Safety, Tolerability, and Efficacy of NVG-2089 in Participants with Immune Thrombocytopenia

Estado	Tipo de Participantes	Rangos de Edad
Reclutando	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase II	4
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia, farmacocinética, farmacodinamica	NO

Información

Identificador
2024-520359-26-00 (CTIS)

Cod. Protocolo
NVG-2089-200

Área terapéutica
Enfermedades [C] - Patologías del sistema inmunitario [C20]|

Enfermedad investigada
Immune Thrombocytopenia (ITP)

Título Científico
An Open-Label, Dose-Ranging Study to Evaluate the Safety, Tolerability, and Efficacy of Intravenous NVG-2089 in Participants with Immune Thrombocytopenia

Justificación

No aportado

Objetivo Principal

To evaluate the safety and tolerability NVG-2089 in participants with ITP

Variables de Evaluación Primaria

Incidence, nature, and severity of TEAEs, and serious adverse events (SAEs)

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

1. To evaluate the of NVG-2089 in participants with ITP
2. To evaluate the population PK of NVG-2089 in participants with ITP

Variables de Evaluación Secundaria

1. Percent of participants achieving a response. For participants with a dose-specific baseline platelet count <30,000 cells/mm3, a response is defined as a doubling of the dose-specific baseline platelet count or a platelet count of 50,000 cells/mm3; For participants with a dose-specific baseline platelet count 30,000 cells/mm3, a response is defined as an increase in the platelet count to 20,000 cells/ mm3 from dose-specific baseline 2. Duration of response 3. Absolute and percent change from the dose specific baseline in platelet count 4. PK parameters of NVG-2089

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

1. Male and female participants, age 18 to 80 years at time of screening. 2. Diagnosis of persistent (>3 months and 12 months), or chronic (>12 months) primary ITP. If the participant has received prior treatment for ITP, they must have a history of response to at least one previous therapy (defined as increase in platelet count to 50,000 cells/mm3 with an increase of 20,000 cells/mm3 relative to platelet count prior to treatment). 3. Asymptomatic or with minor mucocutaneous bleeding AND platelet count <50,000 cells/mm3, measured on 2 occasions at least 5 days apart

during the screeninig period. 4. If participant has received prior IVIg therapy participant must have shown a sufficient platelet response (doubling of platelet count within 7 days of IVIg infusion) and must not have lost response to IVIg therapy while on treatment. 5. Female participants of childbearing potential must have a negative serum pregnancy test at Screening and a negative urine pregnancy test on Day 1. 6. Female participants who are sexually active with a male partner of reproductive potential must use double contraception (including a barrier contraceptive and another method) from at least 28 days prior to Screening and for 90 days after last dose of study drug; female participants must also refrain from oocyte donation for the purpose of reproduction during this period. Exceptions are made for surgically sterile participants, or post-menopausal females (defined as 12 months of spontaneous amenorrhea or 6 months of spontaneous amenorrhea with serum follicle-stimulating hormone levels >40 mIU/mL or 6 weeks postsurgical bilateral oophorectomy with or without hysterectomy). Abstinence is acceptable if this is the usual lifestyle and preferred contraception for the participant. 7. Participant is capable or has a legally authorized representative(s) (LAR[s]) capable of providing a signed informed consent which includes compliance with the requirements and restrictions listed in the informed consent form (ICF). 8. Participant is capable or has a legally authorized representative(s) (LAR[s]) capable of providing a signed informed consent which includes compliance with the requirements and restrictions listed in the informed consent form (ICF).

