



## Clinical trial results:

### A Phase 2, Open-Label, Single-Arm Study to Evaluate the Efficacy and Safety of Camidanlumab Tesirine (ADCT-301) in Patients with Relapsed or Refractory Hodgkin Lymphoma

#### Summary

|                          |                            |
|--------------------------|----------------------------|
| EudraCT number           | 2018-002556-32             |
| Trial protocol           | DE BE PL FR CZ HU ES GB IT |
| Global end of trial date | 19 January 2023            |

#### Results information

|                                |                  |
|--------------------------------|------------------|
| Result version number          | v1               |
| This version publication date  | 01 February 2024 |
| First version publication date | 01 February 2024 |

#### Trial information

##### Trial identification

|                       |              |
|-----------------------|--------------|
| Sponsor protocol code | ADCT-301-201 |
|-----------------------|--------------|

##### Additional study identifiers

|                                    |                    |
|------------------------------------|--------------------|
| ISRCTN number                      | -                  |
| ClinicalTrials.gov id (NCT number) | NCT04052997        |
| WHO universal trial number (UTN)   | -                  |
| Other trial identifiers            | IND number: 121912 |

Notes:

##### Sponsors

|                              |   |
|------------------------------|---|
| Sponsor organisation name    | ADC Therapeutics SA   |
| Sponsor organisation address | Route de la Corniche, 3B, Epalinges, Switzerland, 1066                                  |
| Public contact               | Clinical Trials Information, ADC Therapeutics SA,<br>clinicaltrials@adctherapeutics.com |
| Scientific contact           | Clinical Trials Information, ADC Therapeutics SA,<br>clinicaltrials@adctherapeutics.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                       | 19 January 2023 |
| Is this the analysis of the primary completion data? | No              |
| Global end of trial reached?                         | Yes             |
| Global end of trial date                             | 19 January 2023 |
| Was the trial ended prematurely?                     | No              |

Notes:

## General information about the trial

Main objective of the trial:

Evaluate the efficacy of single agent camidanlumab tesirine in participants with relapsed or refractory Hodgkin Lymphoma.

Protection of trial subjects:

Before initiating the study, an Investigator was required to have written and dated approval from the appropriate Institutional Review Board (IRB)/Independent Ethics Committee (IEC) for the study protocol, (i.e., a review panel responsible for ensuring the protection of the rights, safety, and well being of human participants involved in a clinical investigation, which was adequately constituted to provide assurance of that protection) according to local regulations. The IECs/IRBs were transparent in their functioning, independent of the researcher, the Sponsor, and any other undue influence, and duly qualified. All protocol amendments were reviewed and approved as required according to local regulations, prior to implementation. Other study documents subject to review during the study, including, but not limited to, serious adverse event (SAE) reports and other safety reports, were also submitted to the IEC/IRB.

Background therapy: -

Evidence for comparator: -

|   |                   |
|---|-------------------|
| Actual start date of recruitment                          | 13 September 2019 |
| Long term follow-up planned                               | Yes               |
| Long term follow-up rationale                             | Safety, Efficacy  |
| Long term follow-up duration                              | 3 Years           |
| Independent data monitoring committee (IDMC) involvement? | Yes               |

Notes:

## Population of trial subjects

### Subjects enrolled per country

|                                      |                    |
|--------------------------------------|--------------------|
| Country: Number of subjects enrolled | Canada: 6          |
| Country: Number of subjects enrolled | United States: 50  |
| Country: Number of subjects enrolled | Spain: 8           |
| Country: Number of subjects enrolled | United Kingdom: 13 |
| Country: Number of subjects enrolled | Belgium: 2         |
| Country: Number of subjects enrolled | Czechia: 3         |
| Country: Number of subjects enrolled | France: 5          |
| Country: Number of subjects enrolled | Hungary: 3         |
| Country: Number of subjects enrolled | Italy: 27          |
| Worldwide total number of subjects   | 117                |
| EEA total number of subjects         | 48                 |

Notes:

| <b>Subjects enrolled per age group</b>    |    |
|---|----|
| 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)                      | 99 |
| From 65 to 84 years                       | 17 |
| 85 years and over                         | 1  |

## Subject disposition

### Recruitment

Recruitment details:

Participants were enrolled from September 2019 to January 2023 across 9 countries (USA, Canada, Belgium, Czech Republic, France, Hungary, Italy, Spain, UK).

### Pre-assignment

Screening details:

Participants with relapsed or refractory Hodgkin Lymphoma received intravenous (IV) infusions of camidanlumab tesirine.

### Period 1

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

### Arms

|           |                       |
|-----------|-----------------------|
| Arm title | Camidanlumab Tesirine |
|-----------|-----------------------|

Arm description:

All participants received intravenous (IV) infusions of camidanlumab tesirine every 3 weeks (Q3W) at a dose of 45 µg/kg on Day 1 of each cycle (one cycle = 21 days) for 2 cycles, followed by 30 µg/kg for subsequent cycles.

|  |                       |
|--|-----------------------|
| Arm type                               | Experimental          |
| Investigational medicinal product name | Camidanlumab Tesirine |
| Investigational medicinal product code |                       |
| Other name                             | ADCT-301              |
| Pharmaceutical forms                   | Infusion              |
| Routes of administration               | Intravenous use       |

Dosage and administration details:

IV Infusion.

| Number of subjects in period 1 | Camidanlumab Tesirine |
|--------------------------------|-----------------------|
| Started                        | 117                   |
| Completed                      | 1                     |
| Not completed                  | 116                   |
| Consent withdrawn by subject   | 17                    |
| Physician decision             | 50                    |
| Progression of Disease         | 1                     |
| Death                          | 43                    |
| Lost to follow-up              | 5                     |

## Baseline characteristics

### Reporting groups

|                       |                       |
|-----------------------|-----------------------|
| Reporting group title | Camidanlumab Tesirine |
|-----------------------|-----------------------|

Reporting group description:

All participants received intravenous (IV) infusions of camidanlumab tesirine every 3 weeks (Q3W) at a dose of 45 µg/kg on Day 1 of each cycle (one cycle = 21 days) for 2 cycles, followed by 30 µg/kg for subsequent cycles.

| Reporting group values  | Camidanlumab<br>Tesirine | Total |  |
|---|--------------------------|-------|--|
| Number of subjects  | 117                      | 117   |  |
| Age categorical<br>Units: Subjects                                    |                          |       |  |
| In utero  | 0                        | 0     |  |
| Preterm newborn infants<br>(gestational age < 37 wks)                 | 0                        | 0     |  |
| Newborns (0-27 days)  | 0                        | 0     |  |
| Infants and toddlers (28 days-23<br>months)                           | 0                        | 0     |  |
| Children (2-11 years)   | 0                        | 0     |  |
| Adolescents (12-17 years)   | 0                        | 0     |  |
| Adults (18-64 years)  | 99                       | 99    |  |
| From 65-84 years  | 17                       | 17    |  |
| 85 years and over   | 1                        | 1     |  |
| Age continuous<br>Units: years  |                          |       |  |
| arithmetic mean   | 42.5                     |       |  |
| standard deviation  | ± 16.24                  | -     |  |
| Gender categorical<br>Units: Subjects                                 |                          |       |  |
| Female  | 44                       | 44    |  |
| Male  | 73                       | 73    |  |
| Ethnicity (NIH/ OMB)<br>Units: Subjects                               |                          |       |  |
| Hispanic or Latino  | 7                        | 7     |  |
| Not Hispanic or Latino  | 104                      | 104   |  |
| Unknown or Not Reported   | 6                        | 6     |  |
| Race (NIH/OMB)<br>Units: Subjects                                     |                          |       |  |
| American Indian or Alaska Native                                      | 0                        | 0     |  |
| Asian   | 3                        | 3     |  |
| Native Hawaiian or Other Pacific<br>Islander                          | 1                        | 1     |  |
| Black or African American   | 5                        | 5     |  |
| White   | 101                      | 101   |  |
| Missing   | 2                        | 2     |  |
| Other   | 5                        | 5     |  |
| Eastern Cooperative Oncology Group<br>(ECOG) Performance Status Score |                          |       |  |

The ECOG Performance Status is a scale used to assess a person's level of functioning in terms of their ability to care for themselves, daily activity, and physical ability. The scale consists of 6 grades, ranging

from 0 to 5. A grade of 0 indicates the person is fully active and able to carry on as normal, and a grade of 5 indicates death.

| Units: Subjects |    |    |  |
|-----------------|----|----|--|
| ECOG Score 0    | 64 | 64 |  |
| ECOG Score 1    | 47 | 47 |  |
| ECOG Score 2    | 6  | 6  |  |
| ECOG Score 3    | 0  | 0  |  |

## End points

### End points reporting groups

|  |                       |
|--|-----------------------|
| Reporting group title  | Camidanlumab Tesirine |
| Reporting group description:<br>All participants received intravenous (IV) infusions of camidanlumab tesirine every 3 weeks (Q3W) at a dose of 45 µg/kg on Day 1 of each cycle (one cycle = 21 days) for 2 cycles, followed by 30 µg/kg for subsequent cycles. |                       |

### Primary: Overall Response Rate (ORR)

|  |  |
|--|--|
| End point title  | Overall Response Rate (ORR) <sup>[1]</sup> |
| End point description:<br>ORR according to the 2014 Lugano classification as determined by central review in all-treated participants. ORR will be defined as the proportion of participants with a best overall response (BOR) of complete response (CR) or partial response (PR). All-Treated Population: All participants who received at least 1 dose of camidanlumab tesirine. This population was used in the primary analyses of efficacy and safety. |  |
| End point type   | Primary                                    |
| End point timeframe:<br>Up to 3 years  |  |
| Notes:<br>[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.<br>Justification: No additional statistical analyses were pre-specified for this endpoint.   |  |

| End point values             | Camidanlumab Tesirine |  |  |  |
|------------------------------|-----------------------|--|--|--|
| Subject group type           | Reporting group       |  |  |  |
| Number of subjects analysed  | 117                   |  |  |  |
| Units: Count of Participants | 82                    |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: CR Rate

|  |           |
|--|-----------|
| End point title  | CR Rate   |
| End point description:<br>CR rate defined as the percentage of treated participants with a BOR of CR. All-Treated Population: All participants who received at least 1 dose of camidanlumab tesirine. This population was used in the primary analyses of efficacy and safety. |           |
| End point type   | Secondary |
| End point timeframe:<br>Up to 3 years  |           |

|                              |                          |  |  |  |
|------------------------------|--------------------------|--|--|--|
| <b>End point values</b>      | Camidanlumab<br>Tesirine |  |  |  |
| Subject group type           | Reporting group          |  |  |  |
| Number of subjects analysed  | 117                      |  |  |  |
| Units: Count of Participants | 39                       |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Duration of Response (DOR)

|  |                            |
|--|----------------------------|
| End point title  | Duration of Response (DOR) |
| End point description:<br>DOR defined as the time from the first documentation of tumor response to disease progression or death. All-Treated Population: All participants who received at least 1 dose of camidanlumab tesirine. This population was used in the primary analyses of efficacy and safety. |                            |
| End point type   | Secondary                  |
| End point timeframe:<br>Up to 3 years  |                            |

|                                  |                          |  |  |  |
|----------------------------------|--------------------------|--|--|--|
| <b>End point values</b>          | Camidanlumab<br>Tesirine |  |  |  |
| Subject group type               | Reporting group          |  |  |  |
| Number of subjects analysed      | 82                       |  |  |  |
| Units: Months                    |                          |  |  |  |
| median (confidence interval 95%) | 13.73 (7.85 to<br>14.65) |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of Participants Who Received Hematopoietic Stem Cell Transplant (HSCT)

|   |   |
|---|---|
| End point title   | Number of Participants Who Received Hematopoietic Stem Cell Transplant (HSCT) |
| End point description:<br>Participants receiving HSCT following camidanlumab tesirine, and without any other anticancer therapy in between, other than the therapies preparing for HSCT, were included in this analysis. All-Treated Population: All participants who received at least 1 dose of camidanlumab tesirine. This population was used in the primary analyses of efficacy and safety. |   |
| End point type  | Secondary   |
| End point timeframe:<br>Up to 3 years   |   |



|                              |                          |  |  |  |
|------------------------------|--------------------------|--|--|--|
| <b>End point values</b>      | Camidanlumab<br>Tesirine |  |  |  |
| Subject group type           | Reporting group          |  |  |  |
| Number of subjects analysed  | 117                      |  |  |  |
| Units: Count of Participants | 18                       |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of Participants Who Experienced At Least One Treatment-emergent Adverse Event (TEAE)

|                 |   |
|-----------------|---|
| End point title | Number of Participants Who Experienced At Least One Treatment-emergent Adverse Event (TEAE) |
|-----------------|---|

End point description:

An adverse event (AE) is defined as any untoward medical occurrence in a patient or clinical investigation participant administered a pharmaceutical product, which does not necessarily have to have a causal relationship with this treatment. A TEAE is defined as an AE that occurs or worsens in the period extending from the first dose of study drug to 30 days after the last dose of study drug in this study or start of a new anticancer therapy/procedure, whichever comes earlier. Clinically significant changes in vital signs, clinical laboratory results, and electrocardiogram were reported as adverse events. All-Treated Population: All participants who received at least 1 dose of camidanlumab tesirine. This population was used in the primary analyses of efficacy and safety.

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

End point timeframe:

Up to 3 years

|                              |                          |  |  |  |
|------------------------------|--------------------------|--|--|--|
| <b>End point values</b>      | Camidanlumab<br>Tesirine |  |  |  |
| Subject group type           | Reporting group          |  |  |  |
| Number of subjects analysed  | 117                      |  |  |  |
| Units: Count of Participants | 116                      |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of Participants Who Experienced At Least One Serious Adverse Event (SAE)

|                 |   |
|-----------------|---|
| End point title | Number of Participants Who Experienced At Least One Serious Adverse Event (SAE) |
|-----------------|---|

End point description:

An SAE is defined as any AE that:

- results in death

- is life threatening
- requires inpatient hospitalization or prolongation of existing hospitalization (hospitalization for elective procedures or for protocol compliance is not considered an SAE)
- results in persistent or significant disability/incapacity
- is a congenital anomaly/birth defect
- important medical events that do not meet the preceding criteria but based on appropriate medical judgement may jeopardize the participant or may require medical or surgical intervention to prevent any of the outcomes listed above.

Clinically significant changes in vital signs, clinical laboratory results, and electrocardiogram were reported as adverse events. All-Treated Population: All participants who received at least 1 dose of camidanlumab tesirine. This population was used in the primary analyses of efficacy and safety.

|                      |           |
|----------------------|-----------|
| End point type       | Secondary |
| End point timeframe: |           |
| Up to 3 years        |           |

|                              |                          |  |  |  |
|------------------------------|--------------------------|--|--|--|
| <b>End point values</b>      | Camidanlumab<br>Tesirine |  |  |  |
| Subject group type           | Reporting group          |  |  |  |
| Number of subjects analysed  | 117                      |  |  |  |
| Units: Count of Participants | 46                       |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Overall Survival (OS)

|                 |                       |
|-----------------|-----------------------|
| End point title | Overall Survival (OS) |
|-----------------|-----------------------|

End point description:

OS defined as the time from first dose of study drug until death due to any cause. All-Treated Population: All participants who received at least 1 dose of camidanlumab tesirine. This population was used in the primary analyses of efficacy and safety. Values of "99999" indicate median and confidence intervals were not reached due to lack of events.

|                      |           |
|----------------------|-----------|
| End point type       | Secondary |
| End point timeframe: |           |
| Up to 3 years        |           |

|                                  |                           |  |  |  |
|----------------------------------|---------------------------|--|--|--|
| <b>End point values</b>          | Camidanlumab<br>Tesirine  |  |  |  |
| Subject group type               | Reporting group           |  |  |  |
| Number of subjects analysed      | 117                       |  |  |  |
| Units: Months                    |                           |  |  |  |
| median (confidence interval 95%) | 99999 (99999<br>to 99999) |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of Participants with ECOG Performance Status Score of 0-3 at the End of Trial (EOT)

|                 |  |
|-----------------|--|
| End point title | Number of Participants with ECOG Performance Status Score of 0-3 at the End of Trial (EOT) |
|-----------------|--|

End point description:

The ECOG Performance Status is a scale used to assess a person's level of functioning in terms of their ability to care for themselves, daily activity, and physical ability. The scale consists of 6 grades, ranging from 0 to 5. A grade of 0 indicates the person is fully active and able to carry on as normal, and a grade of 5 indicates death. All-Treated Population: All participants who received at least 1 dose of camidanlumab tesirine. This population was used in the primary analyses of efficacy and safety.

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

End point timeframe:

EoT (up to 3 years)

|                              |                          |  |  |  |
|------------------------------|--------------------------|--|--|--|
| <b>End point values</b>      | Camidanlumab<br>Tesirine |  |  |  |
| Subject group type           | Reporting group          |  |  |  |
| Number of subjects analysed  | 117                      |  |  |  |
| Units: Count of Participants |                          |  |  |  |
| Score 0                      | 43                       |  |  |  |
| Score 1                      | 37                       |  |  |  |
| Score 2                      | 12                       |  |  |  |
| Score 3                      | 4                        |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Relapse-Free Survival (RFS)

|                 |                             |
|-----------------|-----------------------------|
| End point title | Relapse-Free Survival (RFS) |
|-----------------|-----------------------------|

End point description:

RFS defined as the time from the documentation of CR to disease progression or death. All-Treated Population: All participants who received at least 1 dose of camidanlumab tesirine. This population was used in the primary analyses of efficacy and safety. Values of "99999" indicate the upper confidence interval was not reached due to lack of events.

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

End point timeframe:

Up to 3 years

|                                    |                          |  |  |  |
|------------------------------------|--------------------------|--|--|--|
| <b>End point values</b>            | Camidanlumab<br>Tesirine |  |  |  |
| Subject group type                 | Reporting group          |  |  |  |
| Number of subjects analysed        | 39                       |  |  |  |
| Units: Relapse-Free Survival (RFS) |                          |  |  |  |
| median (confidence interval 95%)   | 11.07 (7.36 to<br>99999) |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Progression-Free Survival (PFS)

|  |                                 |
|--|---------------------------------|
| End point title  | Progression-Free Survival (PFS) |
| End point description:<br>PFS defined as the time from first dose of study drug until the first date of either disease progression or death due to any cause. All-Treated Population: All participants who received at least 1 dose of camidanlumab tesirine. This population was used in the primary analyses of efficacy and safety. |                                 |
| End point type   | Secondary                       |
| End point timeframe:<br>Up to 3 years  |                                 |

|                                  |                          |  |  |  |
|----------------------------------|--------------------------|--|--|--|
| <b>End point values</b>          | Camidanlumab<br>Tesirine |  |  |  |
| Subject group type               | Reporting group          |  |  |  |
| Number of subjects analysed      | 117                      |  |  |  |
| Units: Months                    |                          |  |  |  |
| median (confidence interval 95%) | 9.13 (5.26 to<br>14.98)  |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Maximum Observed Plasma Concentration (Cmax) of Camidanlumab Tesirine Total Antibody, PBD-Conjugated Antibody, and Unconjugated Warhead SG3199

|                 |  |
|-----------------|--|
| End point title | Maximum Observed Plasma Concentration (Cmax) of<br>Camidanlumab Tesirine Total Antibody, PBD-Conjugated<br>Antibody, and Unconjugated Warhead SG3199 |
|-----------------|--|

End point description:

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

End point timeframe:

Cycle 1 and 2: Day 1 (pre-dose, EOI and post-dose), Day 8 and Day 15. Cycles 3 to 6: Day 1 (pre-dose and EOI). For remaining cycles: Day 1 (pre-dose) of each cycle until EOT, maximum of 30 days after the last dose of study drug. Each cycle is 21 days.

|   |                          |  |  |  |
|---|--------------------------|--|--|--|
| <b>End point values</b>                             | Camidanlumab<br>Tesirine |  |  |  |
| Subject group type                                  | Reporting group          |  |  |  |
| Number of subjects analysed                         | 114                      |  |  |  |
| Units: µg/L   |                          |  |  |  |
| geometric mean (geometric coefficient of variation) |                          |  |  |  |
| Cycle 1 - Total Antibody                            | 825 (± 66.7)             |  |  |  |
| Cycle 1 - Conjugated Antibody                       | 696 (± 66.5)             |  |  |  |
| Cycle 1 - SG3199                                    | 0.0170 (± 31.6)          |  |  |  |
| Cycle 2 - Total Antibody                            | 792 (± 62.3)             |  |  |  |
| Cycle 2 - Conjugated Antibody                       | 685 (± 61.7)             |  |  |  |
| Cycle 2 - SG3199                                    | 0.0180 (± 38.3)          |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Area Under the Plasma Concentration-Time Curve From Time 0 to the End of the Dosing Interval (AUC<sub>tau</sub>) For Camidanlumab Tesirine Total Antibody, PBD-Conjugated Antibody, and Unconjugated Warhead SG3199

|                 |   |
|-----------------|---|
| End point title | Area Under the Plasma Concentration-Time Curve From Time 0 to the End of the Dosing Interval (AUC <sub>tau</sub> ) For Camidanlumab Tesirine Total Antibody, PBD-Conjugated Antibody, and Unconjugated Warhead SG3199 |
|-----------------|---|

End point description:

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

End point timeframe:

Cycle 2: Day 1 (pre-dose, EOI and post-dose), Day 8 and Day 15. Cycles 3 to 6: Day 1 (pre-dose and EOI). For remaining cycles: Day 1 (pre-dose) of each cycle until EOT, maximum of 30 days after the last dose of study drug. Each cycle is 21 days.

|   |                          |  |  |  |
|---|--------------------------|--|--|--|
| <b>End point values</b>                             | Camidanlumab<br>Tesirine |  |  |  |
| Subject group type                                  | Reporting group          |  |  |  |
| Number of subjects analysed                         | 114                      |  |  |  |
| Units: day*ug/L                                     |                          |  |  |  |
| geometric mean (geometric coefficient of variation) |                          |  |  |  |
| Cycle 2 - Total Antibody                            | 4037 ( $\pm$ 73.2)       |  |  |  |
| Cycle 2 - Conjugated Antibody                       | 3067 ( $\pm$ 65.8)       |  |  |  |
| Cycle 2 - SG3199                                    | 0 ( $\pm$ 0)             |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Area Under the Plasma Concentration-Time Curve From Time 0 to Infinity (AUCinf) For Camidanlumab Tesirine Total Antibody, PBD-Conjugated Antibody, and Unconjugated Warhead SG3199

|                 |  |
|-----------------|--|
| End point title | Area Under the Plasma Concentration-Time Curve From Time 0 to Infinity (AUCinf) For Camidanlumab Tesirine Total Antibody, PBD-Conjugated Antibody, and Unconjugated Warhead SG3199 |
|-----------------|--|

End point description:

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

End point timeframe:

Cycle 1: Day 1 (pre-dose, EOI and post-dose), Day 8 and Day 15. Cycles 3 to 6: Day 1 (pre-dose and EOI). For remaining cycles: Day 1 (pre-dose) of each cycle until EOT, maximum of 30 days after the last dose of study drug. Each cycle is 21 days.

|   |                          |  |  |  |
|---|--------------------------|--|--|--|
| <b>End point values</b>                             | Camidanlumab<br>Tesirine |  |  |  |
| Subject group type                                  | Reporting group          |  |  |  |
| Number of subjects analysed                         | 8                        |  |  |  |
| Units: day*µg/L                                     |                          |  |  |  |
| geometric mean (geometric coefficient of variation) |                          |  |  |  |
| Cycle 1 - Total Antibody                            | 6473 ( $\pm$ 11.9)       |  |  |  |
| Cycle 1 - Conjugated Antibody                       | 5478 ( $\pm$ 31.2)       |  |  |  |
| Cycle 1 - SG3199                                    | 0 ( $\pm$ 0)             |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Area Under the Plasma Concentration-Time Curve From Time 0 to the Time of the Last Quantifiable Concentration (AUClast) For Camidanlumab Tesirine Total Antibody, PBD-Conjugated Antibody, and Unconjugated Warhead SG3199

|                 |  |
|-----------------|--|
| End point title | Area Under the Plasma Concentration-Time Curve From Time 0 to the Time of the Last Quantifiable Concentration (AUClast) For Camidanlumab Tesirine Total Antibody, PBD-Conjugated Antibody, and Unconjugated Warhead SG3199 |
|-----------------|--|

End point description:

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

End point timeframe:

Cycle 1 and 2: Day 1 (pre-dose, EOI and post-dose), Day 8 and Day 15. Cycles 3 to 6: Day 1 (pre-dose and EOI). For remaining cycles: Day 1 (pre-dose) of each cycle until EOT, maximum of 30 days after the last dose of study drug. Each cycle is 21 days.

| End point values                                    | Camidanlumab Tesirine |  |  |  |
|---|-----------------------|--|--|--|
| Subject group type                                  | Reporting group       |  |  |  |
| Number of subjects analysed                         | 114                   |  |  |  |
| Units: day*ug/L                                     |                       |  |  |  |
| geometric mean (geometric coefficient of variation) |                       |  |  |  |
| Cycle 1 - Total Antibody                            | 489 (± 788)           |  |  |  |
| Cycle 1 - Conjugated Antibody                       | 345 (± 607)           |  |  |  |
| Cycle 1 - SG3199                                    | 0 (± 104)             |  |  |  |
| Cycle 2 - Total Antibody                            | 725 (± 897)           |  |  |  |
| Cycle 2 - Conjugated Antibody                       | 497 (± 824)           |  |  |  |
| Cycle 2 - SG3199                                    | 0 (± 211)             |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Clearance at Steady State (CLss) For Camidanlumab Tesirine Total Antibody, PBD-Conjugated Antibody, and Unconjugated Warhead SG3199

|                 |   |
|-----------------|---|
| End point title | Clearance at Steady State (CLss) For Camidanlumab Tesirine Total Antibody, PBD-Conjugated Antibody, and Unconjugated Warhead SG3199 |
|-----------------|---|

End point description:

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

End point timeframe:

Cycle 2: Day 1 (pre-dose, EOI and post-dose), Day 8 and Day 15. Cycles 3 to 6: Day 1 (pre-dose and EOI). For remaining cycles: Day 1 (pre-dose) of each cycle until EOT, maximum of 30 days after the last dose of study drug. Each cycle is 21 days.

|   |                          |  |  |  |
|---|--------------------------|--|--|--|
| <b>End point values</b>                             | Camidanlumab<br>Tesirine |  |  |  |
| Subject group type                                  | Reporting group          |  |  |  |
| Number of subjects analysed                         | 55                       |  |  |  |
| Units: L/day  |                          |  |  |  |
| geometric mean (geometric coefficient of variation) |                          |  |  |  |
| Total Antibody                                      | 0.874 (± 75.6)           |  |  |  |
| Conjugated Antibody                                 | 0.958 (± 64.1)           |  |  |  |
| SG3199  | 0 (± 0)                  |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Clearance (CL) For Camidanlumab Tesirine Total Antibody, PBD-Conjugated Antibody, and Unconjugated Warhead SG3199

|                 |   |
|-----------------|---|
| End point title | Clearance (CL) For Camidanlumab Tesirine Total Antibody, PBD-Conjugated Antibody, and Unconjugated Warhead SG3199 |
|-----------------|---|

End point description:

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

End point timeframe:

Cycle 1: Day 1 (pre-dose, EOI and post-dose), Day 8 and Day 15. Cycles 3 to 6: Day 1 (pre-dose and EOI). For remaining cycles: Day 1 (pre-dose) of each cycle until EOT, maximum of 30 days after the last dose of study drug. Each cycle is 21 days.

|   |                          |  |  |  |
|---|--------------------------|--|--|--|
| <b>End point values</b>                             | Camidanlumab<br>Tesirine |  |  |  |
| Subject group type                                  | Reporting group          |  |  |  |
| Number of subjects analysed                         | 8                        |  |  |  |
| Units: L/day  |                          |  |  |  |
| geometric mean (geometric coefficient of variation) |                          |  |  |  |
| Cycle 1 - Total antibody                            | 0.556 (± 47.9)           |  |  |  |
| Cycle 1 - Conjugated Antibody                       | 0.733 (± 34.7)           |  |  |  |
| Cycle 1 - SG3199                                    | 0 (± 0)                  |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Apparent Terminal Elimination Half-Life (T1/2) For Camidanlumab Tesirine Total Antibody, PBD-Conjugated Antibody, and Unconjugated Warhead SG3199

|                 |   |
|-----------------|---|
| End point title | Apparent Terminal Elimination Half-Life (T1/2) For Camidanlumab Tesirine Total Antibody, PBD-Conjugated |
|-----------------|---|



End point description:

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

End point timeframe:

Cycle 1 and 2: Day 1 (pre-dose, EOI and post-dose), Day 8 and Day 15. Cycles 3 to 6: Day 1 (pre-dose and EOI). For remaining cycles: Day 1 (pre-dose) of each cycle until EOT, maximum of 30 days after the last dose of study drug. Each cycle is 21 days.

|   |                          |  |  |  |
|---|--------------------------|--|--|--|
| <b>End point values</b>                             | Camidanlumab<br>Tesirine |  |  |  |
| Subject group type                                  | Reporting group          |  |  |  |
| Number of subjects analysed                         | 8                        |  |  |  |
| Units: day  |                          |  |  |  |
| geometric mean (geometric coefficient of variation) |                          |  |  |  |
| Cycle 1 - Total Antibody                            | 5.91 ( $\pm$ 68.6)       |  |  |  |
| Cycle 1 - Conjugated Antibody                       | 3.89 ( $\pm$ 17.5)       |  |  |  |
| Cycle 1 - SG3199                                    | 0 ( $\pm$ 0)             |  |  |  |
| Cycle 2 - Total Antibody                            | 4.46 ( $\pm$ 24.6)       |  |  |  |
| Cycle 2 - Conjugated Antibody                       | 4.05 ( $\pm$ 26.1)       |  |  |  |
| Cycle 2 - SG3199                                    | 0 ( $\pm$ 0)             |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Volume of Distribution at Steady State (Vss) For Camidanlumab Tesirine Total Antibody, PBD-Conjugated Antibody, and Unconjugated Warhead SG3199

|                 |   |
|-----------------|---|
| End point title | Volume of Distribution at Steady State (Vss) For Camidanlumab Tesirine Total Antibody, PBD-Conjugated Antibody, and Unconjugated Warhead SG3199 |
|-----------------|---|

End point description:

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

End point timeframe:

Cycle 1 and 2: Day 1 (pre-dose, EOI and post-dose), Day 8 and Day 15. Cycles 3 to 6: Day 1 (pre-dose and EOI). For remaining cycles: Day 1 (pre-dose) of each cycle until EOT, maximum of 30 days after the last dose of study drug. Each cycle is 21 days.

|   |                          |  |  |  |
|---|--------------------------|--|--|--|
| <b>End point values</b>                             | Camidanlumab<br>Tesirine |  |  |  |
| Subject group type                                  | Reporting group          |  |  |  |
| Number of subjects analysed                         | 8                        |  |  |  |
| Units: Liters                                       |                          |  |  |  |
| geometric mean (geometric coefficient of variation) |                          |  |  |  |
| Cycle 1 - Total Antibody                            | 5.91 (± 68.6)            |  |  |  |
| Cycle 1 - Conjugated Antibody                       | 2.81 (± 24.9)            |  |  |  |
| Cycle 1 - SG3199                                    | 0 (± 0)                  |  |  |  |
| Cycle 2 - Total Antibody                            | 3.14 (± 44.1)            |  |  |  |
| Cycle 2 - Conjugated Antibody                       | 3.17 (± 37.6)            |  |  |  |
| Cycle 2 SG3199                                      | 0 (± 0)                  |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Accumulation Index (AI) For Camidanlumab Tesirine Total Antibody, PBD-Conjugated Antibody, and Unconjugated Warhead SG3199

|                 |  |
|-----------------|--|
| End point title | Accumulation Index (AI) For Camidanlumab Tesirine Total Antibody, PBD-Conjugated Antibody, and Unconjugated Warhead SG3199 |
|-----------------|--|

End point description:

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

End point timeframe:

Cycle 2: Day 1 (pre-dose, EOI and post-dose), Day 8 and Day 15. Cycles 3 to 6: Day 1 (pre-dose and EOI). For remaining cycles: Day 1 (pre-dose) of each cycle until EOT, maximum of 30 days after the last dose of study drug. Each cycle is 21 days.

