

# 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<sup>a</sup> (N≈733)**

## OPEN LABEL INTERVENTION

**Part 1A: non-randomized**  
Odronextamab dose escalation

**Part 1B: randomized**  
Odronextamab + chemotherapy<sup>b</sup>  
dose optimization with 2 regimens

**Part 2: randomized**

**Arm A**  
Odronextamab (IV)  
+ chemotherapy<sup>b</sup>

No maintenance

**Arm B**  
Odronextamab (IV)  
+ chemotherapy<sup>b</sup>

Odronextamab (IV)  
maintenance

**Arm C<sup>c</sup>**  
Rituximab (IV or SC)  
+ chemotherapy<sup>b</sup>

Rituximab (IV or SC)  
maintenance

## Primary Endpoints

**Part 1:** Safety, tolerability, and DLT

**Part 2:** Complete response rate at 30 months (CR30)<sup>d</sup>

## Key Secondary Endpoints (Part 2)

Progression-free survival<sup>d,e</sup>

Event-free survival<sup>d,e</sup>

Complete response rate<sup>e</sup>

Patient-reported outcomes

Overall survival

Best overall response<sup>d,e</sup>

Duration of response<sup>d,e</sup>

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.**

<sup>a</sup>Patients with relapsed or refractory FL who have not received R-CHOP before will be enrolled in Part 1A along with previously untreated patients.

<sup>b</sup>Includes cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP); or cyclophosphamide, vincristine, prednisone (CVP).

<sup>c</sup>Active comparator arm for Arm A and Arm B. Arm A and Arm B are not compared to each other.

<sup>d</sup>Based on Independent Central Review (ICR). <sup>e</sup>Based on investigator assessment.

DLT, dose limiting toxicity; FL, follicular lymphoma; IV, intravenous; 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 cells<sup>1</sup>

### SELECTED INCLUSION CRITERIA<sup>a</sup>



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  $\leq 2$



Adequate bone marrow and hepatic function

### SELECTED EXCLUSION CRITERIA<sup>a</sup>



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](http://www.clinicaltrials.gov) or please call [+353 (0)61 533 400 or 844 REGN-MID].  
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<sup>a</sup>Inclusion/exclusion criteria include a summary of selected criteria. Please review the complete study design on [clinicaltrials.gov](http://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; MRI, magnetic resonance imaging; R-CHOP, rituximab, cyclophosphamide, doxorubicin hydrochloride, vincristine sulfate, and prednisone; R-CVP, rituximab, cyclophosphamide, vincristine sulfate, and prednisone.

Current per [clinicaltrials.gov](http://clinicaltrials.gov) as of January 22, 2024.

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

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