

NCT04409080

PHASE 1/2 ENROLLING

Study of investigational REGN7257 in patients with **severe aplastic anemia**



Primary Objective: evaluate the safety and tolerability of REGN7257, an IL-2RG monoclonal antibody, in patients with relapsed/refractory severe aplastic anemia



PATIENTS WITH SEVERE APLASTIC ANEMIA

OPEN LABEL INTERVENTION

Part A:
Single Ascending Dose
REGN7257 (IV)

Part B:
Dosing regimen informed by Part A
REGN7257 (IV)

Primary Endpoints

Safety and tolerability
Objective response rate

Key Secondary Endpoints

Complete response
Partial response
Blood cell counts
Platelet/RBC transfusions



FIND OUT MORE

Scan here to find out more about this study at <http://clinicaltrials.gov/ct2/show/NCT04409080>

This information is intended for investigators interested in open clinical trials.
REGN7257 is an investigational agent and has not been evaluated by any regulatory authority.

*Based on Blinded Independent Central Review (BICR).
IV, intravenous; N, number of patients; RBC, red blood cell, IL-2RG, interleukin 2 receptor subunit gamma.

REGENERON[®]
MEDICAL AFFAIRS

NCT04409080

PHASE 1/2 ENROLLING

REGN7257

An Investigational IL-2RG Monoclonal Antibody

Designed to bind IL-2RG on T cells to block gamma chain cytokine signaling and suppress immune cell activation and proliferation¹

SELECTED INCLUSION CRITERIA^a



Severe aplastic anemia that is IST-refractory or IST-relapsed



Hematopoietic stem cell transplant is not available or suitable as a treatment option



Adequate hepatic and renal function

SELECTED EXCLUSION CRITERIA^a



Diagnosis of Fanconi anemia or other congenital bone marrow failure syndrome



Evidence of myelodysplastic syndrome



PNH with evidence of clinically significant hemolysis or history of PNH-associated thrombosis



Treatment with a T-cell depleting agent within 6 month prior to dosing



Treatment with eltrombopag or investigational thrombopoietin receptor agonist, G-CSF, or an androgen within 2 weeks prior to dosing



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.

IST, immunosuppressive therapy; PNH, paroxysmal nocturnal hemoglobinuria; G-CSF, granulocyte-colony stimulating factor; DLBCL, diffuse large B-cell lymphoma; ECOG PS, Eastern Cooperative Oncology Group performance status; FL, follicular lymphoma; MRI, magnetic resonance imaging.

1. Le Floch A et al. *Sci Transl Med*. 2023;15(678):eabo0205.

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