Safety and Preliminary Efficacy Assessment of AZD7789 in Patients With Relapsed or Refractory Classical Hodgkin Lymphoma

Estado	Tipo de Participantes	Rangos de Edad
EC Finalizado	Sujetos incapaces de otorgar consentimiento	Menores de 18 , Mayores de 64 , Adultos (18-64 años) , Adolescentes (12-17 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase I , Fase II	190
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Tiene resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Multicéntrico internacional	seguridad, eficacia, farmacocinética, farmacodinamica, dosis	NO

Información

Identificador

2022-502773-41-00 (CTIS)

Cod. Protocolo

D9571C00001

Transicionado 2021-003569-36

Área terapéutica

Enfermedades [C] - Hematología [C15]|

Enfermedad investigada

Relapsed/Refractory Classical Hodgkin Lymphoma

Título Científico

A Phase I/II Open-label, Multi-center Study to Assess Safety, Tolerability, Pharmacokinetics and Preliminary Efficacy

of AZD7789, an anti-PD-1 and anti-TIM-3 Bispecific Antibody, in Patients with Relapsed or Refractory Classical Hodgkin Lymphoma

Justificación

No aportado

Objetivo Principal

Part A Dose Escalation: To assess the safety and tolerability of sabestomig in participants with r/r cHL. To establish the maximum tolerated dose, or optimal biological dose, and recommended Phase 2 dose.
Part B Dose Expansion (all): To assess the safety and tolerability of sabestomig in participants with r/r cHL.
Part B Dose Expansion (B1): To assess the preliminary antitumor activity of sabestomig in participants with r/r cHL (anti-PD-1/PD-L1 exposed).
Part B Dose Expansion (B2): To assess the preliminary antitumor activity of sabestomig in patients with r/r cHL (anti PD-1/PD-L1 naïve).

Variables de Evaluación Primaria

Part A Dose Escalation: Incidence of AEs, imAEs, and SAEs Incidence of AEs leading to discontinuation of sabestomig Changes from baseline and clinically significant alterations in vital signs, laboratory parameters, and ECG results Incidence of dose-limiting toxicities
Part B Dose Expansion (all): Incidence of AEs, imAEs, and SAEs Incidence of AEs leading to discontinuation of sabestomig Changes from baseline and clinically significant alterations in vital signs, laboratory parameters, and ECG results
Part B Dose Expansion (B1): Objective Response Rate (defined as the proportion of patients with complete remission or partial remission)
Part B Dose Expansion (B2): Complete Response Rate (defined as the proportion of patients with complete remission)

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

Part A Dose Escalation: To assess the preliminary antitumor activity of sabestomig in participants with r/r cHL
Part B Dose Expansion: To further assess the preliminary antitumor activity of sabestomig in participants with r/r cHL To evaluate Patient Reported treatment-related symptoms, overall side-effect impact and overall global health status while on sabestomig.
Part A Dose Escalation and Part B Dose Expansion: To assess the PK of sabestomig in participants with r/r cHL To assess the immunogenicity of sabestomig in participants with r/r cHL

Variables de Evaluación Secundaria

Part A Dose Escalation: Complete Response Rate, Objective Response Rate, DoR, and DoCR and PFS including landmarks at 12 and 24 months OS including landmarks at 12 and 24 months
Part B Dose Expansion: DoR, DoCR and PFS including landmarks at 12 and 24 months OS including landmarks at 12 and 24 months Proportion of dosed subjects over time with: diarrhea, rash, and fatigue (PRO-CTCAE or Peds-PROCTCAE) overall side-effect bother (PGI-TT) quality of life/health (EORTC ILXX QL2)
Part A Dose Escalation and Part B Dose Expansion: PK parameters including the maximum observed concentration, area under the concentration-time curve, clearance and terminal elimination half life Incidence of anti-drug antibodies against sabestomig in serum

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

1. Must be 16 years of age at the time of obtaining informed consent
2. Eastern Cooperative Oncology Group performance status of 0 or 1 at screening
3. Must have at least one PET-avid measurable lesion according to Modified Lugano Criteria after the last line of therapy.
4. Confirmed histological diagnosis of active relapse/refractory cHL
5. Must have failed at least 2 prior lines of systemic therapy. In part A dose escalation the prior lines of therapy must include at least 3 cycles of anti-PD- 1/PD-L1 and in part B dose expansion at least 2 cycles of an anti-PD-1/PD-L1. In part B dose expansion cohort B2, prior antiPD-1/PD-L1 therapy is excluded. For all participants, no previous treatment with anti- TIM-3 is allowed. Previous anti-CTLA-4 treatment is acceptable with at least 2 months washout period prior to study entry.
6. Adequate organ and bone marrow function
7. Non-pregnant women and willingness of female participants to avoid pregnancy or male participants willing to avoid fathering children through highly effective methods of contraception
8. Minimum body weight 40 kg for all participants.

Criterios de Exclusión

1. Unresolved toxicities of Grade 2 from prior therapy, unless immune-mediated. 10. Past medical history of interstitial lung disease (ILD), drug-induced ILD, radiation pneumonitis requiring steroid treatment, or any evidence of clinically active ILD or active pneumonitis. 11. Other invasive malignancy within 2 years prior to screening 12. Congenital long QT syndrome or history of QT prolongation associated with other medications that cannot be changed or discontinued based on a cardiologist assessment 13. Current or prior use of immunosuppressive medication within 14 days prior to the first dose of study intervention 14. Any concurrent chemotherapy, radiotherapy, investigational, biologic, or hormonal therapy for cancer treatment. Concurrent use of hormonal therapy for noncancer-related conditions is acceptable 2. Any prior Grade 3 imAE while receiving prior checkpoint inhibitor immunotherapy or any unresolved imAE Grade 2 3. Participants with CNS involvement or leptomeningeal disease. 4. History of organ transplant or allogeneic stem cell transplant; autologous stem cell transplant and CAR-T based therapies are permitted if completed >3 months prior to study entry 5. Any venous or arterial thromboembolic event within 6 months prior to the first dose of study intervention. 6. Infectious disease exclusions: Active infection including TB, HIV, active hepatitis A, chronic or active hepatitis B, chronic or active hepatitis C, active COVID-19 infection 7. History of arrhythmia which is requires treatment; symptomatic or uncontrolled atrial fibrillation despite treatment, or asymptomatic sustained ventricular tachycardia 8. Uncontrolled intercurrent illness including, but not limited to,

ongoing or active infection requiring IV antibiotics, cardiomyopathy of any etiology, symptomatic congestive heart failure, uncontrolled hypertension, uncontrolled diabetes mellitus, unstable angina pectoris, history of myocardial infarction within the past 6 months, history of myocarditis, serious chronic gastrointestinal conditions associated with diarrhea, active noninfectious skin disease. 9. Active or prior documented pathologically confirmed autoimmune or inflammatory disorders, including inflammatory bowel disease (e.g, colitis or Crohn's disease), diverticulitis, systemic lupus erythematosus, Sarcoidosis syndrome, or Wegener syndrome (granulomatosis with polyangiitis), Graves' disease, rheumatoid arthritis, hypophysitis, uveitis, etc. some exceptions have been specified in the protocol

Calendario

(Última actualización: 17/09/2025)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
25/04/2022	16/06/2022	18/09/2023	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
28/11/2023	No aportado	No aportado	28/11/2023	05/09/2025

Promotor

AstraZeneca AB Sweden

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Contact Person

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Monetary support: N/A

Tipo de promotor: Comercial

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Centros

Cerrado (21/10/2024)

HOSPITAL CLINICO UNIVERSITARIO DE VALENCIA

València

VALENCIA

Servicio de Oncología y Hematología Médica

Cerrado (12/09/2024)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

Medicamentos

INFLIXIMAB
POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS INFUSION

-

Principios Activos: N/A

Experimental

PARACETAMOL
ORAL SOLUTION
ORAL

-

Principios Activos: N/A

Experimental

AZD7789
SOLUTION FOR INFUSION
SOLUTION FOR INFUSION

-

Principios Activos: N/A

Experimental

EPINEPHRINE
SOLUTION FOR INJECTION
INTRAMUSCULAR INJECTION

-

Principios Activos: N/A

Experimental

DIPHENHYDRAMINE
COATED TABLET
ORAL

-

Principios Activos: N/A

Experimental

TOCILIZUMAB
CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS INFUSION

-

Principios Activos: N/A

Experimental

Tiene resultados

Safety and Preliminary Efficacy Assessment of AZD7789 in Patients With Relapsed or Refractory Classical Hodgkin Lymphoma

State	Type of participants	Age Ranges
Finished CT	Incapable subjects of giving consent	Less than 18 , Older than 64 , Adults (18-64 years) , Teens (12-17 years)
Gender	**Phases**	**Expected Participants**
Both	Phase I , Phase II	190
Results	**Low level of intervention**	**Rare disease**
Has results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
International multicenter	safety, effectiveness, pharmacokinetics, pharmacodynamics, dose	NO

Information

Identifier
2022-502773-41-00 (CTIS)

Protocol Code
D9571C00001

Transitioned 2021-003569-36

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

Investigated Disease
Relapsed/Refractory Classical Hodgkin Lymphoma

Scientific Title
A Phase I/II Open-label, Multi-center Study to Assess Safety, Tolerability, Pharmacokinetics and Preliminary Efficacy

of AZD7789, an anti-PD-1 and anti-TIM-3 Bispecific Antibody, in Patients with Relapsed or Refractory Classical Hodgkin Lymphoma

Rationale

Not provided

Main Objective

Part A Dose Escalation: To assess the safety and tolerability of sabestomig in participants with r/r cHL. To establish the maximum tolerated dose, or optimal biological dose, and recommended Phase 2 dose.
Part B Dose Expansion (all): To assess the safety and tolerability of sabestomig in participants with r/r cHL.
Part B Dose Expansion (B1): To assess the preliminary antitumor activity of sabestomig in participants with r/r cHL (anti-PD-1/PD-L1 exposed).
Part B Dose Expansion (B2): To assess the preliminary antitumor activity of sabestomig in patients with r/r cHL (anti PD-1/PD-L1 naïve).

Primary Endpoints

Part A Dose Escalation: Incidence of AEs, imAEs, and SAEs Incidence of AEs leading to discontinuation of sabestomig Changes from baseline and clinically significant alterations in vital signs, laboratory parameters, and ECG results Incidence of dose-limiting toxicities
Part B Dose Expansion (all): Incidence of AEs, imAEs, and SAEs Incidence of AEs leading to discontinuation of sabestomig Changes from baseline and clinically significant alterations in vital signs, laboratory parameters, and ECG results
Part B Dose Expansion (B1): Objective Response Rate (defined as the proportion of patients with complete remission or partial remission)
Part B Dose Expansion (B2): Complete Response Rate (defined as the proportion of patients with complete remission)

Temporary moments of secondary assessment

Not provided

Secondary Objective

Part A Dose Escalation: To assess the preliminary antitumor activity of sabestomig in participants with r/r cHL
Part B Dose Expansion: To further assess the preliminary antitumor activity of sabestomig in participants with r/r cHL To evaluate Patient Reported treatment-related symptoms, overall side-effect impact and overall global health status while on sabestomig.
Part A Dose Escalation and Part B Dose Expansion: To assess the PK of sabestomig in participants with r/r cHL To assess the immunogenicity of sabestomig in participants with r/r cHL

Secondary Endpoints

Part A Dose Escalation: Complete Response Rate, Objective Response Rate, DoR, and DoCR and PFS including landmarks at 12 and 24 months OS including landmarks at 12 and 24 months
Part B Dose Expansion: DoR, DoCR and PFS including landmarks at 12 and 24 months OS including landmarks at 12 and 24 months Proportion of dosed subjects over time with: diarrhea, rash, and fatigue (PRO-CTCAE or Peds-PROCTCAE) overall side-effect bother (PGI-TT) quality of life/health (EORTC ILXX QL2)
Part A Dose Escalation and Part B Dose Expansion: PK parameters including the maximum observed concentration, area under the concentration-time curve, clearance and terminal elimination half life Incidence of anti-drug antibodies against sabestomig in serum

Temporary moments of secondary assessment

Not provided

Inclusion criteria

1. Must be 16 years of age at the time of obtaining informed consent
2. Eastern Cooperative Oncology Group performance status of 0 or 1 at screening
3. Must have at least one PET-avid measurable lesion according to Modified Lugano Criteria after the last line of therapy.
4. Confirmed histological diagnosis of active relapse/refractory cHL
5. Must have failed at least 2 prior lines of systemic therapy. In part A dose escalation the prior lines of therapy must include at least 3 cycles of anti-PD- 1/PD-L1 and in part B dose expansion at least 2 cycles of an anti-PD-1/PD-L1. In part B dose expansion cohort B2, prior antiPD-1/PD-L1 therapy is excluded. For all participants, no previous treatment with anti- TIM-3 is allowed. Previous anti-CTLA-4 treatment is acceptable with at least 2 months washout period prior to study entry.
6. Adequate organ and bone marrow function
7. Non-pregnant women and willingness of female participants to avoid pregnancy or male participants willing to avoid fathering children through highly effective methods of contraception
8. Minimum body weight 40 kg for all participants.

Exclusion criteria

1. Unresolved toxicities of Grade 2 from prior therapy, unless immune-mediated. 10. Past medical history of interstitial lung disease (ILD), drug-induced ILD, radiation pneumonitis requiring steroid treatment, or any evidence of clinically active ILD or active pneumonitis. 11. Other invasive malignancy within 2 years prior to screening 12. Congenital long QT syndrome or history of QT prolongation associated with other medications that cannot be changed or discontinued based on a cardiologist assessment 13. Current or prior use of immunosuppressive medication within 14 days prior to the first dose of study intervention 14. Any concurrent chemotherapy, radiotherapy, investigational, biologic, or hormonal therapy for cancer treatment. Concurrent use of hormonal therapy for noncancer-related conditions is acceptable 2. Any prior Grade 3 imAE while receiving prior checkpoint inhibitor immunotherapy or any unresolved imAE Grade 2 3. Participants with CNS involvement or leptomeningeal disease. 4. History of organ transplant or allogeneic stem cell transplant; autologous stem cell transplant and CAR-T based therapies are permitted if completed >3 months prior to study entry 5. Any venous or arterial thromboembolic event within 6 months prior to the first dose of study intervention. 6. Infectious disease exclusions: Active infection including TB, HIV, active hepatitis A, chronic or active hepatitis B, chronic or active hepatitis C, active COVID-19 infection 7. History of arrhythmia which is requires treatment; symptomatic or uncontrolled atrial fibrillation despite treatment, or asymptomatic sustained ventricular tachycardia 8. Uncontrolled intercurrent illness including, but not limited to,

ongoing or active infection requiring IV antibiotics, cardiomyopathy of any etiology, symptomatic congestive heart failure, uncontrolled hypertension, uncontrolled diabetes mellitus, unstable angina pectoris, history of myocardial infarction within the past 6 months, history of myocarditis, serious chronic gastrointestinal conditions associated with diarrhea, active noninfectious skin disease. 9. Active or prior documented pathologically confirmed autoimmune or inflammatory disorders, including inflammatory bowel disease (e.g, colitis or Crohn's disease), diverticulitis, systemic lupus erythematosus, Sarcoidosis syndrome, or Wegener syndrome (granulomatosis with polyangiitis), Graves' disease, rheumatoid arthritis, hypophysitis, uveitis, etc. some exceptions have been specified in the protocol

Calendar

(Last Update: 17/09/2025)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
25/04/2022	16/06/2022	18/09/2023	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
28/11/2023	Not aported	Not aported	28/11/2023	05/09/2025

Sponsor

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Contact Person

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Monetary support: N/A

Sponsor type: Commercial

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Sites

Closed (21/10/2024)

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VALENCIA

Servicio de Oncología y Hematología Médica

Closed (12/09/2024)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

Medication

INFLIXIMAB

POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION

INTRAVENOUS INFUSION

-

Active Principles: N/A

Experimental

PARACETAMOL

ORAL SOLUTION

ORAL

-

Active Principles: N/A

Experimental

AZD7789

SOLUTION FOR INFUSION

SOLUTION FOR INFUSION

-

Active Principles: N/A

Experimental

EPINEPHRINE

SOLUTION FOR INJECTION

INTRAMUSCULAR INJECTION

-

Active Principles: N/A

Experimental

DIPHENHYDRAMINE

COATED TABLET

ORAL

-

Active Principles: N/A

Experimental

TOCILIZUMAB

CONCENTRATE FOR SOLUTION FOR INFUSION

INTRAVENOUS INFUSION

-

Active Principles: N/A

Experimental

Has results