Estudio fase 1b de regímenes de daratumumab subcutáneo en combinación con anticuerpos biespecíficos de redirección de los células T para el tratamiento de sujetos con mieloma múltiple.

Estado	**Tipo de Participantes**	**Rangos de Edad**
Fin Reclutamiento	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase I	179
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia, farmacocinética, farmacodinamica, dosis	NO

Información

Identificador
2023-503468-17-00 (CTIS)

Cod. Protocolo
64407564MMY1002

Transicionado 2019-000330-19

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

Enfermedad investigada
Mieloma múltiple

Título Científico
A Phase 1b Study of Subcutaneous Daratumumab Regimens in Combination with Bispecific T Cell Redirection Antibodies for the Treatment of Subjects with Multiple Myeloma

Justificación

No aportado

Objetivo Principal

Part 1: To identify RP2Ds for each treatment combination
Part 2: To characterize the safety of each RP2D for selected treatment combination(s)

Variables de Evaluación Primaria

Frequency and severity of dose-limiting toxicities
Frequency and severity of adverse events and serious adverse events

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

Documented initial diagnosis of multiple myeloma according to International Myeloma Working Group (IMWG) diagnostic criteria Must have either of the following: a) received at least 3 prior lines of therapy including a proteasome inhibitor (PI) (greater than or equal to [>=] 2 cycles or 2 months of treatment) and an immunomodulatory drug (IMiD) (>=2 cycles or 2 months of treatment) in any order during the treatment or b) disease that is double refractory to a PI and an IMiD Measurable disease at screening as defined by any of the following: Serum monoclonal protein (M-protein) level >=1.0 grams per deciliter (g/dL) (in non- immunoglobulin G (IgG) myeloma, an M-protein level >=0.5 g/dL); or Urine M-protein level >=200 milligrams (mg)/24 hours; or Light chain multiple myeloma: Serum immunoglobulin (Ig) free light chain (FLC) >=10 milligrams per deciliter (mg/dL) and abnormal

serum Ig kappa lambda FLC ratio order during the treatment Eastern Cooperative Oncology Group (ECOG) performance status grade of 0 or 1 at screening and at Cycle 1, Day 1 predose Female participants of childbearing potential must have a negative highly-sensitive serum beta-human chorionic gonadotropin (beta-hCG) pregnancy test (less than [<] 5 international units per milliliter [IU/mL]) at screening and a negative urine or serum pregnancy test within 1 day before the first dose of study drug

Criterios de Exclusión

Treatment in the prior 3 months with an anti- cluster of differentiation 38 (CD38) therapy (example, daratumumab), or discontinuation of a prior anti-CD38 therapy at any time due to an adverse event related to the anti-CD38 therapy
Live, attenuated vaccine within 4 weeks prior to the first dose of study drug unless approved by sponsor
Active Central nervous system involvement or exhibits clinical signs of meningeal involvement of multiple myeloma. If either is suspected, brain magnetic resonance imaging (MRI) and lumbar cytology are required
Seropositive for hepatitis B (defined by a positive test for hepatitis B surface antigen [HBsAg]). Participants with resolved infection must be screened using real-time polymerase chain reaction (PCR) measurement of hepatitis B virus (HBV) deoxyribonucleic acid (DNA) levels. Those who are PCR positive will be excluded
Active hepatitis C infection as measured by positive hepatitis C virus- ribonucleotide (HCV)-RNA testing. Participants with a history of Hepatitis C virus antibody positivity must undergo HCV-RNA testing

Calendario

(Última actualización: 01/09/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
27/09/2019	02/03/2020	03/03/2020	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
28/09/2022	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 (02/03/2020)

CLINICA UNIVERSIDAD DE NAVARRA

Pamplona/Iruña

NAVARRA

Cerrado (15/04/2026)

HOSPITAL CLÍNIC DE BARCELONA

Barcelona

BARCELONA

Activo (04/03/2020)

HOSPITAL UNIVERSITARI GERMANS TRIAS I PUJOL DE BADALONA

Badalona

BARCELONA

Activo (05/03/2020)

HOSPITAL UNIVERSITARIO DE SALAMANCA

Salamanca

SALAMANCA

Activo (17/04/2020)

HOSPITAL UNIVERSITARIO FUNDACIÓN JIMÉNEZ DÍAZ

Madrid

MADRID

Activo (02/07/2020)

Institut Catala D'oncologia

Hospitalet de Llobregat, L'

BARCELONA

Medicamentos

teclistamab
SOLUTION FOR INJECTION
SUBCUTANEOUS USE

-

Principios Activos: N/A

Experimental

JNJ-64407564
SOLUTION FOR INJECTION
SUBCUTANEOUS USE

-

Principios Activos: N/A

Huérfano

Experimental

Imnovid 3 mg hard capsules
CAPSULE, HARD
ORAL USE

Código ATC: L04AX06 - POMALIDOMIDA

Principios Activos: N/A

Experimental

Privigen 100 mg/ml solution for infusion
SOLUTION FOR INFUSION
INTRAVENOUS USE

Código ATC: J06BA02 - INMUNOGLOBULINAS HUMANAS NORMALES PARA ADM. INTRAVASCULAR

Principios Activos: N/A

Experimental

JNJ-64407564
SOLUTION FOR INJECTION
SUBCUTANEOUS USE

-

Principios Activos: N/A

Huérfano

Experimental

Imnovid 1 mg hard capsules
CAPSULE, HARD
ORAL USE

Código ATC: L04AX06 - POMALIDOMIDA

Principios Activos: N/A

Experimental

Imnovid 2 mg hard capsules
CAPSULE, HARD
ORAL USE

Código ATC: L04AX06 - POMALIDOMIDA

Principios Activos: N/A

Experimental

teclistamab
SOLUTION FOR INJECTION
SUBCUTANEOUS USE

-

Principios Activos: N/A

Experimental

Imnovid 4 mg hard capsules

CAPSULE, HARD
ORAL USE

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

Experimental

DARZALEX 1800 mg solution for injection

SOLUTION FOR INJECTION
SUBCUTANEOUS USE

Código ATC: L01FC01 - DARATUMUMAB
Principios Activos: N/A

Huérfano **Experimental**

Sin resultados

A Phase 1b Study of Subcutaneous Daratumumab Regimens in Combination with Bispecific T Cell Redirection Antibodies for the Treatment of Subjects with Multiple Myeloma

State	Type of participants	Age Ranges
End of recruitment	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase I	179
Results	**Low level of intervention**	**Rare disease**
No results	No	Yes
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness, pharmacokinetics, pharmacodynamics, dose	NO

Information

Identifier
2023-503468-17-00 (CTIS)

Protocol Code
64407564MMY1002

Transitioned 2019-000330-19

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

Investigated Disease
Multiple myeloma

Scientific Title
A Phase 1b Study of Subcutaneous Daratumumab Regimens in Combination with Bispecific T Cell Redirection Antibodies for the Treatment of Subjects with Multiple Myeloma

Rationale

Not provided

Main Objective

Part 1: To identify RP2Ds for each treatment combination
Part 2: To characterize the safety of each RP2D for selected treatment combination(s)

Primary Endpoints

Frequency and severity of dose-limiting toxicities
Frequency and severity of adverse events and serious adverse events

Temporary moments of secondary assessment

Not provided

Secondary Objective

Not provided

Secondary Endpoints

Not provided

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Documented initial diagnosis of multiple myeloma according to International Myeloma Working Group (IMWG) diagnostic criteria Must have either of the following: a) received at least 3 prior lines of therapy including a proteasome inhibitor (PI) (greater than or equal to [>=] 2 cycles or 2 months of treatment) and an immunomodulatory drug (IMiD) (>=2 cycles or 2 months of treatment) in any order during the treatment or b) disease that is double refractory to a PI and an IMiD Measurable disease at screening as defined by any of the following: Serum monoclonal protein (M-protein) level >=1.0 grams per deciliter (g/dL) (in non- immunoglobulin G (IgG) myeloma, an M-protein level >=0.5 g/dL); or Urine M-protein level >=200 milligrams (mg)/24 hours; or Light chain multiple myeloma: Serum immunoglobulin (Ig) free light chain (FLC) >=10 milligrams per deciliter (mg/dL) and abnormal

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Active hepatitis C infection as measured by positive hepatitis C virus- ribonucleotide (HCV)-RNA testing. Participants with a history of Hepatitis C virus antibody positivity must undergo HCV-RNA testing

Calendar

(Last Update: 01/09/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
27/09/2019	02/03/2020	03/03/2020	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
28/09/2022	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

CEIm de la Comunidad Foral de Navarra

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ceic@cfnavarra.es

Sites

Active (02/03/2020)

CLINICA UNIVERSIDAD DE NAVARRA

Pamplona/Iruña

NAVARRA

Closed (15/04/2026)

HOSPITAL CLÍNIC DE BARCELONA

Barcelona

BARCELONA

Active (04/03/2020)

HOSPITAL UNIVERSITARI GERMANS TRIAS I PUJOL DE BADALONA

Badalona

BARCELONA

Active (05/03/2020)

HOSPITAL UNIVERSITARIO DE SALAMANCA

Salamanca

SALAMANCA

Active (17/04/2020)

HOSPITAL UNIVERSITARIO FUNDACIÓN JIMÉNEZ DÍAZ

Madrid

MADRID

Active (02/07/2020)

Institut Catala D'oncologia

Hospitalet de Llobregat, L'

BARCELONA

Medication

teclistamab
SOLUTION FOR INJECTION
SUBCUTANEOUS USE

-

Active Principles: N/A

Experimental

JNJ-64407564
SOLUTION FOR INJECTION
SUBCUTANEOUS USE

-

Active Principles: N/A

Orphan

Experimental

Imnovid 3 mg hard capsules
CAPSULE, HARD
ORAL USE

ATC code: L04AX06 - POMALIDOMIDA

Active Principles: N/A

Experimental

Privigen 100 mg/ml solution for infusion
SOLUTION FOR INFUSION
INTRAVENOUS USE

ATC code: J06BA02 - INMUNOGLOBULINAS HUMANAS NORMALES PARA ADM. INTRAVASCULAR

Active Principles: N/A

Experimental

JNJ-64407564
SOLUTION FOR INJECTION
SUBCUTANEOUS USE

-

Active Principles: N/A

Orphan

Experimental

Imnovid 1 mg hard capsules
CAPSULE, HARD
ORAL USE

ATC code: L04AX06 - POMALIDOMIDA

Active Principles: N/A

Experimental

Imnovid 2 mg hard capsules
CAPSULE, HARD
ORAL USE

ATC code: L04AX06 - POMALIDOMIDA

Active Principles: N/A

Experimental

teclistamab
SOLUTION FOR INJECTION
SUBCUTANEOUS USE

-

Active Principles: N/A

Experimental

Imnovid 4 mg hard capsules

CAPSULE, HARD

ORAL USE

ATC code: L04AX06 - POMALIDOMIDA

Active Principles: N/A

Experimental

DARZALEX 1800 mg solution for injection

SOLUTION FOR INJECTION

SUBCUTANEOUS USE

ATC code: L01FC01 - DARATUMUMAB

Active Principles: N/A

Orphan **Experimental**

No results