Clinical trial results:
A Randomized Phase 2 Placebo-Controlled Study of LY2495655 in Patients with Advanced or Metastatic Pancreatic Cancer Receiving Chemotherapy

Summary

EudraCT number	2011-003822-29
Trial protocol	BE GB NO
Global end of trial date	28 December 2015

Results information

Result version number	v1 (current)
This version publication date	05 January 2020
First version publication date	05 January 2020

Trial information

Trial identification

Sponsor protocol code	I1Q-MC-JDDG

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01505530
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 12552

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	28 December 2015
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	28 December 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This phase 2 study is a multicenter, randomized, double-blind, placebo-controlled trial in participants with locally advanced/inoperable or metastatic pancreatic cancer, and will investigate 2 different doses of LY2495655 in combination with standard of care chemotherapy.

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	13 December 2011
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	Canada: 5
Country: Number of subjects enrolled	United Kingdom: 31
Country: Number of subjects enrolled	United States: 27
Country: Number of subjects enrolled	Israel: 57
Country: Number of subjects enrolled	Norway: 5
Worldwide total number of subjects	125
EEA total number of subjects	36

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)	48
From 65 to 84 years	77
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

No Text Available

Pre-assignment

Screening details:

The reasons for discontinuation listed in the participant flow are the reasons the participant discontinued treatment and a participant was considered to have "completed" the trial if they died due to any cause while on study or completed treatment and was known to be alive at the last scheduled follow-up.

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, Carer

Arms

Are arms mutually exclusive?	Yes
Arm title	300 mg LY2495655 + chemotherapy

Arm description:

300 milligram (mg) LY2495655 intravenous (IV) in combination with standard of care chemotherapy (investigator's choice).

Arm type	Experimental
Investigational medicinal product name	LY2495655
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous (IV) treatment every 14 days while on study.
Number of Cycles: until treatment options are exhausted or unacceptable toxicity develops.

Investigational medicinal product name	Standard of Care Chemotherapy
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Standard of care, gemcitabine-based regimen (single-agent gemcitabine or gemcitabine plus erlotinib) or FOLFIRINOX (combination chemotherapy regimen including 5-fluorouracil, leucovorin, oxaliplatin, and irinotecan). The choice of gemcitabine-based regimen or FOLFIRINOX will be determined by the investigator (based on the standard of care used at the treating institution or as directed by local regulatory authorities).

Arm title	100 mg LY2495655 + chemotherapy

Arm description:

100 mg LY2495655 intravenous (IV) in combination with standard of care chemotherapy (investigator's choice).

Arm type	Experimental

Investigational medicinal product name	LY2495655
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous (IV) treatment every 14 days while on study.
Number of Cycles: until treatment options are exhausted or unacceptable toxicity develops.

Investigational medicinal product name	Standard of Care Chemotherapy
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Standard of care, gemcitabine-based regimen (single-agent gemcitabine or gemcitabine plus erlotinib) or FOLFIRINOX (combination chemotherapy regimen including 5-fluorouracil, leucovorin, oxaliplatin, and irinotecan). The choice of gemcitabine-based regimen or FOLFIRINOX will be determined by the investigator (based on the standard of care used at the treating institution or as directed by local regulatory authorities).

Arm title	Placebo + chemotherapy

Arm description:

Placebo in combination with standard of care chemotherapy (investigator's choice).

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous (IV) treatment every 14 days while on study.
Number of Cycles: until treatment options are exhausted or unacceptable toxicity develops.

Investigational medicinal product name	Standard of Care Chemotherapy
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Standard of care, gemcitabine-based regimen (single-agent gemcitabine or gemcitabine plus erlotinib) or FOLFIRINOX (combination chemotherapy regimen including 5-fluorouracil, leucovorin, oxaliplatin, and irinotecan). The choice of gemcitabine-based regimen or FOLFIRINOX will be determined by the investigator (based on the standard of care used at the treating institution or as directed by local regulatory authorities).

Number of subjects in period 1	300 mg LY2495655 + chemotherapy	100 mg LY2495655 + chemotherapy	Placebo + chemotherapy
Started	41	43	41
Received At Least One Dose of Study Drug	41	42	41
Completed One Cycle of Study Drug	29	27	31
Completed	0	0	0
Not completed	41	43	41

Adverse event, serious fatal	7	6	5
Consent withdrawn by subject	7	8	6
Physician decision	6	2	5
entry criteria not met	-	1	-
Adverse event, non-fatal	1	1	-
Progressive Disease	19	17	18
Sponsor Decision	1	8	7

Baseline characteristics

Reporting groups	
Reporting group title	300 mg LY2495655 + chemotherapy
Reporting group description:	
300 milligram (mg) LY2495655 intravenous (IV) in combination with standard of care chemotherapy (investigator's choice).	
Reporting group title	100 mg LY2495655 + chemotherapy
Reporting group description:	
100 mg LY2495655 intravenous (IV) in combination with standard of care chemotherapy (investigator's choice).	
Reporting group title	Placebo + chemotherapy
Reporting group description:	
Placebo in combination with standard of care chemotherapy (investigator's choice).	

Reporting group values	300 mg LY2495655 + chemotherapy	100 mg LY2495655 + chemotherapy	Placebo + chemotherapy
Number of subjects	41	43	41
Age categorical Units: Subjects			
Adults (18-64 years old)			
Adults (65-84 years old)			
Age Continuous Units: years			
arithmetic mean	65.0	67.4	68.4
standard deviation	± 11.3	± 10.7	± 9.1
Gender, Male/Female Units:			
Female	16	13	15
Male	25	30	26
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	3	0
Not Hispanic or Latino	20	19	27
Unknown or Not Reported	21	21	14
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	1
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	3	1	5
White	38	42	35
More than one race	0	0	0
Unknown or Not Reported	0	0	0

Reporting group values	Total		
Number of subjects	125		

Age categorical Units: Subjects			
Adults (18-64 years old)	0		
Adults (65-84 years old)	0		
Age Continuous Units: years arithmetic mean standard deviation	 -		
Gender, Male/Female Units:			
Female	44		
Male	81		
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	3		
Not Hispanic or Latino	66		
Unknown or Not Reported	56		
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0		
Asian	1		
Native Hawaiian or Other Pacific Islander	0		
Black or African American	9		
White	115		
More than one race	0		
Unknown or Not Reported	0		

End points

End points reporting groups

Reporting group title	300 mg LY2495655 + chemotherapy
Reporting group description:	
300 milligram (mg) LY2495655 intravenous (IV) in combination with standard of care chemotherapy (investigator's choice).	
Reporting group title	100 mg LY2495655 + chemotherapy
Reporting group description:	
100 mg LY2495655 intravenous (IV) in combination with standard of care chemotherapy (investigator's choice).	
Reporting group title	Placebo + chemotherapy
Reporting group description:	
Placebo in combination with standard of care chemotherapy (investigator's choice).	

Primary: Overall survival (OS)

End point title	Overall survival (OS)
End point description:	
Overall survival (OS) duration was measured from the date of randomization to the date of death from any cause. Participants who were alive at data cut-off for the OS analysis or lost to follow-up were censored on the last date the participant was known to be alive. Censored participants; 300 mg LY2495655 = 9,100 mg LY2495655 =13, Placebo= 16.	
End point type	Primary
End point timeframe:	
Baseline to Death from Any Cause (Up to 23 months)	

End point values	300 mg LY2495655 + chemotherapy	100 mg LY2495655 + chemotherapy	Placebo + chemotherapy	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	41[1]	43[2]	41[3]	
Units: months				
median (confidence interval 90%)	8.02 (5.95 to 10.02)	9.82 (5.85 to 13.54)	10.45 (8.38 to 14.49)	

Notes:

[1] - All randomized participants.

[2] - All randomized participants.

[3] - All randomized participants.

Statistical analyses

Statistical analysis title	Statistical Analysis of Primary Endpoint
Statistical analysis description:	
Hazard ratio and 90% CI are obtained from an unstratified Cox model adjusted for the following covariates: first line therapy, weight loss prior to study entry, disease stage at study entry, and Eastern Cooperative Oncology Group (ECOG) performance status at study entry.	
Comparison groups	300 mg LY2495655 + chemotherapy v Placebo + chemotherapy

Number of subjects included in analysis	82
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Hazard ratio (HR)
Point estimate	1.7
Confidence interval	
level	90 %
sides	2-sided
lower limit	1.08
upper limit	2.65

Statistical analysis title	Statistical Analysis of Primary Endpoint

Statistical analysis description:

Hazard ratio and 90% CI are obtained from an unstratified Cox model adjusted for the following covariates: first line therapy,
weight loss prior to study entry, disease stage at study entry, and ECOG performance status at study entry.

Comparison groups	100 mg LY2495655 + chemotherapy v Placebo + chemotherapy
Number of subjects included in analysis	84
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Hazard ratio (HR)
Point estimate	1.3
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.82
upper limit	2.05

Secondary: Progression free survival (PFS)

End point title	Progression free survival (PFS)

End point description:

PFS was defined as the time from date of first dose to the first observation of disease progression or death from any cause. PD was determined using Response Evaluation Criteria In Solid Tumors (RECIST version 1.1) criteria. PD is ≥20% increase in sum of longest diameter of target lesions and/or a new lesion.

End point type	Secondary

End point timeframe:

Baseline to Disease Progression or Death from Any Cause (Up to 16 months)

End point values	300 mg LY2495655 + chemotherapy	100 mg LY2495655 + chemotherapy	Placebo + chemotherapy	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	41[4]	43[5]	41[6]	
Units: months				
median (confidence interval 90%)	4.90 (3.32 to 6.01)	6.87 (5.36 to 7.89)	8.21 (4.99 to 9.36)	

Notes:

[4] - All randomized participants.

[5] - All randomized participants.

[6] - All randomized participants.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Tumor Response Rate (RR)

End point title	Percentage of Participants with Tumor Response Rate (RR)

End point description:

Response rate (RR) was defined using Response Evaluation Criteria In Solid Tumors (RECIST, version 1.1) criteria. Complete Response (CR) was defined as the disappearance of all target and non-target lesions and any pathological lymph nodes (whether target or non-target) must have reduction in short axis to <10 millimeter (mm) and normalization of tumor marker level of non-target lesions; Partial Response (PR) was defined as having at least a 30% decrease in sum of longest diameter of target lesions; Progressive Disease (PD) was defined as having at least 20% increase in sum of longest diameter of target lesions and minimum 5 mm increase above nadir; Stable Disease (SD) was defined as small changes that did not meet above criteria.

End point type	Secondary

End point timeframe:

Baseline to Disease Progression (Up to 11 months)

End point values	300 mg LY2495655 + chemotherapy	100 mg LY2495655 + chemotherapy	Placebo + chemotherapy	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	41[7]	43[8]	41[9]	
Units: percentage of participants				
number (not applicable)	22	25.6	26.8	

Notes:

[7] - All randomized participants.

[8] - All randomized participants.

[9] - All randomized participants.

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response

End point title	Duration of Response

End point description:

The duration of a complete response (CR) or partial response (PR) was defined as the time from first objective status assessment of CR or PR to the first time of progression or death as a result of any

cause. Response was defined using Response Evaluation Criteria In Solid Tumors (RECIST, version 1.1) criteria. Complete Response (CR) was defined as the disappearance of all non-nodal target lesions, with the short axes of any target lymph nodes reduced to <10 millimeters (mm). Partial Response (PR) was defined as having at least a 30% decrease in the sum of the diameters of target lesions (including the short axes of any target lymph nodes), taking as reference the baseline sum diameter.

End point type	Secondary

End point timeframe:

First CR or PR to Disease Progression (Up to 11 months)

End point values	300 mg LY2495655 + chemotherapy	100 mg LY2495655 + chemotherapy	Placebo + chemotherapy	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	41[10]	43[11]	41[12]	
Units: months				
median (confidence interval 90%)	5.86 (3.91 to 5.98)	8.02 (3.09 to 9.63)	9.20 (9.03 to 10.45)	

Notes:

[10] - All randomized participants.

[11] - All randomized participants.

[12] - All randomized participants.

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Lean Body Mass

End point title	Change in Lean Body Mass

End point description:

Change in lean body mass was assessed using dual-energy x-ray absorptiometry (DXA).

End point type	Secondary

End point timeframe:

Baseline, Cycles 3, 5, 7, 9 and 11; Day 1

End point values	300 mg LY2495655 + chemotherapy	100 mg LY2495655 + chemotherapy	Placebo + chemotherapy	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	41[13]	42[14]	41[15]	
Units: grams (g)				
arithmetic mean (standard deviation)				
Baseline	43742.92 (± 10460.69)	44307.12 (± 9853.15)	42870.99 (± 8971.73)	
Cycle 3	42629.79 (± 10263.53)	44250.67 (± 11600.33)	42282.45 (± 8523.35)	
Cycle 5	43121.85 (± 11249.28)	45697.82 (± 12035.96)	43041.45 (± 7649.44)	
Cycle 7	44407.02 (± 11685.15)	45486.34 (± 11424.00)	45997.59 (± 9429.50)	

Cycle 9	46879.22 (± 12316.64)	43656.49 (± 12335.08)	43405.26 (± 7217.48)	
Cycle 11	46155.53 (± 9984.09)	433316.42 (± 11436.93)	45667.63 (± 8100.86)	

Notes:

[13] - All participants that received at least one dose of study drug and had evaluable post-baseline data.

[14] - All participants that received at least one dose of study drug and had evaluable post-baseline data.

[15] - All participants that received at least one dose of study drug and had evaluable post-baseline data.

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Physical Performance Measures Using Hand Grip Strength

End point title	Change in Physical Performance Measures Using Hand Grip Strength

End point description:

Hand grip strength (HGS) of the non-dominant hand measured using a hand dynamometer.

End point type	Secondary

End point timeframe:

Baseline, Cycles 2, 4, 6, 8 and 10; Day 1

End point values	300 mg LY2495655 + chemotherapy	100 mg LY2495655 + chemotherapy	Placebo + chemotherapy	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	41[16]	42[17]	41[18]	
Units: kilogram (kg)				
arithmetic mean (standard deviation)				
Baseline	28.59 (± 11.99)	29.00 (± 11.35)	27.46 (± 12.54)	
Cycle 2	25.90 (± 13.49)	26.70 (± 12.27)	25.26 (± 11.80)	
Cycle 4	25.56 (± 13.67)	24.47 (± 10.46)	28.02 (± 13.10)	
Cycle 6	26.58 (± 9.65)	26.32 (± 14.33)	27.43 (± 14.01)	
Cycle 8	27.89 (± 11.46)	26.22 (± 14.92)	25.44 (± 12.05)	
Cycle 10	25.13 (± 13.15)	29.23 (± 14.81)	33.27 (± 14.25)	

Notes:

[16] - All participants that received at least one dose of study drug and had evaluable post-baseline data.

[17] - All participants that received at least one dose of study drug and had evaluable post-baseline data.

[18] - All participants that received at least one dose of study drug and had evaluable post-baseline data.

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Physical Performance Measures Using the Time Up and Go (TUG) Test

End point title	Change in Physical Performance Measures Using the Time Up and Go (TUG) Test

End point description:

Time Up and Go (TUG) is a timed walking test designed to measure gait performance and balance. It measures in seconds the time taken by an individual to stand up from a standard arm chair (approximate seat height of 46 cm [18in], arm height 65 cm [25.6 in]), walk a distance of 3 meters (118 inches, approximately 10 feet), turn, walk back to the chair, and sit down.

End point type	Secondary

End point timeframe:

Baseline, Cycles 2, 4, 6, 8 and 10; Day 1

End point values	300 mg LY2495655 + chemotherapy	100 mg LY2495655 + chemotherapy	Placebo + chemotherapy	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	41[19]	42[20]	41[21]	
Units: seconds				
arithmetic mean (standard deviation)				
Baseline	10.70 (± 5.06)	10.16 (± 4.53)	10.04 (± 4.04)	
Cycle 2	9.19 (± 2.60)	10.15 (± 3.93)	10.64 (± 4.46)	
Cycle 4	9.33 (± 3.23)	12.19 (± 8.96)	9.18 (± 2.60)	
Cycle 6	10.14 (± 2.02)	8.84 (± 2.94)	9.77 (± 3.96)	
Cycle 8	9.28 (± 2.51)	7.26 (± 2.13)	9.03 (± 4.30)	
Cycle 10	10.56 (± 1.40)	7.75 (± 2.38)	9.76 (± 5.75)	

Notes:

[19] - All participants that received at least one dose of study drug and had evaluable post-baseline data.

