Clinical trial results:
A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of GS-5245 for the Treatment of COVID-19 in Participants With High-Risk for Disease Progression

Summary

EudraCT number	2022-002741-18
Trial protocol	FR HU ES BG IT
Global end of trial date	07 November 2023

Results information

Result version number	v2 (current)
This version publication date	07 February 2025
First version publication date	13 November 2024
Version creation reason	• New data added to full data set • Correction of full data set To update analysis population description and result values for outcome measure no 3 "Percentage of Participants Experiencing Laboratory Abnormalities"

Trial information

Trial identification

Sponsor protocol code	GS-US-611-6273

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05603143
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Gilead Sciences
Sponsor organisation address	333 Lakeside Drive, Foster City, CA, United States, 94404
Public contact	Gilead Clinical Study Information Center, Gilead Sciences, GileadClinicalTrials@gilead.com
Scientific contact	Gilead Clinical Study Information Center, Gilead Sciences, GileadClinicalTrials@gilead.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	07 November 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	07 November 2023
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The goal of this clinical study was to test how well the study drug, obeldesivir (GS-5245), worked and how safe it was in treating coronavirus disease 2019 (COVID-19) in participants that have a higher risk of getting a serious illness.

Protection of trial subjects:

The protocol and consent/assent forms were submitted by each investigator to a duly constituted Independent Ethics Committee (IEC) or Institutional Review Board (IRB) for review and approval before study initiation. All revisions to the consent/assent forms (if applicable) after initial IEC/IRB approval were submitted by the investigator to the IEC/IRB for review and approval before implementation in accordance with regulatory requirements. This study was conducted in accordance with recognized international scientific and ethical standards, including but not limited to the International Conference on Harmonization guideline for Good Clinical Practice (ICH GCP) and the original principles embodied in the Declaration of Helsinki.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	05 November 2022
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Singapore: 1
Country: Number of subjects enrolled	United Kingdom: 8
Country: Number of subjects enrolled	Bulgaria: 196
Country: Number of subjects enrolled	France: 1
Country: Number of subjects enrolled	Hungary: 1
Country: Number of subjects enrolled	Italy: 2
Country: Number of subjects enrolled	Poland: 19
Country: Number of subjects enrolled	Portugal: 9
Country: Number of subjects enrolled	Romania: 53
Country: Number of subjects enrolled	Spain: 23
Country: Number of subjects enrolled	Türkiye: 2
Country: Number of subjects enrolled	Taiwan: 40
Country: Number of subjects enrolled	Brazil: 8
Country: Number of subjects enrolled	Canada: 18
Country: Number of subjects enrolled	Japan: 5
Country: Number of subjects enrolled	Korea, Republic of: 3

Country: Number of subjects enrolled	Mexico: 48
Country: Number of subjects enrolled	South Africa: 31
Worldwide total number of subjects	468
EEA total number of subjects	304

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	332
From 65 to 84 years	130
85 years and over	6

Subject disposition

Recruitment

Recruitment details:

Participants were enrolled at study sites in the South America, Europe, North America, Africa and Asia.

Pre-assignment

Screening details:

515 participants were screened.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Obeldesivir

Arm description:

Participants received obeldesivir 350 mg orally twice daily for 5 days.

Arm type	Experimental
Investigational medicinal product name	Obeldesivir
Investigational medicinal product code	
Other name	GS-5245
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Tablets administered orally without regard to food.

Arm title	Placebo

Arm description:

Participants received placebo-to-match obeldesivir orally twice daily for 5 days.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Placebo tablets administered orally without regard to food.

Number of subjects in period 1	Obeldesivir	Placebo
Started	233	235
Completed	224	227
Not completed	9	8
Adverse event, non-fatal	2	-

Death	-	1
Withdrew consent	6	2
Investigator's discretion	1	-
Randomized but never treated	-	3
Lost to follow-up	-	1
Protocol deviation	-	1

Baseline characteristics

Reporting groups	
Reporting group title	Obeldesivir
Reporting group description:	
Participants received obeldesivir 350 mg orally twice daily for 5 days.	
Reporting group title	Placebo
Reporting group description:	
Participants received placebo-to-match obeldesivir orally twice daily for 5 days.	

