

Study of Brexucabtagene Autoleucel (KTE-X19) in Participants With Relapsed/Refractory Mantle Cell Lymphoma (Cohort 3) (ZUMA-2)

Estado
EC Finalizado

Tipo de Participantes
No aportado

Rangos de Edad
Mayores de 64 , Adultos (18-64 años)

Género
Ambos

Fases
Fase II

Participantes esperados
183

Resultados
Tiene resultados

Bajo nivel intervención
No

Enfermedad rara
No

Cobertura geográfica
Multicéntrico internacional

Ámbitos del ensayo
seguridad, eficacia

Terapia avanzada
Terapia génica

Información

Identificador
2023-506641-35-00 (CTIS)

Cod. Protocolo
KTE-C19-102

Transicionado 2015-005008-27

Área terapéutica
Enfermedades [C] - Cáncer [C04]

Enfermedad investigada
Relapsed/Refractory Mantle Cell Lymphoma

Título Científico
A Phase 2 Multicenter Study Evaluating the Efficacy of KTE-X19 in Subjects with Relapsed/Refractory Mantle Cell Lymphoma (ZUMA-2)

Justificación

No aportado

Objetivo Principal

To evaluate the efficacy of KTE-X19, as measured by objective response rate (ORR), in subjects with r/r MCL

Variables de Evaluación Primaria

ORR (complete response [CR] + partial response [PR]) per the Lugano Classification per Independent Radiology Review Committee (IRRC) review

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To assess the safety and tolerability of KTE-X19

Patient-reported outcomes (PROs) in Cohort 1 and Cohort 2 will include change in the European Quality of Life-5 Dimensions (EQ-5D) scores from baseline to Month 6

PROs in Cohort 3 will include change in EQ-5D and European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC-QLQ-C30) scores from baseline over time.

Variables de Evaluación Secundaria

DOR

Best objective response (BOR)

ORR as determined by study investigators

Progression-free survival

Overall survival

Incidence of adverse events (AEs) and clinically significant changes in laboratory values

Incidence of anti-CD19 CAR antibodies

Levels of anti-CD19 CAR T cells in blood

Levels of cytokines in serum

Changes over time in the EQ-5D scale score and visual analogue scale score

Changes over time in the EORTC-QLQ-C30 score (Cohort 3 only)

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Up to 5 prior regimens for MCL. Prior therapy must have included anthracycline- or bendamustine-containing chemotherapy and anti-CD20 monoclonal antibody therapy. Individuals must not have received prior therapy with a BTKi. At least 1 measurable lesion Platelet count 75,000/uL Creatinine clearance (as estimated by Cockcroft Gault) to 60 cc/min Cardiac ejection fraction 50%, no evidence of pericardial effusion as determined by an echocardiogram (ECHO) or multigated acquisition (MUGA), and no clinically significant electrocardiogram (ECG) findings Baseline oxygen saturation > 92% on room air

Criterios de Exclusión

Known history of infection with human immunodeficiency virus (HIV) or hepatitis B (HBsAG positive) or hepatitis C virus (anti-HCV positive). Individuals with a history of hepatitis infection must have cleared their infection as determined by standard serological and genetic testing

History of a seizure disorder, cerebrovascular ischemia/hemorrhage, dementia, cerebellar disease, cerebral edema, posterior reversible encephalopathy syndrome, or any autoimmune disease with central nervous system (CNS) involvement

Presence of fungal, bacterial, viral, or other infection that is uncontrolled or requiring IV antimicrobials for management Note: Other protocol defined Inclusion/Exclusion criteria may apply.

Calendario

(Última actualización: 08/10/2025)

Autorización 25/05/2021	Inicio de Ensayo 05/11/2021	Inclusión Primer Paciente 23/12/2021	Interrumpido No aportado	Reiniciado No aportado
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Fin de reclutamiento 19/04/2023	Fin prematuro (España) No aportado	Fin prematuro (Global) No aportado	Fin del ensayo en España No aportado	Fin del ensayo global 18/06/2025
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Promotor

Kite Pharma Inc. United States

2400 Broadway

Contact Person

EU CT Support

+441223897300

clinical.trials@gilead.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Hospital Universitario La Paz

Paseo de la Castellana, 261 28046 Madrid

ceic.hulp@salud.madrid.org

917277413

Centros

Cerrado (08/10/2025)	HOSPITAL CLINIC DE BARCELONA Barcelona BARCELONA	Hospital Clinic De Barcelona Barcelona BARCELONA Oncology
No iniciado (25/05/2021)	HOSPITAL CLINICO UNIVERSITARIO DE SALAMANCA (COMPLEJO ASISTENCIAL UNIV.SA) Salamanca SALAMANCA	Hospital Universitari Vall D Hebron Barcelona BARCELONA Oncology
No iniciado (25/05/2021)	HOSPITAL UNIVERSITARI VALL D'HEBRON Barcelona BARCELONA	Hospital Universitario De Salamanca Salamanca SALAMANCA Oncology

Medicamentos

IMBRUVICA 140 mg hard capsules

CAPSULE, HARD
ORAL

Código ATC: L01EL01 - IBRUTINIB

Principios Activos: N/A

Experimental

Calquence 100 mg hard capsules

CAPSULE, HARD
ORAL

Código ATC: L01EL02 - ACALABRUTINIB

Principios Activos: N/A

Experimental

Cyclophosphamide 500 mg Powder for Solution for Injection or Infusion

SOLUTION FOR INJECTION/INFUSION
INTRAVENIOUS INFUSION

Código ATC: L01AA01 - CICLOFOSFAMIDA

Principios Activos: N/A

Experimental

Fludarabine phosphate 25 mg/ml Concentrate for Solution for Injection or Infusion

SOLUTION FOR INJECTION/INFUSION
INTRAVENIOUS INFUSION

Código ATC: L01BB05 - FLUDARABINA

Principios Activos: N/A

Experimental

Panadol 500 mg Film Coated Tablets

TABLET
ORAL

Código ATC: N02BE01 - PARACETAMOL

Principios Activos: N/A

Experimental

Methylprednisolone 1000 mg powder and solvent for solution for injection/infusion

SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS USE

Código ATC: H02AB04 - METILPREDNISOLONA

Principios Activos: N/A

Experimental

RoActemra 20 mg/mL concentrate for solution for infusion

SOLUTION FOR INFUSION
INTRAVENIOUS INFUSION

Código ATC: L04AC07 - TOCILIZUMAB

Principios Activos: N/A

Experimental

Histergan Tablets

COATED TABLET
ORAL AND IV

Código ATC: R06AA02 - DIFENHIDRAMINA

Principios Activos: N/A

Experimental

Mesna Injection

SOLUTION FOR INJECTION

INTRAVENOUS INJECTION

Código ATC: V03AF01 - MESNA

Principios Activos: N/A

Experimental

Tecartus 0.4 - 2 x 10e8 cells dispersion for infusion

DISPERSION FOR INFUSION

INTRAVENIOUS INFUSION

Código ATC: L01XL06 - BREXUCABTAGEN AUTOLEUCEL

Principios Activos: N/A

Huérfano

Experimental

Cytarabine 20 mg/ml Solution for Injection or Infusion

SOLUTION FOR INJECTION/INFUSION

INTRAVENIOUS INFUSION

Código ATC: L01BC01 - CITARABINA

Principios Activos: N/A

Experimental

Dexamethasone 4 mg tablets

TABLET

ORAL AND IV

Código ATC: H02AB02 - DEXAMETASONA

Principios Activos: N/A

Experimental

Tiene resultados

Study of Brexucabtagene Autoleucel (KTE-X19) in Participants With Relapsed/Refractory Mantle Cell Lymphoma (Cohort 3) (ZUMA-2)

State
Finished CT

Type of participants
Not provided

Age Ranges
Older than 64 , Adults (18-64 years)

Gender
Both

Phases
Phase II

Expected Participants
183

Results
Has results

Low level of intervention
No

Rare disease
No

Geographic coverage
International multicenter

Areas of the study
safety, effectiveness

Advanced therapy
Gene therapy

Information

Identifier
2023-506641-35-00 (CTIS)

Protocol Code
KTE-C19-102

Transitioned 2015-005008-27

Therapeutic area
Diseases [C] - Cancer [C04]

Investigated Disease
Relapsed/Refractory Mantle Cell Lymphoma

Scientific Title
A Phase 2 Multicenter Study Evaluating the Efficacy of KTE-X19 in Subjects with Relapsed/Refractory Mantle Cell Lymphoma (ZUMA-2)

Rationale

Not provided

Main Objective

To evaluate the efficacy of KTE-X19, as measured by objective response rate (ORR), in subjects with r/r MCL

Primary Endpoints

ORR (complete response [CR] + partial response [PR]) per the Lugano Classification per Independent Radiology Review Committee (IRRC) review

Temporary moments of secondary assessment

Not provided

Secondary Objective

To assess the safety and tolerability of KTE-X19

Patient-reported outcomes (PROs) in Cohort 1 and Cohort 2 will include change in the European Quality of Life-5 Dimensions (EQ-5D) scores from baseline to Month 6

PROs in Cohort 3 will include change in EQ-5D and European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC-QLQ-C30) scores from baseline over time.

Secondary Endpoints

DOR

Best objective response (BOR)

ORR as determined by study investigators

Progression-free survival

Overall survival

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Incidence of anti-CD19 CAR antibodies

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Levels of cytokines in serum

Changes over time in the EQ-5D scale score and visual analogue scale score

Changes over time in the EORTC-QLQ-C30 score (Cohort 3 only)

Temporary moments of secondary assessment

Not provided

Inclusion criteria

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Exclusion criteria

Known history of infection with human immunodeficiency virus (HIV) or hepatitis B (HBsAG positive) or hepatitis C virus (anti-HCV positive). Individuals with a history of hepatitis infection must have cleared their infection as determined by standard serological and genetic testing

History of a seizure disorder, cerebrovascular ischemia/hemorrhage, dementia, cerebellar disease, cerebral edema, posterior reversible encephalopathy syndrome, or any autoimmune disease with central nervous system (CNS) involvement

Presence of fungal, bacterial, viral, or other infection that is uncontrolled or requiring IV antimicrobials for management Note: Other protocol defined Inclusion/Exclusion criteria may apply.

Calendar

(Last Update: 08/10/2025)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
25/05/2021	05/11/2021	23/12/2021	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
19/04/2023	Not aported	Not aported	Not aported	18/06/2025

Sponsor

Kite Pharma Inc. United States

2400 Broadway

Contact Person

EU CT Support

+441223897300

clinical.trials@gilead.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Hospital Universitario La Paz

Paseo de la Castellana, 261 28046 Madrid

ceic.hulp@salud.madrid.org

917277413

Sites

Closed (08/10/2025)	HOSPITAL CLINIC DE BARCELONA Barcelona BARCELONA	Hospital Clinic De Barcelona Barcelona BARCELONA Oncology
not initialized (25/05/2021)	HOSPITAL CLINICO UNIVERSITARIO DE SALAMANCA (COMPLEJO ASISTENCIAL UNIV.SA) Salamanca SALAMANCA	Hospital Universitari Vall D Hebron Barcelona BARCELONA Oncology
not initialized (25/05/2021)	HOSPITAL UNIVERSITARI VALL D'HEBRON Barcelona BARCELONA	Hospital Universitario De Salamanca Salamanca SALAMANCA Oncology

Medication

IMBRUVICA 140 mg hard capsules

CAPSULE, HARD
ORAL

ATC code: L01EL01 - IBRUTINIB

Active Principles: N/A

Experimental

Calquence 100 mg hard capsules

CAPSULE, HARD
ORAL

ATC code: L01EL02 - ACALABRUTINIB

Active Principles: N/A

Experimental

Cyclophosphamide 500 mg Powder for Solution for Injection or Infusion

SOLUTION FOR INJECTION/INFUSION
INTRAVENIOUS INFUSION

ATC code: L01AA01 - CICLOFOSFAMIDA

Active Principles: N/A

Experimental

Fludarabine phosphate 25 mg/ml Concentrate for Solution for Injection or Infusion

SOLUTION FOR INJECTION/INFUSION
INTRAVENIOUS INFUSION

ATC code: L01BB05 - FLUDARABINA

Active Principles: N/A

Experimental

Panadol 500 mg Film Coated Tablets

TABLET
ORAL

ATC code: N02BE01 - PARACETAMOL

Active Principles: N/A

Experimental

Methylprednisolone 1000 mg powder and solvent for solution for injection/infusion

SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS USE

ATC code: H02AB04 - METILPREDNISOLONA

Active Principles: N/A

Experimental

RoActemra 20 mg/mL concentrate for solution for infusion

SOLUTION FOR INFUSION
INTRAVENIOUS INFUSION

ATC code: L04AC07 - TOCILIZUMAB

Active Principles: N/A

Experimental

Histergan Tablets

COATED TABLET
ORAL AND IV

ATC code: R06AA02 - DIFENHIDRAMINA

Active Principles: N/A

Experimental

Mesna Injection
SOLUTION FOR INJECTION
INTRAVENOUS INJECTION

ATC code: V03AF01 - MESNA
Active Principles: N/A

Experimental

Tecartus 0.4 - 2 x 10e8 cells dispersion for infusion
DISPERSION FOR INFUSION
INTRAVENOUS INFUSION

ATC code: L01XL06 - BREXUCABTAGEN AUTOLEUCEL
Active Principles: N/A

Orphan

Experimental

Cytarabine 20 mg/ml Solution for Injection or Infusion
SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS INFUSION

ATC code: L01BC01 - CITARABINA
Active Principles: N/A

Experimental

Dexamethasone 4 mg tablets
TABLET
ORAL AND IV

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

Experimental

Has results