A Randomized Study of Azetukalner Versus Placebo in Depressive Episodes Associated With Bipolar I or II Disorder (Bipolar Depression) - X-CEED

Estado
Interrumpido

Tipo de Participantes
No aportado

Rangos de Edad
Mayores de 64 , Adultos (18-64 años)

Género
Ambos

Fases
Fase III

Participantes esperados
256

Resultados
Sin resultados

Bajo nivel intervención
No

Enfermedad rara
No

Cobertura geográfica
Sin determinar

Ámbitos del ensayo
seguridad, eficacia

Terapia avanzada
NO

Información

Identificador
2025-522775-29-00 (CTIS)

Cod. Protocolo
XPF-010-B301

Área terapéutica
Psiquiatría y Psicología [F] - Desórdenes mentales [F03]|

Enfermedad investigada
Depressive episodes associated with Bipolar disorder I or II (Bipolar Depression)

Título Científico
A Phase 3, Randomized, Double-blind, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Azetukalner in Depressive Episodes Associated With Bipolar I or II Disorder (Bipolar Depression)

Justificación

No aportado

Objetivo Principal

To assess the efficacy and safety of 20 mg azetukalner QD versus placebo for the treatment of bipolar depression.

Variables de Evaluación Primaria

Change from baseline in the MADRS total score at Week 6.

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To assess clinician-perceived efficacy of 20 mg azetukalner once daily VS placebo for the treatment of bipolar depression; To assess the rapidity of efficacy onset of 20 mg azetukalner once daily VS placebo for the treatment of bipolar depression; and To assess the efficacy of 20 mg azetukalner once daily VS placebo for the treatment of anhedonia.

Variables de Evaluación Secundaria

Change from baseline in the CGI-S score at Week 6.
Change from baseline in the MADRS total score at Week 1.
Change from baseline in the SHAPS total score at Week 6.

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

3. Adults 18 and 74 years of age who experienced their first major depressive episode (MDE) prior to 50 years of age.
4. Body Mass Index (BMI) 18 kg/m2 and 40 kg/m2.
5. Meets the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision (DSM-5-TR) criteria for bipolar I or II disorder and is currently in a MDE, confirmed using the Mini International Neuropsychiatric Interview

(MINI).
6. Current MDE must has a duration of 4 weeks and 12 months.

Criterios de Exclusión

1. Participant has any type of MDD, including MDD with psychotic features, MDD with catatonia, MDD with seasonal pattern, or postpartum depression. 27. Participant is pregnant, breastfeeding, or planning to become pregnant. 2. Participant has any nonbipolar psychiatric diagnosis. 3. Participant has a substance use disorder (excluding tobacco) within the 6 months prior to screening visit. 5. Participant has a YMRS score >12 points at screening visit or randomization. 6. Participant has been hospitalized for mania within the 30 days prior to screening visit. 7. Participant is considered treatment-resistant in the current bipolar depressive episode, defined as having treatment resistance (no remission) to 2 different medications approved by the regional regulatory authority at an adequate dose (per regulatory-approved label) and for an adequate duration (at least 6 weeks). 9. Participant has had an active suicidal plan/intent prior to screening, presence of suicidal behavior. 11. Participant has used antidepressants, mood stabilizers, anticonvulsants, antipsychotics, or other prohibited medications within the 1 week prior to randomization or within a period less than 5-times the drug's half-life prior to randomization, whichever is longer. Participants with medical conditions that may interfere with the purpose or conduct of the study.

Calendario

(Última actualización: 26/09/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
13/03/2026	05/06/2026	No aportado	11/09/2026	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

Xenon Pharmaceuticals Inc. Canada

3650 Gilmore Way

Contact Person

Clinical Trial responsible person: Senior Director, Trial Operations

+18574180357

ksarma@xenon-pharma.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Hospital General Universitario Gregorio Marañón

C/ Doctor Esquerdo, 46 28007 Madrid

ceim.hgugm@salud.madrid.org

915867007

Centros

Activo (24/06/2026)

Hospital Alvaro Cunqueiro

Vigo

PONTEVEDRA

Psychiatry

Activo (27/07/2026)

Hospital General Universitario Gregorio Maranon

Madrid

MADRID

Psychiatry

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

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Psychiatry

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

Hospital Universitario Infanta Elena

Madrid

MADRID

Psychiatry

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

Instituto De Investigaciones Neuropsiquiatricas Doctor Lopez Ibor S.A.

Madrid

MADRID

Psychiatry

Activo (05/06/2026)

University Hospital Son Espases

Palma

BALEARES

Psychiatry

Medicamentos

XPF-010
CAPSULE
ORAL

Código ATC: N03AX - OTROS ANTIEPILEPTICOS
Principios Activos: N/A

Experimental

Sin resultados

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State	**Type of participants**	**Age Ranges**
Halted	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	256
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
2025-522775-29-00 (CTIS)

Protocol Code
XPF-010-B301

Therapeutic area
Psychiatry and Psychology [F] - Mental Disorders [F03]|

Investigated Disease
Depressive episodes associated with Bipolar disorder I or II (Bipolar Depression)

Scientific Title
A Phase 3, Randomized, Double-blind, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Azetukalner in Depressive Episodes Associated With Bipolar I or II Disorder (Bipolar Depression)

Rationale

Not provided

Main Objective

To assess the efficacy and safety of 20 mg azetukalner QD versus placebo for the treatment of bipolar depression.

Primary Endpoints

Change from baseline in the MADRS total score at Week 6.

Temporary moments of secondary assessment

Not provided

Secondary Objective

To assess clinician-perceived efficacy of 20 mg azetukalner once daily VS placebo for the treatment of bipolar depression; To assess the rapidity of efficacy onset of 20 mg azetukalner once daily VS placebo for the treatment of bipolar depression; and To assess the efficacy of 20 mg azetukalner once daily VS placebo for the treatment of anhedonia.

Secondary Endpoints

Change from baseline in the CGI-S score at Week 6.
Change from baseline in the MADRS total score at Week 1.
Change from baseline in the SHAPS total score at Week 6.

Temporary moments of secondary assessment

Not provided

Inclusion criteria

3. Adults 18 and 74 years of age who experienced their first major depressive episode (MDE) prior to 50 years of age.
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Calendar

(Last Update: 26/09/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
13/03/2026	05/06/2026	Not aported	11/09/2026	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

Xenon Pharmaceuticals Inc. Canada

3650 Gilmore Way

Contact Person

Clinical Trial responsible person: Senior Director, Trial Operations

+18574180357

ksarma@xenon-pharma.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

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Sites

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Salamanca

SALAMANCA

Psychiatry

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

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MADRID

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

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Psychiatry

Active (05/06/2026)

University Hospital Son Espases

Palma

BALEARES

Psychiatry

Medication

XPF-010
CAPSULE
ORAL

ATC code: N03AX - OTROS ANTIEPILEPTICOS
Active Principles: N/A

Experimental

No results