A trial to learn if AZD0486 alone or with other anticancer drugs is safe and works in adults with certain blood cancers

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	246
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia, farmacocinética, dosis	NO

Información

Identificador
2024-515034-33-00 (CTIS)

Cod. Protocolo
D7407C00001

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

Enfermedad investigada
Chronic Lymphocytic Leukaemia
Large B-Cell Lymphoma
Mantle Cell Lymphoma
Small Lymphocytic Lymphoma

Título Científico
A Phase I/II Open-Label Multi-Centre Master Protocol to Evaluate the Safety and Efficacy of AZD0486 Monotherapy

or in Combination with Other Anticancer Agents in Participants with Mature B-Cell Malignancies
Substudy 1: Chronic Lymphocytic Leukaemia and Small Lymphocytic Lymphoma
Substudy 2: Mantle Cell Lymphoma
Substudy 3: Large B-Cell Lymphoma

Justificación

No aportado

Objetivo Principal

To assess safety and tolerability and determine the RP2D (recommended Phase II dose) of surovatamig (administered as IV or SC) as monotherapy and in combination with other anticancer agents across mature B-cell malignancies

Variables de Evaluación Primaria

Incidence, nature and severity of AEs/SAEs based on NCI CTCAE v5.0/ASTCT criteria; changes in laboratory data, and vital signs compared with baseline
Incidence of Dose Limiting Toxicity (DLTs)
Incidence and severity of AESIs
Incidence and nature of study drug discontinuation, dose reduction and dose delay due to AEs

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

No aportado

Variables de Evaluación Secundaria

No aportado

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

All sub- studies: Age 18 years Sub- study 2, Cohort 2A and Cohort 2C: Relapsed or Progressed after 2 or more prior systemic therapy for MCL including BTKi Sub-study 3A: Previously untreated LBCL by WHO 2022 classification of lymphoid neoplasms OR Relapsed or refractory B-cell NHL after at least 1 prior lines of systemic therapy, Histologically confirmed according to WHO 2022 classification (excluding some B-NHL subtypes) Sub-study 3: LVEF >50% Sub-study 3A: IPI 2-5 for participants with untreated LBCL diagnoses Sub-study 3: At least 1 measurable site as per Lugano Sub-study 1B: Contraception during treatment and until at least x days after the last dose of Surovatamig and until 2 days after the last dose of acalabrutinib, whichever is longer. All sub- studies: ECOG performance status 0 to 2 Sub-study 3: Contraception until x days after the last dose of surovatamig, 4 months after the last dose of vincristine, and 6 months after the last dose of cyclophosphamide or doxorubicin, (or as required by local prescribing information) whichever is longer. All sub-studies: Contraception during treatment and at least x days after final dose All sub- studies: Confirmed CD19 expression if prior anti-CD19 therapy Sub-study 1, Cohort 1A and Cohort 1C: at least 2 prior lines of systemic therapy for CLL/SLL including treatment with a BTKi and BCL2i Sub-study 1: CLL/SLL diagnosis and meets iwCLL criteria for treatment Sub-study 1: SLL: at least 1 measurable site per Lugano Sub-study 1: Absolute lymphocytes <25,000 cells/mcl Sub study 3B: Histologically confirmed diagnosis of previously untreated LBCL by WHO 2022 classification of lymphoid neoplasms Sub study 3B: For all participants: IPI score of 2 to 5. Sub-study 3: Participant must be no older than 79 years of age at the time of signing ICF Sub-study 1, Cohort 1B: at least 1 prior line of therapy and BTKi sensitive Sub-study 2: MCL diagnosis per WHO Sub-study 3: Absolute lymphocytes count of < 5 × 109 cells/L Sub-study 3: Haemoglobin 9 g/dL Sub-study 2: Clinical Stage II, III, or IV per Ann Arbor classification Sub-study 2: At least 1 measurable site per Lugano Sub-study 2: ALC < 25,000 cells/mcL

Criterios de Exclusión

All sub- studies: CNS lymphoma Sub-study 3: Cumulative dose of anthracycline > 150 mg/m2 All sub- studies: Major Surgical procedure within 14 days before the first dose of study drug All sub- studies: Clinically significant CV disease All sub- studies: Unresolved non-haematological Grade 2 AEs (NCI CTCAE V5.0) from prior anticancer therapy (except alopecia or fatigue) All sub-studies: Any anticancer systemic therapy within 5 half-lives or 21 days (whichever is shorter) prior to Cycle 1 Day 1 Prior allogenic HSCT or solid organ transplantation within 24 weeks of starting Cycle 1 Day 1 All sub-studies: Radiation therapy within 28 days of Cycle 1 Day 1 All sub-studies: Prior CAR-T therapy or auto-HSCT within 12 weeks or prior TCE within 8 weeks of Cycle 1 Day 1 All sub-studies: Prior Grade 3 CRS or ICANS event Sub-study 1: CLL transformation to more aggressive lymphoma All sub-studies: Active, significant, or uncontrolled infection or autoimmune disease requiring systemic therapy which places participant at unacceptable risk if he/she were to participate in the study Sub-study 1, Cohort 1B: bleeding diathesis, treatment with strong CYP3A inhibitor or inducer, history of ICH or stroke within 24 weeks, GI malabsorption, receiving vitamin K antagonist Sub-study 2 Exclusion Criteria Refer to Section 5.2 of the Master Protocol. Sub-study 3: Mediastinal grey-zone lymphoma, Burkitt, Richters transformation, primary effusion LBCL

Calendario

(Última actualización: 05/06/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
07/01/2025	05/03/2025	01/04/2025	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

AstraZeneca AB Sweden

-

Contact Person

AstraZeneca Clinical Study Information Center

+18772409479

Information.center@astrazeneca.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Parc Tauli

Plaça de la Torre de lAigua, s/n 08208 Sabadell

ceic@tauli.cat

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Centros

Activo (04/06/2025)

Complexo Hospitalario Universitario De Santiago

Santiago De Compostela

CORUÑA

7003: Hematología

Activo (24/02/2025)

Hospital Clinic De Barcelona

Barcelona

BARCELONA

7004: Hematología

Activo (10/03/2025)

Hospital Universitario Fundacion Jimenez Diaz

Madrid

MADRID

7001: Hematología y Hemoterapia

Activo (07/02/2025)

Hospital Universitario Ramon Y Cajal

Madrid

MADRID

7006: Hematología

Activo (26/02/2025)

Hospital Universitario Y Politecnico La Fe

Valencia

VALENCIA

7005: Hematología

Activo (06/02/2025)

University Hospital Son Espases

Palma

BALEARES

7002: Hematologia

Medicamentos

-
-
ORAL USE

Código ATC: H02AB07 - PREDNISONA
Principios Activos: N/A

Experimental

AZD0486
SOLUTION FOR INJECTION
SUBCUTANEOUS

-
Principios Activos: N/A

Experimental

Calquence 100 mg film-coated tablets
FILM-COATED TABLET
ORAL USE

Código ATC: L01EL02 - ACALABRUTINIB
Principios Activos: N/A

Experimental

AZD0486
SOLUTION FOR INFUSION
INTRAVENOUS

-
Principios Activos: N/A

Experimental

AZD0486
SOLUTION FOR INJECTION
SUBCUTANEOUS

-
Principios Activos: N/A

Experimental

AZD0486
SOLUTION FOR INFUSION
INTRAVENOUS

-
Principios Activos: N/A

Experimental

-
-
ORAL USE

Código ATC: H02AB06 - PREDNISOLONA
Principios Activos: N/A

Experimental

-
-
INTRAVENOUS

Código ATC: L01XC02 - RITUXIMAB
Principios Activos: N/A

Experimental

-
-
INTRAVENOUS

Código ATC: L01CA02 - VINCRISTINA
Principios Activos: N/A

Experimental

-
-
INTRAVENOUS

Código ATC: L01AA01 - CICLOFOSFAMIDA
Principios Activos: N/A

Experimental

-
-
INTRAVENOUS

Código ATC: L01DB01 - DOXORUBICINA
Principios Activos: N/A

Experimental

Calquence 100 mg film-coated tablets
FILM-COATED TABLET
ORAL USE

Código ATC: L01EL02 - ACALABRUTINIB
Principios Activos: N/A

Experimental

-
-
INTRAVENOUS

Código ATC: L01FA01 - RITUXIMAB
Principios Activos: N/A

Experimental

Sin resultados

A trial to learn if AZD0486 alone or with other anticancer drugs is safe and works in adults with certain blood cancers

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	246
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness, pharmacokinetics, dose	NO

Information

Identifier
2024-515034-33-00 (CTIS)

Protocol Code
D7407C00001

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

Investigated Disease
Chronic Lymphocytic Leukaemia
Large B-Cell Lymphoma
Mantle Cell Lymphoma
Small Lymphocytic Lymphoma

Scientific Title
A Phase I/II Open-Label Multi-Centre Master Protocol to Evaluate the Safety and Efficacy of AZD0486 Monotherapy

or in Combination with Other Anticancer Agents in Participants with Mature B-Cell Malignancies
Substudy 1: Chronic Lymphocytic Leukaemia and Small Lymphocytic Lymphoma
Substudy 2: Mantle Cell Lymphoma
Substudy 3: Large B-Cell Lymphoma

Rationale

Not provided

Main Objective

To assess safety and tolerability and determine the RP2D (recommended Phase II dose) of surovatamig (administered as IV or SC) as monotherapy and in combination with other anticancer agents across mature B-cell malignancies

Primary Endpoints

Incidence, nature and severity of AEs/SAEs based on NCI CTCAE v5.0/ASTCT criteria; changes in laboratory data, and vital signs compared with baseline
Incidence of Dose Limiting Toxicity (DLTs)
Incidence and severity of AESIs
Incidence and nature of study drug discontinuation, dose reduction and dose delay due to AEs

Temporary moments of secondary assessment

Not provided

Secondary Objective

Not provided

Secondary Endpoints

Not provided

Temporary moments of secondary assessment

Not provided

Inclusion criteria

All sub- studies: Age 18 years Sub- study 2, Cohort 2A and Cohort 2C: Relapsed or Progressed after 2 or more prior systemic therapy for MCL including BTKi Sub-study 3A: Previously untreated LBCL by WHO 2022 classification of lymphoid neoplasms OR Relapsed or refractory B-cell NHL after at least 1 prior lines of systemic therapy, Histologically confirmed according to WHO 2022 classification (excluding some B-NHL subtypes) Sub-study 3: LVEF >50% Sub-study 3A: IPI 2-5 for participants with untreated LBCL diagnoses Sub-study 3: At least 1 measurable site as per Lugano Sub-study 1B: Contraception during treatment and until at least x days after the last dose of Surovatamig and until 2 days after the last dose of acalabrutinib, whichever is longer. All sub- studies: ECOG performance status 0 to 2 Sub-study 3: Contraception until x days after the last dose of surovatamig, 4 months after the last dose of vincristine, and 6 months after the last dose of cyclophosphamide or doxorubicin, (or as required by local prescribing information) whichever is longer. All sub-studies: Contraception during treatment and at least x days after final dose All sub- studies: Confirmed CD19 expression if prior anti-CD19 therapy Sub-study 1, Cohort 1A and Cohort 1C: at least 2 prior lines of systemic therapy for CLL/SLL including treatment with a BTKi and BCL2i Sub-study 1: CLL/SLL diagnosis and meets iwCLL criteria for treatment Sub-study 1: SLL: at least 1 measurable site per Lugano Sub-study 1: Absolute lymphocytes <25,000 cells/mcl Sub study 3B: Histologically confirmed diagnosis of previously untreated LBCL by WHO 2022 classification of lymphoid neoplasms Sub study 3B: For all participants: IPI score of 2 to 5. Sub-study 3: Participant must be no older than 79 years of age at the time of signing ICF Sub-study 1, Cohort 1B: at least 1 prior line of therapy and BTKi sensitive Sub-study 2: MCL diagnosis per WHO Sub-study 3: Absolute lymphocytes count of < 5 × 109 cells/L Sub-study 3: Haemoglobin 9 g/dL Sub-study 2: Clinical Stage II, III, or IV per Ann Arbor classification Sub-study 2: At least 1 measurable site per Lugano Sub-study 2: ALC < 25,000 cells/mcL

Exclusion criteria

All sub- studies: CNS lymphoma Sub-study 3: Cumulative dose of anthracycline > 150 mg/m2 All sub- studies: Major Surgical procedure within 14 days before the first dose of study drug All sub- studies: Clinically significant CV disease All sub- studies: Unresolved non-haematological Grade 2 AEs (NCI CTCAE V5.0) from prior anticancer therapy (except alopecia or fatigue) All sub-studies: Any anticancer systemic therapy within 5 half-lives or 21 days (whichever is shorter) prior to Cycle 1 Day 1 Prior allogenic HSCT or solid organ transplantation within 24 weeks of starting Cycle 1 Day 1 All sub-studies: Radiation therapy within 28 days of Cycle 1 Day 1 All sub-studies: Prior CAR-T therapy or auto-HSCT within 12 weeks or prior TCE within 8 weeks of Cycle 1 Day 1 All sub-studies: Prior Grade 3 CRS or ICANS event Sub-study 1: CLL transformation to more aggressive lymphoma All sub-studies: Active, significant, or uncontrolled infection or autoimmune disease requiring systemic therapy which places participant at unacceptable risk if he/she were to participate in the study Sub-study 1, Cohort 1B: bleeding diathesis, treatment with strong CYP3A inhibitor or inducer, history of ICH or stroke within 24 weeks, GI malabsorption, receiving vitamin K antagonist Sub-study 2 Exclusion Criteria Refer to Section 5.2 of the Master Protocol. Sub-study 3: Mediastinal grey-zone lymphoma, Burkitt, Richters transformation, primary effusion LBCL

Calendar

(Last Update: 05/06/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
07/01/2025	05/03/2025	01/04/2025	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

AstraZeneca AB Sweden

-

Contact Person

AstraZeneca Clinical Study Information Center

+18772409479

Information.center@astrazeneca.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Parc Tauli

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Sites

Active (04/06/2025)

Complexo Hospitalario Universitario De Santiago

Santiago De Compostela

CORUÑA

7003: Hematología

Active (24/02/2025)

Hospital Clinic De Barcelona

Barcelona

BARCELONA

7004: Hematología

Active (10/03/2025)

Hospital Universitario Fundacion Jimenez Diaz

Madrid

MADRID

7001: Hematología y Hemoterapia

Active (07/02/2025)

Hospital Universitario Ramon Y Cajal

Madrid

MADRID

7006: Hematología

Active (26/02/2025)

Hospital Universitario Y Politecnico La Fe

Valencia

VALENCIA

7005: Hematología

Active (06/02/2025)

University Hospital Son Espases

Palma

BALEARES

7002: Hematologia

Medication

-
-
ORAL USE

ATC code: H02AB07 - PREDNISONA
Active Principles: N/A

Experimental

AZD0486
SOLUTION FOR INJECTION
SUBCUTANEOUS

-
Active Principles: N/A

Experimental

Calquence 100 mg film-coated tablets
FILM-COATED TABLET
ORAL USE

ATC code: L01EL02 - ACALABRUTINIB
Active Principles: N/A

Experimental

AZD0486
SOLUTION FOR INFUSION
INTRAVENOUS

-
Active Principles: N/A

Experimental

AZD0486
SOLUTION FOR INJECTION
SUBCUTANEOUS

-
Active Principles: N/A

Experimental

AZD0486
SOLUTION FOR INFUSION
INTRAVENOUS

-
Active Principles: N/A

Experimental

-
-
ORAL USE

ATC code: H02AB06 - PREDNISOLONA
Active Principles: N/A

Experimental

-
-
INTRAVENOUS

ATC code: L01XC02 - RITUXIMAB
Active Principles: N/A

Experimental

-
-
INTRAVENOUS

ATC code: L01CA02 - VINCRISTINA
Active Principles: N/A

Experimental

-
-
INTRAVENOUS

ATC code: L01AA01 - CICLOFOSFAMIDA
Active Principles: N/A

Experimental

-
-
INTRAVENOUS

ATC code: L01DB01 - DOXORUBICINA
Active Principles: N/A

Experimental

Calquence 100 mg film-coated tablets
FILM-COATED TABLET
ORAL USE

ATC code: L01EL02 - ACALABRUTINIB
Active Principles: N/A

Experimental

-
-
INTRAVENOUS

ATC code: L01FA01 - RITUXIMAB
Active Principles: N/A

Experimental

No results