

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



Primary Objective: evaluate the safety and tolerability, 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

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.

^aPhase 1 part B will be randomized 1:1. All other participants will be non-randomized. ^bUsing the International Myeloma Working Group (IMWG) response criteria. BCMA, B-cell mature 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.

LINVOSELTAMAB

An Investigational BCMAxCD3 Bispecific Antibody

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

SELECTED INCLUSION CRITERIA^a



ECOG PS ≤2



Confirmed diagnosis of 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



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 844 REGN-MID.
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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.

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 November 8, 2023.

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

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