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: Recommended Phase 2 dose

Phase 1: DLT Phase 2: VGPR^b

Phase 2: MRD-negative status

Key Secondary Endpoints

Pharmacokinetics Phase 1: ORRb, DORb, PFSb, MRD-negative status

Soluble BCMA concentration **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.

Phase 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 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.



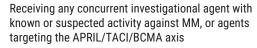
LINVOSELTAMAB

An Investigational BCMAxCD3 Bispecific Antibody
Designed to simultaneously engage BCMA on MM cells with CD3 on T cells¹

SELECTED INCLUSION CRITERIA^a



ECOG PS ≤2



SELECTED EXCLUSION CRITERIA^a



Confirmed diagnosis of symptomatic MM that is response-evaluable according to IMWG criteria



Known CNS involvement with MM, neurocognitive conditions, CNS movement disorder, or history of seizure within 12 months prior to study enrollment



No prior therapy for MM, with the exception of prior emergent or palliative radiation and up to 1 month of single-agent corticosteroids



Rapidly progressive symptomatic disease urgently requiring chemotherapy treatment



Adequate bone marrow reserves and hepatic, renal, and cardiac function



Diagnosis of non-secretory MM, active plasma cell leukemia, primary light-chain amyloidosis, Waldenström macroglobulinemia, or known POEMS syndrome



Transplant eligible: age <70 with adequate hepatic, renal, pulmonary, and cardiac function



For more information, visit <u>www.clinicaltrials.gov</u> or please call [+353 (0)61 533 400 or 844 REGN-MID]. NCT05828511

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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. ©2024 Regeneron Pharmaceuticals, Inc. All rights reserved.

