Study of MEN1703 in Patients with Relapsed or Refractory Aggressive B-cell Non-Hodgkin Lymphoma

Estado	Tipo de Participantes	Rangos de Edad
Reclutando	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase II	44
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
2024-513098-31-00 (CTIS)

Cod. Protocolo
JASPIS-01

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

Enfermedad investigada
Relapsed or Refractory Aggressive B-cell Non-Hodgkin Lymphoma

Título Científico
An Open Label, Phase 2 Clinical Trial of MEN1703 as Monotherapy and in Combination with Glofitamab in Patients with Relapsed or Refractory Aggressive B-cell Non-Hodgkin Lymphoma (JASPIS-01)

Justificación

No aportado

Objetivo Principal

Group 1: Part 1 (Safety Run-in): To evaluate safety and tolerability of MEN1703 given in combination with glofitamab
Group 1: Part 2 and Part 3: To evaluate anti-lymphoma activity of MEN1703 given in combination with glofitamab
Group 2: Part 1 (Safety Run-in): To evaluate safety and tolerability of MEN1703 monotherapy
Group 2: Part 2: To evaluate anti-lymphoma activity of MEN1703 monotherapy

Variables de Evaluación Primaria

Group 1 and 2: Incidence and severity of adverse events (AE)
Group 1: Complete Response (CR) rate, assessed by Independent Review Committee (IRC) following the Lugano Classification (see Section16)
Group 2: Over all response rate (ORR), assessed by Independent Review Committee (IRC) following the Lugano Classification (see Section 16 of the protocol)

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

Group 1: To evaluate anti-lymphoma activity and/or clinical benefit of MEN1703 when given in combination with glofitamab; To evaluate safety and tolerability of MEN1703 when given in combination with glofitamab (Part 2 and Part 3); To characterize single and multiple dose pharmacokinetics (PK) of MEN1703 when given in combination with glofitamab; To evaluate patient reported outcomes (PRO) related to lymphoma symptoms, well-being, and general health status in participants receiving MEN1703 given in combination with glofitamab Group 2: To evaluate anti-lymphoma activity and/or clinical benefit of MEN1703 monotherapy; To evaluate safety and tolerability of MEN1703 monotherapy (Part 2); To characterize single and multiple dose pharmacokinetics (PK) of MEN1703 monotherapy; To evaluate patient reported outcomes (PRO) related to lymphoma symptoms, well-being, and general health status in participants receiving MEN1703 monotherapy

Variables de Evaluación Secundaria

Group 1: Complete Response (CR) rate, assessed locally following the Lugano classification (see Section16)
Group 2: Overall Response Rate (ORR), assessed locally following the Lugano classification (see Section 16 of the protocol)
Group 1: The following endpoint measures are assessed by IRC and locally following the Lugano Classification (see Section16): Overall Response Rate (ORR); Duration of Response (DoR); Duration of Complete Response (DoCR); Progression-free survival (PFS); Overall survival (OS); Time to response; Time to next treatment)
Group 2: The following endpoint measures are assessed by IRC and locally following the Lugano Classification (see

Section 16 of the protocol): Complete Response (CR) Rate; Duration of Response (DoR); Duration of Complete Response (DoCR); Progression-free survival (PFS); Overall survival (OS); Time to response; Time to next treatment) Group 1 and 2: Incidence and severity of AEs; PK of MEN1703 including Cmax, tmax, AUCtau, AUCinf, and t½; Changes in lymphoma symptoms, well-being, and general health status measured by FACTLym and EORTC QLQ C30

