

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



PATIENTS WITH HIGH-RISK SMM (N≈40)

OPEN LABEL INTERVENTION LIVOSELTAMAB (IV) MONOTHERAPY

Safety run-in (part 1) followed by expansion (part 2)

Primary Endpoints

Safety and tolerability
Complete response^a
MRD-negative status

Secondary Endpoints

Safety and tolerability
Overall response rate^{a,b}
Duration of response^a
Progression-free survival^a

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



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.

^aAccording to IMWG response criteria. ^bPartial response (PR) or better.

IMWG, International Myeloma Working Group; 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 simultaneously engage BCMA on aberrant plasma cells with CD3 on T cells¹

SELECTED INCLUSION CRITERIA^a



ECOG PS 0 or 1



SMM diagnosis within 5 years of study enrollment per IMWG criteria^b; high-risk SMM at screening



Adequate hematologic and hepatic function



Estimated glomerular filtration rate ≥ 30 mL/min/1.73 m²

SELECTED EXCLUSION CRITERIA^a



Evidence of myeloma-defining events as defined by SLiM CRAB^c



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 or please call [+353 (0)61 533 400 or 844 REGN-MID].
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^aInclusion/exclusion criteria include a summary of selected criteria. Please review the full study design on clinicaltrials.gov for complete details. ^bPer IMWG criteria defined as: Serum M-protein ≥ 30 g/L or urinary M-protein ≥ 500 mg per 24 hours or BMPCs 10% to $<60\%$ AND Absence of myeloma-defining events or amyloidosis (SLiM CRAB); Rajkumar SV et al. *Lancet Oncol.* 2014;15(12):e538-e548. ^cSLiM defined as greater than or equal to 60% clonal plasma cells in the bone marrow, involved/uninvolved free light chain ratio of ≥ 100 with the involved free light chain (FLC) being ≥ 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 as of January 3, 2024.

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

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