ForPatients
by Roche

Antiphospholipid Syndrome

A Study to Evaluate Crovalimab in People With Antiphospholipid Syndrome (APS)

Trial Status	Trial Runs In	Trial Identifier
Not yet recruiting		NCT07172022 2025-522980-14-00 BO46107

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Phase II, Randomized, Double-blind, Placebo-controlled, Multicenter Study Evaluating Efficacy, Safety, and Pharmacokinetics of Crovalimab in Patients With Antiphospholipid Syndrome (APS)

Trial Summary:

The main purpose of this study is to evaluate the efficacy of crovalimab compared with placebo as an add-on therapy to vitamin K antagonist (VKA) in participants with APS.

Hoffmann-La Roche	Phase 2
Sponsor	Phase

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Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years & # 70 Years	No

Inclusion Criteria:

- Age #18 years and #70 years, and body weight #40 kilograms (kg), at the time of signing Informed Consent Form
- Vaccination against N. meningitidis, H. influenzae type B, and S. pneumoniae
- Participants classified with APS who have experienced at least two prior arterial and/or venous thrombotic events, based on the 2023 American College of Rheumatology/European Alliance of Associations for Rheumatology (ACR/EULAR) criteria, positive for at least two of the following: lupus anticoagulant (LAC) test, anticardiolipin antibodies (aCL), anti-#2-glycoprotein 1 antibodies (a#2GP1)

- Participants receiving corticosteroids, antimalarial treatment, non-biologic disease-modifying rheumatic drugs, statins, and low dose aspirin must be on a stable dose prior to the first dose of study treatment
- Willingness and ability to comply with a VKA regimen titrated to a therapeutic target internal normalized ratio (INR)
- Agreement to adhere to the contraception requirements

Exclusion Criteria:

- Pregnant or breastfeeding, or intention of becoming pregnant during the study or within the time frame in which contraception is required
- Treatment with investigational therapy, complement inhibitor, and/or other immune-suppressive biologic therapy within 5 half-lives of that agent prior to screening visit, or plans to participate in another investigational trial
- Presence of another systemic autoimmune disease that is unstable and requires additional treatment, and constitutes the principal illness and may impact evaluation of the concurrent APS
- Inadequate renal and hepatic function
- Uncontrolled hyperlipidemia and/or hypertension, known diabetes mellitus, and/or serious infection requiring hospitalization or antibiotics prior to Week 1 Day 1
- History or condition associated with increased bleeding risk