

Clinical trial results:

Multicenter, Open-Label, Early Access Program of Telaprevir in Combination With Peginterferon Alfa and Ribavirin in Genotype 1 Chronic Hepatitis C Subjects With Severe Fibrosis and Compensated Cirrhosis

Summary

Results information

Trial information

Trial identification Additional study identifiers

Sponsors

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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	

Reporting groups

Reporting group values		

End points

End points reporting groups		

End point values		

End point values		

Primary: Percentage of Participants Achieving Sustained Virologic Response (SVR						
24actual (Snapshot, 'less than [<] lower limit of quantification [LLOQ], target not detected') 24 Weeks After the Last Actual Dose of Hepatitis C Virus (HCV) Drug						

End point values		

End point values		

Primary: Percentage of Participants Achieving Sustained Virologic Response (SVR) 24actual (Classic) 24 Weeks After the Last Actual Dose of Hepatitis C Virus (HCV) Drug

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End point values		

End point values		

Primary: Log10 Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) Values at Each Time Point During Treatment

End point values		

Statistical analyses

Primary: Percentage of Participants Achieving Rapid Virologic Response (RVR) at Week 4

End point values		

Primary: Percentage of Participants Achieving Extended Rapid Virologic Response	2
(eRVR) at Weeks 4 and 12	

End point values		

Statistical analyses

Primary: Percentage of Participants Having Virologic Response at End of Treatment (Week 24 or 48)

End point values		

End point values		

Primary: Percentage of Participants With Viral Breakthrough

End point values		

End point values		

Primary: Percentage of Participants who Relapsed						

End point values		

End point values		

Primary: Percentage	of Participants who m	et a Virologic Stopping Rule
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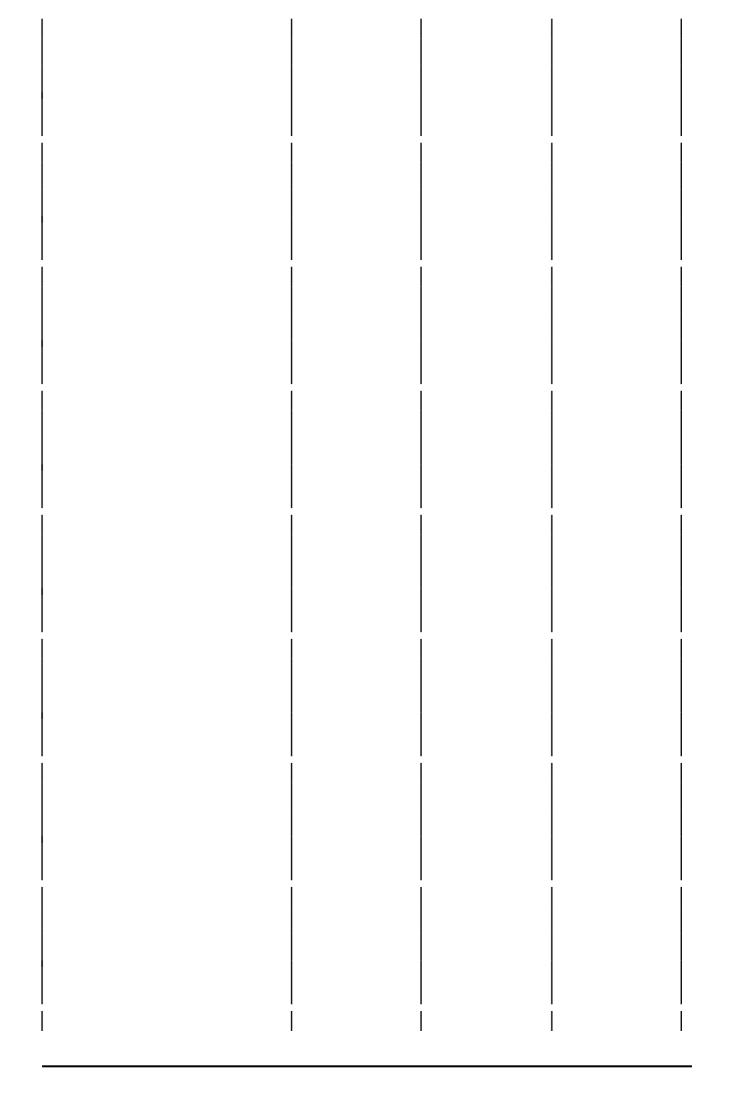
End point values		

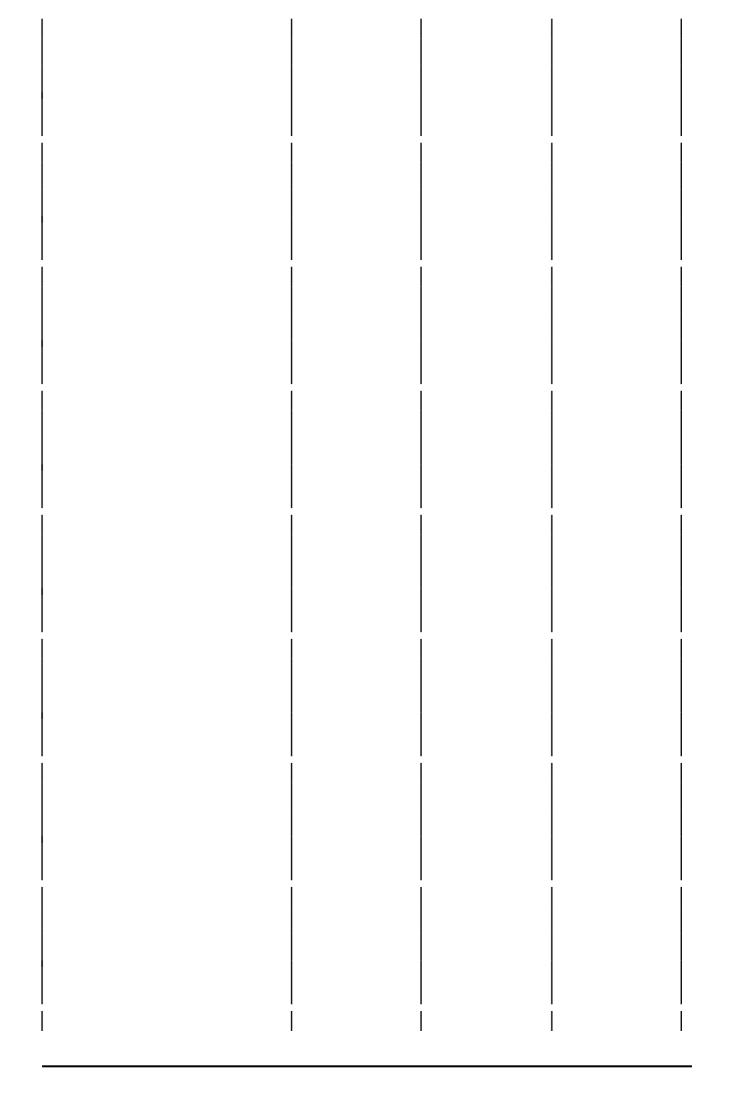
End point values		

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