Clinical trial results:
A Double-Blind, Placebo-Controlled Parallel-Group Study to Assess the Efficacy, Safety and Tolerability of CAT-354

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			

Number of subjects in period 1	

Baseline characteristics

Reporting groups	

Reporting group values			

End points

End points reporting groups

Primary: Change From Baseline in Doubling Concentration of Methacholine at Day 28

End point values				

Statistical analyses

Secondary: Change From Baseline in Doubling concentration of Methacholine at Day 56, 84 or Early Termination

End point values				

Statistical analyses

Secondary: Forced expiratory volume in 1 second (FEV1)

End point values				

Statistical analyses

Secondary: Forced Vital Capacity (FVC)

End point values				

Statistical analyses

Secondary: Forced Expiratory Volume in 1 second (FEV1) as Percentage of Forced Vital Capacity (FVC)

End point values				

Statistical analyses

Secondary: Asthma Control Questionnaire (ACQ) Total Score

End point values				

Statistical analyses

Secondary: Post-bronchodilator Forced Expiratory Volume in 1 Second (FEV1)

End point values				

Statistical analyses

Secondary: Number of Participants With Diary Data

End point values				

Statistical analyses

Secondary: Number of Participants With Exacerbations

End point values				

Statistical analyses

Secondary: Morning Peak Flow and Peak Flow Variability

End point values				

Statistical analyses

Secondary: Adult Asthma Quality of Life (QoL) Questionnaire Final Score

End point values				

Statistical analyses

Secondary: Maximum Observed Serum Concentration (Cmax) for CAT-354	

End point values				

Statistical analyses

Secondary: Minimum Observed Serum Concentration (Cmin) for CAT-354	

End point values				

End point values				

Statistical analyses

Secondary: Accumulation Ratio for CAT-354 (RA)	

End point values				

Statistical analyses

Secondary: Number of Participants Reporting Treatment-Emergent Adverse Events (TEAEs) and Treatment-Emergent Serious Adverse Events (TESAEs)

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)

Date	Interruption	Restart date

Limitations and caveats