Clinical trial results:
A Phase II/III seamless, randomised, double-blind, placebo-controlled, parallel-group, group-sequential study to evaluate efficacy, safety and tolerability of BI 767551 for the treatment of symptomatic, non-hospitalized adults with mild to moderate COVID-19

Summary

EudraCT number	2020-005588-29
Trial protocol	BE DK NL PT DE ES
Global end of trial date	04 October 2021

Results information

Result version number	v2 (current)
This version publication date	04 September 2022
First version publication date	14 July 2022
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	1487-0001

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04822701
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Boehringer Ingelheim
Sponsor organisation address	Binger Strasse 173, Ingelheim am Rhein, Germany, 55216
Public contact	Boehringer Ingelheim Call Center, Boehringer Ingelheim, +1 18002430127, clintriage.rdg@boehringer-ingelheim.com
Scientific contact	Boehringer Ingelheim Call Center, Boehringer Ingelheim, +1 18002430127, clintriage.rdg@boehringer-ingelheim.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	16 November 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	02 July 2021
Global end of trial reached?	Yes
Global end of trial date	04 October 2021
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To evaluate the concept of pharmacological activity of BI 767551 in non-hospitalised patients with mild to moderate COVID-19 symptoms and to identify a potentially efficacious and safe dose regimen from the Phase II part to take into the Phase III part. To evaluate the efficacy, safety, and tolerability of BI 767551 for the treatment of symptomatic, non-hospitalised adults with mild to moderate COVID-19.

Protection of trial subjects:

Only subjects that met all the study inclusion and none of the exclusion criteria were to be entered in the study. All subjects were free to withdraw from the clinical trial at any time for any reason given. Close monitoring of all subjects was adhered to throughout the trial conduct. Rescue medication was allowed for all patients as required.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	17 June 2021
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	Spain: 1
Country: Number of subjects enrolled	United States: 6
Worldwide total number of subjects	7
EEA total number of subjects	1

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)	7
From 65 to 84 years	0

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This study was planned to evaluate the concept of pharmacological activity of BI 767551 in non-hospitalised patients with mild to moderate COVID-19 symptoms. The study was terminated early. 5 patients total participated in phase II and phase III was not conducted.

Pre-assignment

Screening details:

All subjects were screened for eligibility prior to participation in the trial. Subjects attended a specialist site which ensured that they (the subjects) strictly met all inclusion and none of the exclusion criteria. Subjects were not to be allocated to a treatment group if any of the entry criteria were violated.

Period 1

Period 1 title	Randomised
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Carer, Data analyst, Assessor

Blinding implementation details:

Patients, investigators, central reviewers, and everyone involved in trial conduct with exception of the pharmacist will remain double-blind with regard to the randomised treatment assignments.

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo intravenous (i.v.) + placebo inhaled

Arm description:

Single dose of sterile normal saline (NaCl 0.9%) used as placebo was administered as intravenous (i.v.) infusion over a period of 60 minutes plus a single inhaled of solvent for dilution of BI 767551 used as placebo for inhalation administered via inhalation through a mouthpiece (Aerogen® Ultra) using a mesh nebulizer (Aerogen® Solo) on Day 1, followed by a 90-day follow-up period. The inhalation procedure was to start approximately 25 min after the start of infusion.

Arm type	Placebo
Investigational medicinal product name	Solvent for BI 767551
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solvent for solution for infusion
Routes of administration	Inhalation use

Dosage and administration details:

A single inhaled of solvent for dilution of BI 767551 used as placebo for inhalation administered via inhalation through a mouthpiece (Aerogen® Ultra) using a mesh nebulizer (Aerogen® Solo) on Day 1.

Investigational medicinal product name	Sterile normal saline (NaCl 0.9%)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Single dose of sterile normal saline (NaCl 0.9%) used as placebo was administered as intravenous (i.v.) infusion over a period of 60 minutes on Day 1

Arm title	Placebo intravenous (i.v.) + BI 767551 250 mg inhaled

Arm description:

Single dose of sterile normal saline (NaCl 0.9%) used as placebo was administered as intravenous (i.v.) infusion over a period of 60 minutes plus a single inhaled of 250 milligrams (mg) of BI 767551 administered via inhalation through a mouthpiece (Aerogen® Ultra) using a mesh nebulizer (Aerogen® Solo) on Day 1, followed by a 90-day follow-up period. The inhalation procedure was to start

approximately 25 min after the start of infusion.

Arm type	Experimental
Investigational medicinal product name	BI 767551
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Inhalation solution
Routes of administration	Inhalation use

Dosage and administration details:

A single inhaled of 250 milligrams (mg) of BI 767551 administered via inhalation through a mouthpiece (Aerogen® Ultra) using a mesh nebulizer (Aerogen® Solo) on Day 1.

Investigational medicinal product name	Sterile normal saline (NaCl 0.9%)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Single dose of sterile normal saline (NaCl 0.9%) used as placebo was administered as intravenous (i.v.) infusion over a period of 60 minutes on Day 1

Number of subjects in period 1	Placebo intravenous (i.v.) + placebo inhaled	Placebo intravenous (i.v.) + BI 767551 250 mg inhaled
Started	4	1
Completed	2	1
Not completed	2	0
Not treated	2	-

Period 2

Period 2 title	Treated
Is this the baseline period?	Yes[1]
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Carer, Data analyst, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo intravenous (i.v.) + placebo inhaled

Arm description:

Single dose of sterile normal saline (NaCl 0.9%) used as placebo was administered as intravenous (i.v.) infusion over a period of 60 minutes plus a single inhaled of solvent for dilution of BI 767551 used as placebo for inhalation administered via inhalation through a mouthpiece (Aerogen® Ultra) using a mesh nebulizer (Aerogen® Solo) on Day 1, followed by a 90-day follow-up period. The inhalation procedure was to start approximately 25 min after the start of infusion.

Arm type	Placebo

Investigational medicinal product name	Solvent for BI 767551
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solvent for solution for infusion
Routes of administration	Inhalation use

Dosage and administration details:

A single inhaled of solvent for dilution of BI 767551 used as placebo for inhalation administered via inhalation through a mouthpiece (Aerogen® Ultra) using a mesh nebulizer (Aerogen® Solo) on Day 1.

Investigational medicinal product name	Sterile normal saline (NaCl 0.9%)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Single dose of sterile normal saline (NaCl 0.9%) used as placebo was administered as intravenous (i.v.) infusion over a period of 60 minutes on Day 1

Arm title	Placebo intravenous (i.v.) + BI 767551 250 mg inhaled

Arm description:

Single dose of sterile normal saline (NaCl 0.9%) used as placebo was administered as intravenous (i.v.) infusion over a period of 60 minutes plus a single inhaled of 250 milligrams (mg) of BI 767551 administered via inhalation through a mouthpiece (Aerogen® Ultra) using a mesh nebulizer (Aerogen® Solo) on Day 1, followed by a 90-day follow-up period. The inhalation procedure was to start approximately 25 min after the start of infusion.

Arm type	Experimental
Investigational medicinal product name	BI 767551
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Inhalation solution
Routes of administration	Inhalation use

Dosage and administration details:

A single inhaled of 250 milligrams (mg) of BI 767551 administered via inhalation through a mouthpiece (Aerogen® Ultra) using a mesh nebulizer (Aerogen® Solo) on Day 1.

Investigational medicinal product name	Sterile normal saline (NaCl 0.9%)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Single dose of sterile normal saline (NaCl 0.9%) used as placebo was administered as intravenous (i.v.) infusion over a period of 60 minutes on Day 1

Notes:

[1] - Period 1 is not the baseline period. It is expected that period 1 will be the baseline period.

Justification: The baseline characteristics were analyzed using treated participants.

Number of subjects in period 2[2]	Placebo intravenous (i.v.) + placebo inhaled	Placebo intravenous (i.v.) + BI 767551 250 mg inhaled
Started	2	1
Completed	0	1
Not completed	2	0
Consent withdrawn by subject	1	-
Lost to follow-up	1	-

Notes:

[2] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: Baseline characteristics are based on patients who were randomised after successfully completing the screening period and received at least one dose of the trial medication.

Baseline characteristics

Reporting groups	
Reporting group title	Placebo intravenous (i.v.) + placebo inhaled
Reporting group description:	
Single dose of sterile normal saline (NaCl 0.9%) used as placebo was administered as intravenous (i.v.) infusion over a period of 60 minutes plus a single inhaled of solvent for dilution of BI 767551 used as placebo for inhalation administered via inhalation through a mouthpiece (Aerogen® Ultra) using a mesh nebulizer (Aerogen® Solo) on Day 1, followed by a 90-day follow-up period. The inhalation procedure was to start approximately 25 min after the start of infusion.	
Reporting group title	Placebo intravenous (i.v.) + BI 767551 250 mg inhaled
Reporting group description:	
Single dose of sterile normal saline (NaCl 0.9%) used as placebo was administered as intravenous (i.v.) infusion over a period of 60 minutes plus a single inhaled of 250 milligrams (mg) of BI 767551 administered via inhalation through a mouthpiece (Aerogen® Ultra) using a mesh nebulizer (Aerogen® Solo) on Day 1, followed by a 90-day follow-up period. The inhalation procedure was to start approximately 25 min after the start of infusion.	

Reporting group values	Placebo intravenous (i.v.) + placebo inhaled	Placebo intravenous (i.v.) + BI 767551 250 mg inhaled	Total
Number of subjects	2	1	3
Age categorical			
Treated set (TS): This subject set includes all subjects who received any amount of study drug.			
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)	2	1	3
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous			
Treated set (TS): This subject set includes all subjects who received any amount of study drug. The "9999" stands for "not applicable".			
Units: years			
arithmetic mean	35.5	37.0	
standard deviation	± 10.6	± 9999	-
Sex: Female, Male			
Treated set (TS): This subject set includes all subjects who received any amount of study drug.			
Units: Participants			
Female	2	1	3
Male	0	0	0
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0

Black or African American	0	0	0
White	2	1	3
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB)			
Treated set (TS): This subject set includes all subjects who received any amount of study drug.			
Units: Subjects			
Hispanic or Latino	2	0	2
Not Hispanic or Latino	0	1	1
Unknown or Not Reported	0	0	0
Log-transformed Nasopharyngeal (NP) swab viral load at baseline			
Each viral load result indicates the number of virus copies in a milliliter, and the raw values were log-transformed, resulting in log10 viral load. The "9999" stands for "not applicable".			
Units: Log10 copies / milliliter			
arithmetic mean	5.24	7.32	
standard deviation	± 2.09	± 9999	-

End points

End points reporting groups

Reporting group title	Placebo intravenous (i.v.) + placebo inhaled

Reporting group description:

Single dose of sterile normal saline (NaCl 0.9%) used as placebo was administered as intravenous (i.v.) infusion over a period of 60 minutes plus a single inhaled of solvent for dilution of BI 767551 used as placebo for inhalation administered via inhalation through a mouthpiece (Aerogen® Ultra) using a mesh nebulizer (Aerogen® Solo) on Day 1, followed by a 90-day follow-up period. The inhalation procedure was to start approximately 25 min after the start of infusion.

Reporting group title	Placebo intravenous (i.v.) + BI 767551 250 mg inhaled

Reporting group description:

Single dose of sterile normal saline (NaCl 0.9%) used as placebo was administered as intravenous (i.v.) infusion over a period of 60 minutes plus a single inhaled of 250 milligrams (mg) of BI 767551 administered via inhalation through a mouthpiece (Aerogen® Ultra) using a mesh nebulizer (Aerogen® Solo) on Day 1, followed by a 90-day follow-up period. The inhalation procedure was to start approximately 25 min after the start of infusion.

Reporting group title	Placebo intravenous (i.v.) + placebo inhaled

Reporting group description:

Single dose of sterile normal saline (NaCl 0.9%) used as placebo was administered as intravenous (i.v.) infusion over a period of 60 minutes plus a single inhaled of solvent for dilution of BI 767551 used as placebo for inhalation administered via inhalation through a mouthpiece (Aerogen® Ultra) using a mesh nebulizer (Aerogen® Solo) on Day 1, followed by a 90-day follow-up period. The inhalation procedure was to start approximately 25 min after the start of infusion.

Reporting group title	Placebo intravenous (i.v.) + BI 767551 250 mg inhaled

Reporting group description:

Single dose of sterile normal saline (NaCl 0.9%) used as placebo was administered as intravenous (i.v.) infusion over a period of 60 minutes plus a single inhaled of 250 milligrams (mg) of BI 767551 administered via inhalation through a mouthpiece (Aerogen® Ultra) using a mesh nebulizer (Aerogen® Solo) on Day 1, followed by a 90-day follow-up period. The inhalation procedure was to start approximately 25 min after the start of infusion.

Primary: Phase II: Time-weighted change from baseline in viral shedding over 8 days in site collected nasopharyngeal (NP) swabs by Quantitative Reverse Transcription Polymerase chain reaction (RT-qPCR)

End point title	Phase II: Time-weighted change from baseline in viral shedding over 8 days in site collected nasopharyngeal (NP) swabs by Quantitative Reverse Transcription Polymerase chain reaction (RT-qPCR)[1]

End point description:

Time-weighted change from baseline in viral shedding over 8 days in site collected nasopharyngeal (NP) swabs by Quantitative Reverse Transcription Polymerase chain reaction (RT-qPCR), defined as a absolute change from baseline in log10 viral load, is reported. The "9999" stands for "not applicable".

Modified Intention-To-Treat set (mITT): This subject set includes all randomised subjects that received any amount of study drug and who have at least a measurable baseline value (above Lower limit of quantification (LLOQ)) and a second measurement in the first week (up to 7 days after drug intake) of SARS-CoV-2 RNA by site collected nasopharyngeal (NP) swab.

End point type	Primary

End point timeframe:

Up to 8 days

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The endpoint was planned to explore descriptively.

End point values	Placebo intravenous (i.v.) + placebo inhaled	Placebo intravenous (i.v.) + BI 767551 250 mg inhaled		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	1[2]		
Units: Log10 copies / milliliter				
arithmetic mean (standard deviation)	0.15 (± 1.25)	-2.84 (± 9999)		

Notes:

[2] - "9999" stands for "not applicable".

Statistical analyses

No statistical analyses for this end point

Primary: Phase II: Time-weighted change from baseline in viral shedding over 29 days in site collected nasopharyngeal (NP) swabs by Quantitative Reverse Transcription Polymerase chain reaction (RT-qPCR)

End point title	Phase II: Time-weighted change from baseline in viral shedding over 29 days in site collected nasopharyngeal (NP) swabs by Quantitative Reverse Transcription Polymerase chain reaction (RT-qPCR)[3]

End point description:

Time-weighted change from baseline in viral shedding over 29 days in site collected nasopharyngeal (NP) swabs by Quantitative Reverse Transcription Polymerase chain reaction (RT-qPCR), defined as a absolute change from baseline in log10 viral load, is reported. The "9999" stands for "not applicable".

Modified Intention-To-Treat set (mITT): This subject set includes all randomised subjects that received any amount of study drug and who have at least a measurable baseline value (above Lower limit of quantification (LLOQ)) and a second measurement in the first week (up to 7 days after drug intake) of SARS-CoV-2 RNA by site collected nasopharyngeal (NP) swab.

End point type	Primary

End point timeframe:

Up to 29 days

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The endpoint was planned to explore descriptively.

End point values	Placebo intravenous (i.v.) + placebo inhaled	Placebo intravenous (i.v.) + BI 767551 250 mg inhaled		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	1[4]		
Units: Log10 copies / milliliter				
arithmetic mean (standard deviation)	-2.09 (± 1.60)	-4.18 (± 9999)		

Notes:

[4] - "9999" stands for "not applicable".

Statistical analyses

No statistical analyses for this end point

Secondary: Phase II: Number of participants with loss of detection of Severe acute respiratory syndrome coronavirus 2 ribonucleic acid (SARS-CoV-2 RNA) by site collected NP swab at Day 4, 8, 15, 22 and 29

End point title	Phase II: Number of participants with loss of detection of Severe acute respiratory syndrome coronavirus 2 ribonucleic acid (SARS-CoV-2 RNA) by site collected NP swab at Day 4, 8, 15, 22 and 29

End point description:

Number of participants with loss of detection of Severe acute respiratory syndrome coronavirus 2 ribonucleic acid (SARS-CoV-2 RNA) by site collected NP swab at Day 4, 8, 15, 22 and 29 is report. The "Yes" = loss of detection of SARS-CoV-2 RNA; "No" = SARS-CoV-2 RNA detected; "Missing" = not evaluable.

Treated set (TS): This subject set includes all subjects who received any amount of study drug.

End point type	Secondary

End point timeframe:

At Day 4, Day 8, Day 15, Day 22, and Day 29

End point values	Placebo intravenous (i.v.) + placebo inhaled	Placebo intravenous (i.v.) + BI 767551 250 mg inhaled		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	1		
Units: Participants				
Day 4|Yes	0	0		
Day 4|No	2	1		
Day 4|Missing	0	0		
Day 8|Yes	0	0		
Day 8|No	2	1		
Day 8|Missing	0	0		
Day 15|Yes	1	1		
Day 15|No	1	0		
Day 15|Missing	0	0		
Day 22|Yes	1	0		
Day 22|No	0	0		
Day 22|Missing	1	1		
Day 29|Yes	0	0		
Day 29|No	0	0		
Day 29|Missing	2	1		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From dosing until end of 90-day follow-up period, up to 91 days.

Adverse event reporting additional description:

Treated set (TS): This subject set includes all subjects who received any amount of study drug.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.1

Reporting groups

Reporting group title	Placebo intravenous (i.v.) + BI 767551 250 mg inhaled

Reporting group description:

Single dose of sterile normal saline (NaCl 0.9%) used as placebo was administered as intravenous (i.v.) infusion over a period of 60 minutes plus a single inhaled of 250 milligrams (mg) of BI 767551 administered via inhalation through a mouthpiece (Aerogen® Ultra) using a mesh nebulizer (Aerogen® Solo) on Day 1, followed by a 90-day follow-up period. The inhalation procedure was to start approximately 25 min after the start of infusion.

Reporting group title	Placebo intravenous (i.v.) + placebo inhaled

Reporting group description:

Single dose of sterile normal saline (NaCl 0.9%) used as placebo was administered as intravenous (i.v.) infusion over a period of 60 minutes plus a single inhaled of solvent for dilution of BI 767551 used as placebo for inhalation administered via inhalation through a mouthpiece (Aerogen® Ultra) using a mesh nebulizer (Aerogen® Solo) on Day 1, followed by a 90-day follow-up period. The inhalation procedure was to start approximately 25 min after the start of infusion.

Serious adverse events	Placebo intravenous (i.v.) + BI 767551 250 mg inhaled	Placebo intravenous (i.v.) + placebo inhaled	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

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

Non-serious adverse events	Placebo intravenous (i.v.) + BI 767551 250 mg inhaled	Placebo intravenous (i.v.) + placebo inhaled	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)	2 / 2 (100.00%)	
Investigations			
Alanine aminotransferase increased			

subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
Nervous system disorders			
Dizziness			
subjects affected / exposed	1 / 1 (100.00%)	1 / 2 (50.00%)	
occurrences (all)	1	1	
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
Infections and infestations			
Parotitis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
20 April 2021	For Phase II, the number of planned patients in each treatment arm was increased from 40:40:40:20 to 50:50:50:50, and the randomisation ratio was changed from 2:2:2:1 to 1:1:1:2, in order to include more patients in the placebo intravenous (i.v.) + BI 767551 250 milligrams (mg) inhaled arm and reach an equal number of patients in each arm at the end of recruitment in Phase II. For Phase III, a treatment arm for inhaled trial drug was added as an option.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

This trial was prematurely discontinued due to sponsor decision. No patients were entered in the planned Phase II "BI 10 mg/kg intravenous (i.v.) + placebo inhaled" and "BI 40 mg/kg i.v. + placebo inhaled" groups. Phase III part was not conducted.

Notes: