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

Estado	**Tipo de Participantes**	**Rangos de Edad**
EC Finalizado	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase II	183
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Tiene resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Multicéntrico internacional	seguridad, eficacia	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	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
25/05/2021	05/11/2021	23/12/2021	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
19/04/2023	No aportado	No aportado	No aportado	18/06/2025

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

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

Hospital Clinic De Barcelona

Barcelona

BARCELONA

Oncology

No iniciado (25/05/2021)

HOSPITAL CLINICO UNIVERSITARIO DE SALAMANCA (COMPLEJO ASISTENCIAL UNIV.SA)

Salamanca

SALAMANCA

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

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Oncology

No iniciado (25/05/2021)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

Cerrado (18/09/2025)

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	**Type of participants**	**Age Ranges**
Finished CT	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase II	183
Results	**Low level of intervention**	**Rare disease**
Has results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
International multicenter	safety, effectiveness	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
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)

Temporary moments of secondary assessment

Not provided

Inclusion criteria

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

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

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

Hospital Clinic De Barcelona

Barcelona

BARCELONA

Oncology

not initialized (25/05/2021)

HOSPITAL CLINICO UNIVERSITARIO DE SALAMANCA (COMPLEJO ASISTENCIAL UNIV.SA)

Salamanca

SALAMANCA

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

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Oncology

not initialized (25/05/2021)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

Closed (18/09/2025)

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

INTRAVENIOUS 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

INTRAVENIOUS 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