|   |                          |  |  |  |
|---|--------------------------|--|--|--|
| <b>End point values</b>                             | Camidanlumab<br>Tesirine |  |  |  |
| Subject group type                                  | Reporting group          |  |  |  |
| Number of subjects analysed                         | 8                        |  |  |  |
| Units: AI   |                          |  |  |  |
| geometric mean (geometric coefficient of variation) |                          |  |  |  |
| Total Antibody                                      | 1.30 (± 52.9)            |  |  |  |
| Conjugated Antibody                                 | 1.04 (± 4.00)            |  |  |  |
| SG3199  | 0 (± 0)                  |  |  |  |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Number of Participants With Confirmed Positive Anti-Drug Antibody (ADA) Responses

|  |   |
|--|---|
| End point title  | Number of Participants With Confirmed Positive Anti-Drug Antibody (ADA) Responses |
| End point description:<br>Detection of ADAs was performed by using a screening assay for identification of antibody positive samples/participants, a confirmation assay, and titer assessment. |   |
| End point type   | Secondary   |
| End point timeframe:<br>Up to 3 years  |   |

|                              |                          |  |  |  |
|------------------------------|--------------------------|--|--|--|
| <b>End point values</b>      | Camidanlumab<br>Tesirine |  |  |  |
| Subject group type           | Reporting group          |  |  |  |
| Number of subjects analysed  | 117                      |  |  |  |
| Units: Count of Participants | 2                        |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Health-Related Quality of Life (HRQoL) as Measured by EuroQoL-5 Dimensions-5 Levels (EQ-5D-5L) Visual Analog Scale (VAS)

|  |  |
|--|--|
| End point title  | Change From Baseline in Health-Related Quality of Life (HRQoL) as Measured by EuroQoL-5 Dimensions-5 Levels (EQ-5D-5L) Visual Analog Scale (VAS) |
| End point description:<br>Participants were asked to indicate their health state on a VAS with scores ranging from 'the worst health you can imagine' (score 0) to 'the best health you can imagine' (score 100). Participants are asked to mark an "X" on the VAS to indicate their own health and then to report the score in a text box. Positive changes from Baseline represent an improvement in health. Patient Reported Outcome (PRO)<br>Population: All participants in the all-treated patients with baseline score (at least one instrument) and at least 1 post-baseline score (in at least one instrument). |  |
| End point type   | Secondary  |
| End point timeframe:<br>Baseline, Day 1 of Cycles 2 to 15 (one cycle = 21 days) and EOT (up to 3 years)  |  |

|                                      |                          |  |  |  |
|--------------------------------------|--------------------------|--|--|--|
| <b>End point values</b>              | Camidanlumab<br>Tesirine |  |  |  |
| Subject group type                   | Reporting group          |  |  |  |
| Number of subjects analysed          | 116                      |  |  |  |
| Units: Score on a scale              |                          |  |  |  |
| arithmetic mean (standard deviation) |                          |  |  |  |
| Cycle 2 (n = 111)                    | 3.6 (± 14.41)            |  |  |  |
| Cycle 3 (n = 90)                     | 5.2 (± 15.14)            |  |  |  |
| Cycle 4 (n = 74)                     | 4.9 (± 17.65)            |  |  |  |
| Cycle 5 (n = 62)                     | 4.6 (± 19.66)            |  |  |  |

|                   |                |  |  |  |
|-------------------|----------------|--|--|--|
| Cycle 6 (n = 44)  | -1.2 (± 14.97) |  |  |  |
| Cycle 7 (n = 32)  | 4.5 (± 11.88)  |  |  |  |
| Cycle 8 (n = 19)  | 4.5 (± 13.24)  |  |  |  |
| Cycle 9 (n = 17)  | 3.3 (± 13.74)  |  |  |  |
| Cycle 10 (n = 11) | 1.3 (± 7.30)   |  |  |  |
| Cycle 11 (n = 7)  | -0.6 (± 10.44) |  |  |  |
| Cycle 12 (n = 6)  | -4.8 (± 5.31)  |  |  |  |
| Cycle 13 (n = 3)  | -1.7 (± 2.89)  |  |  |  |
| Cycle 14 (n = 3)  | -1.7 (± 10.41) |  |  |  |
| Cycle 15 (n = 3)  | -3.3 (± 7.64)  |  |  |  |
| EOT (n = 80)      | -3.1 (± 20.06) |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in HRQoL as Measured by Functional Assessment of Cancer Therapy - Lymphoma (FACT-Lym)

|                 |  |
|-----------------|--|
| End point title | Change From Baseline in HRQoL as Measured by Functional Assessment of Cancer Therapy - Lymphoma (FACT-Lym) |
|-----------------|--|

End point description:

The FACT-Lym consists of a 27-item general core questionnaire (i.e., Functional Assessment of Cancer Therapy - General [FACT-G]) and a 15-item disease-specific questionnaire (Lymphoma Subscale). The FACT-G includes 4 domains: physical well-being, social/family well-being, emotional well-being, and functional well-being. The total FACT Lym score (0-168) was obtained by summing individual subscale scores. Higher scores for the scales indicate better quality of life. Change was calculated as the value at the last observation minus the value at baseline. PRO Population: All participants in the all-treated patients with baseline score (at least one instrument) and at least 1 post-baseline score (in at least one instrument).

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

End point timeframe:

Baseline, Day 1 of Cycles 2 to 15 (one cycle = 21 days) and EOT (up to 3 years)

| End point values                     | Camidanlumab Tesirine |  |  |  |
|--------------------------------------|-----------------------|--|--|--|
| Subject group type                   | Reporting group       |  |  |  |
| Number of subjects analysed          | 116                   |  |  |  |
| Units: Score on a scale              |                       |  |  |  |
| arithmetic mean (standard deviation) |                       |  |  |  |
| Cycle 2 (n = 108)                    | -0.45 (± 4.079)       |  |  |  |
| Cycle 3 (n = 89)                     | -0.02 (± 4.935)       |  |  |  |
| Cycle 4 (n = 73)                     | -0.20 (± 5.384)       |  |  |  |
| Cycle 5 (n = 57)                     | -0.13 (± 4.906)       |  |  |  |
| Cycle 6 (n = 42)                     | -1.29 (± 4.318)       |  |  |  |
| Cycle 7 (n = 30)                     | 0.39 (± 3.892)        |  |  |  |
| Cycle 8 (n = 19)                     | 0.40 (± 4.419)        |  |  |  |

|                   |                 |  |  |  |
|-------------------|-----------------|--|--|--|
| Cycle 9 (n = 17)  | -1.38 (± 6.262) |  |  |  |
| Cycle 10 (n = 10) | 1.16 (± 2.374)  |  |  |  |
| Cycle 11 (n = 6)  | 1.50 (± 5.167)  |  |  |  |
| Cycle 12 (n = 5)  | -1.40 (± 0.548) |  |  |  |
| Cycle 13 (n = 2)  | 0.00 (± 0.000)  |  |  |  |
| Cycle 14 (n = 2)  | 0.00 (± 0.000)  |  |  |  |
| Cycle 15 (n = 2)  | 0.00 (± 0.000)  |  |  |  |
| EOT (n = 77)      | -3.06 (± 6.802) |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Up to 3 years

Adverse event reporting additional description:

All AEs, AESIs, and SAEs regardless of relationship to study drug were reported from the time a participant signed the ICF until 30 days after the last dose of study drug. After 30 days following the last dose of study drug, only related SAEs were reported.

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

### Dictionary used

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

|                    |       |
|--------------------|-------|
| Dictionary version | 22.0. |
|--------------------|-------|

### Reporting groups

|                       |                       |
|-----------------------|-----------------------|
| Reporting group title | Camidanlumab Tesirine |
|-----------------------|-----------------------|

Reporting group description:

All participants received intravenous (IV) infusions of camidanlumab tesirine every 3 weeks (Q3W) at a dose of 45 µg/kg on Day 1 of each cycle (one cycle = 21 days) for 2 cycles, followed by 30 µg/kg for subsequent cycles.

| Serious adverse events  | Camidanlumab<br>Tesirine |  |  |
|---|--------------------------|--|--|
| Total subjects affected by serious adverse events                   |                          |  |  |
| subjects affected / exposed   | 46 / 117 (39.32%)        |  |  |
| number of deaths (all causes)                                       | 3                        |  |  |
| number of deaths resulting from adverse events                      | 0                        |  |  |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                          |  |  |
| Cancer pain   |                          |  |  |
| subjects affected / exposed   | 1 / 117 (0.85%)          |  |  |
| occurrences causally related to treatment / all                     | 0 / 1                    |  |  |
| deaths causally related to treatment / all                          | 0 / 0                    |  |  |
| Vascular disorders  |                          |  |  |
| Shock haemorrhagic  |                          |  |  |
| subjects affected / exposed   | 1 / 117 (0.85%)          |  |  |
| occurrences causally related to treatment / all                     | 0 / 1                    |  |  |
| deaths causally related to treatment / all                          | 0 / 0                    |  |  |
| Superior vena cava occlusion  |                          |  |  |
| subjects affected / exposed   | 1 / 117 (0.85%)          |  |  |
| occurrences causally related to treatment / all                     | 0 / 1                    |  |  |
| deaths causally related to treatment / all                          | 0 / 0                    |  |  |
| General disorders and administration                                |                          |  |  |

|   |                 |  |  |
|---|-----------------|--|--|
| site conditions                                 |                 |  |  |
| Pyrexia   |                 |  |  |
| subjects affected / exposed                     | 3 / 117 (2.56%) |  |  |
| occurrences causally related to treatment / all | 1 / 3           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Respiratory, thoracic and mediastinal disorders |                 |  |  |
| Acute respiratory failure                       |                 |  |  |
| subjects affected / exposed                     | 1 / 117 (0.85%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Dyspnoea  |                 |  |  |
| subjects affected / exposed                     | 1 / 117 (0.85%) |  |  |
| occurrences causally related to treatment / all | 1 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Respiratory failure                             |                 |  |  |
| subjects affected / exposed                     | 1 / 117 (0.85%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 1           |  |  |
| Pneumonitis                                     |                 |  |  |
| subjects affected / exposed                     | 2 / 117 (1.71%) |  |  |
| occurrences causally related to treatment / all | 1 / 2           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Product issues                                  |                 |  |  |
| Device occlusion                                |                 |  |  |
| subjects affected / exposed                     | 1 / 117 (0.85%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Injury, poisoning and procedural complications  |                 |  |  |
| Transplant failure                              |                 |  |  |
| subjects affected / exposed                     | 1 / 117 (0.85%) |  |  |
| occurrences causally related to treatment / all | 1 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Cardiac disorders                               |                 |  |  |
| Acute myocardial infarction                     |                 |  |  |

|   |                 |  |  |
|---|-----------------|--|--|
| subjects affected / exposed                     | 1 / 117 (0.85%) |  |  |
| occurrences causally related to treatment / all | 1 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Cardiac arrest                                  |                 |  |  |
| subjects affected / exposed                     | 1 / 117 (0.85%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 1           |  |  |
| Myocardial infarction                           |                 |  |  |
| subjects affected / exposed                     | 1 / 117 (0.85%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 1           |  |  |
| Left ventricular failure                        |                 |  |  |
| subjects affected / exposed                     | 1 / 117 (0.85%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 1           |  |  |
| Nervous system disorders                        |                 |  |  |
| Guillain-Barre syndrome                         |                 |  |  |
| subjects affected / exposed                     | 4 / 117 (3.42%) |  |  |
| occurrences causally related to treatment / all | 4 / 4           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Epilepsy  |                 |  |  |
| subjects affected / exposed                     | 1 / 117 (0.85%) |  |  |
| occurrences causally related to treatment / all | 1 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Peripheral motor neuropathy                     |                 |  |  |
| subjects affected / exposed                     | 1 / 117 (0.85%) |  |  |
| occurrences causally related to treatment / all | 1 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Peripheral sensory neuropathy                   |                 |  |  |
| subjects affected / exposed                     | 1 / 117 (0.85%) |  |  |
| occurrences causally related to treatment / all | 1 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Radiculopathy                                   |                 |  |  |



|   |                 |  |  |
|---|-----------------|--|--|
| subjects affected / exposed                     | 1 / 117 (0.85%) |  |  |
| occurrences causally related to treatment / all | 1 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Syncope   |                 |  |  |
| subjects affected / exposed                     | 1 / 117 (0.85%) |  |  |
| occurrences causally related to treatment / all | 1 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Blood and lymphatic system disorders            |                 |  |  |
| Febrile neutropenia                             |                 |  |  |
| subjects affected / exposed                     | 1 / 117 (0.85%) |  |  |
| occurrences causally related to treatment / all | 1 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Bone marrow failure                             |                 |  |  |
| subjects affected / exposed                     | 1 / 117 (0.85%) |  |  |
| occurrences causally related to treatment / all | 1 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Gastrointestinal disorders                      |                 |  |  |
| Duodenal ulcer                                  |                 |  |  |
| subjects affected / exposed                     | 1 / 117 (0.85%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Duodenal ulcer perforation                      |                 |  |  |
| subjects affected / exposed                     | 1 / 117 (0.85%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Diarrhoea                                       |                 |  |  |
| subjects affected / exposed                     | 2 / 117 (1.71%) |  |  |
| occurrences causally related to treatment / all | 0 / 2           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Intestinal obstruction                          |                 |  |  |
| subjects affected / exposed                     | 1 / 117 (0.85%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Inguinal hernia                                 |                 |  |  |

|   |                 |  |  |
|---|-----------------|--|--|
| subjects affected / exposed                     | 1 / 117 (0.85%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Small intestinal obstruction                    |                 |  |  |
| subjects affected / exposed                     | 1 / 117 (0.85%) |  |  |
| occurrences causally related to treatment / all | 0 / 2           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Hepatobiliary disorders                         |                 |  |  |
| Drug-induced liver injury                       |                 |  |  |
| subjects affected / exposed                     | 1 / 117 (0.85%) |  |  |
| occurrences causally related to treatment / all | 1 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Skin and subcutaneous tissue disorders          |                 |  |  |
| Parakeratosis                                   |                 |  |  |
| subjects affected / exposed                     | 1 / 117 (0.85%) |  |  |
| occurrences causally related to treatment / all | 1 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Photosensitivity reaction                       |                 |  |  |
| subjects affected / exposed                     | 1 / 117 (0.85%) |  |  |
| occurrences causally related to treatment / all | 1 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Rash maculo-papular                             |                 |  |  |
| subjects affected / exposed                     | 3 / 117 (2.56%) |  |  |
| occurrences causally related to treatment / all | 3 / 3           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Eczema  |                 |  |  |
| subjects affected / exposed                     | 1 / 117 (0.85%) |  |  |
| occurrences causally related to treatment / all | 1 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Dermatosis                                      |                 |  |  |
| subjects affected / exposed                     | 1 / 117 (0.85%) |  |  |
| occurrences causally related to treatment / all | 1 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Dermatitis exfoliative generalised              |                 |  |  |

|   |                 |  |  |
|---|-----------------|--|--|
| subjects affected / exposed                     | 1 / 117 (0.85%) |  |  |
| occurrences causally related to treatment / all | 1 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Lichenoid keratosis                             |                 |  |  |
| subjects affected / exposed                     | 1 / 117 (0.85%) |  |  |
| occurrences causally related to treatment / all | 1 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Renal and urinary disorders                     |                 |  |  |
| Acute kidney injury                             |                 |  |  |
| subjects affected / exposed                     | 1 / 117 (0.85%) |  |  |
| occurrences causally related to treatment / all | 1 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Tubulointerstitial nephritis                    |                 |  |  |
| subjects affected / exposed                     | 1 / 117 (0.85%) |  |  |
| occurrences causally related to treatment / all | 1 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Endocrine disorders                             |                 |  |  |
| Thyroiditis                                     |                 |  |  |
| subjects affected / exposed                     | 1 / 117 (0.85%) |  |  |
| occurrences causally related to treatment / all | 1 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Musculoskeletal and connective tissue disorders |                 |  |  |
| Myositis  |                 |  |  |
| subjects affected / exposed                     | 1 / 117 (0.85%) |  |  |
| occurrences causally related to treatment / all | 1 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Muscular weakness                               |                 |  |  |
| subjects affected / exposed                     | 1 / 117 (0.85%) |  |  |
| occurrences causally related to treatment / all | 1 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Infections and infestations                     |                 |  |  |
| Pneumonia pneumococcal                          |                 |  |  |

|   |                 |  |  |
|---|-----------------|--|--|
| subjects affected / exposed                     | 1 / 117 (0.85%) |  |  |
| occurrences causally related to treatment / all | 1 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Lung infection                                  |                 |  |  |
| subjects affected / exposed                     | 1 / 117 (0.85%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Varicella zoster virus infection                |                 |  |  |
| subjects affected / exposed                     | 1 / 117 (0.85%) |  |  |
| occurrences causally related to treatment / all | 1 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Tooth infection                                 |                 |  |  |
| subjects affected / exposed                     | 1 / 117 (0.85%) |  |  |
| occurrences causally related to treatment / all | 1 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Rash pustular                                   |                 |  |  |
| subjects affected / exposed                     | 1 / 117 (0.85%) |  |  |
| occurrences causally related to treatment / all | 1 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Sepsis  |                 |  |  |
| subjects affected / exposed                     | 1 / 117 (0.85%) |  |  |
| occurrences causally related to treatment / all | 1 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Pneumonia bacterial                             |                 |  |  |
| subjects affected / exposed                     | 1 / 117 (0.85%) |  |  |
| occurrences causally related to treatment / all | 1 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Septic shock                                    |                 |  |  |
| subjects affected / exposed                     | 1 / 117 (0.85%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| JC virus infection                              |                 |  |  |

|   |                 |  |  |
|---|-----------------|--|--|
| subjects affected / exposed                     | 1 / 117 (0.85%) |  |  |
| occurrences causally related to treatment / all | 1 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Bronchopulmonary aspergillosis                  |                 |  |  |
| subjects affected / exposed                     | 1 / 117 (0.85%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Adenovirus infection                            |                 |  |  |
| subjects affected / exposed                     | 1 / 117 (0.85%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Pneumonia                                       |                 |  |  |
| subjects affected / exposed                     | 2 / 117 (1.71%) |  |  |
| occurrences causally related to treatment / all | 1 / 2           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Cellulitis                                      |                 |  |  |
| subjects affected / exposed                     | 2 / 117 (1.71%) |  |  |
| occurrences causally related to treatment / all | 1 / 2           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Metabolism and nutrition disorders              |                 |  |  |
| Diabetic ketoacidosis                           |                 |  |  |
| subjects affected / exposed                     | 2 / 117 (1.71%) |  |  |
| occurrences causally related to treatment / all | 2 / 2           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Type 1 diabetes mellitus                        |                 |  |  |
| subjects affected / exposed                     | 1 / 117 (0.85%) |  |  |
| occurrences causally related to treatment / all | 1 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Hyperglycaemia                                  |                 |  |  |
| subjects affected / exposed                     | 1 / 117 (0.85%) |  |  |
| occurrences causally related to treatment / all | 1 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Electrolyte imbalance                           |                 |  |  |

|   |                 |  |  |
|---|-----------------|--|--|
| subjects affected / exposed                     | 1 / 117 (0.85%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Dehydration                                     |                 |  |  |
| subjects affected / exposed                     | 1 / 117 (0.85%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Acidosis  |                 |  |  |
| subjects affected / exposed                     | 1 / 117 (0.85%) |  |  |
| occurrences causally related to treatment / all | 1 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |

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

| <b>Non-serious adverse events</b>                     | Camidanlumab<br>Tesirine |  |  |
|---|--------------------------|--|--|
| Total subjects affected by non-serious adverse events |                          |  |  |
| subjects affected / exposed                           | 112 / 117 (95.73%)       |  |  |
| Vascular disorders                                    |                          |  |  |
| Hypertension  |                          |  |  |
| subjects affected / exposed                           | 6 / 117 (5.13%)          |  |  |
| occurrences (all)                                     | 9                        |  |  |
| General disorders and administration site conditions  |                          |  |  |
| Fatigue   |                          |  |  |
| subjects affected / exposed                           | 45 / 117 (38.46%)        |  |  |
| occurrences (all)                                     | 53                       |  |  |
| Asthenia  |                          |  |  |
| subjects affected / exposed                           | 8 / 117 (6.84%)          |  |  |
| occurrences (all)                                     | 8                        |  |  |
| Chills  |                          |  |  |
| subjects affected / exposed                           | 12 / 117 (10.26%)        |  |  |
| occurrences (all)                                     | 14                       |  |  |
| Face oedema   |                          |  |  |
| subjects affected / exposed                           | 7 / 117 (5.98%)          |  |  |
| occurrences (all)                                     | 7                        |  |  |
| Oedema peripheral                                     |                          |  |  |

|   |  |  |  |
|---|--|--|--|
| <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Pyrexia</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>  | <p>14 / 117 (11.97%)</p> <p>15</p> <p>34 / 117 (29.06%)</p> <p>47</p>  |  |  |
| <p>Respiratory, thoracic and mediastinal disorders</p> <p>Dyspnoea</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Oropharyngeal pain</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Cough</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>   | <p>16 / 117 (13.68%)</p> <p>18</p> <p>10 / 117 (8.55%)</p> <p>11</p> <p>12 / 117 (10.26%)</p> <p>12</p>                                |  |  |
| <p>Psychiatric disorders</p> <p>Anxiety</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Insomnia</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>   | <p>6 / 117 (5.13%)</p> <p>8</p> <p>16 / 117 (13.68%)</p> <p>17</p>   |  |  |
| <p>Investigations</p> <p>Gamma-glutamyltransferase increased</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Amylase increased</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Alanine aminotransferase increased</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Weight decreased</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Lipase increased</p> | <p>20 / 117 (17.09%)</p> <p>26</p> <p>9 / 117 (7.69%)</p> <p>12</p> <p>15 / 117 (12.82%)</p> <p>16</p> <p>9 / 117 (7.69%)</p> <p>9</p> |  |  |

|                                      |                   |  |  |
|--------------------------------------|-------------------|--|--|
| subjects affected / exposed          | 9 / 117 (7.69%)   |  |  |
| occurrences (all)                    | 11                |  |  |
| Blood alkaline phosphatase increased |                   |  |  |
| subjects affected / exposed          | 11 / 117 (9.40%)  |  |  |
| occurrences (all)                    | 15                |  |  |
| Aspartate aminotransferase increased |                   |  |  |
| subjects affected / exposed          | 14 / 117 (11.97%) |  |  |
| occurrences (all)                    | 17                |  |  |
| Cardiac disorders                    |                   |  |  |
| Sinus tachycardia                    |                   |  |  |
| subjects affected / exposed          | 8 / 117 (6.84%)   |  |  |
| occurrences (all)                    | 8                 |  |  |
| Nervous system disorders             |                   |  |  |
| Headache                             |                   |  |  |
| subjects affected / exposed          | 19 / 117 (16.24%) |  |  |
| occurrences (all)                    | 22                |  |  |
| Dysgeusia                            |                   |  |  |
| subjects affected / exposed          | 6 / 117 (5.13%)   |  |  |
| occurrences (all)                    | 6                 |  |  |
| Dizziness                            |                   |  |  |
| subjects affected / exposed          | 12 / 117 (10.26%) |  |  |
| occurrences (all)                    | 13                |  |  |
| Neuropathy peripheral                |                   |  |  |
| subjects affected / exposed          | 6 / 117 (5.13%)   |  |  |
| occurrences (all)                    | 6                 |  |  |
| Peripheral sensory neuropathy        |                   |  |  |
| subjects affected / exposed          | 7 / 117 (5.98%)   |  |  |
| occurrences (all)                    | 7                 |  |  |
| Blood and lymphatic system disorders |                   |  |  |
| Thrombocytopenia                     |                   |  |  |
| subjects affected / exposed          | 24 / 117 (20.51%) |  |  |
| occurrences (all)                    | 34                |  |  |
| Neutropenia                          |                   |  |  |
| subjects affected / exposed          | 19 / 117 (16.24%) |  |  |
| occurrences (all)                    | 29                |  |  |
| Lymphopenia                          |                   |  |  |



|  |                   |  |  |
|--|-------------------|--|--|
| subjects affected / exposed            | 18 / 117 (15.38%) |  |  |
| occurrences (all)                      | 26                |  |  |
| Anaemia                                |                   |  |  |
| subjects affected / exposed            | 29 / 117 (24.79%) |  |  |
| occurrences (all)                      | 39                |  |  |
| Gastrointestinal disorders             |                   |  |  |
| Constipation                           |                   |  |  |
| subjects affected / exposed            | 20 / 117 (17.09%) |  |  |
| occurrences (all)                      | 23                |  |  |
| Dyspepsia                              |                   |  |  |
| subjects affected / exposed            | 6 / 117 (5.13%)   |  |  |
| occurrences (all)                      | 6                 |  |  |
| Nausea                                 |                   |  |  |
| subjects affected / exposed            | 32 / 117 (27.35%) |  |  |
| occurrences (all)                      | 40                |  |  |
| Stomatitis                             |                   |  |  |
| subjects affected / exposed            | 6 / 117 (5.13%)   |  |  |
| occurrences (all)                      | 6                 |  |  |
| Dry mouth                              |                   |  |  |
| subjects affected / exposed            | 7 / 117 (5.98%)   |  |  |
| occurrences (all)                      | 7                 |  |  |
| Abdominal pain                         |                   |  |  |
| subjects affected / exposed            | 12 / 117 (10.26%) |  |  |
| occurrences (all)                      | 14                |  |  |
| Diarrhoea                              |                   |  |  |
| subjects affected / exposed            | 19 / 117 (16.24%) |  |  |
| occurrences (all)                      | 26                |  |  |
| Vomiting                               |                   |  |  |
| subjects affected / exposed            | 13 / 117 (11.11%) |  |  |
| occurrences (all)                      | 17                |  |  |
| Skin and subcutaneous tissue disorders |                   |  |  |
| Rash                                   |                   |  |  |
| subjects affected / exposed            | 31 / 117 (26.50%) |  |  |
| occurrences (all)                      | 36                |  |  |
| Rash maculo-papular                    |                   |  |  |

|   |                   |  |  |
|---|-------------------|--|--|
| subjects affected / exposed                     | 38 / 117 (32.48%) |  |  |
| occurrences (all)                               | 46                |  |  |
| Dry skin  |                   |  |  |
| subjects affected / exposed                     | 7 / 117 (5.98%)   |  |  |
| occurrences (all)                               | 8                 |  |  |
| Erythema  |                   |  |  |
| subjects affected / exposed                     | 14 / 117 (11.97%) |  |  |
| occurrences (all)                               | 19                |  |  |
| Pruritus  |                   |  |  |
| subjects affected / exposed                     | 28 / 117 (23.93%) |  |  |
| occurrences (all)                               | 30                |  |  |
| Endocrine disorders                             |                   |  |  |
| Hypothyroidism                                  |                   |  |  |
| subjects affected / exposed                     | 12 / 117 (10.26%) |  |  |
| occurrences (all)                               | 12                |  |  |
| Hyperthyroidism                                 |                   |  |  |
| subjects affected / exposed                     | 8 / 117 (6.84%)   |  |  |
| occurrences (all)                               | 8                 |  |  |
| Thyroiditis                                     |                   |  |  |
| subjects affected / exposed                     | 6 / 117 (5.13%)   |  |  |
| occurrences (all)                               | 6                 |  |  |
| Musculoskeletal and connective tissue disorders |                   |  |  |
| Arthralgia                                      |                   |  |  |
| subjects affected / exposed                     | 19 / 117 (16.24%) |  |  |
| occurrences (all)                               | 22                |  |  |
| Pain in extremity                               |                   |  |  |
| subjects affected / exposed                     | 6 / 117 (5.13%)   |  |  |
| occurrences (all)                               | 9                 |  |  |
| Myalgia   |                   |  |  |
| subjects affected / exposed                     | 11 / 117 (9.40%)  |  |  |
| occurrences (all)                               | 15                |  |  |
| Infections and infestations                     |                   |  |  |
| Upper respiratory tract infection               |                   |  |  |
| subjects affected / exposed                     | 7 / 117 (5.98%)   |  |  |
| occurrences (all)                               | 8                 |  |  |
| Metabolism and nutrition disorders              |                   |  |  |

|                             |                   |  |  |
|-----------------------------|-------------------|--|--|
| Decreased appetite          |                   |  |  |
| subjects affected / exposed | 12 / 117 (10.26%) |  |  |
| occurrences (all)           | 12                |  |  |
| Dehydration                 |                   |  |  |
| subjects affected / exposed | 6 / 117 (5.13%)   |  |  |
| occurrences (all)           | 7                 |  |  |
| Hyperglycaemia              |                   |  |  |
| subjects affected / exposed | 14 / 117 (11.97%) |  |  |
| occurrences (all)           | 21                |  |  |
| Hypokalaemia                |                   |  |  |
| subjects affected / exposed | 14 / 117 (11.97%) |  |  |
| occurrences (all)           | 18                |  |  |
| Hypomagnesaemia             |                   |  |  |
| subjects affected / exposed | 9 / 117 (7.69%)   |  |  |
| occurrences (all)           | 10                |  |  |
| Hyponatraemia               |                   |  |  |
| subjects affected / exposed | 7 / 117 (5.98%)   |  |  |
| occurrences (all)           | 9                 |  |  |
| Hypophosphataemia           |                   |  |  |
| subjects affected / exposed | 21 / 117 (17.95%) |  |  |
| occurrences (all)           | 29                |  |  |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date             | Amendment   |
|------------------|---|
| 24 June 2019     | The primary reason for Protocol Amendment 1 was to include changes based on recommendations by the United States (US) Food and Drug Administration (FDA). In addition, substantial updates in line with study needs had been introduced, e.g., revision of study drug instructions or clarifications of male participant contraception methods.   |
| 24 April 2020    | The primary reason for this global Protocol Amendment 2 was to combine the updates required by the Regulatory Authorities and IRB/IEC received to date in one global protocol version. In addition, updates in line with study needs had been introduced, such as the inclusion of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) added to the list of pathogens associated to Guillain-Barré syndrome (GBS), additional recommendation to capture early signs of polyradiculopathy/GBS, and the update of the study stopping rule. |
| 01 July 2020     | The primary reason for this global Protocol Amendment 3 was to update the stopping rule and to exclude participants that are tested positive for influenza and SARS-CoV-2 before initiating study treatment, based on the recommendations by the FDA.   |
| 06 November 2020 | The primary reasons for this global Protocol Amendment 4 were to implement the recommendations from the independent Data and Safety Monitoring Board (iDSMB), including the addition of varicella zoster virus prophylaxis, an update of the management guidance in respect to specific autoimmune toxicities, and to address the requests from the French and Belgian regulatory authorities.  |
| 16 February 2022 | The primary reason for Protocol Amendment 5 is to extend the contraception period after last dose of camidanlumab tesirine, following an urgent safety measure. The contraception period is determined based on the compound properties and half-life, and has been updated due to a recently revised half-life value of camidanlumab tesirine.   |

Notes:

### Interruptions (globally)

Were there any global interruptions to the trial? Yes

| Date | Interruption | Restart date |
|------|--------------|--------------|
|------|--------------|--------------|

|               |  |              |
|---------------|--|--------------|
| 17 April 2020 | <p>The US FDA placed the trial ADCT-301-201 on a partial clinical hold following 2 cases of GBS/polyradiculopathy. An ad hoc iDSMB meeting to perform comprehensive safety evaluation was held on 15 Apr 2020 (recommendations issued: accrual can continue; create a stopping rule that rules out a probability of <math>\geq 20\%</math> of GBS).</p> <p>ADCT applied the conditions set out by the US FDA in the partial clinical hold to all investigator sites. Under the partial clinical hold, no new participants were treated with camidanlumab tesirine. All ongoing participants at the time of the clinical hold were informed and consented to continue, with the following specifications: Ongoing participants who were deriving clinical benefit (includes participants with an objective response and stable disease) were permitted to continue treatment per protocol if they chose after being re-consented.</p> <p>In the EU, all countries were notified about the clinical hold in mid Apr 2020. The clinical hold was subsequently lifted in the EU countries in Aug-Oct 2020.</p> | 02 July 2020 |
|---------------|--|--------------|

Notes:

## Limitations and caveats

None reported