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

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[a]

Primary Endpoint

Objective response rate[b,c]

Secondary Endpoints

- Objective response rate[b,d]
- Complete response rate[b,c,d]
- Progression-free survival[b,c,d]
- Overall survival
- Duration of response[b,c,d]
- Disease control rate[b,c,d]
- Patient reported outcomes
- 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]Patients with B-NHL other than FL grade 1-3a, DLBCL, MCL, or MZL that has relapsed after or is refractory to at least 2 prior lines of systemic therapy as defined in the protocol. Patients with a current diagnosis of mixed histology of B-NHL with an aggressive component (such as concurrent FL and DLBCL) will be allowed.
[b]According to the Lugano Classification of response in malignant lymphoma (Cheson BD, et al. *J Clin Oncol* 2014;32:3059-3067).
[c]Based on Independent Central Review (ICR). [d]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
- DLBCL and MZL cohorts: patients that have relapsed after or are refractory to at least 2 prior lines of systemic therapy
- MCL after BTK inhibitor therapy cohort: New enrollment is paused until further notice
- 0 or 1 ECOG PS 0 or 1
- 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 [+353 (0)61 533 400 or 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; CAR, chimeric antigen receptor; CD, cluster of differentiation; CNS, central nervous system; CT, computed tomography; ECOG PS, Eastern Cooperative Oncology Group performance status; 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 v2.0 February 2024.

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