



## Clinical trial results:

### A Randomized, Double-Blind, Parallel-Group, Phase 3 Study to Demonstrate Noninferiority in Efficacy and to Assess Safety of CT-P13 Compared to Remicade in Patients With Active Crohn's Disease

#### Summary

|                          |                         |
|--------------------------|-------------------------|
| EudraCT number           | 2013-004497-10          |
| Trial protocol           | BE HU GB IT ES RO DK NL |
| Global end of trial date | 15 February 2017        |

#### Results information

|                                |               |
|--------------------------------|---------------|
| Result version number          | v1 (current)  |
| This version publication date  | 02 March 2018 |
| First version publication date | 02 March 2018 |

#### Trial information

##### Trial identification

|                       |            |
|-----------------------|------------|
| Sponsor protocol code | CT-P13 3.4 |
|-----------------------|------------|

##### Additional study identifiers

|                                    |             |
|------------------------------------|-------------|
| ISRCTN number                      | -           |
| ClinicalTrials.gov id (NCT number) | NCT02096861 |
| WHO universal trial number (UTN)   | -           |

Notes:

##### Sponsors

|                              |                                                                                                     |
|------------------------------|-----------------------------------------------------------------------------------------------------|
| Sponsor organisation name    | Celltrion, Inc.                                                                                     |
| Sponsor organisation address | 23 Academy-ro, Yeonsu-gu, Incheon, Korea, Republic of, 22014                                        |
| Public contact               | Clinical Operations Management Department, CELLTRION, Inc., +82 328506724, SuEun.Song@celltrion.com |
| Scientific contact           | Clinical Planning Department, CELLTRION, Inc., +82 328506532, SungYoung.Lee@celltrion.com           |

Notes:

##### Paediatric regulatory details

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

Notes:

## Results analysis stage

|                                                      |                  |
|------------------------------------------------------|------------------|
| Analysis stage                                       | Final            |
| Date of interim/final analysis                       | 08 December 2017 |
| Is this the analysis of the primary completion data? | Yes              |
| Primary completion date                              | 11 January 2016  |
| Global end of trial reached?                         | Yes              |
| Global end of trial date                             | 15 February 2017 |
| Was the trial ended prematurely?                     | No               |

Notes:

## General information about the trial

Main objective of the trial:

To demonstrate that CT-P13 (Remsima) is non-inferior to Remicade at Week 6 (Dose 3), in terms of efficacy, as determined by the CDAI-70 response rate

Protection of trial subjects:

Additional vital signs including blood pressure, heart and respiratory rates, and temperature were measured to monitor for possible hypersensitivity reactions on each dosing day and recorded at the following time points:

- 15 minutes ( $\pm$  5 minutes) before the beginning of the study drug infusion
- At the start of the study drug infusion ( $\pm$  5 minutes)
- Every 30 minutes ( $\pm$  5 minutes) after the start of the study drug infusion
- At the end of the study drug infusion ( $\pm$  5 minutes) and 30, 60, and 120 minutes ( $\pm$  10 minutes) after the end of the study drug infusion

In addition, hypersensitivity was monitored by routine continuous clinical monitoring, which had to be performed after the patient had rested quietly for at least 5 minutes in the supine position. Emergency equipment, such as adrenaline, antihistamines, corticosteroids, and respiratory support including inhalational therapy, oxygen, and artificial ventilator, had to be available. For patients who experienced or developed life-threatening infusion-related anaphylactic reactions, study drug was stopped immediately and the patient withdrawn from the study.

Background therapy: -

Evidence for comparator: -

|                                                           |              |
|-----------------------------------------------------------|--------------|
| Actual start date of recruitment                          | 01 July 2014 |
| Long term follow-up planned                               | No           |
| Independent data monitoring committee (IDMC) involvement? | Yes          |

Notes:

## Population of trial subjects

### Subjects enrolled per country

|                                      |                        |
|--------------------------------------|------------------------|
| Country: Number of subjects enrolled | Netherlands: 3         |
| Country: Number of subjects enrolled | Poland: 5              |
| Country: Number of subjects enrolled | Romania: 8             |
| Country: Number of subjects enrolled | Belgium: 2             |
| Country: Number of subjects enrolled | Denmark: 1             |
| Country: Number of subjects enrolled | France: 5              |
| Country: Number of subjects enrolled | Germany: 2             |
| Country: Number of subjects enrolled | Hungary: 11            |
| Country: Number of subjects enrolled | Italy: 12              |
| Country: Number of subjects enrolled | Russian Federation: 50 |
| Country: Number of subjects enrolled | Korea, Republic of: 54 |

|                                      |                  |
|--------------------------------------|------------------|
| Country: Number of subjects enrolled | Ukraine: 32      |
| Country: Number of subjects enrolled | Israel: 26       |
| Country: Number of subjects enrolled | United States: 3 |
| Country: Number of subjects enrolled | Brazil: 2        |
| Country: Number of subjects enrolled | Mexico: 4        |
| Worldwide total number of subjects   | 220              |
| EEA total number of subjects         | 49               |

Notes:

| <b>Subjects enrolled per age group</b>    |     |
|-------------------------------------------|-----|
| In utero                                  | 0   |
| Preterm newborn - gestational age < 37 wk | 0   |
| Newborns (0-27 days)                      | 0   |
| Infants and toddlers (28 days-23 months)  | 0   |
| Children (2-11 years)                     | 0   |
| Adolescents (12-17 years)                 | 0   |
| Adults (18-64 years)                      | 216 |
| From 65 to 84 years                       | 4   |
| 85 years and over                         | 0   |

## Subject disposition

### Recruitment

Recruitment details:

First patient randomly assigned to treatment: 19 September 2014

A total of 99 study centers were initiated in 4 geographical regions (Europe, North America, Latin America, and Asia Pacific)

### Pre-assignment

Screening details:

Key Inclusion Criteria

1. Patient is male or female between 18 to 75 years old, inclusive
2. Patient has a diagnosis of CD according to CDAI 220 - 450 points for least 12 weeks prior to randomisation
3. Patient has not responded despite a full and adequate therapy/intolerant/has contraindications with corticosteroid and/or immunosuppressant

### Pre-assignment period milestones

|                                            |                       |
|--------------------------------------------|-----------------------|
| Number of subjects started                 | 308 <sup>[1]</sup>    |
| Intermediate milestone: Number of subjects | Subject screened: 308 |
| Intermediate milestone: Number of subjects | Enrolled: 220         |
| Number of subjects completed               | 220                   |

### Pre-assignment subject non-completion reasons

|                            |                       |
|----------------------------|-----------------------|
| Reason: Number of subjects | Screening Failure: 88 |
|----------------------------|-----------------------|

Notes:

[1] - The number of subjects reported to have started the pre-assignment period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: The 'Number of subjects reported to have started the pre-assignment period' means subjects who consented to participate in this trial through the Screening procedure. If these subjects meet Inclusion and Exclusion criteria defined by the protocol, they can be randomized which will have study drug administration.

### Period 1

|                              |                                                               |
|------------------------------|---------------------------------------------------------------|
| Period 1 title               | Before switching                                              |
| Is this the baseline period? | Yes                                                           |
| Allocation method            | Randomised - controlled                                       |
| Blinding used                | Double blind                                                  |
| Roles blinded                | Subject, Investigator, Monitor, Data analyst, Carer, Assessor |

Blinding implementation details:

Data analyst became unblinded at Week 6 for reporting purpose. Other members were remained blinded.

### Arms

|                              |        |
|------------------------------|--------|
| Are arms mutually exclusive? | Yes    |
| Arm title                    | CT-P13 |

Arm description:

Patients who were randomized to CT-P13-CT-P13 or CT-P13-Remicade treatment groups at Week0

|                                        |                                                  |
|----------------------------------------|--------------------------------------------------|
| Arm type                               | Experimental                                     |
| Investigational medicinal product name | CT-P13                                           |
| Investigational medicinal product code |                                                  |
| Other name                             | Remsima, Inflectra                               |
| Pharmaceutical forms                   | Powder for concentrate for solution for infusion |
| Routes of administration               | Intravenous use                                  |

Dosage and administration details:

CT-P13 (5 mg/kg) by intravenous (IV) infusion administered as a 2 hour IV infusion per dose

|                                                                                                |                                                  |
|------------------------------------------------------------------------------------------------|--------------------------------------------------|
| <b>Arm title</b>                                                                               | Remicade                                         |
| Arm description:                                                                               |                                                  |
| Patients who were randomized to Remicade-Remicade or Remicade-CT-P13 treatment groups at Week0 |                                                  |
| Arm type                                                                                       | Active comparator                                |
| Investigational medicinal product name                                                         | Remicade                                         |
| Investigational medicinal product code                                                         |                                                  |
| Other name                                                                                     |                                                  |
| Pharmaceutical forms                                                                           | Powder for concentrate for solution for infusion |
| Routes of administration                                                                       | Intravenous use                                  |

Dosage and administration details:

Remicade (5 mg/kg) by intravenous (IV) infusion administered as a 2 hour IV infusion per dose

| <b>Number of subjects in period 1</b> | CT-P13 | Remicade |
|---------------------------------------|--------|----------|
| Started                               | 111    | 109      |
| Completed                             | 92     | 88       |
| Not completed                         | 19     | 21       |
| Non-responder at Week 14              | 9      | 8        |
| PATIENT NON COMPLIANCE                | 1      | -        |
| Consent withdrawn by subject          | -      | 1        |
| Physician decision                    | -      | 1        |
| Disease progression                   | 2      | 4        |
| Adverse event, non-fatal              | 4      | 6        |
| Lost to follow-up                     | 1      | -        |
| Protocol deviation                    | 2      | 1        |

## Period 2

|                              |                                                 |
|------------------------------|-------------------------------------------------|
| Period 2 title               | After switching                                 |
| Is this the baseline period? | No                                              |
| Allocation method            | Randomised - controlled                         |
| Blinding used                | Double blind                                    |
| Roles blinded                | Subject, Investigator, Monitor, Carer, Assessor |

## Arms

|                              |     |
|------------------------------|-----|
| Are arms mutually exclusive? | Yes |
|------------------------------|-----|

|                                                                                                                                     |                                                  |
|-------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|
| <b>Arm title</b>                                                                                                                    | CT-P13 - CT-P13                                  |
| Arm description:<br>CT-P13 followed by CT-P13 from Week 30                                                                          |                                                  |
| Arm type                                                                                                                            | Experimental                                     |
| Investigational medicinal product name                                                                                              | CT-P13                                           |
| Investigational medicinal product code                                                                                              |                                                  |
| Other name                                                                                                                          | Remsima, Inflectra                               |
| Pharmaceutical forms                                                                                                                | Powder for concentrate for solution for infusion |
| Routes of administration                                                                                                            | Intravenous use                                  |
| Dosage and administration details:<br>CT-P13 (5 mg/kg) by intravenous (IV) infusion administered as a 2 hour IV infusion per dose   |                                                  |
| <b>Arm title</b>                                                                                                                    | CT-P13 - Remicade                                |
| Arm description:<br>CT-P13 followed by Remicade from Week 30                                                                        |                                                  |
| Arm type                                                                                                                            | Experimental                                     |
| Investigational medicinal product name                                                                                              | Remicade                                         |
| Investigational medicinal product code                                                                                              |                                                  |
| Other name                                                                                                                          |                                                  |
| Pharmaceutical forms                                                                                                                | Powder for concentrate for solution for infusion |
| Routes of administration                                                                                                            | Intravenous use                                  |
| Dosage and administration details:<br>Remicade (5 mg/kg) by intravenous (IV) infusion administered as a 2 hour IV infusion per dose |                                                  |
| <b>Arm title</b>                                                                                                                    | Remicade - Remicade                              |
| Arm description:<br>Remicade followed by Remicade from Week 30                                                                      |                                                  |
| Arm type                                                                                                                            | Active comparator                                |
| Investigational medicinal product name                                                                                              | Remicade                                         |
| Investigational medicinal product code                                                                                              |                                                  |
| Other name                                                                                                                          |                                                  |
| Pharmaceutical forms                                                                                                                | Powder for concentrate for solution for infusion |
| Routes of administration                                                                                                            | Intravenous use                                  |
| Dosage and administration details:<br>Remicade (5 mg/kg) by intravenous (IV) infusion administered as a 2 hour IV infusion per dose |                                                  |
| <b>Arm title</b>                                                                                                                    | Remicade - CT-P13                                |
| Arm description:<br>Remicade followed by CT-P13 from Week 30                                                                        |                                                  |
| Arm type                                                                                                                            | Experimental                                     |
| Investigational medicinal product name                                                                                              | CT-P13                                           |
| Investigational medicinal product code                                                                                              |                                                  |
| Other name                                                                                                                          | Remsima, Inflectra                               |
| Pharmaceutical forms                                                                                                                | Powder for concentrate for solution for infusion |
| Routes of administration                                                                                                            | Intravenous use                                  |
| Dosage and administration details:<br>CT-P13 (5 mg/kg) by intravenous (IV) infusion administered as a 2 hour IV infusion per dose   |                                                  |

| <b>Number of subjects in period 2</b>   | CT-P13 - CT-P13 | CT-P13 - Remicade | Remicade - Remicade |
|-----------------------------------------|-----------------|-------------------|---------------------|
| Started                                 | 48              | 44                | 41                  |
| Completed                               | 44              | 40                | 37                  |
| Not completed                           | 4               | 4                 | 4                   |
| Consent withdrawn by subject            | -               | 1                 | -                   |
| Disease progression                     | 1               | 2                 | 1                   |
| PATIENT WENT ABROAD SO ESV WAS NOT DONE | -               | 1                 | -                   |
| Pregnancy                               | -               | -                 | 1                   |
| Lost to follow-up                       | 2               | -                 | 2                   |
| Protocol deviation                      | 1               | -                 | -                   |

| <b>Number of subjects in period 2</b>   | Remicade - CT-P13 |
|-----------------------------------------|-------------------|
| Started                                 | 47                |
| Completed                               | 45                |
| Not completed                           | 2                 |
| Consent withdrawn by subject            | -                 |
| Disease progression                     | -                 |
| PATIENT WENT ABROAD SO ESV WAS NOT DONE | -                 |
| Pregnancy                               | -                 |
| Lost to follow-up                       | 2                 |
| Protocol deviation                      | -                 |

## Baseline characteristics

### Reporting groups

|                                                                                                |          |
|------------------------------------------------------------------------------------------------|----------|
| Reporting group title                                                                          | CT-P13   |
| Reporting group description:                                                                   |          |
| Patients who were randomized to CT-P13-CT-P13 or CT-P13-Remicade treatment groups at Week0     |          |
| Reporting group title                                                                          | Remicade |
| Reporting group description:                                                                   |          |
| Patients who were randomized to Remicade-Remicade or Remicade-CT-P13 treatment groups at Week0 |          |

| Reporting group values | CT-P13   | Remicade | Total |
|------------------------|----------|----------|-------|
| Number of subjects     | 111      | 109      | 220   |
| Age categorical        |          |          |       |
| Units: Subjects        |          |          |       |
| Adults (18-64 years)   | 108      | 108      | 216   |
| From 65-84 years       | 3        | 1        | 4     |
| Age continuous         |          |          |       |
| Units: years           |          |          |       |
| median                 | 35       | 32       |       |
| full range (min-max)   | 18 to 69 | 18 to 69 | -     |
| Gender categorical     |          |          |       |
| Units: Subjects        |          |          |       |
| Female                 | 48       | 49       | 97    |
| Male                   | 63       | 60       | 123   |

### Subject analysis sets

|                                                                                                                                     |                     |
|-------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Subject analysis set title                                                                                                          | CT-P13 - CT-P13     |
| Subject analysis set type                                                                                                           | Intention-to-treat  |
| Subject analysis set description:                                                                                                   |                     |
| The number of patients who randomized to CT-P13-CT-P13 treatment group at Week 0.<br>CT-P13 followed by CT-P13 from Week 30         |                     |
| Subject analysis set title                                                                                                          | CT-P13 - Remicade   |
| Subject analysis set type                                                                                                           | Intention-to-treat  |
| Subject analysis set description:                                                                                                   |                     |
| The number of patients who randomized to CT-P13-Remicade treatment group at Week 0.<br>CT-P13 followed by Remicade from Week 30     |                     |
| Subject analysis set title                                                                                                          | Remicade - Remicade |
| Subject analysis set type                                                                                                           | Intention-to-treat  |
| Subject analysis set description:                                                                                                   |                     |
| The number of patients who randomized to Remicade-Remicade treatment group at Week 0.<br>Remicade followed by Remicade from Week 30 |                     |
| Subject analysis set title                                                                                                          | Remicade - CT-P13   |
| Subject analysis set type                                                                                                           | Intention-to-treat  |
| Subject analysis set description:                                                                                                   |                     |
| The number of patients who randomized to Remicade-CT-P13 treatment group at Week 0.<br>Remicade followed by CT-P13 from Week 30     |                     |



| <b>Reporting group values</b>         | CT-P13 - CT-P13 | CT-P13 - Remicade | Remicade - Remicade |
|---------------------------------------|-----------------|-------------------|---------------------|
| Number of subjects                    | 56              | 55                | 54                  |
| Age categorical<br>Units: Subjects    |                 |                   |                     |
| Adults (18-64 years)                  | 54              | 54                | 53                  |
| From 65-84 years                      | 2               | 1                 | 1                   |
| Age continuous<br>Units: years        |                 |                   |                     |
| median                                | 39              | 31                | 31                  |
| full range (min-max)                  | 19 to 68        | 18 to 69          | 18 to 69            |
| Gender categorical<br>Units: Subjects |                 |                   |                     |
| Female                                | 27              | 21                | 28                  |
| Male                                  | 29              | 34                | 26                  |

| <b>Reporting group values</b>         | Remicade - CT-P13 |  |  |
|---------------------------------------|-------------------|--|--|
| Number of subjects                    | 55                |  |  |
| Age categorical<br>Units: Subjects    |                   |  |  |
| Adults (18-64 years)                  | 55                |  |  |
| From 65-84 years                      | 0                 |  |  |
| Age continuous<br>Units: years        |                   |  |  |
| median                                | 35                |  |  |
| full range (min-max)                  | 19 to 63          |  |  |
| Gender categorical<br>Units: Subjects |                   |  |  |
| Female                                | 21                |  |  |
| Male                                  | 34                |  |  |

## End points

### End points reporting groups

|                                                                                                                                                                          |                     |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Reporting group title                                                                                                                                                    | CT-P13              |
| Reporting group description:<br>Patients who were randomized to CT-P13-CT-P13 or CT-P13-Remicade treatment groups at Week0                                               |                     |
| Reporting group title                                                                                                                                                    | Remicade            |
| Reporting group description:<br>Patients who were randomized to Remicade-Remicade or Remicade-CT-P13 treatment groups at Week0                                           |                     |
| Reporting group title                                                                                                                                                    | CT-P13 - CT-P13     |
| Reporting group description:<br>CT-P13 followed by CT-P13 from Week 30                                                                                                   |                     |
| Reporting group title                                                                                                                                                    | CT-P13 - Remicade   |
| Reporting group description:<br>CT-P13 followed by Remicade from Week 30                                                                                                 |                     |
| Reporting group title                                                                                                                                                    | Remicade - Remicade |
| Reporting group description:<br>Remicade followed by Remicade from Week 30                                                                                               |                     |
| Reporting group title                                                                                                                                                    | Remicade - CT-P13   |
| Reporting group description:<br>Remicade followed by CT-P13 from Week 30                                                                                                 |                     |
| Subject analysis set title                                                                                                                                               | CT-P13 - CT-P13     |
| Subject analysis set type                                                                                                                                                | Intention-to-treat  |
| Subject analysis set description:<br>The number of patients who randomized to CT-P13-CT-P13 treatment group at Week 0.<br>CT-P13 followed by CT-P13 from Week 30         |                     |
| Subject analysis set title                                                                                                                                               | CT-P13 - Remicade   |
| Subject analysis set type                                                                                                                                                | Intention-to-treat  |
| Subject analysis set description:<br>The number of patients who randomized to CT-P13-Remicade treatment group at Week 0.<br>CT-P13 followed by Remicade from Week 30     |                     |
| Subject analysis set title                                                                                                                                               | Remicade - Remicade |
| Subject analysis set type                                                                                                                                                | Intention-to-treat  |
| Subject analysis set description:<br>The number of patients who randomized to Remicade-Remicade treatment group at Week 0.<br>Remicade followed by Remicade from Week 30 |                     |
| Subject analysis set title                                                                                                                                               | Remicade - CT-P13   |
| Subject analysis set type                                                                                                                                                | Intention-to-treat  |
| Subject analysis set description:<br>The number of patients who randomized to Remicade-CT-P13 treatment group at Week 0.<br>Remicade followed by CT-P13 from Week 30     |                     |

### Primary: CDAI-70

|                                                                                                             |         |
|-------------------------------------------------------------------------------------------------------------|---------|
| End point title                                                                                             | CDAI-70 |
| End point description:<br>Proportion of patients achieving response according to CDAI-70 criteria at Week 6 |         |
| End point type                                                                                              | Primary |
| End point timeframe:<br>At Week 6                                                                           |         |

| End point values            | CT-P13          | Remicade        |  |  |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type          | Reporting group | Reporting group |  |  |
| Number of subjects analysed | 111             | 109             |  |  |
| Units: Participant          | 77              | 81              |  |  |

### Statistical analyses

| Statistical analysis title              | Primary efficacy endpoint - CDAI-70 response rate |
|-----------------------------------------|---------------------------------------------------|
| Comparison groups                       | CT-P13 v Remicade                                 |
| Number of subjects included in analysis | 220                                               |
| Analysis specification                  | Pre-specified                                     |
| Analysis type                           | non-inferiority <sup>[1]</sup>                    |
| Parameter estimate                      | Difference in response rate                       |
| Point estimate                          | -4.9                                              |
| Confidence interval                     |                                                   |
| level                                   | Other: 97.5 %                                     |
| sides                                   | 1-sided                                           |
| lower limit                             | -17                                               |

Notes:

[1] - Non-inferiority margin is -20%.

### Secondary: CDAI-70

|                                                                                    |           |
|------------------------------------------------------------------------------------|-----------|
| End point title                                                                    | CDAI-70   |
| End point description:                                                             |           |
| Proportion of patients achieving response according to CDAI-70 criteria at Week 30 |           |
| End point type                                                                     | Secondary |
| End point timeframe:                                                               |           |
| At Week 30                                                                         |           |

| End point values            | CT-P13          | Remicade        |  |  |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type          | Reporting group | Reporting group |  |  |
| Number of subjects analysed | 111             | 109             |  |  |
| Units: Participants         | 85              | 82              |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: CDAI-70

|                        |                                                                                    |
|------------------------|------------------------------------------------------------------------------------|
| End point title        | CDAI-70                                                                            |
| End point description: | Proportion of patients achieving response according to CDAI-70 criteria at Week 54 |
| End point type         | Secondary                                                                          |
| End point timeframe:   | At Week 54                                                                         |

| End point values            | CT-P13 - CT-P13      | CT-P13 - Remicade    | Remicade - Remicade  | Remicade - CT-P13    |
|-----------------------------|----------------------|----------------------|----------------------|----------------------|
| Subject group type          | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 56                   | 55                   | 54                   | 55                   |
| Units: Participants         | 44                   | 39                   | 38                   | 42                   |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Clinical remission

|                        |                                                               |
|------------------------|---------------------------------------------------------------|
| End point title        | Clinical remission                                            |
| End point description: | Proportion of patients achieving clinical remission at Week 6 |
| End point type         | Secondary                                                     |
| End point timeframe:   | At Week 6                                                     |

| End point values            | CT-P13          | Remicade        |  |  |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type          | Reporting group | Reporting group |  |  |
| Number of subjects analysed | 111             | 109             |  |  |
| Units: Participants         | 47              | 49              |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Clinical remission

|                        |                                                                |
|------------------------|----------------------------------------------------------------|
| End point title        | Clinical remission                                             |
| End point description: | Proportion of patients achieving clinical remission at Week 30 |
| End point type         | Secondary                                                      |
| End point timeframe:   | At Week 30                                                     |

| End point values            | CT-P13          | Remicade        |  |  |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type          | Reporting group | Reporting group |  |  |
| Number of subjects analysed | 111             | 109             |  |  |
| Units: Participants         | 61              | 62              |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Clinical remission

|                        |                                                                |
|------------------------|----------------------------------------------------------------|
| End point title        | Clinical remission                                             |
| End point description: | Proportion of patients achieving clinical remission at Week 54 |
| End point type         | Secondary                                                      |
| End point timeframe:   | At Week 54                                                     |

| End point values            | CT-P13 - CT-P13      | CT-P13 - Remicade    | Remicade - Remicade  | Remicade - CT-P13    |
|-----------------------------|----------------------|----------------------|----------------------|----------------------|
| Subject group type          | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 56                   | 55                   | 54                   | 55                   |
| Units: Participants         | 35                   | 32                   | 29                   | 33                   |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Short Inflammatory Bowel Disease Questionnaire

|                        |                                                |
|------------------------|------------------------------------------------|
| End point title        | Short Inflammatory Bowel Disease Questionnaire |
| End point description: |                                                |
| End point type         | Secondary                                      |
| End point timeframe:   | Baseline                                       |

| End point values                     | CT-P13              | Remicade           |  |  |
|--------------------------------------|---------------------|--------------------|--|--|
| Subject group type                   | Reporting group     | Reporting group    |  |  |
| Number of subjects analysed          | 111                 | 109                |  |  |
| Units: score                         |                     |                    |  |  |
| arithmetic mean (standard deviation) | 34.3 ( $\pm$ 10.92) | 33.9 ( $\pm$ 9.27) |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Short Inflammatory Bowel Disease Questionnaire

|                        |                                                |
|------------------------|------------------------------------------------|
| End point title        | Short Inflammatory Bowel Disease Questionnaire |
| End point description: |                                                |
| End point type         | Secondary                                      |
| End point timeframe:   |                                                |
| At Week 6              |                                                |

| End point values                     | CT-P13              | Remicade            |  |  |
|--------------------------------------|---------------------|---------------------|--|--|
| Subject group type                   | Reporting group     | Reporting group     |  |  |
| Number of subjects analysed          | 107 <sup>[2]</sup>  | 107 <sup>[3]</sup>  |  |  |
| Units: score                         |                     |                     |  |  |
| arithmetic mean (standard deviation) | 46.4 ( $\pm$ 10.86) | 45.8 ( $\pm$ 12.54) |  |  |

Notes:

[2] - The number of patients who had SIBDQ score at Week 6

[3] - The number of patients who had SIBDQ score at Week 6

### Statistical analyses

No statistical analyses for this end point

### Secondary: Short Inflammatory Bowel Disease Questionnaire

|                        |                                                |
|------------------------|------------------------------------------------|
| End point title        | Short Inflammatory Bowel Disease Questionnaire |
| End point description: |                                                |
| End point type         | Secondary                                      |
| End point timeframe:   |                                                |
| At Week 30             |                                                |

| End point values                     | CT-P13            | Remicade          |  |  |
|--------------------------------------|-------------------|-------------------|--|--|
| Subject group type                   | Reporting group   | Reporting group   |  |  |
| Number of subjects analysed          | 92 <sup>[4]</sup> | 88 <sup>[5]</sup> |  |  |
| Units: score                         |                   |                   |  |  |
| arithmetic mean (standard deviation) | 51.1 (± 11.96)    | 52.5 (± 10.68)    |  |  |

Notes:

[4] - The number of patients who had SIBDQ score at Week 30

[5] - The number of patients who had SIBDQ score at Week 30

## Statistical analyses

No statistical analyses for this end point

## Secondary: Short Inflammatory Bowel Disease Questionnaire

|                                                      |                                                |
|------------------------------------------------------|------------------------------------------------|
| End point title                                      | Short Inflammatory Bowel Disease Questionnaire |
| End point description:                               |                                                |
| Arithmetic mean value of SIBDQ by 4 treatment groups |                                                |
| End point type                                       | Secondary                                      |
| End point timeframe:                                 |                                                |
| Baseline                                             |                                                |

| End point values                     | CT-P13 - CT-P13      | CT-P13 - Remicade    | Remicade - Remicade  | Remicade - CT-P13    |
|--------------------------------------|----------------------|----------------------|----------------------|----------------------|
| Subject group type                   | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed          | 56                   | 55                   | 54                   | 55                   |
| Units: score                         |                      |                      |                      |                      |
| arithmetic mean (standard deviation) | 34.7 (± 10.61)       | 33.8 (± 11.31)       | 33.3 (± 9.77)        | 34.5 (± 8.81)        |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Short Inflammatory Bowel Disease Questionnaire

|                        |                                                |
|------------------------|------------------------------------------------|
| End point title        | Short Inflammatory Bowel Disease Questionnaire |
| End point description: |                                                |
|                        |                                                |
| End point type         | Secondary                                      |
| End point timeframe:   |                                                |
| At Week 54             |                                                |

| End point values                     | CT-P13 - CT-P13      | CT-P13 - Remicade    | Remicade - Remicade  | Remicade - CT-P13    |
|--------------------------------------|----------------------|----------------------|----------------------|----------------------|
| Subject group type                   | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed          | 45 <sup>[6]</sup>    | 41 <sup>[7]</sup>    | 37 <sup>[8]</sup>    | 47 <sup>[9]</sup>    |
| Units: score                         |                      |                      |                      |                      |
| arithmetic mean (standard deviation) | 54.4 (± 10.28)       | 54.1 (± 11.07)       | 52.6 (± 11.35)       | 51.2 (± 11.26)       |

Notes:

[6] - The number of patients who had SIBDQ score at Week 54

[7] - The number of patients who had SIBDQ score at Week 54

[8] - The number of patients who had SIBDQ score at Week 54

[9] - The number of patients who had SIBDQ score at Week 54

## Statistical analyses

No statistical analyses for this end point



## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Up to End-of-Study Visit (8 weeks after Week 54 infusion)

Adverse event reporting additional description:

Adverse events was based on Treatment Emergent (Serious) Adverse Event

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

### Dictionary used

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

|                    |      |
|--------------------|------|
| Dictionary version | 19.1 |
|--------------------|------|

### Reporting groups

|                       |                 |
|-----------------------|-----------------|
| Reporting group title | CT-P13 - CT-P13 |
|-----------------------|-----------------|

Reporting group description:

CT-P13 followed by CT-P13 from Week 30

|                       |                   |
|-----------------------|-------------------|
| Reporting group title | CT-P13 - Remicade |
|-----------------------|-------------------|

Reporting group description:

CT-P13 followed by Remicade from Week 30

|                       |                     |
|-----------------------|---------------------|
| Reporting group title | Remicade - Remicade |
|-----------------------|---------------------|

Reporting group description:

Remicade followed by Remicade from Week 30

|                       |                   |
|-----------------------|-------------------|
| Reporting group title | Remicade - CT-P13 |
|-----------------------|-------------------|

Reporting group description:

Remicade followed by CT-P13 from Week 30

| Serious adverse events                            | CT-P13 - CT-P13 | CT-P13 - Remicade | Remicade - Remicade |
|---------------------------------------------------|-----------------|-------------------|---------------------|
| Total subjects affected by serious adverse events |                 |                   |                     |
| subjects affected / exposed                       | 4 / 56 (7.14%)  | 4 / 55 (7.27%)    | 4 / 54 (7.41%)      |
| number of deaths (all causes)                     | 0               | 0                 | 0                   |
| number of deaths resulting from adverse events    | 0               | 0                 | 0                   |
| Injury, poisoning and procedural complications    |                 |                   |                     |
| Infusion related reaction                         |                 |                   |                     |
| subjects affected / exposed                       | 0 / 56 (0.00%)  | 0 / 55 (0.00%)    | 1 / 54 (1.85%)      |
| occurrences causally related to treatment / all   | 0 / 0           | 0 / 0             | 1 / 1               |
| deaths causally related to treatment / all        | 0 / 0           | 0 / 0             | 0 / 0               |
| Road traffic accident                             |                 |                   |                     |
| subjects affected / exposed                       | 0 / 56 (0.00%)  | 0 / 55 (0.00%)    | 1 / 54 (1.85%)      |
| occurrences causally related to treatment / all   | 0 / 0           | 0 / 0             | 0 / 1               |
| deaths causally related to treatment / all        | 0 / 0           | 0 / 0             | 0 / 0               |
| Nervous system disorders                          |                 |                   |                     |

|                                                      |                |                |                |
|------------------------------------------------------|----------------|----------------|----------------|
| Syncope                                              |                |                |                |
| subjects affected / exposed                          | 0 / 56 (0.00%) | 0 / 55 (0.00%) | 0 / 54 (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 / 56 (1.79%) | 0 / 55 (0.00%) | 0 / 54 (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          |
| General disorders and administration site conditions |                |                |                |
| Generalised oedema                                   |                |                |                |
| subjects affected / exposed                          | 0 / 56 (0.00%) | 0 / 55 (0.00%) | 1 / 54 (1.85%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          | 1 / 1          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Gastrointestinal disorders                           |                |                |                |
| Abdominal pain                                       |                |                |                |
| subjects affected / exposed                          | 0 / 56 (0.00%) | 1 / 55 (1.82%) | 0 / 54 (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          |
| Anal fissure                                         |                |                |                |
| subjects affected / exposed                          | 1 / 56 (1.79%) | 0 / 55 (0.00%) | 1 / 54 (1.85%) |
| occurrences causally related to treatment / all      | 0 / 1          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Anal fistula                                         |                |                |                |
| subjects affected / exposed                          | 0 / 56 (0.00%) | 0 / 55 (0.00%) | 1 / 54 (1.85%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Constipation                                         |                |                |                |
| subjects affected / exposed                          | 0 / 56 (0.00%) | 0 / 55 (0.00%) | 0 / 54 (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          |
| Duodenal ulcer haemorrhage                           |                |                |                |

|                                                 |                |                |                |
|-------------------------------------------------|----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 56 (0.00%) | 0 / 55 (0.00%) | 0 / 54 (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          |
| Gastritis haemorrhagic                          |                |                |                |
| subjects affected / exposed                     | 0 / 56 (0.00%) | 0 / 55 (0.00%) | 0 / 54 (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          |
| Haematochezia                                   |                |                |                |
| subjects affected / exposed                     | 0 / 56 (0.00%) | 0 / 55 (0.00%) | 0 / 54 (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          |
| Haemorrhoids                                    |                |                |                |
| subjects affected / exposed                     | 1 / 56 (1.79%) | 0 / 55 (0.00%) | 0 / 54 (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          |
| Lower gastrointestinal haemorrhage              |                |                |                |
| subjects affected / exposed                     | 0 / 56 (0.00%) | 0 / 55 (0.00%) | 0 / 54 (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          |
| Hepatobiliary disorders                         |                |                |                |
| Hepatitis                                       |                |                |                |
| subjects affected / exposed                     | 0 / 56 (0.00%) | 1 / 55 (1.82%) | 0 / 54 (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          |
| Infections and infestations                     |                |                |                |
| Abscess intestinal                              |                |                |                |
| subjects affected / exposed                     | 0 / 56 (0.00%) | 0 / 55 (0.00%) | 0 / 54 (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          |
| Acute sinusitis                                 |                |                |                |
| subjects affected / exposed                     | 0 / 56 (0.00%) | 1 / 55 (1.82%) | 0 / 54 (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          |
| Anal abscess                                    |                |                |                |

|                                                 |                |                |                |
|-------------------------------------------------|----------------|----------------|----------------|
| subjects affected / exposed                     | 1 / 56 (1.79%) | 0 / 55 (0.00%) | 0 / 54 (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          |
| Cellulitis                                      |                |                |                |
| subjects affected / exposed                     | 0 / 56 (0.00%) | 1 / 55 (1.82%) | 0 / 54 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 1 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Peritoneal tuberculosis                         |                |                |                |
| subjects affected / exposed                     | 1 / 56 (1.79%) | 0 / 55 (0.00%) | 0 / 54 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Tuberculous pleurisy                            |                |                |                |
| subjects affected / exposed                     | 0 / 56 (0.00%) | 0 / 55 (0.00%) | 0 / 54 (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>                     | Remicade - CT-P13 |  |  |
|---------------------------------------------------|-------------------|--|--|
| Total subjects affected by serious adverse events |                   |  |  |
| subjects affected / exposed                       | 7 / 55 (12.73%)   |  |  |
| number of deaths (all causes)                     | 0                 |  |  |
| number of deaths resulting from adverse events    | 0                 |  |  |
| Injury, poisoning and procedural complications    |                   |  |  |
| Infusion related reaction                         |                   |  |  |
| subjects affected / exposed                       | 0 / 55 (0.00%)    |  |  |
| occurrences causally related to treatment / all   | 0 / 0             |  |  |
| deaths causally related to treatment / all        | 0 / 0             |  |  |
| Road traffic accident                             |                   |  |  |
| subjects affected / exposed                       | 0 / 55 (0.00%)    |  |  |
| occurrences causally related to treatment / all   | 0 / 0             |  |  |
| deaths causally related to treatment / all        | 0 / 0             |  |  |
| Nervous system disorders                          |                   |  |  |
| Syncope                                           |                   |  |  |

|                                                      |                |  |  |
|------------------------------------------------------|----------------|--|--|
| subjects affected / exposed                          | 1 / 55 (1.82%) |  |  |
| occurrences causally related to treatment / all      | 0 / 1          |  |  |
| deaths causally related to treatment / all           | 0 / 0          |  |  |
| Blood and lymphatic system disorders                 |                |  |  |
| Anaemia                                              |                |  |  |
| subjects affected / exposed                          | 0 / 55 (0.00%) |  |  |
| occurrences causally related to treatment / all      | 0 / 0          |  |  |
| deaths causally related to treatment / all           | 0 / 0          |  |  |
| General disorders and administration site conditions |                |  |  |
| Generalised oedema                                   |                |  |  |
| subjects affected / exposed                          | 0 / 55 (0.00%) |  |  |
| occurrences causally related to treatment / all      | 0 / 0          |  |  |
| deaths causally related to treatment / all           | 0 / 0          |  |  |
| Gastrointestinal disorders                           |                |  |  |
| Abdominal pain                                       |                |  |  |
| subjects affected / exposed                          | 0 / 55 (0.00%) |  |  |
| occurrences causally related to treatment / all      | 0 / 0          |  |  |
| deaths causally related to treatment / all           | 0 / 0          |  |  |
| Anal fissure                                         |                |  |  |
| subjects affected / exposed                          | 0 / 55 (0.00%) |  |  |
| occurrences causally related to treatment / all      | 0 / 0          |  |  |
| deaths causally related to treatment / all           | 0 / 0          |  |  |
| Anal fistula                                         |                |  |  |
| subjects affected / exposed                          | 0 / 55 (0.00%) |  |  |
| occurrences causally related to treatment / all      | 0 / 0          |  |  |
| deaths causally related to treatment / all           | 0 / 0          |  |  |
| Constipation                                         |                |  |  |
| subjects affected / exposed                          | 1 / 55 (1.82%) |  |  |
| occurrences causally related to treatment / all      | 0 / 1          |  |  |
| deaths causally related to treatment / all           | 0 / 0          |  |  |
| Duodenal ulcer haemorrhage                           |                |  |  |
| subjects affected / exposed                          | 1 / 55 (1.82%) |  |  |
| occurrences causally related to treatment / all      | 0 / 1          |  |  |
| deaths causally related to treatment / all           | 0 / 0          |  |  |

|                                                 |                |  |  |
|-------------------------------------------------|----------------|--|--|
| Gastritis haemorrhagic                          |                |  |  |
| subjects affected / exposed                     | 1 / 55 (1.82%) |  |  |
| occurrences causally related to treatment / all | 0 / 1          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Haematochezia                                   |                |  |  |
| subjects affected / exposed                     | 1 / 55 (1.82%) |  |  |
| occurrences causally related to treatment / all | 0 / 1          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Haemorrhoids                                    |                |  |  |
| subjects affected / exposed                     | 0 / 55 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Lower gastrointestinal haemorrhage              |                |  |  |
| subjects affected / exposed                     | 1 / 55 (1.82%) |  |  |
| occurrences causally related to treatment / all | 0 / 1          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Hepatobiliary disorders                         |                |  |  |
| Hepatitis                                       |                |  |  |
| subjects affected / exposed                     | 0 / 55 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Infections and infestations                     |                |  |  |
| Abscess intestinal                              |                |  |  |
| subjects affected / exposed                     | 1 / 55 (1.82%) |  |  |
| occurrences causally related to treatment / all | 0 / 1          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Acute sinusitis                                 |                |  |  |
| subjects affected / exposed                     | 0 / 55 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Anal abscess                                    |                |  |  |
| subjects affected / exposed                     | 0 / 55 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |

|                                                 |                |  |  |
|-------------------------------------------------|----------------|--|--|
| Cellulitis                                      |                |  |  |
| subjects affected / exposed                     | 0 / 55 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Peritoneal tuberculosis                         |                |  |  |
| subjects affected / exposed                     | 0 / 55 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Tuberculous pleurisy                            |                |  |  |
| subjects affected / exposed                     | 1 / 55 (1.82%) |  |  |
| occurrences causally related to treatment / all | 1 / 1          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |

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

| <b>Non-serious adverse events</b>                     | CT-P13 - CT-P13  | CT-P13 - Remicade | Remicade - Remicade |
|-------------------------------------------------------|------------------|-------------------|---------------------|
| Total subjects affected by non-serious adverse events |                  |                   |                     |
| subjects affected / exposed                           | 37 / 56 (66.07%) | 36 / 55 (65.45%)  | 36 / 54 (66.67%)    |
| Investigations                                        |                  |                   |                     |
| Aspartate aminotransferase increased                  |                  |                   |                     |
| subjects affected / exposed                           | 1 / 56 (1.79%)   | 1 / 55 (1.82%)    | 0 / 54 (0.00%)      |
| occurrences (all)                                     | 1                | 1                 | 0                   |
| Blood creatine phosphokinase increase                 |                  |                   |                     |
| subjects affected / exposed                           | 1 / 56 (1.79%)   | 1 / 55 (1.82%)    | 4 / 54 (7.41%)      |
| occurrences (all)                                     | 1                | 1                 | 5                   |
| Gamma-glutamyltransferase increased                   |                  |                   |                     |
| subjects affected / exposed                           | 3 / 56 (5.36%)   | 1 / 55 (1.82%)    | 0 / 54 (0.00%)      |
| occurrences (all)                                     | 3                | 1                 | 0                   |
| Injury, poisoning and procedural complications        |                  |                   |                     |
| Infusion related reaction                             |                  |                   |                     |
| subjects affected / exposed                           | 8 / 56 (14.29%)  | 2 / 55 (3.64%)    | 5 / 54 (9.26%)      |
| occurrences (all)                                     | 13               | 2                 | 7                   |
| Nervous system disorders                              |                  |                   |                     |

|                                                                                                                   |                     |                      |                     |
|-------------------------------------------------------------------------------------------------------------------|---------------------|----------------------|---------------------|
| Dizziness<br>subjects affected / exposed<br>occurrences (all)                                                     | 2 / 56 (3.57%)<br>2 | 0 / 55 (0.00%)<br>0  | 0 / 54 (0.00%)<br>0 |
| Headache<br>subjects affected / exposed<br>occurrences (all)                                                      | 3 / 56 (5.36%)<br>3 | 1 / 55 (1.82%)<br>1  | 2 / 54 (3.70%)<br>2 |
| Blood and lymphatic system disorders<br>Anaemia<br>subjects affected / exposed<br>occurrences (all)               | 5 / 56 (8.93%)<br>5 | 5 / 55 (9.09%)<br>5  | 5 / 54 (9.26%)<br>5 |
| Gastrointestinal disorders<br>Abdominal pain<br>subjects affected / exposed<br>occurrences (all)                  | 3 / 56 (5.36%)<br>3 | 8 / 55 (14.55%)<br>9 | 5 / 54 (9.26%)<br>7 |
| Diarrhoea<br>subjects affected / exposed<br>occurrences (all)                                                     | 1 / 56 (1.79%)<br>2 | 3 / 55 (5.45%)<br>3  | 3 / 54 (5.56%)<br>3 |
| Frequent bowel movements<br>subjects affected / exposed<br>occurrences (all)                                      | 1 / 56 (1.79%)<br>2 | 3 / 55 (5.45%)<br>4  | 0 / 54 (0.00%)<br>0 |
| Nausea<br>subjects affected / exposed<br>occurrences (all)                                                        | 0 / 56 (0.00%)<br>0 | 3 / 55 (5.45%)<br>4  | 3 / 54 (5.56%)<br>3 |
| Pyrexia<br>subjects affected / exposed<br>occurrences (all)                                                       | 0 / 56 (0.00%)<br>0 | 3 / 55 (5.45%)<br>3  | 0 / 54 (0.00%)<br>0 |
| Skin and subcutaneous tissue disorders<br>Rash<br>subjects affected / exposed<br>occurrences (all)                | 0 / 56 (0.00%)<br>0 | 1 / 55 (1.82%)<br>1  | 3 / 54 (5.56%)<br>4 |
| Musculoskeletal and connective tissue disorders<br>Arthralgia<br>subjects affected / exposed<br>occurrences (all) | 3 / 56 (5.36%)<br>4 | 1 / 55 (1.82%)<br>1  | 4 / 54 (7.41%)<br>5 |
| Infections and infestations                                                                                       |                     |                      |                     |



|                                   |                |                |                |
|-----------------------------------|----------------|----------------|----------------|
| Gastroenteritis                   |                |                |                |
| subjects affected / exposed       | 1 / 56 (1.79%) | 1 / 55 (1.82%) | 1 / 54 (1.85%) |
| occurrences (all)                 | 1              | 1              | 1              |
| Influenza                         |                |                |                |
| subjects affected / exposed       | 2 / 56 (3.57%) | 1 / 55 (1.82%) | 1 / 54 (1.85%) |
| occurrences (all)                 | 3              | 1              | 1              |
| Upper respiratory tract infection |                |                |                |
| subjects affected / exposed       | 3 / 56 (5.36%) | 1 / 55 (1.82%) | 0 / 54 (0.00%) |
| occurrences (all)                 | 3              | 1              | 0              |

|                                                       |                   |  |  |
|-------------------------------------------------------|-------------------|--|--|
| <b>Non-serious adverse events</b>                     | Remicade - CT-P13 |  |  |
| Total subjects affected by non-serious adverse events |                   |  |  |
| subjects affected / exposed                           | 40 / 55 (72.73%)  |  |  |
| Investigations                                        |                   |  |  |
| Aspartate aminotransferase increased                  |                   |  |  |
| subjects affected / exposed                           | 3 / 55 (5.45%)    |  |  |
| occurrences (all)                                     | 3                 |  |  |
| Blood creatine phosphokinase increase                 |                   |  |  |
| subjects affected / exposed                           | 3 / 55 (5.45%)    |  |  |
| occurrences (all)                                     | 3                 |  |  |
| Gamma-glutamyltransferase increased                   |                   |  |  |
| subjects affected / exposed                           | 1 / 55 (1.82%)    |  |  |
| occurrences (all)                                     | 1                 |  |  |
| Injury, poisoning and procedural complications        |                   |  |  |
| Infusion related reaction                             |                   |  |  |
| subjects affected / exposed                           | 4 / 55 (7.27%)    |  |  |
| occurrences (all)                                     | 4                 |  |  |
| Nervous system disorders                              |                   |  |  |
| Dizziness                                             |                   |  |  |
| subjects affected / exposed                           | 4 / 55 (7.27%)    |  |  |
| occurrences (all)                                     | 4                 |  |  |
| Headache                                              |                   |  |  |
| subjects affected / exposed                           | 3 / 55 (5.45%)    |  |  |
| occurrences (all)                                     | 3                 |  |  |
| Blood and lymphatic system disorders                  |                   |  |  |

|                                                                              |                     |  |  |
|------------------------------------------------------------------------------|---------------------|--|--|
| Anaemia<br>subjects affected / exposed<br>occurrences (all)                  | 4 / 55 (7.27%)<br>4 |  |  |
| Gastrointestinal disorders                                                   |                     |  |  |
| Abdominal pain<br>subjects affected / exposed<br>occurrences (all)           | 4 / 55 (7.27%)<br>6 |  |  |
| Diarrhoea<br>subjects affected / exposed<br>occurrences (all)                | 0 / 55 (0.00%)<br>0 |  |  |
| Frequent bowel movements<br>subjects affected / exposed<br>occurrences (all) | 1 / 55 (1.82%)<br>1 |  |  |
| Nausea<br>subjects affected / exposed<br>occurrences (all)                   | 0 / 55 (0.00%)<br>0 |  |  |
| Pyrexia<br>subjects affected / exposed<br>occurrences (all)                  | 1 / 55 (1.82%)<br>1 |  |  |
| Skin and subcutaneous tissue disorders                                       |                     |  |  |
| Rash<br>subjects affected / exposed<br>occurrences (all)                     | 0 / 55 (0.00%)<br>0 |  |  |
| Musculoskeletal and connective tissue disorders                              |                     |  |  |
| Arthralgia<br>subjects affected / exposed<br>occurrences (all)               | 4 / 55 (7.27%)<br>4 |  |  |
| Infections and infestations                                                  |                     |  |  |
| Gastroenteritis<br>subjects affected / exposed<br>occurrences (all)          | 3 / 55 (5.45%)<br>3 |  |  |
| Influenza<br>subjects affected / exposed<br>occurrences (all)                | 5 / 55 (9.09%)<br>6 |  |  |
| Upper respiratory tract infection                                            |                     |  |  |

|                             |                |  |  |
|-----------------------------|----------------|--|--|
| subjects affected / exposed | 0 / 55 (0.00%) |  |  |
| occurrences (all)           | 0              |  |  |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date             | Amendment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 01 December 2014 | Summary of significant changes included the following: <ul style="list-style-type: none"><li>• Patient who has a Stoma (e.g., ileostomy or colostomy) within 6 months prior to randomization cannot enrolled in this study</li><li>• Deletion of Cav, Swing, Degree of fluctuation as PK endpoints</li><li>• Revision of the wording on margin justification, and define the population for primary efficacy analysis</li><li>• Biomarker analysis was added as tertiary endpoint</li><li>• Deletion of time to loss of response up to and including Week 54 in the Week 13 responders as endpoint.</li><li>• To define per-protocol definition in regarding to major deviations</li><li>• Other administrative changes</li></ul> |
| 22 December 2014 | Summary of significant changes included the following: <ul style="list-style-type: none"><li>• To exclude patients who have been administered with any TNFa inhibitors.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 10 February 2015 | Summary of significant changes included the following: <ul style="list-style-type: none"><li>• Deleted PK time point after Week 22</li><li>• To exclude enteral or parenteral nutrition use during the study</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported