

A PHASE 1/2 STUDY OF ALX148 IN COMBINATION WITH AZACITIDINE IN PATIENTS WITH HIGHER RISK MYELODYSPLASTIC SYNDROME (MDS) (ASPEN-02)

Estado
EC Finalizado

Tipo de Participantes
Sujetos incapaces de otorgar consentimiento

Rangos de Edad
Mayores de 64 , Adultos (18-64 años)

Género
Ambos

Fases
Fase I , Fase II

Participantes esperados
6

Resultados
Tiene resultados

Bajo nivel intervención
No

Enfermedad rara
Si

Cobertura geográfica
Multicéntrico nacional

Ámbitos del ensayo
tratamiento, seguridad, eficacia,
farmacocinética, farmacodinamica

Terapia avanzada
NO

Información

Identificador
2024-513993-23-00 (CTIS)

Cod. Protocolo
AT148002

Transicionado 2021-000705-25

Área terapéutica
Enfermedades [C] - Cáncer [C04]

Enfermedad investigada
Patients with higher risk myelodysplastic syndrome (MDS) who have not yet been treated for their disease

Título Científico
A PHASE 1/2 STUDY OF ALX148 IN COMBINATION WITH AZACITIDINE IN PATIENTS WITH HIGHER RISK MYELODYSPLASTIC SYNDROME (MDS) (ASPEN-02)

Justificación

No aportado

Objetivo Principal

Phase 1: To evaluate the safety and tolerability of ALX148 administered in combination with AZA in adult patients with relapsed/refractory MDS or previously untreated higher risk MDS as defined by IPSS-R score >3.5 ; To identify the RP2D of ALX148 in combination with AZA Phase 2: To assess the effect of ALX148 administered at the RP2D determined in Phase 1 in combination with AZA versus AZA alone on the investigator-assessed complete response rate (CRR) per modified IWG 2006 criteria in adult patients with previously-untreated higher risk MDS (IPSS-R score >3.5)

Variables de Evaluación Primaria

Phase 1, Dose escalation: First Cycle DLTs using CTCAE v5.0

Phase 1, Dose expansion: Adverse Events as characterized by type, frequency, severity (as graded by National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE v. 5.0), timing, seriousness, and relationship to study therapy

Phase 2 part of the study is complete response rate (CRR), assessed by investigator using modified IWG 2006 response criteria for MDS, defined as a best response of CR, with the final analysis to be performed after the last patient has completed 6 cycles of treatment or is considered evaluable for response.

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

Phase 1: Evaluate overall safety profile of ALX148 in combination with AZA; Phase 1: Characterize safety profile of MTD or RP2D of ALX148 in combination with AZA; Phase 1: Characterize single/multiple-dose pharmacokinetics (PK) of ALX148 in combination with AZA; Phase 1: Evaluate immunogenicity of ALX148; Phase 1: Document any evidence of antitumor activity; Phase 2: Assess the effect of ALX148 administered at the RP2D determined in Phase 1 in combination with AZA versus AZA alone on the complete response rate (CRR) per modified IWG 2006 criteria as determined by independent central review in adult patients with previously-untreated higher risk MDS (IPSS-R score >3.5); Phase 2: Assess secondary measures of efficacy for ALX148 administered in combination with AZA versus AZA alone; Phase 2: Assess the safety and tolerability of ALX148 administered in combination with AZA versus AZA alone;

Variables de Evaluación Secundaria

Incidence of marrow CR, objective response rate (ORR), hematologic improvement (HI) in erythrocytes (E), platelets (P), and neutrophils (N), red blood cell (RBC) and platelet (PLT) transfusion independence, frequency and level of measurable residual disease (MRD)

Duration of response (DOR), event-free survival (EFS), progression-free survival (PFS), overall survival (OS), time to progression (TTP).

