Clinical trial results:
A Phase II, Open-label Study of Efficacy and Safety of the Selective Inhibitor of Nuclear Export/SINE™ Compound KPT-330 (Selinexor) in Patients With Advanced Gynaecologic Malignancies

Summary

EudraCT number	2013-003650-24
Trial protocol	DK BE
Global end of trial date	29 March 2017

Results information

Result version number	v1 (current)
This version publication date	20 May 2021
First version publication date	20 May 2021

Trial information

Trial identification

Sponsor protocol code	KCP-330-005

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02025985
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Karyopharm Therapeutics Inc.
Sponsor organisation address	85 Wells Avenue, Newton MA, United States, 02459
Public contact	Clinical Trials Information, Karyopharm Therapeutics Inc., +1 617-658-0557, sharon@karyopharm.com
Scientific contact	Clinical Trials Information, Karyopharm Therapeutics Inc., +1 617-658-0557, sharon@karyopharm.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	29 March 2017
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	29 March 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To determine the efficacy of Selinexor in subjects with advanced or metastatic gynaecological cancers by disease control rate.

Protection of trial subjects:

The study was conducted in accordance with ethical principles that had their origin in the Declaration of Helsinki and were consistent with the International Council for Harmonisation Guideline for Good Clinical Practice, and applicable regulatory requirements.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	09 April 2014
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Belgium: 63
Country: Number of subjects enrolled	Denmark: 51
Worldwide total number of subjects	114
EEA total number of subjects	114

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)	70
From 65 to 84 years	44
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was conducted between 09-April-2014 and 29-March-2017.

Pre-assignment

Screening details:

A total of 116 subjects were enrolled out of which 2 subjects discontinued the study before the start of the treatment (1 subject due to death and 1 subject due to other reason). Total 114 subjects started the study treatment.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Part1: Cohort A-Ovarian Carcinoma: Selinexor upto 60 mg/m2 BIW

Arm description:

Subjects with ovarian carcinoma who were platinum refractory or platinum resistant and had received at least one line of chemotherapy for relapsed disease received a dose of 50 milligram per meter square (mg/m^2) of selinexor oral tablets twice weekly (BIW) (doses at least 36 hours apart) with light meal and 120 milliliters (mL) of water in a 4-week treatment cycles. After 12 weeks of treatment, a dose of 60 mg/m^2 of selinexor oral tablets BIW were administrated if the subjects had no major toxicity. During dose reduction, subjects received a minimum dose of 35 mg/m^2 once weekly (QW). This treatment continued until progression of disease (PD) or unacceptable toxicity or any discontinuation criteria or withdrawal of consent by the subject, or non-compliance by the subject with protocol requirements.

Arm type	Experimental
Investigational medicinal product name	Selinexor
Investigational medicinal product code	KPT-330
Other name	XPOVIO, NEXPOVIO
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Oral tablets at doses of 50 mg/m^2 BIW and 60 mg/m^2 BIW. Treatment cycles were 4 weeks each i.e., 28 day cycle.

Arm title	Part1:CohortB-Endometrial Carcinoma:Selinexor upto 60mg/m2 BIW

Arm description:

Subjects with endometrial carcinoma who had received at least one line of chemotherapy for relapsed or advanced (Stage IVb, IIIc) disease received a dose of 50 mg/m^2 of selinexor oral tablets BIW (doses at least 36 hours apart) with light meal and 120 mL of water in a 4-week treatment cycles. After 12 weeks of treatment, a dose of 60 mg/m^2 of selinexor oral tablets BIW were administrated if the subjects had no major toxicity. During dose reduction, subjects received a minimum dose of 35 mg/m^2 QW. This treatment continued until PD or unacceptable toxicity or any discontinuation criteria or withdrawal of consent by the subject, or non-compliance by the subject with protocol requirements.

Arm type	Experimental
Investigational medicinal product name	Selinexor
Investigational medicinal product code	KPT-330
Other name	XPOVIO, NEXPOVIO
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Oral tablets at doses of 50 mg/m^2 BIW and 60 mg/m^2 BIW. Treatment cycles were 4 weeks each i.e., 28 day cycle.

Arm title	Part1:CohortC-Cervical Carcinoma:Selinexor upto 60 mg/m2 BIW

Arm description:

Subjects with cervical carcinoma who had received at least one line of chemotherapy for relapsed or advanced (Stage IV) disease received a dose of 50 mg/m^2 of selinexor oral tablets BIW (doses at least 36 hours apart) with light meal and 120 mL of water in a 4-week treatment cycles. After 12 weeks of treatment, a dose of 60 mg/m^2 of selinexor oral tablets BIW were administrated if the subjects had no major toxicity. During dose reduction, subjects received a minimum dose of 35 mg/m^2 QW. This treatment continued until PD or unacceptable toxicity or any discontinuation criteria or withdrawal of consent by the subject, or non-compliance by the subject with protocol requirements.

Arm type	Experimental
Investigational medicinal product name	Selinexor
Investigational medicinal product code	KPT-330
Other name	XPOVIO, NEXPOVIO
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Oral tablets at doses of 50 mg/m^2 BIW and 60 mg/m^2 BIW. Treatment cycles were 4 weeks each i.e., 28 day cycle.

Arm title	Part2:CohortA-OvarianCarcinoma Sch.1:Selinexor upto 50mg/m2BIW

Arm description:

Subjects in Cohort A Schedule (Sch) 1 with ovarian carcinoma who were platinum refractory or platinum resistant and had received at least one line of chemotherapy for relapsed disease received a dose of 35 mg/m^2 of selinexor oral tablets BIW (doses at least 36 hours apart) with light meal and 120 mL of water in a 4-week treatment cycles. After 6 weeks of treatment, a dose of 50 mg/m^2 of selinexor oral tablets BIW were administrated if the subjects had no major toxicity. During dose reduction, subjects received a minimum dose of 35 mg/m^2 QW. This treatment continued until PD or unacceptable toxicity or any discontinuation criteria or withdrawal of consent by the subject, or non-compliance by the subject with protocol requirements.

Arm type	Experimental
Investigational medicinal product name	Selinexor
Investigational medicinal product code	KPT-330
Other name	XPOVIO, NEXPOVIO
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Oral tablets at doses of 35 mg/m^2 BIW, 50 mg/m^2 BIW, and 35 mg/m^2 QW. Treatment cycles were 4 weeks each i.e., 28 day cycle.

Arm title	Part2:Cohort A-OvarianCarcinoma Sch.2:Selinexor upto 60mg/m2QW

Arm description:

Subjects in Cohort A Schedule (Sch) 2 with ovarian carcinoma who were platinum refractory or platinum resistant and had received at least one line of chemotherapy for relapsed disease received a dose of 50 mg/m^2 of selinexor oral tablets QW (doses at least 5 days apart) with light meal and 120 mL of water in a 4-week treatment cycles. After 6 weeks of treatment, a dose of 60 mg/m^2 of selinexor oral tablets QW were administrated if the subjects had no major toxicity. During dose reduction, subjects received a minimum dose of 35 mg/m^2 QW. This treatment continued until PD or unacceptable toxicity or any discontinuation criteria or withdrawal of consent by the subject, or non-compliance by the subject with protocol requirements.

Arm type	Experimental

Investigational medicinal product name	Selinexor
Investigational medicinal product code	KPT-330
Other name	XPOVIO, NEXPOVIO
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Oral tablets at doses of 50 mg/m^2 QW, 60 mg/m^2 QW, and 35 mg/m^2 QW. Treatment cycles were 4 weeks each i.e., 28 day cycle.

Number of subjects in period 1	Part1: Cohort A-Ovarian Carcinoma: Selinexor upto 60 mg/m2 BIW	Part1:CohortB-Endometrial Carcinoma:Selinexor upto 60mg/m2 BIW	Part1:CohortC-Cervical Carcinoma:Selinexor upto 60 mg/m2 BIW
Started	25	23	25
Modified Intent-to-treat(mITT)Population	23	22	25
Completed	0	0	0
Not completed	25	23	25
Consent withdrawn by subject	-	-	1
Death	21	20	23
Termination of study by Sponsor	4	3	1

Number of subjects in period 1	Part2:CohortA-OvarianCarcinoma Sch.1:Selinexor upto 50mg/m2BIW	Part2:Cohort A-OvarianCarcinoma Sch.2:Selinexor upto 60mg/m2QW
Started	21	20
Modified Intent-to-treat(mITT)Population	21	20
Completed	0	0
Not completed	21	20
Consent withdrawn by subject	-	-
Death	20	17
Termination of study by Sponsor	1	3

Baseline characteristics

Reporting groups

Reporting group title	Part1: Cohort A-Ovarian Carcinoma: Selinexor upto 60 mg/m2 BIW

Reporting group description:

Subjects with ovarian carcinoma who were platinum refractory or platinum resistant and had received at least one line of chemotherapy for relapsed disease received a dose of 50 milligram per meter square (mg/m^2) of selinexor oral tablets twice weekly (BIW) (doses at least 36 hours apart) with light meal and 120 milliliters (mL) of water in a 4-week treatment cycles. After 12 weeks of treatment, a dose of 60 mg/m^2 of selinexor oral tablets BIW were administrated if the subjects had no major toxicity. During dose reduction, subjects received a minimum dose of 35 mg/m^2 once weekly (QW). This treatment continued until progression of disease (PD) or unacceptable toxicity or any discontinuation criteria or withdrawal of consent by the subject, or non-compliance by the subject with protocol requirements.

Reporting group title	Part1:CohortB-Endometrial Carcinoma:Selinexor upto 60mg/m2 BIW

Reporting group description:

Subjects with endometrial carcinoma who had received at least one line of chemotherapy for relapsed or advanced (Stage IVb, IIIc) disease received a dose of 50 mg/m^2 of selinexor oral tablets BIW (doses at least 36 hours apart) with light meal and 120 mL of water in a 4-week treatment cycles. After 12 weeks of treatment, a dose of 60 mg/m^2 of selinexor oral tablets BIW were administrated if the subjects had no major toxicity. During dose reduction, subjects received a minimum dose of 35 mg/m^2 QW. This treatment continued until PD or unacceptable toxicity or any discontinuation criteria or withdrawal of consent by the subject, or non-compliance by the subject with protocol requirements.

Reporting group title	Part1:CohortC-Cervical Carcinoma:Selinexor upto 60 mg/m2 BIW

Reporting group description:

Subjects with cervical carcinoma who had received at least one line of chemotherapy for relapsed or advanced (Stage IV) disease received a dose of 50 mg/m^2 of selinexor oral tablets BIW (doses at least 36 hours apart) with light meal and 120 mL of water in a 4-week treatment cycles. After 12 weeks of treatment, a dose of 60 mg/m^2 of selinexor oral tablets BIW were administrated if the subjects had no major toxicity. During dose reduction, subjects received a minimum dose of 35 mg/m^2 QW. This treatment continued until PD or unacceptable toxicity or any discontinuation criteria or withdrawal of consent by the subject, or non-compliance by the subject with protocol requirements.

