Clinical trial results:
A Phase 3, Randomized, 3-Part Study to Investigate the Efficacy and Safety of Dupilumab in Adult and Adolescent Patients with Eosinophilic Esophagitis (EoE)

Summary

Results information

Trial information

Trial identification

Additional study identifiers

Sponsors

Paediatric regulatory details

Results analysis stage

General information about the trial

Population of trial subjects

Subjects enrolled per country

Subjects enrolled per age group	

Subject disposition

Recruitment

Pre-assignment

Period 1	

Arms	
Arm title	

Arm title	

Arm title	

Arm title	

Arm title	

Number of subjects in period 1			

Arm title	

Arm title	

Arm title	

Arm title	

Arm title	

Number of subjects in period 2[1]			

Number of subjects in period 2[1]			

Baseline characteristics

Reporting groups	

Reporting group values			

Reporting group values			

End points

End points reporting groups

Primary: Percentage of participants achieving peak esophageal intraepithelial eosinophil count of ≤6 eosinophils per high-power field (eos/hpf) in all three regions at week 24

End point values				

End point values				

Statistical analyses

Statistical analysis title	

Statistical analysis title	

Statistical analysis title	

Primary: Absolute change from baseline in Dysphagia Symptom Questionnaire (DSQ) total score at week 24	

End point values				

End point values				

Statistical analyses	
Statistical analysis title	

Statistical analysis title	

Statistical analysis title	

Secondary: Percent change from baseline in DSQ total score at week 24	

End point values				

End point values				

Statistical analyses

Statistical analysis title	

Statistical analysis title	

Statistical analysis title	

Secondary: Absolute change from baseline in Eosinophilic Esophagitis Histology Scoring System (EoEHSS) mean Grade score at week 24	

End point values				

End point values				

Statistical analyses

Statistical analysis title	

Statistical analysis title	

Statistical analysis title	

Secondary: Absolute change from baseline in EoEHSS mean Stage score at week 24	

End point values				

End point values				

Statistical analyses

Statistical analysis title	

Statistical analysis title	

Statistical analysis title	

Secondary: Absolute change from baseline in EoE Endoscopic Reference total Score (EoE-EREFS) at week 24	

End point values				

End point values				

Statistical analyses

Statistical analysis title	

Statistical analysis title	

Statistical analysis title	

Secondary: Percentage of participants achieving peak esophageal intraepithelial eosinophil count of <15 eos/hpf in all three regions at week 24	

End point values				

End point values				

Statistical analyses

Statistical analysis title	

Secondary: Normalized Enrichment Score (NES) for the relative change from baseline in EoE Diagnostic Panel (EDP) at week 24	

End point values				

End point values				

Statistical analyses

Statistical analysis title	

Statistical analysis title	

Statistical analysis title	

Secondary: NES for the relative change from baseline in type 2 inflammation signature at week 24	

End point values				

End point values				

Statistical analyses

Statistical analysis title	

Statistical analysis title	

Statistical analysis title	

Secondary: Percentage of participants achieving peak esophageal intraepithelial eosinophil count of ≤1 eos/hpf in all three regions at week 24	

End point values				

End point values				

Statistical analyses

Statistical analysis title	

Statistical analysis title	

Statistical analysis title	

Secondary: Absolute change from baseline in health-related quality of life (QOL) average score as measured by EoE Impact Questionnaire (EoE-IQ) at week 24	

End point values				

End point values				

Statistical analyses

Statistical analysis title	

Statistical analysis title	

Statistical analysis title	

Secondary: Absolute change from baseline in Severity of EoE symptoms other than dysphagia as measured by EoE Symptom Questionnaire (EoE-SQ) at week 24	

End point values				

End point values				

Statistical analyses

Statistical analysis title	

Statistical analysis title	

Statistical analysis title	

Secondary: Absolute change from baseline in Frequency of EoE symptoms other than dysphagia as measured by EoE-SQ at week 24	

End point values				

End point values				

Statistical analyses

Statistical analysis title	

Secondary: Percentage of participants who received rescue medication during the 24-week double-blind, placebo-controlled treatment period	

End point values				

End point values				

Statistical analyses

Statistical analysis title	

Statistical analysis title	

Statistical analysis title	

Secondary: Concentration of functional dupilumab in serum at week 24

End point values				

End point values				

Statistical analyses

Secondary: Percentage of participants achieving peak esophageal intraepithelial eosinophil count of ≤6 eosinophils per high-power field (eos/hpf) in all three regions at week 52

End point values				

End point values				

Statistical analyses

Secondary: Absolute change in DSQ total score at week 52

End point values				

End point values				

Statistical analyses

Secondary: Percent change in DSQ total score at week 52

End point values				

End point values				

Statistical analyses

Secondary: Absolute change in EoE-EREFS total score at week 52

End point values				

End point values				

Statistical analyses

Secondary: Percent change in peak esophageal intraepithelial eosinophil count (eos/hpf) in all three regions at week 52

End point values				

End point values				

Statistical analyses

Secondary: Absolute change in EoEHSS mean Grade score at week 52

End point values				

End point values				

Statistical analyses

Secondary: Absolute change in EoEHSS mean Stage score at week 52

End point values				

End point values				

Statistical analyses

Secondary: Percentage of participants achieving peak esophageal intraepithelial eosinophil count of <15 eos/hpf in all three regions at week 52

End point values				

End point values				

Statistical analyses

Secondary: Percentage of participants achieving peak esophageal intraepithelial eosinophil count of ≤1 eos/hpf in all three regions at week 52

End point values				

End point values	

Statistical analyses

Secondary: Absolute change from baseline in Severity of EoE symptoms other than dysphagia as measured by EoE-SQ at week 52

End point values				

End point values				

Statistical analyses

Secondary: Absolute change from baseline in Frequency of EoE symptoms other than dysphagia as measured by EoE-SQ at week 52

End point values				

End point values				

Statistical analyses

Secondary: Percentage of participants who received rescue medication during the 28-week extended active treatment period

End point values				

End point values				

Statistical analyses

Secondary: NES for the relative change from baseline in EoE Diagnostic Panel (EDP) at week 52

End point values				

End point values				

Statistical analyses

Secondary: NES for the relative change in type 2 inflammation signature at week 52

End point values				

End point values				

Statistical analyses

Secondary: Concentration of functional dupilumab in serum at week 52

End point values				

End point values				

Statistical analyses

Secondary: Incidence of treatment-emergent anti-drug antibody (ADA) response

End point values				

End point values				

End point values				

Statistical analyses

Adverse events

Adverse events information

Dictionary used

Reporting groups

Serious adverse events			

Serious adverse events			

Serious adverse events			

Non-serious adverse events			

Non-serious adverse events			

Non-serious adverse events			

More information

Substantial protocol amendments (globally)

Date	Amendment

Interruptions (globally)

Date	Interruption	Restart date

Limitations and caveats