Clinical trial results:
A Phase 2, Multicenter, Open-Label Study to Evaluate the Efficacy and Safety of Sofosbuvir/Velpatasvir Fixed Dose Combination in Subjects with Chronic HCV Infection who have Received a Liver Transplant

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	

Number of subjects in period 1	

Baseline characteristics

Reporting groups	

Reporting group values			

End points

End points reporting groups	

Primary: Percentage of Participants With Sustained Virologic Response (SVR) 12 Weeks After Cessation of Therapy (SVR12)	

End point values				

Statistical analyses

Secondary: Percentage of Participants With Sustained Virologic Response 4 Weeks After Cessation of Therapy (SVR4)

End point values				

Statistical analyses

Secondary: Percentage of Participants With HCV RNA < LLOQ at Week 2

End point values				

Statistical analyses

Secondary: Percentage of Participants With HCV RNA < LLOQ at Week 4

End point values				

Statistical analyses

Secondary: Percentage of Participants With HCV RNA < LLOQ at Week 8

End point values				

Statistical analyses

Secondary: Percentage of Participants With HCV RNA < LLOQ at Week 12

End point values				

Statistical analyses

Secondary: HCV RNA at Week 2

End point values				

Statistical analyses

Secondary: HCV RNA at Week 4

End point values				

Statistical analyses

Secondary: HCV RNA at Week 8

End point values				

Statistical analyses

Secondary: HCV RNA at Week 12

End point values				

Statistical analyses

Secondary: Change From Baseline in HCV RNA at Week 2

End point values				

Statistical analyses

Secondary: Change From Baseline in HCV RNA at Week 4

End point values				

Statistical analyses

Secondary: Change From Baseline in HCV RNA at Week 8

End point values				

Statistical analyses

Secondary: Change From Baseline in HCV RNA at Week 12

End point values				

Statistical analyses

Secondary: Percentage of Participants With Virologic Failure

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)

Interruptions (globally)

Limitations and caveats