A multicenter, phase 2 randomized, open label study to evaluate the efficacy and security of zanubrutinib in combination with obinutuzumab in previously untreated patients with Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL) (GELLC-10-ZANUBIO)

Estado	**Tipo de Participantes**	**Rangos de Edad**
Reclutando	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase II	106
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia	NO

Información

Identificador
2023-504647-14-00 (CTIS)

Cod. Protocolo
GELLC-10-ZANUBIO

Área terapéutica
Enfermedades [C] - Hematología [C15]|

Enfermedad investigada
Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL)

Título Científico
A multicenter, phase 2 randomized, open label study to evaluate the efficacy and security of zanubrutinib in combination with obinutuzumab in previously untreated patients with Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL) (GELLC-10-ZANUBIO)

Justificación

No aportado

Objetivo Principal

To compare the rate of complete remission (CR) with undetectable minimal residual disease (uMRD) obtained with zanubrutinib combined with obinutuzumab with two different schedules of administration of obinutuzumab (starting obinutuzumab at cycle 2 or 12 months) in patients with previously untreated CLL or SLL.

Variables de Evaluación Primaria

The primary endpoint of the study is the complete response rate (CRR) with undetectable minimal residual disease (uMRD).

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To further assess the efficacy and safety of the combination therapy with two different administration schedules of obinutuzumab through the following outcome measures. Overall response rate (ORR), including Complete Remission (CR); CR with incomplete marrow recovery (CRi); Partial Remission (PR), and partial response with lymphocytosis. MRD analysis by flow cytometry and molecular biology. Duration of response and Progression-free survival (PFS). [Time Frame: the time from randomization until symptomatic disease progression (as defined by the updated iwCLL-guidelines) or death by any cause, whichever occurs first] Overall survival (OS). [Time Frame: time between the day of randomization to death from any cause]. Immunological recovery. Safety: type, frequency, and severity of adverse events (AEs) and relationship of AEs to zanubrutinib or the combination of zanubrutinib and obinutuzumab, including the assessment of infusion related reactions (IRR) and tumour lysis syndrome (TLS). The rate and severity of IRR and TLS will be analyzed also according to the two different schedules of administration of obinutuzumab (arm A and arm B). Biomarkers for response

Variables de Evaluación Secundaria

Overall response rate (ORR), including partial response with lymphocytosis.
Progression-free survival (PFS), defined as the time from randomization until symptomatic disease progression (as defined by the updated iwCLL-guidelines) or death by any cause, whichever occurs first.
Overall survival (OS), defined as the time between the day of randomization to death from any cause.
Immunological recovery
Safety: type, frequency, and severity of adverse events (AEs) and relationship of AEs to zanubrutinib or the combination of zanubrutinib and obinutuzumab, including the assessment of tumour lysis syndrome.
Potential predictive biomarkers of response to zanubrutinib and obinutuzumab and mechanisms of resistance in patients diagnosed with CLL [Visits: Baseline, cycle 20, and at progression].

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Patients with treatment-naïve chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). 1. Adult patients with previously untreated CLL defined following IWCLL criteria.
Must understand and voluntarily sign an informed consent form.
Age 18 years at the time of signing the informed consent form and must be able to adhere to the study visit schedule and other protocol requirements.
Must have a documented diagnosis of CLL or SLL [IWCLL guidelines for diagnosis and treatment of CLL] meeting at least one of the following criteria: Evidence of progressive marrow failure as manifested by the development of, or worsening of, anemia and/or thrombocytopenia. Massive (i.e. 6 cm below the left costal margin) or progressive or symptomatic splenomegaly. Massive nodes (i.e. 10 cm in longest diameter) or progressive or symptomatic lymphadenopathy. Progressive lymphocytosis with an increase of 50% over a 2-month period, or lymphocyte doubling time (LDT) of less than 6 months. A minimum of any one of the following disease-related symptoms: unintentional weight loss 10% within the previous 6 months, significant fatigue (i.e., ECOG PS 2 or worse; cannot work or unable to perform usual activities), fevers of greater than 38.0°C for 2 or more weeks without other evidence of infection, or night sweats for more than 1 month without evidence of infection. Autoimmune complications including anemia or thrombocytopenia poorly responsive to corticosteroids. Symptomatic or functional extranodal involvement (eg, skin, kidney, lung, spine).
Must have an Eastern Cooperative Oncology Group (ECOG) performance status score of 2.
Female patients of childbearing potential must practice highly effective methods of contraception initiated prior to first dose of study drug, for the duration of the study, and for 90 days after the last dose of zanubrutinib and 18 months after last dose of obinutuzumab. Male patients are eligible if vasectomized or if they agree to the use of barrier contraception with other applicable highly effective methods described below during the study treatment period and for 90 days after the last dose of zanubrutinib and 18 months after last dose of obinutuzumab. A woman is considered of childbearing potential, ie, fertile, following menarche and until becoming postmenopausal unless permanently sterile. Permanent sterilization methods include hysterectomy, bilateral salpingectomy, and bilateral oophorectomy. Contraception methods include the following: Combined (estrogen- and progestogen- containing) hormonal contraception associated with the inhibition of ovulation Oral, intravaginal, or transdermal. Progestogen-only hormonal contraception associated with the inhibition of ovulation Oral, injectable, implantable. An intrauterine device Intrauterine hormone-releasing system Bilateral tubal occlusion Vasectomized partner (provided that the vasectomized partner is the sole sexual partner of the woman of childbearing potential study participant and that the vasectomized partner has received medical assessment of surgical success). Sexual abstinence (defined as refraining from heterosexual intercourse during the entire period of risk associated with the study treatment, starting the day prior to first dose of study drug, for the duration of the study, and for 90 days after the last dose of zanubrutinib or ibrutinib. Total sexual abstinence should only be used as a contraceptive method if it is in line with the patients usual and preferred lifestyle. Periodic abstinence (eg, calendar, ovulation, symptothermal, post-ovulation methods), declaration of abstinence for the duration of exposure to investigational medicinal product, and withdrawal are not acceptable methods of contraception. Of note, barrier contraception (including male and female condoms with or without spermicide) is not considered a highly effective method of contraception, and, if used, this method must be used in combination with another acceptable method listed above. If patient is using hormonal contraceptives such as birth control pills or devices, a barrier method of contraception (eg, condoms) must also be used. A postmenopausal state is defined as no menses for 12 months without an alternative medical cause. A high follicle-stimulating hormone level in the postmenopausal range may be used to confirm a postmenopausal state in women not using hormonal contraception or hormonal replacement therapy. However, in the absence of 12 months of amenorrhea, a single follicle-stimulating hormone measurement is insufficient.
Female subjects of childbearing potential must have a negative pregnancy test at screening. Females of child bearing potential are defined as sexually mature women without prior hysterectomy or who have had any evidence of menses in the past 12 months. However, women who have been amenorrheic for 12 or more months are still considered to be of childbearing potential if the amenorrhea is possibly due to other causes, including prior

chemotherapy, anti-estrogens, or ovarian suppression.

Criterios de Exclusión

Prior treatment for CLL. Unable to swallow capsules, or has disease significantly affecting gastrointestinal function that would limit absorption of oral medication. Currently active, clinically significant cardiovascular disease or a history of myocardial infarction within 3 months prior to enrollment. Exception: Subjects with controlled, asymptomatic atrial fibrillation during screening can enrol on study. Requires or receiving anticoagulation with warfarin or equivalent vitamin K antagonists (eg, phenprocoumon) within 7 days of first dose of study drug. Systemic infection that has not resolved prior to initiating study treatment in spite of adequate anti-infective therapy. Pregnant or lactating females. Participation in any clinical study or having taken any investigational therapy within 28 days prior to initiating study therapy. Central nervous system (CNS) involvement as documented by spinal fluid cytology or imaging. Prior history of malignancies, other than CLL, unless the patient has been free of the disease for 3 years. Exceptions include the following: - Basal cell carcinoma of the skin - Squamous cell carcinoma of the skin - Carcinoma in situ of the cervix - Carcinoma in situ of the breast - Incidental histologic finding of prostate cancer (TNM stage of T1a or T1b) Presence of autoimmune haemolytic anaemia or autoimmune thrombocytopenia. Major surgery within the last 28 days prior to registration. Known Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV) and/or Hepatitis C Virus (HCV) infection. Subjects who are hepatitis B core antibody (anti-HBc) positive and who are surface antigen negative could be eligible if they have an undetectable HBV DNA (negative polymerase chain reaction (PCR) <20 IU). Those who are hepatitis B surface antigen (HbsAg) positive or hepatitis B PCR positive will be excluded. Subjects who are hepatitis C antibody positive will need to have a negative PCR result. Those who are hepatitis C PCR positive will be excluded. Per published guidelines (NCCN 2012) or institutional guidelines, patients should be closely monitored for hepatitis B reactivation. Obtaining repeated hepatitis B PCR every 3 months during treatment and for the 12 months after last dose of study drug according to usual clinical practice in order to monitor for reactivation of hepatitis B is recommended. History of stroke or intracranial haemorrhage within 6 months prior to enrollment. Requires treatment with strong CYP3A4/5 Inhibitors. Known history of drug-specific hypersensitivity or anaphylaxis to study drug (including active product or excipient components). Any life-threatening illness, medical condition, or organ system dysfunction which, in the Investigator's opinion, could compromise the subject's safety, interfere with the absorption or metabolism of zanubrutinib, or put the study outcomes at undue risk. Estimated Glomerular Filtration Rate (Cockcroft-Gault Appendix C) 30 mL/min/1.73m2 Absolute neutrophil count (ANC) < 1.0 X 109/L. Platelet count < 75 X 109/L, except for patients with bone marrow involvement by CLL in which case the platelet count must be 30 X 109/L. Serum aspartate aminotransferase (AST)/serum glutamic-oxaloacetic transaminase (SGOT) or alanine transaminase (ALT)/serum glutamate pyruvate transaminase (SGPT) >2.5 x upper limit of normal (ULN). Serum total bilirubin > 1.5 x ULN, except in cases of Gilberts syndrome. Prothrombin time/INR or aPTT (in the absence of Lupus anticoagulant) > 2x ULN. Active bleeding, history of bleeding diathesis (eg, haemophilia or von Willebrand disease).

Calendario

(Última actualización: 14/07/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
29/07/2024	02/09/2024	22/10/2024	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

Pethema Fundacion Spain

Calle Del Professor Martin Lagos Sn

Contact Person

Dr. Juan José Lahuerta

+34916266232

gerencia@fundacionpethema.es

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Hospital Universitari Vall d Hebron

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

ceic@vhir.org

934894010

Centros

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

El Hospital Universitario De Gran Canaria Dr. Negrin

Las Palmas De Gran Canaria

LAS PALMAS

Servicio de Hematología

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

Hospital Alvaro Cunqueiro

Vigo

PONTEVEDRA

Servicio de Hematología

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

Hospital Clinic De Barcelona

Barcelona

BARCELONA

Servicio de Hematología

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

Hospital Clinico Universitario De Valencia

Valencia

VALENCIA

Servicio de Hematología

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

Hospital Costa Del Sol

Marbella

MÁLAGA

Servicio de Hematología

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

Hospital De La Santa Creu I Sant Pau

Barcelona

BARCELONA

Servicio de Hematología

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

Hospital Del Mar

Barcelona

BARCELONA

Servicio de Hematología

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

Hospital Germans Trias I Pujol

Badalona

BARCELONA

Servicio de Hematología

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

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Servicio de Hematología

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

Hospital Universitario Central De Asturias

Oviedo

ASTURIAS

Servicio de Hematología

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

Hospital Universitario De La Princesa

Madrid

MADRID

Servicio de Hematología

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

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Servicio de Hematología

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

Hospital Universitario Infanta Leonor

Madrid

MADRID

Servicio de Hematología

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

Hospital Universitario La Paz

Madrid

MADRID

Servicio de Hematología

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

Hospital Universitario Marques De Valdecilla

Santander

CANTABRIA

Servicio de Hematología

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

Hospital Universitario Regional De Malaga

Malaga

MÁLAGA

Servicio de Hematología

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

Hospital Universitario Reina Sofia

Cordoba

CÓRDOBA

Servicio de Hematología

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

Hospital Universitario Virgen De Valme

Sevilla

SEVILLA

Servicio de Hematología

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

Hospital Universitario 12 De Octubre

Madrid

MADRID

Servicio de Hematología

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

ICO L'HOSPITALET HOSPITAL DURAN I REYNALS

Barcelona

BARCELONA

Servicio de Hematología

Medicamentos

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

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

Experimental

Zanubrutinib
CAPSULE
ORAL

-
Principios Activos: N/A

Experimental

Sin resultados

A multicenter, phase 2 randomized, open label study to evaluate the efficacy and security of zanubrutinib in combination with obinutuzumab in previously untreated patients with Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL) (GELLC-10-ZANUBIO)

State	**Type of participants**	**Age Ranges**
Recruiting	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase II	106
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness	NO

Information

Identifier
2023-504647-14-00 (CTIS)

Protocol Code
GELLC-10-ZANUBIO

Therapeutic area
Diseases [C] - Hemic and Lymphatic Diseases [C15]|

Investigated Disease
Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL)

Scientific Title
A multicenter, phase 2 randomized, open label study to evaluate the efficacy and security of zanubrutinib in combination with obinutuzumab in previously untreated patients with Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL) (GELLC-10-ZANUBIO)

Rationale

Not provided

Main Objective

To compare the rate of complete remission (CR) with undetectable minimal residual disease (uMRD) obtained with zanubrutinib combined with obinutuzumab with two different schedules of administration of obinutuzumab (starting obinutuzumab at cycle 2 or 12 months) in patients with previously untreated CLL or SLL.

Primary Endpoints

The primary endpoint of the study is the complete response rate (CRR) with undetectable minimal residual disease (uMRD).

Temporary moments of secondary assessment

Not provided

Secondary Objective

To further assess the efficacy and safety of the combination therapy with two different administration schedules of obinutuzumab through the following outcome measures. Overall response rate (ORR), including Complete Remission (CR); CR with incomplete marrow recovery (CRi); Partial Remission (PR), and partial response with lymphocytosis. MRD analysis by flow cytometry and molecular biology. Duration of response and Progression-free survival (PFS). [Time Frame: the time from randomization until symptomatic disease progression (as defined by the updated iwCLL-guidelines) or death by any cause, whichever occurs first] Overall survival (OS). [Time Frame: time between the day of randomization to death from any cause]. Immunological recovery. Safety: type, frequency, and severity of adverse events (AEs) and relationship of AEs to zanubrutinib or the combination of zanubrutinib and obinutuzumab, including the assessment of infusion related reactions (IRR) and tumour lysis syndrome (TLS). The rate and severity of IRR and TLS will be analyzed also according to the two different schedules of administration of obinutuzumab (arm A and arm B). Biomarkers for response

Secondary Endpoints

Overall response rate (ORR), including partial response with lymphocytosis.
Progression-free survival (PFS), defined as the time from randomization until symptomatic disease progression (as defined by the updated iwCLL-guidelines) or death by any cause, whichever occurs first.
Overall survival (OS), defined as the time between the day of randomization to death from any cause.
Immunological recovery
Safety: type, frequency, and severity of adverse events (AEs) and relationship of AEs to zanubrutinib or the combination of zanubrutinib and obinutuzumab, including the assessment of tumour lysis syndrome.
Potential predictive biomarkers of response to zanubrutinib and obinutuzumab and mechanisms of resistance in patients diagnosed with CLL [Visits: Baseline, cycle 20, and at progression].

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Patients with treatment-naïve chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). 1. Adult patients with previously untreated CLL defined following IWCLL criteria.
Must understand and voluntarily sign an informed consent form.
Age 18 years at the time of signing the informed consent form and must be able to adhere to the study visit schedule and other protocol requirements.
Must have a documented diagnosis of CLL or SLL [IWCLL guidelines for diagnosis and treatment of CLL] meeting at least one of the following criteria: Evidence of progressive marrow failure as manifested by the development of, or worsening of, anemia and/or thrombocytopenia. Massive (i.e. 6 cm below the left costal margin) or progressive or symptomatic splenomegaly. Massive nodes (i.e. 10 cm in longest diameter) or progressive or symptomatic lymphadenopathy. Progressive lymphocytosis with an increase of 50% over a 2-month period, or lymphocyte doubling time (LDT) of less than 6 months. A minimum of any one of the following disease-related symptoms: unintentional weight loss 10% within the previous 6 months, significant fatigue (i.e., ECOG PS 2 or worse; cannot work or unable to perform usual activities), fevers of greater than 38.0°C for 2 or more weeks without other evidence of infection, or night sweats for more than 1 month without evidence of infection. Autoimmune complications including anemia or thrombocytopenia poorly responsive to corticosteroids. Symptomatic or functional extranodal involvement (eg, skin, kidney, lung, spine).
Must have an Eastern Cooperative Oncology Group (ECOG) performance status score of 2.
Female patients of childbearing potential must practice highly effective methods of contraception initiated prior to first dose of study drug, for the duration of the study, and for 90 days after the last dose of zanubrutinib and 18 months after last dose of obinutuzumab. Male patients are eligible if vasectomized or if they agree to the use of barrier contraception with other applicable highly effective methods described below during the study treatment period and for 90 days after the last dose of zanubrutinib and 18 months after last dose of obinutuzumab. A woman is considered of childbearing potential, ie, fertile, following menarche and until becoming postmenopausal unless permanently sterile. Permanent sterilization methods include hysterectomy, bilateral salpingectomy, and bilateral oophorectomy. Contraception methods include the following: Combined (estrogen- and progestogen- containing) hormonal contraception associated with the inhibition of ovulation Oral, intravaginal, or transdermal. Progestogen-only hormonal contraception associated with the inhibition of ovulation Oral, injectable, implantable. An intrauterine device Intrauterine hormone-releasing system Bilateral tubal occlusion Vasectomized partner (provided that the vasectomized partner is the sole sexual partner of the woman of childbearing potential study participant and that the vasectomized partner has received medical assessment of surgical success). Sexual abstinence (defined as refraining from heterosexual intercourse during the entire period of risk associated with the study treatment, starting the day prior to first dose of study drug, for the duration of the study, and for 90 days after the last dose of zanubrutinib or ibrutinib. Total sexual abstinence should only be used as a contraceptive method if it is in line with the patients usual and preferred lifestyle. Periodic abstinence (eg, calendar, ovulation, symptothermal, post-ovulation methods), declaration of abstinence for the duration of exposure to investigational medicinal product, and withdrawal are not acceptable methods of contraception. Of note, barrier contraception (including male and female condoms with or without spermicide) is not considered a highly effective method of contraception, and, if used, this method must be used in combination with another acceptable method listed above. If patient is using hormonal contraceptives such as birth control pills or devices, a barrier method of contraception (eg, condoms) must also be used. A postmenopausal state is defined as no menses for 12 months without an alternative medical cause. A high follicle-stimulating hormone level in the postmenopausal range may be used to confirm a postmenopausal state in women not using hormonal contraception or hormonal replacement therapy. However, in the absence of 12 months of amenorrhea, a single follicle-stimulating hormone measurement is insufficient.
Female subjects of childbearing potential must have a negative pregnancy test at screening. Females of child bearing potential are defined as sexually mature women without prior hysterectomy or who have had any evidence of menses in the past 12 months. However, women who have been amenorrheic for 12 or more months are still considered to be of childbearing potential if the amenorrhea is possibly due to other causes, including prior

chemotherapy, anti-estrogens, or ovarian suppression.

Exclusion criteria

Prior treatment for CLL. Unable to swallow capsules, or has disease significantly affecting gastrointestinal function that would limit absorption of oral medication. Currently active, clinically significant cardiovascular disease or a history of myocardial infarction within 3 months prior to enrollment. Exception: Subjects with controlled, asymptomatic atrial fibrillation during screening can enrol on study. Requires or receiving anticoagulation with warfarin or equivalent vitamin K antagonists (eg, phenprocoumon) within 7 days of first dose of study drug. Systemic infection that has not resolved prior to initiating study treatment in spite of adequate anti-infective therapy. Pregnant or lactating females. Participation in any clinical study or having taken any investigational therapy within 28 days prior to initiating study therapy. Central nervous system (CNS) involvement as documented by spinal fluid cytology or imaging. Prior history of malignancies, other than CLL, unless the patient has been free of the disease for 3 years. Exceptions include the following: - Basal cell carcinoma of the skin - Squamous cell carcinoma of the skin - Carcinoma in situ of the cervix - Carcinoma in situ of the breast - Incidental histologic finding of prostate cancer (TNM stage of T1a or T1b) Presence of autoimmune haemolytic anaemia or autoimmune thrombocytopenia. Major surgery within the last 28 days prior to registration. Known Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV) and/or Hepatitis C Virus (HCV) infection. Subjects who are hepatitis B core antibody (anti-HBc) positive and who are surface antigen negative could be eligible if they have an undetectable HBV DNA (negative polymerase chain reaction (PCR) <20 IU). Those who are hepatitis B surface antigen (HbsAg) positive or hepatitis B PCR positive will be excluded. Subjects who are hepatitis C antibody positive will need to have a negative PCR result. Those who are hepatitis C PCR positive will be excluded. Per published guidelines (NCCN 2012) or institutional guidelines, patients should be closely monitored for hepatitis B reactivation. Obtaining repeated hepatitis B PCR every 3 months during treatment and for the 12 months after last dose of study drug according to usual clinical practice in order to monitor for reactivation of hepatitis B is recommended. History of stroke or intracranial haemorrhage within 6 months prior to enrollment. Requires treatment with strong CYP3A4/5 Inhibitors. Known history of drug-specific hypersensitivity or anaphylaxis to study drug (including active product or excipient components). Any life-threatening illness, medical condition, or organ system dysfunction which, in the Investigator's opinion, could compromise the subject's safety, interfere with the absorption or metabolism of zanubrutinib, or put the study outcomes at undue risk. Estimated Glomerular Filtration Rate (Cockcroft-Gault Appendix C) 30 mL/min/1.73m2 Absolute neutrophil count (ANC) < 1.0 X 109/L. Platelet count < 75 X 109/L, except for patients with bone marrow involvement by CLL in which case the platelet count must be 30 X 109/L. Serum aspartate aminotransferase (AST)/serum glutamic-oxaloacetic transaminase (SGOT) or alanine transaminase (ALT)/serum glutamate pyruvate transaminase (SGPT) >2.5 x upper limit of normal (ULN). Serum total bilirubin > 1.5 x ULN, except in cases of Gilberts syndrome. Prothrombin time/INR or aPTT (in the absence of Lupus anticoagulant) > 2x ULN. Active bleeding, history of bleeding diathesis (eg, haemophilia or von Willebrand disease).

Calendar

(Last Update: 14/07/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
29/07/2024	02/09/2024	22/10/2024	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

Pethema Fundacion Spain

Calle Del Professor Martin Lagos Sn

Contact Person

Dr. Juan José Lahuerta

+34916266232

gerencia@fundacionpethema.es

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Hospital Universitari Vall d Hebron

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

ceic@vhir.org

934894010

Sites

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

El Hospital Universitario De Gran Canaria Dr. Negrin

Las Palmas De Gran Canaria

LAS PALMAS

Servicio de Hematología

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

Hospital Alvaro Cunqueiro

Vigo

PONTEVEDRA

Servicio de Hematología

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

Hospital Clinic De Barcelona

Barcelona

BARCELONA

Servicio de Hematología

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

Hospital Clinico Universitario De Valencia

Valencia

VALENCIA

Servicio de Hematología

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

Hospital Costa Del Sol

Marbella

MÁLAGA

Servicio de Hematología

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

Hospital De La Santa Creu I Sant Pau

Barcelona

BARCELONA

Servicio de Hematología

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

Hospital Del Mar

Barcelona

BARCELONA

Servicio de Hematología

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

Hospital Germans Trias I Pujol

Badalona

BARCELONA

Servicio de Hematología

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

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Servicio de Hematología

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

Hospital Universitario Central De Asturias

Oviedo

ASTURIAS

Servicio de Hematología

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

Hospital Universitario De La Princesa

Madrid

MADRID

Servicio de Hematología

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

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Servicio de Hematología

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

Hospital Universitario Infanta Leonor

Madrid

MADRID

Servicio de Hematología

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

Hospital Universitario La Paz

Madrid

MADRID

Servicio de Hematología

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

Hospital Universitario Marques De Valdecilla

Santander

CANTABRIA

Servicio de Hematología

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

Hospital Universitario Regional De Malaga

Malaga

MÁLAGA

Servicio de Hematología

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

Hospital Universitario Reina Sofia

Cordoba

CÓRDOBA

Servicio de Hematología

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

Hospital Universitario Virgen De Valme

Sevilla

SEVILLA

Servicio de Hematología

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

Hospital Universitario 12 De Octubre

Madrid

MADRID

Servicio de Hematología

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

ICO L'HOSPITALET HOSPITAL DURAN I REYNALS

Barcelona

BARCELONA

Servicio de Hematología

Medication

Gazyvaro 1,000 mg concentrate for solution for infusion.

SOLUTION FOR INFUSION

INTRAVENIOUS INFUSION

ATC code: L01XC15 - OBINUTUZUMAB

Active Principles: N/A

Experimental

Zanubrutinib

CAPSULE

ORAL

-

Active Principles: N/A

Experimental

No results