A Phase 1b Open-Label Study to Evaluate the Safety and Tolerability of Eganelisib as Monotherapy and in Combination with Cytarabine in Patients with Relapsed/Refractory Acute Myeloid Leukemia

Estado	Tipo de Participantes	Rangos de Edad
Reclutando	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase I , Fase II	97
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia, farmacocinética, farmacodinamica, dosis	NO

Información

Identificador
2024-518071-58-00 (CTIS)

Cod. Protocolo
STLX-EGA-001

Área terapéutica
Enfermedades [C] - Hematología [C15]|

Enfermedad investigada
Relapsed/refractory (r/r) acute myeloid leukemia (AML) or r/r higher-risk myelodysplastic syndromes (HR-MDS)

Título Científico
A Phase 1b Open-Label Study to Evaluate the Safety and Tolerability of Eganelisib as Monotherapy and in Combination with Cytarabine in Patients with Relapsed/Refractory Acute Myeloid Leukemia

Justificación

No aportado

Objetivo Principal

Part 1 Monotherapy and Combination Dose Escalation (DE): Assess the safety and tolerability of eganelisib administered as monotherapy and in combination with cytarabine
Determine the recommended dose for expansion (RDE) of eganelisib as monotherapy and in combination with cytarabine
Part 2 Dose Optimization (OPT):
Evaluate preliminary clinical activity of eganelisib administered as monotherapy and in combination with cytarabine

Variables de Evaluación Primaria

Part 1 Monotherapy and Combination Dose Escalation (DE): Incidence and severity of adverse events (AEs), graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE), Version 5.0
Part 1 Monotherapy and Combination Dose Escalation (DE): Incidence and severity of dose-limiting toxicities (DLTs) in DLT-evaluable patients during Cycle 1
Part 2 Dose Optimization (OPT): AML: per ELN 2022 criteria CR rate
Part 2 Dose Optimization (OPT): HR-MDS: per IWG 2023 criteria CR rate, defined as CR + CR equivalent

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

Part 1 Monotherapy and Combination Dose Escalation (DE): Evaluate the preliminary clinical activity of eganelisib administered as monotherapy and in combination with cytarabine
Part 1 Monotherapy and Combination Dose Escalation (DE): Characterize the plasma pharmacokinetics (PK) of eganelisib administered as monotherapy and in combination with cytarabine
Part 1 - Combination DE ONLY: Characterize the plasma PK of cytarabine in combination with eganelisib
Part 2 Dose Optimization (OPT): Assess the safety and tolerability of eganelisib administered as monotherapy and in combination with cytarabine
Part 2 Dose Optimization (OPT): Determine the recommended Phase 2 dose (RP2D) of eganelisib administered as monotherapy and in combination with cytarabine
Part 2-Dose Optimization (OPT): Evaluate further the preliminary clinical activity of eganelisib administered as monotherapy and in combination with cytarabine
Part 2 Dose Optimization (OPT): Measure plasma concentrations of eganelisib and determine model-based PK parameters

