Studies testing Ziftomenib together with standard treatments in adults with newly diagnosed acute myeloid leukemia (AML) that has specific genetic changes (NPM1 or KMT2A)

Estado	Tipo de Participantes	Rangos de Edad
Reclutando	Sujetos incapaces de otorgar consentimiento	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	601
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	tratamiento, seguridad, eficacia, farmacocinética	NO

Información

Identificador
2025-521314-25-00 (CTIS)

Cod. Protocolo
KO-MEN-017

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

Enfermedad investigada
NPM1-m and KMT2A-r Acute Myeloid Leukemia

Título Científico
Phase 3 Randomized, Double-blind, Placebo-controlled Studies Assessing Ziftomenib in Combination with Either Standard of Care Nonintensive (Venetoclax+Azacitidine) or Intensive (7+3) Therapy in Patients with Untreated NPM1 Mutated or KMT2A Rearranged Acute Myeloid Leukemia

Justificación

No aportado

Objetivo Principal

Nonintensive Therapy Study - To evaluate the effect of ziftomenib combined with SOC ven+aza on patient survival in untreated NPM1 m AML
Intensive Therapy Study (7+3)
- To evaluate the effect of ziftomenib combined with SOC 7+3 on patient EFS in untreated NPM1 m and KMT2A-r AML

Variables de Evaluación Primaria

Nonintensive Therapy Study - Overall survival (OS) Intensive Therapy Study (7+3) - EFS, defined as the time from randomization to treatment failurea, hematologic relapse following CR, or death from any cause, whichever comes first

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

Nonintensive Therapy Study - To determine the efficacy of ziftomenib combined with SOC ven+aza in untreated NPM1 m AML - To determine the rate of MRD negativity achieved with ziftomenib combined with SOC ven+aza in untreated NPM1 m AML - To evaluate CR/CRh as an additional measure of efficacy of ziftomenib in combination with SOC ven+aza in untreated NPM1 m AML Intensive Therapy Study (7+3) - To determine the efficacy of ziftomenib combined with SOC 7+3 in untreated NPM1 m AML - To evaluate the effect of ziftomenib combined with SOC 7+3 on patient survival in untreated NPM1 m and KMT2A-r AML

Variables de Evaluación Secundaria

Nonintensive Therapy Study - CR rate per the ELN 2022 criteria per Investigator assessment - Percentage of patients achieving centrally defined BM MRD negativity - Rates of CR+CRh per ELN 2022 per Investigator assessment
Intensive Therapy Study (7+3) - Percentage of patients achieving CR per ELN 2022 criteria with centrally defined BM MRD negativity (CRMRD-) - Overall survival (OS)

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

1. Age 18 years at time of signing the informed consent form (ICF). 10. Patients must be able to understand and provide informed consent, understand protocol requirements, and be willing to comply with study requirements, in the opinion of the Investigator. 11. NONINTENSIVE THERAPY STUDY ONLY (VEN+AZA): a. Documented NPM1-m. b. Patients considered ineligible for IC defined by the following i. Age 75, OR ii. Age <75 and unfit for IC. Must meet one of these comorbidity exceptions which prevents them from being treated with IC: 1. ECOG performance status of 2, or 2. Cardiac history of congestive heart failure (CHF) requiring treatment or ejection fraction of 50% or chronic stable angina, or 3. Diffusing capacity of the lungs for carbon monoxide 65% or forced expiratory volume in 1 second 65%, or 4. Creatinine clearance <45 mL/min and >30 mL/min, or 5.Moderate hepatic impairment with total bilirubin 1.5 to 3.0×ULN, not related to AML involvement or Gilberts syndrome, or 6. Other comorbidities that, in the opinion of the Investigator, cause the patient to be incompatible with IC (prior approval by the Medical Monitor is required before enrollment). 12. INTENSIVE THERAPY STUDY ONLY (7+3): a. Documented NPM1-m or KMT2A-r (patients with a partial tandem duplication [PTD] are not eligible). b. Documented FLT3 wild-type or ITD ratio <0.05 OR ineligible to receive FLT3 targeted therapy (medically ineligible or mutation in which FLT3 inhibition is not SOC). Lack of access to an FLT3 inhibitor is not considered ineligible for FLT3 targeted therapy. c. Ejection fraction of >50% by transthoracic echocardiogram (ECHO) or multigated acquisition scan (MUGA). d. Fit for IC per Investigator opinion. 2. Diagnosis of AML per the 2022 WHO Classification of Hematolymphoid Tumors (5th Edition). 3. Patients with therapy-related AML (t-AML) or secondary AML (prior myelodysplastic syndrome [MDS] or myeloproliferative neoplasm [MPN]) are eligible. 1. Note: Prior MDS eligibility requires that at the time of MDS diagnosis the patient did not have evidence of either NPM1-m or KMT2A-r (now classified as AML by WHO 5th Edition). 4. Patients with prior MDS who have received a single line of treatment with single agent HMA, lenalidomide, luspatercept, or imetelstat are eligible. 5. Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1, or 2. 6. Adequate liver function defined as: AST <5×upper limit of normal (ULN), and ALT <5×ULN, and Total bilirubin <1.5×ULN (except for patients with known Gilberts syndrome or presumed leukemic involvement). Note: If the patient does not meet this criterion but the liver function abnormalities are presumed to be due to AML, this may be discussed with the Medical Monitor to determine eligibility. 7. Adequate renal function defined by calculated creatinine clearance 30 mL/min (according to the 2021 Chronic Kidney Disease Epidemiology-Collaboration [CKD-EPI] creatinine equation). 8. If the patient has comorbid illness, life expectancy attributed to this other condition(s) must be greater than 2 years in the opinion of the Investigator. 9. Patient agrees to the following contraception requirements: a. A male patient is eligible to participate if they agree to the following during the study treatment period and for 180 days after the last dose of study treatment: Refrain from donating sperm. plus, either: Be abstinent from intercourse where pregnancy can occur (abstinent on a long term and persistent basis) and agree to remain abstinent. or Agree to use highly effective contraception plus barrier as follows: o Use an external condom (barrier) with female partner of childbearing potential using additional highly effective contraceptive method with a failure rate of <1% per year as described in Appendix 2 when having sexual intercourse with a partner able to give birth who is not currently pregnant. plus o Use an external condom when engaging in any activity that allows for passage of ejaculate to another person. b. A female patient is eligible to participate if not pregnant or breastfeeding, and one of the following conditions applies: Is of nonchildbearing potential as defined in Appendix 2. or Is of childbearing potential as defined in Appendix 2 and agrees to the following during the study treatment period and for 180 days after the last dose of study treatment: o Agrees to use a contraceptive method that is highly effective (with a failure rate of <1% per year), preferably with low user dependency, as described in Appendix 2 in addition to male partner either using an external condom (barrier) or male partner confirmed azoospermic. plus o Agrees not to donate eggs (ova, oocytes) for the purpose of reproduction. Note: The Investigator should evaluate the potential for contraceptive method failure (eg, noncompliance or recently started) in relationship to the first dose of study treatment.

Criterios de Exclusión

1. Diagnosis of either acute promyelocytic leukemia (APL), blast phase chronic myeloid leukemia, or isolated myeloid sarcoma. Note: Patients with myeloid sarcoma in addition to BM disease are eligible. 10. Diagnosis with any of the following per Investigator opinion: uncontrolled intercurrent illness including but not limited: Symptomatic CHF Unstable angina pectoris Serious cardiac arrhythmia Myocardial infarction with evidence of residual abnormalities within 6 months prior to enrollment (troponin leak alone not included if no residual dysfunction) New York Heart

Association Class III or IV heart failure Severe uncontrolled ventricular arrhythmias, or electrocardiographic evidence of acute ischemia Mean QTcF >480 ms on triplicate ECGs Note: If a patient has bundle branch block or QRS >120 ms, the QTcF must be either calculated by cardiology, calculated using a QTc calculator (eg, the Mayo Clinic QTc calculator [https://www.mayoclinic.org/medical-professionals/cardiovascular-diseases/calculators/corrected-qt-interval-qtc-calculator/itt-20487211]), or calculated using the Boghossian simplified formula (QTc=QT-0.5*QRS). 11. Diagnosis of an uncontrolled infection. Note: Patients with an active infection may be eligible provided that the infection is controlled by appropriate antimicrobial therapy in the opinion of the Investigator. 12. Known severe hypersensitivity to the product or similar chemical structure and class to the study drugs evaluated in this study or 1 of the active or inactive excipients. 13. Women who are pregnant or breastfeeding. 2. Known history of BCR-ABL mutation. 3. History of other active concurrent malignancies prior to study entry except: Basal cell skin cancer or localized squamous cell cancer of the skin Previous malignancy confined and locally resected (or treated with other modalities) with curative intent Prostate or breast cancer receiving adjuvant hormonal therapy (see Section 7.5.1 for permitted medications) 4. Active central nervous system (CNS) involvement by AML. Note: Those patients with evidence of CNS AML involvement at baseline/screening now controlled (cerebrospinal fluid [CSF] cleared and no symptoms) with intrathecal chemotherapy or those who are at high risk of developing CNS disease (including KMT2A-r, high white blood cells [WBC], high lactate dehydrogenase [LDH], presence of extramedullary disease [EMD]) may continue to receive intrathecal chemotherapy as treatment or prophylaxis, respectively, as per institutional practice. 5. Clinical signs/symptoms of leukostasis or WBC >25×109/L prior to start of ziftomenib/placebo. Note: Hydroxyurea and/or leukapheresis are permitted to meet this criterion. Cytotoxic therapy in addition to the SOC protocol backbones (7+3 or ven+aza) is not permitted to manage leukocytosis. 6. Prior therapy for AML (except hydroxyurea or leukapheresis for WBC control). Patients may have received ATRA if there is an early suspicion of APL. Patients with a confirmed diagnosis of APL are not eligible. 7. Prior ven+HMA therapy, isocitrate dehydrogenase 1 inhibitor, or intensive chemotherapy for MDS. Note: Prior MDS treatment with either single agent HMA, lenalidomide, luspatercept, or imetelstat is allowed. Any of these agents for prior MDS treatment must have been discontinued 14 days prior to Cycle 1 Day 1. 8. Known uncontrolled HIV infection or known active hepatitis B virus (HBV) or hepatitis C virus (HCV) infection. Viral serologies for HIV, HBV, HCV are not required. However, for patients with a known medical history of HIV/HBV/HCV infection, an undetectable viral load must be confirmed. Patients with serologic evidence of prior vaccination to HBV (HBV surface antigen negative and anti-HBV surface antibody positive) may participate. 9. Any other significant ongoing medical condition, including psychiatric illness or laboratory abnormality, that would preclude the patient from participating in the study or would confound the interpretation of the results of the study in the opinion of the Investigator.

Calendario

(Última actualización: 01/09/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
04/03/2026	19/03/2026	22/05/2026	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

Kura Oncology Inc. United States

12730 High Bluff Drive Suite 400

Contact Person

Kura Oncology Inc.

+16175883755

KO-MEN-017@kuraoncology.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Hospital Fundación Jiménez Díaz

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ceic@fjd.es

915443720

Centros

Activo (15/05/2026)

Hospital Clinico Universitario De Valencia

Valencia

VALENCIA

Hematology

Activo (27/06/2026)

Hospital Clinico Universitario Lozano Blesa

Zaragoza

ZARAGOZA

Hematology

Activo (30/05/2026)

Hospital General Universitario De Albacete

Albacete

ALBACETE

Hematology

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

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Hematology

Activo (11/08/2026)

Hospital Universitario Central De Asturias

Oviedo

ASTURIAS

Hematology

Activo (19/05/2026)

Hospital Universitario De Burgos

Burgos

BURGOS

Hematology

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

Hospital Universitario De Jaen

Jaen

JAÉN

Hematology

Activo (22/08/2026)

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Hematology

Activo (25/07/2026)

Hospital Universitario Fundacion Jimenez Diaz

Madrid

MADRID

Hematology

Activo (16/05/2026)

Hospital Universitario Infanta Leonor

Madrid

MADRID

Hematology

Activo (30/04/2026)

Hospital Universitario Y Politecnico La Fe

Valencia

VALENCIA

Hematology

Activo (30/04/2026)

Hospital Universitario 12 De Octubre

Madrid

MADRID

Hematology

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

Institut Catala D'oncologia

L'hospitalet De Llobregat

BARCELONA

Hematology

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

Institut Catala D'oncologia

Badalona

BARCELONA

Hematology

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

MD Anderson Cancer Center

Madrid

MADRID

Hematology

Activo (07/04/2026)

University Hospital Virgen Del Rocio S.L.

Sevilla

SEVILLA

Hematology

Medicamentos

VENETOCLAX
FILM-COATED TABLET
ORAL USE

-
Principios Activos: N/A
Experimental

VENETOCLAX
FILM-COATED TABLET
ORAL USE

-
Principios Activos: N/A
Experimental

CYTARABINE
SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS USE

-
Principios Activos: N/A
Experimental

VENETOCLAX
FILM-COATED TABLET
ORAL USE

-
Principios Activos: N/A
Experimental

Ziftomenib
CAPSULE, HARD
ORAL

-
Principios Activos: N/A
Huérfano
Experimental

Daunoblastin® 20 mg Pulver zur Herstellung einer Infusions- oder Injektionslösung
SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS USE

Código ATC: L01DB02 - DAUNORUBICINA
Principios Activos: N/A
Experimental

AZACITIDINE
POWDER FOR SUSPENSION FOR INJECTION
INTRAVENOUS USE

-
Principios Activos: N/A
Experimental

CYTARABINE
SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS USE

-
Principios Activos: N/A
Experimental

Sin resultados

Studies testing Ziftomenib together with standard treatments in adults with newly diagnosed acute myeloid leukemia (AML) that has specific genetic changes (NPM1 or KMT2A)

State	**Type of participants**	**Age Ranges**
Recruiting	Incapable subjects of giving consent	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	601
Results	**Low level of intervention**	**Rare disease**
No results	No	Yes
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	treatment, safety, effectiveness, pharmacokinetics	NO

Information

Identifier
2025-521314-25-00 (CTIS)

Protocol Code
KO-MEN-017

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

Investigated Disease
NPM1-m and KMT2A-r Acute Myeloid Leukemia

Scientific Title
Phase 3 Randomized, Double-blind, Placebo-controlled Studies Assessing Ziftomenib in Combination with Either Standard of Care Nonintensive (Venetoclax+Azacitidine) or Intensive (7+3) Therapy in Patients with Untreated NPM1 Mutated or KMT2A Rearranged Acute Myeloid Leukemia

Rationale

Not provided

Main Objective

Nonintensive Therapy Study - To evaluate the effect of ziftomenib combined with SOC ven+aza on patient survival in untreated NPM1 m AML
Intensive Therapy Study (7+3)
- To evaluate the effect of ziftomenib combined with SOC 7+3 on patient EFS in untreated NPM1 m and KMT2A-r AML

Primary Endpoints

Nonintensive Therapy Study - Overall survival (OS) Intensive Therapy Study (7+3) - EFS, defined as the time from randomization to treatment failurea, hematologic relapse following CR, or death from any cause, whichever comes first

Temporary moments of secondary assessment

Not provided

Secondary Objective

Nonintensive Therapy Study - To determine the efficacy of ziftomenib combined with SOC ven+aza in untreated NPM1 m AML - To determine the rate of MRD negativity achieved with ziftomenib combined with SOC ven+aza in untreated NPM1 m AML - To evaluate CR/CRh as an additional measure of efficacy of ziftomenib in combination with SOC ven+aza in untreated NPM1 m AML Intensive Therapy Study (7+3) - To determine the efficacy of ziftomenib combined with SOC 7+3 in untreated NPM1 m AML - To evaluate the effect of ziftomenib combined with SOC 7+3 on patient survival in untreated NPM1 m and KMT2A-r AML

Secondary Endpoints

Nonintensive Therapy Study - CR rate per the ELN 2022 criteria per Investigator assessment - Percentage of patients achieving centrally defined BM MRD negativity - Rates of CR+CRh per ELN 2022 per Investigator assessment
Intensive Therapy Study (7+3) - Percentage of patients achieving CR per ELN 2022 criteria with centrally defined BM MRD negativity (CRMRD-) - Overall survival (OS)

Temporary moments of secondary assessment

Not provided

Inclusion criteria

1. Age 18 years at time of signing the informed consent form (ICF). 10. Patients must be able to understand and provide informed consent, understand protocol requirements, and be willing to comply with study requirements, in the opinion of the Investigator. 11. NONINTENSIVE THERAPY STUDY ONLY (VEN+AZA): a. Documented NPM1-m. b. Patients considered ineligible for IC defined by the following i. Age 75, OR ii. Age <75 and unfit for IC. Must meet one of these comorbidity exceptions which prevents them from being treated with IC: 1. ECOG performance status of 2, or 2. Cardiac history of congestive heart failure (CHF) requiring treatment or ejection fraction of 50% or chronic stable angina, or 3. Diffusing capacity of the lungs for carbon monoxide 65% or forced expiratory volume in 1 second 65%, or 4. Creatinine clearance <45 mL/min and >30 mL/min, or 5.Moderate hepatic impairment with total bilirubin 1.5 to 3.0×ULN, not related to AML involvement or Gilberts syndrome, or 6. Other comorbidities that, in the opinion of the Investigator, cause the patient to be incompatible with IC (prior approval by the Medical Monitor is required before enrollment). 12. INTENSIVE THERAPY STUDY ONLY (7+3): a. Documented NPM1-m or KMT2A-r (patients with a partial tandem duplication [PTD] are not eligible). b. Documented FLT3 wild-type or ITD ratio <0.05 OR ineligible to receive FLT3 targeted therapy (medically ineligible or mutation in which FLT3 inhibition is not SOC). Lack of access to an FLT3 inhibitor is not considered ineligible for FLT3 targeted therapy. c. Ejection fraction of >50% by transthoracic echocardiogram (ECHO) or multigated acquisition scan (MUGA). d. Fit for IC per Investigator opinion. 2. Diagnosis of AML per the 2022 WHO Classification of Hematolymphoid Tumors (5th Edition). 3. Patients with therapy-related AML (t-AML) or secondary AML (prior myelodysplastic syndrome [MDS] or myeloproliferative neoplasm [MPN]) are eligible. 1. Note: Prior MDS eligibility requires that at the time of MDS diagnosis the patient did not have evidence of either NPM1-m or KMT2A-r (now classified as AML by WHO 5th Edition). 4. Patients with prior MDS who have received a single line of treatment with single agent HMA, lenalidomide, luspatercept, or imetelstat are eligible. 5. Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1, or 2. 6. Adequate liver function defined as: AST <5×upper limit of normal (ULN), and ALT <5×ULN, and Total bilirubin <1.5×ULN (except for patients with known Gilberts syndrome or presumed leukemic involvement). Note: If the patient does not meet this criterion but the liver function abnormalities are presumed to be due to AML, this may be discussed with the Medical Monitor to determine eligibility. 7. Adequate renal function defined by calculated creatinine clearance 30 mL/min (according to the 2021 Chronic Kidney Disease Epidemiology-Collaboration [CKD-EPI] creatinine equation). 8. If the patient has comorbid illness, life expectancy attributed to this other condition(s) must be greater than 2 years in the opinion of the Investigator. 9. Patient agrees to the following contraception requirements: a. A male patient is eligible to participate if they agree to the following during the study treatment period and for 180 days after the last dose of study treatment: Refrain from donating sperm. plus, either: Be abstinent from intercourse where pregnancy can occur (abstinent on a long term and persistent basis) and agree to remain abstinent. or Agree to use highly effective contraception plus barrier as follows: o Use an external condom (barrier) with female partner of childbearing potential using additional highly effective contraceptive method with a failure rate of <1% per year as described in Appendix 2 when having sexual intercourse with a partner able to give birth who is not currently pregnant. plus o Use an external condom when engaging in any activity that allows for passage of ejaculate to another person. b. A female patient is eligible to participate if not pregnant or breastfeeding, and one of the following conditions applies: Is of nonchildbearing potential as defined in Appendix 2. or Is of childbearing potential as defined in Appendix 2 and agrees to the following during the study treatment period and for 180 days after the last dose of study treatment: o Agrees to use a contraceptive method that is highly effective (with a failure rate of <1% per year), preferably with low user dependency, as described in Appendix 2 in addition to male partner either using an external condom (barrier) or male partner confirmed azoospermic. plus o Agrees not to donate eggs (ova, oocytes) for the purpose of reproduction. Note: The Investigator should evaluate the potential for contraceptive method failure (eg, noncompliance or recently started) in relationship to the first dose of study treatment.

Exclusion criteria

1. Diagnosis of either acute promyelocytic leukemia (APL), blast phase chronic myeloid leukemia, or isolated myeloid sarcoma. Note: Patients with myeloid sarcoma in addition to BM disease are eligible. 10. Diagnosis with any of the following per Investigator opinion: uncontrolled intercurrent illness including but not limited: Symptomatic CHF Unstable angina pectoris Serious cardiac arrhythmia Myocardial infarction with evidence of residual abnormalities within 6 months prior to enrollment (troponin leak alone not included if no residual dysfunction) New York Heart

Association Class III or IV heart failure Severe uncontrolled ventricular arrhythmias, or electrocardiographic evidence of acute ischemia Mean QTcF >480 ms on triplicate ECGs Note: If a patient has bundle branch block or QRS >120 ms, the QTcF must be either calculated by cardiology, calculated using a QTc calculator (eg, the Mayo Clinic QTc calculator [https://www.mayoclinic.org/medical-professionals/cardiovascular-diseases/calculators/corrected-qt-interval-qtc-calculator/itt-20487211]), or calculated using the Boghossian simplified formula (QTc=QT-0.5*QRS). 11. Diagnosis of an uncontrolled infection. Note: Patients with an active infection may be eligible provided that the infection is controlled by appropriate antimicrobial therapy in the opinion of the Investigator. 12. Known severe hypersensitivity to the product or similar chemical structure and class to the study drugs evaluated in this study or 1 of the active or inactive excipients. 13. Women who are pregnant or breastfeeding. 2. Known history of BCR-ABL mutation. 3. History of other active concurrent malignancies prior to study entry except: Basal cell skin cancer or localized squamous cell cancer of the skin Previous malignancy confined and locally resected (or treated with other modalities) with curative intent Prostate or breast cancer receiving adjuvant hormonal therapy (see Section 7.5.1 for permitted medications) 4. Active central nervous system (CNS) involvement by AML. Note: Those patients with evidence of CNS AML involvement at baseline/screening now controlled (cerebrospinal fluid [CSF] cleared and no symptoms) with intrathecal chemotherapy or those who are at high risk of developing CNS disease (including KMT2A-r, high white blood cells [WBC], high lactate dehydrogenase [LDH], presence of extramedullary disease [EMD]) may continue to receive intrathecal chemotherapy as treatment or prophylaxis, respectively, as per institutional practice. 5. Clinical signs/symptoms of leukostasis or WBC >25×109/L prior to start of ziftomenib/placebo. Note: Hydroxyurea and/or leukapheresis are permitted to meet this criterion. Cytotoxic therapy in addition to the SOC protocol backbones (7+3 or ven+aza) is not permitted to manage leukocytosis. 6. Prior therapy for AML (except hydroxyurea or leukapheresis for WBC control). Patients may have received ATRA if there is an early suspicion of APL. Patients with a confirmed diagnosis of APL are not eligible. 7. Prior ven+HMA therapy, isocitrate dehydrogenase 1 inhibitor, or intensive chemotherapy for MDS. Note: Prior MDS treatment with either single agent HMA, lenalidomide, luspatercept, or imetelstat is allowed. Any of these agents for prior MDS treatment must have been discontinued 14 days prior to Cycle 1 Day 1. 8. Known uncontrolled HIV infection or known active hepatitis B virus (HBV) or hepatitis C virus (HCV) infection. Viral serologies for HIV, HBV, HCV are not required. However, for patients with a known medical history of HIV/HBV/HCV infection, an undetectable viral load must be confirmed. Patients with serologic evidence of prior vaccination to HBV (HBV surface antigen negative and anti-HBV surface antibody positive) may participate. 9. Any other significant ongoing medical condition, including psychiatric illness or laboratory abnormality, that would preclude the patient from participating in the study or would confound the interpretation of the results of the study in the opinion of the Investigator.

Calendar

(Last Update: 01/09/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
04/03/2026	19/03/2026	22/05/2026	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

Kura Oncology Inc. United States

12730 High Bluff Drive Suite 400

Contact Person

Kura Oncology Inc.

+16175883755

KO-MEN-017@kuraoncology.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Hospital Fundación Jiménez Díaz

Avda. Reyes Católicos, 2 - 5ª Ascensores 4-5 28040 Madrid

ceic@fjd.es

915443720

Sites

Active (15/05/2026)

Hospital Clinico Universitario De Valencia

Valencia

VALENCIA

Hematology

Active (27/06/2026)

Hospital Clinico Universitario Lozano Blesa

Zaragoza

ZARAGOZA

Hematology

Active (30/05/2026)

Hospital General Universitario De Albacete

Albacete

ALBACETE

Hematology

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

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Hematology

Active (11/08/2026)

Hospital Universitario Central De Asturias

Oviedo

ASTURIAS

Hematology

Active (19/05/2026)

Hospital Universitario De Burgos

Burgos

BURGOS

Hematology

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

Hospital Universitario De Jaen

Jaen

JAÉN

Hematology

Active (22/08/2026)

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Hematology

Active (25/07/2026)

Hospital Universitario Fundacion Jimenez Diaz

Madrid

MADRID

Hematology

Active (16/05/2026)

Hospital Universitario Infanta Leonor

Madrid

MADRID

Hematology

Active (30/04/2026)

Hospital Universitario Y Politecnico La Fe

Valencia

VALENCIA

Hematology

Active (30/04/2026)

Hospital Universitario 12 De Octubre

Madrid

MADRID

Hematology

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

Institut Catala D'oncologia

L'hospitalet De Llobregat

BARCELONA

Hematology

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

Institut Catala D'oncologia

Badalona

BARCELONA

Hematology

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

MD Anderson Cancer Center

Madrid

MADRID

Hematology

Active (07/04/2026)

University Hospital Virgen Del Rocio S.L.

Sevilla

SEVILLA

Hematology

Medication

VENETOCLAX
FILM-COATED TABLET
ORAL USE

-
Active Principles: N/A
Experimental

VENETOCLAX
FILM-COATED TABLET
ORAL USE

-
Active Principles: N/A
Experimental

CYTARABINE
SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS USE

-
Active Principles: N/A
Experimental

VENETOCLAX
FILM-COATED TABLET
ORAL USE

-
Active Principles: N/A
Experimental

Ziftomenib
CAPSULE, HARD
ORAL

-
Active Principles: N/A
Orphan
Experimental

Daunoblastin® 20 mg Pulver zur Herstellung einer Infusions- oder Injektionslösung
SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS USE

ATC code: L01DB02 - DAUNORUBICINA
Active Principles: N/A
Experimental

AZACITIDINE
POWDER FOR SUSPENSION FOR INJECTION
INTRAVENOUS USE

-
Active Principles: N/A
Experimental

CYTARABINE
SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS USE

-
Active Principles: N/A
Experimental

No results