

A Phase 1/2 study of Enzomenib (DSP-5336) in Adult Patients with Acute leukemia

Estado

Reclutando

Tipo de Participantes

No aportado

Rangos de Edad

Mayores de 64 , Adultos (18-64 años)

Género

Ambos

Fases

Fase I , Fase II

Participantes esperados

404

Resultados

Sin resultados

Bajo nivel intervención

No

Enfermedad rara

Si

Cobertura geográfica

Sin determinar

Ámbitos del ensayo

seguridad, eficacia, farmacocinética,
farmacodinámica

Terapia avanzada

NO

Información

Identificador

2022-502741-10-00 (CTIS)

Cod. Protocolo

DSP-5336-101

Área terapéutica

Enfermedades [C] - Cáncer [C04]

Enfermedad investigada

Acute Leukemia with Mixed Lineage Leukemia (MLL)-rearrangement or Nucleophosmin 1 (NPM1) Mutation

Título Científico

A Phase 1/2, Open-Label, Dose-Escalation, Dose-Expansion Study of Enzomenib (DSP 5336) in Adult Patients with Acute Leukemia and Other Selected Hematologic Malignancies, with and without Mixed Lineage Leukemia (MLL) rearrangement or Nucleophosmin 1 (NPM1) Mutation

Justificación

FIH; Phase 1/2<br/

Objetivo Principal

Phase 1: To assess the safety and tolerability of DSP-5336 monotherapy in patients with relapsed or refractory AML, ALL, or acute leukemia of ambiguous lineage. To determine the recommended Phase 2 dose (RP2D) of DSP-5336 based on the lowest dose of DSP-5336 that provides the maximum biologic and clinical effect, or the maximum tolerated dose (MTD), whichever is lower

Phase 2: To evaluate the clinical activity of DSP-5336 monotherapy in patients with relapsed/refractory acute leukemia with an MLLr or patients with relapsed/refractory AML with an NPM1m

Variables de Evaluación Primaria

Phase 1: Safety: Dose-limiting toxicities (DLTs) as assessed by (NCI CTCAE), version 5.0 Phase 2: CR + CRh

Phase 1: Safety: Treatment-emergent adverse events (TEAEs) and serious adverse events (SAEs)

Phase 1: Safety: Changes in vital signs, clinical laboratory values (hematology, clinical chemistry, urinalysis), electrocardiogram (ECG) parameters, echocardiogram (ECHO) parameters

Phase 1: Tolerability: Dose interruptions, dose reductions, and/or dose discontinuations

Phase 1: Biologic Efficacy: see corresponding secondary endpoints for PK and clinical activity

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

Phase 1: To characterize the PK profiles of DSP-5336, including the PK profile in the presence of concomitant use of selected azoles, ie, posaconazole, voriconazole, or fluconazole Phase 2: To evaluate the additional clinical activity of DSP-5336 monotherapy in patients with relapsed/refractory acute leukemia with an MLLr or patients with relapsed/refractory AML with an NPM1m

Phase 1: To evaluate the preliminary clinical activity of DSP-5336 monotherapy in patients with AML, ALL, or acute leukemia of ambiguous lineage Phase 2: To further assess the safety and tolerability of DSP-5336

Phase 1: To determine the cardiac safety of DSP-5336 administered as a single agent by 12-lead safety and intensive ECG monitoring, and in the presence of azoles by 12-lead safety ECG monitoring

Variables de Evaluación Secundaria

Phase 1: Plasma DSP-5336 concentration-time profiles, plasma PK parameters of DSP-5336 (ie, AUC, Cmax, tmax, t1/2, and other parameters, as data allow) Phase 2: CR; CRi; PR; MLFS defined by ELN 2017. CRc (CR or CRh or CRi); ORR (= CR or CRi or MLFS); time to CR/CRh; time to ORR; duration of CR/CRh, duration of ORR; TI; OS; EFS

Phase 1: For acute leukemias: Response according to ELN 2017 criteria and criteria for CRh defined by the FDA

guidance: CR; CRh; CRi; PR; MLFS; CR+ CRh; ; CRc (CR or CRh or Cri); ORR (=CR or CRi or MLFS); time to CR/CRh; time to ORR; duration of CR/CRh, duration of ORR; TI; OS; EFS Phase2: TEAEs and SAEs Changes in vital signs, clinical laboratory values (hematology, clinical chemistry), ECG parameters, Dose modifications
Phase 1: QT interval changes and morphology, assessed in patients receiving DSP-5336 as a single agent or in the presence of azoles QT interval correction will be performed using Fridericias formula (QTcF) from triplicate ECGs

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

For patients in Phase 1: Have a confirmed diagnosis of refractory or relapsed AML, ALL, or acute leukemia of ambiguous lineage and whose disease has progressed after available standard therapies known to be active for their AML, ALL, or acute leukemia of ambiguous lineage. Participants must have a documented KMT2A (MLL) fusion or NPM1 mutation including those with coexisting FLT3 genomic alterations and/or IDH1/2 mutation. Participants who are candidates for stem cell transplantation must have been offered this therapeutic option

For all patients: Have an estimated life expectancy 3 months, based on the investigators assessment For all patients: Females of childbearing potential must have a negative serum or urine pregnancy test.

For all patients: Must agree to use one highly effective contraception method or 2 acceptable methods of birth control (each partner to use one method) or use prevention of pregnancy measures (ie, sexual abstinence, when this is the usual and preferred lifestyle of the patient) during the study and for 6 months (for females and males alike) after the last dose of study drug, if the male or female patient is of child-producing potential

For all patients: Have bone marrow material suitable for genomic analysis (eg, MLLr or NPM1 mutations) of AML or ALL genetic alterations. Note: if a bone marrow material is insufficient, an alternative suitable tissue (eg, peripheral blood) must be provided.

For patients in Phase 2: Have a confirmed diagnosis of refractory or relapsed AML or ALL according to WHO 2022 classification, as determined by pathology review at the treating institution, and who have 5% blasts by morphologic assessment in the bone marrow. Patients must have received clinically applicable standard therapies with confirmed survival benefit. Patients must not have had prior exposure to a menin inhibitor

For patients in Phase 2: Have a documented KMT2A (MLL)-fusion or NPM1 mutation assessed at relapse or immediately prior to the determination of refractory status

For all patients: Be 18 years of age

For all patients: Have an Eastern Cooperative Oncology Group (ECOG) performance status 2.

For all patients: For DSP-5336 monotherapy, white blood cell (WBC) count must be below 30,000/L at the time of enrollment and prior to starting study treatment. (Hydroxyurea and steroid for cytoreduction purpose will be allowed prior to enrollment and during study treatment).

For all patients: Any prior treatment-related toxicities resolved to Grade 1 prior to enrollment, with the exception of Grade 2 alopecia or neuropathy For all patients: Have adequate renal and hepatic function at Screening as determined by: a. Clearance of creatinine (CLcr) level 50 ml/min, assessed by the Cockcroft-Gault formula b. Total bilirubin 1.5 times the upper limit of normal (ULN) (or 2.0 times ULN for patients with known Gilberts syndrome) c. Aspartate aminotransferase (AST) 3.0 times ULN d. Alanine aminotransferase (ALT) 3.0 times ULN

For all patients: Be willing to attend study visits as required by the protocol

Criterios de Exclusión

Have a histologic diagnosis of acute promyelocytic leukemia Have a cognitive, psychologic, or psychosocial impediment that would impair the ability of the patient to receive therapy according to the protocol, or adversely affect the ability of the patient to comply with the informed consent/assent process, protocol, or protocol-required visits and

procedures Have a history of Grade 2 drug-induced interstitial lung disease or Grade 2 non-infectious pneumonitis within 6 months of starting study treatment. Underwent HSCT or chimeric antigen receptor cell (CAR-T) therapy or other modified T-cell therapy within 60 days prior to the first dose of DSP-5336. Receive concurrent sensitive substrates with a narrow safety window or strong inhibitors or inducers of CYP3A4/5. Other antifungals that are used as standard of care to prevent or treat infections are permitted Note: If a patient is on one of the excluded azole class antifungals and can be switched to a permitted azole 7 or more days prior to study, that patient could be allowed on study (Arm B). Have a known detectable viral load for human immunodeficiency virus or hepatitis C, or evidence of a hepatitis B surface antigen, all being indicative of active infection. In the opinion of the treating investigator, have any concurrent conditions that could pose an undue medical hazard or interfere with interpretation of study results; these conditions include, but are not limited to: clinically significant non-healing or healing wounds; concurrent congestive heart failure (New York Heart Association Functional Classification Class III or IV; see Section 21.7); concurrent unstable angina; concurrent cardiac arrhythmia requiring treatment (excluding asymptomatic atrial fibrillation); recent (within the prior 6 months) myocardial infarction; acute coronary syndrome within the previous 6 months; significant pulmonary disease (shortness of breath at rest or on mild exertion), eg, due to concurrent severe obstructive pulmonary disease, concurrent hypertension not controlled with concomitant medication, or diabetes mellitus with more than 2 episodes of ketoacidosis in the prior 6 months. Have a history of Torsades de Pointes Have abnormal ECGs at screening that are clinically significant, such as QTc >480 with QTc corrected according to Fridericia's formula [QTcF]). Are pregnant or breastfeeding or planning to become pregnant Note: Patients who are breastfeeding may be enrolled if they interrupt breastfeeding prior to the first dose of any study drugs and do not feed the baby with breast milk expressed after receiving the first dose of any study drugs. Breastfeeding should not be resumed for at least 6 months after the last dose of study drug. . Underwent HSCT or chimeric antigen receptor cell (CAR-T) therapy or other modified T-cell therapy within 60 days prior to the first dose of DSP-5336 Underwent HSCT or chimeric antigen receptor cell (CAR-T) therapy or other modified T-cell therapy within 60 days prior to the first dose of DSP-5336. Received a donor lymphocyte infusion within 28 days prior to the first dose of DSP 5336, or receiving immunosuppressive therapy post-HSCT at the time of Screening, or with clinically active GVHD or GVHD requiring active medical intervention other than the use of topical steroids for ongoing cutaneous GVHD. Received antineoplastic agents (except hormonal therapies as adjuvant maintenance for breast or prostate cancers if a patient is taking before starting study treatment, and hydroxyurea given for controlling blast cells) or other investigational treatment within 14 days or 5 half-lives, whichever is shortest, prior to the first dose of DSP-5336 Received systemic calcineurin inhibitors within 2 weeks prior to the first dose of DSP 5336 Had major surgery within 28 days prior to the first dose of DSP-5336 Have active central nervous system leukemia (prophylactic intrathecal chemotherapy is allowed). Have any history or complication of interstitial lung disease (for sites in Japan only) and, for clinical sites operating under the European Medicines Agencies, a history of Grade 2 drug-induced interstitial lung disease or Grade 2 non-infectious pneumonitis within 6 months of starting study treatment Have a known intolerance or hypersensitivity reaction to components of any of the investigational medicinal products Have a left ventricular ejection fraction (LVEF) <50%, as determined by ECHO Received antineoplastic agents (except hormonal therapies as adjuvant maintenance for breast or prostate cancers if a patient is taking before starting study treatment, and hydroxyurea given for controlling blast cells) or other investigational treatment within 14 days or 5 half-lives, whichever is shortest, prior to the first dose of DSP-5336 . Received systemic calcineurin inhibitors within 42 weeks prior to the first dose of DSP 5336. Have an active and uncontrolled, bacterial, viral, or fungal infection requiring parenteral therapy Have known severe dysphagia, short-gut syndrome, gastroparesis, or other conditions that limit the ingestion or gastrointestinal absorption of drugs administered orally, including the inability to swallow oral medication

Calendario

(Última actualización: 21/01/2026)

Autorización 01/09/2023	Inicio de Ensayo 26/01/2024	Inclusión Primer Paciente 13/02/2024	Interrumpido No aportado	Reiniciado No aportado
Fin de reclutamiento No aportado	Fin prematuro (España) No aportado	Fin prematuro (Global) No aportado	Fin del ensayo en España No aportado	Fin del ensayo global No aportado

Promotor

Sumitomo Pharma America Inc. United States

84 Waterford Drive

Contact Person

Clinical Development

+15084816700

DL-clinicaltrials@us.sumitomo-pharma.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm del Hospital Universitario y Politécnico la Fe

Avda de Fernando Abril Martorell, n.106, Hospital U. i P. La Fe, Torre A, Planta 7, despacho 7.12, 46026 Valencia

ceic@iislafe.es

961246605

Centros

Activo (31/10/2025)	Complejo Hospitalario Universitario De Santiago Santiago De Compostela CORUÑA ES052A: Hematología
Activo (26/01/2024)	Hospital General Universitario De Albacete Albacete ALBACETE Hematología
Activo (23/01/2024)	Hospital San Pedro De Alcantara Caceres CÁCERES Hematología
Activo (20/08/2024)	Hospital Universitari Vall D Hebron Barcelona BARCELONA Hematologia
Activo (11/03/2024)	Hospital Universitario Central De Asturias Oviedo ASTURIAS Hematología
Activo (04/03/2024)	Hospital Universitario De Gran Canaria Dr. Negrin Las Palmas De Gran Canaria LAS PALMAS Hematología
Activo (27/02/2024)	Hospital Universitario De Salamanca Salamanca SALAMANCA Hematología
Activo (12/08/2025)	Hospital Universitario Marques De Valdecilla Santander CANTABRIA ES053A: Hematología

Activo (18/01/2024)

Hospital Universitario Y Politecnico La Fe

Valencia

VALENCIA

Hematología

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

Institut Catala D''oncologia

Badalona

BARCELONA

ES001A: Hematología

Activo (10/03/2024)

Institut Catala D'oncologia

Badalona

BARCELONA

Hematología

Activo (11/03/2024)

MD Anderson Cancer Center

Madrid

MADRID

Oncología

Medicamentos

Enzomenib

TABLET

ORAL

Principios Activos: N/A

Experimental

Enzomenib

TABLET

ORAL

Principios Activos: N/A

Experimental

Sin resultados

A Phase 1/2 study of Enzomenib (DSP-5336) in Adult Patients with Acute leukemia

State
Recruiting

Type of participants
Not provided

Age Ranges
Older than 64 , Adults (18-64 years)

Gender
Both

Phases
Phase I , Phase II

Expected Participants
404

Results
No results

Low level of intervention
No

Rare disease
Yes

Geographic coverage
Undetermined

Areas of the study
safety, effectiveness, pharmacokinetics,
pharmacodynamics

Advanced therapy
NO

Information

Identifier
2022-502741-10-00 (CTIS)

Protocol Code
DSP-5336-101

Therapeutic area
Diseases [C] - Cancer [C04]

Investigated Disease
Acute Leukemia with Mixed Lineage Leukemia (MLL)-rearrangement or Nucleophosmin 1 (NPM1) Mutation

Scientific Title
A Phase 1/2, Open-Label, Dose-Escalation, Dose-Expansion Study of Enzomenib (DSP 5336) in Adult Patients with Acute Leukemia and Other Selected Hematologic Malignancies, with and without Mixed Lineage Leukemia (MLL) rearrangement or Nucleophosmin 1 (NPM1) Mutation

Rationale

FIH; Phase 1/2<br/

Main Objective

Phase 1: To assess the safety and tolerability of DSP-5336 monotherapy in patients with relapsed or refractory AML, ALL, or acute leukemia of ambiguous lineage. To determine the recommended Phase 2 dose (RP2D) of DSP-5336 based on the lowest dose of DSP-5336 that provides the maximum biologic and clinical effect, or the maximum tolerated dose (MTD), whichever is lower

Phase 2: To evaluate the clinical activity of DSP-5336 monotherapy in patients with relapsed/refractory acute leukemia with an MLLr or patients with relapsed/refractory AML with an NPM1m

Primary Endpoints

Phase 1: Safety: Dose-limiting toxicities (DLTs) as assessed by (NCI CTCAE), version 5.0 Phase 2: CR + CRh

Phase 1: Safety: Treatment-emergent adverse events (TEAEs) and serious adverse events (SAEs)

Phase 1: Safety: Changes in vital signs, clinical laboratory values (hematology, clinical chemistry, urinalysis), electrocardiogram (ECG) parameters, echocardiogram (ECHO) parameters

Phase 1: Tolerability: Dose interruptions, dose reductions, and/or dose discontinuations

Phase 1: Biologic Efficacy: see corresponding secondary endpoints for PK and clinical activity

Temporary moments of secondary assessment

Not provided

Secondary Objective

Phase 1: To characterize the PK profiles of DSP-5336, including the PK profile in the presence of concomitant use of selected azoles, ie, posaconazole, voriconazole, or fluconazole Phase 2: To evaluate the additional clinical activity of DSP-5336 monotherapy in patients with relapsed/refractory acute leukemia with an MLLr or patients with relapsed/refractory AML with an NPM1m

Phase 1: To evaluate the preliminary clinical activity of DSP-5336 monotherapy in patients with AML, ALL, or acute leukemia of ambiguous lineage Phase 2: To further assess the safety and tolerability of DSP-5336

Phase 1: To determine the cardiac safety of DSP-5336 administered as a single agent by 12-lead safety and intensive ECG monitoring, and in the presence of azoles by 12-lead safety ECG monitoring

Secondary Endpoints

Phase 1: Plasma DSP-5336 concentration-time profiles, plasma PK parameters of DSP-5336 (ie, AUC, Cmax, tmax, t1/2, and other parameters, as data allow) Phase 2: CR; CRi; PR; MLFS defined by ELN 2017. CRc (CR or CRh or CRi); ORR (= CR or CRi or MLFS); time to CR/CRh; time to ORR; duration of CR/CRh, duration of ORR; TI; OS; EFS

Phase 1: For acute leukemias: Response according to ELN 2017 criteria and criteria for CRh defined by the FDA

guidance: CR; CRh; CRi; PR; MLFS; CR+ CRh; ; CRc (CR or CRh or Cri); ORR (=CR or CRi or MLFS); time to CR/CRh; time to ORR; duration of CR/CRh, duration of ORR; TI; OS; EFS Phase2: TEAEs and SAEs Changes in vital signs, clinical laboratory values (hematology, clinical chemistry), ECG parameters, Dose modifications
Phase 1: QT interval changes and morphology, assessed in patients receiving DSP-5336 as a single agent or in the presence of azoles QT interval correction will be performed using Fridericias formula (QTcF) from triplicate ECGs

Temporary moments of secondary assessment

Not provided

Inclusion criteria

For patients in Phase 1: Have a confirmed diagnosis of refractory or relapsed AML, ALL, or acute leukemia of ambiguous lineage and whose disease has progressed after available standard therapies known to be active for their AML, ALL, or acute leukemia of ambiguous lineage. Participants must have a documented KMT2A (MLL) fusion or NPM1 mutation including those with coexisting FLT3 genomic alterations and/or IDH1/2 mutation. Participants who are candidates for stem cell transplantation must have been offered this therapeutic option

For all patients: Have an estimated life expectancy 3 months, based on the investigators assessment For all patients: Females of childbearing potential must have a negative serum or urine pregnancy test.

For all patients: Must agree to use one highly effective contraception method or 2 acceptable methods of birth control (each partner to use one method) or use prevention of pregnancy measures (ie, sexual abstinence, when this is the usual and preferred lifestyle of the patient) during the study and for 6 months (for females and males alike) after the last dose of study drug, if the male or female patient is of child-producing potential

For all patients: Have bone marrow material suitable for genomic analysis (eg, MLLr or NPM1 mutations) of AML or ALL genetic alterations. Note: if a bone marrow material is insufficient, an alternative suitable tissue (eg, peripheral blood) must be provided.

For patients in Phase 2: Have a confirmed diagnosis of refractory or relapsed AML or ALL according to WHO 2022 classification, as determined by pathology review at the treating institution, and who have 5% blasts by morphologic assessment in the bone marrow. Patients must have received clinically applicable standard therapies with confirmed survival benefit. Patients must not have had prior exposure to a menin inhibitor

For patients in Phase 2: Have a documented KMT2A (MLL)-fusion or NPM1 mutation assessed at relapse or immediately prior to the determination of refractory status

For all patients: Be 18 years of age

For all patients: Have an Eastern Cooperative Oncology Group (ECOG) performance status 2.

For all patients: For DSP-5336 monotherapy, white blood cell (WBC) count must be below 30,000/L at the time of enrollment and prior to starting study treatment. (Hydroxyurea and steroid for cyto reduction purpose will be allowed prior to enrollment and during study treatment).

For all patients: Any prior treatment-related toxicities resolved to Grade 1 prior to enrollment, with the exception of Grade 2 alopecia or neuropathy For all patients: Have adequate renal and hepatic function at Screening as determined by: a. Clearance of creatinine (CLcr) level 50 ml/min, assessed by the Cockcroft-Gault formula b. Total bilirubin 1.5 times the upper limit of normal (ULN) (or 2.0 times ULN for patients with known Gilberts syndrome) c. Aspartate aminotransferase (AST) 3.0 times ULN d. Alanine aminotransferase (ALT) 3.0 times ULN

For all patients: Be willing to attend study visits as required by the protocol

Exclusion criteria

Have a histologic diagnosis of acute promyelocytic leukemia Have a cognitive, psychologic, or psychosocial impediment that would impair the ability of the patient to receive therapy according to the protocol, or adversely affect the ability of the patient to comply with the informed consent/assent process, protocol, or protocol-required visits and

procedures Have a history of Grade 2 drug-induced interstitial lung disease or Grade 2 non-infectious pneumonitis within 6 months of starting study treatment. Underwent HSCT or chimeric antigen receptor cell (CAR-T) therapy or other modified T-cell therapy within 60 days prior to the first dose of DSP-5336. Receive concurrent sensitive substrates with a narrow safety window or strong inhibitors or inducers of CYP3A4/5. Other antifungals that are used as standard of care to prevent or treat infections are permitted Note: If a patient is on one of the excluded azole class antifungals and can be switched to a permitted azole 7 or more days prior to study, that patient could be allowed on study (Arm B). Have a known detectable viral load for human immunodeficiency virus or hepatitis C, or evidence of a hepatitis B surface antigen, all being indicative of active infection. In the opinion of the treating investigator, have any concurrent conditions that could pose an undue medical hazard or interfere with interpretation of study results; these conditions include, but are not limited to: clinically significant non-healing or healing wounds; concurrent congestive heart failure (New York Heart Association Functional Classification Class III or IV; see Section 21.7); concurrent unstable angina; concurrent cardiac arrhythmia requiring treatment (excluding asymptomatic atrial fibrillation); recent (within the prior 6 months) myocardial infarction; acute coronary syndrome within the previous 6 months; significant pulmonary disease (shortness of breath at rest or on mild exertion), eg, due to concurrent severe obstructive pulmonary disease, concurrent hypertension not controlled with concomitant medication, or diabetes mellitus with more than 2 episodes of ketoacidosis in the prior 6 months. Have a history of Torsades de Pointes Have abnormal ECGs at screening that are clinically significant, such as QTc >480 with QTc corrected according to Fridericia's formula [QTcF]). Are pregnant or breastfeeding or planning to become pregnant Note: Patients who are breastfeeding may be enrolled if they interrupt breastfeeding prior to the first dose of any study drugs and do not feed the baby with breast milk expressed after receiving the first dose of any study drugs. Breastfeeding should not be resumed for at least 6 months after the last dose of study drug. . Underwent HSCT or chimeric antigen receptor cell (CAR-T) therapy or other modified T-cell therapy within 60 days prior to the first dose of DSP-5336 Underwent HSCT or chimeric antigen receptor cell (CAR-T) therapy or other modified T-cell therapy within 60 days prior to the first dose of DSP-5336. Received a donor lymphocyte infusion within 28 days prior to the first dose of DSP 5336, or receiving immunosuppressive therapy post-HSCT at the time of Screening, or with clinically active GVHD or GVHD requiring active medical intervention other than the use of topical steroids for ongoing cutaneous GVHD. Received antineoplastic agents (except hormonal therapies as adjuvant maintenance for breast or prostate cancers if a patient is taking before starting study treatment, and hydroxyurea given for controlling blast cells) or other investigational treatment within 14 days or 5 half-lives, whichever is shortest, prior to the first dose of DSP-5336 Received systemic calcineurin inhibitors within 2 weeks prior to the first dose of DSP 5336 Had major surgery within 28 days prior to the first dose of DSP-5336 Have active central nervous system leukemia (prophylactic intrathecal chemotherapy is allowed). Have any history or complication of interstitial lung disease (for sites in Japan only) and, for clinical sites operating under the European Medicines Agencies, a history of Grade 2 drug-induced interstitial lung disease or Grade 2 non-infectious pneumonitis within 6 months of starting study treatment Have a known intolerance or hypersensitivity reaction to components of any of the investigational medicinal products Have a left ventricular ejection fraction (LVEF) <50%, as determined by ECHO Received antineoplastic agents (except hormonal therapies as adjuvant maintenance for breast or prostate cancers if a patient is taking before starting study treatment, and hydroxyurea given for controlling blast cells) or other investigational treatment within 14 days or 5 half-lives, whichever is shortest, prior to the first dose of DSP-5336 . Received systemic calcineurin inhibitors within 42 weeks prior to the first dose of DSP 5336. Have an active and uncontrolled, bacterial, viral, or fungal infection requiring parenteral therapy Have known severe dysphagia, short-gut syndrome, gastroparesis, or other conditions that limit the ingestion or gastrointestinal absorption of drugs administered orally, including the inability to swallow oral medication

Calendar

(Last Update: 21/01/2026)

Authorization 01/09/2023	Start of Trial 26/01/2024	First patient inclusion 13/02/2024	Halted Not aported	Restarted Not aported
End of recruitment Not aported	Premature end (Spain) Not aported	Premature End (Global) Not aported	Trial end (Spain) Not aported	Trial end (Global) Not aported

Sponsor

Sumitomo Pharma America Inc. United States

84 Waterford Drive

Contact Person

Clinical Development

+15084816700

DL-clinicaltrials@us.sumitomo-pharma.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm del Hospital Universitario y Politécnico la Fe

Avda de Fernando Abril Martorell, n.106, Hospital U. i P. La Fe, Torre A, Planta 7, despacho 7.12, 46026 Valencia

ceic@iislafe.es

961246605

Sites

Active (31/10/2025)	Complejo Hospitalario Universitario De Santiago Santiago De Compostela CORUÑA ES052A: Hematolog&iacute;a
Active (26/01/2024)	Hospital General Universitario De Albacete Albacete ALBACETE Hematolog&iacute;a
Active (23/01/2024)	Hospital San Pedro De Alcantara Caceres CÁCERES Hematolog&iacute;a
Active (20/08/2024)	Hospital Universitari Vall D Hebron Barcelona BARCELONA Hematologia
Active (11/03/2024)	Hospital Universitario Central De Asturias Oviedo ASTURIAS Hematolog&iacute;a
Active (04/03/2024)	Hospital Universitario De Gran Canaria Dr. Negrin Las Palmas De Gran Canaria LAS PALMAS Hematolog&iacute;a
Active (27/02/2024)	Hospital Universitario De Salamanca Salamanca SALAMANCA Hematolog&iacute;a
Active (12/08/2025)	Hospital Universitario Marques De Valdecilla Santander CANTABRIA ES053A: Hematolog&iacute;a

Active (18/01/2024)

Hospital Universitario Y Politecnico La Fe

Valencia

VALENCIA

Hematología

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

Institut Catala D'oncologia

Badalona

BARCELONA

ES001A: Hematología

Active (10/03/2024)

Institut Catala D'oncologia

Badalona

BARCELONA

Hematología

Active (11/03/2024)

MD Anderson Cancer Center

Madrid

MADRID

Oncología

Medication

Enzomenib

TABLET

ORAL

Active Principles: N/A

Experimental

Enzomenib

TABLET

ORAL

Active Principles: N/A

Experimental

No results