A study to compare Efficacy, Safety and How the Body Absorbs, Distributes, and Eliminates of Subcutaneous CT-P44 and Darzalex Faspro in Combination with Lenalidomide and Dexamethasone in Patients with Refractory or Relapsed Multiple Myeloma

Estado	Tipo de Participantes	Rangos de Edad
Reclutando	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	444
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia, farmacocinética, bioequivalencia	NO

Información

Identificador
2024-518588-36-00 (CTIS)

Cod. Protocolo
CT-P44 3.1

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

Enfermedad investigada
Refractory or Relapsed Multiple Myeloma

Título Científico
A Double-Blind, Randomized, Active Controlled, Parallel-group, Phase 1/3 Study to Compare Pharmacokinetics, Efficacy and Safety of Subcutaneous CT-P44 and Darzalex Faspro in Combination with Lenalidomide and Dexamethasone in Patients with Refractory or Relapsed Multiple Myeloma

Justificación

No aportado

Objetivo Principal

The primary objective of this study is to demonstrate the PK similarity of CT-P44 and Darzalex Faspro in the PK Group and therapeutic equivalence of CT-P44 and Darzalex Faspro in the Main Study Group. All patients in the PK Group and non-PK Group will be included in the Main Study Group. The PK equivalence of CT-P44 and Darzalex Faspro will be demonstrated in terms of area under the concentration-time curve from Week 0 to Week 1 (AUCWeek0-1) and area under the concentration-time curve from Week 8 to Week 10 (AUCWeek8-10) of daratumumab in the PK setPK Group at 1st dose, and PK setPK Group up to 9th doses, respectively. The therapeutic equivalence of CT-P44 and Darzalex Faspro will be demonstrated in terms of proportion of patients who will achieve very good partial response (VGPR) or better based on the confirmed best overall response (BOR) up to Week 24 from the last patients randomization according to the IMWG criteria in the intent-to-treat (ITT) set.

Variables de Evaluación Primaria

AUCWeek0-1 and AUCWeek8-10 of daratumumab in the PK setPK Group at 1st dose, and PK setPK Group up to 9th doses, respectively.
Very good partial response (VGPR) or better based on the confirmed best overall response (BOR) up to Week 24 from the last patients randomization according to the IMWG criteria in the intent-to-treat (ITT) set.

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

[PK Group] 1. The secondary PK objective of this study is to evaluate the PK profudyile in terms of Cmax at the 1st and 9th doses of daratumumab.
[Main Study Group] 1. The secondary efficacy objective of this study is to evaluate additional efficacy profiles of CT-P44 and Darzalex Faspro in terms of proportion of patients who will achieve VGPR or better (sCR + CR + VGPR), overall response rate (ORR), MRD negativity rate, time-to-event analysis including PFS, TTP, DoR, and OS, and EORTC QLQ-C30.
[Main Study Group] 2. The secondary PK objective of this study is to evaluate the PK profile in terms of Ctrough of daratumumab.
[Main Study Group] 3. The secondary immunogenicity objective of this study is to evaluate immunogenicity profiles in terms of incidence of ADA and neutralizing antibody and titer of ADA of daratumumab and rHuPH20 for CT-P44 and Darzalex Faspro treatment groups.
[Main Study Group] 4. The secondary safety objective of this study is to evaluate safety profiles in terms of AEs (including SAEs), AESIs, vital signs and weight, ECG, Physical examination findings, serum or urine pregnancy testing, clinical laboratory (hematology, chemistry and urinalysis), ECOG PS, prior and concomitant medications.

Variables de Evaluación Secundaria

No aportado

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Male or female with 18 years of age or older.
Patient must have documented multiple myeloma (MM).
Patient must have a documented relapsed or refractory disease.
Patient must have achieved a response (PR or better based on investigators determination of response by the IMWG criteria) to at least one prior regimen.
Patient must have a PD as defined by the IMWG criteria on or after their last line of therapy.
Patient must have received at least 1, but maximum 3 prior lines of therapy for MM.

Criterios de Exclusión

Patient has received daratumumab or any other drug specifically targeting CD38 previously.
Patients disease shows evidence of refractoriness or intolerance to lenalidomide. If previously treated with a lenalidomide-containing regimen, the patient is excluded if he or she: a)Discontinued due to any AEs related to prior lenalidomide treatment, or b)If, at any time point, the patient was refractory to any dose of lenalidomide.
Patient has received a prior treatment with one or more of the followings: a)Approved anti-myeloma agents within 14 days or 5 PK half-lives of the treatment, whichever is longer, before the date of randomization. Note. The only exception is emergency use of a short course of corticosteroids (equivalent of dexamethasone 40 mg/day for a maximum 4 days) before Day 1 of Cycle 1. b)Current or recent treatment (within 28 days before randomization or 5 half-lives, whichever is longer) with any other investigational medicinal product or device. c)Radiation therapy within 14 days of randomization. Patients must have recovered from all radiation-related toxicities. d)Plasmapheresis within 28 days of randomization. e)Live or live-attenuated vaccine, or all coronavirus disease-19 (COVID-19) vaccines within 14 days prior to randomization.
Patient has received ASCT within 12 weeks before the date of randomization, or the patients immune system has not sufficiently recovered after ASCT under the investigator's judgment.
Patient has previously received an allogenic stem cell transplant regardless of timing.

Calendario

(Última actualización: 25/08/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
27/08/2025	13/05/2026	19/08/2026	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

Celltrion Inc. Korea, Republic of

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Contact Person

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Monetary support: N/A

Tipo de promotor: Comercial

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915867007

Centros

No iniciado (--/--/----)

Hospital Moncloa Grupo Hla S.A.

Madrid

MADRID

Oncología

Activo (13/05/2026)

Hospital Universitario Virgen De La Macarena

Sevilla

SEVILLA

Oncología

No iniciado (--/--/----)

Institut Catala D'oncologia

Badalona

BARCELONA

Oncología

Medicamentos

DEXAMETHASONE SODIUM PHOSPHATE
SOLUTION FOR INJECTION
INTRAVENOUS

-
Principios Activos: N/A
Experimental

DARATUMUMAB
SOLUTION FOR INJECTION
SUBCUTANEOUS INJECTION

-
Principios Activos: N/A
Experimental

Daratumumab
SOLUTION FOR INJECTION
SUBCUTANEOUS INJECTION

-
Principios Activos: N/A
Experimental

DEXAMETHASONE
TABLET
ORAL

-
Principios Activos: N/A
Experimental

LENALIDOMIDE
HARD CAPSULES
ORAL

-
Principios Activos: N/A
Experimental

Sin resultados

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State	**Type of participants**	**Age Ranges**
Recruiting	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	444
Results	**Low level of intervention**	**Rare disease**
No results	No	Yes
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness, pharmacokinetics, bioequivalence	NO

Information

Identifier
2024-518588-36-00 (CTIS)

Protocol Code
CT-P44 3.1

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

Investigated Disease
Refractory or Relapsed Multiple Myeloma

Scientific Title
A Double-Blind, Randomized, Active Controlled, Parallel-group, Phase 1/3 Study to Compare Pharmacokinetics, Efficacy and Safety of Subcutaneous CT-P44 and Darzalex Faspro in Combination with Lenalidomide and Dexamethasone in Patients with Refractory or Relapsed Multiple Myeloma

Rationale

Not provided

Main Objective

The primary objective of this study is to demonstrate the PK similarity of CT-P44 and Darzalex Faspro in the PK Group and therapeutic equivalence of CT-P44 and Darzalex Faspro in the Main Study Group. All patients in the PK Group and non-PK Group will be included in the Main Study Group. The PK equivalence of CT-P44 and Darzalex Faspro will be demonstrated in terms of area under the concentration-time curve from Week 0 to Week 1 (AUCWeek0-1) and area under the concentration-time curve from Week 8 to Week 10 (AUCWeek8-10) of daratumumab in the PK setPK Group at 1st dose, and PK setPK Group up to 9th doses, respectively. The therapeutic equivalence of CT-P44 and Darzalex Faspro will be demonstrated in terms of proportion of patients who will achieve very good partial response (VGPR) or better based on the confirmed best overall response (BOR) up to Week 24 from the last patients randomization according to the IMWG criteria in the intent-to-treat (ITT) set.

Primary Endpoints

AUCWeek0-1 and AUCWeek8-10 of daratumumab in the PK setPK Group at 1st dose, and PK setPK Group up to 9th doses, respectively.
Very good partial response (VGPR) or better based on the confirmed best overall response (BOR) up to Week 24 from the last patients randomization according to the IMWG criteria in the intent-to-treat (ITT) set.

Temporary moments of secondary assessment

Not provided

Secondary Objective

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[Main Study Group] 1. The secondary efficacy objective of this study is to evaluate additional efficacy profiles of CT-P44 and Darzalex Faspro in terms of proportion of patients who will achieve VGPR or better (sCR + CR + VGPR), overall response rate (ORR), MRD negativity rate, time-to-event analysis including PFS, TTP, DoR, and OS, and EORTC QLQ-C30.
[Main Study Group] 2. The secondary PK objective of this study is to evaluate the PK profile in terms of Ctrough of daratumumab.
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Secondary Endpoints

Not provided

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Male or female with 18 years of age or older.
Patient must have documented multiple myeloma (MM).
Patient must have a documented relapsed or refractory disease.
Patient must have achieved a response (PR or better based on investigators determination of response by the IMWG criteria) to at least one prior regimen.
Patient must have a PD as defined by the IMWG criteria on or after their last line of therapy.
Patient must have received at least 1, but maximum 3 prior lines of therapy for MM.

Exclusion criteria

Patient has received daratumumab or any other drug specifically targeting CD38 previously.
Patients disease shows evidence of refractoriness or intolerance to lenalidomide. If previously treated with a lenalidomide-containing regimen, the patient is excluded if he or she: a)Discontinued due to any AEs related to prior lenalidomide treatment, or b)If, at any time point, the patient was refractory to any dose of lenalidomide.
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Patient has received ASCT within 12 weeks before the date of randomization, or the patients immune system has not sufficiently recovered after ASCT under the investigator's judgment.
Patient has previously received an allogenic stem cell transplant regardless of timing.

Calendar

(Last Update: 25/08/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
27/08/2025	13/05/2026	19/08/2026	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

Celltrion Inc. Korea, Republic of

23 Academy-RoYeonsu-Gu

Contact Person

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Monetary support: N/A

Sponsor type: Commercial

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Sites

not initialized (--/--/----)

Hospital Moncloa Grupo Hla S.A.

Madrid

MADRID

Oncología

Active (13/05/2026)

Hospital Universitario Virgen De La Macarena

Sevilla

SEVILLA

Oncología

not initialized (--/--/----)

Institut Catala D'oncologia

Badalona

BARCELONA

Oncología

Medication

DEXAMETHASONE SODIUM PHOSPHATE
SOLUTION FOR INJECTION
INTRAVENOUS

-
Active Principles: N/A
Experimental

DARATUMUMAB
SOLUTION FOR INJECTION
SUBCUTANEOUS INJECTION

-
Active Principles: N/A
Experimental

Daratumumab
SOLUTION FOR INJECTION
SUBCUTANEOUS INJECTION

-
Active Principles: N/A
Experimental

DEXAMETHASONE
TABLET
ORAL

-
Active Principles: N/A
Experimental

LENALIDOMIDE
HARD CAPSULES
ORAL

-
Active Principles: N/A
Experimental

No results