A Randomized Study Comparing JNJ-68284528 versus Pomalidomide, Bortezomib and Dexamethasone (PVd) or Daratumumab, Pomalidomide and Dexamethasone (DPd) in Subjects with Relapsed and Lenalidomide-Refractory Multiple Myeloma

Estado	**Tipo de Participantes**	**Rangos de Edad**
Fin Reclutamiento	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	164
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	tratamiento, seguridad, eficacia, farmacocinética, farmacodinamica	NO

Información

Identificador
2023-506588-32-00 (CTIS)

Cod. Protocolo
68284528MMY3002

Transicionado 2019-001413-16

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

Enfermedad investigada
Relapsed and Lenalidomide-Refractory Multiple Myeloma

Título Científico
A Phase 3 Randomized Study Comparing JNJ-68284528, a Chimeric Antigen Receptor T cell (CAR-T) Therapy Directed Against BCMA, versus Pomalidomide, Bortezomib and Dexamethasone (PVd) or Daratumumab,

Pomalidomide and Dexamethasone (DPd) in Subjects with Relapsed and Lenalidomide-Refractory Multiple Myeloma CARTITUDE-4

Justificación

No aportado

Objetivo Principal

To compare the efficacy of cilta-cel with standard therapy, either PVd or DPd

Variables de Evaluación Primaria

Progression-free survival (PFS)

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

Be at least 18 years of age.
Have documented diagnosis of MM as defined by the criteria below:-Multiple myeloma diagnosis according to the IMWG diagnostic criteria -Measurable disease at screening
Have received 1 to 3 prior lines of therapy including a PI and IMiD. Subject must have undergone at least 1 complete cycle of treatment for each line of therapy, unless PD was the best response to the line of therapy
Have documented evidence of PD by IMWG criteria based on investigator's determination on or within 6 months of

their last regimen.
Subjects with only 1 prior line of therapy must have progressed within 36 months of a stem cell transplant or if not transplanted, then within 42 months of starting initial therapy.
Be refractory to lenalidomide per IMWG consensus guidelines in at least one prior line of therapy.
Have an ECOG Performance Status score of 0 or 1
Have clinical laboratory values as specified in the protocol. For additional information see section 5.1 of the protocol

Criterios de Exclusión

Prior treatment with CAR-T therapy directed at any target.
Stroke or seizure within 6 months of signing ICF.
Received either of the following:-An allogenic stem cell transplant within 6 months before apheresis. Subjects who received an allogeneic transplant must have stopped all immunosuppressive medications for 6 weeks without signs of graftversus-host disease. Subjects with active graft-versus-host disease are excluded.-An autologous stem cell transplantation 12 weeks before apheresis.
Known active, or prior history of central nervous system (CNS) involvement or exhibits clinical signs of meningeal involvement of MM. For additional information, see section 5.2 of the protocol
Any previous therapy that is targeted to BCMA.
Ongoing toxicity from previous anticancer therapy that has not resolved to baseline levels or to Grade 1 or less; except for alopecia.
Subjects with ongoing peripheral neuropathy may be limited to DPd as standard therapy or bridging therapy
Was vaccinated with live attenuated vaccines within 6 weeks prior to randomization
Subject received any antitumor therapy as specified in the protocol, prior to randomization
Active malignancies other than the disease being treated under study. Refer to the protocol for allowed exceptions.
Plasma cell leukemia at the time of screening, Waldenström's macroglobulinemia, POEMS syndrome (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, and skin changes), or primary AL amyloidosis.
Contraindications or life-threatening allergies, hypersensitivity, or intolerance to cilta-cel or its excipients, including dimethylsulfoxide, or to fludarabine, cyclophosphamide, tocilizumab, pomalidomide, dexamethasone.- Subjects with contraindications or life-threatening allergies, hypersensitivity, or intolerance to daratumumab will not be permitted to receive DPd as standard therapy or bridging therapy; however, subjects may receive PVd as standard therapy or bridging therapy. Likewise, subjects with contraindications or life-threatening allergies, hypersensitivity, or intolerance to bortezomib will not be permitted to receive PVd as standard therapy or bridging therapy; but may receive DPd as standard therapy or bridging therapy.

Calendario

(Última actualización: 29/06/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
24/01/2020	12/06/2020	30/06/2020	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
20/10/2021	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 (12/06/2020)

CLINICA UNIVERSIDAD DE NAVARRA

Pamplona/Iruña

NAVARRA

Activo (15/06/2020)

COMPLEJO ASISTENCIAL UNIVERSITARIO DE SALAMANCA

Salamanca

SALAMANCA

Activo (21/09/2020)

HOSPITAL CLÍNIC DE BARCELONA

Barcelona

BARCELONA

Activo (17/06/2021)

HOSPITAL GENERAL UNIVERSITARIO GREGORIO MARAÑON

Madrid

MADRID

Activo (01/07/2020)

HOSPITAL UNIVERSITARI GERMANS TRIAS I PUJOL DE BADALONA

Badalona

BARCELONA

Activo (06/07/2021)

Hospital Universitario Virgen Del Rocio

Sevilla

SEVILLA

Activo (04/08/2020)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

Medicamentos

Imnovid 2 mg hard capsules
CAPSULE, HARD
ORAL USE

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

-
-
INTRAVENOUS USE

Código ATC: L01BB05 - FLUDARABINA
Principios Activos: N/A
Experimental

Imnovid 3 mg hard capsules
CAPSULE, HARD
ORAL USE

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

Imnovid 2 mg hard capsules
CAPSULE, HARD
ORAL USE

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

DARZALEX 1800 mg solution for injection
SOLUTION FOR INJECTION
SUBCUTANEOUS USE

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

Pomalidomide
CAPSULE, HARD
ORAL USE

-
Principios Activos: N/A
Experimental

Imnovid 1 mg hard capsules
CAPSULE, HARD
ORAL USE

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

Dexamethasone Tablets BP 2.0mg
TABLET
ORAL USE

Código ATC: H02AB02 - DEXAMETASONA
Principios Activos: N/A
Experimental

Imnovid 4 mg hard capsules
CAPSULE, HARD
ORAL USE

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

Imnovid 4 mg hard capsules
CAPSULE, HARD
ORAL USE

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

CARVYKTI 3.2 × 10^6 1.0 × 10^8 cells dispersion for infusion
DISPERSION FOR INFUSION
INTRAVENOUS USE

Código ATC: L01XL05 - CILTACABTAGEN AUTOLEUCEL
Principios Activos: N/A
Huérfano Experimental

Pomalidomide
CAPSULE, HARD
ORAL USE

-
Principios Activos: N/A
Experimental

Pomalidomide
CAPSULE, HARD
ORAL USE

-
Principios Activos: N/A
Experimental

Pomalidomide
CAPSULE, HARD
ORAL USE

-
Principios Activos: N/A
Experimental

Imnovid 3 mg hard capsules
CAPSULE, HARD
ORAL USE

-
-
SUBCUTANEOUS USE

Código ATC: L04AX06 - POMALIDOMIDA
Principios Activos: N/A
Huérfano **Experimental**

Código ATC: L01XX32 - BORTEZOMIB
Principios Activos: N/A
Experimental

Imnovid 1 mg hard capsules
CAPSULE, HARD
ORAL USE

Código ATC: L04AX06 - POMALIDOMIDA
Principios Activos: N/A
Huérfano **Experimental**

Dexamethason 4 mg JENAPHARM®
TABLET
ORAL

Código ATC: H02AB02 - DEXAMETASONA
Principios Activos: N/A
Experimental

-
-
INTRAVENOUS USE

Código ATC: L01AA01 - CICLOFOSFAMIDA
Principios Activos: N/A
Experimental

Fortecortin® 2 mg Tabletten
TABLET
ORAL USE

Código ATC: H02AB02 - DEXAMETASONA
Principios Activos: N/A
Experimental

Sin resultados

A Randomized Study Comparing JNJ-68284528 versus Pomalidomide, Bortezomib and Dexamethasone (PVd) or Daratumumab, Pomalidomide and Dexamethasone (DPd) in Subjects with Relapsed and Lenalidomide-Refractory 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 III	164
Results	**Low level of intervention**	**Rare disease**
No results	No	Yes
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	treatment, safety, effectiveness, pharmacokinetics, pharmacodynamics	NO

Information

Identifier
2023-506588-32-00 (CTIS)

Protocol Code
68284528MMY3002

Transitioned 2019-001413-16

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

Investigated Disease
Relapsed and Lenalidomide-Refractory Multiple Myeloma

Scientific Title
A Phase 3 Randomized Study Comparing JNJ-68284528, a Chimeric Antigen Receptor T cell (CAR-T) Therapy Directed Against BCMA, versus Pomalidomide, Bortezomib and Dexamethasone (PVd) or Daratumumab,

Pomalidomide and Dexamethasone (DPd) in Subjects with Relapsed and Lenalidomide-Refractory Multiple Myeloma CARTITUDE-4

Rationale

Not provided

Main Objective

To compare the efficacy of cilta-cel with standard therapy, either PVd or DPd

Primary Endpoints

Progression-free survival (PFS)

Temporary moments of secondary assessment

Not provided

Secondary Objective

Not provided

Secondary Endpoints

Not provided

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Be at least 18 years of age.
Have documented diagnosis of MM as defined by the criteria below:-Multiple myeloma diagnosis according to the IMWG diagnostic criteria -Measurable disease at screening
Have received 1 to 3 prior lines of therapy including a PI and IMiD. Subject must have undergone at least 1 complete cycle of treatment for each line of therapy, unless PD was the best response to the line of therapy
Have documented evidence of PD by IMWG criteria based on investigator's determination on or within 6 months of

their last regimen.
Subjects with only 1 prior line of therapy must have progressed within 36 months of a stem cell transplant or if not transplanted, then within 42 months of starting initial therapy.
Be refractory to lenalidomide per IMWG consensus guidelines in at least one prior line of therapy.
Have an ECOG Performance Status score of 0 or 1
Have clinical laboratory values as specified in the protocol. For additional information see section 5.1 of the protocol

Exclusion criteria

Prior treatment with CAR-T therapy directed at any target.
Stroke or seizure within 6 months of signing ICF.
Received either of the following:-An allogenic stem cell transplant within 6 months before apheresis. Subjects who received an allogeneic transplant must have stopped all immunosuppressive medications for 6 weeks without signs of graftversus-host disease. Subjects with active graft-versus-host disease are excluded.-An autologous stem cell transplantation 12 weeks before apheresis.
Known active, or prior history of central nervous system (CNS) involvement or exhibits clinical signs of meningeal involvement of MM. For additional information, see section 5.2 of the protocol
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Active malignancies other than the disease being treated under study. Refer to the protocol for allowed exceptions.
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Contraindications or life-threatening allergies, hypersensitivity, or intolerance to cilta-cel or its excipients, including dimethylsulfoxide, or to fludarabine, cyclophosphamide, tocilizumab, pomalidomide, dexamethasone.- Subjects with contraindications or life-threatening allergies, hypersensitivity, or intolerance to daratumumab will not be permitted to receive DPd as standard therapy or bridging therapy; however, subjects may receive PVd as standard therapy or bridging therapy. Likewise, subjects with contraindications or life-threatening allergies, hypersensitivity, or intolerance to bortezomib will not be permitted to receive PVd as standard therapy or bridging therapy; but may receive DPd as standard therapy or bridging therapy.

Calendar

(Last Update: 29/06/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
24/01/2020	12/06/2020	30/06/2020	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
20/10/2021	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

C/ Irunlarrea, 3 31008 Pamplona

ceic@cfnavarra.es

Sites

Active (12/06/2020)

CLINICA UNIVERSIDAD DE NAVARRA

Pamplona/Iruña

NAVARRA

Active (15/06/2020)

COMPLEJO ASISTENCIAL UNIVERSITARIO DE SALAMANCA

Salamanca

SALAMANCA

Active (21/09/2020)

HOSPITAL CLÍNIC DE BARCELONA

Barcelona

BARCELONA

Active (17/06/2021)

HOSPITAL GENERAL UNIVERSITARIO GREGORIO MARAÑON

Madrid

MADRID

Active (01/07/2020)

HOSPITAL UNIVERSITARI GERMANS TRIAS I PUJOL DE BADALONA

Badalona

BARCELONA

Active (06/07/2021)

Hospital Universitario Virgen Del Rocio

Sevilla

SEVILLA

Active (04/08/2020)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

Medication

Imnovid 2 mg hard capsules
CAPSULE, HARD
ORAL USE

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

-
-
INTRAVENOUS USE

ATC code: L01BB05 - FLUDARABINA
Active Principles: N/A
Experimental

Imnovid 3 mg hard capsules
CAPSULE, HARD
ORAL USE

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

Imnovid 2 mg hard capsules
CAPSULE, HARD
ORAL USE

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

DARZALEX 1800 mg solution for injection
SOLUTION FOR INJECTION
SUBCUTANEOUS USE

ATC code: L01FC01 - DARATUMUMAB
Active Principles: N/A
Orphan Experimental

Pomalidomide
CAPSULE, HARD
ORAL USE

-
Active Principles: N/A
Experimental

Imnovid 1 mg hard capsules
CAPSULE, HARD
ORAL USE

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

Dexamethasone Tablets BP 2.0mg
TABLET
ORAL USE

ATC code: H02AB02 - DEXAMETASONA
Active Principles: N/A
Experimental

Imnovid 4 mg hard capsules
CAPSULE, HARD
ORAL USE

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

Imnovid 4 mg hard capsules
CAPSULE, HARD
ORAL USE

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

CARVYKTI 3.2 × 10^6 1.0 × 10^8 cells dispersion for infusion
DISPERSION FOR INFUSION
INTRAVENOUS USE

ATC code: L01XL05 - CILTACABTAGEN AUTOLEUCEL
Active Principles: N/A
Orphan Experimental

Pomalidomide
CAPSULE, HARD
ORAL USE

-
Active Principles: N/A
Experimental

Pomalidomide
CAPSULE, HARD
ORAL USE

-
Active Principles: N/A
Experimental

Pomalidomide
CAPSULE, HARD
ORAL USE

-
Active Principles: N/A
Experimental

Imnovid 3 mg hard capsules
CAPSULE, HARD
ORAL USE

-
-
SUBCUTANEOUS USE

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

ATC code: L01XX32 - BORTEZOMIB
Active Principles: N/A
Experimental

Imnovid 1 mg hard capsules
CAPSULE, HARD
ORAL USE

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

Dexamethason 4 mg JENAPHARM®
TABLET
ORAL

ATC code: H02AB02 - DEXAMETASONA
Active Principles: N/A
Experimental

-
-
INTRAVENOUS USE

ATC code: L01AA01 - CICLOFOSFAMIDA
Active Principles: N/A
Experimental

Fortecortin® 2 mg Tabletten
TABLET
ORAL USE

ATC code: H02AB02 - DEXAMETASONA
Active Principles: N/A
Experimental

No results