotuzumab, pomalidomide, and dexamethasone (EPd) in patients with relapsed or refractory multiple myeloma

PATIENTS WITH R/R MM

OPEN LABEL INTERVENTION

R 1:1

Linvoseltamab (IV)

Elotuzumab (IV), pomalidomide (PO), and dexamethasone (PO/IV)

Primary Endpoint

Progression-free survival[a]

Key Secondary Endpoints

- Objective response[a]
- MRD-negative status
- Overall survival
- Pain score measured by the BPI-SF Item 3
- Progression-free survival
- Duration of response[a]
- PGIC and PGIS
- Safety and tolerability

FIND OUT MORE

Scan here to find out more about this study at https://clinicaltrials.gov/ct2/show/NCT05730036

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 based on ICR.
BPI-SF, Brief Pain Inventory-Short Form; CR, complete response; EU, European Union; ICR, Independent Central Review; IV, intravenous; MM, multiple myeloma; MRD, minimal residual disease; N, number of patients; PGIC, Patient-Reported Outcomes in Patient Global Impression of Change; PGIS, Patient-Reported Outcomes in Patient Global Impression of Symptom Severity; PO, taken orally; PR, partial response; R, randomized; R/R, relapsed or refractory; UK, United Kingdom; 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 0 or 1[b]
- Measurable disease as defined in the protocol according to 2016 IMWG response assessment criteria
- Adequate hematologic, hepatic, renal and cardiac function, and evidence of adequate bone marrow reserves
- Life expectancy ≥6 months
- 1-4 prior lines of therapy, including lenalidomide and a PI, and demonstrated disease progression on or after the last therapy[c]
- Patients in the EU and the UK must have previously received 2 to 4 prior lines of therapy, including a CD38 antibody[2]

SELECTED EXCLUSION CRITERIA[a]

- 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 28 days prior to first administration of study drug
- History of allogeneic stem cell transplantation within 6 months or autologous stem cell transplantation within 12 weeks of the start of study treatment
- Prior treatment with BCMA-directed immunotherapies
- Prior treatment with elotuzumab and/or pomalidomide
- Any infection requiring hospitalization or treatment with IV anti-infectives within 2 weeks of first administration of study drug
- Uncontrolled infection with HIV, hepatitis B or hepatitis C; or another uncontrolled infection, as defined in the protocol

For more information, visit www.clinicaltrials.gov or please call [+353 (0)61 533 400 or 844 REGN-MID]. NCT05730036
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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]Patients with ECOG 2 solely due to local symptoms of myeloma (eg, pain) may be allowed after discussion with the Medical Monitor. [c]Participants who have received only 1 prior line of anti-myeloma therapy must be lenalidomide refractory, as described in the protocol.

BCMA, B-cell maturation antigen; CD, cluster of differentiation; ECOG PS, Eastern Cooperative Oncology Group performance status; EU, European Union; HIV, human immunodeficiency virus; IMWG, International Myeloma Working Group; IV, intravenous; MM, multiple myeloma; PI, proteasome inhibitor; POEMS, polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, and skin changes; UK, United Kingdom.

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

1. DiLillo DJ et al. *Blood Adv*. 2021;5(5):1291-04; 2. P-052: LINKER-MM3. Poster presented at The 20th International Myeloma Workshop. 2023.
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