



Clinical trial results:

A randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of dupilumab in patients with uncontrolled, chronic rhinosinusitis without nasal polyposis (CRSsNP)

Summary

EudraCT number	2020-003117-35
Trial protocol	BE PT SE HU PL
Global end of trial date	29 January 2024

Results information

Result version number	v1 (current)
This version publication date	05 January 2025
First version publication date	05 January 2025

Trial information

Trial identification

Sponsor protocol code	EFC16723
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04678856
WHO universal trial number (UTN)	U1111-1246-7522

Notes:

Sponsors

Sponsor organisation name	Sanofi aventis recherche & développement
Sponsor organisation address	82 Avenue Raspail, Gentilly, France, 94250
Public contact	Trial Transparency Team, Sanofi aventis recherche & développement, Contact-US@sanofi.com
Scientific contact	Trial Transparency Team, Sanofi aventis recherche & développement, Contact-US@sanofi.com

Notes:

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	12 March 2024
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	29 January 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the efficacy of dupilumab as assessed by the reduction at Week 24 in sinus opacification on computerized tomography (CT) scan in the dupilumab group only.

Protection of trial subjects:

Participants were fully informed of all pertinent aspects of clinical trial as well as the possibility to discontinue at any time in language and terms appropriate for the participant and considering the local culture. During the course of the trial, participants were provided with individual participant cards indicating the nature of the trial the participant is participating, contact details and any information needed in the event of a medical emergency. Collected personal data and human biological samples were processed in compliance with the Sanofi-Aventis Group Personal Data Protection Charter ensuring that the Group abides by the laws governing personal data protection in force in all countries in which it operates.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 December 2020
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 2
Country: Number of subjects enrolled	Belgium: 2
Country: Number of subjects enrolled	Canada: 12
Country: Number of subjects enrolled	Chile: 5
Country: Number of subjects enrolled	China: 7
Country: Number of subjects enrolled	Hungary: 4
Country: Number of subjects enrolled	Korea, Republic of: 1
Country: Number of subjects enrolled	Portugal: 13
Country: Number of subjects enrolled	Russian Federation: 8
Country: Number of subjects enrolled	Spain: 5
Country: Number of subjects enrolled	Sweden: 1
Country: Number of subjects enrolled	Ukraine: 7
Country: Number of subjects enrolled	United States: 4
Worldwide total number of subjects	71
EEA total number of subjects	25

Notes:

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)	57
From 65 to 84 years	14
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was conducted at 57 centers in 13 countries. A total of 269 participants were screened between 02 December 2020 to 26 April 2023, of which 198 participants were screen failures. Screen failures were mainly due to not meeting the eligibility criteria.

Pre-assignment

Screening details:

A total of 71 participants were randomized in a ratio of 1:1 to receive dupilumab or matching placebo. Randomization was stratified by screening blood eosinophil count (≥ 300 cells per cubic millimeter [$/\text{mm}^3$] or < 300 cells/ mm^3), background intranasal corticosteroids (INCS) use (yes or no), and region.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Participants received matching placebo via subcutaneous (SC) injection every 2 weeks (q2w) for up to 53.2 weeks.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Placebo matched to dupilumab was available as pre-filled syringe and was administered as a SC injection q2w.

Arm title	Dupilumab 300 mg q2w
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Arm description:

Participants received dupilumab 300 milligrams (mg) via SC injection q2w for up to 53.1 weeks.

Arm type	Experimental
Investigational medicinal product name	SAR231893, Dupixent, REGN668
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Dupilumab was available as pre-filled syringe and was administered as a SC injection q2w.

Number of subjects in period 1	Placebo	Dupilumab 300 mg q2w
Started	33	38
Completed	25	37
Not completed	8	1
Consent withdrawn by subject	5	1
Not related to Coronavirus Disease- 2019 (COVID-19)	3	-

Baseline characteristics

Reporting groups

Reporting group title	Placebo
Reporting group description:	
Participants received matching placebo via subcutaneous (SC) injection every 2 weeks (q2w) for up to 53.2 weeks.	
Reporting group title	Dupilumab 300 mg q2w
Reporting group description:	
Participants received dupilumab 300 milligrams (mg) via SC injection q2w for up to 53.1 weeks.	

Reporting group values	Placebo	Dupilumab 300 mg q2w	Total
Number of subjects	33	38	71
Age categorical			
Units: Subjects			
Adults (18-64 years)	24	33	57
From 65-84 years	9	5	14
Age Continuous			
Units: Years			
arithmetic mean	47.45	46.45	
standard deviation	± 17.46	± 12.60	-
Sex: Female, Male			
Units: Participants			
Female	16	25	41
Male	17	13	30
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	3	5	8
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	1	1
White	30	31	61
More than one race	0	0	0
Unknown or Not Reported	0	1	1
Lund-Mackay (LMK) Score			
Units: Score on a scale			
arithmetic mean	11.50	11.41	
standard deviation	± 3.19	± 3.69	-

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description: Participants received matching placebo via subcutaneous (SC) injection every 2 weeks (q2w) for up to 53.2 weeks.	
Reporting group title	Dupilumab 300 mg q2w
Reporting group description: Participants received dupilumab 300 milligrams (mg) via SC injection q2w for up to 53.1 weeks.	
Subject analysis set title	Placebo
Subject analysis set type	Intention-to-treat
Subject analysis set description: Participants received matching placebo via SC injection q2w for up to 53.2 weeks (Intent-to-treat [ITT] population with screening blood eosinophil count ≥ 300 cells/mm ³).	
Subject analysis set title	Dupilumab 300 mg q2w
Subject analysis set type	Intention-to-treat
Subject analysis set description: Participants received dupilumab 300 mg via SC injection q2w for up to 53.1 weeks (ITT population with screening blood eosinophil count ≥ 300 cells/mm ³).	

Primary: Change From Baseline to Week 24 in Opacification of Sinuses Assessed by Computed Tomography (CT) Scan Using the Lund Mackay (LMK) Score in Dupilumab Group

End point title	Change From Baseline to Week 24 in Opacification of Sinuses Assessed by Computed Tomography (CT) Scan Using the Lund Mackay (LMK) Score in Dupilumab Group ^[1]
End point description: The CT scan LMK staging system represented most widely established method of sinus CT scoring. LMK total score is based on assessment of CT scan findings for each sinus area(maxillary, anterior ethmoid, posterior ethmoid, sphenoid, and frontal sinus on each side).Extent of mucosal opacification is rated on a 3-point scale ranging from 0=normal to 2=total opacification. In addition,ostioameatal complex is graded as 0=not occluded or 2=occluded.The maximum score is therefore 12 per side; total score ranges=0 (normal) to 24 (more opacified),corresponding to the sum of all sinuses and the ostioameatal unit. Higher score=worse outcome.Baseline=last available value up to randomization date and prior to first dose of study medication.ITT population with screening blood eosinophil count ≥ 300 cells/mm ³ =all randomized participants with screening blood eosinophil count ≥ 300 cells/mm ³ analyzed according to treatment group allocated by randomization regardless if treatment kit was used or not.	
End point type	Primary
End point timeframe: Baseline (Day 1) and Week 24	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: As the endpoint was descriptive in nature, no statistical analysis was reported.

End point values	Dupilumab 300 mg q2w			
Subject group type	Subject analysis set			
Number of subjects analysed	16			
Units: Score on a scale				
arithmetic mean (standard deviation)	-6.63 (\pm 3.91)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline to Week 24 in Opacification of Sinuses Assessed by CT Scan Using the LMK Score

End point title	Change From Baseline to Week 24 in Opacification of Sinuses Assessed by CT Scan Using the LMK Score
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End point description:

LMK total score is based on assessment of CT scan findings for each sinus area (maxillary, anterior ethmoid, posterior ethmoid, sphenoid, and frontal sinus on each side). Extent of mucosal opacification is rated on a 3-point scale ranging from 0 = normal to 2 = total opacification. In addition, the ostiomeatal complex is graded as 0 = not occluded or 2 = occluded. Maximum score is therefore 12 per side; total score ranges from 0 (normal) to 24 (more opacified), corresponding to sum of all sinuses and the ostiomeatal unit. Higher score=worse outcome. Baseline=last available value up to randomization date and prior to the first dose of study medication. ITT population with screening blood eosinophil count ≥ 300 cells/mm³ included all randomized participants with screening blood eosinophil count ≥ 300 cells/mm³ analyzed according to treatment group allocated by randomization regardless if treatment kit was used or not. Only those participants with data collected at Week 24 are reported.

End point type	Secondary
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End point timeframe:

Baseline (Day 1) and Week 24

End point values	Placebo	Dupilumab 300 mg q2w		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	14	16		
Units: Score on a scale				
arithmetic mean (standard deviation)	-0.68 (± 2.26)	-6.63 (± 3.91)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline to Week 24 in Sinus Total Symptom Score (sTSS)

End point title	Change From Baseline to Week 24 in Sinus Total Symptom Score (sTSS)
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End point description:

The sTSS is a composite score derived from the following individual items: nasal congestion (NC), anterior/posterior rhinorrhea, and facial pain/pressure. Each of the individual items were scored from 0 (no symptoms) to 3 (severe symptoms). The total score ranges from 0 to 9 and consists of the sum of NC, the averaged rhinorrhea item scores, and facial pain/pressure scores. Higher scores on sTSS indicated greater overall symptom severity. Baseline was defined as the last available value up to randomization date and prior to the first dose of study medication. ITT population with screening blood eosinophil count ≥ 300 cells/mm³ included all randomized participants with screening blood eosinophil

count ≥ 300 cells/mm³ analyzed according to the treatment group allocated by randomization regardless if treatment kit was used or not. Only those participants with data collected at Week 24 are reported.

End point type	Secondary
End point timeframe:	
Baseline (Day 1) and Week 24	

End point values	Placebo	Dupilumab 300 mg q2w		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	14	16		
Units: Score on a scale				
arithmetic mean (standard deviation)	-1.75 (\pm 2.19)	-3.18 (\pm 2.68)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Treatment-Emergent Adverse Events (TEAEs), Treatment-Emergent Serious AEs (TESAEs), and TEAEs Leading to Treatment Discontinuation

End point title	Number of Participants with Treatment-Emergent Adverse Events (TEAEs), Treatment-Emergent Serious AEs (TESAEs), and TEAEs Leading to Treatment Discontinuation
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End point description:

An AE was any untoward medical occurrence in a participant or clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. TEAEs were AEs that developed, worsened or became serious during the treatment-emergent period. A SAE was defined as any untoward medical occurrence that, at any dose: resulted in death, was life-threatening, required inpatient hospitalization or prolongation of existing hospitalization, resulted in persistent disability/incapacity, was a congenital anomaly/birth defect, was a medically important event. Safety population included all participants randomly assigned to study intervention and who took at least 1 dose of study intervention.

End point type	Secondary
End point timeframe:	
From the first dose of study drug (Day 1) up to the last dose of study drug administration (373 days) + 98 days, up to 471 days	

End point values	Placebo	Dupilumab 300 mg q2w		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	33	38		
Units: Participants				
TEAEs	27	29		
TESAEs	6	3		
TEAEs leading to treatment discontinuation	0	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Concentration of Dupilumab Over Time

End point title	Serum Concentration of Dupilumab Over Time ^[2]
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End point description:

Blood samples were collected at the specified timepoints to evaluate serum concentration of dupilumab. Pharmacokinetic (PK) population included all participants in the safety population with at least 1 non-missing result for functional dupilumab concentration in serum after the first dose of the study intervention. Only those participants with data collected at specified timepoints are reported. Here, n = number of participants with data collected for each specified category.

End point type	Secondary
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End point timeframe:

Baseline (Day 1) and Weeks 12, 24 and 52

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Only those participants in the dupilumab group were involved in this analysis.

End point values	Dupilumab 300 mg q2w			
Subject group type	Reporting group			
Number of subjects analysed	28			
Units: Nanograms per milliliter				
arithmetic mean (standard deviation)				
Baseline (n=22)	0.00 (± 0.00)			
Week 12 (n=25)	54733.20 (± 26222.53)			
Week 24 (n=28)	62192.86 (± 23979.23)			
Week 52 (n=20)	68365.00 (± 30613.86)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Antidrug Antibody (ADA) Response to Dupilumab and Positive Neutralizing Antibody (Nab)

End point title	Number of Participants With Antidrug Antibody (ADA) Response to Dupilumab and Positive Neutralizing Antibody (Nab)
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End point description:

Plasma samples were collected to evaluate antibodies to dupilumab. Pre-existing immunoreactivity was defined as an ADA positive response in the assay at baseline with all post first dose ADA results negative, OR an ADA positive response at baseline with all post first dose ADA responses less than 4-fold over baseline titer levels. Treatment-emergent ADA responses were defined as a positive response

in the ADA assay post first dose, when baseline results were negative or missing. Treatment-boosted response was defined as an ADA positive response in the assay post first dose that was greater-than or equal to 4-fold over baseline titer levels, when baseline results were positive. Samples positive in the ADA assay were further characterized for the presence of NABs. ADA population included all participants in the safety population who had at least 1 non-missing result in the ADA assay after the first dose of the study intervention.

End point type	Secondary
End point timeframe:	
Baseline (Day 1) and up to Week 52	

End point values	Placebo	Dupilumab 300 mg q2w		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	33	38		
Units: Participants				
Pre-existing immunoreactivity	1	0		
Treatment-emergent ADA response	1	1		
Treatment-boosted ADA response	1	0		
Positive Nab	3	1		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

TEAEs and TSEAEs: first dose of study drug (Day 1) up to last dose of study drug administration (373 days) + 98 days, up to 471 days. All-cause mortality (deaths): participant's screening (Day -28) to end of follow-up for each participant, up to 476 days.

Adverse event reporting additional description:

Analysis was performed on safety population.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	26.1
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Reporting groups

Reporting group title	Dupilumab 300 mg q2w
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Reporting group description:

Participants received dupilumab 300 mg via SC injection q2w for up to 53.1 weeks.

Reporting group title	Placebo
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Reporting group description:

Participants received matching placebo via SC injection q2w for up to 53.2 weeks.

Serious adverse events	Dupilumab 300 mg q2w	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 38 (7.89%)	6 / 33 (18.18%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Congenital, familial and genetic disorders			
Myocardial Bridging			
subjects affected / exposed	1 / 38 (2.63%)	0 / 33 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Peripheral Arterial Occlusive Disease			
subjects affected / exposed	0 / 38 (0.00%)	1 / 33 (3.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Syncope			

subjects affected / exposed	0 / 38 (0.00%)	1 / 33 (3.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic Neuropathy			
subjects affected / exposed	0 / 38 (0.00%)	1 / 33 (3.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Chronic Gastritis			
subjects affected / exposed	1 / 38 (2.63%)	0 / 33 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholecystitis Acute			
subjects affected / exposed	1 / 38 (2.63%)	0 / 33 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biloma			
subjects affected / exposed	1 / 38 (2.63%)	0 / 33 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 38 (0.00%)	1 / 33 (3.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Foot Deformity			
subjects affected / exposed	0 / 38 (0.00%)	1 / 33 (3.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal Osteoarthritis			

subjects affected / exposed	0 / 38 (0.00%)	1 / 33 (3.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Chronic Sinusitis			
subjects affected / exposed	0 / 38 (0.00%)	1 / 33 (3.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Dupilumab 300 mg q2w	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	20 / 38 (52.63%)	12 / 33 (36.36%)	
Injury, poisoning and procedural complications			
Accidental Overdose			
subjects affected / exposed	2 / 38 (5.26%)	3 / 33 (9.09%)	
occurrences (all)	2	3	
Fall			
subjects affected / exposed	1 / 38 (2.63%)	2 / 33 (6.06%)	
occurrences (all)	1	2	
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 38 (5.26%)	2 / 33 (6.06%)	
occurrences (all)	2	2	
General disorders and administration site conditions			
Injection Site Swelling			
subjects affected / exposed	0 / 38 (0.00%)	2 / 33 (6.06%)	
occurrences (all)	0	23	
Fatigue			
subjects affected / exposed	2 / 38 (5.26%)	0 / 33 (0.00%)	
occurrences (all)	3	0	
Injection Site Erythema			
subjects affected / exposed	4 / 38 (10.53%)	1 / 33 (3.03%)	
occurrences (all)	9	20	

Injection Site Reaction subjects affected / exposed occurrences (all)	3 / 38 (7.89%) 12	1 / 33 (3.03%) 8	
Gastrointestinal disorders Gastrooesophageal Reflux Disease subjects affected / exposed occurrences (all)	2 / 38 (5.26%) 2	0 / 33 (0.00%) 0	
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all) Back Pain subjects affected / exposed occurrences (all)	2 / 38 (5.26%) 2 2 / 38 (5.26%) 3	1 / 33 (3.03%) 1 0 / 33 (0.00%) 0	
Infections and infestations Bronchitis subjects affected / exposed occurrences (all) Covid-19 subjects affected / exposed occurrences (all) Gastroenteritis subjects affected / exposed occurrences (all) Nasopharyngitis subjects affected / exposed occurrences (all) Otitis Media subjects affected / exposed occurrences (all) Upper Respiratory Tract Infection subjects affected / exposed occurrences (all) Viral Upper Respiratory Tract Infection subjects affected / exposed occurrences (all)	2 / 38 (5.26%) 2 8 / 38 (21.05%) 9 2 / 38 (5.26%) 3 2 / 38 (5.26%) 3 2 / 38 (5.26%) 2 0 / 38 (0.00%) 0 2 / 38 (5.26%) 2	0 / 33 (0.00%) 0 7 / 33 (21.21%) 8 0 / 33 (0.00%) 0 2 / 33 (6.06%) 2 1 / 33 (3.03%) 1 3 / 33 (9.09%) 3 2 / 33 (6.06%) 2	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
08 July 2021	Changed the primary analysis population to the ITT population in Part A and removed comorbid asthma as inclusion criterion as per a Health Authority request. Changed the handling of sinonasal surgery from composite strategy to hypothetical strategy in the primary estimand to better reflect the clinical scenario.
23 February 2023	Removed Part B. Updated the primary analysis population to the elevated baseline eosinophils population in Part A, and consequently update the sample size to have approximately 30 participants with elevated eosinophils (≥ 300 cells/mm ³), which coupled to the existing low eosinophils population will bring the total sample size to 70. Modified primary objectives and endpoints: Removed comparison to placebo group at Week 24 in reduction at Week 24 in sinus opacification in the primary objective; Removed assessing of the sTSS at Week 24 in the primary objective and moved sTSS as an endpoint to secondary endpoint. For all the secondary objective and endpoints, deleted the Week 52 objective/endpoints and requalified to exploratory, except the following endpoints: Change from baseline to Week 24 in opacification of sinuses assessed by CT scan using LMK score; Change from baseline to Week 24 in sTSS. In addition, in the asthma subgroup objective and endpoints removed comparison to placebo, and for endpoints evaluating the ≥ 300 cells/mm ³ population changed to ITT. Shortened treatment period from 52 weeks to at least 24 and no more than 52 weeks. Modified overall study phase from Phase 2/3 to Phase 2.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported