NCT05955508 PHASE 2

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 LINVOSELTAMAB MONOTHERAPY

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

Primary Endpoints

Safety and tolerability
Complete response[e]
MRD negative-status

Secondary Endpoints

Safety and tolerability
Overall response[b]
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.

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

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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[1]

SELECTED INCLUSION CRITERIA[a]

- ECOG PS 0 or 1
- High-risk SMM diagnosis within 5 years of study enrollment per IMWG criteria[b]
- Adequate hematologic and hepatic function
- Estimated glomerular filtration rate ≥30 mL/min/1.73 m^2

SELECTED EXCLUSION CRITERIA[a]

- Evidence of myeloma 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 844 REGN-MID.
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[a]Inclusion/exclusion criteria include a summary of selected criteria. Please review the complete study design on clinicaltrials.gov for complete details. [b]Per 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 other related conditions (SLiM CRAB); Rajkumar SV et al. Lancet Oncol. 2014;15(12):e538-e548. [c]SLiM 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 July 21, 2023.

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

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