



## 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  |
| <b>Arm title</b>             | Part1: Cohort A-Ovarian Carcinoma: Selinexor upto 60 mg/m <sup>2</sup> 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<sup>2</sup>) 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<sup>2</sup> 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<sup>2</sup> 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<sup>2</sup> BIW and 60 mg/m<sup>2</sup> BIW. Treatment cycles were 4 weeks each i.e., 28 day cycle.

|                  |  |
|------------------|--|
| <b>Arm title</b> | Part1:CohortB-Endometrial Carcinoma:Selinexor upto 60mg/m <sup>2</sup> 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<sup>2</sup> 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<sup>2</sup> 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<sup>2</sup> 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<sup>2</sup> BIW and 60 mg/m<sup>2</sup> BIW. Treatment cycles were 4 weeks each i.e., 28 day cycle.

|                  |  |
|------------------|--|
| <b>Arm title</b> | Part1:CohortC-Cervical Carcinoma:Selinexor upto 60 mg/m <sup>2</sup> 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<sup>2</sup> 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<sup>2</sup> of selinexor oral tablets BIW were administered if the subjects had no major toxicity. During dose reduction, subjects received a minimum dose of 35 mg/m<sup>2</sup> 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<sup>2</sup> BIW and 60 mg/m<sup>2</sup> BIW. Treatment cycles were 4 weeks each i.e., 28 day cycle.

|                  |   |
|------------------|---|
| <b>Arm title</b> | Part2:CohortA-OvarianCarcinoma Sch.1:Selinexor upto 50mg/m <sup>2</sup> BIW |
|------------------|---|

**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<sup>2</sup> 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<sup>2</sup> of selinexor oral tablets BIW were administered if the subjects had no major toxicity. During dose reduction, subjects received a minimum dose of 35 mg/m<sup>2</sup> 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<sup>2</sup> BIW, 50 mg/m<sup>2</sup> BIW, and 35 mg/m<sup>2</sup> QW. Treatment cycles were 4 weeks each i.e., 28 day cycle.

|                  |   |
|------------------|---|
| <b>Arm title</b> | Part2:Cohort A-OvarianCarcinoma Sch.2:Selinexor upto 60mg/m <sup>2</sup> QW |
|------------------|---|

**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<sup>2</sup> 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<sup>2</sup> of selinexor oral tablets QW were administered if the subjects had no major toxicity. During dose reduction, subjects received a minimum dose of 35 mg/m<sup>2</sup> 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<sup>2</sup> QW, 60 mg/m<sup>2</sup> QW, and 35 mg/m<sup>2</sup> QW. Treatment cycles were 4 weeks each i.e., 28 day cycle.

| <b>Number of subjects in period 1</b>        | Part1: Cohort A-<br>Ovarian Carcinoma:<br>Selinexor upto 60<br>mg/m2 BIW | Part1:CohortB-<br>Endometrial<br>Carcinoma:Selinexor<br>upto 60mg/m2 BIW | Part1:CohortC-<br>Cervical<br>Carcinoma:Selinexor<br>upto 60 mg/m2 BIW |
|--|--|--|--|
| Started                                      | 25   | 23   | 25   |
| Modified Intent-to-<br>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  |

| <b>Number of subjects in period 1</b>        | Part2:CohortA-<br>OvarianCarcinoma<br>Sch.1:Selinexor<br>upto 50mg/m2BIW | Part2:Cohort A-<br>OvarianCarcinoma<br>Sch.2:Selinexor upto<br>60mg/m2QW |
|--|--|--|
| Started                                      | 21   | 20   |
| Modified Intent-to-<br>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/m <sup>2</sup> 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<sup>2</sup>) 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<sup>2</sup> 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<sup>2</sup> 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/m <sup>2</sup> 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<sup>2</sup> 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<sup>2</sup> 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<sup>2</sup> 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/m <sup>2</sup> 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<sup>2</sup> 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<sup>2</sup> 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<sup>2</sup> 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/m <sup>2</sup> BIW |
|-----------------------|---|

#### 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<sup>2</sup> 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<sup>2</sup> 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<sup>2</sup> 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/m <sup>2</sup> QW |
|-----------------------|---|

#### 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<sup>2</sup> 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<sup>2</sup> 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<sup>2</sup> 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-<br>Ovarian Carcinoma:<br>Selinexor upto 60<br>mg/m2 BIW | Part1:CohortB-<br>Endometrial<br>Carcinoma:Selinexor<br>upto 60mg/m2 BIW | Part1:CohortC-<br>Cervical<br>Carcinoma:Selinexor<br>upto 60 mg/m2 BIW |
|---------------------------------------|--|--|--|
| Number of subjects                    | 25   | 23   | 25   |
| Age categorical<br>Units: Subjects    |  |  |  |
| <=18 years                            | 0  | 0  | 0  |
| Between 18 and 65 years               | 17   | 6  | 20   |
| >=65 years                            | 8  | 17   | 5  |
| Gender categorical<br>Units: Subjects |  |  |  |
| Female                                | 25   | 23   | 25   |
| Male                                  | 0  | 0  | 0  |
| Ethnicity<br>Units: Subjects          |  |  |  |
| Hispanic or Latino                    | 0  | 0  | 0  |
| Not Hispanic or Latino                | 25   | 23   | 25   |
| Unknown or Not Reported               | 0  | 0  | 0  |
| Race<br>Units: Subjects               |  |  |  |
| White                                 | 25   | 23   | 24   |
| Other-unspecified                     | 0  | 0  | 1  |

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

#### 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<sup>2</sup> 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<sup>2</sup> 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<sup>2</sup> 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/m <sup>2</sup> QW |
|-----------------------|---|

#### 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<sup>2</sup> 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<sup>2</sup> 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<sup>2</sup> 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) <sup>[1]</sup> |
|-----------------|---|

### 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:<br>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:<br>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 <sup>[2]</sup> |
| End point description:<br>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 <sup>[3]</sup> |
|-----------------|---|

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

**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: Cohort B-Endometrial Carcinoma: Selinexor upto 60mg/m2 BIW | Part1: Cohort C-Cervical Carcinoma: Selinexor upto 60 mg/m2 BIW | Part2: Cohort A-Ovarian Carcinoma 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-Ovarian Carcinoma 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<br>function:EOT(n=2,11,4,7,6)            | -16.7 (±<br>11.79) | -0.8 (± 38.27) | 12.5 (± 14.43)     | -13.9 (±<br>23.07) |
| FS/Cognitive<br>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<br>function:EOT(n=2,11,4,7,6)            | -33.3 (±<br>23.57) | -6.1 (± 29.13) | 4.2 (± 20.97)      | -16.7 (±<br>38.49) |
| FS/Social<br>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 (±<br>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-<br>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 (±<br>23.57) | -9.1 (± 30.15) | -16.7 (±<br>33.33) | -19.0 (±<br>26.23) |
| SS/Appetite<br>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<br>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<br>difficulty:EOT(n=2,11,4,7,6)          | 16.7 (± 23.57)     | 3.0 (± 17.98)  | 0.0 (± 0.00)       | 4.8 (± 29.99)      |

|  |  |  |  |  |
|--|--|--|--|--|
| <b>End point values</b>                            | Part2:Cohort<br>A-<br>OvarianCarcino<br>ma<br>Sch.2:Selinexo<br>r 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 (±<br>15.52)   |  |  |  |
| FS/Physical<br>function:Baseline(n=21,21,22,21,20) | 70.7 (± 25.26)   |  |  |  |
| FS/Physical function:EOT(n=2,1,4,7,6)              | -18.9 (±<br>14.25)   |  |  |  |

|   |                 |  |  |  |
|---|-----------------|--|--|--|
| FS/Role<br>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<br>function:Baseline(n=21,21,22,21,20)   | 66.3 (± 23.33)  |  |  |  |
| FS/Emotional<br>function:EOT(n=2,11,4,7,6)            | -2.8 (± 17.21)  |  |  |  |
| FS/Cognitive<br>function:Baseline(n=21,21,22,21,20)   | 80.8 (± 23.12)  |  |  |  |
| FS/Cognitive<br>function:EOT(n=2,11,4,7,6)            | 0.0 (± 0.00)    |  |  |  |
| FS/Social<br>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-<br>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<br>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<br>difficulty:Baseline(n=21,21,22,21,20) | 5.0 (± 12.21)   |  |  |  |
| SS/Financial<br>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:<br>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/m <sup>2</sup> 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<sup>2</sup> 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<sup>2</sup> 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<sup>2</sup> 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/m <sup>2</sup> 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<sup>2</sup> 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<sup>2</sup> 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<sup>2</sup> 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/m <sup>2</sup> 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<sup>2</sup> 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<sup>2</sup> 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<sup>2</sup> 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/m <sup>2</sup> 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 35 mg/m<sup>2</sup> 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<sup>2</sup> 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<sup>2</sup> 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/m <sup>2</sup> QW |
|-----------------------|---|

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<sup>2</sup> 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<sup>2</sup> 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<sup>2</sup> 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.

| <b>Serious adverse events</b>                                       | Part1:Cohort A-<br>Ovarian<br>Carcinoma:Selinexor<br>up to 60 mg/m2 | Part1:CohortB-<br>Endometrial<br>Carcinoma:Selinexor<br>upto 60mg/m2 BIW | Part1:CohortC-<br>Cervical<br>Carcinoma:Selinexor<br>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          |
| <b>Hypokalaemia</b>                             |                |                |                |
| 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          |
| <b>Hyponatraemia</b>                            |                |                |                |
| 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          |

| <b>Serious adverse events</b>  | Part2:CohortA-OvarianCarcinoma<br>Sch.1:Selinexor<br>upto 50mg/m2BIW | Part2:Cohort A-OvarianCarcinoma<br>Sch.2:Selinexor upto<br>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  |  |
| <b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b> |  |  |  |
| <b>Intracranial Tumour Haemorrhage</b>                                     |  |  |  |
| 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  |  |
| <b>Vascular disorders</b>  |  |  |  |
| <b>Deep Vein Thrombosis</b>  |  |  |  |
| 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  |  |
| <b>Embolism</b>  |  |  |  |
| 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  |  |
| <b>Surgical and medical procedures</b>                                     |  |  |  |
| <b>Drain Placement</b>   |  |  |  |

|  |                |                 |  |
|--|----------------|-----------------|--|
| 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 %

| <b>Non-serious adverse events</b>                     | Part1:Cohort A-<br>Ovarian<br>Carcinoma:Selinexor<br>up to 60 mg/m2 | Part1:CohortB-<br>Endometrial<br>Carcinoma:Selinexor<br>upto 60mg/m2 BIW | Part1:CohortC-<br>Cervical<br>Carcinoma:Selinexor<br>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<br>occurrences (all)        | 2 / 25 (8.00%)<br>2 | 2 / 23 (8.70%)<br>2 | 0 / 25 (0.00%)<br>0 |
| General disorders and administration<br>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<br>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<br>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<br>occurrences (all)  | 1 / 25 (4.00%)<br>1    | 0 / 23 (0.00%)<br>0    | 2 / 25 (8.00%)<br>2    |
| Insomnia<br>subjects affected / exposed<br>occurrences (all)  | 7 / 25 (28.00%)<br>7   | 1 / 23 (4.35%)<br>1    | 5 / 25 (20.00%)<br>5   |
| Product issues<br>Device Occlusion<br>subjects affected / exposed<br>occurrences (all)                          | 2 / 25 (8.00%)<br>2    | 0 / 23 (0.00%)<br>0    | 2 / 25 (8.00%)<br>2    |
| Investigations<br>Weight Decreased<br>subjects affected / exposed<br>occurrences (all)                          | 12 / 25 (48.00%)<br>12 | 13 / 23 (56.52%)<br>13 | 18 / 25 (72.00%)<br>18 |
| Injury, poisoning and procedural complications<br>Contusion<br>subjects affected / exposed<br>occurrences (all) | 1 / 25 (4.00%)<br>1    | 0 / 23 (0.00%)<br>0    | 0 / 25 (0.00%)<br>0    |
| Humerus Fracture<br>subjects affected / exposed<br>occurrences (all)  | 0 / 25 (0.00%)<br>0    | 0 / 23 (0.00%)<br>0    | 0 / 25 (0.00%)<br>0    |
| Procedural Pain<br>subjects affected / exposed<br>occurrences (all)   | 0 / 25 (0.00%)<br>0    | 0 / 23 (0.00%)<br>0    | 0 / 25 (0.00%)<br>0    |
| Nervous system disorders<br>Aphasia<br>subjects affected / exposed<br>occurrences (all)                         | 0 / 25 (0.00%)<br>0    | 0 / 23 (0.00%)<br>0    | 0 / 25 (0.00%)<br>0    |
| Dizziness<br>subjects affected / exposed<br>occurrences (all)   | 7 / 25 (28.00%)<br>7   | 5 / 23 (21.74%)<br>5   | 6 / 25 (24.00%)<br>6   |
| Dysgeusia<br>subjects affected / exposed<br>occurrences (all)   | 7 / 25 (28.00%)<br>7   | 5 / 23 (21.74%)<br>5   | 11 / 25 (44.00%)<br>11 |
| Headache<br>subjects affected / exposed<br>occurrences (all)  | 3 / 25 (12.00%)<br>3   | 1 / 23 (4.35%)<br>1    | 3 / 25 (12.00%)<br>3   |

