A Study to Evaluate the Efficacy and Safety of Multiple Treatment Combinations in Patients with Breast Cancer (Morpheus- Breast Cancer)

Estado	**Tipo de Participantes**	**Rangos de Edad**
Reclutando	Sujetos incapaces de otorgar consentimiento , Mujeres embarazas	Menores de 18 , Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Mujeres	Fase I , Fase II	159
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia	NO

Información

Identificador

2023-507495-48-00 (CTIS)

Cod. Protocolo

CO42867

Transicionado 2020-004889-19

Área terapéutica

Enfermedades [C] - Cáncer [C04]|

Enfermedad investigada

Breast cancer

Título Científico

A Phase Ib/II, Open-Label, Multicenter, Randomized Umbrella Study Evaluating the Efficacy and Safety of Multiple Treatment Combinations in Patients with Breast Cancer (Morpheus-Breast Cancer)

Justificación

No aportado

Objetivo Principal

To evaluate the efficacy (overall response), and safety, of treatment combinations during Stage 1

Variables de Evaluación Primaria

1. Objective response rate
2. Incidence, nature, and severity of adverse events and laboratory abnormalities, with severity determined according to National Cancer Institute Common Terminology Criteria for Adverse Events, Version 5.0

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To evaluate the efficacy of treatment combinations during Stage 1 based on progression-free survival, disease control rate, clinical benefit rate, overall survival, duration of response

Variables de Evaluación Secundaria

1. Progression-free survival
2. Disease control rate
3. Clinical benefit rate
4. Overall Survival
5. Duration of response

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Cohort-1: Documented estrogen receptor+ tumor according to American Society of Clinical Oncology/College of American Pathologists guidelines, assessed locally and defined as >= 1% of tumor cells stained positive based on the most recent tumor biopsy or archived tumor sample Cohort-1: Patients for whom endocrine therapy is

recommended and treatment with cytotoxic chemotherapy is not indicated at time of entry into the study, as per national or local treatment guidelines Cohort-1: Radiologic/objective evidence of recurrence or progression after the most recent systemic therapy for breast cancer Cohort-2: Documented ER + tumor according to ASCO/CAP guidelines, assessed locally and defined as >= 1% of tumor cells stained positive based on the most recent tumor biopsy. Patient must be considered appropriate for ET and anti-HER2 therapy Cohort-1 and Cohort 2: Measurable disease according to RECIST v1.1 Cohort 3: Histologically or cytologically confirmed adenocarcinoma of the breast that is locally advanced or metastatic and is not amenable to surgical or radiation therapy with curative intent

Criterios de Exclusión

Cohort-1: Known HER2-positive breast cancer
Cohort-1: Prior treatment with cytotoxic chemotherapy for metastatic breast cancer (except for single agent capecitabine, which will count as a line of therapy)
Cohort-1: Prior treatment with SERD (except fulvestrant)
Cohort-2: Prior treatment with any of the protocol specified study treatments
Cohort-2: Systemic treatment for breast cancer within 2 weeks of Day 1 of Cycle 1 or 5 half-lives of the drug (whichever is longer) prior to Day 1 of Cycle 1
Cohort 1, Cohort-2 and Cohort 3: Major surgical procedure other than for diagnosis within 4 weeks prior to initiation of study treatment or anticipation of need for a major surgical procedure during the course of the study

Calendario

(Última actualización: 20/04/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
23/02/2021	28/05/2021	28/07/2021	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

F. Hoffmann-La Roche AG Switzerland

Grenzacherstrasse 124

Contact Person

Trial Information System - TISL

41616881111

global.eudract@roche.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm de la Comunidad Foral de Navarra

C/ Irunlarrea, 3 31008 Pamplona

ceic@cfnavarra.es

Centros

Activo (16/06/2021)

Centro Integral Oncológico Clara Campal

Madrid

MADRID

-

Activo (19/04/2021)

HOSPITAL CLINICO UNIVERSITARIO DE VALENCIA

Valencia

VALENCIA

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

Hospital Clinico Universitario De Valencia

Valencia

VALENCIA

Oncology

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

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Medical Oncology

Activo (12/03/2021)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

-

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

Hospital Universitario Hm Sanchinarro

Madrid

MADRID

Medical Oncology

Activo (17/12/2021)

