

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



Primary Objective: compare the efficacy of livoseltamab versus the combination of elotuzumab, pomalidomide, and dexamethasone (EPd) in patients with relapsed or refractory multiple myeloma



PATIENTS WITH R/R MM (N=286)

OPEN LABEL INTERVENTION

R
1:1

Livoseltamab (IV)

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

Primary Endpoint

Progression-free survival^a

Key Secondary Endpoints

Objective response^a
≥VGPR, PR, and CR^a
MRD-negative status
Overall survival

Pain score measured by the BPI-SF Item 3
Progression-free survival^a
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.

Livoseltamab is an investigational agent and has not been evaluated by any regulatory authority.

^aUsing the International Myeloma Working Group (IMWG) response criteria based on Independent Central Review (ICR).
BPI-SF, Brief Pain Inventory-Short Form; CR, complete response; 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;
VGPR, very good partial response.

LINVOSELTAMAB

An Investigational BCMAxCD3 Bispecific Antibody

Designed to bridge BCMA on MM cells with CD3 on T cells¹

SELECTED INCLUSION CRITERIA^a



ECOG 0 or 1^b



Measurable disease as defined in the protocol according to IMWG response assessment criteria



Adequate creatinine clearance, hematologic function, and hepatic function



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

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 844 REGN-MID.

NCT05730036

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^aInclusion/exclusion criteria include a summary of selected criteria. Please review the complete study design on clinicaltrials.gov for complete details. ^bPatients with ECOG 2 solely due to local symptoms of myeloma (eg, pain) may be allowed after discussion with the Medical Monitor. ^cParticipants 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; 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.

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

1. DiLillo DJ et al. *Blood Adv*. 2021;5(5):1291-04.

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