Reporting group values	Obeldesivir	Placebo	Total
Number of subjects	233	235	468
Age categorical Units: Subjects			
Adults (18 – 64 Years)	159	173	332
Geriatrics (65 – 84 Years)	71	59	130
Geriatrics (85 Years and Over)	3	3	6
Age continuous Units: years			
arithmetic mean	57	53	
standard deviation	± 14.9	± 16.6	-
Gender categorical Units: Subjects			
Female	147	117	264
Male	86	118	204
Race Units: Subjects			
White	178	168	346
Asian	24	32	56
American Indian or Alaska Native	21	19	40
Black or African American	9	10	19
Other or More Than One Race	1	4	5
Native Hawaiian or Other Pacific Islander	0	2	2
Ethnicity Units: Subjects			
Hispanic or Latino	36	43	79
Not Hispanic or Latino	197	192	389
Unknown or Not Reported	0	0	0
Baseline Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Nasal Swab Viral Load			
The Safety Analysis Set included all participants who received at least 1 dose of study drug with data available were analyzed. One participant randomized to placebo arm received obeldesivir and was counted in obeldesivir group for the analysis of this baseline measure. For obeldesivir arm N=218, placebo arm N=215.			
Units: log10 copies/mL			
arithmetic mean	6.15	6.15	
standard deviation	± 1.629	± 1.622	-

End points

End points reporting groups

Reporting group title	Obeldesivir
Reporting group description:	
Participants received obeldesivir 350 mg orally twice daily for 5 days.	
Reporting group title	Placebo
Reporting group description:	
Participants received placebo-to-match obeldesivir orally twice daily for 5 days.	

Primary: Percentage of Participants With Coronavirus Disease 2019 (COVID-19) Related Hospitalization or All-Cause Death by Day 29

End point title	Percentage of Participants With Coronavirus Disease 2019 (COVID-19) Related Hospitalization or All-Cause Death by Day 29

End point description:

COVID-19–related hospitalization was defined as ≥ 24 hours of acute care for a reason related to COVID-19, in a hospital or similar acute care facility, including emergency rooms or temporary facilities instituted to address medical needs of those with COVID-19. This included specialized acute medical care units within an assisted living facility or nursing home. This did not include hospitalization for the purposes of public health and/or clinical trial execution. The date and duration of hospital admission, and primary reason for hospitalization (including if the hospitalization was related to COVID-19) were recorded.
Full Analysis Positive Set included all randomized participants who received at least 1 dose of study drug and were SARS-CoV-2 positive at baseline as confirmed by cepheid's xpert xpress coronavirus-2/flu/respiratory syncytial virus plus test or SARS-CoV-2 reverse transcriptase quantitative polymerase chain reaction test from the central laboratory.

End point type	Primary
End point timeframe:	
Up to Day 29	

End point values	Obeldesivir	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	211	207		
Units: percentage of participants				
number (not applicable)	0	0.5		

Statistical analyses

Statistical analysis title	Statistical Analysis Obeldesivir vs Placebo
Comparison groups	Obeldesivir v Placebo

Number of subjects included in analysis	418
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.3161 [1]
Method	Logrank

Notes:

[1] - PLACEHOLDER1

Secondary: Percentage of Participants With Treatment-Emergent Adverse Events

End point title	Percentage of Participants With Treatment-Emergent Adverse Events

End point description:

TEAEs were defined as 1 or both of the following:
Any AEs with an onset date on or after the study drug start date and no later than 30 days after permanent discontinuation of study drug. Any AEs leading to premature discontinuation of study drug.
Percentages were rounded off.
Analysis Population Description: The Safety Analysis Set included all participants who received at least 1 dose of study drug. One participant randomized to placebo arm received obeldesivir and was counted in obeldesivir group for the analysis of this endpoint

End point type	Secondary

End point timeframe:

First dose date up to 5 Days plus 30 Days

End point values	Obeldesivir	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	233[2]	231		
Units: percentage of participants				
number (not applicable)	22.2	20.8		

Notes:

[2] - N=234, one participant in placebo group received obeldesivir and was counted in obeldesivir group.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Experiencing Laboratory Abnormalities

End point title	Percentage of Participants Experiencing Laboratory Abnormalities

End point description:

Treatment-emergent laboratory abnormalities were defined as values that increase at least 1 toxicity grade from baseline at any postbaseline time point, up to and including the date of last dose of study drug plus 30 days. Percentages were rounded off.
Analysis Population Description: Participants from the Safety Analysis Set who had available post baseline data were analyzed. One participant randomized to placebo arm received obeldesivir and was counted in obeldesivir group for the analysis of this outcome measure.

End point type	Secondary

End point timeframe:

First dose date up to 5 Days plus 30 Days

End point values	Obeldesivir	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	230	227		
Units: percentage of participants				
number (not applicable)				
Any grade	56.1	61.7		
Grade 3 or 4	6.5	4.8		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Experiencing Serious Adverse Events (SAEs) and Adverse Events (AEs) Leading to Study Drug Discontinuation

End point title	Percentage of Participants Experiencing Serious Adverse Events (SAEs) and Adverse Events (AEs) Leading to Study Drug Discontinuation

End point description:

A treatment emergent AE is defined as an AE that occurs or worsens in severity on or after the date of the first dose of study drug but no later than 30 days after the permanent discontinuation of study drug or an AE leading to discontinuation of study drug. A SAE is defined as an event that, at any dose, resulted in any of the following: death, life-threatening, in-patient hospitalization or prolongation of existing hospitalization, persistent or significant disability/incapacity, a congenital anomaly/birth defect, or a medically important event or reaction. Percentages were rounded off.
Analysis Population Description: Participants in the Safety Analysis Set were analyzed. One participant randomized to placebo arm received obeldesivir and was counted in obeldesivir group for the analysis of this endpoint.

End point type	Secondary

End point timeframe:

First dose date up to 5 Days plus 30 Days

End point values	Obeldesivir	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	233[3]	231		
Units: percentage of participants				
number (not applicable)				
AEs Leading to Study Drug Discontinuation	1.7	0.9		
SAEs Leading to Study Drug Discontinuation	0.9	0.9		

Notes:

[3] - One participant randomized to placebo arm received ODV and was counted in ODV group for the analysis

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With All-Cause Hospitalization by Day 29

End point title	Percentage of Participants With All-Cause Hospitalization by Day 29

End point description:

All-cause hospitalization was defined as ≥ 24 hours of acute care, in a hospital or similar acute care facility, including emergency rooms or temporary facilities instituted to address medical needs of those with COVID-19. This includes specialized acute medical care units within an assisted living facility or nursing home. This does not include hospitalization for the purposes of public health and/or clinical study execution. The date and duration of hospital admission, and primary reason for hospitalization (including if the hospitalization is related to COVID-19) were recorded. Percentages were rounded off.
Analysis Population Description: Participants in the Full Analysis Positive Set were analyzed.

End point type	Secondary

End point timeframe:

Up to Day 29

End point values	Obeldesivir	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	211	207		
Units: percentage of participants				
number (not applicable)	0.5	0		

Statistical analyses

Statistical analysis title	Statistical Analysis Obeldesivir vs Placebo
Comparison groups	Obeldesivir v Placebo
Number of subjects included in analysis	418
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.3219
Method	Logrank

Secondary: Percentage of Participants With COVID-19–Related Medically Attended Visits (MAVs) or All-Cause Death by Day 29

End point title	Percentage of Participants With COVID-19–Related Medically Attended Visits (MAVs) or All-Cause Death by Day 29

End point description:

Medically attended visits were defined as interactions with health care professionals other than study staff or designees including hospitalization; in-person emergency, urgent, or primary care visits; or any other in-person visit attended by the participant and a health care professional. The nature and cause of the visit were identified. KM estimates were used in the outcome measure analysis. Percentages were rounded off.
Analysis Population Description: Participants in the Full Analysis Positive Set were analyzed.

End point type	Secondary

End point timeframe:

Up to Day 29

End point values	Obeldesivir	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	211	207		
Units: percentage of participants				
number (not applicable)	1.0	1.0		

Statistical analyses

Statistical analysis title	Statistical Analysis Obeldesivir vs Placebo
Comparison groups	Obeldesivir v Placebo
Number of subjects included in analysis	418
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.6568 [4]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	1.496
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.25
upper limit	8.952

Notes:

[4] - Hazard ratio and two-sided 95% CI for hazard ratio were estimated using the Cox regression.

Secondary: Percentage of Participants With COVID-19–Related MAVs by Day 29

End point title	Percentage of Participants With COVID-19–Related MAVs by Day 29

End point description:

Medically attended visits were defined as interactions with health care professionals other than study staff or designees including hospitalization; in-person emergency, urgent, or primary care visits; or any other in-person visit attended by the participant and a health care professional. The nature and cause of the visit were identified. KM estimates were used in the outcome measure analysis. Percentages were rounded off.
Analysis Population Description: Participants in the Full Analysis Positive Set were analyzed.

End point type	Secondary

End point timeframe:

Up to Day 29

End point values	Obeldesivir	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	211	207		
Units: percentage of participants				
number (not applicable)	1	0.5		

Statistical analyses

Statistical analysis title	Statistical Analysis Obeldesivir vs Placebo
Comparison groups	Obeldesivir v Placebo
Number of subjects included in analysis	418
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.319 [5]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	2.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.311
upper limit	28.74

Notes:

[5] - Hazard ratio and two-sided 95% CI for hazard ratio were estimated using the Cox regression.

Secondary: Percentage of Participants With All-cause Death by Day 29

End point title	Percentage of Participants With All-cause Death by Day 29

End point description:

Percentages were rounded off. Analysis Population Description: Participants in the Full Analysis Positive Set were analyzed.

End point type	Secondary

End point timeframe:

Up to Day 29

End point values	Obeldesivir	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	211	207		
Units: percentage of participants				
number (not applicable)	0	0.5		

Statistical analyses

Statistical analysis title	Statistical Analysis Obeldesivir vs Placebo
Comparison groups	Obeldesivir v Placebo
Number of subjects included in analysis	418
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.3161
Method	Logrank

Secondary: Time to COVID-19 Symptom Alleviation by Day 15

End point title	Time to COVID-19 Symptom Alleviation by Day 15

End point description:

Time to COVID-19 symptom alleviation was calculated as symptom alleviation date/time minus the first dose date/time. Symptom alleviation was evaluated for the 15 targeted symptoms using symptoms of infection with coronavirus-19 (SIC) questionnaire. The SIC questionnaire assessed all targeted symptoms, alleviation was defined as the SIC rating of 0, or at least 3 points decrease in rating from baseline, or an answer "No" to the question for at least 48 consecutive hours.
Analysis Population Description: Participants in the Full Analysis Positive Set with Covid19 symptoms who completed Symptoms of Infection With Coronavirus-19 at baseline were analyzed.
1111: Upper limit of CI did not reach due to low number of participants with events.

End point type	Secondary

End point timeframe:

Up to Day 15

End point values	Obeldesivir	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	84	78		
Units: Days				
median (confidence interval 95%)	7.3 (5.4 to 9.4)	9.3 (6.5 to 1111)		

Statistical analyses

Statistical analysis title	Statistical Analysis Obeldesivir vs Placebo
Comparison groups	Obeldesivir v Placebo
Number of subjects included in analysis	162
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0859 [6]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	1.425

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.961
upper limit	2.112

Notes:

[6] - P-value was based on stratified Log-rank test with randomization stratification factors as the strata.

Secondary: Change from Baseline in Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Nasal Swab Viral Load at Day 5

End point title	Change from Baseline in Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Nasal Swab Viral Load at Day 5

End point description:

The mixed model for repeated measures (MMRM) was used for analysis.. Analysis Population Description: Virology Analysis Set included all randomized participants who received at least 1 dose of study drug and had baseline SARS-CoV-2 viral load greater than or equal to lower limit of quantitation.

End point type	Secondary

End point timeframe:

Day 5

End point values	Obeldesivir	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	193	192		
Units: log10 copies/mL				
least squares mean (standard error)	-2.80 (± 0.092)	-2.22 (± 0.092)		

Statistical analyses

Statistical analysis title	Statistical Analysis Obeldesivir vs Placebo
Comparison groups	Obeldesivir v Placebo
Number of subjects included in analysis	385
Analysis specification	Pre-specified
Analysis type	other[7]
P-value	< 0.0001
Method	Mixed Models Analysis
Parameter estimate	Treatment Difference (vs Placebo)
Point estimate	-0.58
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.83
upper limit	-0.33

Notes:

[7] - Least-squares mean (SE), 95% CI and P value were from MMRM with baseline viral load and randomization strata as covariates.

Secondary: Plasma Concentrations of GS-441524 (Metabolite of Obeldesivir)

End point title	Plasma Concentrations of GS-441524 (Metabolite of Obeldesivir)[8]

End point description:

Pharmacokinetic Analysis Set included all randomized participants who received at least 1 dose of study drug and had at least 1 non missing concentration value reported by the PK laboratory with available data were analyzed .

End point type	Secondary

End point timeframe:

Day 1, 0.75 and 2 hours postdose and Day 5 predose and 0.75 hours postdose

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: No statistical comparison was planned or performed.

End point values	Obeldesivir			
Subject group type	Reporting group			
Number of subjects analysed	224			
Units: ng/mL				
arithmetic mean (standard deviation)				
D 1, 0.75 h N=216	2330.42 (± 1709.560)			
D 1, 2 h N=95	2535.84 (± 1370.131)			
D 5, Predose N=170	1116.81 (± 1101.371)			
D 5, 0.75 h N=174	3089.09 (± 1839.992)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

All-cause mortality, AE's: First dose date up to 5 Days plus 30 Days

Adverse event reporting additional description:

All-cause mortality: All Randomized Analysis Set; Adverse events: Safety Analysis Set. 1 participant randomized to placebo arm accidentally received obeldesivir and was counted in obeldesivir arm for the analysis of all-cause mortality and adverse events.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.1

Reporting groups

Reporting group title	Obeldesivir

Reporting group description:

Patients who received ODV

Reporting group title	Placebo

Reporting group description:

Patients who received Placebo

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: The participants did not experience any non-serious adverse events.

Serious adverse events	Obeldesivir	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 234 (0.85%)	2 / 231 (0.87%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Nervous system disorders			
Dizziness			
subjects affected / exposed	1 / 234 (0.43%)	0 / 231 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Death			
subjects affected / exposed	0 / 234 (0.00%)	1 / 231 (0.43%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Gastrointestinal disorders			
Vomiting			

subjects affected / exposed	0 / 234 (0.00%)	1 / 231 (0.43%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	1 / 234 (0.43%)	0 / 231 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Obeldesivir	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 234 (0.00%)	0 / 231 (0.00%)	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
29 March 2023	Key changes included in Amendment 1 were the addition and modification of risk factors and targeted signs and symptoms of COVID-19 to the inclusion criteria, aligning with the Centers for Disease Control and Prevention. Additional relevant nonclinical toxicology, pharmacology, and PK language were included based on Phase 1 drug-drug interactions and radiolabeled ADME. Consequently, restrictions on the coadministration of acid-reducing agents were removed, hormonal contraceptive measures were amended, and phototoxicity results demonstrating that GS-5245 was not considered a photosafety risk were incorporated. Updates to secondary and exploratory objectives and endpoints were made to capture omissions (PK) and reflect additional analyses (PROs, viral titer, and coinfections)..

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported