

Treatment with Acalabrutinib in patients with chronic lymphocytic leukemia

Estado EC Finalizado	Tipo de Participantes Sujetos incapaces de otorgar consentimiento	Rangos de Edad Mayores de 64 , Adultos (18-64 años)
Género Ambos	Fases Fase III	Participantes esperados 629
Resultados Tiene resultados	Bajo nivel intervención No	Enfermedad rara No
Cobertura geográfica Multicéntrico internacional	Ámbitos del ensayo seguridad, eficacia, farmacocinética	Terapia avanzada NO

Información

Identificador
2023-507669-24-00 (CTIS)

Cod. Protocolo
D8220C00008

Transicionado 2019-001573-89

Área terapéutica
Enfermedades [C] - Cáncer [C04]

Enfermedad investigada
Chronic lymphocytic leukemia

Título Científico
A Phase 3b, Multicenter, Open-Label, Single-Arm Study of Acalabrutinib (ACP-196) in Subjects with Chronic Lymphocytic Leukemia

Justificación

No aportado

Objetivo Principal

To evaluate the safety and tolerability of acalabrutinib monotherapy in participants with treatment-naive or relapsed/refractory chronic lymphocytic leukemia

Variables de Evaluación Primaria

Frequency, severity and relatedness of all AEs, which will also include: - Grade 3 AEs - SAEs - AESI defined as ventricular arrhythmias - AEs that lead to discontinuation of treatment - ECIs defined as cardiac events, hepatotoxicity, hypertension, infections, interstitial lung disease/pneumonitis, hemorrhage (major hemorrhage), cytopenias (anemia, leukopenia, thrombocytopenia), second primary malignancies, and tumor lysis syndrome.

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To evaluate the investigator-assessed overall response, duration of response, and progression-free survival in participants receiving acalabrutinib monotherapy

Variables de Evaluación Secundaria

Overall response; Duration of response; Progression-free survival.

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Men and women 18 years of age (or the legal age of consent in the jurisdiction in which the study is taking place) Diagnosis of CLL that meets all published diagnostic criteria (Hallek et al. 2018): 1. Monoclonal B-cells (either kappa or lambda light chain restricted) that are clonally co-expressing 1 B-cell marker (CD19, CD20, and CD23) and CD5 during screening 2. Prolymphocytes may comprise <55% of blood lymphocytes during screening 3. Presence of 5×10^9 B lymphocytes/L (5000/L) in the peripheral blood (at any point since the initial diagnosis) Active disease per at

least 1 of the following iwCLL 2018 criteria 1. Evidence of progressive marrow failure as manifested by the development of, or worsening of, anemia (hemoglobin <10 g/dL) and/or thrombocytopenia (platelets <100,000/L). 2. Massive (i.e., 6 cm below the left costal margin), progressive, or symptomatic splenomegaly. 3. Massive nodes (i.e., 10 cm in the longest diameter), progressive, or symptomatic lymphadenopathy 4. Progressive lymphocytosis with an increase of >50% over a 2-month period or a lymphocyte doubling time (LDT) of <6 months. LDT may be obtained by linear regression extrapolation of absolute lymphocyte count obtained at intervals of 2 weeks over an observation period of 2 to 3 months. In participants with initial blood lymphocyte counts of <30x10⁹/L (30,000/L), LDT should not be used as a single parameter to define indication for treatment. In addition, factors contributing to lymphocytosis or lymphadenopathy other than CLL (e.g., infections) should be excluded. 5. Autoimmune anemia and/or thrombocytopenia that is poorly responsive to standard therapy 6. B-symptoms documented in the participant's chart with supportive objective measures, as appropriate, defined as 1 of the following disease-related symptoms or signs: o- Unintentional weight loss 10% within the previous 6 months before screening o- Significant fatigue (Eastern Cooperative Oncology Group [ECOG] performance status 2; inability to work or perform usual activities) o- Fevers higher than 100.5°F or 38.0°C for 2 weeks o- Night sweats for 1 month before screening without evidence of infection Must meet one of the following criteria: a. Have received no prior therapy for treatment of CLL and meets one of the following criteria (for this study, participants in the UK will be enrolled ONLY in the R/R or the prior ibrutinib cohort): i. A score of >6 on the Cumulative Illness Rating Scale (CIRS) ii. Creatinine clearance of 30 to 69 mL/min using the Cockcroft-Gault equation b. Have previously received therapy for CLL and have either refractory or relapsed CLL c. Have received prior ibrutinib therapy (i.e., defined as a participant who discontinued a ibrutinib for any reason prior to disease progression) for CLL (participants in the US will not be enrolled into the prior ibrutinib therapy cohort) ECOG performance status of 2 Female participants of childbearing potential (i.e., not surgically sterile or postmenopausal) who are sexually active with a non-sterilized male partner must use 1 highly effective method of contraception from the time of screening and must agree to continue using such precautions for 2 days after the last dose of study intervention. Contraception measures and restrictions on sperm donation are not required for male participants. Fluorescence in situ hybridization (FISH) for which the next-generation sequencing (NGS) method is preferred) within 60 days during screening up to before the first dose reflecting the presence or absence of del(17p), del(13q), del(11q), and trisomy of chromosome 12 along with the percentage of cells with the deletion, along with TP53 sequencing. Participants must also have molecular analysis to detect IGHV mutation status (NGS is the preferred method) at screening if not done at any time point before that since diagnosis. Each participant (or legally authorized representative if allowed per local regulations) must be willing and able to adhere to the study visit schedule, understand and comply with other protocol requirements, and provide written informed consent and authorization to use protected health information.

Criterios de Exclusión

Participants who have had disease progression while on a BTKi for any malignant or nonmalignant condition History of stroke or intracranial hemorrhage within 6 months before the first dose of study intervention. History of bleeding diathesis (e.g., hemophilia or von Willebrand disease). Presence of a gastrointestinal ulcer diagnosed by endoscopy within 3 months before screening. Major surgical procedure within 4 weeks before first dose of study intervention. Note: Participants who have had major surgery must have recovered adequately from any toxicity and/or complications from the intervention before the first dose of study intervention. Requires treatment with proton-pump inhibitors (e.g., omeprazole, esomeprazole, lansoprazole, dexlansoprazole, rabeprazole, or pantoprazole). Participants receiving proton-pump inhibitors who switch to H2-receptor antagonists or antacids are eligible for enrollment in this study. All participants requiring or receiving anticoagulation with warfarin or equivalent vitamin K antagonists (e.g., phenprocoumon) within 7 days before first dose of study intervention. Based on the known metabolic/transport pathways involved in the disposition of acalabrutinib and the commonly known novel oral anticoagulants (eg, apixaban, rivaroxaban, and edoxaban), no clinically relevant interaction is expected following coadministration of these agents. Absolute neutrophil count (ANC) <0.50 x 10⁹/L or platelet count <30 x 10⁹/L, unless proven due to CLL and raised above the limits by granulocyte colony-stimulating factor (G-CSF) therapy and/or pooled platelet transfusion. Total bilirubin >3.0x upper limit of normal (ULN); or aspartate aminotransferase or alanine aminotransferase >3.0x ULN. Exception will be for Gilbert syndrome; if an investigator feels that a participant's total bilirubin is elevated secondary to Gilbert's, the participant must have a documented unconjugated bilirubin being >80% of the total bilirubin number. The investigator must also document that hemolysis has been ruled out along with (near)-normal lactate dehydrogenase and haptoglobin. Estimated creatinine clearance of <30

mL/min, calculated using the formula of Cockcroft and Gault or by direct assessment (i.e., creatinine clearance or ethylene diamine tetra-acetic acid (EDTA) clearance measurement). Breastfeeding or pregnant. Prior malignancy (other than CLL), except for adequately treated basal cell or squamous cell skin cancer, in situ cancer, early stage prostate cancer, or other cancer from which the participant has been disease-free for 2 years Received any chemotherapy, external beam radiation, investigational drug, or any other anti-CLL therapy within 30 days before first dose of study intervention. Concurrent participation in another therapeutic clinical study History of or ongoing interstitial lung disease Requiring long-term (> 1 week) treatment with a strong cytochrome CYP3A inhibitor/inducer. In addition, the use of strong or moderate CYP3A inhibitors or inducers within 7 days of the first dose of study intervention is prohibited. History of confirmed progressive multifocal leukoencephalopathy Significant cardiovascular disease such as symptomatic arrhythmias, congestive heart failure, or myocardial infarction within 6 months before screening, or any Class 3 or 4 cardiac disease as defined by the New York Heart Association Functional Classification, or corrected QT interval using Fridericia's formula (QTcF) >480 msec at screening. Note: Participants with rate-controlled, asymptomatic atrial fibrillation are allowed to enroll in the study (For prior ibrutinib therapy cohort only, except in Finland and the Republic of South Korea, where this is applicable to all 3 cohorts; also, the prior ibrutinib therapy cohort will not be enrolled in the US). Malabsorption syndrome, disease significantly affecting gastrointestinal (GI) function, resection of the stomach, extensive small bowel resection that is likely to affect absorption, symptomatic inflammatory bowel disease, partial or complete bowel obstruction, or gastric restrictions and bariatric surgery, such as gastric bypass. Evidence of active Richter's transformation. If Richter's transformation is suspected (i.e., lactate dehydrogenase [LDH] increased, asymmetric fast lymph node growth or clinical suspicion), it should be ruled out with positron emission tomography/computed tomography (PET-CT) and/or biopsy according to guidelines. Central nervous system (CNS) involvement by CLL Known history of human immunodeficiency virus, serologic status reflecting active hepatitis B virus or hepatitis C virus infection, any uncontrolled active systemic infection along with participants who are on ongoing anti-infective treatment and participants who have received vaccination with a live attenuated vaccine within 4 weeks before the first dose of study intervention. 1. Participants who are hepatitis B core antibody (anti-HBc) positive and who are hepatitis B surface antibody (anti-HBs) negative will need to have a negative hepatitis B virus PCR result before enrollment. Those who are hepatitis B surface antigen (HBsAg) positive or hepatitis B virus PCR positive will be excluded. 2. Participants who are hepatitis C virus antibody positive will need to have a negative hepatitis C virus PCR result before enrollment. Those who are hepatitis C virus PCR positive will be excluded. Uncontrolled autoimmune hemolytic anemia or idiopathic thrombocytopenic purpura defined as declining hemoglobin or platelet count secondary to autoimmune destruction within the screening period or requirement for high doses of steroids (>20 mg daily of prednisone or equivalent for longer than 2 weeks).

Calendario

(Última actualización: 11/11/2025)

Autorización 09/09/2019	Inicio de Ensayo 05/11/2019	Inclusión Primer Paciente 03/12/2019	Interrumpido No aportado	Reiniciado No aportado
Fin de reclutamiento 14/04/2021	Fin prematuro (España) No aportado	Fin prematuro (Global) No aportado	Fin del ensayo en España 31/05/2025	Fin del ensayo global 05/11/2025

Promotor

Astrazeneca AB Sweden

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Monetary support: N/A

Tipo de promotor: Comercial

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Centros

Activo (09/10/2019)	COMPLEXO HOSPITALARIO UNIVERSITARIO DE OURENSE Ourense OURENSE Hematología
Activo (20/11/2019)	HOSPITAL CLÍNIC DE BARCELONA Barcelona BARCELONA Hematology
Cerrado (16/09/2021)	HOSPITAL CLÍNICO UNIVERSITARIO DE VALENCIA Valencia VALENCIA
Activo (02/12/2019)	HOSPITAL CLÍNICO UNIVERSITARIO LOZANO BLESÀ Zaragoza ZARAGOZA Hematología
Activo (25/11/2019)	HOSPITAL COSTA DEL SOL Marbella MÁLAGA Hematology
Activo (21/02/2020)	HOSPITAL UNIVERSITARIO ARABA (SEDE TXAGORRITXU) Vitoria-Gasteiz ALAVA Hematology
Activo (20/01/2020)	HOSPITAL UNIVERSITARIO CENTRAL DE ASTURIAS Oviedo ASTURIAS Hematology
Cerrado (25/09/2024)	HOSPITAL UNIVERSITARIO DE LA PRINCESA Madrid MADRID Hematology

Activo (19/12/2019)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

Hematology

Medicamentos

Calquence 100 mg hard capsules

CAPSULE, HARD

ORAL USE

Código ATC: L01EL02 - ACALABRUTINIB

Principios Activos: N/A

Experimental

Tiene resultados

Treatment with Acalabrutinib in patients with chronic lymphocytic leukemia

State

Finished CT

Type of participants

Incapable subjects of giving consent

Age Ranges

Older than 64 , Adults (18-64 years)

Gender

Both

Phases

Phase III

Expected Participants

629

Results

Has results

Low level of intervention

No

Rare disease

No

Geographic coverage

International multicenter

Areas of the study

safety, effectiveness, pharmacokinetics

Advanced therapy

NO

Information

Identifier

2023-507669-24-00 (CTIS)

Protocol Code

D8220C00008

Transitioned 2019-001573-89

Therapeutic area

Diseases [C] - Cancer [C04]

Investigated Disease

Chronic lymphocytic leukemia

Scientific Title

A Phase 3b, Multicenter, Open-Label, Single-Arm Study of Acalabrutinib (ACP-196) in Subjects with Chronic Lymphocytic Leukemia

Rationale

Not provided

Main Objective

To evaluate the safety and tolerability of acalabrutinib monotherapy in participants with treatment-naïve or relapsed/refractory chronic lymphocytic leukemia

Primary Endpoints

Frequency, severity and relatedness of all AEs, which will also include: - Grade 3 AEs - SAEs - AESI defined as ventricular arrhythmias - AEs that lead to discontinuation of treatment - ECIs defined as cardiac events, hepatotoxicity, hypertension, infections, interstitial lung disease/pneumonitis, hemorrhage (major hemorrhage), cytopenias (anemia, leukopenia, thrombocytopenia), second primary malignancies, and tumor lysis syndrome.

Temporary moments of secondary assessment

Not provided

Secondary Objective

To evaluate the investigator-assessed overall response, duration of response, and progression-free survival in participants receiving acalabrutinib monotherapy

Secondary Endpoints

Overall response; Duration of response; Progression-free survival.

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Men and women 18 years of age (or the legal age of consent in the jurisdiction in which the study is taking place) Diagnosis of CLL that meets all published diagnostic criteria (Hallek et al. 2018): 1. Monoclonal B-cells (either kappa or lambda light chain restricted) that are clonally co-expressing 1 B-cell marker (CD19, CD20, and CD23) and CD5 during screening 2. Prolymphocytes may comprise <55% of blood lymphocytes during screening 3. Presence of 5×10^9 B lymphocytes/L (5000/L) in the peripheral blood (at any point since the initial diagnosis) Active disease per at

least 1 of the following iwCLL 2018 criteria 1. Evidence of progressive marrow failure as manifested by the development of, or worsening of, anemia (hemoglobin <10 g/dL) and/or thrombocytopenia (platelets $<100,000/L$). 2. Massive (i.e., 6 cm below the left costal margin), progressive, or symptomatic splenomegaly. 3. Massive nodes (i.e., 10 cm in the longest diameter), progressive, or symptomatic lymphadenopathy 4. Progressive lymphocytosis with an increase of $>50\%$ over a 2-month period or a lymphocyte doubling time (LDT) of <6 months. LDT may be obtained by linear regression extrapolation of absolute lymphocyte count obtained at intervals of 2 weeks over an observation period of 2 to 3 months. In participants with initial blood lymphocyte counts of $<30 \times 10^9/L$ ($30,000/L$), LDT should not be used as a single parameter to define indication for treatment. In addition, factors contributing to lymphocytosis or lymphadenopathy other than CLL (e.g., infections) should be excluded. 5. Autoimmune anemia and/or thrombocytopenia that is poorly responsive to standard therapy 6. B-symptoms documented in the participant's chart with supportive objective measures, as appropriate, defined as 1 of the following disease-related symptoms or signs: o- Unintentional weight loss 10% within the previous 6 months before screening o- Significant fatigue (Eastern Cooperative Oncology Group [ECOG] performance status 2; inability to work or perform usual activities) o- Fevers higher than $100.5^\circ F$ or $38.0^\circ C$ for 2 weeks o- Night sweats for 1 month before screening without evidence of infection Must meet one of the following criteria: a. Have received no prior therapy for treatment of CLL and meets one of the following criteria (for this study, participants in the UK will be enrolled ONLY in the R/R or the prior ibrutinib cohort): i. A score of >6 on the Cumulative Illness Rating Scale (CIRS) ii. Creatinine clearance of 30 to 69 mL/min using the Cockcroft-Gault equation b. Have previously received therapy for CLL and have either refractory or relapsed CLL c. Have received prior ibrutinib therapy (i.e., defined as a participant who discontinued a ibrutinib for any reason prior to disease progression) for CLL (participants in the US will not be enrolled into the prior ibrutinib therapy cohort) ECOG performance status of 2 Female participants of childbearing potential (i.e., not surgically sterile or postmenopausal) who are sexually active with a non-sterilized male partner must use 1 highly effective method of contraception from the time of screening and must agree to continue using such precautions for 2 days after the last dose of study intervention. Contraception measures and restrictions on sperm donation are not required for male participants. Fluorescence in situ hybridization (FISH) for which the next-generation sequencing (NGS) method is preferred) within 60 days during screening up to before the first dose reflecting the presence or absence of del(17p), del(13q), del(11q), and trisomy of chromosome 12 along with the percentage of cells with the deletion, along with TP53 sequencing. Participants must also have molecular analysis to detect IGHV mutation status (NGS is the preferred method) at screening if not done at any time point before that since diagnosis. Each participant (or legally authorized representative if allowed per local regulations) must be willing and able to adhere to the study visit schedule, understand and comply with other protocol requirements, and provide written informed consent and authorization to use protected health information.

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mL/min, calculated using the formula of Cockcroft and Gault or by direct assessment (i.e., creatinine clearance or ethylene diamine tetra-acetic acid (EDTA) clearance measurement). Breastfeeding or pregnant. Prior malignancy (other than CLL), except for adequately treated basal cell or squamous cell skin cancer, in situ cancer, early stage prostate cancer, or other cancer from which the participant has been disease-free for 2 years Received any chemotherapy, external beam radiation, investigational drug, or any other anti-CLL therapy within 30 days before first dose of study intervention. Concurrent participation in another therapeutic clinical study History of or ongoing interstitial lung disease Requiring long-term (> 1 week) treatment with a strong cytochrome CYP3A inhibitor/inducer. In addition, the use of strong or moderate CYP3A inhibitors or inducers within 7 days of the first dose of study intervention is prohibited. History of confirmed progressive multifocal leukoencephalopathy Significant cardiovascular disease such as symptomatic arrhythmias, congestive heart failure, or myocardial infarction within 6 months before screening, or any Class 3 or 4 cardiac disease as defined by the New York Heart Association Functional Classification, or corrected QT interval using Fridericia's formula (QTcF) >480 msec at screening. Note: Participants with rate-controlled, asymptomatic atrial fibrillation are allowed to enroll in the study (For prior ibrutinib therapy cohort only, except in Finland and the Republic of South Korea, where this is applicable to all 3 cohorts; also, the prior ibrutinib therapy cohort will not be enrolled in the US). Malabsorption syndrome, disease significantly affecting gastrointestinal (GI) function, resection of the stomach, extensive small bowel resection that is likely to affect absorption, symptomatic inflammatory bowel disease, partial or complete bowel obstruction, or gastric restrictions and bariatric surgery, such as gastric bypass. Evidence of active Richter's transformation. If Richter's transformation is suspected (i.e., lactate dehydrogenase [LDH] increased, asymmetric fast lymph node growth or clinical suspicion), it should be ruled out with positron emission tomography/computed tomography (PET-CT) and/or biopsy according to guidelines. Central nervous system (CNS) involvement by CLL Known history of human immunodeficiency virus, serologic status reflecting active hepatitis B virus or hepatitis C virus infection, any uncontrolled active systemic infection along with participants who are on ongoing anti-infective treatment and participants who have received vaccination with a live attenuated vaccine within 4 weeks before the first dose of study intervention. 1. Participants who are hepatitis B core antibody (anti-HBc) positive and who are hepatitis B surface antibody (anti-HBs) negative will need to have a negative hepatitis B virus PCR result before enrollment. Those who are hepatitis B surface antigen (HBsAg) positive or hepatitis B virus PCR positive will be excluded. 2. Participants who are hepatitis C virus antibody positive will need to have a negative hepatitis C virus PCR result before enrollment. Those who are hepatitis C virus PCR positive will be excluded. Uncontrolled autoimmune hemolytic anemia or idiopathic thrombocytopenic purpura defined as declining hemoglobin or platelet count secondary to autoimmune destruction within the screening period or requirement for high doses of steroids (>20 mg daily of prednisone or equivalent for longer than 2 weeks).

Calendar

(Last Update: 11/11/2025)

Authorization 09/09/2019	Start of Trial 05/11/2019	First patient inclusion 03/12/2019	Halted Not aported	Restarted Not aported
End of recruitment 14/04/2021	Premature end (Spain) Not aported	Premature End (Global) Not aported	Trial end (Spain) 31/05/2025	Trial end (Global) 05/11/2025

Sponsor

Astrazeneca AB Sweden

Astraallen GartunaKarlebyhus Byggnad 674

Contact Person

AstraZeneca Clinical Study Information Center

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information.center@astrazeneca.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

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Sites

Active (09/10/2019)	COMPLEXO HOSPITALARIO UNIVERSITARIO DE OURENSE Ourense OURENSE Hematología
Active (20/11/2019)	HOSPITAL CLÍNIC DE BARCELONA Barcelona BARCELONA Hematology
Closed (16/09/2021)	HOSPITAL CLÍNICO UNIVERSITARIO DE VALENCIA Valencia VALENCIA
Active (02/12/2019)	HOSPITAL CLÍNICO UNIVERSITARIO LOZANO Blesa Zaragoza ZARAGOZA Hematología
Active (25/11/2019)	HOSPITAL COSTA DEL SOL Marbella MÁLAGA Hematology
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Closed (25/09/2024)	HOSPITAL UNIVERSITARIO DE LA PRINCESA Madrid MADRID Hematology

Active (19/12/2019)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

Hematology

Medication

Calquence 100 mg hard capsules

CAPSULE, HARD

ORAL USE

ATC code: L01EL02 - ACALABRUTINIB

Active Principles: N/A

Experimental

Has results