ELM-1 (NCT02290951) PHASE 1

Study of investigational odronextamab in patients with **B-cell malignancies**

Primary Objective: evaluate the safety and tolerability of odronextamab in patients with CD20+ B-cell malignancies

PATIENTS WITH B-NHL OR CLL (N≈200)

OPEN LABEL INTERVENTION

Part A

Dose escalation + dose expansion

Odronextamab (IV)

DLBCL post CAR-T therapy, B-NHL, and CLL cohorts

No longer enrolling

Primary Endpoints

- Safety
- Tolerability
- **DLBCL after failure of CAR-T therapy expansion cohort:** Objective response rate

Key Secondary Endpoints

- Pharmacokinetics
- Immunogenicity
- Objective response rate
- Progression-free survival
- Overall survival
- Duration of complete response

FIND OUT MORE

Scan here to find out more about this study at https://classic.clinicaltrials.gov/ct2/show/NCT02290951

This information is intended for investigators interested in open clinical trials.
Odronextamab is an investigational asset and has not been fully evaluated by any regulatory authority.

B-NHL, B-cell non-Hodgkin lymphoma; CAR-T, chimeric antigen receptor T cell; CD, cluster of differentiation; CLL, chronic lymphocytic leukemia; DLBCL, diffuse large B-cell lymphoma; IV, intravenous; N, number of patients; SC, subcutaneous.

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ELM-1 (NCT02290951) **PHASE 1**

ODRONEXTAMAB

An Investigational CD20xCD3 Bispecific Antibody

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

SELECTED INCLUSION CRITERIA[a]

- CD20+ B-cell malignancy, with active disease not responsive to prior therapy
- 0 or 1 — ECOG PS 0 or 1
- Measurable lesion ≥1.5 cm documented by CT or MRI scan
- Life expectancy of at least 6 months
- Patients with B-NHL must have had prior treatment with an anti-CD20 antibody therapy
- Adequate bone marrow and organ function

SELECTED EXCLUSION CRITERIA[a]

- Primary CNS lymphoma or CNS pathology
- Non-biologic anti-lymphoma chemotherapy or radiotherapy within 28 days prior to first administration of study drug
- Infection with HIV or chronic infection with HBV, HCV, or CMV infection

For more information, visit www.clinicaltrials.gov or please call [+353 (0)61 533 400 or 844 REGN-MID].
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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 September 7, 2023.

Odronextamab-EM-0008 v2.0 February 2024.

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