Variables de Evaluación Secundaria

Part 1 Monotherapy and Combination Dose Escalation (DE): AML: per European LeukemiaNet (ELN) 2022 criteria (Dohner et al., 2022); Complete response [CR] rate; Composite CR (CR + CRh); Composite CRMRD- (CRMRD- + CRhMRD-); ORR (CR + CRi + CRh + partial response [PR] + morphologic leukemia-free status [MLFS]); Duration of response; Time to CR, time to composite CRs; Transfusion-independence (TI); Duration of TI
Part 1 Monotherapy and Combination Dose Escalation (DE): HR-MDS: per International Working Group (IWG) 2023 criteria (Zeidan et al., 2023); CR rate, defined as CR + CR equivalent; ORR (CR + CR equivalent + CRh + CRL + PR + hematologic improvement [HI]); Duration of response; Time to CR; TI; Duration of TI
Part 1 Monotherapy and Combination Dose Escalation (DE): Both AML and HR-MDS: Frequency of transition to allogeneic hematopoietic stem cell transplant (HSCT); Early death rate; Event-free survival (EFS); Overall survival (OS)
Part 1 Monotherapy and Combination Dose Escalation (DE): Noncompartmental PK parameters of eganelisib (eg, area-under-the-curve [AUC0-24h, AUC0-], maximum concentration [Cmax], time of Cmax [Tmax], half-life [t1/2])
Part 1 Combination Dose Escalation (DE): Noncompartmental PK parameters of cytarabine (eg, Cmax, Tmax, AUC, possibly t1/2, volume of distribution [Vd], and clearance [CL])
Part 2 Dose Optimization (OPT): Incidence and severity of AEs, graded according to the NCI CTCAE, Version 5.0
Part 2 Dose Optimization (OPT): AML: per ELN 2022 criteria: Composite CR (CR + CRh); Composite CRMRD- (CRMRD- + CRhMRD-); ORR (CR + CRi + CRh + PR + MLFS); Duration of response; Time to CR: time to composite CRs; TI; Duration of TI
Part 2 Dose Optimization (OPT): HR-MDS: per IWG 2023 criteria: ORR (CR + CR equivalent + CRh + CRL + PR + HI); Duration of response; Time to CR; TI; Duration of TI
Part 2 Dose Optimization (OPT): Both AML and HR-MDS; Frequency of transition to allogeneic HSCT; Early death rate; EFS; OS
Part 2 Dose Optimization (OPT): Plasma concentrations and population pharmacokinetic (PopPK) assessment of possible covariates of exposure, safety, and efficacy

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Provision of written informed consent.
Male patients and female patients/women of childbearing potential (WCBP) must agree to use an effective method of contraception per institutional standard for the study duration and for 30 days after the last dose of eganelisib and 6 months after the last dose of cytarabine.
WCBP must have a negative serum beta human chorionic gonadotropin (HCG) test measured within 7 days prior to the first dose of eganelisib and consent to ongoing pregnancy testing during the study.
Willingness to practice adequate sun protection (use of sunscreen or sun-protective clothing, limitation of sun and artificial ultraviolet [UV] exposure) for the study duration and for 30 days after the last dose of eganelisib.
Pathological diagnosis of either - AML according to WHO 2022 revised criteria (Khoury et al., 2022) per the local pathology report and with 10% bone marrow blasts. Acute promyelocytic leukemia is excluded but secondary AML (including treated secondary AML, i.e., treatment included a hypomethylating agent [HMA] based therapy for MDS but transformed into AML) and treatment-related AML can be included. - Higher-risk (IPSS-R Intermediate, High or Very High Risk at time of study entry) myelodysplastic syndromes (HR-MDS) according to WHO 2022 revised criteria per the local pathology report and with 10% bone marrow blasts.
Relapsed/refractory disease. Patients must not be eligible for, or must have exhausted, other therapies known to be effective for treatment of their disease. - Hydroxyurea administered for white blood cell (WBC)/blast control will not be considered a prior line of therapy. - Treatments with erythroid-stimulating agents (eg, EPO, luspatercept, lenalidomide) will not be considered a prior line of therapy.
Male or female patients age 18 years.
Eastern Cooperative Oncology Group performance status (ECOG PS) 2.

Adequate hepatic function measured within 7 days prior to the first dose of eganelisib: - Total serum bilirubin 1.5 × institutional upper limit of normal (ULN) or 3 × ULN in case of Gilberts disease. -AST and ALT 2.5 × ULN.
Adequate renal function measured within 7 days prior to the first dose of eganelisib: Measured or calculated creatinine clearance (CrCl) 30 mL/min (calculation by Cockcroft-Gault formula).
Acceptable coagulation profile, measured within 7 days prior to the first dose of eganelisib: - Prothrombin time (PT) or International Normalized Ratio (INR) 1.5 × ULN. - Activated partial thromboplastin time (aPTT) 1.5 × ULN.
Willing and able to comply with scheduled visits, treatment plan, laboratory tests, and other study procedures, including to undergo a pre-treatment and subsequent on treatment bone marrow examinations.

Criterios de Exclusión

Any of the following within the specified time frame: -Prior systemic cancer therapy is allowed regardless of the stop date, but the patient must have recovered to eligibility levels from prior toxicity. --> Hydroxyurea is allowed for patients with rapidly proliferative disease for peripheral blast control, up to Cycle 1 Day 7. - Major surgery within 28 days prior to Cycle 1 Day 1. - Autologous or allogeneic stem cell transplant within 6 months prior to Cycle 1 Day 1. - Receiving immunosuppressants (eg, cyclosporin or calcineurin inhibitors) or systemic steroids (except for steroid use as cortisol replacement therapy in documented adrenal insufficiency or low-dose steroids with a maximum of an equivalent of 10 mg prednisone/day) within 28 days prior to Cycle 1 Day 1. - Active fungal disease or uncontrolled infection of any kind; patients receiving antibiotic, antifungal or antiviral treatment must be afebrile and hemodynamically stable for >72 hours prior to treatment. - Active graft-versus-host disease (GVHD) after allogeneic stem cell transplantation, or chronic GVHD requiring systemic steroid administration. - Current use (including within 5 half-lives) of an investigational agent. History or current evidence of any acute or chronic condition, therapy, or laboratory abnormality that may increase the risk associated with study participation or study drug administration, or might confound the results of the trial, interfere with participation for the full duration of the trial, or render trial participation not compatible with the patients best interest, in the opinion of the Investigator. Administration of any of the following within 14 days prior to the first dose of eganelisib and for the study duration: - Moderate or strong inhibitors or inducers of CYP2C8 and CYP3A4, including grapefruit, grapefruit juice, Seville oranges, St. Johns wort and herbal supplements, except for antibiotics, antifungals, or antivirals that are moderate or strong inhibitors of CYP3A if they cannot be avoided. - P-glycoprotein (P-gp) inhibitors, except for antibiotics, antifungals, or antivirals if they cannot be avoided. - Breast cancer resistance protein (BCRP) inhibitors. Administration of any of the following as of Cycle 1 Day 1 and for the study duration: - P-gp substrates with a narrow therapeutic index. - Warfarin, phenytoin, or other CYP2C8 or CYP2C9 substrates with a narrow therapeutic index. Corrected QT with Fridericias method (QTcF) interval on screening electrocardiogram (ECG) 450 msec for males and 470 msec for females, except for patients with atrioventricular pacemakers or other conditions (eg, right bundle branch block) that render the QT measurement invalid. WBC count >25 × 10^9/L measured within 7 days prior to the first dose of eganelisib (hydroxyurea is permitted to decrease the WBC count). Presence of a clinically significant non-hematologic toxicity of prior therapy that has not resolved to Grade 1 or Baseline, whichever is worst, as determined by NCI CTCAE, except alopecia or skin pigmentation. Fatigue and neuropathy must have resolved to Grade 2. History of another primary malignancy that is currently clinically significant or currently requires active intervention. Known hypersensitivity to any excipient in the study drugs. Pregnant or lactating female. Known central nervous system (CNS) leukemia. Known isolated extramedullary disease. Significant gastrointestinal abnormalities, including requirement for IV alimentation, active peptic ulcer, chronic diarrhea or vomiting considered to be clinically significant in the judgment of the Investigator, or malabsorption syndrome or prior surgical procedures affecting drug absorption (eg, gastric bypass surgery, gastrectomy).

Calendario

(Última actualización: 02/12/2025)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
11/04/2025	16/05/2025	25/06/2025	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

Stelexis Biosciences Inc. United States

345 Park Avenue South Floor 12th

Contact Person

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Monetary support: N/A

Tipo de promotor: Comercial

Ceim

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Centros

Activo (16/05/2025)

Hospital San Pedro De Alcantara

Caceres

CÁCERES

Hematology

Activo (18/06/2025)

Hospital Universitario Y Politecnico La Fe

Valencia

VALENCIA

Hematology

Medicamentos

Eganelisib 30mg Capsules
CAPSULE
ORAL USE

-

Principios Activos: N/A

Experimental

Eganelisib 5mg Capsules
CAPSULE
ORAL USE

-

Principios Activos: N/A

Experimental

Cytarabine 20 mg/ml Injection
SOLUTION FOR INJECTION
INTRAVENOUS INFUSION

Código ATC: L01BC01 - CITARABINA
Principios Activos: N/A

Experimental

Sin resultados

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State	Type of participants	Age Ranges
Recruiting	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase I , Phase II	97
Results	**Low level of intervention**	**Rare disease**
No results	No	Yes
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness, pharmacokinetics, pharmacodynamics, dose	NO

Information

Identifier
2024-518071-58-00 (CTIS)

Protocol Code
STLX-EGA-001

Therapeutic area
Diseases [C] - Hemic and Lymphatic Diseases [C15]|

Investigated Disease
Relapsed/refractory (r/r) acute myeloid leukemia (AML) or r/r higher-risk myelodysplastic syndromes (HR-MDS)

Scientific Title
A Phase 1b Open-Label Study to Evaluate the Safety and Tolerability of Eganelisib as Monotherapy and in Combination with Cytarabine in Patients with Relapsed/Refractory Acute Myeloid Leukemia

Rationale

Not provided

Main Objective

Part 1 Monotherapy and Combination Dose Escalation (DE): Assess the safety and tolerability of eganelisib administered as monotherapy and in combination with cytarabine
Determine the recommended dose for expansion (RDE) of eganelisib as monotherapy and in combination with cytarabine
Part 2 Dose Optimization (OPT):
Evaluate preliminary clinical activity of eganelisib administered as monotherapy and in combination with cytarabine

Primary Endpoints

Part 1 Monotherapy and Combination Dose Escalation (DE): Incidence and severity of adverse events (AEs), graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE), Version 5.0
Part 1 Monotherapy and Combination Dose Escalation (DE): Incidence and severity of dose-limiting toxicities (DLTs) in DLT-evaluable patients during Cycle 1
Part 2 Dose Optimization (OPT): AML: per ELN 2022 criteria CR rate
Part 2 Dose Optimization (OPT): HR-MDS: per IWG 2023 criteria CR rate, defined as CR + CR equivalent

Temporary moments of secondary assessment

Not provided

Secondary Objective

Part 1 Monotherapy and Combination Dose Escalation (DE): Evaluate the preliminary clinical activity of eganelisib administered as monotherapy and in combination with cytarabine
Part 1 Monotherapy and Combination Dose Escalation (DE): Characterize the plasma pharmacokinetics (PK) of eganelisib administered as monotherapy and in combination with cytarabine
Part 1 - Combination DE ONLY: Characterize the plasma PK of cytarabine in combination with eganelisib
Part 2 Dose Optimization (OPT): Assess the safety and tolerability of eganelisib administered as monotherapy and in combination with cytarabine
Part 2 Dose Optimization (OPT): Determine the recommended Phase 2 dose (RP2D) of eganelisib administered as monotherapy and in combination with cytarabine
Part 2-Dose Optimization (OPT): Evaluate further the preliminary clinical activity of eganelisib administered as monotherapy and in combination with cytarabine
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Secondary Endpoints

Part 1 Monotherapy and Combination Dose Escalation (DE): AML: per European LeukemiaNet (ELN) 2022 criteria (Dohner et al., 2022); Complete response [CR] rate; Composite CR (CR + CRh); Composite CRMRD- (CRMRD- + CRhMRD-); ORR (CR + CRi + CRh + partial response [PR] + morphologic leukemia-free status [MLFS]); Duration of response; Time to CR, time to composite CRs; Transfusion-independence (TI); Duration of TI
Part 1 Monotherapy and Combination Dose Escalation (DE): HR-MDS: per International Working Group (IWG) 2023 criteria (Zeidan et al., 2023); CR rate, defined as CR + CR equivalent; ORR (CR + CR equivalent + CRh + CRL + PR + hematologic improvement [HI]); Duration of response; Time to CR; TI; Duration of TI
Part 1 Monotherapy and Combination Dose Escalation (DE): Both AML and HR-MDS: Frequency of transition to allogeneic hematopoietic stem cell transplant (HSCT); Early death rate; Event-free survival (EFS); Overall survival (OS)
Part 1 Monotherapy and Combination Dose Escalation (DE): Noncompartmental PK parameters of eganelisib (eg, area-under-the-curve [AUC0-24h, AUC0-], maximum concentration [Cmax], time of Cmax [Tmax], half-life [t1/2])
Part 1 Combination Dose Escalation (DE): Noncompartmental PK parameters of cytarabine (eg, Cmax, Tmax, AUC, possibly t1/2, volume of distribution [Vd], and clearance [CL])
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Part 2 Dose Optimization (OPT): Plasma concentrations and population pharmacokinetic (PopPK) assessment of possible covariates of exposure, safety, and efficacy

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Provision of written informed consent.
Male patients and female patients/women of childbearing potential (WCBP) must agree to use an effective method of contraception per institutional standard for the study duration and for 30 days after the last dose of eganelisib and 6 months after the last dose of cytarabine.
WCBP must have a negative serum beta human chorionic gonadotropin (HCG) test measured within 7 days prior to the first dose of eganelisib and consent to ongoing pregnancy testing during the study.
Willingness to practice adequate sun protection (use of sunscreen or sun-protective clothing, limitation of sun and artificial ultraviolet [UV] exposure) for the study duration and for 30 days after the last dose of eganelisib.
Pathological diagnosis of either - AML according to WHO 2022 revised criteria (Khoury et al., 2022) per the local pathology report and with 10% bone marrow blasts. Acute promyelocytic leukemia is excluded but secondary AML (including treated secondary AML, i.e., treatment included a hypomethylating agent [HMA] based therapy for MDS but transformed into AML) and treatment-related AML can be included. - Higher-risk (IPSS-R Intermediate, High or Very High Risk at time of study entry) myelodysplastic syndromes (HR-MDS) according to WHO 2022 revised criteria per the local pathology report and with 10% bone marrow blasts.
Relapsed/refractory disease. Patients must not be eligible for, or must have exhausted, other therapies known to be effective for treatment of their disease. - Hydroxyurea administered for white blood cell (WBC)/blast control will not be considered a prior line of therapy. - Treatments with erythroid-stimulating agents (eg, EPO, luspatercept, lenalidomide) will not be considered a prior line of therapy.
Male or female patients age 18 years.
Eastern Cooperative Oncology Group performance status (ECOG PS) 2.

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Adequate renal function measured within 7 days prior to the first dose of eganelisib: Measured or calculated creatinine clearance (CrCl) 30 mL/min (calculation by Cockcroft-Gault formula).
Acceptable coagulation profile, measured within 7 days prior to the first dose of eganelisib: - Prothrombin time (PT) or International Normalized Ratio (INR) 1.5 × ULN. - Activated partial thromboplastin time (aPTT) 1.5 × ULN.
Willing and able to comply with scheduled visits, treatment plan, laboratory tests, and other study procedures, including to undergo a pre-treatment and subsequent on treatment bone marrow examinations.

