



## Clinical trial results:

### A Phase 2, Randomized, Double-Blind, Dose-Ranging Study to Determine the Pharmacokinetics, Safety and Tolerability of Vedolizumab IV in Pediatric Subjects with Ulcerative Colitis or Crohn's Disease

#### Summary

|                          |                      |
|--------------------------|----------------------|
| EudraCT number           | 2017-002231-41       |
| Trial protocol           | GB DE BE HU NL PL FR |
| Global end of trial date | 26 May 2020          |

#### Results information

|                                |                  |
|--------------------------------|------------------|
| Result version number          | v1 (current)     |
| This version publication date  | 11 December 2020 |
| First version publication date | 11 December 2020 |

#### Trial information

##### Trial identification

|                       |              |
|-----------------------|--------------|
| Sponsor protocol code | MLN0002-2003 |
|-----------------------|--------------|

##### Additional study identifiers

|                                    |  |
|------------------------------------|--|
| ISRCTN number                      | -  |
| ClinicalTrials.gov id (NCT number) | NCT03138655  |
| WHO universal trial number (UTN)   | U1111-1174-2041  |
| Other trial identifiers            | Israel: MLN0002-2003CTIL, NRES: 17/NE/0257, CRS: MOH_2017-09-18_000675 |

Notes:

#### Sponsors

|                              |   |
|------------------------------|---|
| Sponsor organisation name    | Takeda Development Centre Europe, Ltd.  |
| Sponsor organisation address | 61 Aldwych, London, United Kingdom, WC2B 4AE  |
| Public contact               | Medical Director, Clinical Science, Takeda, +1 877-825-3327, clinicaltrialregistry@tpna.com |
| Scientific contact           | Medical Director, Clinical Science, Takeda, +1 877-825-3327, clinicaltrialregistry@tpna.com |

Notes:

#### Paediatric regulatory details

|  |                     |
|--|---------------------|
| Is trial part of an agreed paediatric investigation plan (PIP)       | Yes                 |
| EMA paediatric investigation plan number(s)                          | EMA-000645-PIP01-09 |
| 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? | Yes                 |

Notes:

## Results analysis stage

|  |             |
|--|-------------|
| Analysis stage                                       | Final       |
| Date of interim/final analysis                       | 26 May 2020 |
| Is this the analysis of the primary completion data? | No          |
| Global end of trial reached?                         | Yes         |
| Global end of trial date                             | 26 May 2020 |
| Was the trial ended prematurely?                     | No          |

Notes:

## General information about the trial

Main objective of the trial:

The objective of this trial was to evaluate vedolizumab pharmacokinetics (PK), safety and tolerability in pediatric participants with moderately to severely active ulcerative colitis (UC) or crohn's disease (CD).

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

|   |                  |
|---|------------------|
| Actual start date of recruitment                          | 08 November 2017 |
| Long term follow-up planned                               | Yes              |
| Long term follow-up rationale                             | Safety, Efficacy |
| Long term follow-up duration                              | 6 Months         |
| Independent data monitoring committee (IDMC) involvement? | Yes              |

Notes:

## Population of trial subjects

### Subjects enrolled per country

|                                      |                   |
|--------------------------------------|-------------------|
| Country: Number of subjects enrolled | Belgium: 5        |
| Country: Number of subjects enrolled | France: 1         |
| Country: Number of subjects enrolled | Hungary: 17       |
| Country: Number of subjects enrolled | Poland: 15        |
| Country: Number of subjects enrolled | United Kingdom: 6 |
| Country: Number of subjects enrolled | Ukraine: 2        |
| Country: Number of subjects enrolled | Israel: 13        |
| Country: Number of subjects enrolled | Canada: 1         |
| Country: Number of subjects enrolled | United States: 29 |
| Worldwide total number of subjects   | 89                |
| EEA total number of subjects         | 44                |

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)                    | 46 |
| Adolescents (12-17 years)                | 43 |
| Adults (18-64 years)                     | 0  |
| From 65 to 84 years                      | 0  |
| 85 years and over                        | 0  |

## Subject disposition

### Recruitment

Recruitment details:

Participants took part in the study at 72 investigative sites in United States, Belgium, Canada, France, Germany, Hungary, Israel, Netherlands, Poland, Ukraine, United Kingdom and European Union from 8 November 2017 to 26 March 2020.

### Pre-assignment

Screening details:

Pediatric participants who weighed >10 kg with a diagnosis of moderately to severely active ulcerative colitis (UC) or Crohn's disease (CD) were enrolled in 1:1 ratio to receive vedolizumab low or high dose groups per weight (<30 kg and >=30 kg).

### Period 1

|                              |                                |
|------------------------------|--------------------------------|
| Period 1 title               | Overall Study (overall period) |
| Is this the baseline period? | Yes                            |
| Allocation method            | Randomised - controlled        |
| Blinding used                | Double blind                   |
| Roles blinded                | Subject, Investigator, Carer   |

### Arms

|                              |   |
|------------------------------|---|
| Are arms mutually exclusive? | Yes   |
| <b>Arm title</b>             | UC: <30 kg Participants, Vedolizumab 100 mg |

Arm description:

Participants with UC having baseline weight of <30 kg were randomized to this low dose group and received vedolizumab 100 mg IV infusion on Day 1 and at Weeks 2, 6 and 14.

|  |                            |
|--|----------------------------|
| Arm type                               | Experimental               |
| Investigational medicinal product name | Vedolizumab                |
| Investigational medicinal product code |                            |
| Other name                             | MLN0002, ENTYVIO, KYNTELES |
| Pharmaceutical forms                   | Infusion                   |
| Routes of administration               | Intravenous use            |

Dosage and administration details:

Vedolizumab IV infusion.

|                  |   |
|------------------|---|
| <b>Arm title</b> | UC: <30 kg Participants, Vedolizumab 200 mg |
|------------------|---|

Arm description:

Participants with UC having baseline weight of <30 kg were randomized to this high dose group and received vedolizumab 200 mg IV infusion on Day 1 and at Weeks 2, 6 and 14.

|  |                            |
|--|----------------------------|
| Arm type                               | Experimental               |
| Investigational medicinal product name | Vedolizumab                |
| Investigational medicinal product code |                            |
| Other name                             | MLN0002, ENTYVIO, KYNTELES |
| Pharmaceutical forms                   | Infusion                   |
| Routes of administration               | Intravenous use            |

Dosage and administration details:

Vedolizumab IV infusion.

|                  |   |
|------------------|---|
| <b>Arm title</b> | CD: <30 kg Participants, Vedolizumab 100 mg |
|------------------|---|

Arm description:

Participants with CD having baseline weight of <30 kg were randomized to this low dose group and received vedolizumab 100 mg IV infusion on Day 1 and at Weeks 2, 6 and 14.

|          |              |
|----------|--------------|
| Arm type | Experimental |
|----------|--------------|

|   |  |
|---|--|
| Investigational medicinal product name  | Vedolizumab                                  |
| Investigational medicinal product code  |  |
| Other name  | MLN0002, ENTYVIO, KYNTELES                   |
| Pharmaceutical forms  | Infusion                                     |
| Routes of administration  | Intravenous use                              |
| Dosage and administration details:<br>Vedolizumab IV infusion.  |  |
| <b>Arm title</b>  | CD: <30 kg Participants, Vedolizumab 200 mg  |
| Arm description:<br>Participants with CD having baseline weight of <30 kg were randomized to this high dose group and received vedolizumab 200 mg IV infusion on Day 1 and at Weeks 2, 6 and 14.  |  |
| Arm type  | Experimental                                 |
| Investigational medicinal product name  | Vedolizumab                                  |
| Investigational medicinal product code  |  |
| Other name  | MLN0002, ENTYVIO, KYNTELES                   |
| Pharmaceutical forms  | Infusion                                     |
| Routes of administration  | Intravenous use                              |
| Dosage and administration details:<br>Vedolizumab IV infusion.  |  |
| <b>Arm title</b>  | UC: >=30 kg Participants, Vedolizumab 150 mg |
| Arm description:<br>Participants with UC having baseline weight of >=30 kg were randomized to this low dose group and received vedolizumab 150 mg IV infusion on Day 1 and at Weeks 2, 6 and 14.  |  |
| Arm type  | Experimental                                 |
| Investigational medicinal product name  | Vedolizumab                                  |
| Investigational medicinal product code  |  |
| Other name  | MLN0002, ENTYVIO, KYNTELES                   |
| Pharmaceutical forms  | Infusion                                     |
| Routes of administration  | Intravenous use                              |
| Dosage and administration details:<br>Vedolizumab IV infusion.  |  |
| <b>Arm title</b>  | UC: >=30 kg Participants, Vedolizumab 300 mg |
| Arm description:<br>Participants with UC having baseline weight of >=30 kg were randomized to this high dose group and received vedolizumab 300 mg IV infusion on Day 1 and at Weeks 2, 6 and 14. |  |
| Arm type  | Experimental                                 |
| Investigational medicinal product name  | Vedolizumab                                  |
| Investigational medicinal product code  |  |
| Other name  | MLN0002, ENTYVIO, KYNTELES                   |
| Pharmaceutical forms  | Infusion                                     |
| Routes of administration  | Intravenous use                              |
| Dosage and administration details:<br>Vedolizumab IV infusion.  |  |
| <b>Arm title</b>  | CD: >=30 kg Participants, Vedolizumab 150 mg |
| Arm description:<br>Participants with CD having baseline weight of >=30 kg were randomized to this low dose group and received vedolizumab 150 mg IV infusion on Day 1 and at Weeks 2, 6 and 14.  |  |
| Arm type  | Experimental                                 |

|  |   |
|--|---|
| Investigational medicinal product name                         | Vedolizumab                                       |
| Investigational medicinal product code                         |   |
| Other name   | MLN0002, ENTYVIO, KYNTELES                        |
| Pharmaceutical forms   | Infusion  |
| Routes of administration                                       | Intravenous use                                   |
| Dosage and administration details:<br>Vedolizumab IV infusion. |   |
| <b>Arm title</b>   | CD: $\geq 30$ kg Participants, Vedolizumab 300 mg |

Arm description:

Participants with CD having baseline weight of  $\geq 30$  kg were randomized to this low dose group and received vedolizumab 300 mg IV infusion on Day 1 and at Weeks 2, 6 and 14.

|  |                            |
|--|----------------------------|
| Arm type                               | Experimental               |
| Investigational medicinal product name | Vedolizumab                |
| Investigational medicinal product code |                            |
| Other name                             | MLN0002, ENTYVIO, KYNTELES |
| Pharmaceutical forms                   | Infusion                   |
| Routes of administration               | Intravenous use            |

Dosage and administration details:

Vedolizumab IV infusion.

| <b>Number of subjects in period 1</b> | UC: $<30$ kg<br>Participants,<br>Vedolizumab 100<br>mg | UC: $<30$ kg<br>Participants,<br>Vedolizumab 200 mg | CD: $<30$ kg<br>Participants,<br>Vedolizumab 100<br>mg |
|---------------------------------------|--|---|--|
| Started                               | 10   | 9   | 11   |
| Completed                             | 7  | 7   | 9  |
| Not completed                         | 3  | 2   | 2  |
| Consent withdrawn by subject          | -  | 1   | -  |
| Adverse event, non-fatal              | 2  | 1   | 2  |
| Reason not Specified                  | 1  | -   | -  |

| <b>Number of subjects in period 1</b> | CD: $<30$ kg<br>Participants,<br>Vedolizumab 200<br>mg | UC: $\geq 30$ kg<br>Participants,<br>Vedolizumab 150 mg | UC: $\geq 30$ kg<br>Participants,<br>Vedolizumab 300<br>mg |
|---------------------------------------|--|---|--|
| Started                               | 10   | 13  | 12   |
| Completed                             | 7  | 11  | 7  |
| Not completed                         | 3  | 2   | 5  |
| Consent withdrawn by subject          | -  | -   | -  |
| Adverse event, non-fatal              | 1  | 1   | 4  |
| Reason not Specified                  | 2  | 1   | 1  |

| <b>Number of subjects in period 1</b> | CD: $\geq 30$ kg<br>Participants,<br>Vedolizumab 150<br>mg | CD: $\geq 30$ kg<br>Participants,<br>Vedolizumab 300 mg |
|---------------------------------------|--|---|
| Started                               | 12   | 12  |
| Completed                             | 9  | 10  |
| Not completed                         | 3  | 2   |

|                              |   |   |
|------------------------------|---|---|
| Consent withdrawn by subject | 1 | - |
| Adverse event, non-fatal     | 2 | 2 |
| Reason not Specified         | - | - |

## Baseline characteristics

### Reporting groups

|  |   |
|--|---|
| Reporting group title  | UC: <30 kg Participants, Vedolizumab 100 mg |
| Reporting group description:<br>Participants with UC having baseline weight of <30 kg were randomized to this low dose group and received vedolizumab 100 mg IV infusion on Day 1 and at Weeks 2, 6 and 14.  |   |
| Reporting group title  | UC: <30 kg Participants, Vedolizumab 200 mg |
| Reporting group description:<br>Participants with UC having baseline weight of <30 kg were randomized to this high dose group and received vedolizumab 200 mg IV infusion on Day 1 and at Weeks 2, 6 and 14. |   |
| Reporting group title  | CD: <30 kg Participants, Vedolizumab 100 mg |
| Reporting group description:<br>Participants with CD having baseline weight of <30 kg were randomized to this low dose group and received vedolizumab 100 mg IV infusion on Day 1 and at Weeks 2, 6 and 14.  |   |
| Reporting group title  | CD: <30 kg Participants, Vedolizumab 200 mg |
| Reporting group description:<br>Participants with CD having baseline weight of <30 kg were randomized to this high dose group and received vedolizumab 200 mg IV infusion on Day 1 and at Weeks 2, 6 and 14. |   |
| Reporting group title  | UC: ≥30 kg Participants, Vedolizumab 150 mg |
| Reporting group description:<br>Participants with UC having baseline weight of ≥30 kg were randomized to this low dose group and received vedolizumab 150 mg IV infusion on Day 1 and at Weeks 2, 6 and 14.  |   |
| Reporting group title  | UC: ≥30 kg Participants, Vedolizumab 300 mg |
| Reporting group description:<br>Participants with UC having baseline weight of ≥30 kg were randomized to this high dose group and received vedolizumab 300 mg IV infusion on Day 1 and at Weeks 2, 6 and 14. |   |
| Reporting group title  | CD: ≥30 kg Participants, Vedolizumab 150 mg |
| Reporting group description:<br>Participants with CD having baseline weight of ≥30 kg were randomized to this low dose group and received vedolizumab 150 mg IV infusion on Day 1 and at Weeks 2, 6 and 14.  |   |
| Reporting group title  | CD: ≥30 kg Participants, Vedolizumab 300 mg |
| Reporting group description:<br>Participants with CD having baseline weight of ≥30 kg were randomized to this low dose group and received vedolizumab 300 mg IV infusion on Day 1 and at Weeks 2, 6 and 14.  |   |

| Reporting group values                   | UC: <30 kg<br>Participants,<br>Vedolizumab 100<br>mg | UC: <30 kg<br>Participants,<br>Vedolizumab 200 mg | CD: <30 kg<br>Participants,<br>Vedolizumab 100<br>mg |
|--|--|---|--|
| Number of subjects                       | 10   | 9   | 11   |
| Age categorical<br>Units: Subjects       |  |   |  |
| Children (2-11 years)                    | 9  | 8   | 9  |
| Adolescents (12-17 years)                | 1  | 1   | 2  |
| Age Continuous<br>Units: years           |  |   |  |
| arithmetic mean                          | 7.0  | 8.0   | 7.4  |
| full range (min-max)                     | 3 to 12  | 2 to 12   | 2 to 12  |
| Sex: Female, Male<br>Units: participants |  |   |  |
| Female                                   | 4  | 4   | 4  |
| Male                                     | 6  | 5   | 7  |



|   |  |  |   |
|---|--|--|---|
| Ethnicity (NIH/OMB)                       |  |  |   |
| Units: Subjects                           |  |  |   |
| Hispanic or Latino                        | 0  | 2  | 2   |
| Not Hispanic or Latino                    | 10   | 7  | 7   |
| Unknown or Not Reported                   | 0  | 0  | 2   |
| Race (NIH/OMB)                            |  |  |   |
| Units: Subjects                           |  |  |   |
| American Indian or Alaska Native          | 0  | 0  | 0   |
| Asian                                     | 0  | 0  | 0   |
| Native Hawaiian or Other Pacific Islander | 0  | 0  | 0   |
| Black or African American                 | 1  | 2  | 1   |
| White                                     | 7  | 7  | 7   |
| More than one race                        | 0  | 0  | 1   |
| Unknown or Not Reported                   | 2  | 0  | 2   |
| Region of Enrollment                      |  |  |   |
| Units: Subjects                           |  |  |   |
| Belgium                                   | 1  | 0  | 0   |
| France                                    | 0  | 0  | 1   |
| Hungary                                   | 1  | 0  | 1   |
| Poland                                    | 2  | 1  | 4   |
| United Kingdom                            | 0  | 0  | 1   |
| Ukraine                                   | 1  | 1  | 0   |
| Israel                                    | 3  | 2  | 0   |
| Canada                                    | 0  | 0  | 0   |
| United States                             | 2  | 5  | 4   |
| Height                                    |  |  |   |
| Units: cm                                 |  |  |   |
| arithmetic mean                           | 119.59   | 122.39   | 120.58  |
| full range (min-max)                      | 82.7 to 146.0  | 84.9 to 143.0                                      | 83.5 to 146.0   |
| Weight                                    |  |  |   |
| Units: kg                                 |  |  |   |
| arithmetic mean                           | 22.38  | 23.23  | 22.06   |
| full range (min-max)                      | 12.8 to 29.6   | 10.2 to 29.8                                       | 12.0 to 29.9  |
| Body Mass Index (BMI)                     |  |  |   |
| BMI = weight (kg) / height^2 (m^2)        |  |  |   |
| Units: kg/m^2                             |  |  |   |
| arithmetic mean                           | 15.63  | 15.29  | 15.04   |
| full range (min-max)                      | 13.4 to 18.7   | 12.4 to 20.0                                       | 13.5 to 17.2  |
| <b>Reporting group values</b>             | CD: <30 kg<br>Participants,<br>Vedolizumab 200<br>mg | UC: >=30 kg<br>Participants,<br>Vedolizumab 150 mg | UC: >=30 kg<br>Participants,<br>Vedolizumab 300<br>mg |
| Number of subjects                        | 10   | 13   | 12  |
| Age categorical                           |  |  |   |
| Units: Subjects                           |  |  |   |
| Children (2-11 years)                     | 9  | 4  | 2   |
| Adolescents (12-17 years)                 | 1  | 9  | 10  |
| Age Continuous                            |  |  |   |
| Units: years                              |  |  |   |
| arithmetic mean                           | 8.1  | 12.4   | 13.9  |
| full range (min-max)                      | 3 to 12  | 8 to 17  | 9 to 17   |

|   |   |  |                |
|---|---|--|----------------|
| Sex: Female, Male<br>Units: participants  |   |  |                |
| Female                                    | 5   | 5  | 6              |
| Male                                      | 5   | 8  | 6              |
| Ethnicity (NIH/OMB)<br>Units: Subjects    |   |  |                |
| Hispanic or Latino                        | 2   | 1  | 1              |
| Not Hispanic or Latino                    | 8   | 12   | 11             |
| Unknown or Not Reported                   | 0   | 0  | 0              |
| Race (NIH/OMB)<br>Units: Subjects         |   |  |                |
| American Indian or Alaska Native          | 0   | 0  | 0              |
| Asian                                     | 0   | 0  | 0              |
| Native Hawaiian or Other Pacific Islander | 0   | 0  | 0              |
| Black or African American                 | 0   | 2  | 0              |
| White                                     | 9   | 11   | 10             |
| More than one race                        | 0   | 0  | 2              |
| Unknown or Not Reported                   | 1   | 0  | 0              |
| Region of Enrollment<br>Units: Subjects   |   |  |                |
| Belgium                                   | 0   | 0  | 1              |
| France                                    | 0   | 0  | 0              |
| Hungary                                   | 1   | 3  | 4              |
| Poland                                    | 2   | 1  | 0              |
| United Kingdom                            | 1   | 1  | 0              |
| Ukraine                                   | 0   | 0  | 0              |
| Israel                                    | 2   | 3  | 2              |
| Canada                                    | 0   | 0  | 0              |
| United States                             | 4   | 5  | 5              |
| Height<br>Units: cm                       |   |  |                |
| arithmetic mean                           | 124.67  | 153.11   | 160.03         |
| full range (min-max)                      | 96.5 to 137.6   | 128.0 to 176.1                                     | 138.3 to 185.4 |
| Weight<br>Units: kg                       |   |  |                |
| arithmetic mean                           | 23.37   | 46.22  | 53.98          |
| full range (min-max)                      | 14.3 to 30.0  | 30.3 to 75.9                                       | 32.0 to 78.9   |
| Body Mass Index (BMI)                     |   |  |                |
| BMI = weight (kg) / height^2 (m^2)        |   |  |                |
| Units: kg/m^2                             |   |  |                |
| arithmetic mean                           | 14.93   | 19.51  | 20.76          |
| full range (min-max)                      | 12.4 to 16.9  | 16.4 to 26.5                                       | 16.7 to 27.1   |
| <b>Reporting group values</b>             | CD: >=30 kg<br>Participants,<br>Vedolizumab 150<br>mg | CD: >=30 kg<br>Participants,<br>Vedolizumab 300 mg | Total          |
| Number of subjects                        | 12  | 12   | 89             |
| Age categorical<br>Units: Subjects        |   |  |                |
| Children (2-11 years)                     | 3   | 2  | 46             |
| Adolescents (12-17 years)                 | 9   | 10   | 43             |

|   |                          |                          |    |
|---|--------------------------|--------------------------|----|
| Age Continuous<br>Units: years<br>arithmetic mean<br>full range (min-max) | 13.4<br>10 to 17         | 14.3<br>11 to 17         | -  |
| Sex: Female, Male<br>Units: participants                                  |                          |                          |    |
| Female  | 8                        | 3                        | 39 |
| Male  | 4                        | 9                        | 50 |
| Ethnicity (NIH/OMB)<br>Units: Subjects                                    |                          |                          |    |
| Hispanic or Latino  | 1                        | 0                        | 9  |
| Not Hispanic or Latino  | 11                       | 12                       | 78 |
| Unknown or Not Reported   | 0                        | 0                        | 2  |
| Race (NIH/OMB)<br>Units: Subjects   |                          |                          |    |
| American Indian or Alaska Native  | 0                        | 0                        | 0  |
| Asian   | 1                        | 1                        | 2  |
| Native Hawaiian or Other Pacific Islander                                 | 0                        | 0                        | 0  |
| Black or African American   | 2                        | 0                        | 8  |
| White   | 9                        | 11                       | 71 |
| More than one race  | 0                        | 0                        | 3  |
| Unknown or Not Reported   | 0                        | 0                        | 5  |
| Region of Enrollment<br>Units: Subjects                                   |                          |                          |    |
| Belgium   | 2                        | 1                        | 5  |
| France  | 0                        | 0                        | 1  |
| Hungary   | 4                        | 3                        | 17 |
| Poland  | 2                        | 3                        | 15 |
| United Kingdom  | 1                        | 2                        | 6  |
| Ukraine   | 0                        | 0                        | 2  |
| Israel  | 0                        | 1                        | 13 |
| Canada  | 1                        | 0                        | 1  |
| United States   | 2                        | 2                        | 29 |
| Height<br>Units: cm<br>arithmetic mean<br>full range (min-max)            | 157.85<br>134.3 to 182.5 | 157.98<br>141.9 to 181.5 | -  |
| Weight<br>Units: kg<br>arithmetic mean<br>full range (min-max)            | 51.53<br>31.4 to 79.0    | 45.89<br>33.9 to 68.0    | -  |
| Body Mass Index (BMI)   |                          |                          |    |
| BMI = weight (kg) / height^2 (m^2)  |                          |                          |    |
| Units: kg/m^2<br>arithmetic mean<br>full range (min-max)                  | 20.50<br>14.4 to 24.5    | 18.26<br>15.8 to 25.9    | -  |

## End points

### End points reporting groups

|  |   |
|--|---|
| Reporting group title  | UC: <30 kg Participants, Vedolizumab 100 mg |
| Reporting group description:<br>Participants with UC having baseline weight of <30 kg were randomized to this low dose group and received vedolizumab 100 mg IV infusion on Day 1 and at Weeks 2, 6 and 14.  |   |
| Reporting group title  | UC: <30 kg Participants, Vedolizumab 200 mg |
| Reporting group description:<br>Participants with UC having baseline weight of <30 kg were randomized to this high dose group and received vedolizumab 200 mg IV infusion on Day 1 and at Weeks 2, 6 and 14. |   |
| Reporting group title  | CD: <30 kg Participants, Vedolizumab 100 mg |
| Reporting group description:<br>Participants with CD having baseline weight of <30 kg were randomized to this low dose group and received vedolizumab 100 mg IV infusion on Day 1 and at Weeks 2, 6 and 14.  |   |
| Reporting group title  | CD: <30 kg Participants, Vedolizumab 200 mg |
| Reporting group description:<br>Participants with CD having baseline weight of <30 kg were randomized to this high dose group and received vedolizumab 200 mg IV infusion on Day 1 and at Weeks 2, 6 and 14. |   |
| Reporting group title  | UC: ≥30 kg Participants, Vedolizumab 150 mg |
| Reporting group description:<br>Participants with UC having baseline weight of ≥30 kg were randomized to this low dose group and received vedolizumab 150 mg IV infusion on Day 1 and at Weeks 2, 6 and 14.  |   |
| Reporting group title  | UC: ≥30 kg Participants, Vedolizumab 300 mg |
| Reporting group description:<br>Participants with UC having baseline weight of ≥30 kg were randomized to this high dose group and received vedolizumab 300 mg IV infusion on Day 1 and at Weeks 2, 6 and 14. |   |
| Reporting group title  | CD: ≥30 kg Participants, Vedolizumab 150 mg |
| Reporting group description:<br>Participants with CD having baseline weight of ≥30 kg were randomized to this low dose group and received vedolizumab 150 mg IV infusion on Day 1 and at Weeks 2, 6 and 14.  |   |
| Reporting group title  | CD: ≥30 kg Participants, Vedolizumab 300 mg |
| Reporting group description:<br>Participants with CD having baseline weight of ≥30 kg were randomized to this low dose group and received vedolizumab 300 mg IV infusion on Day 1 and at Weeks 2, 6 and 14.  |   |

### Primary: AUCWeek 14: Area Under the Serum Concentration-time Curve at Week 14

|  |   |
|--|---|
| End point title  | AUCWeek 14: Area Under the Serum Concentration-time Curve at Week 14 <sup>[1]</sup> |
| End point description:<br>Pharmacokinetic (PK) Analysis Set included all participants who received at least 1 dose of study drug and had at least 1 measurable concentration of vedolizumab. Number of participants analyzed is the number of participants with data available for analyses. |   |
| End point type   | Primary   |
| End point timeframe:<br>From Day 43 (week 6) post-dose up to pre-dose Day 99 (Week 14)   |   |
| 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 statistical analyses data were available for this endpoint.                               |   |

| End point values                     | UC: <30 kg<br>Participants,<br>Vedolizumab<br>100 mg | UC: <30 kg<br>Participants,<br>Vedolizumab<br>200 mg | CD: <30 kg<br>Participants,<br>Vedolizumab<br>100 mg | CD: <30 kg<br>Participants,<br>Vedolizumab<br>200 mg |
|--------------------------------------|--|--|--|--|
| Subject group type                   | Reporting group                                      | Reporting group                                      | Reporting group                                      | Reporting group                                      |
| Number of subjects analysed          | 8  | 7  | 7  | 8  |
| Units: h*ng/mL                       |  |  |  |  |
| arithmetic mean (standard deviation) | 1933.5076 ( $\pm$ 1184.36284)                        | 3231.1001 ( $\pm$ 1152.06628)                        | 2344.4204 ( $\pm$ 1216.58345)                        | 3091.7957 ( $\pm$ 1732.34795)                        |

| End point values                     | UC: $\geq$ 30 kg<br>Participants,<br>Vedolizumab<br>150 mg | UC: $\geq$ 30 kg<br>Participants,<br>Vedolizumab<br>300 mg | CD: $\geq$ 30 kg<br>Participants,<br>Vedolizumab<br>150 mg | CD: $\geq$ 30 kg<br>Participants,<br>Vedolizumab<br>300 mg |
|--------------------------------------|--|--|--|--|
| Subject group type                   | Reporting group  | Reporting group  | Reporting group  | Reporting group  |
| Number of subjects analysed          | 11   | 10   | 9  | 10   |
| Units: h*ng/mL                       |  |  |  |  |
| arithmetic mean (standard deviation) | 2449.9433 ( $\pm$ 772.66677)                               | 4182.4869 ( $\pm$ 1751.87940)                              | 1865.0004 ( $\pm$ 509.68268)                               | 3176.6971 ( $\pm$ 928.32630)                               |

## Statistical analyses

No statistical analyses for this end point

### Primary: Cav,Week 14: Average Serum Concentration During a Dosing Interval at Week 14

|                 |   |
|-----------------|---|
| End point title | Cav,Week 14: Average Serum Concentration During a Dosing Interval at Week 14 <sup>[2]</sup> |
|-----------------|---|

End point description:

PK Analysis Set included all participants who received at least 1 dose of study drug and had at least 1 measurable concentration of vedolizumab. Number of participants analyzed is the number of participants with data available for analyses.

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

From Day 43 (week 6) post-dose up to pre-dose Day 99 (Week 14)

Notes:

[2] - 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: No statistical analyses data were available for this endpoint.

| End point values                     | UC: <30 kg<br>Participants,<br>Vedolizumab<br>100 mg | UC: <30 kg<br>Participants,<br>Vedolizumab<br>200 mg | CD: <30 kg<br>Participants,<br>Vedolizumab<br>100 mg | CD: <30 kg<br>Participants,<br>Vedolizumab<br>200 mg |
|--------------------------------------|--|--|--|--|
| Subject group type                   | Reporting group                                      | Reporting group                                      | Reporting group                                      | Reporting group                                      |
| Number of subjects analysed          | 9  | 8  | 7  | 8  |
| Units: ng/mL                         |  |  |  |  |
| arithmetic mean (standard deviation) | 39.3143 ( $\pm$ 21.34097)                            | 61.2934 ( $\pm$ 18.14446)                            | 46.8716 ( $\pm$ 23.07334)                            | 63.6275 ( $\pm$ 28.29116)                            |

| End point values                     | UC: $\geq 30$ kg<br>Participants,<br>Vedolizumab<br>150 mg | UC: $\geq 30$ kg<br>Participants,<br>Vedolizumab<br>300 mg | CD: $\geq 30$ kg<br>Participants,<br>Vedolizumab<br>150 mg | CD: $\geq 30$ kg<br>Participants,<br>Vedolizumab<br>300 mg |
|--------------------------------------|--|--|--|--|
| Subject group type                   | Reporting group  | Reporting group  | Reporting group  | Reporting group  |
| Number of subjects analysed          | 11   | 10   | 9  | 10   |
| Units: ng/mL                         |  |  |  |  |
| arithmetic mean (standard deviation) | 44.6465 ( $\pm$<br>11.48500)                               | 77.2452 ( $\pm$<br>28.49511)                               | 37.4752 ( $\pm$<br>18.26528)                               | 63.1734 ( $\pm$<br>15.08119)                               |

## Statistical analyses

No statistical analyses for this end point

### Primary: Ctrough, Week 14: Observed Serum Concentration at the end of a Dosing Interval at Week 14

|                 |  |
|-----------------|--|
| End point title | Ctrough, Week 14: Observed Serum Concentration at the end of a Dosing Interval at Week 14 <sup>[3]</sup> |
|-----------------|--|

End point description:

PK Analysis Set included all participants who received at least 1 dose of study drug and had at least 1 measurable concentration of vedolizumab. Number of participants analyzed is the number of participants with data available for analyses.

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

At the end of a dosing interval at Week 14

Notes:

[3] - 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: No statistical analyses data were available for this endpoint.

| End point values                     | UC: $< 30$ kg<br>Participants,<br>Vedolizumab<br>100 mg | UC: $< 30$ kg<br>Participants,<br>Vedolizumab<br>200 mg | CD: $< 30$ kg<br>Participants,<br>Vedolizumab<br>100 mg | CD: $< 30$ kg<br>Participants,<br>Vedolizumab<br>200 mg |
|--------------------------------------|---|---|---|---|
| Subject group type                   | Reporting group   | Reporting group   | Reporting group   | Reporting group   |
| Number of subjects analysed          | 8   | 7   | 8   | 8   |
| Units: ng/mL                         |   |   |   |   |
| arithmetic mean (standard deviation) | 9.3100 ( $\pm$<br>9.48045)                              | 10.7226 ( $\pm$<br>10.35423)                            | 8.7395 ( $\pm$<br>7.77386)                              | 10.3685 ( $\pm$<br>11.30124)                            |

| End point values                     | UC: $\geq 30$ kg<br>Participants,<br>Vedolizumab<br>150 mg | UC: $\geq 30$ kg<br>Participants,<br>Vedolizumab<br>300 mg | CD: $\geq 30$ kg<br>Participants,<br>Vedolizumab<br>150 mg | CD: $\geq 30$ kg<br>Participants,<br>Vedolizumab<br>300 mg |
|--------------------------------------|--|--|--|--|
| Subject group type                   | Reporting group  | Reporting group  | Reporting group  | Reporting group  |
| Number of subjects analysed          | 11   | 10   | 10   | 10   |
| Units: ng/mL                         |  |  |  |  |
| arithmetic mean (standard deviation) | 16.3645 ( $\pm$ )  | 21.4860 ( $\pm$ )  | 3.9006 ( $\pm$ )   | 7.8310 ( $\pm$ )   |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of UC Participants who Achieve Clinical Response Based on Complete Mayo Score

|                 |   |
|-----------------|---|
| End point title | Percentage of UC Participants who Achieve Clinical Response Based on Complete Mayo Score <sup>[4]</sup> |
|-----------------|---|

End point description:

Clinical response was defined as a reduction in complete Mayo score of  $\geq 3$  points and  $\geq 30\%$  from Baseline with an accompanying decrease in rectal bleeding sub-score of  $\geq 1$  point(s) or absolute rectal bleeding sub-score of  $\leq 1$  point. Mayo score was used in to assess UC disease activity. It consisted of 4 subscales: stool frequency, rectal bleeding, findings on endoscopy and physician's global assessment. Each subscale was scored on a scale of 0 to 3, where 0 = normal condition and 3 = severe disease condition. The total Mayo score ranged from 0 to 12, with higher scores indicating more severe disease. Full Analysis Set (FAS) included all randomized participants who received at least 1 dose of study drug. Number of participants analyzed is the number of participants with data available for analyses.

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

End point timeframe:

Baseline (Day 1) and Week 14

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Data is reported by dose in this endpoint.

| End point values                  | UC: <30 kg Participants, Vedolizumab 100 mg | UC: <30 kg Participants, Vedolizumab 200 mg | UC: $\geq 30$ kg Participants, Vedolizumab 150 mg | UC: $\geq 30$ kg Participants, Vedolizumab 300 mg |
|-----------------------------------|---|---|---|---|
| Subject group type                | Reporting group                             | Reporting group                             | Reporting group                                   | Reporting group                                   |
| Number of subjects analysed       | 10  | 9   | 13  | 12  |
| Units: percentage of participants |   |   |   |   |
| number (confidence interval 95%)  | 40.0 (12.2 to 73.8)                         | 66.7 (29.9 to 92.5)                         | 69.2 (38.6 to 90.9)                               | 41.7 (15.2 to 72.3)                               |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of CD Participants who Achieve Clinical Response Based on Crohn's Disease Activity Index (CDAI)

|                 |   |
|-----------------|---|
| End point title | Percentage of CD Participants who Achieve Clinical Response Based on Crohn's Disease Activity Index (CDAI) <sup>[5]</sup> |
|-----------------|---|

End point description:

Clinical response was defined as  $\geq 70$  points decrease from Baseline in CDAI score at Week 14. The CDAI evaluated severity of signs and symptoms of CD. Information was collected on number of liquid stools, intensity of abdominal pain, general well-being, presence of comorbid conditions, use of medications for diarrhea, physical examination, and laboratory, yielding 8 items that were combined

with data from a 7-day diary to obtain total CDAI score. Index values of 150 and below were associated with quiescent disease; values above that indicated active disease, values  $\geq 220$  indicated moderate to severe disease, and values above 450 were seen with extremely severe disease. FAS included all randomized participants who received at least 1 dose of study drug. Number of participants analyzed is the number of participants with data available for analyses.

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

End point timeframe:

Baseline (Day 1) and Week 14

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Data is reported by dose in this endpoint.

| End point values                  | CD: <30 kg<br>Participants,<br>Vedolizumab<br>100 mg | CD: <30 kg<br>Participants,<br>Vedolizumab<br>200 mg | CD: $\geq$ 30 kg<br>Participants,<br>Vedolizumab<br>150 mg | CD: $\geq$ 30 kg<br>Participants,<br>Vedolizumab<br>300 mg |
|-----------------------------------|--|--|--|--|
| Subject group type                | Reporting group                                      | Reporting group                                      | Reporting group  | Reporting group  |
| Number of subjects analysed       | 11   | 10   | 11   | 12   |
| Units: percentage of participants |  |  |  |  |
| number (confidence interval 95%)  | 63.6 (30.8 to 89.1)                                  | 40.0 (12.2 to 73.8)                                  | 45.5 (16.7 to 76.6)  | 33.3 (9.9 to 65.1)   |

## Statistical analyses

No statistical analyses for this end point



## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

From first dose of study drug up to Week 32

Adverse event reporting additional description:

At each visit investigator had to document any occurrence of AEs and abnormal laboratory findings. Any event spontaneously reported by participant or observed by investigator was recorded, irrespective of relation to study treatment. Safety Analysis Set: all participants who received  $\geq 1$  dose of study drug. MedDRA v22.0:  $>30$  kg group; v23.0:  $<30$  kg group).

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

### Dictionary used

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

|                    |           |
|--------------------|-----------|
| Dictionary version | 22.0 23.0 |
|--------------------|-----------|

### Reporting groups

|                       |   |
|-----------------------|---|
| Reporting group title | $<30$ kg Participants, Vedolizumab 200 mg |
|-----------------------|---|

Reporting group description:

Participants with UC or CD having baseline weight of  $<30$  kg, were randomized to this high dose group and received vedolizumab 200 mg IV infusion on Day 1 and at Weeks 2, 6 and 14.

|                       |   |
|-----------------------|---|
| Reporting group title | $<30$ kg Participants, Vedolizumab 100 mg |
|-----------------------|---|

Reporting group description:

Participants with UC or CD having baseline weight of  $<30$  kg, were randomized to this low dose group and received vedolizumab 100 mg IV infusion on Day 1 and at Weeks 2, 6 and 14.

|                       |   |
|-----------------------|---|
| Reporting group title | $\geq 30$ kg Participants, Vedolizumab 300 mg |
|-----------------------|---|

Reporting group description:

Participants with UC or CD having baseline weight of  $\geq 30$  kg, were randomized to this low dose group and received vedolizumab 300 mg IV infusion on Day 1 and at Weeks 2, 6 and 14.

|                       |   |
|-----------------------|---|
| Reporting group title | $<30$ kg Participants, Vedolizumab 100 mg to 200 mg |
|-----------------------|---|

Reporting group description:

Participants from ' $<30$  kg Participants, Vedolizumab 100 mg' low dose group who did not achieve Clinical Response at Week 14 were escalated to receive vedolizumab 200 mg IV infusion at Week 14.

|                       |   |
|-----------------------|---|
| Reporting group title | $\geq 30$ kg Participants, Vedolizumab 150 mg |
|-----------------------|---|

Reporting group description:

Participants with UC or CD having baseline weight of  $\geq 30$  kg, were randomized to this low dose group and received vedolizumab 150 mg IV infusion on Day 1 and at Weeks 2, 6 and 14.

|                       |   |
|-----------------------|---|
| Reporting group title | $\geq 30$ kg Participants, Vedolizumab 150 mg to 300 mg |
|-----------------------|---|

Reporting group description:

Participants from ' $\geq 30$  kg Participants, Vedolizumab 150 mg' low dose group who did not achieve Clinical Response at Week 14 were escalated to receive vedolizumab 300 mg IV infusion at Week 14.

| Serious adverse events                            | $<30$ kg Participants, Vedolizumab 200 mg | $<30$ kg Participants, Vedolizumab 100 mg | $\geq 30$ kg Participants, Vedolizumab 300 mg |
|---|---|---|---|
| Total subjects affected by serious adverse events |   |   |   |
| subjects affected / exposed                       | 6 / 19 (31.58%)                           | 4 / 17 (23.53%)                           | 8 / 24 (33.33%)                               |
| number of deaths (all causes)                     | 0   | 0   | 0   |
| number of deaths resulting from adverse events    | 0   | 0   | 0   |
| Injury, poisoning and procedural complications    |   |   |   |

|   |                 |                |                 |
|---|-----------------|----------------|-----------------|
| Procedural intestinal perforation<br>subjects affected / exposed                | 0 / 19 (0.00%)  | 1 / 17 (5.88%) | 0 / 24 (0.00%)  |
| occurrences causally related to<br>treatment / all                              | 0 / 0           | 0 / 1          | 0 / 0           |
| deaths causally related to<br>treatment / all                                   | 0 / 0           | 0 / 0          | 0 / 0           |
| Stoma site inflammation<br>subjects affected / exposed                          | 0 / 19 (0.00%)  | 0 / 17 (0.00%) | 1 / 24 (4.17%)  |
| occurrences causally related to<br>treatment / all                              | 0 / 0           | 0 / 0          | 0 / 1           |
| deaths causally related to<br>treatment / all                                   | 0 / 0           | 0 / 0          | 0 / 0           |
| Blood and lymphatic system disorders<br>Anaemia<br>subjects affected / exposed  | 1 / 19 (5.26%)  | 0 / 17 (0.00%) | 1 / 24 (4.17%)  |
| occurrences causally related to<br>treatment / all                              | 0 / 5           | 0 / 0          | 0 / 1           |
| deaths causally related to<br>treatment / all                                   | 0 / 0           | 0 / 0          | 0 / 0           |
| Gastrointestinal disorders<br>Colitis ulcerative<br>subjects affected / exposed | 2 / 19 (10.53%) | 0 / 17 (0.00%) | 3 / 24 (12.50%) |
| occurrences causally related to<br>treatment / all                              | 0 / 2           | 0 / 0          | 0 / 3           |
| deaths causally related to<br>treatment / all                                   | 0 / 0           | 0 / 0          | 0 / 0           |
| Crohn's disease<br>subjects affected / exposed                                  | 3 / 19 (15.79%) | 0 / 17 (0.00%) | 2 / 24 (8.33%)  |
| occurrences causally related to<br>treatment / all                              | 0 / 5           | 0 / 0          | 0 / 3           |
| deaths causally related to<br>treatment / all                                   | 0 / 0           | 0 / 0          | 0 / 0           |
| Abdominal pain<br>subjects affected / exposed                                   | 1 / 19 (5.26%)  | 0 / 17 (0.00%) | 0 / 24 (0.00%)  |
| occurrences causally related to<br>treatment / all                              | 0 / 1           | 0 / 0          | 0 / 0           |
| deaths causally related to<br>treatment / all                                   | 0 / 0           | 0 / 0          | 0 / 0           |
| Colitis<br>subjects affected / exposed  | 0 / 19 (0.00%)  | 0 / 17 (0.00%) | 0 / 24 (0.00%)  |
| occurrences causally related to<br>treatment / all                              | 0 / 0           | 0 / 0          | 0 / 0           |
| deaths causally related to<br>treatment / all                                   | 0 / 0           | 0 / 0          | 0 / 0           |
| Gastrointestinal obstruction<br>subjects affected / exposed                     | 0 / 19 (0.00%)  | 0 / 17 (0.00%) | 1 / 24 (4.17%)  |
| occurrences causally related to<br>treatment / all                              | 0 / 0           | 0 / 0          | 0 / 2           |
| deaths causally related to<br>treatment / all                                   | 0 / 0           | 0 / 0          | 0 / 0           |

|   |                |                |                |
|---|----------------|----------------|----------------|
| Small intestinal obstruction                    |                |                |                |
| subjects affected / exposed                     | 0 / 19 (0.00%) | 0 / 17 (0.00%) | 1 / 24 (4.17%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Musculoskeletal and connective tissue disorders |                |                |                |
| Pleural mass                                    |                |                |                |
| subjects affected / exposed                     | 0 / 19 (0.00%) | 0 / 17 (0.00%) | 1 / 24 (4.17%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Infections and infestations                     |                |                |                |
| Clostridium difficile infection                 |                |                |                |
| subjects affected / exposed                     | 0 / 19 (0.00%) | 1 / 17 (5.88%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Enterobacter sepsis                             |                |                |                |
| subjects affected / exposed                     | 1 / 19 (5.26%) | 0 / 17 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Pelvic abscess                                  |                |                |                |
| subjects affected / exposed                     | 0 / 19 (0.00%) | 1 / 17 (5.88%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Septic shock                                    |                |                |                |
| subjects affected / exposed                     | 1 / 19 (5.26%) | 0 / 17 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Varicella                                       |                |                |                |
| subjects affected / exposed                     | 0 / 19 (0.00%) | 1 / 17 (5.88%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Bacterial infection                             |                |                |                |
| subjects affected / exposed                     | 0 / 19 (0.00%) | 0 / 17 (0.00%) | 1 / 24 (4.17%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |

|   |                |                |                |
|---|----------------|----------------|----------------|
| Pneumonia                                       |                |                |                |
| subjects affected / exposed                     | 0 / 19 (0.00%) | 0 / 17 (0.00%) | 1 / 24 (4.17%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Staphylococcal sepsis                           |                |                |                |
| subjects affected / exposed                     | 0 / 19 (0.00%) | 0 / 17 (0.00%) | 1 / 24 (4.17%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Viral infection                                 |                |                |                |
| subjects affected / exposed                     | 0 / 19 (0.00%) | 0 / 17 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Metabolism and nutrition disorders              |                |                |                |
| Malnutrition                                    |                |                |                |
| subjects affected / exposed                     | 0 / 19 (0.00%) | 0 / 17 (0.00%) | 1 / 24 (4.17%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Decreased appetite                              |                |                |                |
| subjects affected / exposed                     | 0 / 19 (0.00%) | 0 / 17 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |

| <b>Serious adverse events</b>                     | <30 kg Participants,<br>Vedolizumab 100 mg to 200 mg | >=30 kg<br>Participants,<br>Vedolizumab 150 mg | >=30 kg<br>Participants,<br>Vedolizumab 150 mg to 300 mg |
|---|--|--|--|
| Total subjects affected by serious adverse events |  |  |  |
| subjects affected / exposed                       | 2 / 4 (50.00%)                                       | 2 / 18 (11.11%)                                | 1 / 6 (16.67%)   |
| number of deaths (all causes)                     | 0  | 0  | 0  |
| number of deaths resulting from adverse events    | 0  | 0  | 0  |
| Injury, poisoning and procedural complications    |  |  |  |
| Procedural intestinal perforation                 |  |  |  |
| subjects affected / exposed                       | 0 / 4 (0.00%)  | 0 / 18 (0.00%)                                 | 0 / 6 (0.00%)  |
| occurrences causally related to treatment / all   | 0 / 0  | 0 / 0  | 0 / 0  |
| deaths causally related to treatment / all        | 0 / 0  | 0 / 0  | 0 / 0  |
| Stoma site inflammation                           |  |  |  |

|   |                |                |               |
|---|----------------|----------------|---------------|
| subjects affected / exposed                     | 0 / 4 (0.00%)  | 0 / 18 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Blood and lymphatic system disorders            |                |                |               |
| Anaemia   |                |                |               |
| subjects affected / exposed                     | 1 / 4 (25.00%) | 0 / 18 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Gastrointestinal disorders                      |                |                |               |
| Colitis ulcerative                              |                |                |               |
| subjects affected / exposed                     | 0 / 4 (0.00%)  | 1 / 18 (5.56%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Crohn's disease                                 |                |                |               |
| subjects affected / exposed                     | 0 / 4 (0.00%)  | 1 / 18 (5.56%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Abdominal pain                                  |                |                |               |
| subjects affected / exposed                     | 1 / 4 (25.00%) | 0 / 18 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 3          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Colitis   |                |                |               |
| subjects affected / exposed                     | 1 / 4 (25.00%) | 0 / 18 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Gastrointestinal obstruction                    |                |                |               |
| subjects affected / exposed                     | 0 / 4 (0.00%)  | 0 / 18 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Small intestinal obstruction                    |                |                |               |
| subjects affected / exposed                     | 0 / 4 (0.00%)  | 0 / 18 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Musculoskeletal and connective tissue           |                |                |               |

|   |               |                |               |
|---|---------------|----------------|---------------|
| disorders                                       |               |                |               |
| Pleural mass                                    |               |                |               |
| subjects affected / exposed                     | 0 / 4 (0.00%) | 0 / 18 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Infections and infestations                     |               |                |               |
| Clostridium difficile infection                 |               |                |               |
| subjects affected / exposed                     | 0 / 4 (0.00%) | 0 / 18 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Enterobacter sepsis                             |               |                |               |
| subjects affected / exposed                     | 0 / 4 (0.00%) | 0 / 18 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Pelvic abscess                                  |               |                |               |
| subjects affected / exposed                     | 0 / 4 (0.00%) | 0 / 18 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Septic shock                                    |               |                |               |
| subjects affected / exposed                     | 0 / 4 (0.00%) | 0 / 18 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Varicella                                       |               |                |               |
| subjects affected / exposed                     | 0 / 4 (0.00%) | 0 / 18 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Bacterial infection                             |               |                |               |
| subjects affected / exposed                     | 0 / 4 (0.00%) | 0 / 18 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |
| Pneumonia                                       |               |                |               |
| subjects affected / exposed                     | 0 / 4 (0.00%) | 0 / 18 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0         |

|   |                |                |                |
|---|----------------|----------------|----------------|
| Staphylococcal sepsis                           |                |                |                |
| subjects affected / exposed                     | 0 / 4 (0.00%)  | 0 / 18 (0.00%) | 0 / 6 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Viral infection                                 |                |                |                |
| subjects affected / exposed                     | 0 / 4 (0.00%)  | 0 / 18 (0.00%) | 1 / 6 (16.67%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 1 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Metabolism and nutrition disorders              |                |                |                |
| Malnutrition                                    |                |                |                |
| subjects affected / exposed                     | 0 / 4 (0.00%)  | 0 / 18 (0.00%) | 0 / 6 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Decreased appetite                              |                |                |                |
| subjects affected / exposed                     | 1 / 4 (25.00%) | 0 / 18 (0.00%) | 0 / 6 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |

Frequency threshold for reporting non-serious adverse events: 4 %

| <b>Non-serious adverse events</b>                                   | <30 kg Participants,<br>Vedolizumab 200 mg | <30 kg Participants,<br>Vedolizumab 100 mg | >=30 kg<br>Participants,<br>Vedolizumab 300 mg |
|---|--|--|--|
| Total subjects affected by non-serious adverse events               |  |  |  |
| subjects affected / exposed   | 13 / 19 (68.42%)                           | 16 / 17 (94.12%)                           | 20 / 24 (83.33%)                               |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |  |  |  |
| Skin papilloma  |  |  |  |
| subjects affected / exposed   | 0 / 19 (0.00%)                             | 1 / 17 (5.88%)                             | 0 / 24 (0.00%)                                 |
| occurrences (all)   | 0  | 1  | 0  |
| Vascular disorders  |  |  |  |
| Hot flush   |  |  |  |
| subjects affected / exposed   | 1 / 19 (5.26%)                             | 0 / 17 (0.00%)                             | 0 / 24 (0.00%)                                 |
| occurrences (all)   | 1  | 0  | 0  |
| Pallor  |  |  |  |
| subjects affected / exposed   | 0 / 19 (0.00%)                             | 1 / 17 (5.88%)                             | 0 / 24 (0.00%)                                 |
| occurrences (all)   | 0  | 1  | 0  |

|  |                      |                     |                      |
|--|----------------------|---------------------|----------------------|
| Haematoma<br>subjects affected / exposed<br>occurrences (all)                  | 0 / 19 (0.00%)<br>0  | 0 / 17 (0.00%)<br>0 | 1 / 24 (4.17%)<br>1  |
| General disorders and administration<br>site conditions                        |                      |                     |                      |
| Pyrexia<br>subjects affected / exposed<br>occurrences (all)                    | 2 / 19 (10.53%)<br>3 | 1 / 17 (5.88%)<br>1 | 3 / 24 (12.50%)<br>9 |
| Face oedema<br>subjects affected / exposed<br>occurrences (all)                | 0 / 19 (0.00%)<br>0  | 0 / 17 (0.00%)<br>0 | 0 / 24 (0.00%)<br>0  |
| Influenza like illness<br>subjects affected / exposed<br>occurrences (all)     | 1 / 19 (5.26%)<br>1  | 0 / 17 (0.00%)<br>0 | 0 / 24 (0.00%)<br>0  |
| Infusion site irritation<br>subjects affected / exposed<br>occurrences (all)   | 0 / 19 (0.00%)<br>0  | 1 / 17 (5.88%)<br>1 | 0 / 24 (0.00%)<br>0  |
| Asthenia<br>subjects affected / exposed<br>occurrences (all)                   | 0 / 19 (0.00%)<br>0  | 0 / 17 (0.00%)<br>0 | 0 / 24 (0.00%)<br>0  |
| Chest pain<br>subjects affected / exposed<br>occurrences (all)                 | 0 / 19 (0.00%)<br>0  | 0 / 17 (0.00%)<br>0 | 1 / 24 (4.17%)<br>1  |
| Malaise<br>subjects affected / exposed<br>occurrences (all)                    | 0 / 19 (0.00%)<br>0  | 0 / 17 (0.00%)<br>0 | 1 / 24 (4.17%)<br>1  |
| Fatigue<br>subjects affected / exposed<br>occurrences (all)                    | 0 / 19 (0.00%)<br>0  | 0 / 17 (0.00%)<br>0 | 1 / 24 (4.17%)<br>1  |
| Immune system disorders  |                      |                     |                      |
| Allergy to arthropod sting<br>subjects affected / exposed<br>occurrences (all) | 0 / 19 (0.00%)<br>0  | 1 / 17 (5.88%)<br>1 | 0 / 24 (0.00%)<br>0  |
| Hypersensitivity<br>subjects affected / exposed<br>occurrences (all)           | 0 / 19 (0.00%)<br>0  | 0 / 17 (0.00%)<br>0 | 1 / 24 (4.17%)<br>1  |
| Seasonal allergy   |                      |                     |                      |



|   |                      |                     |                     |
|---|----------------------|---------------------|---------------------|
| subjects affected / exposed<br>occurrences (all)                                | 0 / 19 (0.00%)<br>0  | 0 / 17 (0.00%)<br>0 | 1 / 24 (4.17%)<br>1 |
| Reproductive system and breast disorders  |                      |                     |                     |
| Menstruation delayed<br>subjects affected / exposed<br>occurrences (all)        | 0 / 19 (0.00%)<br>0  | 0 / 17 (0.00%)<br>0 | 1 / 24 (4.17%)<br>1 |
| Vulvovaginal pruritus<br>subjects affected / exposed<br>occurrences (all)       | 0 / 19 (0.00%)<br>0  | 0 / 17 (0.00%)<br>0 | 1 / 24 (4.17%)<br>1 |
| Vulvovaginal swelling<br>subjects affected / exposed<br>occurrences (all)       | 0 / 19 (0.00%)<br>0  | 0 / 17 (0.00%)<br>0 | 1 / 24 (4.17%)<br>1 |
| Respiratory, thoracic and mediastinal disorders                                 |                      |                     |                     |
| Oropharyngeal pain<br>subjects affected / exposed<br>occurrences (all)          | 3 / 19 (15.79%)<br>3 | 1 / 17 (5.88%)<br>1 | 1 / 24 (4.17%)<br>1 |
| Cough<br>subjects affected / exposed<br>occurrences (all)                       | 2 / 19 (10.53%)<br>2 | 0 / 17 (0.00%)<br>0 | 1 / 24 (4.17%)<br>1 |
| Rhinorrhoea<br>subjects affected / exposed<br>occurrences (all)                 | 1 / 19 (5.26%)<br>1  | 1 / 17 (5.88%)<br>1 | 1 / 24 (4.17%)<br>1 |
| Nasal congestion<br>subjects affected / exposed<br>occurrences (all)            | 1 / 19 (5.26%)<br>2  | 0 / 17 (0.00%)<br>0 | 0 / 24 (0.00%)<br>0 |
| Tonsillar hypertrophy<br>subjects affected / exposed<br>occurrences (all)       | 1 / 19 (5.26%)<br>1  | 0 / 17 (0.00%)<br>0 | 0 / 24 (0.00%)<br>0 |
| Upper-airway cough syndrome<br>subjects affected / exposed<br>occurrences (all) | 1 / 19 (5.26%)<br>1  | 0 / 17 (0.00%)<br>0 | 0 / 24 (0.00%)<br>0 |
| Asthma<br>subjects affected / exposed<br>occurrences (all)                      | 0 / 19 (0.00%)<br>0  | 0 / 17 (0.00%)<br>0 | 0 / 24 (0.00%)<br>0 |
| Dyspnoea exertional   |                      |                     |                     |

|  |                     |                     |                     |
|--|---------------------|---------------------|---------------------|
| subjects affected / exposed<br>occurrences (all) | 0 / 19 (0.00%)<br>0 | 0 / 17 (0.00%)<br>0 | 0 / 24 (0.00%)<br>0 |
| Psychiatric disorders                            |                     |                     |                     |
| Depression                                       |                     |                     |                     |
| subjects affected / exposed                      | 0 / 19 (0.00%)      | 0 / 17 (0.00%)      | 1 / 24 (4.17%)      |
| occurrences (all)                                | 0                   | 0                   | 1                   |
| Anxiety  |                     |                     |                     |
| subjects affected / exposed                      | 0 / 19 (0.00%)      | 1 / 17 (5.88%)      | 0 / 24 (0.00%)      |
| occurrences (all)                                | 0                   | 1                   | 0                   |
| Fear of injection                                |                     |                     |                     |
| subjects affected / exposed                      | 1 / 19 (5.26%)      | 0 / 17 (0.00%)      | 0 / 24 (0.00%)      |
| occurrences (all)                                | 1                   | 0                   | 0                   |
| Insomnia   |                     |                     |                     |
| subjects affected / exposed                      | 0 / 19 (0.00%)      | 1 / 17 (5.88%)      | 0 / 24 (0.00%)      |
| occurrences (all)                                | 0                   | 1                   | 0                   |
| Investigations                                   |                     |                     |                     |
| C-reactive protein increased                     |                     |                     |                     |
| subjects affected / exposed                      | 1 / 19 (5.26%)      | 1 / 17 (5.88%)      | 0 / 24 (0.00%)      |
| occurrences (all)                                | 1                   | 1                   | 0                   |
| Blood albumin decreased                          |                     |                     |                     |
| subjects affected / exposed                      | 0 / 19 (0.00%)      | 1 / 17 (5.88%)      | 1 / 24 (4.17%)      |
| occurrences (all)                                | 0                   | 1                   | 1                   |
| Blood bicarbonate decreased                      |                     |                     |                     |
| subjects affected / exposed                      | 0 / 19 (0.00%)      | 1 / 17 (5.88%)      | 0 / 24 (0.00%)      |
| occurrences (all)                                | 0                   | 1                   | 0                   |
| Blood glucose increased                          |                     |                     |                     |
| subjects affected / exposed                      | 0 / 19 (0.00%)      | 1 / 17 (5.88%)      | 0 / 24 (0.00%)      |
| occurrences (all)                                | 0                   | 1                   | 0                   |
| Body temperature increased                       |                     |                     |                     |
| subjects affected / exposed                      | 1 / 19 (5.26%)      | 0 / 17 (0.00%)      | 0 / 24 (0.00%)      |
| occurrences (all)                                | 3                   | 0                   | 0                   |
| Clostridium test positive                        |                     |                     |                     |
| subjects affected / exposed                      | 1 / 19 (5.26%)      | 0 / 17 (0.00%)      | 0 / 24 (0.00%)      |
| occurrences (all)                                | 1                   | 0                   | 0                   |
| Haematocrit decreased                            |                     |                     |                     |

|  |                |                |                |
|--|----------------|----------------|----------------|
| subjects affected / exposed                    | 0 / 19 (0.00%) | 1 / 17 (5.88%) | 0 / 24 (0.00%) |
| occurrences (all)                              | 0              | 1              | 0              |
| Haemoglobin decreased                          |                |                |                |
| subjects affected / exposed                    | 0 / 19 (0.00%) | 1 / 17 (5.88%) | 2 / 24 (8.33%) |
| occurrences (all)                              | 0              | 1              | 3              |
| Weight decreased                               |                |                |                |
| subjects affected / exposed                    | 0 / 19 (0.00%) | 0 / 17 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all)                              | 0              | 0              | 0              |
| Amylase increased                              |                |                |                |
| subjects affected / exposed                    | 0 / 19 (0.00%) | 0 / 17 (0.00%) | 1 / 24 (4.17%) |
| occurrences (all)                              | 0              | 0              | 1              |
| Liver function test increased                  |                |                |                |
| subjects affected / exposed                    | 0 / 19 (0.00%) | 0 / 17 (0.00%) | 1 / 24 (4.17%) |
| occurrences (all)                              | 0              | 0              | 1              |
| Red blood cell count decreased                 |                |                |                |
| subjects affected / exposed                    | 0 / 19 (0.00%) | 0 / 17 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all)                              | 0              | 0              | 0              |
| Blood calcium decreased                        |                |                |                |
| subjects affected / exposed                    | 0 / 19 (0.00%) | 0 / 17 (0.00%) | 1 / 24 (4.17%) |
| occurrences (all)                              | 0              | 0              | 1              |
| Injury, poisoning and procedural complications |                |                |                |
| Torus fracture                                 |                |                |                |
| subjects affected / exposed                    | 0 / 19 (0.00%) | 0 / 17 (0.00%) | 1 / 24 (4.17%) |
| occurrences (all)                              | 0              | 0              | 1              |
| Arthropod bite                                 |                |                |                |
| subjects affected / exposed                    | 1 / 19 (5.26%) | 0 / 17 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all)                              | 1              | 0              | 0              |
| Joint injury                                   |                |                |                |
| subjects affected / exposed                    | 0 / 19 (0.00%) | 0 / 17 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all)                              | 0              | 0              | 0              |
| Limb injury                                    |                |                |                |
| subjects affected / exposed                    | 0 / 19 (0.00%) | 1 / 17 (5.88%) | 0 / 24 (0.00%) |
| occurrences (all)                              | 0              | 1              | 0              |
| Procedural dizziness                           |                |                |                |

|   |                      |                     |                      |
|---|----------------------|---------------------|----------------------|
| subjects affected / exposed<br>occurrences (all)  | 1 / 19 (5.26%)<br>1  | 0 / 17 (0.00%)<br>0 | 0 / 24 (0.00%)<br>0  |
| Procedural pain<br>subjects affected / exposed<br>occurrences (all)                                 | 0 / 19 (0.00%)<br>0  | 1 / 17 (5.88%)<br>1 | 0 / 24 (0.00%)<br>0  |
| Nervous system disorders<br>Headache<br>subjects affected / exposed<br>occurrences (all)            | 2 / 19 (10.53%)<br>2 | 1 / 17 (5.88%)<br>2 | 3 / 24 (12.50%)<br>4 |
| Dizziness<br>subjects affected / exposed<br>occurrences (all)                                       | 0 / 19 (0.00%)<br>0  | 1 / 17 (5.88%)<br>1 | 0 / 24 (0.00%)<br>0  |
| Blood and lymphatic system disorders<br>Anaemia<br>subjects affected / exposed<br>occurrences (all) | 3 / 19 (15.79%)<br>3 | 1 / 17 (5.88%)<br>1 | 1 / 24 (4.17%)<br>2  |
| Lymphopenia<br>subjects affected / exposed<br>occurrences (all)                                     | 1 / 19 (5.26%)<br>1  | 1 / 17 (5.88%)<br>1 | 2 / 24 (8.33%)<br>3  |
| Microcytic anaemia<br>subjects affected / exposed<br>occurrences (all)                              | 0 / 19 (0.00%)<br>0  | 0 / 17 (0.00%)<br>0 | 1 / 24 (4.17%)<br>1  |
| Ear and labyrinth disorders<br>Ear pain<br>subjects affected / exposed<br>occurrences (all)         | 0 / 19 (0.00%)<br>0  | 0 / 17 (0.00%)<br>0 | 0 / 24 (0.00%)<br>0  |
| Eye disorders<br>Swelling of eyelid<br>subjects affected / exposed<br>occurrences (all)             | 0 / 19 (0.00%)<br>0  | 1 / 17 (5.88%)<br>1 | 0 / 24 (0.00%)<br>0  |
| Eye swelling<br>subjects affected / exposed<br>occurrences (all)                                    | 0 / 19 (0.00%)<br>0  | 0 / 17 (0.00%)<br>0 | 0 / 24 (0.00%)<br>0  |
| Ocular hyperaemia<br>subjects affected / exposed<br>occurrences (all)                               | 0 / 19 (0.00%)<br>0  | 0 / 17 (0.00%)<br>0 | 0 / 24 (0.00%)<br>0  |
| Gastrointestinal disorders  |                      |                     |                      |

|                             |                 |                 |                |
|-----------------------------|-----------------|-----------------|----------------|
| Abdominal pain              |                 |                 |                |
| subjects affected / exposed | 3 / 19 (15.79%) | 5 / 17 (29.41%) | 1 / 24 (4.17%) |
| occurrences (all)           | 3               | 8               | 2              |
| Vomiting                    |                 |                 |                |
| subjects affected / exposed | 1 / 19 (5.26%)  | 1 / 17 (5.88%)  | 0 / 24 (0.00%) |
| occurrences (all)           | 1               | 4               | 0              |
| Crohn's disease             |                 |                 |                |
| subjects affected / exposed | 1 / 19 (5.26%)  | 2 / 17 (11.76%) | 2 / 24 (8.33%) |
| occurrences (all)           | 1               | 2               | 2              |
| Abdominal distension        |                 |                 |                |
| subjects affected / exposed | 1 / 19 (5.26%)  | 0 / 17 (0.00%)  | 0 / 24 (0.00%) |
| occurrences (all)           | 1               | 0               | 0              |
| Diarrhoea                   |                 |                 |                |
| subjects affected / exposed | 0 / 19 (0.00%)  | 0 / 17 (0.00%)  | 1 / 24 (4.17%) |
| occurrences (all)           | 0               | 0               | 1              |
| Abdominal rigidity          |                 |                 |                |
| subjects affected / exposed | 1 / 19 (5.26%)  | 0 / 17 (0.00%)  | 0 / 24 (0.00%) |
| occurrences (all)           | 1               | 0               | 0              |
| Abdominal tenderness        |                 |                 |                |
| subjects affected / exposed | 1 / 19 (5.26%)  | 0 / 17 (0.00%)  | 0 / 24 (0.00%) |
| occurrences (all)           | 1               | 0               | 0              |
| Abnormal faeces             |                 |                 |                |
| subjects affected / exposed | 0 / 19 (0.00%)  | 0 / 17 (0.00%)  | 0 / 24 (0.00%) |
| occurrences (all)           | 0               | 0               | 0              |
| Anal fissure                |                 |                 |                |
| subjects affected / exposed | 0 / 19 (0.00%)  | 0 / 17 (0.00%)  | 0 / 24 (0.00%) |
| occurrences (all)           | 0               | 0               | 0              |
| Anal fistula                |                 |                 |                |
| subjects affected / exposed | 1 / 19 (5.26%)  | 0 / 17 (0.00%)  | 0 / 24 (0.00%) |
| occurrences (all)           | 1               | 0               | 0              |
| Chapped lips                |                 |                 |                |
| subjects affected / exposed | 1 / 19 (5.26%)  | 0 / 17 (0.00%)  | 0 / 24 (0.00%) |
| occurrences (all)           | 1               | 0               | 0              |
| Colitis ulcerative          |                 |                 |                |
| subjects affected / exposed | 0 / 19 (0.00%)  | 1 / 17 (5.88%)  | 1 / 24 (4.17%) |
| occurrences (all)           | 0               | 1               | 1              |

|                                  |                |                |                |
|----------------------------------|----------------|----------------|----------------|
| Gastritis                        |                |                |                |
| subjects affected / exposed      | 0 / 19 (0.00%) | 1 / 17 (5.88%) | 0 / 24 (0.00%) |
| occurrences (all)                | 0              | 1              | 0              |
| Lip swelling                     |                |                |                |
| subjects affected / exposed      | 0 / 19 (0.00%) | 0 / 17 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all)                | 0              | 0              | 0              |
| Melaena                          |                |                |                |
| subjects affected / exposed      | 0 / 19 (0.00%) | 0 / 17 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all)                | 0              | 0              | 0              |
| Mouth ulceration                 |                |                |                |
| subjects affected / exposed      | 1 / 19 (5.26%) | 0 / 17 (0.00%) | 1 / 24 (4.17%) |
| occurrences (all)                | 1              | 0              | 1              |
| Nausea                           |                |                |                |
| subjects affected / exposed      | 0 / 19 (0.00%) | 1 / 17 (5.88%) | 0 / 24 (0.00%) |
| occurrences (all)                | 0              | 1              | 0              |
| Rectal haemorrhage               |                |                |                |
| subjects affected / exposed      | 0 / 19 (0.00%) | 0 / 17 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all)                | 0              | 0              | 0              |
| Constipation                     |                |                |                |
| subjects affected / exposed      | 0 / 19 (0.00%) | 0 / 17 (0.00%) | 2 / 24 (8.33%) |
| occurrences (all)                | 0              | 0              | 2              |
| Abdominal pain upper             |                |                |                |
| subjects affected / exposed      | 0 / 19 (0.00%) | 0 / 17 (0.00%) | 1 / 24 (4.17%) |
| occurrences (all)                | 0              | 0              | 1              |
| Gastrointestinal inflammation    |                |                |                |
| subjects affected / exposed      | 0 / 19 (0.00%) | 0 / 17 (0.00%) | 1 / 24 (4.17%) |
| occurrences (all)                | 0              | 0              | 1              |
| Gastrointestinal obstruction     |                |                |                |
| subjects affected / exposed      | 0 / 19 (0.00%) | 0 / 17 (0.00%) | 1 / 24 (4.17%) |
| occurrences (all)                | 0              | 0              | 1              |
| Gastrooesophageal reflux disease |                |                |                |
| subjects affected / exposed      | 0 / 19 (0.00%) | 0 / 17 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all)                | 0              | 0              | 0              |
| Glossodynia                      |                |                |                |
| subjects affected / exposed      | 0 / 19 (0.00%) | 0 / 17 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all)                | 0              | 0              | 0              |

|  |                |                |                |
|--|----------------|----------------|----------------|
| Haemorrhoids                           |                |                |                |
| subjects affected / exposed            | 0 / 19 (0.00%) | 0 / 17 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all)                      | 0              | 0              | 0              |
| Stomatitis                             |                |                |                |
| subjects affected / exposed            | 0 / 19 (0.00%) | 0 / 17 (0.00%) | 1 / 24 (4.17%) |
| occurrences (all)                      | 0              | 0              | 1              |
| Toothache                              |                |                |                |
| subjects affected / exposed            | 0 / 19 (0.00%) | 0 / 17 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all)                      | 0              | 0              | 0              |
| Skin and subcutaneous tissue disorders |                |                |                |
| Dermatitis                             |                |                |                |
| subjects affected / exposed            | 0 / 19 (0.00%) | 0 / 17 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all)                      | 0              | 0              | 0              |
| Nail bed inflammation                  |                |                |                |
| subjects affected / exposed            | 1 / 19 (5.26%) | 0 / 17 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all)                      | 1              | 0              | 0              |
| Rash pruritic                          |                |                |                |
| subjects affected / exposed            | 1 / 19 (5.26%) | 0 / 17 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all)                      | 1              | 0              | 0              |
| Skin lesion                            |                |                |                |
| subjects affected / exposed            | 0 / 19 (0.00%) | 1 / 17 (5.88%) | 0 / 24 (0.00%) |
| occurrences (all)                      | 0              | 2              | 0              |
| Eczema                                 |                |                |                |
| subjects affected / exposed            | 0 / 19 (0.00%) | 0 / 17 (0.00%) | 1 / 24 (4.17%) |
| occurrences (all)                      | 0              | 0              | 1              |
| Miliaria                               |                |                |                |
| subjects affected / exposed            | 0 / 19 (0.00%) | 0 / 17 (0.00%) | 1 / 24 (4.17%) |
| occurrences (all)                      | 0              | 0              | 1              |
| Night sweats                           |                |                |                |
| subjects affected / exposed            | 0 / 19 (0.00%) | 0 / 17 (0.00%) | 1 / 24 (4.17%) |
| occurrences (all)                      | 0              | 0              | 1              |
| Psoriasis                              |                |                |                |
| subjects affected / exposed            | 0 / 19 (0.00%) | 0 / 17 (0.00%) | 1 / 24 (4.17%) |
| occurrences (all)                      | 0              | 0              | 1              |
| Skin exfoliation                       |                |                |                |

|   |                     |                      |                     |
|---|---------------------|----------------------|---------------------|
| subjects affected / exposed<br>occurrences (all)  | 0 / 19 (0.00%)<br>0 | 0 / 17 (0.00%)<br>0  | 0 / 24 (0.00%)<br>0 |
| Erythema nodosum<br>subjects affected / exposed<br>occurrences (all)                          | 0 / 19 (0.00%)<br>0 | 0 / 17 (0.00%)<br>0  | 1 / 24 (4.17%)<br>1 |
| Renal and urinary disorders   |                     |                      |                     |
| Nephrolithiasis<br>subjects affected / exposed<br>occurrences (all)                           | 0 / 19 (0.00%)<br>0 | 1 / 17 (5.88%)<br>1  | 0 / 24 (0.00%)<br>0 |
| Acute kidney injury<br>subjects affected / exposed<br>occurrences (all)                       | 0 / 19 (0.00%)<br>0 | 0 / 17 (0.00%)<br>0  | 1 / 24 (4.17%)<br>1 |
| Dysuria<br>subjects affected / exposed<br>occurrences (all)                                   | 0 / 19 (0.00%)<br>0 | 0 / 17 (0.00%)<br>0  | 1 / 24 (4.17%)<br>4 |
| Proteinuria<br>subjects affected / exposed<br>occurrences (all)                               | 0 / 19 (0.00%)<br>0 | 0 / 17 (0.00%)<br>0  | 1 / 24 (4.17%)<br>1 |
| Endocrine disorders   |                     |                      |                     |
| Cushingoid<br>subjects affected / exposed<br>occurrences (all)                                | 1 / 19 (5.26%)<br>1 | 0 / 17 (0.00%)<br>0  | 0 / 24 (0.00%)<br>0 |
| Secondary adrenocortical<br>insufficiency<br>subjects affected / exposed<br>occurrences (all) | 0 / 19 (0.00%)<br>0 | 0 / 17 (0.00%)<br>0  | 0 / 24 (0.00%)<br>0 |
| Musculoskeletal and connective tissue<br>disorders  |                     |                      |                     |
| Arthralgia<br>subjects affected / exposed<br>occurrences (all)                                | 0 / 19 (0.00%)<br>0 | 2 / 17 (11.76%)<br>2 | 2 / 24 (8.33%)<br>2 |
| Back pain<br>subjects affected / exposed<br>occurrences (all)                                 | 0 / 19 (0.00%)<br>0 | 0 / 17 (0.00%)<br>0  | 0 / 24 (0.00%)<br>0 |
| Costochondritis<br>subjects affected / exposed<br>occurrences (all)                           | 0 / 19 (0.00%)<br>0 | 0 / 17 (0.00%)<br>0  | 0 / 24 (0.00%)<br>0 |
| Myalgia   |                     |                      |                     |



|   |                     |                     |                     |
|---|---------------------|---------------------|---------------------|
| subjects affected / exposed<br>occurrences (all)                                      | 0 / 19 (0.00%)<br>0 | 0 / 17 (0.00%)<br>0 | 0 / 24 (0.00%)<br>0 |
| Pain in extremity<br>subjects affected / exposed<br>occurrences (all)                 | 1 / 19 (5.26%)<br>1 | 1 / 17 (5.88%)<br>1 | 1 / 24 (4.17%)<br>1 |
| Fistula discharge<br>subjects affected / exposed<br>occurrences (all)                 | 1 / 19 (5.26%)<br>1 | 0 / 17 (0.00%)<br>0 | 0 / 24 (0.00%)<br>0 |
| Joint swelling<br>subjects affected / exposed<br>occurrences (all)                    | 0 / 19 (0.00%)<br>0 | 1 / 17 (5.88%)<br>2 | 0 / 24 (0.00%)<br>0 |
| <b>Infections and infestations</b>  |                     |                     |                     |
| Respiratory tract infection viral<br>subjects affected / exposed<br>occurrences (all) | 1 / 19 (5.26%)<br>1 | 1 / 17 (5.88%)<br>1 | 0 / 24 (0.00%)<br>0 |
| Upper respiratory tract infection<br>subjects affected / exposed<br>occurrences (all) | 1 / 19 (5.26%)<br>1 | 1 / 17 (5.88%)<br>2 | 1 / 24 (4.17%)<br>1 |
| Viral infection<br>subjects affected / exposed<br>occurrences (all)                   | 1 / 19 (5.26%)<br>1 | 1 / 17 (5.88%)<br>1 | 2 / 24 (8.33%)<br>2 |
| Bronchitis<br>subjects affected / exposed<br>occurrences (all)                        | 1 / 19 (5.26%)<br>1 | 0 / 17 (0.00%)<br>0 | 0 / 24 (0.00%)<br>0 |
| Ear infection<br>subjects affected / exposed<br>occurrences (all)                     | 1 / 19 (5.26%)<br>1 | 0 / 17 (0.00%)<br>0 | 0 / 24 (0.00%)<br>0 |
| Gastroenteritis norovirus<br>subjects affected / exposed<br>occurrences (all)         | 0 / 19 (0.00%)<br>0 | 1 / 17 (5.88%)<br>1 | 0 / 24 (0.00%)<br>0 |
| Hordeolum<br>subjects affected / exposed<br>occurrences (all)                         | 1 / 19 (5.26%)<br>1 | 0 / 17 (0.00%)<br>0 | 0 / 24 (0.00%)<br>0 |
| Influenza<br>subjects affected / exposed<br>occurrences (all)                         | 1 / 19 (5.26%)<br>1 | 0 / 17 (0.00%)<br>0 | 0 / 24 (0.00%)<br>0 |

|                                 |                |                |                 |
|---------------------------------|----------------|----------------|-----------------|
| Nasopharyngitis                 |                |                |                 |
| subjects affected / exposed     | 1 / 19 (5.26%) | 0 / 17 (0.00%) | 2 / 24 (8.33%)  |
| occurrences (all)               | 1              | 0              | 2               |
| Pharyngitis                     |                |                |                 |
| subjects affected / exposed     | 1 / 19 (5.26%) | 0 / 17 (0.00%) | 3 / 24 (12.50%) |
| occurrences (all)               | 1              | 0              | 4               |
| Pneumonia                       |                |                |                 |
| subjects affected / exposed     | 0 / 19 (0.00%) | 1 / 17 (5.88%) | 0 / 24 (0.00%)  |
| occurrences (all)               | 0              | 1              | 0               |
| Oral herpes                     |                |                |                 |
| subjects affected / exposed     | 0 / 19 (0.00%) | 0 / 17 (0.00%) | 1 / 24 (4.17%)  |
| occurrences (all)               | 0              | 0              | 1               |
| Pharyngitis streptococcal       |                |                |                 |
| subjects affected / exposed     | 0 / 19 (0.00%) | 0 / 17 (0.00%) | 0 / 24 (0.00%)  |
| occurrences (all)               | 0              | 0              | 0               |
| Clostridium difficile infection |                |                |                 |
| subjects affected / exposed     | 0 / 19 (0.00%) | 0 / 17 (0.00%) | 1 / 24 (4.17%)  |
| occurrences (all)               | 0              | 0              | 1               |
| Fungal skin infection           |                |                |                 |
| subjects affected / exposed     | 0 / 19 (0.00%) | 0 / 17 (0.00%) | 1 / 24 (4.17%)  |
| occurrences (all)               | 0              | 0              | 1               |
| Gastroenteritis                 |                |                |                 |
| subjects affected / exposed     | 0 / 19 (0.00%) | 0 / 17 (0.00%) | 0 / 24 (0.00%)  |
| occurrences (all)               | 0              | 0              | 0               |
| Gastrointestinal candidiasis    |                |                |                 |
| subjects affected / exposed     | 0 / 19 (0.00%) | 0 / 17 (0.00%) | 1 / 24 (4.17%)  |
| occurrences (all)               | 0              | 0              | 1               |
| Gastrointestinal infection      |                |                |                 |
| subjects affected / exposed     | 0 / 19 (0.00%) | 0 / 17 (0.00%) | 0 / 24 (0.00%)  |
| occurrences (all)               | 0              | 0              | 0               |
| Herpes zoster                   |                |                |                 |
| subjects affected / exposed     | 0 / 19 (0.00%) | 0 / 17 (0.00%) | 1 / 24 (4.17%)  |
| occurrences (all)               | 0              | 0              | 1               |
| Infected bite                   |                |                |                 |
| subjects affected / exposed     | 0 / 19 (0.00%) | 0 / 17 (0.00%) | 1 / 24 (4.17%)  |
| occurrences (all)               | 0              | 0              | 1               |

|   |                     |                     |                     |
|---|---------------------|---------------------|---------------------|
| Molluscum contagiosum<br>subjects affected / exposed<br>occurrences (all) | 0 / 19 (0.00%)<br>0 | 0 / 17 (0.00%)<br>0 | 1 / 24 (4.17%)<br>1 |
| Otitis externa<br>subjects affected / exposed<br>occurrences (all)        | 0 / 19 (0.00%)<br>0 | 0 / 17 (0.00%)<br>0 | 0 / 24 (0.00%)<br>0 |
| Peritonitis<br>subjects affected / exposed<br>occurrences (all)           | 0 / 19 (0.00%)<br>0 | 0 / 17 (0.00%)<br>0 | 1 / 24 (4.17%)<br>1 |
| Salmonellosis<br>subjects affected / exposed<br>occurrences (all)         | 0 / 19 (0.00%)<br>0 | 0 / 17 (0.00%)<br>0 | 1 / 24 (4.17%)<br>1 |
| Metabolism and nutrition disorders  |                     |                     |                     |
| Decreased appetite<br>subjects affected / exposed<br>occurrences (all)    | 0 / 19 (0.00%)<br>0 | 0 / 17 (0.00%)<br>0 | 0 / 24 (0.00%)<br>0 |
| Iron deficiency<br>subjects affected / exposed<br>occurrences (all)       | 0 / 19 (0.00%)<br>0 | 0 / 17 (0.00%)<br>0 | 1 / 24 (4.17%)<br>1 |
| Hypoalbuminaemia<br>subjects affected / exposed<br>occurrences (all)      | 0 / 19 (0.00%)<br>0 | 0 / 17 (0.00%)<br>0 | 1 / 24 (4.17%)<br>1 |
| Hypophosphataemia<br>subjects affected / exposed<br>occurrences (all)     | 0 / 19 (0.00%)<br>0 | 0 / 17 (0.00%)<br>0 | 0 / 24 (0.00%)<br>0 |
| Weight gain poor<br>subjects affected / exposed<br>occurrences (all)      | 0 / 19 (0.00%)<br>0 | 0 / 17 (0.00%)<br>0 | 1 / 24 (4.17%)<br>1 |

| <b>Non-serious adverse events</b>  | <30 kg Participants,<br>Vedolizumab 100<br>mg to 200 mg | >=30 kg<br>Participants,<br>Vedolizumab 150 mg | >=30 kg<br>Participants,<br>Vedolizumab 150<br>mg to 300 mg |
|--|---|--|---|
| Total subjects affected by non-serious<br>adverse events<br>subjects affected / exposed  | 3 / 4 (75.00%)  | 15 / 18 (83.33%)                               | 6 / 6 (100.00%)   |
| Neoplasms benign, malignant and<br>unspecified (incl cysts and polyps)<br>Skin papilloma |   |  |   |

|   |                     |                     |                     |
|---|---------------------|---------------------|---------------------|
| subjects affected / exposed<br>occurrences (all)        | 0 / 4 (0.00%)<br>0  | 0 / 18 (0.00%)<br>0 | 0 / 6 (0.00%)<br>0  |
| Vascular disorders                                      |                     |                     |                     |
| Hot flush   |                     |                     |                     |
| subjects affected / exposed<br>occurrences (all)        | 0 / 4 (0.00%)<br>0  | 0 / 18 (0.00%)<br>0 | 0 / 6 (0.00%)<br>0  |
| Pallor  |                     |                     |                     |
| subjects affected / exposed<br>occurrences (all)        | 0 / 4 (0.00%)<br>0  | 0 / 18 (0.00%)<br>0 | 0 / 6 (0.00%)<br>0  |
| Haematoma   |                     |                     |                     |
| subjects affected / exposed<br>occurrences (all)        | 0 / 4 (0.00%)<br>0  | 0 / 18 (0.00%)<br>0 | 0 / 6 (0.00%)<br>0  |
| General disorders and administration<br>site conditions |                     |                     |                     |
| Pyrexia   |                     |                     |                     |
| subjects affected / exposed<br>occurrences (all)        | 1 / 4 (25.00%)<br>1 | 0 / 18 (0.00%)<br>0 | 0 / 6 (0.00%)<br>0  |
| Face oedema   |                     |                     |                     |
| subjects affected / exposed<br>occurrences (all)        | 1 / 4 (25.00%)<br>1 | 0 / 18 (0.00%)<br>0 | 0 / 6 (0.00%)<br>0  |
| Influenza like illness                                  |                     |                     |                     |
| subjects affected / exposed<br>occurrences (all)        | 0 / 4 (0.00%)<br>0  | 0 / 18 (0.00%)<br>0 | 0 / 6 (0.00%)<br>0  |
| Infusion site irritation                                |                     |                     |                     |
| subjects affected / exposed<br>occurrences (all)        | 0 / 4 (0.00%)<br>0  | 0 / 18 (0.00%)<br>0 | 0 / 6 (0.00%)<br>0  |
| Asthenia  |                     |                     |                     |
| subjects affected / exposed<br>occurrences (all)        | 0 / 4 (0.00%)<br>0  | 0 / 18 (0.00%)<br>0 | 1 / 6 (16.67%)<br>1 |
| Chest pain  |                     |                     |                     |
| subjects affected / exposed<br>occurrences (all)        | 0 / 4 (0.00%)<br>0  | 0 / 18 (0.00%)<br>0 | 0 / 6 (0.00%)<br>0  |
| Malaise   |                     |                     |                     |
| subjects affected / exposed<br>occurrences (all)        | 0 / 4 (0.00%)<br>0  | 0 / 18 (0.00%)<br>0 | 0 / 6 (0.00%)<br>0  |
| Fatigue   |                     |                     |                     |

|  |                    |                     |                     |
|--|--------------------|---------------------|---------------------|
| subjects affected / exposed<br>occurrences (all)                               | 0 / 4 (0.00%)<br>0 | 0 / 18 (0.00%)<br>0 | 0 / 6 (0.00%)<br>0  |
| Immune system disorders  |                    |                     |                     |
| Allergy to arthropod sting<br>subjects affected / exposed<br>occurrences (all) | 0 / 4 (0.00%)<br>0 | 0 / 18 (0.00%)<br>0 | 0 / 6 (0.00%)<br>0  |
| Hypersensitivity<br>subjects affected / exposed<br>occurrences (all)           | 0 / 4 (0.00%)<br>0 | 0 / 18 (0.00%)<br>0 | 0 / 6 (0.00%)<br>0  |
| Seasonal allergy<br>subjects affected / exposed<br>occurrences (all)           | 0 / 4 (0.00%)<br>0 | 0 / 18 (0.00%)<br>0 | 0 / 6 (0.00%)<br>0  |
| Reproductive system and breast disorders                                       |                    |                     |                     |
| Menstruation delayed<br>subjects affected / exposed<br>occurrences (all)       | 0 / 4 (0.00%)<br>0 | 0 / 18 (0.00%)<br>0 | 0 / 6 (0.00%)<br>0  |
| Vulvovaginal pruritus<br>subjects affected / exposed<br>occurrences (all)      | 0 / 4 (0.00%)<br>0 | 0 / 18 (0.00%)<br>0 | 0 / 6 (0.00%)<br>0  |
| Vulvovaginal swelling<br>subjects affected / exposed<br>occurrences (all)      | 0 / 4 (0.00%)<br>0 | 0 / 18 (0.00%)<br>0 | 0 / 6 (0.00%)<br>0  |
| Respiratory, thoracic and mediastinal disorders                                |                    |                     |                     |
| Oropharyngeal pain<br>subjects affected / exposed<br>occurrences (all)         | 0 / 4 (0.00%)<br>0 | 0 / 18 (0.00%)<br>0 | 1 / 6 (16.67%)<br>2 |
| Cough<br>subjects affected / exposed<br>occurrences (all)                      | 0 / 4 (0.00%)<br>0 | 0 / 18 (0.00%)<br>0 | 2 / 6 (33.33%)<br>2 |
| Rhinorrhoea<br>subjects affected / exposed<br>occurrences (all)                | 0 / 4 (0.00%)<br>0 | 0 / 18 (0.00%)<br>0 | 1 / 6 (16.67%)<br>1 |
| Nasal congestion<br>subjects affected / exposed<br>occurrences (all)           | 0 / 4 (0.00%)<br>0 | 0 / 18 (0.00%)<br>0 | 0 / 6 (0.00%)<br>0  |
| Tonsillar hypertrophy  |                    |                     |                     |

|  |                    |                     |                    |
|--|--------------------|---------------------|--------------------|
| subjects affected / exposed<br>occurrences (all)   | 0 / 4 (0.00%)<br>0 | 0 / 18 (0.00%)<br>0 | 0 / 6 (0.00%)<br>0 |
| Upper-airway cough syndrome<br>subjects affected / exposed<br>occurrences (all)                    | 0 / 4 (0.00%)<br>0 | 0 / 18 (0.00%)<br>0 | 0 / 6 (0.00%)<br>0 |
| Asthma<br>subjects affected / exposed<br>occurrences (all)   | 0 / 4 (0.00%)<br>0 | 1 / 18 (5.56%)<br>1 | 0 / 6 (0.00%)<br>0 |
| Dyspnoea exertional<br>subjects affected / exposed<br>occurrences (all)                            | 0 / 4 (0.00%)<br>0 | 1 / 18 (5.56%)<br>1 | 0 / 6 (0.00%)<br>0 |
| Psychiatric disorders<br>Depression<br>subjects affected / exposed<br>occurrences (all)            | 0 / 4 (0.00%)<br>0 | 0 / 18 (0.00%)<br>0 | 0 / 6 (0.00%)<br>0 |
| Anxiety<br>subjects affected / exposed<br>occurrences (all)  | 0 / 4 (0.00%)<br>0 | 0 / 18 (0.00%)<br>0 | 0 / 6 (0.00%)<br>0 |
| Fear of injection<br>subjects affected / exposed<br>occurrences (all)                              | 0 / 4 (0.00%)<br>0 | 0 / 18 (0.00%)<br>0 | 0 / 6 (0.00%)<br>0 |
| Insomnia<br>subjects affected / exposed<br>occurrences (all)                                       | 0 / 4 (0.00%)<br>0 | 0 / 18 (0.00%)<br>0 | 0 / 6 (0.00%)<br>0 |
| Investigations<br>C-reactive protein increased<br>subjects affected / exposed<br>occurrences (all) | 0 / 4 (0.00%)<br>0 | 0 / 18 (0.00%)<br>0 | 0 / 6 (0.00%)<br>0 |
| Blood albumin decreased<br>subjects affected / exposed<br>occurrences (all)                        | 0 / 4 (0.00%)<br>0 | 0 / 18 (0.00%)<br>0 | 0 / 6 (0.00%)<br>0 |
| Blood bicarbonate decreased<br>subjects affected / exposed<br>occurrences (all)                    | 0 / 4 (0.00%)<br>0 | 0 / 18 (0.00%)<br>0 | 0 / 6 (0.00%)<br>0 |
| Blood glucose increased  |                    |                     |                    |

|  |                |                |               |
|--|----------------|----------------|---------------|
| subjects affected / exposed                    | 0 / 4 (0.00%)  | 0 / 18 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all)                              | 0              | 0              | 0             |
| Body temperature increased                     |                |                |               |
| subjects affected / exposed                    | 0 / 4 (0.00%)  | 0 / 18 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all)                              | 0              | 0              | 0             |
| Clostridium test positive                      |                |                |               |
| subjects affected / exposed                    | 0 / 4 (0.00%)  | 0 / 18 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all)                              | 0              | 0              | 0             |
| Haematocrit decreased                          |                |                |               |
| subjects affected / exposed                    | 0 / 4 (0.00%)  | 1 / 18 (5.56%) | 0 / 6 (0.00%) |
| occurrences (all)                              | 0              | 1              | 0             |
| Haemoglobin decreased                          |                |                |               |
| subjects affected / exposed                    | 0 / 4 (0.00%)  | 1 / 18 (5.56%) | 0 / 6 (0.00%) |
| occurrences (all)                              | 0              | 1              | 0             |
| Weight decreased                               |                |                |               |
| subjects affected / exposed                    | 1 / 4 (25.00%) | 0 / 18 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all)                              | 1              | 0              | 0             |
| Amylase increased                              |                |                |               |
| subjects affected / exposed                    | 0 / 4 (0.00%)  | 0 / 18 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all)                              | 0              | 0              | 0             |
| Liver function test increased                  |                |                |               |
| subjects affected / exposed                    | 0 / 4 (0.00%)  | 0 / 18 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all)                              | 0              | 0              | 0             |
| Red blood cell count decreased                 |                |                |               |
| subjects affected / exposed                    | 0 / 4 (0.00%)  | 1 / 18 (5.56%) | 0 / 6 (0.00%) |
| occurrences (all)                              | 0              | 1              | 0             |
| Blood calcium decreased                        |                |                |               |
| subjects affected / exposed                    | 0 / 4 (0.00%)  | 0 / 18 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all)                              | 0              | 0              | 0             |
| Injury, poisoning and procedural complications |                |                |               |
| Torus fracture                                 |                |                |               |
| subjects affected / exposed                    | 0 / 4 (0.00%)  | 0 / 18 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all)                              | 0              | 0              | 0             |
| Arthropod bite                                 |                |                |               |

|                                      |                |                 |                |
|--------------------------------------|----------------|-----------------|----------------|
| subjects affected / exposed          | 0 / 4 (0.00%)  | 0 / 18 (0.00%)  | 0 / 6 (0.00%)  |
| occurrences (all)                    | 0              | 0               | 0              |
| Joint injury                         |                |                 |                |
| subjects affected / exposed          | 1 / 4 (25.00%) | 0 / 18 (0.00%)  | 0 / 6 (0.00%)  |
| occurrences (all)                    | 1              | 0               | 0              |
| Limb injury                          |                |                 |                |
| subjects affected / exposed          | 0 / 4 (0.00%)  | 0 / 18 (0.00%)  | 0 / 6 (0.00%)  |
| occurrences (all)                    | 0              | 0               | 0              |
| Procedural dizziness                 |                |                 |                |
| subjects affected / exposed          | 0 / 4 (0.00%)  | 0 / 18 (0.00%)  | 0 / 6 (0.00%)  |
| occurrences (all)                    | 0              | 0               | 0              |
| Procedural pain                      |                |                 |                |
| subjects affected / exposed          | 0 / 4 (0.00%)  | 0 / 18 (0.00%)  | 0 / 6 (0.00%)  |
| occurrences (all)                    | 0              | 0               | 0              |
| Nervous system disorders             |                |                 |                |
| Headache                             |                |                 |                |
| subjects affected / exposed          | 0 / 4 (0.00%)  | 2 / 18 (11.11%) | 2 / 6 (33.33%) |
| occurrences (all)                    | 0              | 2               | 2              |
| Dizziness                            |                |                 |                |
| subjects affected / exposed          | 0 / 4 (0.00%)  | 0 / 18 (0.00%)  | 2 / 6 (33.33%) |
| occurrences (all)                    | 0              | 0               | 2              |
| Blood and lymphatic system disorders |                |                 |                |
| Anaemia                              |                |                 |                |
| subjects affected / exposed          | 0 / 4 (0.00%)  | 0 / 18 (0.00%)  | 0 / 6 (0.00%)  |
| occurrences (all)                    | 0              | 0               | 0              |
| Lymphopenia                          |                |                 |                |
| subjects affected / exposed          | 0 / 4 (0.00%)  | 1 / 18 (5.56%)  | 0 / 6 (0.00%)  |
| occurrences (all)                    | 0              | 1               | 0              |
| Microcytic anaemia                   |                |                 |                |
| subjects affected / exposed          | 0 / 4 (0.00%)  | 0 / 18 (0.00%)  | 0 / 6 (0.00%)  |
| occurrences (all)                    | 0              | 0               | 0              |
| Ear and labyrinth disorders          |                |                 |                |
| Ear pain                             |                |                 |                |
| subjects affected / exposed          | 0 / 4 (0.00%)  | 0 / 18 (0.00%)  | 1 / 6 (16.67%) |
| occurrences (all)                    | 0              | 0               | 1              |
| Eye disorders                        |                |                 |                |



|  |                     |                     |                    |
|--|---------------------|---------------------|--------------------|
| Swelling of eyelid<br>subjects affected / exposed<br>occurrences (all)   | 0 / 4 (0.00%)<br>0  | 0 / 18 (0.00%)<br>0 | 0 / 6 (0.00%)<br>0 |
| Eye swelling<br>subjects affected / exposed<br>occurrences (all)         | 0 / 4 (0.00%)<br>0  | 1 / 18 (5.56%)<br>1 | 0 / 6 (0.00%)<br>0 |
| Ocular hyperaemia<br>subjects affected / exposed<br>occurrences (all)    | 0 / 4 (0.00%)<br>0  | 1 / 18 (5.56%)<br>1 | 0 / 6 (0.00%)<br>0 |
| Gastrointestinal disorders   |                     |                     |                    |
| Abdominal pain<br>subjects affected / exposed<br>occurrences (all)       | 1 / 4 (25.00%)<br>1 | 0 / 18 (0.00%)<br>0 | 0 / 6 (0.00%)<br>0 |
| Vomiting<br>subjects affected / exposed<br>occurrences (all)             | 2 / 4 (50.00%)<br>3 | 1 / 18 (5.56%)<br>1 | 0 / 6 (0.00%)<br>0 |
| Crohn's disease<br>subjects affected / exposed<br>occurrences (all)      | 0 / 4 (0.00%)<br>0  | 1 / 18 (5.56%)<br>1 | 0 / 6 (0.00%)<br>0 |
| Abdominal distension<br>subjects affected / exposed<br>occurrences (all) | 1 / 4 (25.00%)<br>1 | 1 / 18 (5.56%)<br>1 | 0 / 6 (0.00%)<br>0 |
| Diarrhoea<br>subjects affected / exposed<br>occurrences (all)            | 2 / 4 (50.00%)<br>2 | 0 / 18 (0.00%)<br>0 | 0 / 6 (0.00%)<br>0 |
| Abdominal rigidity<br>subjects affected / exposed<br>occurrences (all)   | 0 / 4 (0.00%)<br>0  | 0 / 18 (0.00%)<br>0 | 0 / 6 (0.00%)<br>0 |
| Abdominal tenderness<br>subjects affected / exposed<br>occurrences (all) | 0 / 4 (0.00%)<br>0  | 0 / 18 (0.00%)<br>0 | 0 / 6 (0.00%)<br>0 |
| Abnormal faeces<br>subjects affected / exposed<br>occurrences (all)      | 1 / 4 (25.00%)<br>1 | 0 / 18 (0.00%)<br>0 | 0 / 6 (0.00%)<br>0 |
| Anal fissure   |                     |                     |                    |

|                               |                |                |                |
|-------------------------------|----------------|----------------|----------------|
| subjects affected / exposed   | 1 / 4 (25.00%) | 0 / 18 (0.00%) | 0 / 6 (0.00%)  |
| occurrences (all)             | 1              | 0              | 0              |
| Anal fistula                  |                |                |                |
| subjects affected / exposed   | 0 / 4 (0.00%)  | 0 / 18 (0.00%) | 0 / 6 (0.00%)  |
| occurrences (all)             | 0              | 0              | 0              |
| Chapped lips                  |                |                |                |
| subjects affected / exposed   | 0 / 4 (0.00%)  | 0 / 18 (0.00%) | 0 / 6 (0.00%)  |
| occurrences (all)             | 0              | 0              | 0              |
| Colitis ulcerative            |                |                |                |
| subjects affected / exposed   | 0 / 4 (0.00%)  | 1 / 18 (5.56%) | 0 / 6 (0.00%)  |
| occurrences (all)             | 0              | 1              | 0              |
| Gastritis                     |                |                |                |
| subjects affected / exposed   | 0 / 4 (0.00%)  | 0 / 18 (0.00%) | 0 / 6 (0.00%)  |
| occurrences (all)             | 0              | 0              | 0              |
| Lip swelling                  |                |                |                |
| subjects affected / exposed   | 1 / 4 (25.00%) | 0 / 18 (0.00%) | 0 / 6 (0.00%)  |
| occurrences (all)             | 1              | 0              | 0              |
| Melaena                       |                |                |                |
| subjects affected / exposed   | 1 / 4 (25.00%) | 0 / 18 (0.00%) | 0 / 6 (0.00%)  |
| occurrences (all)             | 1              | 0              | 0              |
| Mouth ulceration              |                |                |                |
| subjects affected / exposed   | 0 / 4 (0.00%)  | 0 / 18 (0.00%) | 0 / 6 (0.00%)  |
| occurrences (all)             | 0              | 0              | 0              |
| Nausea                        |                |                |                |
| subjects affected / exposed   | 0 / 4 (0.00%)  | 0 / 18 (0.00%) | 2 / 6 (33.33%) |
| occurrences (all)             | 0              | 0              | 2              |
| Rectal haemorrhage            |                |                |                |
| subjects affected / exposed   | 1 / 4 (25.00%) | 0 / 18 (0.00%) | 0 / 6 (0.00%)  |
| occurrences (all)             | 1              | 0              | 0              |
| Constipation                  |                |                |                |
| subjects affected / exposed   | 0 / 4 (0.00%)  | 0 / 18 (0.00%) | 0 / 6 (0.00%)  |
| occurrences (all)             | 0              | 0              | 0              |
| Abdominal pain upper          |                |                |                |
| subjects affected / exposed   | 0 / 4 (0.00%)  | 0 / 18 (0.00%) | 0 / 6 (0.00%)  |
| occurrences (all)             | 0              | 0              | 0              |
| Gastrointestinal inflammation |                |                |                |

|  |                |                |                |
|--|----------------|----------------|----------------|
| subjects affected / exposed            | 0 / 4 (0.00%)  | 0 / 18 (0.00%) | 0 / 6 (0.00%)  |
| occurrences (all)                      | 0              | 0              | 0              |
| Gastrointestinal obstruction           |                |                |                |
| subjects affected / exposed            | 0 / 4 (0.00%)  | 0 / 18 (0.00%) | 0 / 6 (0.00%)  |
| occurrences (all)                      | 0              | 0              | 0              |
| Gastrooesophageal reflux disease       |                |                |                |
| subjects affected / exposed            | 0 / 4 (0.00%)  | 0 / 18 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all)                      | 0              | 0              | 1              |
| Glossodynia                            |                |                |                |
| subjects affected / exposed            | 0 / 4 (0.00%)  | 0 / 18 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all)                      | 0              | 0              | 1              |
| Haemorrhoids                           |                |                |                |
| subjects affected / exposed            | 0 / 4 (0.00%)  | 1 / 18 (5.56%) | 0 / 6 (0.00%)  |
| occurrences (all)                      | 0              | 1              | 0              |
| Stomatitis                             |                |                |                |
| subjects affected / exposed            | 0 / 4 (0.00%)  | 0 / 18 (0.00%) | 0 / 6 (0.00%)  |
| occurrences (all)                      | 0              | 0              | 0              |
| Toothache                              |                |                |                |
| subjects affected / exposed            | 0 / 4 (0.00%)  | 0 / 18 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all)                      | 0              | 0              | 1              |
| Skin and subcutaneous tissue disorders |                |                |                |
| Dermatitis                             |                |                |                |
| subjects affected / exposed            | 1 / 4 (25.00%) | 0 / 18 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all)                      | 1              | 0              | 1              |
| Nail bed inflammation                  |                |                |                |
| subjects affected / exposed            | 0 / 4 (0.00%)  | 0 / 18 (0.00%) | 0 / 6 (0.00%)  |
| occurrences (all)                      | 0              | 0              | 0              |
| Rash pruritic                          |                |                |                |
| subjects affected / exposed            | 0 / 4 (0.00%)  | 0 / 18 (0.00%) | 0 / 6 (0.00%)  |
| occurrences (all)                      | 0              | 0              | 0              |
| Skin lesion                            |                |                |                |
| subjects affected / exposed            | 0 / 4 (0.00%)  | 1 / 18 (5.56%) | 0 / 6 (0.00%)  |
| occurrences (all)                      | 0              | 1              | 0              |
| Eczema                                 |                |                |                |
| subjects affected / exposed            | 0 / 4 (0.00%)  | 1 / 18 (5.56%) | 0 / 6 (0.00%)  |
| occurrences (all)                      | 0              | 1              | 0              |

|   |               |                |               |
|---|---------------|----------------|---------------|
| Miliaria  |               |                |               |
| subjects affected / exposed                     | 0 / 4 (0.00%) | 0 / 18 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all)                               | 0             | 0              | 0             |
| Night sweats                                    |               |                |               |
| subjects affected / exposed                     | 0 / 4 (0.00%) | 0 / 18 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all)                               | 0             | 0              | 0             |
| Psoriasis                                       |               |                |               |
| subjects affected / exposed                     | 0 / 4 (0.00%) | 0 / 18 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all)                               | 0             | 0              | 0             |
| Skin exfoliation                                |               |                |               |
| subjects affected / exposed                     | 0 / 4 (0.00%) | 1 / 18 (5.56%) | 0 / 6 (0.00%) |
| occurrences (all)                               | 0             | 1              | 0             |
| Erythema nodosum                                |               |                |               |
| subjects affected / exposed                     | 0 / 4 (0.00%) | 0 / 18 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all)                               | 0             | 0              | 0             |
| Renal and urinary disorders                     |               |                |               |
| Nephrolithiasis                                 |               |                |               |
| subjects affected / exposed                     | 0 / 4 (0.00%) | 0 / 18 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all)                               | 0             | 0              | 0             |
| Acute kidney injury                             |               |                |               |
| subjects affected / exposed                     | 0 / 4 (0.00%) | 0 / 18 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all)                               | 0             | 0              | 0             |
| Dysuria   |               |                |               |
| subjects affected / exposed                     | 0 / 4 (0.00%) | 0 / 18 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all)                               | 0             | 0              | 0             |
| Proteinuria                                     |               |                |               |
| subjects affected / exposed                     | 0 / 4 (0.00%) | 0 / 18 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all)                               | 0             | 0              | 0             |
| Endocrine disorders                             |               |                |               |
| Cushingoid                                      |               |                |               |
| subjects affected / exposed                     | 0 / 4 (0.00%) | 0 / 18 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all)                               | 0             | 0              | 0             |
| Secondary adrenocortical insufficiency          |               |                |               |
| subjects affected / exposed                     | 0 / 4 (0.00%) | 1 / 18 (5.56%) | 0 / 6 (0.00%) |
| occurrences (all)                               | 0             | 1              | 0             |
| Musculoskeletal and connective tissue disorders |               |                |               |

|                                   |               |                 |                |
|-----------------------------------|---------------|-----------------|----------------|
| Arthralgia                        |               |                 |                |
| subjects affected / exposed       | 0 / 4 (0.00%) | 0 / 18 (0.00%)  | 1 / 6 (16.67%) |
| occurrences (all)                 | 0             | 0               | 1              |
| Back pain                         |               |                 |                |
| subjects affected / exposed       | 0 / 4 (0.00%) | 1 / 18 (5.56%)  | 0 / 6 (0.00%)  |
| occurrences (all)                 | 0             | 1               | 0              |
| Costochondritis                   |               |                 |                |
| subjects affected / exposed       | 0 / 4 (0.00%) | 1 / 18 (5.56%)  | 0 / 6 (0.00%)  |
| occurrences (all)                 | 0             | 1               | 0              |
| Myalgia                           |               |                 |                |
| subjects affected / exposed       | 0 / 4 (0.00%) | 0 / 18 (0.00%)  | 1 / 6 (16.67%) |
| occurrences (all)                 | 0             | 0               | 1              |
| Pain in extremity                 |               |                 |                |
| subjects affected / exposed       | 0 / 4 (0.00%) | 0 / 18 (0.00%)  | 0 / 6 (0.00%)  |
| occurrences (all)                 | 0             | 0               | 0              |
| Fistula discharge                 |               |                 |                |
| subjects affected / exposed       | 0 / 4 (0.00%) | 0 / 18 (0.00%)  | 0 / 6 (0.00%)  |
| occurrences (all)                 | 0             | 0               | 0              |
| Joint swelling                    |               |                 |                |
| subjects affected / exposed       | 0 / 4 (0.00%) | 0 / 18 (0.00%)  | 0 / 6 (0.00%)  |
| occurrences (all)                 | 0             | 0               | 0              |
| Infections and infestations       |               |                 |                |
| Respiratory tract infection viral |               |                 |                |
| subjects affected / exposed       | 0 / 4 (0.00%) | 0 / 18 (0.00%)  | 0 / 6 (0.00%)  |
| occurrences (all)                 | 0             | 0               | 0              |
| Upper respiratory tract infection |               |                 |                |
| subjects affected / exposed       | 0 / 4 (0.00%) | 1 / 18 (5.56%)  | 1 / 6 (16.67%) |
| occurrences (all)                 | 0             | 1               | 1              |
| Viral infection                   |               |                 |                |
| subjects affected / exposed       | 0 / 4 (0.00%) | 1 / 18 (5.56%)  | 1 / 6 (16.67%) |
| occurrences (all)                 | 0             | 1               | 1              |
| Bronchitis                        |               |                 |                |
| subjects affected / exposed       | 0 / 4 (0.00%) | 2 / 18 (11.11%) | 0 / 6 (0.00%)  |
| occurrences (all)                 | 0             | 2               | 0              |
| Ear infection                     |               |                 |                |

|                                 |               |                 |                |
|---------------------------------|---------------|-----------------|----------------|
| subjects affected / exposed     | 0 / 4 (0.00%) | 3 / 18 (16.67%) | 0 / 6 (0.00%)  |
| occurrences (all)               | 0             | 3               | 0              |
| Gastroenteritis norovirus       |               |                 |                |
| subjects affected / exposed     | 0 / 4 (0.00%) | 0 / 18 (0.00%)  | 0 / 6 (0.00%)  |
| occurrences (all)               | 0             | 0               | 0              |
| Hordeolum                       |               |                 |                |
| subjects affected / exposed     | 0 / 4 (0.00%) | 0 / 18 (0.00%)  | 1 / 6 (16.67%) |
| occurrences (all)               | 0             | 0               | 2              |
| Influenza                       |               |                 |                |
| subjects affected / exposed     | 0 / 4 (0.00%) | 0 / 18 (0.00%)  | 0 / 6 (0.00%)  |
| occurrences (all)               | 0             | 0               | 0              |
| Nasopharyngitis                 |               |                 |                |
| subjects affected / exposed     | 0 / 4 (0.00%) | 0 / 18 (0.00%)  | 1 / 6 (16.67%) |
| occurrences (all)               | 0             | 0               | 2              |
| Pharyngitis                     |               |                 |                |
| subjects affected / exposed     | 0 / 4 (0.00%) | 0 / 18 (0.00%)  | 0 / 6 (0.00%)  |
| occurrences (all)               | 0             | 0               | 0              |
| Pneumonia                       |               |                 |                |
| subjects affected / exposed     | 0 / 4 (0.00%) | 0 / 18 (0.00%)  | 0 / 6 (0.00%)  |
| occurrences (all)               | 0             | 0               | 0              |
| Oral herpes                     |               |                 |                |
| subjects affected / exposed     | 0 / 4 (0.00%) | 0 / 18 (0.00%)  | 1 / 6 (16.67%) |
| occurrences (all)               | 0             | 0               | 1              |
| Pharyngitis streptococcal       |               |                 |                |
| subjects affected / exposed     | 0 / 4 (0.00%) | 2 / 18 (11.11%) | 0 / 6 (0.00%)  |
| occurrences (all)               | 0             | 2               | 0              |
| Clostridium difficile infection |               |                 |                |
| subjects affected / exposed     | 0 / 4 (0.00%) | 0 / 18 (0.00%)  | 0 / 6 (0.00%)  |
| occurrences (all)               | 0             | 0               | 0              |
| Fungal skin infection           |               |                 |                |
| subjects affected / exposed     | 0 / 4 (0.00%) | 0 / 18 (0.00%)  | 0 / 6 (0.00%)  |
| occurrences (all)               | 0             | 0               | 0              |
| Gastroenteritis                 |               |                 |                |
| subjects affected / exposed     | 0 / 4 (0.00%) | 0 / 18 (0.00%)  | 1 / 6 (16.67%) |
| occurrences (all)               | 0             | 0               | 1              |
| Gastrointestinal candidiasis    |               |                 |                |

|                                    |                |                |                |
|------------------------------------|----------------|----------------|----------------|
| subjects affected / exposed        | 0 / 4 (0.00%)  | 0 / 18 (0.00%) | 0 / 6 (0.00%)  |
| occurrences (all)                  | 0              | 0              | 0              |
| Gastrointestinal infection         |                |                |                |
| subjects affected / exposed        | 0 / 4 (0.00%)  | 1 / 18 (5.56%) | 0 / 6 (0.00%)  |
| occurrences (all)                  | 0              | 1              | 0              |
| Herpes zoster                      |                |                |                |
| subjects affected / exposed        | 0 / 4 (0.00%)  | 0 / 18 (0.00%) | 0 / 6 (0.00%)  |
| occurrences (all)                  | 0              | 0              | 0              |
| Infected bite                      |                |                |                |
| subjects affected / exposed        | 0 / 4 (0.00%)  | 0 / 18 (0.00%) | 0 / 6 (0.00%)  |
| occurrences (all)                  | 0              | 0              | 0              |
| Molluscum contagiosum              |                |                |                |
| subjects affected / exposed        | 0 / 4 (0.00%)  | 0 / 18 (0.00%) | 0 / 6 (0.00%)  |
| occurrences (all)                  | 0              | 0              | 0              |
| Otitis externa                     |                |                |                |
| subjects affected / exposed        | 0 / 4 (0.00%)  | 1 / 18 (5.56%) | 0 / 6 (0.00%)  |
| occurrences (all)                  | 0              | 2              | 0              |
| Peritonitis                        |                |                |                |
| subjects affected / exposed        | 0 / 4 (0.00%)  | 0 / 18 (0.00%) | 0 / 6 (0.00%)  |
| occurrences (all)                  | 0              | 0              | 0              |
| Salmonellosis                      |                |                |                |
| subjects affected / exposed        | 0 / 4 (0.00%)  | 0 / 18 (0.00%) | 0 / 6 (0.00%)  |
| occurrences (all)                  | 0              | 0              | 0              |
| Metabolism and nutrition disorders |                |                |                |
| Decreased appetite                 |                |                |                |
| subjects affected / exposed        | 1 / 4 (25.00%) | 0 / 18 (0.00%) | 0 / 6 (0.00%)  |
| occurrences (all)                  | 1              | 0              | 0              |
| Iron deficiency                    |                |                |                |
| subjects affected / exposed        | 0 / 4 (0.00%)  | 1 / 18 (5.56%) | 1 / 6 (16.67%) |
| occurrences (all)                  | 0              | 1              | 1              |
| Hypoalbuminaemia                   |                |                |                |
| subjects affected / exposed        | 0 / 4 (0.00%)  | 0 / 18 (0.00%) | 0 / 6 (0.00%)  |
| occurrences (all)                  | 0              | 0              | 0              |
| Hypophosphataemia                  |                |                |                |
| subjects affected / exposed        | 0 / 4 (0.00%)  | 0 / 18 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all)                  | 0              | 0              | 1              |

|  |                    |                     |                    |
|--|--------------------|---------------------|--------------------|
| Weight gain poor<br>subjects affected / exposed<br>occurrences (all) | 0 / 4 (0.00%)<br>0 | 0 / 18 (0.00%)<br>0 | 0 / 6 (0.00%)<br>0 |
|--|--------------------|---------------------|--------------------|



## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date            | Amendment  |
|-----------------|--|
| 07 April 2017   | Amendment 1: The primary purpose of this amendment was to make following changes. <ul style="list-style-type: none"><li>• Updated administrative details</li><li>• Updated exposure information</li><li>• Updated to allow enrollment of of pediatric participants who weigh &lt;30 kg</li></ul>   |
| 17 January 2018 | Amendment 3: The primary purpose of this amendment was to make following changes. <ul style="list-style-type: none"><li>• Amended references to Study Vedolizumab-2005 to include blinded dosing</li><li>• Specified that tumor necrosis factor (TNF)-<math>\alpha</math> antagonists may not be administered after participant consents to participate</li><li>• Defined chronic nonsteroidal anti-inflammatory drug use</li><li>• Amended the concomitant oral corticosteroid dosing information.</li><li>• Added specific details regarding provision of study drug and associated supplies.</li><li>• Specified that the erythrocyte sedimentation rate may be performed at a local laboratory</li><li>• Removed urinalysis</li><li>• Removed electrocardiogram assessments</li><li>• Amended pharmacokinetic sample collection information</li><li>• Amended immunogenicity sample information</li><li>• Deleted pharmacogenomics assessment</li><li>• Specified that no endoscopy is required if a subject withdraws before Week 6</li><li>• Amended the interim analyses information</li><li>• Updated the protocol deviation information</li></ul> |

Notes:

### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported