A Phase 2 Multicohort Trial to Further Characterize the Efficacy and Safety of Ciltacabtagene Autoleucel

Estado	Tipo de Participantes	Rangos de Edad
Reclutando	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase II	32
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia, farmacocinética, dosis	Terapia génica

Información

Identificador
2025-521975-30-00 (CTIS)

Cod. Protocolo
68284528MMY2012

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

Enfermedad investigada
Newly Diagnosed Multiple Myeloma

Título Científico
A Phase 2 Multicohort Trial to Further Characterize the Efficacy and Safety of Ciltacabtagene Autoleucel

Justificación

No aportado

Objetivo Principal

To characterize the efficacy of cilta-cel infusion following a fludarabine free LD regimen (Cohort A) or a low-dose cilta-cel infusion following a standard cyclophosphamide and fludarabine LD regimen (Cohort B)

Variables de Evaluación Primaria

MRD-negative CR at 12 months after cilta-cel infusion with a sensitivity of 10^-5

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. At the time of informed consent, be 18 years of age (or at least the legal age of consent in the jurisdiction in which the study is taking place) but 80 years of age.
2. Documented diagnosis of NDMM according to the most recent IMWG diagnostic criteria and measurable disease at diagnosis (prior to start of any anti-myeloma therapy)
3. Not considered a candidate for high-dose chemotherapy with stem cell transplantation due to: -Advanced age; or -Presence of comorbid condition(s) likely to have a negative impact on tolerability of high-dose chemotherapy with stem cell transplantation; or -Participant refusal of high-dose chemotherapy with stem cell transplantation as initial treatment.

4. Participant must have received induction therapy. Initially, only participants receiving triplet induction therapy with DRd or VRd will be enrolled. Only after sponsor notification, participants receiving quadruplet DVRd induction therapy may be enrolled.Participants must have achieved PR to be enrolled on the most recent disease assessment.
5. ECOG Performance Status score of 0 or 1
6. Clinical laboratory values as defined in the protocol

Criterios de Exclusión

1. Prior systemic therapy for multiple myeloma or smoldering myeloma other than VRd, DRd or DVRd as per inclusion 4a and short course of corticosteroids . For participants who require emergency treatment, refer to protocol Section 4.4. 2. Radiation therapy for treatment of plasmacytoma within 14 days before enrollment. Palliative radiation for pain control secondary to lytic lesion is allowed within 14 days of enrollment, if the radiation portal covered 5% of the bone marrow reserve 3. Frailty index of 2 according to Myeloma Geriatric Assessment score 4. The following cardiac conditions: - New York Heart Association stage III or IV congestive heart failure. - Myocardial infarction or coronary artery bypass graft 6 months prior to enrollment. - History of clinically significant ventricular arrhythmia or unexplained syncope, not believed to be vasovagal in nature or due to dehydration. - History of severe non-ischemic cardiomyopathy. - Impaired cardiac function (LVEF <45%) as assessed by echocardiogram or multiple-gated acquisition scan (performed 60 days prior to apheresis). 5. Grade 2 or higher ongoing non-hematologic toxicity due to induction therapy, with the exception of grade 2 peripheral neuropathy due to bortezomib. 6. Participants who require continuous supplemental oxygen.

Calendario

(Última actualización: 24/07/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
20/08/2025	03/10/2025	03/10/2025	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

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 Cantabria

Edificio IFIMAV 3ª Planta Avda Cardenal Herrera Oria s/n 39011 Santander

ceim@idival.org

942315514

Centros

Activo (01/09/2025)

Clinica Universidad De Navarra

Pamplona

NAVARRA

Hematologia

Activo (29/08/2025)

Hospital Clinic De Barcelona

Barcelona

BARCELONA

Hematologia

Activo (23/01/2026)

Hospital Germans Trias I Pujol

Badalona

BARCELONA

Hematologia

Activo (25/02/2026)

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Hematologia

Activo (28/08/2025)

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Hematologia

Activo (30/09/2025)

Hospital Universitario Marques De Valdecilla

Santander

CANTABRIA

Hematologia

Activo (27/08/2025)

Hospital Universitario 12 De Octubre

Madrid

MADRID

Hematologia

Activo (30/09/2025)

University Hospital Virgen Del Rocio S.L.

Sevilla

SEVILLA

Hematologia

Medicamentos

JNJ-68284528
DISPERSION FOR INFUSION
INTRAVENOUS USE

-
Principios Activos: N/A
Huérfano Experimental

CARVYKTI 3.2 × 10^6 1 × 10^8 cells dispersion for infusion
DISPERSION FOR INFUSION
INTRAVENOUS USE

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

Sin resultados

A Phase 2 Multicohort Trial to Further Characterize the Efficacy and Safety of Ciltacabtagene Autoleucel

State	Type of participants	Age Ranges
Recruiting	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase II	32
Results	**Low level of intervention**	**Rare disease**
No results	No	Yes
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness, pharmacokinetics, dose	Gene therapy

Information

Identifier
2025-521975-30-00 (CTIS)

Protocol Code
68284528MMY2012

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

Investigated Disease
Newly Diagnosed Multiple Myeloma

Scientific Title
A Phase 2 Multicohort Trial to Further Characterize the Efficacy and Safety of Ciltacabtagene Autoleucel

Rationale

Not provided

Main Objective

To characterize the efficacy of cilta-cel infusion following a fludarabine free LD regimen (Cohort A) or a low-dose cilta-cel infusion following a standard cyclophosphamide and fludarabine LD regimen (Cohort B)

Primary Endpoints

MRD-negative CR at 12 months after cilta-cel infusion with a sensitivity of 10^-5

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. At the time of informed consent, be 18 years of age (or at least the legal age of consent in the jurisdiction in which the study is taking place) but 80 years of age.
2. Documented diagnosis of NDMM according to the most recent IMWG diagnostic criteria and measurable disease at diagnosis (prior to start of any anti-myeloma therapy)
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5. ECOG Performance Status score of 0 or 1
6. Clinical laboratory values as defined in the protocol

Exclusion criteria

1. Prior systemic therapy for multiple myeloma or smoldering myeloma other than VRd, DRd or DVRd as per inclusion 4a and short course of corticosteroids . For participants who require emergency treatment, refer to protocol Section 4.4. 2. Radiation therapy for treatment of plasmacytoma within 14 days before enrollment. Palliative radiation for pain control secondary to lytic lesion is allowed within 14 days of enrollment, if the radiation portal covered 5% of the bone marrow reserve 3. Frailty index of 2 according to Myeloma Geriatric Assessment score 4. The following cardiac conditions: - New York Heart Association stage III or IV congestive heart failure. - Myocardial infarction or coronary artery bypass graft 6 months prior to enrollment. - History of clinically significant ventricular arrhythmia or unexplained syncope, not believed to be vasovagal in nature or due to dehydration. - History of severe non-ischemic cardiomyopathy. - Impaired cardiac function (LVEF <45%) as assessed by echocardiogram or multiple-gated acquisition scan (performed 60 days prior to apheresis). 5. Grade 2 or higher ongoing non-hematologic toxicity due to induction therapy, with the exception of grade 2 peripheral neuropathy due to bortezomib. 6. Participants who require continuous supplemental oxygen.

Calendar

(Last Update: 24/07/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
20/08/2025	03/10/2025	03/10/2025	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

Janssen Cilag International Belgium

Turnhoutseweg 30

Contact Person

CTIS Point of Contact

+31717996133

CTISadmin@its.jnj.com

Monetary support: N/A

Sponsor type: Commercial

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Sites

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Hospital Clinic De Barcelona

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Hospital Germans Trias I Pujol

Badalona

BARCELONA

Hematologia

Active (25/02/2026)

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Hematologia

Active (28/08/2025)

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Hematologia

Active (30/09/2025)

Hospital Universitario Marques De Valdecilla

Santander

CANTABRIA

Hematologia

Active (27/08/2025)

Hospital Universitario 12 De Octubre

Madrid

MADRID

Hematologia

Active (30/09/2025)

University Hospital Virgen Del Rocio S.L.

Sevilla

SEVILLA

Hematologia

Medication

JNJ-68284528
DISPERSION FOR INFUSION
INTRAVENOUS USE

-

Active Principles: N/A

Orphan Experimental

CARVYKTI 3.2 × 10^6 1 × 10^8 cells dispersion for infusion
DISPERSION FOR INFUSION
INTRAVENOUS USE

ATC code: L01XL05 - CILTACABTAGEN AUTOLEUCEL

Active Principles: N/A

Orphan Experimental

No results