Clinical trial results:
A Phase I, Open Label, Randomised, Balanced, Single-dose, Two-period, Two-sequence Crossover-design Study to Evaluate Effects of Food on the Bioavailability of 80mg Elafibranor (IPN60190) To-be-marketed Tablet Formulation after Single Oral Administration in Healthy Adult Participants.

Summary

EudraCT number	2022-001883-91
Trial protocol	FR
Global end of trial date	14 January 2023

Results information

Result version number	v1 (current)
This version publication date	16 December 2023
First version publication date	16 December 2023

Trial information

Trial identification

Sponsor protocol code	CLIN-60190-452

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05564208
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Ipsen Bioscience, Inc.
Sponsor organisation address	One Main Street 7th Floor Cambridge, Massachusetts, United States, 02142
Public contact	Medical Director, Ipsen Bioscience Inc, clinical.trials@ipsen.com
Scientific contact	Medical Director, Ipsen Bioscience Inc, clinical.trials@ipsen.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	14 January 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	14 January 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To compare the bioavailability of a single dose of the to-be-marketed tablet of elafibranor 80 milligrams (mg) administered in fasting and fed conditions and to assess the pharmacokinetic (PK) parameters of elafibranor for total exposure and peak exposure.

Protection of trial subjects:

The study was conducted under the provisions of the Declaration of Helsinki, Version 2013 in accordance with the International Conference on Harmonisation Consolidated Guideline on Good Clinical Practice and in compliance with International Ethics Committees/Institutional Review Boards and informed consent regulations. In addition, this study adhered to all local regulatory requirements.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	11 October 2022
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	France: 34
Worldwide total number of subjects	34
EEA total number of subjects	34

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)	34
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This Phase I, randomized, single-dose, 2-period, 2-sequence crossover design study was conducted in healthy participants to evaluate effects of food on the bioavailability of elafibranor 80 mg. A total of 34 participants were randomized in this study in a 1:1 ratio (fed followed by fasting: fasting followed by fed).

Pre-assignment

Screening details:

This study consisted of a screening period (up to 4 weeks); 2 intervention periods (single doses in 2 periods [approximately 3 weeks] were separated by a washout phase [21-28 days]) and a final end-of-study (EOS) visit (21 days after last dose of study treatment). The maximum duration of the study was up to approximately 10 to 11 weeks.

Period 1

Period 1 title	Overall study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Elafibranor 80 mg fed/Elafibranor 80 mg fasting

Arm description:

Participants received 1 tablet of elafibranor 80 mg following an overnight fast of at least 10 hours and high-fat, high-calorie breakfast, on Day 1 of Period 1 followed by a washout period of at least 21 days up to a maximum of 28 days. On Day 1 of Period 2, those participants received 1 tablet of elafibranor 80 mg following an overnight fast of at least 10 hours.

Arm type	Experimental
Investigational medicinal product name	Elafibranor
Investigational medicinal product code	
Other name	GFT505, IPN60190
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Elafibranor was administered as 80 mg film-coated tablet with 240 milliliters (mL) of still water under fed and fasted conditions on Day 1 in each intervention period.

Arm title	Elafibranor 80 mg fasting/Elafibranor 80 mg fed

Arm description:

Participants received 1 tablet of elafibranor 80 mg following an overnight fast of at least 10 hours on Day 1 of Period 1 followed by a washout period of at least 21 days up to a maximum of 28 days. On Day 1 of Period 2, those participants received 1 tablet of elafibranor 80 mg following an overnight fast of at least 10 hours and high-fat, high-calorie breakfast.

Arm type	Experimental
Investigational medicinal product name	Elafibranor
Investigational medicinal product code	
Other name	GFT505, IPN60190
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Elafibranor was administered as 80 mg film-coated tablet with 240 mL of still water under fed and fasted conditions on Day 1 in each intervention period.

Number of subjects in period 1	Elafibranor 80 mg fed/Elafibranor 80 mg fasting	Elafibranor 80 mg fasting/Elafibranor 80 mg fed
Started	17	17
Completed	16	17
Not completed	1	0
Consent withdrawn by subject	1	-

Baseline characteristics

Reporting groups	
Reporting group title	Elafibranor 80 mg fed/Elafibranor 80 mg fasting
Reporting group description:	
Participants received 1 tablet of elafibranor 80 mg following an overnight fast of at least 10 hours and high-fat, high-calorie breakfast, on Day 1 of Period 1 followed by a washout period of at least 21 days up to a maximum of 28 days. On Day 1 of Period 2, those participants received 1 tablet of elafibranor 80 mg following an overnight fast of at least 10 hours.	
Reporting group title	Elafibranor 80 mg fasting/Elafibranor 80 mg fed
Reporting group description:	
Participants received 1 tablet of elafibranor 80 mg following an overnight fast of at least 10 hours on Day 1 of Period 1 followed by a washout period of at least 21 days up to a maximum of 28 days. On Day 1 of Period 2, those participants received 1 tablet of elafibranor 80 mg following an overnight fast of at least 10 hours and high-fat, high-calorie breakfast.	

Reporting group values	Elafibranor 80 mg fed/Elafibranor 80 mg fasting	Elafibranor 80 mg fasting/Elafibranor 80 mg fed	Total
Number of subjects	17	17	34
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	28.6	32.1	
standard deviation	± 6.6	± 8.0	-
Gender categorical Units: Subjects			
Female	9	9	18
Male	8	8	16
Race Units: Subjects			
Asian	0	0	0
Black or African American	4	2	6
White	13	14	27
Native Hawaiian or Other Pacific Islander	0	0	0
American Indian or Alaska Native	0	1	1
Not Reported	0	0	0
Other	0	0	0
Ethnicity Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	17	17	34
Not Reported	0	0	0

End points

End points reporting groups

Reporting group title	Elafibranor 80 mg fed/Elafibranor 80 mg fasting

Reporting group description:

Participants received 1 tablet of elafibranor 80 mg following an overnight fast of at least 10 hours and high-fat, high-calorie breakfast, on Day 1 of Period 1 followed by a washout period of at least 21 days up to a maximum of 28 days. On Day 1 of Period 2, those participants received 1 tablet of elafibranor 80 mg following an overnight fast of at least 10 hours.

Reporting group title	Elafibranor 80 mg fasting/Elafibranor 80 mg fed

Reporting group description:

Participants received 1 tablet of elafibranor 80 mg following an overnight fast of at least 10 hours on Day 1 of Period 1 followed by a washout period of at least 21 days up to a maximum of 28 days. On Day 1 of Period 2, those participants received 1 tablet of elafibranor 80 mg following an overnight fast of at least 10 hours and high-fat, high-calorie breakfast.

Subject analysis set title	Elafibranor 80 mg fed cohort
Subject analysis set type	Per protocol

Subject analysis set description:

All participants who received elafibranor 80 mg following an overnight fast of at least 10 hours, and high-fat, high-calorie breakfast irrespective of intervention period were included in this set. The PK analysis set consisted of all participants who completed both periods and had sufficient data to calculate maximum observed plasma concentration (Cmax), area under the plasma concentration-time curve from zero to the last quantifiable concentration (AUC0-t) and area under the plasma concentration-time curve from time zero to infinity (AUC0-∞). Participants were excluded from the PK set if they experienced emesis during the first 4 hours following any elafibranor administration.

Subject analysis set title	Elafibranor 80 mg fasting cohort
Subject analysis set type	Per protocol

Subject analysis set description:

All participants who received elafibranor 80 mg following an overnight fast of at least 10 hours irrespective of intervention period were included in this set. The PK analysis set consisted of all participants who completed both periods and had sufficient data to calculate Cmax, AUC0-t and AUC0-∞. Participants were excluded from the PK set if they experienced emesis during the first 4 hours following any elafibranor administration.

Primary: AUC0-t of Elafibranor

End point title	AUC0-t of Elafibranor

End point description:

Plasma samples were collected for assessing AUC0-t by non-compartmental analysis (NCA). Participants were classified according to the actual treatment sequence/each condition of treatment administration.

End point type	Primary

End point timeframe:

Pre-dose, 10, 20, 30 minutes, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 12, 24, 48, 72, 120, 168, 216 hours post-dose

End point values	Elafibranor 80 mg fed cohort	Elafibranor 80 mg fasting cohort		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	33	33		
Units: hour*nanogram/milliliter (h*ng/mL)				
arithmetic mean (standard deviation)	1374 (± 416)	1596 (± 488)		

Statistical analyses

Statistical analysis title	Geometric mean ratio between fed-fasting cohort

Statistical analysis description:

It was calculated using a linear mixed model including treatment, sequence and period as fixed effects and participant within sequence as a random effect. The same 33 subjects contribute to both fed and fasting periods.

Comparison groups	Elafibranor 80 mg fed cohort v Elafibranor 80 mg fasting cohort
Number of subjects included in analysis	66
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.0004 [1]
Method	ANOVA
Parameter estimate	geometric mean ratio
Point estimate	0.86
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.81
upper limit	0.92

Notes:

[1] - p-value of treatment is considered.

Primary: AUC0-∞ of Elafibranor

End point title	AUC0-∞ of Elafibranor

End point description:

Plasma samples were collected for assessing AUC0-∞ by NCA. Participants were classified according to the actual treatment sequence/each condition of treatment administration.

End point type	Primary

End point timeframe:

Pre-dose, 10, 20, 30 minutes, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 12, 24, 48, 72, 120, 168, 216 hours post-dose

End point values	Elafibranor 80 mg fed cohort	Elafibranor 80 mg fasting cohort		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	33	33		
Units: h*ng/mL				
arithmetic mean (standard deviation)	1531 (± 451)	1793 (± 564)		

Statistical analyses

Statistical analysis title	Geometric mean ratio between fed-fasting cohort

Statistical analysis description:

It was calculated using a linear mixed model including treatment, sequence and period as fixed effects and participant within sequence as a random effect. The same 33 subjects contribute to both fed and fasting periods.

Comparison groups	Elafibranor 80 mg fed cohort v Elafibranor 80 mg fasting cohort
Number of subjects included in analysis	66
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.0003 [2]
Method	ANOVA
Parameter estimate	geometric mean ratio
Point estimate	0.86
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.8
upper limit	0.91

Notes:

[2] - p-value of treatment is considered.

Primary: Cmax of Elafibranor

End point title	Cmax of Elafibranor

End point description:

Plasma samples were collected for assessing Cmax by NCA. Participants were classified according to the actual treatment sequence/each condition of treatment administration.

End point type	Primary

End point timeframe:

Pre-dose, 10, 20, 30 minutes, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 12, 24, 48, 72, 120, 168, 216 hours post-dose

End point values	Elafibranor 80 mg fed cohort	Elafibranor 80 mg fasting cohort		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	33	33		
Units: ng/mL				
arithmetic mean (standard deviation)	195 (± 118)	352 (± 155)		

Statistical analyses

Statistical analysis title	Geometric mean ratio between fed-fasting cohort

Statistical analysis description:

It was calculated using a linear mixed model including treatment, sequence and period as fixed effects and participant within sequence as a random effect. The same 33 subjects contribute to both fed and fasting periods.

Comparison groups	Elafibranor 80 mg fed cohort v Elafibranor 80 mg fasting cohort
Number of subjects included in analysis	66
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	< 0.0001 [3]
Method	ANOVA
Parameter estimate	geometric mean ratio
Point estimate	0.52
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.41
upper limit	0.66

Notes:

[3] - p-value of treatment is considered.

Secondary: AUC0-t of GFT1007

End point title	AUC0-t of GFT1007

End point description:

Plasma samples were collected for assessing AUC0-t by NCA. Participants were classified according to the actual treatment sequence/each condition of treatment administration.

End point type	Secondary

End point timeframe:

Pre-dose, 10, 20, 30 minutes, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 12, 24, 48, 72, 120, and 168 hours post-dose

End point values	Elafibranor 80 mg fed cohort	Elafibranor 80 mg fasting cohort		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	33	33		
Units: h*ng/mL				
arithmetic mean (standard deviation)	7040 (± 1403)	7024 (± 2119)		

Statistical analyses

Statistical analysis title	Geometric mean ratio between fed-fasting cohort

Statistical analysis description:

It was calculated using a linear mixed model including treatment, sequence and period as fixed effects and participant within sequence as a random effect. The same 33 subjects contribute to both fed and fasting periods.

Comparison groups	Elafibranor 80 mg fed cohort v Elafibranor 80 mg fasting cohort

Number of subjects included in analysis	66
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.4379 [4]
Method	ANOVA
Parameter estimate	geometric mean ratio
Point estimate	1.02
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.97
upper limit	1.08

Notes:

[4] - p-value of treatment is considered.

Secondary: AUC0-∞ of GFT1007

End point title	AUC0-∞ of GFT1007

End point description:

Plasma samples were collected for the collection of AUC0-∞ by NCA. Participants were classified according to the actual treatment sequence/each condition of treatment administration. Only those participants with data available were included in the analysis.

End point type	Secondary

End point timeframe:

Pre-dose, 10, 20, 30 minutes, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 12, 24, 48, 72, 120, and 168 hours post-dose

End point values	Elafibranor 80 mg fed cohort	Elafibranor 80 mg fasting cohort		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	30	24		
Units: h*ng/mL				
arithmetic mean (standard deviation)	7374 (± 1425)	7506 (± 1786)		

Statistical analyses

Statistical analysis title	Geometric mean ratio between fed-fasting cohort

Statistical analysis description:

It was calculated using a linear mixed model including treatment, sequence and period as fixed effects and participant within sequence as a random effect. The same 33 subjects contribute to both fed and fasting periods.

Comparison groups	Elafibranor 80 mg fed cohort v Elafibranor 80 mg fasting cohort
Number of subjects included in analysis	54
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.6177
Method	ANOVA
Parameter estimate	geometric mean ratio
Point estimate	0.99

Confidence interval	
level	90 %
sides	2-sided
lower limit	0.94
upper limit	1.03

Secondary: Cmax of GFT1007

End point title	Cmax of GFT1007

End point description:

Plasma samples were collected for assessing Cmax by NCA. Participants were classified according to the actual treatment sequence/each condition of treatment administration.

End point type	Secondary

End point timeframe:

Pre-dose, 10, 20, 30 minutes, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 12, 24, 48, 72, 120, and 168 hours post-dose

End point values	Elafibranor 80 mg fed cohort	Elafibranor 80 mg fasting cohort		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	33	33		
Units: ng/mL				
arithmetic mean (standard deviation)	1383 (± 651)	1823 (± 576)		

Statistical analyses

Statistical analysis title	Geometric mean ratio between fed-fasting cohort

Statistical analysis description:

It was calculated using a linear mixed model including treatment, sequence and period as fixed effects and participant within sequence as a random effect. The same 33 subjects contribute to both fed and fasting periods.

Comparison groups	Elafibranor 80 mg fed cohort v Elafibranor 80 mg fasting cohort
Number of subjects included in analysis	66
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	< 0.0001 [5]
Method	ANOVA
Parameter estimate	geometric mean ratio
Point estimate	0.72
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.64
upper limit	0.81

Notes:

[5] - p-value of treatment is considered.

Secondary: Terminal Elimination Half-Life (t1/2) of Elafibranor and GFT1007

End point title	Terminal Elimination Half-Life (t1/2) of Elafibranor and GFT1007

End point description:

Plasma samples were collected for assessing t1/2 by NCA. Participants were classified according to the actual treatment sequence/each condition of treatment administration. Only those participants with data available were included in the analysis and denoted by 'n' in the categories.

End point type	Secondary

End point timeframe:

Pre-dose, 10, 20, 30 minutes, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 12, 24, 48, 72, 120, 168 (GFT1007), and 216 hours post-dose (elafibranor)

End point values	Elafibranor 80 mg fed cohort	Elafibranor 80 mg fasting cohort		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	33	33		
Units: hours				
median (full range (min-max))				
Elafibranor (n= 33,33)	66.3 (44.2 to 90.0)	70.2 (37.1 to 92.2)		
GFT1007 (n=30, 24)	11.1 (6.72 to 26.9)	15.4 (9.39 to 21.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Maximum Observed Drug Concentration (Tmax) of Elafibranor and GFT1007

End point title	Time to Maximum Observed Drug Concentration (Tmax) of Elafibranor and GFT1007

End point description:

Plasma samples were collected for assessing Tmax by NCA. Participants were classified according to the actual treatment sequence/each condition of treatment administration.

End point type	Secondary

End point timeframe:

Pre-dose, 10, 20, 30 minutes, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 12, 24, 48, 72, 120, 168 (GFT1007), 216 hours post-dose (elafibranor)

End point values	Elafibranor 80 mg fed cohort	Elafibranor 80 mg fasting cohort		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	33	33		
Units: hours				
median (full range (min-max))				
Elafibranor	2.0 (0.33 to 8.0)	1.5 (0.33 to 4.0)		
GFT1007	2.5 (1.0 to 8.0)	1.5 (0.50 to 5.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Time of Observation Prior to the First Observation With a Measurable (Nonzero) Concentration (Tlag) of Elafibranor and GFT1007

End point title	Time of Observation Prior to the First Observation With a Measurable (Nonzero) Concentration (Tlag) of Elafibranor and GFT1007

End point description:

Plasma samples were collected for assessing Tlag by NCA. Participants were classified according to the actual treatment sequence/each condition of treatment administration.

End point type	Secondary

End point timeframe:

Pre-dose, 10, 20, 30 minutes, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 12, 24, 48, 72, 120, 168 (GFT1007), 216 hours post-dose (elafibranor)

End point values	Elafibranor 80 mg fed cohort	Elafibranor 80 mg fasting cohort		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	33	33		
Units: hours				
median (full range (min-max))				
Elafibranor	0.17 (0 to 2.0)	0 (0 to 0.33)		
GFT1007	0.17 (0 to 1.5)	0.17 (0 to 0.33)		

Statistical analyses

No statistical analyses for this end point

Secondary: Terminal Elimination Rate Constant (λz) of Elafibranor and GFT1007

End point title	Terminal Elimination Rate Constant (λz) of Elafibranor and GFT1007

End point description:

Plasma samples were collected for assessing λz by NCA. Participants were classified according to the actual treatment sequence/each condition of treatment administration. Only those participants with data available were included in the analysis denoted by 'n' in the categories.

End point type	Secondary

End point timeframe:

Pre-dose, 10, 20, 30 minutes, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 12, 24, 48, 72, 120, 168 (GFT1007), 216 hours post-dose (elafibranor)

End point values	Elafibranor 80 mg fed cohort	Elafibranor 80 mg fasting cohort		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	33	33		
Units: per hour (/h)				
arithmetic mean (standard deviation)				
Elafibranor (n=33, 33)	0.0108 (± 0.00194)	0.0106 (± 0.00245)		
GFT1007 (n=30, 24)	0.0605 (± 0.0189)	0.0477 (± 0.0124)		

Statistical analyses

No statistical analyses for this end point

Secondary: Total Body Clearance (Cl/F) of Elafibranor

End point title	Total Body Clearance (Cl/F) of Elafibranor

End point description:

Plasma samples were collected for assessing Cl/F by NCA. Participants were classified according to the actual treatment sequence/each condition of treatment administration.

End point type	Secondary

End point timeframe:

Pre-dose, 10, 20, 30 minutes, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 12, 24, 48, 72, 120, 168, 216 hours post-dose

End point values	Elafibranor 80 mg fed cohort	Elafibranor 80 mg fasting cohort		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	33	33		
Units: liter/hour				
arithmetic mean (standard deviation)	57.8 (± 21.0)	50.0 (± 19.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Volume of Distribution (Vd/F) of Elafibranor

End point title	Volume of Distribution (Vd/F) of Elafibranor

End point description:

Plasma samples were collected for assessing Vd/F by NCA. Participants were classified according to the actual treatment sequence/each condition of treatment administration.

End point type	Secondary

End point timeframe:

Pre-dose, 10, 20, 30 minutes, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 12, 24, 48, 72, 120, 168, 216 hours post-dose

End point values	Elafibranor 80 mg fed cohort	Elafibranor 80 mg fasting cohort		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	33	33		
Units: liter				
arithmetic mean (standard deviation)	5389 (± 1661)	4731 (± 1486)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From the start of treatment administration up to end-of-study, approximately 3 months.

Adverse event reporting additional description:

The Safety set consisted of all participants who received at least 1 dose of study treatment.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.1

Reporting groups

Reporting group title	Elafibranor 80 mg fed

Reporting group description:

All participants who received elafibranor 80 mg following an overnight fast of at least 10 hours, and high-fat, high-calorie breakfast irrespective of intervention period were included in this set.

Reporting group title	Elafibranor 80 mg fasting

Reporting group description:

All participants who received elafibranor 80 mg following an overnight fast of at least 10 hours irrespective of intervention period were included in this set.

Serious adverse events	Elafibranor 80 mg fed	Elafibranor 80 mg fasting	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 34 (0.00%)	0 / 33 (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: 0 %

Non-serious adverse events	Elafibranor 80 mg fed	Elafibranor 80 mg fasting	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 34 (20.59%)	8 / 33 (24.24%)	
Investigations			
SARS-CoV-2 test positive			
subjects affected / exposed	3 / 34 (8.82%)	1 / 33 (3.03%)	
occurrences (all)	3	1	
Nervous system disorders			
Headache			

subjects affected / exposed occurrences (all)	2 / 34 (5.88%) 2	4 / 33 (12.12%) 4	
Gastrointestinal disorders Abdominal pain subjects affected / exposed occurrences (all) Diarrhoea subjects affected / exposed occurrences (all) Nausea subjects affected / exposed occurrences (all)	 0 / 34 (0.00%) 0 1 / 34 (2.94%) 1 1 / 34 (2.94%) 1	 1 / 33 (3.03%) 1 0 / 33 (0.00%) 0 0 / 33 (0.00%) 0	
Skin and subcutaneous tissue disorders Dermatitis contact subjects affected / exposed occurrences (all)	 0 / 34 (0.00%) 0	 1 / 33 (3.03%) 1	
Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all)	 0 / 34 (0.00%) 0	 2 / 33 (6.06%) 2	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
15 September 2022	Protocol was amended to implement the changes requested by the Competent Authority during the submission of the clinical trial application.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported