A study to evaluate the efficacy of APG-2575 (Lisaftoclax) plus azacitidine (AZA) vs. placebo plus AZA in newly diagnosed adult subjects with higher risk myelodysplastic syndrome (Higher Risk-MDS).

Estado	Tipo de Participantes	Rangos de Edad
Reclutando	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	131
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia, farmacocinética	NO

Información

Identificador
2024-517247-31-00 (CTIS)

Cod. Protocolo
APG2575MG301

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

Enfermedad investigada
Newly Diagnosed Higher Risk Myelodysplastic Syndrome

Título Científico
A Global Multicenter, Double-Blind, Randomized, Registrational Phase 3 Study of Lisaftoclax(APG-2575) in Combination with Azacitidine (AZA) in Patients with Newly Diagnosed Higher Risk Myelodysplastic Syndrome (HR-MDS) (GLORA-4)

Justificación

No aportado

Objetivo Principal

To evaluate the efficacy of xxx

Variables de Evaluación Primaria

xxx
xxx

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To compare the effect of xxx
To evaluate the safety of xxx
To evaluate the population pharmacokinetics (Pop PK) following treatment with xxx
To evaluate Patient-Reported Outcome (PRO) measures of xxxx based on EORTC QLQ C30 (V3).
To evaluate Health Economics Outcomes Research (HEOR) measures of xxx based on EuroQol 5 Dimension (EQ-5D).

Variables de Evaluación Secundaria

To compare the efficacy of xxx
To evaluate the safety of xxx
To evaluate the population pharmacokinetics (Pop PK) following treatment with xxx
To evaluate Health Economics Outcomes Research (HEOR) measures of lisaftoclax xxx based on EuroQol 5 Dimension (EQ-5D).

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Aged 18 years old. Newly Diagnosed MDS is defined according to 2022 World Health Organization classification (5th Edition) Eastern Cooperative Oncology Group (ECOG) performance status 2. Life expectancy 3 months. Able to receive oral medication. Adequate organ functions as defined below: - Creatinine clearance 30 ml/min (calculated with Cockcroft formula, as shown in Annex 3) - Total bilirubin < 1.5 × ULN (except Gilbert's syndrome, hyperbilirubinemia due to regular blood transfusions as assessed by the investigator) - Aspartate aminotransferase (ALT) and alanine aminotransferase (AST) 2.5 × ULN Negative urine or serum pregnancy test prior to dosing in women of childbearing potential. Women of childbearing potential (postmenopausal women must have been postmenopausal for at least 12 months to be considered of non-childbearing potential) and their partners are willing to use contraception as deemed effective by the investigator during treatment and for at least 6 months after the last dose of study drug. Subjects must have the ability to understand and voluntarily sign a written informed consent form that must be signed prior to performing any trial-specific study procedures. Subjects must be willing to participate in the study and are able to complete study procedures and follow-up examinations.

Criterios de Exclusión

Previous diagnosis of xxx Any of the following cardiac abnormalities (as determined by the study physician based on clinical examination assessments): - Any history of myocardial infarction within 6 months - Congestive heart failure (CHF) (New York Heart Association [NYHA] Class III or IV) or left ventricular ejection fraction (LVEF) < 40% - Symptomatic ventricular arrhythmia uncontrolled by medication - Any history of familial long QT syndrome - The mean QT interval calculated from 3 electrocardiogram (ECG) readings (1 to 3 minutes apart) is > 470 (Using Fridercia's correction: QTcF = QT/RR0.33) Second malignancies or previous malignancies with a disease-free interval of less than 1 year at the time of signing the informed consent (except for subjects with adequately resected cutaneous basal cell or squamous cell carcinoma or resected carcinoma in situ). Have history of HSCT. Other clinically significant uncontrolled symptoms, including but not limited to: uncontrolled active systemic infection (virus, bacteria or fungi), known clinically active hepatitis B or C, or HIV infection. (as determined by the study physician based on clinical examination assessments). Have malabsorption syndrome or other conditions and are not suitable for enteral drug administration. Have any other conditions or illnesses which, in the investigator's judgment, makes them unsuitable for participation in this study, , including but not limited to; Women who are breast feeding or planning to donate eggs within 6 months after the end of the study treatment History of hypersensitivity to compounds related to lisaftoclax or AZA or to any of their excipients History of bleeding disorders or active uncontrolled coagulopathy.

Calendario

(Última actualización: 07/07/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
24/04/2025	10/07/2025	16/07/2025	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

Ascentage Pharma Group Inc. United States

700 King Farm Boulevard

Contact Person

Yifan Zhai

3015496188

yzhai@ascentage.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm del Hospital Clínico Universitario de Valencia

Avda. Vicente Blasco Ibáñez, 17 46010 Valencia

ceic_hcv@gva.es

Centros

Activo (12/06/2025)

Clinica Universidad De Navarra

Pamplona

NAVARRA

Hematology

Activo (12/06/2025)

Clinica Universidad De Navarra

Madrid

MADRID

Hematology

Activo (10/10/2025)

Complejo Hospitalario Universitario De Ourense

Ourense

OURENSE

Hematology

Activo (29/08/2025)

Hospital Clinico Universitario De Valencia

Valencia

VALENCIA

Hematology

Activo (29/08/2025)

Hospital General Universitario Gregorio Maranon

Madrid

MADRID

Hematology

Activo (23/10/2025)

Hospital Moncloa Grupo Hla S.A.

Madrid

MADRID

Hematology

Activo (01/12/2025)

Hospital San Pedro De Alcantara

Caceres

CÁCERES

Hematology

Activo (06/06/2025)

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Hematology

Activo (18/09/2025)

Hospital Universitario Central De Asturias

Oviedo

ASTURIAS

Hematology

Activo (20/05/2025)

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Hematology

Activo (20/11/2025)

Hospital Universitario La Paz

Madrid

MADRID

Hematology

Activo (20/11/2025)

Hospital Universitario Ramon Y Cajal

Madrid

MADRID

Hematology

Activo (15/05/2025)

Hospital Universitario Virgen De La Victoria

Malaga

MÁLAGA

Hematology

Activo (07/07/2025)

Hospital Universitario Y Politecnico La Fe

Valencia

VALENCIA

Hematology

Activo (17/09/2025)

Institut Catala D´oncologia

Girona

GERONA

Hematology

Activo (21/10/2025)

Institut Catala D´oncologia

L'hospitalet De Llobregat

BARCELONA

Hematology

Activo (14/08/2025)

Institut Catala D´oncologia

Badalona

BARCELONA

Hematology

Activo (20/10/2025)

MD Anderson Cancer Center

Madrid

MADRID

Hematology

Activo (02/07/2025)

University Hospital Virgen Del Rocio S.L.

Sevilla

SEVILLA

Hematology

Medicamentos

Lisaftoclax
TABLET
ORAL USE

-

Principios Activos: N/A

Experimental

Azacitidine Seacross 25 mg/mL powder for suspension for injection
SUSPENSION FOR INJECTION
INTRAVENOUS/SUBCUTANEOUS/INTRAMUSCULAR

Código ATC: L01BC07 - AZACITIDINA
Principios Activos: N/A

Experimental

Sin resultados

A study to evaluate the efficacy of APG-2575 (Lisaftoclax) plus azacitidine (AZA) vs. placebo plus AZA in newly diagnosed adult subjects with higher risk myelodysplastic syndrome (Higher Risk-MDS).

State	**Type of participants**	**Age Ranges**
Recruiting	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	131
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness, pharmacokinetics	NO

Information

Identifier
2024-517247-31-00 (CTIS)

Protocol Code
APG2575MG301

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

Investigated Disease
Newly Diagnosed Higher Risk Myelodysplastic Syndrome

Scientific Title
A Global Multicenter, Double-Blind, Randomized, Registrational Phase 3 Study of Lisaftoclax(APG-2575) in Combination with Azacitidine (AZA) in Patients with Newly Diagnosed Higher Risk Myelodysplastic Syndrome (HR-MDS) (GLORA-4)

Rationale

Not provided

Main Objective

To evaluate the efficacy of xxx

Primary Endpoints

xxx
xxx

Temporary moments of secondary assessment

Not provided

Secondary Objective

To compare the effect of xxx
To evaluate the safety of xxx
To evaluate the population pharmacokinetics (Pop PK) following treatment with xxx
To evaluate Patient-Reported Outcome (PRO) measures of xxxx based on EORTC QLQ C30 (V3).
To evaluate Health Economics Outcomes Research (HEOR) measures of xxx based on EuroQol 5 Dimension (EQ-5D).

Secondary Endpoints

To compare the efficacy of xxx
To evaluate the safety of xxx
To evaluate the population pharmacokinetics (Pop PK) following treatment with xxx
To evaluate Health Economics Outcomes Research (HEOR) measures of lisaftoclax xxx based on EuroQol 5 Dimension (EQ-5D).

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Aged 18 years old. Newly Diagnosed MDS is defined according to 2022 World Health Organization classification (5th Edition) Eastern Cooperative Oncology Group (ECOG) performance status 2. Life expectancy 3 months. Able to receive oral medication. Adequate organ functions as defined below: - Creatinine clearance 30 ml/min (calculated with Cockcroft formula, as shown in Annex 3) - Total bilirubin < 1.5 × ULN (except Gilbert's syndrome, hyperbilirubinemia due to regular blood transfusions as assessed by the investigator) - Aspartate aminotransferase (ALT) and alanine aminotransferase (AST) 2.5 × ULN Negative urine or serum pregnancy test prior to dosing in women of childbearing potential. Women of childbearing potential (postmenopausal women must have been postmenopausal for at least 12 months to be considered of non-childbearing potential) and their partners are willing to use contraception as deemed effective by the investigator during treatment and for at least 6 months after the last dose of study drug. Subjects must have the ability to understand and voluntarily sign a written informed consent form that must be signed prior to performing any trial-specific study procedures. Subjects must be willing to participate in the study and are able to complete study procedures and follow-up examinations.

Exclusion criteria

Previous diagnosis of xxx Any of the following cardiac abnormalities (as determined by the study physician based on clinical examination assessments): - Any history of myocardial infarction within 6 months - Congestive heart failure (CHF) (New York Heart Association [NYHA] Class III or IV) or left ventricular ejection fraction (LVEF) < 40% - Symptomatic ventricular arrhythmia uncontrolled by medication - Any history of familial long QT syndrome - The mean QT interval calculated from 3 electrocardiogram (ECG) readings (1 to 3 minutes apart) is > 470 (Using Fridercia's correction: QTcF = QT/RR0.33) Second malignancies or previous malignancies with a disease-free interval of less than 1 year at the time of signing the informed consent (except for subjects with adequately resected cutaneous basal cell or squamous cell carcinoma or resected carcinoma in situ). Have history of HSCT. Other clinically significant uncontrolled symptoms, including but not limited to: uncontrolled active systemic infection (virus, bacteria or fungi), known clinically active hepatitis B or C, or HIV infection. (as determined by the study physician based on clinical examination assessments). Have malabsorption syndrome or other conditions and are not suitable for enteral drug administration. Have any other conditions or illnesses which, in the investigator's judgment, makes them unsuitable for participation in this study, , including but not limited to; Women who are breast feeding or planning to donate eggs within 6 months after the end of the study treatment History of hypersensitivity to compounds related to lisaftoclax or AZA or to any of their excipients History of bleeding disorders or active uncontrolled coagulopathy.

Calendar

(Last Update: 07/07/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
24/04/2025	10/07/2025	16/07/2025	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

Ascentage Pharma Group Inc. United States

700 King Farm Boulevard

Contact Person

Yifan Zhai

3015496188

yzhai@ascentage.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm del Hospital Clínico Universitario de Valencia

Avda. Vicente Blasco Ibáñez, 17 46010 Valencia

ceic_hcv@gva.es

Sites

Active (12/06/2025)

Clinica Universidad De Navarra

Pamplona

NAVARRA

Hematology

Active (12/06/2025)

Clinica Universidad De Navarra

Madrid

MADRID

Hematology

Active (10/10/2025)

Complejo Hospitalario Universitario De Ourense

Ourense

OURENSE

Hematology

Active (29/08/2025)

Hospital Clinico Universitario De Valencia

Valencia

VALENCIA

Hematology

Active (29/08/2025)

Hospital General Universitario Gregorio Maranon

Madrid

MADRID

Hematology

Active (23/10/2025)

Hospital Moncloa Grupo Hla S.A.

Madrid

MADRID

Hematology

Active (01/12/2025)

Hospital San Pedro De Alcantara

Caceres

CÁCERES

Hematology

Active (06/06/2025)

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Hematology

Active (18/09/2025)

Hospital Universitario Central De Asturias

Oviedo

ASTURIAS

Hematology

Active (20/05/2025)

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Hematology

Active (20/11/2025)

Hospital Universitario La Paz

Madrid

MADRID

Hematology

Active (20/11/2025)

Hospital Universitario Ramon Y Cajal

Madrid

MADRID

Hematology

Active (15/05/2025)

Hospital Universitario Virgen De La Victoria

Malaga

MÁLAGA

Hematology

Active (07/07/2025)

Hospital Universitario Y Politecnico La Fe

Valencia

VALENCIA

Hematology

Active (17/09/2025)

Institut Catala D´oncologia

Girona

GERONA

Hematology

Active (21/10/2025)

Institut Catala D´oncologia

L'hospitalet De Llobregat

BARCELONA

Hematology

Active (14/08/2025)

Institut Catala D´oncologia

Badalona

BARCELONA

Hematology

Active (20/10/2025)

MD Anderson Cancer Center

Madrid

MADRID

Hematology

Active (02/07/2025)

University Hospital Virgen Del Rocio S.L.

Sevilla

SEVILLA

Hematology

Medication

Lisaftoclax
TABLET
ORAL USE

-

Active Principles: N/A

Experimental

Azacitidine Seacross 25 mg/mL powder for suspension for injection
SUSPENSION FOR INJECTION
INTRAVENOUS/SUBCUTANEOUS/INTRAMUSCULAR

ATC code: L01BC07 - AZACITIDINA
Active Principles: N/A

Experimental

No results