Clinical trial results:
A Phase 3, Randomized, Double-blind, Controlled Study Evaluating the Efficacy and Safety of VX-445 Combination Therapy in Subjects With Cystic Fibrosis Who Are Heterozygous for the F508del Mutation and a Minimal Function Mutation (F/MF)

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	

Number of subjects in period 1[1]		

Baseline characteristics

Reporting groups	

Reporting group values			

End points

End points reporting groups

Primary: Absolute Change in Percent Predicted Forced Expiratory Volume in 1 Second (ppFEV1)

End point values				

Statistical analyses

Statistical analysis title	

Secondary: Absolute Change in Percent Predicted Forced Expiratory Volume in 1 Second (ppFEV1)	

End point values				

Statistical analyses

Statistical analysis title	

Secondary: Number of Pulmonary Exacerbations (PEx)

End point values				

Statistical analyses

Statistical analysis title	

Secondary: Absolute Change in Sweat Chloride (SwCl)

End point values				

Statistical analyses

Statistical analysis title	

Secondary: Absolute Change in Cystic Fibrosis Questionnaire Revised (CFQ-R) Respiratory Domain Score

End point values				

Statistical analyses

Statistical analysis title	

Secondary: Absolute Change in Body Mass Index (BMI)	

End point values				

Statistical analyses

Statistical analysis title	

Secondary: Absolute Change in Sweat Chloride

End point values				

Statistical analyses

Statistical analysis title	

Secondary: Absolute Change in Cystic Fibrosis Questionnaire Revised (CFQ-R) Respiratory Domain Score

End point values				

Statistical analyses

Statistical analysis title	

Secondary: Time-to-first Pulmonary Exacerbation (PEx)

End point values				

Statistical analyses

Secondary: Absolute Change in BMI Z-score for Subjects <=20 Years of Age at Baseline

End point values				

Statistical analyses

Statistical analysis title	

Secondary: Absolute Change in Body Weight	

End point values				

Statistical analyses

Statistical analysis title	

Secondary: Safety and Tolerability as Assessed by Number of Subjects With Treatment-Emergent Adverse Events (AEs) and Serious Adverse Events (SAEs)

End point values				

Statistical analyses

Secondary: Observed Pre-dose Concentration (Ctrough) of VX-445, TEZ, M1-TEZ, and IVA

End point values				

Statistical analyses

Adverse events

Adverse events information

Dictionary used	
Reporting groups	

Serious adverse events			

Non-serious adverse events			

More information

Substantial protocol amendments (globally)

Date	Amendment

Interruptions (globally)

Limitations and caveats