A Phase 3, Randomized Study to Compare Nemtabrutinib Versus Comparator (Investigators Choice of Ibrutinib or Acalabrutinib) in Participants With Untreated Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (BELLWAVE 011)

Estado	Tipo de Participantes	Rangos de Edad
Reclutando	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	948
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia, farmacocinética, farmacodinamica, farmacogenómica	NO

Información

Identificador
2022-501697-19-01 (CTIS)

Cod. Protocolo
MK-1026-011

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

Enfermedad investigada
Small Lymphocytic Lymphoma (SLL) / Untreated Chronic Lymphocytic Leukemia (CLL)

Título Científico
A Phase 3, Randomized Study to Compare Nemtabrutinib Versus Comparator (Investigators Choice of Ibrutinib or Acalabrutinib) in Participants With Untreated Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (BELLWAVE-011)

Justificación

No aportado

Objetivo Principal

1. To compare nemtabrutinib to ibrutinib or acalabrutinib with respect to ORR per iwCLL criteria 2018 as assessed by BICR.
2. To compare nemtabrutinib to ibrutinib or acalabrutinib with respect to PFS per iwCLL criteria 2018 as assessed by BICR.

Variables de Evaluación Primaria

Objective Response Rate (ORR) per Chronic Lymphocytic Leukemia (iwCLL) Criteria 2018 as assessed by Blinded Independent Central Review (BICR)
Progression-Free Survival (PFS) per iwCLL Criteria 2018 as assessed by BICR

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To compare nemtabrutinib to ibrutinib or acalabrutinib with respect to OS.
To evaluate DOR per iwCLL criteria 2018 as assessed by BICR.
To evaluate the safety and tolerability of nemtabrutinib.

Variables de Evaluación Secundaria

Overall Survival (OS)
Duration of Response (DOR) per iwCLL Criteria 2018 as assessed by BICR
Number of Participants Who Experience One or More Adverse Events (AEs)
Number of Participants Who Discontinue Study Treatment Due to an AE

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Confirmed diagnosis of chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) and active disease clearly documented to have a need to initiate therapy.
Has at least 1 marker of disease burden.
Has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2 within 7 days before randomization.
Has the ability to swallow and retain oral medication.
Participants who are hepatitis B surface antigen (HBsAg) positive are eligible if they have received hepatitis B virus (HBV) antiviral therapy for at least 4 weeks and have undetectable HBV deoxyribonucleic acid (DNA) viral load before randomization.
Participants with history of hepatitis C virus (HCV) infection are eligible if HCV ribonucleic acid (RNA) viral load is undetectable at screening.
Participants with human immunodeficiency virus (HIV) who meet ALL eligibility criteria.

Criterios de Exclusión

Has an active hepatitis B virus/ hepatitis C virus (HBV/HCV) infection.
Is currently being treated with p-glycoprotein (P-gp) substrates with a narrow therapeutic index, cytochrome P450 3A (CYP3A) strong or moderate inducers or CYP3A strong inhibitors.
Received prior radiotherapy within 2 weeks of start of study intervention, or radiation-related toxicities, requiring corticosteroids.
Received a live or live-attenuated vaccine within 30 days before the first dose of study intervention. Administration of killed vaccines are allowed.
Has received an investigational agent or has used an investigational device within 4 weeks before study intervention administration.
Has active infection requiring systemic therapy, including intravenous (IV) antibiotics during screening.
Participants who have not adequately recovered from major surgery or have ongoing surgical complications.
Has gastrointestinal (GI) dysfunction that may affect drug absorption.
Has diagnosis of Richter Transformation or active central nervous system (CNS) involvement by CLL/SLL.
Has had acquired immune deficiency syndrome (AIDS)-defining opportunistic infection in the past 12 months before screening.
Has clinically significant cardiovascular disease.
Has hypersensitivity to nemtabrutinib or contraindication to ibrutinib or acalabrutinib, or any of the excipients.
Has history of severe bleeding disorder.
Has known additional malignancy that is progressing or has required active treatment within the past 2 years.
Has received any systemic anticancer therapy for CLL/SLL.

Calendario

(Última actualización: 04/05/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
17/06/2024	08/07/2024	24/07/2024	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

Merck Sharp & Dohme LLC United States

126 East Lincoln Avenue

Contact Person

Siyang Leng

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Monetary support: N/A

Tipo de promotor: Comercial

Ceim

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917044160

Centros

Activo (23/07/2024)

Hospital Clinic De Barcelona

Barcelona

BARCELONA

Hematology

Activo (08/07/2024)

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Hematology

Activo (23/07/2024)

Hospital Universitario Puerta De Hierro De Majadahonda

Majadahonda

MADRID

Hematology

Activo (08/07/2024)

Hospital Universitario Quironsalud Madrid

Pozuelo De Alarcon

MADRID

Hematology

Activo (08/07/2024)

Institut Catala D'oncologia

L'hospitalet De Llobregat

BARCELONA

Hematology

Activo (23/07/2024)

University Hospital Of Canary Islands

San Cristobal De La Laguna

STA. CRUZ DE TENERIFE

Hematology

Activo (08/08/2024)

Vall D'hebron Institut De Recerca

Barcelona

BARCELONA

Hematology

Medicamentos

Nemtabrutinib
TABLET
ORAL USE

-
Principios Activos: N/A
Experimental

Nemtabrutinib
FILM-COATED TABLET
ORAL USE

-
Principios Activos: N/A
Experimental

Nemtabrutinib
TABLET
ORAL USE

-
Principios Activos: N/A
Experimental

Nemtabrutinib
FILM-COATED TABLET
ORAL USE

-
Principios Activos: N/A
Experimental

-
-
ORAL USE

Código ATC: L01EL02 - ACALABRUTINIB
Principios Activos: N/A
Experimental

-
-
ORAL USE

Código ATC: L01EL01 - IBRUTINIB
Principios Activos: N/A
Experimental

Sin resultados

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State	Type of participants	Age Ranges
Recruiting	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	948
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness, pharmacokinetics, pharmacodynamics, pharmacogenomics	NO

Information

Identifier
2022-501697-19-01 (CTIS)

Protocol Code
MK-1026-011

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

Investigated Disease
Small Lymphocytic Lymphoma (SLL) / Untreated Chronic Lymphocytic Leukemia (CLL)

Scientific Title
A Phase 3, Randomized Study to Compare Nemtabrutinib Versus Comparator (Investigators Choice of Ibrutinib or Acalabrutinib) in Participants With Untreated Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (BELLWAVE-011)

Rationale

Not provided

Main Objective

1. To compare nemtabrutinib to ibrutinib or acalabrutinib with respect to ORR per iwCLL criteria 2018 as assessed by BICR.
2. To compare nemtabrutinib to ibrutinib or acalabrutinib with respect to PFS per iwCLL criteria 2018 as assessed by BICR.

Primary Endpoints

Objective Response Rate (ORR) per Chronic Lymphocytic Leukemia (iwCLL) Criteria 2018 as assessed by Blinded Independent Central Review (BICR)
Progression-Free Survival (PFS) per iwCLL Criteria 2018 as assessed by BICR

Temporary moments of secondary assessment

Not provided

Secondary Objective

To compare nemtabrutinib to ibrutinib or acalabrutinib with respect to OS.
To evaluate DOR per iwCLL criteria 2018 as assessed by BICR.
To evaluate the safety and tolerability of nemtabrutinib.

Secondary Endpoints

Overall Survival (OS)
Duration of Response (DOR) per iwCLL Criteria 2018 as assessed by BICR
Number of Participants Who Experience One or More Adverse Events (AEs)
Number of Participants Who Discontinue Study Treatment Due to an AE

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Confirmed diagnosis of chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) and active disease clearly documented to have a need to initiate therapy.
Has at least 1 marker of disease burden.
Has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2 within 7 days before randomization.
Has the ability to swallow and retain oral medication.
Participants who are hepatitis B surface antigen (HBsAg) positive are eligible if they have received hepatitis B virus (HBV) antiviral therapy for at least 4 weeks and have undetectable HBV deoxyribonucleic acid (DNA) viral load before randomization.
Participants with history of hepatitis C virus (HCV) infection are eligible if HCV ribonucleic acid (RNA) viral load is undetectable at screening.
Participants with human immunodeficiency virus (HIV) who meet ALL eligibility criteria.

Exclusion criteria

Has an active hepatitis B virus/ hepatitis C virus (HBV/HCV) infection.
Is currently being treated with p-glycoprotein (P-gp) substrates with a narrow therapeutic index, cytochrome P450 3A (CYP3A) strong or moderate inducers or CYP3A strong inhibitors.
Received prior radiotherapy within 2 weeks of start of study intervention, or radiation-related toxicities, requiring corticosteroids.
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Has diagnosis of Richter Transformation or active central nervous system (CNS) involvement by CLL/SLL.
Has had acquired immune deficiency syndrome (AIDS)-defining opportunistic infection in the past 12 months before screening.
Has clinically significant cardiovascular disease.
Has hypersensitivity to nemtabrutinib or contraindication to ibrutinib or acalabrutinib, or any of the excipients.
Has history of severe bleeding disorder.
Has known additional malignancy that is progressing or has required active treatment within the past 2 years.
Has received any systemic anticancer therapy for CLL/SLL.

Calendar

(Last Update: 04/05/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
17/06/2024	08/07/2024	24/07/2024	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

Merck Sharp & Dohme LLC United States

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Contact Person

Siyang Leng

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siyang.leng@merck.com

Monetary support: N/A

Sponsor type: Commercial

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Sites

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STA. CRUZ DE TENERIFE

Hematology

Active (08/08/2024)

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BARCELONA

Hematology

Medication

Nemtabrutinib
TABLET
ORAL USE

-
Active Principles: N/A
Experimental

Nemtabrutinib
FILM-COATED TABLET
ORAL USE

-
Active Principles: N/A
Experimental

Nemtabrutinib
TABLET
ORAL USE

-
Active Principles: N/A
Experimental

Nemtabrutinib
FILM-COATED TABLET
ORAL USE

-
Active Principles: N/A
Experimental

-
-
ORAL USE

ATC code: L01EL02 - ACALABRUTINIB
Active Principles: N/A
Experimental

-
-
ORAL USE

ATC code: L01EL01 - IBRUTINIB
Active Principles: N/A
Experimental

No results