



Clinical trial results:

A Phase Ib/Ila open-label, repeated dose, metabolic balance study of FE 203799 in patients with short bowel syndrome

Summary

EudraCT number	2017-002487-41
Trial protocol	DK
Global end of trial date	28 October 2019

Results information

Result version number	v1 (current)
This version publication date	03 January 2021
First version publication date	03 January 2021

Trial information

Trial identification

Sponsor protocol code	GLY-321-2017
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	GLyPharma Therapeutic Inc.
Sponsor organisation address	1188 Avenue Union, Suite 504/505, Montreal, Canada, H3B 0E5
Public contact	Christian Meyer, GLyPharma Therapeutic Inc. (a wholly owned subsidiary of VectivBio Holding AG), 0041 796543455, christian.meyer@vectivbio.com
Scientific contact	Christian Meyer, GLyPharma Therapeutic Inc. (a wholly owned subsidiary of VectivBio Holding AG), 0041 796543455, christian.meyer@vectivbio.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 April 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	28 October 2019
Global end of trial reached?	Yes
Global end of trial date	28 October 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the safety and tolerability of FE 203799 in patients with short bowel syndrome (SBS)

Protection of trial subjects:

This trial was conducted in accordance with the ICH GCP guidelines, including the archiving of essential documents, and with the ethical principles that have their origin in the Declaration of Helsinki. Personal data included in the clinical trial report were collected and processed in accordance with the EU General Data Protection Regulation.

Background therapy:

None, this was a one-arm trial.

Evidence for comparator:

There was no comparator.

Actual start date of recruitment	02 May 2018
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	Denmark: 8
Worldwide total number of subjects	8
EEA total number of subjects	8

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)	4
From 65 to 84 years	4

Subject disposition

Recruitment

Recruitment details:

The subjects were recruited at a single trial centre in Denmark.

Pre-assignment

Screening details:

A total of 9 subjects were screened and 8 were enrolled in the trial. The reason for the screen failure was due to not fulfilling inclusion criteria 3 (average faecal wet weight excretion of ≥ 1500 g/day during the baseline balance study) and 4 (average urine production < 2000 mL/day during the baseline balance study).

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Blinding implementation details:

Not applicable as this was a one-arm open-label trial.

Arms

Are arms mutually exclusive?	Yes
Arm title	SBS-II

Arm description:

Subjects with short bowel syndrome and intestinal insufficiency

Arm type	Experimental
Investigational medicinal product name	Apraglutide
Investigational medicinal product code	FE 203799
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

The subjects were to receive a subcutaneous dose of 5 mg FE 203799 once weekly for 4 weeks

Arm title	SBS-IF
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Arm description:

Subjects with short bowel syndrome and intestinal failure

Arm type	Experimental
Investigational medicinal product name	Apraglutide
Investigational medicinal product code	FE 203799
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

The subjects were to receive a subcutaneous dose of 5 mg FE 203799 once weekly for 4 weeks

Number of subjects in period 1	SBS-II	SBS-IF
Started	4	4
Completed	4	4

Baseline characteristics

Reporting groups

Reporting group title	SBS-II
Reporting group description:	
Subjects with short bowel syndrome and intestinal insufficiency	
Reporting group title	SBS-IF
Reporting group description:	
Subjects with short bowel syndrome and intestinal failure	

Reporting group values	SBS-II	SBS-IF	Total
Number of subjects	4	4	8
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)	2	2	4
From 65-84 years	2	2	4
85 years and over	0	0	0
Age continuous			
Units: years			
arithmetic mean	64.50	57.50	-
standard deviation	± 3.40	± 20.00	-
Gender categorical			
Units: Subjects			
Female	2	3	5
Male	2	1	3
Race			
Units: Subjects			
White	4	4	8
Body weight			
Units: kg			
arithmetic mean	83.20	62.50	-
standard deviation	± 18.50	± 11.20	-
Body mass index			
A subject's weight in kilograms divided by the square of height in meters			
Units: kg/m ²			
arithmetic mean	28.60	22.70	-
standard deviation	± 5.10	± 4.20	-

Subject analysis sets

Subject analysis set title	Full analysis set
Subject analysis set type	Full analysis

Subject analysis set description:

The full analysis set comprised all subjects who had received at least 1 dose of trial drug and who, at least, had provided data for at least 1 post-baseline efficacy or pharmacokinetic endpoint.

Subject analysis set title	Safety analysis set
Subject analysis set type	Safety analysis

Subject analysis set description:

The safety analysis set comprised all subjects who received an investigational medicinal product injection at least once.

Reporting group values	Full analysis set	Safety analysis set	
Number of subjects	8	8	
Age categorical			
Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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)	4		
From 65-84 years	4		
85 years and over	0		
Age continuous			
Units: years			
arithmetic mean	61.00		
standard deviation	± 13.80	±	
Gender categorical			
Units: Subjects			
Female	5		
Male	3		
Race			
Units: Subjects			
White	8		
Body weight			
Units: kg			
arithmetic mean	72.80		
standard deviation	± 18.00	±	
Body mass index			
A subject's weight in kilograms divided by the square of height in meters			
Units: kg/m ²			
arithmetic mean	25.60		
standard deviation	± 5.40	±	

End points

End points reporting groups

Reporting group title	SBS-II
Reporting group description:	
Subjects with short bowel syndrome and intestinal insufficiency	
Reporting group title	SBS-IF
Reporting group description:	
Subjects with short bowel syndrome and intestinal failure	
Subject analysis set title	Full analysis set
Subject analysis set type	Full analysis
Subject analysis set description:	
The full analysis set comprised all subjects who had received at least 1 dose of trial drug and who, at least, had provided data for at least 1 post-baseline efficacy or pharmacokinetic endpoint.	
Subject analysis set title	Safety analysis set
Subject analysis set type	Safety analysis
Subject analysis set description:	
The safety analysis set comprised all subjects who received an investigational medicinal product injection at least once.	

Primary: Adverse events

End point title	Adverse events ^[1]
End point description:	
Number of subjects experiencing adverse events	
End point type	Primary
End point timeframe:	
Treatment-emergent adverse events were defined as those with onset after dosing at visit 3 until the end-of-trial visit (visit 8).	
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: No formal statistical comparisons of adverse event incidence rates between the reporting groups were performed.	

End point values	SBS-II	SBS-IF	Safety analysis set	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	4	4	8	
Units: Subjects	4	4	8	

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute change in faecal excretion of wet weight

End point title	Absolute change in faecal excretion of wet weight
End point description:	
Absolute change in faecal excretion of wet weight from baseline to end of treatment	
End point type	Secondary

End point timeframe:

Over 72 hours from baseline to end of treatment

End point values	SBS-II	SBS-IF	Full analysis set	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	4	4	8	
Units: g/day				
arithmetic mean (standard deviation)	-866.4 (\pm 835.0)	-492.5 (\pm 339.8)	-679.4 (\pm 623.1)	

Statistical analyses

Statistical analysis title	Absolute change in faecal wet weight excretion
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Statistical analysis description:

An analysis of the mean change from baseline to end of treatment for the full population of 8 subjects was derived using a paired t-test and the corresponding mean value together with the 95% confidence interval.

Comparison groups	SBS-II v SBS-IF
Number of subjects included in analysis	8
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0177
Method	t-test, 2-sided
Parameter estimate	Mean difference (net)
Point estimate	-679.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1200.4
upper limit	-158.5

Secondary: Absolute change in urinary output

End point title	Absolute change in urinary output
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End point description:

Absolute change in urinary output from baseline to end of treatment

End point type	Secondary
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End point timeframe:

Over 72 hours from baseline to end of treatment

End point values	SBS-II	SBS-IF	Full analysis set	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	4	4	8	
Units: g/day				
arithmetic mean (standard deviation)	560.0 (± 614.3)	560.0 (± 646.2)	560.0 (± 583.7)	

Statistical analyses

Statistical analysis title	Absolute change in urinary output
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Statistical analysis description:

An analysis of the mean change from baseline to end of treatment for the full population of 8 subjects was derived using a paired t-test and the corresponding mean value together with the 95% confidence interval.

Comparison groups	SBS-II v SBS-IF
Number of subjects included in analysis	8
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0301
Method	t-test, 2-sided
Parameter estimate	Mean difference (net)
Point estimate	560
Confidence interval	
level	95 %
sides	2-sided
lower limit	72
upper limit	1048

Secondary: Absolute change in absorption of wet weight

End point title	Absolute change in absorption of wet weight
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End point description:

Absolute change in absorption of wet weight from baseline to end of treatment

End point type	Secondary
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End point timeframe:

Over 72 hours from baseline to end of treatment

End point values	SBS-II	SBS-IF	Full analysis set	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	4	4	8	
Units: g/day				
arithmetic mean (standard deviation)	888.0 (± 903.8)	593.3 (± 349.5)	740.7 (± 653.6)	

Statistical analyses

Statistical analysis title	Absolute change in absorption of wet weight
Statistical analysis description: An analysis of the mean change from baseline to end of treatment for the full population of 8 subjects was derived using a paired t-test and the corresponding mean value together with the 95% confidence interval.	
Comparison groups	SBS-II v SBS-IF
Number of subjects included in analysis	8
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.015
Method	t-test, 2-sided
Parameter estimate	Mean difference (net)
Point estimate	740.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	194.2
upper limit	1287.2

Secondary: Absolute change in energy absorption

End point title	Absolute change in energy absorption
End point description: Absolute change in energy absorption from baseline to end of treatment	
End point type	Secondary
End point timeframe: Over 72 hours from baseline to end of treatment	

End point values	SBS-II	SBS-IF	Full analysis set	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	4	4	8	
Units: kJ/day				
arithmetic mean (standard deviation)	1356.2 (± 1497.5)	833.4 (± 521.0)	1094.8 (± 1075.0)	

Statistical analyses

Statistical analysis title	Absolute change in energy absorption
Statistical analysis description: An analysis of the mean change from baseline to end of treatment for the full population of 8 subjects was derived using a paired t-test and the corresponding mean value together with the 95% confidence interval.	
Comparison groups	SBS-II v SBS-IF
Number of subjects included in analysis	8
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0236
Method	t-test, 2-sided
Parameter estimate	Mean difference (net)
Point estimate	1094.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	196.1
upper limit	1993.6

Secondary: Absolute change in sodium absorption

End point title	Absolute change in sodium absorption
End point description: Absolute change in sodium absorption from baseline to end of treatment	
End point type	Secondary
End point timeframe: Over 72 hours from baseline to end of treatment	

End point values	SBS-II	SBS-IF	Full analysis set	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	4	4	8	
Units: mmol/day				
arithmetic mean (standard deviation)	66.3 (± 41.6)	9.8 (± 18.1)	38.0 (± 42.3)	

Statistical analyses

Statistical analysis title	Absolute change in sodium absorption
Statistical analysis description: An analysis of the mean change from baseline to end of treatment for the full population of 8 subjects was derived using a paired t-test and the corresponding mean value together with the 95% confidence interval.	
Comparison groups	SBS-II v SBS-IF

Number of subjects included in analysis	8
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0386
Method	t-test, 2-sided
Parameter estimate	Mean difference (net)
Point estimate	38.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.6
upper limit	73.5

Secondary: Absolute change in potassium absorption

End point title	Absolute change in potassium absorption
End point description:	Absolute change in potassium absorption from baseline to end of treatment
End point type	Secondary
End point timeframe:	Over 72 hours from baseline to end of treatment

End point values	SBS-II	SBS-IF	Full analysis set	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	4	4	8	
Units: mmol/day				
arithmetic mean (standard deviation)	19.9 (± 20.9)	16.2 (± 15.0)	18.1 (± 17.0)	

Statistical analyses

Statistical analysis title	Absolute change in potassium absorption
Statistical analysis description:	An analysis of the mean change from baseline to end of treatment for the full population of 8 subjects was derived using a paired t-test and the corresponding mean value together with the 95% confidence interval.
Comparison groups	SBS-II v SBS-IF
Number of subjects included in analysis	8
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0196
Method	t-test, 2-sided
Parameter estimate	Mean difference (net)
Point estimate	18.1

Confidence interval	
level	95 %
sides	2-sided
lower limit	3.9
upper limit	32.3

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events (AE) s were recorded from screening until the final visit 4-6 weeks after the last dose.

Adverse event reporting additional description:

An AE having onset on or after the day of the first administration of trial drug was considered treatment emergent. Adverse events were reported for the safety analysis set, comprising all subjects who received a treatment injection at least once.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	20.0
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Reporting groups

Reporting group title	SBS-II
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Reporting group description:

Subjects with short bowel syndrome and intestinal insufficiency

Reporting group title	SBS-IF
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Reporting group description:

Subjects with short bowel syndrome and intestinal failure

Serious adverse events	SBS-II	SBS-IF	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 4 (25.00%)	1 / 4 (25.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Device related sepsis			

subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	SBS-II	SBS-IF	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 4 (100.00%)	4 / 4 (100.00%)	
Vascular disorders			
Hot flush			
subjects affected / exposed	2 / 4 (50.00%)	0 / 4 (0.00%)	
occurrences (all)	2	0	
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	2 / 4 (50.00%)	1 / 4 (25.00%)	
occurrences (all)	2	1	
Injection site pruritus			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	1	
Injection site erythema			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	1	
Energy increased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	
occurrences (all)	1	0	
Thirst decreased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	
occurrences (all)	1	0	
Early satiety			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	
occurrences (all)	1	0	
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	1	

Investigations			
Gastrointestinal stoma output decreased			
subjects affected / exposed	3 / 4 (75.00%)	3 / 4 (75.00%)	
occurrences (all)	3	3	
Gastrointestinal stoma output abnormal			
subjects affected / exposed	3 / 4 (75.00%)	1 / 4 (25.00%)	
occurrences (all)	3	1	
Weight increased			
subjects affected / exposed	2 / 4 (50.00%)	0 / 4 (0.00%)	
occurrences (all)	2	0	
International normalised ratio increased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	
occurrences (all)	1	0	
Blood bilirubin increased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	1	
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	1	
Injury, poisoning and procedural complications			
Stoma complication			
subjects affected / exposed	3 / 4 (75.00%)	3 / 4 (75.00%)	
occurrences (all)	4	3	
Gastrointestinal stoma complication			
subjects affected / exposed	3 / 4 (75.00%)	2 / 4 (50.00%)	
occurrences (all)	3	2	
Cardiac disorders			
Palpitations			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	
occurrences (all)	1	0	
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	1	
Ear and labyrinth disorders			

Vertigo subjects affected / exposed occurrences (all)	2 / 4 (50.00%) 2	0 / 4 (0.00%) 0	
Gastrointestinal disorders			
Nausea subjects affected / exposed occurrences (all)	2 / 4 (50.00%) 2	4 / 4 (100.00%) 5	
Abdominal pain subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 3	1 / 4 (25.00%) 1	
Flatulence subjects affected / exposed occurrences (all)	3 / 4 (75.00%) 3	1 / 4 (25.00%) 1	
Constipation subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1	0 / 4 (0.00%) 0	
Vomiting subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 4 (25.00%) 1	
Abdominal pain upper subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 4 (25.00%) 1	
Rectal discharge subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1	0 / 4 (0.00%) 0	
Renal and urinary disorders			
Polyuria subjects affected / exposed occurrences (all)	2 / 4 (50.00%) 2	1 / 4 (25.00%) 1	
Musculoskeletal and connective tissue disorders			
Muscle spasms subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1	1 / 4 (25.00%) 1	
Back pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 4 (25.00%) 1	

<p>Infections and infestations</p> <p>Urinary tract infection</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>2 / 4 (50.00%)</p> <p>2</p>	<p>0 / 4 (0.00%)</p> <p>0</p>	
<p>Metabolism and nutrition disorders</p> <p>Fluid retention</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Hypokalaemia</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Hyperkalaemia</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Decreased appetite</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Dehydration</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Hyponatraemia</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Iron deficiency</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 4 (25.00%)</p> <p>1</p> <p>1 / 4 (25.00%)</p> <p>1</p> <p>0 / 4 (0.00%)</p> <p>0</p> <p>1 / 4 (25.00%)</p> <p>0</p> <p>1 / 4 (25.00%)</p> <p>1</p> <p>0 / 4 (0.00%)</p> <p>1</p> <p>1 / 4 (25.00%)</p> <p>1</p> <p>0 / 4 (0.00%)</p> <p>0</p>	<p>1 / 4 (25.00%)</p> <p>1</p> <p>0 / 4 (0.00%)</p> <p>0</p> <p>1 / 4 (25.00%)</p> <p>0</p> <p>1 / 4 (25.00%)</p> <p>0</p> <p>1 / 4 (25.00%)</p> <p>1</p>	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
09 April 2018	The dose was reduced from 25 mg to 5 mg, to change the approach for the first dosing in patients to a lower dose, which would be optimal for a first-in-patient trial, avoiding exposure of patients to potentially unnecessary elevated concentrations of the active compound. The change was based on thorough analyses of older and recent pharmacology data collected in nonclinical studies which suggested that a lower dose of FE 203799, such as 5 mg, could also show pharmacological activity.
06 December 2018	The substantial changes of the amendment were: <ul style="list-style-type: none">• The possibility to conduct interim analyses during the trial, if deemed necessary by the sponsor, was introduced. It was stated that any potential influence of interim analysis on the continued trial conduct would be minimised by appropriate measures.• The sponsor of the trial was changed from GlyPharma Therapeutic Inc. to GlyPharma Therapeutic Inc. (a wholly owned subsidiary of Therachon AG, Aeschenvorstadt 36, CH-4051 Basel Switzerland). Consequently, the sponsor medical officer and list of trial personnel were changed.• An additional laboratory was included in order to analyse all exploratory biomarkers.
01 February 2019	The substantial change of the amendment was: <ul style="list-style-type: none">• The inclusion of SBS patients with intestinal insufficiency (IF)• Addition of an inclusion criterion for male contraception• Change of exclusion criterion 16: Patients with changes in the use of systemic corticosteroids, methotrexate, cyclosporine, tacrolimus, sirolimus, infliximab, or other biologic therapy/immune modifiers within 3 months of screening were to be excluded from the protocol
27 June 2019	The substantial changes of the amendment were: <ul style="list-style-type: none">• A change in the company that owns the sponsor, GlyPharma Therapeutic Inc., from Therachon AG to VectivBio Holding AG.• A change of company name of one of the analysis laboratories was dated 09-Apr-2018 and approved prior to enrolment of the first patient.

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.

None.

Notes: