A phase 3, randomized, double-blind, study to assess efficacy and safety of ianalumab (VAY736) versus placebo in warm autoimmune hemolytic anemia (wAIHA) patients who failed at least one line of treatment (VAYHIA)

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: 18 years and over
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- people with documented primary or secondary wAIHA - had an insufficient response to or relapsed after one or more treatments - Hemoglobin concentration at screening between 5 g/dL and 10 g/dL and experiencing symptoms of anemia - dose of supportive medication must be stable for at least 4 weeks

Exclusion Criteria:

- wAIHA due to disease involving bone marrow - prior use of B-cell depleting therapy (e.g., rituximab) within 12 weeks prior to starting the study - active viral, bacterial or other infections that require systemic treatment at time of screening, or a history of recurrent clinically significant infection - positive for hepatitis C virus, hepatitis B surface antigen (HBsAg), or hepatitis B core antibody (HBcAb) - contact study staff for additional criteria

Conditions & Interventions

Conditions:
Blood Disorders
Keywords:
hemolytic anemia, wAIHA, warm autoimmune hemolytic anemia

More Information

Description: The purpose of the study is to see if ianalumab, compared to placebo, is effective and safe for treating wAIHA. A placebo looks like the study drug, ianalumab, but does not contain any active ingredient. Ianalumab belongs to a class of drugs called monoclonal antibodies. Monoclonal antibodies are molecules that can recognize and stick to a specific protein expressed on the cell surface or released free in the body. Participants will receive study drug (ianalumab or placebo) through the vein every 4 weeks (4 doses in total) during the treatment period.
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