A multicentre clinical trial to assess the safety and tolerability of the combination of low-dose cytarabine or azacitidine, plus Venetoclax and Quizartinib in newly diagnosed acute myeloid leukemia patients aged equal or more than 60 years old ineligible for standard induction chemotherapy

Estado	**Tipo de Participantes**	**Rangos de Edad**
EC Finalizado	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase I , Fase II	84
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Multicéntrico nacional	seguridad, dosis	NO

Información

Identificador
2024-519275-26-00 (CTIS)

Cod. Protocolo
VEN-A-QUI

Transicionado 2020-000406-28

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

Enfermedad investigada
Newly diagnosed acute myeloid leukemia patients aged equal or more than 60 years old

Título Científico
A phase I-II, multicentre, open label clinical trial to assess the safety and tolerability of the combination of low-dose

cytarabine or azacitidine, plus Venetoclax and Quizartinib in newly diagnosed acute myeloid leukemia patients aged equal or more than 60 years old ineligible for standard induction chemotherapy

Justificación

No aportado

Objetivo Principal

-For the phase I: to establish the RP2D of AZA based and LDAC based triple combination with Quizartinib and Venetoclax schedules.
-For the phase II: to assess and to compare the CR/CRi rate of AZA based and LDAC based triple combination with Quizartinib and Venetoclax schedules.

Variables de Evaluación Primaria

Phase I: Recommended phase 2 dose (RP2D) of AZA based and LDAC based triple combination with Quizartinib and Venetoclax schedules -Phase II: CR/CRi rate of AZA based and LDAC based triple combination with Quizartinib and Venetoclax schedules

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To evaluate the CR/CRi rate after 1 and 4 cycles of AZA based and LDAC based triple combination with Quizartinib and Venetoclax schedules.
To compare the median OS between AZA based and LDAC based triple combination with Quizartinib and Venetoclax schedules.
To evaluate the safety and tolerability of AZA based and LDAC based triple combination with Quizartinib and Venetoclax schedules (overall hematologic and non-hematologic toxicity).
To estimate 1, 2 and 3 years event-free, disease-free, and relapse-free survival, as well as on the cumulative incidence of relapse.
To evaluate the impact on the quality of life, using the EQ5D and the EORTC Quality of Life Questionnaire-Core 30 (QLQ-C30) forms, of AZA based and LDAC based triple combination with Quizartinib and Venetoclax schedules.
To evaluate the impact on the use of medical resources during treatment phase (ie, antibiotics, transfusions, duration of hospitalization, need of central venous line, use of strong or moderate CYP3A inhibitors and moderate CYP3A inducers).
To evaluate the quality of CR (by study of minimal residual disease percentages in the bone marrow (BM) using multiparametric flow cytometry [MPFC] and NGS-MRD).
To evaluate the CRh rate in AZA based and LDAC based triple combination with Quizartinib and Venetoclax schedules.
To evaluate early mortality (first 30 and 60 days).
Separate analyses in secondary AML, CBF, FLT3-ITD, NPM1, P53, and IDH1/IDH2 subsets.

Exploration of biomarkers predictive of drug activity and duration of response may be performed. These analyses maybe part of a multi-study assessment to compare responses to the therapies and/or disease state. Potential analyses may include: o To evaluate the MRD negativity rate in the BM using MPFC and NGS-MRD o To evaluate the MRD negativity in PB using NGS-MRD o Immune recovery o Exhaustive biomarker plan including baseline and relapse molecular characterization by next generation sequencing (NGS).

Variables de Evaluación Secundaria

CR/CRi rate after 1, and 4 cycles Overall survival (OS) Safety and tolerability of the AZA based and LDAC based triple combination with Quizartinib and Venetoclax schedules (overall hematologic and non-hematologic toxicity) Event-free survival (EFS) Disease-free survival (DFS) Relapse-free survival (RFS) Quality of life (from the EuroQoL Group EQ-5D-5L and the EORTC QLQ-C30 instruments) Medical resources during treatment phase Minimal residual disease (MRD) CRh rate (Bone marrow blasts <5% with partial hematologic recovery defined as ANC 0.5 × 109/L and platelet count 50 × 109/L, with no evidence of extramedullary leukemia and cannot be classified as CR) Early mortality (first 30 and 60 days) Separate analyses in secondary AML, CBF, FLT3-ITD, NPM1, P53, and IDH1/IDH2 subsets. Exploration of biomarkers predictive of drug activity and duration of response. Potential analyses may include: o To evaluate the MRD negativity rate in the BM using MPFC and NGS o Immune recovery o Exhaustive biomarker plan including baseline and relapse molecular characterization by NGS

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Newly diagnosed AML. Morphological diagnosis of AML (WHO criteria 2008). Patient must be considered be ineligible for treatment with a standard cytarabine and anthracycline induction regimen due to age or co-morbidities defined by the following criteria: 3.1. 71 years of age; 3.2. 60 to 70 years of age with at least one of the following co-morbidities: ECOG Performance Status of 2 or 3; Cardiac history of CHF requiring treatment or Ejection Fraction 55% or chronic stable angina; DLCO 65% or FEV1 65% or significant history of chronic pulmonary obstructive; Creatinine clearance 30 mL/min to < 50 ml/min Moderate hepatic impairment with total bilirubin, SGPT or SGOT > 1.5 to 3.0 × ULN Non active/controlled prior neoplastic disease Any other patient´s comorbidity or disease condition that the physician judges to be incompatible with intensive chemotherapy must be reviewed and approved by the Trial Coordinators before study enrollment (e.g, prior MDS or MPS, high-risk cytogenetics) ECOG performance status 3. Male subjects who are sexually active, must agree, from Study Day 1 through at least 120 days after the last dose of study drug, to practice the protocol specified contraception. Female subjects must be either postmenopausal for at least 1 year before screening OR permanently surgical sterile (bilateral oophorectomy, bilateral salpingectomy or hysterectomy) OR Women of Childbearing Potential (WOCBP) must agree to practice 1 highly effective method and 1 additional effective (barrier) method of contraception, at the same time, from the time of signing the informed consent through 4 months after the last dose of study drug (female and male condoms should not be used together), or Agree to practice true abstinence, when this is in line with the preferred and usual lifestyle of the subject. (Periodic abstinence [e.g., calendar, ovulation, symptothermal, postovulation methods] withdrawal, spermicides only, and lactational amenorrhea are not acceptable methods of contraception). Female subjects of childbearing potential must have negative results for pregnancy test performed and must not be lactating and breastfeeding Subject must voluntarily sign and date an informed consent, approved by an Independent Ethics Committee (IEC) prior to the initiation of any screening or study specific procedures, with the understanding that consent may be withdrawn by the patient at any time without prejudice to future medical care.

Criterios de Exclusión

Age <60 years. Prior treatment with any investigational drug or device within 30 days prior to Randomization (within 2 weeks for investigational or approved immunotherapy) or currently participating in other investigational procedures Prior treatment with other FLT3-ITD or BCL-2 inhibitors. Known uncontrolled or significant cardiovascular disease, including any of the following: a) Bradycardia of less than 50 beats per minute, unless the subject has a pacemaker; b) QTcF interval >450 msec; c) Diagnosis of or suspicion of long QT syndrome (including family history of long QT syndrome); d) Systolic blood pressure 180 mmHg or diastolic blood pressure 110 mmHg; e) History of clinically relevant ventricular arrhythmias (eg, ventricular tachycardia, ventricular fibrillation, or Torsade de Pointes); f) History of second (Mobitz II) or third degree heart block (subjects with pacemakers are eligible if they have no history of fainting or clinically relevant arrhythmias while using the pacemaker); g) History of uncontrolled angina pectoris or myocardial infarction within 6 months prior to Screening; h) History of New York Heart Association Class 3 or 4 heart failure; i) Known history of left ventricular ejection fraction (LVEF) 45% or less than the institutional lower limit of normal; j) Complete left bundle branch block; Prior therapy for AML (except hydroxiurea). Subject enrolling into a dose-escalation cohort must not have received a known strong or moderate inducer or inhibitor of cytochrome P450 (CYP) 3A within 7 days before the first Quizartinib or Venetoclax dose. Subject enrolling into a safety expansion cohort must not have received a known strong or moderate inducer or strong inhibitor of CYP3A within 7 days before the first Quizartinib or Venetoclax dose. Subject must not have consumed grapefruit, grapefruit products, Seville oranges (including marmalade-containing Seville oranges), or star fruit within 3 days before anticipated first dose of Venetoclax and must consent not to consume through the last dose of Venetoclax. Active acute or chronic systemic fungal, bacterial, or viral infection not well controlled by antifungal, antibacterial or antiviral therapy at physician discretion; Known active clinically relevant liver disease (eg, active hepatitis B, or active hepatitis C) Known history of human immunodeficiency virus (HIV). History of hypersensitivity to any excipients in the Quizartinib, Venetoclax or other study medication. Genetic diagnosis of acute promyelocytic leukemia. Non mutated FLT3-ITD subjects will be considered ineligible during the randomized Phase II after 48 non mutated FLT3-ITD subjects have been randomized. Treated (excluding surgery or hormone-therapy) for another malignancy within 6 months before randomization or previously diagnosed with another malignancy and have any evidence of disease which may compromise the administration of investigational treatment schedule. Presence of any severe psychiatric disease or physical condition that, according to the physician´s criteria, contraindicates the inclusion of the patient into the clinical trial. Serum creatinine 2.5 mg/dL or creatinine clearance < 30 mL/min (unless it is attributable to AML activity). Bilirubin, SGPT or SGOT > 3 times the upper normal limit (unless it is attributable to AML activity). WBC> 50 x 109/L. Subject should have white blood cell count <50 × 109/L before starting therapy. Patients who are cytoreduced with leukapheresis or with hydroxyurea may be enrolled if they meet the eligibility criteria before starting therapy. Contraindications for Quizartinib or Venetoclax. History of known CNS leukemia, including cerebrospinal fluid positive for AML blasts.

Calendario

(Última actualización: 09/01/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
18/09/2020	04/11/2020	09/11/2020	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
23/09/2022	No aportado	No aportado	30/09/2025	No aportado

Promotor

Fundacion PETHEMA Spain

Calle Del Professor Martin Lagos Sn

Contact Person

Dr. Juan José Lahuerta

+34916266232

gerencia@fundacionpethema.es

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 (12/05/2021)

HOSPITAL CLINIC DE BARCELONA

Barcelona

BARCELONA

Hematología

Activo (01/12/2020)

HOSPITAL CLINICO UNIVERSITARIO VIRGEN DE LA ARRIXACA

Murcia

MURCIA

Cerrado (23/10/2024)

HOSPITAL DE LEON COMPLEJO ASISTENCIAL UNIVERSITARIO DE LEON

León

LEÓN

Cerrado (26/08/2024)

HOSPITAL DE SANT JOAN DE DEU (MANRESA)

Manresa

BARCELONA

Activo (19/11/2020)

HOSPITAL SAN PEDRO DE ALCANTARA

Cáceres

CÁCERES

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

Hospital San Pedro De Alcantara

Caceres

CÁCERES

Hematología

Cerrado (27/08/2024)

HOSPITAL UNIVERSITARI ARNAU DE VILANOVA DE LLEIDA.

Lleida

LÉRIDA

Activo (12/11/2020)

HOSPITAL UNIVERSITARI MUTUA DE TERRASSA

Terrassa

BARCELONA

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

Hospital Universitari Mutua Terrassa

Terrassa

BARCELONA

Hematología

Cerrado (29/09/2025)

HOSPITAL UNIVERSITARI SON ESPASES

Palma de Mallorca

BALEARES

Cerrado (29/08/2024)

HOSPITAL UNIVERSITARIO DE JEREZ DE LA FRONTERA

Jerez de la Frontera

CÁDIZ

Cerrado (20/01/2023)

HOSPITAL UNIVERSITARIO LA ZARZUELA

Madrid

MADRID

Cerrado (28/08/2025)

HOSPITAL UNIVERSITARIO MARQUES DE VALDECILLA

Santander

CANTABRIA

Cerrado (27/09/2024)

Hospital Universitario Virgen Macarena

Sevilla

SEVILLA

Hematología

Activo (29/10/2020)

HOSPITAL UNIVERSITARIO Y POLITECNICO LA FE

Valencia

VALENCIA

Medicamentos

QUIZARTINIB DIHYDROCHLORIDE
TABLET
ORAL USE

-
Principios Activos: N/A

Experimental

Quizartinib
FILM-COATED TABLET
ORAL USE

-
Principios Activos: N/A

Experimental

Quizartinib
FILM-COATED TABLET
ORAL USE

-
Principios Activos: N/A

Experimental

Venclyxto 100 mg film-coated tablets
FILM-COATED TABLET
ORAL USE

Código ATC: L01XX52 - VENETOCLAX
Principios Activos: N/A

Experimental

Venclyxto 10 mg film-coated tablets
FILM-COATED TABLET
ORAL USE

Código ATC: L01XX52 - VENETOCLAX
Principios Activos: N/A

Experimental

Venclyxto 50 mg film-coated tablets
FILM-COATED TABLET
ORAL USE

Código ATC: L01XX52 - VENETOCLAX
Principios Activos: N/A

Experimental

Sin resultados

A multicentre clinical trial to assess the safety and tolerability of the combination of low-dose cytarabine or azacitidine, plus Venetoclax and Quizartinib in newly diagnosed acute myeloid leukemia patients aged equal or more than 60 years old ineligible for standard induction chemotherapy

State	**Type of participants**	**Age Ranges**
Finished CT	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase I , Phase II	84
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
National multicenter	safety, dose	NO

Information

Identifier
2024-519275-26-00 (CTIS)

Protocol Code
VEN-A-QUI

Transitioned 2020-000406-28

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

Investigated Disease
Newly diagnosed acute myeloid leukemia patients aged equal or more than 60 years old

Scientific Title
A phase I-II, multicentre, open label clinical trial to assess the safety and tolerability of the combination of low-dose

cytarabine or azacitidine, plus Venetoclax and Quizartinib in newly diagnosed acute myeloid leukemia patients aged equal or more than 60 years old ineligible for standard induction chemotherapy

Rationale

Not provided

Main Objective

-For the phase I: to establish the RP2D of AZA based and LDAC based triple combination with Quizartinib and Venetoclax schedules.
-For the phase II: to assess and to compare the CR/CRi rate of AZA based and LDAC based triple combination with Quizartinib and Venetoclax schedules.

Primary Endpoints

Phase I: Recommended phase 2 dose (RP2D) of AZA based and LDAC based triple combination with Quizartinib and Venetoclax schedules -Phase II: CR/CRi rate of AZA based and LDAC based triple combination with Quizartinib and Venetoclax schedules

