CLIO-1 (NCT02651662) PHASE 1

Study of investigational odronextamab + cemiplimab in patients with **relapsed or refractory aggressive B-cell non-Hodgkin lymphoma**

Primary Objective: evaluate the safety and tolerability, and identify the recommended dose regimen of the combination of odronextamab and cemiplimab in patients with R/R aggressive B-cell non-Hodgkin lymphoma

PATIENTS WITH R/R AGGRESSIVE B-CELL NON-HODGKIN LYMPHOMA (N≈62)

OPEN LABEL INTERVENTION

Dose Escalation
Odronextamab (IV) + cemiplimab (IV)

→

Dose Expansion
Recomended Phase 2 dose
odronextamab (IV) + cemiplimab (IV)

Primary Endpoints

DLTs, TEAEs, AESIs

Secondary Endpoints

Pharmacokinetics
Immunogenicity

Anti-tumor activity:
Overall response rate[a]
Complete response rate[a]
Duration of response[a]

FIND OUT MORE
Scan here to find out more about this study at https://classic.clinicaltrials.gov/ct2/show/NCT02651662

This information is intended for investigators interested in open clinical trials.
The use of odronextamab + cemiplimab described herein is investigational and has not been evaluated by any regulatory authority.
Please see full prescribing information in your country for cemiplimab.

[a]Assessed by investigator.
AESI, adverse event of special interest; DLT, dose limiting toxicity; IV, intravenous; R/R, relapsed or refractory; TEAE, treatment-emergent adverse event.

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ODRONEXTAMAB

An Investigational CD20xCD3 Bispecific Antibody
Simultaneously engages CD20 on B cells and CD3 on cytotoxic T cells[1]

+

CEMIPLIMAB

An Investigational, Fully Human PD-1 Monoclonal Antibody
Designed to inhibit cancer cells from exploiting the PD-1 pathway, ensuring T cell activation remains unhindered for an effective immune response against cancer cells[2]

SELECTED INCLUSION CRITERIA[a]

- Documented CD20+ aggressive B-cell NHL that is either not responsive to or relapsed after at least 2 prior lines of systemic therapy that must include an anti-CD20 antibody and an alkylating agent
- At least 1 nodal lesion (≥1.5 cm), or at least one extranodal lesion with longest transverse diameter greater than 1.0 cm, documented by diagnostic imaging CT or MRI
- 0 or 1 — ECOG PS 0 or 1
- Adequate bone marrow and hepatic function

SELECTED EXCLUSION CRITERIA[a]

- Primary CNS lymphoma, or known or suspected CNS involvement by nonprimary CNS NHL
- History of or current relevant CNS pathology
- Evidence of significant autoimmune disease that required treatment with systemic immunosuppressive treatment within 2 years
- Uncontrolled infection with HIV, hepatitis B or hepatitis C infection or other uncontrolled infection
- Known hypersensitivity to both allopurinol

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.

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; NHL, non-Hodgkin lymphoma; PD-1, programmed cell death ligand 1.

Current per clinicaltrials.gov as of January 30, 2024.

1. Smith EJ et al. *Sci Rep*. 2015;5:17943. 2. Markham A, Duggan S. *Drugs*. 2018;78(17):1841-1846.
Odronextamab-EM-0011 v2.0 February 2024.

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