HOSPITAL UNIVERSITARIO RAMON Y CAJAL

Madrid

MADRID

-

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

Hospital Universitario Ramon Y Cajal

Madrid

MADRID

Medical Oncology

Medicamentos

RO7197597
CAPSULE, HARD
ORAL

-
Principios Activos: N/A

Experimental

RO7563363
CAPSULE, HARD
ORAL

-
Principios Activos: N/A

Experimental

Afinitor 10 mg tablets
TABLET
ORAL

Código ATC: L01EG02 - EVEROLIMUS
Principios Activos: N/A

Experimental

Verzenios 150 mg film-coated tablets
FILM-COATED TABLET
ORAL

Código ATC: L01EF03 - ABEMACICLIB
Principios Activos: N/A

Experimental

IBRANCE 100 mg film-coated tablets
FILM-COATED TABLET
ORAL

Código ATC: L01EF01 - PALBOCICLIB
Principios Activos: N/A

Experimental

INAVOLISIB
FILM-COATED TABLET
ORAL

-
Principios Activos: N/A

Experimental

INAVOLISIB
FILM-COATED TABLET
ORAL

-
Principios Activos: N/A

Experimental

IBRANCE 75 mg film-coated tablets
FILM-COATED TABLET
ORAL

Código ATC: L01EF01 - PALBOCICLIB
Principios Activos: N/A

Experimental

Afinitor 5 mg tablets
TABLET
ORAL

Código ATC: L01EG02 - EVEROLIMUS
Principios Activos: N/A

Experimental

Afinitor 10 mg tablets
TABLET
ORAL

Código ATC: L01EG02 - EVEROLIMUS
Principios Activos: N/A

Experimental

Verzenios 50 mg film-coated tablets
FILM-COATED TABLET
ORAL

Código ATC: L01EF03 - ABEMACICLIB
Principios Activos: N/A

Experimental

INAVOLISIB
FILM-COATED TABLET
ORAL

-

Principios Activos: N/A

Experimental

Tecentriq 840 mg concentrate for solution for infusion
SOLUTION FOR INFUSION
IV INFUSION

Código ATC: L01FF05 - ATEZOLIZUMAB
Principios Activos: N/A

Experimental

Kisqali 200 mg film-coated tablets
FILM-COATED TABLET
ORAL

Código ATC: L01EF02 - RIBOCICLIB
Principios Activos: N/A

Experimental

Verzenios 100 mg film-coated tablets
FILM-COATED TABLET
ORAL

IBRANCE 125 mg film-coated tablets
FILM-COATED TABLET
ORAL

Código ATC: L01EF03 - ABEMACICLIB
Principios Activos: N/A

Experimental

Código ATC: L01EF01 - PALBOCICLIB
Principios Activos: N/A

Experimental

Phesgo 600 mg/600 mg solution for injection

SOLUTION FOR INJECTION
SUBCUTANEOUS

Código ATC: L01XY02 - PERTUZUMAB Y TRASTUZUMAB
Principios Activos: N/A

Experimental

Ipatasertib

FILM-COATED TABLET
ORAL

-

Principios Activos: N/A

Experimental

Afinitor 5 mg tablets

TABLET
ORAL

Código ATC: L01EG02 - EVEROLIMUS
Principios Activos: N/A

Experimental

INAVOLISIB

FILM-COATED TABLET
ORAL

-

Principios Activos: N/A

Experimental

Phesgo 1200 mg/600 mg solution for injection

SOLUTION FOR INJECTION
SUBCUTANEOUS

Código ATC: L01XY02 - PERTUZUMAB Y TRASTUZUMAB
Principios Activos: N/A

Experimental

Sin resultados

A Study to Evaluate the Efficacy and Safety of Multiple Treatment Combinations in Patients with Breast Cancer (Morpheus- Breast Cancer)

State	Type of participants	Age Ranges
Recruiting	Incapable subjects of giving consent , Pregnant women	Less than 18 , Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Women	Phase I , Phase II	159
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness	NO

Information

Identifier
2023-507495-48-00 (CTIS)

Protocol Code
CO42867

Transitioned 2020-004889-19

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

Investigated Disease
Breast cancer

Scientific Title
A Phase Ib/II, Open-Label, Multicenter, Randomized Umbrella Study Evaluating the Efficacy and Safety of Multiple Treatment Combinations in Patients with Breast Cancer (Morpheus-Breast Cancer)

Rationale

Not provided

Main Objective

To evaluate the efficacy (overall response), and safety, of treatment combinations during Stage 1

Primary Endpoints

1. Objective response rate
2. Incidence, nature, and severity of adverse events and laboratory abnormalities, with severity determined according to National Cancer Institute Common Terminology Criteria for Adverse Events, Version 5.0

Temporary moments of secondary assessment

Not provided

Secondary Objective

To evaluate the efficacy of treatment combinations during Stage 1 based on progression-free survival, disease control rate, clinical benefit rate, overall survival, duration of response

Secondary Endpoints

1. Progression-free survival
2. Disease control rate
3. Clinical benefit rate
4. Overall Survival
5. Duration of response

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Cohort-1: Documented estrogen receptor+ tumor according to American Society of Clinical Oncology/College of American Pathologists guidelines, assessed locally and defined as >= 1% of tumor cells stained positive based on the most recent tumor biopsy or archived tumor sample Cohort-1: Patients for whom endocrine therapy is

recommended and treatment with cytotoxic chemotherapy is not indicated at time of entry into the study, as per national or local treatment guidelines Cohort-1: Radiologic/objective evidence of recurrence or progression after the most recent systemic therapy for breast cancer Cohort-2: Documented ER + tumor according to ASCO/CAP guidelines, assessed locally and defined as >= 1% of tumor cells stained positive based on the most recent tumor biopsy. Patient must be considered appropriate for ET and anti-HER2 therapy Cohort-1 and Cohort 2: Measurable disease according to RECIST v1.1 Cohort 3: Histologically or cytologically confirmed adenocarcinoma of the breast that is locally advanced or metastatic and is not amenable to surgical or radiation therapy with curative intent

Exclusion criteria

Cohort-1: Known HER2-positive breast cancer
Cohort-1: Prior treatment with cytotoxic chemotherapy for metastatic breast cancer (except for single agent capecitabine, which will count as a line of therapy)
Cohort-1: Prior treatment with SERD (except fulvestrant)
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Cohort 1, Cohort-2 and Cohort 3: Major surgical procedure other than for diagnosis within 4 weeks prior to initiation of study treatment or anticipation of need for a major surgical procedure during the course of the study

Calendar

(Last Update: 20/04/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
23/02/2021	28/05/2021	28/07/2021	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

F. Hoffmann-La Roche AG Switzerland

Grenzacherstrasse 124

Contact Person

Trial Information System - TISL

41616881111

global.eudract@roche.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm de la Comunidad Foral de Navarra

C/ Irunlarrea, 3 31008 Pamplona

ceic@cfnavarra.es

Sites

Active (16/06/2021)

Centro Integral Oncológico Clara Campal

Madrid

MADRID

-

Active (19/04/2021)

HOSPITAL CLINICO UNIVERSITARIO DE VALENCIA

Valencia

VALENCIA

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

Hospital Clinico Universitario De Valencia

Valencia

VALENCIA

Oncology

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

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Medical Oncology

Active (12/03/2021)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

-

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

Hospital Universitario Hm Sanchinarro

Madrid

MADRID

Medical Oncology

Active (17/12/2021)

HOSPITAL UNIVERSITARIO RAMON Y CAJAL

Madrid

MADRID

-

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

Hospital Universitario Ramon Y Cajal

Madrid

MADRID

Medical Oncology

Medication

RO7197597
CAPSULE, HARD
ORAL

-

Active Principles: N/A

Experimental

RO7563363
CAPSULE, HARD
ORAL

-

Active Principles: N/A

Experimental

Afinitor 10 mg tablets
TABLET
ORAL

ATC code: L01EG02 - EVEROLIMUS
Active Principles: N/A

Experimental

Verzenios 150 mg film-coated tablets
FILM-COATED TABLET
ORAL

ATC code: L01EF03 - ABEMACICLIB
Active Principles: N/A

Experimental

IBRANCE 100 mg film-coated tablets
FILM-COATED TABLET
ORAL

ATC code: L01EF01 - PALBOCICLIB
Active Principles: N/A

Experimental

INAVOLISIB
FILM-COATED TABLET
ORAL

-

Active Principles: N/A

Experimental

INAVOLISIB
FILM-COATED TABLET
ORAL

-

Active Principles: N/A

Experimental

IBRANCE 75 mg film-coated tablets
FILM-COATED TABLET
ORAL

ATC code: L01EF01 - PALBOCICLIB
Active Principles: N/A

Experimental

Afinitor 5 mg tablets
TABLET
ORAL

ATC code: L01EG02 - EVEROLIMUS
Active Principles: N/A

Experimental

Afinitor 10 mg tablets
TABLET
ORAL

ATC code: L01EG02 - EVEROLIMUS
Active Principles: N/A

Experimental

Verzenios 50 mg film-coated tablets
FILM-COATED TABLET
ORAL

ATC code: L01EF03 - ABEMACICLIB
Active Principles: N/A

Experimental

INAVOLISIB
FILM-COATED TABLET
ORAL

-

Active Principles: N/A

Experimental

Tecentriq 840 mg concentrate for solution for infusion
SOLUTION FOR INFUSION
IV INFUSION

ATC code: L01FF05 - ATEZOLIZUMAB
Active Principles: N/A

Experimental

Kisqali 200 mg film-coated tablets
FILM-COATED TABLET
ORAL

ATC code: L01EF02 - RIBOCICLIB
Active Principles: N/A

Experimental

Verzenios 100 mg film-coated tablets
FILM-COATED TABLET
ORAL

IBRANCE 125 mg film-coated tablets
FILM-COATED TABLET
ORAL

ATC code: L01EF03 - ABEMACICLIB
Active Principles: N/A

Experimental

ATC code: L01EF01 - PALBOCICLIB
Active Principles: N/A

Experimental

Phesgo 600 mg/600 mg solution for injection

SOLUTION FOR INJECTION
SUBCUTANEOUS

ATC code: L01XY02 - PERTUZUMAB Y TRASTUZUMAB
Active Principles: N/A

Experimental

Ipatasertib

FILM-COATED TABLET
ORAL

-

Active Principles: N/A

Experimental

Afinitor 5 mg tablets

TABLET
ORAL

ATC code: L01EG02 - EVEROLIMUS
Active Principles: N/A

Experimental

INAVOLISIB

FILM-COATED TABLET
ORAL

-

Active Principles: N/A

Experimental

Phesgo 1200 mg/600 mg solution for injection

SOLUTION FOR INJECTION
SUBCUTANEOUS

ATC code: L01XY02 - PERTUZUMAB Y TRASTUZUMAB
Active Principles: N/A

Experimental

No results