Percentage of patients able to proceed to allogeneic hematopoietic stem cell transplant (allo-HSCT)

Changes in global health status/quality of life (GHS/QoL) status based on patient reported outcome (PRO) assessment (Phase 2 only)

Phase 1 dose escalation and Phase 2: Adverse Events as characterized by type, frequency, severity (as graded by National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE v. 5.0), timing, seriousness, and relationship to study therapy;

Laboratory abnormalities as characterized by type, frequency, severity (as graded by NCI CTCAE v. 5.0) and timing

Pharmacokinetic parameters of ALX148 such as Cmax, Tmax, AUC, CL, and t1/2 as data permit

Immunogenicity; Human serum ADA (anti-ALX148 antibody) samples will be analyzed for the presence or absence of anti-ALX148 antibodies

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Phase 1 dose escalation part: Adult patients with documented diagnosis of relapsed/refractory MDS or higher risk MDS (IPSS-R score >3.5) that is previously untreated. For patients with relapsed/refractory MDS, prior exposure to hypomethylating agents is allowed. Patients with previously untreated disease must have had no prior exposure to hypomethylating agents or cytotoxic chemotherapy (prior use of single agent lenalidomide for low or intermediate-1 risk MDS with deletion 5q abnormality is allowed) for the treatment of MDS and be appropriate candidates for single-agent AZA. Phase 1 dose expansion part and phase II: Adult patients with documented diagnosis of higher risk MDS (IPSS-R score >3.5) who have had no prior exposure to hypomethylating agents or cytotoxic chemotherapy (prior use of single agent lenalidomide for low or intermediate-1 risk MDS with deletion 5q abnormality is allowed) for the treatment of MDS, and are considered appropriate candidates for single-agent AZA. Serum pregnancy test (for females of childbearing potential) negative at screening. Male and female patients of childbearing potential must agree to use a highly effective method of contraception throughout the study and for at least 120 days after the last dose of assigned treatment. A patient is of childbearing potential if, in the opinion of the Investigator, he/she is biologically capable of having children and is sexually active. Evidence of a personally signed and dated informed consent document indicating that the patient (or legal representative) has been informed of all pertinent aspects of the study before any study-specific activity is performed. Patients who are willing and able to comply with scheduled visits, treatment plans, laboratory, tests and other procedures. Phase 1 dose expansion part and phase II: Bone marrow with $<20\%$ myeloblasts. Adequate Renal Function with estimated creatinine clearance $> \text{ or } =30$ mL/min as calculated using the method standard for the institution. Adequate Liver Function, including: a. Total serum bilirubin $< \text{ or } =1.5 \times \text{ULN}$ ($< \text{ or } =3.0 \times \text{ULN}$ if the patient has documented Gilbert syndrome); b. Aspartate and alanine transaminase (AST and ALT) $< \text{ or } =3.0 \times \text{ULN}$; $< \text{ or } =5.0 \times \text{ULN}$ if due to leukemic organ involvement; c. Alkaline phosphatase $< \text{ or } =2.5 \times \text{ULN}$; ($< \text{ or } =5.0 \times \text{ULN}$ if bone or liver metastasis). WBC $< 20,000/\text{microL}$. Administration of hydroxyurea for WBC control is permitted during the screening period up to and including treatment day -1 of the study (ie, one day prior to starting study treatment). QTcF interval of $< \text{ or } =480$ msec (Based upon mean value from triplicate ECGs). Age $> \text{ or } = 18$ years because MDS is extremely rare in the pediatric (<18 yrs) population. Eastern Cooperative Oncology Group (ECOG) Performance Status (PS) must be 0, 1 or 2. Resolved acute effects of any prior therapy to baseline severity or Grade $< \text{ or } =1$ NCI CTCAE v.5.0 except for AEs not constituting a safety risk by Investigator judgment.

Criterios de Exclusión

Patients with a history of autoimmune hemolytic anemia, autoimmune thrombocytopenia, or hemolytic transfusion reaction secondary to an acquired allo-antibody

Prior treatment with myeloid growth factors and erythropoiesis stimulating agents (ESAs) must be discontinued a minimum of 4-5 half-lives prior to initiation of study treatment.

Patients with intolerance to or who have had a severe allergic or anaphylactic reaction to antibodies or infused therapeutic proteins or patients who have had a severe allergic or anaphylactic reaction to any of the substances included in the study drug (including excipients).

Any experimental antibodies or live vaccines in the last 28 days prior to the first dose of study drug. Examples of live vaccines include, but are not limited to, the following: measles, mumps, rubella, varicella/zoster, yellow fever, rabies, Bacillus CalmetteGuérin (BCG), and typhoid vaccine. Seasonal influenza vaccines for injection are generally killed virus vaccines and are allowed; however, intranasal influenza vaccines (e.g., FluMist) are live attenuated vaccines and are not allowed.

Known active viral infections, including hepatitis B (HBV), hepatitis C (HCV), human immunodeficiency virus (HIV), acquired immunodeficiency syndrome (AIDS) related illness, or known active infection with SARS-CoV-2 (testing to be performed per local criteria).

Other severe acute or chronic medical or psychiatric condition, including uncontrolled systemic infection, recent (within the past year) or active suicidal ideation or behavior, or laboratory abnormality that may increase the risk associated with study participation or investigational product administration or may interfere with the interpretation of study results and, in the judgment of the Investigator, would make the patient inappropriate for entry into this study. Please refer to section 4.2 of the protocol for exclusion criteria 15 and 16.

Any of the following in the previous 6 months: myocardial infarction, severe/unstable angina, coronary/peripheral artery bypass graft, NYHA Class II or greater congestive heart failure, uncontrolled hypertension, cerebrovascular accident, transient ischemic attack, deep venous thrombosis (except for thrombi considered device-associated and not clinically significant), arterial thrombosis, symptomatic pulmonary embolism, or any other significant thromboembolism. Any major surgery, within 28 days prior to enrollment.

Current active treatment in another interventional therapeutic clinical study.

Prior malignancy, except for adequately treated basal cell or squamous cell skin cancer, in situ cervical cancer, prostate/breast/other cancer under control with hormone therapy alone, or other cancer from which the subject has been disease free for at least 2 years and felt to be at low risk for recurrence by the treating physician.

Has an active autoimmune disease that has required systemic treatment in past 2 years (i.e., with use of disease modifying agents, corticosteroids or immunosuppressive drugs). Replacement therapy (e.g., thyroxine, insulin, or physiologic corticosteroid replacement therapy for adrenal or pituitary insufficiency) is not considered a form of systemic treatment and is allowed.

Previous allogeneic hematopoietic stem cell transplant (allo-HSCT) for MDS or AML. If allo-HSCT was performed for another disease, patient must be at least a year post-HSCT, off all treatment for graft-versus-host disease (GVHD), and without any active GVHD.

Prior treatment with any anti-CD47 or anti-SIRPalpha agent.

Phase 1 dose escalation only: prior cytotoxic chemotherapy, CAR-T, or other cellular or experimental therapy within 4 weeks of starting study treatment. If any of these therapies (except hydroxyurea up to day -1 of study) was given within 4 weeks, patient may be included if at least 4 times the elimination half-life of the drug has passed Phase 1 dose expansion part and Phase 2: Prior treatment with any hypomethylating agents or cytotoxic chemotherapy for MDS (except hydroxyurea up to day -1 of study and lenalidomide for low or intermediate-1 risk MDS with deletion 5q abnormality).

Phase 1 dose expansion part and Phase 2: Patients with MPN/MDS overlap syndromes, including CMML.

Calendario

(Última actualización: 17/06/2025)

Autorización 11/08/2021	Inicio de Ensayo 27/09/2022	Inclusión Primer Paciente 06/10/2022	Interrumpido No aportado	Reiniciado No aportado
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Fin de reclutamiento 15/08/2023	Fin prematuro (España) No aportado	Fin prematuro (Global) No aportado	Fin del ensayo en España No aportado	Fin del ensayo global 11/06/2025
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Promotor

Alx Oncology Holdings Inc. United States
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Contact Person

Sr. VP of Clinical Development
16504667125
info@alxoncology.com

Monetary support: N/A
Tipo de promotor: Comercial

Ceim

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934978956

Centros

Activo (07/10/2022)	HOSPITAL CLINICO UNIVERSITARIO DE SALAMANCA (COMPLEJO ASISTENCIAL UNIV.SA) Salamanca SALAMANCA Hematología
No iniciado (11/08/2021)	HOSPITAL DE LA SANTA CREU I SANT PAU Barcelona BARCELONA Hematología
Activo (21/09/2021)	HOSPITAL GENERAL UNIVERSITARIO DE ALICANTE Alicante/Alacant ALICANTE Hematología
Activo (04/10/2022)	HOSPITAL SAN PEDRO DE ALCANTARA Cáceres CÁCERES Hematología
No iniciado (11/08/2021)	HOSPITAL UNIVERSITARI VALL D'HEBRON Barcelona BARCELONA Hematología
Activo (17/10/2022)	HOSPITAL UNIVERSITARIO Y POLITECNICO LA FE València VALENCIA Hematología
No iniciado (11/08/2021)	HOSPITAL UNIVERSITARIO 12 DE OCTUBRE Madrid MADRID Hematología
No iniciado (11/08/2021)	Institut Catala D'oncologia Badalona BARCELONA Hematología

Medicamentos

PRD8805872 INJECTION INTRAVENOUS USE - Principios Activos: N/A Experimental	- - INTRAVENOUS USE Código ATC: L01BC07 - AZACITIDINA Principios Activos: N/A Experimental
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Tiene resultados

A PHASE 1/2 STUDY OF ALX148 IN COMBINATION WITH AZACITIDINE IN PATIENTS WITH HIGHER RISK MYELOYDYSPLASTIC SYNDROME (MDS) (ASPEN-02)

State Finished CT	Type of participants Incapable subjects of giving consent	Age Ranges Older than 64 , Adults (18-64 years)
Gender Both	Phases Phase I , Phase II	Expected Participants 6
Results Has results	Low level of intervention No	Rare disease Yes
Geographic coverage National multicenter	Areas of the study treatment, safety, effectiveness, pharmacokinetics, pharmacodynamics	Advanced therapy NO

Information

Identifier

2024-513993-23-00 (CTIS)

Protocol Code

AT148002

Transitioned 2021-000705-25

Therapeutic area

Diseases [C] - Cancer [C04]

Investigated Disease

Patients with higher risk myelodysplastic syndrome (MDS) who have not yet been treated for their disease

Scientific Title

A PHASE 1/2 STUDY OF ALX148 IN COMBINATION WITH AZACITIDINE IN PATIENTS WITH HIGHER RISK MYELOYDYSPLASTIC SYNDROME (MDS) (ASPEN-02)

Rationale

Not provided

Main Objective

Phase 1: To evaluate the safety and tolerability of ALX148 administered in combination with AZA in adult patients with relapsed/refractory MDS or previously untreated higher risk MDS as defined by IPSS-R score >3.5 ; To identify the RP2D of ALX148 in combination with AZA Phase 2: To assess the effect of ALX148 administered at the RP2D determined in Phase 1 in combination with AZA versus AZA alone on the investigator-assessed complete response rate (CRR) per modified IWG 2006 criteria in adult patients with previously-untreated higher risk MDS (IPSS-R score >3.5)

Primary Endpoints

Phase 1, Dose escalation: First Cycle DLTs using CTCAE v5.0

Phase 1, Dose expansion: Adverse Events as characterized by type, frequency, severity (as graded by National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE v. 5.0), timing, seriousness, and relationship to study therapy

Phase 2 part of the study is complete response rate (CRR), assessed by investigator using modified IWG 2006 response criteria for MDS, defined as a best response of CR, with the final analysis to be performed after the last patient has completed 6 cycles of treatment or is considered evaluable for response.