Reporting group title	Part2:CohortA-OvarianCarcinoma Sch.1:Selinexor upto 50mg/m2BIW

Reporting group description:

Subjects in Cohort A Schedule (Sch) 1 with ovarian carcinoma who were platinum refractory or platinum resistant and had received at least one line of chemotherapy for relapsed disease received a dose of 35 mg/m^2 of selinexor oral tablets BIW (doses at least 36 hours apart) with light meal and 120 mL of water in a 4-week treatment cycles. After 6 weeks of treatment, a dose of 50 mg/m^2 of selinexor oral tablets BIW were administrated if the subjects had no major toxicity. During dose reduction, subjects received a minimum dose of 35 mg/m^2 QW. This treatment continued until PD or unacceptable toxicity or any discontinuation criteria or withdrawal of consent by the subject, or non-compliance by the subject with protocol requirements.

Reporting group title	Part2:Cohort A-OvarianCarcinoma Sch.2:Selinexor upto 60mg/m2QW

Reporting group description:

Subjects in Cohort A Schedule (Sch) 2 with ovarian carcinoma who were platinum refractory or platinum resistant and had received at least one line of chemotherapy for relapsed disease received a dose of 50 mg/m^2 of selinexor oral tablets QW (doses at least 5 days apart) with light meal and 120 mL of water in a 4-week treatment cycles. After 6 weeks of treatment, a dose of 60 mg/m^2 of selinexor oral tablets QW were administrated if the subjects had no major toxicity. During dose reduction, subjects received a minimum dose of 35 mg/m^2 QW. This treatment continued until PD or unacceptable toxicity or any discontinuation criteria or withdrawal of consent by the subject, or non-compliance by the subject with protocol requirements.

Reporting group values	Part1: Cohort A-Ovarian Carcinoma: Selinexor upto 60 mg/m2 BIW	Part1:CohortB-Endometrial Carcinoma:Selinexor upto 60mg/m2 BIW	Part1:CohortC-Cervical Carcinoma:Selinexor upto 60 mg/m2 BIW
Number of subjects	25	23	25
Age categorical Units: Subjects			
<=18 years	0	0	0
Between 18 and 65 years	17	6	20
>=65 years	8	17	5
Gender categorical Units: Subjects			
Female	25	23	25
Male	0	0	0
Ethnicity Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	25	23	25
Unknown or Not Reported	0	0	0
Race Units: Subjects			
White	25	23	24
Other-unspecified	0	0	1

Reporting group values	Part2:CohortA-OvarianCarcinoma Sch.1:Selinexor upto 50mg/m2BIW	Part2:Cohort A-OvarianCarcinoma Sch.2:Selinexor upto 60mg/m2QW	Total
Number of subjects	21	20	114
Age categorical Units: Subjects			
<=18 years	0	0	0
Between 18 and 65 years	13	14	70
>=65 years	8	6	44
Gender categorical Units: Subjects			
Female	21	20	114
Male	0	0	0
Ethnicity Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	21	20	114
Unknown or Not Reported	0	0	0
Race Units: Subjects			
White	21	20	113
Other-unspecified	0	0	1

End points

End points reporting groups

Reporting group title	Part1: Cohort A-Ovarian Carcinoma: Selinexor upto 60 mg/m2 BIW

Reporting group description:

Subjects with ovarian carcinoma who were platinum refractory or platinum resistant and had received at least one line of chemotherapy for relapsed disease received a dose of 50 milligram per meter square (mg/m^2) of selinexor oral tablets twice weekly (BIW) (doses at least 36 hours apart) with light meal and 120 milliliters (mL) of water in a 4-week treatment cycles. After 12 weeks of treatment, a dose of 60 mg/m^2 of selinexor oral tablets BIW were administrated if the subjects had no major toxicity. During dose reduction, subjects received a minimum dose of 35 mg/m^2 once weekly (QW). This treatment continued until progression of disease (PD) or unacceptable toxicity or any discontinuation criteria or withdrawal of consent by the subject, or non-compliance by the subject with protocol requirements.

Reporting group title	Part1:CohortB-Endometrial Carcinoma:Selinexor upto 60mg/m2 BIW

Reporting group description:

Subjects with endometrial carcinoma who had received at least one line of chemotherapy for relapsed or advanced (Stage IVb, IIIc) disease received a dose of 50 mg/m^2 of selinexor oral tablets BIW (doses at least 36 hours apart) with light meal and 120 mL of water in a 4-week treatment cycles. After 12 weeks of treatment, a dose of 60 mg/m^2 of selinexor oral tablets BIW were administrated if the subjects had no major toxicity. During dose reduction, subjects received a minimum dose of 35 mg/m^2 QW. This treatment continued until PD or unacceptable toxicity or any discontinuation criteria or withdrawal of consent by the subject, or non-compliance by the subject with protocol requirements.

Reporting group title	Part1:CohortC-Cervical Carcinoma:Selinexor upto 60 mg/m2 BIW

Reporting group description:

Subjects with cervical carcinoma who had received at least one line of chemotherapy for relapsed or advanced (Stage IV) disease received a dose of 50 mg/m^2 of selinexor oral tablets BIW (doses at least 36 hours apart) with light meal and 120 mL of water in a 4-week treatment cycles. After 12 weeks of treatment, a dose of 60 mg/m^2 of selinexor oral tablets BIW were administrated if the subjects had no major toxicity. During dose reduction, subjects received a minimum dose of 35 mg/m^2 QW. This treatment continued until PD or unacceptable toxicity or any discontinuation criteria or withdrawal of consent by the subject, or non-compliance by the subject with protocol requirements.

Reporting group title	Part2:CohortA-OvarianCarcinoma Sch.1:Selinexor upto 50mg/m2BIW

Reporting group description:

Subjects in Cohort A Schedule (Sch) 1 with ovarian carcinoma who were platinum refractory or platinum resistant and had received at least one line of chemotherapy for relapsed disease received a dose of 35 mg/m^2 of selinexor oral tablets BIW (doses at least 36 hours apart) with light meal and 120 mL of water in a 4-week treatment cycles. After 6 weeks of treatment, a dose of 50 mg/m^2 of selinexor oral tablets BIW were administrated if the subjects had no major toxicity. During dose reduction, subjects received a minimum dose of 35 mg/m^2 QW. This treatment continued until PD or unacceptable toxicity or any discontinuation criteria or withdrawal of consent by the subject, or non-compliance by the subject with protocol requirements.

Reporting group title	Part2:Cohort A-OvarianCarcinoma Sch.2:Selinexor upto 60mg/m2QW

Reporting group description:

Subjects in Cohort A Schedule (Sch) 2 with ovarian carcinoma who were platinum refractory or platinum resistant and had received at least one line of chemotherapy for relapsed disease received a dose of 50 mg/m^2 of selinexor oral tablets QW (doses at least 5 days apart) with light meal and 120 mL of water in a 4-week treatment cycles. After 6 weeks of treatment, a dose of 60 mg/m^2 of selinexor oral tablets QW were administrated if the subjects had no major toxicity. During dose reduction, subjects received a minimum dose of 35 mg/m^2 QW. This treatment continued until PD or unacceptable toxicity or any discontinuation criteria or withdrawal of consent by the subject, or non-compliance by the subject with protocol requirements.

Primary: Percentage of Subjects With Disease Control Response According to Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST v1.1)

End point title	Percentage of Subjects With Disease Control Response According to Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST v1.1)[1]

End point description:

Disease Control Rate (DCR) was defined as point estimate of the percentage of subjects who had complete response (CR), partial response (PR), or stable disease (SD) for at least 12 weeks, assessed according to RECIST v1.1. CR: disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to less than (<) 10 millimeters (mm). PR: at least a 30 percent (%) decrease in the sum of diameters of target lesions, taking as reference baseline sum diameters. SD: neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for PD, taking as reference smallest sum diameters while on study. Subjects without documented disease progression were censored on date of last radiologic assessment. Analysis was modified intent-to-treat (mITT) population:all subjects who received at least 1 dose of study drug,had measurable disease per RECIST at baseline, and had at least 1 post-baseline efficacy follow-up information.

End point type	Primary

End point timeframe:

Baseline up to 30 days after last dose administration, assessed after 6 weeks and 12 weeks (approximately 35 months)

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per protocol, only descriptive analyses was planned for this endpoint.

End point values	Part1: Cohort A-Ovarian Carcinoma: Selinexor upto 60 mg/m2 BIW	Part1:CohortB-Endometrial Carcinoma:Selinexor upto 60mg/m2 BIW	Part1:CohortC-Cervical Carcinoma:Selinexor upto 60 mg/m2 BIW	Part2:CohortA-OvarianCarcinoma Sch.1:Selinexor upto
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	23	22	25	21
Units: percentage of subjects				
number (confidence interval 95%)	30.4 (13.2 to 52.9)	36.4 (17.2 to 59.3)	24.0 (9.4 to 45.1)	33.3 (14.6 to 57.0)

End point values	Part2:Cohort A-OvarianCarcinoma Sch.2:Selinexor upto			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: percentage of subjects				
number (confidence interval 95%)	30.0 (11.9 to 54.3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Overall Response According to RECIST v1.1

End point title	Percentage of Subjects With Overall Response According to RECIST v1.1

End point description:

Overall Response Rate (ORR) was defined as the point estimate of the percentage of subjects who had CR or PR, assessed according to RECIST v1.1. CR was defined as disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) had reduction in short axis to <10 mm. PR was defined as at least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters. Analysis was performed on mITT population that included all subjects who received at least 1 dose of study drug, had measurable disease per RECIST at baseline, and had at least 1 post-baseline efficacy follow-up information.

End point type	Secondary

End point timeframe:

Baseline up to the date of progression or recurrence (approximately 35 months)

End point values	Part1: Cohort A-Ovarian Carcinoma: Selinexor upto 60 mg/m2 BIW	Part1:CohortB-Endometrial Carcinoma:Selinexor upto 60mg/m2 BIW	Part1:CohortC-Cervical Carcinoma:Selinexor upto 60 mg/m2 BIW	Part2:CohortA-OvarianCarcinoma Sch.1:Selinexor upto
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	23	22	25	21
Units: percentage of subjects				
number (confidence interval 95%)	8.7 (1.1 to 28.0)	13.6 (2.9 to 34.9)	4.0 (0.1 to 20.4)	9.5 (1.2 to 30.4)

End point values	Part2:Cohort A-OvarianCarcinoma Sch.2:Selinexor upto			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: percentage of subjects				
number (confidence interval 95%)	15.0 (3.2 to 37.9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Disease Control According to Gynecological Cancer Intergroup (GCIG) Response Criteria

End point title	Percentage of Subjects With Disease Control According to Gynecological Cancer Intergroup (GCIG) Response Criteria[2]

End point description:

DCR was defined as the point estimate of the percentage of subjects who had CR, PR, or SD for at least 12 weeks, assessed according to GCIG response criteria (RECIST v1.1 and CA-125). Analysis was performed on GCIG evaluable population that included all subjects in the ovarian cancer cohort (Cohort A) who had received at least 1 dose of study drug, had measurable disease per RECIST at baseline or

baseline CA-125 assessment, and had at least 1 post-baseline efficacy follow-up information (i.e., either post-baseline scan or CA-125 assessment). Data for this outcome measure was not planned to be collected and analysed for Cohort B and Cohort C, as pre-specified in protocol.

End point type	Secondary

End point timeframe:

Baseline up to 30 days after last dose administration, assessed after 6 weeks and 12 weeks (approximately 35 months)

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: Data for this outcome measure were not planned to be collected and analysed for Cohort B and Cohort C, as pre-specified in protocol.

End point values	Part1: Cohort A-Ovarian Carcinoma: Selinexor upto 60 mg/m2 BIW	Part2:CohortA-OvarianCarcinoma Sch.1:Selinexor upto	Part2:Cohort A-OvarianCarcinoma Sch.2:Selinexor upto	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	25	16	20	
Units: percentage of subjects				
number (confidence interval 95%)	16.0 (4.5 to 36.1)	23.8 (8.2 to 47.2)	20.0 (5.7 to 43.7)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Overall Response According to GCIG Response Criteria

End point title	Percentage of Subjects With Overall Response According to GCIG Response Criteria[3]

End point description:

ORR was defined as the point estimate of the percentage of subjects who had CR or PR, assessed according to GCIG response criteria (RECIST v1.1 and CA-125). Analysis was performed on GCIG evaluable population that included all subjects in the ovarian cancer cohort (Cohort A) who had received at least 1 dose of study drug, had measurable disease per RECIST at baseline or baseline CA-125 assessment, and had at least 1 post-baseline efficacy follow-up information (i.e., either post-baseline scan or CA-125 assessment). Data for this outcome measure were not planned to be collected and analysed for Cohort B and Cohort C, as pre-specified in protocol.

End point type	Secondary

End point timeframe:

Baseline up to the date of progression or recurrence (approximately 35 months)

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: Data for this outcome measure were not planned to be collected and analysed for Cohort B and Cohort C, as pre-specified in protocol.

End point values	Part1: Cohort A-Ovarian Carcinoma: Selinexor upto 60 mg/m2 BIW	Part2:CohortA-OvarianCarcinoma Sch.1:Selinexor upto	Part2:Cohort A-OvarianCarcinoma Sch.2:Selinexor upto	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	25	21	20	
Units: percentage of subjects				
number (confidence interval 95%)	4.0 (0.1 to 20.4)	9.5 (1.2 to 30.4)	10.0 (1.2 to 31.7)	

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-free Survival (PFS) According to RECIST v1.1

End point title	Progression-free Survival (PFS) According to RECIST v1.1

End point description:

PFS was defined as the time from date of start of study therapy to the date of tumor disease progression (i.e., radiological only) or date of death due to any cause. Subjects without documented disease progression were censored at the time of last radiologic assessment. Subjects without any post baseline assessments were censored at date of start of study therapy. Analysis was performed on mITT population that included all subjects who received at least 1 dose of study drug, had measurable disease per RECIST at baseline, and had at least 1 post-baseline efficacy follow-up information.

End point type	Secondary

End point timeframe:

From start of study drug administration until PD or discontinuation from the study or death, whichever occurred first (approximately 35 months)

End point values	Part1: Cohort A-Ovarian Carcinoma: Selinexor upto 60 mg/m2 BIW	Part1:CohortB-Endometrial Carcinoma:Selinexor upto 60mg/m2 BIW	Part1:CohortC-Cervical Carcinoma:Selinexor upto 60 mg/m2 BIW	Part2:CohortA-OvarianCarcinoma Sch.1:Selinexor upto
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	23	22	25	21
Units: days				
median (confidence interval 95%)	79.0 (45.0 to 99.0)	86.5 (43.0 to 182.0)	44.0 (43.0 to 141.0)	85.0 (44.0 to 148.0)

End point values	Part2:Cohort A-OvarianCarcinoma Sch.2:Selinexor upto			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: days				

median (confidence interval 95%)	44.5 (43.0 to 140.0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival (OS)

End point title	Overall Survival (OS)

End point description:

OS was defined as time from the date of start of study therapy to the date of death due to any cause. Subjects who were alive at the time of the analysis or were lost to follow-up were censored at the day they were last known to be alive. Kaplan-Maier method was used for estimation. Analysis was performed on mITT population that included all subjects who received at least 1 dose of study drug, had measurable disease per RECIST at baseline, and had at least 1 post-baseline efficacy follow-up information.

End point type	Secondary

End point timeframe:

From start of study treatment up to the date of death, assessed every 3 months (approximately 35 months)

End point values	Part1: Cohort A-Ovarian Carcinoma: Selinexor upto 60 mg/m2 BIW	Part1:CohortB-Endometrial Carcinoma:Selinexor upto 60mg/m2 BIW	Part1:CohortC-Cervical Carcinoma:Selinexor upto 60 mg/m2 BIW	Part2:CohortA-OvarianCarcinoma Sch.1:Selinexor upto
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	23	22	25	21
Units: days				
median (confidence interval 95%)	172.0 (62.0 to 372.0)	226.0 (111.0 to 449.0)	152.0 (83.0 to 254.0)	348.0 (149.0 to 401.0)

End point values	Part2:Cohort A-OvarianCarcinoma Sch.2:Selinexor upto			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: days				
median (confidence interval 95%)	173.0 (105.0 to 353.0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Survived at 12 and 24 Months

End point title	Percentage of Subjects Who Survived at 12 and 24 Months

End point description:

OS rate was reported as the percentage of subjects who were alive at 12 and 24 months. OS was defined as time from the date of start of study therapy to the date of death due to any cause. Subjects who were alive at the time of the analysis or are lost to follow-up were censored at the day they were last known to be alive. Survival rate were estimated by Kaplan-Maier method. Analysis was performed on mITT population that included all subjects who received at least 1 dose of study drug, had measurable disease per RECIST at baseline, and had at least 1 post-baseline efficacy follow-up information.

End point type	Secondary

End point timeframe:

12 and 24 months

End point values	Part1: Cohort A-Ovarian Carcinoma: Selinexor upto 60 mg/m2 BIW	Part1:CohortB-Endometrial Carcinoma:Selinexor upto 60mg/m2 BIW	Part1:CohortC-Cervical Carcinoma:Selinexor upto 60 mg/m2 BIW	Part2:CohortA-OvarianCarcinoma Sch.1:Selinexor upto
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	23	22	25	21
Units: percentage of subjects				
number (confidence interval 95%)				
12 months	34.8 (16.6 to 53.7)	31.8 (14.2 to 51.1)	13.2 (3.4 to 29.9)	33.3 (14.9 to 53.1)
24 months	21.7 (7.9 to 39.9)	13.6 (3.4 to 30.9)	4.4 (0.3 to 18.4)	19.0 (5.9 to 37.7)

End point values	Part2:Cohort A-OvarianCarcinoma Sch.2:Selinexor upto			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: percentage of subjects				
number (confidence interval 95%)				
12 months	25.0 (9.1 to 44.9)			
24 months	15.0 (3.7 to 33.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Treatment-emergent Adverse Events (TEAE) and Treatment-emergent Serious Adverse Events (TESAE) According to National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE), Version 4.03

End point title	Number of Subjects With Treatment-emergent Adverse Events (TEAE) and Treatment-emergent Serious Adverse Events (TESAE) According to National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE), Version 4.03

End point description:

Adverse event (AE) was defined as any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with use of medicinal product, whether or not related to medicinal product. Serious adverse event (SAE) was defined as AE that meets one or more of mentioned criteria, i.e., fatal, life threatening (places the subjects at immediate risk of death), required in-patient hospitalisation or prolongation of existing hospitalisation, resulted in persistent or significant disability/incapacity, congenital anomaly/birth defect, or important medical events. TEAE was defined as any AE (serious/non-serious) with onset or worsening of pre-existing condition on or after the first administration of study drug through 30 days after last dose or any event considered drug-related by the investigator through the end of study. Analysis was performed on safety population that included all subjects who had received any amount of study drug.

End point type	Secondary

End point timeframe:

From start of study treatment up to 30 days after the last dose administration (approximately 35 months)

End point values	Part1: Cohort A-Ovarian Carcinoma: Selinexor upto 60 mg/m2 BIW	Part1:CohortB-Endometrial Carcinoma:Selinexor upto 60mg/m2 BIW	Part1:CohortC-Cervical Carcinoma:Selinexor upto 60 mg/m2 BIW	Part2:CohortA-OvarianCarcinoma Sch.1:Selinexor upto
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	23	25	21
Units: subjects				
Subjects with TEAE	25	23	25	21
Subjects with TESAE	14	14	6	12

End point values	Part2:Cohort A-OvarianCarcinoma Sch.2:Selinexor upto			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: subjects				
Subjects with TEAE	20			
Subjects with TESAE	12			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Treatment-emergent Adverse Events by Severity According to National Cancer Institute Common Terminology Criteria for Adverse Events NCI CTCAE, Version 4.03

End point title	Number of Subjects With Treatment-emergent Adverse Events by Severity According to National Cancer Institute Common Terminology Criteria for Adverse Events NCI CTCAE, Version 4.03

End point description:

AE:any unfavorable and unintended sign, symptom, or disease temporally associated with use of medicinal product, whether or not considered related to medicinal product. TEAE:any AE (serious/non-serious) with onset or worsening of a pre-existing condition on/after 1st study drug administration to 30 days after last dose or any event considered drug-related by investigator until end of study. Per NCI-CTCAE 4.03, Grade1: asymptomatic/mild symptoms, clinical/diagnostic observations only, intervention not indicated; Grade2: moderate, minimal, local/noninvasive intervention indicated, limiting age-appropriate instrumental activities of daily life (ADL); Grade3: severe or medically significant but not immediately life-threatening, hospitalisation/prolongation of existing hospitalisation indicated,disabling, limiting self-care ADL; Grade4:life-threatening consequence, urgent intervention indicated; Grade5:death related to AE. Safety population:all subjects who had received any amount of drug.

End point type	Secondary

End point timeframe:

From start of study treatment up to 30 days after the last dose administration (approximately 35 months)

End point values	Part1: Cohort A-Ovarian Carcinoma: Selinexor upto 60 mg/m2 BIW	Part1:CohortB-Endometrial Carcinoma:Selinexor upto 60mg/m2 BIW	Part1:CohortC-Cervical Carcinoma:Selinexor upto 60 mg/m2 BIW	Part2:CohortA-OvarianCarcinoma Sch.1:Selinexor upto
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	23	25	21
Units: subjects				
Mild (Grade 1)	0	0	0	0
Moderate (Grade 2)	3	3	5	5
Severe (Grade 3)	19	17	17	15
Life threatening (Grade 4)	3	2	2	1
Fatal (Grade 5)	0	1	1	0

End point values	Part2:Cohort A-OvarianCarcinoma Sch.2:Selinexor upto			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: subjects				
Mild (Grade 1)	0			
Moderate (Grade 2)	7			
Severe (Grade 3)	13			

Life threatening (Grade 4)	0			
Fatal (Grade 5)	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Quality of Life (QoL): Change From Baseline in European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-C30 (EORTC QLQC30) Scores

End point title	Quality of Life (QoL): Change From Baseline in European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-C30 (EORTC QLQC30) Scores

End point description:

EORTC QLQC30: Disease specific indication to rate overall QoL in cancer subjects, consists of 30 questions (Q) in 3 domains; 1) global health status (GHS), 2) functioning scales (FS) (physical, emotional, cognitive, social, role functioning), 3) symptom scales (SS) (fatigue, nausea, vomiting, pain, dyspnoea, insomnia, appetite loss, constipation, diarrhea, financial difficulty). Of 30Q, 28Q were scored on scale of 1-4, (not at all, a little, quite a bit, and very much); remaining 2Q for GHS were scored on scale of 1-7, range ‘very poor' to 'excellent' to evaluate overall health and QoL. All scales and single-item measures range from 0-100, higher score=higher response level. Higher score for FS=high level of functioning, GHS=high QoL and SS=high level of symptoms/problems, respectively. Analysis was performed on mITT population. Here, 'Number of subjects analyzed'=subjects with available data for endpoint; ‘n' = subjects with available data for specified categories.

End point type	Secondary

End point timeframe:

Baseline up to End of treatment (EOT) i.e., 30 days after last dose of study drug administration (up to 31 months)

End point values	Part1: Cohort A-Ovarian Carcinoma: Selinexor upto 60 mg/m2 BIW	Part1:CohortB-Endometrial Carcinoma:Selinexor upto 60mg/m2 BIW	Part1:CohortC-Cervical Carcinoma:Selinexor upto 60 mg/m2 BIW	Part2:CohortA-OvarianCarcinoma Sch.1:Selinexor upto
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	21	22	21
Units: scores on a scale				
arithmetic mean (standard deviation)				
GHS/QoL:Baseline(n=21,21,22,21,20)	52.8 (± 22.41)	59.5 (± 20.63)	60.2 (± 24.25)	61.5 (± 22.89)
GHS/QoL:EOT (n=2,11,4,7,6)	-8.3 (± 11.79)	-11.4 (± 29.88)	-14.6 (± 10.49)	-27.4 (± 31.81)
FS/Physical function:Baseline(n=21,21,22,21,20)	69.5 (± 19.16)	70.9 (± 21.54)	66.1 (± 26.02)	67.1 (± 21.14)
FS/Physical function:EOT(n=2,1,4,7,6)	-26.7 (± 28.28)	-16.4 (± 27.55)	-24.2 (± 21.32)	-7.6 (± 16.97)
FS/Role function:Baseline(n=21,21,22,21,20)	54.0 (± 29.77)	59.5 (± 31.87)	55.6 (± 35.49)	59.5 (± 28.66)
FS/Role function:EOT(n=2,11,4,7,6)	-33.3 (± 47.14)	-3.0 (± 49.90)	-20.8 (± 36.96)	-9.5 (± 39.51)
FS/Emotional function:Baseline(n=21,21,22,21,20)	62.3 (± 24.81)	69.8 (± 24.65)	71.2 (± 23.81)	74.2 (± 19.53)

FS/Emotional function:EOT(n=2,11,4,7,6)	-16.7 (± 11.79)	-0.8 (± 38.27)	12.5 (± 14.43)	-13.9 (± 23.07)
FS/Cognitive function:Baseline(n=21,21,22,21,20)	81.0 (± 22.54)	86.5 (± 16.35)	83.3 (± 25.20)	83.3 (± 19.00)
FS/Cognitive function:EOT(n=2,11,4,7,6)	-33.3 (± 23.57)	-6.1 (± 29.13)	4.2 (± 20.97)	-16.7 (± 38.49)
FS/Social function:Baseline(n=21,21,22,21,20)	61.1 (± 29.97)	76.2 (± 32.31)	72.7 (± 28.89)	69.0 (± 30.86)
FS/Social function:EOT(n=2,11,4,7,6)	-33.3 (± 0.00)	-6.1 (± 48.46)	-20.8 (± 20.97)	-7.1 (± 18.90)
SS/Fatigue:Baseline(n=21,21,22,21,20)	46.6 (± 27.80)	43.4 (± 27.42)	44.9 (± 27.75)	46.0 (± 27.28)
SS/Fatigue:EOT(n=2,11,4,7,6)	33.3 (± 47.14)	6.1 (± 41.09)	1.4 (± 17.20)	23.8 (± 30.38)
SS/Nausea-vomiting:Baseline(n=21,21,22,21,20)	13.5 (± 24.51)	17.5 (± 30.04)	9.8 (± 15.99)	5.6 (± 14.27)
SS/Nausea-vomiting:EOT(n=2,11,4,7,6)	8.3 (± 11.79)	-0.0 (± 40.82)	16.7 (± 19.25)	9.5 (± 23.29)
SS/Pain:Baseline(n=21,21,22,21,20)	34.9 (± 27.84)	37.3 (± 27.34)	32.6 (± 27.93)	31.0 (± 29.48)
SS/Pain:EOT(n=2,11,4,7,6)	-8.3 (± 11.79)	-4.5 (± 21.20)	4.2 (± 8.33)	-2.4 (± 17.82)
SS/Dyspnoea:Baseline(n=21,21,22,21,20)	23.8 (± 31.87)	30.2 (± 36.37)	19.7 (± 30.27)	33.3 (± 38.01)
SS/Dyspnoea:EOT(n=2,11,4,7,6)	50.0 (± 23.57)	6.1 (± 32.72)	8.3 (± 16.67)	-0.0 (± 47.14)
SS/Insomnia:Baseline(n=21,21,22,21,20)	31.7 (± 34.12)	36.5 (± 31.46)	30.3 (± 32.38)	20.6 (± 26.82)
SS/Insomnia:EOT(n=2,11,4,7,6)	-16.7 (± 23.57)	-9.1 (± 30.15)	-16.7 (± 33.33)	-19.0 (± 26.23)
SS/Appetite loss:Baseline(n=21,21,22,21,20)	25.4 (± 31.46)	34.9 (± 32.45)	30.3 (± 36.96)	23.8 (± 28.17)
SS/Appetite loss:EOT(n=2,11,4,7,6)	16.7 (± 23.57)	0.0 (± 53.75)	16.7 (± 43.03)	33.3 (± 47.14)
SS/Constipation:Baseline(n=21,21,22,21,20)	27.0 (± 27.12)	15.9 (± 24.99)	15.2 (± 26.68)	17.5 (± 30.95)
SS/Constipation:EOT(n=2,11,4,7,6)	0.0 (± 47.14)	6.7 (± 43.89)	8.3 (± 16.67)	9.5 (± 31.71)
SS/Diarrhoea:Baseline(n=21,21,22,21,20)	17.5 (± 30.95)	9.5 (± 26.13)	18.2 (± 24.62)	18.3 (± 31.48)
SS/Diarrhoea:EOT(n=2,11,4,7,6)	0.0 (± 0.00)	-3.0 (± 34.82)	0.0 (± 27.22)	23.8 (± 25.20)
SS/Financial difficulty:Baseline(n=21,21,22,21,20)	7.9 (± 17.97)	4.8 (± 15.94)	16.7 (± 26.73)	9.5 (± 18.69)
SS/Financial difficulty:EOT(n=2,11,4,7,6)	16.7 (± 23.57)	3.0 (± 17.98)	0.0 (± 0.00)	4.8 (± 29.99)

End point values	Part2:Cohort A-OvarianCarcinoma Sch.2:Selinexor upto			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: scores on a scale				
arithmetic mean (standard deviation)				
GHS/QoL:Baseline(n=21,21,22,21,20)	57.5 (± 21.95)			
GHS/QoL:EOT (n=2,11,4,7,6)	-13.9 (± 15.52)			
FS/Physical function:Baseline(n=21,21,22,21,20)	70.7 (± 25.26)			
FS/Physical function:EOT(n=2,1,4,7,6)	-18.9 (± 14.25)			

FS/Role function:Baseline(n=21,21,22,21,20)	63.3 (± 34.45)			
FS/Role function:EOT(n=2,11,4,7,6)	-25.0 (± 9.13)			
FS/Emotional function:Baseline(n=21,21,22,21,20)	66.3 (± 23.33)			
FS/Emotional function:EOT(n=2,11,4,7,6)	-2.8 (± 17.21)			
FS/Cognitive function:Baseline(n=21,21,22,21,20)	80.8 (± 23.12)			
FS/Cognitive function:EOT(n=2,11,4,7,6)	0.0 (± 0.00)			
FS/Social function:Baseline(n=21,21,22,21,20)	77.5 (± 29.75)			
FS/Social function:EOT(n=2,11,4,7,6)	-30.6 (± 32.35)			
SS/Fatigue:Baseline(n=21,21,22,21,20)	41.7 (± 27.89)			
SS/Fatigue:EOT(n=2,11,4,7,6)	16.7 (± 11.65)			
SS/Nausea-vomiting:Baseline(n=21,21,22,21,20)	10.8 (± 21.81)			
SS/Nausea-vomiting:EOT(n=2,11,4,7,6)	13.9 (± 16.39)			
SS/Pain:Baseline(n=21,21,22,21,20)	32.5 (± 26.75)			
SS/Pain:EOT(n=2,11,4,7,6)	2.8 (± 26.70)			
SS/Dyspnoea:Baseline(n=21,21,22,21,20)	21.7 (± 29.17)			
SS/Dyspnoea:EOT(n=2,11,4,7,6)	16.7 (± 18.26)			
SS/Insomnia:Baseline(n=21,21,22,21,20)	38.3 (± 29.17)			
SS/Insomnia:EOT(n=2,11,4,7,6)	5.6 (± 32.77)			
SS/Appetite loss:Baseline(n=21,21,22,21,20)	15.0 (± 27.52)			
SS/Appetite loss:EOT(n=2,11,4,7,6)	16.7 (± 34.96)			
SS/Constipation:Baseline(n=21,21,22,21,20)	11.7 (± 16.31)			
SS/Constipation:EOT(n=2,11,4,7,6)	-5.6 (± 13.61)			
SS/Diarrhoea:Baseline(n=21,21,22,21,20)	8.3 (± 14.81)			
SS/Diarrhoea:EOT(n=2,11,4,7,6)	27.8 (± 32.77)			
SS/Financial difficulty:Baseline(n=21,21,22,21,20)	5.0 (± 12.21)			
SS/Financial difficulty:EOT(n=2,11,4,7,6)	-5.6 (± 13.61)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Individual Clinically Significant Abnormalities in Laboratory Tests

End point title	Number of Subjects With Individual Clinically Significant Abnormalities in Laboratory Tests

End point description:

Clinically significant laboratory tests abnormalities were analysed and reported for this outcome measure. Analysis was performed on safety population that included all subjects who had received any amount of study drug.

End point type	Secondary

End point timeframe:

From start of study treatment up to 30 days after the last dose administration (approximately 35 months)

End point values	Part1: Cohort A-Ovarian Carcinoma: Selinexor upto 60 mg/m2 BIW	Part1:CohortB-Endometrial Carcinoma:Selinexor upto 60mg/m2 BIW	Part1:CohortC-Cervical Carcinoma:Selinexor upto 60 mg/m2 BIW	Part2:CohortA-OvarianCarcinoma Sch.1:Selinexor upto
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	23	22	25	21
Units: subjects	21	20	19	14

End point values	Part2:Cohort A-OvarianCarcinoma Sch.2:Selinexor upto			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: subjects	11			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From start of study treatment up to 30 days after last dose administration (approximately 35 months)

Adverse event reporting additional description:

Analysis was performed on safety population that included all Subjects who had received any amount of study medication.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	20.1

Reporting groups

Reporting group title	Part1:Cohort A-Ovarian Carcinoma:Selinexor up to 60 mg/m2 BIW

Reporting group description:

Subjects with ovarian carcinoma who were platinum refractory or platinum resistant and had received at least one line of chemotherapy for relapsed disease received a dose of 50 mg/m^2 of selinexor oral tablets BIW (doses at least 36 hours apart) with light meal and 120 mL of water in a 4-week treatment cycles. After 12 weeks of treatment, a dose of 60 mg/m^2 of selinexor oral tablets BIW were administrated if the Subjects had no major toxicity. During dose reduction, Subjects received a minimum dose of 35 mg/m^2 QW. This treatment continued until PD or unacceptable toxicity or any discontinuation criteria or withdrawal of consent by the Subject, or non-compliance by the Subject with protocol requirements.

Reporting group title	Part1:CohortB-Endometrial Carcinoma:Selinexor upto 60mg/m2 BIW

Reporting group description:

Subjects with endometrial carcinoma who had received at least one line of chemotherapy for relapsed or advanced (Stage IVb, IIIc) disease received a dose of 50 mg/m^2 of selinexor oral tablets BIW (doses at least 36 hours apart) with light meal and 120 mL of water in a 4-week treatment cycles. After 12 weeks of treatment, a dose of 60 mg/m^2 of selinexor oral tablets BIW were administrated if the Subjects had no major toxicity. During dose reduction, Subjects received a minimum dose of 35 mg/m^2 QW. This treatment continued until PD or unacceptable toxicity or any discontinuation criteria or withdrawal of consent by the Subject, or non-compliance by the Subject with protocol requirements.

Reporting group title	Part1:CohortC-Cervical Carcinoma:Selinexor upto 60 mg/m2 BIW

Reporting group description:

Subjects with cervical carcinoma who had received at least one line of chemotherapy for relapsed or advanced (Stage IV) disease received a dose of 50 mg/m^2 of selinexor oral tablets BIW (doses at least 36 hours apart) with light meal and 120 mL of water in a 4-week treatment cycles. After 12 weeks of treatment, a dose of 60 mg/m^2 of selinexor oral tablets BIW were administrated if the Subjects had no major toxicity. During dose reduction, Subjects received a minimum dose of 35 mg/m^2 QW. This treatment continued until PD or unacceptable toxicity or any discontinuation criteria or withdrawal of consent by the Subject, or non-compliance by the Subject with protocol requirements.

Reporting group title	Part2:CohortA-OvarianCarcinoma Sch.1:Selinexor upto 50mg/m2BIW

Reporting group description:

Subjects with ovarian carcinoma who were platinum refractory or platinum resistant and had received at least one line of chemotherapy for relapsed disease received a dose of 35 mg/m^2 of selinexor oral tablets BIW (doses at least 36 hours apart) with light meal and 120 mL of water in a 4-week treatment cycles. After 6 weeks of treatment, a dose of 50 mg/m^2 of selinexor oral tablets BIW were administrated if the Subjects had no major toxicity. During dose reduction, Subjects received a minimum dose of 35 mg/m^2 QW. This treatment continued until PD or unacceptable toxicity or any discontinuation criteria or withdrawal of consent by the Subject, or non-compliance by the Subject with protocol requirements.

Reporting group title	Part2:Cohort A-OvarianCarcinoma Sch.2:Selinexor upto 60mg/m2QW

Reporting group description:

Subjects with ovarian carcinoma who were platinum refractory or platinum resistant and had received at

least one line of chemotherapy for relapsed disease received a dose of 50 mg/m^2 of selinexor oral tablets QW (doses at least 5 days apart) with light meal and 120 mL of water in a 4-week treatment cycles. After 6 weeks of treatment, a dose of 60 mg/m^2 of selinexor oral tablets QW were administrated if the Subjects had no major toxicity. During dose reduction, Subjects received a minimum dose of 35 mg/m^2 QW. This treatment continued until PD or unacceptable toxicity or any discontinuation criteria or withdrawal of consent by the Subject, or non-compliance by the Subject with protocol requirements.

Serious adverse events	Part1:Cohort A-Ovarian Carcinoma:Selinexor up to 60 mg/m2	Part1:CohortB-Endometrial Carcinoma:Selinexor upto 60mg/m2 BIW	Part1:CohortC-Cervical Carcinoma:Selinexor upto 60 mg/m2 BIW
Total subjects affected by serious adverse events			
subjects affected / exposed	14 / 25 (56.00%)	14 / 23 (60.87%)	6 / 25 (24.00%)
number of deaths (all causes)	21	20	23
number of deaths resulting from adverse events	0	1	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Intracranial Tumour Haemorrhage			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep Vein Thrombosis			
subjects affected / exposed	0 / 25 (0.00%)	2 / 23 (8.70%)	0 / 25 (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
Embolism			
subjects affected / exposed	1 / 25 (4.00%)	0 / 23 (0.00%)	0 / 25 (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
Surgical and medical procedures			
Drain Placement			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 25 (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
General disorders and administration site conditions			
Discomfort			

subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 25 (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
Gait Disturbance			
subjects affected / exposed	0 / 25 (0.00%)	1 / 23 (4.35%)	0 / 25 (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
General Physical Health Deterioration			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 25 (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
Inflammation			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 25 (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
Malaise			
subjects affected / exposed	0 / 25 (0.00%)	1 / 23 (4.35%)	0 / 25 (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
Pyrexia			
subjects affected / exposed	1 / 25 (4.00%)	1 / 23 (4.35%)	0 / 25 (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
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	1 / 25 (4.00%)	1 / 23 (4.35%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural Effusion			
subjects affected / exposed	2 / 25 (8.00%)	0 / 23 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			

subjects affected / exposed	1 / 25 (4.00%)	0 / 23 (0.00%)	0 / 25 (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
Pulmonary Embolism			
subjects affected / exposed	1 / 25 (4.00%)	0 / 23 (0.00%)	0 / 25 (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
Injury, poisoning and procedural complications			
Femoral Neck Fracture			
subjects affected / exposed	0 / 25 (0.00%)	1 / 23 (4.35%)	0 / 25 (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
Cardiac disorders			
Supraventricular Tachycardia			
subjects affected / exposed	0 / 25 (0.00%)	1 / 23 (4.35%)	0 / 25 (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
Nervous system disorders			
Aphasia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 25 (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
Cognitive Disorder			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 25 (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
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 25 (4.00%)	1 / 23 (4.35%)	0 / 25 (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
Thrombocytopenia			

subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 25 (0.00%)	1 / 23 (4.35%)	0 / 25 (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
Vision Blurred			
subjects affected / exposed	0 / 25 (0.00%)	1 / 23 (4.35%)	0 / 25 (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
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 25 (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
Anal Haemorrhage			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	2 / 25 (8.00%)	0 / 23 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	1 / 25 (4.00%)	0 / 23 (0.00%)	0 / 25 (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
Gastrointestinal Disorder			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 25 (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
Haematemesis			

subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	2 / 25 (8.00%)	0 / 23 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal Obstruction			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 25 (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
Nausea			
subjects affected / exposed	0 / 25 (0.00%)	1 / 23 (4.35%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstruction Gastric			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 25 (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
Rectal Haemorrhage			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Intestinal Obstruction			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 25 (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
Vomiting			
subjects affected / exposed	5 / 25 (20.00%)	1 / 23 (4.35%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	5 / 5	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute Kidney Injury			

subjects affected / exposed	1 / 25 (4.00%)	0 / 23 (0.00%)	0 / 25 (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
Cystitis Noninfective			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Failure			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Urinary Retention			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back Pain			
subjects affected / exposed	1 / 25 (4.00%)	0 / 23 (0.00%)	0 / 25 (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
Infections and infestations			
Bacteraemia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia Infection			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 25 (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
Lung Infection			
subjects affected / exposed	1 / 25 (4.00%)	0 / 23 (0.00%)	0 / 25 (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

Peritonitis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 25 (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			
subjects affected / exposed	1 / 25 (4.00%)	1 / 23 (4.35%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Respiratory Tract Infection			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 25 (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
Urinary Tract Infection			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 25 (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
Urosepsis			
subjects affected / exposed	0 / 25 (0.00%)	1 / 23 (4.35%)	0 / 25 (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
Varicella Zoster Virus Infection			
subjects affected / exposed	0 / 25 (0.00%)	1 / 23 (4.35%)	0 / 25 (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
Metabolism and nutrition disorders			
Decreased Appetite			
subjects affected / exposed	0 / 25 (0.00%)	1 / 23 (4.35%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	2 / 25 (8.00%)	1 / 23 (4.35%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	2 / 2	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			

subjects affected / exposed	2 / 25 (8.00%)	1 / 23 (4.35%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	2 / 2	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 25 (0.00%)	1 / 23 (4.35%)	0 / 25 (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
Hyponatraemia			
subjects affected / exposed	0 / 25 (0.00%)	2 / 23 (8.70%)	0 / 25 (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

Serious adverse events	Part2:CohortA-OvarianCarcinoma Sch.1:Selinexor upto 50mg/m2BIW	Part2:Cohort A-OvarianCarcinoma Sch.2:Selinexor upto 60mg/m2QW	
Total subjects affected by serious adverse events			
subjects affected / exposed	12 / 21 (57.14%)	12 / 20 (60.00%)	
number of deaths (all causes)	20	17	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Intracranial Tumour Haemorrhage			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Deep Vein Thrombosis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolism			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Drain Placement			

subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Discomfort			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gait Disturbance			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General Physical Health Deterioration			
subjects affected / exposed	0 / 21 (0.00%)	2 / 20 (10.00%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inflammation			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malaise			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Pleural Effusion			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary Embolism			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Femoral Neck Fracture			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Supraventricular Tachycardia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Aphasia			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cognitive Disorder			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			

subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Cataract			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vision Blurred			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	1 / 21 (4.76%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal Haemorrhage			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ascites			
subjects affected / exposed	0 / 21 (0.00%)	4 / 20 (20.00%)	
occurrences causally related to treatment / all	0 / 0	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal Disorder			

subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematemesis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal Obstruction			
subjects affected / exposed	1 / 21 (4.76%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	0 / 21 (0.00%)	2 / 20 (10.00%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstruction Gastric			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal Haemorrhage			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small Intestinal Obstruction			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			

subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis Noninfective			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal Failure			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary Retention			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Back Pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Bacteraemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia Infection			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Lung Infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonitis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory Tract Infection			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary Tract Infection			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicella Zoster Virus Infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Decreased Appetite			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			

subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypokalaemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Part1:Cohort A-Ovarian Carcinoma:Selinexor up to 60 mg/m2	Part1:CohortB-Endometrial Carcinoma:Selinexor upto 60mg/m2 BIW	Part1:CohortC-Cervical Carcinoma:Selinexor upto 60 mg/m2 BIW
Total subjects affected by non-serious adverse events			
subjects affected / exposed	25 / 25 (100.00%)	23 / 23 (100.00%)	25 / 25 (100.00%)
Vascular disorders			
Deep Vein Thrombosis			
subjects affected / exposed	0 / 25 (0.00%)	1 / 23 (4.35%)	1 / 25 (4.00%)
occurrences (all)	0	1	1
Hot Flush			
subjects affected / exposed	0 / 25 (0.00%)	1 / 23 (4.35%)	2 / 25 (8.00%)
occurrences (all)	0	1	2
Hypertension			
subjects affected / exposed	1 / 25 (4.00%)	0 / 23 (0.00%)	1 / 25 (4.00%)
occurrences (all)	1	0	1
Hypotension			

subjects affected / exposed	2 / 25 (8.00%)	2 / 23 (8.70%)	0 / 25 (0.00%)
occurrences (all)	2	2	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	7 / 25 (28.00%)	7 / 23 (30.43%)	5 / 25 (20.00%)
occurrences (all)	7	7	5
Chills			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Face Oedema			
subjects affected / exposed	2 / 25 (8.00%)	2 / 23 (8.70%)	2 / 25 (8.00%)
occurrences (all)	2	2	2
Fatigue			
subjects affected / exposed	12 / 25 (48.00%)	15 / 23 (65.22%)	15 / 25 (60.00%)
occurrences (all)	12	15	15
General Physical Health Deterioration			
subjects affected / exposed	0 / 25 (0.00%)	2 / 23 (8.70%)	0 / 25 (0.00%)
occurrences (all)	0	2	0
Malaise			
subjects affected / exposed	3 / 25 (12.00%)	3 / 23 (13.04%)	2 / 25 (8.00%)
occurrences (all)	3	3	2
Oedema			
subjects affected / exposed	2 / 25 (8.00%)	0 / 23 (0.00%)	0 / 25 (0.00%)
occurrences (all)	2	0	0
Oedema Peripheral			
subjects affected / exposed	3 / 25 (12.00%)	2 / 23 (8.70%)	2 / 25 (8.00%)
occurrences (all)	3	2	2
Pyrexia			
subjects affected / exposed	3 / 25 (12.00%)	1 / 23 (4.35%)	4 / 25 (16.00%)
occurrences (all)	3	1	4
Reproductive system and breast disorders			
Vaginal Haemorrhage			
subjects affected / exposed	1 / 25 (4.00%)	1 / 23 (4.35%)	2 / 25 (8.00%)
occurrences (all)	1	1	2
Respiratory, thoracic and mediastinal disorders			

Cough			
subjects affected / exposed	3 / 25 (12.00%)	2 / 23 (8.70%)	3 / 25 (12.00%)
occurrences (all)	3	2	3
Dyspnoea			
subjects affected / exposed	6 / 25 (24.00%)	3 / 23 (13.04%)	6 / 25 (24.00%)
occurrences (all)	6	3	6
Dyspnoea Exertional			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal Pain			
subjects affected / exposed	0 / 25 (0.00%)	1 / 23 (4.35%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Pleural Effusion			
subjects affected / exposed	2 / 25 (8.00%)	0 / 23 (0.00%)	0 / 25 (0.00%)
occurrences (all)	2	0	0
Pulmonary Embolism			
subjects affected / exposed	3 / 25 (12.00%)	2 / 23 (8.70%)	1 / 25 (4.00%)
occurrences (all)	3	2	1
Psychiatric disorders			
Agitation			
subjects affected / exposed	2 / 25 (8.00%)	0 / 23 (0.00%)	0 / 25 (0.00%)
occurrences (all)	2	0	0
Anxiety			
subjects affected / exposed	3 / 25 (12.00%)	0 / 23 (0.00%)	3 / 25 (12.00%)
occurrences (all)	3	0	3
Confusional State			
subjects affected / exposed	1 / 25 (4.00%)	2 / 23 (8.70%)	2 / 25 (8.00%)
occurrences (all)	1	2	2
Depression			
subjects affected / exposed	1 / 25 (4.00%)	1 / 23 (4.35%)	2 / 25 (8.00%)
occurrences (all)	1	1	2
Hallucination			

subjects affected / exposed	1 / 25 (4.00%)	0 / 23 (0.00%)	2 / 25 (8.00%)
occurrences (all)	1	0	2
Insomnia			
subjects affected / exposed	7 / 25 (28.00%)	1 / 23 (4.35%)	5 / 25 (20.00%)
occurrences (all)	7	1	5
Product issues			
Device Occlusion			
subjects affected / exposed	2 / 25 (8.00%)	0 / 23 (0.00%)	2 / 25 (8.00%)
occurrences (all)	2	0	2
Investigations			
Weight Decreased			
subjects affected / exposed	12 / 25 (48.00%)	13 / 23 (56.52%)	18 / 25 (72.00%)
occurrences (all)	12	13	18
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	1 / 25 (4.00%)	0 / 23 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Humerus Fracture			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Procedural Pain			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Aphasia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	7 / 25 (28.00%)	5 / 23 (21.74%)	6 / 25 (24.00%)
occurrences (all)	7	5	6
Dysgeusia			
subjects affected / exposed	7 / 25 (28.00%)	5 / 23 (21.74%)	11 / 25 (44.00%)
occurrences (all)	7	5	11
Headache			
subjects affected / exposed	3 / 25 (12.00%)	1 / 23 (4.35%)	3 / 25 (12.00%)
occurrences (all)	3	1	3

Paraesthesia			
subjects affected / exposed	0 / 25 (0.00%)	2 / 23 (8.70%)	2 / 25 (8.00%)
occurrences (all)	0	2	2
Peripheral Sensory Neuropathy			
subjects affected / exposed	1 / 25 (4.00%)	4 / 23 (17.39%)	3 / 25 (12.00%)
occurrences (all)	1	4	3
Somnolence			
subjects affected / exposed	2 / 25 (8.00%)	0 / 23 (0.00%)	0 / 25 (0.00%)
occurrences (all)	2	0	0
Syncope			
subjects affected / exposed	0 / 25 (0.00%)	2 / 23 (8.70%)	0 / 25 (0.00%)
occurrences (all)	0	2	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	13 / 25 (52.00%)	11 / 23 (47.83%)	14 / 25 (56.00%)
occurrences (all)	13	11	14
Neutropenia			
subjects affected / exposed	2 / 25 (8.00%)	3 / 23 (13.04%)	0 / 25 (0.00%)
occurrences (all)	2	3	0
Pancytopenia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	12 / 25 (48.00%)	10 / 23 (43.48%)	13 / 25 (52.00%)
occurrences (all)	12	10	13
Ear and labyrinth disorders			
Auditory Disorder			
subjects affected / exposed	0 / 25 (0.00%)	2 / 23 (8.70%)	0 / 25 (0.00%)
occurrences (all)	0	2	0
Ear Discomfort			
subjects affected / exposed	0 / 25 (0.00%)	2 / 23 (8.70%)	1 / 25 (4.00%)
occurrences (all)	0	2	1
Vertigo			
subjects affected / exposed	1 / 25 (4.00%)	1 / 23 (4.35%)	1 / 25 (4.00%)
occurrences (all)	1	1	1
Eye disorders			

Cataract			
subjects affected / exposed	0 / 25 (0.00%)	1 / 23 (4.35%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Dry Eye			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Vision Blurred			
subjects affected / exposed	7 / 25 (28.00%)	8 / 23 (34.78%)	5 / 25 (20.00%)
occurrences (all)	7	8	5
Visual Impairment			
subjects affected / exposed	2 / 25 (8.00%)	1 / 23 (4.35%)	1 / 25 (4.00%)
occurrences (all)	2	1	1
Gastrointestinal disorders			
Abdominal Discomfort			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Abdominal Distension			
subjects affected / exposed	3 / 25 (12.00%)	1 / 23 (4.35%)	2 / 25 (8.00%)
occurrences (all)	3	1	2
Abdominal Pain			
subjects affected / exposed	7 / 25 (28.00%)	1 / 23 (4.35%)	3 / 25 (12.00%)
occurrences (all)	7	1	3
Abdominal Pain Lower			
subjects affected / exposed	0 / 25 (0.00%)	1 / 23 (4.35%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Abdominal Pain Upper			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	2 / 25 (8.00%)
occurrences (all)	0	0	2
Ascites			
subjects affected / exposed	2 / 25 (8.00%)	1 / 23 (4.35%)	0 / 25 (0.00%)
occurrences (all)	2	1	0
Constipation			
subjects affected / exposed	7 / 25 (28.00%)	6 / 23 (26.09%)	6 / 25 (24.00%)
occurrences (all)	7	6	6
Defaecation Urgency			

subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	6 / 25 (24.00%)	7 / 23 (30.43%)	6 / 25 (24.00%)
occurrences (all)	6	7	6
Dry Mouth			
subjects affected / exposed	1 / 25 (4.00%)	1 / 23 (4.35%)	1 / 25 (4.00%)
occurrences (all)	1	1	1
Dyspepsia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Gastrooesophageal Reflux Disease			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Intestinal Obstruction			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Mouth Ulceration			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	22 / 25 (88.00%)	15 / 23 (65.22%)	17 / 25 (68.00%)
occurrences (all)	22	15	17
Oesophageal Irritation			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Oesophageal Pain			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Oral Mucosal Blistering			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	3 / 25 (12.00%)	1 / 23 (4.35%)	1 / 25 (4.00%)
occurrences (all)	3	1	1
Vomiting			

subjects affected / exposed	18 / 25 (72.00%)	14 / 23 (60.87%)	11 / 25 (44.00%)
occurrences (all)	18	14	11
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	1 / 25 (4.00%)	0 / 23 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Night Sweats			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	2 / 25 (8.00%)
occurrences (all)	0	0	2
Skin Fissures			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	1 / 25 (4.00%)	0 / 23 (0.00%)	4 / 25 (16.00%)
occurrences (all)	1	0	4
Haematuria			
subjects affected / exposed	1 / 25 (4.00%)	0 / 23 (0.00%)	3 / 25 (12.00%)
occurrences (all)	1	0	3
Hydronephrosis			
subjects affected / exposed	2 / 25 (8.00%)	0 / 23 (0.00%)	0 / 25 (0.00%)
occurrences (all)	2	0	0
Pollakiuria			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	4 / 25 (16.00%)
occurrences (all)	0	0	4
Polyurea			
subjects affected / exposed	0 / 25 (0.00%)	1 / 23 (4.35%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 25 (4.00%)	1 / 23 (4.35%)	2 / 25 (8.00%)
occurrences (all)	1	1	2
Back Pain			
subjects affected / exposed	2 / 25 (8.00%)	3 / 23 (13.04%)	4 / 25 (16.00%)
occurrences (all)	2	3	4
Muscle Spasms			

subjects affected / exposed	1 / 25 (4.00%)	0 / 23 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Muscular Weakness			
subjects affected / exposed	2 / 25 (8.00%)	0 / 23 (0.00%)	1 / 25 (4.00%)
occurrences (all)	2	0	1
Musculoskeletal Chest Pain			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	3 / 25 (12.00%)
occurrences (all)	0	0	3
Musculoskeletal Pain			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Pain In Extremity			
subjects affected / exposed	0 / 25 (0.00%)	2 / 23 (8.70%)	0 / 25 (0.00%)
occurrences (all)	0	2	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Cystitis			
subjects affected / exposed	2 / 25 (8.00%)	3 / 23 (13.04%)	1 / 25 (4.00%)
occurrences (all)	2	3	1
Device Related Infection			
subjects affected / exposed	1 / 25 (4.00%)	0 / 23 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Helicobacter Infection			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Herpes Simplex			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	0 / 25 (0.00%)	1 / 23 (4.35%)	0 / 25 (0.00%)
occurrences (all)	0	1	0

Laryngitis			
subjects affected / exposed	2 / 25 (8.00%)	0 / 23 (0.00%)	0 / 25 (0.00%)
occurrences (all)	2	0	0
Lung Infection			
subjects affected / exposed	2 / 25 (8.00%)	0 / 23 (0.00%)	1 / 25 (4.00%)
occurrences (all)	2	0	1
Nasopharyngitis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	3 / 25 (12.00%)
occurrences (all)	0	0	3
Oral Candidiasis			
subjects affected / exposed	0 / 25 (0.00%)	1 / 23 (4.35%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Peritonitis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	1 / 25 (4.00%)	1 / 23 (4.35%)	0 / 25 (0.00%)
occurrences (all)	1	1	0
Respiratory Tract Infection			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Urinary Tract Infection			
subjects affected / exposed	4 / 25 (16.00%)	2 / 23 (8.70%)	2 / 25 (8.00%)
occurrences (all)	4	2	2
Metabolism and nutrition disorders			
Decreased Appetite			
subjects affected / exposed	12 / 25 (48.00%)	18 / 23 (78.26%)	12 / 25 (48.00%)
occurrences (all)	12	18	12
Dehydration			
subjects affected / exposed	0 / 25 (0.00%)	4 / 23 (17.39%)	0 / 25 (0.00%)
occurrences (all)	0	4	0
Hyperglycaemia			
subjects affected / exposed	2 / 25 (8.00%)	2 / 23 (8.70%)	1 / 25 (4.00%)
occurrences (all)	2	2	1
Hyperkalaemia			

subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Hypoalbuminaemia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	6 / 25 (24.00%)	8 / 23 (34.78%)	3 / 25 (12.00%)
occurrences (all)	6	8	3
Hypomagnesaemia			
subjects affected / exposed	3 / 25 (12.00%)	5 / 23 (21.74%)	3 / 25 (12.00%)
occurrences (all)	3	5	3
Hyponatraemia			
subjects affected / exposed	4 / 25 (16.00%)	5 / 23 (21.74%)	2 / 25 (8.00%)
occurrences (all)	4	5	2
Hypophosphataemia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part2:CohortA-OvarianCarcinoma Sch.1:Selinexor upto 50mg/m2BIW	Part2:Cohort A-OvarianCarcinoma Sch.2:Selinexor upto 60mg/m2QW	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	21 / 21 (100.00%)	20 / 20 (100.00%)	
Vascular disorders			
Deep Vein Thrombosis			
subjects affected / exposed	3 / 21 (14.29%)	1 / 20 (5.00%)	
occurrences (all)	3	1	
Hot Flush			
subjects affected / exposed	3 / 21 (14.29%)	2 / 20 (10.00%)	
occurrences (all)	3	2	
Hypertension			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Hypotension			
subjects affected / exposed	3 / 21 (14.29%)	0 / 20 (0.00%)	
occurrences (all)	3	0	
General disorders and administration site conditions			

Asthenia			
subjects affected / exposed	6 / 21 (28.57%)	3 / 20 (15.00%)	
occurrences (all)	6	3	
Chills			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Face Oedema			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Fatigue			
subjects affected / exposed	14 / 21 (66.67%)	14 / 20 (70.00%)	
occurrences (all)	14	14	
General Physical Health Deterioration			
subjects affected / exposed	1 / 21 (4.76%)	1 / 20 (5.00%)	
occurrences (all)	1	1	
Malaise			
subjects affected / exposed	1 / 21 (4.76%)	2 / 20 (10.00%)	
occurrences (all)	1	2	
Oedema			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Oedema Peripheral			
subjects affected / exposed	6 / 21 (28.57%)	2 / 20 (10.00%)	
occurrences (all)	6	2	
Pyrexia			
subjects affected / exposed	3 / 21 (14.29%)	1 / 20 (5.00%)	
occurrences (all)	3	1	
Reproductive system and breast disorders			
Vaginal Haemorrhage			
subjects affected / exposed	1 / 21 (4.76%)	1 / 20 (5.00%)	
occurrences (all)	1	1	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	3 / 21 (14.29%)	5 / 20 (25.00%)	
occurrences (all)	3	5	
Dyspnoea			

subjects affected / exposed	7 / 21 (33.33%)	4 / 20 (20.00%)	
occurrences (all)	7	4	
Dyspnoea Exertional			
subjects affected / exposed	1 / 21 (4.76%)	1 / 20 (5.00%)	
occurrences (all)	1	1	
Hiccups			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Oropharyngeal Pain			
subjects affected / exposed	1 / 21 (4.76%)	1 / 20 (5.00%)	
occurrences (all)	1	1	
Pleural Effusion			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Pulmonary Embolism			
subjects affected / exposed	2 / 21 (9.52%)	1 / 20 (5.00%)	
occurrences (all)	2	1	
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Anxiety			
subjects affected / exposed	2 / 21 (9.52%)	0 / 20 (0.00%)	
occurrences (all)	2	0	
Confusional State			
subjects affected / exposed	2 / 21 (9.52%)	1 / 20 (5.00%)	
occurrences (all)	2	1	
Depression			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Hallucination			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Insomnia			
subjects affected / exposed	3 / 21 (14.29%)	0 / 20 (0.00%)	
occurrences (all)	3	0	

Product issues			
Device Occlusion			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Investigations			
Weight Decreased			
subjects affected / exposed	11 / 21 (52.38%)	6 / 20 (30.00%)	
occurrences (all)	11	6	
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Humerus Fracture			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Procedural Pain			
subjects affected / exposed	1 / 21 (4.76%)	1 / 20 (5.00%)	
occurrences (all)	1	1	
Nervous system disorders			
Aphasia			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Dizziness			
subjects affected / exposed	4 / 21 (19.05%)	2 / 20 (10.00%)	
occurrences (all)	4	2	
Dysgeusia			
subjects affected / exposed	4 / 21 (19.05%)	6 / 20 (30.00%)	
occurrences (all)	4	6	
Headache			
subjects affected / exposed	1 / 21 (4.76%)	4 / 20 (20.00%)	
occurrences (all)	1	4	
Paraesthesia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Peripheral Sensory Neuropathy			

subjects affected / exposed	0 / 21 (0.00%)	3 / 20 (15.00%)	
occurrences (all)	0	3	
Somnolence			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Syncope			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	9 / 21 (42.86%)	5 / 20 (25.00%)	
occurrences (all)	9	5	
Neutropenia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Pancytopenia			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Thrombocytopenia			
subjects affected / exposed	4 / 21 (19.05%)	1 / 20 (5.00%)	
occurrences (all)	4	1	
Ear and labyrinth disorders			
Auditory Disorder			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Ear Discomfort			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Vertigo			
subjects affected / exposed	1 / 21 (4.76%)	1 / 20 (5.00%)	
occurrences (all)	1	1	
Eye disorders			
Cataract			
subjects affected / exposed	2 / 21 (9.52%)	1 / 20 (5.00%)	
occurrences (all)	2	1	
Dry Eye			

subjects affected / exposed	1 / 21 (4.76%)	1 / 20 (5.00%)	
occurrences (all)	1	1	
Vision Blurred			
subjects affected / exposed	7 / 21 (33.33%)	5 / 20 (25.00%)	
occurrences (all)	7	5	
Visual Impairment			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal disorders			
Abdominal Discomfort			
subjects affected / exposed	2 / 21 (9.52%)	2 / 20 (10.00%)	
occurrences (all)	2	2	
Abdominal Distension			
subjects affected / exposed	2 / 21 (9.52%)	0 / 20 (0.00%)	
occurrences (all)	2	0	
Abdominal Pain			
subjects affected / exposed	5 / 21 (23.81%)	7 / 20 (35.00%)	
occurrences (all)	5	7	
Abdominal Pain Lower			
subjects affected / exposed	1 / 21 (4.76%)	1 / 20 (5.00%)	
occurrences (all)	1	1	
Abdominal Pain Upper			
subjects affected / exposed	3 / 21 (14.29%)	5 / 20 (25.00%)	
occurrences (all)	3	5	
Ascites			
subjects affected / exposed	1 / 21 (4.76%)	3 / 20 (15.00%)	
occurrences (all)	1	3	
Constipation			
subjects affected / exposed	11 / 21 (52.38%)	7 / 20 (35.00%)	
occurrences (all)	11	7	
Defaecation Urgency			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Diarrhoea			
subjects affected / exposed	10 / 21 (47.62%)	8 / 20 (40.00%)	
occurrences (all)	10	8	

Dry Mouth			
subjects affected / exposed	2 / 21 (9.52%)	1 / 20 (5.00%)	
occurrences (all)	2	1	
Dyspepsia			
subjects affected / exposed	0 / 21 (0.00%)	4 / 20 (20.00%)	
occurrences (all)	0	4	
Gastrooesophageal Reflux Disease			
subjects affected / exposed	1 / 21 (4.76%)	1 / 20 (5.00%)	
occurrences (all)	1	1	
Intestinal Obstruction			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Mouth Ulceration			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Nausea			
subjects affected / exposed	17 / 21 (80.95%)	15 / 20 (75.00%)	
occurrences (all)	17	15	
Oesophageal Irritation			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Oesophageal Pain			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Oral Mucosal Blistering			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Stomatitis			
subjects affected / exposed	3 / 21 (14.29%)	1 / 20 (5.00%)	
occurrences (all)	3	1	
Vomiting			
subjects affected / exposed	13 / 21 (61.90%)	12 / 20 (60.00%)	
occurrences (all)	13	12	
Skin and subcutaneous tissue disorders			
Alopecia			

subjects affected / exposed	0 / 21 (0.00%)	2 / 20 (10.00%)	
occurrences (all)	0	2	
Night Sweats			
subjects affected / exposed	2 / 21 (9.52%)	0 / 20 (0.00%)	
occurrences (all)	2	0	
Skin Fissures			
subjects affected / exposed	2 / 21 (9.52%)	0 / 20 (0.00%)	
occurrences (all)	2	0	
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Haematuria			
subjects affected / exposed	1 / 21 (4.76%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Hydronephrosis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Pollakiuria			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Polyurea			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	3 / 21 (14.29%)	0 / 20 (0.00%)	
occurrences (all)	3	0	
Back Pain			
subjects affected / exposed	1 / 21 (4.76%)	4 / 20 (20.00%)	
occurrences (all)	1	4	
Muscle Spasms			
subjects affected / exposed	2 / 21 (9.52%)	1 / 20 (5.00%)	
occurrences (all)	1	1	
Muscular Weakness			

subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Musculoskeletal Chest Pain			
subjects affected / exposed	1 / 21 (4.76%)	1 / 20 (5.00%)	
occurrences (all)	1	1	
Musculoskeletal Pain			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Osteoarthritis			
subjects affected / exposed	2 / 21 (9.52%)	0 / 20 (0.00%)	
occurrences (all)	2	0	
Pain In Extremity			
subjects affected / exposed	1 / 21 (4.76%)	1 / 20 (5.00%)	
occurrences (all)	1	1	
Infections and infestations			
Bronchitis			
subjects affected / exposed	2 / 21 (9.52%)	0 / 20 (0.00%)	
occurrences (all)	2	0	
Cystitis			
subjects affected / exposed	1 / 21 (4.76%)	1 / 20 (5.00%)	
occurrences (all)	1	1	
Device Related Infection			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Helicobacter Infection			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Herpes Simplex			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Infection			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Laryngitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	

Lung Infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Nasopharyngitis			
subjects affected / exposed	2 / 21 (9.52%)	0 / 20 (0.00%)	
occurrences (all)	2	0	
Oral Candidiasis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Peritonitis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Pneumonia			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Respiratory Tract Infection			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Urinary Tract Infection			
subjects affected / exposed	2 / 21 (9.52%)	2 / 20 (10.00%)	
occurrences (all)	2	2	
Metabolism and nutrition disorders			
Decreased Appetite			
subjects affected / exposed	16 / 21 (76.19%)	10 / 20 (50.00%)	
occurrences (all)	16	10	
Dehydration			
subjects affected / exposed	3 / 21 (14.29%)	1 / 20 (5.00%)	
occurrences (all)	3	1	
Hyperglycaemia			
subjects affected / exposed	1 / 21 (4.76%)	1 / 20 (5.00%)	
occurrences (all)	1	1	
Hyperkalaemia			
subjects affected / exposed	2 / 21 (9.52%)	0 / 20 (0.00%)	
occurrences (all)	2	0	
Hypoalbuminaemia			

subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Hypokalaemia			
subjects affected / exposed	5 / 21 (23.81%)	4 / 20 (20.00%)	
occurrences (all)	5	4	
Hypomagnesaemia			
subjects affected / exposed	1 / 21 (4.76%)	3 / 20 (15.00%)	
occurrences (all)	1	3	
Hyponatraemia			
subjects affected / exposed	2 / 21 (9.52%)	2 / 20 (10.00%)	
occurrences (all)	2	2	
Hypophosphataemia			
subjects affected / exposed	0 / 21 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
09 September 2014	1. Revised to specify that Carcinosarcomas were allowed. 2. Revised to specify that chemotherapy for relapsed or advanced (stage IIIc) disease was allowed for endometrium subjects. 3. Revised to define liver function and age at time of enrollment from >18 years to ≥18 years. 4. Revised to specify that subjects of childbearing potential must agree to use effective contraception during treatment and up to 3 months from last dose. 5. Expanded number of subjects in the ovarian cohort, to an additional 32 subjects. 6. Added overall survival to secondary objectives and removed it from exploratory objectives. 7. Removed male contraception text. 8. Revised PK sample collection to specify that samples for PK assessment will only be collected from subjects with impaired liver function. 9. Additional collection of CA-125 blood test for clinical chemistry for ovarian subjects only. 10. Removal of cell functionality biomarkers, pharmacodynamics. 11. Ophthalmological examination assessment was revised to specify that if a cataract is seen during the examination, the cataract will be graded according to the Lens Opacities Classification System (LOCS III). 12. Change in frequency of several assessments: They would be done at baseline and if clinically indicated. 13. Addition of optional PET scan at baseline. 14. Updated the electronic mail address to which the SAE forms would be sent to signsae@gso-hamburg.com. 15. Supportive care and prophylactic guidelines were updated based on recent Phase 1 clinical trial results and Investigator input. 16. Added Classification of Adverse Events by Causality. 17. The dose adjustment guidelines have been updated based on recent results of the Phase 1 clinical trials and new enrollment schedule added to this clinical trial. 18. Updated information related to the MTD to specify that escalating beyond 70 mg/m^2 BIW is prohibited in any study. 19. Added intra-subject dose escalation.

12 November 2014	1. Subjects with ovarian cancer must have had disease that was measurable according to RECIST or assessable according to the GCIG CA-125 criteria. 2. Receiving of a study drug within 3 weeks prior to Cycle 1 Day 1 was prohibited; however, participation in an anti-cancer study within 3 weeks prior to receiving study drug is acceptable. 3. Dosing schedule for Part 2 was revised. 4. CA-125 response definition was added. 5. Removed the acetaminophen restriction as ongoing clinical safety evaluations on the use of selinexor in combination with acetaminophen have not shown any significant clinical or laboratory abnormalities with doses of acetaminophen up to 1 gram and selinexor up to 55 mg/m^2 (approximately 80-100 mg). 6. Prophylactic and supportive care was revised. 7. Dose modification table was revised to include revised dose modification guidance for thrombocytopenia and nausea/emesis, and specified that guidance used for Grade 3 toxicities should also be used for toxicities that are Grade ≥ 3, table included specific guidance for Part 1 and Part 2 (Schedules 1 and 2). 8. Pre-specified dose/schedule modifications for adverse events (AEs) related to study drug for Part 2, Schedules 1 and 2 was revised. For both schedules, it is specified that upon the discontinuation of dosing, subjects would continue to be assessed. 9. Number of blood samples that will be collected for plasma proteins and PDn (whole blood RNA) for the convenience of subjects on the trial was revised. 10. Collection of blood for the assessment of CTCs as a direct correlation was made between the presence of CTC in the blood of subjects on this trial to their response was reactivated. 11. Collection of blood for PK assessments from the study as the already obtained PK data set from this and other Phase 1 and 2 studies is considered sufficient, and further evaluation of selinexor plasma analysis in this study is not required.
08 January 2016	1. Clarified the definitions of platinum refractory and platinum resistant in the inclusion criteria. 2. Clarified that dose escalation can occur if there is tolerability and no sign of progression after 12 weeks of treatment for patients in Parts 1 and 2. 3. Revised wording related to the number of subjects to specify that 21 and 32 evaluable patients are needed in Parts 1 and Part 2, respectively. 4. Consolidated and reformatted guidance for restricted and prohibited medications into one section. 5. Clarified that the overall survival objective will include overall survival rates at 12 and 24 months. 6. Clarified reasons for which the study could be discontinued. 7. Clarified primary and secondary parameters, including details of the efficacy evaluation. 8. Added total abstinence as a method of prevention of pregnancy. 9. Modified the definitions of the ITT population. 10. Added a provision to perform a primary analysis for submission in a CSR when patients are still on treatment, and subsequently perform a final analysis (to be reported in a final CSR) after all patients have completed treatment. 11. A table of GSH-, NAC-, and SAM-containing products was added as an appendix based on FDA feedback on a different protocol. 12. Clarified the timing of collection of AEs and SAEs. 13. Revised the window for assessments to be completed following 6 weeks of treatment for gynaecological cancers from ±5 days to ±7 days. 14. Added a baseline assessment for CA-125 to comply with CGIG CA-125 response criteria requirements. 15. The use of 20 mg tablets was added for increased tolerability based on the results of the ongoing Phase 1 studies. 16. Clarified that doses of selinexor must be at least 36 hours apart for twice weekly dosing and at least 5 days apart for once weekly dosing.
04 August 2016	1. Due to the termination of the Primary Treatment Phase of the study, a maintenance schedule had been added to allow the existing patients on the study to continue treatment with selinexor and/or survival follow-up. The revised Maintenance Phase included study treatment, schedule of assessments, supportive care, dose modification and data collection for separate Maintenance Phase database.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported