



## Clinical trial results:

### A Phase Ib/II Study Evaluating the Safety and Efficacy of Atezolizumab in Combination with Obinutuzumab plus Lenalidomide in Patients with Relapsed or Refractory Follicular Lymphoma.

#### Summary

|                          |                 |
|--------------------------|-----------------|
| EudraCT number           | 2015-002467-42  |
| Trial protocol           | FR              |
| Global end of trial date | 07 October 2020 |

#### Results information

|                                |                   |
|--------------------------------|-------------------|
| Result version number          | v2 (current)      |
| This version publication date  | 30 September 2021 |
| First version publication date | 31 October 2019   |
| Version creation reason        |                   |

#### Trial information

##### Trial identification

|                       |         |
|-----------------------|---------|
| Sponsor protocol code | BO29562 |
|-----------------------|---------|

##### Additional study identifiers

|                                    |             |
|------------------------------------|-------------|
| ISRCTN number                      | -           |
| ClinicalTrials.gov id (NCT number) | NCT02631577 |
| WHO universal trial number (UTN)   | -           |

Notes:

#### Sponsors

|                              |                                                                                                    |
|------------------------------|----------------------------------------------------------------------------------------------------|
| Sponsor organisation name    | F. Hoffmann-La Roche AG                                                                            |
| Sponsor organisation address | Grenzacherstrasse 124., Basel, Switzerland, CH-4070                                                |
| Public contact               | F. Hoffmann-La Roche AG, F. Hoffmann-La Roche AG, 41 616878333, global.trial_information@roche.com |
| Scientific contact           | F. Hoffmann-La Roche AG, F. Hoffmann-La Roche AG, 41 616878333, global.trial_information@roche.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                       | 07 October 2020 |
| Is this the analysis of the primary completion data? | No              |
| Global end of trial reached?                         | Yes             |
| Global end of trial date                             | 07 October 2020 |
| Was the trial ended prematurely?                     | No              |

Notes:

## General information about the trial

Main objective of the trial:

The main objective of this study was to evaluate the safety, efficacy, pharmacokinetics (PK), and immunogenicity of induction treatment consisting of atezolizumab (Atezo) in combination with obinutuzumab (G) plus lenalidomide (Len; Atezo-G-Len) in subjects with relapsed or refractory follicular lymphoma (r/r FL), followed by maintenance treatment with Atezo-G-Len in subjects who achieved a complete response (CR), a partial response (PR), or stable disease at end of induction (EOI).

Protection of trial subjects:

All study subjects were required to read and sign an Informed Consent Form.

Background therapy: -

Evidence for comparator: -

|                                                           |                 |
|-----------------------------------------------------------|-----------------|
| Actual start date of recruitment                          | 11 January 2016 |
| 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 | France: 24        |
| Country: Number of subjects enrolled | United States: 14 |
| Worldwide total number of subjects   | 38                |
| EEA total number of subjects         | 24                |

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)                      | 25 |
| From 65 to 84 years                       | 13 |
| 85 years and over                         | 0  |

## Subject disposition

### Recruitment

Recruitment details:

The study was conducted at 14 sites in France (9) and USA (5).

### Pre-assignment

Screening details:

All subjects received daily low-dose aspirin (81-100 mg) during lenalidomide treatment and until 28 days after the last dose of lenalidomide. Subjects who are unable to tolerate aspirin, who have a history of thromboembolism (TE), and who are at high risk of TE, received warfarin or low-molecular-weight heparin (LMWH).

### Period 1

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

### Arms

|                              |                          |
|------------------------------|--------------------------|
| Are arms mutually exclusive? | Yes                      |
| <b>Arm title</b>             | Atezolizumab-G-lena 15mg |

Arm description:

Subjects were administered obinutuzumab, atezolizumab, and 15 mg of lenalidomide

|                                        |                                       |
|----------------------------------------|---------------------------------------|
| Arm type                               | Experimental                          |
| Investigational medicinal product name | Obinutuzumab                          |
| Investigational medicinal product code |                                       |
| Other name                             | Gazyvaro                              |
| Pharmaceutical forms                   | Concentrate for solution for infusion |
| Routes of administration               | Intravenous use                       |

Dosage and administration details:

Subjects were administered obinutuzumab by IV infusion at an absolute (flat) dose of 1000 mg on Days 1, 8, and 15 of the first cycle and on Day 1 of each subsequent cycle during induction treatment, and on Day 1 of every other month (i.e., every 2 months) during maintenance treatment.

|                                        |                       |
|----------------------------------------|-----------------------|
| Investigational medicinal product name | Atezolizumab          |
| Investigational medicinal product code |                       |
| Other name                             | Tecentriq             |
| Pharmaceutical forms                   | Solution for infusion |
| Routes of administration               | Intravenous use       |

Dosage and administration details:

Subjects were administered at a flat dose of atezolizumab consisting of one of the following:  
a) 840 mg every 2 weeks (Q2W) (840 mg on Days 1 and 15 of Cycles 26, given in 28-day cycles as induction treatment) and b) 1680 mg every 4 weeks (Q4W) (840 mg on Days 1 and 2 of each month, given as maintenance treatment).

|                                        |               |
|----------------------------------------|---------------|
| Investigational medicinal product name | Lenalidomid   |
| Investigational medicinal product code |               |
| Other name                             | Revlimid      |
| Pharmaceutical forms                   | Capsule, hard |
| Routes of administration               | Oral use      |

Dosage and administration details:

Subjects were administered lenalidomide orally once daily on Days 1-21 of Cycles 1-6 (28-day cycles) during induction treatment and on Days 1-21 of each month during maintenance treatment. During the dose-escalation phase, lenalidomide was administered at a dose of 15 or 20 mg during induction treatment and at 10 mg during maintenance treatment. During the expansion phase, lenalidomide was administered at the recommended phase 2 dose (RP2D) during induction treatment and at 10 mg during

maintenance treatment.

|                  |                          |
|------------------|--------------------------|
| <b>Arm title</b> | Atezolizumab-G-lena 20mg |
|------------------|--------------------------|

Arm description:

Subjects were administered obinutuzumab, atezolizumab, and 20 mg of lenalidomide.

|                                        |                                       |
|----------------------------------------|---------------------------------------|
| Arm type                               | Experimental                          |
| Investigational medicinal product name | Obinutuzumab                          |
| Investigational medicinal product code |                                       |
| Other name                             | Gazyvaro                              |
| Pharmaceutical forms                   | Concentrate for solution for infusion |
| Routes of administration               | Intravenous use                       |

Dosage and administration details:

Subjects were administered obinutuzumab by IV infusion at an absolute (flat) dose of 1000 mg on Days 1, 8, and 15 of the first cycle and on Day 1 of each subsequent cycle during induction treatment, and on Day 1 of every other month (i.e., every 2 months) during maintenance treatment.

|                                        |                       |
|----------------------------------------|-----------------------|
| Investigational medicinal product name | Atezolizumab          |
| Investigational medicinal product code |                       |
| Other name                             | Tecentriq             |
| Pharmaceutical forms                   | Solution for infusion |
| Routes of administration               | Intravenous use       |

Dosage and administration details:

Subjects were administered at a flat dose of atezolizumab consisting of one of the following:  
a) 840 mg Q2W (840 mg on Days 1 and 15 of Cycles 26, given in 28-day cycles as induction treatment) and b) 1680 mg Q4W (840 mg on Days 1 and 2 of each month, given as maintenance treatment).

|                                        |               |
|----------------------------------------|---------------|
| Investigational medicinal product name | Lenalidomid   |
| Investigational medicinal product code |               |
| Other name                             | Revlimid      |
| Pharmaceutical forms                   | Capsule, hard |
| Routes of administration               | Oral use      |

Dosage and administration details:

Subjects were administered lenalidomide orally once daily on Days 1-21 of Cycles 1-6 (28-day cycles) during induction treatment and on Days 1-21 of each month during maintenance treatment. During the dose-escalation phase, lenalidomide was administered at a dose of 15 or 20 mg during induction treatment and at 10 mg during maintenance treatment. During the expansion phase, lenalidomide was administered at the recommended phase 2 dose (RP2D) during induction treatment and at 10 mg during maintenance treatment.

| <b>Number of subjects in period 1</b> | Atezolizumab-G-lena 15mg | Atezolizumab-G-lena 20mg |
|---------------------------------------|--------------------------|--------------------------|
| Started                               | 4                        | 34                       |
| Completed                             | 3                        | 24                       |
| Not completed                         | 1                        | 10                       |
| Consent withdrawn by subject          | -                        | 3                        |
| Death                                 | 1                        | 7                        |



## Baseline characteristics

### Reporting groups

|                                                                                   |                          |
|-----------------------------------------------------------------------------------|--------------------------|
| Reporting group title                                                             | Atezolizumab-G-lena 15mg |
| Reporting group description:                                                      |                          |
| Subjects were administered obinutuzumab, atezolizumab, and 15 mg of lenalidomide  |                          |
| Reporting group title                                                             | Atezolizumab-G-lena 20mg |
| Reporting group description:                                                      |                          |
| Subjects were administered obinutuzumab, atezolizumab, and 20 mg of lenalidomide. |                          |

| Reporting group values                                | Atezolizumab-G-lena<br>15mg | Atezolizumab-G-lena<br>20mg | Total |
|-------------------------------------------------------|-----------------------------|-----------------------------|-------|
| Number of subjects                                    | 4                           | 34                          | 38    |
| Age categorical<br>Units: Subjects                    |                             |                             |       |
| In utero                                              | 0                           | 0                           | 0     |
| Preterm newborn infants<br>(gestational age < 37 wks) | 0                           | 0                           | 0     |
| Newborns (0-27 days)                                  | 0                           | 0                           | 0     |
| Infants and toddlers (28 days-23<br>months)           | 0                           | 0                           | 0     |
| Children (2-11 years)                                 | 0                           | 0                           | 0     |
| Adolescents (12-17 years)                             | 0                           | 0                           | 0     |
| Adults (18-64 years)                                  | 3                           | 22                          | 25    |
| From 65-84 years                                      | 1                           | 12                          | 13    |
| 85 years and over                                     | 0                           | 0                           | 0     |
| Age Continuous<br>Units: Years                        |                             |                             |       |
| arithmetic mean                                       | 56.5                        | 60.4                        |       |
| standard deviation                                    | ± 9.1                       | ± 9.7                       | -     |
| Sex: Female, Male<br>Units: Subjects                  |                             |                             |       |
| Female                                                | 1                           | 18                          | 19    |
| Male                                                  | 3                           | 16                          | 19    |
| Race/Ethnicity, Customized<br>Units: Subjects         |                             |                             |       |
| Hispanic or Latino                                    | 1                           | 0                           | 1     |
| Not Hispanic or Latino                                | 3                           | 13                          | 16    |
| Not Stated                                            | 0                           | 21                          | 21    |
| Race/Ethnicity, Customized<br>Units: Subjects         |                             |                             |       |
| Unknown                                               | 0                           | 20                          | 20    |
| White                                                 | 4                           | 14                          | 18    |

## End points

### End points reporting groups

|                                                                                                                                                                                                                                                                    |                                  |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|
| Reporting group title                                                                                                                                                                                                                                              | Atezolizumab-G-lena 15mg         |
| Reporting group description:<br>Subjects were administered obinutuzumab, atezolizumab, and 15 mg of lenalidomide                                                                                                                                                   |                                  |
| Reporting group title                                                                                                                                                                                                                                              | Atezolizumab-G-lena 20mg         |
| Reporting group description:<br>Subjects were administered obinutuzumab, atezolizumab, and 20 mg of lenalidomide.                                                                                                                                                  |                                  |
| Subject analysis set title                                                                                                                                                                                                                                         | Intent-to-treat (ITT) population |
| Subject analysis set type                                                                                                                                                                                                                                          | Intention-to-treat               |
| Subject analysis set description:<br>The intent-to-treat (ITT) population included all subjects enrolled in the study.                                                                                                                                             |                                  |
| Subject analysis set title                                                                                                                                                                                                                                         | Safety Evaluable Population      |
| Subject analysis set type                                                                                                                                                                                                                                          | Safety analysis                  |
| Subject analysis set description:<br>The Safety Evaluable Population that included subjects who received at least one dose of any study treatment.                                                                                                                 |                                  |
| Subject analysis set title                                                                                                                                                                                                                                         | Efficacy Evaluable Population    |
| Subject analysis set type                                                                                                                                                                                                                                          | Sub-group analysis               |
| Subject analysis set description:<br>The Efficacy Evaluable population that included subjects who received at least one dose of each component of the combination. Only subjects who received lenalidomide induction at the RP2D were included in this population. |                                  |

### Primary: Percentage of Subjects Achieving Complete Response (CR) at End of Induction (EOI), as Determined by the Independent Review Committee (IRC) Using Modified Lugano 2014 Criteria

|                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                               |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title                                                                                                                                                                                                                                                                                                                                                                               | Percentage of Subjects Achieving Complete Response (CR) at End of Induction (EOI), as Determined by the Independent Review Committee (IRC) Using Modified Lugano 2014 Criteria <sup>[1]</sup> |
| End point description:<br>Complete response (CR) was evaluated through use of PET-CT scans alone, using the Modified Lugano 2014 criteria. Response was determined by the IRC. The Efficacy Evaluable population included all subjects who received at least one dose of each of the three study drugs and who received lenalidomide induction at the 20 mg recommended Phase II dose (RP2D). |                                                                                                                                                                                               |
| End point type                                                                                                                                                                                                                                                                                                                                                                                | Primary                                                                                                                                                                                       |
| End point timeframe:<br>6 months (up to clinical cut-off date (CCOD) of 23 October 2018)                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                               |

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: Only descriptive statistics was planned to be reported in the endpoint.

| End point values                               | Efficacy Evaluable Population |  |  |  |
|------------------------------------------------|-------------------------------|--|--|--|
| Subject group type                             | Subject analysis set          |  |  |  |
| Number of subjects analysed                    | 32                            |  |  |  |
| Units: Percentage                              |                               |  |  |  |
| number (confidence interval 90%)               |                               |  |  |  |
| Positron emission-computed tomography (PET-CT) | 71.9 (56.06 to 84.47)         |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Subjects Achieving CR at EOI, as Determined by the Investigator Using Modified Lugano 2014 Criteria

|                 |                                                                                                                   |
|-----------------|-------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Achieving CR at EOI, as Determined by the Investigator Using Modified Lugano 2014 Criteria |
|-----------------|-------------------------------------------------------------------------------------------------------------------|

End point description:

CR was evaluated through use of PET-CT scans, using the Modified Lugano 2014 criteria. Response was determined by the Investigator. The Efficacy Evaluable population included all subjects who received at least one dose of each of the three study drugs and who received lenalidomide induction at the 20 mg RP2D.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

6 months (up to CCOD of 23 October 2018)

| End point values                 | Efficacy Evaluable Population |  |  |  |
|----------------------------------|-------------------------------|--|--|--|
| Subject group type               | Subject analysis set          |  |  |  |
| Number of subjects analysed      | 32                            |  |  |  |
| Units: Percentage                |                               |  |  |  |
| number (confidence interval 90%) |                               |  |  |  |
| Based on PET-CT                  | 75 (59.39 to 86.91)           |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Subjects Achieving CR at EOI, as Determined by the IRC and Investigator Using Lugano 2014 Criteria

|                 |                                                                                                                  |
|-----------------|------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Achieving CR at EOI, as Determined by the IRC and Investigator Using Lugano 2014 Criteria |
|-----------------|------------------------------------------------------------------------------------------------------------------|

End point description:

CR was evaluated through use of CT scans, using the Lugano 2014 criteria. Response was determined by the IRC and by the Investigator. The Efficacy Evaluable population included all subjects who received at least one dose of each of the three study drugs and who received lenalidomide induction at the 20 mg RP2D.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

6 months (up to CCOD of 23 October 2018)

| End point values                          | Efficacy<br>Evaluable<br>Population |  |  |  |
|-------------------------------------------|-------------------------------------|--|--|--|
| Subject group type                        | Subject analysis set                |  |  |  |
| Number of subjects analysed               | 32                                  |  |  |  |
| Units: Percentage                         |                                     |  |  |  |
| number (confidence interval 90%)          |                                     |  |  |  |
| Determined by the IRC with CT or MRI      | 31.3 (18.04 to 47.21)               |  |  |  |
| Determined by Investigator with CT or MRI | 50 (34.41 to 65.59)                 |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Subjects With Objective Response (CR or PR) at EOI

|                 |                                                                  |
|-----------------|------------------------------------------------------------------|
| End point title | Percentage of Subjects With Objective Response (CR or PR) at EOI |
|-----------------|------------------------------------------------------------------|

End point description:

Objective response was evaluated through use of PET-CT scans or CT scans alone, using the Lugano 2014 or modified Lugano 2014 criteria. Response was determined by the IRC and by the Investigator. The Efficacy Evaluable population included all subjects who received at least one dose of each of the three study drugs and who received lenalidomide induction at the 20 mg RP2D.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

6 months (up to CCOD of 23 October 2018)

| End point values                                 | Efficacy<br>Evaluable<br>Population |  |  |  |
|--------------------------------------------------|-------------------------------------|--|--|--|
| Subject group type                               | Subject analysis set                |  |  |  |
| Number of subjects analysed                      | 32                                  |  |  |  |
| Units: Percentage                                |                                     |  |  |  |
| number (confidence interval 90%)                 |                                     |  |  |  |
| Determined by IRC, based on Lugano 2014 - PET    | 81.3 (66.31 to 91.50)               |  |  |  |
| Determined by Inv., based on Lugano 2014 - PET   | 84.4 (69.92 to 93.63)               |  |  |  |
| Determined by IRC, based on Lugano 2014 - CT     | 81.3 (66.31 to 91.50)               |  |  |  |
| Determined by Inv., based on Lugano 2014 - CT    | 87.5 (73.64 to 95.62)               |  |  |  |
| Determined by IRC, Modified Lugano 2014 - PET-CT | 78.1 (62.81 to 89.26)               |  |  |  |
| Determined by Inv, Modified Lugano 2014 - PET-CT | 84.4 (69.92 to 93.63)               |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Participants With Best Response (CR or PR) During the Study as Determined by the Investigator on the Basis of CT Scans Alone

|                 |                                                                                                                                            |
|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Participants With Best Response (CR or PR) During the Study as Determined by the Investigator on the Basis of CT Scans Alone |
|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

Best Response was evaluated through use of CT scans alone, using the Lugano 2014. Response was determined by the Investigator. The Efficacy Evaluable population included all subjects who received at least one dose of each of the three study drugs and who received lenalidomide induction at the 20 mg RP2D.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline up to approximately 59 months

| End point values                 | Efficacy Evaluable Population |  |  |  |
|----------------------------------|-------------------------------|--|--|--|
| Subject group type               | Subject analysis set          |  |  |  |
| Number of subjects analysed      | 32                            |  |  |  |
| Units: Percentage                |                               |  |  |  |
| number (confidence interval 90%) |                               |  |  |  |
| Best Response (CR,PR)            | 87.5 (73.64 to 95.62)         |  |  |  |
| CR                               | 68.8 (52.79 to 81.96)         |  |  |  |
| PR                               | 18.8 (8.50 to 33.69)          |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Participants With Adverse Events and Serious Adverse Events

|                 |                                                                           |
|-----------------|---------------------------------------------------------------------------|
| End point title | Percentage of Participants With Adverse Events and Serious Adverse Events |
|-----------------|---------------------------------------------------------------------------|

End point description:

An adverse event is any untoward medical occurrence in a participant administered a pharmaceutical product and which does not necessarily have to have a causal relationship with the treatment. An adverse event can therefore be any unfavorable and unintended sign (including an abnormal laboratory

finding, for example), symptom, or disease temporally associated with the use of a pharmaceutical product, whether or not considered related to the pharmaceutical product. Preexisting conditions which worsen during a study are also considered as adverse events. The Safety Evaluable Population included participants who received at least one dose of any study treatment.

|                                        |           |
|----------------------------------------|-----------|
| End point type                         | Secondary |
| End point timeframe:                   |           |
| Baseline up to approximately 59 months |           |

| End point values            | Atezolizumab-G-lena 15mg | Atezolizumab-G-lena 20mg |  |  |
|-----------------------------|--------------------------|--------------------------|--|--|
| Subject group type          | Reporting group          | Reporting group          |  |  |
| Number of subjects analysed | 4                        | 34                       |  |  |
| Units: Participants         |                          |                          |  |  |
| number (not applicable)     |                          |                          |  |  |
| Adverse Events              | 4                        | 34                       |  |  |
| Serious Adverse Events      | 2                        | 16                       |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with dose-limiting toxicities (DLTs) during cycle 2 of study treatment

|                 |                                                                                           |
|-----------------|-------------------------------------------------------------------------------------------|
| End point title | Number of subjects with dose-limiting toxicities (DLTs) during cycle 2 of study treatment |
|-----------------|-------------------------------------------------------------------------------------------|

End point description:

Does limiting toxicity (DLT) is defined as any one of the following events occurring during Cycle 2 of treatment and assessed by the investigator as related to study treatment: - Adverse event of any grade that leads to a delay of more than 14 days at the start of the next treatment cycle; - Hematologic adverse events (neutropenia, thrombocytopenia); - Non-hematologic adverse event, except IRRs, diarrhea, nausea or vomiting. The Safety Evaluable Population included subjects who received at least one dose of any study treatment.

|                                |           |
|--------------------------------|-----------|
| End point type                 | Secondary |
| End point timeframe:           |           |
| Day 1 - Day 28 of second cycle |           |

| End point values            | Atezolizumab-G-lena 15mg | Atezolizumab-G-lena 20mg |  |  |
|-----------------------------|--------------------------|--------------------------|--|--|
| Subject group type          | Reporting group          | Reporting group          |  |  |
| Number of subjects analysed | 4                        | 34                       |  |  |
| Units: Subjects             | 0                        | 0                        |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Serum concentration of obinutuzumab (mcg/mL)

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                              |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|
| End point title                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Serum concentration of obinutuzumab (mcg/mL) |
| End point description:<br>The following abbreviations apply in the table: Ind C = Induction Cycle; D = Day; Maint M = Maintenance Month; TRTC = Study Drug Completion or Early Discontinuation; PK FU = Pharmacokinetics and Immunogenicity Follow-up; YR = Year. The Safety Evaluable Population included participants who received at least one dose of any study treatment. 9999999 = the standard deviation couldn't be calculated from the data of 1 participant. |                                              |
| End point type                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Secondary                                    |
| End point timeframe:<br>Baseline up to approximately 59 months                                                                                                                                                                                                                                                                                                                                                                                                         |                                              |

| End point values                      | Atezolizumab-G-lena 15mg | Atezolizumab-G-lena 20mg |  |  |
|---------------------------------------|--------------------------|--------------------------|--|--|
| Subject group type                    | Reporting group          | Reporting group          |  |  |
| Number of subjects analysed           | 4                        | 34                       |  |  |
| Units: mcg/mL                         |                          |                          |  |  |
| arithmetic mean (standard deviation)  |                          |                          |  |  |
| Ind C1 D1 - Predose (n=0,2)           | 0 (± 0)                  | 0.634 (± 0.857)          |  |  |
| Ind C1 D1 - 30 min. Postdose (n=4,30) | 364 (± 45.9)             | 375 (± 163)              |  |  |
| Ind C2 D1 - Predose (n=4,32)          | 288 (± 84.2)             | 392 (± 164)              |  |  |
| Ind C2 D1 - Postdose (n=4,31)         | 606 (± 62.4)             | 753 (± 225)              |  |  |
| Ind C4 D1 - Predose (n=3,25)          | 175 (± 38.5)             | 301 (± 150)              |  |  |
| Ind C4 D1 - Postdose (n=3,23)         | 509 (± 47.0)             | 657 (± 198)              |  |  |
| Ind C6 D1 - Predose (n=3,20)          | 230 (± 12.3)             | 272 (± 106)              |  |  |
| Ind C6 D1 - Postdose (n=3,20)         | 503 (± 25.5)             | 652 (± 177)              |  |  |
| Maint M1 - Predose (n=3,20)           | 114 (± 16.7)             | 201 (± 104)              |  |  |
| Maint M7 - Predose (n=2,17)           | 66.1 (± 20.4)            | 112 (± 52.1)             |  |  |
| Maint M13 - Predose (n=1,18)          | 77.9 (± 9999999)         | 104 (± 62.9)             |  |  |
| Maint M19 - Predose (n=2,12)          | 94.0 (± 24.0)            | 111 (± 49.8)             |  |  |
| TRTC (n=0,12)                         | 0 (± 0)                  | 148 (± 103)              |  |  |
| OD120FU (n=1,10)                      | 23.3 (± 9999999)         | 46.2 (± 38.6)            |  |  |
| O1YFU (n=2,4)                         | 46.9 (± 66.2)            | 57.9 (± 115)             |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Serum concentration of atezolizumab (mcg/mL)

|                                                                                                                                                                                                                                                                                                                             |                                              |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|
| End point title                                                                                                                                                                                                                                                                                                             | Serum concentration of atezolizumab (mcg/mL) |
| End point description:<br>The following abbreviations apply in the table: Ind C = Induction Cycle; D = Day; Maint M = Maintenance Month; TRTC = Study Drug Completion or Early Discontinuation; PK FU = Pharmacokinetics and Immunogenicity Follow-up; YR = Year. The Safety Evaluable Population included participants who |                                              |

received at least one dose of any study treatment. 9999999 = the standard deviation couldn't be calculated from the data of 1 participant.

|                                        |           |
|----------------------------------------|-----------|
| End point type                         | Secondary |
| End point timeframe:                   |           |
| Baseline up to approximately 59 months |           |

| End point values                            | Atezolizumab-G-lena 15mg | Atezolizumab-G-lena 20mg |  |  |
|---------------------------------------------|--------------------------|--------------------------|--|--|
| Subject group type                          | Reporting group          | Reporting group          |  |  |
| Number of subjects analysed                 | 4                        | 34                       |  |  |
| Units: mcg/mL                               |                          |                          |  |  |
| arithmetic mean (standard deviation)        |                          |                          |  |  |
| Ind C2 D1 - Predose (n=0,1)                 | 0 (± 0)                  | 0.184 (± 9999999)        |  |  |
| Ind C2 D1 - 30 min. Postdose (n=4,32)       | 345 (± 195)              | 279 (± 123)              |  |  |
| Ind C2 D15 - Predose (n=3,32)               | 73.8 (± 6.47)            | 90.0 (± 33.8)            |  |  |
| Ind C4 D1 - Predose (n=2,29)                | 128 (± 33.9)             | 226 (± 93.9)             |  |  |
| Ind C4 D1 - 30 min. Postdose (n=2,27)       | 340 (± 38.2)             | 477 (± 126)              |  |  |
| Ind C6 D1 - Predose (n=3,28)                | 194 (± 40.6)             | 279 (± 117)              |  |  |
| Maint M1 - Predose (n=3,27)                 | 79.0 (± 67.6)            | 172 (± 76.5)             |  |  |
| Maint M1 - Day 2, 30 min. Postdose (n=3,23) | 653 (± 106)              | 666 (± 185)              |  |  |
| Maint M4 - Predose (n=3,25)                 | 174 (± 32.9)             | 292 (± 97.1)             |  |  |
| Maint M7 - Predose (n=2,20)                 | 209 (± 12.7)             | 322 (± 109)              |  |  |
| Maint M13 - Predose (n=1,19)                | 203 (± 9999999)          | 309 (± 140)              |  |  |
| Maint M19 - Predose (n=1,11)                | 351 (± 9999999)          | 327 (± 140)              |  |  |
| TRTC (n=0,13)                               | 0 (± 0)                  | 116 (± 81.9)             |  |  |
| PK FU 120D (n=1,11)                         | 46.0 (± 9999999)         | 38.4 (± 24.6)            |  |  |
| PK FU 1YR (n=0,0)                           | 0 (± 0)                  | 0 (± 0)                  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Serum concentration of lenalidomide (ng/mL)

|                                                                                                                                                                                                           |                                             |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|
| End point title                                                                                                                                                                                           | Serum concentration of lenalidomide (ng/mL) |
| End point description:                                                                                                                                                                                    |                                             |
| The following abbreviations apply in the table: Ind C = Induction Cycle; D = Day; HR = Hour. The Safety Evaluable Population included participants who received at least one dose of any study treatment. |                                             |
| End point type                                                                                                                                                                                            | Secondary                                   |
| End point timeframe:                                                                                                                                                                                      |                                             |
| Baseline up to approximately 59 months                                                                                                                                                                    |                                             |

| End point values                       | Atezolizumab-G-lena 15mg | Atezolizumab-G-lena 20mg |  |  |
|----------------------------------------|--------------------------|--------------------------|--|--|
| Subject group type                     | Reporting group          | Reporting group          |  |  |
| Number of subjects analysed            | 4                        | 34                       |  |  |
| Units: nanograms/milliliter (ng/mL)    |                          |                          |  |  |
| arithmetic mean (standard deviation)   |                          |                          |  |  |
| Ind C1 D1 - Predose (n=0,0)            | 0 (± 0)                  | 0 (± 0)                  |  |  |
| Ind C1 D15 - Predose (n=4,17)          | 12.6 (± 14.3)            | 13.0 (± 11.4)            |  |  |
| Ind C1 D15 - 2.0 hr. Postdose (n=4,18) | 254 (± 115)              | 294 (± 114)              |  |  |
| Ind C2 D15 - Predose (n=3,21)          | 3.57 (± 3.25)            | 15.0 (± 13.0)            |  |  |
| Ind C2 D15 - 30 min. Postdose (n=3,19) | 241 (± 116)              | 293 (± 233)              |  |  |
| Ind C2 D15 -1.0 hr. Postdose (n=3,20)  | 224 (± 43.1)             | 354 (± 120)              |  |  |
| Ind C2 D15 - 2.0 hr. Postdose (n=3,19) | 146 (± 41.9)             | 262 (± 82.1)             |  |  |
| Ind C2 D15 - 4.0 hr. Postdose (n=3,20) | 95.8 (± 18.3)            | 150 (± 47.1)             |  |  |
| Ind C2 D15 - 8.0 hr. Postdose (n=3,20) | 45.9 (± 23.9)            | 68.4 (± 33.6)            |  |  |
| Ind C6 D15 - Predose (n=3,12)          | 5.72 (± 3.73)            | 9.17 (± 6.87)            |  |  |
| Ind C6 D15 - 2.0 hr. Postdose (n=3,12) | 200 (± 57.5)             | 214 (± 77.6)             |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of participants positive for human anti-human antibodies (HAHA) to obinutuzumab

|                 |                                                                                        |
|-----------------|----------------------------------------------------------------------------------------|
| End point title | Number of participants positive for human anti-human antibodies (HAHA) to obinutuzumab |
|-----------------|----------------------------------------------------------------------------------------|

End point description:

The following abbreviations apply in the table: Ind C = Induction Cycle; D = Day; Maint M = Maintenance Month; TRTC = Study Drug Completion or Early Discontinuation; PK FU = Pharmacokinetics and Immunogenicity Follow-up; YR = Year. All baseline and post-baseline samples from participants were negative for HAHA to obinutuzumab and the results are shown below. The Safety Evaluable Population included participants who received at least one dose of any study treatment.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline up to approximately 59 months

| End point values            | Atezolizumab-G-lena 15mg | Atezolizumab-G-lena 20mg |  |  |
|-----------------------------|--------------------------|--------------------------|--|--|
| Subject group type          | Reporting group          | Reporting group          |  |  |
| Number of subjects analysed | 4                        | 34                       |  |  |
| Units: Participants         |                          |                          |  |  |
| number (not applicable)     |                          |                          |  |  |
| Baseline - Negative         | 4                        | 34                       |  |  |
| Ind C6 D1 - Negative        | 3                        | 27                       |  |  |

|                                   |   |    |  |  |
|-----------------------------------|---|----|--|--|
| TRTC - Negative                   | 0 | 15 |  |  |
| OB, PK, IMMUNO FU 120D - Negative | 1 | 11 |  |  |
| OB, PK, IMMUNO FU 1YR - Negative  | 2 | 4  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of participants positive for anti-therapeutic antibodies (ATAs) to atezolizumab

|                 |                                                                                        |
|-----------------|----------------------------------------------------------------------------------------|
| End point title | Number of participants positive for anti-therapeutic antibodies (ATAs) to atezolizumab |
|-----------------|----------------------------------------------------------------------------------------|

End point description:

The following abbreviations apply in the table: Ind C = Induction Cycle; D = Day; Maint M = Maintenance Month; TRTC = Study Drug Completion or Early Discontinuation; PK FU = Pharmacokinetics and Immunogenicity Follow-up; YR = Year. All baseline and post-baseline samples were negative for ATAs to atezolizumab and the results are shown below. The Safety Evaluable Population included participants who received at least one dose of any study treatment.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline up to approximately 59 months

| End point values                     | Atezolizumab-G-lena 15mg | Atezolizumab-G-lena 20mg |  |  |
|--------------------------------------|--------------------------|--------------------------|--|--|
| Subject group type                   | Reporting group          | Reporting group          |  |  |
| Number of subjects analysed          | 4                        | 34                       |  |  |
| Units: Participants                  |                          |                          |  |  |
| number (not applicable)              |                          |                          |  |  |
| Ind C2 D1 - Negative                 | 4                        | 31                       |  |  |
| Ind C2 D15 - Negative                | 2                        | 32                       |  |  |
| Ind C4 D1 - Negative                 | 3                        | 29                       |  |  |
| Ind C6 D1 - Negative                 | 3                        | 28                       |  |  |
| Maint M1 - Negative                  | 3                        | 27                       |  |  |
| Maint M4 - Negative                  | 3                        | 25                       |  |  |
| Maint M7 - Negative                  | 2                        | 21                       |  |  |
| Maint M13 - Negative                 | 1                        | 20                       |  |  |
| Maint M19 - Negative                 | 2                        | 12                       |  |  |
| TRTC - Negative                      | 2                        | 15                       |  |  |
| ATEZO, PK, IMMUNO FU 120D - Negative | 1                        | 11                       |  |  |
| ATEZO, PK, IMMUNO FU 1YR - Negative  | 2                        | 3                        |  |  |

## Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Baseline up to approximately 59 months

Adverse event reporting additional description:

The safety population included all subjects who received at least one treatment with study medication. The adverse event severity grading scale for the NCI CTCAE v4.0 was used.

|                 |            |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

### Dictionary used

|                 |        |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

|                    |      |
|--------------------|------|
| Dictionary version | 23.1 |
|--------------------|------|

### Reporting groups

|                       |                          |
|-----------------------|--------------------------|
| Reporting group title | Atezolizumab-G-lena 15mg |
|-----------------------|--------------------------|

Reporting group description:

Participants were administered obinutuzumab, atezolizumab, and 15 mg of lenalidomide

|                       |                          |
|-----------------------|--------------------------|
| Reporting group title | Atezolizumab-G-lena 20mg |
|-----------------------|--------------------------|

Reporting group description:

Participants were administered obinutuzumab, atezolizumab, and 20 mg of lenalidomide.

| Serious adverse events                                              | Atezolizumab-G-lena 15mg | Atezolizumab-G-lena 20mg |  |
|---------------------------------------------------------------------|--------------------------|--------------------------|--|
| Total subjects affected by serious adverse events                   |                          |                          |  |
| subjects affected / exposed                                         | 2 / 4 (50.00%)           | 16 / 34 (47.06%)         |  |
| number of deaths (all causes)                                       | 1                        | 7                        |  |
| number of deaths resulting from adverse events                      |                          |                          |  |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                          |                          |  |
| MENINGIOMA                                                          |                          |                          |  |
| subjects affected / exposed                                         | 0 / 4 (0.00%)            | 1 / 34 (2.94%)           |  |
| occurrences causally related to treatment / all                     | 0 / 0                    | 0 / 1                    |  |
| deaths causally related to treatment / all                          | 0 / 0                    | 0 / 0                    |  |
| TUMOUR FLARE                                                        |                          |                          |  |
| subjects affected / exposed                                         | 0 / 4 (0.00%)            | 1 / 34 (2.94%)           |  |
| occurrences causally related to treatment / all                     | 0 / 0                    | 1 / 1                    |  |
| deaths causally related to treatment / all                          | 0 / 0                    | 0 / 0                    |  |
| ACUTE MYELOID LEUKAEMIA                                             |                          |                          |  |
| subjects affected / exposed                                         | 0 / 4 (0.00%)            | 1 / 34 (2.94%)           |  |
| occurrences causally related to treatment / all                     | 0 / 0                    | 0 / 1                    |  |
| deaths causally related to treatment / all                          | 0 / 0                    | 0 / 0                    |  |
| ATYPICAL FIBROXANTHOMA                                              |                          |                          |  |

|                                                       |               |                |  |
|-------------------------------------------------------|---------------|----------------|--|
| subjects affected / exposed                           | 0 / 4 (0.00%) | 1 / 34 (2.94%) |  |
| occurrences causally related to treatment / all       | 0 / 0         | 0 / 1          |  |
| deaths causally related to treatment / all            | 0 / 0         | 0 / 0          |  |
| <b>BASAL CELL CARCINOMA</b>                           |               |                |  |
| subjects affected / exposed                           | 0 / 4 (0.00%) | 1 / 34 (2.94%) |  |
| occurrences causally related to treatment / all       | 0 / 0         | 1 / 1          |  |
| deaths causally related to treatment / all            | 0 / 0         | 0 / 0          |  |
| <b>LUNG NEOPLASM MALIGNANT</b>                        |               |                |  |
| subjects affected / exposed                           | 0 / 4 (0.00%) | 1 / 34 (2.94%) |  |
| occurrences causally related to treatment / all       | 0 / 0         | 0 / 1          |  |
| deaths causally related to treatment / all            | 0 / 0         | 0 / 0          |  |
| <b>NEUROENDOCRINE CARCINOMA OF THE SKIN</b>           |               |                |  |
| subjects affected / exposed                           | 0 / 4 (0.00%) | 1 / 34 (2.94%) |  |
| occurrences causally related to treatment / all       | 0 / 0         | 0 / 1          |  |
| deaths causally related to treatment / all            | 0 / 0         | 0 / 1          |  |
| <b>SARCOMATOID CARCINOMA</b>                          |               |                |  |
| subjects affected / exposed                           | 0 / 4 (0.00%) | 1 / 34 (2.94%) |  |
| occurrences causally related to treatment / all       | 0 / 0         | 0 / 1          |  |
| deaths causally related to treatment / all            | 0 / 0         | 0 / 1          |  |
| <b>Injury, poisoning and procedural complications</b> |               |                |  |
| <b>INFUSION RELATED REACTION</b>                      |               |                |  |
| subjects affected / exposed                           | 0 / 4 (0.00%) | 1 / 34 (2.94%) |  |
| occurrences causally related to treatment / all       | 0 / 0         | 1 / 1          |  |
| deaths causally related to treatment / all            | 0 / 0         | 0 / 0          |  |
| <b>LUMBAR VERTEBRAL FRACTURE</b>                      |               |                |  |
| subjects affected / exposed                           | 0 / 4 (0.00%) | 1 / 34 (2.94%) |  |
| occurrences causally related to treatment / all       | 0 / 0         | 0 / 1          |  |
| deaths causally related to treatment / all            | 0 / 0         | 0 / 0          |  |
| <b>Vascular disorders</b>                             |               |                |  |
| <b>DEEP VEIN THROMBOSIS</b>                           |               |                |  |
| subjects affected / exposed                           | 0 / 4 (0.00%) | 1 / 34 (2.94%) |  |
| occurrences causally related to treatment / all       | 0 / 0         | 1 / 1          |  |
| deaths causally related to treatment / all            | 0 / 0         | 0 / 0          |  |

|                                                      |                |                |  |
|------------------------------------------------------|----------------|----------------|--|
| ORTHOSTATIC HYPOTENSION                              |                |                |  |
| subjects affected / exposed                          | 1 / 4 (25.00%) | 0 / 34 (0.00%) |  |
| occurrences causally related to treatment / all      | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          |  |
| Nervous system disorders                             |                |                |  |
| ISCHAEMIC STROKE                                     |                |                |  |
| subjects affected / exposed                          | 0 / 4 (0.00%)  | 1 / 34 (2.94%) |  |
| occurrences causally related to treatment / all      | 0 / 0          | 1 / 1          |  |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          |  |
| Blood and lymphatic system disorders                 |                |                |  |
| FEBRILE NEUTROPENIA                                  |                |                |  |
| subjects affected / exposed                          | 0 / 4 (0.00%)  | 1 / 34 (2.94%) |  |
| occurrences causally related to treatment / all      | 0 / 0          | 2 / 2          |  |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          |  |
| General disorders and administration site conditions |                |                |  |
| ADMINISTRATION SITE EXTRAVASATION                    |                |                |  |
| subjects affected / exposed                          | 0 / 4 (0.00%)  | 1 / 34 (2.94%) |  |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 1          |  |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          |  |
| Gastrointestinal disorders                           |                |                |  |
| ABDOMINAL PAIN                                       |                |                |  |
| subjects affected / exposed                          | 1 / 4 (25.00%) | 0 / 34 (0.00%) |  |
| occurrences causally related to treatment / all      | 0 / 2          | 0 / 0          |  |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          |  |
| Respiratory, thoracic and mediastinal disorders      |                |                |  |
| DYSPNOEA                                             |                |                |  |
| subjects affected / exposed                          | 0 / 4 (0.00%)  | 1 / 34 (2.94%) |  |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 1          |  |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          |  |
| LUNG DISORDER                                        |                |                |  |
| subjects affected / exposed                          | 0 / 4 (0.00%)  | 2 / 34 (5.88%) |  |
| occurrences causally related to treatment / all      | 0 / 0          | 1 / 2          |  |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          |  |
| Infections and infestations                          |                |                |  |

|                                                 |                |                |  |
|-------------------------------------------------|----------------|----------------|--|
| EAR INFECTION                                   |                |                |  |
| subjects affected / exposed                     | 0 / 4 (0.00%)  | 1 / 34 (2.94%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 1 / 1          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| EPIDIDYMITIS                                    |                |                |  |
| subjects affected / exposed                     | 1 / 4 (25.00%) | 0 / 34 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| INFLUENZA                                       |                |                |  |
| subjects affected / exposed                     | 0 / 4 (0.00%)  | 1 / 34 (2.94%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 1 / 1          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| PNEUMONIA PARAINFLUENZAE VIRAL                  |                |                |  |
| subjects affected / exposed                     | 1 / 4 (25.00%) | 0 / 34 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| CELLULITIS                                      |                |                |  |
| subjects affected / exposed                     | 0 / 4 (0.00%)  | 1 / 34 (2.94%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| PNEUMONIA                                       |                |                |  |
| subjects affected / exposed                     | 0 / 4 (0.00%)  | 1 / 34 (2.94%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 1 / 1          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Metabolism and nutrition disorders              |                |                |  |
| DEHYDRATION                                     |                |                |  |
| subjects affected / exposed                     | 1 / 4 (25.00%) | 0 / 34 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1          | 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>                                                              | Atezolizumab-G-lena<br>15mg | Atezolizumab-G-lena<br>20mg |  |
|------------------------------------------------------------------------------------------------|-----------------------------|-----------------------------|--|
| Total subjects affected by non-serious adverse events                                          |                             |                             |  |
| subjects affected / exposed                                                                    | 4 / 4 (100.00%)             | 34 / 34 (100.00%)           |  |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps)<br>SQUAMOUS CELL CARCINOMA |                             |                             |  |
| subjects affected / exposed                                                                    | 0 / 4 (0.00%)               | 2 / 34 (5.88%)              |  |
| occurrences (all)                                                                              | 0                           | 4                           |  |
| Vascular disorders                                                                             |                             |                             |  |
| HYPERTENSION                                                                                   |                             |                             |  |
| subjects affected / exposed                                                                    | 1 / 4 (25.00%)              | 2 / 34 (5.88%)              |  |
| occurrences (all)                                                                              | 1                           | 2                           |  |
| DEEP VEIN THROMBOSIS                                                                           |                             |                             |  |
| subjects affected / exposed                                                                    | 1 / 4 (25.00%)              | 0 / 34 (0.00%)              |  |
| occurrences (all)                                                                              | 1                           | 0                           |  |
| HOT FLUSH                                                                                      |                             |                             |  |
| subjects affected / exposed                                                                    | 0 / 4 (0.00%)               | 2 / 34 (5.88%)              |  |
| occurrences (all)                                                                              | 0                           | 2                           |  |
| General disorders and administration site conditions                                           |                             |                             |  |
| ASTHENIA                                                                                       |                             |                             |  |
| subjects affected / exposed                                                                    | 0 / 4 (0.00%)               | 14 / 34 (41.18%)            |  |
| occurrences (all)                                                                              | 0                           | 20                          |  |
| AXILLARY PAIN                                                                                  |                             |                             |  |
| subjects affected / exposed                                                                    | 1 / 4 (25.00%)              | 0 / 34 (0.00%)              |  |
| occurrences (all)                                                                              | 2                           | 0                           |  |
| FATIGUE                                                                                        |                             |                             |  |
| subjects affected / exposed                                                                    | 1 / 4 (25.00%)              | 8 / 34 (23.53%)             |  |
| occurrences (all)                                                                              | 1                           | 10                          |  |
| INFLUENZA LIKE ILLNESS                                                                         |                             |                             |  |
| subjects affected / exposed                                                                    | 1 / 4 (25.00%)              | 2 / 34 (5.88%)              |  |
| occurrences (all)                                                                              | 2                           | 2                           |  |
| NON-CARDIAC CHEST PAIN                                                                         |                             |                             |  |
| subjects affected / exposed                                                                    | 1 / 4 (25.00%)              | 0 / 34 (0.00%)              |  |
| occurrences (all)                                                                              | 1                           | 0                           |  |
| OEDEMA PERIPHERAL                                                                              |                             |                             |  |
| subjects affected / exposed                                                                    | 1 / 4 (25.00%)              | 5 / 34 (14.71%)             |  |
| occurrences (all)                                                                              | 1                           | 8                           |  |

|                                                                                                                 |                     |                        |  |
|-----------------------------------------------------------------------------------------------------------------|---------------------|------------------------|--|
| PERIPHERAL SWELLING<br>subjects affected / exposed<br>occurrences (all)                                         | 0 / 4 (0.00%)<br>0  | 2 / 34 (5.88%)<br>2    |  |
| PYREXIA<br>subjects affected / exposed<br>occurrences (all)                                                     | 3 / 4 (75.00%)<br>3 | 5 / 34 (14.71%)<br>6   |  |
| XEROSIS<br>subjects affected / exposed<br>occurrences (all)                                                     | 0 / 4 (0.00%)<br>0  | 2 / 34 (5.88%)<br>2    |  |
| MALAISE<br>subjects affected / exposed<br>occurrences (all)                                                     | 0 / 4 (0.00%)<br>0  | 2 / 34 (5.88%)<br>2    |  |
| Immune system disorders<br>HYPOGAMMAGLOBULINAEMIA<br>subjects affected / exposed<br>occurrences (all)           | 0 / 4 (0.00%)<br>0  | 2 / 34 (5.88%)<br>2    |  |
| Respiratory, thoracic and mediastinal disorders<br>DYSпноEA<br>subjects affected / exposed<br>occurrences (all) | 1 / 4 (25.00%)<br>1 | 5 / 34 (14.71%)<br>5   |  |
| COUGH<br>subjects affected / exposed<br>occurrences (all)                                                       | 2 / 4 (50.00%)<br>4 | 12 / 34 (35.29%)<br>14 |  |
| NASAL CONGESTION<br>subjects affected / exposed<br>occurrences (all)                                            | 2 / 4 (50.00%)<br>2 | 4 / 34 (11.76%)<br>5   |  |
| EPISTAXIS<br>subjects affected / exposed<br>occurrences (all)                                                   | 0 / 4 (0.00%)<br>0  | 2 / 34 (5.88%)<br>2    |  |
| OROPHARYNGEAL PAIN<br>subjects affected / exposed<br>occurrences (all)                                          | 1 / 4 (25.00%)<br>1 | 1 / 34 (2.94%)<br>1    |  |
| PRODUCTIVE COUGH<br>subjects affected / exposed<br>occurrences (all)                                            | 1 / 4 (25.00%)<br>1 | 0 / 34 (0.00%)<br>0    |  |
| PNEUMONITIS                                                                                                     |                     |                        |  |

|                                                                                                                               |                                |                                 |  |
|-------------------------------------------------------------------------------------------------------------------------------|--------------------------------|---------------------------------|--|
| <p>subjects affected / exposed</p> <p>occurrences (all)</p>                                                                   | <p>1 / 4 (25.00%)</p> <p>1</p> | <p>0 / 34 (0.00%)</p> <p>0</p>  |  |
| <p>RHINORRHOEA</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>                                                | <p>1 / 4 (25.00%)</p> <p>1</p> | <p>3 / 34 (8.82%)</p> <p>4</p>  |  |
| <p>SINUS CONGESTION</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>                                           | <p>0 / 4 (0.00%)</p> <p>0</p>  | <p>2 / 34 (5.88%)</p> <p>2</p>  |  |
| <p>Psychiatric disorders</p> <p>INSOMNIA</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>                      | <p>1 / 4 (25.00%)</p> <p>1</p> | <p>4 / 34 (11.76%)</p> <p>5</p> |  |
| <p>DEPRESSION</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>                                                 | <p>2 / 4 (50.00%)</p> <p>2</p> | <p>2 / 34 (5.88%)</p> <p>2</p>  |  |
| <p>Investigations</p> <p>ALANINE AMINOTRANSFERASE INCREASED</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>   | <p>1 / 4 (25.00%)</p> <p>2</p> | <p>2 / 34 (5.88%)</p> <p>2</p>  |  |
| <p>AMYLASE INCREASED</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>                                          | <p>1 / 4 (25.00%)</p> <p>2</p> | <p>2 / 34 (5.88%)</p> <p>2</p>  |  |
| <p>ASPARTATE AMINOTRANSFERASE INCREASED</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>                       | <p>1 / 4 (25.00%)</p> <p>1</p> | <p>2 / 34 (5.88%)</p> <p>2</p>  |  |
| <p>LIPASE INCREASED</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>                                           | <p>1 / 4 (25.00%)</p> <p>2</p> | <p>4 / 34 (11.76%)</p> <p>6</p> |  |
| <p>WEIGHT DECREASED</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>                                           | <p>1 / 4 (25.00%)</p> <p>1</p> | <p>0 / 34 (0.00%)</p> <p>0</p>  |  |
| <p>Injury, poisoning and procedural complications</p> <p>FALL</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>1 / 4 (25.00%)</p> <p>1</p> | <p>2 / 34 (5.88%)</p> <p>2</p>  |  |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                         |                                                                                                                                                                                            |  |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| <p>INFUSION RELATED REACTION</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <p>1 / 4 (25.00%)</p> <p>2</p>                                                                                                                                                          | <p>11 / 34 (32.35%)</p> <p>12</p>                                                                                                                                                          |  |
| <p>SKIN ABRASION</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | <p>1 / 4 (25.00%)</p> <p>1</p>                                                                                                                                                          | <p>0 / 34 (0.00%)</p> <p>0</p>                                                                                                                                                             |  |
| <p>SPINAL COMPRESSION FRACTURE</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <p>1 / 4 (25.00%)</p> <p>1</p>                                                                                                                                                          | <p>0 / 34 (0.00%)</p> <p>0</p>                                                                                                                                                             |  |
| <p>Cardiac disorders</p> <p>TACHYCARDIA</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <p>1 / 4 (25.00%)</p> <p>1</p>                                                                                                                                                          | <p>0 / 34 (0.00%)</p> <p>0</p>                                                                                                                                                             |  |
| <p>Nervous system disorders</p> <p>DIZZINESS</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>NEUROPATHY PERIPHERAL</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>PARAESTHESIA</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>POST HERPETIC NEURALGIA</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>PERIPHERAL SENSORY NEUROPATHY</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>TREMOR</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 4 (0.00%)</p> <p>0</p> <p>1 / 4 (25.00%)</p> <p>1</p> <p>1 / 4 (25.00%)</p> <p>1</p> <p>1 / 4 (25.00%)</p> <p>1</p> <p>1 / 4 (25.00%)</p> <p>1</p> <p>0 / 4 (0.00%)</p> <p>0</p> | <p>3 / 34 (8.82%)</p> <p>4</p> <p>2 / 34 (5.88%)</p> <p>3</p> <p>4 / 34 (11.76%)</p> <p>4</p> <p>1 / 34 (2.94%)</p> <p>1</p> <p>0 / 34 (0.00%)</p> <p>0</p> <p>2 / 34 (5.88%)</p> <p>2</p> |  |
| <p>Blood and lymphatic system disorders</p> <p>ANAEMIA</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>LEUKOPENIA</p>                                                                                                                                                                                                                                                                                                                                                                                                                    | <p>1 / 4 (25.00%)</p> <p>1</p>                                                                                                                                                          | <p>6 / 34 (17.65%)</p> <p>6</p>                                                                                                                                                            |  |

|                             |                |                  |  |
|-----------------------------|----------------|------------------|--|
| subjects affected / exposed | 0 / 4 (0.00%)  | 2 / 34 (5.88%)   |  |
| occurrences (all)           | 0              | 2                |  |
| NEUTROPENIA                 |                |                  |  |
| subjects affected / exposed | 3 / 4 (75.00%) | 14 / 34 (41.18%) |  |
| occurrences (all)           | 4              | 43               |  |
| THROMBOCYTOPENIA            |                |                  |  |
| subjects affected / exposed | 1 / 4 (25.00%) | 9 / 34 (26.47%)  |  |
| occurrences (all)           | 1              | 14               |  |
| Ear and labyrinth disorders |                |                  |  |
| VERTIGO                     |                |                  |  |
| subjects affected / exposed | 0 / 4 (0.00%)  | 2 / 34 (5.88%)   |  |
| occurrences (all)           | 0              | 2                |  |
| Eye disorders               |                |                  |  |
| LACRIMATION INCREASED       |                |                  |  |
| subjects affected / exposed | 1 / 4 (25.00%) | 0 / 34 (0.00%)   |  |
| occurrences (all)           | 1              | 0                |  |
| DRY EYE                     |                |                  |  |
| subjects affected / exposed | 0 / 4 (0.00%)  | 2 / 34 (5.88%)   |  |
| occurrences (all)           | 0              | 3                |  |
| Gastrointestinal disorders  |                |                  |  |
| ABDOMINAL DISTENSION        |                |                  |  |
| subjects affected / exposed | 0 / 4 (0.00%)  | 2 / 34 (5.88%)   |  |
| occurrences (all)           | 0              | 2                |  |
| ABDOMINAL PAIN              |                |                  |  |
| subjects affected / exposed | 1 / 4 (25.00%) | 8 / 34 (23.53%)  |  |
| occurrences (all)           | 2              | 10               |  |
| ABDOMINAL PAIN UPPER        |                |                  |  |
| subjects affected / exposed | 2 / 4 (50.00%) | 1 / 34 (2.94%)   |  |
| occurrences (all)           | 3              | 2                |  |
| CONSTIPATION                |                |                  |  |
| subjects affected / exposed | 3 / 4 (75.00%) | 12 / 34 (35.29%) |  |
| occurrences (all)           | 5              | 13               |  |
| DIARRHOEA                   |                |                  |  |
| subjects affected / exposed | 3 / 4 (75.00%) | 19 / 34 (55.88%) |  |
| occurrences (all)           | 9              | 42               |  |
| DYSPEPSIA                   |                |                  |  |

|                                        |                 |                 |  |
|----------------------------------------|-----------------|-----------------|--|
| subjects affected / exposed            | 0 / 4 (0.00%)   | 3 / 34 (8.82%)  |  |
| occurrences (all)                      | 0               | 6               |  |
| DYSPHAGIA                              |                 |                 |  |
| subjects affected / exposed            | 0 / 4 (0.00%)   | 2 / 34 (5.88%)  |  |
| occurrences (all)                      | 0               | 2               |  |
| HAEMATOCHESIA                          |                 |                 |  |
| subjects affected / exposed            | 0 / 4 (0.00%)   | 2 / 34 (5.88%)  |  |
| occurrences (all)                      | 0               | 2               |  |
| NAUSEA                                 |                 |                 |  |
| subjects affected / exposed            | 4 / 4 (100.00%) | 4 / 34 (11.76%) |  |
| occurrences (all)                      | 4               | 7               |  |
| RECTAL HAEMORRHOGE                     |                 |                 |  |
| subjects affected / exposed            | 1 / 4 (25.00%)  | 2 / 34 (5.88%)  |  |
| occurrences (all)                      | 1               | 2               |  |
| STOMATITIS                             |                 |                 |  |
| subjects affected / exposed            | 2 / 4 (50.00%)  | 0 / 34 (0.00%)  |  |
| occurrences (all)                      | 2               | 0               |  |
| VOMITING                               |                 |                 |  |
| subjects affected / exposed            | 4 / 4 (100.00%) | 3 / 34 (8.82%)  |  |
| occurrences (all)                      | 8               | 4               |  |
| HAEMORRHOIDS                           |                 |                 |  |
| subjects affected / exposed            | 0 / 4 (0.00%)   | 4 / 34 (11.76%) |  |
| occurrences (all)                      | 0               | 6               |  |
| Hepatobiliary disorders                |                 |                 |  |
| CHOLECYSTITIS                          |                 |                 |  |
| subjects affected / exposed            | 1 / 4 (25.00%)  | 0 / 34 (0.00%)  |  |
| occurrences (all)                      | 1               | 0               |  |
| HEPATOCELLULAR INJURY                  |                 |                 |  |
| subjects affected / exposed            | 0 / 4 (0.00%)   | 3 / 34 (8.82%)  |  |
| occurrences (all)                      | 0               | 4               |  |
| Skin and subcutaneous tissue disorders |                 |                 |  |
| ERYTHEMA                               |                 |                 |  |
| subjects affected / exposed            | 0 / 4 (0.00%)   | 2 / 34 (5.88%)  |  |
| occurrences (all)                      | 0               | 2               |  |
| NIGHT SWEATS                           |                 |                 |  |

|                                                                                                                   |                     |                       |  |
|-------------------------------------------------------------------------------------------------------------------|---------------------|-----------------------|--|
| subjects affected / exposed<br>occurrences (all)                                                                  | 1 / 4 (25.00%)<br>1 | 4 / 34 (11.76%)<br>4  |  |
| PRURITUS<br>subjects affected / exposed<br>occurrences (all)                                                      | 2 / 4 (50.00%)<br>2 | 5 / 34 (14.71%)<br>6  |  |
| RASH<br>subjects affected / exposed<br>occurrences (all)                                                          | 0 / 4 (0.00%)<br>0  | 7 / 34 (20.59%)<br>8  |  |
| RASH MACULO-PAPULAR<br>subjects affected / exposed<br>occurrences (all)                                           | 0 / 4 (0.00%)<br>0  | 3 / 34 (8.82%)<br>6   |  |
| Renal and urinary disorders<br>HYDRONEPHROSIS<br>subjects affected / exposed<br>occurrences (all)                 | 1 / 4 (25.00%)<br>1 | 0 / 34 (0.00%)<br>0   |  |
| URINARY RETENTION<br>subjects affected / exposed<br>occurrences (all)                                             | 1 / 4 (25.00%)<br>1 | 0 / 34 (0.00%)<br>0   |  |
| DYSURIA<br>subjects affected / exposed<br>occurrences (all)                                                       | 0 / 4 (0.00%)<br>0  | 3 / 34 (8.82%)<br>3   |  |
| Endocrine disorders<br>HYPERTHYROIDISM<br>subjects affected / exposed<br>occurrences (all)                        | 1 / 4 (25.00%)<br>1 | 7 / 34 (20.59%)<br>9  |  |
| HYPOTHYROIDISM<br>subjects affected / exposed<br>occurrences (all)                                                | 0 / 4 (0.00%)<br>0  | 6 / 34 (17.65%)<br>6  |  |
| Musculoskeletal and connective tissue disorders<br>ARTHRALGIA<br>subjects affected / exposed<br>occurrences (all) | 2 / 4 (50.00%)<br>3 | 7 / 34 (20.59%)<br>10 |  |
| BACK PAIN<br>subjects affected / exposed<br>occurrences (all)                                                     | 1 / 4 (25.00%)<br>2 | 2 / 34 (5.88%)<br>2   |  |
| BONE PAIN                                                                                                         |                     |                       |  |

|                             |                |                  |  |
|-----------------------------|----------------|------------------|--|
| subjects affected / exposed | 0 / 4 (0.00%)  | 3 / 34 (8.82%)   |  |
| occurrences (all)           | 0              | 4                |  |
| FLANK PAIN                  |                |                  |  |
| subjects affected / exposed | 1 / 4 (25.00%) | 0 / 34 (0.00%)   |  |
| occurrences (all)           | 1              | 0                |  |
| GROIN PAIN                  |                |                  |  |
| subjects affected / exposed | 1 / 4 (25.00%) | 1 / 34 (2.94%)   |  |
| occurrences (all)           | 1              | 1                |  |
| MUSCULAR WEAKNESS           |                |                  |  |
| subjects affected / exposed | 1 / 4 (25.00%) | 1 / 34 (2.94%)   |  |
| occurrences (all)           | 1              | 1                |  |
| MUSCLE SPASMS               |                |                  |  |
| subjects affected / exposed | 0 / 4 (0.00%)  | 8 / 34 (23.53%)  |  |
| occurrences (all)           | 0              | 15               |  |
| MUSCULOSKELETAL CHEST PAIN  |                |                  |  |
| subjects affected / exposed | 1 / 4 (25.00%) | 0 / 34 (0.00%)   |  |
| occurrences (all)           | 1              | 0                |  |
| MYALGIA                     |                |                  |  |
| subjects affected / exposed | 0 / 4 (0.00%)  | 5 / 34 (14.71%)  |  |
| occurrences (all)           | 0              | 9                |  |
| PAIN IN EXTREMITY           |                |                  |  |
| subjects affected / exposed | 1 / 4 (25.00%) | 5 / 34 (14.71%)  |  |
| occurrences (all)           | 1              | 5                |  |
| Infections and infestations |                |                  |  |
| BRONCHIOLITIS               |                |                  |  |
| subjects affected / exposed | 1 / 4 (25.00%) | 0 / 34 (0.00%)   |  |
| occurrences (all)           | 1              | 0                |  |
| BRONCHITIS                  |                |                  |  |
| subjects affected / exposed | 0 / 4 (0.00%)  | 10 / 34 (29.41%) |  |
| occurrences (all)           | 0              | 13               |  |
| CONJUNCTIVITIS              |                |                  |  |
| subjects affected / exposed | 1 / 4 (25.00%) | 2 / 34 (5.88%)   |  |
| occurrences (all)           | 1              | 2                |  |
| FUNGAL SKIN INFECTION       |                |                  |  |
| subjects affected / exposed | 2 / 4 (50.00%) | 0 / 34 (0.00%)   |  |
| occurrences (all)           | 2              | 0                |  |

|                                      |                 |                 |
|--------------------------------------|-----------------|-----------------|
| GASTROENTERITIS                      |                 |                 |
| subjects affected / exposed          | 1 / 4 (25.00%)  | 2 / 34 (5.88%)  |
| occurrences (all)                    | 1               | 2               |
| HERPES ZOSTER                        |                 |                 |
| subjects affected / exposed          | 1 / 4 (25.00%)  | 1 / 34 (2.94%)  |
| occurrences (all)                    | 1               | 1               |
| INFLUENZA                            |                 |                 |
| subjects affected / exposed          | 1 / 4 (25.00%)  | 6 / 34 (17.65%) |
| occurrences (all)                    | 1               | 6               |
| NASOPHARYNGITIS                      |                 |                 |
| subjects affected / exposed          | 0 / 4 (0.00%)   | 6 / 34 (17.65%) |
| occurrences (all)                    | 0               | 10              |
| RHINITIS                             |                 |                 |
| subjects affected / exposed          | 0 / 4 (0.00%)   | 9 / 34 (26.47%) |
| occurrences (all)                    | 0               | 12              |
| PHARYNGITIS                          |                 |                 |
| subjects affected / exposed          | 0 / 4 (0.00%)   | 3 / 34 (8.82%)  |
| occurrences (all)                    | 0               | 3               |
| SINUSITIS                            |                 |                 |
| subjects affected / exposed          | 4 / 4 (100.00%) | 7 / 34 (20.59%) |
| occurrences (all)                    | 5               | 13              |
| UPPER RESPIRATORY TRACT<br>INFECTION |                 |                 |
| subjects affected / exposed          | 1 / 4 (25.00%)  | 5 / 34 (14.71%) |
| occurrences (all)                    | 1               | 8               |
| TINEA INFECTION                      |                 |                 |
| subjects affected / exposed          | 1 / 4 (25.00%)  | 0 / 34 (0.00%)  |
| occurrences (all)                    | 1               | 0               |
| URINARY TRACT INFECTION              |                 |                 |
| subjects affected / exposed          | 0 / 4 (0.00%)   | 3 / 34 (8.82%)  |
| occurrences (all)                    | 0               | 4               |
| ACUTE SINUSITIS                      |                 |                 |
| subjects affected / exposed          | 0 / 4 (0.00%)   | 2 / 34 (5.88%)  |
| occurrences (all)                    | 0               | 2               |
| CYSTITIS                             |                 |                 |

|                                    |                |                 |  |
|------------------------------------|----------------|-----------------|--|
| subjects affected / exposed        | 0 / 4 (0.00%)  | 2 / 34 (5.88%)  |  |
| occurrences (all)                  | 0              | 2               |  |
| PNEUMONIA                          |                |                 |  |
| subjects affected / exposed        | 0 / 4 (0.00%)  | 5 / 34 (14.71%) |  |
| occurrences (all)                  | 0              | 5               |  |
| Metabolism and nutrition disorders |                |                 |  |
| FLUID OVERLOAD                     |                |                 |  |
| subjects affected / exposed        | 1 / 4 (25.00%) | 0 / 34 (0.00%)  |  |
| occurrences (all)                  | 2              | 0               |  |
| DECREASED APPETITE                 |                |                 |  |
| subjects affected / exposed        | 0 / 4 (0.00%)  | 3 / 34 (8.82%)  |  |
| occurrences (all)                  | 0              | 3               |  |
| HYPERGLYCAEMIA                     |                |                 |  |
| subjects affected / exposed        | 2 / 4 (50.00%) | 0 / 34 (0.00%)  |  |
| occurrences (all)                  | 3              | 0               |  |
| HYPOKALAEMIA                       |                |                 |  |
| subjects affected / exposed        | 1 / 4 (25.00%) | 3 / 34 (8.82%)  |  |
| occurrences (all)                  | 2              | 3               |  |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date              | Amendment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 08 June 2016      | The protocol was amended in response to a health authority request. The exclusion criterion related to history of prior malignancy other than lymphoma was updated, second primary malignancies were included as events immediately reportable to the Sponsor, and the Schedule of Assessments was updated to include urinalysis and a complete physical examination on Cycle 1 Day 1.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 20 September 2016 | Obinutuzumab exposure data was updated to reflect the latest information from clinical studies. It was clarified that atezolizumab could be given on Day 15 of induction Cycles 2 to 6 regardless of cytopenia. Based on the latest atezolizumab Investigator's Brochure (IB; version 9), the summary of clinical safety, summary of clinical activity, the use of live vaccines after discontinuation of atezolizumab, management guidelines for non-hematologic AEs, and the list of AESIs were updated. In addition, the classification of diabetes mellitus and pancreatitis changed from 'important potential risks' to 'important identified risks'.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 05 May 2017       | The classification of second malignancies was changed from a selected AE to AESI to more closely monitor this AE. In addition, conditions for resuming study treatment in case of Grade $\geq 3$ laboratory abnormalities were clarified, and the list of AESIs for atezolizumab were updated to align with the latest Atezolizumab IB (version 9).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 04 December 2017  | On 3 July 2017, two clinical trials, KEYNOTE-183 and KEYNOTE-185, evaluating pembrolizumab (PD-1 inhibitor) in combination with an immunomodulatory agent (pomalidomide or lenalidomide) for the treatment of multiple myeloma were placed on clinical hold by the U.S. Food and Drug Administration (FDA). The clinical hold was issued because interim results demonstrated a worse overall survival in the investigational pembrolizumab arm compared to the control arm. Based on these emerging data, on 1 September 2017 the FDA also requested that other studies of PD-1/PDL-1 inhibitors and immunomodulatory agents, including study BO29562 should be placed on partial clinical hold. Although study BO29562 is conducted in a different hematologic malignancy (i.e., relapsed or refractory follicular lymphoma) and a similar safety signal has not been seen to date, the Sponsor revised the protocol to maximize patient safety. FDA removed the partial clinical hold as of 21 November 2017. Changes to the protocol, along with a rationale for each change: 1) Available Clinical Data was updated with the most recent efficacy and safety data. Stopping rules for excess toxicity and the roles of the IMC were updated, and the frequency of interim safety and efficacy analyses were amended to occur every 4 months; 2) Risks associated with obinutuzumab were updated to reflect recent updates to the obinutuzumab IB (version 12); 3) Risks associated with atezolizumab and management guidelines for atezolizumab-associated AEs were updated according to updates to the atezolizumab IB (version 10). |
| 07 November 2018  | Protocol was amended to include new safety information: 1) Lists of risks for atezolizumab and guidelines for managing patients who experience atezolizumab-associated adverse events were revised to include nephritis; 2) Considering no new safety signals have been identified with atezolizumab in combination with obinutuzumab plus lenalidomide, once all patients have completed/discontinued maintenance, regular Internal Monitoring Committee assessments would no longer take place and ad hoc meetings maybe called at the discretion of the Medical Monitor in case of newly identified safety signals; 3) Post-trial access language was changed allowing patients still under study treatment to enter an extension study in case of earlier closure of Study BO29562; 4) The Medical Monitor information was updated; 5) The Lenalidomide Summary of Product Characteristics has replaced local labels as the reference document for determining reporting requirements for single adverse events                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |

|                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 26 October 2019 | <p>The protocol was amended to include new safety information: 1) Background information on atezolizumab was revised to include the additional approved indications; 2) List of risks was updated to include myositis; 3) "Immune-related" was changed to "immune-mediated" when describing events associated with atezolizumab; 4) Language was added to clarify that, after withdrawal of consent for participation in the Roche Clinical Repository (RCR), remaining RCR samples were destroyed or were no longer linked to the participant; 5) To address a request by the French National Agency for the Safety of Medicines and Health Products, language regarding atezolizumab risks was revised to remove the description and management guidelines for systemic immune activation and added descriptions and management guidelines for hemophagocytic lymphohistiocytosis and macrophage activation syndrome; 6) Language was revised to account for the fact that some sites did not allow follow-up on partner pregnancies; 7) Language was updated to indicate that therapeutic or elective abortions were not considered AEs unless performed because of an underlying maternal or embryofetal toxicity; 8) Language was added for consistency with Roche's current data retention policy and to accommodate more stringent local requirements (if applicable); 9) Language was added to indicate that the study would comply with applicable local, regional, and national laws; 10) Language was revised to clarify that redacted Clinical Study Reports and other summary reports would be made available upon request; 11) Appendix 7 (Anaphylaxis Precautions) was modified to remove the requirement for use of a tourniquet; 12) Guidelines for managing participants who experienced atezolizumab-associated AEs was provided in Appendix 10.</p> |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

Notes:

## Interruptions (globally)

Were there any global interruptions to the trial? No

## Limitations and caveats

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

Enrollment for this study was stopped early as the Sponsor chose not to claim superiority over existing therapies.

Notes: