

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

Estado

Reclutando

Tipo de Participantes

No aportado

Rangos de Edad

Mayores de 64 , Adultos (18-64 años)

Género

Ambos

Fases

Fase II

Participantes esperados

44

Resultados

Sin resultados

Bajo nivel intervención

No

Enfermedad rara

No

Cobertura geográfica

Sin determinar

Ámbitos del ensayo

seguridad, eficacia, farmacocinética

Terapia avanzada

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 1 month 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 Cockcroft-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 $5.0 \times 10^9/L$ b) Platelet count $75 \times 10^9/L$ (or, in the presence of bone marrow involvement or splenomegaly, $50 \times 10^9/L$), 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) $1.0 \times 10^9/L$, 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 10/02/2025	Inicio de Ensayo 18/03/2025	Inclusión Primer Paciente 09/04/2025	Interrumpido No aportado	Reiniciado No aportado
Fin de reclutamiento No aportado	Fin prematuro (España) No aportado	Fin prematuro (Global) No aportado	Fin del ensayo en España No aportado	Fin del ensayo global 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

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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
Recruiting

Type of participants
Not provided

Age Ranges
Older than 64 , Adults (18-64 years)

Gender
Both

Phases
Phase II

Expected Participants
44

Results
No results

Low level of intervention
No

Rare disease
No

Geographic coverage
Undetermined

Areas of the study
safety, effectiveness, pharmacokinetics

Advanced therapy
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 1 month 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 Cockcroft-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 $<5.0 \times 10^9/L$ b) Platelet count $75 \times 10^9/L$ (or, in the presence of bone marrow involvement or splenomegaly, $50 \times 10^9/L$), 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) $1.0 \times 10^9/L$, 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 10/02/2025	Start of Trial 18/03/2025	First patient inclusion 09/04/2025	Halted Not aported	Restarted Not aported
End of recruitment Not aported	Premature end (Spain) Not aported	Premature End (Global) Not aported	Trial end (Spain) Not aported	Trial end (Global) Not aported

Sponsor

Ryvu Therapeutics S.A. Poland
Ul. Leona Henryka Sternbacha 2

Contact Person

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Monetary support: N/A
Sponsor type: Commercial

Ceim

CEIm Regional de la Comunidad de Madrid
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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