

Number of subjects in period 1	PC786	Placebo
Started	28	28
Completed	28	28

Baseline characteristics

Reporting groups

Reporting group title	PC786
Reporting group description:	
Twice daily doses of PC786 5 mg for a total of 10 doses	
Reporting group title	Placebo
Reporting group description:	
Twice daily doses of placebo for a total of 10 doses	

Reporting group values	PC786	Placebo	Total
Number of subjects	28	28	56
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	28	28	56
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	25.4	26.3	
standard deviation	± 5.63	± 5.89	-
Gender categorical Units: Subjects			
Female	10	9	19
Male	18	19	37

End points

End points reporting groups

Reporting group title	PC786
Reporting group description: Twice daily doses of PC786 5 mg for a total of 10 doses	
Reporting group title	Placebo
Reporting group description: Twice daily doses of placebo for a total of 10 doses	

Primary: Primary efficacy endpoint

End point title	Primary efficacy endpoint
End point description: The analysis of viral load AUC (time zero to Day 12) by nasal wash RT-qPCR for the ITT-IA analysis set described as all randomised subjects who received the challenge virus and at least one dose of study medication who had a positive quantitative PCR value >1.0 Log PFUe/mL immediately before dosing OR any subject who was qPCR negative before dosing and who subsequently had two or more qPCR positive results (>1.0 Log PFUe/mL) after the first dose dose of study medication.	
End point type	Primary
End point timeframe: From the last RT-qPCR measurement collected prior to the first dose of IMP until the last RT-qPCR measurement collected to to Day 12	

End point values	PC786	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	15		
Units: log10 PFUe x hr/mL				
least squares mean (standard deviation)	325.8 (± 199.19)	495.5 (± 199.22)		

Statistical analyses

Statistical analysis title	Descriptive statistics
Statistical analysis description: AUC descriptive statistics for derived RSV viral load parameters by treatment group (n, mean, SD, median (quartiles 1 and 3), minimum and maximum and comparison of treatment group means (mean, SE, 95% CI and p-value) were summarised.	
Comparison groups	PC786 v Placebo

Number of subjects included in analysis	34
Analysis specification	Post-hoc
Analysis type	other ^[1]
P-value	= 0.0209
Method	t-test, 2-sided

Notes:

[1] - In this post-hoc analysis, an RSV viral load cut-off value of 1.0 Log10 PFUe/mL was used to define a new population, the Intent-to-Treat Infected Alternative (ITT-IA) population. This cut-off was designed to avoid the PCR detection of the inoculum itself in the absence of infection and improved the specificity of the assay to identify subjects truly infected with RSV.

subjects affected / exposed occurrences (all)	2 / 28 (7.14%) 3	2 / 28 (7.14%) 2	
Blood creatine phosphokinase increased subjects affected / exposed occurrences (all)	1 / 28 (3.57%) 1	1 / 28 (3.57%) 1	
Forced vital capacity decreased subjects affected / exposed occurrences (all)	0 / 28 (0.00%) 0	1 / 28 (3.57%) 1	
Injury, poisoning and procedural complications Nasal injury subjects affected / exposed occurrences (all)	1 / 28 (3.57%) 1	0 / 28 (0.00%) 0	
Head injury subjects affected / exposed occurrences (all)	1 / 28 (3.57%) 1	0 / 28 (0.00%) 0	
Cardiac disorders Palpitations subjects affected / exposed occurrences (all)	0 / 28 (0.00%) 0	1 / 28 (3.57%) 1	
Nervous system disorders Dizziness subjects affected / exposed occurrences (all)	0 / 28 (0.00%) 0	3 / 28 (10.71%) 3	
Headache subjects affected / exposed occurrences (all)	1 / 28 (3.57%) 1	1 / 28 (3.57%) 1	
General disorders and administration site conditions Application site erythema subjects affected / exposed occurrences (all)	0 / 28 (0.00%) 0	1 / 28 (3.57%) 1	
Application site rash subjects affected / exposed occurrences (all)	0 / 28 (0.00%) 0	1 / 28 (3.57%) 1	
Non-cardiac chest pain			

subjects affected / exposed occurrences (all) Pyrexia subjects affected / exposed occurrences (all)	0 / 28 (0.00%) 0 0 / 28 (0.00%) 0	1 / 28 (3.57%) 1 1 / 28 (3.57%) 1	
Ear and labyrinth disorders Ear discomfort subjects affected / exposed occurrences (all)	0 / 28 (0.00%) 0	1 / 28 (3.57%) 1	
Eye disorders Ocular hyperaemia subjects affected / exposed occurrences (all) Photophobia subjects affected / exposed occurrences (all)	2 / 28 (7.14%) 2 0 / 28 (0.00%) 0	0 / 28 (0.00%) 0 1 / 28 (3.57%) 1	
Gastrointestinal disorders Nausea subjects affected / exposed occurrences (all)	0 / 28 (0.00%) 0	1 / 28 (3.57%) 1	
Respiratory, thoracic and mediastinal disorders Epistaxis subjects affected / exposed occurrences (all) Cough subjects affected / exposed occurrences (all) Dyspnoea subjects affected / exposed occurrences (all) Productive cough subjects affected / exposed occurrences (all)	1 / 28 (3.57%) 1 1 / 28 (3.57%) 1 0 / 28 (0.00%) 0 0 / 28 (0.00%) 0	2 / 28 (7.14%) 2 0 / 28 (0.00%) 0 1 / 28 (3.57%) 1 1 / 28 (3.57%) 1	
Skin and subcutaneous tissue disorders Skin mass			

subjects affected / exposed	1 / 28 (3.57%)	0 / 28 (0.00%)	
occurrences (all)	1	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported