ELM-2 (NCT03888105) PHASE 2

Study of investigational odronextamab in patients with **B-cell non-Hodgkin lymphoma**

Primary Objective: evaluate the safety and efficacy of odronextamab in patients with relapsed or refractory B-NHL

PATIENTS WITH B-NHL (N≈512)

OPEN LABEL INTERVENTION

Odronextamab (IV)

- **FL (Grade 1-3a) Cohort**
- **DLBCL Cohort**
- **MCL Cohort**
- **MZL Cohort**
- **Other B-NHL Cohort**

Primary Endpoint

Objective response rate[a,b]

Secondary Endpoints

- Objective response rate[a,c]
- Complete response rate[a,b,c]
- Progression-free survival[a,b,c]
- Overall survival
- Duration of response[a,b,c]
- Disease control rate[a,b,c]
- Quality of life
- Pharmacokinetics
- Immunogenicity
- Safety and tolerability

FIND OUT MORE

Scan here to find out more about this study at https://classic.clinicaltrials.gov/ct2/show/NCT03888105

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]According to the Lugano Classification of response in malignant lymphoma. [b]Based on Independent Central Review (ICR).
[c]Based on investigator assessment.
B-NHL, B-cell non-Hodgkin lymphoma; DLBCL, diffuse large B-cell lymphoma; FL, follicular lymphoma; IV, intravenous; MCL, mantle cell lymphoma; MZL, marginal zone lymphoma; N, number of patients.

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ELM-2 (NCT03888105) **PHASE 2**

ODRONEXTAMAB

An Investigational CD20xCD3 Bispecific Antibody

Simultaneously engages CD20 on malignant B cells and CD3 on cytotoxic T cells[1]

SELECTED INCLUSION CRITERIA[a]

- FL grade 1-3a cohort: Central histopathologic confirmation of the FL grade 1 to 3a diagnosis
- 0 or 1 — ECOG PS 0 or 1
- Disease-specific cohorts that have relapsed after or are refractory to at least 2 prior lines of systemic therapy
- Adequate bone marrow, hepatic, and renal function
- Measurable disease on cross sectional imaging documented by diagnostic CT or MRI

SELECTED EXCLUSION CRITERIA[a]

- Primary CNS lymphoma, known involvement by non-primary CNS NHL, or history of CNS movement disorder
- Prior treatment with a CD20xCD3 bispecific antibody therapy
- Prior treatment with any CAR T-cell therapy
- History of allogeneic stem cell transplantation
- Treatment with any systemic anti-lymphoma therapy within 5 half-lives or within 28 days prior to administration of study drug
- Uncontrolled infection with HIV, hepatitis B or hepatitis C infection, or cytomegalovirus infection

For more information, visit www.clinicaltrials.gov or please call 844 REGN-MID.
NCT03888105
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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.

B-NHL, B-cell non-Hodgkin lymphoma; CD, cluster of differentiation; CMV, cytomegalovirus; CNS, central nervous system; CT, computed tomography; ECOG PS, Eastern Cooperative Oncology Group performance status; HBV, hepatitis B virus; HIV, human immunodeficiency virus; MRI, magnetic resonance imaging.

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

Current per clinicaltrials.gov as of April 20, 2023.

Odronextamab-EM-0009 November 2023.

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