A trial to learn how well surovatamig (AZD0486) works and how safe it is 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 II	188
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	tratamiento, seguridad, eficacia, farmacocinética, farmacodinamica, farmacogenética, farmacogenómica	NO

Información

Identificador
2023-505789-27-00 (CTIS)

Cod. Protocolo
No aportado

Área terapéutica
Enfermedades [C] - Hematología [C15]|

Enfermedad investigada
Relapsed or Refractory Non-Hodgkin Lymphoma

Título Científico
A Modular Phase II, Single-arm, Multicenter, Open-label Study to Evaluate the Efficacy and Safety of Surovatamig (AZD0486) in Participants with Relapsed or Refractory B-cell Non-Hodgkin Lymphoma (SOUNDTRACK-B))

Justificación

No aportado

Objetivo Principal

To evaluate the efficacy of surovatamig (AZD0486) single therapy administered at the Recommended Phase 2 Dose (RP2D) in relapsed or refractory B-cell NHL

Variables de Evaluación Primaria

ORR, defined as the proportion of participants achieving either a PR or CR based on Lugano 2014 Response Criteria as determined by an IRC

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

1. To assess the safety and tolerability of surovatamig
2.To further evaluate the efficacy of surovatamig by assessment of DoR and CR rate
3. To evaluate ORR and CR rate
4. To evaluate the efficacy of surovatamig by evaluation of additional efficacy measures based on Lugano 2014 Response Criteria
5. To characterize the PK of surovatamig
6. To describe the incidence of immunogenicity
7. To evaluate patient-reported tolerability of surovatamig, including severity of key treatment-related symptoms and overall side-effect burden
8. To evaluate patient-reported severity of key disease-related symptoms, as well as the impact of disease on lymphoma-specific concerns and general HRQoL, while on surovatamig
9.Evaluate the impact of surovatamig on MRD-negative CR rate

Variables de Evaluación Secundaria

1. Safety and tolerability of surovatamig - incidence, nature, and severity of AEs/SAEs/AESI, changes in laboratory data, vital signs, and ECGs compared with baseline, incidence and nature of study drug discontinuation, dose reduction, and dose delay due to AEs
2. Efficacy - DoR and CR, ORR and CR rates
3. Efficacy - DoCR, TTR, EFS, PFS, TTNT, OS
4. PK - PK parameters such as such as Cmax, Tmax, Ctrough of surovatamig (at predefined intervals)
5. Immunogenicity -pre-existing and induced ADA for surovatamig
6. PROs - difference in severity levels in fatigue, pain, cognition and overall side-effect burden
7. MRD-negative CR rate

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

1. Participant must be 18 years old and above at the time of signing the ICF.
2. ECOG performance status of 0 to 2
3. Relapsed or refractory disease after at least 2 prior lines of systemic therapy
4. Histologically confirmed diagnosis of B-NHL, based on local pathology report, as determined by WHO 2022 classification
5. FDG-avid and measurable disease
6. Adequate liver, hematological, renal and cardiac function.

The above is a summary, other inclusion criteria details may apply

Criterios de Exclusión

1. Diagnosis of chronic lymphocytic leukemia, Burkitt lymphoma, or Richters transformation
2. Active CNS involvement by B-NHL.
3. Leukemic presentation of disease
4. Prior neurotoxicity/ICANS or CRS
5. History or presence of clinically relevant CNS pathology (based on investigator assessment)
6. Prior allogeneic HSCT or solid organ transplantation within 24 weeks of first planned dose of surovatamig

The above is a summary, other exclusion criteria details may apply

Calendario

(Última actualización: 01/04/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
18/02/2025	09/05/2025	31/12/2025	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

AstraZeneca Clinical Study Information Center

+18772409479

information.center@astrazeneca.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Hospital Universitari de Bellvitge

Feixa Llarga, s/n - Antiguo Módulo Banco de Santander 08907 Hospitalet de Llobregat

mcruz@idibell.cat

Centros

Activo (26/05/2025)

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Hematología

Activo (09/05/2025)

Hospital Universitario Fundacion Jimenez Diaz

Madrid

MADRID

Hematología

Activo (15/01/2026)

Hospital Universitario Quironsalud Madrid

Pozuelo De Alarcon

MADRID

Hematología

Medicamentos

AZD0486
SOLUTION FOR INFUSION
INTRAVENOUS INFUSION

-

Principios Activos: N/A

Experimental

AZD0486
SOLUTION FOR INFUSION
INTRAVENOUS INFUSION

-

Principios Activos: N/A

Experimental

Sin resultados

A trial to learn how well surovatamig (AZD0486) works and how safe it is 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 II	188
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, pharmacogenetics, pharmacogenomics	NO

Information

Identifier
2023-505789-27-00 (CTIS)

Protocol Code
No aportado

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

Investigated Disease
Relapsed or Refractory Non-Hodgkin Lymphoma

Scientific Title
A Modular Phase II, Single-arm, Multicenter, Open-label Study to Evaluate the Efficacy and Safety of Surovatamig (AZD0486) in Participants with Relapsed or Refractory B-cell Non-Hodgkin Lymphoma (SOUNDTRACK-B))

Rationale

Not provided

Main Objective

To evaluate the efficacy of surovatamig (AZD0486) single therapy administered at the Recommended Phase 2 Dose (RP2D) in relapsed or refractory B-cell NHL

Primary Endpoints

ORR, defined as the proportion of participants achieving either a PR or CR based on Lugano 2014 Response Criteria as determined by an IRC

Temporary moments of secondary assessment

Not provided

Secondary Objective

1. To assess the safety and tolerability of surovatamig
2.To further evaluate the efficacy of surovatamig by assessment of DoR and CR rate
3. To evaluate ORR and CR rate
4. To evaluate the efficacy of surovatamig by evaluation of additional efficacy measures based on Lugano 2014 Response Criteria
5. To characterize the PK of surovatamig
6. To describe the incidence of immunogenicity
7. To evaluate patient-reported tolerability of surovatamig, including severity of key treatment-related symptoms and overall side-effect burden
8. To evaluate patient-reported severity of key disease-related symptoms, as well as the impact of disease on lymphoma-specific concerns and general HRQoL, while on surovatamig
9.Evaluate the impact of surovatamig on MRD-negative CR rate

Secondary Endpoints

1. Safety and tolerability of surovatamig - incidence, nature, and severity of AEs/SAEs/AESI, changes in laboratory data, vital signs, and ECGs compared with baseline, incidence and nature of study drug discontinuation, dose reduction, and dose delay due to AEs
2. Efficacy - DoR and CR, ORR and CR rates
3. Efficacy - DoCR, TTR, EFS, PFS, TTNT, OS
4. PK - PK parameters such as such as Cmax, Tmax, Ctrough of surovatamig (at predefined intervals)
5. Immunogenicity -pre-existing and induced ADA for surovatamig
6. PROs - difference in severity levels in fatigue, pain, cognition and overall side-effect burden
7. MRD-negative CR rate

Temporary moments of secondary assessment

Not provided

Inclusion criteria

1. Participant must be 18 years old and above at the time of signing the ICF.
2. ECOG performance status of 0 to 2
3. Relapsed or refractory disease after at least 2 prior lines of systemic therapy
4. Histologically confirmed diagnosis of B-NHL, based on local pathology report, as determined by WHO 2022 classification
5. FDG-avid and measurable disease
6. Adequate liver, hematological, renal and cardiac function.

The above is a summary, other inclusion criteria details may apply

Exclusion criteria

1. Diagnosis of chronic lymphocytic leukemia, Burkitt lymphoma, or Richters transformation
2. Active CNS involvement by B-NHL.
3. Leukemic presentation of disease
4. Prior neurotoxicity/ICANS or CRS
5. History or presence of clinically relevant CNS pathology (based on investigator assessment)
6. Prior allogeneic HSCT or solid organ transplantation within 24 weeks of first planned dose of surovatamig

The above is a summary, other exclusion criteria details may apply

Calendar

(Last Update: 01/04/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
18/02/2025	09/05/2025	31/12/2025	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

Astraallen GartunaKarlebyhus Byggnad 674

Contact Person

AstraZeneca Clinical Study Information Center

+18772409479

information.center@astrazeneca.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Hospital Universitari de Bellvitge

Feixa Llarga, s/n - Antiguo Módulo Banco de Santander 08907 Hospitalet de Llobregat

mcruz@idibell.cat

Sites

Active (26/05/2025)

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Hematología

Active (09/05/2025)

Hospital Universitario Fundacion Jimenez Diaz

Madrid

MADRID

Hematología

Active (15/01/2026)

Hospital Universitario Quironsalud Madrid

Pozuelo De Alarcon

MADRID

Hematología

Medication

AZD0486
SOLUTION FOR INFUSION
INTRAVENOUS INFUSION

-

Active Principles: N/A

Experimental

AZD0486
SOLUTION FOR INFUSION
INTRAVENOUS INFUSION

-

Active Principles: N/A

Experimental

No results