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A Phase I study evaluating the safety and effects of QX031N in healthy participants, participants with chronic obstructive pulmonary disease and participants with asthma

Submission date
10/02/2026

Recruitment status
Recruiting

Registration date
25/02/2026

Overall study status
Ongoing

Last Edited
24/02/2026

Condition category
Respiratory

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

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Study information

Scientific Title
A Phase I, first in human, randomized, investigator and participant-blind, placebo-controlled, single- and multiple dose escalation, parallel group study to evaluate safety, tolerability, pharmacokinetics and pharmacodynamics of QX031N in healthy participants, participants with chronic obstructive pulmonary disease (COPD) and asthma participants

Acronym
QX031N-101

Study objectives
Part A (SAD, healthy adult participants):
To evaluate the safety and tolerability of single ascending SC or intravenous (IV) administration of QX031N in healthy participants.

Part B (MAD, healthy adult participants):
To evaluate the safety and tolerability of multiple SC administrations of QX031N in healthy participants.

Part C (COPD participants) (optional):
To evaluate the safety and tolerability of multiple SC administrations of QX031N in participants with COPD.

Part D (asthma participants) (optional):
To evaluate the safety and tolerability of multiple SC administrations of QX031N in participants with asthma.

Ethics approval required

Ethics approval required

Ethics approval(s)
Approved 23/12/2025, Health and Disability Ethics Committees (Ministry of Health, 133 Molesworth Street (PO Box 5013), Wellington, 6011, New Zealand; +64 (0)800 400 569; hdecs@health.govt.nz), ref: 2025 FULL 24407

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Chronic obstructive pulmonary disease, asthma

Interventions
Part A: SAD, healthy adult participants:
Eligible healthy participants for the SAD part will be enrolled and randomized to receive a single administration (SC) of QX031N or placebo at a ratio of 3:1. Part A provisionally plans for 5 sequential escalating single SC dose cohorts and one single IV dose cohort.

Part B: MAD, healthy adult participants:
Eligible participants for the Part B MAD study will be enrolled and randomized at a ratio of 3:1 to receive multiple doses of QX031N or placebo.

Part C and D: COPD and asthma participants (optional):
Eligible participants for Parts C and D will be enrolled and randomized at a ratio of 2:1 to receive multiple subcutaneous administrations of QX031N or placebo.

Please note that the dose range, frequency and randomisation process are considered Confidential Commercial Information and cannot be disclosed.

Intervention Type
Biological/Vaccine

Phase

Phase I

Drug/device/biological/vaccine name(s)
QX031N

Primary outcome(s)
1. Nature and incidence of dose-limiting adverse events (DLAEs) measured using by the investigator on the electronic case report form (eCRF) at Day 1 up to the end of the study

2. Nature, frequency, and severity of adverse events (AEs) measured using the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) v5.0 at Day 1 up to the end of the study

3. Incidence of abnormal clinical laboratory, abnormal vital signs and ECG measured using by the investigator at Day 1 up to the end of the study

Key secondary outcome(s)

Completion date
01/12/2028

Eligibility

Key inclusion criteria
All participants:
1. Signed Informed Consent Form (ICF), and ability and willingness to comply with all aspects of the protocol according to the International Council for Harmonisation (ICH) and local regulations, including completion of procedures, interviews, questionnaires, assessments for the duration of the study.
2. Agreement to adhere to the contraception requirements described in Section 5.4.2 of the protocol.
3. Male participants weighing ≥50 kg, female participants weighing ≥45 kg, with a body mass index (BMI) between 18 and 32 kg/m2 (inclusive).
4. Healthy participants must be 18 to 65 years of age, inclusive, at the time of signing the Informed Consent Form (ICF).
5. Health status is defined by absence of evidence of any active or chronic disease following a detailed medical and surgical history, a complete physical examination including vital signs, 12-lead ECG, hematology, blood chemistry, serology, coagulation, and urinalysis.

COPD participants:
6. Between 40 and 75 years of age inclusive, at the time of signing the informed consent.
7. Confirmed diagnosis of COPD for >6 months, as defined by the GOLD guidelines.
8. Documented history of COPD with a post-bronchodilator FEV1/FVC <0.70 and a post bronchodilator FEV1 ≥50% predicted at screening.
9. Using maintenance inhaled therapy that may include inhaled corticosteroids and/or long-acting beta-agonist and/or long-acting muscarinic antagonist as separate inhaler(s) or in combination preparation(s).
10. Smoker or an ex-smoker with a smoking history of at least 10 pack years. The following equation should be used to calculate pack years: Pack years = (cigarettes smoked per day/20)* number of years of smoking

Asthma participants:
11. Between 18 and 75 years of age inclusive, at the time of signing the informed consent.
12. A physician diagnosis of asthma (mild or moderate, as defined by the Global Initiative for Asthma [GINA], 2025) at least 12 months prior to the start of the study.
13. Demonstrated post-bronchodilator reversibility of FEV1 ≥12% and ≥200 ml at Screening or at least one of the following documented historic evidence of lung function variability within 5 years prior to Screening:
13.1. Post-bronchodilator reversibility of FEV1 ≥12% and ≥200 ml
13.2. Positive response to methacholine/histamine challenge (provocative concentration causing a decrease in FEV1 by ≥20% [PC20] of <8 mg/mL)
13.3. Positive response to mannitol challenge (decrease in FEV1 by ≥15% with ≤635 mg of cumulative mannitol dosing, or a 10% decrease in FEV1 between two consecutive mannitol doses)
13.4. Positive response to hypertonic saline challenge (decrease in FEV1 by ≥15% with inhalation of a provocation dose of ≤23 g 4.5% hypertonic saline)
13.5. Positive response to exercise challenge test (decrease in FEV1 by ≥10% and ≥200 ml)
13.6. Variation of FEV1 of ≥12% and ≥ 200 mL between any two clinical visits, outside of respiratory infections
13.7. Increase in FEV1 by ≥12% and ≥200 mL from baseline after 4 weeks of ICS containing treatment, outside of respiratory infections
14. Using the following asthma therapy:
14.1. As needed only short-acting beta-agonist or as needed only inhaled corticosteroid-long acting beta-agonist combination therapy OR
14.2. Regular maintenance inhaled asthma therapy that is stable for at least 3 months prior to screening. Acceptable maintenance inhaler options include:
14.2.1. Low to medium daily dose inhaled corticosteroid (≤500 mcg of fluticasone propionate or comparable inhaled corticosteroid total daily dosage) alone or in combination with a long-acting beta-agonist
14.2.2. Low to medium daily dose inhaled corticosteroid (≤500 mcg of fluticasone propionate or comparable inhaled corticosteroid total daily dosage) in combination with a long-acting beta-agonist, plus a long-acting muscarinic antagonist given as a separate additional inhaler device or in a combination device (inhaled corticosteroid plus long-acting beta agonist plus long-acting muscarinic antagonist single inhaler) OR
14.3. Daily leukotriene receptor antagonist in combination with inhaled therapies listed above.
15. Prebronchodilator forced expiratory volume in 1 second (FEV1) ≥60% of predicted normal at screening.
16. Elevated fractional exhaled nitric oxide (FeNO) level defined as ≥25 ppb at screening.

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
18 Years

Upper age limit
75 Years

Sex

All

Total final enrolment
0

Key exclusion criteria
All Participants:
1. Pregnant, breastfeeding, or intending to become pregnant during the study or within the timeframe in which contraception is required (see Section 5.4.2 of the protocol). Participants of childbearing potential (POCBP) must have a negative blood (serum) pregnancy test result at the screening visit.
2. Those who previously received drugs targeting TSLP and IL-33.
3. Those with known diseases prior to screening, with the exception of COPD in Part C and with the exception of asthma in Part D, that are considered clinically significant or affect the study by the Investigator, including but not limited to nervous system, cardiovascular system, respiratory system, hematological system, endocrine system, urinary system, digestive system, skeletal system, metabolic, psychiatric, infectious, ophthalmic, gynecological (female participants) diseases.
4. Current or chronic history of clinically significant liver disease or known hepatic or biliary abnormalities (with the exception of Gilbert's syndrome or asymptomatic gallstones).
5. Those who have a known allergy history to drugs or other substances, or clinically significant, acute and/or uncontrolled allergic disease, and are considered by the Investigator to be at high risk if participating in this study or judged by the Investigator to be possibly allergic to the study drug or any component of the study drug.
6. Infections:
6.1. Those with known or suspected history of immunosuppression, including opportunistic infections (e.g., histoplasmosis, listeriosis, coccidioidomycosis, pneumocystis, and aspergillosis), should be excluded even if the infection has resolved;
6.2. Those with a history of recurrent severe infections and underlying conditions predisposing to infections (with the exception of COPD in part C and with the exception of asthma in Part D),
6.3. Those with a history of disseminated herpes simplex infection, or recurrent (>1 episode) or disseminated herpes zoster,
6.4. Those who have systemic acute or chronic infection requiring treatment with antibiotics, antivirals, antiparasitics, antiprotozoals, or antifungals within 4 weeks prior to screening, or herpes simplex infection within 2 weeks prior to screening, or any infections (including chronic or localized infections) within the 7 days prior to screening,
6.5. Those with parasitic infestation within 6 months prior to screening.
7. Those with autoimmune disease or using systemic immunosuppressive therapy for autoimmune disease.
8. A personal history of severe hypertension, arrhythmia, or a family history of sudden unexplained death, long QT, familial cardiac syndrome, or cardiomyopathy.
9. Those with a history of malignant neoplasm within 5 years of screening or any evidence of active malignancy, except for completely excised or treated localised carcinoma of the skin or carcinoma in situ.
10. Treatment with immunomodulatory, immunosuppressive therapy (e.g., methotrexate, leflunomide, sulfasalazine, troleandomycin, oral gold, cyclosporine, azathioprine) within 3 months or 5 drug half-lives prior to the screening visit (whichever is longer) or planned during the study.
11. Treatment with a licensed biologic agent for any indication, including COPD or asthma (e.g., omalizumab, dupilumab, tezepelumab, anti-tumor necrosis factor (TNF) therapies, and/or anti-IL-5 therapies) within 3 months or 5 drug-elimination half-lives (whichever is longer) prior to

screening or planned during the study.
12. Treatment with maintenance macrolide therapy within 4 weeks prior to the screening visit or planned during the study.
13. Initiation of a methylxanthine preparation and/ or phosphodiesterase 4 (PDE4) inhibitor within 4 weeks prior to screening or planned during the study.
14. Participant requires regular treatment with oral corticosteroids or has received a course of oral or parenteral corticosteroids within 4 weeks prior to screening.
15. Those who have participated in any clinical study of a drug or medical device within 3 months or 5 half-lives (whichever is longer) prior to screening.
16. Positive results for Hepatitis B infection, defined as meeting either of the following criteria:
16.1. Positive hepatitis B surface antigen (HBsAg) test result.
16.2. A negative HBsAg test result and a positive total hepatitis B core antibody test result in combination with quantitative hepatitis B virus (HBV) deoxyribonucleic acid (DNA) above the lower limit of quantification.
17. Positive human immunodeficiency virus (HIV) test results.
18. Positive hepatitis C antibody test result at screening, with the following exception: Participants with a positive HCV antibody test result and quantitative HCV ribonucleic acid (RNA) levels below the lower limit of quantification, confirmed by an RNA polymerase chain reaction will not be excluded provided they have completed a successful course of HCV antiviral treatment with no HCV recurrence for ≥6 months.
19. Evidence of tuberculosis infection or disease (previously known as active or latent tuberculosis) as documented by medical history and examination.
20. Clinically significant abnormalities in laboratory test results (including complete blood count, chemistry panel, liver enzymes, and urinalysis), unless the Investigator considers an abnormality to be clinically irrelevant.

Healthy Participants Only:
21. Those who have used any over-the-counter (OTC) or prescription drugs or herbal medicines (including vitamins and dietary or herbal supplements) within 7 days or 5 half-lives (whichever is longer) before the start of study treatment.
COPD Participants Only
22. Participant has poorly controlled or unstable COPD, defined as the occurrence of any of the following:
22.1. Acute worsening of COPD (an exacerbation) that is managed with oral corticosteroids and /or antibiotics within 4 weeks of screening. OR
22.2. More than two exacerbations in the previous 3 months before screening that required a course of oral corticosteroids and/or antibiotics, or one exacerbation in the prior 3 months for which the participant was hospitalized.
23. Evidence of concurrent significant pulmonary diseases, other than COPD, in the opinion of the Investigator, may compromise the safety of the participants or affect the interpretation of results

Prior/Concomitant Therapy:
24. Participant requires long-term oxygen therapy or non-invasive ventilation.

Asthma Participants Only:
25. History of life-threatening asthma (i.e., severe exacerbation that requires intubation).
26. Asthma exacerbation or use of systemic steroids within 4 weeks prior to screening visit.
27. More than two exacerbations in the previous 3 months before screening that required a course of oral corticosteroids, or one exacerbation in the prior 3 months for which the participant was hospitalized.
28. Worsening of asthma (e.g., increased use of asthma medications) or respiratory infection

within the last 4 weeks prior to the screening visit.
29. Significant pulmonary diseases, other than asthma, including (but not limited to): pneumonia previously requiring hospital admission, pulmonary fibrosis, bronchopulmonary dysplasia, chronic bronchitis, emphysema, chronic obstructive pulmonary disease, or other significant respiratory abnormalities.
30. Current smoker or cessation of smoking within the 6 months prior to the screening visit.

Date of first enrolment
26/03/2026

Date of final enrolment
01/09/2027

Locations

Countries of recruitment
New Zealand

Sponsor information

Organisation
Qyuns Therapeutics Co., Ltd

Funder(s)

Funder type

Funder Name
Qyuns Therapeutics Co., Ltd

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available