**OLYMPIA-3 (NCT06091865)** **PHASE 3 ENROLLING**

# 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 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**

R 1:1

**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]
- Best overall response[c,d]
- Duration of response[c,d]
- Pharmacokinetics
- Immunogenicity

**Part 2 only:**

- Event-free survival[c,d]
- Progression-free survival[d]
- MRD-negative status
- Patient-reported outcomes
- Overall survival
- 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.**

[a]Patients with relapsed or refractory DLBCL will be included in Part 1. [b]Consisting of cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP).
[c]Based on Independent Central Review (ICR) in part 2 only. [d]Based on investigator assessment.
DLBCL; diffuse larger B-cell lymphoma; IV, intravenous; MRD, minimal residual disease; N, number of patients; R, randomized; SC, subcutaneous.

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# ODRONEXTAMAB

**An Investigational CD20xCD3 Bispecific Antibody**

Simultaneously engages CD20 on malignant B cells and CD3 on cytotoxic T cells[1]

## 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
- 3-5 **Part 1:** IPI 3 to 5
- ≥2 **Part 2:** IPI ≥ 2
- ≤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
- ≥3 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 [+353 (0)61 533 400 OR 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.

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.
ODRO-EM-0003 November 2023.


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