

## 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)

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

## Información

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| <b>Identificador</b><br>2022-501697-19-01 (CTIS) | <b>Cod. Protocolo</b><br>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

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## 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.
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## 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

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## Momentos temporales de evaluación primaria

No aportado

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## 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.

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## 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

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## Momentos temporales de evaluación secundaria

No aportado

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## Criterios de Inclusión

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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.

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### 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)

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|---------------------------------------------------|-----------------------------------------------------|-------------------------------------------------------|-------------------------------------------------------|----------------------------------------------------|
| <b>Autorización</b><br><b>17/06/2024</b>          | <b>Inicio de Ensayo</b><br><b>08/07/2024</b>        | <b>Inclusión Primer Paciente</b><br><b>24/07/2024</b> | <b>Interrumpido</b><br><b>No aportado</b>             | <b>Reiniciado</b><br><b>No aportado</b>            |
| <b>Fin de reclutamiento</b><br><b>No aportado</b> | <b>Fin prematuro (España)</b><br><b>No aportado</b> | <b>Fin prematuro (Global)</b><br><b>No aportado</b>   | <b>Fin del ensayo en España</b><br><b>No aportado</b> | <b>Fin del ensayo global</b><br><b>No aportado</b> |

## Promotor

**Merck Sharp & Dohme LLC United States**

126 East Lincoln Avenue

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**Contact Person**

Siyang Leng

+17325945796

siyang.leng@merck.com

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Monetary support: N/A

Tipo de promotor: Comercial

## Ceim

### CEIm Hospital Clínico San Carlos

C/ Doctor Martín Lagos, s/n - Ciudad Universitaria 28040 Madrid

ceic.hcsc@salud.madrid.org

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## Centros

|                     |                                                                                                      |                     |                                                                                                                   |
|---------------------|------------------------------------------------------------------------------------------------------|---------------------|-------------------------------------------------------------------------------------------------------------------|
| Activo (23/07/2024) | <b>Hospital Clinic De Barcelona</b><br>Barcelona<br>BARCELONA<br>Hematology                          | Activo (08/07/2024) | <b>Hospital Universitario De Salamanca</b><br>Salamanca<br>SALAMANCA<br>Hematology                                |
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| Activo (23/07/2024) | <b>Hospital Universitario Puerta De Hierro De Majadahonda</b><br>Majadahonda<br>MADRID<br>Hematology | Activo (08/07/2024) | <b>Hospital Universitario Quironsalud Madrid</b><br>Pozuelo De Alarcon<br>MADRID<br>Hematology                    |
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| Activo (08/07/2024) | <b>Institut Catala D'oncologia</b><br>L'hospitalet De Llobregat<br>BARCELONA<br>Hematology           | Activo (23/07/2024) | <b>University Hospital Of Canary Islands</b><br>San Cristobal De La Laguna<br>STA. CRUZ DE TENERIFE<br>Hematology |
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| Activo (08/08/2024) | <b>Vall D&amp;#39;hebron Institut De Recerca</b><br>Barcelona<br>BARCELONA<br>Hematology             |                     |                                                                                                                   |
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## Medicamentos

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| <div><div>Nemtabrutinib<br/>TABLET<br/>ORAL USE</div><div>-</div><div>Principios Activos: N/A</div><div>Experimental</div></div>            | <div><div>Nemtabrutinib<br/>FILM-COATED TABLET<br/>ORAL USE</div><div>-</div><div>Principios Activos: N/A</div><div>Experimental</div></div> |
| <div><div>Nemtabrutinib<br/>TABLET<br/>ORAL USE</div><div>-</div><div>Principios Activos: N/A</div><div>Experimental</div></div>            | <div><div>Nemtabrutinib<br/>FILM-COATED TABLET<br/>ORAL USE</div><div>-</div><div>Principios Activos: N/A</div><div>Experimental</div></div> |
| <div><div>-<br/>-<br/>ORAL USE</div><div>Código ATC: L01EL02 - ACALABRUTINIB<br/>Principios Activos: N/A</div><div>Experimental</div></div> | <div><div>-<br/>-<br/>ORAL USE</div><div>Código ATC: L01EL01 - IBRUTINIB<br/>Principios Activos: N/A</div><div>Experimental</div></div>      |

## Sin resultados

## 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)

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

## Information

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|-----------------------------------------------|-------------------------------------|
| <b>Identifier</b><br>2022-501697-19-01 (CTIS) | <b>Protocol Code</b><br>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

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## 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

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## Temporary moments of secondary assessment

Not provided

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## 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.

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## 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

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## Temporary moments of secondary assessment

Not provided

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## Inclusion criteria

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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.

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Participants with human immunodeficiency virus (HIV) who meet ALL eligibility criteria.

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### 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.

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Has clinically significant cardiovascular disease.

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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)

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|-------------------------------------------------|----------------------------------------------------|-----------------------------------------------------|------------------------------------------------|-------------------------------------------------|
| <b>Authorization</b><br><b>17/06/2024</b>       | <b>Start of Trial</b><br><b>08/07/2024</b>         | <b>First patient inclusion</b><br><b>24/07/2024</b> | <b>Halted</b><br><b>Not aported</b>            | <b>Restarted</b><br><b>Not aported</b>          |
| <b>End of recruitment</b><br><b>Not aported</b> | <b>Premature end (Spain)</b><br><b>Not aported</b> | <b>Premature End (Global)</b><br><b>Not aported</b> | <b>Trial end (Spain)</b><br><b>Not aported</b> | <b>Trial end (Global)</b><br><b>Not aported</b> |

## Sponsor

**Merck Sharp & Dohme LLC United States**  
126 East Lincoln Avenue

**Contact Person**

Siyang Leng  
+17325945796  
siyang.leng@merck.com

Monetary support: N/A  
Sponsor type: Commercial

## Ceim

**CEIm Hospital Clínico San Carlos**  
C/ Doctor Martín Lagos, s/n - Ciudad Universitaria 28040 Madrid  
ceic.hcsc@salud.madrid.org  
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## Sites

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## Medication

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| <div><div>Nemtabrutinib</div><div>TABLET</div><div>ORAL USE</div></div> <div>-</div> <div>Active Principles: N/A</div> <div>Experimental</div>                | <div><div>Nemtabrutinib</div><div>FILM-COATED TABLET</div><div>ORAL USE</div></div> <div>-</div> <div>Active Principles: N/A</div> <div>Experimental</div> |
| <div><div>Nemtabrutinib</div><div>TABLET</div><div>ORAL USE</div></div> <div>-</div> <div>Active Principles: N/A</div> <div>Experimental</div>                | <div><div>Nemtabrutinib</div><div>FILM-COATED TABLET</div><div>ORAL USE</div></div> <div>-</div> <div>Active Principles: N/A</div> <div>Experimental</div> |
| <div><div>-</div><div>-</div><div>ORAL USE</div></div> <div>ATC code: L01EL02 - ACALABRUTINIB</div> <div>Active Principles: N/A</div> <div>Experimental</div> | <div><div>-</div><div>-</div><div>ORAL USE</div></div> <div>ATC code: L01EL01 - IBRUTINIB</div> <div>Active Principles: N/A</div> <div>Experimental</div>  |

No results