

A Study of Efficacy and Safety of Ianalumab in Previously Treated Patients With Warm Autoimmune Hemolytic Anemia

Last Update: Apr 11, 2025

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

ClinicalTrials.gov Identifier:

[NCT05648968](#)

Novartis Reference Number: CVAY736O12301

[See if you Pre-qualify](#)

All compounds are either investigational or being studied for (a) new use(s). Efficacy and safety have not been established. There is no guarantee that they will become commercially available for the use(s) under investigation.

Study Description

The purpose of this study is to evaluate efficacy and safety of Ianalumab compared to placebo in patients with warm autoimmune hemolytic anemia, who failed at least one line of treatment. The primary objective is to demonstrate that either dose of Ianalumab induces a durable hemoglobin response compared to placebo in patients with wAIHA.

The key secondary objective is to demonstrate that either dose of Ianalumab maintains a durable hemoglobin response that is sustained beyond end of the treatment period, compared to placebo.

Participants are randomized to two different doses of Ianalumab or placebo. Participants who were assigned to placebo arm and not responding to treatment may be treated with open label Ianalumab using the higher dose.

The investigational treatment will be supplied in a double-blinded manner. For the open label period, Ianalumab will be provided in an open label manner.

In addition to the randomized treatment (Ianalumab or placebo), specific supportive care medication as defined in the protocol is allowed. If clinically indicated (e.g., to ensure patient safety), the treating physician may also administer rescue medication.

The study consists of the treatment period, efficacy and safety follow-up periods. The visit frequency will be every other week during the treatment and primary endpoint follow up period; for safety monitoring monthly during the first 20 weeks after last dose and afterwards quarterly up to 2 years from the last dose. For participants in durable response, additional visits for efficacy will occur monthly during the first 2 years after the last dose, and afterwards quarterly until loss of response or end of study, latest until up to 39 months post randomization of the last participant.

Condition

Warm Autoimmune Hemolytic Anemia (wAIHA)

Phase

Phase3

Overall Status

Recruiting

Number of Participants

90

Start Date

Dec 30, 2022

Completion Date

May 02, 2029

Gender

All

Age(s)

18 Years - 100 Years (Adult, Older Adult)

Interventions

Biological

Ianalumab

i.v. infusion, prepared from concentrate solution

Drug

Placebo

i.v. infusion, prepared from matching placebo

Eligibility Criteria

Key Inclusion Criteria:

- * 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

Key Exclusion Criteria:

- * 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: $\leq 1000/\text{mm}^3$
- * Serum creatinine $\leq 1.5 \times$ upper limit of normal (ULN)
- * Immunoglobulin G (IgG) $\leq 5\text{g/L}$
- * 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

Other protocol-defined Inclusion/Exclusion may apply.

Argentina

Novartis Investigative Site

Recruiting

Ciudad Autonoma de Bs As, Buenos Aires, C1015abo, Argentina

Novartis Investigative Site

Recruiting

Buenos aires, C1039aac, Argentina

Novartis Investigative Site

Recruiting

Caba, Buenos Aires, C1414drk, Argentina

Australia

Novartis Investigative Site

Recruiting

Fitzroy, Victoria, 3065, Australia

Novartis Investigative Site

Recruiting

Canberra, Australian Capital Territory, 2605, Australia

Novartis Investigative Site

Recruiting

Melbourne, Victoria, 3004, Australia

China

Novartis Investigative Site

Recruiting

Suzhou, Jiangsu, 215004, China

Novartis Investigative Site

Recruiting

Kunming, Yunnan, 650101, China

Novartis Investigative Site

Recruiting

Hangzhou, Zhejiang, 310003, China

Novartis Investigative Site

Recruiting

Dalian, 116000, China

Novartis Investigative Site

Recruiting

Tianjin, 300020, China

Novartis Investigative Site

Recruiting

Guangzhou, Guangdong, 510515, China

Novartis Investigative Site

Recruiting

Tianjin, 300052, China

Novartis Investigative Site

Recruiting

Wuhan, Hubei, 430022, China

France

Novartis Investigative Site

Recruiting

Blois Cedex,41000,France

Novartis Investigative Site

Recruiting

Toulouse,31059,France

Novartis Investigative Site

Recruiting

Caen,14033,France

Novartis Investigative Site

Recruiting

Vandoeuvre Les Nancy,54511,France

Novartis Investigative Site

Recruiting

Creteil,94010,France

Novartis Investigative Site

Recruiting

Le Mans,72000,France

Novartis Investigative Site

Recruiting

Lille,59037,France

Novartis Investigative Site

Recruiting

Nantes Cedex 1,44093,France

Novartis Investigative Site

Recruiting

Nice,06202,France

Germany

Novartis Investigative Site

Recruiting

Frankfurt am Main,Hessen,60590,Germany

Novartis Investigative Site

Recruiting

Dresden,01307,Germany

Novartis Investigative Site

Recruiting

Essen,45147,Germany

Novartis Investigative Site

Recruiting

Giessen,35392,Germany

Novartis Investigative Site

Recruiting

Hannover,30161,Germany

Hungary

Novartis Investigative Site

Recruiting

Debrecen,4032,Hungary

Israel

Novartis Investigative Site

Recruiting

Afula,1834111,Israel

Novartis Investigative Site

Recruiting

Kfar Saba,44281,Israel

Novartis Investigative Site

Recruiting

Petach Tikva,4941492,Israel

Novartis Investigative Site

Recruiting

Zerifin,7030000,Israel

Italy

Novartis Investigative Site

Recruiting

Milano,MI,20100,Italy

Novartis Investigative Site

Recruiting

Milano,MI,20122,Italy

Novartis Investigative Site

Recruiting

Bassano Del Grappa,Vicenza,36061,Italy

Novartis Investigative Site

Recruiting

Novara,28100,Italy

Novartis Investigative Site

Recruiting

Avellino,AV,83100,Italy

Novartis Investigative Site

Recruiting

Bari,BA,70124,Italy

Japan

Novartis Investigative Site

Recruiting

Itabashi-ku,Tokyo,173-8610,Japan

Novartis Investigative Site

Recruiting

Matsuyama-city,Ehime,790-0024,Japan

Novartis Investigative Site

Recruiting

Shinjuku Ku,Tokyo,160-0023,Japan

Novartis Investigative Site

Recruiting

Fukuoka city,Fukuoka,812-8582,Japan

Novartis Investigative Site

Recruiting

Aomori,030 8553,Japan

Novartis Investigative Site

Recruiting

Gifu-city,Gifu,501-1194,Japan

Novartis Investigative Site

Recruiting

Yamagata,990 9585,Japan

Novartis Investigative Site

Recruiting

Kobe,Hyogo,650-0047,Japan

Novartis Investigative Site

Recruiting

Narita,Chiba,286-8523,Japan

Novartis Investigative Site

Recruiting

Isehara,Kanagawa,259-1193,Japan

Novartis Investigative Site

Recruiting

Suita,Osaka,565 0871,Japan

Malaysia

Novartis Investigative Site

Recruiting

Pulau Pinang,10990,Malaysia

Novartis Investigative Site

Recruiting

Selangor,68000,Malaysia

Novartis Investigative Site

Recruiting

Kuala Lumpur,56000,Malaysia

Novartis Investigative Site

Recruiting

Penang,10050,Malaysia

Romania

Novartis Investigative Site

Recruiting

Bucuresti,013975,Romania

Singapore

Novartis Investigative Site

Recruiting

Singapore,119074,Singapore

Novartis Investigative Site

Recruiting

Singapore,S308433,Singapore

Spain

Novartis Investigative Site

Recruiting

Murcia,30008,Spain

Novartis Investigative Site

Recruiting

Barcelona,Catalunya,08035,Spain

Taiwan

Novartis Investigative Site

Recruiting

Taoyuan,33305,Taiwan

United Kingdom

Novartis Investigative Site

Recruiting

Birmingham,B15 2th,United Kingdom

Novartis Investigative Site

Recruiting

Leeds,Ls1 3ex,United Kingdom

Novartis Investigative Site

Recruiting

London,E1 1bb,United Kingdom

Novartis Investigative Site

Recruiting

London,W12 0hs,United Kingdom

United States

University of Colorado Anschutz

University of Colorado Anschutz

Recruiting

Aurora, Colorado, 80045, United States

Phone: [303-724-1695](tel:303-724-1695)

George Gemlyn

Gabrail Cancer Center

Recruiting

Canton, Ohio, 44718, United States

Phone: [330-492-3345](tel:330-492-3345)

Nashat Y Gabrail

University of Minnesota Med Center

Recruiting

Minneapolis, Minnesota, 55455, United States

Diondra Howard

Email: howar709@umn.edu

Marshall Mazepa

Montefiore Medical Center

Recruiting

Bronx, New York, 10461, United States

Irina Murakhovskaya

Noelle Townsend

Phone: [718-920-2680](tel:718-920-2680)

Email: noelle.townsend@einsteinmed.edu

Napa Research

Recruiting

Margate, Florida, 33063, United States

Emilio Araujo-Mino

Maria Marin

Email: Maria@napa-trials.com

Texas Oncology-Baylor Scott and White

Recruiting

Dallas,Texas,75231,United States

Phone: [+1 214 987 6915](tel:+12149876915)

Moshe Yair Levy

STAT Research Inc

Recruiting

Dayton,Ohio,45402,United States

Charles Bane

Summit Health

Recruiting

Florham Park,New Jersey,07932,United States

Phone: [973-437-2597](tel:9734372597)

David Gallinson

Brody School of Medicine

Recruiting

Greenville,North Carolina,27834,United States

Phone: [252-744-3587](tel:2527443587)

Darla Liles

NorthShore University Health System

Recruiting

Evanston,Illinois,60201,United States

Phone: [847-570-2109](tel:8475702109)

Amy Wang

Fred Hutchinson Cancer Center

Recruiting

Seattle, Washington, 98109, United States

Phone: 206-288-6938

Sandhya Panch

Inspira Medical Cent Mullica Hill

Recruiting

Mullica Hill, New Jersey, 08062, United States

Erev Tubb

Jennifer Hart

Phone: 856-641-7526

Email: KartJ@ihn.org

Baylor College Of Medicine

Recruiting

Houston, Texas, 77030, United States

Senthil Sukumar

Michigan Center of Medical Research

Recruiting

Farmington Hills, Michigan, 48334, United States

Faisal Musa

Parkview Research Center

Recruiting

Fort Wayne, Indiana, 46845, United States

Jeffrey Letzer

Worldwide Contacts

If the location of your choosing does not feature any contact detail, please reach out using the information below.

Novartis Pharmaceuticals

Phone: +41613241111

Email:

Novartis Pharmaceuticals

Phone: [1-888-669-6682](tel:1-888-669-6682)

Email: novartis.email@novartis.com

Source URL: <https://prod1.novartis.com/clinicaltrials/study/nct05648968>

List of links present in page

1. <https://clinicaltrials.gov/ct2/show/NCT05648968>
2. [#trial-eligibility](#)
3. <tel:303-724-1695>
4. <tel:330-492-3345>
5. <mailto:howar709@umn.edu>
6. <tel:718-920-2680>
7. <mailto:noelle.townsend@einsteinmed.edu>
8. <mailto:Maria@napa-trials.com>
9. [tel:+1 214 987 6915](tel:+12149876915)
10. <tel:973-437-2597>
11. <tel:252-744-3587>
12. <tel:847-570-2109>
13. <tel:206-288-6938>
14. <tel:856-641-7526>
15. <mailto:KartJ@ihn.org>
16. <tel:+41613241111>
17. <mailto:>
18. <tel:1-888-669-6682>
19. <mailto:novartis.email@novartis.com>