Clinical trial results:
A randomized, double-blind, open for active comparator, parallel-group, multicenter Phase 2b study to assess the efficacy and safety of three different doses of P2X3 antagonist (BAY 1817080) versus placebo and elagolix 150 mg in women with symptomatic endometriosis

Summary

EudraCT number	2020-003131-16
Trial protocol	DE CZ SK FI NO AT LT PL BE BG HU GR EE LV IT
Global end of trial date	03 May 2022

Results information

Result version number	v1 (current)
This version publication date	09 May 2023
First version publication date	09 May 2023

Trial information

Trial identification

Sponsor protocol code	20584

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04614246
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Bayer AG
Sponsor organisation address	Kaiser-Wilhelm-Allee, Leverkusen, Germany, 51368
Public contact	Therapeutic Area Head, Bayer AG, clinical-trials-contact@bayer.com
Scientific contact	Therapeutic Area Head, Bayer AG, clinical-trials-contact@bayer.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	03 May 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	03 May 2022
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To assess the dose-response relationship and demonstrate efficacy of eliapixant compared to placebo in women with symptomatic endometriosis.

Protection of trial subjects:

The conduct of this clinical study met all local legal and regulatory requirements. The study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and the International Conference on Harmonization guideline E6: Good Clinical Practice. Before entering the study, the informed consent form was read by and explained to all subjects. Participating subjects signed informed consent form and could withdraw from the study at any time without any disadvantage and without having to provide a reason for this decision. Only investigators qualified by training and experience were selected as appropriate experts to investigate the study drug.

Background therapy: -

Evidence for comparator:

1. A placebo-controlled design was considered scientifically necessary to differentiate drug effects from the natural course of the disease and placebo effects.
2. Elagolix 150 mg once daily is approved for the treatment of the disease and was given as an active comparator open-label.

Actual start date of recruitment	29 January 2021
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	Austria: 9
Country: Number of subjects enrolled	Belgium: 4
Country: Number of subjects enrolled	Bulgaria: 8
Country: Number of subjects enrolled	Canada: 2
Country: Number of subjects enrolled	China: 6
Country: Number of subjects enrolled	Czechia: 26
Country: Number of subjects enrolled	Finland: 1
Country: Number of subjects enrolled	Germany: 18
Country: Number of subjects enrolled	Greece: 1
Country: Number of subjects enrolled	Hungary: 2
Country: Number of subjects enrolled	Italy: 7
Country: Number of subjects enrolled	Japan: 42
Country: Number of subjects enrolled	Lithuania: 3
Country: Number of subjects enrolled	Latvia: 2

Country: Number of subjects enrolled	Norway: 9
Country: Number of subjects enrolled	Poland: 39
Country: Number of subjects enrolled	Slovakia: 4
Country: Number of subjects enrolled	Spain: 4
Country: Number of subjects enrolled	United States: 28
Worldwide total number of subjects	215
EEA total number of subjects	137

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)	215
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This multinational study was conducted between 29 JAN 2021 First Patient First Visit (FPFV) and 03 MAY 2022 Last Patient Last Visit (LPLV) in 20 countries/regions:
Austria, Belgium, Bulgaria, Canada, China, Czech Republic, Finland , Germany, Greece, Hungary, Italy, Japan, Lithuania, Latvia, Norway, Poland, Slovakia, Spain, United States

Pre-assignment

Screening details:

Participant disposition was generally well balanced between the treatment arms. 504 participants were enrolled with 289 participants failed screening or were not assigned to treatment. A total of 215 participants were randomized to 5 treatment arms (44 to eliapixant, 44 to eliapixant, 43 to eliapixant, 43 to placebo, and 41 to Elagolix).

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	Eliapixant (BAY1817080) 25 mg

Arm description:

25mg eliapixant twice daily for 12 weeks

Arm type	Experimental
Investigational medicinal product name	Eliapixant
Investigational medicinal product code	BAY1817080
Other name	
Pharmaceutical forms	Coated tablet
Routes of administration	Oral use

Dosage and administration details:

25mg eliapixant twice daily for 12 weeks

Arm title	Eliapixant (BAY1817080) 75 mg

Arm description:

75mg eliapixant twice daily for 12 weeks

Arm type	Experimental
Investigational medicinal product name	Eliapixant
Investigational medicinal product code	BAY1817080
Other name	
Pharmaceutical forms	Coated tablet
Routes of administration	Oral use

Dosage and administration details:

75mg eliapixant twice daily for 12 weeks

Arm title	Eliapixant (BAY1817080) 150 mg

Arm description:

150mg eliapixant twice daily for 12 weeks

Arm type	Experimental

Investigational medicinal product name	Eliapixant
Investigational medicinal product code	BAY1817080
Other name	
Pharmaceutical forms	Coated tablet
Routes of administration	Oral use

Dosage and administration details:

150mg eliapixant twice daily for 12 weeks

Arm title	Placebo

Arm description:

Placebo for eliapixant twice daily for 12 weeks

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

Dosage and administration details:

Placebo for eliapixant twice daily for 12 weeks

Arm title	Elagolix 150mg

Arm description:

150mg Elagolix once daily for 12 weeks

Arm type	Active comparator
Investigational medicinal product name	Elagolix
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Coated tablet
Routes of administration	Oral use

Dosage and administration details:

150mg Elagolix once daily for 12 weeks

Number of subjects in period 1	Eliapixant (BAY1817080) 25 mg	Eliapixant (BAY1817080) 75 mg	Eliapixant (BAY1817080) 150 mg
Started	44	44	43
Completed	28	22	22
Not completed	16	22	21
Consent withdrawn by subject	4	2	4
Physician decision	-	2	1
Adverse event, non-fatal	-	1	1
Pregnancy	2	-	1
Study terminated by sponsor	-	15	12
Other reason	-	1	2
Lost to follow-up	-	1	-
Excluded by sponsor due to safety reasons	10	-	-

Number of subjects in period 1	Placebo	Elagolix 150mg
Started	43	41
Completed	24	24
Not completed	19	17
Consent withdrawn by subject	3	4
Physician decision	-	-
Adverse event, non-fatal	2	1
Pregnancy	-	-
Study terminated by sponsor	13	9
Other reason	-	-
Lost to follow-up	1	3
Excluded by sponsor due to safety reasons	-	-

Baseline characteristics

Reporting groups	
Reporting group title	Eliapixant (BAY1817080) 25 mg
Reporting group description:	
25mg eliapixant twice daily for 12 weeks	
Reporting group title	Eliapixant (BAY1817080) 75 mg
Reporting group description:	
75mg eliapixant twice daily for 12 weeks	
Reporting group title	Eliapixant (BAY1817080) 150 mg
Reporting group description:	
150mg eliapixant twice daily for 12 weeks	
Reporting group title	Placebo
Reporting group description:	
Placebo for eliapixant twice daily for 12 weeks	
Reporting group title	Elagolix 150mg
Reporting group description:	
150mg Elagolix once daily for 12 weeks	

Reporting group values	Eliapixant (BAY1817080) 25 mg	Eliapixant (BAY1817080) 75 mg	Eliapixant (BAY1817080) 150 mg
Number of subjects	44	44	43
Age Categorical Units: Participants			
<=18 years	0	0	0
Between 18 and 65 years	44	44	43
>=65 years	0	0	0
Sex: Female, Male Units: Participants			
Female	44	44	43
Male	0	0	0

Reporting group values	Placebo	Elagolix 150mg	Total
Number of subjects	43	41	215
Age Categorical Units: Participants			
<=18 years	0	0	0
Between 18 and 65 years	43	41	215
>=65 years	0	0	0
Sex: Female, Male Units: Participants			
Female	43	41	215
Male	0	0	0

End points

End points reporting groups

Reporting group title	Eliapixant (BAY1817080) 25 mg
Reporting group description: 25mg eliapixant twice daily for 12 weeks	
Reporting group title	Eliapixant (BAY1817080) 75 mg
Reporting group description: 75mg eliapixant twice daily for 12 weeks	
Reporting group title	Eliapixant (BAY1817080) 150 mg
Reporting group description: 150mg eliapixant twice daily for 12 weeks	
Reporting group title	Placebo
Reporting group description: Placebo for eliapixant twice daily for 12 weeks	
Reporting group title	Elagolix 150mg
Reporting group description: 150mg Elagolix once daily for 12 weeks	

Primary: Absolute change in mean worst EAPP from baseline to week 12 - pPPS

End point title	Absolute change in mean worst EAPP from baseline to week 12 - pPPS[1][2]

End point description:

The worst EAPP was measured daily on the 0-10 Numerical Rating Scale (NRS) by item 1 of the Endometriosis Symptom Diary (ESD). In question 1, participants were asked to rate the pain in the target area during the past 24 hours, where 0= no pain and 10= worst imaginable pain and responses were recorded in ESD. The absolute change in mean worst EAPP was from baseline (last 28 days before the first intake of study drug) to end of intervention (last 28 days ending with the last intake of study drug planned on Day 84 [+3]). The time frame of 28 days captures a menstrual cycle on average.

End point type	Primary

End point timeframe:

from baseline to week 12

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: Statistical analysis is given as an add-on endpoint to the primary endpoint, because the statistics on changes between different time points within one arm cannot be correctly displayed in the "Statistical Analysis Section", due to database constraints.
[2] - 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: Active comparator Elagolix not part of Primary per protocol set (pPPS)

End point values	Eliapixant (BAY1817080) 25 mg	Eliapixant (BAY1817080) 75 mg	Eliapixant (BAY1817080) 150 mg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	31	31	31	30
Units: units on a scale				
arithmetic mean (standard deviation)				
Baseline	6.40 (± 1.66)	6.13 (± 1.77)	6.95 (± 1.38)	6.14 (± 1.96)
Week 12	4.57 (± 2.10)	4.15 (± 2.49)	5.15 (± 2.42)	4.29 (± 1.71)
Week 12: Change from Baseline	-1.56 (± 1.35)	-2.12 (± 2.66)	-1.88 (± 2.03)	-1.89 (± 1.91)

Statistical analyses

No statistical analyses for this end point

Primary: Absolute change in mean worst EAPP from baseline to week 12 - pPPS: Mean (SE)

End point title	Absolute change in mean worst EAPP from baseline to week 12 - pPPS: Mean (SE)[3][4]

End point description:

Least square-mean of change obtained by mixed model repeated measures (MMRM) from baseline to Week 12 (End of intervention) in the pPPS. The worst EAPP was measured daily on the 0-10 Numerical Rating Scale (NRS) by item 1 of the Endometriosis Symptom Diary (ESD). In question 1, participants were asked to rate the pain in the target area during the past 24 hours, where 0= no pain and 10= worst imaginable pain and responses were recorded in ESD. The absolute change in mean worst EAPP was from baseline (last 28 days before the first intake of study drug) to end of intervention (last 28 days ending with the last intake of study drug planned on Day 84 [+3]). The time frame of 28 days captures a menstrual cycle on average.

End point type	Primary

End point timeframe:

change from baseline to week 12

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: Statistical analysis is given as an add-on endpoint to the primary endpoint, because the statistics on changes between different time points within one arm cannot be correctly displayed in the "Statistical Analysis Section", due to database constraints.
[4] - 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: Active comparator Elagolix not part of Primary per protocol set (pPPS)

End point values	Eliapixant (BAY1817080) 25 mg	Eliapixant (BAY1817080) 75 mg	Eliapixant (BAY1817080) 150 mg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	31	31	31	30
Units: units on a scale				
least squares mean (standard error)				
week 12	-1.63 (± 0.38)	-2.13 (± 0.41)	-1.96 (± 0.41)	-1.94 (± 0.38)

Statistical analyses

No statistical analyses for this end point

Primary: Absolute change in mean worst EAPP from baseline to week 12 - pPPS: 80% confidence interval (CI)

End point title	Absolute change in mean worst EAPP from baseline to week 12 - pPPS: 80% confidence interval (CI)[5][6]

End point description:

Least square-mean (LS-mean, Confidence Interval) of change obtained by mixed model repeated measures (MMRM) from baseline to Week 12 (End of intervention) in the pPPS. The worst EAPP was measured daily on the 0-10 Numerical Rating Scale (NRS) by item 1 of the Endometriosis Symptom Diary (ESD). In question 1, participants were asked to rate the pain in the target area during the past 24 hours, where 0= no pain and 10= worst imaginable pain and responses were recorded in ESD. The absolute change in mean worst EAPP was from baseline (last 28 days before the first intake of study drug) to end of intervention (last 28 days ending with the last intake of study drug planned on Day 84 [+3]). The time frame of 28 days captures a menstrual cycle on average.

End point type	Primary

End point timeframe:

change from baseline to week 12

Notes:

[5] - 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: Statistical analysis is given as an add-on endpoint to the primary endpoint, because the statistics on changes between different time points within one arm cannot be correctly displayed in the "Statistical Analysis Section", due to database constraints.
[6] - 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: Active comparator Elagolix not part of Primary per protocol set (pPPS)

End point values	Eliapixant (BAY1817080) 25 mg	Eliapixant (BAY1817080) 75 mg	Eliapixant (BAY1817080) 150 mg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	31	31	31	30
Units: units on a scale				
least squares mean (confidence interval 80%)				
week 12	-1.63 (-2.13 to -1.14)	-2.13 (-2.66 to -1.61)	-1.96 (-2.48 to -1.43)	-1.94 (-2.44 to -1.45)

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute change in mean worst EAPP from baseline to week 12 - PPS: Mean (SE)

End point title	Absolute change in mean worst EAPP from baseline to week 12 - PPS: Mean (SE)

End point description:

Least square-mean (LS-mean, SD) of change obtained by mixed model repeated measures (MMRM) from baseline to Week 12 (End of intervention) in the PPS, based on descriptive statistics. The worst EAPP was measured daily on the 0-10 Numerical Rating Scale (NRS) by item 1 of the Endometriosis Symptom Diary (ESD). In question 1, participants were asked to rate the pain in the target area during the past 24 hours, where 0= no pain and 10= worst imaginable pain and responses were recorded in ESD. The absolute change in mean worst EAPP was from baseline (last 28 days before the first intake of study drug) to end of intervention (last 28 days ending with the last intake of study drug planned on Day 84 [+3]). The time frame of 28 days captures a menstrual cycle on average.

End point type	Secondary

End point timeframe:

up to 12 weeks

End point values	Eliapixant (BAY1817080) 25 mg	Eliapixant (BAY1817080) 75 mg	Eliapixant (BAY1817080) 150 mg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	31	31	31	30
Units: units on a scale				
least squares mean (standard error)				
week 12	-1.60 (± 0.40)	-2.07 (± 0.42)	-1.97 (± 0.42)	-1.89 (± 0.40)

End point values	Elagolix 150mg			
Subject group type	Reporting group			
Number of subjects analysed	37			
Units: units on a scale				
least squares mean (standard error)				
week 12	-2.69 (± 0.41)			

Statistical analyses

No statistical analyses for this end point

Secondary: Difference of least square-mean - Eliapixant arms vs Placebo arm (pairwise comparison) - change in mean worst EAPP from baseline to Week 12 - pPPS

End point title	Difference of least square-mean - Eliapixant arms vs Placebo arm (pairwise comparison) - change in mean worst EAPP from baseline to Week 12 - pPPS[7]

End point description:

Least square-mean of change (pairwise comparison between treatment arms and placebo arm) obtained by mixed model repeated measures (MMRM) from baseline to Week 12 (End of intervention) in the pPPS. The worst EAPP was measured daily on the 0-10 Numerical Rating Scale (NRS) by item 1 of the Endometriosis Symptom Diary (ESD). In question 1, participants were asked to rate the pain in the target area during the past 24 hours, where 0= no pain and 10= worst imaginable pain and responses were recorded in ESD. The absolute change in mean worst EAPP was from baseline (last 28 days before the first intake of study drug) to end of intervention (last 28 days ending with the last intake of study drug planned on Day 84 [+3]). The time frame of 28 days captures a menstrual cycle on average.

End point type	Secondary

End point timeframe:

change from baseline to week 12

Notes:

[7] - 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: Active comparator Elagolix not part of Primary per protocol set (pPPS)

End point values	Eliapixant (BAY1817080) 25 mg	Eliapixant (BAY1817080) 75 mg	Eliapixant (BAY1817080) 150 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	31	31	37	
Units: units on a scale				
least squares mean (standard error)				
12 weeks - treatment vs placebo	0.29 (± 0.54)	-0.18 (± 0.55)	-0.08 (± 0.56)	

Statistical analyses

No statistical analyses for this end point

Secondary: Difference of least square-mean (95% Confidence Interval, CI) - Eliapixant arms vs Placebo arm (pairwise comparison) - change in mean worst EAPP from baseline to Week 12 - pPPS

End point title	Difference of least square-mean (95% Confidence Interval, CI) - Eliapixant arms vs Placebo arm (pairwise comparison) - change in mean worst EAPP from baseline to Week 12 - pPPS[8]

End point description:

Least square-mean of change (LS-mean, 95% Confidence Interval, CI); pairwise comparison between treatment arms and placebo arm) obtained by mixed model repeated measures (MMRM) from baseline to Week 12 (End of intervention) in the pPPS. The worst EAPP was measured daily on the 0-10 Numerical Rating Scale (NRS) by item 1 of the Endometriosis Symptom Diary (ESD). In question 1, participants were asked to rate the pain in the target area during the past 24 hours, where 0= no pain and 10= worst imaginable pain and responses were recorded in ESD. The absolute change in mean worst EAPP was from baseline (last 28 days before the first intake of study drug) to end of intervention (last 28 days ending with the last intake of study drug planned on Day 84 [+3]). The time frame of 28 days captures a menstrual cycle on average.

End point type	Secondary

End point timeframe:

change from baseline to week 12

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: Active comparator Elagolix not part of Primary per protocol set (pPPS)

End point values	Eliapixant (BAY1817080) 25 mg	Eliapixant (BAY1817080) 75 mg	Eliapixant (BAY1817080) 150 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	31	31	37	
Units: units on a scale				
least squares mean (confidence interval 95%)				
12 weeks - treatment vs placebo	0.29 (-0.77 to 1.35)	-0.18 (-1.27 to 0.91)	-0.08 (-1.17 to 1.02)	

Statistical analyses

No statistical analyses for this end point

Secondary: Difference of least square-mean (80% Confidence Interval, CI) - Eliapixant arms vs Placebo arm (pairwise comparison) - change in mean worst EAPP from baseline to Week 12 - pPPS

End point title	Difference of least square-mean (80% Confidence Interval, CI) - Eliapixant arms vs Placebo arm (pairwise comparison) - change in mean worst EAPP from baseline to Week 12 - pPPS[9]

End point description:

Least square-mean of change (LS-mean, 80% Confidence Interval, CI); pairwise comparison between treatment arms and placebo arm) obtained by mixed model repeated measures (MMRM) from baseline to Week 12 (End of intervention) in the PPS. The worst EAPP was measured daily on the 0-10 Numerical Rating Scale (NRS) by item 1 of the Endometriosis Symptom Diary (ESD). In question 1, participants were asked to rate the pain in the target area during the past 24 hours, where 0= no pain and 10= worst imaginable pain and responses were recorded in ESD. The absolute change in mean worst EAPP was from baseline (last 28 days before the first intake of study drug) to end of intervention (last 28 days ending with the last intake of study drug planned on Day 84 [+3]). The time frame of 28 days captures a menstrual cycle on average.

End point type	Secondary

End point timeframe:

change from baseline to week 12

Notes:

[9] - 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: Active comparator Elagolix not part of Primary per protocol set (pPPS)

End point values	Eliapixant (BAY1817080) 25 mg	Eliapixant (BAY1817080) 75 mg	Eliapixant (BAY1817080) 150 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	31	31	37	
Units: units on a scale				
least squares mean (confidence interval 80%)				
12 weeks - treatment vs placebo	0.29 (-0.40 to 0.98)	-0.18 (-0.8 to 0.53)	-0.08 (-0.79 to 0.64)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with adverse events

End point title	Number of participants with adverse events

End point description:

A treatment-emergent AE (TEAE) was defined as any event arising or worsening after the start of study drug administration until 14 days after the last study medication intake.

BID = twice daily
OD = once daily

End point type	Secondary

End point timeframe:

From start of study drug administration up to 14 days after last study medication intake

End point values	Eliapixant (BAY1817080) 25 mg	Eliapixant (BAY1817080) 75 mg	Eliapixant (BAY1817080) 150 mg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	38	38	37
Units: Participants				
Any AE	33	28	32	30
Any SAE	1	2	3	1
Any AE with outcome death	0	0	0	0
Any AE: permanent discontinuation of study drug	0	1	1	2
Any TEAE	23	21	29	27
Any drug related TEAE	4	6	10	10
Any serious TEAE	0	2	2	1
Any drug related serious TEAE	0	0	1	0
Any TEAE with outcome death	0	0	0	0
Any TEAE: permanent discontinuation of studly drug	0	1	1	2

End point values	Elagolix 150mg			
Subject group type	Reporting group			
Number of subjects analysed	38			
Units: Participants				
Any AE	32			
Any SAE	2			
Any AE with outcome death	0			
Any AE: permanent discontinuation of study drug	1			
Any TEAE	28			
Any drug related TEAE	13			
Any serious TEAE	1			
Any drug related serious TEAE	1			
Any TEAE with outcome death	0			
Any TEAE: permanent discontinuation of studly drug	1			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Only TEAEs, that were arising or worsening after the start of study drug administration until 14 days after the last study medication intake with an average of 14 weeks, are reported in below adverse events table.

Adverse event reporting additional description:

While for the all-cause deaths that occurred at any time during the study before the last contact, up to 285 days are reported.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.0

Reporting groups

Reporting group title	Eliapixant (BAY1817080) 25 mg

Reporting group description:

25 mg Eliapixant twice daily for 12 weeks

Reporting group title	Eliapixant (BAY1817080) 75 mg

Reporting group description:

75 mg Eliapixant twice daily for 12 weeks

Reporting group title	150 mg Elagolix

Reporting group description:

150 mg Elagolix once daily for 12 weeks

Reporting group title	Placebo

Reporting group description:

Placebo for 12 weeks

Reporting group title	Eliapixant (BAY1817080) 150 mg

Reporting group description:

75 mg Eliapixant twice daily for 12 weeks

Serious adverse events	Eliapixant (BAY1817080) 25 mg	Eliapixant (BAY1817080) 75 mg	150 mg Elagolix
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 39 (0.00%)	2 / 38 (5.26%)	1 / 38 (2.63%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Investigations			
Liver function test increased			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertensive crisis			

subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Endometriosis ablation			
subjects affected / exposed	0 / 39 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain lower			
subjects affected / exposed	0 / 39 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Ovarian cyst ruptured			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Carbuncle			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Placebo	Eliapixant (BAY1817080) 150 mg	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 37 (2.70%)	2 / 38 (5.26%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Investigations			
Liver function test increased			
subjects affected / exposed	0 / 37 (0.00%)	1 / 38 (2.63%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			

Hypertensive crisis			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Endometriosis ablation			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain lower			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Ovarian cyst ruptured			
subjects affected / exposed	1 / 37 (2.70%)	0 / 38 (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			
Carbuncle			
subjects affected / exposed	0 / 37 (0.00%)	1 / 38 (2.63%)	
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: 2 %

Non-serious adverse events	Eliapixant (BAY1817080) 25 mg	Eliapixant (BAY1817080) 75 mg	150 mg Elagolix
Total subjects affected by non-serious adverse events			
subjects affected / exposed	23 / 39 (58.97%)	20 / 38 (52.63%)	28 / 38 (73.68%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Uterine leiomyoma			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1

Vascular disorders			
Varicose vein			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Hot flush			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	7 / 38 (18.42%)
occurrences (all)	0	0	7
Hypertension			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Hypertensive crisis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Discomfort			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	1 / 39 (2.56%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	2	0	0
Oedema			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	3 / 39 (7.69%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	3	1	0
Peripheral swelling			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Vaccination site pain			

subjects affected / exposed	0 / 39 (0.00%)	4 / 38 (10.53%)	0 / 38 (0.00%)
occurrences (all)	0	6	0
Malaise			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	1 / 39 (2.56%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Injection site reaction			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 39 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Injection site pain			
subjects affected / exposed	0 / 39 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Vaccination site swelling			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Immunisation reaction			
subjects affected / exposed	0 / 39 (0.00%)	2 / 38 (5.26%)	0 / 38 (0.00%)
occurrences (all)	0	3	0
Reproductive system and breast disorders			
Amenorrhoea			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Heavy menstrual bleeding			
subjects affected / exposed	0 / 39 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Fibrocystic breast disease			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Intermenstrual bleeding			

subjects affected / exposed	0 / 39 (0.00%)	2 / 38 (5.26%)	0 / 38 (0.00%)
occurrences (all)	0	2	0
Pelvic pain			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	2
Adnexa uteri cyst			
subjects affected / exposed	1 / 39 (2.56%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Haemorrhagic ovarian cyst			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Dysmenorrhoea			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Cervix disorder			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Genital haemorrhage			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Oligomenorrhoea			
subjects affected / exposed	1 / 39 (2.56%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 39 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			

Anxiety			
subjects affected / exposed	0 / 39 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Sleep disorder			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Panic attack			
subjects affected / exposed	0 / 39 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Nightmare			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Mood altered			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Depressed mood			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Irritability			
subjects affected / exposed	0 / 39 (0.00%)	1 / 38 (2.63%)	1 / 38 (2.63%)
occurrences (all)	0	1	1
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 39 (0.00%)	2 / 38 (5.26%)	0 / 38 (0.00%)
occurrences (all)	0	2	0
Activated partial thromboplastin time prolonged			
subjects affected / exposed	3 / 39 (7.69%)	2 / 38 (5.26%)	5 / 38 (13.16%)
occurrences (all)	3	2	6
Activated partial thromboplastin time abnormal			
subjects affected / exposed	1 / 39 (2.56%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Amylase increased			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			

subjects affected / exposed	0 / 39 (0.00%)	2 / 38 (5.26%)	0 / 38 (0.00%)
occurrences (all)	0	2	0
Blood fibrinogen decreased			
subjects affected / exposed	3 / 39 (7.69%)	0 / 38 (0.00%)	3 / 38 (7.89%)
occurrences (all)	3	0	3
Blood fibrinogen increased			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Blood glucose abnormal			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Full blood count abnormal			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 39 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Lipase increased			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Prothrombin time abnormal			
subjects affected / exposed	1 / 39 (2.56%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Prothrombin time prolonged			
subjects affected / exposed	0 / 39 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Coronavirus test positive			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Coagulation test abnormal			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Lymphocyte count decreased			
subjects affected / exposed	1 / 39 (2.56%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0

Haemoglobin decreased			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Neutrophil count increased			
subjects affected / exposed	1 / 39 (2.56%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	2	0	0
Liver function test increased			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
White blood cell count increased			
subjects affected / exposed	1 / 39 (2.56%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Platelet count increased			
subjects affected / exposed	1 / 39 (2.56%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Anosmia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Cervicobrachial syndrome			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Paraesthesia			
subjects affected / exposed	0 / 39 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Dysgeusia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	7 / 39 (17.95%)	7 / 38 (18.42%)	8 / 38 (21.05%)
occurrences (all)	15	11	15
Migraine			

subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	2 / 38 (5.26%)
occurrences (all)	0	0	4
Hypogeusia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	1 / 39 (2.56%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Taste disorder			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Psychogenic seizure			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Coagulopathy			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Anaemia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	2 / 39 (5.13%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	2	0	0
Bone marrow oedema			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Eustachian tube dysfunction			

subjects affected / exposed	1 / 39 (2.56%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Ear swelling			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 39 (0.00%)	2 / 38 (5.26%)	0 / 38 (0.00%)
occurrences (all)	0	2	0
Toothache			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Nausea			
subjects affected / exposed	0 / 39 (0.00%)	1 / 38 (2.63%)	2 / 38 (5.26%)
occurrences (all)	0	1	2
Gastritis			
subjects affected / exposed	0 / 39 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Food poisoning			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	2 / 39 (5.13%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	2	1	0

Dental caries			
subjects affected / exposed	0 / 39 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Angular cheilitis			
subjects affected / exposed	0 / 39 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Constipation			
subjects affected / exposed	0 / 39 (0.00%)	3 / 38 (7.89%)	1 / 38 (2.63%)
occurrences (all)	0	3	1
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 39 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Abdominal discomfort			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Abdominal pain upper			
subjects affected / exposed	0 / 39 (0.00%)	1 / 38 (2.63%)	1 / 38 (2.63%)
occurrences (all)	0	2	1
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Eczema			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Dermatitis atopic			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Eczema asteatotic			
subjects affected / exposed	0 / 39 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Alopecia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			

Bladder pain			
subjects affected / exposed	1 / 39 (2.56%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 39 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Back pain			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Spinal pain			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	1 / 39 (2.56%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Tenosynovitis			
subjects affected / exposed	0 / 39 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Influenza			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Hordeolum			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Carbuncle			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
COVID-19			

subjects affected / exposed	3 / 39 (7.69%)	2 / 38 (5.26%)	1 / 38 (2.63%)
occurrences (all)	3	2	1
Gastroenteritis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Bacterial vaginosis			
subjects affected / exposed	1 / 39 (2.56%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Bronchitis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	2 / 38 (5.26%)
occurrences (all)	0	0	2
Ear infection			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Genital herpes			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Urinary tract infection			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	2 / 38 (5.26%)
occurrences (all)	0	0	2
Upper respiratory tract infection			
subjects affected / exposed	1 / 39 (2.56%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	1	0	1
Lice infestation			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Pneumonia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Pulpitis dental			

subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 39 (2.56%)	4 / 38 (10.53%)	2 / 38 (5.26%)
occurrences (all)	1	4	3
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Metabolic syndrome			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Gout			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Dehydration			
subjects affected / exposed	0 / 39 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1

Non-serious adverse events	Placebo	Eliapixant (BAY1817080) 150 mg	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	27 / 37 (72.97%)	29 / 38 (76.32%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Uterine leiomyoma			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Vascular disorders			
Varicose vein			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Hot flush			
subjects affected / exposed	2 / 37 (5.41%)	0 / 38 (0.00%)	
occurrences (all)	2	0	
Hypertension			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	

Hypertensive crisis			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 37 (0.00%)	1 / 38 (2.63%)	
occurrences (all)	0	1	
Fatigue			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Discomfort			
subjects affected / exposed	1 / 37 (2.70%)	0 / 38 (0.00%)	
occurrences (all)	1	0	
Influenza like illness			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Oedema			
subjects affected / exposed	0 / 37 (0.00%)	1 / 38 (2.63%)	
occurrences (all)	0	1	
Pyrexia			
subjects affected / exposed	3 / 37 (8.11%)	2 / 38 (5.26%)	
occurrences (all)	3	2	
Peripheral swelling			
subjects affected / exposed	2 / 37 (5.41%)	0 / 38 (0.00%)	
occurrences (all)	2	0	
Vaccination site pain			
subjects affected / exposed	4 / 37 (10.81%)	0 / 38 (0.00%)	
occurrences (all)	7	0	
Malaise			
subjects affected / exposed	0 / 37 (0.00%)	1 / 38 (2.63%)	
occurrences (all)	0	1	
Pain			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Injection site reaction			

subjects affected / exposed	0 / 37 (0.00%)	1 / 38 (2.63%)	
occurrences (all)	0	2	
Chest pain			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Injection site pain			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Vaccination site swelling			
subjects affected / exposed	1 / 37 (2.70%)	0 / 38 (0.00%)	
occurrences (all)	1	0	
Immune system disorders			
Immunisation reaction			
subjects affected / exposed	1 / 37 (2.70%)	0 / 38 (0.00%)	
occurrences (all)	2	0	
Reproductive system and breast disorders			
Amenorrhoea			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Heavy menstrual bleeding			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Fibrocystic breast disease			
subjects affected / exposed	1 / 37 (2.70%)	0 / 38 (0.00%)	
occurrences (all)	1	0	
Intermenstrual bleeding			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Pelvic pain			
subjects affected / exposed	0 / 37 (0.00%)	2 / 38 (5.26%)	
occurrences (all)	0	2	
Vaginal haemorrhage			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Adnexa uteri cyst			

subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Haemorrhagic ovarian cyst			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Dysmenorrhoea			
subjects affected / exposed	0 / 37 (0.00%)	1 / 38 (2.63%)	
occurrences (all)	0	1	
Cervix disorder			
subjects affected / exposed	0 / 37 (0.00%)	1 / 38 (2.63%)	
occurrences (all)	0	1	
Genital haemorrhage			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Oligomenorrhoea			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	1 / 37 (2.70%)	0 / 38 (0.00%)	
occurrences (all)	1	0	
Epistaxis			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 37 (0.00%)	1 / 38 (2.63%)	
occurrences (all)	0	1	
Sleep disorder			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Panic attack			
subjects affected / exposed	0 / 37 (0.00%)	1 / 38 (2.63%)	
occurrences (all)	0	1	
Nightmare			

subjects affected / exposed	1 / 37 (2.70%)	0 / 38 (0.00%)	
occurrences (all)	1	0	
Mood altered			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Depressed mood			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Irritability			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 37 (2.70%)	0 / 38 (0.00%)	
occurrences (all)	1	0	
Activated partial thromboplastin time prolonged			
subjects affected / exposed	4 / 37 (10.81%)	2 / 38 (5.26%)	
occurrences (all)	4	2	
Activated partial thromboplastin time abnormal			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Amylase increased			
subjects affected / exposed	0 / 37 (0.00%)	1 / 38 (2.63%)	
occurrences (all)	0	1	
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 37 (2.70%)	0 / 38 (0.00%)	
occurrences (all)	1	0	
Blood fibrinogen decreased			
subjects affected / exposed	1 / 37 (2.70%)	0 / 38 (0.00%)	
occurrences (all)	1	0	
Blood fibrinogen increased			
subjects affected / exposed	0 / 37 (0.00%)	3 / 38 (7.89%)	
occurrences (all)	0	3	
Blood glucose abnormal			

subjects affected / exposed	1 / 37 (2.70%)	0 / 38 (0.00%)	
occurrences (all)	1	0	
Full blood count abnormal			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Lipase increased			
subjects affected / exposed	0 / 37 (0.00%)	1 / 38 (2.63%)	
occurrences (all)	0	1	
Prothrombin time abnormal			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Prothrombin time prolonged			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Coronavirus test positive			
subjects affected / exposed	0 / 37 (0.00%)	1 / 38 (2.63%)	
occurrences (all)	0	1	
Coagulation test abnormal			
subjects affected / exposed	0 / 37 (0.00%)	1 / 38 (2.63%)	
occurrences (all)	0	1	
Lymphocyte count decreased			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Haemoglobin decreased			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Neutrophil count increased			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Liver function test increased			
subjects affected / exposed	0 / 37 (0.00%)	1 / 38 (2.63%)	
occurrences (all)	0	1	

White blood cell count increased			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Platelet count increased			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
SARS-CoV-2 test positive			
subjects affected / exposed	2 / 37 (5.41%)	0 / 38 (0.00%)	
occurrences (all)	2	0	
Nervous system disorders			
Anosmia			
subjects affected / exposed	1 / 37 (2.70%)	0 / 38 (0.00%)	
occurrences (all)	1	0	
Cervicobrachial syndrome			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Paraesthesia			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Dysgeusia			
subjects affected / exposed	1 / 37 (2.70%)	2 / 38 (5.26%)	
occurrences (all)	1	3	
Headache			
subjects affected / exposed	9 / 37 (24.32%)	6 / 38 (15.79%)	
occurrences (all)	17	9	
Migraine			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Hypogeusia			
subjects affected / exposed	0 / 37 (0.00%)	3 / 38 (7.89%)	
occurrences (all)	0	3	
Dizziness			
subjects affected / exposed	1 / 37 (2.70%)	1 / 38 (2.63%)	
occurrences (all)	1	1	
Taste disorder			

subjects affected / exposed	1 / 37 (2.70%)	2 / 38 (5.26%)	
occurrences (all)	1	2	
Somnolence			
subjects affected / exposed	1 / 37 (2.70%)	1 / 38 (2.63%)	
occurrences (all)	1	1	
Psychogenic seizure			
subjects affected / exposed	0 / 37 (0.00%)	1 / 38 (2.63%)	
occurrences (all)	0	1	
Blood and lymphatic system disorders			
Coagulopathy			
subjects affected / exposed	1 / 37 (2.70%)	0 / 38 (0.00%)	
occurrences (all)	1	0	
Anaemia			
subjects affected / exposed	1 / 37 (2.70%)	1 / 38 (2.63%)	
occurrences (all)	1	1	
Leukopenia			
subjects affected / exposed	0 / 37 (0.00%)	1 / 38 (2.63%)	
occurrences (all)	0	2	
Neutropenia			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Bone marrow oedema			
subjects affected / exposed	1 / 37 (2.70%)	0 / 38 (0.00%)	
occurrences (all)	1	0	
Ear and labyrinth disorders			
Eustachian tube dysfunction			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Ear swelling			
subjects affected / exposed	1 / 37 (2.70%)	0 / 38 (0.00%)	
occurrences (all)	1	0	
Ear pain			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			

Abdominal distension			
subjects affected / exposed	1 / 37 (2.70%)	0 / 38 (0.00%)	
occurrences (all)	1	0	
Abdominal pain			
subjects affected / exposed	1 / 37 (2.70%)	0 / 38 (0.00%)	
occurrences (all)	1	0	
Toothache			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Vomiting			
subjects affected / exposed	0 / 37 (0.00%)	3 / 38 (7.89%)	
occurrences (all)	0	3	
Nausea			
subjects affected / exposed	1 / 37 (2.70%)	5 / 38 (13.16%)	
occurrences (all)	2	6	
Gastritis			
subjects affected / exposed	0 / 37 (0.00%)	1 / 38 (2.63%)	
occurrences (all)	0	1	
Food poisoning			
subjects affected / exposed	1 / 37 (2.70%)	0 / 38 (0.00%)	
occurrences (all)	1	0	
Dyspepsia			
subjects affected / exposed	1 / 37 (2.70%)	0 / 38 (0.00%)	
occurrences (all)	1	0	
Diarrhoea			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Dental caries			
subjects affected / exposed	0 / 37 (0.00%)	1 / 38 (2.63%)	
occurrences (all)	0	1	
Angular cheilitis			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Constipation			
subjects affected / exposed	0 / 37 (0.00%)	1 / 38 (2.63%)	
occurrences (all)	0	1	

Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 37 (0.00%)	1 / 38 (2.63%)	
occurrences (all)	0	1	
Abdominal discomfort			
subjects affected / exposed	1 / 37 (2.70%)	0 / 38 (0.00%)	
occurrences (all)	1	0	
Abdominal pain upper			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	1 / 37 (2.70%)	0 / 38 (0.00%)	
occurrences (all)	1	0	
Eczema			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Dermatitis atopic			
subjects affected / exposed	1 / 37 (2.70%)	0 / 38 (0.00%)	
occurrences (all)	1	0	
Eczema asteatotic			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Alopecia			
subjects affected / exposed	0 / 37 (0.00%)	1 / 38 (2.63%)	
occurrences (all)	0	1	
Renal and urinary disorders			
Bladder pain			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 37 (2.70%)	1 / 38 (2.63%)	
occurrences (all)	1	1	
Back pain			
subjects affected / exposed	1 / 37 (2.70%)	0 / 38 (0.00%)	
occurrences (all)	1	0	

Spinal pain			
subjects affected / exposed	1 / 37 (2.70%)	0 / 38 (0.00%)	
occurrences (all)	2	0	
Myalgia			
subjects affected / exposed	2 / 37 (5.41%)	0 / 38 (0.00%)	
occurrences (all)	2	0	
Tenosynovitis			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
Influenza			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Hordeolum			
subjects affected / exposed	1 / 37 (2.70%)	1 / 38 (2.63%)	
occurrences (all)	1	1	
Laryngitis			
subjects affected / exposed	1 / 37 (2.70%)	0 / 38 (0.00%)	
occurrences (all)	1	0	
Tonsillitis			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Carbuncle			
subjects affected / exposed	0 / 37 (0.00%)	1 / 38 (2.63%)	
occurrences (all)	0	1	
COVID-19			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Gastroenteritis			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Bacterial vaginosis			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Bronchitis			

subjects affected / exposed	0 / 37 (0.00%)	1 / 38 (2.63%)	
occurrences (all)	0	1	
Ear infection			
subjects affected / exposed	1 / 37 (2.70%)	0 / 38 (0.00%)	
occurrences (all)	1	0	
Cystitis			
subjects affected / exposed	1 / 37 (2.70%)	0 / 38 (0.00%)	
occurrences (all)	1	0	
Genital herpes			
subjects affected / exposed	1 / 37 (2.70%)	0 / 38 (0.00%)	
occurrences (all)	1	0	
Vaginal infection			
subjects affected / exposed	1 / 37 (2.70%)	0 / 38 (0.00%)	
occurrences (all)	1	0	
Urinary tract infection			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Upper respiratory tract infection			
subjects affected / exposed	2 / 37 (5.41%)	3 / 38 (7.89%)	
occurrences (all)	2	3	
Lice infestation			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Pneumonia			
subjects affected / exposed	1 / 37 (2.70%)	1 / 38 (2.63%)	
occurrences (all)	1	1	
Pulpitis dental			
subjects affected / exposed	0 / 37 (0.00%)	1 / 38 (2.63%)	
occurrences (all)	0	1	
Nasopharyngitis			
subjects affected / exposed	2 / 37 (5.41%)	1 / 38 (2.63%)	
occurrences (all)	2	1	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	

Metabolic syndrome			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Gout			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	
Dehydration			
subjects affected / exposed	0 / 37 (0.00%)	0 / 38 (0.00%)	
occurrences (all)	0	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
22 June 2021	• Adapted Visit schedule to allow for testing of liver parameters every 2 weeks during the treatment period as precautionary measure • Adaptation of exclusion criterion 7 with addition of an example for extremely low body weight to support the investigator decisions on participant selection.
27 January 2022	• Adapted Visit schedule to allow for a comprehensive safety follow up of study participants exposed to eliapixant. • Update on risk of potential changes in liver function laboratory parameters with eliapixant use. • Updated benefit/risk assessment to indicate that the benefit-risk ratio for this study was no longer considered to be positive and a clinical hold with an immediate stop of treatment and enrolment was decided. • Indicating that abnormal laboratory results meeting the criteria of transaminases (alanine aminotransferase [ALT] and/or aspartate aminotransferase [AST]) >8x ULN or >3x ULN with total bilirubin >2x ULN should be reported as adverse events of special interest to ensure a comprehensive safety follow up of exposed study participants • Liver imaging was added to the close observation assessments, and hepatitis C virus Ribonucleic acid (HCV-RNA) was added to the parameters for samples to be analyzed for initial close liver observation to ensure a comprehensive safety follow up of exposed study participants

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
27 January 2022	study was stopped due to safety reasons.	-

Notes:

Limitations and caveats

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

Study was prematurely terminated due to safety reasons.

Notes: