Relatlimab + Nivolumab in Pediatric and Young Adult Lymphomas (RELATIVITY-069)

Estado	**Tipo de Participantes**	**Rangos de Edad**
EC Finalizado	No aportado	Adultos (18-64 años) , Adolescentes (12-17 años) , Niños (2-11 años) , Lactantes y preescolar (28 días - 23 meses)
Género	**Fases**	**Participantes esperados**
Ambos	Fase I , Fase II	64
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Tiene resultados	No	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia, farmacocinética, farmacogenómica	NO

Información

Identificador
2023-503715-14-00 (CTIS)

Cod. Protocolo
CA224-069

Transicionado 2021-000493-29

Área terapéutica
Enfermedades [C] - Cáncer [C04]|

Enfermedad investigada
Recurrent or Refractory Classical Hodgkin Lymphoma and Non-Hodgkin Lymphoma

Título Científico

A Phase 1/2 Study of the Safety, Tolerability, Pharmacokinetics and Preliminary Efficacy of Relatlimab Plus Nivolumab in Pediatric and Young Adult Participants with Recurrent or Refractory Classical Hodgkin Lymphoma and Non-Hodgkin Lymphoma

Justificación

No aportado

Objetivo Principal

Part A: To characterize the safety, tolerability, and define the MTD or RP2D for the combination of relatlimab + nivolumab in pediatric participants less than 18 years of age with R/R cHL and NHL.
Part A: To characterize the PK of relatlimab for the combination of relatlimab + nivolumab in pediatric participants less than 18 years of age with R/R cHL and NHL.
Part B: To assess the preliminary efficacy of relatlimab + nivolumab based on the RP2D from part A in participants less than or equal to 30 years old with cHL (Cohort 1).

Variables de Evaluación Primaria

1/Part A- Dose-limiting toxicities (DLTs), Maximum Tolerated Dose/Recommended Phase 2 Dose; (MTD/RP2D), and incidences of Adverse Events (AEs), Serious Adverse Events (SAEs), AEs leading to discontinuation, deaths and laboratory abnormalities
2/Part A- maximum observed serum concentration (Cmax), trough observed concentration (Ctrough), time to maximum concentration (Tmax), and area under the curve within a dosing interval (AUC(TAU)) for relatlimab
3/Part B- Complete Metabolic Response (CMR) rate

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

Part B: To assess the safety of relatlimab + nivolumab in R/R cHL (Cohort 1) and NHL (Cohort2) Part B: To evaluate the ORR of relatlimab + nivolumab in participants 30 years of age with cHL (Cohort 1)

Variables de Evaluación Secundaria

1/Part B: Incidences of AEs, SAEs, AEs leading to discontinuation, deaths, and laboratory abnormalities
2/Part B: Overall Response Rate (ORR)

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Male and female participants less than 18 years of age (Part A), and less than or equal to 30 years of age (Part B) with Recurrent or Refractory Classical Hodgkin Lymphoma (R/R cHL) (Cohort 1) and Non Hodgkin Lymphoma (NHL) (Cohort 2). Participants with pathologically confirmed high-risk R/R cHL, after non-response to or failure of 1 or more lines of standard therapy. Participants with pathologically confirmed R/R NHL after non-response to or failure of 1 or more lines of standard therapy, including, but not limited to, R/R primary mediastinal B-cell lymphoma, diffuse large B-cell lymphoma (DLBCL), mediastinal gray zone lymphoma (MGZL), anaplastic large cell lymphoma (ALCL), or peripheral T-cell lymphoma (PTCL). The participant's current disease state must be R/R to standard therapy. Participants must have measurable PET positive disease in both cHL and NHL cohorts. Participants with pathologically confirmed R/R NHL after non-response to or failure of 2 or more lines of standard therapy, including Burkitt lymphoma (blast count < 25% malignant Burkitt cells and/or per the investigator's clinical assessment of risk status), lymphoblastic lymphoma (blast count < 25% of marrow nucleated cells and/or per the investigator's clinical assessment of risk status), NK/T-cell lymphoma (nasal and non-nasal NK/T-cell lymphoma subtypes, but not aggressive NK/T-cell leukemia/lymphoma subtype).

Criterios de Exclusión

Primary CNS lymphoma of the brain or spinal cord, and secondary CNS lymphoma (ie, from systemic non-Hodgkin lymphoma) involving the brain, spinal cord, or with leptomeningeal seeding.
Prior treatment with an anti-cytotoxic T-lymphocyte-associated protein 4 antibody, or any other antibody or drug specifically targeting T-cell costimulation or checkpoint pathways, with the exception of anti-PD(L)-1 targeted therapies.
Prior treatment with LAG-3-targeted agents.
Participants with a history of allogeneic bone marrow transplantation.
Participants with clinically significant systemic illnesses unrelated to the cancer as judged by the investigators, which would compromise the participant's ability to tolerate the study treatment.
Participants with autoimmune disease.
Participants who are pregnant or breastfeeding.

Calendario

(Última actualización: 29/05/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
23/05/2022	29/07/2022	31/10/2024	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
10/07/2025	No aportado	No aportado	No aportado	04/12/2025

Promotor

Bristol Myers Squibb International Corporation Belgium

Terhulpsesteenweg 185

Contact Person

GSM-CT

00322527611

mg-gsm-ct@bms.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Hospital General Universitario Gregorio Marañón

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915867007

Centros

Cerrado (03/12/2025)

Clinica Universidad De Navarra

Pamplona

NAVARRA

Pediatric

Cerrado (03/12/2025)

Clinica Universidad De Navarra

Madrid

MADRID

Pediatric

Cerrado (19/02/2026)

Hospital Infantil Universitario Nino Jesus

Madrid

MADRID

Oncology

Cerrado (11/02/2026)

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Oncology

No iniciado (--/--/----)

Hospital Universitario Fundacion Jimenez Diaz

Madrid

MADRID

Hematology

Cerrado (02/12/2025)

Hospital Universitario La Paz

Madrid

MADRID

Oncology

Cerrado (16/04/2026)

Hospital Universitario Y Politecnico La Fe

Valencia

VALENCIA

Oncology

Cerrado (20/11/2025)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

Cerrado (20/10/2025)

Hospital Universitario 12 De Octubre

Madrid

MADRID

Hemato-oncology

Cerrado (24/02/2026)

Sant Joan De Deu Barcelona Hospital

Esplugues De Llobregat

BARCELONA

Oncology

Cerrado (26/11/2025)

University Hospital Virgen Del Rocio S.L.

Sevilla

SEVILLA

Oncology

Medicamentos

OPDIVO 10 mg/mL concentrate for solution for infusion.

SOLUTION FOR INFUSION

INTRAVENOUS USE

Código ATC: L01FF01 - NIVOLUMAB

Principios Activos: N/A

Experimental

Relatlimab

SOLUTION FOR INJECTION

INTRAVENOUS USE

-

Principios Activos: N/A

Experimental

Tiene resultados

Relatlimab + Nivolumab in Pediatric and Young Adult Lymphomas (RELATIVITY-069)

State	Type of participants	Age Ranges
Finished CT	Not provided	Adults (18-64 years) , Teens (12-17 years) , Children (2-11 years) , Infants and preschool (28 days - 23 months)
Gender	**Phases**	**Expected Participants**
Both	Phase I , Phase II	64
Results	**Low level of intervention**	**Rare disease**
Has results	No	Yes
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness, pharmacokinetics, pharmacogenomics	NO

Information

Identifier
2023-503715-14-00 (CTIS)

Protocol Code
CA224-069

Transitioned 2021-000493-29

Therapeutic area
Diseases [C] - Cancer [C04]|

Investigated Disease
Recurrent or Refractory Classical Hodgkin Lymphoma and Non-Hodgkin Lymphoma

Scientific Title

A Phase 1/2 Study of the Safety, Tolerability, Pharmacokinetics and Preliminary Efficacy of Relatlimab Plus Nivolumab in Pediatric and Young Adult Participants with Recurrent or Refractory Classical Hodgkin Lymphoma and Non-Hodgkin Lymphoma

Rationale

Not provided

Main Objective

Part A: To characterize the safety, tolerability, and define the MTD or RP2D for the combination of relatlimab + nivolumab in pediatric participants less than 18 years of age with R/R cHL and NHL.
Part A: To characterize the PK of relatlimab for the combination of relatlimab + nivolumab in pediatric participants less than 18 years of age with R/R cHL and NHL.
Part B: To assess the preliminary efficacy of relatlimab + nivolumab based on the RP2D from part A in participants less than or equal to 30 years old with cHL (Cohort 1).

Primary Endpoints

1/Part A- Dose-limiting toxicities (DLTs), Maximum Tolerated Dose/Recommended Phase 2 Dose; (MTD/RP2D), and incidences of Adverse Events (AEs), Serious Adverse Events (SAEs), AEs leading to discontinuation, deaths and laboratory abnormalities
2/Part A- maximum observed serum concentration (Cmax), trough observed concentration (Ctrough), time to maximum concentration (Tmax), and area under the curve within a dosing interval (AUC(TAU)) for relatlimab
3/Part B- Complete Metabolic Response (CMR) rate

Temporary moments of secondary assessment

Not provided

Secondary Objective

Part B: To assess the safety of relatlimab + nivolumab in R/R cHL (Cohort 1) and NHL (Cohort2) Part B: To evaluate the ORR of relatlimab + nivolumab in participants 30 years of age with cHL (Cohort 1)

Secondary Endpoints

1/Part B: Incidences of AEs, SAEs, AEs leading to discontinuation, deaths, and laboratory abnormalities
2/Part B: Overall Response Rate (ORR)

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Male and female participants less than 18 years of age (Part A), and less than or equal to 30 years of age (Part B) with Recurrent or Refractory Classical Hodgkin Lymphoma (R/R cHL) (Cohort 1) and Non Hodgkin Lymphoma (NHL) (Cohort 2). Participants with pathologically confirmed high-risk R/R cHL, after non-response to or failure of 1 or more lines of standard therapy. Participants with pathologically confirmed R/R NHL after non-response to or failure of 1 or more lines of standard therapy, including, but not limited to, R/R primary mediastinal B-cell lymphoma, diffuse large B-cell lymphoma (DLBCL), mediastinal gray zone lymphoma (MGZL), anaplastic large cell lymphoma (ALCL), or peripheral T-cell lymphoma (PTCL). The participant's current disease state must be R/R to standard therapy. Participants must have measurable PET positive disease in both cHL and NHL cohorts. Participants with pathologically confirmed R/R NHL after non-response to or failure of 2 or more lines of standard therapy, including Burkitt lymphoma (blast count < 25% malignant Burkitt cells and/or per the investigator's clinical assessment of risk status), lymphoblastic lymphoma (blast count < 25% of marrow nucleated cells and/or per the investigator's clinical assessment of risk status), NK/T-cell lymphoma (nasal and non-nasal NK/T-cell lymphoma subtypes, but not aggressive NK/T-cell leukemia/lymphoma subtype).

Exclusion criteria

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Participants with autoimmune disease.
Participants who are pregnant or breastfeeding.

Calendar

(Last Update: 29/05/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
23/05/2022	29/07/2022	31/10/2024	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
10/07/2025	Not aported	Not aported	Not aported	04/12/2025

Sponsor

Bristol Myers Squibb International Corporation Belgium

Terhulpsesteenweg 185

Contact Person

GSM-CT

00322527611

mg-gsm-ct@bms.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Hospital General Universitario Gregorio Marañón

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915867007

Sites

Closed (03/12/2025)

Clinica Universidad De Navarra

Pamplona

NAVARRA

Pediatric

Closed (03/12/2025)

Clinica Universidad De Navarra

Madrid

MADRID

Pediatric

Closed (19/02/2026)

Hospital Infantil Universitario Nino Jesus

Madrid

MADRID

Oncology

Closed (11/02/2026)

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Oncology

not initialized (--/--/----)

Hospital Universitario Fundacion Jimenez Diaz

Madrid

MADRID

Hematology

Closed (02/12/2025)

Hospital Universitario La Paz

Madrid

MADRID

Oncology

Closed (16/04/2026)

Hospital Universitario Y Politecnico La Fe

Valencia

VALENCIA

Oncology

Closed (20/11/2025)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

Closed (20/10/2025)

Hospital Universitario 12 De Octubre

Madrid

MADRID

Hemato-oncology

Closed (24/02/2026)

Sant Joan De Deu Barcelona Hospital

Esplugues De Llobregat

BARCELONA

Oncology

Closed (26/11/2025)

University Hospital Virgen Del Rocio S.L.

Sevilla

SEVILLA

Oncology

Medication

OPDIVO 10 mg/mL concentrate for solution for infusion.

SOLUTION FOR INFUSION

INTRAVENOUS USE

ATC code: L01FF01 - NIVOLUMAB

Active Principles: N/A

Experimental

Relatlimab

SOLUTION FOR INJECTION

INTRAVENOUS USE

-

Active Principles: N/A

Experimental

Has results