A Phase 1/2 Study of Bleximenib in Participants with Acute Leukemia

Estado	Tipo de Participantes	Rangos de Edad
Reclutando	Sujetos incapaces de otorgar consentimiento	Menores de 18 , Mayores de 64 , Adultos (18-64 años) , Adolescentes (12-17 años) , Niños (2-11 años) , Lactantes y preescolar (28 días - 23 meses)
Género	**Fases**	**Participantes esperados**
Ambos	Fase I	58
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia, farmacocinética, farmacodinamica, dosis	NO

Información

Identificador
2023-506581-31-00 (CTIS)

Cod. Protocolo
75276617ALE1001

Transicionado 2020-005967-30

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

Enfermedad investigada
Acute Leukemia

Título Científico
A Phase 1/2, First-in-Human Study of theMenin-KMT2A (MLL1)Inhibitor Bleximenib in Participants with Acute Leukemia

Justificación

No aportado

Objetivo Principal

Phase 1: Part 1 (Dose Escalation): Determine the (RP2Ds of bleximenib
Phase 1: Part 2 (Dose Expansion): Determine the safety and tolerability at the RP2D(s)
Phase 2: To evaluate the efficacy of bleximenib at the RP2D

Variables de Evaluación Primaria

Phase 1: Part 1 (Dose Escalation): Incidence and severity of adverse events, including dose-limiting toxicity
Phase 1: Part 2 (Dose Expansion): Incidence and severity of adverse events
Phase 2: Rate of CR/CRh assessed by the IRC.

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

1. Phase 1 and Phase 2 adult cohorts: 18 years of age and Phase 1 adolescent cohort 12 to <18 years of age 2. Phase 1: R/R acute leukemia and has exhausted, or is ineligible for, available therapeutic options. 3. Phase 1: Acute leukemia harboring KMT2A, NPM1 or nucleoporin alterations. Phase 2: AML harboring KMT2A-r or NPM1 mutations only. 4. Pretreatment clinical laboratory values meeting the criteria 5. ECOG performance status grade of 0, 1 or 2. 6. A female of childbearing potential must have a negative highly sensitive serum -human chorionic gonadotropin at screening and within 48 hours prior to the first dose of study treatment

Criterios de Exclusión

1. Diagnosed with acute promyelocytic leukemia, Down syndrome associated leukemia or juvenile myelomonocytic leukemia. 2. Active CNS involvement 3. Prior solid organ transplantation 4. Cardiovascular disease that increases the risk for torsades de pointes or that was diagnosed within 6 months prior to the first dose of study treatment. 5. QTc 450 milliseconds for males or 470 milliseconds for females 6. Any toxicity from previous anticancer therapy that has not resolved to baseline or to Grade 1 or less 7. Pulmonary compromise that requires the need for supplemental oxygen use to maintain adequate oxygenation 8. Reported temperature >100.5ºF/38ºC within 48 hours prior to the first dose of study treatment 9. Known allergies, hypersensitivity, or intolerance to bleximenib or its excipients.

Calendario

(Última actualización: 20/08/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
26/07/2021	02/08/2021	15/11/2021	19/08/2021	12/10/2021

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

Janssen - Cilag International Belgium

Turnhoutseweg 30

Contact Person

CTIS Point of Contact

+31717996133

CTISadmin@its.jnj.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm de la Comunidad Foral de Navarra

C/ Irunlarrea, 3 31008 Pamplona

ceic@cfnavarra.es

Centros

Activo (02/08/2021)

CLINICA UNIVERSIDAD DE NAVARRA

Pamplona/Iruña

NAVARRA

Activo (19/11/2021)

HOSPITAL CLINIC DE BARCELONA

Barcelona

BARCELONA

Activo (16/10/2024)

Hospital Clinico Universitario De Valencia

Valencia

VALENCIA

Hematology

Activo (06/11/2024)

Hospital General Universitario Gregorio Maranon

Madrid

MADRID

Hematology

Activo (02/03/2026)

Hospital Infantil Universitario Nino Jesus

Madrid

MADRID

Hematology - Pediatric

Activo (10/11/2021)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

Activo (23/10/2024)

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Hematology

Activo (02/08/2021)

HOSPITAL UNIVERSITARIO FUNDACION JIMENEZ DIAZ

Madrid

MADRID

Activo (31/10/2024)

University Hospital Virgen Del Rocio S.L.

Sevilla

SEVILLA

Hematology

Medicamentos

JNJ-75276617
FILM-COATED TABLET
ORAL USE

-
Principios Activos: N/A

Experimental

JNJ-75276617 (G008)
FILM-COATED TABLET
ORAL USE

-
Principios Activos: N/A

Experimental

JNJ-75276617
FILM-COATED TABLET
ORAL USE

-
Principios Activos: N/A

Experimental

JNJ-75276617 (G024)
CAPSULE
ORAL USE

-
Principios Activos: N/A

Experimental

JNJ-75276617 (G021)
CAPSULE
ORAL USE

-
Principios Activos: N/A

Experimental

JNJ-75276617 (G023)
CAPSULE
ORAL USE

-
Principios Activos: N/A

Experimental

JNJ-75276617 (G007)
FILM-COATED TABLET
ORAL USE

-
Principios Activos: N/A

Experimental

JNJ-75276617
FILM-COATED TABLET
ORAL USE

-
Principios Activos: N/A

Experimental

JNJ-75276617 (G011)
POWDER FOR ORAL SOLUTION
ORAL USE

-
Principios Activos: N/A

Experimental

JNJ-75276617 (G016)
CAPSULE
ORAL USE

-
Principios Activos: N/A

Experimental

JNJ-75276617 (G002)
TABLET
ORAL USE

-
Principios Activos: N/A

Experimental

JNJ-75276617 (G010)
POWDER FOR ORAL SOLUTION
ORAL USE

-
Principios Activos: N/A

Experimental

JNJ-75276617 (G003)
TABLET
ORAL USE

-
Principios Activos: N/A

Experimental

JNJ-75276617 (G022)
CAPSULE
ORAL USE

-
Principios Activos: N/A

Experimental

JNJ-75276617 (G001)
TABLET
ORAL USE

JNJ-75276617
FILM-COATED TABLET
ORAL USE

-
Principios Activos: N/A
Experimental

-
Principios Activos: N/A
Experimental

Sin resultados

A Phase 1/2 Study of Bleximenib in Participants with Acute Leukemia

State	Type of participants	Age Ranges
Recruiting	Incapable subjects of giving consent	Less than 18 , Older than 64 , Adults (18-64 years) , Teens (12-17 years) , Children (2-11 years) , Infants and preschool (28 days - 23 months)
Gender	**Phases**	**Expected Participants**
Both	Phase I	58
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness, pharmacokinetics, pharmacodynamics, dose	NO

Information

Identifier
2023-506581-31-00 (CTIS)

Protocol Code
75276617ALE1001

Transitioned 2020-005967-30

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

Investigated Disease
Acute Leukemia

Scientific Title
A Phase 1/2, First-in-Human Study of theMenin-KMT2A (MLL1)Inhibitor Bleximenib in Participants with Acute Leukemia

Rationale

Not provided

Main Objective

Phase 1: Part 1 (Dose Escalation): Determine the (RP2Ds of bleximenib
Phase 1: Part 2 (Dose Expansion): Determine the safety and tolerability at the RP2D(s)
Phase 2: To evaluate the efficacy of bleximenib at the RP2D

Primary Endpoints

Phase 1: Part 1 (Dose Escalation): Incidence and severity of adverse events, including dose-limiting toxicity
Phase 1: Part 2 (Dose Expansion): Incidence and severity of adverse events
Phase 2: Rate of CR/CRh assessed by the IRC.

Temporary moments of secondary assessment

Not provided

Secondary Objective

Not provided

Secondary Endpoints

Not provided

Temporary moments of secondary assessment

Not provided

Inclusion criteria

1. Phase 1 and Phase 2 adult cohorts: 18 years of age and Phase 1 adolescent cohort 12 to <18 years of age 2. Phase 1: R/R acute leukemia and has exhausted, or is ineligible for, available therapeutic options. 3. Phase 1: Acute leukemia harboring KMT2A, NPM1 or nucleoporin alterations. Phase 2: AML harboring KMT2A-r or NPM1 mutations only. 4. Pretreatment clinical laboratory values meeting the criteria 5. ECOG performance status grade of 0, 1 or 2. 6. A female of childbearing potential must have a negative highly sensitive serum -human chorionic gonadotropin at screening and within 48 hours prior to the first dose of study treatment

Exclusion criteria

1. Diagnosed with acute promyelocytic leukemia, Down syndrome associated leukemia or juvenile myelomonocytic leukemia. 2. Active CNS involvement 3. Prior solid organ transplantation 4. Cardiovascular disease that increases the risk for torsades de pointes or that was diagnosed within 6 months prior to the first dose of study treatment. 5. QTc 450 milliseconds for males or 470 milliseconds for females 6. Any toxicity from previous anticancer therapy that has not resolved to baseline or to Grade 1 or less 7. Pulmonary compromise that requires the need for supplemental oxygen use to maintain adequate oxygenation 8. Reported temperature >100.5ºF/38ºC within 48 hours prior to the first dose of study treatment 9. Known allergies, hypersensitivity, or intolerance to bleximenib or its excipients.

Calendar

(Last Update: 20/08/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
26/07/2021	02/08/2021	15/11/2021	19/08/2021	12/10/2021

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

Janssen - Cilag International Belgium

Turnhoutseweg 30

Contact Person

CTIS Point of Contact

+31717996133

CTISadmin@its.jnj.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

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ceic@cfnavarra.es

Sites

Active (02/08/2021)

CLINICA UNIVERSIDAD DE NAVARRA

Pamplona/Iruña

NAVARRA

Active (19/11/2021)

HOSPITAL CLINIC DE BARCELONA

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Active (02/03/2026)

Hospital Infantil Universitario Nino Jesus

Madrid

MADRID

Hematology - Pediatric

Active (10/11/2021)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

Active (23/10/2024)

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Hematology

Active (02/08/2021)

HOSPITAL UNIVERSITARIO FUNDACION JIMENEZ DIAZ

Madrid

MADRID

Active (31/10/2024)

University Hospital Virgen Del Rocio S.L.

Sevilla

SEVILLA

Hematology

Medication

JNJ-75276617
FILM-COATED TABLET
ORAL USE

-
Active Principles: N/A
Experimental

JNJ-75276617 (G008)
FILM-COATED TABLET
ORAL USE

-
Active Principles: N/A
Experimental

JNJ-75276617
FILM-COATED TABLET
ORAL USE

-
Active Principles: N/A
Experimental

JNJ-75276617 (G024)
CAPSULE
ORAL USE

-
Active Principles: N/A
Experimental

JNJ-75276617 (G021)
CAPSULE
ORAL USE

-
Active Principles: N/A
Experimental

JNJ-75276617 (G023)
CAPSULE
ORAL USE

-
Active Principles: N/A
Experimental

JNJ-75276617 (G007)
FILM-COATED TABLET
ORAL USE

-
Active Principles: N/A
Experimental

JNJ-75276617
FILM-COATED TABLET
ORAL USE

-
Active Principles: N/A
Experimental

JNJ-75276617 (G011)
POWDER FOR ORAL SOLUTION
ORAL USE

-
Active Principles: N/A
Experimental

JNJ-75276617 (G016)
CAPSULE
ORAL USE

-
Active Principles: N/A
Experimental

JNJ-75276617 (G002)
TABLET
ORAL USE

-
Active Principles: N/A
Experimental

JNJ-75276617 (G010)
POWDER FOR ORAL SOLUTION
ORAL USE

-
Active Principles: N/A
Experimental

JNJ-75276617 (G003)
TABLET
ORAL USE

-
Active Principles: N/A
Experimental

JNJ-75276617 (G022)
CAPSULE
ORAL USE

-
Active Principles: N/A
Experimental

JNJ-75276617 (G001)
TABLET
ORAL USE

JNJ-75276617
FILM-COATED TABLET
ORAL USE

-

Active Principles: N/A

Experimental

-

Active Principles: N/A

Experimental

No results