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Age 18 years old at time of written informed consent, provided prior to Screening. Agree not to donate blood or eggs (ova) during treatment and for 1 month after the last dose of MEN1703, 2 months after the last dose of glofitamab, or 18 months after last dose of obinutuzumab, whichever is longer; or not to donate sperm during treatment with MEN1703 and for 1month after the last dose of MEN1703. Documented histological confirmation of aggressive B-cell non-Hodgkin lymphoma including DLBCL NOS and transformed indolent B-cell lymphoma, according to the 5th edition of the WHO classification of lymphoid neoplasms. R/R disease having received at least 2 prior lines of systemic treatment for aggressive B-cell non-Hodgkin lymphoma, and: Additional for Group 1: anti-CD3xCD20 bispecific antibody treatment naïve Additional for Group 2: exhausted all standard, available treatment options. At least 1 measurable site of disease based on computed tomography (CT) or positron emission tomography (PET)-CT scan with involvement of 2 or more clearly demarcated lesions and or nodes. Life expectancy of 12 weeks. Eastern Cooperative Oncology Group (ECOG) Performance Status 0, 1 or 2. Adequate organ function at Screening, including: a) Aspartate aminotransferase (AST) or alanine aminotransferase (ALT) 2.5X the upper limit of normal (ULN); b) Total bilirubin 1.5X ULN Note: Total bilirubin 3.0X ULN is acceptable in patients with documented history of Gilberts syndrome. c) Adequate renal function: serum creatinine 1.5X ULN or a creatinine clearance (CrCl) calculated by Cockroft-Gault formula of 50 mL/min for patients in whom, in the investigators judgment, serum creatinine levels do not adequately reflect renal function; d) Left ventricular ejection fraction (LVEF) 40% as per local assessment practice. Adequate hematologic function defined as the following: a) Lymphocyte count <5.0 ×109/L b) Platelet count 75 ×109/L (or, in the presence of bone marrow involvement or splenomegaly, 50 ×109/L), and platelet transfusion free within 14 days prior to first dose of study drug c) Hemoglobin 10.0 g/dL (6.2 mmol/L) and transfusion free within 21 days prior to first dose of study drug d) Absolute neutrophil count (ANC) 1.0 ×109/L, with growth factor support permitted per local, institutional standards. Capable of providing written informed consent Coagulation parameters as follows: prothrombin time (PT)/international normalized ratio (INR) and partial thromboplastin time (PTT) <1.5X ULN. Negative serum pregnancy test at Screening and within 3 days of first dose of drug (applies to women of child-bearing potential [WOCBP] only; menopausal status is defined as serum follicle stimulating hormone level 30 IU/L in the absence of hormone replacement therapy, or complete absence of menses for at least 12 consecutive months which is not due to medication; or successful surgical sterilization). Women of child-bearing potential must agree to use highly effective contraceptive methods during treatment and for 1 month after the last dose of MEN1703, 2 months after the last dose of glofitamab, or 18 months after the last dose of obinutuzumab, whichever is longer. or Male participants who are sexually active must use condoms during treatment with MEN1703 and for 1 month after the last dose of MEN1703. Sexually active male participants are asked to advise their female partners of childbearing potential to also use highly effective contraception for the same time period. Contraception guidance for male participants taking glofitamab and obinutuzumab should be according to the current EU SmPC (Columvi Summary of Product Characteristics) or the USPI (COLUMVI [glofitamab-gxbm] Prescribing Information).

Criterios de Exclusión

Primary central nervous system (CNS) lymphoma or CNS involvement by lymphoma at screening Hematopoietic

stem cell transplant within 4 months prior to first dose of study drug. Requires systemic immune-modulating therapy (regardless of dose) or has confirmed history or current autoimmune disease or other diseases resulting in permanent immunosuppression. Exposed to live or live attenuated vaccine(s) within 4 weeks prior to signing the informed consent form (ICF). Evidence of ongoing and uncontrolled systemic bacterial, fungal, or viral infection, except for documented Grade Common Terminology Criteria for Adverse Events (CTCAE) 2 infections with evidence of improvement or without evidence of worsening infection. Known human immunodeficiency virus (HIV) infection defined as any of the following: a) CD4+ T-cell count of less than 350 cells/L at Screening b) AIDS defining opportunistic infection within the past 12 months c) On established antiretroviral therapy (ART) for less than 4 weeks or presenting with a viral load of more than 400 copies/mL prior to Screening d) On ART or prophylactic antimicrobials that are expected to cause significant drug-drug interactions or overlapping toxicities with study treatment. Note: HIV testing is not required unless mandated locally. Current active liver disease from any cause including hepatitis A (hepatitis A virus IgM positive), hepatitis B (hepatitis B virus [HBV] surface antigen positive), or hepatitis C (hepatitis C virus [HCV] antibody positive, confirmed by HCV RNA). Subjects with HCV with undetectable virus after treatment are eligible. Subjects with a prior history of HBV are eligible if quantitative PCR for HBV DNA is negative. Ongoing drug-induced pneumonitis. Ongoing inflammatory bowel disease. Active known second malignancy, except for any of the following: a) Adequately treated basal cell carcinoma, squamous cell carcinoma of the skin, or in situ cervical cancer b) Adequately treated Stage 1 cancer from which the participant is currently in remission and has been in remission for 2 years c) Low-risk prostate cancer with a Gleason score <7 and a prostate-specific antigen (PSA) level <10 ng/mL d) Any other cancer from which the participant has been disease-free for 3 years. Received an agent known to be a sensitive CYP2D6 substrate or a CYP2D6 substrate with a narrow therapeutic range, a strong or moderate CYP2D6 inhibitor, or a BCRP inhibitor within 14 days or 5 half-lives (whichever is shorter), prior to the first dose of study drug. Received anti-cancer treatments, including cytotoxic chemotherapy, radiotherapy, hormonal therapy, biologic, immunotherapy, or investigational drugs within 14 days or 5 half-lives (whichever is shorter) before the first dose of study drug. Prior treatment with CAR-T cell or an anti-CD3xCD20 bispecific antibody therapy (permitted for Group 2 only), requires a wash out period of 4 weeks. Cardiac dysfunction is defined as myocardial infarction within 6 months of study entry, New York Heart Association (NYHA) Class III or IV heart failure, uncontrolled dysrhythmias, or poorly controlled angina. Receiving treatment for active, ongoing thromboembolic event. Note: Does not apply to prophylactic treatment to prevent or avoid reoccurrence of a prior resolved event. To review with Medical Monitor where further risk assessment is needed. History of serious ventricular arrhythmia (e.g., VT or VF, 3 beats in a row), or QT interval corrected for heart rate (QTc) 480 ms. Note: QTc values up to 500 ms will be acceptable where patients medical history e.g., bundle branch block, is known to cause mild QTc prolongation and the condition is well controlled. Any disease, syndrome or condition which may significantly affect drug intake via oral route. Currently pregnant or breast-feeding or planning to become pregnant or breastfeed during treatment and for 1 month after the last dose of study drug. Any other prior or current medical condition, intercurrent illness, surgical history, physical or 12-lead electrocardiogram (ECG) findings, laboratory abnormalities, or extenuating circumstance (e.g., alcohol or drug addiction) that, in the investigators opinion, could jeopardize patient safety or interfere with the objectives of the study. Concurrent participation in another therapeutic clinical study. Ongoing clinically significant toxicity (for example, alopecia is not clinically significant) from any prior anti-cancer therapy that has not resolved to Grade 1 or less prior to the first dose of study drug Prior treatment with a PIM inhibitor. Group 1 only: Any prior therapy with a bispecific antibody targeting CD3 and CD20. Known risk of allergy to: Group 1 and Group 2: MEN1703 or its excipients Group 1 only: obinutuzumab or its excipients, or glofitamab or its excipients. Contraindication to all uric acid lowering agents. Major surgery within 1 month prior to first dose of study drug.

Calendario

(Última actualización: 30/07/2025)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
10/02/2025	18/03/2025	09/04/2025	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

Ryvu Therapeutics S.A. Poland

Ul. Leona Henryka Sternbacha 2

Contact Person

Ryvu ClinicalTrials

+48123140200

clinicaltrials@ryvu.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Regional de la Comunidad de Madrid

C/ Aduana 29 3ª planta 28013 Madrid

comite.regional@salud.madrid.org

913702824

Centros

Activo (24/03/2025)

Clinica Universidad De Navarra

Pamplona

NAVARRA

Hematology

Activo (25/03/2025)

Clinica Universidad De Navarra

Madrid

MADRID

Hematology

Activo (08/04/2025)

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Hematology

Activo (09/04/2025)

Hospital Universitario De Navarra

Pamplona

NAVARRA

Hematology

Activo (20/05/2025)

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Hematology

Activo (30/07/2025)

Hospital Universitario Miguel Servet

Zaragoza

ZARAGOZA

Hematology

Activo (01/07/2025)

Hospital Universitario Puerta De Hierro De Majadahonda

Majadahonda

MADRID

Hematology

Activo (04/04/2025)

Hospital Universitario Virgen De La Macarena

Sevilla

SEVILLA

Hematology

Activo (08/05/2025)

MD Anderson Cancer Center

Madrid

MADRID

Hematology

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

University Clinical Hospital Virgen De La Arrixaca

Murcia

MURCIA

Hematology

Medicamentos

Columvi 2.5 mg concentrate for solution for infusion
SOLUTION FOR INFUSION
INTRAVENIOUS INFUSION

-

Principios Activos: N/A

Huérfano Experimental

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

Código ATC: L01XC15 - OBINUTUZUMAB

Principios Activos: N/A

Huérfano Experimental

MEN1703 oral capsule 25 mg
CAPSULE
ORAL

-

Principios Activos: N/A

Experimental

Columvi 10 mg concentrate for solution for infusion
SOLUTION FOR INFUSION
INTRAVENIOUS INFUSION

-

Principios Activos: N/A

Huérfano Experimental

MEN1703 oral capsule 100 mg
CAPSULE
ORAL

-

Principios Activos: N/A

Experimental

Sin resultados

Study of MEN1703 in Patients with Relapsed or Refractory Aggressive B-cell Non-Hodgkin Lymphoma

State	Type of participants	Age Ranges
Recruiting	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase II	44
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
2024-513098-31-00 (CTIS)

Protocol Code
JASPIS-01

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

Investigated Disease
Relapsed or Refractory Aggressive B-cell Non-Hodgkin Lymphoma

Scientific Title
An Open Label, Phase 2 Clinical Trial of MEN1703 as Monotherapy and in Combination with Glofitamab in Patients with Relapsed or Refractory Aggressive B-cell Non-Hodgkin Lymphoma (JASPIS-01)

Rationale

Not provided

Main Objective

Group 1: Part 1 (Safety Run-in): To evaluate safety and tolerability of MEN1703 given in combination with glofitamab
Group 1: Part 2 and Part 3: To evaluate anti-lymphoma activity of MEN1703 given in combination with glofitamab
Group 2: Part 1 (Safety Run-in): To evaluate safety and tolerability of MEN1703 monotherapy
Group 2: Part 2: To evaluate anti-lymphoma activity of MEN1703 monotherapy

Primary Endpoints

Group 1 and 2: Incidence and severity of adverse events (AE)
Group 1: Complete Response (CR) rate, assessed by Independent Review Committee (IRC) following the Lugano Classification (see Section16)
Group 2: Over all response rate (ORR), assessed by Independent Review Committee (IRC) following the Lugano Classification (see Section 16 of the protocol)

Temporary moments of secondary assessment

Not provided

Secondary Objective

Group 1: To evaluate anti-lymphoma activity and/or clinical benefit of MEN1703 when given in combination with glofitamab; To evaluate safety and tolerability of MEN1703 when given in combination with glofitamab (Part 2 and Part 3); To characterize single and multiple dose pharmacokinetics (PK) of MEN1703 when given in combination with glofitamab; To evaluate patient reported outcomes (PRO) related to lymphoma symptoms, well-being, and general health status in participants receiving MEN1703 given in combination with glofitamab Group 2: To evaluate anti-lymphoma activity and/or clinical benefit of MEN1703 monotherapy; To evaluate safety and tolerability of MEN1703 monotherapy (Part 2); To characterize single and multiple dose pharmacokinetics (PK) of MEN1703 monotherapy; To evaluate patient reported outcomes (PRO) related to lymphoma symptoms, well-being, and general health status in participants receiving MEN1703 monotherapy

Secondary Endpoints

Group 1: Complete Response (CR) rate, assessed locally following the Lugano classification (see Section16)
Group 2: Overall Response Rate (ORR), assessed locally following the Lugano classification (see Section 16 of the protocol)
Group 1: The following endpoint measures are assessed by IRC and locally following the Lugano Classification (see Section16): Overall Response Rate (ORR); Duration of Response (DoR); Duration of Complete Response (DoCR); Progression-free survival (PFS); Overall survival (OS); Time to response; Time to next treatment)
Group 2: The following endpoint measures are assessed by IRC and locally following the Lugano Classification (see

Section 16 of the protocol): Complete Response (CR) Rate; Duration of Response (DoR); Duration of Complete Response (DoCR); Progression-free survival (PFS); Overall survival (OS); Time to response; Time to next treatment) Group 1 and 2: Incidence and severity of AEs; PK of MEN1703 including Cmax, tmax, AUCtau, AUCinf, and t½; Changes in lymphoma symptoms, well-being, and general health status measured by FACTLym and EORTC QLQ C30

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Age 18 years old at time of written informed consent, provided prior to Screening. Agree not to donate blood or eggs (ova) during treatment and for 1 month after the last dose of MEN1703, 2 months after the last dose of glofitamab, or 18 months after last dose of obinutuzumab, whichever is longer; or not to donate sperm during treatment with MEN1703 and for 1month after the last dose of MEN1703. Documented histological confirmation of aggressive B-cell non-Hodgkin lymphoma including DLBCL NOS and transformed indolent B-cell lymphoma, according to the 5th edition of the WHO classification of lymphoid neoplasms. R/R disease having received at least 2 prior lines of systemic treatment for aggressive B-cell non-Hodgkin lymphoma, and: Additional for Group 1: anti-CD3xCD20 bispecific antibody treatment naïve Additional for Group 2: exhausted all standard, available treatment options. At least 1 measurable site of disease based on computed tomography (CT) or positron emission tomography (PET)-CT scan with involvement of 2 or more clearly demarcated lesions and or nodes. Life expectancy of 12 weeks. Eastern Cooperative Oncology Group (ECOG) Performance Status 0, 1 or 2. Adequate organ function at Screening, including: a) Aspartate aminotransferase (AST) or alanine aminotransferase (ALT) 2.5X the upper limit of normal (ULN); b) Total bilirubin 1.5X ULN Note: Total bilirubin 3.0X ULN is acceptable in patients with documented history of Gilberts syndrome. c) Adequate renal function: serum creatinine 1.5X ULN or a creatinine clearance (CrCl) calculated by Cockroft-Gault formula of 50 mL/min for patients in whom, in the investigators judgment, serum creatinine levels do not adequately reflect renal function; d) Left ventricular ejection fraction (LVEF) 40% as per local assessment practice. Adequate hematologic function defined as the following: a) Lymphocyte count <5.0 ×109/L b) Platelet count 75 ×109/L (or, in the presence of bone marrow involvement or splenomegaly, 50 ×109/L), and platelet transfusion free within 14 days prior to first dose of study drug c) Hemoglobin 10.0 g/dL (6.2 mmol/L) and transfusion free within 21 days prior to first dose of study drug d) Absolute neutrophil count (ANC) 1.0 ×109/L, with growth factor support permitted per local, institutional standards. Capable of providing written informed consent Coagulation parameters as follows: prothrombin time (PT)/international normalized ratio (INR) and partial thromboplastin time (PTT) <1.5X ULN. Negative serum pregnancy test at Screening and within 3 days of first dose of drug (applies to women of child-bearing potential [WOCBP] only; menopausal status is defined as serum follicle stimulating hormone level 30 IU/L in the absence of hormone replacement therapy, or complete absence of menses for at least 12 consecutive months which is not due to medication; or successful surgical sterilization). Women of child-bearing potential must agree to use highly effective contraceptive methods during treatment and for 1 month after the last dose of MEN1703, 2 months after the last dose of glofitamab, or 18 months after the last dose of obinutuzumab, whichever is longer. or Male participants who are sexually active must use condoms during treatment with MEN1703 and for 1 month after the last dose of MEN1703. Sexually active male participants are asked to advise their female partners of childbearing potential to also use highly effective contraception for the same time period. Contraception guidance for male participants taking glofitamab and obinutuzumab should be according to the current EU SmPC (Columvi Summary of Product Characteristics) or the USPI (COLUMVI [glofitamab-gxbm] Prescribing Information).

Exclusion criteria

Primary central nervous system (CNS) lymphoma or CNS involvement by lymphoma at screening Hematopoietic

stem cell transplant within 4 months prior to first dose of study drug. Requires systemic immune-modulating therapy (regardless of dose) or has confirmed history or current autoimmune disease or other diseases resulting in permanent immunosuppression. Exposed to live or live attenuated vaccine(s) within 4 weeks prior to signing the informed consent form (ICF). Evidence of ongoing and uncontrolled systemic bacterial, fungal, or viral infection, except for documented Grade Common Terminology Criteria for Adverse Events (CTCAE) 2 infections with evidence of improvement or without evidence of worsening infection. Known human immunodeficiency virus (HIV) infection defined as any of the following: a) CD4+ T-cell count of less than 350 cells/L at Screening b) AIDS defining opportunistic infection within the past 12 months c) On established antiretroviral therapy (ART) for less than 4 weeks or presenting with a viral load of more than 400 copies/mL prior to Screening d) On ART or prophylactic antimicrobials that are expected to cause significant drug-drug interactions or overlapping toxicities with study treatment. Note: HIV testing is not required unless mandated locally. Current active liver disease from any cause including hepatitis A (hepatitis A virus IgM positive), hepatitis B (hepatitis B virus [HBV] surface antigen positive), or hepatitis C (hepatitis C virus [HCV] antibody positive, confirmed by HCV RNA). Subjects with HCV with undetectable virus after treatment are eligible. Subjects with a prior history of HBV are eligible if quantitative PCR for HBV DNA is negative. Ongoing drug-induced pneumonitis. Ongoing inflammatory bowel disease. Active known second malignancy, except for any of the following: a) Adequately treated basal cell carcinoma, squamous cell carcinoma of the skin, or in situ cervical cancer b) Adequately treated Stage 1 cancer from which the participant is currently in remission and has been in remission for 2 years c) Low-risk prostate cancer with a Gleason score <7 and a prostate-specific antigen (PSA) level <10 ng/mL d) Any other cancer from which the participant has been disease-free for 3 years. Received an agent known to be a sensitive CYP2D6 substrate or a CYP2D6 substrate with a narrow therapeutic range, a strong or moderate CYP2D6 inhibitor, or a BCRP inhibitor within 14 days or 5 half-lives (whichever is shorter), prior to the first dose of study drug. Received anti-cancer treatments, including cytotoxic chemotherapy, radiotherapy, hormonal therapy, biologic, immunotherapy, or investigational drugs within 14 days or 5 half-lives (whichever is shorter) before the first dose of study drug. Prior treatment with CAR-T cell or an anti-CD3xCD20 bispecific antibody therapy (permitted for Group 2 only), requires a wash out period of 4 weeks. Cardiac dysfunction is defined as myocardial infarction within 6 months of study entry, New York Heart Association (NYHA) Class III or IV heart failure, uncontrolled dysrhythmias, or poorly controlled angina. Receiving treatment for active, ongoing thromboembolic event. Note: Does not apply to prophylactic treatment to prevent or avoid reoccurrence of a prior resolved event. To review with Medical Monitor where further risk assessment is needed. History of serious ventricular arrhythmia (e.g., VT or VF, 3 beats in a row), or QT interval corrected for heart rate (QTc) 480 ms. Note: QTc values up to 500 ms will be acceptable where patients medical history e.g., bundle branch block, is known to cause mild QTc prolongation and the condition is well controlled. Any disease, syndrome or condition which may significantly affect drug intake via oral route. Currently pregnant or breast-feeding or planning to become pregnant or breastfeed during treatment and for 1 month after the last dose of study drug. Any other prior or current medical condition, intercurrent illness, surgical history, physical or 12-lead electrocardiogram (ECG) findings, laboratory abnormalities, or extenuating circumstance (e.g., alcohol or drug addiction) that, in the investigators opinion, could jeopardize patient safety or interfere with the objectives of the study. Concurrent participation in another therapeutic clinical study. Ongoing clinically significant toxicity (for example, alopecia is not clinically significant) from any prior anti-cancer therapy that has not resolved to Grade 1 or less prior to the first dose of study drug Prior treatment with a PIM inhibitor. Group 1 only: Any prior therapy with a bispecific antibody targeting CD3 and CD20. Known risk of allergy to: Group 1 and Group 2: MEN1703 or its excipients Group 1 only: obinutuzumab or its excipients, or glofitamab or its excipients. Contraindication to all uric acid lowering agents. Major surgery within 1 month prior to first dose of study drug.

Calendar

(Last Update: 30/07/2025)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
10/02/2025	18/03/2025	09/04/2025	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

Ryvu Therapeutics S.A. Poland

Ul. Leona Henryka Sternbacha 2

Contact Person

Ryvu ClinicalTrials

+48123140200

clinicaltrials@ryvu.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Regional de la Comunidad de Madrid

C/ Aduana 29 3ª planta 28013 Madrid

comite.regional@salud.madrid.org

913702824

Sites

Active (24/03/2025)

Clinica Universidad De Navarra

Pamplona

NAVARRA

Hematology

Active (25/03/2025)

Clinica Universidad De Navarra

Madrid

MADRID

Hematology

Active (08/04/2025)

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Hematology

Active (09/04/2025)

Hospital Universitario De Navarra

Pamplona

NAVARRA

Hematology

Active (20/05/2025)

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Hematology

Active (30/07/2025)

Hospital Universitario Miguel Servet

Zaragoza

ZARAGOZA

Hematology

Active (01/07/2025)

Hospital Universitario Puerta De Hierro De Majadahonda

Majadahonda

MADRID

Hematology

Active (04/04/2025)

Hospital Universitario Virgen De La Macarena

Sevilla

SEVILLA

Hematology

Active (08/05/2025)

MD Anderson Cancer Center

Madrid

MADRID

Hematology

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

University Clinical Hospital Virgen De La Arrixaca

Murcia

MURCIA

Hematology

Medication

Columvi 2.5 mg concentrate for solution for infusion
SOLUTION FOR INFUSION
INTRAVENIOUS INFUSION

-

Active Principles: N/A

Orphan Experimental

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

ATC code: L01XC15 - OBINUTUZUMAB

Active Principles: N/A

Orphan Experimental

MEN1703 oral capsule 25 mg
CAPSULE
ORAL

-

Active Principles: N/A

Experimental

Columvi 10 mg concentrate for solution for infusion
SOLUTION FOR INFUSION
INTRAVENIOUS INFUSION

-

Active Principles: N/A

Orphan Experimental

MEN1703 oral capsule 100 mg
CAPSULE
ORAL

-

Active Principles: N/A

Experimental

No results