Temporary moments of secondary assessment

Not provided

Secondary Objective

To evaluate the CR/CRi rate after 1 and 4 cycles of AZA based and LDAC based triple combination with Quizartinib and Venetoclax schedules.
To compare the median OS between AZA based and LDAC based triple combination with Quizartinib and Venetoclax schedules.
To evaluate the safety and tolerability of AZA based and LDAC based triple combination with Quizartinib and Venetoclax schedules (overall hematologic and non-hematologic toxicity).
To estimate 1, 2 and 3 years event-free, disease-free, and relapse-free survival, as well as on the cumulative incidence of relapse.
To evaluate the impact on the quality of life, using the EQ5D and the EORTC Quality of Life Questionnaire-Core 30 (QLQ-C30) forms, of AZA based and LDAC based triple combination with Quizartinib and Venetoclax schedules.
To evaluate the impact on the use of medical resources during treatment phase (ie, antibiotics, transfusions, duration of hospitalization, need of central venous line, use of strong or moderate CYP3A inhibitors and moderate CYP3A inducers).
To evaluate the quality of CR (by study of minimal residual disease percentages in the bone marrow (BM) using multiparametric flow cytometry [MPFC] and NGS-MRD).
To evaluate the CRh rate in AZA based and LDAC based triple combination with Quizartinib and Venetoclax schedules.
To evaluate early mortality (first 30 and 60 days).
Separate analyses in secondary AML, CBF, FLT3-ITD, NPM1, P53, and IDH1/IDH2 subsets.

Exploration of biomarkers predictive of drug activity and duration of response may be performed. These analyses maybe part of a multi-study assessment to compare responses to the therapies and/or disease state. Potential analyses may include: o To evaluate the MRD negativity rate in the BM using MPFC and NGS-MRD o To evaluate the MRD negativity in PB using NGS-MRD o Immune recovery o Exhaustive biomarker plan including baseline and relapse molecular characterization by next generation sequencing (NGS).

Secondary Endpoints

CR/CRi rate after 1, and 4 cycles Overall survival (OS) Safety and tolerability of the AZA based and LDAC based triple combination with Quizartinib and Venetoclax schedules (overall hematologic and non-hematologic toxicity) Event-free survival (EFS) Disease-free survival (DFS) Relapse-free survival (RFS) Quality of life (from the EuroQoL Group EQ-5D-5L and the EORTC QLQ-C30 instruments) Medical resources during treatment phase Minimal residual disease (MRD) CRh rate (Bone marrow blasts <5% with partial hematologic recovery defined as ANC 0.5 × 109/L and platelet count 50 × 109/L, with no evidence of extramedullary leukemia and cannot be classified as CR) Early mortality (first 30 and 60 days) Separate analyses in secondary AML, CBF, FLT3-ITD, NPM1, P53, and IDH1/IDH2 subsets. Exploration of biomarkers predictive of drug activity and duration of response. Potential analyses may include: o To evaluate the MRD negativity rate in the BM using MPFC and NGS o Immune recovery o Exhaustive biomarker plan including baseline and relapse molecular characterization by NGS

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Newly diagnosed AML. Morphological diagnosis of AML (WHO criteria 2008). Patient must be considered be ineligible for treatment with a standard cytarabine and anthracycline induction regimen due to age or co-morbidities defined by the following criteria: 3.1. 71 years of age; 3.2. 60 to 70 years of age with at least one of the following co-morbidities: ECOG Performance Status of 2 or 3; Cardiac history of CHF requiring treatment or Ejection Fraction 55% or chronic stable angina; DLCO 65% or FEV1 65% or significant history of chronic pulmonary obstructive; Creatinine clearance 30 mL/min to < 50 ml/min Moderate hepatic impairment with total bilirubin, SGPT or SGOT > 1.5 to 3.0 × ULN Non active/controlled prior neoplastic disease Any other patient´s comorbidity or disease condition that the physician judges to be incompatible with intensive chemotherapy must be reviewed and approved by the Trial Coordinators before study enrollment (e.g, prior MDS or MPS, high-risk cytogenetics) ECOG performance status 3. Male subjects who are sexually active, must agree, from Study Day 1 through at least 120 days after the last dose of study drug, to practice the protocol specified contraception. Female subjects must be either postmenopausal for at least 1 year before screening OR permanently surgical sterile (bilateral oophorectomy, bilateral salpingectomy or hysterectomy) OR Women of Childbearing Potential (WOCBP) must agree to practice 1 highly effective method and 1 additional effective (barrier) method of contraception, at the same time, from the time of signing the informed consent through 4 months after the last dose of study drug (female and male condoms should not be used together), or Agree to practice true abstinence, when this is in line with the preferred and usual lifestyle of the subject. (Periodic abstinence [e.g., calendar, ovulation, symptothermal, postovulation methods] withdrawal, spermicides only, and lactational amenorrhea are not acceptable methods of contraception). Female subjects of childbearing potential must have negative results for pregnancy test performed and must not be lactating and breastfeeding Subject must voluntarily sign and date an informed consent, approved by an Independent Ethics Committee (IEC) prior to the initiation of any screening or study specific procedures, with the understanding that consent may be withdrawn by the patient at any time without prejudice to future medical care.

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Calendar

(Last Update: 09/01/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
18/09/2020	04/11/2020	09/11/2020	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
23/09/2022	Not aported	Not aported	30/09/2025	Not aported

Sponsor

Fundacion PETHEMA Spain

Calle Del Professor Martin Lagos Sn

Contact Person

Dr. Juan José Lahuerta

+34916266232

gerencia@fundacionpethema.es

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 (12/05/2021)

HOSPITAL CLINIC DE BARCELONA

Barcelona

BARCELONA

Hematología

Active (01/12/2020)

HOSPITAL CLINICO UNIVERSITARIO VIRGEN DE LA ARRIXACA

Murcia

MURCIA

Closed (23/10/2024)

HOSPITAL DE LEON COMPLEJO ASISTENCIAL UNIVERSITARIO DE LEON

León

LEÓN

Closed (26/08/2024)

HOSPITAL DE SANT JOAN DE DEU (MANRESA)

Manresa

BARCELONA

Active (19/11/2020)

HOSPITAL SAN PEDRO DE ALCANTARA

Cáceres

CÁCERES

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

Hospital San Pedro De Alcantara

Caceres

CÁCERES

Hematología

Closed (27/08/2024)

HOSPITAL UNIVERSITARI ARNAU DE VILANOVA DE LLEIDA.

Lleida

LÉRIDA

Active (12/11/2020)

HOSPITAL UNIVERSITARI MUTUA DE TERRASSA

Terrassa

BARCELONA

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

Hospital Universitari Mutua Terrassa

Terrassa

BARCELONA

Hematología

Closed (29/09/2025)

HOSPITAL UNIVERSITARI SON ESPASES

Palma de Mallorca

BALEARES

Closed (29/08/2024)

HOSPITAL UNIVERSITARIO DE JEREZ DE LA FRONTERA

Jerez de la Frontera

CÁDIZ

Closed (20/01/2023)

HOSPITAL UNIVERSITARIO LA ZARZUELA

Madrid

MADRID

Closed (28/08/2025)

HOSPITAL UNIVERSITARIO MARQUES DE VALDECILLA

Santander

CANTABRIA

Closed (27/09/2024)

Hospital Universitario Virgen Macarena

Sevilla

SEVILLA

Hematología

Active (29/10/2020)

HOSPITAL UNIVERSITARIO Y POLITECNICO LA FE

Valencia

VALENCIA

Medication

QUIZARTINIB DIHYDROCHLORIDE
TABLET
ORAL USE

-

Active Principles: N/A

Experimental

Quizartinib
FILM-COATED TABLET
ORAL USE

-

Active Principles: N/A

Experimental

Quizartinib
FILM-COATED TABLET
ORAL USE

-

Active Principles: N/A

Experimental

Venclyxto 100 mg film-coated tablets
FILM-COATED TABLET
ORAL USE

ATC code: L01XX52 - VENETOCLAX

Active Principles: N/A

Experimental

Venclyxto 10 mg film-coated tablets
FILM-COATED TABLET
ORAL USE

ATC code: L01XX52 - VENETOCLAX

Active Principles: N/A

Experimental

Venclyxto 50 mg film-coated tablets
FILM-COATED TABLET
ORAL USE

ATC code: L01XX52 - VENETOCLAX

Active Principles: N/A

Experimental

No results