A 52-week Clinical Trial to Study the Effect of Dexpramipexole in Adolescents and Adults With Severe Eosinophilic Asthma (EXHALE-3)

Estado	**Tipo de Participantes**	**Rangos de Edad**
Reclutando	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	745
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia	NO

Información

Identificador
2023-503693-20-01 (CTIS)

Cod. Protocolo
AR-DEX-22-02

Área terapéutica
Enfermedades [C] - Tracto respiratorio [C08]|

Enfermedad investigada
Severe eosinophilic asthma

Título Científico
A randomized, double-blind, placebo-controlled, parallel-group study to assess the efficacy, safety, and tolerability of dexpramipexole administered orally for 52 weeks in participants with severe eosinophilic asthma (EXHALE-3)

Justificación

No aportado

Objetivo Principal

The primary objective of the study is to demonstrate the efficacy of dexpramipexole in reducing severe asthma exacerbations.

Variables de Evaluación Primaria

Annualized rate of severe asthma exacerbations (AAER) over 52 weeks.

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To demonstrate the efficacy of dexpramipexole on pulmonary function.
To demonstrate the efficacy of dexpramipexole on asthma control and quality of life
To evaluate the effect of dexpramipexole on blood eosinophils

Variables de Evaluación Secundaria

Pre-BD FEV1, absolute change from baseline, averaged across visits at Weeks 36, 44, and 52.
Asthma Control Questionnaire-6 (ACQ-6), change from baseline, averaged across visits at Weeks 36, 44, and 52.
Standardized version of the Asthma Quality of Life Questionnaire for 12 years and older (AQLQ+12), change from baseline to Week 52.

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Signed informed consent form and assent form, as appropriate. Negative urine pregnancy test for women of childbearing potential (WOCBP) at the Screening and Baseline visits. WOCBP (after menarche) must use either of the following methods of birth control, from Screening Visit 1 through the End of Study Visit (refer to Section 8.3.3.1 for details): a. A highly effective form of birth control (confirmed by the investigator). Highly effective forms of birth

control include: true sexual abstinence, a vasectomized sexual partner, Implanon, female sterilization by tubal occlusion, any effective intrauterine device (IUD), IUD/intrauterine system (IUS), Levonorgestrel IUS, or oral contraceptive. OR b. Two protocol acceptable methods of contraception in tandem. Women not of childbearing potential are defined as women who are either permanently sterilized (hysterectomy, bilateral oophorectomy, or bilateral salpingectomy) or who are postmenopausal. Women will be considered postmenopausal if they have been amenorrheic for 12 or more months prior to the planned date of the Baseline Visit without an alternative medical cause. The following age specific requirements apply: c. Women <50 years old will be considered postmenopausal if they have been amenorrheic for 12 months or more following cessation of exogenous hormonal treatment and follicle stimulating hormone (FSH) levels in the postmenopausal range. d. Women 50 years old will be considered postmenopausal if they have been amenorrheic for 12 months or more following cessation of all exogenous hormonal treatment. Male or female 18 years of age at Screening Visit 1. Documented physician diagnosis of asthma for 12 months prior to Screening Visit 1. Eosinophil count of 0.30x10^9/L at Screening Visit 1. If the initial value is between0.250x10^9/L to 0.299x10^9/L, then this may be repeated once at an unscheduled visit (priorto Screening Visit 2). Treatment of asthma, participants must satisfy all the below (items a to c): a.Participants who have received asthma controller medication with medium orhigh dose ICS (500 g/day fluticasone propionate dry powder formulation dailyor clinically comparable, per GINA 2021) on a regular basis for at least12 months prior to Screening Visit 1. Equivalent medium and high dose ICSdoses are detailed in Appendix C. b.Documented treatment with a stable dose of either medium or high dose ICS forat least 3 months prior to Screening Visit 1. The ICS may be contained within anICS/LABA combination product. As noted in Section 5.2.2, daily oralcorticosteroids are an allowed concomitant medication; participants on daily oralcorticosteroids must be on a stable dose for 3 months before Screening Visit 1. c.Use of one or more additional daily maintenance asthma controller medicationsaccording to standard practice of care is required; eg, LABA, leukotrieneantagonist, theophylline, long-acting muscarinic antagonists. Use of a stable doseof any additional asthma controller medications must be documented for at least3 months prior to Screening Visit 1. Pre-BD FEV1 40% and <80% of predicted at Screening Visit 2. Variable airflow obstruction documented with at least one of the following criteria: a.Bronchodilator reversibility at Screening Visit 2, as evidenced by 12% and200 mL improvement in FEV1, 15 to 30 minutes following inhalation of 400 g(four puffs) of albuterol/salbutamol. Participants who do not meet thebronchodilator reversibility inclusion criterion but have 10% and 160 mLreversibility may repeat the reversibility spirometry assessment once during theScreening period, at an unscheduled visit at least 7 days prior to baseline. b. Bronchodilator reversibility, using the criteria above, documented in the past 24 months prior to Screening Visit 1 or during screening. c. Peak flow variation of 20% over a 2-week period, documented in the past 24 months prior to Screening Visit 1 or during screening. d. Airflow variability in clinic FEV1 20% between two consecutive clinic visits, documented in the past 24 months prior to Screening Visit 1 or during screening. e. Airway hyperresponsiveness (provocative concentration causing a 20% fall in FEV1 of methacholine <8 mg/mL, or other clinically relevant bronchoprovocation testing) documented in the past 24 months prior to Screening Visit 1. ACQ-6 1.5 at Screening Visit 2. Documented history of at least two asthma exacerbations requiring treatment with systemic corticosteroids (intramuscular, intravenous, or oral) within the past 12-month period prior to Screening Visit 1.

Criterios de Exclusión

A participant who experiences a severe asthma exacerbation (defined as a deterioration of asthma that results in emergency treatment, hospitalization due to asthma, or treatment with systemic corticosteroids) at any time from 4 weeks prior to Screening Visit 1. Participants who experience an asthma exacerbation during the Screening/Run-in Period may remain in screening and proceed with study visits 14 days after they have completed their course of oral steroids or returned to their pre-Screening Visit maintenance dose of oral steroids and the investigator considers participant has returned to baseline status. Current smoking within 12 months prior to Screening Visit 1 or a smoking history of >10 pack-years. Smoking includes tobacco, vaping, and/or marijuana use. Known or suspected alcohol or drug abuse Uncontrolled severe hypertension: systolic blood pressure >180 mmHg or diastolic blood pressure >110 mmHg prior to the Baseline Visit despite anti-hypertensive therapy. History of malignancy that required surgery (excluding local and wide-local excision), radiation therapy, and/or systemic therapy during the 5 years prior to the Baseline Visit. History of human immunodeficiency virus (HIV) infection or chronic infection with hepatitis B or C or positive serology at Screening Visit 2 (in EU countries). A helminth parasitic infection diagnosed within 24 weeks prior to Screening Visit 1 that has not been treated with or has failed to respond to SoC therapy. Medical or other condition likely to interfere with participants ability to undergo study procedures, adhere to visit schedule, or comply with study requirements. Known or suspected noncompliance with medication. Unwillingness or inability to follow the

procedures outlined in the protocol. Absolute neutrophil count (ANC) <2.000x10^9/L at Screening Visit 1 or Screening Visit 2. Current diagnosis of diseases which may confound interpretation of this studys findings such as allergic bronchopulmonary aspergillosis, eosinophilic granulomatosis with polyangiitis, eosinophilic gastrointestinal diseases, hypereosinophilic syndrome, or lung diseases (eg, chronic obstructive pulmonary disease, idiopathic pulmonary fibrosis). Renal dysfunction, defined as an estimated glomerular filtration rate (eGFR) <60 mL/min/1.73m2 at Screening Visit 2 (using the Chronic Kidney Disease Epidemiology Collaboration [CKD-EPI] formula Active liver disease defined as any known current infectious, neoplastic, or metabolic pathology of the liver or unexplained elevations in alanine aminotransferase (ALT), aspartate aminotransferase (AST), >3x the upper limit of normal (ULN), or total bilirubin >2x ULN at Screening Visit 2 confirmed by a repeat abnormal measurement of the relevant value(s), at least 1 week apart. History of New York Heart Association class IV heart failure or last known left ventricular ejection fraction <25%. History of major adverse cardiovascular event (MACE) within 3 months prior to the Baseline Visit. History of cardiac arrhythmia within 3 months prior to the Baseline Visit that is not controlled by medication or via ablation. History of long QT syndrome. Corrected QT interval by Fridericia (QTcF) interval >450 ms for males and >470 ms for females at Screening Visit 2 QTcF 480 ms for participants with bundle branch block. Clinically important abnormalities in resting ECG that may interfere with the interpretation of QTcF interval changes at Screening Visit 2, including resting heart rate <45 beats per minute (bpm) or >100 bpm. Pregnant women or women breast feeding Males who are unwilling to use an acceptable method of birth control during the entire study period (ie, condom with spermicide). Respiratory infection: Upper or lower respiratory tract, sinus, or middle ear infection within the 4 weeks before Screening Visit 1. Allergy or hypersensitivity to dexpramipexole or any of its components. Treatment with a biologic investigational drug in the last 5 months prior to Screening Visit 1. Treatment with non-biologic investigational drugs in the previous 30 days or five-half-lives prior to Screening Visit 1, whichever is longer. Treatment with GSK3511294 (long-acting anti-IL-5) in the past 12 months. Treatment with any of the following monoclonal antibody therapies within 120 days prior to Baseline: benralizumab, dupilumab, mepolizumab, reslizumab, omalizumab, tezepelumab, or tralokinumab. Monoclonal antibody therapies should not be delayed or excluded for the sole purpose of inclusion in this clinical trial. Treatment with pramipexole (Mirapex®) within 30 days of Baseline. Treatment with selected drugs known to have a substantial risk of neutropenia in the past 30 days prior to Screening Visit 1. Bronchial thermoplasty procedure in the past 12 months prior to Screening Visit 1 or planned during the coming year. Weight <40 kg at Screening Visit 2.

Calendario

(Última actualización: 17/12/2025)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
12/03/2024	10/04/2024	30/04/2024	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

Areteia Therapeutics Inc. United States

1200 Morris Turnpike Suite 3005

Contact Person

Andrew Friedman

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andrew.friedman@populationhp.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Hospital Clínico San Carlos

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917044160

Centros

Activo (20/05/2024)

Complexo Hospitalario Universitario A Coruna

A Coruna

CORUÑA

Pneumology

Activo (08/05/2024)

Complexo Hospitalario Universitario De Santiago

Santiago De Compostela

CORUÑA

Pneumology

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

Complexo Hospitalario Universitario De Santiago

Santiago De Compostela

CORUÑA

Respiratory

Cerrado (06/10/2025)

Hospital Clinic De Barcelona

Barcelona

BARCELONA

Pneumology

Activo (22/05/2024)

Hospital De La Santa Creu I Sant Pau

Barcelona

BARCELONA

Pneumology

Activo (05/06/2024)

Hospital Povisa S.A.

Vigo

PONTEVEDRA

Pneumology

Activo (10/06/2024)

Hospital Universitario Dr Peset Aleixandre

Valencia

VALENCIA

Pneumology

Activo (07/05/2024)

Hospital Universitario Fundacion Jimenez Diaz

Madrid

MADRID

Pneumology

Activo (03/06/2024)

Hospital Universitario Infanta Leonor

Madrid

MADRID

Pneumologist

Activo (20/05/2024)

Hospital Universitario La Paz

Madrid

MADRID

Pneumology

Activo (03/06/2024)

Hospital Universitario Lucus Augusti

Lugo

LUGO

Pneumology Service

Activo (30/04/2024)

Hospital Universitario Marques De Valdecilla

Santander

CANTABRIA

Pulmonology department

Activo (22/05/2024)

Pectus Respiratory Health S.L.

Barcelona

BARCELONA

Pneumologist

Medicamentos

Ventolin 100 mikrogram/ipurkime suslgtoji kvepiamoji suspensija
PRESSURISED INHALATION, SUSPENSION
INHALATION USE

Código ATC: R03AC02 - SALBUTAMOL
Principios Activos: N/A

Experimental

Sultanol Dosier-Aerosol 100 Mikrogramm/Dosis Druckgasinhalation, Suspension
PRESSURISED INHALATION, SUSPENSION
INHALATION USE

Código ATC: R03AC02 - SALBUTAMOL
Principios Activos: N/A

Experimental

Ventolin 100 microgramos/inhalación suspensión para inhalación en envase a presión* (*) sin CFC
PRESSURISED INHALATION, SUSPENSION
INHALATION USE

Código ATC: R03AC02 - SALBUTAMOL
Principios Activos: N/A

Experimental

Ventolin Evohaler túlnyomásos inhalációs szuszpenzió
PRESSURISED INHALATION, SUSPENSION
INHALATION USE

Código ATC: R03AC02 - SALBUTAMOL
Principios Activos: N/A

Experimental

Novolizer Salbutamol Meda 100 Mikrogramm/Dosis Pulver zur Inhalation
INHALATION POWDER
INHALATION USE

Código ATC: R03AC02 - SALBUTAMOL
Principios Activos: N/A

Experimental

Budesonide/Formoterol Teva Pharma B.V. 160 micrograms / 4.5 micrograms inhalation powder
INHALATION POWDER
INHALATION USE

Código ATC: R03AK07 - FORMOTEROL Y BUDESONIDA
Principios Activos: N/A

Experimental

Dexpramipexole (KNS-760704)
FILM-COATED TABLET
ORAL USE

-

Ventolin Inhaler N Suspenze k inhalaci v tlakovém obalu
PRESSURISED INHALATION, SUSPENSION
INHALATION USE

Código ATC: R03AC02 - SALBUTAMOL
Principios Activos: N/A

Principios Activos: N/A

Experimental

Experimental

Dexpramipexole (KNS-760704)
FILM-COATED TABLET
ORAL USE

-

Principios Activos: N/A

Experimental

Sin resultados

A 52-week Clinical Trial to Study the Effect of Dexpramipexole in Adolescents and Adults With Severe Eosinophilic Asthma (EXHALE-3)

State	Type of participants	Age Ranges
Recruiting	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	745
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness	NO

Information

Identifier
2023-503693-20-01 (CTIS)

Protocol Code
AR-DEX-22-02

Therapeutic area
Diseases [C] - Respiratory Tract Diseases [C08]|

Investigated Disease
Severe eosinophilic asthma

Scientific Title
A randomized, double-blind, placebo-controlled, parallel-group study to assess the efficacy, safety, and tolerability of dexpramipexole administered orally for 52 weeks in participants with severe eosinophilic asthma (EXHALE-3)

Rationale

Not provided

Main Objective

The primary objective of the study is to demonstrate the efficacy of dexpramipexole in reducing severe asthma exacerbations.

Primary Endpoints

Annualized rate of severe asthma exacerbations (AAER) over 52 weeks.

Temporary moments of secondary assessment

Not provided

Secondary Objective

To demonstrate the efficacy of dexpramipexole on pulmonary function.
To demonstrate the efficacy of dexpramipexole on asthma control and quality of life
To evaluate the effect of dexpramipexole on blood eosinophils

Secondary Endpoints

Pre-BD FEV1, absolute change from baseline, averaged across visits at Weeks 36, 44, and 52.
Asthma Control Questionnaire-6 (ACQ-6), change from baseline, averaged across visits at Weeks 36, 44, and 52.
Standardized version of the Asthma Quality of Life Questionnaire for 12 years and older (AQLQ+12), change from baseline to Week 52.

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Signed informed consent form and assent form, as appropriate. Negative urine pregnancy test for women of childbearing potential (WOCBP) at the Screening and Baseline visits. WOCBP (after menarche) must use either of the following methods of birth control, from Screening Visit 1 through the End of Study Visit (refer to Section 8.3.3.1 for details): a. A highly effective form of birth control (confirmed by the investigator). Highly effective forms of birth

control include: true sexual abstinence, a vasectomized sexual partner, Implanon, female sterilization by tubal occlusion, any effective intrauterine device (IUD), IUD/intrauterine system (IUS), Levonorgestrel IUS, or oral contraceptive. OR b. Two protocol acceptable methods of contraception in tandem. Women not of childbearing potential are defined as women who are either permanently sterilized (hysterectomy, bilateral oophorectomy, or bilateral salpingectomy) or who are postmenopausal. Women will be considered postmenopausal if they have been amenorrheic for 12 or more months prior to the planned date of the Baseline Visit without an alternative medical cause. The following age specific requirements apply: c. Women <50 years old will be considered postmenopausal if they have been amenorrheic for 12 months or more following cessation of exogenous hormonal treatment and follicle stimulating hormone (FSH) levels in the postmenopausal range. d. Women 50 years old will be considered postmenopausal if they have been amenorrheic for 12 months or more following cessation of all exogenous hormonal treatment. Male or female 18 years of age at Screening Visit 1. Documented physician diagnosis of asthma for 12 months prior to Screening Visit 1. Eosinophil count of 0.30x10^9/L at Screening Visit 1. If the initial value is between0.250x10^9/L to 0.299x10^9/L, then this may be repeated once at an unscheduled visit (priorto Screening Visit 2). Treatment of asthma, participants must satisfy all the below (items a to c): a.Participants who have received asthma controller medication with medium orhigh dose ICS (500 g/day fluticasone propionate dry powder formulation dailyor clinically comparable, per GINA 2021) on a regular basis for at least12 months prior to Screening Visit 1. Equivalent medium and high dose ICSdoses are detailed in Appendix C. b.Documented treatment with a stable dose of either medium or high dose ICS forat least 3 months prior to Screening Visit 1. The ICS may be contained within anICS/LABA combination product. As noted in Section 5.2.2, daily oralcorticosteroids are an allowed concomitant medication; participants on daily oralcorticosteroids must be on a stable dose for 3 months before Screening Visit 1. c.Use of one or more additional daily maintenance asthma controller medicationsaccording to standard practice of care is required; eg, LABA, leukotrieneantagonist, theophylline, long-acting muscarinic antagonists. Use of a stable doseof any additional asthma controller medications must be documented for at least3 months prior to Screening Visit 1. Pre-BD FEV1 40% and <80% of predicted at Screening Visit 2. Variable airflow obstruction documented with at least one of the following criteria: a.Bronchodilator reversibility at Screening Visit 2, as evidenced by 12% and200 mL improvement in FEV1, 15 to 30 minutes following inhalation of 400 g(four puffs) of albuterol/salbutamol. Participants who do not meet thebronchodilator reversibility inclusion criterion but have 10% and 160 mLreversibility may repeat the reversibility spirometry assessment once during theScreening period, at an unscheduled visit at least 7 days prior to baseline. b. Bronchodilator reversibility, using the criteria above, documented in the past 24 months prior to Screening Visit 1 or during screening. c. Peak flow variation of 20% over a 2-week period, documented in the past 24 months prior to Screening Visit 1 or during screening. d. Airflow variability in clinic FEV1 20% between two consecutive clinic visits, documented in the past 24 months prior to Screening Visit 1 or during screening. e. Airway hyperresponsiveness (provocative concentration causing a 20% fall in FEV1 of methacholine <8 mg/mL, or other clinically relevant bronchoprovocation testing) documented in the past 24 months prior to Screening Visit 1. ACQ-6 1.5 at Screening Visit 2. Documented history of at least two asthma exacerbations requiring treatment with systemic corticosteroids (intramuscular, intravenous, or oral) within the past 12-month period prior to Screening Visit 1.

Exclusion criteria

A participant who experiences a severe asthma exacerbation (defined as a deterioration of asthma that results in emergency treatment, hospitalization due to asthma, or treatment with systemic corticosteroids) at any time from 4 weeks prior to Screening Visit 1. Participants who experience an asthma exacerbation during the Screening/Run-in Period may remain in screening and proceed with study visits 14 days after they have completed their course of oral steroids or returned to their pre-Screening Visit maintenance dose of oral steroids and the investigator considers participant has returned to baseline status. Current smoking within 12 months prior to Screening Visit 1 or a smoking history of >10 pack-years. Smoking includes tobacco, vaping, and/or marijuana use. Known or suspected alcohol or drug abuse Uncontrolled severe hypertension: systolic blood pressure >180 mmHg or diastolic blood pressure >110 mmHg prior to the Baseline Visit despite anti-hypertensive therapy. History of malignancy that required surgery (excluding local and wide-local excision), radiation therapy, and/or systemic therapy during the 5 years prior to the Baseline Visit. History of human immunodeficiency virus (HIV) infection or chronic infection with hepatitis B or C or positive serology at Screening Visit 2 (in EU countries). A helminth parasitic infection diagnosed within 24 weeks prior to Screening Visit 1 that has not been treated with or has failed to respond to SoC therapy. Medical or other condition likely to interfere with participants ability to undergo study procedures, adhere to visit schedule, or comply with study requirements. Known or suspected noncompliance with medication. Unwillingness or inability to follow the

procedures outlined in the protocol. Absolute neutrophil count (ANC) <2.000x10^9/L at Screening Visit 1 or Screening Visit 2. Current diagnosis of diseases which may confound interpretation of this studys findings such as allergic bronchopulmonary aspergillosis, eosinophilic granulomatosis with polyangiitis, eosinophilic gastrointestinal diseases, hypereosinophilic syndrome, or lung diseases (eg, chronic obstructive pulmonary disease, idiopathic pulmonary fibrosis). Renal dysfunction, defined as an estimated glomerular filtration rate (eGFR) <60 mL/min/1.73m2 at Screening Visit 2 (using the Chronic Kidney Disease Epidemiology Collaboration [CKD-EPI] formula Active liver disease defined as any known current infectious, neoplastic, or metabolic pathology of the liver or unexplained elevations in alanine aminotransferase (ALT), aspartate aminotransferase (AST), >3x the upper limit of normal (ULN), or total bilirubin >2x ULN at Screening Visit 2 confirmed by a repeat abnormal measurement of the relevant value(s), at least 1 week apart. History of New York Heart Association class IV heart failure or last known left ventricular ejection fraction <25%. History of major adverse cardiovascular event (MACE) within 3 months prior to the Baseline Visit. History of cardiac arrhythmia within 3 months prior to the Baseline Visit that is not controlled by medication or via ablation. History of long QT syndrome. Corrected QT interval by Fridericia (QTcF) interval >450 ms for males and >470 ms for females at Screening Visit 2 QTcF 480 ms for participants with bundle branch block. Clinically important abnormalities in resting ECG that may interfere with the interpretation of QTcF interval changes at Screening Visit 2, including resting heart rate <45 beats per minute (bpm) or >100 bpm. Pregnant women or women breast feeding Males who are unwilling to use an acceptable method of birth control during the entire study period (ie, condom with spermicide). Respiratory infection: Upper or lower respiratory tract, sinus, or middle ear infection within the 4 weeks before Screening Visit 1. Allergy or hypersensitivity to dexpramipexole or any of its components. Treatment with a biologic investigational drug in the last 5 months prior to Screening Visit 1. Treatment with non-biologic investigational drugs in the previous 30 days or five-half-lives prior to Screening Visit 1, whichever is longer. Treatment with GSK3511294 (long-acting anti-IL-5) in the past 12 months. Treatment with any of the following monoclonal antibody therapies within 120 days prior to Baseline: benralizumab, dupilumab, mepolizumab, reslizumab, omalizumab, tezepelumab, or tralokinumab. Monoclonal antibody therapies should not be delayed or excluded for the sole purpose of inclusion in this clinical trial. Treatment with pramipexole (Mirapex®) within 30 days of Baseline. Treatment with selected drugs known to have a substantial risk of neutropenia in the past 30 days prior to Screening Visit 1. Bronchial thermoplasty procedure in the past 12 months prior to Screening Visit 1 or planned during the coming year. Weight <40 kg at Screening Visit 2.

Calendar

(Last Update: 17/12/2025)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
12/03/2024	10/04/2024	30/04/2024	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

Areteia Therapeutics Inc. United States

1200 Morris Turnpike Suite 3005

Contact Person

Andrew Friedman

+16099550467

andrew.friedman@populationhp.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Hospital Clínico San Carlos

C/ Doctor Martín Lagos, s/n - Ciudad Universitaria 28040 Madrid

ceic.hcsc@salud.madrid.org

917044160

Sites

Active (20/05/2024)

Complexo Hospitalario Universitario A Coruna

A Coruna

CORUÑA

Pneumology

Active (08/05/2024)

Complexo Hospitalario Universitario De Santiago

Santiago De Compostela

CORUÑA

Pneumology

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

Complexo Hospitalario Universitario De Santiago

Santiago De Compostela

CORUÑA

Respiratory

Closed (06/10/2025)

Hospital Clinic De Barcelona

Barcelona

BARCELONA

Pneumology

Active (22/05/2024)

Hospital De La Santa Creu I Sant Pau

Barcelona

BARCELONA

Pneumology

Active (05/06/2024)

Hospital Povisa S.A.

Vigo

PONTEVEDRA

Pneumology

Active (10/06/2024)

Hospital Universitario Dr Peset Aleixandre

Valencia

VALENCIA

Pneumology

Active (07/05/2024)

Hospital Universitario Fundacion Jimenez Diaz

Madrid

MADRID

Pneumology

Active (03/06/2024)

Hospital Universitario Infanta Leonor

Madrid

MADRID

Pneumologist

Active (20/05/2024)

Hospital Universitario La Paz

Madrid

MADRID

Pneumology

Active (03/06/2024)

Hospital Universitario Lucus Augusti

Lugo

LUGO

Pneumology Service

Active (30/04/2024)

Hospital Universitario Marques De Valdecilla

Santander

CANTABRIA

Pulmonology department

Active (22/05/2024)

Pectus Respiratory Health S.L.

Barcelona

BARCELONA

Pneumologist

Medication

Ventolin 100 mikrogram/ipurkime suslgtoji kvepiamoji suspensija
PRESSURISED INHALATION, SUSPENSION
INHALATION USE

ATC code: R03AC02 - SALBUTAMOL
Active Principles: N/A

Experimental

Sultanol Dosier-Aerosol 100 Mikrogramm/Dosis Druckgasinhalation, Suspension
PRESSURISED INHALATION, SUSPENSION
INHALATION USE

ATC code: R03AC02 - SALBUTAMOL
Active Principles: N/A

Experimental

Ventolin 100 microgramos/inhalación suspensión para inhalación en envase a presión* (*) sin CFC
PRESSURISED INHALATION, SUSPENSION
INHALATION USE

ATC code: R03AC02 - SALBUTAMOL
Active Principles: N/A

Experimental

Ventolin Evohaler túlnyomásos inhalációs szuszpenzió
PRESSURISED INHALATION, SUSPENSION
INHALATION USE

ATC code: R03AC02 - SALBUTAMOL
Active Principles: N/A

Experimental

Novolizer Salbutamol Meda 100 Mikrogramm/Dosis Pulver zur Inhalation
INHALATION POWDER
INHALATION USE

ATC code: R03AC02 - SALBUTAMOL
Active Principles: N/A

Experimental

Budesonide/Formoterol Teva Pharma B.V. 160 micrograms / 4.5 micrograms inhalation powder
INHALATION POWDER
INHALATION USE

ATC code: R03AK07 - FORMOTEROL Y BUDESONIDA
Active Principles: N/A

Experimental

Dexpramipexole (KNS-760704)
FILM-COATED TABLET
ORAL USE

-

Ventolin Inhaler N Suspenze k inhalaci v tlakovém obalu
PRESSURISED INHALATION, SUSPENSION
INHALATION USE

ATC code: R03AC02 - SALBUTAMOL
Active Principles: N/A

Active Principles: N/A

Experimental

Experimental

Dexpramipexole (KNS-760704)
FILM-COATED TABLET
ORAL USE

-

Active Principles: N/A

Experimental

No results