A study for subjects after organ or cell transplantation after failure of prior treatment

Estado	Tipo de Participantes	Rangos de Edad
Reclutando	Sujetos incapaces de otorgar consentimiento	Menores de 18 , Mayores de 64 , Adultos (18-64 años) , Adolescentes (12-17 años) , Niños (2-11 años) , Lactantes y preescolar (28 días - 23 meses) , Recién nacidos (0-27 días)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	48
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	tratamiento, seguridad, eficacia, farmacocinética, farmacodinamica	Terapia celular

Información

Identificador

2024-516622-57-00 (CTIS)

Cod. Protocolo

ATA129-EBV-302

Transicionado 2017-002949-30

Área terapéutica

Enfermedades [C] - Patologías del sistema inmunitario [C20]|

Enfermedad investigada

Epstein-Barr Virus-Associated Post-Transplant Lymphoproliferative Disease

Título Científico

Multicenter, Open Label, Phase 3 Study of Tabelecleucel for Solid Organ or Allogeneic Hematopoietic Cell Transplant Subjects with Epstein-Barr VirusAssociated Post-Transplant Lymphoproliferative Disease after Failure of

Rituximab or Rituximab and Chemotherapy (ALLELE Study)

Justificación

No aportado

Objetivo Principal

To determine the clinical benefit of tabelecleucel (ATA129; allogeneic Epstein-Barr virus specific cytotoxic T lymphocytes [EBV-CTLs]) as measured by the objective response rate (ORR) in participants with EBV associated post-transplant lymphoproliferative disease (EBV+ PTLD) in the following analysis cohorts (1) solid organ transplant (SOT) after failure of the following: a) rituximab (SOT-R), which includes participants who did not receive chemotherapy and did not have a documented medical reason not to receive chemotherapy (SOT-Ro); or who were considered chemotherapy ineligible/inappropriate (SOT-R-Ci). b) rituximab plus chemotherapy (SOT-R+C) or (2) allogeneic hematopoietic cell transplant (HCT) after failure of rituximab or (3) A combined population of SOT-R-Ci, SOT-R+C, and HCT who received commercial product or a product manufactured using a comparable process version (PV).

Variables de Evaluación Primaria

ORR (CR or PR) obtained following administration of tabelecleucel with up to 2 different HLA restrictions in each of the following analysis cohorts: SOT HCT A combined population (SOT-R-Ci, SOT-R+C, and HCT) following administration of commercial product or a product manufactured using a comparable PV

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To evaluate duration of response (DOR) in the SOT and HCT cohorts separately
To evaluate ORR and DOR in the SOT and HCT cohorts combined
To evaluate ORR and DOR in subjects who received commercial product or a product manufactured using a comparable PV in the following: SOTR-Ci and SOT-R+C combined, and separately, HCT
To evaluate DOR in a combined population (SOT-R-Ci, SOT-R+C, and HCT) who received commercial product or a product manufactured using a comparable PV
To evaluate rates of complete response (CR) and partial response (PR)
To evaluate time to response and time to best response
To evaluate overall survival (OS)
To evaluate graft status (SOT participants only)
To characterize the safety profile of tabelecleucel in this participant population

Variables de Evaluación Secundaria

DOR in the SOT and HCT cohorts separately.
ORR and DOR in SOT and HCT cohorts combined.
ORR and DOR in subjects who received commercial product or a product manufactured using a comparable PV in the following: SOT-R-Ci and SOT-R+C combined, and separately, HCT
DOR in a combined population (SOT-R-Ci, SOT-R+C, and HCT) who received commercial product or a product manufactured using a comparable PV
Rates of CR and PR
Time to response and time to best response
OS
Rates of allograft loss/rejection episodes (for SOT cohort only)

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Prior SOT of kidney, liver, heart, lung, pancreas, small bowel, or any combination of these (SOT cohort); or prior allogeneic HCT (HCT cohort). Participant or participant's representative is willing and able to provide written informed consent. A diagnosis of locally-assessed, biopsy-proven EBV+ PTLD. Availability of appropriate partially HLA-matched and restricted tabelecleucel has been confirmed by the sponsor. Measurable, 18F-deoxyglucose (FDG)-avid (Deauville score 3) systemic disease using Lugano Classification response criteria by positron emission tomography -diagnostic computed tomography, except when contraindicated or mandated by local practice, then magnetic resonance imaging may be used. For Participants with treated central nervous system (CNS) disease, head diagnostic computed tomography and/or brain/spinal magnetic resonance imaging as clinically appropriate will be required to follow CNS disease response per Lugano Classification response criteria. Treatment failure of rituximab or interchangeable commercially available biosimilar monotherapy (SOT-R or HCT cohort) or rituximab plus any concurrent or sequentially administered chemotherapy regimen (SOT-R+C) for treatment of PTLD. Treatment failure is defined based on rituximab response as follows: a. Radiographic disease progression per Lugano Classification following a minimum cumulative dose of 1125 mg/m2 rituximab (typically, 3 weekly doses of 375 mg/m2), or b. Failure to achieve CR or PR, defined by Lugano radiographic criteria, after a minimum cumulative dose of 1500 mg/m2 rituximab (typically, 4 weekly doses of 375 mg/m2), or c. Relapse/progression of PTLD after a response to rituximab (SOT-R or HCT cohort) or rituximab plus chemotherapy (SOT-R+C), defined as radiographic and/or biopsy evidence of relapse/progression consistent with PTLD; if the underlying disease for which the subject underwent allogeneic HCT (HCT cohort) was lymphoma, biopsy confirmation of relapsed EBV+ PTLD is required. Males and females of any age. Eastern Cooperative Oncology Group performance status 3 for Participants aged 16 years; Lansky score 20 for Participants < 16 years. For HCT cohort only: If allogeneic HCT was performed as treatment for an acute lymphoid or myeloid malignancy, the underlying primary disease for which the participant underwent transplant must be in morphologic remission. Adequate organ function: a. Absolute neutrophil count 1000/L (SOT cohort) or 500/L (HCT cohort), with or without cytokine support b. Platelet count 50,000/L, with or without transfusion or cytokine support. For HCT cohort, platelet count < 50,000/L but 20,000/L, with or without transfusion support, is permissible if the participant has not had grade 2 bleeding in the prior 4 weeks (where grading of the bleeding is determined per the National Cancer Institute's Common Terminology Criteria for Adverse Events, version 5.0) c. Alanine aminotransferase (ALT), aspartate aminotransferase (AST), and total bilirubin each < 5 × the upper limit of normal; however, ALT, AST, and total bilirubin each 10 × the upper limit of normal is acceptable if the elevation is considered by the investigator to be due to EBV and/or PTLD involvement of the liver as long as there is no known evidence of significant liver dysfunction (e.g., elevated prothrombin time due to liver dysfunction, signs/symptoms of liver dysfunction such as asterixis, or similar).

Criterios de Exclusión

Currently active Burkitt, T cell, NK/T-cell lymphoma/LPD, Hodgkin, plasmablastic, transformed lymphoma, active hemophagocytic lymphohistiocytosis, or other malignancies requiring systemic therapy. Female who is breastfeeding or pregnant or female of childbearing potential or male with a female partner of childbearing potential unwilling to use a highly effective method of contraception. Inability to comply with study-related procedures Any medical condition, or organ system dysfunction that, in the investigator's opinion, could compromise the participant's safety or ability to complete the study. Daily steroids of > 0.5 mg/kg prednisone or glucocorticoid equivalent, ongoing methotrexate, or extracorporeal photopheresis. Untreated CNS PTLD or CNS PTLD for which the participant is actively receiving CNS-directed chemotherapy (systemic or intrathecal) or radiotherapy at enrollment. NOTE: Participants with previously treated CNS PTLD may enroll if CNS-directed therapy is complete. Suspected or confirmed grade 2 graft-versus-host disease per the Center for International Blood and Marrow Transplant Research consensus grading system at enrollment. Ongoing or recent use of a checkpoint inhibitor agent (eg, ipilimumab, pembrolizumab, nivolumab) within 3 drug half-lives from the most recent dose to enrollment. For HCT cohort only: Active adenovirus viremia. Need for vasopressor or ventilatory support. Antithymocyte globulin or similar anti-T-cell antibody therapy 4 weeks prior to enrollment. Treatment with EBV-CTLs or chimeric antigen receptor T cells directed against B cells within 8 weeks of enrollment (SOT or HCT cohorts); or unselected donor lymphocyte infusion within 8 weeks of enrollment (HCT cohort only).

Calendario

(Última actualización: 10/07/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
31/01/2020	06/05/2020	15/01/2021	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

Pierre Fabre Medicament France

Les Cauquillous

Contact Person

Pierre Fabre Medicament

+19735212686

ATA129-EBV-302_medical.team@pierre-fabre.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

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961246605

Centros

No iniciado (22/09/2020)

HOSPITAL GENERAL UNIVERSITARIO GREGORIO MARAÑON

Madrid

MADRID

Hematologia

Activo (09/07/2020)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

Hematologia

Activo (29/09/2020)

HOSPITAL UNIVERSITARIO MARQUÉS DE VALDECILLA

Santander

CANTABRIA

Hematologia

Activo (06/05/2020)

HOSPITAL UNIVERSITARIO VIRGEN DEL ROCÍO

Sevilla

SEVILLA

Hematologia

Activo (26/08/2020)

HOSPITAL UNIVERSITARIO Y POLITÉCNICO LA FE

Valencia

VALENCIA

Hematologia

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

Institut Catala D'oncologia

L'hospitalet De Llobregat

BARCELONA

Hematology

Medicamentos

EBVALLO
DISPERSION FOR INJECTION
INTRAVENOUS USE

-

Principios Activos: N/A

Huérfano **Experimental**

Sin resultados

A study for subjects after organ or cell transplantation after failure of prior treatment

State	Type of participants	Age Ranges
Recruiting	Incapable subjects of giving consent	Less than 18 , Older than 64 , Adults (18-64 years) , Teens (12-17 years) , Children (2-11 years) , Infants and preschool (28 days - 23 months) , Newborn infants (0-27 days)
Gender	**Phases**	**Expected Participants**
Both	Phase III	48
Results	**Low level of intervention**	**Rare disease**
No results	No	Yes
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	treatment, safety, effectiveness, pharmacokinetics, pharmacodynamics	Cellular therapy

Information

Identifier
2024-516622-57-00 (CTIS)

Protocol Code
ATA129-EBV-302

Transitioned 2017-002949-30

Therapeutic area
Diseases [C] - Immune System Diseases [C20]|

Investigated Disease
Epstein-Barr Virus-Associated Post-Transplant Lymphoproliferative Disease

Scientific Title
Multicenter, Open Label, Phase 3 Study of Tabelecleucel for Solid Organ or Allogeneic Hematopoietic Cell Transplant Subjects with Epstein-Barr VirusAssociated Post-Transplant Lymphoproliferative Disease after Failure of

Rituximab or Rituximab and Chemotherapy (ALLELE Study)

Rationale

Not provided

Main Objective

To determine the clinical benefit of tabelecleucel (ATA129; allogeneic Epstein-Barr virus specific cytotoxic T lymphocytes [EBV-CTLs]) as measured by the objective response rate (ORR) in participants with EBV associated post-transplant lymphoproliferative disease (EBV+ PTLD) in the following analysis cohorts (1) solid organ transplant (SOT) after failure of the following: a) rituximab (SOT-R), which includes participants who did not receive chemotherapy and did not have a documented medical reason not to receive chemotherapy (SOT-Ro); or who were considered chemotherapy ineligible/inappropriate (SOT-R-Ci). b) rituximab plus chemotherapy (SOT-R+C) or (2) allogeneic hematopoietic cell transplant (HCT) after failure of rituximab or (3) A combined population of SOT-R-Ci, SOT-R+C, and HCT who received commercial product or a product manufactured using a comparable process version (PV).

Primary Endpoints

ORR (CR or PR) obtained following administration of tabelecleucel with up to 2 different HLA restrictions in each of the following analysis cohorts: SOT HCT A combined population (SOT-R-Ci, SOT-R+C, and HCT) following administration of commercial product or a product manufactured using a comparable PV

Temporary moments of secondary assessment

Not provided

Secondary Objective

To evaluate duration of response (DOR) in the SOT and HCT cohorts separately
To evaluate ORR and DOR in the SOT and HCT cohorts combined
To evaluate ORR and DOR in subjects who received commercial product or a product manufactured using a comparable PV in the following: SOTR-Ci and SOT-R+C combined, and separately, HCT
To evaluate DOR in a combined population (SOT-R-Ci, SOT-R+C, and HCT) who received commercial product or a product manufactured using a comparable PV
To evaluate rates of complete response (CR) and partial response (PR)
To evaluate time to response and time to best response
To evaluate overall survival (OS)
To evaluate graft status (SOT participants only)
To characterize the safety profile of tabelecleucel in this participant population

Secondary Endpoints

DOR in the SOT and HCT cohorts separately.
ORR and DOR in SOT and HCT cohorts combined.
ORR and DOR in subjects who received commercial product or a product manufactured using a comparable PV in the following: SOT-R-Ci and SOT-R+C combined, and separately, HCT
DOR in a combined population (SOT-R-Ci, SOT-R+C, and HCT) who received commercial product or a product manufactured using a comparable PV
Rates of CR and PR
Time to response and time to best response
OS
Rates of allograft loss/rejection episodes (for SOT cohort only)

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Prior SOT of kidney, liver, heart, lung, pancreas, small bowel, or any combination of these (SOT cohort); or prior allogeneic HCT (HCT cohort). Participant or participant's representative is willing and able to provide written informed consent. A diagnosis of locally-assessed, biopsy-proven EBV+ PTLD. Availability of appropriate partially HLA-matched and restricted tabelecleucel has been confirmed by the sponsor. Measurable, 18F-deoxyglucose (FDG)-avid (Deauville score 3) systemic disease using Lugano Classification response criteria by positron emission tomography -diagnostic computed tomography, except when contraindicated or mandated by local practice, then magnetic resonance imaging may be used. For Participants with treated central nervous system (CNS) disease, head diagnostic computed tomography and/or brain/spinal magnetic resonance imaging as clinically appropriate will be required to follow CNS disease response per Lugano Classification response criteria. Treatment failure of rituximab or interchangeable commercially available biosimilar monotherapy (SOT-R or HCT cohort) or rituximab plus any concurrent or sequentially administered chemotherapy regimen (SOT-R+C) for treatment of PTLD. Treatment failure is defined based on rituximab response as follows: a. Radiographic disease progression per Lugano Classification following a minimum cumulative dose of 1125 mg/m2 rituximab (typically, 3 weekly doses of 375 mg/m2), or b. Failure to achieve CR or PR, defined by Lugano radiographic criteria, after a minimum cumulative dose of 1500 mg/m2 rituximab (typically, 4 weekly doses of 375 mg/m2), or c. Relapse/progression of PTLD after a response to rituximab (SOT-R or HCT cohort) or rituximab plus chemotherapy (SOT-R+C), defined as radiographic and/or biopsy evidence of relapse/progression consistent with PTLD; if the underlying disease for which the subject underwent allogeneic HCT (HCT cohort) was lymphoma, biopsy confirmation of relapsed EBV+ PTLD is required. Males and females of any age. Eastern Cooperative Oncology Group performance status 3 for Participants aged 16 years; Lansky score 20 for Participants < 16 years. For HCT cohort only: If allogeneic HCT was performed as treatment for an acute lymphoid or myeloid malignancy, the underlying primary disease for which the participant underwent transplant must be in morphologic remission. Adequate organ function: a. Absolute neutrophil count 1000/L (SOT cohort) or 500/L (HCT cohort), with or without cytokine support b. Platelet count 50,000/L, with or without transfusion or cytokine support. For HCT cohort, platelet count < 50,000/L but 20,000/L, with or without transfusion support, is permissible if the participant has not had grade 2 bleeding in the prior 4 weeks (where grading of the bleeding is determined per the National Cancer Institute's Common Terminology Criteria for Adverse Events, version 5.0) c. Alanine aminotransferase (ALT), aspartate aminotransferase (AST), and total bilirubin each < 5 × the upper limit of normal; however, ALT, AST, and total bilirubin each 10 × the upper limit of normal is acceptable if the elevation is considered by the investigator to be due to EBV and/or PTLD involvement of the liver as long as there is no known evidence of significant liver dysfunction (e.g., elevated prothrombin time due to liver dysfunction, signs/symptoms of liver dysfunction such as asterixis, or similar).

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Calendar

(Last Update: 10/07/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
31/01/2020	06/05/2020	15/01/2021	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

Pierre Fabre Medicament France

Les Cauquillous

Contact Person

Pierre Fabre Medicament

+19735212686

ATA129-EBV-302_medical.team@pierre-fabre.com

Monetary support: N/A

Sponsor type: Commercial

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Sites

not initialized (22/09/2020)

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Madrid

MADRID

Hematologia

Active (09/07/2020)

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Active (06/05/2020)

HOSPITAL UNIVERSITARIO VIRGEN DEL ROCÍO

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SEVILLA

Hematologia

Active (26/08/2020)

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Valencia

VALENCIA

Hematologia

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

Institut Catala D'oncologia

L'hospitalet De Llobregat

BARCELONA

Hematology

Medication

EBVALLO

DISPERSION FOR INJECTION

INTRAVENOUS USE

-

Active Principles: N/A

Orphan **Experimental**

No results