Study to Assess Change in Disease Activity and Adverse Events of Oral Venetoclax With Intravenous (IV) Obinutuzumab in Adult Participants With Recurring Chronic

Estado	**Tipo de Participantes**	**Rangos de Edad**
Reclutando	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase II	31
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Unicéntrico nacional	seguridad, eficacia	NO

Información

Identificador

2023-504599-10-00 (CTIS)

Cod. Protocolo

M20-356

Transicionado 2021-001037-39

Área terapéutica

Enfermedades [C] - Hematología [C15]|

Enfermedad investigada

Chronic lymphocytic leukemia recurrent

Título Científico

A Multicenter, Open-Label, Phase 2 Study to Evaluate the Efficacy and Safety of VenetoclaxObinutuzumab Retreatment in Patients with Recurring Chronic Lymphocytic Leukemia

Justificación

No aportado

Objetivo Principal

The primary objective of the study is to assess the efficacy of VenG retreatment in Cohort 1.
The corresponding primary estimand is the ORR achieved by "all treated subjects" in Cohort 1 by their EOCT assessment (i.e., EOCT + 3 months, or "EOCT + 3").

Variables de Evaluación Primaria

The primary efficacy endpoint is the overall response of CR, CRi, nPR, or PR in Cohort 1 subjects as assessed by the investigator at the EOCT, evaluated 3 months after the EOCT with VenG (EOCT + 3, i.e., Cycle 9).
Disease assessments will be based on the 2018 International Workshop for Chronic Lymphocytic Leukemia criteria for tumor response.
Overall response rate is defined as the proportion of subjects achieving a best response of CR, CRi, nPR, or PR.

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

The secondary efficacy objective is to quantify the efficacy of treatment with VenG in Cohort 1 via the secondary endpoints specified.
No hypothesis testing framework or any formal statistical comparisons will be conducted during this study.
Appropriate summaries including descriptive statistics and CIs will serve as the basis for our analysis.
Assessing the safety of retreatment with VenG is also a secondary objective of this study.

Variables de Evaluación Secundaria

Overall response of CR or CRi at end of treatment assessment (EOT, assessed at EOT + 3) Overall response of CR, CRi, nPR, or PR at EOT (assessed at EOT + 3) Time to response (TTR) Duration of response (DOR) Time to next treatment (TTNT) for CLL Progression-free survival (PFS) Overall survival (OS) uMRD rate (< 10-4) at EOCT, measured in PB (assessed at EOCT+ 3) uMRD rate (< 10-4) at EOT, measured in PB (assessed at EOT + 3)

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Subjects must voluntarily sign and date an informed consent, approved by an independent ethics committee (IEC)/institutional review board (IRB), prior to the initiation of any screening or study-specific procedures.
Subjects must not be incarcerated and must be freely willing and able to provide informed consent (e.g., adults under legal protection measure [e.g., under guardianship/curatorship] or unable to express their consent and select adults under psychiatric care). Investigator's discretion should be applied.
Documented diagnosis of CLL that requires retreatment according to iwCLL criteria.
Previously completed venetoclax + anti-CD20 antibody ± X (where X is any additional drug) regimen as 1L fixed duration therapy and achieved documented response, defined as CR, CRi, PR, or nPR. Subjects who stopped 1L therapy earlier but completed at least 9 months of therapy and had a documented clinical response may be eligible based on the investigator's discretion. In Cohort 1, a maximum of approximately 20 subjects who previously received rituximab in 1L may be enrolled; in Cohort 2, there is no maximum number of subjects who previously received rituximab.
Patients who will not receive approved second-line therapies as assessed by the investigator and patient preference may be eligible for the study.
a) For Cohort 1: More than 24 months between the last dose of venetoclax and progression requiring treatment after completion of 1L venetoclax + anti-CD20 antibody ± X treatment; b) for Cohort 2: 12- 24 months between the last dose of venetoclax and progression requiring treatment after completion of 1L venetoclax + anti-CD20 antibody ± X treatment.
Subject has not received an intervening treatment for CLL after completing previous treatment with venetoclax + anti-CD20 antibody ± X.
Subject has not discontinued prior venetoclax + anti-CD20 antibody ± X treatment due to PD during treatment.
No active or uncontrolled autoimmune hemolytic anemia or immune thrombocytopenic purpura.
No transformation of CLL to aggressive NHL (Richter's transformation or pro-lymphocytic leukemia).

Criterios de Exclusión

NA

Calendario

(Última actualización: 07/07/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
30/11/2021	29/03/2022	No aportado	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

AbbVie Deutschland GmbH & Co. KG Germany

Mainzer Strasse 81

Contact Person

Global Clinial Trial Helpdesk

+4961117201520

global-clinical-trials@abbvie.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Hospital Universitario de La Princesa

C/ Diego de León, 62 28006 Madrid

ceim.hlpr@salud.madrid.org

Centros

Activo (29/03/2022)

HOSPITAL UNIVERSITARIO DE LA PRINCESA

Madrid

MADRID

Servicio de Hematología

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

Hospital Universitario De La Princesa

Madrid

MADRID

not applicable

Medicamentos

Venetoclax
FILM-COATED TABLET
ORAL USE

-
Principios Activos: N/A

Experimental

Venetoclax
FILM-COATED TABLET
ORAL USE

-
Principios Activos: N/A

Experimental

Gazyvaro 1,000 mg concentrate for solution for infusion.
SOLUTION FOR INFUSION
INTRAVENOUS INFUSION

Código ATC: L01XC15 - OBINUTUZUMAB
Principios Activos: N/A

Experimental

Venetoclax
FILM-COATED TABLET
ORAL USE

-
Principios Activos: N/A

Experimental

Sin resultados

Study to Assess Change in Disease Activity and Adverse Events of Oral Venetoclax With Intravenous (IV) Obinutuzumab in Adult Participants With Recurring Chronic

State	**Type of participants**	**Age Ranges**
Recruiting	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase II	31
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
National One-center	safety, effectiveness	NO

Information

Identifier

2023-504599-10-00 (CTIS)

Protocol Code

M20-356

Transitioned 2021-001037-39

Therapeutic area

Diseases [C] - Hemic and Lymphatic Diseases [C15]|

Investigated Disease

Chronic lymphocytic leukemia recurrent

Scientific Title

A Multicenter, Open-Label, Phase 2 Study to Evaluate the Efficacy and Safety of VenetoclaxObinutuzumab Retreatment in Patients with Recurring Chronic Lymphocytic Leukemia

Rationale

Not provided

Main Objective

The primary objective of the study is to assess the efficacy of VenG retreatment in Cohort 1.
The corresponding primary estimand is the ORR achieved by "all treated subjects" in Cohort 1 by their EOCT assessment (i.e., EOCT + 3 months, or "EOCT + 3").

Primary Endpoints

The primary efficacy endpoint is the overall response of CR, CRi, nPR, or PR in Cohort 1 subjects as assessed by the investigator at the EOCT, evaluated 3 months after the EOCT with VenG (EOCT + 3, i.e., Cycle 9).
Disease assessments will be based on the 2018 International Workshop for Chronic Lymphocytic Leukemia criteria for tumor response.
Overall response rate is defined as the proportion of subjects achieving a best response of CR, CRi, nPR, or PR.

Temporary moments of secondary assessment

Not provided

Secondary Objective

The secondary efficacy objective is to quantify the efficacy of treatment with VenG in Cohort 1 via the secondary endpoints specified.
No hypothesis testing framework or any formal statistical comparisons will be conducted during this study.
Appropriate summaries including descriptive statistics and CIs will serve as the basis for our analysis.
Assessing the safety of retreatment with VenG is also a secondary objective of this study.

Secondary Endpoints

Overall response of CR or CRi at end of treatment assessment (EOT, assessed at EOT + 3) Overall response of CR, CRi, nPR, or PR at EOT (assessed at EOT + 3) Time to response (TTR) Duration of response (DOR) Time to next treatment (TTNT) for CLL Progression-free survival (PFS) Overall survival (OS) uMRD rate (< 10-4) at EOCT, measured in PB (assessed at EOCT+ 3) uMRD rate (< 10-4) at EOT, measured in PB (assessed at EOT + 3)

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Subjects must voluntarily sign and date an informed consent, approved by an independent ethics committee (IEC)/institutional review board (IRB), prior to the initiation of any screening or study-specific procedures.
Subjects must not be incarcerated and must be freely willing and able to provide informed consent (e.g., adults under legal protection measure [e.g., under guardianship/curatorship] or unable to express their consent and select adults under psychiatric care). Investigator's discretion should be applied.
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No transformation of CLL to aggressive NHL (Richter's transformation or pro-lymphocytic leukemia).

Exclusion criteria

NA

Calendar

(Last Update: 07/07/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
30/11/2021	29/03/2022	Not aported	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

AbbVie Deutschland GmbH & Co. KG Germany

Mainzer Strasse 81

Contact Person

Global Clinial Trial Helpdesk

+4961117201520

global-clinical-trials@abbvie.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

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Sites

Active (29/03/2022)

HOSPITAL UNIVERSITARIO DE LA PRINCESA

Madrid

MADRID

Servicio de Hematología

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

Hospital Universitario De La Princesa

Madrid

MADRID

not applicable

Medication

Venetoclax
FILM-COATED TABLET
ORAL USE

-
Active Principles: N/A
Experimental

Venetoclax
FILM-COATED TABLET
ORAL USE

-
Active Principles: N/A
Experimental

Gazyvaro 1,000 mg concentrate for solution for infusion.
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INTRAVENOUS INFUSION

ATC code: L01XC15 - OBINUTUZUMAB
Active Principles: N/A
Experimental

Venetoclax
FILM-COATED TABLET
ORAL USE

-
Active Principles: N/A
Experimental

No results