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 PREVIOUSLY UNTREATED DLBCL[a] (N≈904)

OPEN LABEL INTERVENTION

Part 1A: non-randomized
Odronextamab dose escalation + chemotherapy

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]

Key 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 1A. [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 large B-cell lymphoma; DLT, dose limiting toxicity; 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.
  Part 1A includes untreated and R/R DLBCL.
- 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 hematologic and organ function
- Life expectancy ≥ 12 months

SELECTED EXCLUSION CRITERIA[a]

- Primary CNS lymphoma or known involvement by non-primary CNS non-Hodgkin lymphoma
- History 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 January 24, 2024.

1. Smith EJ et al. *Sci Rep*. 2015;5:17943.
ODRO-EM-0003 v2.0 February 2024.

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