



Clinical trial results:

A multi-center, open-label study to investigate the efficacy and safety of CDP870 in active Crohn's disease patients, who showed no clinical efficacy in a remission induction study (Study CDP870-037) but showed clinical efficacy after additional remission induction therapy was applied, at Week 26 after subcutaneous administration of CDP870 400mg from Week 8 until Week 24 at 4-week intervals

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2014-004400-30 |
| Trial protocol | Outside EU/EEA |
| Global end of trial date | 11 May 2008 |

Results information

| | |
|--------------------------------|--------------|
| Result version number | v1 (current) |
| This version publication date | 28 June 2016 |
| First version publication date | 10 July 2015 |

Trial information

Trial identification

| | |
|-----------------------|--------|
| Sponsor protocol code | C87048 |
|-----------------------|--------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT00329420 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | UCB Japan Co., Ltd. |
| Sponsor organisation address | 2-2 Kanda Surugadai, Tokyo, Japan, 101-0062 |
| Public contact | Clinical Trial Registries and Results Disclosure, UCB BIOSCIENCES GmbH, +49 2173 4815 15, clinicaltrials@ucb.com |
| Scientific contact | Clinical Trial Registries and Results Disclosure, UCB BIOSCIENCES GmbH, +49 2173 48 15 15, clinicaltrials@ucb.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? | Yes |

Notes:

Results analysis stage

| | |
|--|----------------|
| Analysis stage | Final |
| Date of interim/final analysis | 27 August 2008 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 11 May 2008 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

The primary objective of the study was to evaluate the efficacy of certolizumab pegol 400mg in subjects with active CD who were non-responders in the induction study (Study CDP870-037), but who responded to a second induction with certolizumab pegol. Subjects underwent re-induction with certolizumab pegol 400mg administered every 2 weeks for 3 doses; subjects who responded to the second induction received certolizumab pegol 400mg administered every 4 weeks for 5 doses.

Protection of trial subjects:

Not applicable

Background therapy:

Not applicable

Evidence for comparator:

Not applicable

| | |
|---|-------------|
| Actual start date of recruitment | 02 May 2006 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | No |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|-----------|
| Country: Number of subjects enrolled | Japan: 46 |
| Worldwide total number of subjects | 46 |
| EEA total number of subjects | 0 |

Notes:

Subjects enrolled per age group

| | |
|---|---|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 0 |
| Children (2-11 years) | 0 |

| | |
|---------------------------|----|
| Adolescents (12-17 years) | 1 |
| Adults (18-64 years) | 45 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

Non-responders at Week 6 of the double-blind main study, C87037 (2014-004399-42) could enter this single-group open-label extension study, C87048 (2014-004400-30). Recruitment into this extension study was between May 2006 and May 2008. Of the 26 hospitals in the main study C87037 16 sites went on to enter subjects into this extension study.

Pre-assignment

Screening details:

Subjects who responded to re-induction (Week 14 visit) in this extension study could enter the 4-weekly dosing phase. Efficacy data are based on these 26 subjects. However, adverse event data are based on all 46 subjects who entered this extension study. Data are presented by the three possible treatment sequences received across both studies.

Period 1

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

Arms

| | |
|------------------------------|----------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | CZP 400 mg / Placebo |

Arm description:

Certolizumab pegol (CZP) 400 mg (3 doses 2-weekly then 5 doses 4-weekly) in this extension study / Placebo (3 doses 2-weekly) in the 6-week double-blind main study (2014-004399-42)

| | |
|--|--|
| Arm type | Experimental |
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | Placebo |
| Other name | |
| Pharmaceutical forms | Solution for injection in pre-filled syringe |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Certolizumab pegol (CZP)400 mg (3 doses 2-weekly then 5 doses 4-weekly) in this extension study / Placebo (3 doses 2-weekly) in the 6-week double-blind main study (2014-004399-42)

| | |
|--|--|
| Investigational medicinal product name | Certolizumab pegol |
| Investigational medicinal product code | Certolizumab pegol CZP |
| Other name | |
| Pharmaceutical forms | Solution for injection in pre-filled syringe |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Certolizumab pegol (CZP)400 mg (3 doses 2-weekly then 5 doses 4-weekly) in this extension study / Placebo (3 doses 2-weekly) in the 6-week double-blind main study (2014-004399-42)

Certolizumab pegol (CZP)400 mg (3 doses 2-weekly then 5 doses 4-weekly) in this extension study / Certolizumab pegol (CZP) 200 mg (3 doses 2-weekly) in the 6-week double-blind main study (2014-004399-42)

Certolizumab pegol (CZP) 400 mg (3 doses 2-weekly then 5 doses 4-weekly) in this extension study / Certolizumab pegol (CZP) 400 mg (3 doses 2-weekly) in the 6-week double-blind main study (2014-004399-42)

| | |
|-----------|-------------------------|
| Arm title | CZP 400 mg / CZP 200 mg |
|-----------|-------------------------|

Arm description:

Certolizumab pegol (CZP) 400 mg (3 doses 2-weekly then 5 doses 4-weekly) in this extension study / Certolizumab pegol (CZP) 200 mg (3 doses 2-weekly) in the 6-week double-blind main study (2014-004399-42)

| | |
|--|--|
| Arm type | Experimental |
| Investigational medicinal product name | Certolizumab pegol |
| Investigational medicinal product code | Certolizumab pegol CZP |
| Other name | |
| Pharmaceutical forms | Solution for injection in pre-filled syringe |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Certolizumab pegol (CZP)400 mg (3 doses 2-weekly then 5 doses 4-weekly) in this extension study / Placebo (3 doses 2-weekly) in the 6-week double-blind main study (2014-004399-42)

Certolizumab pegol (CZP)400 mg (3 doses 2-weekly then 5 doses 4-weekly) in this extension study / Certolizumab pegol (CZP) 200 mg (3 doses 2-weekly) in the 6-week double-blind main study (2014-004399-42)

Certolizumab pegol (CZP) 400 mg (3 doses 2-weekly then 5 doses 4-weekly) in this extension study / Certolizumab pegol (CZP) 400 mg (3 doses 2-weekly) in the 6-week double-blind main study (2014-004399-42)

| | |
|------------------|-------------------------|
| Arm title | CZP 400 mg / CZP 400 mg |
|------------------|-------------------------|

Arm description:

Certolizumab pegol (CZP) 400 mg (3 doses 2-weekly then 5 doses 4-weekly) in this extension study / Certolizumab pegol (CZP) 400 mg (3 doses 2-weekly) in the 6-week double-blind main study (2014-004399-42)

| | |
|--|--|
| Arm type | Experimental |
| Investigational medicinal product name | Certolizumab pegol |
| Investigational medicinal product code | Certolizumab pegol CZP |
| Other name | |
| Pharmaceutical forms | Solution for injection in pre-filled syringe |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Certolizumab pegol (CZP)400 mg (3 doses 2-weekly then 5 doses 4-weekly) in this extension study / Placebo (3 doses 2-weekly) in the 6-week double-blind main study (2014-004399-42)

Certolizumab pegol (CZP)400 mg (3 doses 2-weekly then 5 doses 4-weekly) in this extension study / Certolizumab pegol (CZP) 200 mg (3 doses 2-weekly) in the 6-week double-blind main study (2014-004399-42)

Certolizumab pegol (CZP) 400 mg (3 doses 2-weekly then 5 doses 4-weekly) in this extension study / Certolizumab pegol (CZP) 400 mg (3 doses 2-weekly) in the 6-week double-blind main study (2014-004399-42)

| Number of subjects in period 1 | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg |
|---------------------------------------|-----------------------------|--------------------------------|--------------------------------|
| Started | 18 | 13 | 15 |
| Moved to maintenance period | 12 | 7 | 7 |
| Completed | 8 | 5 | 6 |
| Not completed | 10 | 8 | 9 |
| Withdrawal of Consent | 1 | - | 1 |
| Did not respond to re-induction | 3 | 5 | 4 |
| AE, non-serious non-fatal | 2 | - | 1 |
| SAE, non-fatal | 1 | 1 | 2 |
| Lack of efficacy | 3 | 2 | 1 |

Baseline characteristics

Reporting groups

| | |
|--|-------------------------|
| Reporting group title | CZP 400 mg / Placebo |
| Reporting group description: Certolizumab pegol (CZP) 400 mg (3 doses 2-weekly then 5 doses 4-weekly) in this extension study / Placebo (3 doses 2-weekly) in the 6-week double-blind main study (2014-004399-42) | |
| Reporting group title | CZP 400 mg / CZP 200 mg |
| Reporting group description: Certolizumab pegol (CZP) 400 mg (3 doses 2-weekly then 5 doses 4-weekly) in this extension study / Certolizumab pegol (CZP) 200 mg (3 doses 2-weekly) in the 6-week double-blind main study (2014-004399-42) | |
| Reporting group title | CZP 400 mg / CZP 400 mg |
| Reporting group description: Certolizumab pegol (CZP) 400 mg (3 doses 2-weekly then 5 doses 4-weekly) in this extension study / Certolizumab pegol (CZP) 400 mg (3 doses 2-weekly) in the 6-week double-blind main study (2014-004399-42) | |

| Reporting group values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg |
|---|----------------------|-------------------------|-------------------------|
| Number of subjects | 18 | 13 | 15 |
| Age Categorical Units: Subjects | | | |
| <=18 years | 1 | 0 | 0 |
| Between 18 and 65 years | 17 | 13 | 15 |
| >=65 years | 0 | 0 | 0 |
| Age Continuous Units: years | | | |
| arithmetic mean | 30.4 | 37.5 | 29.9 |
| standard deviation | ± 7.5 | ± 8.2 | ± 5.9 |
| Gender Categorical Units: Subjects | | | |
| Female | 4 | 4 | 3 |
| Male | 14 | 9 | 12 |
| Region of Enrollment Units: Subjects | | | |
| Japan | 18 | 13 | 15 |

| Reporting group values | Total | | |
|------------------------------------|-------|--|--|
| Number of subjects | 46 | | |
| Age Categorical Units: Subjects | | | |
| <=18 years | 1 | | |
| Between 18 and 65 years | 45 | | |
| >=65 years | 0 | | |
| Age Continuous Units: years | | | |
| arithmetic mean | | | |
| standard deviation | - | | |

| | | | |
|---|----|--|--|
| Gender Categorical Units: Subjects | | | |
| Female | 11 | | |
| Male | 35 | | |
| Region of Enrollment Units: Subjects | | | |
| Japan | 46 | | |

End points

End points reporting groups

| | |
|--|-------------------------|
| Reporting group title | CZP 400 mg / Placebo |
| Reporting group description: Certolizumab pegol (CZP) 400 mg (3 doses 2-weekly then 5 doses 4-weekly) in this extension study / Placebo (3 doses 2-weekly) in the 6-week double-blind main study (2014-004399-42) | |
| Reporting group title | CZP 400 mg / CZP 200 mg |
| Reporting group description: Certolizumab pegol (CZP) 400 mg (3 doses 2-weekly then 5 doses 4-weekly) in this extension study / Certolizumab pegol (CZP) 200 mg (3 doses 2-weekly) in the 6-week double-blind main study (2014-004399-42) | |
| Reporting group title | CZP 400 mg / CZP 400 mg |
| Reporting group description: Certolizumab pegol (CZP) 400 mg (3 doses 2-weekly then 5 doses 4-weekly) in this extension study / Certolizumab pegol (CZP) 400 mg (3 doses 2-weekly) in the 6-week double-blind main study (2014-004399-42) | |

Primary: Percentage of Crohn's Disease Activity Index (CDAI) Responders at Week 34

| | |
|---|--|
| End point title | Percentage of Crohn's Disease Activity Index (CDAI) Responders at Week 34 ^[1] |
| End point description: Crohn's disease activity index (CDAI) responders are subjects achieving either clinical response (a reduction in CDAI score of ≥ 100 points from Week 0), or remission ($\text{CDAI} \leq 150$). CDAI is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease. | |
| End point type | Primary |
| End point timeframe: Week 0 and Week 34 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 34' is 26 weeks after the first visit in this extension study. | |

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No formal statistical hypothesis testing was planned for this study. Results were summarized in tables as descriptive statistics only.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|-----------------------------------|----------------------|-------------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: Percentage of subjects | | | | |
| number (not applicable) | | | | |
| Percentage of CDAI responders | 66.7 | 28.6 | 42.9 | |
| Percentage of CDAI non-responders | 33.3 | 71.4 | 57.1 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Crohn's Disease Activity Index (CDAI) Score at Week 8

| | |
|-----------------|---|
| End point title | Change from Week 0 in Crohn's Disease Activity Index (CDAI) Score at Week 8 |
|-----------------|---|

End point description:

Crohn's disease activity index (CDAI) is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease. A decrease in CDAI over time indicates improvement in disease activity.

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

End point timeframe:

Week 0 and Week 8 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 8' is the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|----------------------|-------------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | -20.5 (± 81.6) | -53.1 (± 38.1) | -63.8 (± 26.4) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Crohn's Disease Activity Index (CDAI) Score at Week 10

| | |
|-----------------|--|
| End point title | Change from Week 0 in Crohn's Disease Activity Index (CDAI) Score at Week 10 |
|-----------------|--|

End point description:

Crohn's disease activity index (CDAI) is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease. A decrease in CDAI over time indicates improvement in disease activity.

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

End point timeframe:

Week 0 and Week 10 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 10' is 2 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|----------------------|-------------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | -96.1 (± 76.1) | -100.3 (± 35.4) | -90 (± 18.2) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Crohn's Disease Activity Index (CDAI) Score at Week 12

| | |
|-----------------|--|
| End point title | Change from Week 0 in Crohn's Disease Activity Index (CDAI) Score at Week 12 |
|-----------------|--|

End point description:

Crohn's disease activity index (CDAI) is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease. A decrease in CDAI over time indicates improvement in disease activity.

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

End point timeframe:

Week 0 and Week 12 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 12' is 4 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | -101.3 (± 56.6) | -100.5 (± 49.3) | -109.9 (± 36.7) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Crohn's Disease Activity Index (CDAI) Score at Week 14

| | |
|-----------------|--|
| End point title | Change from Week 0 in Crohn's Disease Activity Index (CDAI) Score at Week 14 |
|-----------------|--|

End point description:

Crohn's disease activity index (CDAI) is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease. A decrease in CDAI over time indicates improvement in disease activity.

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

End point timeframe:

Week 0 and Week 14 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 14' is 6 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | -124.3 (± 50.4) | -131.7 (± 41.3) | -147 (± 45.2) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Crohn's Disease Activity Index (CDAI) Score at Week 16

| | |
|-----------------|--|
| End point title | Change from Week 0 in Crohn's Disease Activity Index (CDAI) Score at Week 16 |
|-----------------|--|

End point description:

Crohn's disease activity index (CDAI) is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease. A decrease in CDAI over time indicates improvement in disease activity.

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

End point timeframe:

Week 0 and Week 16 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 16' is 8 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | -121 (± 57.7) | -70.4 (± 84.1) | -136.2 (± 32.2) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Crohn's Disease Activity Index (CDAI) Score at Week 20

| | |
|-----------------|--|
| End point title | Change from Week 0 in Crohn's Disease Activity Index (CDAI) Score at Week 20 |
|-----------------|--|

End point description:

Crohn's disease activity index (CDAI) is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease. A decrease in CDAI over time indicates improvement in disease activity.

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

End point timeframe:

Week 0 and Week 20 (relative to the start of the 6-week double-blind main study (NCT00291668)).
'Week 20' is 12 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 11 | 7 | 7 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | -105.3 (± 82.9) | -79.6 (± 60.9) | -130.9 (± 62.5) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Crohn's Disease Activity Index (CDAI) Score at Week 24

| | |
|-----------------|--|
| End point title | Change from Week 0 in Crohn's Disease Activity Index (CDAI) Score at Week 24 |
|-----------------|--|

End point description:

Crohn's disease activity index (CDAI) is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease. A decrease in CDAI over time indicates improvement in disease activity.

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

End point timeframe:

Week 0 and Week 24 (relative to the start of the 6-week double-blind main study (NCT00291668)).
'Week 24' is 16 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 9 | 7 | 7 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | -89.8 (± 79.8) | -70.6 (± 91.3) | -150.2 (± 48) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Crohn's Disease Activity Index (CDAI) Score at Week 28

| | |
|-----------------|--|
| End point title | Change from Week 0 in Crohn's Disease Activity Index (CDAI) Score at Week 28 |
|-----------------|--|

End point description:

Crohn's disease activity index (CDAI) is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease. A decrease in CDAI over time indicates improvement in disease activity.

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

End point timeframe:

Week 0 and Week 28 (relative to the start of the 6-week double-blind main study (NCT00291668)).
'Week 28' is 20 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 9 | 7 | 7 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | -118.2 (± 62.6) | -67.3 (± 77.1) | -154.8 (± 74.2) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Crohn's Disease Activity Index (CDAI) Score at Week 32

| | |
|-----------------|--|
| End point title | Change from Week 0 in Crohn's Disease Activity Index (CDAI) Score at Week 32 |
|-----------------|--|

End point description:

Crohn's disease activity index (CDAI) is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease. A decrease in CDAI over time indicates improvement in disease activity.

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

End point timeframe:

Week 0 and Week 32 (relative to the start of the 6-week double-blind main study (NCT00291668)).
'Week 32' is 24 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 8 | 5 | 6 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | -89 (± 88.3) | -77.3 (± 70.9) | -128.3 (± 75.3) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Crohn's Disease Activity Index (CDAI) Score at Week 34

| | |
|-----------------|--|
| End point title | Change from Week 0 in Crohn's Disease Activity Index (CDAI) Score at Week 34 |
|-----------------|--|

End point description:

Crohn's disease activity index (CDAI) is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease. A decrease in CDAI over time indicates improvement in disease activity.

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

End point timeframe:

Week 0 and Week 34 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 34' is 26 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 8 | 5 | 5 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | -134.9 (± 39.3) | -97.4 (± 33.1) | -132.7 (± 89.7) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Crohn's Disease Activity Index (CDAI) Score at Last Visit (Week 34 for completers or the Withdrawal Visit for premature withdrawals)

| | |
|-----------------|--|
| End point title | Change from Week 0 in Crohn's Disease Activity Index (CDAI) Score at Last Visit (Week 34 for completers or the Withdrawal Visit for premature withdrawals) |
|-----------------|--|

End point description:

Crohn's disease activity index (CDAI) is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease.

A decrease in CDAI over time indicates improvement in disease activity.

| | |
|--|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Week 0 and Last Visit (Week 34 relative to the start of the 6-week double-blind main study (NCT00291668) for completers or the Withdrawal Visit for premature withdrawals). 'Week 34' is 26 weeks after the first visit in this extension study. | |

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 11 | 6 | 5 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | -112 (± 75.6) | -61 (± 93.7) | -132.7 (± 89.7) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Crohn's Disease Activity Index (CDAI) responders at Week 8

| | |
|-----------------|--|
| End point title | Percentage of Crohn's Disease Activity Index (CDAI) responders at Week 8 |
|-----------------|--|

End point description:

Crohn's disease activity index (CDAI) responders are subjects achieving either clinical response (a reduction in CDAI score of ≥ 100 points from Week 0), or remission (CDAI ≤ 150). CDAI is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease.

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

End point timeframe:

Week 0 and Week 8 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 8' is the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|-----------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: Percentage of subjects | | | | |
| number (not applicable) | | | | |
| Percentage of CDAI responders | 8.3 | 14.3 | 14.3 | |
| Percentage of CDAI non-responders | 91.7 | 85.7 | 85.7 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Crohn's Disease Activity Index (CDAI) responders at Week 10

| | |
|-----------------|---|
| End point title | Percentage of Crohn's Disease Activity Index (CDAI) responders at Week 10 |
|-----------------|---|

End point description:

Crohn's disease activity index (CDAI) responders are subjects achieving either clinical response (a reduction in CDAI score of ≥ 100 points from Week 0), or remission (CDAI ≤ 150). CDAI is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease.

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

End point timeframe:

Week 0 and Week 10 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 10' is 2 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|-----------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: Percentage of subjects | | | | |
| number (not applicable) | | | | |
| Percentage of CDAI responders | 41.7 | 71.4 | 42.9 | |
| Percentage of CDAI non-responders | 58.3 | 28.6 | 57.1 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Crohn's Disease Activity Index (CDAI) responders at Week 12

| | |
|-----------------|---|
| End point title | Percentage of Crohn's Disease Activity Index (CDAI) responders at Week 12 |
|-----------------|---|

End point description:

Crohn's disease activity index (CDAI) responders are subjects achieving either clinical response (a reduction in CDAI score of ≥ 100 points from Week 0), or remission (CDAI ≤ 150). CDAI is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease.

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

End point timeframe:

Week 0 and Week 12 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 12' is 4 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|-----------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: Percentage of subjects | | | | |
| number (not applicable) | | | | |
| Percentage of CDAI responders | 50 | 71.4 | 57.1 | |
| Percentage of CDAI non-responders | 50 | 28.6 | 42.9 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Crohn's Disease Activity Index (CDAI) responders at Week 14

| | |
|-----------------|---|
| End point title | Percentage of Crohn's Disease Activity Index (CDAI) responders at Week 14 |
|-----------------|---|

End point description:

Crohn's disease activity index (CDAI) responders are subjects achieving either clinical response (a reduction in CDAI score of ≥ 100 points from Week 0), or remission (CDAI ≤ 150). CDAI is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease.

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

End point timeframe:

Week 0 and Week 14 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 14' is 6 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|-----------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: Percentage of subjects | | | | |
| number (not applicable) | | | | |
| Percentage of CDAI responders | 100 | 100 | 100 | |
| Percentage of CDAI non-responders | 0 | 0 | 0 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Crohn's Disease Activity Index (CDAI) responders at Week 16

| | |
|-----------------|---|
| End point title | Percentage of Crohn's Disease Activity Index (CDAI) responders at Week 16 |
|-----------------|---|

End point description:

Crohn's disease activity index (CDAI) responders are subjects achieving either clinical response (a reduction in CDAI score of ≥ 100 points from Week 0), or remission (CDAI ≤ 150). CDAI is used to

quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease.

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

End point timeframe:

Week 0 and Week 16 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 16' is 8 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|-----------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: Percentage of subjects | | | | |
| number (not applicable) | | | | |
| Percentage of CDAI responders | 66.7 | 42.9 | 85.7 | |
| Percentage of CDAI non-responders | 33.3 | 57.1 | 14.3 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Crohn's Disease Activity Index (CDAI) responders at Week 20

| | |
|-----------------|---|
| End point title | Percentage of Crohn's Disease Activity Index (CDAI) responders at Week 20 |
|-----------------|---|

End point description:

Crohn's disease activity index (CDAI) responders are subjects achieving either clinical response (a reduction in CDAI score of ≥ 100 points from Week 0), or remission (CDAI ≤ 150). CDAI is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease.

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

End point timeframe:

Week 0 and Week 20 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 20' is 12 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|-----------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: Percentage of subjects | | | | |
| number (not applicable) | | | | |
| Percentage of CDAI responders | 41.7 | 28.6 | 85.7 | |
| Percentage of CDAI non-responders | 58.3 | 71.4 | 14.3 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Crohn's Disease Activity Index (CDAI) responders at Week 24

| | |
|-----------------|---|
| End point title | Percentage of Crohn's Disease Activity Index (CDAI) responders at Week 24 |
|-----------------|---|

End point description:

Crohn's disease activity index (CDAI) responders are subjects achieving either clinical response (a reduction in CDAI score of ≥ 100 points from Week 0), or remission (CDAI ≤ 150). CDAI is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease.

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

End point timeframe:

Week 0 and Week 24 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 24' is 16 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|-----------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: Percentage of subjects | | | | |
| number (not applicable) | | | | |
| Percentage of CDAI responders | 41.7 | 57.1 | 71.4 | |
| Percentage of CDAI non-responders | 58.3 | 42.9 | 28.6 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Crohn's Disease Activity Index (CDAI) responders at Week 28

| | |
|-----------------|---|
| End point title | Percentage of Crohn's Disease Activity Index (CDAI) responders at Week 28 |
|-----------------|---|

End point description:

Crohn's disease activity index (CDAI) responders are subjects achieving either clinical response (a reduction in CDAI score of ≥ 100 points from Week 0), or remission (CDAI ≤ 150). CDAI is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease.

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

End point timeframe:

Week 0 and Week 28 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 28' is 20 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|-----------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: Percentage of subjects | | | | |
| number (not applicable) | | | | |
| Percentage of CDAI responders | 50 | 28.6 | 57.1 | |
| Percentage of CDAI non-responders | 50 | 71.4 | 42.9 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Crohn's Disease Activity Index (CDAI) responders at Week 32

| | |
|-----------------|---|
| End point title | Percentage of Crohn's Disease Activity Index (CDAI) responders at Week 32 |
|-----------------|---|

End point description:

Crohn's disease activity index (CDAI) responders are subjects achieving either clinical response (a reduction in CDAI score of ≥ 100 points from Week 0), or remission (CDAI ≤ 150). CDAI is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease.

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

End point timeframe:

Week 0 and Week 32 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 32' is 24 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|-----------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: Percentage of subjects | | | | |
| number (not applicable) | | | | |
| Percentage of CDAI responders | 33.3 | 28.6 | 57.1 | |
| Percentage of CDAI non-responders | 66.7 | 71.4 | 42.9 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Crohn's Disease Activity Index (CDAI) responders at Last Visit (Week 34 for completers or the Withdrawal Visit for premature withdrawals)

| | |
|-----------------|---|
| End point title | Percentage of Crohn's Disease Activity Index (CDAI) responders at Last Visit (Week 34 for completers or the Withdrawal Visit for premature withdrawals) |
|-----------------|---|

End point description:

Crohn's disease activity index (CDAI) responders are subjects achieving either clinical response (a

reduction in CDAI score of ≥ 100 points from Week 0), or remission (CDAI ≤ 150). CDAI is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease.

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

End point timeframe:

Week 0 and Last Visit (Week 34 relative to the start of the 6-week double-blind main study (NCT00291668) for completers or the Withdrawal Visit for premature withdrawals). 'Week 34' is 26 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|-----------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: Percentage of subjects | | | | |
| number (not applicable) | | | | |
| Percentage of CDAI responders | 66.7 | 28.6 | 42.9 | |
| Percentage of CDAI non-responders | 33.3 | 71.4 | 57.1 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving remission at Week 8

| | |
|-----------------|--|
| End point title | Percentage of subjects achieving remission at Week 8 |
|-----------------|--|

End point description:

Crohn's disease activity index (CDAI) is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease.

