

Study of investigational odronextamab + chemotherapy in patients with **previously untreated diffuse large B-cell lymphoma**



Primary Objective: evaluate the efficacy and safety of odronextamab + chemotherapy vs rituximab + chemotherapy in patients with previously untreated DLBCL



PATIENTS WITH PREVIOUSLY UNTREATED DLBCL^a (N≈904)

OPEN LABEL INTERVENTION

Part 1A: non-randomized
Odronextamab dose escalation

Part 1B: randomized
Odronextamab + chemotherapy^b dose optimization with 2 regimens

Part 2: randomized

Arm 1
Odronextamab (IV)
+ chemotherapy^b

Arm 2
Rituximab (IV or SC)
+ chemotherapy^b

Primary Endpoints

Part 1: Safety, tolerability, and DLT

Part 2: Progression-free survival^c

Secondary Endpoints

Part 1 and 2:

Complete response rate^{c,d} Pharmacokinetics
Best overall response^{c,d} Immunogenicity
Duration of response^{c,d}

Part 2 only:

Event-free survival^{c,d} Patient-reported outcomes
Progression-free survival^d Overall survival
MRD-negative status Safety



FIND OUT MORE

Scan here to find out more about this study at <https://clinicaltrials.gov/ct2/show/NCT06091865>

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

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

^aPatients with relapsed or refractory DLBCL will be included in Part 1A. ^bConsisting of cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP).

^cBased on Independent Central Review (ICR) in part 2 only. ^dBased on investigator assessment.

DLBCL; diffuse large B-cell lymphoma; IV, intravenous; MRD, minimal residual disease; N, number of patients; R, randomized; 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



Previously untreated CD20+ DLBCL or R/R DLBCL (Part 1A only)



Measurable disease with at least one nodal or extranodal lesion



Part 1: IPI 3 to 5



Part 2: IPI ≥ 2



ECOG PS ≤ 2



Adequate organ function



Life expectancy ≥ 12 months

SELECTED EXCLUSION CRITERIA^a



Primary CNS lymphoma or known involvement by non-primary CNS non-Hodgkin lymphoma



History of or current relevant CNS pathology



Peripheral neuropathy Grade ≥ 3



Treatment with any systemic anti-lymphoma therapy



Any investigational therapy within 28 days or 5 half-lives of the drug prior to the start of study treatment



Recent major surgery, prior organ transplantation, or standard radiotherapy



Allergy/hypersensitivity to study drugs



Evidence of any active infection



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

CD, cluster of differentiation; CNS, central nervous system; DLBCL, diffuse large B-cell lymphoma; ECOG PS, Eastern Cooperative Oncology Group performance status; IPI, International Prognostic Index; R/R, relapsed or refractory.

Current per clinicaltrials.gov as of November 3, 2023.

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

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