|   |                        |                        |                        |
|---|------------------------|------------------------|------------------------|
| Paraesthesia<br>subjects affected / exposed<br>occurrences (all)                  | 0 / 25 (0.00%)<br>0    | 2 / 23 (8.70%)<br>2    | 2 / 25 (8.00%)<br>2    |
| Peripheral Sensory Neuropathy<br>subjects affected / exposed<br>occurrences (all) | 1 / 25 (4.00%)<br>1    | 4 / 23 (17.39%)<br>4   | 3 / 25 (12.00%)<br>3   |
| Somnolence<br>subjects affected / exposed<br>occurrences (all)                    | 2 / 25 (8.00%)<br>2    | 0 / 23 (0.00%)<br>0    | 0 / 25 (0.00%)<br>0    |
| Syncope<br>subjects affected / exposed<br>occurrences (all)                       | 0 / 25 (0.00%)<br>0    | 2 / 23 (8.70%)<br>2    | 0 / 25 (0.00%)<br>0    |
| Blood and lymphatic system disorders  |                        |                        |                        |
| Anaemia<br>subjects affected / exposed<br>occurrences (all)                       | 13 / 25 (52.00%)<br>13 | 11 / 23 (47.83%)<br>11 | 14 / 25 (56.00%)<br>14 |
| Neutropenia<br>subjects affected / exposed<br>occurrences (all)                   | 2 / 25 (8.00%)<br>2    | 3 / 23 (13.04%)<br>3   | 0 / 25 (0.00%)<br>0    |
| Pancytopenia<br>subjects affected / exposed<br>occurrences (all)                  | 0 / 25 (0.00%)<br>0    | 0 / 23 (0.00%)<br>0    | 0 / 25 (0.00%)<br>0    |
| Thrombocytopenia<br>subjects affected / exposed<br>occurrences (all)              | 12 / 25 (48.00%)<br>12 | 10 / 23 (43.48%)<br>10 | 13 / 25 (52.00%)<br>13 |
| Ear and labyrinth disorders   |                        |                        |                        |
| Auditory Disorder<br>subjects affected / exposed<br>occurrences (all)             | 0 / 25 (0.00%)<br>0    | 2 / 23 (8.70%)<br>2    | 0 / 25 (0.00%)<br>0    |
| Ear Discomfort<br>subjects affected / exposed<br>occurrences (all)                | 0 / 25 (0.00%)<br>0    | 2 / 23 (8.70%)<br>2    | 1 / 25 (4.00%)<br>1    |
| Vertigo<br>subjects affected / exposed<br>occurrences (all)                       | 1 / 25 (4.00%)<br>1    | 1 / 23 (4.35%)<br>1    | 1 / 25 (4.00%)<br>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<br>occurrences (all) | 18 / 25 (72.00%)<br>18 | 14 / 23 (60.87%)<br>14 | 11 / 25 (44.00%)<br>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               |

| <b>Non-serious adverse events</b>                     | Part2:CohortA-OvarianCarcinoma<br>Sch.1:Selinexor<br>upto 50mg/m2BIW | Part2:Cohort A-OvarianCarcinoma<br>Sch.2:Selinexor upto<br>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<br>Device Occlusion<br>subjects affected / exposed<br>occurrences (all)   | 0 / 21 (0.00%)<br>0   | 0 / 20 (0.00%)<br>0  |  |
| Investigations<br>Weight Decreased<br>subjects affected / exposed<br>occurrences (all)   | 11 / 21 (52.38%)<br>11  | 6 / 20 (30.00%)<br>6   |  |
| Injury, poisoning and procedural complications<br>Contusion<br>subjects affected / exposed<br>occurrences (all)<br><br>Humerus Fracture<br>subjects affected / exposed<br>occurrences (all)<br><br>Procedural Pain<br>subjects affected / exposed<br>occurrences (all)   | 0 / 21 (0.00%)<br>0<br><br>0 / 21 (0.00%)<br>0<br><br>1 / 21 (4.76%)<br>1   | 1 / 20 (5.00%)<br>1<br><br>1 / 20 (5.00%)<br>1<br><br>1 / 20 (5.00%)<br>1  |  |
| Nervous system disorders<br>Aphasia<br>subjects affected / exposed<br>occurrences (all)<br><br>Dizziness<br>subjects affected / exposed<br>occurrences (all)<br><br>Dysgeusia<br>subjects affected / exposed<br>occurrences (all)<br><br>Headache<br>subjects affected / exposed<br>occurrences (all)<br><br>Paraesthesia<br>subjects affected / exposed<br>occurrences (all)<br><br>Peripheral Sensory Neuropathy | 0 / 21 (0.00%)<br>0<br><br>4 / 21 (19.05%)<br>4<br><br>4 / 21 (19.05%)<br>4<br><br>1 / 21 (4.76%)<br>1<br><br>0 / 21 (0.00%)<br>0 | 1 / 20 (5.00%)<br>1<br><br>2 / 20 (10.00%)<br>2<br><br>6 / 20 (30.00%)<br>6<br><br>4 / 20 (20.00%)<br>4<br><br>0 / 20 (0.00%)<br>0 |  |

|  |                      |                      |  |
|--|----------------------|----------------------|--|
| subjects affected / exposed<br>occurrences (all)   | 0 / 21 (0.00%)<br>0  | 3 / 20 (15.00%)<br>3 |  |
| Somnolence<br>subjects affected / exposed<br>occurrences (all)                                       | 0 / 21 (0.00%)<br>0  | 0 / 20 (0.00%)<br>0  |  |
| Syncope<br>subjects affected / exposed<br>occurrences (all)  | 0 / 21 (0.00%)<br>0  | 1 / 20 (5.00%)<br>1  |  |
| Blood and lymphatic system disorders<br>Anaemia<br>subjects affected / exposed<br>occurrences (all)  | 9 / 21 (42.86%)<br>9 | 5 / 20 (25.00%)<br>5 |  |
| Neutropenia<br>subjects affected / exposed<br>occurrences (all)                                      | 0 / 21 (0.00%)<br>0  | 0 / 20 (0.00%)<br>0  |  |
| Pancytopenia<br>subjects affected / exposed<br>occurrences (all)                                     | 0 / 21 (0.00%)<br>0  | 1 / 20 (5.00%)<br>1  |  |
| Thrombocytopenia<br>subjects affected / exposed<br>occurrences (all)                                 | 4 / 21 (19.05%)<br>4 | 1 / 20 (5.00%)<br>1  |  |
| Ear and labyrinth disorders<br>Auditory Disorder<br>subjects affected / exposed<br>occurrences (all) | 0 / 21 (0.00%)<br>0  | 0 / 20 (0.00%)<br>0  |  |
| Ear Discomfort<br>subjects affected / exposed<br>occurrences (all)                                   | 0 / 21 (0.00%)<br>0  | 0 / 20 (0.00%)<br>0  |  |
| Vertigo<br>subjects affected / exposed<br>occurrences (all)  | 1 / 21 (4.76%)<br>1  | 1 / 20 (5.00%)<br>1  |  |
| Eye disorders<br>Cataract<br>subjects affected / exposed<br>occurrences (all)                        | 2 / 21 (9.52%)<br>2  | 1 / 20 (5.00%)<br>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<br>occurrences (all)  | 0 / 21 (0.00%)<br>0  | 2 / 20 (10.00%)<br>2 |  |
| Night Sweats<br>subjects affected / exposed<br>occurrences (all)  | 2 / 21 (9.52%)<br>2  | 0 / 20 (0.00%)<br>0  |  |
| Skin Fissures<br>subjects affected / exposed<br>occurrences (all)   | 2 / 21 (9.52%)<br>2  | 0 / 20 (0.00%)<br>0  |  |
| Renal and urinary disorders<br>Dysuria<br>subjects affected / exposed<br>occurrences (all)                        | 0 / 21 (0.00%)<br>0  | 0 / 20 (0.00%)<br>0  |  |
| Haematuria<br>subjects affected / exposed<br>occurrences (all)  | 1 / 21 (4.76%)<br>1  | 0 / 20 (0.00%)<br>0  |  |
| Hydronephrosis<br>subjects affected / exposed<br>occurrences (all)  | 0 / 21 (0.00%)<br>0  | 0 / 20 (0.00%)<br>0  |  |
| Pollakiuria<br>subjects affected / exposed<br>occurrences (all)   | 0 / 21 (0.00%)<br>0  | 1 / 20 (5.00%)<br>1  |  |
| Polyurea<br>subjects affected / exposed<br>occurrences (all)  | 0 / 21 (0.00%)<br>0  | 1 / 20 (5.00%)<br>1  |  |
| Musculoskeletal and connective tissue disorders<br>Arthralgia<br>subjects affected / exposed<br>occurrences (all) | 3 / 21 (14.29%)<br>3 | 0 / 20 (0.00%)<br>0  |  |
| Back Pain<br>subjects affected / exposed<br>occurrences (all)   | 1 / 21 (4.76%)<br>1  | 4 / 20 (20.00%)<br>4 |  |
| Muscle Spasms<br>subjects affected / exposed<br>occurrences (all)   | 2 / 21 (9.52%)<br>1  | 1 / 20 (5.00%)<br>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 | <ol style="list-style-type: none"><li>1. Revised to specify that Carcinosarcomas were allowed.</li><li>2. Revised to specify that chemotherapy for relapsed or advanced (stage IIIC) disease was allowed for endometrium subjects.</li><li>3. Revised to define liver function and age at time of enrollment from &gt;18 years to ≥18 years.</li><li>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.</li><li>5. Expanded number of subjects in the ovarian cohort, to an additional 32 subjects.</li><li>6. Added overall survival to secondary objectives and removed it from exploratory objectives.</li><li>7. Removed male contraception text.</li><li>8. Revised PK sample collection to specify that samples for PK assessment will only be collected from subjects with impaired liver function.</li><li>9. Additional collection of CA-125 blood test for clinical chemistry for ovarian subjects only.</li><li>10. Removal of cell functionality biomarkers, pharmacodynamics.</li><li>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).</li><li>12. Change in frequency of several assessments: They would be done at baseline and if clinically indicated.</li><li>13. Addition of optional PET scan at baseline.</li><li>14. Updated the electronic mail address to which the SAE forms would be sent to signsae@gso-hamburg.com.</li><li>15. Supportive care and prophylactic guidelines were updated based on recent Phase 1 clinical trial results and Investigator input.</li><li>16. Added Classification of Adverse Events by Causality.</li><li>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.</li><li>18. Updated information related to the MTD to specify that escalating beyond 70 mg/m<sup>2</sup> BIW is prohibited in any study.</li><li>19. Added intra-subject dose escalation.</li></ol> |

|                  |  |
|------------------|--|
| 12 November 2014 | <ol style="list-style-type: none"> <li>1. Subjects with ovarian cancer must have had disease that was measurable according to RECIST or assessable according to the GCIG CA-125 criteria.</li> <li>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.</li> <li>3. Dosing schedule for Part 2 was revised.</li> <li>4. CA-125 response definition was added.</li> <li>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<sup>2</sup> (approximately 80-100 mg).</li> <li>6. Prophylactic and supportive care was revised.</li> <li>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 <math>\geq</math> 3, table included specific guidance for Part 1 and Part 2 (Schedules 1 and 2).</li> <li>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.</li> <li>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.</li> <li>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.</li> <li>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.</li> </ol> |
| 08 January 2016  | <ol style="list-style-type: none"> <li>1. Clarified the definitions of platinum refractory and platinum resistant in the inclusion criteria.</li> <li>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.</li> <li>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.</li> <li>4. Consolidated and reformatted guidance for restricted and prohibited medications into one section.</li> <li>5. Clarified that the overall survival objective will include overall survival rates at 12 and 24 months.</li> <li>6. Clarified reasons for which the study could be discontinued.</li> <li>7. Clarified primary and secondary parameters, including details of the efficacy evaluation.</li> <li>8. Added total abstinence as a method of prevention of pregnancy.</li> <li>9. Modified the definitions of the ITT population.</li> <li>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.</li> <li>11. A table of GSH-, NAC-, and SAM-containing products was added as an appendix based on FDA feedback on a different protocol.</li> <li>12. Clarified the timing of collection of AEs and SAEs.</li> <li>13. Revised the window for assessments to be completed following 6 weeks of treatment for gynaecological cancers from <math>\pm</math>5 days to <math>\pm</math>7 days.</li> <li>14. Added a baseline assessment for CA-125 to comply with CGIG CA-125 response criteria requirements.</li> <li>15. The use of 20 mg tablets was added for increased tolerability based on the results of the ongoing Phase 1 studies.</li> <li>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.</li> </ol>  |
| 04 August 2016   | <ol style="list-style-type: none"> <li>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.</li> </ol>  |

---

Notes:

---

### **Interruptions (globally)**

Were there any global interruptions to the trial? No

### **Limitations and caveats**

None reported