A Phase I/II with Ruxolitinib in Patients with Myelofibrosis (MF) who are Unresponsive to JAK inhibitors (HEMA-MED)

Estado	**Tipo de Participantes**	**Rangos de Edad**
Reclutando	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase I , Fase II	14
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, dosis	NO

Información

Identificador
2024-515252-20-00 (CTIS)

Cod. Protocolo
No aportado

Área terapéutica
·Enfermedades [C] - Hematología [C15]
·Enfermedades [C] - Cáncer [C04]

Enfermedad investigada
Myelofibrosis (MF) unresponsive to JAK inhibitors

Título Científico
A Phase I/II Open-Label, Multi-centre Study to Assess the Safety and Tolerability of Roginolisib in Combination with an Approved JAK inhibitor in Patients with Myelofibrosis (MF) who are Unresponsive to JAK inhibitors (HEMA-MED)

Justificación

No aportado

Objetivo Principal

To evaluate the safety and tolerability of roginolisib when administered in combination with ruxolitinib in patients with MF

Variables de Evaluación Primaria

Safety measured by AEs, 12-lead ECG, serum chemistry and haematology laboratory parameters, vital signs, physical examinations

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To evaluate biomarker responses (e.g., Treg reduction) when roginolisib is administered in combination with ruxolitinib in patients with MF.
Spleen reduction responses of roginolisib when administered in combination with ruxolitinib in patients with MF.
To evaluate preliminary signs of clinical efficacy of roginolisib when given in combination with ruxolitinib
To determine the improvements of MF related symptoms when roginolisib is given in combination with ruxolitinib as assessed by the Myelofibrosis Symptom Assessment Form (MFSAF)
To determine the pharmacokinetic (PK) parameters of roginolisib when given in combination with ruxolitinib to allow exposure/response and/or exposure/safety assessment

Variables de Evaluación Secundaria

Changes in peripheral blood Tregs from baseline at Week 12 and continued reduction over time
Splenic response rate (SRR) of 15%, 25% and 35% reduction in spleen volume at 12 and 24 weeks compared to baseline, as assessed by MRI/CT
Duration of spleen response as determined every 12 weeks
Proportion of patients with transfusion independence at 12 and 24 weeks where applicable
Overall Survival (OS) defined as the time from the date of the first dose of study treatment until death from any cause
Proportion of patients who have any reduction in Total Symptom Score (TSS) at 12 and 24 weeks compared to baseline as measured by Myelofibrosis Symptom Assessment Form (MFSAF)
Proportion of patients who have a reduction of 25% and 50% in TSS at 12 and 24 weeks compared to baseline as measured by Myelofibrosis Symptom Assessment Form (MFSAF)
Mean change in TSS as measured by Myelofibrosis Symptom Assessment Form (MFSAF) from baseline at 12 and 24 weeks
Time to the first 50% reduction compared to baseline in TSS as measured by Myelofibrosis Symptom Assessment

Form (MFSAF)
Duration of TSS response as measured by MFSAF (e.g., duration of TSS 25% and 50%)
Concentration of roginolisib at pre-dose and steady state levels (including Area under the curve [AUC], population PK)

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

18 years of age inclusive, at the time of signing the informed consent. Act to avoid pregnancy or fathering children based on the criteria below:a. Women of non-childbearing potential (i.e., surgically sterile with a hysterectomy and/or bilateral oophorectomy OR 12 months of amenorrhea and at least 50 years of age). b. Women of childbearing potential who had a negative serum pregnancy test at screening and who agree to take appropriate precautions to avoid pregnancy (with at least 99% certainty) from screening through safety follow-up, at least 1 month after the last dose of study treatment. Permitted methods that are at least 99% effective in preventing pregnancy should be communicated to the patient and their understanding confirmed. c. Men who agree to take appropriate precautions to avoid fathering from screening through safety follow-up, at least 1 month after the last dose of study treatment. Permitted methods that are at least 99% effective in preventing pregnancy (see protocol Appendix 3) should be communicated to the patient and their understanding confirmed. Capable of giving signed informed consent, which includes compliance with the requirements of this protocol. Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2. Diagnosis of MF, Post-Polycythaemia Vera Myelofibrosis MF (PPV-MF), or post-essential thrombocythemia MF (PET-MF) Dynamic International Prognostic Scoring System (DIPSS) risk category of intermediate-1, intermediate-2, or high Treated with ruxolitinib for 3 months with a stable dose 10 mg for a minimum of 8 weeks prior to Day 1. Furthermore, patients must show an unsatisfactory spleen reduction, such as a reduction of less than 25%, and spleen must be palpable 10 cm below the left costal margin on physical examination. Did not receive experimental drug therapy for MF or any other drug considered as an effective treatment for MF (e.g., danazol, hydroxyurea, interferon products) with the exception of ruxolitinib, within 3 months of starting study drug (except in conditions where other effective treatments for MF were completed 6 months prior to starting ruxolitinib) Independent of spleen size, active symptoms of MF at the screening visit, as demonstrated by the presence of a Total Symptom Score (TSS) of 10 using the Screening Symptom Form. Peripheral blast count < 10%

Criterios de Exclusión

Inability to swallow food or any condition of the upper gastrointestinal tract that precludes administration of oral medications. Receiving an immune-suppressive based treatment for any reason (including chronic use of systemic corticosteroid at doses > 10 mg/day prednisone equivalent) within 14 days prior to the first dose of study treatment. Use of inhaled or topical steroids (including but not limited to creams or intra-articular injection) or brief corticosteroid use for radiographic procedures or systemic corticosteroids 10 mg is permitted. Have received a live vaccine within 30 days of planned start of study therapy while on trial. Other type of vaccines, including SARS-Co2 vaccines, are allowed. Known allergy or reaction to any component of either study drugs or formulation components. Currently breastfeeding. Known alcohol or other substance abuse. Laboratory and medical history parameters not within Protocol-defined range. a. Absolute neutrophil count < 1.5 × 109/L. b. Platelet count < 100 × 109/L. c. Haemoglobin < 8 g/dL (transfusion is acceptable to meet this criterion). d. Serum creatinine 1.5 × institutional ULN or measured or calculated creatinine clearance (glomerular filtration rate can also be used in place of creatinine or CrCl) < 50 mL/min for patients with creatinine levels > 1.5 × institutional ULN. e. Aspartate aminotransferase (AST) or Alanine transaminase (ALT) 2.5 × ULN in the absence of hepatic metastases or 5 × ULN with hepatic metastases at screening. f. Total bilirubin 1.2 × ULN are excluded unless direct bilirubin is ULN. If there is no institutional ULN, then

direct bilirubin must be < 40% of total bilirubin to be eligible (except patients with Gilbert syndrome, who must have total bilirubin < 51.3 mol/L). g. International normalized ratio or prothrombin time (PT) > 1.5 × ULN. h. Activated partial thromboplastin time (aPTT) > 1.5 × ULN. i. Evidence of acute infection of hepatitis B virus (HBV), (for example: positive for HBsAg, anti-HBc, IgM anti-HBc and negative for anti-HBs), hepatitis C virus (HCV) (for example: HCV antibody reactive; HCV RNA detected) and HIV. Patients who are on stable antiviral therapy, in good clinical control (ie for HIV a viral load < 400 copie/ml and a CD4+ count of > 350 cells/uL) and asymptomatic are eligible for the study. Presence of active or inactive latent tuberculosis. History of a prior Grade 3 or 4 AE which did not respond to therapy or resolved with treatment interruptions and returned to at least Grade 1, other than fatigue. Note: Patients with Grade 2 neuropathy or alopecia are an exception and may enrol Active autoimmune process (e.g., rheumatoid arthritis, moderate or severe psoriasis, multiple sclerosis, inflammatory bowel disease, immune colitis) for which systemic treatment (i.e., use of disease-modifying agents, corticosteroids, or immunosuppressive drugs) is required. Replacement therapy (e.g., thyroxine, insulin, or physiologic corticosteroid replacement therapy for adrenal or pituitary insufficiency, etc.) is not considered a form of systemic treatment. History or presence of an abnormal ECG that, in the Investigator's opinion, is clinically meaningful. Screening QTc interval > 480 milliseconds is excluded (corrected by Fridericia). In the event that a single QTc is > 480 milliseconds, the patient may enrol if the average QTc for the 3 ECGs is < 480 milliseconds. For patients with an intraventricular conduction delay (QRS interval > 120 msec), the JTc interval may be used in place of the QTc with Sponsor approval. The JTc must be < 340 milliseconds if JTc is used in place of the QTc. Patients with left bundle branch block are excluded. Clinically significant (i.e., active) cardiovascular disease: cerebral vascular accident/stroke (< 6 months prior to enrolment), myocardial infarction (< 6 months prior to enrolment), unstable angina, congestive heart failure (New York Heart Association Classification Class II), or serious cardiac arrhythmia requiring medication. Patients with active malignancy requiring concurrent intervention or previous malignancies unless a complete remission was achieved at least 2 years prior to study entry and no additional therapy is required during the study period and the patient is assessed at low risk of relapse by the investigator. Note: Patients with a slow progressing cancer (e.g. prostate) or an in situ cancers (e.g. cervical dysplasia) are permitted. Any serious or uncontrolled medical disorder or active infection that, in the opinion of the Investigator, may increase the risk associated with study participation, study drug administration, or would impair the ability of the patient to receive protocol therapy. Use of the following treatments within the time periods noted: a. Erythropoiesis stimulating agent (ESA) within 4 weeks prior to start of rogilonisib. b. Splenic irradiation within 3 months prior to start of rogilonisib. Major surgery within 2 weeks of the first dose of study drug (minimally invasive procedures such as bronchoscopy, bone marrow biopsy, insertion of a central venous access device, and insertion of a feeding tube are not considered major surgery and are not exclusionary)

Calendario

(Última actualización: 17/07/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
17/01/2025	01/10/2025	22/10/2025	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

iOnctura SA Switzerland

Campus Biotech Innovation ParkAvenue De Secheron 15/f2

Contact Person

Michael Lhan

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Monetary support: N/A

Tipo de promotor: Comercial

Ceim

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presidenciaceic@bellvitgehospital.cat

Centros

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

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Hematology

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

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Hematology

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

Hospital Universitario Hm Sanchinarro

Madrid

MADRID

Hematology

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

Institut Catala D´oncologia

L'hospitalet De Llobregat

BARCELONA

Hematology

Medicamentos

FEDRATINIB
CAPSULE, HARD
ORAL

-
Principios Activos: N/A
Experimental

RUXOLITINIB
TABLET
ORAL

-
Principios Activos: N/A
Experimental

MOMELOTINIB DIHYDROCHLORIDE MONOHYDRATE
FILM-COATED TABLET
ORAL

-
Principios Activos: N/A
Experimental

IOA-244
TABLET
ORAL

-
Principios Activos: N/A
Experimental

Sin resultados

A Phase I/II with Ruxolitinib in Patients with Myelofibrosis (MF) who are Unresponsive to JAK inhibitors (HEMA-MED)

State	Type of participants	Age Ranges
Recruiting	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase I , Phase II	14
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, dose	NO

Information

Identifier
2024-515252-20-00 (CTIS)

Protocol Code
No aportado

Therapeutic area
·Diseases [C] - Hemic and Lymphatic Diseases [C15]
·Diseases [C] - Cancer [C04]

Investigated Disease
Myelofibrosis (MF) unresponsive to JAK inhibitors

Scientific Title
A Phase I/II Open-Label, Multi-centre Study to Assess the Safety and Tolerability of Roginolisib in Combination with an Approved JAK inhibitor in Patients with Myelofibrosis (MF) who are Unresponsive to JAK inhibitors (HEMA-MED)

Rationale

Not provided

Main Objective

To evaluate the safety and tolerability of roginolisib when administered in combination with ruxolitinib in patients with MF

Primary Endpoints

Safety measured by AEs, 12-lead ECG, serum chemistry and haematology laboratory parameters, vital signs, physical examinations

Temporary moments of secondary assessment

Not provided

Secondary Objective

To evaluate biomarker responses (e.g., Treg reduction) when roginolisib is administered in combination with ruxolitinib in patients with MF.
Spleen reduction responses of roginolisib when administered in combination with ruxolitinib in patients with MF.
To evaluate preliminary signs of clinical efficacy of roginolisib when given in combination with ruxolitinib
To determine the improvements of MF related symptoms when roginolisib is given in combination with ruxolitinib as assessed by the Myelofibrosis Symptom Assessment Form (MFSAF)
To determine the pharmacokinetic (PK) parameters of roginolisib when given in combination with ruxolitinib to allow exposure/response and/or exposure/safety assessment

Secondary Endpoints

Changes in peripheral blood Tregs from baseline at Week 12 and continued reduction over time
Splenic response rate (SRR) of 15%, 25% and 35% reduction in spleen volume at 12 and 24 weeks compared to baseline, as assessed by MRI/CT
Duration of spleen response as determined every 12 weeks
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Overall Survival (OS) defined as the time from the date of the first dose of study treatment until death from any cause
Proportion of patients who have any reduction in Total Symptom Score (TSS) at 12 and 24 weeks compared to baseline as measured by Myelofibrosis Symptom Assessment Form (MFSAF)
Proportion of patients who have a reduction of 25% and 50% in TSS at 12 and 24 weeks compared to baseline as measured by Myelofibrosis Symptom Assessment Form (MFSAF)
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Time to the first 50% reduction compared to baseline in TSS as measured by Myelofibrosis Symptom Assessment

Form (MFSAF)
Duration of TSS response as measured by MFSAF (e.g., duration of TSS 25% and 50%)
Concentration of roginolisib at pre-dose and steady state levels (including Area under the curve [AUC], population PK)

Temporary moments of secondary assessment

Not provided

Inclusion criteria

18 years of age inclusive, at the time of signing the informed consent. Act to avoid pregnancy or fathering children based on the criteria below:a. Women of non-childbearing potential (i.e., surgically sterile with a hysterectomy and/or bilateral oophorectomy OR 12 months of amenorrhea and at least 50 years of age). b. Women of childbearing potential who had a negative serum pregnancy test at screening and who agree to take appropriate precautions to avoid pregnancy (with at least 99% certainty) from screening through safety follow-up, at least 1 month after the last dose of study treatment. Permitted methods that are at least 99% effective in preventing pregnancy should be communicated to the patient and their understanding confirmed. c. Men who agree to take appropriate precautions to avoid fathering from screening through safety follow-up, at least 1 month after the last dose of study treatment. Permitted methods that are at least 99% effective in preventing pregnancy (see protocol Appendix 3) should be communicated to the patient and their understanding confirmed. Capable of giving signed informed consent, which includes compliance with the requirements of this protocol. Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2. Diagnosis of MF, Post-Polycythaemia Vera Myelofibrosis MF (PPV-MF), or post-essential thrombocythemia MF (PET-MF) Dynamic International Prognostic Scoring System (DIPSS) risk category of intermediate-1, intermediate-2, or high Treated with ruxolitinib for 3 months with a stable dose 10 mg for a minimum of 8 weeks prior to Day 1. Furthermore, patients must show an unsatisfactory spleen reduction, such as a reduction of less than 25%, and spleen must be palpable 10 cm below the left costal margin on physical examination. Did not receive experimental drug therapy for MF or any other drug considered as an effective treatment for MF (e.g., danazol, hydroxyurea, interferon products) with the exception of ruxolitinib, within 3 months of starting study drug (except in conditions where other effective treatments for MF were completed 6 months prior to starting ruxolitinib) Independent of spleen size, active symptoms of MF at the screening visit, as demonstrated by the presence of a Total Symptom Score (TSS) of 10 using the Screening Symptom Form. Peripheral blast count < 10%

Exclusion criteria

Inability to swallow food or any condition of the upper gastrointestinal tract that precludes administration of oral medications. Receiving an immune-suppressive based treatment for any reason (including chronic use of systemic corticosteroid at doses > 10 mg/day prednisone equivalent) within 14 days prior to the first dose of study treatment. Use of inhaled or topical steroids (including but not limited to creams or intra-articular injection) or brief corticosteroid use for radiographic procedures or systemic corticosteroids 10 mg is permitted. Have received a live vaccine within 30 days of planned start of study therapy while on trial. Other type of vaccines, including SARS-Co2 vaccines, are allowed. Known allergy or reaction to any component of either study drugs or formulation components. Currently breastfeeding. Known alcohol or other substance abuse. Laboratory and medical history parameters not within Protocol-defined range. a. Absolute neutrophil count < 1.5 × 109/L. b. Platelet count < 100 × 109/L. c. Haemoglobin < 8 g/dL (transfusion is acceptable to meet this criterion). d. Serum creatinine 1.5 × institutional ULN or measured or calculated creatinine clearance (glomerular filtration rate can also be used in place of creatinine or CrCl) < 50 mL/min for patients with creatinine levels > 1.5 × institutional ULN. e. Aspartate aminotransferase (AST) or Alanine transaminase (ALT) 2.5 × ULN in the absence of hepatic metastases or 5 × ULN with hepatic metastases at screening. f. Total bilirubin 1.2 × ULN are excluded unless direct bilirubin is ULN. If there is no institutional ULN, then

direct bilirubin must be < 40% of total bilirubin to be eligible (except patients with Gilbert syndrome, who must have total bilirubin < 51.3 mol/L). g. International normalized ratio or prothrombin time (PT) > 1.5 × ULN. h. Activated partial thromboplastin time (aPTT) > 1.5 × ULN. i. Evidence of acute infection of hepatitis B virus (HBV), (for example: positive for HBsAg, anti-HBc, IgM anti-HBc and negative for anti-HBs), hepatitis C virus (HCV) (for example: HCV antibody reactive; HCV RNA detected) and HIV. Patients who are on stable antiviral therapy, in good clinical control (ie for HIV a viral load < 400 copie/ml and a CD4+ count of > 350 cells/uL) and asymptomatic are eligible for the study. Presence of active or inactive latent tuberculosis. History of a prior Grade 3 or 4 AE which did not respond to therapy or resolved with treatment interruptions and returned to at least Grade 1, other than fatigue. Note: Patients with Grade 2 neuropathy or alopecia are an exception and may enrol Active autoimmune process (e.g., rheumatoid arthritis, moderate or severe psoriasis, multiple sclerosis, inflammatory bowel disease, immune colitis) for which systemic treatment (i.e., use of disease-modifying agents, corticosteroids, or immunosuppressive drugs) is required. Replacement therapy (e.g., thyroxine, insulin, or physiologic corticosteroid replacement therapy for adrenal or pituitary insufficiency, etc.) is not considered a form of systemic treatment. History or presence of an abnormal ECG that, in the Investigator's opinion, is clinically meaningful. Screening QTc interval > 480 milliseconds is excluded (corrected by Fridericia). In the event that a single QTc is > 480 milliseconds, the patient may enrol if the average QTc for the 3 ECGs is < 480 milliseconds. For patients with an intraventricular conduction delay (QRS interval > 120 msec), the JTc interval may be used in place of the QTc with Sponsor approval. The JTc must be < 340 milliseconds if JTc is used in place of the QTc. Patients with left bundle branch block are excluded. Clinically significant (i.e., active) cardiovascular disease: cerebral vascular accident/stroke (< 6 months prior to enrolment), myocardial infarction (< 6 months prior to enrolment), unstable angina, congestive heart failure (New York Heart Association Classification Class II), or serious cardiac arrhythmia requiring medication. Patients with active malignancy requiring concurrent intervention or previous malignancies unless a complete remission was achieved at least 2 years prior to study entry and no additional therapy is required during the study period and the patient is assessed at low risk of relapse by the investigator. Note: Patients with a slow progressing cancer (e.g. prostate) or an in situ cancers (e.g. cervical dysplasia) are permitted. Any serious or uncontrolled medical disorder or active infection that, in the opinion of the Investigator, may increase the risk associated with study participation, study drug administration, or would impair the ability of the patient to receive protocol therapy. Use of the following treatments within the time periods noted: a. Erythropoiesis stimulating agent (ESA) within 4 weeks prior to start of rogilonisib. b. Splenic irradiation within 3 months prior to start of rogilonisib. Major surgery within 2 weeks of the first dose of study drug (minimally invasive procedures such as bronchoscopy, bone marrow biopsy, insertion of a central venous access device, and insertion of a feeding tube are not considered major surgery and are not exclusionary)

Calendar

(Last Update: 17/07/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
17/01/2025	01/10/2025	22/10/2025	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

iOnctura SA Switzerland

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Contact Person

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Monetary support: N/A

Sponsor type: Commercial

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Sites

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

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Hematology

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

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Hematology

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

Hospital Universitario Hm Sanchinarro

Madrid

MADRID

Hematology

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

Institut Catala D´oncologia

L'hospitalet De Llobregat

BARCELONA

Hematology

Medication

FEDRATINIB
CAPSULE, HARD
ORAL

-
Active Principles: N/A
Experimental

RUXOLITINIB
TABLET
ORAL

-
Active Principles: N/A
Experimental

MOMELOTINIB DIHYDROCHLORIDE MONOHYDRATE
FILM-COATED TABLET
ORAL

-
Active Principles: N/A
Experimental

IOA-244
TABLET
ORAL

-
Active Principles: N/A
Experimental

No results