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

End point timeframe:

Week 8 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 8' is the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|---|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: Percentage of subjects | | | | |
| number (not applicable) | | | | |
| Percentage of subjects in remission | 0 | 0 | 14.3 | |
| Percentage of subjects not in remission | 100 | 100 | 85.7 | |

Statistical analyses

Secondary: Percentage of subjects achieving remission at Week 10

| | |
|-----------------|---|
| End point title | Percentage of subjects achieving remission at Week 10 |
|-----------------|---|

End point description:

Crohn's disease activity index (CDAI) is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease.

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

End point timeframe:

Week 10 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 10' is 2 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|---|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: Percentage of subjects | | | | |
| number (not applicable) | | | | |
| Percentage of subjects in remission | 33.3 | 42.9 | 14.3 | |
| Percentage of subjects not in remission | 66.7 | 57.1 | 85.7 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving remission at Week 12

| | |
|-----------------|---|
| End point title | Percentage of subjects achieving remission at Week 12 |
|-----------------|---|

End point description:

Crohn's disease activity index (CDAI) is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease.

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

End point timeframe:

Week 12 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 12' is 4 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|---|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: Percentage of subjects | | | | |
| number (not applicable) | | | | |
| Percentage of subjects in remission | 25 | 42.9 | 42.9 | |
| Percentage of subjects not in remission | 75 | 57.1 | 57.1 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving remission at Week 14

| | |
|-----------------|---|
| End point title | Percentage of subjects achieving remission at Week 14 |
|-----------------|---|

End point description:

Crohn's disease activity index (CDAI) is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease.

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

End point timeframe:

Week 14 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 14' is 6 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|---|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: Percentage of subjects | | | | |
| number (not applicable) | | | | |
| Percentage of subjects in remission | 66.7 | 71.4 | 71.4 | |
| Percentage of subjects not in remission | 33.3 | 28.6 | 28.6 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving remission at Week 16

| | |
|-----------------|---|
| End point title | Percentage of subjects achieving remission at Week 16 |
|-----------------|---|

End point description:

Crohn's disease activity index (CDAI) is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease.

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

End point timeframe:

Week 16 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 16' is 8 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|---|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: Percentage of subjects | | | | |
| number (not applicable) | | | | |
| Percentage of subjects in remission | 33.3 | 28.6 | 57.1 | |
| Percentage of subjects not in remission | 66.7 | 71.4 | 42.9 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving remission at Week 20

| | |
|--|---|
| End point title | Percentage of subjects achieving remission at Week 20 |
| End point description: Crohn's disease activity index (CDAI) is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease. | |
| End point type | Secondary |
| End point timeframe: Week 20 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 20' is 12 weeks after the first visit in this extension study. | |

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|---|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: Percentage of subjects | | | | |
| number (not applicable) | | | | |
| Percentage of subjects in remission | 33.3 | 28.6 | 57.1 | |
| Percentage of subjects not in remission | 66.7 | 71.4 | 42.9 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving remission at Week 24

| | |
|--|---|
| End point title | Percentage of subjects achieving remission at Week 24 |
| End point description: Crohn's disease activity index (CDAI) is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease. | |
| End point type | Secondary |
| End point timeframe: Week 24 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 24' is 16 weeks after the first visit in this extension study. | |

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|---|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: Percentage of subjects | | | | |
| number (not applicable) | | | | |
| Percentage of subjects in remission | 16.7 | 42.9 | 71.4 | |
| Percentage of subjects not in remission | 83.3 | 57.1 | 28.6 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving remission at Week 28

| | |
|--|---|
| End point title | Percentage of subjects achieving remission at Week 28 |
| End point description: | |
| Crohn's disease activity index (CDAI) is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease. | |
| End point type | Secondary |
| End point timeframe: | |
| Week 28 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 28' is 20 weeks after the first visit in this extension study. | |

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|---|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: Percentage of subjects | | | | |
| number (not applicable) | | | | |
| Percentage of subjects in remission | 25 | 28.6 | 57.1 | |
| Percentage of subjects not in remission | 75 | 71.4 | 42.9 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving remission at Week 32

| | |
|--|---|
| End point title | Percentage of subjects achieving remission at Week 32 |
| End point description: | |
| Crohn's disease activity index (CDAI) is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease. | |
| End point type | Secondary |

End point timeframe:

Week 32 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 32' is 24 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|---|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: Percentage of subjects | | | | |
| number (not applicable) | | | | |
| Percentage of subjects in remission | 16.7 | 28.6 | 42.9 | |
| Percentage of subjects not in remission | 83.3 | 71.4 | 57.1 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving remission at Week 34

| | |
|-----------------|---|
| End point title | Percentage of subjects achieving remission at Week 34 |
|-----------------|---|

End point description:

Crohn's disease activity index (CDAI) is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease.

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

End point timeframe:

Week 34 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 34' is 26 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|---|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: Percentage of subjects | | | | |
| number (not applicable) | | | | |
| Percentage of subjects in remission | 33.3 | 28.6 | 42.9 | |
| Percentage of subjects not in remission | 66.7 | 71.4 | 57.1 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving remission at Last Visit (Week 34 for completers or the Withdrawal Visit for premature withdrawals)

| | |
|-----------------|--|
| End point title | Percentage of subjects achieving remission at Last Visit (Week |
|-----------------|--|

34 for completers or the Withdrawal Visit for premature withdrawals)

End point description:

Crohn's disease activity index (CDAI) is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease.

End point type Secondary

End point timeframe:

Last Visit (Week 34 relative to the start of the 6-week double-blind main study (NCT00291668) for completers or the Withdrawal Visit for premature withdrawals). 'Week 34' is 26 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|---|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: Percentage of subjects | | | | |
| number (not applicable) | | | | |
| Percentage of subjects in remission | 33.3 | 28.6 | 42.9 | |
| Percentage of subjects not in remission | 66.7 | 71.4 | 57.1 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Time to disease progression

End point title Time to disease progression

End point description:

Time to disease progression is defined as the earliest of:

- time to an increase from Week 14 of ≥ 100 points in Crohn's Disease Activity Index (CDAI) score and CDAI > 175 points for at least 2 consecutive visits,
- time to use of rescue therapy, or,
- time to subject withdrawal from the study.

End point type Secondary

End point timeframe:

Week 14 to Week 34 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 14' is the visit at which response to re-induction is assessed and 'Week 34' is 26 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|----------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 0 ^[2] | 0 ^[3] | 0 ^[4] | |
| Units: days | | | | |
| median (confidence interval 95%) | | | | |
| median (95% CI) | (to) | (to) | (to) | |

Notes:

[2] - No data displayed because Outcome Measure has zero total participants analyzed.

[3] - No data displayed because Outcome Measure has zero total participants analyzed.

[4] - No data displayed because Outcome Measure has zero total participants analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score at Week 8

| | |
|-----------------|--|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score at Week 8 |
|-----------------|--|

End point description:

The IBDQ Global Score is the sum of 32 responses, each ranging from 0 to 7, thus the Global Score ranges from 0 to 224; a higher score indicating a better quality of life.

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

End point timeframe:

Week 0 and Week 8 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 8' is the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 4.6 (± 15.3) | 9.1 (± 7.5) | 5.3 (± 13.8) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score at Week 10

| | |
|-----------------|---|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score at Week 10 |
|-----------------|---|

End point description:

The IBDQ Global Score is the sum of 32 responses, each ranging from 0 to 7, thus the Global Score ranges from 0 to 224; a higher score indicating a better quality of life.

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

End point timeframe:

Week 0 and Week 10 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 10' is 2 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 17 (± 17.5) | 20.9 (± 24.9) | 15.1 (± 13.4) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score at Week 12

| | |
|------------------------|---|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score at Week 12 |
| End point description: | The IBDQ Global Score is the sum of 32 responses, each ranging from 0 to 7, thus the Global Score ranges from 0 to 224; a higher score indicating a better quality of life. |
| End point type | Secondary |
| End point timeframe: | Week 0 and Week 12 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 12' is 4 weeks after the first visit in this extension study. |

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 17.3 (± 12) | 26.3 (± 33.6) | 20.1 (± 16.6) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score at Week 14

| | |
|------------------------|---|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score at Week 14 |
| End point description: | The IBDQ Global Score is the sum of 32 responses, each ranging from 0 to 7, thus the Global Score ranges from 0 to 224; a higher score indicating a better quality of life. |
| End point type | Secondary |
| End point timeframe: | Week 0 and Week 14 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 14' is 6 weeks after the first visit in this extension study. |

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 20.1 (± 12.3) | 28.6 (± 22.9) | 26.3 (± 16.1) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score at Week 16

| | |
|-----------------|---|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score at Week 16 |
|-----------------|---|

End point description:

The IBDQ Global Score is the sum of 32 responses, each ranging from 0 to 7, thus the Global Score ranges from 0 to 224; a higher score indicating a better quality of life.

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

End point timeframe:

Week 0 and Week 16 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 16' is 8 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 16.3 (± 12.2) | 15.3 (± 19.1) | 20 (± 16.4) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score at Week 20

| | |
|-----------------|---|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score at Week 20 |
|-----------------|---|

End point description:

The IBDQ Global Score is the sum of 32 responses, each ranging from 0 to 7, thus the Global Score ranges from 0 to 224; a higher score indicating a better quality of life.

| | |
|---|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Week 0 and Week 20 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 20' is 12 weeks after the first visit in this extension study. | |

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 11 | 7 | 7 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 12.2 (± 16) | 18.4 (± 27.5) | 15.9 (± 14.7) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score at Week 24

| | |
|---|---|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score at Week 24 |
| End point description: | |
| The IBDQ Global Score is the sum of 32 responses, each ranging from 0 to 7, thus the Global Score ranges from 0 to 224; a higher score indicating a better quality of life. | |
| End point type | Secondary |
| End point timeframe: | |
| Week 0 and Week 24 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 24' is 16 weeks after the first visit in this extension study. | |

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 9 | 7 | 7 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 8.3 (± 14.5) | 7.6 (± 23.3) | 18.4 (± 18) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score at Week 28

| | |
|---|---|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score at Week 28 |
| End point description: The IBDQ Global Score is the sum of 32 responses, each ranging from 0 to 7, thus the Global Score ranges from 0 to 224; a higher score indicating a better quality of life. | |
| End point type | Secondary |
| End point timeframe: Week 0 and Week 28 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 28' is 20 weeks after the first visit in this extension study. | |

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|----------------------|-------------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 9 | 7 | 7 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 14.9 (± 20) | 11.4 (± 24.3) | 15.9 (± 19.3) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score at Week 32

| | |
|---|---|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score at Week 32 |
| End point description: The IBDQ Global Score is the sum of 32 responses, each ranging from 0 to 7, thus the Global Score ranges from 0 to 224; a higher score indicating a better quality of life. | |
| End point type | Secondary |
| End point timeframe: Week 0 and Week 32 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 32' is 24 weeks after the first visit in this extension study. | |

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|----------------------|-------------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 8 | 5 | 6 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 11.3 (± 17.8) | 11.2 (± 21.7) | 25.3 (± 17) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score at Week 34

| | |
|-----------------|---|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score at Week 34 |
|-----------------|---|

End point description:

The IBDQ Global Score is the sum of 32 responses, each ranging from 0 to 7, thus the Global Score ranges from 0 to 224; a higher score indicating a better quality of life.

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

End point timeframe:

Week 0 and Week 34 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 34' is 26 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 8 | 5 | 5 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 21.6 (± 16.9) | 14.8 (± 23.6) | 20.6 (± 17.6) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score at Last Visit (Week 34 for completers or the Withdrawal Visit for premature withdrawals)

| | |
|-----------------|---|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score at Last Visit (Week 34 for completers or the Withdrawal Visit for premature withdrawals) |
|-----------------|---|

End point description:

The Inflammatory Bowel Disease Questionnaire (IBDQ) Global Score is the sum of 32 responses, each ranging from 0 to 7, thus the Global Score ranges from 0 to 224; a higher score indicating a better quality of life.

