Phase 3 Study of Revumenib in Combination with Intensive Chemotherapy in Newly Diagnosed NPM1-mutated AML

Estado	Tipo de Participantes	Rangos de Edad
Reclutando	No aportado	Mayores de 64 , Adultos (18-64 años) , Adolescentes (12-17 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	139
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	tratamiento, seguridad, eficacia, farmacocinética, farmacodinamica	NO

Información

Identificador
2025-522279-27-00 (CTIS)

Cod. Protocolo
SNDX-5613-0710

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

Enfermedad investigada
Newly Diagnosed AML with an NPM1 mutation

Título Científico
A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study of Revumenib in Combination with Intensive Chemotherapy in Participants with Newly Diagnosed AML with an NPM1 mutation (REVEAL-ND NPM1)

Justificación

No aportado

Objetivo Principal

-To evaluate if revumenib + IC (intensive chemotherapy) improves EFS (event-free survival) compared to placebo + IC.
-To evaluate if revumenib + IC improves MRDBM (-) (Measurable Residual Disease in Bone Marrow) CR (complete remission) rate, compared to placebo + IC.

Variables de Evaluación Primaria

EFS: Defined as the time from the date of randomization to the date of Induction treatment failure, relapse or death due to any cause, whichever occurs first. MRDBM (-) CR rate: Defined as the percentage of participants with CR

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To evaluate if revumenib + IC improves OS (overall survival) compared to placebo + IC.
To evaluate if revumenib + IC improves EFS compared to placebo + IC.
To evaluate if revumenib + IC improves MRDBM (-) CR rate compared to placebo + IC.
To evaluate the MRDPB (-) CR rate for revumenib + IC compared to placebo + IC
To evaluate the MRDBM (-) CR rate for revumenib + IC compared to placebo + IC.
To evaluate if revumenib in combination with IC improves CR rate compared to placebo + IC.
To evaluate CRc (composite complete remission) rate for revumenib + IC compared to placebo + IC.
To evaluate ORR (overall response rate) in revumenib + IC compared to placebo + IC.
To evaluate Duration of CR for revumenib + IC compared to placebo + IC.
To evaluate Duration of CRc for revumenib + IC compared to placebo + IC
To evaluate DOR (duration of response) for revumenib + IC compared to placebo + IC.
To evaluate the safety and tolerability of revumenib + IC compared to placebo + IC.
To evaluate patient-reported fatigue for revumenib + IC compared to placebo + IC.

Variables de Evaluación Secundaria

OS: Defined as the time from the date of randomization to the date of death from any cause.
EFS (Investigator-assessed): Defined as the time from the date of randomization to the date of Induction treatment failure, relapse or death due to any cause, whichever occurs first.
MRDBM (-) CR rate: Defined as the percentage of participants with CR (Investigator-assessed) who achieve MRDBM (-) status by molecular assay
MRDPB (-) CR rate: Defined as the percent of participants with CR (Investigator assessed) who achieve MRDPB (-)

status by molecular assay
MRDBM (-) CR rate: Defined as the percent of participants with CR who achieve MRDBM (-) status.
CR rate (Investigator-assessed): Defined as the percentage of participants who achieve CR
CRc rate (Investigator-assessed): Defined as the rate of CR + CRh (complete remission with partial hematologic recovery) + Cri (complete remission with incomplete hematologic recovery).
ORR (Investigator-assessed): Defined as the rate of CR + CRh + CRi + MLFS (morphologic leukemia-free state) + PR (partial response).
Duration of CR: Defined as time from first date of first CR to relapse or death.
Duration of CRc: Defined as time from first date of first CRc to relapse or death.
DOR: Defined as time from date of first documented response (CR, CRh, CRi, PR, or MLFS) to the first documented relapse or death.
Frequency, duration, and severity of TEAEs (treatment-emergent adverse events), TRAEs (treatment-related adverse event), and SAEs. Incidence and shifts from baseline of clinically significant clinical laboratory abnormalities. Change from baseline in other observations related to safety, including ECGs, vital signs, and performance status.

