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

Odronextamab (IV) + chemotherapy^b

-

No maintenance

Arm B

Odronextamab (IV) + chemotherapy^b



Odronextamab (IV) maintenance

Arm C

Rituximab (IV or SC) + chemotherapy^b



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.

 $\label{lem:convex} \textbf{Odronextamab} \ \textbf{is an investigational agent and has not been evaluated by any regulatory authority}.$

*Patients with relapsed or refractory FL will be enrolled in Part 1A. Includes cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP); or cyclophosphamide, vincristine, prednisone (CVP). Based on Independent Central Review (ICR). 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 cells¹

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

SELECTED EXCLUSION CRITERIA^a



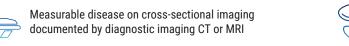
CNS lymphoma or leptomenigial lymphoma



Histological evidence of transformation to high-grade or diffuse large B-cell lymphoma

Waldenström macroglobulinemia, Grade 3b follicular

lymphoma, chronic lymphocytic leukemia, or small







ECOG PS ≤ 2



Recent major surgery and history or organ transplantation

lymphocytic lymphoma



Adequate bone marrow and hepatic function



For more information, visit www.clinicaltrials.gov or please call [+353 (0)61 533 400 OR 844 REGN-MID]. NCT06097364

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alnclusion/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 ©2023 Regeneron Pharmaceuticals, Inc. All rights reserved