Criterios de Exclusión

1. Secondary forms of ITP (e.g., ITP secondary to infection, autoimmune diseases, lymphoproliferative diseases and medications) 18. Receipt of another investigational drug within 4-weeks or 5 half-lives (whichever is longer) prior to screening. 19. Concurrent treatment with other monoclonal antibody and/or Fc therapies. 2. History of splenectomy. 21. Current or past history (within 12 months of screening) of alcohol, drug, or medication abuse. Positive urine drug screen at screening visit unless due to medication prescribed by a treating physician for pre-existing ongoing medical condition. 22. Pregnant or lactating women and those intending to become pregnant during the study or are unwilling to apply an effective birth control method (such as implants, injectables, combined oral contraceptives, intrauterine devices [IUDs], sexual abstinence, or vasectomized partner) up to 90 days after last study drug administration. 23. Poor venous access. 24. A known allergy to study drug (NVG-2089) and/or any of its components. 3. History of malignancy within 2 years of screeninig, unless the participant received treatment with curative intent that was completed prior to study screening. Participants with fully excised non-melanoma skin cancer or cervical cancer are allowed. 4. History of solid organ transplant or hematopoietic stem cell transplantation. 5. Planned or anticipated medical or surgical procedure, including dental procedure, during the timeframe of study conduct. 10. Any of the following at screening: a. Active Hepatitis B Virus (HBV): Hepatitis surface antigen (HBsAg) positive b. Active Hepatitis C Virus (HCV): serology positive for HCV-antibody c. Human Immunodeficiency Virus (HIV) positive serology" 6. Clinically significant active or chronic uncontrolled bacterial, viral, or fungal infection at screening, including active viral infection at screening. 7. Any medical condition that, in the opinion of the investigator, would interfere with study evaluations or procedures, and/or put the participant at increased risk. 8. ECG findings of QTcF > 450 msec (males) or > 470 msec (females), poorly controlled atrial fibrillation or other clinically significant abnormalities." 9. Other significant organ dysfunction, including but not limited to, hematologic, renal, or hepatic dysfunction, as evidenced by: a. Absolute neutrophil count 1.5 x 10^9/L b. Hemoglobin (Hgb) < 9 g/dL c. Aspartate aminotransaminase and/or alanine aminotransferase 2 x the upper limit of normal (ULN), d. Albumin 3 g/dL e. Total bilirubin 1.5 x ULN f. Estimated glomerular filtration rate < 50 mL/min/1.73m2 using the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) method 20. Prior treatment with study drug (NVG-2089) 11. Transfusion of blood, blood products (including immune globulin), or plasmapheresis within 4 weeks prior to screening. 12. Change in current ITP therapy (e.g., prednisone, methylprednisone, mycophenolate, dapsone, danazol, azathioprine, or TPO receptor agonist) or dose within 4 weeks prior to screening." 13. Receipt of dexamethasone within 4 weeks prior to screening. 14. Receipt of rituximab or an anti-CD20 agent within 6 months prior to screening. 15. Receipt of an neonatal Fc receptor (FcRn) inhibitor within 12 weeks prior to screening. 16. Receipt of IVIg within 4 weeks prior to screening. 17. Receipt of anticoagulants within 4 weeks prior to screening

Calendario

(Última actualización: 29/09/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
12/08/2025	25/08/2025	07/10/2025	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
No aportado	No aportado	No aportado	No aportado	No aportado

Promotor

Nuvig Therapeutics Inc. United States

4200 Bohannon Drive Suite 250

Contact Person

Yvonne Coffey

16503943990

info@nuvigtx.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Hospital General Universitario Gregorio Marañón

C/ Doctor Esquerdo, 46 28007 Madrid

ceim.hgugm@salud.madrid.org

915867007

Centros

Activo (12/11/2025)

Hospital Del Mar

Barcelona

BARCELONA

Hematology

Cerrado (15/04/2026)

Hospital General Universitario Gregorio Maranon

Madrid

MADRID

Hematology

Activo (07/10/2025)

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Hematology

Cerrado (29/09/2026)

Hospital Universitario De Burgos

Burgos

BURGOS

Hematology

Activo (26/09/2025)

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Hematology

Activo (26/08/2025)

University Clinical Hospital Virgen De La Arrixaca

Murcia

MURCIA

Hematology

Medicamentos

NVG-2089
SOLUTION FOR INFUSION
INTRAVENIOUS INFUSION

-

Principios Activos: N/A

Experimental

-
-
INTRAVENIOUS INFUSION

Código ATC: J06BA02 - INMUNOGLOBULINAS HUMANAS NORMALES PARA ADM. INTRAVASCULAR

Principios Activos: N/A

Experimental

Sin resultados

Safety, Tolerability, and Efficacy of NVG-2089 in Participants with Immune Thrombocytopenia

State	Type of participants	Age Ranges
Recruiting	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase II	4
Results	**Low level of intervention**	**Rare disease**
No results	No	Yes
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness, pharmacokinetics, pharmacodynamics	NO

Information

Identifier
2024-520359-26-00 (CTIS)

Protocol Code
NVG-2089-200

Therapeutic area
Diseases [C] - Immune System Diseases [C20]|

Investigated Disease
Immune Thrombocytopenia (ITP)

Scientific Title
An Open-Label, Dose-Ranging Study to Evaluate the Safety, Tolerability, and Efficacy of Intravenous NVG-2089 in Participants with Immune Thrombocytopenia

Rationale

Not provided

Main Objective

To evaluate the safety and tolerability NVG-2089 in participants with ITP

Primary Endpoints

Incidence, nature, and severity of TEAEs, and serious adverse events (SAEs)

Temporary moments of secondary assessment

Not provided

Secondary Objective

1. To evaluate the of NVG-2089 in participants with ITP
2. To evaluate the population PK of NVG-2089 in participants with ITP

Secondary Endpoints

1. Percent of participants achieving a response. For participants with a dose-specific baseline platelet count <30,000 cells/mm3, a response is defined as a doubling of the dose-specific baseline platelet count or a platelet count of 50,000 cells/mm3; For participants with a dose-specific baseline platelet count 30,000 cells/mm3, a response is defined as an increase in the platelet count to 20,000 cells/ mm3 from dose-specific baseline 2. Duration of response 3. Absolute and percent change from the dose specific baseline in platelet count 4. PK parameters of NVG-2089

Temporary moments of secondary assessment

Not provided

Inclusion criteria

1. Male and female participants, age 18 to 80 years at time of screening. 2. Diagnosis of persistent (>3 months and 12 months), or chronic (>12 months) primary ITP. If the participant has received prior treatment for ITP, they must have a history of response to at least one previous therapy (defined as increase in platelet count to 50,000 cells/mm3 with an increase of 20,000 cells/mm3 relative to platelet count prior to treatment). 3. Asymptomatic or with minor mucocutaneous bleeding AND platelet count <50,000 cells/mm3, measured on 2 occasions at least 5 days apart

during the screeninig period. 4. If participant has received prior IVIg therapy participant must have shown a sufficient platelet response (doubling of platelet count within 7 days of IVIg infusion) and must not have lost response to IVIg therapy while on treatment. 5. Female participants of childbearing potential must have a negative serum pregnancy test at Screening and a negative urine pregnancy test on Day 1. 6. Female participants who are sexually active with a male partner of reproductive potential must use double contraception (including a barrier contraceptive and another method) from at least 28 days prior to Screening and for 90 days after last dose of study drug; female participants must also refrain from oocyte donation for the purpose of reproduction during this period. Exceptions are made for surgically sterile participants, or post-menopausal females (defined as 12 months of spontaneous amenorrhea or 6 months of spontaneous amenorrhea with serum follicle-stimulating hormone levels >40 mIU/mL or 6 weeks postsurgical bilateral oophorectomy with or without hysterectomy). Abstinence is acceptable if this is the usual lifestyle and preferred contraception for the participant. 7. Participant is capable or has a legally authorized representative(s) (LAR[s]) capable of providing a signed informed consent which includes compliance with the requirements and restrictions listed in the informed consent form (ICF). 8. Participant is capable or has a legally authorized representative(s) (LAR[s]) capable of providing a signed informed consent which includes compliance with the requirements and restrictions listed in the informed consent form (ICF).

