Clinical trial results:
A Phase 2 Study of Once-Daily LY3502970 Compared with Placebo and Once-Weekly Dulaglutide in Participants with Type 2 Diabetes Mellitus

Summary

EudraCT number	2021-002806-29
Trial protocol	HU SK PL
Global end of trial date	30 September 2022

Results information

Result version number	v1 (current)
This version publication date	15 October 2023
First version publication date	15 October 2023

Trial information

Trial identification

Sponsor protocol code	J2A-MC-GZGE

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05048719
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 17787

Notes:

Sponsors

Sponsor organisation name	Eli Lilly and Company
Sponsor organisation address	Lilly Corporate Center, Indianapolis, IN, United States, 46285
Public contact	Available Mon Fri 9 AM 5 PM EST, Eli Lilly and Company, 1 877CTLilly,
Scientific contact	Available Mon Fri 9 AM 5 PM EST, Eli Lilly and Company, 1 8772854559,

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	30 September 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	30 September 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main purpose of this study is to evaluate the efficacy and safety of LY3502970 in participants with type 2 diabetes (T2D) who failed to achieve adequate glycemic control on diet and exercise alone or on a stable dose of metformin. This study will last about 30 weeks.

Protection of trial subjects:

This study was conducted in accordance with International Conference on Harmonization (ICH) Good Clinical Practice, and the principles of the Declaration of Helsinki, in addition to following the laws and regulations of the country or countries in which a study is conducted.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 September 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	Hungary: 63
Country: Number of subjects enrolled	Poland: 85
Country: Number of subjects enrolled	Slovakia: 65
Country: Number of subjects enrolled	United States: 170
Worldwide total number of subjects	383
EEA total number of subjects	213

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)	251
From 65 to 84 years	132
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

No Text Available

Pre-assignment

Screening details:

For maintenance doses of LY3502970: 3, 12, 24, 36, and 45 milligrams (mg), the initial dose will be 2 or 3 mg followed by additional escalation steps as appropriate. The dose escalation varied by dose group where the target maintenance dose was achieved between Weeks 4 and 12.

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	Placebo

Arm description:

Participants received matching placebo administered orally or subcutaneously.

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

Dosage and administration details:

Administered orally

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Administered subcutaneously

Arm title	3 mg LY3502970

Arm description:

Participants received maintenance dose of 3 mg with dose escalation starting from 2 mg LY3502970 administered orally once daily (QD).

Arm type	Experimental
Investigational medicinal product name	LY3502970
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Administered orally

Arm title	12 mg LY3502970

Arm description:

Participants received maintenance dose 12 mg with dose escalation starting from 2 mg, 6 mg and then 12 mg LY3502970 administered orally QD.

Arm type	Experimental
Investigational medicinal product name	LY3502970
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Administered orally

Arm title	24 mg LY3502970

Arm description:

Participants received maintenance dose 24 mg with dose escalation starting from 3 mg, 6 mg, 8 mg,12 mg and then 24 mg LY3502970 administered orally QD.

Arm type	Experimental
Investigational medicinal product name	LY3502970
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Administered orally

Arm title	36 mg LY3502970 - 1

Arm description:

Participants received maintenance dose 36 mg with dose escalation starting from 2 mg, 3 mg, 6 mg, 8 mg, 12 mg, 24 mg and then 36 mg LY3502970 administered orally QD.

Arm type	Experimental
Investigational medicinal product name	LY3502970
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Administered orally

Arm title	36 mg LY3502970 - 2

Arm description:

Participants received maintenance dose 36 mg with dose escalation starting from 3 mg, 6 mg,12 mg, 24 mg and then 36 mg LY3502970 administered orally QD.

Arm type	Experimental
Investigational medicinal product name	LY3502970
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Administered orally

Arm title	45 mg LY3502970 - 1

Arm description:

Participants received maintenance dose 45 mg with dose escalation starting from 3 mg, 6 mg, 8 mg, 12 mg, 24 mg, 36 mg and then 45 mg LY3502970 administered orally QD.

Arm type	Experimental

Investigational medicinal product name	LY3502970
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Administered orally

Arm title	45 mg LY3502970 - 2

Arm description:

Participants received maintenance dose 45 mg with dose escalation starting from 2 mg, 3 mg, 6 mg, 12 mg, 24 mg, 36 mg and then 45 mg LY3502970 administered orally QD.

Arm type	Active comparator
Investigational medicinal product name	LY3502970
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Administered orally

Arm title	1.5 mg Dulaglutide

Arm description:

Participants received 1.5 mg Dulaglutide administered subcutaneously (SC) once weekly (QW).

Arm type	Placebo
Investigational medicinal product name	Dulaglutide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Administered subcutaneously

Number of subjects in period 1	Placebo	3 mg LY3502970	12 mg LY3502970
Started	55	51	56
Received At Least One Dose of Study Drug	55	51	56
Completed	51	47	50
Not completed	4	4	6
Adverse event, serious fatal	1	-	-
Sponsor decision due To inadvertent Enrollment	-	1	-
Consent withdrawn by subject	2	1	3
Physician decision	-	-	-
Participant decided to Discontinue Treatment	-	-	-
Adverse event, non-fatal	-	1	2
Participant was Unresponsive	-	1	-

Patient Decision due To Changes in Personal Life	1	-	-
Lost to follow-up	-	-	1
Site Terminated Participant due to Sponsor	-	-	-

Number of subjects in period 1	24 mg LY3502970	36 mg LY3502970 - 1	36 mg LY3502970 - 2
Started	47	27	34
Received At Least One Dose of Study Drug	47	27	34
Completed	42	25	30
Not completed	5	2	4
Adverse event, serious fatal	-	-	-
Sponsor decision due To inadvertent Enrollment	-	-	-
Consent withdrawn by subject	1	-	2
Physician decision	-	-	-
Participant decided to Discontinue Treatment	1	-	-
Adverse event, non-fatal	-	1	-
Participant was Unresponsive	-	-	-
Patient Decision due To Changes in Personal Life	-	-	-
Lost to follow-up	3	1	1
Site Terminated Participant due to Sponsor	-	-	1

Number of subjects in period 1	45 mg LY3502970 - 1	45 mg LY3502970 - 2	1.5 mg Dulaglutide
Started	31	32	50
Received At Least One Dose of Study Drug	31	32	50
Completed	29	29	49
Not completed	2	3	1
Adverse event, serious fatal	-	-	-
Sponsor decision due To inadvertent Enrollment	-	-	-
Consent withdrawn by subject	1	1	-
Physician decision	-	1	1
Participant decided to Discontinue Treatment	-	-	-
Adverse event, non-fatal	-	-	-
Participant was Unresponsive	-	-	-
Patient Decision due To Changes in Personal Life	-	-	-
Lost to follow-up	1	1	-
Site Terminated Participant due to Sponsor	-	-	-

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Participants received matching placebo administered orally or subcutaneously.	
Reporting group title	3 mg LY3502970
Reporting group description:	
Participants received maintenance dose of 3 mg with dose escalation starting from 2 mg LY3502970 administered orally once daily (QD).	
Reporting group title	12 mg LY3502970
Reporting group description:	
Participants received maintenance dose 12 mg with dose escalation starting from 2 mg, 6 mg and then 12 mg LY3502970 administered orally QD.	
Reporting group title	24 mg LY3502970
Reporting group description:	
Participants received maintenance dose 24 mg with dose escalation starting from 3 mg, 6 mg, 8 mg,12 mg and then 24 mg LY3502970 administered orally QD.	
Reporting group title	36 mg LY3502970 - 1
Reporting group description:	
Participants received maintenance dose 36 mg with dose escalation starting from 2 mg, 3 mg, 6 mg, 8 mg, 12 mg, 24 mg and then 36 mg LY3502970 administered orally QD.	
Reporting group title	36 mg LY3502970 - 2
Reporting group description:	
Participants received maintenance dose 36 mg with dose escalation starting from 3 mg, 6 mg,12 mg, 24 mg and then 36 mg LY3502970 administered orally QD.	
Reporting group title	45 mg LY3502970 - 1
Reporting group description:	
Participants received maintenance dose 45 mg with dose escalation starting from 3 mg, 6 mg, 8 mg, 12 mg, 24 mg, 36 mg and then 45 mg LY3502970 administered orally QD.	
Reporting group title	45 mg LY3502970 - 2
Reporting group description:	
Participants received maintenance dose 45 mg with dose escalation starting from 2 mg, 3 mg, 6 mg, 12 mg, 24 mg, 36 mg and then 45 mg LY3502970 administered orally QD.	
Reporting group title	1.5 mg Dulaglutide
Reporting group description:	
Participants received 1.5 mg Dulaglutide administered subcutaneously (SC) once weekly (QW).	

Reporting group values	Placebo	3 mg LY3502970	12 mg LY3502970
Number of subjects	55	51	56
Age categorical Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			

85 years and over			

Age continuous Units: years			
arithmetic mean	58.30	59.00	57.40
standard deviation	± 9.52	± 9.43	± 9.23
Gender categorical Units: Subjects			
Female	27	25	20
Male	28	26	36
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	14	7	15
Not Hispanic or Latino	41	44	41
Unknown or Not Reported	0	0	0
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	1	0	1
Asian	0	1	1
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	4	2	5
White	50	47	49
More than one race	0	1	0
Unknown or Not Reported	0	0	0
Region of Enrollment Units: Subjects			
Hungary	10	8	9
Poland	11	13	11
Slovakia	10	8	10
United States	24	22	26

Reporting group values	24 mg LY3502970	36 mg LY3502970 - 1	36 mg LY3502970 - 2
Number of subjects	47	27	34
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous Units: years			
arithmetic mean	60.50	59.20	60.10
standard deviation	± 9.11	± 9.07	± 9.37

Gender categorical Units: Subjects			
Female	17	9	16
Male	30	18	18
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	5	6	7
Not Hispanic or Latino	42	21	27
Unknown or Not Reported	0	0	0
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	1	0	0
Asian	1	1	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	2	0	0
White	43	25	33
More than one race	0	1	1
Unknown or Not Reported	0	0	0
Region of Enrollment Units: Subjects			
Hungary	8	3	6
Poland	10	6	9
Slovakia	9	5	5
United States	20	13	14

Reporting group values	45 mg LY3502970 - 1	45 mg LY3502970 - 2	1.5 mg Dulaglutide
Number of subjects	31	32	50
Age categorical Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age continuous Units: years			
arithmetic mean	58.10	58.90	58.80
standard deviation	± 10.63	± 8.18	± 10.19
Gender categorical Units: Subjects			
Female	10	13	20
Male	21	19	30
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	7	6	7

Not Hispanic or Latino	24	26	43
Unknown or Not Reported	0	0	0
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	1	0
Asian	0	0	1
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	2	3	4
White	29	28	44
More than one race	0	0	1
Unknown or Not Reported	0	0	0
Region of Enrollment			
Units: Subjects			
Hungary	6	4	9
Poland	7	6	12
Slovakia	5	6	7
United States	13	16	22

Reporting group values	Total		
Number of subjects	383		
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)	0		
From 65-84 years	0		
85 years and over	0		
Age continuous			
Units: years			
arithmetic mean			
standard deviation	-		
Gender categorical			
Units: Subjects			
Female	157		
Male	226		
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	74		
Not Hispanic or Latino	309		
Unknown or Not Reported	0		
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	4		
Asian	5		

Native Hawaiian or Other Pacific Islander	0		
Black or African American	22		
White	348		
More than one race	4		
Unknown or Not Reported	0		
Region of Enrollment Units: Subjects			
Hungary	63		
Poland	85		
Slovakia	65		
United States	170		

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Participants received matching placebo administered orally or subcutaneously.	
Reporting group title	3 mg LY3502970
Reporting group description:	
Participants received maintenance dose of 3 mg with dose escalation starting from 2 mg LY3502970 administered orally once daily (QD).	
Reporting group title	12 mg LY3502970
Reporting group description:	
Participants received maintenance dose 12 mg with dose escalation starting from 2 mg, 6 mg and then 12 mg LY3502970 administered orally QD.	
Reporting group title	24 mg LY3502970
Reporting group description:	
Participants received maintenance dose 24 mg with dose escalation starting from 3 mg, 6 mg, 8 mg,12 mg and then 24 mg LY3502970 administered orally QD.	
Reporting group title	36 mg LY3502970 - 1
Reporting group description:	
Participants received maintenance dose 36 mg with dose escalation starting from 2 mg, 3 mg, 6 mg, 8 mg, 12 mg, 24 mg and then 36 mg LY3502970 administered orally QD.	
Reporting group title	36 mg LY3502970 - 2
Reporting group description:	
Participants received maintenance dose 36 mg with dose escalation starting from 3 mg, 6 mg,12 mg, 24 mg and then 36 mg LY3502970 administered orally QD.	
Reporting group title	45 mg LY3502970 - 1
Reporting group description:	
Participants received maintenance dose 45 mg with dose escalation starting from 3 mg, 6 mg, 8 mg, 12 mg, 24 mg, 36 mg and then 45 mg LY3502970 administered orally QD.	
Reporting group title	45 mg LY3502970 - 2
Reporting group description:	
Participants received maintenance dose 45 mg with dose escalation starting from 2 mg, 3 mg, 6 mg, 12 mg, 24 mg, 36 mg and then 45 mg LY3502970 administered orally QD.	
Reporting group title	1.5 mg Dulaglutide
Reporting group description:	
Participants received 1.5 mg Dulaglutide administered subcutaneously (SC) once weekly (QW).	
Subject analysis set title	36 mg LY3502970
Subject analysis set type	Per protocol
Subject analysis set description:	
Participants received maintenance dose 36 mg with dose escalation starting from 2 mg, 3 mg, 6 mg, 8 mg, 12 mg, 24 mg and then 36 mg LY3502970 in LY 36mg-1 and dose escalation starting from 3 mg, 6 mg,12 mg, 24 mg and then 36 mg LY3502970 in LY 36mg-2 administered orally QD.	
Subject analysis set title	45 mg LY3502970
Subject analysis set type	Per protocol
Subject analysis set description:	
Participants received maintenance dose 45 mg with dose escalation starting from 3 mg, 6 mg, 8 mg, 12 mg, 24 mg, 36 mg and then 45 mg LY3502970 in LY 45mg-1 and dose escalation starting from 2 mg, 3 mg, 6 mg, 12 mg, 24 mg, 36 mg and then 45 mg LY3502970 in LY 45mg-2 administered orally QD.	

Primary: Change from Baseline in HbA1c in LY3502970 as Compared to Placebo

End point title	Change from Baseline in HbA1c in LY3502970 as Compared to Placebo[1]

End point description:

HbA1c is the glycosylated fraction of hemoglobin A. HbA1c is measured to identify average plasma glucose concentration over prolonged periods of time. Least Squares (LS) mean was determined by mixed model repeated measures (MMRM) model with Baseline + Country + Baseline HbA1c Group (<=8.0%, >8.0%) + Treatment + Time + Treatment*Time (Type III sum of squares) as variables.
Analysis Population Description (APD): All participants who received at least one dose of LY3502970 or placebo and had baseline and at least one post-baseline value for HbA1c.
The statistical analyses were conducted to compare LY3502970 against placebo i.e., comparison groups = LY3502970 vs Placebo.
Comparison groups in the individual statistical analyses below may be disregarded.

End point type	Primary

End point timeframe:

Baseline, Week 26

Notes:

[1] - 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: Descriptive statistics was added in baseline period reporting arms, subject analysis set with evaluable endpoint data.

End point values	Placebo	3 mg LY3502970	12 mg LY3502970	24 mg LY3502970
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	55	46	49	42
Units: Percentage of HbA1c				
least squares mean (standard error)	-0.43 (± 0.128)	-1.19 (± 0.137)	-1.91 (± 0.133)	-1.79 (± 0.149)

End point values	36 mg LY3502970	45 mg LY3502970		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	57	58		
Units: Percentage of HbA1c				
least squares mean (standard error)	-2.03 (± 0.127)	-2.10 (± 0.124)		

Statistical analyses

Statistical analysis title	Outcome measure No.1
Comparison groups	Placebo v 3 mg LY3502970
Number of subjects included in analysis	101
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Least square mean difference
Point estimate	-0.77

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.13
upper limit	-0.4

Statistical analysis title	Outcome measure No.1
Comparison groups	Placebo v 12 mg LY3502970
Number of subjects included in analysis	104
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Least square mean difference
Point estimate	-1.49
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.85
upper limit	-1.12

Statistical analysis title	Outcome measure No.1
Comparison groups	Placebo v 24 mg LY3502970
Number of subjects included in analysis	97
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Least square mean difference
Point estimate	-1.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.75
upper limit	-0.98

Statistical analysis title	Outcome measure No.1
Comparison groups	Placebo v 36 mg LY3502970

Number of subjects included in analysis	112
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Least square mean difference
Point estimate	-1.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.96
upper limit	-1.25

Statistical analysis title	Outcome measure No.1
Comparison groups	Placebo v 45 mg LY3502970
Number of subjects included in analysis	113
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Least square mean difference
Point estimate	-1.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.02
upper limit	-1.32

Secondary: Change from Baseline in HbA1c in LY3502970 as Compared to Dulaglutide

End point title	Change from Baseline in HbA1c in LY3502970 as Compared to Dulaglutide[2]

End point description:

HbA1c is the glycosylated fraction of hemoglobin A. HbA1c is measured to identify average plasma glucose concentration over prolonged periods of time. Least Squares (LS) mean was determined by mixed model repeated measures (MMRM) model with Baseline + Country + Baseline HbA1c Group (<=8.0%, >8.0%) + Treatment + Time + Treatment*Time (Type III sum of squares) as variables.
APD: All participants who received at least one dose of LY3502970 or dulaglutide, had a baseline, and at least one post-baseline value for HbA1c.
The statistical analyses were conducted to compare LY3502970 against Dulaglutide i.e., comparison groups= LY3502970 vs Dulaglutide.
Comparison groups in the individual statistical analyses below may be disregarded.

End point type	Secondary

End point timeframe:

Baseline, Week 26

Notes:

[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: Descriptive statistics was added in baseline period reporting arms, subject analysis set with evaluable endpoint data.

End point values	3 mg LY3502970	12 mg LY3502970	24 mg LY3502970	1.5 mg Dulaglutide
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	46	49	42	49
Units: Percentage of HbA1c				
least squares mean (standard error)	-1.19 (± 0.137)	-1.91 (± 0.133)	-1.79 (± 0.149)	-1.10 (± 0.131)

End point values	36 mg LY3502970	45 mg LY3502970		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	57	58		
Units: Percentage of HbA1c				
least squares mean (standard error)	-2.03 (± 0.127)	-2.10 (± 0.124)		

Statistical analyses

Statistical analysis title	Outcome measure No.2
Comparison groups	3 mg LY3502970 v 1.5 mg Dulaglutide
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.626
Method	Mixed models analysis
Parameter estimate	Least square mean difference
Point estimate	-0.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.47
upper limit	0.28

Statistical analysis title	Outcome measure No.2
Comparison groups	12 mg LY3502970 v 1.5 mg Dulaglutide
Number of subjects included in analysis	98
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Least square mean difference
Point estimate	-0.81

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.18
upper limit	-0.44

Statistical analysis title	Outcome measure No.2
Comparison groups	24 mg LY3502970 v 1.5 mg Dulaglutide
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Least square mean difference
Point estimate	-0.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.08
upper limit	-0.3

Statistical analysis title	Outcome measure No.2
Comparison groups	1.5 mg Dulaglutide v 36 mg LY3502970
Number of subjects included in analysis	106
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Least square mean difference
Point estimate	-0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.29
upper limit	-0.57

Statistical analysis title	Outcome measure No.2
Comparison groups	1.5 mg Dulaglutide v 45 mg LY3502970

Number of subjects included in analysis	107
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Least square mean difference
Point estimate	-1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.36
upper limit	-0.64

Secondary: Percentage of Participants with HbA1c <7.0%

End point title	Percentage of Participants with HbA1c <7.0%[3]

End point description:

Percentage of Participants with HbA1c <7.0%. Odds ratio was calculated using logistic regression model.
APD: All participants who received at least one dose of study drug, had a baseline and at least one post-baseline HbA1c value.
The statistical analyses were conducted to compare LY3502970 against placebo i.e., comparison groups = LY3502970 vs Placebo, and LY3502970 against Dulaglutide i.e., comparison groups= LY3502970 vs Dulaglutide.
Comparison groups in the individual statistical analyses below may be disregarded.

End point type	Secondary

End point timeframe:

Week 26

Notes:

[3] - 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: Descriptive statistics was added in baseline period reporting arms, subject analysis set with evaluable endpoint data.

End point values	Placebo	3 mg LY3502970	12 mg LY3502970	24 mg LY3502970
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	55	46	49	42
Units: Percentage of participants				
number (not applicable)	24.27	65.17	78.92	91.24

End point values	1.5 mg Dulaglutide	36 mg LY3502970	45 mg LY3502970	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	49	57	58	
Units: Percentage of participants				
number (not applicable)	64.06	92.75	95.76	

Statistical analyses

Statistical analysis title	Outcome measure No.3
Comparison groups	3 mg LY3502970 v Placebo
Number of subjects included in analysis	101
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	8.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.93
upper limit	22.9

Statistical analysis title	Outcome measure No.3
Comparison groups	Placebo v 12 mg LY3502970
Number of subjects included in analysis	104
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	25.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.57
upper limit	82.69

Statistical analysis title	Outcome measure No.3
Comparison groups	24 mg LY3502970 v Placebo
Number of subjects included in analysis	97
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	62.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	12.26
upper limit	316.63

Statistical analysis title	Outcome measure No.3
Comparison groups	Placebo v 36 mg LY3502970
Number of subjects included in analysis	112
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	67.57
Confidence interval	
level	95 %
sides	2-sided
lower limit	17.56
upper limit	259.97

Statistical analysis title	Outcome measure No.3
Comparison groups	Placebo v 45 mg LY3502970
Number of subjects included in analysis	113
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	129.55
Confidence interval	
level	95 %
sides	2-sided
lower limit	26.72
upper limit	628.09

Statistical analysis title	Outcome measure No.3
Comparison groups	3 mg LY3502970 v 1.5 mg Dulaglutide
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.802
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.13

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.43
upper limit	2.96

Statistical analysis title	Outcome measure No.3
Comparison groups	12 mg LY3502970 v 1.5 mg Dulaglutide
Number of subjects included in analysis	98
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.026
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	3.46
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.16
upper limit	10.31

Statistical analysis title	Outcome measure No.3
Comparison groups	24 mg LY3502970 v 1.5 mg Dulaglutide
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.006
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	8.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.83
upper limit	40.51

Statistical analysis title	Outcome measure No.3
Comparison groups	1.5 mg Dulaglutide v 36 mg LY3502970

Number of subjects included in analysis	106
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	9.34
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.67
upper limit	32.71

Statistical analysis title	Outcome measure No.3
Comparison groups	1.5 mg Dulaglutide v 45 mg LY3502970
Number of subjects included in analysis	107
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	17.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.02
upper limit	79.7

Secondary: Percentage of Participants with HbA1c ≤ 6.5%

End point title	Percentage of Participants with HbA1c ≤ 6.5%[4]

End point description:

Percentage of Participants with HbA1c ≤ 6.5%. Odds ratio was calculated using logistic regression model.
APD: All participants who received at least one dose of study drug, had a baseline and at least one post-baseline HbA1c value.
The statistical analyses were conducted to compare LY3502970 against placebo i.e., comparison groups = LY3502970 vs Placebo, and LY3502970 against Dulaglutide i.e., comparison groups= LY3502970 vs Dulaglutide.
Comparison groups in the individual statistical analyses below may be disregarded.

End point type	Secondary

End point timeframe:

Week 26

Notes:

[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: Descriptive statistics was added in baseline period reporting arms, subject analysis set with evaluable endpoint data.

End point values	Placebo	3 mg LY3502970	12 mg LY3502970	24 mg LY3502970
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	55	46	49	42
Units: Percentage of participants				
number (not applicable)	14.56	45.30	70.73	80.12

End point values	1.5 mg Dulaglutide	36 mg LY3502970	45 mg LY3502970	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	49	57	58	
Units: Percentage of participants				
number (not applicable)	41.04	79.39	83.52	

Statistical analyses

Statistical analysis title	Outcome measure No.4
Comparison groups	3 mg LY3502970 v Placebo
Number of subjects included in analysis	101
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	6.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.21
upper limit	20.75

Statistical analysis title	Outcome measure No.4
Comparison groups	12 mg LY3502970 v Placebo
Number of subjects included in analysis	104
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	34.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	9.92
upper limit	117.16

Statistical analysis title	Outcome measure No.4
Comparison groups	24 mg LY3502970 v Placebo
Number of subjects included in analysis	97
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	48.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	11.9
upper limit	196.24

Statistical analysis title	Outcome measure No.4
Comparison groups	Placebo v 36 mg LY3502970
Number of subjects included in analysis	112
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	45.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	13.61
upper limit	153.64

Statistical analysis title	Outcome measure No.4
Comparison groups	Placebo v 45 mg LY3502970
Number of subjects included in analysis	113
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	77.23

Confidence interval	
level	95 %
sides	2-sided
lower limit	20.26
upper limit	294.48

Statistical analysis title	Outcome measure No.4
Comparison groups	3 mg LY3502970 v 1.5 mg Dulaglutide
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.678
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.48
upper limit	3.13

Statistical analysis title	Outcome measure No.4
Comparison groups	12 mg LY3502970 v 1.5 mg Dulaglutide
Number of subjects included in analysis	98
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	6.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.19
upper limit	17.24

Statistical analysis title	Outcome measure No.4
Comparison groups	24 mg LY3502970 v 1.5 mg Dulaglutide

Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	8.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.55
upper limit	29.79

Statistical analysis title	Outcome measure No.4
Comparison groups	1.5 mg Dulaglutide v 36 mg LY3502970
Number of subjects included in analysis	106
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	8.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.05
upper limit	22.3

Statistical analysis title	Outcome measure No.4
Comparison groups	1.5 mg Dulaglutide v 45 mg LY3502970
Number of subjects included in analysis	107
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	13.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.51
upper limit	43.01

Secondary: Change From Baseline in Fasting Serum Glucose

End point title	Change From Baseline in Fasting Serum Glucose[5]

End point description:

Fasting glucose is a test to determine sugar levels in blood sample after an overnight fast. LS mean was determined by MMRM model with Baseline + Country + Baseline HbA1c Group (<=8.0%, 8.0%) + Treatment + Time + Treatment*Time (Type III sum of squares) as variables.
APD: All participants who received at least one dose of study drug, had baseline and at least one post-baseline fasting glucose data.
The statistical analyses were conducted to compare LY3502970 against placebo i.e., comparison groups = LY3502970 vs Placebo, and LY3502970 against Dulaglutide i.e., comparison groups= LY3502970 vs Dulaglutide.
Comparison groups in the individual statistical analyses below may be disregarded.

End point type	Secondary

End point timeframe:

Baseline, Week 26

Notes:

[5] - 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: Descriptive statistics was added in baseline period reporting arms, subject analysis set with evaluable endpoint data.

End point values	Placebo	3 mg LY3502970	12 mg LY3502970	24 mg LY3502970
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	55	46	49	42
Units: milligrams per deciliter (mg/dL)				
least squares mean (standard error)	-11.1 (± 3.90)	-32.6 (± 4.14)	-53.7 (± 3.92)	-52.2 (± 4.49)

End point values	1.5 mg Dulaglutide	36 mg LY3502970	45 mg LY3502970	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	49	57	58	
Units: milligrams per deciliter (mg/dL)				
least squares mean (standard error)	-33.2 (± 3.91)	-53.9 (± 3.79)	-55.9 (± 3.69)	

Statistical analyses

Statistical analysis title	Outcome measure No.5
Comparison groups	Placebo v 3 mg LY3502970
Number of subjects included in analysis	101
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Least square mean difference
Point estimate	-21.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-32.7
upper limit	-10.3

Statistical analysis title	Outcome measure No.5
Comparison groups	Placebo v 12 mg LY3502970
Number of subjects included in analysis	104
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Least square mean difference
Point estimate	-42.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-53.4
upper limit	-31.7

Statistical analysis title	Outcome measure No.5
Comparison groups	Placebo v 24 mg LY3502970
Number of subjects included in analysis	97
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Least square mean difference
Point estimate	-41
Confidence interval	
level	95 %
sides	2-sided
lower limit	-52.7
upper limit	-29.3

Statistical analysis title	Outcome measure No.5
Comparison groups	Placebo v 36 mg LY3502970
Number of subjects included in analysis	112
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Least square mean difference
Point estimate	-42.7

Confidence interval	
level	95 %
sides	2-sided
lower limit	-53.5
upper limit	-32

Statistical analysis title	Outcome measure No.5
Comparison groups	Placebo v 45 mg LY3502970
Number of subjects included in analysis	113
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Least square mean difference
Point estimate	-44.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-55.3
upper limit	-34.2

Statistical analysis title	Outcome measure No.5
Comparison groups	3 mg LY3502970 v 1.5 mg Dulaglutide
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Least square mean difference
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.6
upper limit	11.8

Statistical analysis title	Outcome measure No.5
Comparison groups	12 mg LY3502970 v 1.5 mg Dulaglutide

Number of subjects included in analysis	98
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Least square mean difference
Point estimate	-20.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-31.4
upper limit	-9.5

Statistical analysis title	Outcome measure No.5
Comparison groups	24 mg LY3502970 v 1.5 mg Dulaglutide
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.002
Method	Mixed models analysis
Parameter estimate	Least square mean difference
Point estimate	-19
Confidence interval	
level	95 %
sides	2-sided
lower limit	-30.7
upper limit	-7.2

Statistical analysis title	Outcome measure No.5
Comparison groups	1.5 mg Dulaglutide v 36 mg LY3502970
Number of subjects included in analysis	106
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Least square mean difference
Point estimate	-20.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-31.4
upper limit	-9.9

Statistical analysis title	Outcome measure No.5

Comparison groups	1.5 mg Dulaglutide v 45 mg LY3502970
Number of subjects included in analysis	107
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Least square mean difference
Point estimate	-22.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-33.2
upper limit	-12.1

Secondary: Change from Baseline in Body Weight

End point title	Change from Baseline in Body Weight[6]

End point description:

LS mean was determined by MMRM model with Baseline + Country + Baseline HbA1c Group (<=8.0%, >8.0%) + Treatment + Time + Treatment*Time (Type III sum of squares) as variables.
APD: All participants who received at least one dose of study drug, had baseline and at least one post-baseline body weight data.
The statistical analyses were conducted to compare LY3502970 against placebo i.e., comparison groups = LY3502970 vs Placebo, and LY3502970 against Dulaglutide i.e., comparison groups= LY3502970 vs Dulaglutide.
Comparison groups in the individual statistical analyses below may be disregarded.

End point type	Secondary

End point timeframe:

Baseline, Week 26

Notes:

[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: Descriptive statistics was added in baseline period reporting arms, subject analysis set with evaluable endpoint data.

End point values	Placebo	3 mg LY3502970	12 mg LY3502970	24 mg LY3502970
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	55	50	53	46
Units: kilograms (kg)				
least squares mean (standard error)	-2.2 (± 0.74)	-3.7 (± 0.79)	-6.5 (± 0.76)	-9.7 (± 0.85)

End point values	1.5 mg Dulaglutide	36 mg LY3502970	45 mg LY3502970	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	50	57	62	
Units: kilograms (kg)				
least squares mean (standard error)	-3.9 (± 0.76)	-9.5 (± 0.73)	-10.1 (± 0.71)	

Statistical analyses

Statistical analysis title	Outcome measure No.6
Comparison groups	Placebo v 3 mg LY3502970
Number of subjects included in analysis	105
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.153
Method	Mixed models analysis
Parameter estimate	Least square mean difference
Point estimate	-1.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.7
upper limit	0.6

Statistical analysis title	Outcome measure No.6
Comparison groups	Placebo v 12 mg LY3502970
Number of subjects included in analysis	108
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Least square mean difference
Point estimate	-4.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.4
upper limit	-2.2

Statistical analysis title	Outcome measure No.6
Comparison groups	Placebo v 24 mg LY3502970

Number of subjects included in analysis	101
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Least square mean difference
Point estimate	-7.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.8
upper limit	-5.3

Statistical analysis title	Outcome measure No.6
Comparison groups	Placebo v 36 mg LY3502970
Number of subjects included in analysis	112
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Least square mean difference
Point estimate	-7.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.4
upper limit	-5.3

Statistical analysis title	Outcome measure No.6
Comparison groups	Placebo v 45 mg LY3502970
Number of subjects included in analysis	117
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Least square mean difference
Point estimate	-7.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.9
upper limit	-5.9

Statistical analysis title	Outcome measure No.6

Comparison groups	3 mg LY3502970 v 1.5 mg Dulaglutide
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.914
Method	Mixed models analysis
Parameter estimate	Least square mean difference
Point estimate	0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2
upper limit	2.3

Statistical analysis title	Outcome measure No.6
Comparison groups	12 mg LY3502970 v 1.5 mg Dulaglutide
Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.015
Method	Mixed models analysis
Parameter estimate	Least square mean difference
Point estimate	-2.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.7
upper limit	-0.5

Statistical analysis title	Outcome measure No.6
Comparison groups	24 mg LY3502970 v 1.5 mg Dulaglutide
Number of subjects included in analysis	96
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Least square mean difference
Point estimate	-5.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.1
upper limit	-3.6

Statistical analysis title	Outcome measure No.6
Comparison groups	1.5 mg Dulaglutide v 36 mg LY3502970
Number of subjects included in analysis	107
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Least square mean difference
Point estimate	-5.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.8
upper limit	-3.6

Statistical analysis title	Outcome measure No.6
Comparison groups	1.5 mg Dulaglutide v 45 mg LY3502970
Number of subjects included in analysis	112
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Least square mean difference
Point estimate	-6.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.3
upper limit	-4.2

Secondary: Pharmacokinetics (PK): Steady State Area Under the Concentration Curve (AUC) of LY3502970

End point title	Pharmacokinetics (PK): Steady State Area Under the Concentration Curve (AUC) of LY3502970[7]

End point description:

PK: Steady State AUC of LY3502970.
APD: All participants who received at least one dose of LY3502970 and had evaluable PK data.

End point type	Secondary

End point timeframe:

Pre-dose (Week (wk) 0, wk 8, wk 12, and wk 26); Post-dose (wk 4, wk 8, wk 16, wk 20, and end of treatment).

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: Descriptive statistics was added in baseline period reporting arms, subject analysis set with evaluable endpoint data.

End point values	3 mg LY3502970	12 mg LY3502970	24 mg LY3502970	36 mg LY3502970 - 1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	45	48	43	24
Units: nanogram hour per milliliter (ng*h/mL)				
geometric mean (geometric coefficient of variation)	364 (± 38.7)	1020 (± 63.5)	1500 (± 84.5)	1830 (± 94.6)

End point values	36 mg LY3502970 - 2	45 mg LY3502970 - 1	45 mg LY3502970 - 2	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	29	25	28	
Units: nanogram hour per milliliter (ng*h/mL)				
geometric mean (geometric coefficient of variation)	2430 (± 39.8)	2230 (± 80.4)	2550 (± 55.3)	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Entire Study

Adverse event reporting additional description:

J2A-MC-GZGE

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.0

Reporting groups

Reporting group title	Placebo

Reporting group description:

Participants received matching placebo.

Reporting group title	3 mg LY3502970

Reporting group description:

Participants received maintenance dose of 3 mg with dose escalation starting from 2 mg LY3502970 administered orally QD.

Reporting group title	12 mg LY3502970

Reporting group description:

Participants received maintenance dose 12 mg with dose escalation starting from 2 mg, 6 mg and then 12 mg LY3502970 administered orally QD.

Reporting group title	24 mg LY3502970

Reporting group description:

Participants received maintenance dose 24 mg with dose escalation starting from 3 mg, 6 mg, 8 mg,12 mg and then 24 mg LY3502970 administered orally QD.

Reporting group title	36 mg LY3502970 - 1

Reporting group description:

Participants received maintenance dose 36 mg with dose escalation starting from 2 mg, 3 mg, 6 mg, 8 mg, 12 mg, 24 mg and then 36 mg LY3502970 administered orally QD.

Reporting group title	36 mg LY3502970 - 2

Reporting group description:

Participants received maintenance dose 36 mg with dose escalation starting from 3 mg, 6 mg,12 mg, 24 mg and then 36 mg LY3502970 administered orally QD.

Reporting group title	45 mg LY3502970 - 1

Reporting group description:

Participants received maintenance dose 45 mg with dose escalation starting from 3 mg, 6 mg, 8 mg, 12 mg, 24 mg, 36 mg and then 45 mg LY3502970 administered orally QD.

Reporting group title	45 mg LY3502970 - 2

Reporting group description:

Participants received maintenance dose 45 mg with dose escalation starting from 2 mg, 3 mg, 6 mg, 12 mg, 24 mg, 36 mg and then 45 mg LY3502970 administered orally QD.

Reporting group title	1.5 mg Dulaglutide

Reporting group description:

Participants received 1.5 mg Dulaglutide administered SC QW.

Serious adverse events	Placebo	3 mg LY3502970	12 mg LY3502970
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 55 (5.45%)	3 / 51 (5.88%)	1 / 56 (1.79%)
number of deaths (all causes)	1	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
facial bones fracture			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	1 / 55 (1.82%)	0 / 51 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fractured coccyx			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 55 (0.00%)	0 / 51 (0.00%)	0 / 56 (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
lumbar vertebral fracture			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 55 (0.00%)	0 / 51 (0.00%)	0 / 56 (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
radius fracture			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	1 / 55 (1.82%)	0 / 51 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
atrial fibrillation			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 55 (0.00%)	1 / 51 (1.96%)	0 / 56 (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
cardiac failure			
alternative dictionary used: MedDRA 25.0			

subjects affected / exposed	1 / 55 (1.82%)	0 / 51 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Nervous system disorders			
ischaemic stroke			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	1 / 55 (1.82%)	0 / 51 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Immune system disorders			
haemophagocytic lymphohistiocytosis			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 55 (0.00%)	1 / 51 (1.96%)	0 / 56 (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			
gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 55 (0.00%)	0 / 51 (0.00%)	0 / 56 (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
pancreatitis acute			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 55 (0.00%)	0 / 51 (0.00%)	0 / 56 (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
pylorospasm			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 55 (0.00%)	0 / 51 (0.00%)	0 / 56 (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
varices oesophageal			
alternative dictionary used: MedDRA 25.0			

subjects affected / exposed	0 / 55 (0.00%)	0 / 51 (0.00%)	0 / 56 (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
Renal and urinary disorders			
urethral haemorrhage			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 55 (0.00%)	0 / 51 (0.00%)	0 / 56 (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
Musculoskeletal and connective tissue disorders			
osteoarthritis			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	1 / 55 (1.82%)	0 / 51 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
appendicitis			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 55 (0.00%)	0 / 51 (0.00%)	0 / 56 (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
covid-19			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 55 (0.00%)	0 / 51 (0.00%)	1 / 56 (1.79%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 55 (0.00%)	1 / 51 (1.96%)	0 / 56 (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
Metabolism and nutrition disorders			
dehydration			
alternative dictionary used: MedDRA 25.0			

subjects affected / exposed	0 / 55 (0.00%)	0 / 51 (0.00%)	0 / 56 (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
diabetic ketoacidosis			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 55 (0.00%)	0 / 51 (0.00%)	0 / 56 (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
hypoglycaemia			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 55 (0.00%)	0 / 51 (0.00%)	0 / 56 (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	24 mg LY3502970	36 mg LY3502970 - 1	36 mg LY3502970 - 2
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 47 (10.64%)	1 / 27 (3.70%)	1 / 34 (2.94%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
facial bones fracture			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 47 (0.00%)	0 / 27 (0.00%)	0 / 34 (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
fractured coccyx			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 47 (0.00%)	0 / 27 (0.00%)	0 / 34 (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
lumbar vertebral fracture			
alternative dictionary used: MedDRA 25.0			

subjects affected / exposed	0 / 47 (0.00%)	0 / 27 (0.00%)	0 / 34 (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
radius fracture			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 47 (0.00%)	0 / 27 (0.00%)	0 / 34 (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
Cardiac disorders			
atrial fibrillation			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 47 (0.00%)	0 / 27 (0.00%)	0 / 34 (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
cardiac failure			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 47 (0.00%)	0 / 27 (0.00%)	0 / 34 (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
Nervous system disorders			
ischaemic stroke			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 47 (0.00%)	1 / 27 (3.70%)	0 / 34 (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
Immune system disorders			
haemophagocytic lymphohistiocytosis			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 47 (0.00%)	0 / 27 (0.00%)	0 / 34 (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
Gastrointestinal disorders			
gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 25.0			

subjects affected / exposed	1 / 47 (2.13%)	0 / 27 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancreatitis acute			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	1 / 47 (2.13%)	0 / 27 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pylorospasm			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	1 / 47 (2.13%)	0 / 27 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
varices oesophageal			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	1 / 47 (2.13%)	0 / 27 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
urethral haemorrhage			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 47 (0.00%)	0 / 27 (0.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
osteoarthritis			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 47 (0.00%)	0 / 27 (0.00%)	0 / 34 (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			
appendicitis			
alternative dictionary used: MedDRA 25.0			

subjects affected / exposed	1 / 47 (2.13%)	0 / 27 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
covid-19			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 47 (0.00%)	0 / 27 (0.00%)	0 / 34 (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
pneumonia			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 47 (0.00%)	0 / 27 (0.00%)	0 / 34 (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
Metabolism and nutrition disorders			
dehydration			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	1 / 47 (2.13%)	0 / 27 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diabetic ketoacidosis			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 47 (0.00%)	0 / 27 (0.00%)	0 / 34 (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
hypoglycaemia			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 47 (0.00%)	0 / 27 (0.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	45 mg LY3502970 - 1	45 mg LY3502970 - 2	1.5 mg Dulaglutide
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 31 (0.00%)	1 / 32 (3.13%)	1 / 50 (2.00%)
number of deaths (all causes)	0	0	0

number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
facial bones fracture			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 32 (0.00%)	0 / 50 (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
fractured coccyx			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 32 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lumbar vertebral fracture			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 32 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
radius fracture			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 32 (0.00%)	0 / 50 (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
Cardiac disorders			
atrial fibrillation			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 32 (0.00%)	0 / 50 (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
cardiac failure			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 32 (0.00%)	0 / 50 (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

Nervous system disorders			
ischaemic stroke			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 32 (0.00%)	0 / 50 (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
Immune system disorders			
haemophagocytic lymphohistiocytosis			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 32 (0.00%)	0 / 50 (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
Gastrointestinal disorders			
gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 32 (0.00%)	0 / 50 (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
pancreatitis acute			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 32 (0.00%)	0 / 50 (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
pylorospasm			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 32 (0.00%)	0 / 50 (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
varices oesophageal			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 32 (0.00%)	0 / 50 (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
Renal and urinary disorders			

urethral haemorrhage			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 32 (0.00%)	0 / 50 (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
Musculoskeletal and connective tissue disorders			
osteoarthritis			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 32 (0.00%)	0 / 50 (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			
appendicitis			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 32 (0.00%)	0 / 50 (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
covid-19			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 32 (0.00%)	0 / 50 (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
pneumonia			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 32 (0.00%)	0 / 50 (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
Metabolism and nutrition disorders			
dehydration			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 32 (0.00%)	0 / 50 (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
diabetic ketoacidosis			

alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 31 (0.00%)	1 / 32 (3.13%)	0 / 50 (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
hypoglycaemia			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 32 (0.00%)	0 / 50 (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

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

Non-serious adverse events	Placebo	3 mg LY3502970	12 mg LY3502970
Total subjects affected by non-serious adverse events			
subjects affected / exposed	25 / 55 (45.45%)	34 / 51 (66.67%)	40 / 56 (71.43%)
Investigations			
haemoglobin decreased			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 55 (0.00%)	0 / 51 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
lipase increased			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	2 / 55 (3.64%)	2 / 51 (3.92%)	5 / 56 (8.93%)
occurrences (all)	2	2	5
weight decreased			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 55 (0.00%)	0 / 51 (0.00%)	2 / 56 (3.57%)
occurrences (all)	0	0	2
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	4 / 55 (7.27%)	3 / 51 (5.88%)	1 / 56 (1.79%)
occurrences (all)	4	3	1
Cardiac disorders			

palpitations			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 55 (0.00%)	1 / 51 (1.96%)	3 / 56 (5.36%)
occurrences (all)	0	1	3
sinus tachycardia			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 55 (0.00%)	1 / 51 (1.96%)	0 / 56 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	1 / 55 (1.82%)	4 / 51 (7.84%)	1 / 56 (1.79%)
occurrences (all)	1	4	1
headache			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 55 (0.00%)	7 / 51 (13.73%)	2 / 56 (3.57%)
occurrences (all)	0	9	2
paraesthesia			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	1 / 55 (1.82%)	0 / 51 (0.00%)	0 / 56 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 55 (0.00%)	0 / 51 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
fatigue			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	2 / 55 (3.64%)	3 / 51 (5.88%)	5 / 56 (8.93%)
occurrences (all)	2	3	5
Gastrointestinal disorders			
abdominal distension			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 55 (0.00%)	2 / 51 (3.92%)	3 / 56 (5.36%)
occurrences (all)	0	2	3

abdominal pain upper			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 55 (0.00%)	3 / 51 (5.88%)	1 / 56 (1.79%)
occurrences (all)	0	5	2
constipation			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	1 / 55 (1.82%)	7 / 51 (13.73%)	7 / 56 (12.50%)
occurrences (all)	1	9	8
diarrhoea			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	4 / 55 (7.27%)	11 / 51 (21.57%)	9 / 56 (16.07%)
occurrences (all)	6	18	10
dyspepsia			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	2 / 55 (3.64%)	6 / 51 (11.76%)	4 / 56 (7.14%)
occurrences (all)	2	6	4
eructation			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 55 (0.00%)	4 / 51 (7.84%)	2 / 56 (3.57%)
occurrences (all)	0	4	3
flatulence			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	1 / 55 (1.82%)	0 / 51 (0.00%)	0 / 56 (0.00%)
occurrences (all)	2	0	0
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 55 (0.00%)	0 / 51 (0.00%)	4 / 56 (7.14%)
occurrences (all)	0	0	4
nausea			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	3 / 55 (5.45%)	12 / 51 (23.53%)	21 / 56 (37.50%)
occurrences (all)	4	15	27
retching			
alternative dictionary used: MedDRA 25.0			

subjects affected / exposed	0 / 55 (0.00%)	0 / 51 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
vomiting			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	1 / 55 (1.82%)	3 / 51 (5.88%)	12 / 56 (21.43%)
occurrences (all)	1	3	16
Reproductive system and breast disorders			
epididymal cyst			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed[1]	0 / 28 (0.00%)	0 / 26 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
urticaria			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 55 (0.00%)	0 / 51 (0.00%)	2 / 56 (3.57%)
occurrences (all)	0	0	3
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 55 (0.00%)	0 / 51 (0.00%)	2 / 56 (3.57%)
occurrences (all)	0	0	2
back pain			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	1 / 55 (1.82%)	1 / 51 (1.96%)	0 / 56 (0.00%)
occurrences (all)	1	1	0
muscle spasms			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	1 / 55 (1.82%)	1 / 51 (1.96%)	1 / 56 (1.79%)
occurrences (all)	1	1	1
Infections and infestations			
bacterial vaginosis			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed[2]	0 / 27 (0.00%)	0 / 25 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
covid-19			

alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	3 / 55 (5.45%)	2 / 51 (3.92%)	5 / 56 (8.93%)
occurrences (all)	3	2	5
upper respiratory tract infection			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	4 / 55 (7.27%)	2 / 51 (3.92%)	1 / 56 (1.79%)
occurrences (all)	5	2	1
urinary tract infection			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 55 (0.00%)	3 / 51 (5.88%)	0 / 56 (0.00%)
occurrences (all)	0	3	0
Metabolism and nutrition disorders			
decreased appetite			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 55 (0.00%)	3 / 51 (5.88%)	3 / 56 (5.36%)
occurrences (all)	0	3	4
hyperglycaemia			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	5 / 55 (9.09%)	1 / 51 (1.96%)	0 / 56 (0.00%)
occurrences (all)	5	1	0

Non-serious adverse events	24 mg LY3502970	36 mg LY3502970 - 1	36 mg LY3502970 - 2
Total subjects affected by non-serious adverse events			
subjects affected / exposed	32 / 47 (68.09%)	21 / 27 (77.78%)	18 / 34 (52.94%)
Investigations			
haemoglobin decreased			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 47 (0.00%)	2 / 27 (7.41%)	0 / 34 (0.00%)
occurrences (all)	0	2	0
lipase increased			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	4 / 47 (8.51%)	1 / 27 (3.70%)	2 / 34 (5.88%)
occurrences (all)	4	1	2
weight decreased			
alternative dictionary used: MedDRA 25.0			

subjects affected / exposed	2 / 47 (4.26%)	3 / 27 (11.11%)	2 / 34 (5.88%)
occurrences (all)	2	3	2
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 47 (0.00%)	1 / 27 (3.70%)	2 / 34 (5.88%)
occurrences (all)	0	1	2
Cardiac disorders			
palpitations			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 47 (0.00%)	1 / 27 (3.70%)	0 / 34 (0.00%)
occurrences (all)	0	1	0
sinus tachycardia			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	2 / 47 (4.26%)	0 / 27 (0.00%)	2 / 34 (5.88%)
occurrences (all)	2	0	2
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	2 / 47 (4.26%)	0 / 27 (0.00%)	1 / 34 (2.94%)
occurrences (all)	2	0	1
headache			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	2 / 47 (4.26%)	0 / 27 (0.00%)	1 / 34 (2.94%)
occurrences (all)	2	0	1
paraesthesia			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	1 / 47 (2.13%)	0 / 27 (0.00%)	0 / 34 (0.00%)
occurrences (all)	2	0	0
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 47 (0.00%)	2 / 27 (7.41%)	0 / 34 (0.00%)
occurrences (all)	0	2	0
fatigue			

alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 47 (0.00%)	1 / 27 (3.70%)	2 / 34 (5.88%)
occurrences (all)	0	2	2
Gastrointestinal disorders			
abdominal distension			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	2 / 47 (4.26%)	2 / 27 (7.41%)	0 / 34 (0.00%)
occurrences (all)	2	3	0
abdominal pain upper			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	3 / 47 (6.38%)	2 / 27 (7.41%)	0 / 34 (0.00%)
occurrences (all)	3	3	0
constipation			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	6 / 47 (12.77%)	6 / 27 (22.22%)	1 / 34 (2.94%)
occurrences (all)	7	6	1
diarrhoea			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	7 / 47 (14.89%)	7 / 27 (25.93%)	2 / 34 (5.88%)
occurrences (all)	11	8	3
dyspepsia			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	3 / 47 (6.38%)	3 / 27 (11.11%)	2 / 34 (5.88%)
occurrences (all)	3	5	2
eructation			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	3 / 47 (6.38%)	5 / 27 (18.52%)	3 / 34 (8.82%)
occurrences (all)	3	11	3
flatulence			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	4 / 47 (8.51%)	3 / 27 (11.11%)	1 / 34 (2.94%)
occurrences (all)	5	5	1
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 25.0			

subjects affected / exposed	3 / 47 (6.38%)	0 / 27 (0.00%)	2 / 34 (5.88%)
occurrences (all)	4	0	3
nausea			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	16 / 47 (34.04%)	10 / 27 (37.04%)	9 / 34 (26.47%)
occurrences (all)	20	20	18
retching			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 47 (0.00%)	2 / 27 (7.41%)	0 / 34 (0.00%)
occurrences (all)	0	3	0
vomiting			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	13 / 47 (27.66%)	9 / 27 (33.33%)	7 / 34 (20.59%)
occurrences (all)	16	28	9
Reproductive system and breast disorders			
epididymal cyst			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed[1]	0 / 30 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
urticaria			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 47 (0.00%)	2 / 27 (7.41%)	0 / 34 (0.00%)
occurrences (all)	0	2	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	1 / 47 (2.13%)	1 / 27 (3.70%)	1 / 34 (2.94%)
occurrences (all)	1	1	1
back pain			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	3 / 47 (6.38%)	0 / 27 (0.00%)	0 / 34 (0.00%)
occurrences (all)	3	0	0
muscle spasms			
alternative dictionary used:			

MedDRA 25.0			
subjects affected / exposed	0 / 47 (0.00%)	0 / 27 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
bacterial vaginosis			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed[2]	0 / 17 (0.00%)	0 / 9 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
covid-19			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	2 / 47 (4.26%)	0 / 27 (0.00%)	2 / 34 (5.88%)
occurrences (all)	2	0	2
upper respiratory tract infection			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	2 / 47 (4.26%)	0 / 27 (0.00%)	2 / 34 (5.88%)
occurrences (all)	2	0	2
urinary tract infection			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	1 / 47 (2.13%)	0 / 27 (0.00%)	1 / 34 (2.94%)
occurrences (all)	1	0	1
Metabolism and nutrition disorders			
decreased appetite			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	2 / 47 (4.26%)	2 / 27 (7.41%)	1 / 34 (2.94%)
occurrences (all)	2	2	1
hyperglycaemia			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 47 (0.00%)	0 / 27 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	45 mg LY3502970 - 1	45 mg LY3502970 - 2	1.5 mg Dulaglutide
Total subjects affected by non-serious adverse events			
subjects affected / exposed	21 / 31 (67.74%)	23 / 32 (71.88%)	23 / 50 (46.00%)
Investigations			
haemoglobin decreased			
alternative dictionary used: MedDRA 25.0			

subjects affected / exposed	0 / 31 (0.00%)	0 / 32 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
lipase increased			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	2 / 31 (6.45%)	0 / 32 (0.00%)	1 / 50 (2.00%)
occurrences (all)	2	0	1
weight decreased			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	1 / 31 (3.23%)	0 / 32 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 31 (0.00%)	1 / 32 (3.13%)	2 / 50 (4.00%)
occurrences (all)	0	1	2
Cardiac disorders			
palpitations			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 31 (0.00%)	1 / 32 (3.13%)	1 / 50 (2.00%)
occurrences (all)	0	1	1
sinus tachycardia			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 32 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 31 (0.00%)	1 / 32 (3.13%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
headache			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	2 / 31 (6.45%)	4 / 32 (12.50%)	0 / 50 (0.00%)
occurrences (all)	2	4	0
paraesthesia			
alternative dictionary used: MedDRA 25.0			

subjects affected / exposed	0 / 31 (0.00%)	2 / 32 (6.25%)	0 / 50 (0.00%)
occurrences (all)	0	3	0
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	1 / 31 (3.23%)	0 / 32 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
fatigue			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	2 / 31 (6.45%)	1 / 32 (3.13%)	0 / 50 (0.00%)
occurrences (all)	2	1	0
Gastrointestinal disorders			
abdominal distension			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 31 (0.00%)	1 / 32 (3.13%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
abdominal pain upper			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 31 (0.00%)	1 / 32 (3.13%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
constipation			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	1 / 31 (3.23%)	4 / 32 (12.50%)	0 / 50 (0.00%)
occurrences (all)	1	5	0
diarrhoea			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	9 / 31 (29.03%)	9 / 32 (28.13%)	6 / 50 (12.00%)
occurrences (all)	10	11	7
dyspepsia			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	2 / 31 (6.45%)	2 / 32 (6.25%)	1 / 50 (2.00%)
occurrences (all)	2	2	1
eructation			
alternative dictionary used: MedDRA 25.0			

subjects affected / exposed	2 / 31 (6.45%)	1 / 32 (3.13%)	1 / 50 (2.00%)
occurrences (all)	2	1	1
flatulence			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	1 / 31 (3.23%)	1 / 32 (3.13%)	1 / 50 (2.00%)
occurrences (all)	1	1	1
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	1 / 31 (3.23%)	1 / 32 (3.13%)	1 / 50 (2.00%)
occurrences (all)	2	1	1
nausea			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	9 / 31 (29.03%)	8 / 32 (25.00%)	9 / 50 (18.00%)
occurrences (all)	15	9	13
retching			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 32 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
vomiting			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	11 / 31 (35.48%)	7 / 32 (21.88%)	4 / 50 (8.00%)
occurrences (all)	18	10	4
Reproductive system and breast disorders			
epididymal cyst			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed[1]	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
urticaria			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 32 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			

arthralgia			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 31 (0.00%)	2 / 32 (6.25%)	0 / 50 (0.00%)
occurrences (all)	0	4	0
back pain			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	1 / 31 (3.23%)	1 / 32 (3.13%)	0 / 50 (0.00%)
occurrences (all)	1	1	0
muscle spasms			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 31 (0.00%)	2 / 32 (6.25%)	0 / 50 (0.00%)
occurrences (all)	0	2	0
Infections and infestations			
bacterial vaginosis			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed[2]	0 / 10 (0.00%)	0 / 13 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
covid-19			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	1 / 31 (3.23%)	2 / 32 (6.25%)	2 / 50 (4.00%)
occurrences (all)	1	2	2
upper respiratory tract infection			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 31 (0.00%)	1 / 32 (3.13%)	2 / 50 (4.00%)
occurrences (all)	0	1	3
urinary tract infection			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	1 / 31 (3.23%)	1 / 32 (3.13%)	2 / 50 (4.00%)
occurrences (all)	1	1	3
Metabolism and nutrition disorders			
decreased appetite			
alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	2 / 31 (6.45%)	3 / 32 (9.38%)	2 / 50 (4.00%)
occurrences (all)	2	4	2
hyperglycaemia			

alternative dictionary used: MedDRA 25.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 32 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Gender specific events occurring only in male or female participants have had the number of participants at risk adjusted accordingly.

[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Gender specific events occurring only in male or female participants have had the number of participants at risk adjusted accordingly.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported