OLYMPIA-1 (NCT06091254) **PHASE 3 ENROLLING**

Study of investigational odronextamab versus investigator's choice in patients with **previously untreated follicular lymphoma**

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

PATIENTS WITH PREVIOUSLY UNTREATED FL (N≈478)

OPEN LABEL INTERVENTION

Part 1: non-randomized

Odronextamab (IV) safety run-in

Part 2: randomized

R 1:1

Arm 1

Odronextamab (IV)

Arm 2

Rituximab (IV or SC) + investigator's choice of chemotherapy[a]

Primary Endpoints

Part 1: Safety, tolerability, and DLT

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

Secondary Endpoints

Part 1:

Pharmacokinetics

Immunogenicity

Part 2:

Progression-free survival[b,c]

Event-free survival[b,c]

Complete response rate at 30 months[c]

Patient-reported outcomes

Overall survival

Objective response rate[b,c]

FIND OUT MORE

Scan here to find out more about this study at https://clinicaltrials.gov/ct2/show/NCT06091254

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]Includes cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP); and cyclophosphamide, vincristine, prednisone (CVP) or bendamustine.
[b]Based on Independent Central Review (ICR). [c]Based on local 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]

- Previously untreated CD20+ FL (Grade 1-3a, stage II bulky, or stage III/IV)
- 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
- Treatment with any systemic anti-lymphoma therapy

For more information, visit www.clinicaltrials.gov or please call 844 REGN-MID
NCT06091254
https://clinicaltrials.gov/ct2/show/NCT06091254

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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; MRI, magnetic resonance imaging.

Current per clinicaltrials.gov as of October 19, 2023.

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