A Multicenter, Open-Label, Dose-Finding Clinical Trial to Assess the Safety, Pharmacokinetics, Pharmacodynamics, and Clinical Efficacy of RVU120 in Combination with Venetoclax in Participants with Acute Myeloid Leukemia Who Failed Prior Therapy with Venetoclax and a Hypomethylating Agent (RIVER-81)

Estado	**Tipo de Participantes**	**Rangos de Edad**
Reclutando	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase II	55
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
2023-505911-19-00 (CTIS)

Cod. Protocolo
RIVER-81

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

Enfermedad investigada
Acute Myeloid Leukemia

Título Científico
A Multicenter, Open-Label, Dose-Finding Clinical Trial to Assess the Safety, Pharmacokinetics, Pharmacodynamics,

and Clinical Efficacy of RVU120 in Combination with Venetoclax in Participants with Acute Myeloid Leukemia Who Failed Prior Therapy with Venetoclax and a Hypomethylating Agent (RIVER-81)

Justificación

No aportado

Objetivo Principal

Part 1 only: To determine the RD of RVU120 plus Ven to be administered in AML patients failing prior Ven + HMA
Parts 2 and 3: To evaluate the anti-leukemic activity of RVU120 when given in combination with Ven in AML patients failing prior Ven + HMA

Variables de Evaluación Primaria

Part 1: Incidence and severity of AE, including events qualifying as DLTs
Part 2 and 3: Complete remission (CR) rate (according to ELN 2022 [Döhner 2022])

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

All parts: To determine the safety and tolerability of RVU120 when given in combination with Ven, in AML patients failing prior Ven + HMA
All parts: To evaluate further efficacy endpoints of RVU120 when given in combination with Ven, in AML patients failing prior Ven + HMA
Part 1: To characterize single and multiple dose PK of RVU120 when given in combination with Ven
Part 2 and 3: To evaluate the effect of RVU120 when given in combination with Ven, on patient-reported outcomes/health-related quality of life (HRQOL)
Part 2 and 3: To evaluate the anti-leukemic activity of RVU120 when given in combination with Ven, including measurable residual disease (MRD) response where applicable, in AML patients failing prior Ven + HMA

Variables de Evaluación Secundaria

All parts: Incidence and severity of AE, including events qualifying as DLTs.
All parts: CR with incomplete hematologic recovery (CRi),Transfusion independence, DoR, PFS, RFS, EFS, Overall survival, Percentage of participants bridged to HSCT
Part 1: PK of RVU120 including Cmax, tmax, AUCtau, and AUCinf, and t½
Part 2 and 3: Changes in patient-reported outcomes as assessed by changes in summary scores of the HM-PRO
Part 2 and 3:Composite complete remission (CCR) rate, including complete remission (CR), CR with partial hematologic recovery (CRh), with and without MRD (according to ELN 2022 [Döhner 2022])

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Written informed consent provided prior to any study-related procedure. Must have recovered from the toxic effects of previous treatments to at least Grade 1, except for neurotoxicity (which should return at least to Grade 2 or baseline) and alopecia. Clinical laboratory parameters as follows: - Peripheral WBC count, no upper limit at Screening, but must be <25 x10^9/L on Day 1 prior to first dose of study drug (see acceptable methods of cytoreduction above) - Platelet (PLT) count >10^9/L at the time of first study drug administration (PLT count < 10^9/L, participant must receive a transfusion within a maximum 24 hours before study drug administration) - Aspartate aminotransferase (AST) and alanine aminotransferase (ALT) 3X the upper limit of normal (ULN) - Creatinine clearance 40 mL/min (Cockcroft and Gault formula; Section 10.7). - Total bilirubin 1.5X ULN Note: Participants with Gilberts syndrome may be enrolled provided that direct bilirubin is within the acceptable range as specified in this protocol, and there is no evidence of clinically significant hepatic dysfunction. Adequate cardiac function confirmed by left ventricular ejection fraction 40% as per echocardiography. For women of childbearing potential (WOCBP), a negative pregnancy test must be confirmed during Screening and within 3 days prior to first dose of study drug. WOCBP must commit to using a highly effective method of contraception during study participation and until 28 weeks (approximately 6.5 months) after the last dose of RVU120 (Section 10.4) OR For males, an effective barrier method of contraception must be used during study participation and until 28 weeks (approximately 6.5 months) after the last dose of RVU120, if the participant is sexually active with a WOCBP (Section 10.4). Agree not to donate blood, eggs (ova) or sperm, during study participation and until 28 weeks (approximately 6.5 months) after the last dose of RVU120 (Section 10.4). Investigator considers the participant to be suitable for participation in the clinical study by assessing that they: - understand the requirements of the clinical study and can give informed consent - can comply with study medication dosing requirements and all study-related procedures and evaluations - are not considered to be potentially unreliable and/or not cooperative. Has received vaccinations in accordance with institutional standards and local regulatory requirements, if applicable. Age 18 years at time of provision of informed consent. AML diagnosis according to the 2022 World Health Organization (WHO) classification (Arber 2022). Relapsed or refractory AML per the ELN 2022 (Döhner 2022) - Participants with <10% bone marrow cellularity may be enrolled where immunophenotyping of the bone marrow demonstrates this is due to underlying disease and not to potential myelotoxicity e.g., where >50% of cells have AML phenotype. Failed first-line treatment with Ven + HMA with or without additional targeted therapy specified as any of the following: - For Cohort B1: Participants who do not achieve at least morphologic leukemia-free state (MLFS) or partial remission (PR), or are progressing after at least 2 cycles of Ven + HMA - For Cohort B2: Participants must have achieved CR, CRh, or CRi, within 4 cycles of Ven + HMA and subsequently experienced relapse during treatment with Ven + HMA or experienced disease progression during or after subsequent salvage treatment. Note: If Ven was the participants most recent line of therapy, no more than 90 days may elapse between the last administered dose of Ven and the first study dose on C1D1. No alternative, approved therapeutic options likely to produce clinical benefit. Eastern Cooperative Oncology Group (ECOG) performance score of 0-2 (Section 10.6). Life expectancy of at least 12 weeks. No other anti-cancer treatment received for 14 days or 5 half-lives, whichever is shorter, prior to first dose of study drug. Note: Use of cytoreductive agents such as hydroxyurea or low dose (up to 40 mg/day) cytarabine is permitted, where discussed and agreed with the Medical Monitor, and provided that a 7-day washout period is observed prior to the first dose of study treatment (Section 6.8.1).

Criterios de Exclusión

1. Active central nervous system (CNS) leukemia. 8. Known seropositivity or history of active viral infection with human immunodeficiency virus (HIV) infection defined as any of the following: CD4+ T-cell count of less than 350 cells/µL at Screening AIDSdefining opportunistic infection within the past 12 months 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 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. 9. Ongoing significant liver disease such as cirrhosis, drug-induced liver injury, active hepatitis, or chronic persistent hepatitis B and/or C - Positive serologic or polymerase chain reaction (PCR) test results for Acute or chronic HBV infection. Participants whose HBV infection status cannot be determined by serologic test results must be negative for HBV by PCR to be eligible for study participation. (https://www.cdc.gov/hepatitis/hbv/interpretationOfHepBSerologicResults.htm) - acute or chronic HCV infection. Participants who are positive for HCV antibody must be negative for HCV by PCR to be eligible for study participation. 10. Impairment of gastrointestinal function or gastrointestinal disease that may significantly alter the absorption of RVU120 (e.g., active inflammatory bowel disease, ulcerative disease, malabsorption syndrome, short bowel syndrome, uncontrolled nausea, vomiting or diarrhea). 11. Ongoing drug-induced pneumonitis. 12. Concurrent participation in another investigational clinical trial. 13. Taking any medications, herbal supplements, or other substances that are known to be strong inhibitors or moderate/strong inducers or sensitive substrates of CYPXXX, within 7 days or 5 half-lives, whichever is longer, prior to first dose and during the treatment with study drug (Section 10.8). 14. Taking medications, over-the-counter medications, foods or herbal supplements that are known to be strong or moderate inhibitors of CYP3A or P-gp, within 7 days or 5 half-lives, whichever is longer, prior to first dose of study drug (Section 5.3.1). Note: Azole antifungals used in clinical practice for prophylaxis or maintenance are allowed (following the Ven prescribing information), except during Cycle 1 for participants enrolled to Part 1. 16. Significant cardiac dysfunction defined as myocardial infarction within 12 months of first dose of study drug, New York Heart Association (NYHA) Class III or IV heart failure, uncontrolled dysrhythmias, poorly controlled angina (Section 10.9) or left ventricular ejection fraction (LVEF) <40% as per echocardiography or multiple gated acquisition (MUGA) scan. 17. History of ventricular arrhythmia, or QTc 470 ms (Fridericias formula; Section 10.10). 18. Prior history of malignancies other than AML, unless the participant has been free of the disease for at least 5 years before Screening. Malignancies that are not expected to interfere with the study objectives are allowed, including: - Basal cell carcinoma of the skin - Non-metastatic squamous cell carcinoma of the skin - Carcinoma in situ of the cervix - Carcinoma in situ of the breast - Carcinoma in situ of the bladder - Incidental histological finding of prostate cancer (Tumor/Node/Metastasis stage of T1a or T1b). Note: Eligibility of participants with history of malignancies other than AML must be discussed with the Medical Monitor. 19. Pregnant or breastfeeding. 15. Systemic corticosteroids exceeding prednisone 10 mg/day (or equivalent) used as physiologic replacement are prohibited. 2. Diagnosis of acute promyelocytic leukemia (APL), the M3 subtype of AML, acute erythroid leukemia, the M6 subtype of AML, or acute megakaryoblastic leukemia, the M7 subtype of AML. 20. Any other prior or current medical condition, intercurrent illness, surgical history, physical or electrocardiogram (ECG) findings, laboratory abnormalities, or extenuating circumstance (e.g., alcohol or drug addiction) that, in the Investigators- or the Sponsors opinion, could jeopardize participant safety or interfere with the objectives of the study. 3. Previous treatment with CDK8 and/or CDK19-targeted therapy. 4. Major surgery within 28 days prior to first dose of study drug. 5. Bone marrow stem cell transplant (BMT) or peripheral blood stem cell transplant (PBSCT) within 120 days prior to first dose of study drug. 6. Active, Grade 2 acute graft versus host disease (GVHD), active moderate-to-severe chronic GVHD, or requirement for systemic immunosuppressive medications for GVHD. 7. Evidence of ongoing and uncontrolled systemic bacterial, fungal, or viral infection and acute inflammatory conditions (including pancreatitis).

Calendario

(Última actualización: 29/07/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
29/04/2024	22/05/2024	03/06/2024	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

Kamil Sitarz

+48539960651

kamil.sitarz@ryvu.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Parc de Salut Mar

Doctor Aiguader, 88 Edificio PRBB 08003 Barcelona

ceic-psmar@researchmar.net

933160679

Centros

Activo (30/04/2024)

Clinica Universidad De Navarra

Pamplona

NAVARRA

Hematology

Activo (05/07/2024)

Hospital De La Santa Creu I Sant Pau

Barcelona

BARCELONA

Hematology

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

Hospital De La Santa Creu I Sant Pau

Barcelona

BARCELONA

Hematology

Activo (20/05/2024)

Hospital Del Mar

Barcelona

BARCELONA

Hematology

Activo (05/07/2024)

Hospital San Pedro De Alcantara

Caceres

CÁCERES

Hematology

Activo (30/04/2024)

Hospital Universitario La Paz

Madrid

MADRID

Hematology

Activo (30/04/2024)

Hospital Universitario Regional De Malaga

Malaga

MÁLAGA

Hematology

Activo (01/07/2024)

Hospital Universitario Y Politecnico La Fe

Valencia

VALENCIA

Hematology

Activo (22/05/2024)

MD Anderson Cancer Center

Madrid

MADRID

Hematology

Activo (30/04/2024)

University Hospital Virgen Del Rocio S.L.

Sevilla

SEVILLA

Hematology

Medicamentos

SEL120 monohydrochloride
CAPSULE
ORAL

-
Principios Activos: N/A

Experimental

VENETOCLAX
FILM-COATED TABLET
ORAL

-
Principios Activos: N/A

Experimental

VENETOCLAX
FILM-COATED TABLET
ORAL

-
Principios Activos: N/A

Experimental

SEL120 monohydrochloride
CAPSULE
ORAL

-
Principios Activos: N/A

Experimental

VENETOCLAX
FILM-COATED TABLET
ORAL

-
Principios Activos: N/A

Experimental

Sin resultados

A Multicenter, Open-Label, Dose-Finding Clinical Trial to Assess the Safety, Pharmacokinetics, Pharmacodynamics, and Clinical Efficacy of RVU120 in Combination with Venetoclax in Participants with Acute Myeloid Leukemia Who Failed Prior Therapy with Venetoclax and a Hypomethylating Agent (RIVER-81)

State	Type of participants	Age Ranges
Recruiting	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase II	55
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
2023-505911-19-00 (CTIS)

Protocol Code
RIVER-81

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

Investigated Disease
Acute Myeloid Leukemia

Scientific Title
A Multicenter, Open-Label, Dose-Finding Clinical Trial to Assess the Safety, Pharmacokinetics, Pharmacodynamics,

and Clinical Efficacy of RVU120 in Combination with Venetoclax in Participants with Acute Myeloid Leukemia Who Failed Prior Therapy with Venetoclax and a Hypomethylating Agent (RIVER-81)

Rationale

Not provided

Main Objective

Part 1 only: To determine the RD of RVU120 plus Ven to be administered in AML patients failing prior Ven + HMA
Parts 2 and 3: To evaluate the anti-leukemic activity of RVU120 when given in combination with Ven in AML patients failing prior Ven + HMA

Primary Endpoints

Part 1: Incidence and severity of AE, including events qualifying as DLTs
Part 2 and 3: Complete remission (CR) rate (according to ELN 2022 [Döhner 2022])

Temporary moments of secondary assessment

Not provided

Secondary Objective

All parts: To determine the safety and tolerability of RVU120 when given in combination with Ven, in AML patients failing prior Ven + HMA
All parts: To evaluate further efficacy endpoints of RVU120 when given in combination with Ven, in AML patients failing prior Ven + HMA
Part 1: To characterize single and multiple dose PK of RVU120 when given in combination with Ven
Part 2 and 3: To evaluate the effect of RVU120 when given in combination with Ven, on patient-reported outcomes/health-related quality of life (HRQOL)
Part 2 and 3: To evaluate the anti-leukemic activity of RVU120 when given in combination with Ven, including measurable residual disease (MRD) response where applicable, in AML patients failing prior Ven + HMA

Secondary Endpoints

All parts: Incidence and severity of AE, including events qualifying as DLTs.
All parts: CR with incomplete hematologic recovery (CRi),Transfusion independence, DoR, PFS, RFS, EFS, Overall survival, Percentage of participants bridged to HSCT
Part 1: PK of RVU120 including Cmax, tmax, AUCtau, and AUCinf, and t½
Part 2 and 3: Changes in patient-reported outcomes as assessed by changes in summary scores of the HM-PRO
Part 2 and 3:Composite complete remission (CCR) rate, including complete remission (CR), CR with partial hematologic recovery (CRh), with and without MRD (according to ELN 2022 [Döhner 2022])

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Written informed consent provided prior to any study-related procedure. Must have recovered from the toxic effects of previous treatments to at least Grade 1, except for neurotoxicity (which should return at least to Grade 2 or baseline) and alopecia. Clinical laboratory parameters as follows: - Peripheral WBC count, no upper limit at Screening, but must be <25 x10^9/L on Day 1 prior to first dose of study drug (see acceptable methods of cytoreduction above) - Platelet (PLT) count >10^9/L at the time of first study drug administration (PLT count < 10^9/L, participant must receive a transfusion within a maximum 24 hours before study drug administration) - Aspartate aminotransferase (AST) and alanine aminotransferase (ALT) 3X the upper limit of normal (ULN) - Creatinine clearance 40 mL/min (Cockcroft and Gault formula; Section 10.7). - Total bilirubin 1.5X ULN Note: Participants with Gilberts syndrome may be enrolled provided that direct bilirubin is within the acceptable range as specified in this protocol, and there is no evidence of clinically significant hepatic dysfunction. Adequate cardiac function confirmed by left ventricular ejection fraction 40% as per echocardiography. For women of childbearing potential (WOCBP), a negative pregnancy test must be confirmed during Screening and within 3 days prior to first dose of study drug. WOCBP must commit to using a highly effective method of contraception during study participation and until 28 weeks (approximately 6.5 months) after the last dose of RVU120 (Section 10.4) OR For males, an effective barrier method of contraception must be used during study participation and until 28 weeks (approximately 6.5 months) after the last dose of RVU120, if the participant is sexually active with a WOCBP (Section 10.4). Agree not to donate blood, eggs (ova) or sperm, during study participation and until 28 weeks (approximately 6.5 months) after the last dose of RVU120 (Section 10.4). Investigator considers the participant to be suitable for participation in the clinical study by assessing that they: - understand the requirements of the clinical study and can give informed consent - can comply with study medication dosing requirements and all study-related procedures and evaluations - are not considered to be potentially unreliable and/or not cooperative. Has received vaccinations in accordance with institutional standards and local regulatory requirements, if applicable. Age 18 years at time of provision of informed consent. AML diagnosis according to the 2022 World Health Organization (WHO) classification (Arber 2022). Relapsed or refractory AML per the ELN 2022 (Döhner 2022) - Participants with <10% bone marrow cellularity may be enrolled where immunophenotyping of the bone marrow demonstrates this is due to underlying disease and not to potential myelotoxicity e.g., where >50% of cells have AML phenotype. Failed first-line treatment with Ven + HMA with or without additional targeted therapy specified as any of the following: - For Cohort B1: Participants who do not achieve at least morphologic leukemia-free state (MLFS) or partial remission (PR), or are progressing after at least 2 cycles of Ven + HMA - For Cohort B2: Participants must have achieved CR, CRh, or CRi, within 4 cycles of Ven + HMA and subsequently experienced relapse during treatment with Ven + HMA or experienced disease progression during or after subsequent salvage treatment. Note: If Ven was the participants most recent line of therapy, no more than 90 days may elapse between the last administered dose of Ven and the first study dose on C1D1. No alternative, approved therapeutic options likely to produce clinical benefit. Eastern Cooperative Oncology Group (ECOG) performance score of 0-2 (Section 10.6). Life expectancy of at least 12 weeks. No other anti-cancer treatment received for 14 days or 5 half-lives, whichever is shorter, prior to first dose of study drug. Note: Use of cytoreductive agents such as hydroxyurea or low dose (up to 40 mg/day) cytarabine is permitted, where discussed and agreed with the Medical Monitor, and provided that a 7-day washout period is observed prior to the first dose of study treatment (Section 6.8.1).

Exclusion criteria

1. Active central nervous system (CNS) leukemia. 8. Known seropositivity or history of active viral infection with human immunodeficiency virus (HIV) infection defined as any of the following: CD4+ T-cell count of less than 350 cells/µL at Screening AIDSdefining opportunistic infection within the past 12 months 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 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. 9. Ongoing significant liver disease such as cirrhosis, drug-induced liver injury, active hepatitis, or chronic persistent hepatitis B and/or C - Positive serologic or polymerase chain reaction (PCR) test results for Acute or chronic HBV infection. Participants whose HBV infection status cannot be determined by serologic test results must be negative for HBV by PCR to be eligible for study participation. (https://www.cdc.gov/hepatitis/hbv/interpretationOfHepBSerologicResults.htm) - acute or chronic HCV infection. Participants who are positive for HCV antibody must be negative for HCV by PCR to be eligible for study participation. 10. Impairment of gastrointestinal function or gastrointestinal disease that may significantly alter the absorption of RVU120 (e.g., active inflammatory bowel disease, ulcerative disease, malabsorption syndrome, short bowel syndrome, uncontrolled nausea, vomiting or diarrhea). 11. Ongoing drug-induced pneumonitis. 12. Concurrent participation in another investigational clinical trial. 13. Taking any medications, herbal supplements, or other substances that are known to be strong inhibitors or moderate/strong inducers or sensitive substrates of CYPXXX, within 7 days or 5 half-lives, whichever is longer, prior to first dose and during the treatment with study drug (Section 10.8). 14. Taking medications, over-the-counter medications, foods or herbal supplements that are known to be strong or moderate inhibitors of CYP3A or P-gp, within 7 days or 5 half-lives, whichever is longer, prior to first dose of study drug (Section 5.3.1). Note: Azole antifungals used in clinical practice for prophylaxis or maintenance are allowed (following the Ven prescribing information), except during Cycle 1 for participants enrolled to Part 1. 16. Significant cardiac dysfunction defined as myocardial infarction within 12 months of first dose of study drug, New York Heart Association (NYHA) Class III or IV heart failure, uncontrolled dysrhythmias, poorly controlled angina (Section 10.9) or left ventricular ejection fraction (LVEF) <40% as per echocardiography or multiple gated acquisition (MUGA) scan. 17. History of ventricular arrhythmia, or QTc 470 ms (Fridericias formula; Section 10.10). 18. Prior history of malignancies other than AML, unless the participant has been free of the disease for at least 5 years before Screening. Malignancies that are not expected to interfere with the study objectives are allowed, including: - Basal cell carcinoma of the skin - Non-metastatic squamous cell carcinoma of the skin - Carcinoma in situ of the cervix - Carcinoma in situ of the breast - Carcinoma in situ of the bladder - Incidental histological finding of prostate cancer (Tumor/Node/Metastasis stage of T1a or T1b). Note: Eligibility of participants with history of malignancies other than AML must be discussed with the Medical Monitor. 19. Pregnant or breastfeeding. 15. Systemic corticosteroids exceeding prednisone 10 mg/day (or equivalent) used as physiologic replacement are prohibited. 2. Diagnosis of acute promyelocytic leukemia (APL), the M3 subtype of AML, acute erythroid leukemia, the M6 subtype of AML, or acute megakaryoblastic leukemia, the M7 subtype of AML. 20. Any other prior or current medical condition, intercurrent illness, surgical history, physical or electrocardiogram (ECG) findings, laboratory abnormalities, or extenuating circumstance (e.g., alcohol or drug addiction) that, in the Investigators- or the Sponsors opinion, could jeopardize participant safety or interfere with the objectives of the study. 3. Previous treatment with CDK8 and/or CDK19-targeted therapy. 4. Major surgery within 28 days prior to first dose of study drug. 5. Bone marrow stem cell transplant (BMT) or peripheral blood stem cell transplant (PBSCT) within 120 days prior to first dose of study drug. 6. Active, Grade 2 acute graft versus host disease (GVHD), active moderate-to-severe chronic GVHD, or requirement for systemic immunosuppressive medications for GVHD. 7. Evidence of ongoing and uncontrolled systemic bacterial, fungal, or viral infection and acute inflammatory conditions (including pancreatitis).

Calendar

(Last Update: 29/07/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
29/04/2024	22/05/2024	03/06/2024	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

Kamil Sitarz

+48539960651

kamil.sitarz@ryvu.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Parc de Salut Mar

Doctor Aiguader, 88 Edificio PRBB 08003 Barcelona

ceic-psmar@researchmar.net

933160679

Sites

Active (30/04/2024)

Clinica Universidad De Navarra

Pamplona

NAVARRA

Hematology

Active (05/07/2024)

Hospital De La Santa Creu I Sant Pau

Barcelona

BARCELONA

Hematology

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

Hospital De La Santa Creu I Sant Pau

Barcelona

BARCELONA

Hematology

Active (20/05/2024)

Hospital Del Mar

Barcelona

BARCELONA

Hematology

Active (05/07/2024)

Hospital San Pedro De Alcantara

Caceres

CÁCERES

Hematology

Active (30/04/2024)

Hospital Universitario La Paz

Madrid

MADRID

Hematology

Active (30/04/2024)

Hospital Universitario Regional De Malaga

Malaga

MÁLAGA

Hematology

Active (01/07/2024)

Hospital Universitario Y Politecnico La Fe

Valencia

VALENCIA

Hematology

Active (22/05/2024)

MD Anderson Cancer Center

Madrid

MADRID

Hematology

Active (30/04/2024)

University Hospital Virgen Del Rocio S.L.

Sevilla

SEVILLA

Hematology

Medication

SEL120 monohydrochloride
CAPSULE
ORAL

-
Active Principles: N/A
Experimental

VENETOCLAX
FILM-COATED TABLET
ORAL

-
Active Principles: N/A
Experimental

VENETOCLAX
FILM-COATED TABLET
ORAL

-
Active Principles: N/A
Experimental

SEL120 monohydrochloride
CAPSULE
ORAL

-
Active Principles: N/A
Experimental

VENETOCLAX
FILM-COATED TABLET
ORAL

-
Active Principles: N/A
Experimental

No results