A Study Evaluating the Safety and Efficacy of KTE-X19 in pediatric and adolescent Subjects with Relapsed/Refractory B-precursor Acute Lymphoblastic Leukemia or Relapsed/Refractory Non-Hodgkin Lymphoma.

Estado	Tipo de Participantes	Rangos de Edad
EC Finalizado	Sujetos incapaces de otorgar consentimiento	Menores de 18 , Adultos (18-64 años) , Adolescentes (12-17 años) , Niños (2-11 años) , Lactantes y preescolar (28 días - 23 meses)
Género	**Fases**	**Participantes esperados**
Ambos	Fase I	72
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Tiene resultados	No	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	tratamiento, seguridad, farmacodinamica	Terapia génica

Información

Identificador
2023-509440-97-00 (CTIS)

Cod. Protocolo
KTE-C19-104

Transicionado 2015-005010-30

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

Enfermedad investigada
Relapsed/Refractory B-precursor Acute Lymphoblastic Leukemia (r/r ALL) Relapsed/Refractory B-cell non-Hodgkin lymphoma (r/r NHL)

Título Científico

A Phase 1/2 Multi-Center Study Evaluating the Safety and Efficacy of KTE-X19 in Pediatric and Adolescent Subjects with Relapsed/Refractory B-precursor Acute Lymphoblastic Leukemia or Relapsed/Refractory BCell Non Hodgkin Lymphoma (ZUMA-4)

Justificación

No aportado

Objetivo Principal

The primary objective of phase 1 is to evaluate the safety of KTE-X19.
The primary objectives of Phase 2 are as follows: ALL Cohort: to evaluate the efficacy of KTE-X19, as measured by the overall complete remission rate defined as complete remission (CR) and complete remission with incomplete hematologic recovery (CRi) in pediatric and adolescent subjects with r/r ALL.
NHL Cohort: to estimate the efficacy of KTE-X19 as measured by the objective response rate (ORR) defined as a complete response (CR) or
zzza partial response (PR) (ie, CR + PR), in pediatric subjects with r/r NHL

Variables de Evaluación Primaria

Phase 1: Incidence of adverse events (AEs) defined as dose-limiting toxicities (DLTs).
Phase 2: a) ALL Cohort: Overall complete remission rate (CR + CRi) per independent review. B)NHL Cohort: ORR per investigator assessment

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

Secondary objectives will include assessing the safety and tolerability of KTE-X19, additional efficacy endpoints, and (for Phase 2 only) changes in PRO scores.

Variables de Evaluación Secundaria

ALL cohort: Overall complete remission rate (CR + CRi) per investigator assessment
Rate of CR within 3 months per independent review
Duration of remission (DOR)
Minimal residual disease (MRD) negative rate
Allogeneic SCT rate
Overall survival (OS)
Relapsed-free survival (RFS)
Incidence of AEs and Common Terminology Criteria for Adverse Events (CTCAE) grade changes in safety laboratory

values
Incidence of anti-KTE-X19 antibodies in blood
Changes over time in patient-reported outcome (PRO) scores (Phase 2 only)
NHL cohort: DOR
OS
Progression-free survival (PFS)
Incidence of AEs and CTCAE grade changes in safety laboratory values
Incidence of anti-KTE-X19 antibodies in blood
Changes over time in PRO scores (Phase 2 only)

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Key Inclusion Criteria for the ALL Cohort Relapsed or refractory histologically confirmed aggressive B-cell NHL per 1 or more of the following: o Primary refractory disease o Any relapse within 18 months after first diagnosis o Relapsed or refractory disease after 1 or more lines of systemic therapy o Relapsed or refractory disease after autologous /allogeneic stem cell transplant provided individual is at least 6 weeks from autologous stem cell transplant and at least 3 months from allogeneic stem cell transplant at the time of enrollment Individuals must have received adequate prior therapy including at a minimum all of the following: o Anti-CD20 monoclonal antibody, unless the investigator determines that the tumor is CD20 negative o An anthracycline-containing chemotherapy regimen Age <18 years old and weight 6kg Lansky (age < 16 years at the time of assent/consent) or Karnofsky (age 16 years at the time of assent/consent) performance status 80 at screening Adequate renal, hepatic, pulmonary, and cardiac function defined as the following: o Creatinine clearance (as estimated by Cockcroft Gault or Schwartz) 60 mL/min o Serum ALT/AST 5 ULN o Total bilirubin 1.5 x ULN except in individuals with Gilbert's syndrome o Left ventricular shortening fraction(LVSF) 30% or left ventricular ejection fraction (LVEF) 50%, as determined by ECHO or MUGA, no evidence of pericardial effusion (except trace or physiological) as determined by an ECHO, and no clinically significant arrhythmias o Baseline oxygen saturation > 92% on room air Relapsed or refractory B-precursor ALL defined as one of the following: o Primary refractory disease o Any relapse within 18 months after first diagnosis o Relapsed or refractory disease after 2 or more lines of systemic therapy o Relapsed or refractory disease after allogeneic transplant provided individual is at least 100 days from stem cell transplant at the time of enrollment Disease burden defined as at least 1 of the following: o Morphological disease in the bone marrow (> 5% blasts) o Minimal/Measurable Residual Disease (MRD) positive (threshold 10^-4 by flow or Polymerase chain reaction (PCR) Individuals with Ph+ disease are eligible if they are intolerant to tyrosine kinase inhibitor (TKI) therapy, or if they have relapsed/refractory disease despite treatment with at least 2 different TKIs Age 21 years and weight 6 kg at the time of assent or consent per Institutional Review Board (IRB) guidelines Lansky (age < 16 years at the time of assent/consent) or Karnofsky (age 16 years at the time of assent/consent) performance status 80 at screening Adequate renal, hepatic, pulmonary and cardiac function defined as: o Creatinine clearance (as estimated by Cockcroft Gault or Schwartz) 60 mL/min o Serum alanine aminotransferase (ALT)/aspartate aminotransferase (AST) 5 x upper limit of normal (ULN) o Total bilirubin 1.5 x ULN, except in individuals with Gilbert's syndrome o Left ventricular shortening fraction (LVSF) 30% or left ventricular ejection fraction (LVEF) 50%, as determined by an echocardiogram or multi-gated acquisition scan (MUGA), no evidence of pericardial effusion (except trace or physiological) as determined by an echocardiogram (ECHO) and no clinically significant arrhythmias o No clinically significant pleural effusion, pericardial effusion or ascites o Baseline oxygen saturation > 92% on room air Key Inclusion Criteria for the NHL Cohort Histologically confirmed aggressive B cell NHL

Criterios de Exclusión

Key Exclusion Criteria for the ALL Cohort History of malignancy other than nonmelanoma skin cancer, carcinoma in situ (eg, cervix, breast), or follicular lymphoma (FL) unless disease free for at least 3 years Autologous stem cell transplant within <6 weeks of planned KTE-X19 infusion; allogeneic stem cell transplant within <3 months of planned KTE-X19 infusion History of human immunodeficiency virus (HIV) infection or acute / chronic active hepatitis B or C infection. Individuals with a history of hepatitis infection must have cleared their infection as determined by standard serological and genetic testing per current Infectious Diseases Society of America guidelines or applicable country guidelines. Prior CD19 targeted therapy other than blinatumomab and loncastuximab tesirine-lpyl History of severe, immediate hypersensitivity reaction attributed to aminoglycosides Presence or suspicion of fungal, bacterial, viral, or other infection that is uncontrolled or requiring IV antimicrobials for management. History of HIV infection or acute/chronic active hepatitis B or C infection. Individuals with a history of hepatitis infection must have cleared their infection as determined by standard serological and genetic testing per current Infectious Diseases Society of America guidelines or applicable country guidelines Acute GVHD grade II-IV by Glucksberg criteria or severity B-D by International Bone Marrow Transplant Registry (IBMTR) index; acute or chronic GVHD requiring systemic treatment within 4 weeks prior to enrollment. CNS involvement and abnormalities: o Any CNS tumor mass and/or parameningeal mass (cranial and/or spinal) by imaging with current or prior history of neurological symptoms within 3 months prior to screening. Note: CNS involvement without neurologic symptoms will be allowed. History or presence of any CNS disorder such as a seizure disorder, cerebrovascular ischemia/hemorrhage, dementia, cerebellar disease, any autoimmune disease with CNS involvement, posterior reversible encephalopathy syndrome (PRES), or cerebral edema with confirmed structural defects by appropriate imaging. History of stroke or transient ischemic attack within 12 months before enrollment. Individuals with seizure disorders requiring active anti-convulsive medication. o History of myocardial infarction, cardiac angioplasty or stenting, unstable angina, or other clinically significant cardiac disease within 12 months of enrollment o Primary immunodeficiency o History of severe immediate hypersensitivity reaction to any of the agents used in this study o Live vaccine 6 weeks prior to planned start of lymphodepleting chemotherapy regimen o Individuals of both genders of child-bearing potential who are not willing to use a birth control considered to be highly effective per protocol from the time of consent through 12 months after the completion of lymphodepleting chemotherapy or brexucabtagene autoleucel (KTE-X19) infusion, whichever is longer. o Prior medication: History of malignancy other than non-melanoma skin cancer or carcinoma in situ (e.g. cervix, bladder, breast) unless disease free for at least 3 years Prior CD19 directed therapy (other than blinatumomab), including CAR+ T cell, BiTE, and ADC, with the exception of individuals who received brexucabtagene autoleucel (KTE-X19) in this study and are eligible for re-treatment Treatment with alemtuzumab within 6 months prior to leukapheresis, or treatment with clofarabine or cladribine within 3 months prior to leukapheresis DLI within 28 days prior to enrollment Presence or suspicion of fungal, bacterial, viral, or other infection that is uncontrolled or requiring IV antimicrobials for management. Prior medication: o Prior CD19 directed therapy (other than blinatumomab), including CAR+ T cell, bispecific T cell engager (BiTE), and antibody drug conjugate (ADC), with the exception of individuals who received brexucabtagene autoleucel (KTE-X19) in this study and are eligible for re-treatment o Treatment with alemtuzumab within 6 months prior to leukapheresis, or treatment with clofarabine or cladribine within 3 months prior to leukapheresis o Donor lymphocyte infusion (DLI) within 28 days prior to enrollment o Any drug used for graft-versus-host disease (GVHD) within 4 weeks prior to enrollment Acute GVHD grade II-IV by Glucksberg criteria or severity B-D by IBMTR index; acute or chronic GVHD requiring systemic treatment within 4 weeks prior to enrollment Live vaccine 6 weeks prior to enrollment Women of child-bearing potential who are pregnant or breastfeeding because of the potentially dangerous effects of the preparative chemotherapy on the fetus or infant. Females who have undergone surgical sterilization are not considered to be of childbearing potential Individuals of both genders of child-bearing potential who are not willing to use a birth control method considered to be highly effective per protocol from the time of consent through 6 months after conditioning chemotherapy or brexucabtagene autoleucel (KTE-X19) infusion, whichever is longer. Diagnosis of Burkitt's leukemia/lymphoma according to the World Health Organization (WHO) classification or chronic myelogenous leukemia lymphoid blast crisis History of severe hypersensitivity reaction to aminoglycosides or any of the agents used in this study Any drug used for GVHD within 4 weeks prior to enrollment Central nervous system (CNS) involvement and abnormalities: o Any CNS tumor mass by imaging and/or parameningeal mass (cranial and/or spinal) o Presence of central nervous system (CNS)-3 disease, defined as white blood cell (WBC) 5/µL in Cerebrospinal Fluid (CSF) with presence of lymphoblasts with or without neurologic symptoms o CNS-2 disease, defined as WBC < 5/µL in CSF with presence of lymphoblasts and with neurologic symptoms (see note below for further clarification). o Note: Neurologic symptoms may include but are not limited to cranial nerve palsy (if not explained by extracranial tumor) and clinical cord compression. o (Individuals with CNS-1 (no detectable lymphoblasts in the CSF) and those with CNS-2 without clinically evident neurological changes are eligible to participate in the study) o History or presence of CNS disorder, such as cerebrovascular ischemia/hemorrhage,

dementia, cerebellar disease, or any autoimmune disease with CNS involvement, posterior reversible encephalopathy syndrome (PRES), or cerebral edema with confirmed structural defects not related to lymphoma by appropriate imaging. History of stroke or transient ischemic attack within 12 months before enrollment. Individuals with seizure disorders requiring active anticonvulsive medication History of concomitant genetic syndrome such as Fanconi anemia, Kostmann syndrome, Shwachman-Diamond syndrome or any other known bone marrow failure syndrome History of myocardial infarction, cardiac angioplasty or stenting, unstable angina, or other clinically significant cardiac disease within 12 months of enrollment History of symptomatic deep vein thrombosis or pulmonary embolism within 6 months of enrollment. Primary immunodeficiency Key Exclusion Criteria for the NHL Cohort

Calendario

(Última actualización: 25/03/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
08/03/2021	30/07/2021	07/01/2022	05/10/2022	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
09/05/2024	No aportado	No aportado	30/05/2025	23/03/2026

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

Activo (26/10/2021)

HOSPITAL DE SANT JOAN DE DEU.

Esplugues de Llobregat

BARCELONA

Activo (30/07/2021)

HOSPITAL UNIVERSITARIO LA PAZ

Madrid

MADRID

Medicamentos

Tecartus 0.4 - 2 x 10e8 cells dispersion for infusion

DISPERSION FOR INFUSION

INTRAVENOUS INFUSION

Código ATC: L01XL06 - BREXUCABTAGEN AUTOLEUCEL

Principios Activos: N/A

Experimental

Tiene resultados

A Study Evaluating the Safety and Efficacy of KTE-X19 in pediatric and adolescent Subjects with Relapsed/Refractory B-precursor Acute Lymphoblastic Leukemia or Relapsed/Refractory Non-Hodgkin Lymphoma.

State	Type of participants	Age Ranges
Finished CT	Incapable subjects of giving consent	Less than 18 , Adults (18-64 years) , Teens (12-17 years) , Children (2-11 years) , Infants and preschool (28 days - 23 months)
Gender	**Phases**	**Expected Participants**
Both	Phase I	72
Results	**Low level of intervention**	**Rare disease**
Has results	No	Yes
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	treatment, safety, pharmacodynamics	Gene therapy

Information

Identifier
2023-509440-97-00 (CTIS)

Protocol Code
KTE-C19-104

Transitioned 2015-005010-30

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

Investigated Disease
Relapsed/Refractory B-precursor Acute Lymphoblastic Leukemia (r/r ALL) Relapsed/Refractory B-cell non-Hodgkin lymphoma (r/r NHL)

Scientific Title

A Phase 1/2 Multi-Center Study Evaluating the Safety and Efficacy of KTE-X19 in Pediatric and Adolescent Subjects with Relapsed/Refractory B-precursor Acute Lymphoblastic Leukemia or Relapsed/Refractory BCell Non Hodgkin Lymphoma (ZUMA-4)

Rationale

Not provided

Main Objective

The primary objective of phase 1 is to evaluate the safety of KTE-X19.
The primary objectives of Phase 2 are as follows: ALL Cohort: to evaluate the efficacy of KTE-X19, as measured by the overall complete remission rate defined as complete remission (CR) and complete remission with incomplete hematologic recovery (CRi) in pediatric and adolescent subjects with r/r ALL.
NHL Cohort: to estimate the efficacy of KTE-X19 as measured by the objective response rate (ORR) defined as a complete response (CR) or
zzza partial response (PR) (ie, CR + PR), in pediatric subjects with r/r NHL

Primary Endpoints

Phase 1: Incidence of adverse events (AEs) defined as dose-limiting toxicities (DLTs).
Phase 2: a) ALL Cohort: Overall complete remission rate (CR + CRi) per independent review. B)NHL Cohort: ORR per investigator assessment

Temporary moments of secondary assessment

Not provided

Secondary Objective

Secondary objectives will include assessing the safety and tolerability of KTE-X19, additional efficacy endpoints, and (for Phase 2 only) changes in PRO scores.

Secondary Endpoints

ALL cohort: Overall complete remission rate (CR + CRi) per investigator assessment
Rate of CR within 3 months per independent review
Duration of remission (DOR)
Minimal residual disease (MRD) negative rate
Allogeneic SCT rate
Overall survival (OS)
Relapsed-free survival (RFS)
Incidence of AEs and Common Terminology Criteria for Adverse Events (CTCAE) grade changes in safety laboratory

values
Incidence of anti-KTE-X19 antibodies in blood
Changes over time in patient-reported outcome (PRO) scores (Phase 2 only)
NHL cohort: DOR
OS
Progression-free survival (PFS)
Incidence of AEs and CTCAE grade changes in safety laboratory values
Incidence of anti-KTE-X19 antibodies in blood
Changes over time in PRO scores (Phase 2 only)

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Key Inclusion Criteria for the ALL Cohort Relapsed or refractory histologically confirmed aggressive B-cell NHL per 1 or more of the following: o Primary refractory disease o Any relapse within 18 months after first diagnosis o Relapsed or refractory disease after 1 or more lines of systemic therapy o Relapsed or refractory disease after autologous /allogeneic stem cell transplant provided individual is at least 6 weeks from autologous stem cell transplant and at least 3 months from allogeneic stem cell transplant at the time of enrollment Individuals must have received adequate prior therapy including at a minimum all of the following: o Anti-CD20 monoclonal antibody, unless the investigator determines that the tumor is CD20 negative o An anthracycline-containing chemotherapy regimen Age <18 years old and weight 6kg Lansky (age < 16 years at the time of assent/consent) or Karnofsky (age 16 years at the time of assent/consent) performance status 80 at screening Adequate renal, hepatic, pulmonary, and cardiac function defined as the following: o Creatinine clearance (as estimated by Cockcroft Gault or Schwartz) 60 mL/min o Serum ALT/AST 5 ULN o Total bilirubin 1.5 x ULN except in individuals with Gilbert's syndrome o Left ventricular shortening fraction(LVSF) 30% or left ventricular ejection fraction (LVEF) 50%, as determined by ECHO or MUGA, no evidence of pericardial effusion (except trace or physiological) as determined by an ECHO, and no clinically significant arrhythmias o Baseline oxygen saturation > 92% on room air Relapsed or refractory B-precursor ALL defined as one of the following: o Primary refractory disease o Any relapse within 18 months after first diagnosis o Relapsed or refractory disease after 2 or more lines of systemic therapy o Relapsed or refractory disease after allogeneic transplant provided individual is at least 100 days from stem cell transplant at the time of enrollment Disease burden defined as at least 1 of the following: o Morphological disease in the bone marrow (> 5% blasts) o Minimal/Measurable Residual Disease (MRD) positive (threshold 10^-4 by flow or Polymerase chain reaction (PCR) Individuals with Ph+ disease are eligible if they are intolerant to tyrosine kinase inhibitor (TKI) therapy, or if they have relapsed/refractory disease despite treatment with at least 2 different TKIs Age 21 years and weight 6 kg at the time of assent or consent per Institutional Review Board (IRB) guidelines Lansky (age < 16 years at the time of assent/consent) or Karnofsky (age 16 years at the time of assent/consent) performance status 80 at screening Adequate renal, hepatic, pulmonary and cardiac function defined as: o Creatinine clearance (as estimated by Cockcroft Gault or Schwartz) 60 mL/min o Serum alanine aminotransferase (ALT)/aspartate aminotransferase (AST) 5 x upper limit of normal (ULN) o Total bilirubin 1.5 x ULN, except in individuals with Gilbert's syndrome o Left ventricular shortening fraction (LVSF) 30% or left ventricular ejection fraction (LVEF) 50%, as determined by an echocardiogram or multi-gated acquisition scan (MUGA), no evidence of pericardial effusion (except trace or physiological) as determined by an echocardiogram (ECHO) and no clinically significant arrhythmias o No clinically significant pleural effusion, pericardial effusion or ascites o Baseline oxygen saturation > 92% on room air Key Inclusion Criteria for the NHL Cohort Histologically confirmed aggressive B cell NHL

Exclusion criteria

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dementia, cerebellar disease, or any autoimmune disease with CNS involvement, posterior reversible encephalopathy syndrome (PRES), or cerebral edema with confirmed structural defects not related to lymphoma by appropriate imaging. History of stroke or transient ischemic attack within 12 months before enrollment. Individuals with seizure disorders requiring active anticonvulsive medication History of concomitant genetic syndrome such as Fanconi anemia, Kostmann syndrome, Shwachman-Diamond syndrome or any other known bone marrow failure syndrome History of myocardial infarction, cardiac angioplasty or stenting, unstable angina, or other clinically significant cardiac disease within 12 months of enrollment History of symptomatic deep vein thrombosis or pulmonary embolism within 6 months of enrollment. Primary immunodeficiency Key Exclusion Criteria for the NHL Cohort

Calendar

(Last Update: 25/03/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
08/03/2021	30/07/2021	07/01/2022	05/10/2022	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
09/05/2024	Not aported	Not aported	30/05/2025	23/03/2026

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

Active (26/10/2021)

HOSPITAL DE SANT JOAN DE DEU.

Esplugues de Llobregat

BARCELONA

Active (30/07/2021)

HOSPITAL UNIVERSITARIO LA PAZ

Madrid

MADRID

Medication

Tecartus 0.4 - 2 x 10e8 cells dispersion for infusion

DISPERSION FOR INFUSION

INTRAVENOUS INFUSION

ATC code: L01XL06 - BREXUCABTAGEN AUTOLEUCEL

Active Principles: N/A

Experimental

Has results