A trial to learn if AZD0305 alone and in combination with other cancer treatments is safe and works in adults with multiple myeloma

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	224
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	tratamiento, seguridad, eficacia, farmacocinética, farmacodinamica, dosis	NO

Información

Identificador
2023-508590-89-00 (CTIS)

Cod. Protocolo
D7230C00001

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

Enfermedad investigada
Multiple Myeloma

Título Científico
A Modular Phase I/II, Open-label, Multicenter Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, Pharmacodynamics, and Preliminary Efficacy of AZD0305 as Monotherapy or in Combination With Anticancer Agent(s) in Participants with Multiple Myeloma

Justificación

No aportado

Objetivo Principal

To assess the safety and tolerability and determine the Recommended Phase 2 Dose (RP2D) of AZD0305 as monotherapy and in combination with other anticancer agents in participants with MM.
This is the core primary objective of the study, module specific primary objectives are available within the CSP

Variables de Evaluación Primaria

Occurrence of dose-limiting toxicities (Phase Ia dose escalation only).
Incidence and severity of AEs and SAEs.
these are the core primary endpoints of the study, module specific endpoints are available within the CSP

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To estimate the preliminary efficacy of AZD0305 as monotherapy and in combination with other anticancer agents in participants with MM.
To evaluate the PK characteristics of AZD0305 as monotherapy and in combination with other anticancer agents in participants with MM.
To assess the immunogenicity of AZD0305 as monotherapy and in combination with other anticancer agents in participants with MM.
These are the core secondary objectives of the study, module-specific secondary objectives are available within the CSP

Variables de Evaluación Secundaria

Preliminary efficacy of AZD0305 according to IMWG 2016 response criteria as assessed by investigator, including response endpoints ORR, CRR (module 2 only), DoR, MRD negative CR rate (Modules 2 and 3 only), PFS, and OS.
PK parameters of AZD0305 (total ADC), total antibody (conjugated and unconjugated) and MMAE, including but not limited to AUC, Cmax, tmax, clearance, and half-life, as data allow.
The number and percentage of participants who develop Anti-Drug Antibody (ADA).
These are the core secondary endpoints of the study, module specific endpoints are available within the CSP

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Participants must be at least 18 years of age or the legal age of consent in the jurisdiction in which the study is taking place.
Eastern Cooperative Oncology Group performance status of 2 in module 1, or 0 or 1 in modules 2 and 3
Documentation of Multiple Myeloma (MM) as defined by International Myeloma Working Group (IMWG) Diagnostic Criteria for Multiple Myeloma. Site should ensure that Multiple Myeloma diagnosis is confirmed in accordance with the IMWG Diagnostic Criteria
Participants must have one or more measurable disease criteria for Serum M-Protein, Urine M-protein, and Serum immunoglobulin free light chains as specified in the relevant module of the CSP;
Adequate organ and bone marrow function assessment at screening according to the hematological, hepatic, and renal parameters listed in the CSP as relevant to each module
Participants must have received at least 3 prior lines of treatment in module 1. In modules 2 and 3, participants must meet the phase-specific requirements for the number of prior lines of therapy.
The above is a summary of key criteria, other inclusion criteria details may apply

Criterios de Exclusión

Amyloidosis, plasma cell leukemia, Waldenstrom Macroglobulinemia, Polyneuropathy Organomegaly Endocrinopathy M-protein and Skin Syndrome, or Smoldering Multiple Myeloma (compliant with WHO criteria);
Participants who have previously received anti-GPRC5D or MMAE-containing treatment.
Participants with a history of prior malignancy other than MM within 3 years prior to first dose of study intervention. some exceptions apply
Participants with previous history of active John Cunningham virus infection resulting in PML
Participants with a known hypersensitivity to AZD0305 or any of the excipients of the product or to any of the drugs included in the respective modules or who experienced Grade 3 or higher hypersensitivity to prior monoclonal antibody therapy
Participants who have uncontrolled severe illness including but not limited to ongoing active infection requiring therapeutic antibiotics and/or other administration
The above is a summary of key criteria, other exclusion criteria details may apply
Participants who have previously received allogenic stem cell transplant, or participant has received autologous stem cell transplant within 3 months before the first dose of study intervention.
Participants exhibiting clinical signs of central nervous system involvement of MM;
Participants with known COPD, or previous history of ILD/pneumonitis
Participants with known moderate or severe persistent asthma within the past 5 years, or uncontrolled asthma of any classification;
Participants who have severe cardiovascular disease which is not adequately controlled.
Participants who have a history of immunodeficiency disease.
Participants with peripheral neuropathy Grade 2.
Primary refractory MM.

Calendario

(Última actualización: 13/05/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
14/05/2024	25/06/2024	07/02/2025	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

Astraallen GartunaKarlebyhus Byggnad 674

Contact Person

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Monetary support: N/A

Tipo de promotor: Comercial

Ceim

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Centros

Activo (22/07/2024)

Clinica Universidad De Navarra

Madrid

MADRID

Hematology

Activo (26/06/2024)

Clinica Universidad De Navarra

Pamplona

NAVARRA

Hematology

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

Hospital Germans Trias I Pujol

Badalona

BARCELONA

Oncology

Activo (25/06/2024)

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Hematology

Activo (15/07/2024)

Hospital Universitario 12 De Octubre

Madrid

MADRID

Hematology

Medicamentos

ELRANATAMAB
SOLUTION FOR INJECTION
SUBCUTANEOUS INJECTION

-
Principios Activos: N/A

Experimental

ELRANATAMAB
SOLUTION FOR INJECTION
SUBCUTANEOUS INJECTION

-
Principios Activos: N/A

Experimental

-
-
ORAL

Código ATC: L04AX06 - POMALIDOMIDA
Principios Activos: N/A

Experimental

AZD0305
SOLUTION FOR INFUSION
INTRAVENOUS INFUSION

-
Principios Activos: N/A

Experimental

Sin resultados

A trial to learn if AZD0305 alone and in combination with other cancer treatments is safe and works in adults with multiple myeloma

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	224
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	treatment, safety, effectiveness, pharmacokinetics, pharmacodynamics, dose	NO

Information

Identifier
2023-508590-89-00 (CTIS)

Protocol Code
D7230C00001

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

Investigated Disease
Multiple Myeloma

Scientific Title
A Modular Phase I/II, Open-label, Multicenter Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, Pharmacodynamics, and Preliminary Efficacy of AZD0305 as Monotherapy or in Combination With Anticancer Agent(s) in Participants with Multiple Myeloma

Rationale

Not provided

Main Objective

To assess the safety and tolerability and determine the Recommended Phase 2 Dose (RP2D) of AZD0305 as monotherapy and in combination with other anticancer agents in participants with MM.
This is the core primary objective of the study, module specific primary objectives are available within the CSP

Primary Endpoints

Occurrence of dose-limiting toxicities (Phase Ia dose escalation only).
Incidence and severity of AEs and SAEs.
these are the core primary endpoints of the study, module specific endpoints are available within the CSP

Temporary moments of secondary assessment

Not provided

Secondary Objective

To estimate the preliminary efficacy of AZD0305 as monotherapy and in combination with other anticancer agents in participants with MM.
To evaluate the PK characteristics of AZD0305 as monotherapy and in combination with other anticancer agents in participants with MM.
To assess the immunogenicity of AZD0305 as monotherapy and in combination with other anticancer agents in participants with MM.
These are the core secondary objectives of the study, module-specific secondary objectives are available within the CSP

Secondary Endpoints

Preliminary efficacy of AZD0305 according to IMWG 2016 response criteria as assessed by investigator, including response endpoints ORR, CRR (module 2 only), DoR, MRD negative CR rate (Modules 2 and 3 only), PFS, and OS.
PK parameters of AZD0305 (total ADC), total antibody (conjugated and unconjugated) and MMAE, including but not limited to AUC, Cmax, tmax, clearance, and half-life, as data allow.
The number and percentage of participants who develop Anti-Drug Antibody (ADA).
These are the core secondary endpoints of the study, module specific endpoints are available within the CSP

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Participants must be at least 18 years of age or the legal age of consent in the jurisdiction in which the study is taking place.
Eastern Cooperative Oncology Group performance status of 2 in module 1, or 0 or 1 in modules 2 and 3
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The above is a summary of key criteria, other inclusion criteria details may apply

Exclusion criteria

Amyloidosis, plasma cell leukemia, Waldenstrom Macroglobulinemia, Polyneuropathy Organomegaly Endocrinopathy M-protein and Skin Syndrome, or Smoldering Multiple Myeloma (compliant with WHO criteria);
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Participants who have severe cardiovascular disease which is not adequately controlled.
Participants who have a history of immunodeficiency disease.
Participants with peripheral neuropathy Grade 2.
Primary refractory MM.

Calendar

(Last Update: 13/05/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
14/05/2024	25/06/2024	07/02/2025	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

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Contact Person

AstraZeneca Clinical Study Information Center

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Monetary support: N/A

Sponsor type: Commercial

Ceim

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Sites

Active (22/07/2024)

Clinica Universidad De Navarra

Madrid

MADRID

Hematology

Active (26/06/2024)

Clinica Universidad De Navarra

Pamplona

NAVARRA

Hematology

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

Hospital Germans Trias I Pujol

Badalona

BARCELONA

Oncology

Active (25/06/2024)

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Hematology

Active (15/07/2024)

Hospital Universitario 12 De Octubre

Madrid

MADRID

Hematology

Medication

ELRANATAMAB
SOLUTION FOR INJECTION
SUBCUTANEOUS INJECTION

-
Active Principles: N/A
Experimental

ELRANATAMAB
SOLUTION FOR INJECTION
SUBCUTANEOUS INJECTION

-
Active Principles: N/A
Experimental

-
-
ORAL

ATC code: L04AX06 - POMALIDOMIDA
Active Principles: N/A
Experimental

AZD0305
SOLUTION FOR INFUSION
INTRAVENOUS INFUSION

-
Active Principles: N/A
Experimental

No results