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

End point timeframe:

Week 0 and Last Visit (Week 34 relative to the start of the 6-week double-blind main study (NCT00291668) for completers or the Withdrawal Visit for premature withdrawals). 'Week 34' is 26 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 11 | 6 | 5 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 15.6 (± 19.5) | 10.8 (± 23.3) | 20.6 (± 17.6) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score at Week 8

| | |
|------------------------|--|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score at Week 8 |
| End point description: | The IBDQ Bowel Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life. |
| End point type | Secondary |
| End point timeframe: | Week 0 and Week 8 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 8' is the first visit in this extension study. |

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 1.9 (± 7.5) | 6.4 (± 5.6) | 2.4 (± 5.3) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score at Week 10

| | |
|------------------------|--|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score at Week 10 |
| End point description: | The IBDQ Bowel Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life. |
| End point type | Secondary |
| End point timeframe: | Week 0 and Week 10 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 10' is 2 weeks after the first visit in this extension study. |

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 6.2 (± 8.4) | 10.6 (± 8.4) | 5.9 (± 7.1) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score at Week 12

| | |
|-----------------|---|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score at Week 12 |
|-----------------|---|

End point description:

The IBDQ Bowel Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

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

End point timeframe:

Week 0 and Week 12 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 12' is 4 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 5.7 (± 4.4) | 11.7 (± 9.7) | 7.4 (± 7.9) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score at Week 14

| | |
|-----------------|---|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score at Week 14 |
|-----------------|---|

End point description:

The IBDQ Bowel Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

| | |
|--|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Week 0 and Week 14 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 14' is 6 weeks after the first visit in this extension study. | |

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 6.9 (± 5.6) | 12.3 (± 9.3) | 9.3 (± 7) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score at Week 16

| | |
|--|---|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score at Week 16 |
| End point description: | |
| The IBDQ Bowel Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life. | |
| End point type | Secondary |
| End point timeframe: | |
| Week 0 and Week 16 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 16' is 8 weeks after the first visit in this extension study. | |

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 5.2 (± 6.3) | 8.4 (± 9.9) | 6.3 (± 7.2) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score at Week 20

| | |
|--|---|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score at Week 20 |
| End point description: The IBDQ Bowel Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life. | |
| End point type | Secondary |
| End point timeframe: Week 0 and Week 20 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 20' is 12 weeks after the first visit in this extension study. | |

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|----------------------|-------------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 11 | 7 | 7 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 3.5 (± 7.4) | 9.9 (± 11.7) | 5.1 (± 5.5) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score at Week 24

| | |
|--|---|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score at Week 24 |
| End point description: The IBDQ Bowel Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life. | |
| End point type | Secondary |
| End point timeframe: Week 0 and Week 24 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 24' is 16 weeks after the first visit in this extension study. | |

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|----------------------|-------------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 9 | 7 | 7 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 0.7 (± 5.3) | 4.7 (± 11) | 5.6 (± 8.2) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score at Week 28

| | |
|-----------------|---|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score at Week 28 |
|-----------------|---|

End point description:

The IBDQ Bowel Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

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

End point timeframe:

Week 0 and Week 28 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 28' is 20 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|----------------------|-------------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 9 | 7 | 7 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 4.6 (± 6) | 8.3 (± 10) | 5.4 (± 8.4) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score at Week 32

| | |
|-----------------|---|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score at Week 32 |
|-----------------|---|

End point description:

The IBDQ Bowel Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

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

End point timeframe:

Week 0 and Week 32 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 32' is 24 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|----------------------|-------------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 8 | 5 | 6 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 3.1 (± 6.7) | 9.6 (± 11) | 7.5 (± 5.1) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score at Week 34

| | |
|-----------------|---|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score at Week 34 |
|-----------------|---|

End point description:

The IBDQ Bowel Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

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

End point timeframe:

Week 0 and Week 34 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 34' is 26 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|----------------------|-------------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 8 | 5 | 5 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 7.1 (± 4.9) | 11.8 (± 9.8) | 5.8 (± 6.5) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score at Last Visit (Week 34 for completers or the Withdrawal Visit for premature withdrawals)

| | |
|-----------------|---|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score at Last Visit (Week 34 for completers or the Withdrawal Visit for premature withdrawals) |
|-----------------|---|

End point description:

The Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

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

End point timeframe:

Week 0 and Last Visit (Week 34 relative to the start of the 6-week double-blind main study (NCT00291668) for completers or the Withdrawal Visit for premature withdrawals). 'Week 34' is 26 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 11 | 6 | 5 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 5.5 (± 6.9) | 8.3 (± 12.2) | 5.8 (± 6.5) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score at Week 8

| | |
|-----------------|---|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score at Week 8 |
|-----------------|---|

End point description:

The IBDQ Systemic Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

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

End point timeframe:

Week 0 and Week 8 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 8' is the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 1.4 (± 3.4) | 0.6 (± 1.7) | 1.7 (± 1.6) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score at Week 10

| | |
|-----------------|--|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score at Week 10 |
|-----------------|--|

End point description:

The IBDQ Systemic Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

| | |
|--|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Week 0 and Week 10 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 10' is 2 weeks after the first visit in this extension study. | |

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 4.6 (± 4.4) | 3.7 (± 6.2) | 3.9 (± 1.3) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score at Week 12

| | |
|---|--|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score at Week 12 |
| End point description: | |
| The IBDQ Systemic Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life. | |
| End point type | Secondary |
| End point timeframe: | |
| Week 0 and Week 12 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 12' is 4 weeks after the first visit in this extension study. | |

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 5.7 (± 3.2) | 5 (± 7.3) | 5.1 (± 2.1) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score at Week 14

| | |
|---|--|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score at Week 14 |
| End point description: The IBDQ Systemic Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life. | |
| End point type | Secondary |
| End point timeframe: Week 0 and Week 14 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 14' is 6 weeks after the first visit in this extension study. | |

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|----------------------|-------------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 5.9 (± 3) | 6.4 (± 4.3) | 6.3 (± 3.1) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score at Week 16

| | |
|---|--|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score at Week 16 |
| End point description: The IBDQ Systemic Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life. | |
| End point type | Secondary |
| End point timeframe: Week 0 and Week 16 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 16' is 8 weeks after the first visit in this extension study. | |

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|----------------------|-------------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 5.5 (± 2.4) | 3.9 (± 3.7) | 5.3 (± 3.5) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score at Week 20

| | |
|-----------------|--|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score at Week 20 |
|-----------------|--|

End point description:

The IBDQ Systemic Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

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

End point timeframe:

Week 0 and Week 20 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 20' is 12 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|----------------------|-------------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 11 | 7 | 7 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 3.6 (± 4) | 3.6 (± 6.3) | 3.6 (± 2.6) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score at Week 24

| | |
|-----------------|--|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score at Week 24 |
|-----------------|--|

End point description:

The IBDQ Systemic Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

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

End point timeframe:

Week 0 and Week 24 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 24' is 16 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|----------------------|-------------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 9 | 7 | 7 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 3.1 (± 2.9) | 2.1 (± 5.9) | 4.1 (± 2.7) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score at Week 28

| | |
|-----------------|--|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score at Week 28 |
|-----------------|--|

End point description:

The IBDQ Systemic Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

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

End point timeframe:

Week 0 and Week 28 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 28' is 20 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 9 | 7 | 7 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 3 (± 6.1) | 3 (± 5.8) | 4.4 (± 3.6) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score at Week 32

| | |
|-----------------|--|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score at Week 32 |
|-----------------|--|

End point description:

The IBDQ Systemic Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

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

End point timeframe:

Week 0 and Week 32 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 32' is 24 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 8 | 5 | 6 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 3.4 (± 4.3) | 0.4 (± 3.1) | 6.8 (± 3.8) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score at Week 34

| | |
|------------------------|---|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score at Week 34 |
| End point description: | The IBDQ Systemic Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life. |
| End point type | Secondary |
| End point timeframe: | Week 0 and Week 34 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 34' is 26 weeks after the first visit in this extension study. |

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 8 | 5 | 5 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 5 (± 3.2) | 3 (± 4.8) | 5.4 (± 2.1) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score at Last Visit (Week 34 for completers or the Withdrawal Visit for premature withdrawals)

| | |
|------------------------|--|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score at Last Visit (Week 34 for completers or the Withdrawal Visit for premature withdrawals) |
| End point description: | The Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life. |

| | |
|--|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Week 0 and Last Visit (Week 34 relative to the start of the 6-week double-blind main study (NCT00291668) for completers or the Withdrawal Visit for premature withdrawals). 'Week 34' is 26 weeks after the first visit in this extension study. | |

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|----------------------|-------------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 11 | 6 | 5 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 4.2 (± 4.1) | 3.2 (± 4.4) | 5.4 (± 2.1) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score at Week 8

| | |
|--|--|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score at Week 8 |
| End point description: | |
| The IBDQ Emotional Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life. | |
| End point type | Secondary |
| End point timeframe: | |
| Week 0 and Week 8 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 8' is the first visit in this extension study. | |

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|----------------------|-------------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | -0.3 (± 6.1) | 2.1 (± 2.3) | 0.4 (± 6.7) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score at Week 10

| | |
|--|---|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score at Week 10 |
| End point description: The IBDQ Emotional Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life. | |
| End point type | Secondary |
| End point timeframe: Week 0 and Week 10 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 10' is 2 weeks after the first visit in this extension study. | |

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|----------------------|-------------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 3.3 (± 4.7) | 4.4 (± 9.7) | 4.3 (± 5.9) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score at Week 12

| | |
|--|---|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score at Week 12 |
| End point description: The IBDQ Emotional Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life. | |
| End point type | Secondary |
| End point timeframe: Week 0 and Week 12 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 12' is 4 weeks after the first visit in this extension study. | |

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|----------------------|-------------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 2.5 (± 5.5) | 7 (± 13.8) | 5.3 (± 6.5) | |

Statistical analyses

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score at Week 14

| | |
|-----------------|---|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score at Week 14 |
|-----------------|---|

End point description:

The IBDQ Emotional Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

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

End point timeframe:

Week 0 and Week 14 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 14' is 6 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|----------------------|-------------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 3.8 (± 4) | 7.1 (± 10.3) | 6.7 (± 8) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score at Week 16

| | |
|-----------------|---|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score at Week 16 |
|-----------------|---|

End point description:

The IBDQ Emotional Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

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

End point timeframe:

Week 0 and Week 16 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 16' is 8 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|----------------------|-------------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 2.5 (± 5.8) | 3 (± 6.2) | 6 (± 8.1) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score at Week 20

| | |
|-----------------|---|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score at Week 20 |
|-----------------|---|

End point description:

The IBDQ Emotional Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

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

End point timeframe:

Week 0 and Week 20 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 20' is 12 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|----------------------|-------------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 11 | 7 | 7 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 1.9 (± 6.5) | 3.4 (± 10.7) | 3.6 (± 6.9) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score at Week 24

| | |
|-----------------|---|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score at Week 24 |
|-----------------|---|

End point description:

The IBDQ Emotional Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

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

End point timeframe:

Week 0 and Week 24 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 24' is 16 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 9 | 7 | 7 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 2.1 (± 5.9) | 1.6 (± 5.7) | 6.1 (± 7.4) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score at Week 28

| | |
|------------------------|--|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score at Week 28 |
| End point description: | The IBDQ Emotional Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life. |
| End point type | Secondary |
| End point timeframe: | Week 0 and Week 28 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 28' is 20 weeks after the first visit in this extension study. |

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 9 | 7 | 7 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 4.3 (± 5.8) | 1.1 (± 8) | 3.6 (± 7.4) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score at Week 32

| | |
|------------------------|--|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score at Week 32 |
| End point description: | The IBDQ Emotional Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life. |
| End point type | Secondary |
| End point timeframe: | Week 0 and Week 32 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 32' is 24 weeks after the first visit in this extension study. |

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 8 | 5 | 6 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 2.9 (± 5.7) | 1.8 (± 6.1) | 7.7 (± 9.5) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score at Week 34

| | |
|-----------------|---|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score at Week 34 |
|-----------------|---|

End point description:

The IBDQ Emotional Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

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

End point timeframe:

Week 0 and Week 34 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 34' is 26 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 8 | 5 | 5 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 5.6 (± 6.7) | 0 (± 8.6) | 6.4 (± 10.9) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score at Last Visit (Week 34 for completers or the Withdrawal Visit for premature withdrawals)

| | |
|-----------------|---|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score at Last Visit (Week 34 for completers or the Withdrawal Visit for premature withdrawals) |
|-----------------|---|

End point description:

The Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

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

End point timeframe:

Week 0 and Last Visit (Week 34 relative to the start of the 6-week double-blind main study (NCT00291668) for completers or the Withdrawal Visit for premature withdrawals). 'Week 34' is 26 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 11 | 6 | 5 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 3.5 (± 7.1) | 0.7 (± 7.9) | 6.4 (± 10.9) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score at Week 8

| | |
|-----------------|---|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score at Week 8 |
|-----------------|---|

End point description:

The IBDQ Social Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

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

End point timeframe:

Week 0 and Week 8 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 8' is the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 11 | 7 | 7 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 1.3 (± 3.6) | 0 (± 2.4) | 0.7 (± 3.7) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score at Week 10

| | |
|-----------------|--|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score at Week 10 |
|-----------------|--|

End point description:

The IBDQ Social Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

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

End point timeframe:

Week 0 and Week 10 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 10' is 2 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|----------------------|-------------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 11 | 7 | 7 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 2.5 (± 3) | 2.1 (± 4.7) | 1.1 (± 3.4) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score at Week 12

| | |
|-----------------|--|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score at Week 12 |
|-----------------|--|

End point description:

The IBDQ Social Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

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

End point timeframe:

Week 0 and Week 12 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 12' is 4 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|----------------------|-------------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 11 | 7 | 7 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 3 (± 3.1) | 2.6 (± 5.1) | 2.3 (± 4) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score at Week 14

| | |
|-----------------|--|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score at Week 14 |
|-----------------|--|

End point description:

The IBDQ Social Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

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

End point timeframe:

Week 0 and Week 14 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 14' is 6 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|----------------------|-------------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 11 | 7 | 7 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 2.8 (± 2.6) | 2.7 (± 3.4) | 4 (± 2) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score at Week 16

| | |
|-----------------|--|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score at Week 16 |
|-----------------|--|

End point description:

The IBDQ Social Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

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

End point timeframe:

Week 0 and Week 16 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 16' is 8 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 11 | 7 | 7 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 2.5 (± 2.1) | 0 (± 3.9) | 2.4 (± 2.1) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score at Week 20

| | |
|------------------------|---|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score at Week 20 |
| End point description: | The IBDQ Social Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life. |
| End point type | Secondary |
| End point timeframe: | Week 0 and Week 20 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 20' is 12 weeks after the first visit in this extension study. |

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 10 | 7 | 7 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 2.8 (± 2.3) | 1.6 (± 3) | 3.6 (± 2.3) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score at Week 24

| | |
|------------------------|---|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score at Week 24 |
| End point description: | The IBDQ Social Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life. |
| End point type | Secondary |
| End point timeframe: | Week 0 and Week 24 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 24' is 16 weeks after the first visit in this extension study. |

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 8 | 7 | 7 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 1.8 (± 2.7) | -0.9 (± 4.9) | 2.6 (± 2.1) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score at Week 28

| | |
|-----------------|--|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score at Week 28 |
|-----------------|--|

End point description:

The IBDQ Social Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

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

End point timeframe:

Week 0 and Week 28 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 28' is 20 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 8 | 7 | 7 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 2.1 (± 2.7) | -1 (± 4.6) | 2.4 (± 3.1) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score at Week 32

| | |
|-----------------|--|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score at Week 32 |
|-----------------|--|

End point description:

The IBDQ Social Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

| | |
|---|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Week 0 and Week 32 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 32' is 24 weeks after the first visit in this extension study. | |

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 7 | 5 | 6 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 1.3 (± 3.4) | -0.6 (± 2.9) | 3.3 (± 2.4) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score at Week 34

| | |
|---|--|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score at Week 34 |
| End point description: | |
| The IBDQ Social Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life. | |
| End point type | Secondary |
| End point timeframe: | |
| Week 0 and Week 34 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 34' is 26 weeks after the first visit in this extension study. | |

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 7 | 5 | 5 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 3 (± 3) | 0 (± 3.4) | 3 (± 3.1) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score at Last Visit (Week 34 for completers or the

Withdrawal Visit for premature withdrawals)

| | |
|-----------------|--|
| End point title | Change from Week 0 in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score at Last Visit (Week 34 for completers or the Withdrawal Visit for premature withdrawals) |
|-----------------|--|

End point description:

The Inflammatory Bowel Disease Questionnaire (IBDQ) Social Domain Sub-Score is the sum of 8 responses, each ranging from 0 to 7, thus the Sub-Score ranges from 0 to 56; a higher score indicating a better quality of life.

