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A study to assess the safety of selnoflast in participants with chronic obstructive pulmonary disease

Submission date 26/08/2021	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 08/12/2021	**Overall study status** Stopped	[_] Statistical analysis plan [_] Results
Last Edited 04/12/2023	**Condition category** Respiratory	[_] Individual participant data [_] Record updated in last year

Plain English Summary

Background and study aims
This is a research study (also known as a clinical trial) of a drug called selnoflast. Selnoflast is being developed for the possible treatment of chronic obstructive pulmonary disease (COPD). COPD is the name for a group of lung conditions that cause breathing difficulties.

Who can participate?
Patients aged 35 and 75 years who have had COPD for at least 1 year); please refer to the inclusion criteria

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in one group will receive selnoflast and those in the other group will receive placebo capsules that look like selnoflast but do not contain active medication. All participants will receive placebo for at least 14 days during the study.

What are the possible benefits and risks of participating?
There is no guarantee that participants will receive any benefits from this study, and taking part in this study may or may not cause their health to improve. Information from this study may help doctors learn more about selnoflast and the treatment of COPD. This information may benefit other patients with COPD or a similar condition in the future. Selnoflast has been tested previously in healthy volunteers. Side effects seen were mild headache and nausea in some patients. The side effects resolved without additional treatment. The following are potential risks that may occur with selnoflast, but they have not been observed so far:
Liver toxicity (deterioration of liver function): some of the healthy volunteers who received selnoflast in a previous study showed mild increase in the laboratory parameters used to evaluate the liver function. If patients have an abnormal blood test of liver function, they will not be included in this study. Liver function will be monitored closely during the study through blood tests.
Infection: selnoflast works by inhibiting a protein complex called the NLRP3 inflammasome, which regulates the immune system. Inhibition of the immune system could result in increased

susceptibility to infections. If patients have a known active infection, they will not be included in this study. Participants will be closely monitored for infections to ensure prompt treatment is received.
Impaired response to vaccinations: the NLRP3 inflammasome is activated by many vaccines and it ensures an adequate immune response to vaccination. Therefore, inhibition of the inflammasome may impair the response to vaccination. If participants require a vaccination, these should be completed at least 4 weeks prior to the first dose of study treatment. If participants plan to be vaccinated shortly after completing this study, they should discuss this with the study doctor.

Where is the study run from?
F. Hoffmann-La Roche Ltd (Switzerland)

When is the study starting and how long is it expected to run for?
June 2021 to March 2024

Who is funding the study?
F. Hoffmann-La Roche Ltd (Switzerland)

Who is the main contact?
global-roche-genentech-trials@gene.com

Study website
https://forpatients.roche.com/en/trials/respiratory-disorder/copd/a-study-to-assess-the-safety-of-ro7486967-in-patients-with-chron.html

Contact information

Type(s)
Public

Contact name
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global-roche-genentech-trials@gene.com

Additional identifiers

EudraCT/CTIS number
2021-000558-25

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
BP43098, CPMS 50074

Study information

Scientific Title
Phase Ib, randomized, double-blind, placebo-controlled, parallel-group study to assess the safety of selnoflast in participants with chronic obstructive pulmonary disease

Study hypothesis
The aim is to assess the safety profile of selnoflast compared with that of placebo.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. UK: Approval pending, East of Scotland Research Ethics Service (Ninewells Hospital & Medical School, Tayside Medical Science Centre (TASC), Residency Block, Level 3, George Pirie Way, Dundee, DD1 9SY, UK; +44 (0)1382 383871; tay.eosres@nhs.scot)
2. Germany: Approval pending, Ethik-Kommission der Landesaerztekammer Hessen (Hanauer Landstraße 152, 60314 Frankfurt am Main, Germany; no telephone number provided; no email provided)
3. USA: Approved 08/07/2021, Advarra (6100 Merriweather Dr., Suite 600, Columbia, MD 21044, USA; +1 (0)410 884 2900, +1 (0)443 283 1522, +1 (0)206 902 3325; rebecca.fisher@advarra.com, andy.basinger@advarra.com)
4. Israel: Approved 17/10/2021, Ethics Helsinki Committee of Barzilai Medical Center (2 Hahistadrout St., Ashkelon, 7830604, Israel; +972 (0)8 6746369, +972 (0)6745550; kerena@bmc.gov.ilmalkam@bmc.gov.il)

Study design
Phase Ib randomized double-blind placebo-controlled parallel-group clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not applicable

Condition

Chronic obstructive pulmonary disease

Interventions
All participants will be centrally assigned to randomized study treatment using an IxRS system. Randomization will be stratified by smoking status (current/former) to obtain an approximately 1:1 ratio between the two treatment arms within each stratum.

Selnoflast: 200 mg by mouth on Days 7, 14, 21, and 28
Placebo: N/A dosage by mouth on Days 7, 14, 21, and 28

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
Selnoflast (RO7486967)

Primary outcome measure
1. Incidence and severity of adverse events (AEs) and serious AEs (SAEs) determined according to National Cancer Institute Common Terminology Criteria for Adverse Events version 5.0 (NCI CTCAE v5.0) and causal relationship of AEs, incidence of SAEs and AEs leading to treatment discontinuation, recorded throughout the study up to 12 weeks
2. Incidence of abnormal laboratory findings
3. Incidence of abnormal vital signs and electrocardiogram (ECG) parameters
Timepoint(s) for 1-3: up to 12 weeks

Secondary outcome measures
1. Pre-bronchodilator (pre-BD) forced expiratory volume in 1 second (FEV1), measured by spirometry
2. Post-bronchodilator (post-BD) FEV1 measured by spirometry
3. Pre-BD FEV1 percentage of predicted measured by spirometry
4. Post-BD FEV1 percentage of predicted measured by spirometry
5. Pre-BD total lung capacity (TLC) measured by body plethysmography
6. Pre-BD residual volume (RV) measured by body plethysmography
7. Pre-BD functional residual capacity (FRC) measured by body plethysmography
8. RV/TLC ratio measured by body plethysmography
9. Pre-BD forced expiratory flow over the middle one half of the FVC (FEF25-75) measured by spirometry
10. Post-BD FEF25-75 measured by spirometry
11. Pharmacokinetic (PK) parameters of selnoflast in blood by PK population analysis

Timepoints for 1-10: Screening (Day-42 to Day -15), Day -14, Day 1, Day 14, Day 28, Day 42, at unscheduled visit, at early termination visit
Timepoints for 11: Day 1, Day 7, Day 14, Day 21, Day 28, at unscheduled visit

Overall study start date
04/06/2021

Overall study end date

22/06/2022

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Participant inclusion criteria
Current inclusion criteria as of 14/06/2022:
1. Between 35 and 75 years of age (inclusive)
2. Participants with >=12-month diagnosis of COPD
3. Radiologic evidence of air trapping at screening based on chest HRCT conducted per imaging acquisition protocol and reviewed by the imaging central reader
4. Extent of emphysema on HRCT at screening is < 25%
5. GOLD 2020 Grade 2/3, characterized by a post-bronchodilator forced expiratory volume in 1 second (FEV1)/ forced vital capacity (FVC) ratio <= 0.70 and a post-bronchodilator FEV1 of >=30% and =< 79% of predicted at screening and with an exacerbation history >= 2 or >= 1 leading to hospitalization within the last 12 months
6. COPD assessment test (CAT) score >=10 and with a clinical diagnosis of chronic bronchitis, characterized by cough and sputum production on most days for a minimum of 3 months during the last year
7. Participant must have a body mass index (BMI) between 18 and 35 kg/m²
8. Abnormal laboratory values high sensitivity CRP (hs-CRP) >= 3 mg/L at screening and absolute neutrophil count >= 6.0 x 109/L in whole blood at screening
9. Vital signs (body temperature, systolic and diastolic blood pressure, pulse rate, and respiratory rate) will be assessed in the sitting position after the subject has rested for at least 3 minutes
10. Unchanged standard regimen of care for >= 4 weeks prior to screening
11. Ex-smokers with at least a 10-pack year smoking history or current smokers with at least a 10 pack-year smoking history who smoke =< 1 pack-year on average in the last 3 months as reported at screening
12. Able to perform reliable, reproducible pulmonary function test maneuvers per American Thoracic Society (ATS)/European Respiratory Society (ERS) guidelines
13. Female participants: a female participant is eligible to participate if she is not pregnant, not breastfeeding, and at least one of the following conditions applies: women of non-childbearing potential or women of childbearing potential who agree to remain abstinent or use at least acceptable contraceptive methods during the treatment period and for at least 14 days after the final dose of selnoflast /placebo
14. Male participants: No contraception required for male participants

Previous inclusion criteria:
1. Between 35 and 75 years of age (inclusive)
2. Patients with >=12-month diagnosis of COPD
3. Radiologic evidence of air trapping at screening based on chest HRCT conducted per imaging acquisition protocol and reviewed by the imaging central reader
4. Extent of emphysema on HRCT at baseline is < 25%
5. GOLD 2020 Grade 2/3, characterized by a post-bronchodilator forced expiratory volume in 1 second (FEV1)/ forced vital capacity (FVC) ratio <= 0.70 and a post-bronchodilator FEV1 of >= 30% and =< 79% of predicted at screening and with an exacerbation history >= 2 or >= 1 leading to hospitalization within the last 12 months
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14. Male participants: No contraception required for male participants

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
106

Total final enrolment
1

Participant exclusion criteria
Current exclusion criteria as of 14/06/2022:
1. Any condition or disease detected during the medical interview/physical examination that would render the patient unsuitable for the study, place the patient at undue risk, or interfere with the ability of the patient to complete the study
2. Known active or uncontrolled bacterial, viral, fungal, mycobacterial, or other infection, excluding fungal infection of nail beds, including participants exhibiting symptoms consistent with SARS-CoV-2 within 2 weeks prior to screening
3. Positive polymerase chain reaction (PCR) test for SARS-CoV-2 within 6 weeks prior to Day 1
4. Diagnosis of severe bronchiectasis in chart or history
5. Participants with another concomitant pulmonary disease, including but not exclusive of, interstitial pulmonary fibrosis, sarcoidosis, or other granulomatous or infectious process
6. Participants treated for active asthma within 2 years prior to the screening visit
7. Any COPD exacerbation or upper or lower respiratory tract infection requiring antibiotics, oral steroids, or hospitalization within 2 weeks prior to screening, during the screening period, or during the run-in period

8. Participants requiring long-term oxygen therapy for daytime hypoxemia
9. Participants with a diagnosis of alpha-1 antitrypsin deficiency
10. History of lung transplant or malignancy of any organ system (other than localized basal cell carcinoma of the skin) within the past 5 years
11. Any surgical or medical condition which might significantly alter the absorption, distribution, metabolism, or excretion of drugs, or which may jeopardize the subject in case of participation in the study
12. History of clinically significant ECG abnormalities, or ECG abnormalities at screening
13. Known family history or known presence of long QT syndrome
14. Participant with a history of acute coronary syndrome in 3 months prior to the screening visit
15. Participants with a history of coronary artery bypass surgery or other major vascular surgery within 6 months prior to the screening visit
16. Evidence of urinary obstruction or difficulty in voiding
17. History of any clinically significant hepatic disease or cirrhosis
18. Significant illness not resolved within 2 weeks prior to screening
19. Use of systemic steroids, ICS, theophylline, and phosphodiesterase 4 (PDE4) inhibitors within 4 weeks of screening
20. Vaccines within 4 weeks prior to the first dose
21. Current treatment with medications that are well known to prolong the QT interval
22. Donation or loss of 450 mL or more of blood within 8 weeks prior to initial dosing, or longer if required by local regulation
23. Plasma donation > 150 mL within 7 days prior to first dosing
24. Use of other investigational drugs at the time of enrollment, or within 5 half-lives of enrollment, or within 30 days, whichever is longer; or longer if required by local regulations
25. History of hypersensitivity to the study drugs or to drugs of similar chemical classes or excipients
26. QTcF > 450 ms in male participants and > 470 ms in female participants
27. Liver function test abnormalities at screening. Re-testing during the screening period is possible once. This laboratory assessment may be repeated once during the screening period, if necessary
28. Anemia (hemoglobin levels >10.0 g/dl at screening). This laboratory assessment may be repeated once during the screening period, if necessary
29. Clinical evidence of impaired renal function as indicated by clinically significantly abnormal creatinine or BUN and/or urea values, or abnormal urinary constituents (e.g., albuminuria) at screening. This laboratory assessment may be repeated once during the screening period, if necessary
30. History of immunodeficiency diseases, including a positive HIV (ELISA and Western blot) test result
31. Presence of hepatitis B surface antigen (HBsAg) or positive for total hepatitis B core antibody (HBcAb), or positive hepatitis C by PCR test result at screening or within 3 months prior to starting study treatment
32. History of tuberculosis or a positive Quantiferon Gold test
33. Participants with a known history of noncompliance to medication, or who are unable or unwilling to complete an electronic patient diary (medication adherence platform), or who are unable to demonstrate good medication compliance during the run-in period
34. Inability to comply with all study requirements and demonstrate good medication compliance during the treatment run-in period
35. Participants with any medical or psychological condition that renders the patient unable to understand the nature, scope, and possible consequences of the study
36. Participants with a history of being unable to swallow size 0 capsules
37. History of drug or alcohol abuse within the 12 months prior to dosing, or evidence of such abuse as indicated by the laboratory assays conducted during screening

38. Clinically significant history of psychiatric disorders that preclude understanding or compliance with the protocol
39. Recent (within the last 3 years) and/or recurrent history of autonomic dysfunction

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26. QTcF > 450 ms in male participants and > 470 ms in female participants demonstrated by at least two ECGs >30 minutes apart
27. Liver function test abnormalities at screening. Re-testing during the screening period is possible once.
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38. Clinically significant history of psychiatric disorders that preclude understanding or compliance with the protocol
39. Recent (within the last 3 years) and/or recurrent history of autonomic dysfunction

Recruitment start date
25/04/2022

Recruitment end date
25/04/2022

Locations

Countries of recruitment
Germany

Israel

Netherlands

Spain

United Kingdom

United States of America

Study participating centre
IKF Pneumologie
Frankfurt am Main
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Study participating centre
Hadassah Medical Center - PPDS
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Israel
91031

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Study participating centre

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Study participating centre
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Germany
83022

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9713

Study participating centre
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AK Dordrecht
Netherlands
3300

Study participating centre

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Madrid
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28223

Study participating centre
Hospital Universitario Virgen de Las Nieves
Granada
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18012

Study participating centre
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B15 2GW

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77429-4696

Study participating centre

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34748-5077

Study participating centre
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United States of America
16602

Study participating centre
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Gastonia, NC
United States of America
28054

Study participating centre
Lundquist Institute for Biomedical Innovation at Harbor-UCLA Medical Center
Torrance, CA
United States of America
90502

Study participating centre
Clinical Research of Rock Hill
Rock Hill, SC
United States of America
29732

Study participating centre
U Health Ball Memorial Physicians Pulmonary & Critical Care Medicine
Muncie, IN
United States of America
47303

Study participating centre
Velocity Clinical Research - Union - ERN - PPDS
Union, SC

United States of America
29379

Study participating centre
Indiana University School of Medicine - Indianapolis
Indianapolis, IN
United States of America
46202

Study participating centre
Hannibal Clinic
Hannibal, MO
United States of America
63401

Study participating centre
North Florida Foundation For Research and Education, Inc.
Florida
United States of America
32608

Study participating centre
Temple Lung Center, Temple University of the Commonwealth System of Higher Education
Philadelphia, PA
United States of America
19140

Study participating centre
University of Cincinnati / University of Cincinnati College of Medicine
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Sponsor information

Organisation
Roche (Switzerland)

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Sponsor type
Industry

Website
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ROR
https://ror.org/00by1q217

Funder(s)

Funder type
Industry

Funder Name
F. Hoffmann-La Roche

Alternative Name(s)
Hoffman-La Roche, F. Hoffmann-La Roche Ltd.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Switzerland

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
29/03/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to participant-level data not being a regulatory requirement for Phase I studies.

IPD sharing plan summary

Not expected to be made available