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Participants must be 12 years of age and weigh 40 kg at the time of signing the informed consent form (ICF). Females of childbearing potential must have a negative serum pregnancy test at Screening and a negative urine or serum pregnancy test within 72 hours before the initiation of protocol therapy. If the urine test is positive or cannot be confirmed as negative, a serum pregnancy test will be obtained. Participants are considered to be not of childbearing potential if they are considered to be post-menopausal or surgically sterilized. Females who have been amenorrheic for at least 12 or more months are still considered to be of childbearing potential if the amenorrhea is possibly due to prior chemotherapy, anti-estrogens, ovarian suppression or any other reversible reason. a. Females of childbearing potential must be willing to use a highly effective method of contraception from the time of first study intervention dose through the required contraceptive period and must be willing to refrain from in vitro fertilization and egg donation during the required contraceptive period. b. Males must be surgically sterile (eg. bilateral orchiectomy or vasectomy) or agree to use barrier contraception (male condoms) from the time of first study intervention dose through the required contraceptive period. Males must be willing to refrain from sperm donation during the required contraceptive period. Participant or participants health care proxy is able and willing to provide written informed consent or assent and able to follow study instructions. Participants must have newly diagnosed and previously untreated AML and be candidates for intensive chemotherapy. The International Consensus Classification AML classification system will be used for this study Presence of an NPM1 mutation consistent with an NPM1c variant. Local mutation testing will be used to determine participant eligibility. Mutation status will subsequently be confirmed centrally. White blood cell (WBC) 25 × 109 /L by the time of the start of revumenib/placebo at Cycle 1 Day 8 (C1D8). Cytoreduction with hydroxyurea, leukapheresis or a single dose of cytarabine is allowed up to and including Induction C1D1. Have a life expectancy of 3 months as judged by the Investigator. Eastern Cooperative Oncology Group (ECOG) performance status score 0 to 2 if 18 to 65 years or 0 to 1 if aged 65 years; Karnofsky Performance Scale of 40 (if aged 16 years and <18 years); Lansky Performance Score of 40 (if aged <16 years) Creatinine Clearance (CLCr) 30 mL/min. CLCr calculation should be based on local institutional practice for age-appropriate determination (Cockcroft Gault formula for adults). A 24-hour urine collection may also be used to CLCr. Adequate liver function defined as: Total bilirubin <1.5 × the upper limit of normal (ULN) for age or normal conjugated bilirubin (unless attributed to leukemic involvement or Gilberts syndrome). Alanine aminotransferase (ALT) and aspartate aminotransferase (AST) <3 × ULN (unless attributed to leukemic involvement). Adequate cardiac function defined as ejection fraction of 50% by echocardiogram or multigated acquisition (MUGA) scan.

Criterios de Exclusión

Not a candidate for anthracycline-based therapy for Induction. Pregnant or nursing females. Participants may not have received AML-directed therapy before randomization, with the following exceptions: hydroxyurea, leukapheresis for the acute management of hyperleukocytosis and Days 1 to 7 of protocol-defined Induction chemotherapy Not a candidate for continuous infusion cytarabine during Induction or intermediate dose cytarabine for Consolidation. The following exclusions apply related to concomitant use of CYP3A4 inhibitors: Participants who will not receive revumenib with coadministration of a strong CYP3A4i (eg, itraconazole, ketoconazole, posaconazole, or voriconazole) must discontinue all strong CYP3A4 inhibitors at least 7 days before the first dose of revumenib or placebo. They will receive the revumenib or placebo and they may continue to receive moderate or weak CYP3A4 inhibitors, including fluconazole and isavuconazole. Participants who will receive revumenib or placebo with coadministration of a strong CYP3A4i (eg, itraconazole, ketoconazole, posaconazole, or voriconazole) must have started the treatment at least 24 hours before the first dose of revumenib or placebo. Participants requiring the concurrent use of medications known or suspected to prolong the QT/QTc interval, with the exception of drugs with low risk of QT/QTc prolongation that are used as standard supportive therapies (eg, diphenhydramine, famotidine, ondansetron, sulfamethoxazole and trimethoprim) and the azoles permitted. Current or future participation in another investigational drug study, scheduled to occur during this study, or has received an investigational agent within 14 days or 5 half-lives of the study intervention, whichever is longer) before dosing on C1D1 (Cycle 1 Day 1). Presence of FLT3 (FMS-like tyrosine kinase 3) mutation (either internal tandem duplication or tyrosine kinase domain) with a VAF 5%. Clinical signs/symptoms of hyperleukocytosis/leukostasis that have failed therapy including hydroxyurea or leukapheresis (of at least 3 days duration). History of prior allogeneic stem cell transplant for another malignancy or solid organ transplant. Diagnosis of active acute promyelocytic leukemia. Cardiac Disease: Any of the following within the 6 months before study entry: myocardial infarction, uncontrolled/unstable angina, congestive heart failure (New York Heart Association Classification Class II), life-threatening, uncontrolled arrhythmia, cerebrovascular accident, or transient ischemic attack. Participants with controlled atrial fibrillation are allowed to enroll. QTcF (Fridericias corrected QT interval) >450 msec at Screening. Diagnosis or suspicion of Long QT syndrome or family history of Long QT syndrome. Isolated extramedullary disease. Presence of life-threatening bleeding or thrombosis. Active central nervous system (CNS) disease (cytologic, eg, any blasts on cytospin or radiographic). Participants who have cleared CNS disease by at least one negative tap before dosing may be randomized, and prophylactic intrathecal chemotherapy may be continued while on study. [EU only] Otherwise considered to be inappropriate for the study by the investigator including where other treatment options, such as gemtuzumab ozogamicin, are preferred according to local institutional practice and prescribing guidelines. Gastrointestinal Disease (GI): Any GI issue of the upper GI tract likely to affect oral drug absorption or ingestion (eg, gastric bypass, gastroparesis). Cirrhosis with a Child-Pugh score of B or C, or National Cancer Institute (NCI) Organ Dysfunction Working Group category of Severe Dysfunction. Inability to swallow oral medications Any concurrent malignancy requiring active therapy (except breast or prostate cancer stable on or responding to endocrine therapy). For participants with therapy-related leukemia, primary disease must be in remission. Participants known to have 1 of the following genetic syndromes: Down syndrome, Bloom syndrome, ataxia-telangiectasia, Fanconi anemia, Kostmann syndrome, Shwachman syndrome, or any other known genetic bone marrow failure syndrome. History of or any concurrent condition, therapy, laboratory abnormality, or allergy to excipients that in the Investigators opinion might confound the results of the study, interfere with the participants participation for the full duration of the study, or is not in the best interest of the participant to participate. If the participant is known to be human immunodeficiency virus (HIV)-positive, the participant must have an undetectable HIV viral load within the previous 6 months. If viral load testing has not been performed within the previous 6 months, it must be performed during Screening. Participant has known active or chronic hepatitis B or active hepatitis C (HCV) infection. Participants with a history of HCV infection who have completed curative therapy for HCVat least 12 weeks before the Screening Visit and have a documented undetectable viral load at the Screening Visit are eligible for randomization. Uncontrolled active infection of any type. Infections under control with antibiotic treatment are acceptable for study entry.

Calendario

(Última actualización: 02/09/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
23/02/2026	29/04/2026	03/06/2026	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

Syndax Pharmaceuticals Inc. United States

730 3rd Avenue Floor 9

Contact Person

Angie Smith, MD, Executive Medical Director

6122071024

Asmith@syndax.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Regional de la Comunidad de Madrid

C/ Aduana 29 3ª planta 28013 Madrid

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913702824

Centros

Activo (02/06/2026)

Clinica Universidad De Navarra

Pamplona

NAVARRA

172413: Hematology and Hemotherapy

Activo (22/06/2026)

El Hospital Universitario De Gran Canaria Dr. Negrin

Las Palmas De Gran Canaria

LAS PALMAS

172418: Hematología

Activo (08/06/2026)

Hospital Clinic De Barcelona

Barcelona

BARCELONA

172412: Hematología

Activo (06/08/2026)

Hospital De La Santa Creu I Sant Pau

Barcelona

BARCELONA

172407: Hematología

Activo (09/07/2026)

Hospital General Universitario Dr. Balmis

Alicante

ALICANTE

172420: Hematología

Activo (14/05/2026)

Hospital General Universitario Gregorio Maranon

Madrid

MADRID

172404: Hematologia

Activo (29/04/2026)

Hospital San Pedro De Alcantara

Caceres

CÁCERES

172401: Hematologia

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

Hospital Universitari Joan XXIII De Tarragona

Tarragona

TARRAGONA

172409: Hematología

Activo (26/08/2026)

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

172417: Hematology and Hemotherapy

Activo (24/06/2026)

Hospital Universitario Central De Asturias

Oviedo

ASTURIAS

172423: Hematology and Hemotherapy

Activo (07/07/2026)

Hospital Universitario De Burgos

Burgos

BURGOS

172422: Hematology and Transfusion Medicine

Activo (21/07/2026)

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

172410: Hematología

Activo (28/08/2026)

Hospital Universitario Fundacion Jimenez Diaz

Madrid

MADRID

172415: Hematología

Activo (01/09/2026)

Hospital Universitario La Paz

Madrid

MADRID

172419: Hematología

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

Hospital Universitario Marques De Valdecilla

Santander

CANTABRIA

172416: Hematología

Activo (08/06/2026)

Hospital Universitario Ramon Y Cajal

Madrid

MADRID

172414: Hematology and Hemotherapy

Activo (29/06/2026)

Hospital Universitario Virgen De La Victoria

Malaga

MÁLAGA

172421: Hematologia y Transfusión

Activo (14/07/2026)

Hospital Universitario Virgen De Las Nieves

Granada

GRANADA

172424: Hematología

Activo (30/04/2026)

Hospital Universitario Y Politecnico La Fe

Valencia

VALENCIA

172402: Hematologia

Activo (02/07/2026)

Institut Catala D'oncologia

Badalona

BARCELONA

172406: Hematología

Activo (03/06/2026)

Institut Catala D'oncologia

L'hospitalet De Llobregat

BARCELONA

172411: Hematologia

Activo (07/05/2026)

MD Anderson Cancer Center

Madrid

MADRID

172408: Hematología

Activo (27/05/2026)

University Hospital Son Espases

Palma

BALEARES

172405: Hematologia

Activo (11/05/2026)

University Hospital Virgen Del Rocio S.L.

Sevilla

SEVILLA

172403: Hematologia

Medicamentos

IDARUBICIN HYDROCHLORIDE
SOLUTION FOR INJECTION
INTRAVENOUS USE

-
Principios Activos: N/A
Experimental

Revumenib
TABLET
ORAL

-
Principios Activos: N/A
Huérfano Experimental

Revumenib
TABLET
ORAL

-
Principios Activos: N/A
Huérfano Experimental

Revumenib
TABLET
ORAL

-
Principios Activos: N/A
Huérfano Experimental

DAUNORUBICIN HYDROCHLORIDE
POWDER FOR SOLUTION FOR INJECTION OR INFUSION
INTRAVENOUS USE

-
Principios Activos: N/A
Experimental

CYTARABINE
SOLUTION FOR INJECTION OR INFUSION
INTRAVENOUS USE

-
Principios Activos: N/A
Experimental

Sin resultados

Phase 3 Study of Revumenib in Combination with Intensive Chemotherapy in Newly Diagnosed NPM1-mutated AML

State	Type of participants	Age Ranges
Recruiting	Not provided	Older than 64 , Adults (18-64 years) , Teens (12-17 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	139
Results	**Low level of intervention**	**Rare disease**
No results	No	Yes
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	treatment, safety, effectiveness, pharmacokinetics, pharmacodynamics	NO

Information

Identifier
2025-522279-27-00 (CTIS)

Protocol Code
SNDX-5613-0710

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

Investigated Disease
Newly Diagnosed AML with an NPM1 mutation

Scientific Title
A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study of Revumenib in Combination with Intensive Chemotherapy in Participants with Newly Diagnosed AML with an NPM1 mutation (REVEAL-ND NPM1)

Rationale

Not provided

Main Objective

-To evaluate if revumenib + IC (intensive chemotherapy) improves EFS (event-free survival) compared to placebo + IC.
-To evaluate if revumenib + IC improves MRDBM (-) (Measurable Residual Disease in Bone Marrow) CR (complete remission) rate, compared to placebo + IC.

Primary Endpoints

EFS: Defined as the time from the date of randomization to the date of Induction treatment failure, relapse or death due to any cause, whichever occurs first. MRDBM (-) CR rate: Defined as the percentage of participants with CR

Temporary moments of secondary assessment

Not provided

Secondary Objective

To evaluate if revumenib + IC improves OS (overall survival) compared to placebo + IC.
To evaluate if revumenib + IC improves EFS compared to placebo + IC.
To evaluate if revumenib + IC improves MRDBM (-) CR rate compared to placebo + IC.
To evaluate the MRDPB (-) CR rate for revumenib + IC compared to placebo + IC
To evaluate the MRDBM (-) CR rate for revumenib + IC compared to placebo + IC.
To evaluate if revumenib in combination with IC improves CR rate compared to placebo + IC.
To evaluate CRc (composite complete remission) rate for revumenib + IC compared to placebo + IC.
To evaluate ORR (overall response rate) in revumenib + IC compared to placebo + IC.
To evaluate Duration of CR for revumenib + IC compared to placebo + IC.
To evaluate Duration of CRc for revumenib + IC compared to placebo + IC
To evaluate DOR (duration of response) for revumenib + IC compared to placebo + IC.
To evaluate the safety and tolerability of revumenib + IC compared to placebo + IC.
To evaluate patient-reported fatigue for revumenib + IC compared to placebo + IC.

Secondary Endpoints

OS: Defined as the time from the date of randomization to the date of death from any cause.
EFS (Investigator-assessed): Defined as the time from the date of randomization to the date of Induction treatment failure, relapse or death due to any cause, whichever occurs first.
MRDBM (-) CR rate: Defined as the percentage of participants with CR (Investigator-assessed) who achieve MRDBM (-) status by molecular assay
MRDPB (-) CR rate: Defined as the percent of participants with CR (Investigator assessed) who achieve MRDPB (-)

status by molecular assay
MRDBM (-) CR rate: Defined as the percent of participants with CR who achieve MRDBM (-) status.
CR rate (Investigator-assessed): Defined as the percentage of participants who achieve CR
CRc rate (Investigator-assessed): Defined as the rate of CR + CRh (complete remission with partial hematologic recovery) + Cri (complete remission with incomplete hematologic recovery).
ORR (Investigator-assessed): Defined as the rate of CR + CRh + CRi + MLFS (morphologic leukemia-free state) + PR (partial response).
Duration of CR: Defined as time from first date of first CR to relapse or death.
Duration of CRc: Defined as time from first date of first CRc to relapse or death.
DOR: Defined as time from date of first documented response (CR, CRh, CRi, PR, or MLFS) to the first documented relapse or death.
Frequency, duration, and severity of TEAEs (treatment-emergent adverse events), TRAEs (treatment-related adverse event), and SAEs. Incidence and shifts from baseline of clinically significant clinical laboratory abnormalities. Change from baseline in other observations related to safety, including ECGs, vital signs, and performance status.

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Participants must be 12 years of age and weigh 40 kg at the time of signing the informed consent form (ICF). Females of childbearing potential must have a negative serum pregnancy test at Screening and a negative urine or serum pregnancy test within 72 hours before the initiation of protocol therapy. If the urine test is positive or cannot be confirmed as negative, a serum pregnancy test will be obtained. Participants are considered to be not of childbearing potential if they are considered to be post-menopausal or surgically sterilized. Females who have been amenorrheic for at least 12 or more months are still considered to be of childbearing potential if the amenorrhea is possibly due to prior chemotherapy, anti-estrogens, ovarian suppression or any other reversible reason. a. Females of childbearing potential must be willing to use a highly effective method of contraception from the time of first study intervention dose through the required contraceptive period and must be willing to refrain from in vitro fertilization and egg donation during the required contraceptive period. b. Males must be surgically sterile (eg. bilateral orchiectomy or vasectomy) or agree to use barrier contraception (male condoms) from the time of first study intervention dose through the required contraceptive period. Males must be willing to refrain from sperm donation during the required contraceptive period. Participant or participants health care proxy is able and willing to provide written informed consent or assent and able to follow study instructions. Participants must have newly diagnosed and previously untreated AML and be candidates for intensive chemotherapy. The International Consensus Classification AML classification system will be used for this study Presence of an NPM1 mutation consistent with an NPM1c variant. Local mutation testing will be used to determine participant eligibility. Mutation status will subsequently be confirmed centrally. White blood cell (WBC) 25 × 109 /L by the time of the start of revumenib/placebo at Cycle 1 Day 8 (C1D8). Cytoreduction with hydroxyurea, leukapheresis or a single dose of cytarabine is allowed up to and including Induction C1D1. Have a life expectancy of 3 months as judged by the Investigator. Eastern Cooperative Oncology Group (ECOG) performance status score 0 to 2 if 18 to 65 years or 0 to 1 if aged 65 years; Karnofsky Performance Scale of 40 (if aged 16 years and <18 years); Lansky Performance Score of 40 (if aged <16 years) Creatinine Clearance (CLCr) 30 mL/min. CLCr calculation should be based on local institutional practice for age-appropriate determination (Cockcroft Gault formula for adults). A 24-hour urine collection may also be used to CLCr. Adequate liver function defined as: Total bilirubin <1.5 × the upper limit of normal (ULN) for age or normal conjugated bilirubin (unless attributed to leukemic involvement or Gilberts syndrome). Alanine aminotransferase (ALT) and aspartate aminotransferase (AST) <3 × ULN (unless attributed to leukemic involvement). Adequate cardiac function defined as ejection fraction of 50% by echocardiogram or multigated acquisition (MUGA) scan.

Exclusion criteria

Not a candidate for anthracycline-based therapy for Induction. Pregnant or nursing females. Participants may not have received AML-directed therapy before randomization, with the following exceptions: hydroxyurea, leukapheresis for the acute management of hyperleukocytosis and Days 1 to 7 of protocol-defined Induction chemotherapy Not a candidate for continuous infusion cytarabine during Induction or intermediate dose cytarabine for Consolidation. The following exclusions apply related to concomitant use of CYP3A4 inhibitors: Participants who will not receive revumenib with coadministration of a strong CYP3A4i (eg, itraconazole, ketoconazole, posaconazole, or voriconazole) must discontinue all strong CYP3A4 inhibitors at least 7 days before the first dose of revumenib or placebo. They will receive the revumenib or placebo and they may continue to receive moderate or weak CYP3A4 inhibitors, including fluconazole and isavuconazole. Participants who will receive revumenib or placebo with coadministration of a strong CYP3A4i (eg, itraconazole, ketoconazole, posaconazole, or voriconazole) must have started the treatment at least 24 hours before the first dose of revumenib or placebo. Participants requiring the concurrent use of medications known or suspected to prolong the QT/QTc interval, with the exception of drugs with low risk of QT/QTc prolongation that are used as standard supportive therapies (eg, diphenhydramine, famotidine, ondansetron, sulfamethoxazole and trimethoprim) and the azoles permitted. Current or future participation in another investigational drug study, scheduled to occur during this study, or has received an investigational agent within 14 days or 5 half-lives of the study intervention, whichever is longer) before dosing on C1D1 (Cycle 1 Day 1). Presence of FLT3 (FMS-like tyrosine kinase 3) mutation (either internal tandem duplication or tyrosine kinase domain) with a VAF 5%. Clinical signs/symptoms of hyperleukocytosis/leukostasis that have failed therapy including hydroxyurea or leukapheresis (of at least 3 days duration). History of prior allogeneic stem cell transplant for another malignancy or solid organ transplant. Diagnosis of active acute promyelocytic leukemia. Cardiac Disease: Any of the following within the 6 months before study entry: myocardial infarction, uncontrolled/unstable angina, congestive heart failure (New York Heart Association Classification Class II), life-threatening, uncontrolled arrhythmia, cerebrovascular accident, or transient ischemic attack. Participants with controlled atrial fibrillation are allowed to enroll. QTcF (Fridericias corrected QT interval) >450 msec at Screening. Diagnosis or suspicion of Long QT syndrome or family history of Long QT syndrome. Isolated extramedullary disease. Presence of life-threatening bleeding or thrombosis. Active central nervous system (CNS) disease (cytologic, eg, any blasts on cytospin or radiographic). Participants who have cleared CNS disease by at least one negative tap before dosing may be randomized, and prophylactic intrathecal chemotherapy may be continued while on study. [EU only] Otherwise considered to be inappropriate for the study by the investigator including where other treatment options, such as gemtuzumab ozogamicin, are preferred according to local institutional practice and prescribing guidelines. Gastrointestinal Disease (GI): Any GI issue of the upper GI tract likely to affect oral drug absorption or ingestion (eg, gastric bypass, gastroparesis). Cirrhosis with a Child-Pugh score of B or C, or National Cancer Institute (NCI) Organ Dysfunction Working Group category of Severe Dysfunction. Inability to swallow oral medications Any concurrent malignancy requiring active therapy (except breast or prostate cancer stable on or responding to endocrine therapy). For participants with therapy-related leukemia, primary disease must be in remission. Participants known to have 1 of the following genetic syndromes: Down syndrome, Bloom syndrome, ataxia-telangiectasia, Fanconi anemia, Kostmann syndrome, Shwachman syndrome, or any other known genetic bone marrow failure syndrome. History of or any concurrent condition, therapy, laboratory abnormality, or allergy to excipients that in the Investigators opinion might confound the results of the study, interfere with the participants participation for the full duration of the study, or is not in the best interest of the participant to participate. If the participant is known to be human immunodeficiency virus (HIV)-positive, the participant must have an undetectable HIV viral load within the previous 6 months. If viral load testing has not been performed within the previous 6 months, it must be performed during Screening. Participant has known active or chronic hepatitis B or active hepatitis C (HCV) infection. Participants with a history of HCV infection who have completed curative therapy for HCVat least 12 weeks before the Screening Visit and have a documented undetectable viral load at the Screening Visit are eligible for randomization. Uncontrolled active infection of any type. Infections under control with antibiotic treatment are acceptable for study entry.

Calendar

(Last Update: 02/09/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
23/02/2026	29/04/2026	03/06/2026	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

Syndax Pharmaceuticals Inc. United States

730 3rd Avenue Floor 9

Contact Person

Angie Smith, MD, Executive Medical Director

6122071024

Asmith@syndax.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Regional de la Comunidad de Madrid

C/ Aduana 29 3ª planta 28013 Madrid

comite.regional@salud.madrid.org

913702824

Sites

Active (02/06/2026)

Clinica Universidad De Navarra

Pamplona

NAVARRA

172413: Hematology and Hemotherapy

Active (22/06/2026)

El Hospital Universitario De Gran Canaria Dr. Negrin

Las Palmas De Gran Canaria

LAS PALMAS

172418: Hematología

Active (08/06/2026)

Hospital Clinic De Barcelona

Barcelona

BARCELONA

172412: Hematología

Active (06/08/2026)

Hospital De La Santa Creu I Sant Pau

Barcelona

BARCELONA

172407: Hematología

Active (09/07/2026)

Hospital General Universitario Dr. Balmis

Alicante

ALICANTE

172420: Hematología

Active (14/05/2026)

Hospital General Universitario Gregorio Maranon

Madrid

MADRID

172404: Hematologia

Active (29/04/2026)

Hospital San Pedro De Alcantara

Caceres

CÁCERES

172401: Hematologia

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

Hospital Universitari Joan XXIII De Tarragona

Tarragona

TARRAGONA

172409: Hematología

Active (26/08/2026)

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

172417: Hematology and Hemotherapy

Active (24/06/2026)

Hospital Universitario Central De Asturias

Oviedo

ASTURIAS

172423: Hematology and Hemotherapy

Active (07/07/2026)

Hospital Universitario De Burgos

Burgos

BURGOS

172422: Hematology and Transfusion Medicine

Active (21/07/2026)

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

172410: Hematología

Active (28/08/2026)

Hospital Universitario Fundacion Jimenez Diaz

Madrid

MADRID

172415: Hematología

Active (01/09/2026)

Hospital Universitario La Paz

Madrid

MADRID

172419: Hematología

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

Hospital Universitario Marques De Valdecilla

Santander

CANTABRIA

172416: Hematología

Active (08/06/2026)

Hospital Universitario Ramon Y Cajal

Madrid

MADRID

172414: Hematology and Hemotherapy

Active (29/06/2026)

Hospital Universitario Virgen De La Victoria

Malaga

MÁLAGA

172421: Hematologia y Transfusión

Active (14/07/2026)

Hospital Universitario Virgen De Las Nieves

Granada

GRANADA

172424: Hematología

Active (30/04/2026)

Hospital Universitario Y Politecnico La Fe

Valencia

VALENCIA

172402: Hematologia

Active (02/07/2026)

Institut Catala D'oncologia

Badalona

BARCELONA

172406: Hematología

Active (03/06/2026)

Institut Catala D'oncologia

L'hospitalet De Llobregat

BARCELONA

172411: Hematologia

Active (07/05/2026)

MD Anderson Cancer Center

Madrid

MADRID

172408: Hematología

Active (27/05/2026)

University Hospital Son Espases

Palma

BALEARES

172405: Hematologia

Active (11/05/2026)

University Hospital Virgen Del Rocio S.L.

Sevilla

SEVILLA

172403: Hematologia

Medication

IDARUBICIN HYDROCHLORIDE
SOLUTION FOR INJECTION
INTRAVENOUS USE

-
Active Principles: N/A
Experimental

Revumenib
TABLET
ORAL

-
Active Principles: N/A
Orphan
Experimental

Revumenib
TABLET
ORAL

-
Active Principles: N/A
Orphan
Experimental

Revumenib
TABLET
ORAL

-
Active Principles: N/A
Orphan
Experimental

DAUNORUBICIN HYDROCHLORIDE
POWDER FOR SOLUTION FOR INJECTION OR INFUSION
INTRAVENOUS USE

-
Active Principles: N/A
Experimental

CYTARABINE
SOLUTION FOR INJECTION OR INFUSION
INTRAVENOUS USE

-
Active Principles: N/A
Experimental

No results