

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

Estado Reclutando	Tipo de Participantes No aportado	Rangos de Edad Mayores de 64 , Adultos (18-64 años)
Género Ambos	Fases Fase I , Fase II	Participantes esperados 224
Resultados Sin resultados	Bajo nivel intervención No	Enfermedad rara No
Cobertura geográfica Sin determinar	Ámbitos del ensayo tratamiento, seguridad, eficacia, farmacocinética, farmacodinamica, dosis	Terapia avanzada NO

Información

Identificador 2023-508590-89-00 (CTIS)	Cod. Protocolo D7230C00001
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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 14/05/2024	Inicio de Ensayo 25/06/2024	Inclusión Primer Paciente 07/02/2025	Interrumpido No aportado	Reiniciado No aportado
Fin de reclutamiento No aportado	Fin prematuro (España) No aportado	Fin prematuro (Global) No aportado	Fin del ensayo en España No aportado	Fin del ensayo global No aportado

Promotor

AstraZeneca AB Sweden Astraallen GartunaKarlebyhus Byggnad 674
Contact Person AstraZeneca Clinical Study Information Center +18772409479 information.center@astrazeneca.com
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 Recruiting	Type of participants Not provided	Age Ranges Older than 64 , Adults (18-64 years)
Gender Both	Phases Phase I , Phase II	Expected Participants 224
Results No results	Low level of intervention No	Rare disease No
Geographic coverage Undetermined	Areas of the study treatment, safety, effectiveness, pharmacokinetics, pharmacodynamics, dose	Advanced therapy 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

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Eastern Cooperative Oncology Group performance status of 2 in module 1, or 0 or 1 in modules 2 and 3

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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 14/05/2024	Start of Trial 25/06/2024	First patient inclusion 07/02/2025	Halted Not aported	Restarted Not aported
End of recruitment Not aported	Premature end (Spain) Not aported	Premature End (Global) Not aported	Trial end (Spain) Not aported	Trial end (Global) Not aported

Sponsor

AstraZeneca AB Sweden

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Contact Person

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Monetary support: N/A

Sponsor type: Commercial

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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