

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

Recommended Phase 2 dose
odronextamab (IV) + cemiplimab (IV)

Primary Endpoints

Safety, tolerability and DLT

Secondary Endpoints

Pharmacokinetics
Immunogenicity
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://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.

^aBased on investigator assessment.

DLT, dose limiting toxicity; IV, intravenous; R/R, relapsed or refractory.

ODRONEXTAMAB

An Investigational CD20xCD3 Bispecific Antibody

Simultaneously engages CD20 on malignant B cells and CD3 on cytotoxic T cells¹



CEMPIPLIMAB

An Investigational, Fully Human PD-1 Monoclonal Antibody

Designed to block cancer cells from using the PD-1 pathway to suppress T-cell activation²

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



Measurable lesion by diagnostic imaging



ECOG PS 0 or 1



Adequate bone marrow and other organ 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 and rasburicase



For more information, visit www.clinicaltrials.gov or please call [+353 (0)61 533 400 OR 844 REGN-MID].
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^aInclusion/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; ECOG PS, Eastern Cooperative Oncology Group performance status; HIV, human immunodeficiency virus; NHL, non-Hodgkin lymphoma; PCR, polymerase chain reaction; PD-1, programmed cell death ligand 1.

Current per clinicaltrials.gov as of June 22, 2023.

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

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