A Phase I Interventional Open-Label, Non-Randomized Dose-Escalation Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, Immunogenicity, and Preliminary Anti-Tumor Activity of Autologous p95HER2.CAR-TECH2Me T Cells in Patients with Selected Advanced Cancers. Catherine Trial

Estado	Tipo de Participantes	Rangos de Edad
Reclutando	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase I	15
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	tratamiento, seguridad, eficacia, farmacocinética, farmacodinamica, dosis	Terapia génica

Información

Identificador
2024-516660-28-01 (CTIS)

Cod. Protocolo
VHIO24001

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

Enfermedad investigada
Locally advanced, recurrent, or metastatic breast, gastric, endometrial, and selected other solid tumors with positive expression for HER-2 (3+)

Título Científico

A Phase I Interventional Open-Label, Non-Randomized Dose-Escalation Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, Immunogenicity, and Preliminary Anti-Tumor Activity of Autologous p95HER2.CAR-TECH2Me T Cells in Patients with Selected Advanced Cancers. Catherine Trial

Justificación

No aportado

Objetivo Principal

To evaluate the safety and tolerability of the administration of p95HER2.CAR-TECH2Me cells in our target patients and to identify the maximum tolerated dose (MTD) and recommended phase-2 dose (RP2D).

Variables de Evaluación Primaria

Nature and frequency of Adverse Events (AE), Serious Adverse Events (SAE), alterations in clinical laboratory test results, ECGs, vital sign measurements, physical examination findings and assessment of ECOG performance status score graded, when applicable, according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) v5.0.
Incidence and nature of Dose-limiting Toxicities (DLT)

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To evaluate the preliminary anti-tumor activity of the p95HER2.CAR-TECH2Me cells and survival in our target patients

Variables de Evaluación Secundaria

Objective Response Rate (ORR), Duration of Response (DOR), and Progression-Free Survival (PFS) per RECIST v1.1 as assessed by the investigator, and Overall Survival (OS).

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

6) Patients must have histologically or cytologically proven unresectable or metastatic tumors. The disease must be refractory to standard therapy or in the first line if they are unable to receive standard therapy or no standard therapy exists for a particular disease. a) Select tumor types: breast, gastric, and endometrial tumors. Other selected solid tumors may be included per investigator discretion 15) Patients who are of childbearing potential (postmenarcheal who has not reached a postmenopausal state and has not undergone surgical sterilization) or have partners of childbearing potential must agree to use a highly effective method of contraception during the study and for at least 12 months after the infusion of the p95HER2.CAR-TECH2Me product. 1) Female participants: a female participant is eligible to participate if she is not pregnant, not breastfeeding, and at least one of the following conditions applies: a) Women of non-childbearing potential (WONCBP). b) Women of childbearing potential (WOCBP), who: i) Agree to remain abstinent (refrain from heterosexual intercourse) or use contraceptive methods that result in a failure rate of <1% per year from screening until 12 months after the infusion of the p95HER2.CAR-TECH2Me product. Have a negative pregnancy test (blood) within one week before the first study treatment administration 17) Male Participants: during the treatment period and for at least 6 months after the last dose of study treatment, agreement to: a) Remain abstinent (refrain from heterosexual intercourse) or use contraceptive measures such as a condom or a contraceptive method that result in a failure rate of <1% per year, with partners who are WOCBP. b) Refrain from donating sperm during the study. c) Inform if his partner gets pregnant during this time. 18) Adequate expanding p95HER2.CAR-TECH2Me cells as defined by the T cell production manual before preparative lymphodepleting chemotherapy infusion (available autologous transduced T lymphocytes with 15% or more expression of p95HER2.CAR-TECH2Me as determined by flow-cytometry and killing of p95HER2-positive targets 20 % or greater in cytotoxicity assay.) 19) Any toxicity related to prior systemic therapy must have recovered to grade 1 or less according to NCI-CTCAE v5.0 at least 4 weeks before treatment enrollment, except for alopecia, vitiligo, or endocrinopathy managed with replacement therapy, and Grade 2 peripheral neuropathy. Note: Other Grade 2 AEs that are deemed clinically insignificant by treating physician and in consultation with Medical Monitor are permitted. 20) Patients may have undergone minor surgical procedures within the past 3 weeks, as long as all toxicities have recovered to grade 1 or less. 7) Positivity for HER-2 expression according to international society guidelines (score in a ISO-certied clinical or equivalent laboratory). To meet study entry eligibility, tumors are required to have at least an intensity score 3+ for HER2 staining following the manufacturers recommendations Measurable disease by the RECIST v. 1.1 criteria 9) Patients are considered medically fit enough to undergo all study procedures and interventions and adequate hematological, renal, and hepatic functions 10) Patients must be seronegative for HIV antibody Patients must be seronegative for active hepatitis B and seronegative for hepatitis C antibody. 12) Patients must have blood tests results negative for active tuberculosis, syphilis, herpes simplex virus, cytomegalovirus, HTLV or Epstein-Barr virus infection. 13) Patients with documented LVEF of 50%. 14) Patients with documented FEV1, FVC, and DLCO 50% tested by a pulmonary function test.

Criterios de Exclusión

1) Patients with symptomatic and/or untreated brain metastases. 10) Patients with current or history within the last 6 months, as determined by the Investigator, of clinically significant, progressive, and/or uncontrolled renal, hepatic, hematological, endocrine, pulmonary, cardiac, gastroenterological or neurological disease. 11) Patients with a history of coronary revascularization or ischemic symptoms. 12) History of idiopathic pulmonary fibrosis or evidence of active pneumonitis (any origin) 13) Patients with allergies to any of the compounds included in any of the treatment products. 14) Patients with contraindications for cyclophosphamide and fludarabine at per protocol doses (see Investigator Brochure for details). 15) Patients who have received any approved anti-cancer cytotoxic, anti-angiogenic and ICB therapy including radiotherapy within 4 weeks before preparative lymphodepleting therapy. 16) Patients who have received any non-cytotoxic drug and molecular targeted therapy within 4 weeks before preparative lymphodepleting therapy (or within five half-lives of the investigational product, whichever is shorter). 17) Patients who have received any investigational agent within 4 weeks before preparative lymphodepleting therapy (or within five half-lives of the investigational product, whichever is shorter). 18) Patients who have received a live, attenuated vaccination within the 4 weeks before lymphodepleting therapy. 19) Patients who have undergone major surgery in the previous 3 weeks before lymphodepleting therapy. 2) Patients with leptomeningeal carcinomatosis. 20) Patients who have previously received any investigational cell or gene therapies. 21) Women of childbearing

potential who are pregnant or breastfeeding. 22) Presence of any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule; those conditions should be discussed with the patient before registration in the trial. 23) Other severe, acute, or chronic medical condition or laboratory abnormality that may increase the risk associated with study assessed by the Investigator. 3) Patients with an active concurrent or history within the past 3 years of invasive malignancy, except for non-melanoma skin cancer, cervical and bladder carcinoma in situ, good prognosis ductal carcinoma in situ of the breast, or prostate carcinoma that is in remission under androgen deprivation therapy for > 2 years. Other exceptions may apply and require discussion between the Investigator and the Medical Monitor. 4) Patients with an active systemic infection requiring anti-infective treatment within 14 days before preparative lymphodepleting therapy. 5) Patients with active hepatitis B or hepatitis C. 6) Patients with active autoimmune disease requiring immunosuppressive treatments. 7) Patients with a history of organ or bone marrow transplantation. 8) Patients with any form of primary immunodeficiency (such as Severe Combined Immunodeficiency Disease and AIDS). 9) Patients requiring regular treatment with steroids.

Calendario

(Última actualización: 25/08/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
17/12/2025	17/04/2026	29/04/2026	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

Vall D Hebron Institute Of Oncology Spain

Calle Natzaret 115

Contact Person

Group Leader, VHIO

+352543450

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Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Hospital Universitari Vall d Hebron

Passeig de la Vall d.Hebron, 119-129 - Edificio Materno-Infantil, planta 13 08035 Barcelona

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Centros

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

Hospital Del Mar

Barcelona

BARCELONA

Oncología Médica

Activo (29/04/2026)

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Oncología Médica

Medicamentos

p95HER2.CAR-TECH2Me
CELL SUSPENSION FOR INJECTION
INTRAVENOUS

-

Principios Activos: N/A

Experimental

Fludarabina Teva 25 mg/ml concentrado para solución para perfusión o inyección EFG
INJECTION
INTRAVENOUS

Código ATC: L01BB05 - FLUDARABINA
Principios Activos: N/A

Experimental

Genoxal 1.000 mg polvo para solución inyectable y para perfusión
SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS

Código ATC: L01AA01 - CICLOFOSFAMIDA
Principios Activos: N/A

Experimental

Sin resultados

A Phase I Interventional Open-Label, Non-Randomized Dose-Escalation Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, Immunogenicity, and Preliminary Anti-Tumor Activity of Autologous p95HER2.CAR-TECH2Me T Cells in Patients with Selected Advanced Cancers. Catherine Trial

State	Type of participants	Age Ranges
Recruiting	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase I	15
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	treatment, safety, effectiveness, pharmacokinetics, pharmacodynamics, dose	Gene therapy

Information

Identifier
2024-516660-28-01 (CTIS)

Protocol Code
VHIO24001

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

Investigated Disease
Locally advanced, recurrent, or metastatic breast, gastric, endometrial, and selected other solid tumors with positive expression for HER-2 (3+)

Scientific Title

A Phase I Interventional Open-Label, Non-Randomized Dose-Escalation Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, Immunogenicity, and Preliminary Anti-Tumor Activity of Autologous p95HER2.CAR-TECH2Me T Cells in Patients with Selected Advanced Cancers. Catherine Trial

Rationale

Not provided

Main Objective

To evaluate the safety and tolerability of the administration of p95HER2.CAR-TECH2Me cells in our target patients and to identify the maximum tolerated dose (MTD) and recommended phase-2 dose (RP2D).

Primary Endpoints

Nature and frequency of Adverse Events (AE), Serious Adverse Events (SAE), alterations in clinical laboratory test results, ECGs, vital sign measurements, physical examination findings and assessment of ECOG performance status score graded, when applicable, according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) v5.0.
Incidence and nature of Dose-limiting Toxicities (DLT)

Temporary moments of secondary assessment

Not provided

Secondary Objective

To evaluate the preliminary anti-tumor activity of the p95HER2.CAR-TECH2Me cells and survival in our target patients

Secondary Endpoints

Objective Response Rate (ORR), Duration of Response (DOR), and Progression-Free Survival (PFS) per RECIST v1.1 as assessed by the investigator, and Overall Survival (OS).

Temporary moments of secondary assessment

Not provided

Inclusion criteria

6) Patients must have histologically or cytologically proven unresectable or metastatic tumors. The disease must be refractory to standard therapy or in the first line if they are unable to receive standard therapy or no standard therapy exists for a particular disease. a) Select tumor types: breast, gastric, and endometrial tumors. Other selected solid tumors may be included per investigator discretion 15) Patients who are of childbearing potential (postmenarcheal who has not reached a postmenopausal state and has not undergone surgical sterilization) or have partners of childbearing potential must agree to use a highly effective method of contraception during the study and for at least 12 months after the infusion of the p95HER2.CAR-TECH2Me product. 1) Female participants: a female participant is eligible to participate if she is not pregnant, not breastfeeding, and at least one of the following conditions applies: a) Women of non-childbearing potential (WONCBP). b) Women of childbearing potential (WOCBP), who: i) Agree to remain abstinent (refrain from heterosexual intercourse) or use contraceptive methods that result in a failure rate of <1% per year from screening until 12 months after the infusion of the p95HER2.CAR-TECH2Me product. Have a negative pregnancy test (blood) within one week before the first study treatment administration 17) Male Participants: during the treatment period and for at least 6 months after the last dose of study treatment, agreement to: a) Remain abstinent (refrain from heterosexual intercourse) or use contraceptive measures such as a condom or a contraceptive method that result in a failure rate of <1% per year, with partners who are WOCBP. b) Refrain from donating sperm during the study. c) Inform if his partner gets pregnant during this time. 18) Adequate expanding p95HER2.CAR-TECH2Me cells as defined by the T cell production manual before preparative lymphodepleting chemotherapy infusion (available autologous transduced T lymphocytes with 15% or more expression of p95HER2.CAR-TECH2Me as determined by flow-cytometry and killing of p95HER2-positive targets 20 % or greater in cytotoxicity assay.) 19) Any toxicity related to prior systemic therapy must have recovered to grade 1 or less according to NCI-CTCAE v5.0 at least 4 weeks before treatment enrollment, except for alopecia, vitiligo, or endocrinopathy managed with replacement therapy, and Grade 2 peripheral neuropathy. Note: Other Grade 2 AEs that are deemed clinically insignificant by treating physician and in consultation with Medical Monitor are permitted. 20) Patients may have undergone minor surgical procedures within the past 3 weeks, as long as all toxicities have recovered to grade 1 or less. 7) Positivity for HER-2 expression according to international society guidelines (score in a ISO-certied clinical or equivalent laboratory). To meet study entry eligibility, tumors are required to have at least an intensity score 3+ for HER2 staining following the manufacturers recommendations Measurable disease by the RECIST v. 1.1 criteria 9) Patients are considered medically fit enough to undergo all study procedures and interventions and adequate hematological, renal, and hepatic functions 10) Patients must be seronegative for HIV antibody Patients must be seronegative for active hepatitis B and seronegative for hepatitis C antibody. 12) Patients must have blood tests results negative for active tuberculosis, syphilis, herpes simplex virus, cytomegalovirus, HTLV or Epstein-Barr virus infection. 13) Patients with documented LVEF of 50%. 14) Patients with documented FEV1, FVC, and DLCO 50% tested by a pulmonary function test.

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1) Patients with symptomatic and/or untreated brain metastases. 10) Patients with current or history within the last 6 months, as determined by the Investigator, of clinically significant, progressive, and/or uncontrolled renal, hepatic, hematological, endocrine, pulmonary, cardiac, gastroenterological or neurological disease. 11) Patients with a history of coronary revascularization or ischemic symptoms. 12) History of idiopathic pulmonary fibrosis or evidence of active pneumonitis (any origin) 13) Patients with allergies to any of the compounds included in any of the treatment products. 14) Patients with contraindications for cyclophosphamide and fludarabine at per protocol doses (see Investigator Brochure for details). 15) Patients who have received any approved anti-cancer cytotoxic, anti-angiogenic and ICB therapy including radiotherapy within 4 weeks before preparative lymphodepleting therapy. 16) Patients who have received any non-cytotoxic drug and molecular targeted therapy within 4 weeks before preparative lymphodepleting therapy (or within five half-lives of the investigational product, whichever is shorter). 17) Patients who have received any investigational agent within 4 weeks before preparative lymphodepleting therapy (or within five half-lives of the investigational product, whichever is shorter). 18) Patients who have received a live, attenuated vaccination within the 4 weeks before lymphodepleting therapy. 19) Patients who have undergone major surgery in the previous 3 weeks before lymphodepleting therapy. 2) Patients with leptomeningeal carcinomatosis. 20) Patients who have previously received any investigational cell or gene therapies. 21) Women of childbearing

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Calendar

(Last Update: 25/08/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
17/12/2025	17/04/2026	29/04/2026	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

Vall D Hebron Institute Of Oncology Spain

Calle Natzaret 115

Contact Person

Group Leader, VHIO

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jarribas@vhio.net

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Hospital Universitari Vall d Hebron

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Sites

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

Hospital Del Mar

Barcelona

BARCELONA

Oncología Médica

Active (29/04/2026)

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Oncología Médica

Medication

p95HER2.CAR-TECH2Me
CELL SUSPENSION FOR INJECTION
INTRAVENOUS

-

Active Principles: N/A

Experimental

Fludarabina Teva 25 mg/ml concentrado para solución para perfusión o inyección EFG
INJECTION
INTRAVENOUS

ATC code: L01BB05 - FLUDARABINA
Active Principles: N/A

Experimental

Genoxal 1.000 mg polvo para solución inyectable y para perfusión
SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS

ATC code: L01AA01 - CICLOFOSFAMIDA
Active Principles: N/A

Experimental

No results