

# Study of investigational linvoseltamab in patients with **smoldering multiple myeloma** at high risk of developing multiple myeloma



Primary Objective: evaluate the safety and efficacy of linvoseltamab in patients with smoldering multiple myeloma at high risk of developing multiple myeloma in a safety run in to make sure the treatment is acceptable, and an expansion to evaluate the ability of linvoseltamab to treat high-risk SMM and prevent progression to MM.



**PATIENTS WITH HIGH-RISK SMM (N≈40)**

**OPEN LABEL INTERVENTION LIVOSELTAMAB MONOTHERAPY**

**Safety run-in (part 1) to expansion (part 2)**

## Primary Endpoints

Safety and tolerability  
Complete response<sup>e</sup>  
MRD negative-status

## Secondary Endpoints

Safety and tolerability  
Overall response<sup>b</sup>  
Duration of response  
Progression-free survival

Overall survival  
Time to any myeloma-defining event  
Immunogenicity  
Sustained MRD negativity



### FIND OUT MORE

Scan here to find out more about this study at <https://classic.clinicaltrials.gov/ct2/show/NCT05955508>

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.

<sup>a</sup>Determined by the investigator. <sup>b</sup>Partial response (PR) or better.  
IV, intravenous; MM, multiple myeloma; MRD, minimal residual disease; N, number of patients; SMM, smoldering multiple myeloma.

# LINVOSELTAMAB

## An Investigational BCMAxCD3 Bispecific Antibody

Designed to bridge BCMA on MM cells with CD3 on T cells to facilitate local T-cell activation and cytotoxicity<sup>1</sup>

### SELECTED INCLUSION CRITERIA<sup>a</sup>



ECOG PS 0 or 1



High-risk SMM diagnosis within 5 years of study enrollment per IMWG criteria<sup>b</sup>



Adequate hematologic and hepatic function



Estimated glomerular filtration rate  $\geq 30$  mL/min/1.73 m<sup>2</sup>

### SELECTED EXCLUSION CRITERIA<sup>a</sup>



Evidence of myeloma as defined by SLiM CRAB<sup>c</sup>



Clinically significant cardiac or vascular disease within 3 months of study enrollment



Any infection requiring hospitalization or treatment with IV anti-infectives within 28 days of first administration of study drug



Uncontrolled infection with HIV, hepatitis B or hepatitis C; or another uncontrolled infection or unexplained signs of infection



History of severe allergic reaction attributed to compounds with a similar chemical or biologic composition as the study drug or excipient



Diagnosis of systemic light chain amyloidosis, Waldenström macroglobulinemia (lymphoplasmacytic lymphoma), soft tissue plasmacytoma, or symptomatic multiple myeloma



For more information, visit [www.clinicaltrials.gov](http://www.clinicaltrials.gov) or please call 844 REGN-MID.  
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<sup>a</sup>Inclusion/exclusion criteria include a summary of selected criteria. Please review the complete study design on [clinicaltrials.gov](http://clinicaltrials.gov) for complete details. <sup>b</sup>Per IMWG criteria defined as: Serum M-protein  $\geq 30$  g/L or urinary M-protein  $\geq 500$  mg per 24 hours or BMPCs 10% to  $<60\%$  AND Absence of myeloma-defining events or other related conditions (SLiM CRAB); Rajkumar SV et al. Lancet Oncol. 2014;15(12):e538-e548. <sup>c</sup>SLiM defined as greater than or equal to 60% clonal plasma cells in the bone marrow, involved/uninvolved free light chain ratio of  $\geq 100$  with the involved free light chain (FLC) being  $\geq 100$  mg/L, MRI with  $>1$  focal lesion, CRAB defined as hyperCalcemia, Renal insufficiency, Anemia, or lytic Bone lesions.

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; MRI, magnetic resonance imaging; SMM, smoldering multiple myeloma.

Current per [clinicaltrials.gov](http://clinicaltrials.gov) as of July 21, 2023.

1. DiLillo DJ et al. *Blood Adv.* 2021;5(5):1291-04.  
Linvoseltamab-EM-0016 October 2023.

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