Exclusion criteria

1. Secondary forms of ITP (e.g., ITP secondary to infection, autoimmune diseases, lymphoproliferative diseases and medications) 18. Receipt of another investigational drug within 4-weeks or 5 half-lives (whichever is longer) prior to screening. 19. Concurrent treatment with other monoclonal antibody and/or Fc therapies. 2. History of splenectomy. 21. Current or past history (within 12 months of screening) of alcohol, drug, or medication abuse. Positive urine drug screen at screening visit unless due to medication prescribed by a treating physician for pre-existing ongoing medical condition. 22. Pregnant or lactating women and those intending to become pregnant during the study or are unwilling to apply an effective birth control method (such as implants, injectables, combined oral contraceptives, intrauterine devices [IUDs], sexual abstinence, or vasectomized partner) up to 90 days after last study drug administration. 23. Poor venous access. 24. A known allergy to study drug (NVG-2089) and/or any of its components. 3. History of malignancy within 2 years of screeninig, unless the participant received treatment with curative intent that was completed prior to study screening. Participants with fully excised non-melanoma skin cancer or cervical cancer are allowed. 4. History of solid organ transplant or hematopoietic stem cell transplantation. 5. Planned or anticipated medical or surgical procedure, including dental procedure, during the timeframe of study conduct. 10. Any of the following at screening: a. Active Hepatitis B Virus (HBV): Hepatitis surface antigen (HBsAg) positive b. Active Hepatitis C Virus (HCV): serology positive for HCV-antibody c. Human Immunodeficiency Virus (HIV) positive serology" 6. Clinically significant active or chronic uncontrolled bacterial, viral, or fungal infection at screening, including active viral infection at screening. 7. Any medical condition that, in the opinion of the investigator, would interfere with study evaluations or procedures, and/or put the participant at increased risk. 8. ECG findings of QTcF > 450 msec (males) or > 470 msec (females), poorly controlled atrial fibrillation or other clinically significant abnormalities." 9. Other significant organ dysfunction, including but not limited to, hematologic, renal, or hepatic dysfunction, as evidenced by: a. Absolute neutrophil count 1.5 x 10^9/L b. Hemoglobin (Hgb) < 9 g/dL c. Aspartate aminotransaminase and/or alanine aminotransferase 2 x the upper limit of normal (ULN), d. Albumin 3 g/dL e. Total bilirubin 1.5 x ULN f. Estimated glomerular filtration rate < 50 mL/min/1.73m2 using the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) method 20. Prior treatment with study drug (NVG-2089) 11. Transfusion of blood, blood products (including immune globulin), or plasmapheresis within 4 weeks prior to screening. 12. Change in current ITP therapy (e.g., prednisone, methylprednisone, mycophenolate, dapsone, danazol, azathioprine, or TPO receptor agonist) or dose within 4 weeks prior to screening." 13. Receipt of dexamethasone within 4 weeks prior to screening. 14. Receipt of rituximab or an anti-CD20 agent within 6 months prior to screening. 15. Receipt of an neonatal Fc receptor (FcRn) inhibitor within 12 weeks prior to screening. 16. Receipt of IVIg within 4 weeks prior to screening. 17. Receipt of anticoagulants within 4 weeks prior to screening

Calendar

(Last Update: 29/09/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
12/08/2025	25/08/2025	07/10/2025	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
Not aported	Not aported	Not aported	Not aported	Not aported

Sponsor

Nuvig Therapeutics Inc. United States

4200 Bohannon Drive Suite 250

Contact Person

Yvonne Coffey

16503943990

info@nuvigtx.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Hospital General Universitario Gregorio Marañón

C/ Doctor Esquerdo, 46 28007 Madrid

ceim.hgugm@salud.madrid.org

915867007

Sites

Active (12/11/2025)

Hospital Del Mar

Barcelona

BARCELONA

Hematology

Closed (15/04/2026)

Hospital General Universitario Gregorio Maranon

Madrid

MADRID

Hematology

Active (07/10/2025)

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Hematology

Closed (29/09/2026)

Hospital Universitario De Burgos

Burgos

BURGOS

Hematology

Active (26/09/2025)

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Hematology

Active (26/08/2025)

University Clinical Hospital Virgen De La Arrixaca

Murcia

MURCIA

Hematology

Medication

NVG-2089
SOLUTION FOR INFUSION
INTRAVENIOUS INFUSION

-

Active Principles: N/A

Experimental

-
-
INTRAVENIOUS INFUSION

ATC code: J06BA02 - INMUNOGLOBULINAS HUMANAS NORMALES PARA ADM. INTRAVASCULAR

Active Principles: N/A

Experimental

No results