

Study of investigational odronextamab in patients with B-cell malignancies



Primary Objective: evaluate the safety and tolerability of odronextamab in patients with CD20+ B-cell malignancies



PATIENTS WITH B-NHL OR CLL (N≈200)

OPEN LABEL INTERVENTION

Part A

Dose escalation + dose expansion

Odronextamab (IV)

DLBCL post CAR-T therapy, B-NHL, and CLL cohorts

No longer enrolling

Primary Endpoints

Safety
Tolerability

DLBCL after failure of CAR-T therapy
expansion cohort: Objective response rate

Secondary Endpoints

Pharmacokinetics
Immunogenicity
Objective response rate

Progression-free survival
Overall survival
Duration of complete response



FIND OUT MORE

Scan here to find out more about this study at <https://classic.clinicaltrials.gov/ct2/show/NCT02290951>

This information is intended for investigators interested in open clinical trials.

Odronextamab is an investigational asset and has not been fully evaluated by any regulatory authority.

B-NHL, B-cell non-Hodgkin lymphoma; CAR-T, chimeric antigen receptor T cell; CD, cluster of differentiation; CLL, chronic lymphocytic leukemia; DLBCL, diffuse large B-cell lymphoma; IV, intravenous; N, number of patients; SC, subcutaneous.

ODRONEXTAMAB

An Investigational CD20xCD3 Bispecific Antibody

Simultaneously engages CD20 on malignant B cells and CD3 on cytotoxic T cells¹

SELECTED INCLUSION CRITERIA^a



CD20+ B-cell malignancy, with active disease not responsive to prior therapy



ECOG PS 0 or 1



Measurable lesion ≥ 1.5 cm documented by CT or MRI scan



Life expectancy of at least 6 months



Patients with B-NHL must have had prior treatment with an anti-CD20 antibody therapy



Adequate bone marrow and organ function

SELECTED EXCLUSION CRITERIA^a



Primary CNS lymphoma or CNS pathology



Non-biologic anti-lymphoma chemotherapy or radiotherapy within 28 days prior to first administration of study drug



Infection with HIV or chronic infection with HBV, HCV, or CMV infection



For more information, visit www.clinicaltrials.gov or please call 844 REGN-MID.
NCT02290951
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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.

B-NHL, B-cell non-Hodgkin lymphoma; CD, cluster of differentiation; CMV, cytomegalovirus; CNS, central nervous system; CT, computed tomography; ECOG PS, Eastern Cooperative Oncology Group performance status; HBV, hepatitis B virus; HIV, human immunodeficiency virus; MRI, magnetic resonance imaging.

1. Smith EJ et al. *Sci Rep.* 2015;5:17943.

Current per clinicaltrials.gov as of September 7, 2023.

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