[20] - All participants that received at least one dose of study drug and had evaluable post-baseline data.

[21] - All participants that received at least one dose of study drug and had evaluable post-baseline data.

Statistical analyses

No statistical analyses for this end point

Secondary: Change in physical performance measures using the 6 minute walk test

End point title	Change in physical performance measures using the 6 minute walk test

End point description:

The 6 minute walk test measured the distance walked in 6 minutes, as quickly as possible, without running.

End point type	Secondary

End point timeframe:

Baseline, Cycles 2, 4, 6, 8 and 10; Day 1

End point values	300 mg LY2495655 + chemotherapy	100 mg LY2495655 + chemotherapy	Placebo + chemotherapy	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	41[22]	42[23]	41[24]	
Units: meter				
arithmetic mean (standard deviation)				
Baseline	351.49 (± 115.18)	382.49 (± 131.41)	381.62 (± 94.68)	
Cycle 2	368.08 (± 137.65)	361.53 (± 143.70)	376.31 (± 107.25)	
Cycle 4	379.90 (± 208.66)	323.79 (± 140.26)	386.48 (± 126.56)	
Cycle 6	354.20 (± 104.74)	416.30 (± 102.49)	376.45 (± 132.05)	
Cycle 8	365.00 (± 75.71)	347.32 (± 203.49)	392.13 (± 113.43)	
Cycle 10	308.19 (± 57.23)	372.15 (± 172.40)	391.41 (± 143.18)	

Notes:

[22] - All participants that received at least one dose of study drug and had evaluable post-baseline data.
[23] - All participants that received at least one dose of study drug and had evaluable post-baseline data.
[24] - All participants that received at least one dose of study drug and had evaluable post-baseline data.

Statistical analyses

No statistical analyses for this end point

Secondary: Change in physical performance measures using stair climbing time (StC)

End point title	Change in physical performance measures using stair climbing time (StC)

End point description:

Stair climbing time (StC) measured the ascend and descend of a flight of 12 steps (each step 18 cm high and 28 cm deep).

End point type	Secondary

End point timeframe:

Baseline, Cycles 3, 5, 7, 9 and 11; Day 1

End point values	300 mg LY2495655 + chemotherapy	100 mg LY2495655 + chemotherapy	Placebo + chemotherapy	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	41[25]	42[26]	41[27]	
Units: joule/second				
arithmetic mean (standard deviation)				
Baseline	211.25 (± 129.57)	206.92 (± 110.52)	178.25 (± 65.18)	
Cycle 3	203.24 (± 113.76)	203.70 (± 87.82)	170.49 (± 76.52)	
Cycle 5	230.23 (± 135.31)	211.99 (± 93.00)	186.55 (± 95.20)	

Cycle 7	198.24 (± 83.19)	235.82 (± 111.95)	200.79 (± 130.74)	
Cycle 9	217.82 (± 131.34)	197.49 (± 102.51)	160.59 (± 87.60)	
Cycle 11	193.24 (± 96.70)	221.59 (± 107.49)	188.78 (± 188.78)	

Notes:

[25] - All participants that received at least one dose of study drug and had evaluable post-baseline data.

[26] - All participants that received at least one dose of study drug and had evaluable post-baseline data.

[27] - All participants that received at least one dose of study drug and had evaluable post-baseline data.

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Patient Reported Outcomes (PRO)

End point title	Change in Patient Reported Outcomes (PRO)

End point description:

Data from PRO scales are not be presented. An error in coding the scales (coded differently early and late in the study) occurred. Unable to determine which results were affected therefore analysis not completed.

End point type	Secondary

End point timeframe:

Baseline, Cycles 2, 4, 6, 8 and 10; Day 1

End point values	300 mg LY2495655 + chemotherapy	100 mg LY2495655 + chemotherapy	Placebo + chemotherapy	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[28]	0[29]	0[30]	
Units: units on a scale				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[28] - Writer To Revise

[29] - Writer To Revise

[30] - Writer To Revise

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Pain Scale Physical Functioning

End point title	Change in Pain Scale Physical Functioning

End point description:

The 36-item Short-Form Health Survey (SF-36) pain scale is a generic, health-related scale assessing participant’s quality of life on 8 domains: physical functioning, social functioning, bodily pain, vitality, mental health, role-physical, role-emotional and general health and 2 summary scores (mental component summary [MCS] and physical component summary [PCS]). The PCS physical functioning domain score ranges from 0 to 100 (higher scores indicate better health status).

End point type	Secondary

End point timeframe:
Baseline, Cycles 2, 4, 6, 8 and 10; Day 1

End point values	300 mg LY2495655 + chemotherapy	100 mg LY2495655 + chemotherapy	Placebo + chemotherapy	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	41[31]	43[32]	41[33]	
Units: units on a scale				
arithmetic mean (standard deviation)				
Baseline	6.62 (± 2.23)	6.81 (± 2.55)	5.89 (± 2.54)	
Cycle 2	4.48 (± 2.09)	5.63 (± 2.81)	5.04 (± 2.03)	
Cycle 4	5.33 (± 1.91)	4.78 (± 2.02)	4.83 (± 2.50)	
Cycle 6	4.38 (± 1.51)	4.65 (± 2.29)	4.25 (± 1.91)	
Cycle 8	4.14 (± 1.46)	5.85 (± 2.44)	5.00 (± 2.26)	
Cycle 10	4.57 (± 2.57)	5.58 (± 2.87)	3.55 (± 1.92)	

Notes:
[31] - All randomized participants with evaluable SF-36 domain scores.
[32] - All randomized participants with evaluable SF-36 domain scores.
[33] - All randomized participants with evaluable SF-36 domain scores.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Anti-LY2495655 Antibodies

End point title	Number of Participants With Anti-LY2495655 Antibodies

End point description:

End point type	Secondary

End point timeframe:
Cycle 1, Day 1 and Day 29 (Pre-Dose); Cycle 6 Day 1

End point values	300 mg LY2495655 + chemotherapy	100 mg LY2495655 + chemotherapy	Placebo + chemotherapy	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	41[34]	43[35]	41[36]	
Units: participants	0	1	1	

Notes:
[34] - All randomized participants.
[35] - All randomized participants.
[36] - All randomized participants.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Up to 16 months	
Adverse event reporting additional description: I1Q-MC-JDDG	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	22.1

Reporting groups	
Reporting group title	300 mg LY2495655
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	
Reporting group title	100 mg LY2495655
Reporting group description: -	

Serious adverse events	300 mg LY2495655	Placebo	100 mg LY2495655
Total subjects affected by serious adverse events			
subjects affected / exposed	26 / 41 (63.41%)	25 / 41 (60.98%)	30 / 42 (71.43%)
number of deaths (all causes)	3	2	5
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
malignant pleural effusion			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	0 / 41 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tumour haemorrhage			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 41 (2.44%)	0 / 41 (0.00%)	0 / 42 (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
tumour pain			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	1 / 41 (2.44%)	0 / 41 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
deep vein thrombosis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 41 (2.44%)	1 / 41 (2.44%)	2 / 42 (4.76%)
occurrences causally related to treatment / all	2 / 2	0 / 1	2 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypotension			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	1 / 41 (2.44%)	0 / 42 (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
phlebitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	0 / 41 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
fatigue			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 41 (2.44%)	0 / 41 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	3 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
general physical health deterioration			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 41 (2.44%)	0 / 41 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
oedema peripheral			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 41 (0.00%)	1 / 41 (2.44%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 41 (2.44%)	0 / 41 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyrexia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	6 / 41 (14.63%)	5 / 41 (12.20%)	7 / 42 (16.67%)
occurrences causally related to treatment / all	2 / 8	5 / 8	4 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
hypersensitivity			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	0 / 41 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
ovarian cyst			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[1]	0 / 16 (0.00%)	0 / 15 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
acute respiratory failure			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 41 (2.44%)	0 / 41 (0.00%)	0 / 42 (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
chronic obstructive pulmonary disease			
alternative dictionary used:			

MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	0 / 41 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dyspnoea			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	2 / 41 (4.88%)	1 / 41 (2.44%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pleural effusion			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 41 (2.44%)	0 / 41 (0.00%)	0 / 42 (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
pneumonitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	1 / 41 (2.44%)	0 / 42 (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
pulmonary congestion			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	1 / 41 (2.44%)	0 / 42 (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
pulmonary embolism			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	3 / 41 (7.32%)	2 / 41 (4.88%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	3 / 4	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	1 / 41 (2.44%)	0 / 41 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
confusional state			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	1 / 41 (2.44%)	0 / 42 (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
Product issues			
device occlusion			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	1 / 41 (2.44%)	0 / 42 (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
Investigations			
blood bilirubin increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 41 (2.44%)	0 / 41 (0.00%)	0 / 42 (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
blood creatinine increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 41 (2.44%)	0 / 41 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
myocardial infarction			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	0 / 41 (0.00%)	2 / 42 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
cerebral haemorrhage			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 41 (0.00%)	1 / 41 (2.44%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebral ischaemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	1 / 41 (2.44%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebrovascular accident			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	0 / 41 (0.00%)	2 / 42 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
syncope			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	1 / 41 (2.44%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 41 (2.44%)	0 / 41 (0.00%)	2 / 42 (4.76%)
occurrences causally related to treatment / all	1 / 1	0 / 0	6 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
neutropenia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	1 / 41 (2.44%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
splenic infarction			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	1 / 41 (2.44%)	0 / 41 (0.00%)	0 / 42 (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
splenic vein thrombosis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 41 (2.44%)	0 / 41 (0.00%)	0 / 42 (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
Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	3 / 41 (7.32%)	0 / 41 (0.00%)	4 / 42 (9.52%)
occurrences causally related to treatment / all	0 / 8	0 / 0	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ascites			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 41 (2.44%)	2 / 41 (4.88%)	2 / 42 (4.76%)
occurrences causally related to treatment / all	0 / 1	1 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diarrhoea			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	3 / 41 (7.32%)	3 / 42 (7.14%)
occurrences causally related to treatment / all	0 / 0	4 / 4	2 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
duodenal obstruction			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 41 (2.44%)	0 / 41 (0.00%)	0 / 42 (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
duodenal perforation			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 41 (0.00%)	0 / 41 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
dysphagia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 41 (2.44%)	0 / 41 (0.00%)	0 / 42 (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
gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	1 / 41 (2.44%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haematemesis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	0 / 41 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
impaired gastric emptying			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 41 (2.44%)	0 / 41 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intestinal obstruction			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	0 / 41 (0.00%)	2 / 42 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intestinal perforation			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	0 / 41 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1

intra-abdominal haematoma alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 41 (2.44%)	0 / 41 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intra-abdominal haemorrhage alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	0 / 41 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
large intestinal obstruction alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	1 / 41 (2.44%)	0 / 42 (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
lower gastrointestinal haemorrhage alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	1 / 41 (2.44%)	0 / 42 (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
nausea alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 41 (2.44%)	0 / 41 (0.00%)	2 / 42 (4.76%)
occurrences causally related to treatment / all	1 / 2	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
obstruction gastric alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	1 / 41 (2.44%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancreatitis alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 41 (0.00%)	1 / 41 (2.44%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
small intestinal obstruction			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	2 / 41 (4.88%)	0 / 41 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vomiting			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	2 / 41 (4.88%)	1 / 41 (2.44%)	4 / 42 (9.52%)
occurrences causally related to treatment / all	2 / 3	1 / 1	6 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
bile duct obstruction			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	2 / 41 (4.88%)	1 / 41 (2.44%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholangitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	4 / 41 (9.76%)	3 / 42 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 4	2 / 15
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholecystitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 41 (2.44%)	0 / 41 (0.00%)	0 / 42 (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
hepatic failure			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 41 (0.00%)	1 / 41 (2.44%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hyperbilirubinaemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 41 (2.44%)	0 / 41 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
acute kidney injury			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	2 / 41 (4.88%)	0 / 41 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hydronephrosis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	0 / 41 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
renal failure			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 41 (2.44%)	0 / 41 (0.00%)	0 / 42 (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
Endocrine disorders			
inappropriate antidiuretic hormone secretion			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	1 / 41 (2.44%)	0 / 42 (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
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	1 / 41 (2.44%)	0 / 41 (0.00%)	0 / 42 (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
back pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 41 (2.44%)	0 / 41 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
bacteraemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	2 / 41 (4.88%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
biliary sepsis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	1 / 41 (2.44%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
biliary tract infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	0 / 41 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bronchitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	1 / 41 (2.44%)	0 / 42 (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
cellulitis			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 41 (0.00%)	1 / 41 (2.44%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
clostridium difficile infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	0 / 41 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diverticulitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	1 / 41 (2.44%)	0 / 42 (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
enterobacter infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	1 / 41 (2.44%)	0 / 42 (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
infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	0 / 41 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
infusion site cellulitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 41 (2.44%)	0 / 41 (0.00%)	0 / 42 (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
liver abscess			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	0 / 41 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

lower respiratory tract infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	1 / 41 (2.44%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
neutropenic sepsis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 41 (2.44%)	1 / 41 (2.44%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	1 / 41 (2.44%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia streptococcal			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	0 / 41 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sepsis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	3 / 41 (7.32%)	1 / 41 (2.44%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
urinary tract infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	0 / 41 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urosepsis			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 41 (0.00%)	0 / 41 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
viral labyrinthitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	0 / 41 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
decreased appetite			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	0 / 41 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dehydration			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 41 (2.44%)	1 / 41 (2.44%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypercalcaemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 41 (2.44%)	1 / 41 (2.44%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hyperglycaemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	1 / 41 (2.44%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypoglycaemia			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 41 (0.00%)	0 / 41 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hyponatraemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	1 / 41 (2.44%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ketoacidosis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	0 / 41 (0.00%)	2 / 42 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: Event is gender specific

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

Non-serious adverse events	300 mg LY2495655	Placebo	100 mg LY2495655
Total subjects affected by non-serious adverse events			
subjects affected / exposed	41 / 41 (100.00%)	41 / 41 (100.00%)	41 / 42 (97.62%)
Vascular disorders			
deep vein thrombosis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	2 / 41 (4.88%)	4 / 41 (9.76%)	2 / 42 (4.76%)
occurrences (all)	5	8	18
hot flush			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	3 / 41 (7.32%)	1 / 41 (2.44%)	2 / 42 (4.76%)
occurrences (all)	14	5	6
hypertension			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 41 (2.44%)	3 / 41 (7.32%)	4 / 42 (9.52%)
occurrences (all)	1	8	22
hypotension			

alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	4 / 41 (9.76%)	2 / 41 (4.88%)	5 / 42 (11.90%)
occurrences (all)	13	2	9
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	2 / 41 (4.88%)	4 / 41 (9.76%)	2 / 42 (4.76%)
occurrences (all)	10	13	5
chest pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	3 / 41 (7.32%)	1 / 41 (2.44%)	2 / 42 (4.76%)
occurrences (all)	18	3	19
fatigue			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	25 / 41 (60.98%)	29 / 41 (70.73%)	28 / 42 (66.67%)
occurrences (all)	132	185	148
influenza like illness			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	5 / 41 (12.20%)	4 / 41 (9.76%)	4 / 42 (9.52%)
occurrences (all)	16	6	5
mucosal inflammation			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	7 / 41 (17.07%)	4 / 41 (9.76%)	6 / 42 (14.29%)
occurrences (all)	26	14	11
oedema peripheral			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	9 / 41 (21.95%)	16 / 41 (39.02%)	14 / 42 (33.33%)
occurrences (all)	46	55	40
pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	5 / 41 (12.20%)	3 / 41 (7.32%)	5 / 42 (11.90%)
occurrences (all)	10	7	36
peripheral swelling			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	4 / 41 (9.76%)	2 / 41 (4.88%)	3 / 42 (7.14%)
occurrences (all)	16	7	6
pyrexia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	13 / 41 (31.71%)	13 / 41 (31.71%)	11 / 42 (26.19%)
occurrences (all)	24	25	41
Immune system disorders			
hypersensitivity			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	3 / 41 (7.32%)	1 / 41 (2.44%)	1 / 42 (2.38%)
occurrences (all)	4	1	2
Reproductive system and breast disorders			
vulvovaginal pruritus			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed[2]	0 / 16 (0.00%)	1 / 15 (6.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	7 / 41 (17.07%)	6 / 41 (14.63%)	7 / 42 (16.67%)
occurrences (all)	26	21	19
dysphonia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	2 / 41 (4.88%)	4 / 41 (9.76%)	1 / 42 (2.38%)
occurrences (all)	14	16	1
dyspnoea			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	14 / 41 (34.15%)	8 / 41 (19.51%)	10 / 42 (23.81%)
occurrences (all)	38	32	47
epistaxis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	2 / 41 (4.88%)	5 / 41 (12.20%)	2 / 42 (4.76%)
occurrences (all)	15	13	5
hiccups			
alternative dictionary used:			

MedDRA 22.1			
subjects affected / exposed	2 / 41 (4.88%)	3 / 41 (7.32%)	3 / 42 (7.14%)
occurrences (all)	8	4	10
oropharyngeal pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	3 / 41 (7.32%)	1 / 41 (2.44%)	1 / 42 (2.38%)
occurrences (all)	3	1	8
pulmonary embolism			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	2 / 41 (4.88%)	2 / 41 (4.88%)	3 / 42 (7.14%)
occurrences (all)	3	9	19
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	4 / 41 (9.76%)	2 / 41 (4.88%)	4 / 42 (9.52%)
occurrences (all)	12	12	31
confusional state			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	4 / 41 (9.76%)	1 / 41 (2.44%)	1 / 42 (2.38%)
occurrences (all)	6	1	3
depression			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	4 / 41 (9.76%)	4 / 41 (9.76%)	5 / 42 (11.90%)
occurrences (all)	9	21	33
insomnia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	6 / 41 (14.63%)	1 / 41 (2.44%)	4 / 42 (9.52%)
occurrences (all)	39	16	21
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	3 / 41 (7.32%)	3 / 42 (7.14%)
occurrences (all)	0	15	18
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 41 (0.00%)	4 / 41 (9.76%)	3 / 42 (7.14%)
occurrences (all)	0	17	18
blood alkaline phosphatase increased alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 41 (2.44%)	3 / 41 (7.32%)	3 / 42 (7.14%)
occurrences (all)	8	16	16
blood bilirubin increased alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	3 / 41 (7.32%)	3 / 41 (7.32%)	4 / 42 (9.52%)
occurrences (all)	6	6	7
gamma-glutamyltransferase increased alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	3 / 41 (7.32%)	0 / 42 (0.00%)
occurrences (all)	0	16	0
neutrophil count decreased alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	4 / 41 (9.76%)	5 / 41 (12.20%)	4 / 42 (9.52%)
occurrences (all)	14	12	7
platelet count decreased alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	8 / 41 (19.51%)	4 / 41 (9.76%)	6 / 42 (14.29%)
occurrences (all)	14	11	18
weight decreased alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	9 / 41 (21.95%)	9 / 41 (21.95%)	6 / 42 (14.29%)
occurrences (all)	25	49	17
white blood cell count decreased alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	2 / 41 (4.88%)	2 / 41 (4.88%)	3 / 42 (7.14%)
occurrences (all)	2	2	16
Nervous system disorders dizziness alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	6 / 41 (14.63%)	4 / 41 (9.76%)	8 / 42 (19.05%)
occurrences (all)	27	21	36
dysgeusia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	6 / 41 (14.63%)	7 / 41 (17.07%)	4 / 42 (9.52%)
occurrences (all)	23	49	11
headache			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	6 / 41 (14.63%)	2 / 41 (4.88%)	3 / 42 (7.14%)
occurrences (all)	22	3	16
neuropathy peripheral			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	4 / 41 (9.76%)	6 / 41 (14.63%)	2 / 42 (4.76%)
occurrences (all)	29	20	21
peripheral sensory neuropathy			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	3 / 41 (7.32%)	5 / 41 (12.20%)	2 / 42 (4.76%)
occurrences (all)	17	66	21
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	12 / 41 (29.27%)	19 / 41 (46.34%)	14 / 42 (33.33%)
occurrences (all)	58	68	67
neutropenia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	12 / 41 (29.27%)	13 / 41 (31.71%)	9 / 42 (21.43%)
occurrences (all)	35	66	50
thrombocytopenia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	9 / 41 (21.95%)	14 / 41 (34.15%)	11 / 42 (26.19%)
occurrences (all)	28	49	37
Gastrointestinal disorders			
abdominal distension			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	0 / 41 (0.00%)	4 / 41 (9.76%)	2 / 42 (4.76%)
occurrences (all)	0	14	10
abdominal pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	12 / 41 (29.27%)	11 / 41 (26.83%)	6 / 42 (14.29%)
occurrences (all)	38	50	26
ascites			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	4 / 41 (9.76%)	7 / 41 (17.07%)	4 / 42 (9.52%)
occurrences (all)	8	22	12
constipation			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	12 / 41 (29.27%)	9 / 41 (21.95%)	15 / 42 (35.71%)
occurrences (all)	40	58	61
diarrhoea			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	22 / 41 (53.66%)	20 / 41 (48.78%)	17 / 42 (40.48%)
occurrences (all)	51	77	82
dry mouth			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	6 / 41 (14.63%)	6 / 41 (14.63%)	4 / 42 (9.52%)
occurrences (all)	20	16	22
dyspepsia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	3 / 41 (7.32%)	4 / 41 (9.76%)	3 / 42 (7.14%)
occurrences (all)	15	14	8
flatulence			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	3 / 41 (7.32%)	4 / 41 (9.76%)	2 / 42 (4.76%)
occurrences (all)	20	12	21
mouth ulceration			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	4 / 41 (9.76%)	2 / 41 (4.88%)	2 / 42 (4.76%)
occurrences (all)	12	2	13

nausea			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	18 / 41 (43.90%)	19 / 41 (46.34%)	19 / 42 (45.24%)
occurrences (all)	54	75	119
stomatitis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	5 / 41 (12.20%)	4 / 41 (9.76%)	4 / 42 (9.52%)
occurrences (all)	20	16	9
vomiting			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	13 / 41 (31.71%)	14 / 41 (34.15%)	15 / 42 (35.71%)
occurrences (all)	24	35	41
Skin and subcutaneous tissue disorders			
alopecia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	6 / 41 (14.63%)	3 / 41 (7.32%)	6 / 42 (14.29%)
occurrences (all)	23	38	49
dermatitis acneiform			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	2 / 41 (4.88%)	3 / 41 (7.32%)	2 / 42 (4.76%)
occurrences (all)	6	7	3
dry skin			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	4 / 41 (9.76%)	4 / 41 (9.76%)	4 / 42 (9.52%)
occurrences (all)	17	24	34
pruritus			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	5 / 41 (12.20%)	2 / 41 (4.88%)	3 / 42 (7.14%)
occurrences (all)	13	9	11
rash			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	7 / 41 (17.07%)	6 / 41 (14.63%)	6 / 42 (14.29%)
occurrences (all)	24	34	13
rash maculo-papular			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	1 / 41 (2.44%)	4 / 41 (9.76%)	2 / 42 (4.76%)
occurrences (all)	4	12	2
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	3 / 41 (7.32%)	2 / 41 (4.88%)	3 / 42 (7.14%)
occurrences (all)	18	17	17
back pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	8 / 41 (19.51%)	4 / 41 (9.76%)	8 / 42 (19.05%)
occurrences (all)	25	11	43
bone pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	0 / 41 (0.00%)	3 / 42 (7.14%)
occurrences (all)	0	0	4
joint swelling			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	3 / 41 (7.32%)	2 / 41 (4.88%)	2 / 42 (4.76%)
occurrences (all)	12	12	9
muscle spasms			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	3 / 41 (7.32%)	3 / 41 (7.32%)	1 / 42 (2.38%)
occurrences (all)	23	17	2
musculoskeletal pain			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	3 / 41 (7.32%)	3 / 41 (7.32%)	1 / 42 (2.38%)
occurrences (all)	24	12	2
myalgia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	3 / 41 (7.32%)	5 / 41 (12.20%)	4 / 42 (9.52%)
occurrences (all)	10	25	19
pain in extremity			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	8 / 41 (19.51%)	3 / 41 (7.32%)	1 / 42 (2.38%)
occurrences (all)	27	26	1
Infections and infestations			
device related infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	3 / 41 (7.32%)	0 / 42 (0.00%)
occurrences (all)	0	6	0
oral candidiasis			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	2 / 41 (4.88%)	4 / 41 (9.76%)	1 / 42 (2.38%)
occurrences (all)	2	14	2
tooth infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	0 / 41 (0.00%)	3 / 42 (7.14%)
occurrences (all)	0	0	6
upper respiratory tract infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	3 / 41 (7.32%)	0 / 42 (0.00%)
occurrences (all)	0	6	0
urinary tract infection			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	1 / 41 (2.44%)	5 / 41 (12.20%)	6 / 42 (14.29%)
occurrences (all)	1	9	10
Metabolism and nutrition disorders			
decreased appetite			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	18 / 41 (43.90%)	21 / 41 (51.22%)	17 / 42 (40.48%)
occurrences (all)	60	114	84
dehydration			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	5 / 41 (12.20%)	6 / 41 (14.63%)	3 / 42 (7.14%)
occurrences (all)	7	11	5
hyperglycaemia			
alternative dictionary used: MedDRA 22.1			

subjects affected / exposed	7 / 41 (17.07%)	3 / 41 (7.32%)	1 / 42 (2.38%)
occurrences (all)	15	25	3
hypoalbuminaemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	3 / 41 (7.32%)	5 / 41 (12.20%)	3 / 42 (7.14%)
occurrences (all)	8	13	5
hypoglycaemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	0 / 41 (0.00%)	1 / 41 (2.44%)	3 / 42 (7.14%)
occurrences (all)	0	1	4
hypokalaemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	3 / 41 (7.32%)	8 / 41 (19.51%)	3 / 42 (7.14%)
occurrences (all)	11	19	9
hypomagnesaemia			
alternative dictionary used: MedDRA 22.1			
subjects affected / exposed	3 / 41 (7.32%)	2 / 41 (4.88%)	5 / 42 (11.90%)
occurrences (all)	15	11	13

Notes:

[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: Event is gender specific

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
24 April 2012	Protocol amendment (b) The study schedule was revised to clarify that cycles should align with study therapy (LY2495655 or placebo) dosing and how data should be captured and assessments performed in order to ensure that data will be captured in a non-discrepant manner. Also, in the study schedule changes the cycle length and requirements for entering the post-discontinuation follow-up period was clarified. In addition, references to the post-first-line therapy days was removed and not determined by the chemotherapy regimen. Added expectation for participants who are discontinued from study therapy to be followed and assessed for primary secondary endpoints. Other clarifying texts regarding the standard of care determination, details regarding assessments, observation period, sourcing of chemotherapy agents, direction when unblinding study therapy, instructions on laboratory testing, and the replacement participants prior to cycle 1.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported