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

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

≤2 ECOG PS ≤ 2

Adequate bone marrow and hepatic function

SELECTED EXCLUSION CRITERIA[a]

CNS lymphoma or leptomenigial 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 [+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; 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 October 24, 2023.

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

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