Temporary moments of secondary assessment

Not provided

Secondary Objective

Phase 1: Evaluate overall safety profile of ALX148 in combination with AZA; Phase 1: Characterize safety profile of MTD or RP2D of ALX148 in combination with AZA; Phase 1: Characterize single/multiple-dose pharmacokinetics (PK) of ALX148 in combination with AZA; Phase 1: Evaluate immunogenicity of ALX148; Phase 1: Document any evidence of antitumor activity; Phase 2: Assess the effect of ALX148 administered at the RP2D determined in Phase 1 in combination with AZA versus AZA alone on the complete response rate (CRR) per modified IWG 2006 criteria as determined by independent central review in adult patients with previously-untreated higher risk MDS (IPSS-R score >3.5); Phase 2: Assess secondary measures of efficacy for ALX148 administered in combination with AZA versus AZA alone; Phase 2: Assess the safety and tolerability of ALX148 administered in combination with AZA versus AZA alone;

Secondary Endpoints

Incidence of marrow CR, objective response rate (ORR), hematologic improvement (HI) in erythrocytes (E), platelets (P), and neutrophils (N), red blood cell (RBC) and platelet (PLT) transfusion independence, frequency and level of measurable residual disease (MRD)

Duration of response (DOR), event-free survival (EFS), progression-free survival (PFS), overall survival (OS), time to progression (TTP).

Percentage of patients able to proceed to allogeneic hematopoietic stem cell transplant (allo-HSCT)

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Pharmacokinetic parameters of ALX148 such as Cmax, Tmax, AUC, CL, and t1/2 as data permit

Immunogenicity; Human serum ADA (anti-ALX148 antibody) samples will be analyzed for the presence or absence of anti-ALX148 antibodies

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Phase 1 dose escalation part: Adult patients with documented diagnosis of relapsed/refractory MDS or higher risk MDS (IPSS-R score >3.5) that is previously untreated. For patients with relapsed/refractory MDS, prior exposure to hypomethylating agents is allowed. Patients with previously untreated disease must have had no prior exposure to hypomethylating agents or cytotoxic chemotherapy (prior use of single agent lenalidomide for low or intermediate-1 risk MDS with deletion 5q abnormality is allowed) for the treatment of MDS and be appropriate candidates for single-agent AZA. Phase 1 dose expansion part and phase II: Adult patients with documented diagnosis of higher risk MDS (IPSS-R score >3.5) who have had no prior exposure to hypomethylating agents or cytotoxic chemotherapy (prior use of single agent lenalidomide for low or intermediate-1 risk MDS with deletion 5q abnormality is allowed) for the treatment of MDS, and are considered appropriate candidates for single-agent AZA. Serum pregnancy test (for females of childbearing potential) negative at screening. Male and female patients of childbearing potential must agree to use a highly effective method of contraception throughout the study and for at least 120 days after the last dose of assigned treatment. A patient is of childbearing potential if, in the opinion of the Investigator, he/she is biologically capable of having children and is sexually active. Evidence of a personally signed and dated informed consent document indicating that the patient (or legal representative) has been informed of all pertinent aspects of the study before any study-specific activity is performed. Patients who are willing and able to comply with scheduled visits, treatment plans, laboratory, tests and other procedures. Phase 1 dose expansion part and phase II: Bone marrow with $<20\%$ myeloblasts. Adequate Renal Function with estimated creatinine clearance $> \text{ or } =30$ mL/min as calculated using the method standard for the institution. Adequate Liver Function, including: a. Total serum bilirubin $< \text{ or } =1.5 \times \text{ULN}$ ($< \text{ or } =3.0 \times \text{ULN}$ if the patient has documented Gilbert syndrome); b. Aspartate and alanine transaminase (AST and ALT) $< \text{ or } =3.0 \times \text{ULN}$; $< \text{ or } =5.0 \times \text{ULN}$ if due to leukemic organ involvement; c. Alkaline phosphatase $< \text{ or } =2.5 \times \text{ULN}$; ($< \text{ or } =5.0 \times \text{ULN}$ if bone or liver metastasis). WBC $< 20,000/\text{microL}$. Administration of hydroxyurea for WBC control is permitted during the screening period up to and including treatment day -1 of the study (ie, one day prior to starting study treatment). QTcF interval of $< \text{ or } =480$ msec (Based upon mean value from triplicate ECGs). Age $> \text{ or } = 18$ years because MDS is extremely rare in the pediatric (<18 yrs) population. Eastern Cooperative Oncology Group (ECOG) Performance Status (PS) must be 0, 1 or 2. Resolved acute effects of any prior therapy to baseline severity or Grade $< \text{ or } =1$ NCI CTCAE v.5.0 except for AEs not constituting a safety risk by Investigator judgment.

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Any experimental antibodies or live vaccines in the last 28 days prior to the first dose of study drug. Examples of live vaccines include, but are not limited to, the following: measles, mumps, rubella, varicella/zoster, yellow fever, rabies, Bacillus CalmetteGuérin (BCG), and typhoid vaccine. Seasonal influenza vaccines for injection are generally killed virus vaccines and are allowed; however, intranasal influenza vaccines (e.g., FluMist) are live attenuated vaccines and are not allowed.

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Other severe acute or chronic medical or psychiatric condition, including uncontrolled systemic infection, recent (within the past year) or active suicidal ideation or behavior, or laboratory abnormality that may increase the risk associated with study participation or investigational product administration or may interfere with the interpretation of study results and, in the judgment of the Investigator, would make the patient inappropriate for entry into this study. Please refer to section 4.2 of the protocol for exclusion criteria 15 and 16.

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Has an active autoimmune disease that has required systemic treatment in past 2 years (i.e., with use of disease modifying agents, corticosteroids or immunosuppressive drugs). Replacement therapy (e.g., thyroxine, insulin, or physiologic corticosteroid replacement therapy for adrenal or pituitary insufficiency) is not considered a form of systemic treatment and is allowed.

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Prior treatment with any anti-CD47 or anti-SIRPalpha agent.

Phase 1 dose escalation only: prior cytotoxic chemotherapy, CAR-T, or other cellular or experimental therapy within 4 weeks of starting study treatment. If any of these therapies (except hydroxyurea up to day -1 of study) was given within 4 weeks, patient may be included if at least 4 times the elimination half-life of the drug has passed Phase 1 dose expansion part and Phase 2: Prior treatment with any hypomethylating agents or cytotoxic chemotherapy for MDS (except hydroxyurea up to day -1 of study and lenalidomide for low or intermediate-1 risk MDS with deletion 5q abnormality).

Phase 1 dose expansion part and Phase 2: Patients with MPN/MDS overlap syndromes, including CMML.

Calendar

(Last Update: 17/06/2025)

Authorization 11/08/2021	Start of Trial 27/09/2022	First patient inclusion 06/10/2022	Halted Not aported	Restarted Not aported
End of recruitment 15/08/2023	Premature end (Spain) Not aported	Premature End (Global) Not aported	Trial end (Spain) Not aported	Trial end (Global) 11/06/2025

Sponsor

Alx Oncology Holdings Inc. United States
323 Allerton Avenue

Contact Person

Sr. VP of Clinical Development
16504667125
info@alxoncology.com

Monetary support: N/A
Sponsor type: Commercial

Ceim

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Sites

Active (07/10/2022)	HOSPITAL CLINICO UNIVERSITARIO DE SALAMANCA (COMPLEJO ASISTENCIAL UNIV.SA) Salamanca SALAMANCA Hematología
not initialized (11/08/2021)	HOSPITAL DE LA SANTA CREU I SANT PAU Barcelona BARCELONA Hematología
Active (21/09/2021)	HOSPITAL GENERAL UNIVERSITARIO DE ALICANTE Alicante/Alacant ALICANTE Hematología
Active (04/10/2022)	HOSPITAL SAN PEDRO DE ALCANTARA Cáceres CÁCERES Hematología
not initialized (11/08/2021)	HOSPITAL UNIVERSITARI VALL D'HEBRON Barcelona BARCELONA Hematología
Active (17/10/2022)	HOSPITAL UNIVERSITARIO Y POLITECNICO LA FE València VALENCIA Hematología
not initialized (11/08/2021)	HOSPITAL UNIVERSITARIO 12 DE OCTUBRE Madrid MADRID Hematología
not initialized (11/08/2021)	Institut Catala D'oncologia Badalona BARCELONA Hematología

Medication

PRD8805872 INJECTION INTRAVENOUS USE - Active Principles: N/A Experimental	- - INTRAVENOUS USE ATC code: L01BC07 - AZACITIDINA Active Principles: N/A Experimental
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Has results