Exclusion criteria

Any of the following within the specified time frame: -Prior systemic cancer therapy is allowed regardless of the stop date, but the patient must have recovered to eligibility levels from prior toxicity. --> Hydroxyurea is allowed for patients with rapidly proliferative disease for peripheral blast control, up to Cycle 1 Day 7. - Major surgery within 28 days prior to Cycle 1 Day 1. - Autologous or allogeneic stem cell transplant within 6 months prior to Cycle 1 Day 1. - Receiving immunosuppressants (eg, cyclosporin or calcineurin inhibitors) or systemic steroids (except for steroid use as cortisol replacement therapy in documented adrenal insufficiency or low-dose steroids with a maximum of an equivalent of 10 mg prednisone/day) within 28 days prior to Cycle 1 Day 1. - Active fungal disease or uncontrolled infection of any kind; patients receiving antibiotic, antifungal or antiviral treatment must be afebrile and hemodynamically stable for >72 hours prior to treatment. - Active graft-versus-host disease (GVHD) after allogeneic stem cell transplantation, or chronic GVHD requiring systemic steroid administration. - Current use (including within 5 half-lives) of an investigational agent. History or current evidence of any acute or chronic condition, therapy, or laboratory abnormality that may increase the risk associated with study participation or study drug administration, or might confound the results of the trial, interfere with participation for the full duration of the trial, or render trial participation not compatible with the patients best interest, in the opinion of the Investigator. Administration of any of the following within 14 days prior to the first dose of eganelisib and for the study duration: - Moderate or strong inhibitors or inducers of CYP2C8 and CYP3A4, including grapefruit, grapefruit juice, Seville oranges, St. Johns wort and herbal supplements, except for antibiotics, antifungals, or antivirals that are moderate or strong inhibitors of CYP3A if they cannot be avoided. - P-glycoprotein (P-gp) inhibitors, except for antibiotics, antifungals, or antivirals if they cannot be avoided. - Breast cancer resistance protein (BCRP) inhibitors. Administration of any of the following as of Cycle 1 Day 1 and for the study duration: - P-gp substrates with a narrow therapeutic index. - Warfarin, phenytoin, or other CYP2C8 or CYP2C9 substrates with a narrow therapeutic index. Corrected QT with Fridericias method (QTcF) interval on screening electrocardiogram (ECG) 450 msec for males and 470 msec for females, except for patients with atrioventricular pacemakers or other conditions (eg, right bundle branch block) that render the QT measurement invalid. WBC count >25 × 10^9/L measured within 7 days prior to the first dose of eganelisib (hydroxyurea is permitted to decrease the WBC count). Presence of a clinically significant non-hematologic toxicity of prior therapy that has not resolved to Grade 1 or Baseline, whichever is worst, as determined by NCI CTCAE, except alopecia or skin pigmentation. Fatigue and neuropathy must have resolved to Grade 2. History of another primary malignancy that is currently clinically significant or currently requires active intervention. Known hypersensitivity to any excipient in the study drugs. Pregnant or lactating female. Known central nervous system (CNS) leukemia. Known isolated extramedullary disease. Significant gastrointestinal abnormalities, including requirement for IV alimentation, active peptic ulcer, chronic diarrhea or vomiting considered to be clinically significant in the judgment of the Investigator, or malabsorption syndrome or prior surgical procedures affecting drug absorption (eg, gastric bypass surgery, gastrectomy).

Calendar

(Last Update: 02/12/2025)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
11/04/2025	16/05/2025	25/06/2025	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

Stelexis Biosciences Inc. United States

345 Park Avenue South Floor 12th

Contact Person

Eric Feldman

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efeldman@stelexis.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

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Sites

Active (16/05/2025)

Hospital San Pedro De Alcantara

Caceres

CÁCERES

Hematology

Active (18/06/2025)

Hospital Universitario Y Politecnico La Fe

Valencia

VALENCIA

Hematology

Medication

Eganelisib 30mg Capsules
CAPSULE
ORAL USE

-

Active Principles: N/A

Experimental

Eganelisib 5mg Capsules
CAPSULE
ORAL USE

-

Active Principles: N/A

Experimental

Cytarabine 20 mg/ml Injection
SOLUTION FOR INJECTION
INTRAVENOUS INFUSION

ATC code: L01BC01 - CITARABINA
Active Principles: N/A

Experimental

No results