A Study to Evaluate Safety, Tolerability, Pharmacokinetics, and Anti-Tumor Activity of Glofitamab in Monotherapy and in Combination with Chemoimmunotherapy in Pediatric and Young Adult Participants with Relapsed/Refractory Mature B-Cell Non-Hodgkin Lymphoma

Estado	Tipo de Participantes	Rangos de Edad
Reclutando	Sujetos incapaces de otorgar consentimiento	Menores de 18 , Adultos (18-64 años) , Adolescentes (12-17 años) , Niños (2-11 años) , Lactantes y preescolar (28 días - 23 meses) , Recién nacidos (0-27 días)
Género	**Fases**	**Participantes esperados**
Ambos	Fase I , Fase II	40
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia, farmacocinética	NO

Información

Identificador

2023-504264-41-00 (CTIS)

Cod. Protocolo

CO43810

Transicionado 2021-006326-48

Área terapéutica

·Enfermedades [C] - Cáncer [C04]
·Atención a la salud [N] - Medio ambiente y salud pública [N06]

Enfermedad investigada

CD20 positive B-Cell Non-Hodgkin Lymphoma (NHL)

Título Científico

A Phase I/II, Open-Label, Single-Arm, Two-Part Trial to Evaluate Safety, Tolerability, Pharmacokinetics, and Anti-Tumor Activity of Glofitamab in Monotherapy and in Combination with Chemoimmunotherapy in Pediatric and Young Adult Participants with Relapsed/Refractory Mature B-Cell NonHodgkin Lymphoma

Justificación

No aportado

Objetivo Principal

To evaluate the efficacy of glofitamab in combination with rituximab, ifosfamide, carboplatin, and etoposide (R-ICE) chemoimmunotherapy, as assessed by the investigator based on achievement of a complete response (CR) To evaluate the safety and tolerability of glofitamab in combination with R-ICE chemoimmunotherapy To determine the pharmacokinetics of glofitamab alone and in combination with R-ICE chemoimmunotherapy

Variables de Evaluación Primaria

Cohort A - Glofitamab Combination Therapy (glofitamab plus R-ICE chemoimmunotherapy) 1. Achievement of a complete response (CR) after up to three cycles of treatment as determined by the investigator according to the International Pediatric NHL Response Criteria for pediatric participants and Lugano Classification for young adult participants
Cohort A - Glofitamab Combination Therapy (glofitamab plus R-ICE chemoimmunotherapy) 2. Incidence, nature, frequency, severity, and timing of adverse events, with severity determined according to National Cancer Institute Common Terminology Criteria for Adverse Events, version 5 (NCI CTCAE v5.0) (glofitamab plus R-ICE chemoimmunotherapy)
Cohort A - Glofitamab Combination Therapy (glofitamab plus R-ICE chemoimmunotherapy) 3. Change from baseline in physical findings, vital signs, clinical laboratory test results and electrocardiogram (ECG) parameters
4. Pharmacokinetics (PK) parameters (as appropriate) and serum concentrations of glofitamab monotherapy at specified timepoints
5. PK parameters (as appropriate) and serum concentrations of glofitamab in combination with R-ICE chemoimmunotherapy at specified timepoints

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To evaluate the anti-tumor activity of glofitamab in combination with R-ICE chemoimmunotherapy and glofitamab monotherapy
To evaluate the safety and tolerability of glofitamab monotherapy
To determine the pharmacokinetics of obinutuzumab and rituximab
To evaluate the immune response to glofitamab

Variables de Evaluación Secundaria

1. For glofitamab plus R-ICE chemoimmunotherapy: Objective response rate (ORR), Duration of complete response (DOCR), Progression-free survival (PFS) after enrollment, Event-free survival (EFS), Overall survival (OS) and percentage of patients who proceed to HSCT after up to three cycles of treatment
2. For glofitamab monotherapy: ORR, Duration of response (DOR) and OS
Glofitamab monotherapy 3. Incidence, nature, frequency, severity, and timing of adverse events, with severity determined according to NCI CTCAE v5.0
Glofitamab monotherapy 4. Change from baseline in physical findings, vital signs, clinical laboratory test results and ECG parameters
5. Serum concentrations of obinutuzumab at specified timepoints
6. Serum concentrations of rituximab at specified timepoints
7. Prevalence of anti-drug antibodies (ADAs) at baseline and incidence of ADAs against glofitamab during the study

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Age 6 months to <18 years at the time of signing Informed Consent for Cohort A Part 1 and Cohort B of the study, and age 6 months to < 30 years old at the time of signing Informed Consent for Cohort A Part 2 of the study Cohort A Part 218 up to < 30 years old, is restricted to young adults with first relapsed or refractory (R/R) aggressive mature B-NHL for whom no alternative standard-of-care treatment is available Histologically re-confirmed diagnosis, via tissue biopsy, or bone marrow aspirate, pleural effusion, or ascites, prior to study entry of aggressive mature B-cell non-Hodgkin lymphoma (B-NHL) that expresses CD20 (reconfirmed by immunohistochemistry [IHC]), or flow cytometry if IHC is not possible including Burkitt lymphoma (BL), Burkitt leukemia (BAL) (mature B-cell leukemia fragment antigen-binding [FAB] L3), diffuse large B-cell lymphoma (DLBCL), and primary mediastinal large B-cell lymphoma (PMBCL), at the time of first relapsed or refractory (R/R) disease for Cohort A and second or greater R/R disease for Cohort B Refractory or relapsed disease (i.e., prior treatment was ineffective or intolerable) following first-line standard-of-care chemoimmunotherapy for Cohort A and following at least two prior systemic chemoimmunotherapy regimens and who have exhausted all available established therapies for Cohort B Measurable disease, defined as At least one bi-dimensionally measurable nodal lesion, defined as > 1.5 cm in its longest dimension, or at least one bi-dimensionally measurable extranodal lesion, defined as > 1.0 cm in its longest dimension or Percentage of bone marrow involvement with lymphoma cells defined by cytomorphological analysis of bone marrow aspirates Adequate performance status, as assessed according to the Lansky or Karnofsky Performance Status scales Adequate bone marrow, liver and renal function Negative test results for hepatitis B and hepatitis C viruses (HBV and HCV), human immunodeficiency virus (HIV) and severe-acute-respiratory-syndrome-related coronavirus 2 (SARS-CoV-2).

Criterios de Exclusión

Exclusion criteria applicable to both Cohorts A and B - Isolated CNS disease of mature B-NHL without systemic involvement, and primary central nervous system (CNS) lymphoma
Exclusion criteria applicable to Cohorts A only - Receipt of glofitamab prior to study enrollment
Exclusion criteria applicable to Cohort A only - Receipt of any R-ICE chemoimmunotherapy prior to study enrollment into Cohort A
Exclusion criteria applicable to Cohort A only - Receipt of more than one prior line of standard-of-care B-NHL chemoimmunotherapy
Exclusion criteria applicable to Cohort B only - Prior treatment with standard radiotherapy (within 2 weeks before Day

1 of Cycle 1), systemic chemotherapy and immunotherapeutic anticancer agents (within 4 weeks or five half-lives of the drug, before Day 1 of Cycle 1)
Exclusion criteria applicable to Cohort B only - Patients with uncontrolled CNS involvement

Calendario

(Última actualización: 28/01/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
27/09/2022	10/11/2022	11/11/2022	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

F. Hoffmann-La Roche AG Switzerland

Grenzacherstrasse 124

Contact Person

Trial Information System - TISL

41616881111

global.eudract@roche.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Hospital Universitari Vall d Hebron

Passeig de la Vall d.Hebron, 119-129 - Edificio Materno-Infantil, planta 13 08035 Barcelona

ceic@vhir.org

934894010

Centros

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

Hospital Infantil Universitario Nino Jesus

Madrid

MADRID

Oncohematology

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

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Pediatric Oncology and Hematology

Activo (24/02/2023)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

Medicamentos

Gazyvaro 1,000 mg concentrate for solution for infusion.
SOLUTION FOR INFUSION
IV INFUSION

Código ATC: L01XC15 - OBINUTUZUMAB
Principios Activos: N/A

Experimental

CD20 CD3 TCB
SOLUTION FOR INFUSION
IV INFUSION

-

Principios Activos: N/A

Huérfano

Experimental

RoActemra 20 mg/mL concentrate for solution for infusion
SOLUTION FOR INFUSION
IV INFUSION

Código ATC: L04AC07 - TOCILIZUMAB
Principios Activos: N/A

Experimental

-
-
IV INFUSION

Código ATC: L01XA02 - CARBOPLATINO
Principios Activos: N/A

Experimental

-
-
IV INFUSION

Código ATC: L01CB01 - ETOPOSIDO
Principios Activos: N/A

Experimental

-
-
INTRAVENOUS USE

Código ATC: L01AA06 - IFOSFAMIDA
Principios Activos: N/A

Experimental

MabThera 500 mg concentrate for solution for infusion
SOLUTION FOR INFUSION
INTRAVENOUS USE

Código ATC: L01XC02 - RITUXIMAB
Principios Activos: N/A

Experimental

Sin resultados

A Study to Evaluate Safety, Tolerability, Pharmacokinetics, and Anti-Tumor Activity of Glofitamab in Monotherapy and in Combination with Chemoimmunotherapy in Pediatric and Young Adult Participants with Relapsed/Refractory Mature B-Cell Non-Hodgkin Lymphoma

State	Type of participants	Age Ranges
Recruiting	Incapable subjects of giving consent	Less than 18 , Adults (18-64 years) , Teens (12-17 years) , Children (2-11 years) , Infants and preschool (28 days - 23 months) , Newborn infants (0-27 days)
Gender	**Phases**	**Expected Participants**
Both	Phase I , Phase II	40
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness, pharmacokinetics	NO

Information

Identifier
2023-504264-41-00 (CTIS)

Protocol Code
CO43810

Transitioned 2021-006326-48

Therapeutic area
·Diseases [C] - Cancer [C04]
·Health Care [N] - Environment and Public Health [N06]

Investigated Disease
CD20 positive B-Cell Non-Hodgkin Lymphoma (NHL)

Scientific Title

A Phase I/II, Open-Label, Single-Arm, Two-Part Trial to Evaluate Safety, Tolerability, Pharmacokinetics, and Anti-Tumor Activity of Glofitamab in Monotherapy and in Combination with Chemoimmunotherapy in Pediatric and Young Adult Participants with Relapsed/Refractory Mature B-Cell NonHodgkin Lymphoma

Rationale

Not provided

Main Objective

To evaluate the efficacy of glofitamab in combination with rituximab, ifosfamide, carboplatin, and etoposide (R-ICE) chemoimmunotherapy, as assessed by the investigator based on achievement of a complete response (CR) To evaluate the safety and tolerability of glofitamab in combination with R-ICE chemoimmunotherapy To determine the pharmacokinetics of glofitamab alone and in combination with R-ICE chemoimmunotherapy

Primary Endpoints

Cohort A - Glofitamab Combination Therapy (glofitamab plus R-ICE chemoimmunotherapy) 1. Achievement of a complete response (CR) after up to three cycles of treatment as determined by the investigator according to the International Pediatric NHL Response Criteria for pediatric participants and Lugano Classification for young adult participants
Cohort A - Glofitamab Combination Therapy (glofitamab plus R-ICE chemoimmunotherapy) 2. Incidence, nature, frequency, severity, and timing of adverse events, with severity determined according to National Cancer Institute Common Terminology Criteria for Adverse Events, version 5 (NCI CTCAE v5.0) (glofitamab plus R-ICE chemoimmunotherapy)
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5. PK parameters (as appropriate) and serum concentrations of glofitamab in combination with R-ICE chemoimmunotherapy at specified timepoints

Temporary moments of secondary assessment

Not provided

Secondary Objective

To evaluate the anti-tumor activity of glofitamab in combination with R-ICE chemoimmunotherapy and glofitamab monotherapy
To evaluate the safety and tolerability of glofitamab monotherapy
To determine the pharmacokinetics of obinutuzumab and rituximab
To evaluate the immune response to glofitamab

Secondary Endpoints

1. For glofitamab plus R-ICE chemoimmunotherapy: Objective response rate (ORR), Duration of complete response (DOCR), Progression-free survival (PFS) after enrollment, Event-free survival (EFS), Overall survival (OS) and percentage of patients who proceed to HSCT after up to three cycles of treatment
2. For glofitamab monotherapy: ORR, Duration of response (DOR) and OS
Glofitamab monotherapy 3. Incidence, nature, frequency, severity, and timing of adverse events, with severity determined according to NCI CTCAE v5.0
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5. Serum concentrations of obinutuzumab at specified timepoints
6. Serum concentrations of rituximab at specified timepoints
7. Prevalence of anti-drug antibodies (ADAs) at baseline and incidence of ADAs against glofitamab during the study

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Age 6 months to <18 years at the time of signing Informed Consent for Cohort A Part 1 and Cohort B of the study, and age 6 months to < 30 years old at the time of signing Informed Consent for Cohort A Part 2 of the study Cohort A Part 218 up to < 30 years old, is restricted to young adults with first relapsed or refractory (R/R) aggressive mature B-NHL for whom no alternative standard-of-care treatment is available Histologically re-confirmed diagnosis, via tissue biopsy, or bone marrow aspirate, pleural effusion, or ascites, prior to study entry of aggressive mature B-cell non-Hodgkin lymphoma (B-NHL) that expresses CD20 (reconfirmed by immunohistochemistry [IHC]), or flow cytometry if IHC is not possible including Burkitt lymphoma (BL), Burkitt leukemia (BAL) (mature B-cell leukemia fragment antigen-binding [FAB] L3), diffuse large B-cell lymphoma (DLBCL), and primary mediastinal large B-cell lymphoma (PMBCL), at the time of first relapsed or refractory (R/R) disease for Cohort A and second or greater R/R disease for Cohort B Refractory or relapsed disease (i.e., prior treatment was ineffective or intolerable) following first-line standard-of-care chemoimmunotherapy for Cohort A and following at least two prior systemic chemoimmunotherapy regimens and who have exhausted all available established therapies for Cohort B Measurable disease, defined as At least one bi-dimensionally measurable nodal lesion, defined as > 1.5 cm in its longest dimension, or at least one bi-dimensionally measurable extranodal lesion, defined as > 1.0 cm in its longest dimension or Percentage of bone marrow involvement with lymphoma cells defined by cytomorphological analysis of bone marrow aspirates Adequate performance status, as assessed according to the Lansky or Karnofsky Performance Status scales Adequate bone marrow, liver and renal function Negative test results for hepatitis B and hepatitis C viruses (HBV and HCV), human immunodeficiency virus (HIV) and severe-acute-respiratory-syndrome-related coronavirus 2 (SARS-CoV-2).

Exclusion criteria

Exclusion criteria applicable to both Cohorts A and B - Isolated CNS disease of mature B-NHL without systemic involvement, and primary central nervous system (CNS) lymphoma
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Exclusion criteria applicable to Cohort A only - Receipt of any R-ICE chemoimmunotherapy prior to study enrollment into Cohort A
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Exclusion criteria applicable to Cohort B only - Prior treatment with standard radiotherapy (within 2 weeks before Day

1 of Cycle 1), systemic chemotherapy and immunotherapeutic anticancer agents (within 4 weeks or five half-lives of the drug, before Day 1 of Cycle 1)
Exclusion criteria applicable to Cohort B only - Patients with uncontrolled CNS involvement

Calendar

(Last Update: 28/01/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
27/09/2022	10/11/2022	11/11/2022	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

F. Hoffmann-La Roche AG Switzerland

Grenzacherstrasse 124

Contact Person

Trial Information System - TISL

41616881111

global.eudract@roche.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Hospital Universitari Vall d Hebron

Passeig de la Vall d.Hebron, 119-129 - Edificio Materno-Infantil, planta 13 08035 Barcelona

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Sites

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

Hospital Infantil Universitario Nino Jesus

Madrid

MADRID

Oncohematology

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

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Pediatric Oncology and Hematology

Active (24/02/2023)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

Medication

Gazyvaro 1,000 mg concentrate for solution for infusion.

SOLUTION FOR INFUSION

IV INFUSION

ATC code: L01XC15 - OBINUTUZUMAB

Active Principles: N/A

Experimental

CD20 CD3 TCB

SOLUTION FOR INFUSION

IV INFUSION

-

Active Principles: N/A

Orphan

Experimental

RoActemra 20 mg/mL concentrate for solution for infusion

SOLUTION FOR INFUSION

IV INFUSION

ATC code: L04AC07 - TOCILIZUMAB

Active Principles: N/A

Experimental

-

-

IV INFUSION

ATC code: L01XA02 - CARBOPLATINO

Active Principles: N/A

Experimental

-

-

IV INFUSION

ATC code: L01CB01 - ETOPOSIDO

Active Principles: N/A

Experimental

-

-

INTRAVENOUS USE

ATC code: L01AA06 - IFOSFAMIDA

Active Principles: N/A

Experimental

MabThera 500 mg concentrate for solution for infusion

SOLUTION FOR INFUSION

INTRAVENOUS USE

ATC code: L01XC02 - RITUXIMAB

Active Principles: N/A

Experimental

No results