OLYMPIA-2 (NCT06097364) **PHASE 3 ENROLLING**

Study of investigational odronextamab + chemotherapy in patients with **previously untreated follicular lymphoma**

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

PATIENTS WITH FL[a] (N≈733)

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 1:1:1

Arm A	Arm B	Arm C
Odronextamab (IV) + chemotherapy[b]	Odronextamab (IV) + chemotherapy[b]	Rituximab (IV or SC) + chemotherapy[b]
No maintenance	Odronextamab (IV) maintenance	Rituximab (IV or SC) maintenance

Primary Endpoints

Part 1: Safety, tolerability, and DLT

Part 2: Complete response rate at 30 months (CR30)[c]

Key Secondary Endpoints

- Progression-free survival[c,d]
- Event-free survival[c,d]
- Complete response rate[d]
- Patient-reported outcomes
- Overall survival
- Best overall response[c,d]
- Duration of response[c,d]
- Safety

FIND OUT MORE

Scan here to find out more about this study at https://clinicaltrials.gov/ct2/show/NCT06097364

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 FL will be enrolled in Part 1A. [b]Includes cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP); or cyclophosphamide, vincristine, prednisone (CVP). [c]Based on Independent Central Review (ICR). [d]Based on investigator assessment.
DLT, dose limiting toxicity; FL, follicular lymphoma; IV, intravenous; 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]

- CD20+ FL (Grade 1-3a, stage II bulky, or stage III/IV)
- **Part 1A:** previously untreated participants who have Follicular Lymphoma International Prognostic Index (FLIPI)-1 score of 3 to 5, or R/R FL who have not received R-CHOP or R-CVP
  Part 1B: previously untreated participants who have FLIPI-1 score of 3 to 5
  Part 2: previously untreated participants who have FLIPI-1 score of 0 to 5
- Measurable disease on cross-sectional imaging documented by diagnostic imaging CT or MRI
- ECOG PS ≤ 2
- Adequate bone marrow and hepatic function

SELECTED EXCLUSION CRITERIA[a]

- CNS lymphoma or leptomeningeal lymphoma
- Histological evidence of transformation to high-grade or diffuse large B-cell lymphoma
- Waldenström macroglobulinemia, Grade 3b follicular lymphoma, chronic lymphocytic leukemia, or small lymphocytic lymphoma
- Recent major surgery and history or organ transplantation

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.

CD, cluster of differentiation; CNS, central nervous system; CT, computed tomography; ECOG PS, Eastern Cooperative Oncology Group performance status; FL, follicular lymphoma; FLIPI, Follicular Lymphoma International Prognostic Index 1; MRI, magnetic resonance imaging.

Current per clinicaltrials.gov as of November 13, 2023.

1. Smith EJ et al. *Sci Rep*. 2015;5:17943.
ODRO-EM-0004 November 2023.

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