Clinical trial results:
A Randomized, Double Blind, Placebo-Controlled, Parallel Group Study to Evaluate the Efficacy and Safety of Dupilumab in Patients with Persistent Asthma

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	

Number of subjects in period 1			

Baseline characteristics

Reporting groups	

Reporting group values			

Reporting group values			

End points

End points reporting groups

Primary: Annualized Rate of Severe Exacerbation Events During The 52-Week Treatment Period: Intent-to-Treat (ITT) Population

End point values				

Statistical analyses

Statistical analysis title	

Statistical analysis title	

Primary: Absolute Change From Baseline in Pre-Bronchodilator Forced Expiratory Volume in 1 Second (FEV1) at Week 12: ITT Population	

End point values				

Statistical analyses

Statistical analysis title	

Statistical analysis title	

Secondary: Percent Change From Baseline in Pre-Bronchodilator FEV1 at Week 12: ITT Population	

End point values				

Statistical analyses

Statistical analysis title	

Secondary: Annualized Rate of Severe Exacerbation Events During The 52-Week Treatment Period: ITT Population With Baseline Eosinophil ≥0.15 Giga/L

End point values				

Statistical analyses

Statistical analysis title	

Secondary: Absolute Change From Baseline in Pre-Bronchodilator FEV1 at Week 12: ITT Population With Baseline Eosinophil ≥0.15 Giga/L

End point values				

Statistical analyses

Statistical analysis title	

Secondary: Annualized Rate of Severe Exacerbation Events During The 52-Week Treatment Period: ITT Population With Baseline Eosinophil ≥0.3 Giga/L

End point values				

Statistical analyses

Statistical analysis title	

End point values				

Statistical analyses

Statistical analysis title	

Secondary: Annualized Rate of Severe Exacerbation Events During The 52-Week Treatment Period: ITT Population With Baseline Eosinophil <0.3 Giga/L

End point values				

Statistical analyses

Statistical analysis title	

Secondary: Annualized Rate of Severe Exacerbation Events During The 52-Week Treatment Period: ITT Population With High Dose ICS at Baseline

End point values				

Statistical analyses

Secondary: Absolute Change From Baseline in Pre-Bronchodilator FEV1 at Week 12: ITT Population With High Dose ICS at Baseline

End point values				

Statistical analyses

Secondary: Change From Baseline in Asthma Quality of Life Questionnaire With Standardized Activities (AQLQ [S]) Self- Administered Global Score at Week 24: ITT Population

End point values				

Statistical analyses

Secondary: Change From Baseline in AQLQ (S) Self- Administered Global Score at Week 24: ITT Population With Baseline Eosinophil ≥0.3 Giga/L

End point values				

Statistical analyses

Secondary: Change From Baseline in Asthma Control Questionnaire 5-item Version (ACQ-5) Score at Week 24: ITT Population

End point values				

Statistical analyses

Secondary: Annualized Rate of Severe Exacerbation Events Resulting in Hospitalization or Emergency Room Visit During The 52-Week Treatment Period: ITT Population

End point values				

Statistical analyses

Secondary: Absolute Change From Baseline in Pre-Bronchodilator FEV1 at Week 12: ITT Population With Baseline Eosinophil <0.3 Giga/L

End point values				

Statistical analyses

Secondary: Percent Change From Baseline in Pre-Bronchodilator FEV1 at Week 12: ITT Population With Baseline Eosinophil ≥0.3 Giga/L

End point values				

Statistical analyses

Secondary: Percent Change From Baseline in Pre-Bronchodilator FEV1 at Week 12: ITT Population With High Dose ICS at Baseline

End point values				

Statistical analyses

Secondary: Percent Change From Baseline in Pre-Bronchodilator FEV1 at Week 12: ITT Population With Baseline Eosinophil ≥0.15 Giga/L

End point values				

Statistical analyses

Secondary: Absolute Change From Baseline in Pre-Bronchodilator FEV1 at Weeks 2, 4, 8, 24, 36, and 52: ITT Population

End point values				

Statistical analyses

Secondary: Percent Change From Baseline in Pre-Bronchodilator FEV1 at Weeks 2, 4, 8, 24, 36, and 52: ITT Population

End point values				

Statistical analyses

Secondary: Change From Baseline in Percent Predicted FEV1 at Weeks 2, 4, 8, 12, 24, 36, and 52: ITT Population

End point values				

Statistical analyses

Secondary: Change From Baseline in Morning (AM)/Evening (PM) Peak Expiratory Flow (PEF) at Weeks 2, 4, 8, 12, 24, 36, and 52: ITT Population

End point values				

Statistical analyses

Secondary: Change From Baseline in Forced Vital Capacity (FVC) at Weeks 2, 4, 8, 12, 24, 36, and 52: ITT Population

End point values				

Statistical analyses

Secondary: Change From Baseline in Forced Expiratory Flow (FEF) 25-75% at Weeks 2, 4, 8, 12, 24, 36, and 52: ITT Population

End point values				

Statistical analyses

Secondary: Change From Baseline in Post-Bronchodilator FEV1 at Weeks 2, 4, 8, 12, 24, 36, and 52: ITT Population

End point values				

Statistical analyses

Secondary: Annualized Rate of Loss of Asthma Control (LOAC) Event During The 52-Week Treatment Period: ITT Population

End point values				

Statistical analyses

Secondary: Time to First Severe Exacerbation Event: Kaplan-Meier Estimates During The 52-Week Treatment Period: ITT Population	

End point values				

Statistical analyses

Secondary: Time to First LOAC Event: Kaplan-Meier Estimates During The 52-Week Treatment Period: ITT Population

End point values				

Statistical analyses

Secondary: Change From Baseline in ACQ-5 Score at Weeks 2, 4, 8, 12, 36, and 52: ITT Population

End point values				

Statistical analyses

Secondary: Change From Baseline in Asthma Control Questionnaire 7-item Version (ACQ-7) Score at Weeks 2, 4, 8, 12, 24, 36, and 52: ITT Population

End point values				

Statistical analyses

Secondary: Change From Baseline in Morning Asthma Symptom Score at Weeks 2, 4, 8, 12, 24, 36, and 52: ITT Population

End point values				

Statistical analyses

Secondary: Change From Baseline in Evening Asthma Symptom Score at Weeks 2, 4, 8, 12, 24, 36, and 52: ITT Population

End point values				

Statistical analyses

Secondary: Change From Baseline in Number of Nocturnal Awakenings Per Night at Weeks 2, 4, 8, 12, 24, 36, and 52: ITT Population

End point values				

Statistical analyses

Secondary: Change From Baseline in Number of Puffs of Daily Reliever Medication Used Per 24 Hours at Weeks 2, 4, 8, 12, 24, 36, and 52: ITT Population

End point values				

Statistical analyses

Secondary: Change From Baseline in European Quality of Life Working Group Health Status Measure 5 Dimensions, 5 Levels (EQ-5D-5L) Scores at Weeks 12, 24, 36, and 52: ITT Population

End point values				

Statistical analyses

Secondary: Change From Baseline in Hospital Anxiety and Depression Scale (HADS) Total Score at Weeks 12, 24, 36, and 52: ITT Population

End point values				

Statistical analyses

Secondary: Change From Baseline in 22-Item Sino Nasal Outcome Test (SNOT-22) Score at Weeks 12, 24, 36, and 52: ITT Population With Bilateral Nasal Polyposis/Chronic Rhinosinusitis

End point values				

Statistical analyses

Secondary: Change From Baseline in Standardized Rhinoconjunctivitis Quality Of Life Questionnaire, Ages 12+ (RQLQ[S]+12) Score at Weeks 12, 24, 36, and 52: ITT Population With Comorbid Allergic Rhinitis

End point values				

Statistical analyses

Adverse events

Adverse events information

Dictionary used	
Reporting groups	

Serious adverse events			

Serious adverse events			

Non-serious adverse events			

Non-serious adverse events			

More information

Substantial protocol amendments (globally)

Date	Amendment

Interruptions (globally)

Limitations and caveats