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

End point timeframe:

Week 0 and Last Visit (Week 34 relative to the start of the 6-week double-blind main study (NCT00291668) for completers or the Withdrawal Visit for premature withdrawals). 'Week 34' is 26 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|--------------------------------------|----------------------|-------------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 10 | 6 | 5 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| mean (standard deviation) | 1.7 (± 3.4) | -1.3 (± 4.5) | 3 (± 3.1) | |

Statistical analyses

No statistical analyses for this end point

Secondary: C-Reactive Protein (CRP) Level at Week 0

| | |
|-----------------|--|
| End point title | C-Reactive Protein (CRP) Level at Week 0 |
|-----------------|--|

End point description:

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

End point timeframe:

Week 0 (relative to the start of the 6-week double-blind main study (N00291668)). 'Week 0' is the Baseline visit in the double-blind main study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|---------------------------------------|----------------------|-------------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: mg/L | | | | |
| geometric mean (full range (min-max)) | | | | |
| geometric mean (full range) | 19.58 (4 to 60) | 14.97 (10 to 25) | 26.45 (16 to 50) | |

Statistical analyses

No statistical analyses for this end point

Secondary: C-Reactive Protein (CRP) Level at Week 8

| | |
|-----------------|--|
| End point title | C-Reactive Protein (CRP) Level at Week 8 |
|-----------------|--|

End point description:

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

End point timeframe:

Week 8 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 8' is the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|---------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: mg/L | | | | |
| geometric mean (full range (min-max)) | | | | |
| geometric mean (full range) | 22.06 (8 to 76) | 11.91 (4 to 41) | 16.7 (1 to 55) | |

Statistical analyses

No statistical analyses for this end point

Secondary: C-Reactive Protein (CRP) Level at Week 10

| | |
|-----------------|---|
| End point title | C-Reactive Protein (CRP) Level at Week 10 |
|-----------------|---|

End point description:

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

End point timeframe:

Week 10 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 10' is 2 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|---------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: mg/L | | | | |
| geometric mean (full range (min-max)) | | | | |
| geometric mean (full range) | 7.76 (2 to 40) | 5.62 (3 to 13) | 12.01 (1 to 34) | |

Statistical analyses

No statistical analyses for this end point

Secondary: C-Reactive Protein (CRP) Level at Week 12

| | |
|-----------------|---|
| End point title | C-Reactive Protein (CRP) Level at Week 12 |
|-----------------|---|

End point description:

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

End point timeframe:

Week 12 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 12' is 4 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|---------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: mg/L | | | | |
| geometric mean (full range (min-max)) | | | | |
| geometric mean (full range) | 7.82 (2 to 31) | 7.06 (3 to 14) | 13.39 (1 to 54) | |

Statistical analyses

No statistical analyses for this end point

Secondary: C-Reactive Protein (CRP) Level at Week 14

| | |
|-----------------|---|
| End point title | C-Reactive Protein (CRP) Level at Week 14 |
|-----------------|---|

End point description:

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

End point timeframe:

Week 14 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 14' is 6 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|---------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: mg/L | | | | |
| geometric mean (full range (min-max)) | | | | |
| geometric mean (full range) | 9.57 (2 to 32) | 6.32 (4 to 14) | 15.3 (1 to 41) | |

Statistical analyses

No statistical analyses for this end point

Secondary: C-Reactive Protein (CRP) Level at Week 16

| | |
|-----------------|---|
| End point title | C-Reactive Protein (CRP) Level at Week 16 |
|-----------------|---|

End point description:

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

End point timeframe:

Week 16 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 16' is 8 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|---------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: mg/L | | | | |
| geometric mean (full range (min-max)) | | | | |
| geometric mean (full range) | 12.54 (3 to 35) | 12.23 (3 to 45) | 15.1 (1 to 36) | |

Statistical analyses

No statistical analyses for this end point

Secondary: C-Reactive Protein (CRP) Level at Week 20

| | |
|-----------------|---|
| End point title | C-Reactive Protein (CRP) Level at Week 20 |
|-----------------|---|

End point description:

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

End point timeframe:

Week 20 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 20' is 12 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|---------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 11 | 7 | 7 | |
| Units: mg/L | | | | |
| geometric mean (full range (min-max)) | | | | |
| geometric mean (full range) | 12.27 (1 to 74) | 13.24 (4 to 50) | 14.99 (1 to 53) | |

Statistical analyses

No statistical analyses for this end point

Secondary: C-Reactive Protein (CRP) Level at Week 24

| | |
|-----------------|---|
| End point title | C-Reactive Protein (CRP) Level at Week 24 |
|-----------------|---|

End point description:

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

End point timeframe:

Week 24 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 24' is 16 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|---------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 9 | 7 | 7 | |
| Units: mg/L | | | | |
| geometric mean (full range (min-max)) | | | | |
| geometric mean (full range) | 9.11 (1 to 45) | 14.16 (4 to 33) | 15.7 (1 to 38) | |

Statistical analyses

No statistical analyses for this end point

Secondary: C-Reactive Protein (CRP) Level at Week 28

| | |
|-----------------|---|
| End point title | C-Reactive Protein (CRP) Level at Week 28 |
|-----------------|---|

End point description:

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

End point timeframe:

Week 28 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 28' is 20 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|---------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 9 | 7 | 7 | |
| Units: mg/L | | | | |
| geometric mean (full range (min-max)) | | | | |
| geometric mean (full range) | 8.79 (1 to 24) | 14.25 (4 to 40) | 26.81 (0 to 33) | |

Statistical analyses

No statistical analyses for this end point

Secondary: C-Reactive Protein (CRP) Level at Week 32

| | |
|-----------------|---|
| End point title | C-Reactive Protein (CRP) Level at Week 32 |
|-----------------|---|

End point description:

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

End point timeframe:

Week 32 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 32' is 24 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|---------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 8 | 5 | 6 | |
| Units: mg/L | | | | |
| geometric mean (full range (min-max)) | | | | |
| geometric mean (full range) | 15.28 (3 to 45) | 10.27 (2 to 24) | 16.71 (1 to 48) | |

Statistical analyses

No statistical analyses for this end point

Secondary: C-Reactive Protein (CRP) Level at Week 34

| | |
|-----------------|---|
| End point title | C-Reactive Protein (CRP) Level at Week 34 |
|-----------------|---|

End point description:

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

End point timeframe:

Week 34 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 34' is 26 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|---------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 8 | 5 | 5 | |
| Units: mg/L | | | | |
| geometric mean (full range (min-max)) | | | | |
| geometric mean (full range) | 9.19 (1 to 40) | 6.23 (2 to 16) | 23.52 (0 to 81) | |

Statistical analyses

No statistical analyses for this end point

Secondary: C-Reactive Protein (CRP) Level at Last Visit (Week 34 for completers or the Withdrawal Visit for premature withdrawals)

| | |
|-----------------|---|
| End point title | C-Reactive Protein (CRP) Level at Last Visit (Week 34 for completers or the Withdrawal Visit for premature withdrawals) |
|-----------------|---|

End point description:

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

End point timeframe:

Last Visit (Week 34 relative to the start of the 6-week double-blind main study (NCT00291668) for completers or the Withdrawal Visit for premature withdrawals). 'Week 34' is 26 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|---------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 11 | 6 | 5 | |
| Units: mg/L | | | | |
| geometric mean (full range (min-max)) | | | | |
| geometric mean (full range) | 11.25 (1 to 75) | 8.46 (2 to 39) | 23.52 (0 to 81) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Ratio of C-Reactive Protein (CRP) level at Week 8 to CRP level at Week 0

| | |
|-----------------|--|
| End point title | Ratio of C-Reactive Protein (CRP) level at Week 8 to CRP level at Week 0 |
|-----------------|--|

End point description:

The ratio is calculated as the C-Reactive Protein (CRP) Level at Week 8 divided by the CRP Level at Week 0

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

End point timeframe:

Week 0 and Week 8 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 8' is the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|---------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: ratio | | | | |
| geometric mean (full range (min-max)) | | | | |
| geometric mean (full range) | 1.13 (0.4 to 4.3) | 0.8 (0.2 to 4.1) | 0.63 (0 to 3.4) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Ratio of C-Reactive Protein (CRP) level at Week 10 to CRP level at Week 0

| | |
|---|---|
| End point title | Ratio of C-Reactive Protein (CRP) level at Week 10 to CRP level at Week 0 |
| End point description: The ratio is calculated as the C-Reactive Protein (CRP) Level at Week 10 divided by the CRP Level at Week 0 | |
| End point type | Secondary |
| End point timeframe: Week 0 and Week 10 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 10' is 2 weeks after the first visit in this extension study. | |

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|---------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: ratio | | | | |
| geometric mean (full range (min-max)) | | | | |
| geometric mean (full range) | 0.4 (0.1 to 1.5) | 0.38 (0.1 to 1.2) | 0.45 (0 to 2) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Ratio of C-Reactive Protein (CRP) level at Week 12 to CRP level at Week 0

| | |
|-----------------|---|
| End point title | Ratio of C-Reactive Protein (CRP) level at Week 12 to CRP level at Week 0 |
|-----------------|---|

End point description:

The ratio is calculated as the C-Reactive Protein (CRP) Level at Week 12 divided by the CRP Level at Week 0

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

End point timeframe:

Week 0 and Week 12 (relative to the start of the 6-week double-blind main study (NCT00291668)).
'Week 12' is 4 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|---------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: ratio | | | | |
| geometric mean (full range (min-max)) | | | | |
| geometric mean (full range) | 0.4 (0.1 to 2) | 0.47 (0.2 to 1.1) | 0.51 (0 to 3.2) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Ratio of C-Reactive Protein (CRP) level at Week 14 to CRP level at Week 0

| | |
|-----------------|---|
| End point title | Ratio of C-Reactive Protein (CRP) level at Week 14 to CRP level at Week 0 |
|-----------------|---|

End point description:

The ratio is calculated as the C-Reactive Protein (CRP) Level at Week 14 divided by the CRP Level at Week 0

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

End point timeframe:

Week 0 and Week 14 (relative to the start of the 6-week double-blind main study (NCT00291668)).
'Week 14' is 6 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|---------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: ratio | | | | |
| geometric mean (full range (min-max)) | | | | |
| geometric mean (full range) | 0.49 (0.1 to 5) | 0.42 (0.2 to 1) | 0.58 (0 to 2.4) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Ratio of C-Reactive Protein (CRP) level at Week 16 to CRP level at Week 0

| | |
|-----------------|---|
| End point title | Ratio of C-Reactive Protein (CRP) level at Week 16 to CRP level at Week 0 |
|-----------------|---|

End point description:

The ratio is calculated as the C-Reactive Protein (CRP) Level at Week 16 divided by the CRP Level at Week 0

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

End point timeframe:

Week 0 and Week 16 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 16' is 8 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|---------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: ratio | | | | |
| geometric mean (full range (min-max)) | | | | |
| geometric mean (full range) | 0.64 (0.1 to 5.3) | 0.82 (0.3 to 4.1) | 0.57 (0 to 2.3) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Ratio of C-Reactive Protein (CRP) level at Week 20 to CRP level at Week 0

| | |
|-----------------|---|
| End point title | Ratio of C-Reactive Protein (CRP) level at Week 20 to CRP level at Week 0 |
|-----------------|---|

End point description:

The ratio is calculated as the C-Reactive Protein (CRP) Level at Week 20 divided by the CRP Level at Week 0

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

End point timeframe:

Week 0 and Week 20 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 20' is 12 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|---------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 11 | 7 | 7 | |
| Units: ratio | | | | |
| geometric mean (full range (min-max)) | | | | |
| geometric mean (full range) | 0.64 (0 to 5.5) | 0.88 (0.3 to 4.5) | 0.57 (0 to 3.1) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Ratio of C-Reactive Protein (CRP) level at Week 24 to CRP level at Week 0

| | |
|-----------------|---|
| End point title | Ratio of C-Reactive Protein (CRP) level at Week 24 to CRP level at Week 0 |
|-----------------|---|

End point description:

The ratio is calculated as the C-Reactive Protein (CRP) Level at Week 24 divided by the CRP Level at Week 0

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

End point timeframe:

Week 0 and Week 24 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 24' is 16 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|---------------------------------------|----------------------|-------------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 9 | 7 | 7 | |
| Units: ratio | | | | |
| geometric mean (full range (min-max)) | | | | |
| geometric mean (full range) | 0.48 (0 to 3.5) | 0.95 (0.4 to 2.4) | 0.59 (0 to 1.7) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Ratio of C-Reactive Protein (CRP) level at Week 28 to CRP level at Week 0

| | |
|-----------------|---|
| End point title | Ratio of C-Reactive Protein (CRP) level at Week 28 to CRP level at Week 0 |
|-----------------|---|

End point description:

The ratio is calculated as the C-Reactive Protein (CRP) Level at Week 28 divided by the CRP Level at Week 0

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

End point timeframe:

Week 0 and Week 28 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 28' is 20 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|---------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 9 | 7 | 7 | |
| Units: ratio | | | | |
| geometric mean (full range (min-max)) | | | | |
| geometric mean (full range) | 0.46 (0 to 2.8) | 0.95 (0.2 to 2.7) | 1.06 (0 to 2.1) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Ratio of C-Reactive Protein (CRP) level at Week 32 to CRP level at Week 0

| | |
|--|---|
| End point title | Ratio of C-Reactive Protein (CRP) level at Week 32 to CRP level at Week 0 |
| End point description: The ratio is calculated as the C-Reactive Protein (CRP) Level at Week 32 divided by the CRP Level at Week 0 | |
| End point type | Secondary |
| End point timeframe: Week 0 and Week 32 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 32' is 24 weeks after the first visit in this extension study. | |

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|---------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 8 | 5 | 6 | |
| Units: ratio | | | | |
| geometric mean (full range (min-max)) | | | | |
| geometric mean (full range) | 0.9 (0.1 to 4.6) | 0.64 (0.2 to 1.2) | 0.62 (0 to 2.8) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Ratio of C-Reactive Protein (CRP) level at Week 34 to CRP level at Week 0

| | |
|-----------------|---|
| End point title | Ratio of C-Reactive Protein (CRP) level at Week 34 to CRP level at Week 0 |
|-----------------|---|

End point description:

The ratio is calculated as the C-Reactive Protein (CRP) Level at Week 34 divided by the CRP Level at Week 0

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

End point timeframe:

Week 0 and Week 34 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 34' is 26 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|---------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 8 | 5 | 5 | |
| Units: ratio | | | | |
| geometric mean (full range (min-max)) | | | | |
| geometric mean (full range) | 0.54 (0 to 2.8) | 0.39 (0.2 to 1.6) | 1.07 (0 to 3.5) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Ratio of C-Reactive Protein (CRP) level at Last Visit (Week 34 for completers or the Withdrawal Visit for premature withdrawals) to CRP level at Week 0

| | |
|-----------------|---|
| End point title | Ratio of C-Reactive Protein (CRP) level at Last Visit (Week 34 for completers or the Withdrawal Visit for premature withdrawals) to CRP level at Week 0 |
|-----------------|---|

End point description:

The ratio is calculated as the C-Reactive Protein (CRP) Level at Last Visit (Week 34 for completers or the Withdrawal Visit for premature withdrawals) divided by the CRP Level at Week 0

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

End point timeframe:

Week 0 and Last Visit (Week 34 relative to the start of the 6-week double-blind main study (NCT00291668) for completers or the Withdrawal Visit for premature withdrawals). 'Week 34' is 26 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|---------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 11 | 6 | 5 | |
| Units: ratio | | | | |
| geometric mean (full range (min-max)) | | | | |
| geometric mean (full range) | 0.59 (0 to 2.8) | 0.54 (0.2 to 2.8) | 1.07 (0 to 3.5) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving a reduction in Crohn's Disease Activity Index (CDAI) score of ≥ 70 points from Week 0 at Week 8

| | |
|-----------------|---|
| End point title | Percentage of subjects achieving a reduction in Crohn's Disease Activity Index (CDAI) score of ≥ 70 points from Week 0 at Week 8 |
|-----------------|---|

End point description:

70-point responders are subjects achieving a reduction in Crohn's Disease Activity Index (CDAI) score of ≥ 70 points from Week 0. CDAI is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease.

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

End point timeframe:

Week 0 and Week 8 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 8' is the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|---------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: percentage of subjects | | | | |
| number (not applicable) | | | | |
| Percentage of 70-point responders | 33.3 | 28.6 | 42.9 | |
| Percentage of 70-point non-responders | 66.7 | 71.4 | 57.1 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving a reduction in Crohn's Disease Activity Index (CDAI) score of ≥ 70 points from Week 0 at Week 10

| | |
|-----------------|--|
| End point title | Percentage of subjects achieving a reduction in Crohn's Disease Activity Index (CDAI) score of ≥ 70 points from Week 0 at Week 10 |
|-----------------|--|

End point description:

70-point responders are subjects achieving a reduction in Crohn's Disease Activity Index (CDAI) score of ≥ 70 points from Week 0. CDAI is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease.

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

End point timeframe:

Week 0 and Week 10 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 10' is 2 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|---------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: percentage of subjects | | | | |
| number (not applicable) | | | | |
| Percentage of 70-point responders | 66.7 | 85.7 | 100 | |
| Percentage of 70-point non-responders | 33.3 | 14.3 | 0 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving a reduction in Crohn's Disease Activity Index (CDAI) score of ≥ 70 points from Week 0 at Week 12

| | |
|-----------------|--|
| End point title | Percentage of subjects achieving a reduction in Crohn's Disease Activity Index (CDAI) score of ≥ 70 points from Week 0 at Week 12 |
|-----------------|--|

End point description:

70-point responders are subjects achieving a reduction in Crohn's Disease Activity Index (CDAI) score of ≥ 70 points from Week 0. CDAI is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease.

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

End point timeframe:

Week 0 and Week 12 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 12' is 4 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|---------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: percentage of subjects | | | | |
| number (not applicable) | | | | |
| Percentage of 70-point responders | 75 | 71.4 | 85.7 | |
| Percentage of 70-point non-responders | 25 | 28.6 | 14.3 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving a reduction in Crohn's Disease Activity Index (CDAI) score of ≥ 70 points from Week 0 at Week 14

| | |
|-----------------|--|
| End point title | Percentage of subjects achieving a reduction in Crohn's Disease Activity Index (CDAI) score of ≥ 70 points from Week 0 at Week 14 |
|-----------------|--|

End point description:

70-point responders are subjects achieving a reduction in Crohn's Disease Activity Index (CDAI) score of

≥70 points from Week 0. CDAI is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease.

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

End point timeframe:

Week 0 and Week 14 (relative to the start of the 6-week double-blind main study (NCT00291668)).
'Week 14' is 6 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|---------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: percentage of subjects | | | | |
| number (not applicable) | | | | |
| Percentage of 70-point responders | 100 | 100 | 100 | |
| Percentage of 70-point non-responders | 0 | 0 | 0 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving a reduction in Crohn's Disease Activity Index (CDAI) score of ≥70 points from Week 0 at Week 16

| | |
|-----------------|--|
| End point title | Percentage of subjects achieving a reduction in Crohn's Disease Activity Index (CDAI) score of ≥70 points from Week 0 at Week 16 |
|-----------------|--|

End point description:

70-point responders are subjects achieving a reduction in Crohn's Disease Activity Index (CDAI) score of ≥70 points from Week 0. CDAI is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease.

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

End point timeframe:

Week 0 and Week 16 (relative to the start of the 6-week double-blind main study (NCT00291668)).
'Week 16' is 8 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|---------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: percentage of subjects | | | | |
| number (not applicable) | | | | |
| Percentage of 70-point responders | 83.3 | 57.1 | 100 | |
| Percentage of 70-point non-responders | 16.7 | 42.9 | 0 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving a reduction in Crohn's Disease Activity Index (CDAI) score of ≥ 70 points from Week 0 at Week 20

| | |
|-----------------|--|
| End point title | Percentage of subjects achieving a reduction in Crohn's Disease Activity Index (CDAI) score of ≥ 70 points from Week 0 at Week 20 |
|-----------------|--|

End point description:

70-point responders are subjects achieving a reduction in Crohn's Disease Activity Index (CDAI) score of ≥ 70 points from Week 0. CDAI is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease.

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

End point timeframe:

Week 0 and Week 20 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 20' is 12 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|---------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: percentage of subjects | | | | |
| number (not applicable) | | | | |
| Percentage of 70-point responders | 75 | 71.4 | 85.7 | |
| Percentage of 70-point non-responders | 25 | 28.6 | 14.3 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving a reduction in Crohn's Disease Activity Index (CDAI) score of ≥ 70 points from Week 0 at Week 24

| | |
|-----------------|--|
| End point title | Percentage of subjects achieving a reduction in Crohn's Disease Activity Index (CDAI) score of ≥ 70 points from Week 0 at Week 24 |
|-----------------|--|

End point description:

70-point responders are subjects achieving a reduction in Crohn's Disease Activity Index (CDAI) score of ≥ 70 points from Week 0. CDAI is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease.

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

End point timeframe:

Week 0 and Week 24 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 24' is 16 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|---------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: percentage of subjects | | | | |
| number (not applicable) | | | | |
| Percentage of 70-point responders | 50 | 71.4 | 100 | |
| Percentage of 70-point non-responders | 50 | 28.6 | 0 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving a reduction in Crohn's Disease Activity Index (CDAI) score of ≥ 70 points from Week 0 at Week 28

| | |
|-----------------|--|
| End point title | Percentage of subjects achieving a reduction in Crohn's Disease Activity Index (CDAI) score of ≥ 70 points from Week 0 at Week 28 |
|-----------------|--|

End point description:

70-point responders are subjects achieving a reduction in Crohn's Disease Activity Index (CDAI) score of ≥ 70 points from Week 0. CDAI is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease.

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

End point timeframe:

Week 0 and Week 28 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 28' is 20 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|---------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: percentage of subjects | | | | |
| number (not applicable) | | | | |
| Percentage of 70-point responders | 58.3 | 71.4 | 85.7 | |
| Percentage of 70-point non-responders | 41.7 | 28.6 | 14.3 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving a reduction in Crohn's Disease Activity Index (CDAI) score of ≥ 70 points from Week 0 at Week 32

| | |
|-----------------|--|
| End point title | Percentage of subjects achieving a reduction in Crohn's Disease Activity Index (CDAI) score of ≥ 70 points from Week 0 at Week 32 |
|-----------------|--|

End point description:

70-point responders are subjects achieving a reduction in Crohn's Disease Activity Index (CDAI) score of

≥70 points from Week 0. CDAI is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease.

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

End point timeframe:

Week 0 and Week 32 (relative to the start of the 6-week double-blind main study (NCT00291668)).
'Week 32' is 24 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|---------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: percentage of subjects | | | | |
| number (not applicable) | | | | |
| Percentage of 70-point responders | 41.7 | 57.1 | 57.1 | |
| Percentage of 70-point non-responders | 58.3 | 42.9 | 42.9 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving a reduction in Crohn's Disease Activity Index (CDAI) score of ≥70 points from Week 0 at Week 34

| | |
|-----------------|--|
| End point title | Percentage of subjects achieving a reduction in Crohn's Disease Activity Index (CDAI) score of ≥70 points from Week 0 at Week 34 |
|-----------------|--|

End point description:

70-point responders are subjects achieving a reduction in Crohn's Disease Activity Index (CDAI) score of ≥70 points from Week 0. CDAI is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease.

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

End point timeframe:

Week 0 and Week 34 (relative to the start of the 6-week double-blind main study (NCT00291668)).
'Week 34' is 26 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|---------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: percentage of subjects | | | | |
| number (not applicable) | | | | |
| Percentage of 70-point responders | 66.7 | 42.9 | 42.9 | |
| Percentage of 70-point non-responders | 33.3 | 57.1 | 57.1 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving a reduction in Crohn's Disease Activity Index (CDAI) score of ≥ 70 points from Week 0 at Last Visit (Week 34 for completers or the Withdrawal Visit for premature withdrawals)

| | |
|-----------------|--|
| End point title | Percentage of subjects achieving a reduction in Crohn's Disease Activity Index (CDAI) score of ≥ 70 points from Week 0 at Last Visit (Week 34 for completers or the Withdrawal Visit for premature withdrawals) |
|-----------------|--|

End point description:

70-point responders are subjects achieving a reduction in Crohn's Disease Activity Index (CDAI) score of ≥ 70 points from Week 0. CDAI is used to quantify the symptoms of subjects with Crohn's disease. A score of 150 or below indicates remission and a score above 450 indicates extremely severe disease.

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

End point timeframe:

Week 0 and Last Visit (Week 34 relative to the start of the 6-week double-blind main study (NCT00291668) for completers or the Withdrawal Visit for premature withdrawals). 'Week 34' is 26 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|---------------------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: percentage of subjects | | | | |
| number (not applicable) | | | | |
| Percentage of 70-point responders | 66.7 | 42.9 | 42.9 | |
| Percentage of 70-point non-responders | 33.3 | 57.1 | 57.1 | |

Statistical analyses

No statistical analyses for this end point

Post-hoc: Number of subjects with disease progression

| | |
|-----------------|---|
| End point title | Number of subjects with disease progression |
|-----------------|---|

End point description:

Disease progression is defined as:

- an increase from Week 14 of ≥ 100 points in Crohn's Disease Activity Index (CDAI) score and CDAI > 175 points for at least 2 consecutive visits,
- use of rescue therapy, or,
- subject withdrawal from the study.

| | |
|----------------|----------|
| End point type | Post-hoc |
|----------------|----------|

End point timeframe:

Week 14 to Week 34 (relative to the start of the 6-week double-blind main study (NCT00291668)). 'Week 14' is the visit at which response to re-induction is assessed and 'Week 34' is 26 weeks after the first visit in this extension study.

| End point values | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg | |
|-----------------------------|-------------------------|----------------------------|----------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 12 | 7 | 7 | |
| Units: subjects | | | | |
| Number of subjects | 1 | 1 | 1 | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse event data summarized in the first four columns were collected from the day after the end of the double-blind main study up to and including 12 weeks following the last dose received in this extension study for each subject (i.e., up to 36 weeks).

Adverse event reporting additional description:

For the fifth column, 'Total 2', this presents the data summarized in 'Total 1' PLUS adverse event data from the double-blind main study for subjects who received certolizumab pegol (CZP) in the main study and then entered this extension study (i.e., up to 44 weeks).

| | |
|-----------------|----------------|
| Assessment type | Non-systematic |
|-----------------|----------------|

Dictionary used

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

| | |
|--------------------|-----|
| Dictionary version | 9.0 |
|--------------------|-----|

Reporting groups

| | |
|-----------------------|----------------------|
| Reporting group title | CZP 400 mg / Placebo |
|-----------------------|----------------------|

Reporting group description:

Certolizumab pegol (CZP) 400 mg (3 doses 2-weekly then 5 doses 4-weekly) in this extension study / Placebo (3 doses 2-weekly) in the 6-week double-blind main study (2014-004399-42)

| | |
|-----------------------|-------------------------|
| Reporting group title | CZP 400 mg / CZP 200 mg |
|-----------------------|-------------------------|

Reporting group description:

Certolizumab pegol (CZP) 400 mg (3 doses 2-weekly then 5 doses 4-weekly) in this extension study / Certolizumab pegol (CZP) 200 mg (3 doses 2-weekly) in the 6-week double-blind main study (2014-004399-42)

| | |
|-----------------------|-------------------------|
| Reporting group title | CZP 400 mg / CZP 400 mg |
|-----------------------|-------------------------|

Reporting group description:

Certolizumab pegol (CZP) 400 mg (3 doses 2-weekly then 5 doses 4-weekly) in this extension study / Certolizumab pegol (CZP) 400 mg (3 doses 2-weekly) in the 6-week double-blind main study (2014-004399-42)

| | |
|-----------------------|-------------------------------------|
| Reporting group title | Total 1 (This extension study only) |
|-----------------------|-------------------------------------|

Reporting group description:

This includes all adverse event data collected in this extension study for all 46 subjects who entered this extension study.

| Serious adverse events | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg |
|---|----------------------|-------------------------|-------------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 1 / 18 (5.56%) | 3 / 13 (23.08%) | 4 / 15 (26.67%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Crohn's disease | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 1 / 13 (7.69%) | 3 / 15 (20.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 2 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders | | | |

| | | | |
|---|----------------|----------------|----------------|
| Psychotic disorder | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 0 / 13 (0.00%) | 1 / 15 (6.67%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Suicide attempt | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 0 / 13 (0.00%) | 1 / 15 (6.67%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Osteomalacia | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 1 / 13 (7.69%) | 0 / 15 (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 | | | |
| Perianal abscess | | | |
| subjects affected / exposed | 1 / 18 (5.56%) | 0 / 13 (0.00%) | 0 / 15 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pulmonary tuberculosis | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 0 / 13 (0.00%) | 1 / 15 (6.67%) |
| 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 | | | |
| Electrolyte imbalance | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 1 / 13 (7.69%) | 0 / 15 (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 |
| Tetany | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 1 / 13 (7.69%) | 0 / 15 (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 |

| | | | |
|------------------------------------|-------------------------------------|--|--|
| Serious adverse events | Total 1 (This extension study only) | | |
| Total subjects affected by serious | | | |

| | | | |
|---|-----------------|--|--|
| adverse events | | | |
| subjects affected / exposed | 8 / 46 (17.39%) | | |
| number of deaths (all causes) | 0 | | |
| number of deaths resulting from adverse events | 0 | | |
| Gastrointestinal disorders | | | |
| Crohn's disease | | | |
| subjects affected / exposed | 4 / 46 (8.70%) | | |
| occurrences causally related to treatment / all | 2 / 4 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Psychiatric disorders | | | |
| Psychotic disorder | | | |
| subjects affected / exposed | 1 / 46 (2.17%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Suicide attempt | | | |
| subjects affected / exposed | 1 / 46 (2.17%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Musculoskeletal and connective tissue disorders | | | |
| Osteomalacia | | | |
| subjects affected / exposed | 1 / 46 (2.17%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Infections and infestations | | | |
| Perianal abscess | | | |
| subjects affected / exposed | 1 / 46 (2.17%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pulmonary tuberculosis | | | |
| subjects affected / exposed | 1 / 46 (2.17%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Metabolism and nutrition disorders | | | |
| Electrolyte imbalance | | | |

| | | | |
|---|----------------|--|--|
| subjects affected / exposed | 1 / 46 (2.17%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Tetany | | | |
| subjects affected / exposed | 1 / 46 (2.17%) | | |
| 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 %

| Non-serious adverse events | CZP 400 mg / Placebo | CZP 400 mg / CZP 200 mg | CZP 400 mg / CZP 400 mg |
|---|-------------------------|----------------------------|----------------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 15 / 18 (83.33%) | 10 / 13 (76.92%) | 13 / 15 (86.67%) |
| General disorders and administration site conditions | | | |
| Chest pain | | | |
| subjects affected / exposed | 1 / 18 (5.56%) | 0 / 13 (0.00%) | 0 / 15 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Injection site erythema | | | |
| subjects affected / exposed | 1 / 18 (5.56%) | 0 / 13 (0.00%) | 0 / 15 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Malaise | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 0 / 13 (0.00%) | 1 / 15 (6.67%) |
| occurrences (all) | 0 | 0 | 1 |
| Pyrexia | | | |
| subjects affected / exposed | 2 / 18 (11.11%) | 6 / 13 (46.15%) | 3 / 15 (20.00%) |
| occurrences (all) | 2 | 9 | 3 |
| Swelling | | | |
| subjects affected / exposed | 1 / 18 (5.56%) | 0 / 13 (0.00%) | 0 / 15 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Immune system disorders | | | |
| Anaphylactic reaction | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 0 / 13 (0.00%) | 1 / 15 (6.67%) |
| occurrences (all) | 0 | 0 | 1 |
| Respiratory, thoracic and mediastinal disorders | | | |

| | | | |
|---|---------------------|----------------------|---------------------|
| Cough subjects affected / exposed occurrences (all) | 0 / 18 (0.00%) 0 | 1 / 13 (7.69%) 1 | 0 / 15 (0.00%) 0 |
| Dyspnoea subjects affected / exposed occurrences (all) | 1 / 18 (5.56%) 1 | 0 / 13 (0.00%) 0 | 0 / 15 (0.00%) 0 |
| Pneumothorax subjects affected / exposed occurrences (all) | 0 / 18 (0.00%) 0 | 0 / 13 (0.00%) 0 | 1 / 15 (6.67%) 1 |
| Rhinitis allergic subjects affected / exposed occurrences (all) | 0 / 18 (0.00%) 0 | 2 / 13 (15.38%) 2 | 0 / 15 (0.00%) 0 |
| Upper respiratory tract inflammation subjects affected / exposed occurrences (all) | 0 / 18 (0.00%) 0 | 1 / 13 (7.69%) 1 | 0 / 15 (0.00%) 0 |
| Psychiatric disorders Depressive symptom subjects affected / exposed occurrences (all) | 0 / 18 (0.00%) 0 | 1 / 13 (7.69%) 1 | 0 / 15 (0.00%) 0 |
| Emotional distress subjects affected / exposed occurrences (all) | 1 / 18 (5.56%) 1 | 0 / 13 (0.00%) 0 | 0 / 15 (0.00%) 0 |
| Initial insomnia subjects affected / exposed occurrences (all) | 0 / 18 (0.00%) 0 | 0 / 13 (0.00%) 0 | 1 / 15 (6.67%) 1 |
| Insomnia subjects affected / exposed occurrences (all) | 0 / 18 (0.00%) 0 | 0 / 13 (0.00%) 0 | 1 / 15 (6.67%) 1 |
| Investigations Blood calcium decreased subjects affected / exposed occurrences (all) | 0 / 18 (0.00%) 0 | 1 / 13 (7.69%) 1 | 0 / 15 (0.00%) 0 |
| Blood potassium decreased subjects affected / exposed occurrences (all) | 0 / 18 (0.00%) 0 | 1 / 13 (7.69%) 1 | 0 / 15 (0.00%) 0 |
| DNA antibody positive | | | |

| | | | |
|--|---------------------|----------------------|---------------------|
| subjects affected / exposed occurrences (all) | 1 / 18 (5.56%) 1 | 0 / 13 (0.00%) 0 | 1 / 15 (6.67%) 1 |
| Haemoglobin decreased subjects affected / exposed occurrences (all) | 1 / 18 (5.56%) 1 | 0 / 13 (0.00%) 0 | 0 / 15 (0.00%) 0 |
| White blood cell count decreased subjects affected / exposed occurrences (all) | 1 / 18 (5.56%) 2 | 0 / 13 (0.00%) 0 | 0 / 15 (0.00%) 0 |
| Injury, poisoning and procedural complications | | | |
| Contusion subjects affected / exposed occurrences (all) | 0 / 18 (0.00%) 0 | 2 / 13 (15.38%) 3 | 0 / 15 (0.00%) 0 |
| Excoriation subjects affected / exposed occurrences (all) | 1 / 18 (5.56%) 1 | 0 / 13 (0.00%) 0 | 0 / 15 (0.00%) 0 |
| Fall subjects affected / exposed occurrences (all) | 1 / 18 (5.56%) 1 | 0 / 13 (0.00%) 0 | 0 / 15 (0.00%) 0 |
| Foot fracture subjects affected / exposed occurrences (all) | 0 / 18 (0.00%) 0 | 1 / 13 (7.69%) 1 | 0 / 15 (0.00%) 0 |
| Rib fracture subjects affected / exposed occurrences (all) | 0 / 18 (0.00%) 0 | 1 / 13 (7.69%) 1 | 0 / 15 (0.00%) 0 |
| Cardiac disorders | | | |
| Palpitations subjects affected / exposed occurrences (all) | 1 / 18 (5.56%) 1 | 0 / 13 (0.00%) 0 | 1 / 15 (6.67%) 1 |
| Tachycardia subjects affected / exposed occurrences (all) | 0 / 18 (0.00%) 0 | 0 / 13 (0.00%) 0 | 1 / 15 (6.67%) 1 |
| Nervous system disorders | | | |
| Dizziness postural subjects affected / exposed occurrences (all) | 0 / 18 (0.00%) 0 | 0 / 13 (0.00%) 0 | 1 / 15 (6.67%) 1 |
| Headache | | | |

| | | | |
|--|---------------------|----------------------|---------------------|
| subjects affected / exposed occurrences (all) | 1 / 18 (5.56%) 1 | 0 / 13 (0.00%) 0 | 0 / 15 (0.00%) 0 |
| Hypoaesthesia subjects affected / exposed occurrences (all) | 1 / 18 (5.56%) 1 | 2 / 13 (15.38%) 2 | 0 / 15 (0.00%) 0 |
| Loss of consciousness subjects affected / exposed occurrences (all) | 0 / 18 (0.00%) 0 | 0 / 13 (0.00%) 0 | 1 / 15 (6.67%) 1 |
| Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all) | 1 / 18 (5.56%) 1 | 0 / 13 (0.00%) 0 | 0 / 15 (0.00%) 0 |
| Ear and labyrinth disorders Ear discomfort subjects affected / exposed occurrences (all) | 0 / 18 (0.00%) 0 | 0 / 13 (0.00%) 0 | 1 / 15 (6.67%) 1 |
| Eye disorders Ocular hyperaemia subjects affected / exposed occurrences (all) | 1 / 18 (5.56%) 1 | 0 / 13 (0.00%) 0 | 0 / 15 (0.00%) 0 |
| Gastrointestinal disorders Abdominal pain lower subjects affected / exposed occurrences (all) | 0 / 18 (0.00%) 0 | 0 / 13 (0.00%) 0 | 1 / 15 (6.67%) 1 |
| Abdominal pain upper subjects affected / exposed occurrences (all) | 0 / 18 (0.00%) 0 | 1 / 13 (7.69%) 1 | 1 / 15 (6.67%) 1 |
| Crohn's disease subjects affected / exposed occurrences (all) | 1 / 18 (5.56%) 1 | 0 / 13 (0.00%) 0 | 0 / 15 (0.00%) 0 |
| Duodenal ulcer subjects affected / exposed occurrences (all) | 0 / 18 (0.00%) 0 | 0 / 13 (0.00%) 0 | 1 / 15 (6.67%) 1 |
| Gastroduodenitis subjects affected / exposed occurrences (all) | 0 / 18 (0.00%) 0 | 1 / 13 (7.69%) 1 | 0 / 15 (0.00%) 0 |
| Nausea | | | |

| | | | |
|--|----------------|----------------|-----------------|
| subjects affected / exposed | 1 / 18 (5.56%) | 0 / 13 (0.00%) | 2 / 15 (13.33%) |
| occurrences (all) | 1 | 0 | 2 |
| Periodontitis | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 0 / 13 (0.00%) | 1 / 15 (6.67%) |
| occurrences (all) | 0 | 0 | 2 |
| Salivary gland disorder | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 1 / 13 (7.69%) | 0 / 15 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Stomatitis | | | |
| subjects affected / exposed | 1 / 18 (5.56%) | 0 / 13 (0.00%) | 0 / 15 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Toothache | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 1 / 13 (7.69%) | 1 / 15 (6.67%) |
| occurrences (all) | 0 | 1 | 1 |
| Vomiting | | | |
| subjects affected / exposed | 1 / 18 (5.56%) | 1 / 13 (7.69%) | 1 / 15 (6.67%) |
| occurrences (all) | 1 | 1 | 1 |
| Hepatobiliary disorders | | | |
| Hepatic function abnormal | | | |
| subjects affected / exposed | 1 / 18 (5.56%) | 0 / 13 (0.00%) | 1 / 15 (6.67%) |
| occurrences (all) | 1 | 0 | 1 |
| Skin and subcutaneous tissue disorders | | | |
| Alopecia | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 0 / 13 (0.00%) | 1 / 15 (6.67%) |
| occurrences (all) | 0 | 0 | 1 |
| Dermatitis atopic | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 1 / 13 (7.69%) | 0 / 15 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Dry skin | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 1 / 13 (7.69%) | 0 / 15 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Eczema | | | |
| subjects affected / exposed | 1 / 18 (5.56%) | 0 / 13 (0.00%) | 1 / 15 (6.67%) |
| occurrences (all) | 1 | 0 | 1 |
| Eczema asteatotic | | | |

| | | | |
|---|------------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 18 (5.56%) | 0 / 13 (0.00%) | 0 / 15 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pruritus | | | |
| subjects affected / exposed | 1 / 18 (5.56%) | 0 / 13 (0.00%) | 0 / 15 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Muscle tightness | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 1 / 13 (7.69%) | 0 / 15 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Infections and infestations | | | |
| Cystitis | | | |
| subjects affected / exposed | 1 / 18 (5.56%) | 1 / 13 (7.69%) | 0 / 15 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Dental caries | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 1 / 13 (7.69%) | 0 / 15 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Herpes zoster | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 0 / 13 (0.00%) | 1 / 15 (6.67%) |
| occurrences (all) | 0 | 0 | 1 |
| Influenza | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 1 / 13 (7.69%) | 0 / 15 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 10 / 18 (55.56%) | 5 / 13 (38.46%) | 6 / 15 (40.00%) |
| occurrences (all) | 15 | 8 | 7 |
| Paronychia | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 0 / 13 (0.00%) | 1 / 15 (6.67%) |
| occurrences (all) | 0 | 0 | 1 |
| Perianal abscess | | | |
| subjects affected / exposed | 0 / 18 (0.00%) | 0 / 13 (0.00%) | 1 / 15 (6.67%) |
| occurrences (all) | 0 | 0 | 2 |
| Pharyngitis | | | |
| subjects affected / exposed | 2 / 18 (11.11%) | 0 / 13 (0.00%) | 1 / 15 (6.67%) |
| occurrences (all) | 2 | 0 | 1 |
| Pulpitis dental | | | |

| | | | |
|---|---------------------|---------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 18 (0.00%) 0 | 0 / 13 (0.00%) 0 | 1 / 15 (6.67%) 1 |
| Urinary tract infection subjects affected / exposed occurrences (all) | 1 / 18 (5.56%) 1 | 0 / 13 (0.00%) 0 | 0 / 15 (0.00%) 0 |
| Metabolism and nutrition disorders | | | |
| Anorexia subjects affected / exposed occurrences (all) | 1 / 18 (5.56%) 1 | 0 / 13 (0.00%) 0 | 0 / 15 (0.00%) 0 |
| Electrolyte imbalance subjects affected / exposed occurrences (all) | 0 / 18 (0.00%) 0 | 1 / 13 (7.69%) 1 | 0 / 15 (0.00%) 0 |
| Hypoalbuminaemia subjects affected / exposed occurrences (all) | 0 / 18 (0.00%) 0 | 1 / 13 (7.69%) 2 | 1 / 15 (6.67%) 1 |
| Vitamin D deficiency subjects affected / exposed occurrences (all) | 0 / 18 (0.00%) 0 | 1 / 13 (7.69%) 1 | 0 / 15 (0.00%) 0 |

| | | | |
|--|-------------------------------------|--|--|
| Non-serious adverse events | Total 1 (This extension study only) | | |
| Total subjects affected by non-serious adverse events subjects affected / exposed | 38 / 46 (82.61%) | | |
| General disorders and administration site conditions | | | |
| Chest pain subjects affected / exposed occurrences (all) | 1 / 46 (2.17%) 1 | | |
| Injection site erythema subjects affected / exposed occurrences (all) | 1 / 46 (2.17%) 1 | | |
| Malaise subjects affected / exposed occurrences (all) | 1 / 46 (2.17%) 1 | | |
| Pyrexia subjects affected / exposed occurrences (all) | 11 / 46 (23.91%) 14 | | |
| Swelling | | | |

| | | | |
|---|---|--|--|
| subjects affected / exposed occurrences (all) | 1 / 46 (2.17%) 1 | | |
| Immune system disorders Anaphylactic reaction subjects affected / exposed occurrences (all) | 1 / 46 (2.17%) 1 | | |
| Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all) Dyspnoea subjects affected / exposed occurrences (all) Pneumothorax subjects affected / exposed occurrences (all) Rhinitis allergic subjects affected / exposed occurrences (all) Upper respiratory tract inflammation subjects affected / exposed occurrences (all) | 1 / 46 (2.17%) 1 1 / 46 (2.17%) 1 1 / 46 (2.17%) 1 2 / 46 (4.35%) 2 1 / 46 (2.17%) 1 | | |
| Psychiatric disorders Depressive symptom subjects affected / exposed occurrences (all) Emotional distress subjects affected / exposed occurrences (all) Initial insomnia subjects affected / exposed occurrences (all) Insomnia subjects affected / exposed occurrences (all) | 1 / 46 (2.17%) 1 1 / 46 (2.17%) 1 1 / 46 (2.17%) 1 1 / 46 (2.17%) 1 | | |
| Investigations | | | |

| | | | |
|--|---------------------|--|--|
| Blood calcium decreased subjects affected / exposed occurrences (all) | 1 / 46 (2.17%) 1 | | |
| Blood potassium decreased subjects affected / exposed occurrences (all) | 1 / 46 (2.17%) 1 | | |
| DNA antibody positive subjects affected / exposed occurrences (all) | 2 / 46 (4.35%) 2 | | |
| Haemoglobin decreased subjects affected / exposed occurrences (all) | 1 / 46 (2.17%) 1 | | |
| White blood cell count decreased subjects affected / exposed occurrences (all) | 1 / 46 (2.17%) 2 | | |
| Injury, poisoning and procedural complications | | | |
| Contusion subjects affected / exposed occurrences (all) | 2 / 46 (4.35%) 3 | | |
| Excoriation subjects affected / exposed occurrences (all) | 1 / 46 (2.17%) 1 | | |
| Fall subjects affected / exposed occurrences (all) | 1 / 46 (2.17%) 1 | | |
| Foot fracture subjects affected / exposed occurrences (all) | 1 / 46 (2.17%) 1 | | |
| Rib fracture subjects affected / exposed occurrences (all) | 1 / 46 (2.17%) 1 | | |
| Cardiac disorders | | | |
| Palpitations subjects affected / exposed occurrences (all) | 2 / 46 (4.35%) 2 | | |
| Tachycardia | | | |

| | | | |
|--|---------------------|--|--|
| subjects affected / exposed occurrences (all) | 1 / 46 (2.17%) 1 | | |
| Nervous system disorders Dizziness postural subjects affected / exposed occurrences (all) | 1 / 46 (2.17%) 1 | | |
| Headache subjects affected / exposed occurrences (all) | 1 / 46 (2.17%) 1 | | |
| Hypoaesthesia subjects affected / exposed occurrences (all) | 3 / 46 (6.52%) 3 | | |
| Loss of consciousness subjects affected / exposed occurrences (all) | 1 / 46 (2.17%) 1 | | |
| Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all) | 1 / 46 (2.17%) 1 | | |
| Ear and labyrinth disorders Ear discomfort subjects affected / exposed occurrences (all) | 1 / 46 (2.17%) 1 | | |
| Eye disorders Ocular hyperaemia subjects affected / exposed occurrences (all) | 1 / 46 (2.17%) 1 | | |
| Gastrointestinal disorders Abdominal pain lower subjects affected / exposed occurrences (all) | 1 / 46 (2.17%) 1 | | |
| Abdominal pain upper subjects affected / exposed occurrences (all) | 2 / 46 (4.35%) 2 | | |
| Crohn's disease subjects affected / exposed occurrences (all) | 1 / 46 (2.17%) 1 | | |

| | | | |
|--|----------------|--|--|
| Duodenal ulcer | | | |
| subjects affected / exposed | 1 / 46 (2.17%) | | |
| occurrences (all) | 1 | | |
| Gastroduodenitis | | | |
| subjects affected / exposed | 1 / 46 (2.17%) | | |
| occurrences (all) | 1 | | |
| Nausea | | | |
| subjects affected / exposed | 3 / 46 (6.52%) | | |
| occurrences (all) | 3 | | |
| Periodontitis | | | |
| subjects affected / exposed | 1 / 46 (2.17%) | | |
| occurrences (all) | 2 | | |
| Salivary gland disorder | | | |
| subjects affected / exposed | 1 / 46 (2.17%) | | |
| occurrences (all) | 1 | | |
| Stomatitis | | | |
| subjects affected / exposed | 1 / 46 (2.17%) | | |
| occurrences (all) | 1 | | |
| Toothache | | | |
| subjects affected / exposed | 2 / 46 (4.35%) | | |
| occurrences (all) | 2 | | |
| Vomiting | | | |
| subjects affected / exposed | 3 / 46 (6.52%) | | |
| occurrences (all) | 3 | | |
| Hepatobiliary disorders | | | |
| Hepatic function abnormal | | | |
| subjects affected / exposed | 2 / 46 (4.35%) | | |
| occurrences (all) | 2 | | |
| Skin and subcutaneous tissue disorders | | | |
| Alopecia | | | |
| subjects affected / exposed | 1 / 46 (2.17%) | | |
| occurrences (all) | 1 | | |
| Dermatitis atopic | | | |
| subjects affected / exposed | 1 / 46 (2.17%) | | |
| occurrences (all) | 1 | | |
| Dry skin | | | |

| | | | |
|---|------------------|--|--|
| subjects affected / exposed | 1 / 46 (2.17%) | | |
| occurrences (all) | 1 | | |
| Eczema | | | |
| subjects affected / exposed | 2 / 46 (4.35%) | | |
| occurrences (all) | 2 | | |
| Eczema asteatotic | | | |
| subjects affected / exposed | 1 / 46 (2.17%) | | |
| occurrences (all) | 1 | | |
| Pruritus | | | |
| subjects affected / exposed | 1 / 46 (2.17%) | | |
| occurrences (all) | 1 | | |
| Musculoskeletal and connective tissue disorders | | | |
| Muscle tightness | | | |
| subjects affected / exposed | 1 / 46 (2.17%) | | |
| occurrences (all) | 2 | | |
| Infections and infestations | | | |
| Cystitis | | | |
| subjects affected / exposed | 2 / 46 (4.35%) | | |
| occurrences (all) | 2 | | |
| Dental caries | | | |
| subjects affected / exposed | 1 / 46 (2.17%) | | |
| occurrences (all) | 1 | | |
| Herpes zoster | | | |
| subjects affected / exposed | 1 / 46 (2.17%) | | |
| occurrences (all) | 1 | | |
| Influenza | | | |
| subjects affected / exposed | 1 / 46 (2.17%) | | |
| occurrences (all) | 1 | | |
| Nasopharyngitis | | | |
| subjects affected / exposed | 21 / 46 (45.65%) | | |
| occurrences (all) | 30 | | |
| Paronychia | | | |
| subjects affected / exposed | 1 / 46 (2.17%) | | |
| occurrences (all) | 1 | | |
| Perianal abscess | | | |

| | | | |
|------------------------------------|----------------|--|--|
| subjects affected / exposed | 1 / 46 (2.17%) | | |
| occurrences (all) | 2 | | |
| Pharyngitis | | | |
| subjects affected / exposed | 3 / 46 (6.52%) | | |
| occurrences (all) | 3 | | |
| Pulpitis dental | | | |
| subjects affected / exposed | 1 / 46 (2.17%) | | |
| occurrences (all) | 1 | | |
| Urinary tract infection | | | |
| subjects affected / exposed | 1 / 46 (2.17%) | | |
| occurrences (all) | 1 | | |
| Metabolism and nutrition disorders | | | |
| Anorexia | | | |
| subjects affected / exposed | 1 / 46 (2.17%) | | |
| occurrences (all) | 1 | | |
| Electrolyte imbalance | | | |
| subjects affected / exposed | 1 / 46 (2.17%) | | |
| occurrences (all) | 1 | | |
| Hypoalbuminaemia | | | |
| subjects affected / exposed | 2 / 46 (4.35%) | | |
| occurrences (all) | 3 | | |
| Vitamin D deficiency | | | |
| subjects affected / exposed | 1 / 46 (2.17%) | | |
| occurrences (all) | 1 | | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

| |
|---|
| Due to the small number of subjects in this study, the percentages of subjects with adverse events may be misleading. |
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Notes: