KURZPROTOKOLL
CVAY736O12301

Öffentlicher Titel	Phase III Studie zu Ianalumab bei Autoimmun-hämolytischer Anämie
Wissenschaftl. Titel	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)
Kurztitel	CVAY736O12301
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, Pharma-Studie, doppelblind, dreiarmig
Studienphase	Phase III
Erkrankung	Blut: Blutbildungs- und Blutabbaustörungen
Einschlusskriterien	- 18 years and older at time of signing consent - Patients with primary or secondary wAIHA documented by positive direct antiglobulin test specific for anti-IgG or anti-IgA, who had an insufficient response to, or relapsed after at least one line of treatment, including patients with steroid resistance, dependence or intolerance - Hemoglobin concentration at screening and at Week 1 >=5 g/dL and <10 g/dL, associated with presence of symptoms related to anemia - The dose of supportive care must be stable for at least 4 weeks prior to randomization into the study
Ausschlusskriterien	- wAIHA secondary to hematologic disease involving bone marrow (e.g., CLL) or another immunologic disease requiring prohibited medication as per protocol. Patients with autoimmune diseases after wash-out from the treatments are allowed. - Presence of other forms of AIHA (cold or intermediate forms), Evans Syndrome or other cytopenias - Prior use of B-cell depleting therapy (e.g., rituximab) within 12 weeks prior to randomization, or without hematological response to the last course of B-cell depleting therapy - Neutrophils: <1000/mm3 - Serum creatinine >1.5 × upper limit of normal (ULN) - Immunoglobulin G (IgG) <5g/L - Active viral, bacterial or other infections (including tuberculosis and SARS-CoV-2) requiring systemic treatment at time of screening, or history of recurrent clinically significant infection - Positivity for hepatitis C virus, hepatitis B surface antigen (HBsAg), or hepatitis B core antibody (HBcAb). HBcAb positive patients can be enrolled if HBsAg negative, HBV DNA negative, no pre-existing liver fibrosis is present and antiviral prophylaxis is given. - Known history of primary or secondary immunodeficiency, or a positive human immune deficiency virus (HIV) test result - Live or live-attenuated vaccination within 4 weeks before randomization - History of splenectomy
Alter	18 Jahre und älter
Prüfzentren	**Innere Medizin 2** (Aktiv) Hämatologie / Medizinische Onkologie Theodor-Stern-Kai 7 60590 Frankfurt am Main Allg. Ansprechpartner der Abteilung Häma/Onko hoa-info@unimedizin-ffm.de
Sponsor	Novartis Pharma
Förderer	Novartis Pharma

Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT05648968 EudraCT 2022-001773-31 (primäres Register)
Links	Zu den Ein- und Ausschlusskriterien Studiendokumente zum Download (roXtra)