Clinical Trial Results:
A Phase Ib, Multicenter, Randomized, Placebo-controlled, Double-blind Study to Evaluate the Safety, Pharmacokinetics and Pharmacodynamics of Selnoflast in Participants With Moderate to Severe Asthma

Summary	
EudraCT number	0000-000000-00
Global end of trial date	13 Nov 2025

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Trial information

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Trial identification	
Sponsor protocol code	BP44551
Additional study identifiers	
ISRCTN number	-
US NCT number	-
WHO universal trial number (UTN)	-
Sponsors	
Sponsor organisation name	F. Hoffmann-La Roche AG
Sponsor organisation address	Grenzacherstrasse, 124, Basel, Switzerland, CH-4058
Public contact	F. Hoffmann-La Roche AG, F. Hoffmann-La Roche AG, +41 616878333, global.trial_information@roche.com
Scientific contact	F. Hoffmann-La Roche AG, F. Hoffmann-La Roche AG, +41 616878333, global.trial_information@roche.com
Paediatric regulatory details	
Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Results analysis stage	
Analysis stage	Final
Date of interim/final analysis	26 Feb 2026
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	13 Nov 2025
Was the trial ended prematurely?	No
General information about the trial	
Main objective of the trial	The main purpose of the study was to evaluate the safety of selnoflast as compared with placebo in subjects with moderate to severe asthma on top of non-biologic standard of care (SOC).

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Protection of trial subjects	All study subjects were required to read and sign an Informed Consent Form (ICF).
Background therapy	-
Evidence for comparator	-
Actual start date of recruitment	20 Mar 2024
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No
Population of trial subjects	
Number of subjects enrolled per country	
Country: Number of subjects enrolled	Belgium: 5
Country: Number of subjects enrolled	Canada: 17
Country: Number of subjects enrolled	Germany: 18
Country: Number of subjects enrolled	United Kingdom: 42
Country: Number of subjects enrolled	Netherlands: 4
Worldwide total number of subjects	86
EEA total number of subjects	27
Number of subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	67
From 65 to 84 years	19
85 years and over	0

Subject Disposition

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Recruitment	
Recruitment details	A total of 86 subjects with moderate to severe asthma on top of non-biologic SOC took part in the placebo run-in period, of which 60 continued to the double-blind treatment (DBT) period. The study was conducted at 21 investigative sites across 5 countries from 20 March 2024 to 13 November 2025.
Pre-assignment	
Screening details	Subjects were enrolled to a 2-week, single-blind placebo run-in to receive placebo. Eligible subjects were then randomized in a 1:1 ratio to receive either placebo or selnoflast during the DBT period, after which they entered safety follow-up (SFU).
Period 1	

Subject Disposition

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Period 1 title	Placebo Run-in Period
Is this the baseline period?	No
Allocation method	Non-Randomised-Controlled
Blinded?	true
Blinding used	Single-blind
Roles blinded	Subject
Arms	
Are arms mutually exclusive	Yes
Arm title	Placebo Run-in
Arm description	Subjects received selnoflast-matching placebo for 2 weeks during the placebo run-in period, as specified in the protocol. Subjects who completed the placebo run-in period and met the required eligibility criteria were randomized to receive either selnoflast or placebo in the DBT period.
Arm type	Experimental
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details	Selnoflast-matching placebo was administered for 2 weeks during the placebo run-in period, as specified in the protocol.
Number of subjects in period 1	Placebo Run-in
Started	86
Completed	60
Not completed	26
Failure to Meet Randomization Criteria	23
Interactive Voice/Web Response System (IxRS) Issue	2
Withdrawal by Subject	1
Period 2	
Period 2 title	DBT Period
Is this the baseline period?	Yes
Allocation method	Randomised-Controlled
Blinded?	true
Blinding used	Double-blind
Roles blinded	Subject, Investigator, Carer
Arms	
Are arms mutually exclusive	Yes

Subject Disposition

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Arm title	DBT: Placebo	
Arm description	Subjects received selnoflast-matching placebo for 4 weeks during the DBT period, as specified in the protocol.	
Arm type	Placebo	
Investigational medicinal product name	Placebo	
Investigational medicinal product code		
Other name		
Pharmaceutical forms	Capsule	
Routes of administration	Oral use	
Dosage and administration details	Selnoflast-matching placebo was administered for 4 weeks during the DBT period, as specified in the protocol.	
Arm title	DBT: Selnoflast	
Arm description	Subjects received selnoflast for 4 weeks during the DBT period, as specified in the protocol.	
Arm type	Experimental	
Investigational medicinal product name	Selnoflast	
Investigational medicinal product code	RO7486967	
Other name		
Pharmaceutical forms	Capsule	
Routes of administration	Oral use	
Dosage and administration details	Selnoflast was administered for 4 weeks during the DBT period, as specified in the protocol.	
Number of subjects in period 2	DBT: Placebo	DBT: Selnoflast
Started	30	30
Completed	29	29
Not completed	1	1
Withdrawal by Subject	1	-
Physician Decision	-	1

Baseline Characteristics

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How are baseline characteristics being reported?	Per Arm in the baseline period
Baseline characteristics reporting groups	
Reporting group title	DBT: Placebo
Reporting group description	Subjects received selnoflast-matching placebo for 4 weeks during the DBT period, as specified in the protocol.
Reporting group title	DBT: Selnoflast
Reporting group description	Subjects received selnoflast for 4 weeks during the DBT period, as specified in the protocol.

Baseline Characteristics

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Reporting group values	DBT: Placebo	DBT: Selnoflast	Total
Number of subjects	30	30	60
Age categorical			
Units: subjects			
Age continuous			
Units: years			
Arithmetic Mean (Standard Deviation)	45.9 ± 15.7	55.5 ± 13.6	-
Sex: Female, Male			
Units: subjects			
Female	13	13	26
Male	17	17	34

End points

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End points reporting groups	
Reporting group title	Placebo Run-in
Reporting group description	Subjects received selnoflast-matching placebo for 2 weeks during the placebo run-in period, as specified in the protocol. Subjects who completed the placebo run-in period and met the required eligibility criteria were randomized to receive either selnoflast or placebo in the DBT period.
Reporting group title	DBT: Placebo
Reporting group description	Subjects received selnoflast-matching placebo for 4 weeks during the DBT period, as specified in the protocol.
Reporting group title	DBT: Selnoflast
Reporting group description	Subjects received selnoflast for 4 weeks during the DBT period, as specified in the protocol.

Primary: DBT: Number of Subjects With AEs

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End point title	DBT: Number of Subjects With AEs
End point description	An AE was defined as any untoward medical occurrence in a subject or clinical investigation subject administered a pharmaceutical product, and that does not necessarily have to have a causal relationship with the treatment. An AE was therefore any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. Safety-evaluable (SE) population included all randomized subjects who received at least one dose of randomized study treatment.
End point type	Primary
End point timeframe	Up to 6 weeks
Countable or measurable?	Countable

	DBT Period	DBT Period
End point values	DBT: Placebo	DBT: Selnoflast
Number of subjects analysed	30	30
Units: subjects	16	19

Primary: DBT: Number of Subjects With AEs	Top of page
No statistical analyses for this end point	

Secondary: DBT: Plasma Trough Concentration (Ctrough) of Selnoflast	Top of page
End point title	DBT: Plasma Trough Concentration (Ctrough) of Selnoflast
End point description	Pharmacokinetic (PK) analysis set included all subjects who received at least one dose of study treatment and had data from at least one post-dose sample. n=number of subjects with data available for analysis at specified timepoints.
End point type	Secondary
End point timeframe	Days 8, 15, 22, and 29
Countable or measurable?	Measurable

	DBT Period
End point values	DBT: Selnoflast
Number of subjects analysed	30
Units: nanograms per milliliter (ng/mL)	
Measure Type: Geometric Mean (Geometric Coefficient of Variation)	
Day 8 (n=29)	5280 ± 38.4
Day 15 (n=30)	5290 ± 47.5
Day 22 (n=29)	5340 ± 58.9
Day 29 (n=29)	4130 ± 96.5
No statistical analyses for this end point	

Secondary: DBT: Change From Baseline in High-sensitivity C-reactive Protein (hs-CRP) to Week 4	Top of page
End point title	DBT: Change From Baseline in High-sensitivity C-reactive Protein (hs-CRP) to Week 4
End point description	hs-CRP is a biomarker of systemic inflammation. Levels of hs-CRP were measured in blood using validated immunoassays at central laboratories. Full analysis set (FAS) included all randomized subjects who received at least one dose of randomized study treatment. n=number of subjects with data available for analysis at specified timepoints.
End point type	Secondary
End point timeframe	Baseline, Days 8, 15, 22, 29, and 43 (Follow-up)
Countable or measurable?	Measurable

	DBT Period	DBT Period
End point values	DBT: Placebo	DBT: Selnoflast
Number of subjects analysed	30	30
Units: milligrams per liter (mg/L)		
Measure Type: Geometric Mean (Geometric Coefficient of Variation)		
Baseline (n=30,30)	2.27 ± 128.41	2.06 ± 96.01
Change on Day 8 (n=29,29)	0.93 ± 134.40	0.44 ± 114.89
Change on Day 15 (n=30,30)	0.95 ± 165.56	0.58 ± 151.70
Change on Day 22 (n=30,29)	0.75 ± 126.15	0.52 ± 134.49

Secondary: DBT: Change From Baseline in High-sensitivity C-reactive Protein (hs-CRP) to Week 4 Top of page		
Change on Day 29 (n=30,29)	1.04 ± 153.97	0.44 ± 128.00
Change on Day 43 Follow-up (n=29,29)	0.94 ± 75.01	0.86 ± 80.92
No statistical analyses for this end point		

Adverse events

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Adverse events information	
Timeframe for reporting adverse events	Run-in period: up to 2 weeks; DBT period: up to 6 weeks
Adverse event reporting additional description	SE population included all randomized subjects who received at least one dose of randomized study treatment. Placebo run-in analysis set included all subjects enrolled in the study who received at least one dose of the single-blind placebo run-in study medication, whether they were randomized to study treatment following the run-in period or not.
Assessment type	Systematic
Dictionary used for adverse event reporting	
Dictionary name	MedDRA
Dictionary version	28.0
Reporting groups	
Reporting group title	DBT: Placebo
Reporting group description	Subjects received selnoflast-matching placebo for 4 weeks during the DBT period, as specified in the protocol.
Reporting group title	DBT: Selnoflast
Reporting group description	Subjects received selnoflast for 4 weeks during the DBT period, as specified in the protocol.
Reporting group title	Placebo Run-in
Reporting group description	Subjects received selnoflast-matching placebo for 2 weeks during the placebo run-in period, as specified in the protocol. Subjects who completed the placebo run-in period and met the required eligibility criteria were randomized to receive either selnoflast or placebo in the DBT period.

Serious adverse events	DBT: Placebo	DBT: Selnoflast	Placebo Run-in
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 86 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Frequency threshold for reporting non-serious adverse events: 5%			
Non-serious adverse events	DBT: Placebo	DBT: Selnoflast	Placebo Run-in
Total subjects affected by non serious adverse events			
subjects affected / exposed	9 / 30 (30.00%)	9 / 30 (30.00%)	0 / 86 (0.00%)
Gastrointestinal disorders			
Dyspepsia			

subjects affected / exposed	0 / 30 (0.00%)	2 / 30 (6.67%)	0 / 86 (0.00%)
occurrences all number	0	2	0
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	0 / 30 (0.00%)	2 / 30 (6.67%)	0 / 86 (0.00%)
occurrences all number	0	2	0
Infective exacerbation of asthma			
subjects affected / exposed	0 / 30 (0.00%)	2 / 30 (6.67%)	0 / 86 (0.00%)
occurrences all number	0	2	0
Nervous system disorders			
Headache			
subjects affected / exposed	3 / 30 (10.00%)	0 / 30 (0.00%)	0 / 86 (0.00%)
occurrences all number	3	0	0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	3 / 30 (10.00%)	0 / 30 (0.00%)	0 / 86 (0.00%)
occurrences all number	3	0	0
Cough			
subjects affected / exposed	1 / 30 (3.33%)	2 / 30 (6.67%)	0 / 86 (0.00%)
occurrences all number	1	2	0
Asthma			
subjects affected / exposed	2 / 30 (6.67%)	2 / 30 (6.67%)	0 / 86 (0.00%)
occurrences all number	2	2	0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	2 / 30 (6.67%)	0 / 30 (0.00%)	0 / 86 (0.00%)
occurrences all number	2	0	0

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Substantial protocol amendments (globally)	
Were there any global substantial amendments to the protocol? Yes	
Date	**Amendment**
06 May 2024	The following major changes were made to the protocol: Inclusion criteria were amended -to lower the threshold for hs-CRP to 1 mg/L at screening, to remove inclusion criterion "Ability to provide an adequate sputum sample at the run-in visit", and to remove inclusion criteria for Asthma Control Questionnaire, 5-item version (ACQ-5) and forced expiratory volume in 1 second (FEV1) at the randomization visit; Exclusion criteria were updated- to clarify that subjects will be excluded from the study if they had a respiratory infection or other infection within 2 weeks prior to screening or during the screening period, and to clarify that treatment with oral (PO), intravenous (IV), or intramuscular (IM) corticosteroids within 4 weeks prior to screening was prohibited; Investigational medicinal product (IMP) and Non-investigational medicinal product (NIMP) designations were updated to clarify that hypertonic saline was an unauthorized auxiliary medicinal product/not approved non-investigational product.
Interruptions (globally)	
Were there any global interruptions to the trial? No	
Limitations and caveats	

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Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.
None reported

Legend: Fields that do not appear on EU Clinical Trials Register