



Clinical trial results:

A MULTI-CENTER, RANDOMIZED, DOUBLE BLIND, PLACEBO-CONTROLLED, PARALLEL GROUP, DOSE RANGING STUDY FOLLOWED BY AN OBSERVATIONAL PERIOD TO EVALUATE THE EFFICACY AND SAFETY OF DAPIROLIZUMAB PEGOL IN SUBJECTS WITH MODERATELY TO SEVERELY ACTIVE SYSTEMIC LUPUS ERYTHEMATOSUS

Summary

| | |
|--------------------------|-------------------|
| EudraCT number | 2015-004457-40 |
| Trial protocol | DE RO HU BG ES PL |
| Global end of trial date | 15 November 2018 |

Results information

| | |
|--------------------------------|------------------|
| Result version number | v2 (current) |
| This version publication date | 26 July 2021 |
| First version publication date | 02 December 2019 |
| Version creation reason | |

Trial information

Trial identification

| | |
|-----------------------|--------|
| Sponsor protocol code | SL0023 |
|-----------------------|--------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT02804763 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|-----------------------------------------------------------------------------------|
| Sponsor organisation name | UCB Biopharma SPRL |
| Sponsor organisation address | Allée de la Recherche 60, Brussels, Belgium, 1070 |
| Public contact | Clin Trial Reg & Results Disclosure, UCB BIOSCIENCES GmbH, clinicaltrials@ucb.com |
| Scientific contact | Clin Trial Reg & Results Disclosure, UCB BIOSCIENCES GmbH, 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? | No |

Notes:

Results analysis stage

| | |
|------------------------------------------------------|-----------------|
| Analysis stage | Final |
| Date of interim/final analysis | 31 January 2019 |
| Is this the analysis of the primary completion data? | No |

| | |
|----------------------------------|------------------|
| Global end of trial reached? | Yes |
| Global end of trial date | 15 November 2018 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To assess the dose-response for the efficacy of intravenous (iv) dapirolizumab pegol (DZP; 3 dose groups) at week 24 in adult subjects with moderately to severely active systemic lupus erythematosus (SLE) receiving stable standard-of-care treatment.

Protection of trial subjects:

During the conduct of the study all participants were closely monitored.

Background therapy:

Mandatory background medication with either antimalarials, immunosuppressants or corticosteroids as stand-alone treatment or in combination. Other Background therapy as permitted in the protocol.

Evidence for comparator:

Not Applicable

| | |
|-----------------------------------------------------------|--------------|
| Actual start date of recruitment | 02 June 2016 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|------------------------|
| Country: Number of subjects enrolled | Bulgaria: 2 |
| Country: Number of subjects enrolled | Colombia: 18 |
| Country: Number of subjects enrolled | Germany: 10 |
| Country: Number of subjects enrolled | Mexico: 13 |
| Country: Number of subjects enrolled | Peru: 26 |
| Country: Number of subjects enrolled | Poland: 16 |
| Country: Number of subjects enrolled | Romania: 12 |
| Country: Number of subjects enrolled | Russian Federation: 15 |
| Country: Number of subjects enrolled | Spain: 2 |
| Country: Number of subjects enrolled | Ukraine: 15 |
| Country: Number of subjects enrolled | United States: 53 |
| Worldwide total number of subjects | 182 |
| EEA total number of subjects | 42 |

Notes:

| Subjects enrolled per age group | |
|-------------------------------------------|-----|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 0 |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 178 |
| From 65 to 84 years | 4 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

The study started to enroll patients in June 2016 and concluded in November 2018.

Pre-assignment

Screening details:

The study included a 4-week Screening Period, a 24-week Double-Blind Treatment Period and a 24-week Observational Period.

Participant Flow refers to the Randomized Set.

Period 1

| | |
|------------------------------|-----------------------------------------|
| Period 1 title | Double-Blind Period (Week 1 to Week 24) |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator, Carer, Assessor |

Arms

| | |
|------------------------------|----------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | SOC + Placebo iv Q4W |

Arm description:

This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive Placebo intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period.

| | |
|----------------------------------------|-----------------------------------|
| Arm type | Placebo |
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | PBO |
| Other name | |
| Pharmaceutical forms | Solvent for solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

During the 24-week Double-Blind Treatment Period participants received an intravenous (iv) infusion of PBO every 4 weeks (Q4W) for a total of 6 doses.

| | |
|------------------|-------------------------|
| Arm title | SOC + DZP 6mg/kg iv Q4W |
|------------------|-------------------------|

Arm description:

This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive dapirolizumab pegol (DZP) 6 milligrams (mg)/kilogram (kg) intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period.

| | |
|----------------------------------------|--------------------------------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Dapirolizumab pegol |
| Investigational medicinal product code | DZP |
| Other name | |
| Pharmaceutical forms | Powder for concentrate for solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

During the 24-week Double-Blind Treatment Period participants received an intravenous (iv) infusion of DZP 6mg/kg, 24mg/kg or 45mg/kg, every 4 weeks (Q4W) for a total of 6 doses.

| | |
|------------------|--------------------------|
| Arm title | SOC + DZP 24mg/kg iv Q4W |
|------------------|--------------------------|

Arm description:

This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive dapirolizumab pegol (DZP) 24mg/kg intravenous

(iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period.

| | |
|----------------------------------------|--------------------------------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Dapirolizumab pegol |
| Investigational medicinal product code | DZP |
| Other name | |
| Pharmaceutical forms | Powder for concentrate for solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

During the 24-week Double-Blind Treatment Period participants received an intravenous (iv) infusion of DZP 6mg/kg, 24mg/kg or 45mg/kg, every 4 weeks (Q4W) for a total of 6 doses.

| | |
|------------------|--------------------------|
| Arm title | SOC + DZP 45mg/kg iv Q4W |
|------------------|--------------------------|

Arm description:

This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive dapirolizumab pegol (DZP) 45mg/kg intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period.

| | |
|----------------------------------------|--------------------------------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Dapirolizumab pegol |
| Investigational medicinal product code | DZP |
| Other name | |
| Pharmaceutical forms | Powder for concentrate for solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

During the 24-week Double-Blind Treatment Period participants received an intravenous (iv) infusion of DZP 6mg/kg, 24mg/kg or 45mg/kg, every 4 weeks (Q4W) for a total of 6 doses.

| Number of subjects in period 1 | SOC + Placebo iv Q4W | SOC + DZP 6mg/kg iv Q4W | SOC + DZP 24mg/kg iv Q4W |
|------------------------------------------|----------------------|-------------------------|--------------------------|
| Started | 45 | 45 | 45 |
| Completed Week 24 | 44 | 45 | 44 |
| Finished Wk24 began Observational Period | 44 | 44 | 44 |
| Completed | 44 | 44 | 44 |
| Not completed | 1 | 1 | 1 |
| Consent withdrawn by subject | - | - | 1 |
| Consent withdrawal after Week 24 | - | 1 | - |
| Adverse event, non-fatal | 1 | - | - |

| Number of subjects in period 1 | SOC + DZP 45mg/kg iv Q4W |
|------------------------------------------|--------------------------|
| Started | 47 |
| Completed Week 24 | 45 |
| Finished Wk24 began Observational Period | 45 |
| Completed | 45 |
| Not completed | 2 |
| Consent withdrawn by subject | 2 |
| Consent withdrawal after Week 24 | - |
| Adverse event, non-fatal | - |

Period 2

| | |
|------------------------------|----------------------------------------|
| Period 2 title | Observational Period (Wk 24 to Wk 48) |
| Is this the baseline period? | No |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator, Carer, Assessor |

Blinding implementation details:

Participants who completed the 24-week Double-Blind Treatment Period continued into a 24-week Observational Period, during which participants didn't receive study drug but received standard-of-care (SOC) treatment.

Sponsor was unblinded during the Observational Period.

Arms

| | |
|------------------------------|----------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | SOC + Placebo iv Q4W |

Arm description:

This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive Placebo intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period.

| | |
|----------------------------------------|-----------------------------------|
| Arm type | Placebo |
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | PBO |
| Other name | |
| Pharmaceutical forms | Solvent for solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

During the 24-week Double-Blind Treatment Period participants received an intravenous (iv) infusion of PBO every 4 weeks (Q4W) for a total of 6 doses.

| | |
|------------------|-------------------------|
| Arm title | SOC + DZP 6mg/kg iv Q4W |
|------------------|-------------------------|

Arm description:

This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive dapirolizumab pegol (DZP) 6 milligrams (mg)/kilogram (kg) intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period.

| | |
|----------------------------------------|--------------------------------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Dapirolizumab pegol |
| Investigational medicinal product code | DZP |
| Other name | |
| Pharmaceutical forms | Powder for concentrate for solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

During the 24-week Double-Blind Treatment Period participants received an intravenous (iv) infusion of DZP 6mg/kg, 24mg/kg or 45mg/kg, every 4 weeks (Q4W) for a total of 6 doses.

| | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|
| Arm title | SOC + DZP 24mg/kg iv Q4W |
| Arm description: This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive dapirolizumab pegol (DZP) 24mg/kg intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period. | |
| Arm type | Experimental |
| Investigational medicinal product name | Dapirolizumab pegol |
| Investigational medicinal product code | DZP |
| Other name | |
| Pharmaceutical forms | Powder for concentrate for solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

During the 24-week Double-Blind Treatment Period participants received an intravenous (iv) infusion of DZP 6mg/kg, 24mg/kg or 45mg/kg, every 4 weeks (Q4W) for a total of 6 doses.

| | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|
| Arm title | SOC + DZP 45mg/kg iv Q4W |
| Arm description: This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive dapirolizumab pegol (DZP) 45mg/kg intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period. | |
| Arm type | Experimental |
| Investigational medicinal product name | Dapirolizumab pegol |
| Investigational medicinal product code | DZP |
| Other name | |
| Pharmaceutical forms | Powder for concentrate for solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

During the 24-week Double-Blind Treatment Period participants received an intravenous (iv) infusion of DZP 6mg/kg, 24mg/kg or 45mg/kg, every 4 weeks (Q4W) for a total of 6 doses.

| Number of subjects in period 2 | SOC + Placebo iv Q4W | SOC + DZP 6mg/kg iv Q4W | SOC + DZP 24mg/kg iv Q4W |
|---------------------------------------|----------------------|-------------------------|--------------------------|
| Started | 44 | 44 | 44 |
| Completed | 38 | 43 | 41 |
| Not completed | 6 | 1 | 3 |
| Consent withdrawn by subject | 4 | - | 2 |
| Patient moved out of state | - | 1 | - |
| Lost to follow-up | 2 | - | 1 |

| Number of subjects in period 2 | SOC + DZP 45mg/kg iv Q4W |
|---------------------------------------|--------------------------|
| Started | 45 |
| Completed | 42 |
| Not completed | 3 |
| Consent withdrawn by subject | 2 |
| Patient moved out of state | - |
| Lost to follow-up | 1 |

Baseline characteristics

Reporting groups

| | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| Reporting group title | SOC + Placebo iv Q4W |
| Reporting group description: This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive Placebo intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period. | |
| Reporting group title | SOC + DZP 6mg/kg iv Q4W |
| Reporting group description: This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive dapirolizumab pegol (DZP) 6 milligrams (mg)/kilogram (kg) intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period. | |
| Reporting group title | SOC + DZP 24mg/kg iv Q4W |
| Reporting group description: This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive dapirolizumab pegol (DZP) 24mg/kg intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period. | |
| Reporting group title | SOC + DZP 45mg/kg iv Q4W |
| Reporting group description: This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive dapirolizumab pegol (DZP) 45mg/kg intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period. | |

| Reporting group values | SOC + Placebo iv Q4W | SOC + DZP 6mg/kg iv Q4W | SOC + DZP 24mg/kg iv Q4W |
|---------------------------------------|----------------------|-------------------------|--------------------------|
| Number of subjects | 45 | 45 | 45 |
| Age categorical Units: Subjects | | | |
| <=18 years | 0 | 0 | 0 |
| Between 18 and 65 years | 44 | 44 | 44 |
| >=65 years | 1 | 1 | 1 |
| Age continuous Units: years | | | |
| arithmetic mean | 43.50 | 40.81 | 42.77 |
| standard deviation | ± 12.79 | ± 11.55 | ± 10.42 |
| Gender categorical Units: Subjects | | | |
| Male | 4 | 3 | 5 |
| Female | 41 | 42 | 40 |

| Reporting group values | SOC + DZP 45mg/kg iv Q4W | Total | |
|------------------------------------|--------------------------|-------|--|
| Number of subjects | 47 | 182 | |
| Age categorical Units: Subjects | | | |
| <=18 years | 0 | 0 | |
| Between 18 and 65 years | 46 | 178 | |
| >=65 years | 1 | 4 | |

| | | | |
|--------------------|---------|-----|--|
| Age continuous | | | |
| Units: years | | | |
| arithmetic mean | 38.94 | | |
| standard deviation | ± 12.92 | - | |
| Gender categorical | | | |
| Units: Subjects | | | |
| Male | 4 | 16 | |
| Female | 43 | 166 | |

End points

End points reporting groups

| | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|
| Reporting group title | SOC + Placebo iv Q4W |
| Reporting group description: This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive Placebo intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period. | |
| Reporting group title | SOC + DZP 6mg/kg iv Q4W |
| Reporting group description: This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive dapirolizumab pegol (DZP) 6 milligrams (mg)/kilogram (kg) intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period. | |
| Reporting group title | SOC + DZP 24mg/kg iv Q4W |
| Reporting group description: This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive dapirolizumab pegol (DZP) 24mg/kg intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period. | |
| Reporting group title | SOC + DZP 45mg/kg iv Q4W |
| Reporting group description: This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive dapirolizumab pegol (DZP) 45mg/kg intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period. | |
| Reporting group title | SOC + Placebo iv Q4W |
| Reporting group description: This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive Placebo intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period. | |
| Reporting group title | SOC + DZP 6mg/kg iv Q4W |
| Reporting group description: This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive dapirolizumab pegol (DZP) 6 milligrams (mg)/kilogram (kg) intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period. | |
| Reporting group title | SOC + DZP 24mg/kg iv Q4W |
| Reporting group description: This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive dapirolizumab pegol (DZP) 24mg/kg intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period. | |
| Reporting group title | SOC + DZP 45mg/kg iv Q4W |
| Reporting group description: This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive dapirolizumab pegol (DZP) 45mg/kg intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period. | |
| Subject analysis set title | SOC + Placebo iv Q4W (FAS) |
| Subject analysis set type | Full analysis |
| Subject analysis set description: This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive Placebo intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period. Participants formed the Full Analysis Set (FAS). | |
| Subject analysis set title | SOC + DZP 6mg/kg iv Q4W (FAS) |
| Subject analysis set type | Full analysis |
| Subject analysis set description: This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive dapirolizumab pegol (DZP) 6mg/kg intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period. | |

Participants formed the FAS.

| | |
|----------------------------|--------------------------------|
| Subject analysis set title | SOC + DZP 24mg/kg iv Q4W (FAS) |
| Subject analysis set type | Full analysis |

Subject analysis set description:

This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive dapirolizumab pegol (DZP) 24mg/kg intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period.

Participants formed the FAS.

| | |
|----------------------------|--------------------------------|
| Subject analysis set title | SOC + DZP 45mg/kg iv Q4W (FAS) |
| Subject analysis set type | Full analysis |

Subject analysis set description:

This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive dapirolizumab pegol (DZP) 45mg/kg intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period. Participants formed the FAS.

| | |
|----------------------------|---------------------------|
| Subject analysis set title | SOC + Placebo iv Q4W (SS) |
| Subject analysis set type | Safety analysis |

Subject analysis set description:

This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive Placebo intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period. Participants formed the Safety Set (SS).

| | |
|----------------------------|------------------------------|
| Subject analysis set title | SOC + DZP 6mg/kg iv Q4W (SS) |
| Subject analysis set type | Safety analysis |

Subject analysis set description:

This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive dapirolizumab pegol (DZP) 6mg/kg intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period.

Participants formed the SS.

| | |
|----------------------------|-------------------------------|
| Subject analysis set title | SOC + DZP 24mg/kg iv Q4W (SS) |
| Subject analysis set type | Safety analysis |

Subject analysis set description:

This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive dapirolizumab pegol (DZP) 24mg/kg intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period.

Participants formed the SS.

| | |
|----------------------------|-------------------------------|
| Subject analysis set title | SOC + DZP 45mg/kg iv Q4W (SS) |
| Subject analysis set type | Safety analysis |

Subject analysis set description:

This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive dapirolizumab pegol (DZP) 45mg/kg intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period.

Participants formed the SS.

Primary: Percentage of participants with British Isles Lupus Assessment Group Disease Activity Index 2004 (BILAG 2004)-based Composite Lupus Assessment (BICLA) (mNRI) response across 3 doses of dapirolizumab pegol (DZP) and placebo (PBO) at Week 24

| | |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of participants with British Isles Lupus Assessment Group Disease Activity Index 2004 (BILAG 2004)-based Composite Lupus Assessment (BICLA) (mNRI) response across 3 doses of dapirolizumab pegol (DZP) and placebo (PBO) at Week 24 |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

Primary efficacy variable was assessed by establishing if there was a dose response relationship between BICLA response at Week 24 and dose, using MCP-Mod. 4 candidate dose-response models were evaluated: linear model, logistic model, 2 Emax models, and MCP-Mod methodology controlled for multiplicity.

BICLA response was defined as meeting all of the following criteria: BILAG 2004 improvement: A scores at Baseline improved to B, C or D; B scores improved to C or D; no new A scores and ≤ 1 new B; No

worsening in SLEDAI-2K, defined as no increase in SLEDAI-2K total score; No worsening in PGA, defined as <10 mm increase on a 100 mm VAS; and No disallowed changes in concomitant medications, including increases in corticosteroids, immunosuppressants and antimalarials.

FAS- all participants in Randomized Set with exception of 1 study participant who received less than 1 full dose during study and 5 study participants who were randomized at Site 321. Missing values were imputed using mNRI.

| | |
|----------------------|---------|
| End point type | Primary |
| End point timeframe: | |
| Week 24 | |

| End point values | SOC + Placebo iv Q4W (FAS) | SOC + DZP 6mg/kg iv Q4W (FAS) | SOC + DZP 24mg/kg iv Q4W (FAS) | SOC + DZP 45mg/kg iv Q4W (FAS) |
|-----------------------------------|-------------------------------|-------------------------------------|--------------------------------------|--------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 43 | 43 | 44 | 46 |
| Units: percentage of participants | | | | |
| number (not applicable) | 0 | 0 | 0 | 0 |

Statistical analyses

| | |
|----------------------------|------------------------|
| Statistical analysis title | Statistical analysis 1 |
|----------------------------|------------------------|

Statistical analysis description:

Multiple contrast testing (Multiple Comparison Procedure - Modelling (MCP-mod) methodology) was used to test for a statistically significant dose-response relationship between the primary endpoint (BICLA at Week 24) and dose, which would indicate a drug effect of DZP over Placebo. The best fitting statistically significant model could be used to estimate the dose needed to achieve desired treatment effect.

| | |
|-----------------------------------------|------------------------------------------------------------------------------------------------------------------------------|
| Comparison groups | SOC + Placebo iv Q4W (FAS) v SOC + DZP 6mg/kg iv Q4W (FAS) v SOC + DZP 24mg/kg iv Q4W (FAS) v SOC + DZP 45mg/kg iv Q4W (FAS) |
| Number of subjects included in analysis | 176 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0727 ^[1] |
| Method | MCP-Mod |

Notes:

[1] - The lowest p-value (z-statistic with the highest value) was used to establish proof of dose response.

Secondary: The percentage of participants with BICLA (mNRI) response in the individual dose groups at Week 24

| | |
|-----------------|----------------------------------------------------------------------------------------------------|
| End point title | The percentage of participants with BICLA (mNRI) response in the individual dose groups at Week 24 |
|-----------------|----------------------------------------------------------------------------------------------------|

End point description:

BICLA response was defined as meeting all of the following criteria:

- (1)BILAG 2004 improvement: A scores at Baseline improved to B, C or D; B scores improved to C or D; no new A scores and ≤ 1 new B.
- (2)No worsening in Systemic Lupus Erythematosus Activity Index 2000 (SLEDAI-2K), defined as no increase in SLEDAI-2K total score.
- (3)No worsening in Physician's Global Assessment of Disease Activity (PGA), defined as < 10 millimeter (mm) increase on a 100 mm visual analog scale (VAS).
- (4)No disallowed changes in concomitant medications, mainly including increases in corticosteroids,

immunosuppressants, and antimalarials.

The Full Analysis Set (FAS) consisted of all participants in the Randomized Set with the exception of 1 study participant who received less than 1 full dose during the study and 5 study participants who were randomized at Site 321.

Missing values were imputed using a modified non-responder imputation (mNRI).

| | |
|----------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Week 24 | |

| End point values | SOC + Placebo iv Q4W (FAS) | SOC + DZP 6mg/kg iv Q4W (FAS) | SOC + DZP 24mg/kg iv Q4W (FAS) | SOC + DZP 45mg/kg iv Q4W (FAS) |
|-----------------------------------|-------------------------------|-------------------------------------|--------------------------------------|--------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 43 | 43 | 44 | 46 |
| Units: percentage of participants | | | | |
| number (not applicable) | 37.2 | 48.8 | 54.5 | 52.2 |

Statistical analyses

| | |
|----------------------------|------------------------|
| Statistical analysis title | Statistical analysis 1 |
|----------------------------|------------------------|

Statistical analysis description:

Missing values were imputed using modified non-responder imputation (mNRI) dataset: at most 1 missing BICLA (mNRI) component (scale) may have been carried forward from the immediately preceding visit, and missing data in the individual items within scales may have been carried forward from the immediately preceding visit. If there was still missing data after this limited imputation, the study participant was counted as a non-responder on the BICLA (mNRI) for that visit.

| | |
|-----------------------------------------|------------------------------------------------------------|
| Comparison groups | SOC + Placebo iv Q4W (FAS) v SOC + DZP 6mg/kg iv Q4W (FAS) |
| Number of subjects included in analysis | 86 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.2699 [2] |
| Method | Chi-squared |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 1.6 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.7 |
| upper limit | 3.8 |

Notes:

[2] - Generalized linear models with factors for treatment and corticosteroid strata were fit using a logit link function for the odds ratios and p-values.

| | |
|----------------------------|------------------------|
| Statistical analysis title | Statistical analysis 2 |
|----------------------------|------------------------|

Statistical analysis description:

Missing values were imputed using modified non-responder imputation (mNRI) dataset: at most 1 missing BICLA (mNRI) component (scale) may have been carried forward from the immediately preceding visit, and missing data in the individual items within scales may have been carried forward from the immediately preceding visit. If there was still missing data after this limited imputation, the study participant was counted as a non-responder on the BICLA (mNRI) for that visit.

| | |
|-----------------------------------------|-------------------------------------------------------------|
| Comparison groups | SOC + Placebo iv Q4W (FAS) v SOC + DZP 24mg/kg iv Q4W (FAS) |
| Number of subjects included in analysis | 87 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.1036 ^[3] |
| Method | Chi-squared |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 2 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.9 |
| upper limit | 4.8 |

Notes:

[3] - Generalized linear models with factors for treatment and corticosteroid strata were fit using a logit link function for the odds ratios and p-values.

| | |
|-----------------------------------|------------------------|
| Statistical analysis title | Statistical analysis 3 |
|-----------------------------------|------------------------|

Statistical analysis description:

Missing values were imputed using modified non-responder imputation (mNRI) dataset: at most 1 missing BICLA (mNRI) component (scale) may have been carried forward from the immediately preceding visit, and missing data in the individual items within scales may have been carried forward from the immediately preceding visit. If there was still missing data after this limited imputation, the study participant was counted as a non-responder on the BICLA (mNRI) for that visit.

| | |
|-----------------------------------------|-------------------------------------------------------------|
| Comparison groups | SOC + Placebo iv Q4W (FAS) v SOC + DZP 45mg/kg iv Q4W (FAS) |
| Number of subjects included in analysis | 89 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.1518 ^[4] |
| Method | Chi-squared |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 1.9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.8 |
| upper limit | 4.3 |

Notes:

[4] - Generalized linear models with factors for treatment and corticosteroid strata were fit using a logit link function for the odds ratios and p-values.

| | |
|-----------------------------------|------------------------|
| Statistical analysis title | Statistical analysis 4 |
|-----------------------------------|------------------------|

Statistical analysis description:

Missing values were imputed using modified non-responder imputation (mNRI) dataset: at most 1 missing BICLA (mNRI) component (scale) may have been carried forward from the immediately preceding visit, and missing data in the individual items within scales may have been carried forward from the immediately preceding visit. If there was still missing data after this limited imputation, the study participant was counted as a non-responder on the BICLA (mNRI) for that visit.

| | |
|-------------------|------------------------------------------------------------|
| Comparison groups | SOC + Placebo iv Q4W (FAS) v SOC + DZP 6mg/kg iv Q4W (FAS) |
|-------------------|------------------------------------------------------------|

| | |
|-----------------------------------------|-------------------|
| Number of subjects included in analysis | 86 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| Method | Chi-squared |
| Parameter estimate | Difference vs PBO |
| Point estimate | 11.6 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -9.2 |
| upper limit | 32.4 |

| | |
|-----------------------------------|------------------------|
| Statistical analysis title | Statistical analysis 5 |
|-----------------------------------|------------------------|

Statistical analysis description:

Missing values were imputed using modified non-responder imputation (mNRI) dataset: at most 1 missing BICLA (mNRI) component (scale) may have been carried forward from the immediately preceding visit, and missing data in the individual items within scales may have been carried forward from the immediately preceding visit. If there was still missing data after this limited imputation, the study participant was counted as a non-responder on the BICLA (mNRI) for that visit.

| | |
|-----------------------------------------|-------------------------------------------------------------|
| Comparison groups | SOC + Placebo iv Q4W (FAS) v SOC + DZP 24mg/kg iv Q4W (FAS) |
| Number of subjects included in analysis | 87 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| Method | Chi-squared |
| Parameter estimate | Difference vs PBO |
| Point estimate | 17.3 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -3.3 |
| upper limit | 38 |

| | |
|-----------------------------------|------------------------|
| Statistical analysis title | Statistical analysis 6 |
|-----------------------------------|------------------------|

Statistical analysis description:

Missing values were imputed using modified non-responder imputation (mNRI) dataset: at most 1 missing BICLA (mNRI) component (scale) may have been carried forward from the immediately preceding visit, and missing data in the individual items within scales may have been carried forward from the immediately preceding visit. If there was still missing data after this limited imputation, the study participant was counted as a non-responder on the BICLA (mNRI) for that visit.

| | |
|-----------------------------------------|-------------------------------------------------------------|
| Comparison groups | SOC + Placebo iv Q4W (FAS) v SOC + DZP 45mg/kg iv Q4W (FAS) |
| Number of subjects included in analysis | 89 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| Method | Chi-squared |
| Parameter estimate | Difference vs PBO |
| Point estimate | 15 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -5.5 |
| upper limit | 35.4 |

| | |
|-----------------------------------|------------------------|
| Statistical analysis title | Statistical analysis 7 |
|-----------------------------------|------------------------|

Statistical analysis description:

Missing values were imputed using modified non-responder imputation (mNRI) dataset: at most 1 missing BICLA (mNRI) component (scale) may have been carried forward from the immediately preceding visit, and missing data in the individual items within scales may have been carried forward from the immediately preceding visit. If there was still missing data after this limited imputation, the study participant was counted as a non-responder on the BICLA (mNRI) for that visit.

| | |
|-----------------------------------------|------------------------------------------------------------|
| Comparison groups | SOC + Placebo iv Q4W (FAS) v SOC + DZP 6mg/kg iv Q4W (FAS) |
| Number of subjects included in analysis | 86 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| Method | Chi-squared |
| Parameter estimate | LS Mean Difference vs PBO |
| Point estimate | 11.9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -8.7 |
| upper limit | 32.5 |

| | |
|-----------------------------------|------------------------|
| Statistical analysis title | Statistical analysis 8 |
|-----------------------------------|------------------------|

Statistical analysis description:

Missing values were imputed using modified non-responder imputation (mNRI) dataset: at most 1 missing BICLA (mNRI) component (scale) may have been carried forward from the immediately preceding visit, and missing data in the individual items within scales may have been carried forward from the immediately preceding visit. If there was still missing data after this limited imputation, the study participant was counted as a non-responder on the BICLA (mNRI) for that visit.

| | |
|-----------------------------------------|-------------------------------------------------------------|
| Comparison groups | SOC + Placebo iv Q4W (FAS) v SOC + DZP 24mg/kg iv Q4W (FAS) |
| Number of subjects included in analysis | 87 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| Method | Chi-squared |
| Parameter estimate | LS Mean Difference vs PBO |
| Point estimate | 17.6 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -3.2 |
| upper limit | 38.3 |

| | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------|
| Statistical analysis title | Statistical analysis 9 |
| Statistical analysis description: | |
| Missing values were imputed using modified non-responder imputation (mNRI) dataset: at most 1 missing BICLA (mNRI) component (scale) may have been carried forward from the immediately preceding visit, and missing data in the individual items within scales may have been carried forward from the immediately preceding visit. If there was still missing data after this limited imputation, the study participant was counted as a non-responder on the BICLA (mNRI) for that visit. | |
| Comparison groups | SOC + Placebo iv Q4W (FAS) v SOC + DZP 45mg/kg iv Q4W (FAS) |
| Number of subjects included in analysis | 89 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| Method | Chi-squared |
| Parameter estimate | LS Mean Difference vs PBO |
| Point estimate | 15.2 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -5.2 |
| upper limit | 35.6 |

| | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| Secondary: Percentage of participants with at least one Adverse Events (AEs) | |
| End point title | Percentage of participants with at least one Adverse Events (AEs) |
| End point description: | |
| An AE was any untoward medical occurrence in a patient or clinical investigation participant administered a pharmaceutical product that did not necessarily have a causal relationship with this treatment. An adverse event (AE) was therefore any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product. All AEs that occurred during the study were considered related unless clearly unrelated. The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. | |
| End point type | Secondary |
| End point timeframe: | |
| From Baseline (Week 1) until end of the study (Week 48) | |

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|-----------------------------------|---------------------------|------------------------------|-------------------------------|-------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: percentage of participants | | | | |
| number (not applicable) | 66.7 | 66.7 | 82.2 | 74.5 |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with a Serious Adverse Event (SAE)

| | |
|-----------------|---------------------------------------------------------------|
| End point title | Percentage of participants with a Serious Adverse Event (SAE) |
|-----------------|---------------------------------------------------------------|

End point description:

A Serious Adverse Event (SAE) must have met 1 or more of the following criteria:

- Death
- Life threatening
- Significant or persistent disability/incapacity
- Congenital anomaly/birth defect (including that occurring in a fetus)
- Important medical event that, based upon appropriate medical judgment, may have jeopardized the study participant, and may have required medical or surgical intervention to prevent 1 of the other outcomes listed in the definition of serious
- Initial inpatient hospitalization or prolongation of hospitalization.

The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug.

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

End point timeframe:

From Baseline (Week 1) until end of the study (Week 48)

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|-----------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: percentage of participants | | | | |
| number (not applicable) | 13.3 | 11.1 | 13.3 | 10.6 |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with at least one Adverse Events (AEs) of interest

| | |
|-----------------|-------------------------------------------------------------------------------|
| End point title | Percentage of participants with at least one Adverse Events (AEs) of interest |
|-----------------|-------------------------------------------------------------------------------|

End point description:

Adverse events of interest (AEOI) were identified by the Investigator based on definitions per protocol, documented on the electronic Case Report Form (eCRF), adequately monitored, and source controlled.

AEOI (regardless of seriousness):

- Moderate to severe infections, including opportunistic infections and tuberculosis (TB)
- Infusion reactions (including hypersensitivity and anaphylaxis)
- Thromboembolic events (including but not limited to cardiovascular events, stroke, myocardial

infarction, pulmonary embolism, and deep vein thrombosis)

- Prespecified neurological events: severe and/or serious headache, positional headache, cranial nerve dysfunction, or signs and symptoms of meningitis (photophobia, neck stiffness)

- Malignancies.

The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug.

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

End point timeframe:

From Baseline (Week 1) until end of the study (Week 48)

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|-----------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: percentage of participants | | | | |
| number (not applicable) | 24.4 | 26.7 | 28.9 | 25.5 |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants who permanently withdrew of study drug due to an Adverse Event (AE)

| | |
|-----------------|------------------------------------------------------------------------------------------------|
| End point title | Percentage of participants who permanently withdrew of study drug due to an Adverse Event (AE) |
|-----------------|------------------------------------------------------------------------------------------------|

End point description:

An AE was any untoward medical occurrence in a patient or clinical investigation participant administered a pharmaceutical product that did not necessarily have a causal relationship with this treatment. An adverse event (AE) was therefore any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product. All AEs that occurred during the study were considered related unless clearly unrelated. The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug.

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

End point timeframe:

From Baseline (Week 1) until end of the study (Week 48)

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|-----------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: percentage of participants | | | | |
| number (not applicable) | 8.9 | 0 | 4.4 | 4.3 |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Systolic Blood Pressure

| | |
|-----------------|------------------------------------------------------|
| End point title | Mean change from baseline in Systolic Blood Pressure |
|-----------------|------------------------------------------------------|

End point description:

Blood pressure was measured in millimetre of mercury (mmHg). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

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

End point timeframe:

From Baseline (Week 1) to Week 48

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|--------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: mmHg | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 (45, 45, 45, 44) | 3.3 (± 12.9) | 5.1 (± 10.5) | 0.7 (± 10.7) | 3.2 (± 9.9) |
| Week 4 (43, 44, 43, 46) | 0.6 (± 10.8) | 1.0 (± 7.9) | -2.0 (± 8.9) | 0.6 (± 12.4) |
| Week 6 (43, 45, 44, 45) | 0.3 (± 11.5) | 4.0 (± 9.9) | 2.3 (± 11.0) | 2.4 (± 10.6) |
| Week 8 (44, 44, 44, 43) | 0.5 (± 12.4) | 3.3 (± 12.6) | -2.4 (± 9.9) | -0.7 (± 11.9) |
| Week 12 (44, 45, 45, 44) | -0.7 (± 10.1) | 3.2 (± 10.5) | -3.0 (± 11.8) | 0.8 (± 9.2) |
| Week 16 (43, 44, 43, 44) | 2.1 (± 12.3) | 2.1 (± 11.6) | -2.8 (± 10.6) | 0.9 (± 11.1) |
| Week 20 (42, 45, 42, 44) | 1.6 (± 9.9) | 2.6 (± 9.8) | -1.7 (± 12.3) | 1.5 (± 11.3) |
| Week 24 (43, 44, 44, 44) | -0.7 (± 14.3) | 1.1 (± 13.1) | 0.3 (± 11.0) | 3.6 (± 9.3) |
| Week 28 (44, 43, 42, 44) | 1.8 (± 12.3) | 3.7 (± 13.1) | 0.9 (± 10.5) | 2.5 (± 11.8) |
| Week 32 (44, 44, 43, 45) | 2.2 (± 11.1) | 3.0 (± 13.2) | 0.4 (± 11.3) | 4.3 (± 13.7) |
| Week 36 (42, 42, 41, 41) | 2.1 (± 11.0) | 3.1 (± 12.6) | 0.2 (± 10.5) | 2.4 (± 12.9) |
| Week 40 (42, 43, 41, 44) | -1.0 (± 14.1) | 6.2 (± 12.9) | -2.0 (± 11.7) | 2.5 (± 11.3) |
| Week 44 (39, 41, 41, 42) | 0.1 (± 12.6) | 3.3 (± 14.1) | 1.3 (± 10.4) | 4.2 (± 11.8) |
| Week 48 (38, 42, 40, 42) | -1.5 (± 11.5) | 4.9 (± 14.3) | 0.1 (± 10.2) | 4.4 (± 12.0) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Diastolic Blood Pressure

| | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|
| End point title | Mean change from baseline in Diastolic Blood Pressure |
| End point description: | |
| Blood pressure was measured in millimetre of mercury (mmHg). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points. | |
| End point type | Secondary |
| End point timeframe: | |
| From Baseline (Week 1) to Week 48 | |

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|--------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: mmHg | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 (45, 45, 45, 44) | 2.1 (± 10.5) | 1.4 (± 8.6) | 1.5 (± 9.3) | 2.4 (± 8.2) |
| Week 4 (43, 44, 43, 46) | -0.7 (± 7.8) | -1.5 (± 6.3) | -1.7 (± 8.2) | -0.1 (± 8.3) |
| Week 6 (43, 45, 44, 45) | 1.0 (± 10.0) | 1.5 (± 8.6) | 1.8 (± 10.0) | 1.9 (± 7.9) |
| Week 8 (44, 44, 44, 43) | 1.1 (± 9.2) | 0.4 (± 9.1) | 0.1 (± 8.6) | 1.0 (± 8.0) |
| Week 12 (44, 45, 45, 44) | -0.9 (± 8.4) | -0.3 (± 6.9) | -2.2 (± 9.6) | -0.3 (± 6.9) |
| Week 16 (43, 44, 43, 44) | -0.3 (± 8.9) | -1.3 (± 7.6) | -0.7 (± 9.5) | -0.1 (± 7.0) |
| Week 20 (42, 45, 42, 44) | 1.5 (± 8.1) | -1.1 (± 8.7) | -0.7 (± 9.6) | 0.9 (± 8.8) |
| Week 24 (43, 44, 44, 44) | 1.9 (± 11.2) | 1.6 (± 8.7) | 2.3 (± 10.7) | 0.6 (± 8.7) |
| Week 28 (44, 43, 42, 44) | 1.5 (± 9.1) | -0.2 (± 8.8) | 1.4 (± 8.4) | 2.5 (± 8.4) |
| Week 32 (44, 44, 43, 45) | 2.3 (± 10.1) | 2.8 (± 9.3) | 0.7 (± 10.2) | 2.3 (± 8.1) |
| Week 36 (42, 42, 41, 41) | 3.4 (± 9.8) | 1.4 (± 10.2) | 1.4 (± 8.4) | 2.2 (± 8.0) |
| Week 40 (42, 43, 41, 44) | 1.0 (± 9.2) | 2.6 (± 7.6) | 0.5 (± 9.9) | 3.6 (± 8.8) |
| Week 44 (39, 41, 41, 42) | 0.8 (± 10.2) | 1.5 (± 8.1) | 0.4 (± 9.4) | 2.2 (± 10.3) |
| Week 48 (38, 42, 40, 42) | 1.4 (± 9.0) | 2.3 (± 8.8) | 1.1 (± 9.4) | 2.4 (± 8.6) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Pulse Rate

| | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|
| End point title | Mean change from baseline in Pulse Rate |
| End point description: | |
| Pulse Rate was measured in beats per minute (beats/min). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points. | |
| End point type | Secondary |
| End point timeframe: | |
| From Baseline (Week 1) to Week 48 | |

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|--------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: beats/min | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 (45, 45, 45, 44) | -0.2 (± 8.3) | 0.2 (± 10.4) | 2.3 (± 9.7) | -0.9 (± 10.4) |
| Week 4 (43, 44, 43, 46) | 1.7 (± 9.6) | 1.5 (± 8.0) | 0.4 (± 8.4) | -3.3 (± 9.7) |
| Week 6 (43, 45, 44, 45) | -0.7 (± 10.2) | 0.1 (± 8.5) | 0.8 (± 8.9) | -0.6 (± 8.8) |
| Week 8 (44, 44, 44, 43) | 1.3 (± 9.0) | 0.3 (± 9.2) | 1.4 (± 10.2) | -2.6 (± 10.2) |
| Week 12 (44, 45, 45, 44) | 0.6 (± 10.3) | 1.1 (± 9.8) | -0.3 (± 10.4) | -1.5 (± 9.7) |
| Week 16 (43, 44, 43, 44) | -0.8 (± 9.2) | 0.3 (± 8.9) | 0.9 (± 10.7) | -1.6 (± 10.6) |
| Week 20 (42, 45, 42, 44) | 0.3 (± 10.6) | 1.1 (± 9.9) | 0.8 (± 9.5) | 0.4 (± 6.6) |
| Week 24 (43, 44, 44, 44) | -1.5 (± 10.7) | 0.8 (± 10.9) | -0.3 (± 10.2) | -1.0 (± 8.7) |
| Week 28 (44, 43, 42, 44) | 0.6 (± 11.8) | 1.3 (± 10.9) | 0.0 (± 9.2) | 0.6 (± 8.8) |
| Week 32 (44, 44, 43, 45) | 0.4 (± 9.8) | 1.3 (± 10.9) | 0.8 (± 11.4) | -2.1 (± 11.0) |
| Week 36 (42, 42, 41, 41) | -0.7 (± 10.9) | 0.2 (± 8.3) | 0.7 (± 10.4) | -0.2 (± 9.8) |
| Week 40 (42, 43, 41, 44) | -0.1 (± 10.9) | -0.1 (± 9.8) | 0.6 (± 10.2) | -1.3 (± 9.6) |
| Week 44 (39, 41, 41, 42) | -0.2 (± 10.2) | -0.1 (± 9.8) | 0.3 (± 11.7) | -0.6 (± 8.9) |
| Week 48 (38, 42, 40, 42) | -0.2 (± 11.1) | -0.7 (± 10.6) | -0.9 (± 11.9) | -2.0 (± 7.7) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Temperature

| | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|
| End point title | Mean change from baseline in Temperature |
| End point description: | |
| Temperature was measured in Grad Celsius (°C). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points. | |
| End point type | Secondary |
| End point timeframe: | |
| From Baseline (Week 1) to Week 48 | |

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|--------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: Temperature (C) | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 (45, 45, 45, 44) | -0.1 (± 0.4) | 0.0 (± 0.3) | 0.1 (± 0.5) | 0.0 (± 0.4) |
| Week 4 (43, 44, 43, 46) | -0.1 (± 0.4) | 0.0 (± 0.4) | 0.0 (± 0.4) | 0.0 (± 0.3) |
| Week 6 (43, 45, 44, 45) | -0.2 (± 0.5) | 0.0 (± 0.4) | 0.1 (± 0.5) | 0.0 (± 0.5) |
| Week 8 (44, 44, 44, 43) | -0.1 (± 0.4) | -0.1 (± 0.3) | 0.0 (± 0.4) | 0.0 (± 0.4) |
| Week 12 (44, 45, 45, 44) | -0.1 (± 0.4) | -0.1 (± 0.4) | 0.0 (± 0.3) | 0.0 (± 0.4) |

| | | | | |
|--------------------------|--------------|-------------|-------------|-------------|
| Week 16 (43, 44, 43, 44) | -0.1 (± 0.4) | 0.0 (± 0.4) | 0.0 (± 0.4) | 0.0 (± 0.3) |
| Week 20 (42, 45, 42, 44) | -0.1 (± 0.4) | 0.0 (± 0.4) | 0.0 (± 0.4) | 0.0 (± 0.5) |
| Week 24 (43, 44, 44, 44) | -0.1 (± 0.5) | 0.0 (± 0.4) | 0.1 (± 0.5) | 0.0 (± 0.4) |
| Week 28 (44, 43, 42, 44) | 0.0 (± 0.4) | 0.0 (± 0.4) | 0.1 (± 0.5) | 0.1 (± 0.5) |
| Week 32 (44, 44, 43, 45) | 0.0 (± 0.4) | 0.0 (± 0.4) | 0.1 (± 0.5) | 0.0 (± 0.4) |
| Week 36 (42, 42, 41, 41) | -0.1 (± 0.3) | 0.0 (± 0.6) | 0.0 (± 0.4) | 0.1 (± 0.4) |
| Week 40 (42, 43, 41, 44) | 0.0 (± 0.4) | 0.0 (± 0.4) | 0.0 (± 0.5) | 0.1 (± 0.3) |
| Week 44 (39, 41, 41, 42) | 0.0 (± 0.6) | 0.0 (± 0.5) | 0.1 (± 0.4) | 0.0 (± 0.4) |
| Week 48 (38, 42, 40, 42) | -0.1 (± 0.4) | 0.0 (± 0.4) | 0.0 (± 0.5) | 0.0 (± 0.4) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Weight

| | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|
| End point title | Mean change from baseline in Weight |
| End point description: Weight was measured in kilograms (kg). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points. | |
| End point type | Secondary |
| End point timeframe: Baseline (Week 1), Week 4, Week 8, Week 12, Week 16, and Week 20 | |

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|--------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: kg | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 4 (43, 44, 43, 46) | 0.0 (± 1.0) | 0.2 (± 1.0) | 0.4 (± 0.9) | 0.3 (± 1.2) |
| Week 8 (44, 44, 43, 43) | 0.3 (± 1.9) | 0.6 (± 1.4) | 0.6 (± 1.8) | 0.4 (± 1.8) |
| Week 12 (43, 45, 44, 44) | 0.4 (± 2.3) | 0.5 (± 1.6) | 0.5 (± 2.0) | 0.6 (± 2.3) |
| Week 16 (43, 44, 43, 44) | 0.3 (± 2.3) | 0.7 (± 2.3) | 0.8 (± 2.3) | 0.5 (± 2.4) |
| Week 20 (42, 45, 42, 44) | 0.3 (± 2.4) | 0.7 (± 2.6) | 1.0 (± 2.6) | 0.5 (± 2.8) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Height

| | |
|--------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|
| End point title | Mean change from baseline in Height |
| End point description: Height was measured in centimeters (cm). The Safety Set (SS) consisted of all study participants who | |

were randomized and received at least 1 dose (any amount) of study drug. Here, '999' was used as a placeholder and signifies that height was only measured at Screening as per planned analysis. Therefore, data was not collected for this outcome measure.

| | |
|-----------------------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| From Baseline (Week 1) to Week 48 | |

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|--------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: cm | | | | |
| arithmetic mean (standard deviation) | 999 (± 999) | 999 (± 999) | 999 (± 999) | 999 (± 999) |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with 12-Lead electrocardiogram (ECG) abnormal findings

| | |
|-----------------|-------------------------------------------------------------------------------|
| End point title | Number of participants with 12-Lead electrocardiogram (ECG) abnormal findings |
|-----------------|-------------------------------------------------------------------------------|

End point description:

Twelve-lead ECG assessments should have been performed prior to dosing (if applicable) and prior to obtaining pharmacokinetic (PK) or other laboratory samples. Electrocardiograms were recorded digitally and read by the Investigator for recording in the electronic Case Report Form (eCRF). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug.

| | |
|--------------------------------------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Screening, Week 4, Week 24, Week 28, and Week 48 | |

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|-----------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: participants | | | | |
| Screening | 8 | 11 | 6 | 6 |
| Week 4 | 11 | 12 | 7 | 10 |
| Week 24 | 9 | 7 | 6 | 10 |
| Week 28 | 1 | 0 | 0 | 0 |
| Week 48 | 8 | 7 | 11 | 9 |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Hemoglobin

| | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|
| End point title | Mean change from baseline in Hemoglobin |
| End point description: Hemoglobin was measured in grams per liter (g/L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points. | |
| End point type | Secondary |
| End point timeframe: From Baseline (Week 1) to Week 48 | |

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|--------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: g/L | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 (44, 42, 45, 42) | 0.4 (± 6.4) | -1.8 (± 5.8) | -0.7 (± 6.9) | -0.7 (± 6.8) |
| Week 4 (44, 44, 43, 46) | -1.0 (± 7.2) | -0.7 (± 7.7) | -1.4 (± 8.6) | -0.8 (± 5.8) |
| Week 8 (43, 44, 44, 44) | -0.3 (± 7.3) | -1.9 (± 7.9) | -1.9 (± 8.6) | -1.3 (± 7.4) |
| Week 12 (44, 44, 44, 44) | -0.5 (± 9.5) | -0.5 (± 8.5) | -0.5 (± 10.1) | 0.2 (± 8.3) |
| Week 16 (44, 43, 43, 45) | 0.3 (± 10.4) | -0.3 (± 10.0) | -0.8 (± 10.6) | -2.7 (± 8.3) |
| Week 20 (43, 43, 41, 43) | -0.7 (± 11.5) | 0.3 (± 9.9) | -0.5 (± 10.1) | -2.4 (± 7.2) |
| Week 24 (42, 43, 44, 44) | -0.4 (± 9.7) | -0.7 (± 11.2) | -0.7 (± 10.5) | -2.9 (± 8.1) |
| Week 28 (44, 41, 41, 44) | 0.7 (± 10.6) | -3.4 (± 11.0) | 0.0 (± 14.1) | -3.1 (± 9.5) |
| Week 32 (43, 43, 43, 42) | 1.6 (± 12.5) | -1.3 (± 9.8) | 1.0 (± 12.5) | -1.3 (± 9.6) |
| Week 40 (42, 43, 41, 44) | 0.7 (± 13.5) | -0.3 (± 13.5) | 1.9 (± 14.9) | 1.1 (± 11.0) |
| Week 48 (38, 42, 39, 42) | -0.5 (± 14.3) | -1.5 (± 11.6) | 0.9 (± 12.5) | -0.7 (± 10.0) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Hematocrit

| | |
|-----------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|
| End point title | Mean change from baseline in Hematocrit |
| End point description: Hematocrit was measured in volume percentage (%) of red blood cells in blood. The Safety Set (SS) | |

consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

| | |
|-----------------------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| From Baseline (Week 1) to Week 48 | |

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|--------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: volume % of red blood cells | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 (44, 42, 45, 42) | 0.42 (± 2.52) | -0.25 (± 2.26) | -0.32 (± 2.37) | 0.00 (± 2.71) |
| Week 4 (44, 44, 43, 46) | -0.46 (± 2.29) | -0.17 (± 2.75) | -0.79 (± 2.92) | -0.11 (± 2.31) |
| Week 8 (43, 44, 44, 44) | -0.27 (± 2.23) | -0.12 (± 2.94) | -0.86 (± 2.72) | -0.42 (± 2.31) |
| Week 12 (44, 44, 44, 44) | -0.23 (± 2.67) | -0.13 (± 2.72) | -0.32 (± 3.39) | -0.02 (± 2.54) |
| Week 16 (44, 43, 43, 45) | -0.12 (± 2.86) | 0.05 (± 3.25) | -0.57 (± 3.32) | -0.84 (± 2.95) |
| Week 20 (43, 43, 41, 43) | -0.41 (± 3.20) | 0.13 (± 2.99) | -0.42 (± 3.32) | -0.80 (± 2.83) |
| Week 24 (42, 43, 44, 44) | -0.09 (± 2.61) | -0.40 (± 3.19) | -0.29 (± 3.14) | -0.76 (± 2.33) |
| Week 28 (44, 41, 41, 44) | 0.03 (± 2.98) | -1.02 (± 3.23) | -0.22 (± 3.99) | -0.89 (± 2.47) |
| Week 32 (43, 43, 43, 42) | 0.29 (± 2.89) | -0.62 (± 2.86) | 0.17 (± 3.43) | -0.21 (± 2.82) |
| Week 40 (42, 43, 41, 44) | -0.20 (± 3.32) | -0.24 (± 4.37) | 0.58 (± 4.11) | 0.37 (± 2.72) |
| Week 48 (38, 42, 39, 42) | -0.59 (± 3.51) | -0.37 (± 3.58) | -0.08 (± 3.21) | -0.11 (± 2.54) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Erythrocytes

| | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|
| End point title | Mean change from baseline in Erythrocytes |
| End point description: | |
| Erythrocytes was measured in number of erythrocytes per liter (10 ¹² /L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points. | |
| End point type | Secondary |
| End point timeframe: | |
| From Baseline (Week 1) to Week 48 | |

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|------------------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: 10 ¹² erythrocytes per liter | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 (44, 42, 45, 42) | -0.004 (± 0.246) | -0.035 (± 0.237) | -0.032 (± 0.223) | -0.028 (± 0.237) |
| Week 4 (44, 44, 43, 46) | -0.080 (± 0.243) | -0.018 (± 0.293) | -0.052 (± 0.273) | -0.033 (± 0.210) |
| Week 8 (43, 44, 44, 44) | -0.039 (± 0.224) | -0.039 (± 0.280) | -0.069 (± 0.262) | -0.044 (± 0.242) |
| Week 12 (44, 44, 44, 44) | -0.024 (± 0.271) | 0.014 (± 0.292) | -0.010 (± 0.267) | 0.019 (± 0.226) |
| Week 16 (44, 43, 43, 45) | -0.002 (± 0.312) | 0.041 (± 0.360) | 0.000 (± 0.302) | -0.051 (± 0.265) |
| Week 20 (43, 43, 41, 43) | -0.029 (± 0.333) | 0.062 (± 0.309) | -0.001 (± 0.325) | -0.047 (± 0.302) |
| Week 24 (42, 43, 44, 44) | 0.005 (± 0.308) | 0.036 (± 0.312) | 0.013 (± 0.319) | -0.038 (± 0.240) |
| Week 28 (44, 41, 41, 44) | 0.018 (± 0.340) | -0.040 (± 0.304) | 0.019 (± 0.346) | -0.050 (± 0.270) |
| Week 32 (43, 43, 43, 42) | 0.048 (± 0.320) | 0.001 (± 0.284) | 0.032 (± 0.289) | 0.027 (± 0.277) |
| Week 40 (42, 43, 41, 44) | -0.005 (± 0.343) | 0.042 (± 0.382) | 0.054 (± 0.368) | 0.060 (± 0.256) |
| Week 48 (38, 42, 39, 42) | -0.024 (± 0.332) | -0.018 (± 0.295) | 0.017 (± 0.299) | -0.028 (± 0.245) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Erythrocytes Mean Corpuscular Volume

| | |
|-----------------|-------------------------------------------------------------------|
| End point title | Mean change from baseline in Erythrocytes Mean Corpuscular Volume |
|-----------------|-------------------------------------------------------------------|

End point description:

Erythrocytes Mean Corpuscular Volume was measured in femtolitres (fL). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

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

End point timeframe:

From Baseline (Week 1) to Week 48

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|--------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: Femtolitres (fL) | | | | |
| arithmetic mean (standard deviation) | | | | |

| | | | | |
|--------------------------|----------------|----------------|----------------|----------------|
| Week 2 (44, 42, 45, 42) | 1.01 (± 2.28) | 0.24 (± 2.40) | -0.09 (± 2.66) | 0.45 (± 2.96) |
| Week 4 (44, 44, 43, 46) | 0.60 (± 2.35) | 0.08 (± 2.66) | -0.68 (± 2.10) | 0.40 (± 3.02) |
| Week 8 (43, 44, 44, 44) | 0.23 (± 3.48) | -0.30 (± 5.36) | -0.54 (± 2.85) | -0.16 (± 2.79) |
| Week 12 (44, 44, 44, 44) | 0.06 (± 3.57) | -0.52 (± 3.44) | -0.55 (± 4.67) | -0.57 (± 3.09) |
| Week 16 (44, 43, 43, 45) | -0.25 (± 3.41) | -0.65 (± 4.38) | -1.38 (± 4.87) | -0.97 (± 3.62) |
| Week 20 (43, 43, 41, 43) | -0.37 (± 3.73) | -0.92 (± 4.58) | -1.00 (± 5.01) | -0.97 (± 3.54) |
| Week 24 (42, 43, 44, 44) | -0.23 (± 3.83) | -1.63 (± 4.07) | -0.92 (± 6.51) | -1.05 (± 4.00) |
| Week 28 (44, 41, 41, 44) | -0.33 (± 3.61) | -1.40 (± 4.61) | -0.96 (± 6.46) | -1.21 (± 4.91) |
| Week 32 (43, 43, 43, 42) | -0.27 (± 4.45) | -1.33 (± 4.32) | -0.45 (± 6.81) | -1.06 (± 4.69) |
| Week 40 (42, 43, 41, 44) | -0.36 (± 5.34) | -1.46 (± 4.72) | 0.07 (± 6.27) | -0.24 (± 4.85) |
| Week 48 (38, 42, 39, 42) | -0.98 (± 5.34) | -0.50 (± 4.97) | -0.63 (± 6.92) | 0.34 (± 4.31) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Erythrocytes Mean Corpuscular Hemoglobin (HGB) Concentration

| | |
|-----------------|-------------------------------------------------------------------------------------------|
| End point title | Mean change from baseline in Erythrocytes Mean Corpuscular Hemoglobin (HGB) Concentration |
|-----------------|-------------------------------------------------------------------------------------------|

End point description:

Erythrocytes Mean Corpuscular Hemoglobin (HGB) Concentration was measured in grams per liter (g/L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

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

End point timeframe:

From Baseline (Week 1) to Week 48

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|--------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: g/L | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 (44, 42, 45, 42) | -2.3 (± 9.8) | -2.6 (± 10.9) | 0.7 (± 9.8) | -1.9 (± 10.1) |
| Week 4 (44, 44, 43, 46) | 1.4 (± 8.7) | -0.9 (± 10.1) | 2.7 (± 8.6) | -1.2 (± 12.5) |
| Week 8 (43, 44, 44, 44) | 1.7 (± 11.5) | -3.8 (± 13.4) | 2.1 (± 8.2) | -0.1 (± 11.5) |
| Week 12 (44, 44, 44, 44) | 0.5 (± 11.1) | -0.6 (± 10.7) | 0.6 (± 12.3) | 0.5 (± 12.7) |
| Week 16 (44, 43, 43, 45) | 1.6 (± 13.8) | -1.5 (± 10.1) | 2.3 (± 11.3) | -0.2 (± 14.1) |
| Week 20 (43, 43, 41, 43) | 1.6 (± 12.9) | -0.9 (± 11.3) | 2.4 (± 11.2) | 0.4 (± 12.6) |
| Week 24 (42, 43, 44, 44) | 0.0 (± 13.7) | 1.0 (± 13.2) | 0.4 (± 12.8) | -1.2 (± 13.1) |
| Week 28 (44, 41, 41, 44) | 1.6 (± 13.4) | -1.3 (± 14.4) | 1.7 (± 13.8) | -0.6 (± 16.5) |
| Week 32 (43, 43, 43, 42) | 1.7 (± 18.9) | 1.1 (± 13.8) | 1.2 (± 15.0) | -1.4 (± 16.0) |
| Week 40 (42, 43, 41, 44) | 3.4 (± 17.6) | 0.8 (± 16.5) | 0.1 (± 15.8) | 0.1 (± 15.4) |
| Week 48 (38, 42, 39, 42) | 3.6 (± 17.1) | -0.6 (± 16.2) | 2.9 (± 14.5) | 0.0 (± 13.5) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Erythrocytes Mean Corpuscular Hemoglobin

| | |
|-----------------|-----------------------------------------------------------------------|
| End point title | Mean change from baseline in Erythrocytes Mean Corpuscular Hemoglobin |
|-----------------|-----------------------------------------------------------------------|

End point description:

Erythrocytes Mean Corpuscular Hemoglobin was measured in picograms (pg). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

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

End point timeframe:

From Baseline (Week 1) to Week 48

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|--------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: Picograms (pg) | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 (44, 42, 45, 42) | 0.12 (± 0.71) | -0.18 (± 0.65) | 0.04 (± 0.43) | 0.00 (± 0.47) |
| Week 4 (44, 44, 43, 46) | 0.31 (± 0.63) | -0.06 (± 0.79) | 0.04 (± 0.64) | 0.02 (± 0.65) |
| Week 8 (43, 44, 44, 44) | 0.20 (± 0.87) | -0.25 (± 0.87) | 0.04 (± 0.81) | -0.04 (± 0.74) |
| Week 12 (44, 44, 44, 44) | 0.04 (± 1.08) | -0.25 (± 1.03) | -0.09 (± 1.25) | -0.12 (± 0.90) |
| Week 16 (44, 43, 43, 45) | 0.03 (± 1.43) | -0.36 (± 1.31) | -0.20 (± 1.52) | -0.31 (± 1.19) |
| Week 20 (43, 43, 41, 43) | 0.00 (± 1.49) | -0.39 (± 1.40) | -0.10 (± 1.63) | -0.26 (± 1.24) |
| Week 24 (42, 43, 44, 44) | -0.13 (± 1.57) | -0.43 (± 1.39) | -0.25 (± 1.96) | -0.44 (± 1.42) |
| Week 28 (44, 41, 41, 44) | 0.01 (± 1.68) | -0.55 (± 1.45) | -0.15 (± 2.09) | -0.44 (± 1.68) |
| Week 32 (43, 43, 43, 42) | 0.01 (± 2.12) | -0.33 (± 1.28) | -0.06 (± 2.39) | -0.48 (± 1.63) |
| Week 40 (42, 43, 41, 44) | 0.17 (± 2.50) | -0.40 (± 1.30) | 0.03 (± 2.32) | -0.09 (± 2.00) |
| Week 48 (38, 42, 39, 42) | 0.02 (± 2.58) | -0.21 (± 1.48) | 0.06 (± 2.55) | 0.10 (± 1.90) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Leukocytes

| | |
|-----------------|-----------------------------------------|
| End point title | Mean change from baseline in Leukocytes |
|-----------------|-----------------------------------------|

End point description:

Leukocytes was measured in number of leukocytes per liter ($10^9/L$). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

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

End point timeframe:

From Baseline (Week 1) to Week 48

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|--------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: 10^9 leukocytes per liter | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 (44, 42, 45, 42) | 0.34 (\pm 2.45) | 0.27 (\pm 1.23) | 0.49 (\pm 1.46) | 0.20 (\pm 1.62) |
| Week 4 (44, 44, 43, 46) | 0.10 (\pm 1.88) | 0.27 (\pm 1.63) | 0.25 (\pm 1.47) | 0.52 (\pm 2.11) |
| Week 8 (43, 44, 44, 44) | -0.25 (\pm 2.12) | 0.46 (\pm 1.41) | -0.05 (\pm 1.50) | -0.10 (\pm 1.65) |
| Week 12 (44, 44, 44, 43) | -0.27 (\pm 1.80) | 0.18 (\pm 1.73) | 0.17 (\pm 2.00) | 0.23 (\pm 2.01) |
| Week 16 (44, 43, 43, 45) | -0.31 (\pm 2.18) | 0.13 (\pm 1.55) | 0.21 (\pm 1.69) | -0.20 (\pm 2.12) |
| Week 20 (43, 43, 41, 43) | -0.24 (\pm 2.27) | -0.06 (\pm 1.59) | -0.22 (\pm 1.74) | 0.30 (\pm 2.61) |
| Week 24 (42, 43, 44, 44) | -0.22 (\pm 2.41) | -0.12 (\pm 1.83) | -0.14 (\pm 1.75) | -0.34 (\pm 1.97) |
| Week 28 (44, 41, 41, 44) | 0.05 (\pm 2.04) | 0.06 (\pm 1.93) | 0.26 (\pm 2.04) | -0.58 (\pm 1.70) |
| Week 32 (43, 43, 43, 42) | -0.14 (\pm 2.20) | 0.08 (\pm 1.64) | 0.19 (\pm 1.67) | -0.44 (\pm 1.68) |
| Week 40 (42, 43, 41, 44) | 0.17 (\pm 2.54) | 0.04 (\pm 1.60) | -0.35 (\pm 1.49) | -0.49 (\pm 1.96) |
| Week 48 (38, 42, 39, 42) | -0.49 (\pm 1.83) | 0.30 (\pm 1.53) | -0.14 (\pm 2.06) | -0.62 (\pm 1.87) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Basophils

| | |
|-----------------|----------------------------------------|
| End point title | Mean change from baseline in Basophils |
|-----------------|----------------------------------------|

End point description:

Basophils was measured in number of basophils per liter ($10^9/L$). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

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

End point timeframe:

From Baseline (Week 1) to Week 48

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|--------------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: 10 ⁹ basophils per liter | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 (42, 39, 44, 41) | 0.01 (± 0.03) | 0.02 (± 0.04) | 0.00 (± 0.03) | 0.00 (± 0.02) |
| Week 4 (43, 43, 41, 46) | 0.01 (± 0.03) | 0.00 (± 0.03) | 0.01 (± 0.04) | 0.00 (± 0.02) |
| Week 8 (42, 41, 43, 43) | 0.01 (± 0.04) | 0.01 (± 0.04) | 0.01 (± 0.03) | 0.00 (± 0.02) |
| Week 12 (44, 40, 44, 42) | 0.01 (± 0.03) | 0.01 (± 0.04) | 0.00 (± 0.03) | 0.00 (± 0.03) |
| Week 16 (43, 42, 43, 44) | 0.01 (± 0.04) | 0.00 (± 0.03) | 0.01 (± 0.03) | 0.00 (± 0.03) |
| Week 20 (42, 40, 40, 42) | 0.00 (± 0.03) | 0.01 (± 0.03) | 0.00 (± 0.03) | 0.00 (± 0.03) |
| Week 24 (41, 40, 44, 44) | 0.00 (± 0.03) | 0.02 (± 0.04) | 0.00 (± 0.03) | 0.00 (± 0.03) |
| Week 28 (44, 39, 40, 44) | 0.02 (± 0.05) | 0.01 (± 0.04) | 0.00 (± 0.02) | 0.00 (± 0.03) |
| Week 32 (41, 40, 43, 42) | 0.00 (± 0.03) | 0.00 (± 0.02) | 0.01 (± 0.03) | 0.00 (± 0.03) |
| Week 40 (41, 42, 40, 43) | 0.00 (± 0.02) | 0.00 (± 0.02) | 0.01 (± 0.03) | 0.00 (± 0.03) |
| Week 48 (37, 41, 39, 41) | 0.00 (± 0.03) | 0.00 (± 0.02) | 0.00 (± 0.03) | 0.01 (± 0.03) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Basophils/Leukocytes

| | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|
| End point title | Mean change from baseline in Basophils/Leukocytes |
| End point description: Basophils/Leukocytes was measured in percentages (%). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points. | |
| End point type | Secondary |
| End point timeframe: From Baseline (Week 1) to Week 48 | |

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|--------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: % of Basophils per Leukocytes | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 (42, 39, 44, 41) | -0.05 (± 0.23) | 0.02 (± 0.20) | -0.05 (± 0.31) | -0.03 (± 0.27) |
| Week 4 (43, 43, 41, 46) | 0.03 (± 0.27) | -0.06 (± 0.26) | -0.01 (± 0.43) | -0.07 (± 0.26) |
| Week 8 (42, 41, 43, 43) | 0.08 (± 0.42) | 0.03 (± 0.32) | 0.00 (± 0.33) | -0.06 (± 0.23) |
| Week 12 (44, 40, 44, 42) | 0.04 (± 0.30) | 0.09 (± 0.48) | 0.00 (± 0.25) | -0.07 (± 0.28) |
| Week 16 (43, 42, 43, 44) | 0.01 (± 0.25) | 0.00 (± 0.28) | -0.02 (± 0.31) | -0.05 (± 0.30) |
| Week 20 (42, 40, 40, 42) | -0.02 (± 0.26) | 0.00 (± 0.27) | -0.07 (± 0.29) | -0.04 (± 0.32) |
| Week 24 (41, 40, 44, 44) | -0.04 (± 0.31) | 0.15 (± 0.44) | -0.03 (± 0.24) | -0.03 (± 0.21) |
| Week 28 (44, 39, 40, 44) | 0.08 (± 0.54) | 0.03 (± 0.29) | 0.00 (± 0.24) | 0.07 (± 0.32) |

| | | | | |
|--------------------------|----------------|----------------|---------------|---------------|
| Week 32 (41, 40, 43, 42) | -0.03 (± 0.29) | 0.00 (± 0.23) | 0.01 (± 0.25) | 0.01 (± 0.25) |
| Week 40 (41, 42, 40, 43) | -0.08 (± 0.24) | -0.03 (± 0.25) | 0.07 (± 0.29) | 0.01 (± 0.29) |
| Week 48 (37, 41, 39, 41) | -0.01 (± 0.29) | -0.08 (± 0.21) | 0.02 (± 0.25) | 0.06 (± 0.28) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Eosinophils

| | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|
| End point title | Mean change from baseline in Eosinophils |
| End point description: Eosinophils was measured in number of eosinophils per liter (10 ⁹ /L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points. | |
| End point type | Secondary |
| End point timeframe: From Baseline (Week 1) to Week 48 | |

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|----------------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: 10 ⁹ eosinophils per liter | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 (42, 39, 44, 41) | -0.01 (± 0.04) | 0.01 (± 0.06) | 0.00 (± 0.09) | -0.01 (± 0.05) |
| Week 4 (43, 43, 41, 46) | -0.01 (± 0.04) | -0.01 (± 0.06) | 0.00 (± 0.04) | -0.01 (± 0.04) |
| Week 8 (42, 41, 43, 43) | -0.01 (± 0.04) | 0.03 (± 0.16) | 0.00 (± 0.04) | 0.01 (± 0.07) |
| Week 12 (44, 40, 44, 42) | 0.00 (± 0.04) | 0.04 (± 0.20) | 0.02 (± 0.10) | 0.02 (± 0.17) |
| Week 16 (43, 42, 43, 44) | 0.00 (± 0.05) | 0.02 (± 0.11) | 0.01 (± 0.05) | 0.00 (± 0.06) |
| Week 20 (42, 40, 40, 42) | 0.00 (± 0.05) | 0.04 (± 0.24) | 0.01 (± 0.05) | -0.01 (± 0.05) |
| Week 24 (41, 40, 44, 44) | -0.01 (± 0.05) | 0.04 (± 0.15) | 0.02 (± 0.07) | -0.02 (± 0.06) |
| Week 28 (44, 39, 40, 44) | -0.01 (± 0.04) | 0.01 (± 0.07) | 0.01 (± 0.05) | 0.00 (± 0.06) |
| Week 32 (41, 40, 43, 42) | -0.01 (± 0.06) | 0.01 (± 0.10) | 0.01 (± 0.05) | -0.02 (± 0.04) |
| Week 40 (41, 42, 40, 43) | 0.00 (± 0.05) | 0.01 (± 0.06) | 0.02 (± 0.06) | 0.00 (± 0.07) |
| Week 48 (37, 41, 39, 41) | 0.00 (± 0.04) | -0.01 (± 0.05) | 0.00 (± 0.06) | 0.00 (± 0.06) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Eosinophils/Leukocytes

| | |
|------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|
| End point title | Mean change from baseline in Eosinophils/Leukocytes |
| End point description: Eosinophils/Leukocytes was measured in percentages (%). The Safety Set (SS) consisted of all study | |

participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

| | |
|-----------------------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| From Baseline (Week 1) to Week 48 | |

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|----------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: % of Eosinophils per Leukocytes | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 (42, 39, 44, 41) | -0.19 (± 1.07) | 0.07 (± 0.86) | -0.18 (± 1.13) | -0.29 (± 1.22) |
| Week 4 (43, 43, 41, 46) | -0.32 (± 0.96) | -0.05 (± 1.26) | -0.12 (± 1.01) | -0.26 (± 0.94) |
| Week 8 (42, 41, 43, 43) | -0.05 (± 1.09) | 0.54 (± 2.13) | 0.10 (± 1.11) | 0.22 (± 1.89) |
| Week 12 (44, 40, 44, 42) | 0.18 (± 1.03) | 0.70 (± 3.12) | 0.33 (± 1.68) | 0.05 (± 1.83) |
| Week 16 (43, 42, 43, 44) | 0.06 (± 1.05) | 0.36 (± 1.24) | 0.20 (± 1.40) | -0.11 (± 1.33) |
| Week 20 (42, 40, 40, 42) | 0.04 (± 1.11) | 0.83 (± 3.58) | 0.11 (± 1.24) | -0.39 (± 1.29) |
| Week 24 (41, 40, 44, 44) | 0.11 (± 1.16) | 0.82 (± 2.89) | -0.01 (± 1.22) | 0.06 (± 1.63) |
| Week 28 (44, 39, 40, 44) | 0.06 (± 1.00) | 0.21 (± 1.33) | 0.18 (± 1.02) | -0.03 (± 1.35) |
| Week 32 (41, 40, 43, 42) | 0.02 (± 1.09) | 0.28 (± 1.60) | 0.16 (± 1.13) | -0.20 (± 1.03) |
| Week 40 (41, 42, 40, 43) | -0.10 (± 0.85) | 0.05 (± 1.09) | 0.40 (± 1.23) | -0.09 (± 1.47) |
| Week 48 (37, 41, 39, 41) | 0.09 (± 1.02) | -0.17 (± 1.08) | 0.06 (± 0.90) | 0.24 (± 1.03) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Lymphocytes

| | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|
| End point title | Mean change from baseline in Lymphocytes |
| End point description: | |
| Lymphocytes was measured in number of lymphocytes per liter (10 ⁹ /L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points. | |
| End point type | Secondary |
| End point timeframe: | |
| From Baseline (Week 1) to Week 48 | |

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|----------------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: 10 ⁹ lymphocytes per liter | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 (42, 39, 44, 41) | -0.03 (± 0.39) | 0.05 (± 0.36) | 0.16 (± 0.29) | 0.24 (± 0.37) |
| Week 4 (43, 43, 41, 46) | -0.04 (± 0.36) | -0.01 (± 0.47) | -0.01 (± 0.41) | 0.23 (± 0.42) |
| Week 8 (42, 41, 43, 43) | -0.15 (± 0.48) | -0.03 (± 0.39) | 0.06 (± 0.46) | 0.14 (± 0.50) |
| Week 12 (44, 40, 44, 42) | -0.06 (± 0.43) | 0.02 (± 0.59) | 0.01 (± 0.42) | 0.21 (± 0.51) |
| Week 16 (43, 42, 43, 44) | -0.09 (± 0.52) | -0.11 (± 0.51) | -0.02 (± 0.47) | 0.04 (± 0.40) |
| Week 20 (42, 40, 40, 42) | -0.14 (± 0.56) | -0.13 (± 0.54) | 0.02 (± 0.39) | 0.13 (± 0.55) |
| Week 24 (41, 40, 44, 44) | -0.11 (± 0.51) | -0.08 (± 0.60) | -0.03 (± 0.45) | 0.05 (± 0.52) |
| Week 28 (44, 39, 40, 44) | -0.04 (± 0.57) | -0.02 (± 0.59) | 0.01 (± 0.53) | 0.03 (± 0.56) |
| Week 32 (41, 40, 43, 42) | -0.11 (± 0.57) | -0.16 (± 0.59) | 0.05 (± 0.45) | -0.02 (± 0.44) |
| Week 40 (41, 42, 40, 43) | -0.11 (± 0.54) | -0.11 (± 0.52) | -0.11 (± 0.43) | -0.03 (± 0.48) |
| Week 48 (37, 41, 39, 41) | -0.19 (± 0.68) | -0.19 (± 0.60) | -0.10 (± 0.44) | -0.02 (± 0.49) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Lymphocytes/Leukocytes

| | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|
| End point title | Mean change from baseline in Lymphocytes/Leukocytes |
| End point description: Lymphocytes/Leukocytes was measured in percentages (%). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points. | |
| End point type | Secondary |
| End point timeframe: From Baseline (Week 1) to Week 48 | |

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|-------------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: % of Lymphocytes per Leukocytes | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 (42, 39, 44, 41) | -1.88 (± 9.01) | 0.19 (± 6.55) | 1.18 (± 6.09) | 2.61 (± 6.11) |
| Week 4 (43, 43, 41, 46) | -0.88 (± 7.09) | -1.02 (± 6.34) | -1.18 (± 9.93) | 0.97 (± 8.00) |
| Week 8 (42, 41, 43, 43) | -1.98 (± 10.59) | -1.40 (± 7.13) | 0.56 (± 10.20) | 1.97 (± 8.51) |
| Week 12 (44, 40, 44, 42) | 0.21 (± 7.87) | 0.56 (± 10.58) | -0.44 (± 9.90) | 2.46 (± 10.18) |
| Week 16 (43, 42, 43, 44) | -0.91 (± 8.33) | -1.49 (± 7.50) | -1.18 (± 9.65) | 0.12 (± 9.34) |
| Week 20 (42, 40, 40, 42) | -1.97 (± 10.37) | -0.66 (± 6.58) | 0.88 (± 10.69) | 0.71 (± 10.32) |

| | | | | |
|--------------------------|-----------------|----------------|-----------------|----------------|
| Week 24 (41, 40, 44, 44) | -0.75 (± 8.69) | -0.56 (± 7.35) | -0.52 (± 10.55) | 1.85 (± 9.67) |
| Week 28 (44, 39, 40, 44) | -1.18 (± 8.27) | -0.05 (± 8.51) | -0.05 (± 9.97) | 1.61 (± 10.55) |
| Week 32 (41, 40, 43, 42) | -1.59 (± 7.69) | -2.56 (± 6.51) | -0.16 (± 7.70) | 0.70 (± 8.74) |
| Week 40 (41, 42, 40, 43) | -2.60 (± 9.18) | -2.02 (± 5.99) | -1.36 (± 10.12) | 0.33 (± 8.41) |
| Week 48 (37, 41, 39, 41) | -1.46 (± 11.29) | -3.71 (± 7.41) | -0.84 (± 9.42) | 1.69 (± 10.05) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Monocytes

| | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|
| End point title | Mean change from baseline in Monocytes |
| End point description: | |
| Monocytes was measured in number of monocytes per liter (10 ⁹ /L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points. | |
| End point type | Secondary |
| End point timeframe: | |
| From Baseline (Week 1) to Week 48 | |

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|--------------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: 10 ⁹ monocytes per liter | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 (42, 39, 44, 41) | -0.01 (± 0.17) | 0.01 (± 0.18) | 0.05 (± 0.14) | 0.01 (± 0.13) |
| Week 4 (43, 43, 41, 46) | 0.01 (± 0.18) | 0.04 (± 0.18) | 0.01 (± 0.14) | 0.06 (± 0.19) |
| Week 8 (42, 41, 43, 43) | -0.03 (± 0.18) | 0.04 (± 0.18) | 0.03 (± 0.16) | 0.02 (± 0.17) |
| Week 12 (44, 40, 44, 42) | -0.01 (± 0.19) | 0.00 (± 0.14) | 0.04 (± 0.18) | 0.06 (± 0.15) |
| Week 16 (43, 42, 43, 44) | -0.01 (± 0.17) | 0.01 (± 0.17) | 0.05 (± 0.18) | 0.03 (± 0.14) |
| Week 20 (42, 40, 40, 42) | -0.03 (± 0.19) | 0.00 (± 0.16) | 0.00 (± 0.13) | 0.05 (± 0.19) |
| Week 24 (41, 40, 44, 44) | 0.00 (± 0.19) | 0.04 (± 0.19) | 0.03 (± 0.17) | 0.00 (± 0.17) |
| Week 28 (44, 39, 40, 44) | 0.00 (± 0.20) | 0.04 (± 0.21) | 0.08 (± 0.19) | 0.02 (± 0.17) |
| Week 32 (41, 40, 43, 42) | -0.01 (± 0.18) | 0.02 (± 0.19) | 0.05 (± 0.23) | -0.01 (± 0.19) |
| Week 40 (41, 42, 40, 43) | 0.03 (± 0.17) | 0.05 (± 0.16) | 0.04 (± 0.16) | -0.01 (± 0.18) |
| Week 48 (37, 41, 39, 41) | -0.02 (± 0.20) | -0.01 (± 0.13) | 0.03 (± 0.15) | -0.02 (± 0.18) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Monocytes/Leukocytes

| | |
|-----------------|---------------------------------------------------|
| End point title | Mean change from baseline in Monocytes/Leukocytes |
|-----------------|---------------------------------------------------|

End point description:

Monocytes/Leukocytes was measured in percentages (%). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

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

End point timeframe:

From Baseline (Week 1) to Week 48

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|--------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: % of Monocytes per Leukocytes | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 (42, 39, 44, 41) | -0.87 (± 2.50) | -0.07 (± 2.46) | 0.23 (± 3.03) | -0.37 (± 2.25) |
| Week 4 (43, 43, 41, 46) | 0.26 (± 3.30) | 0.27 (± 2.41) | -0.16 (± 3.11) | -0.24 (± 2.82) |
| Week 8 (42, 41, 43, 43) | -0.21 (± 3.47) | 0.07 (± 3.61) | 0.51 (± 3.83) | 0.08 (± 3.12) |
| Week 12 (44, 40, 44, 42) | 0.07 (± 2.79) | -0.11 (± 2.38) | 0.22 (± 3.37) | 0.45 (± 2.74) |
| Week 16 (43, 42, 43, 44) | 0.06 (± 3.30) | 0.59 (± 2.85) | 0.43 (± 3.31) | 0.28 (± 3.13) |
| Week 20 (42, 40, 40, 42) | -0.27 (± 3.84) | 0.56 (± 3.08) | 0.33 (± 3.81) | 0.43 (± 3.39) |
| Week 24 (41, 40, 44, 44) | 0.06 (± 3.45) | 0.84 (± 2.97) | 0.46 (± 3.00) | 0.41 (± 3.24) |
| Week 28 (44, 39, 40, 44) | -0.24 (± 3.54) | 0.69 (± 3.24) | 0.64 (± 3.67) | 0.94 (± 3.78) |
| Week 32 (41, 40, 43, 42) | -0.08 (± 3.11) | 0.13 (± 2.62) | 0.46 (± 3.91) | -0.03 (± 3.76) |
| Week 40 (41, 42, 40, 43) | 0.49 (± 3.55) | 0.64 (± 2.92) | 0.83 (± 3.69) | 0.59 (± 3.07) |
| Week 48 (37, 41, 39, 41) | -0.04 (± 3.79) | -0.13 (± 2.41) | 0.47 (± 3.82) | 0.29 (± 3.30) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Neutrophils

| | |
|-----------------|------------------------------------------|
| End point title | Mean change from baseline in Neutrophils |
|-----------------|------------------------------------------|

End point description:

Neutrophils was measured in number of neutrophils per liter ($10^9/L$). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

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

End point timeframe:

From Baseline (Week 1) to Week 48

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|----------------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: 10 ⁹ neutrophils per liter | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 (43, 39, 44, 41) | 0.28 (± 2.43) | 0.26 (± 1.17) | 0.17 (± 1.33) | -0.01 (± 1.46) |
| Week 4 (43, 43, 41, 46) | 0.07 (± 1.82) | 0.27 (± 1.40) | 0.21 (± 1.64) | 0.23 (± 1.96) |
| Week 8 (42, 41, 43, 43) | -0.13 (± 2.20) | 0.41 (± 1.32) | -0.07 (± 1.53) | -0.20 (± 1.49) |
| Week 12 (44, 41, 44, 42) | -0.24 (± 1.56) | 0.20 (± 1.65) | 0.10 (± 1.94) | -0.01 (± 2.03) |
| Week 16 (43, 42, 43, 44) | -0.22 (± 2.13) | 0.20 (± 1.41) | 0.15 (± 1.61) | -0.20 (± 2.14) |
| Week 20 (42, 41, 40, 42) | -0.07 (± 2.21) | 0.01 (± 1.22) | -0.39 (± 1.69) | 0.09 (± 2.51) |
| Week 24 (41, 40, 44, 44) | -0.12 (± 2.24) | -0.06 (± 1.54) | -0.16 (± 1.77) | -0.38 (± 1.92) |
| Week 28 (44, 39, 40, 44) | 0.04 (± 1.81) | 0.13 (± 1.64) | 0.10 (± 1.91) | -0.62 (± 1.78) |
| Week 32 (41, 40, 43, 42) | -0.07 (± 1.87) | 0.33 (± 1.27) | 0.07 (± 1.54) | -0.40 (± 1.67) |
| Week 40 (41, 42, 40, 43) | 0.16 (± 2.37) | 0.16 (± 1.31) | -0.32 (± 1.57) | -0.41 (± 1.88) |
| Week 48 (37, 41, 39, 41) | -0.29 (± 1.58) | 0.55 (± 1.15) | -0.09 (± 2.02) | -0.54 (± 1.78) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Neutrophils/Leukocytes

| | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|
| End point title | Mean change from baseline in Neutrophils/Leukocytes |
| End point description: Neutrophils/Leukocytes was measured in percentages (%). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points. | |
| End point type | Secondary |
| End point timeframe: From Baseline (Week 1) to Week 48 | |

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|----------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: % of Neutrophils per Leukocytes | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 (42, 39, 44, 41) | 2.99 (± 10.73) | -0.21 (± 7.94) | -1.20 (± 8.40) | -1.93 (± 8.18) |
| Week 4 (43, 43, 41, 46) | 0.91 (± 9.37) | 0.89 (± 7.82) | 1.47 (± 12.70) | -0.37 (± 10.27) |
| Week 8 (42, 41, 43, 43) | 2.15 (± 12.95) | 0.79 (± 8.80) | -1.17 (± 13.28) | -2.23 (± 10.92) |
| Week 12 (44, 40, 44, 42) | -0.52 (± 9.44) | -1.25 (± 11.78) | -0.12 (± 13.18) | -2.90 (± 12.85) |
| Week 16 (43, 42, 43, 44) | 0.77 (± 11.02) | 0.54 (± 8.50) | 0.56 (± 12.48) | -0.24 (± 12.23) |

| | | | | |
|--------------------------|----------------|-----------------|-----------------|-----------------|
| Week 20 (42, 40, 40, 42) | 2.22 (± 13.21) | -0.73 (± 8.42) | -1.25 (± 14.29) | -0.71 (± 13.91) |
| Week 24 (41, 40, 44, 44) | 0.65 (± 11.48) | -1.25 (± 8.74) | 0.10 (± 13.20) | -2.30 (± 12.41) |
| Week 28 (44, 39, 40, 44) | 1.28 (± 10.38) | -0.88 (± 10.56) | -0.77 (± 13.27) | -2.60 (± 13.79) |
| Week 32 (41, 40, 43, 42) | 1.67 (± 9.93) | 2.15 (± 7.42) | -0.47 (± 9.80) | -0.48 (± 12.08) |
| Week 40 (41, 42, 40, 43) | 2.29 (± 11.66) | 1.36 (± 6.95) | 0.07 (± 13.23) | -0.93 (± 11.50) |
| Week 48 (37, 41, 39, 41) | 1.41 (± 13.58) | 4.09 (± 8.40) | 0.30 (± 12.47) | -2.28 (± 12.38) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Platelets

| | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|
| End point title | Mean change from baseline in Platelets |
| End point description: | |
| Platelets was measured in number of platelets per liter (10 ⁹ /L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points. | |
| End point type | Secondary |
| End point timeframe: | |
| From Baseline (Week 1) to Week 48 | |

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|--------------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: 10 ⁹ platelets per liter | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 (41, 42, 45, 42) | 5.9 (± 33.2) | 10.0 (± 40.0) | 1.4 (± 47.5) | -1.0 (± 52.0) |
| Week 4 (43, 44, 43, 46) | -5.2 (± 51.3) | 0.0 (± 32.4) | 4.9 (± 43.8) | 8.1 (± 42.6) |
| Week 8 (42, 44, 44, 44) | 0.2 (± 45.3) | -0.3 (± 40.3) | 3.9 (± 52.0) | -6.4 (± 40.5) |
| Week 12 (43, 43, 43, 44) | -4.3 (± 50.6) | -1.7 (± 38.8) | -2.7 (± 49.0) | 1.8 (± 49.4) |
| Week 16 (44, 43, 43, 45) | 0.7 (± 57.7) | -0.7 (± 40.5) | -1.5 (± 66.7) | -2.3 (± 68.1) |
| Week 20 (42, 43, 41, 42) | 9.2 (± 57.1) | -3.3 (± 43.0) | 0.5 (± 44.6) | 0.8 (± 64.4) |
| Week 24 (42, 41, 44, 43) | 0.2 (± 60.2) | -5.2 (± 43.8) | 2.4 (± 68.6) | 1.7 (± 67.0) |
| Week 28 (42, 41, 41, 44) | 3.6 (± 64.6) | 1.8 (± 52.6) | -5.8 (± 71.9) | 1.5 (± 64.4) |
| Week 32 (42, 42, 42, 40) | 4.0 (± 71.8) | -1.9 (± 55.4) | -4.6 (± 57.5) | 9.9 (± 93.8) |
| Week 40 (42, 43, 41, 43) | 10.3 (± 74.9) | 14.2 (± 52.7) | -8.8 (± 63.2) | -1.5 (± 67.4) |
| Week 48 (37, 42, 39, 42) | 7.1 (± 67.4) | 3.5 (± 58.2) | -9.5 (± 70.9) | -8.8 (± 66.5) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in cluster of differentiation 3 (CD3)

| | |
|-----------------|-----------------------------------------------------------------|
| End point title | Mean change from baseline in cluster of differentiation 3 (CD3) |
|-----------------|-----------------------------------------------------------------|

End point description:

Cluster of differentiation 3 (CD3) was measured in cells per microliter (cells/ μ L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

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

End point timeframe:

From Baseline (Week 1) to Week 48

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|--------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: cells/ μ L | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 (38, 40, 42, 40) | 33.0 (\pm 313.6) | 77.7 (\pm 383.6) | 106.6 (\pm 283.1) | 126.9 (\pm 338.9) |
| Week 4 (39, 40, 40, 39) | -30.6 (\pm 293.5) | -47.7 (\pm 504.3) | 24.0 (\pm 394.9) | 227.2 (\pm 412.1) |
| Week 8 (38, 40, 39, 40) | -64.7 (\pm 405.7) | -58.6 (\pm 422.8) | -20.5 (\pm 403.2) | 78.3 (\pm 560.0) |
| Week 12 (41, 41, 40, 40) | -44.2 (\pm 283.2) | -48.8 (\pm 452.1) | -57.8 (\pm 385.1) | 43.7 (\pm 599.3) |
| Week 16 (38, 42, 38, 42) | -81.9 (\pm 479.4) | -141.2 (\pm 516.1) | -4.5 (\pm 383.2) | -45.4 (\pm 520.8) |
| Week 20 (40, 40, 39, 42) | -92.7 (\pm 391.1) | -173.4 (\pm 490.9) | 5.9 (\pm 352.9) | -89.9 (\pm 577.7) |
| Week 24 (39, 39, 42, 43) | -85.8 (\pm 472.5) | -128.9 (\pm 569.4) | -88.5 (\pm 462.1) | -78.3 (\pm 570.7) |
| Week 28 (41, 40, 39, 38) | -27.6 (\pm 507.3) | -81.2 (\pm 652.7) | 46.1 (\pm 482.2) | 7.4 (\pm 561.2) |
| Week 32 (41, 41, 41, 41) | -70.9 (\pm 428.4) | -173.6 (\pm 565.8) | 18.0 (\pm 415.0) | -90.5 (\pm 504.0) |
| Week 40 (40, 41, 39, 43) | -110.5 (\pm 526.4) | -166.9 (\pm 542.2) | -1.8 (\pm 410.7) | 31.7 (\pm 528.8) |
| Week 48 (35, 40, 35, 41) | -115.6 (\pm 581.1) | -253.1 (\pm 637.0) | 36.1 (\pm 492.3) | 22.3 (\pm 558.0) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in CD3/Lymphocytes

| | |
|-----------------|----------------------------------------------|
| End point title | Mean change from baseline in CD3/Lymphocytes |
|-----------------|----------------------------------------------|

End point description:

CD3/Lymphocytes was measured in percentages (%). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

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

End point timeframe:

From Baseline (Week 1) to Week 48

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|--------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: % of CD3 per Leukocytes | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 (38, 40, 42, 40) | -0.7 (± 6.1) | -0.9 (± 4.6) | -2.0 (± 5.7) | -0.2 (± 7.8) |
| Week 4 (39, 40, 40, 39) | -2.1 (± 7.3) | -0.5 (± 6.0) | -1.9 (± 5.0) | -0.5 (± 6.8) |
| Week 8 (38, 40, 39, 40) | -0.9 (± 6.1) | -1.2 (± 4.8) | -2.6 (± 5.9) | 0.6 (± 9.5) |
| Week 12 (41, 41, 40, 40) | -0.4 (± 5.6) | -1.1 (± 8.2) | -2.4 (± 6.0) | -0.1 (± 9.2) |
| Week 16 (38, 42, 38, 42) | -1.9 (± 5.8) | -1.6 (± 7.8) | -1.9 (± 7.6) | -1.4 (± 7.9) |
| Week 20 (40, 40, 39, 42) | -0.8 (± 5.0) | 0.0 (± 8.6) | -2.3 (± 6.9) | 0.6 (± 9.2) |
| Week 24 (39, 39, 42, 43) | 0.0 (± 6.5) | -0.1 (± 8.8) | -1.8 (± 6.6) | 18.7 (± 114.3) |
| Week 28 (41, 40, 39, 38) | -0.2 (± 6.9) | 0.2 (± 8.3) | -2.9 (± 7.2) | 0.9 (± 10.2) |
| Week 32 (41, 41, 41, 41) | -1.3 (± 7.0) | 0.2 (± 7.9) | -1.8 (± 6.8) | 1.4 (± 8.5) |
| Week 40 (40, 41, 39, 43) | 0.2 (± 6.7) | 1.4 (± 6.9) | 0.5 (± 6.5) | 3.3 (± 7.9) |
| Week 48 (35, 40, 35, 41) | 1.3 (± 8.0) | 0.3 (± 7.6) | 0.1 (± 6.2) | 4.5 (± 7.3) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in cluster of differentiation 19 (CD19)

| | |
|-----------------|-------------------------------------------------------------------|
| End point title | Mean change from baseline in cluster of differentiation 19 (CD19) |
|-----------------|-------------------------------------------------------------------|

End point description:

Cluster of differentiation 19 (CD19) was measured in cells per microliter (cells/ μ L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

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

End point timeframe:

From Baseline (Week 1) to Week 48

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|--------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: cells/ μ L | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 (38, 40, 42, 40) | 9.6 (\pm 56.7) | 12.3 (\pm 76.2) | 24.8 (\pm 71.0) | 63.4 (\pm 133.5) |
| Week 4 (39, 40, 40, 39) | -2.8 (\pm 46.3) | -31.2 (\pm 177.0) | 9.2 (\pm 60.5) | 82.8 (\pm 154.5) |
| Week 8 (38, 40, 39, 40) | -13.3 (\pm 72.9) | -29.4 (\pm 183.5) | 8.7 (\pm 70.8) | 19.4 (\pm 146.4) |
| Week 12 (41, 41, 40, 40) | -2.6 (\pm 83.4) | -48.1 (\pm 207.1) | -17.9 (\pm 77.8) | 53.2 (\pm 203.6) |
| Week 16 (38, 42, 38, 42) | -12.5 (\pm 84.3) | -50.1 (\pm 201.5) | -10.0 (\pm 92.4) | 13.2 (\pm 147.8) |
| Week 20 (40, 40, 39, 42) | -15.1 (\pm 86.0) | -75.4 (\pm 216.6) | -2.5 (\pm 57.1) | 2.7 (\pm 132.6) |
| Week 24 (39, 39, 42, 43) | -15.0 (\pm 89.3) | -77.2 (\pm 231.9) | -20.3 (\pm 72.0) | -1.1 (\pm 135.0) |
| Week 28 (41, 40, 39, 38) | -20.6 (\pm 106.7) | -69.6 (\pm 206.7) | -13.1 (\pm 84.5) | -13.0 (\pm 123.2) |
| Week 32 (41, 41, 41, 41) | -14.3 (\pm 106.3) | -75.8 (\pm 225.7) | -10.4 (\pm 93.0) | -20.9 (\pm 168.1) |
| Week 40 (40, 41, 39, 43) | -24.8 (\pm 103.3) | -68.6 (\pm 211.0) | -26.9 (\pm 83.0) | -46.9 (\pm 138.0) |
| Week 48 (35, 40, 35, 41) | -37.0 (\pm 132.7) | -82.4 (\pm 243.7) | -15.5 (\pm 83.2) | -41.2 (\pm 120.0) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in CD19/Lymphocytes

| | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| End point title | Mean change from baseline in CD19/Lymphocytes |
| End point description: CD19/Lymphocytes was measured in percentages (%). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points. | |
| End point type | Secondary |
| End point timeframe: From Baseline (Week 1) to Week 48 | |

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|--------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: % of CD19 per Leukocytes | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 (38, 40, 42, 40) | -0.3 (\pm 2.1) | -0.1 (\pm 3.0) | 1.0 (\pm 3.5) | 1.5 (\pm 5.9) |

| | | | | |
|--------------------------|--------------|--------------|--------------|--------------|
| Week 4 (39, 40, 40, 39) | 0.0 (± 2.9) | -0.5 (± 3.7) | 0.7 (± 3.3) | 2.8 (± 5.7) |
| Week 8 (38, 40, 39, 40) | 0.1 (± 2.8) | -0.5 (± 4.2) | 0.7 (± 2.5) | 0.4 (± 6.4) |
| Week 12 (41, 41, 40, 40) | -0.2 (± 3.2) | -1.0 (± 3.9) | -0.4 (± 3.1) | 1.7 (± 7.9) |
| Week 16 (38, 42, 38, 42) | 0.0 (± 4.7) | -1.2 (± 5.0) | -0.4 (± 3.3) | 0.7 (± 5.9) |
| Week 20 (40, 40, 39, 42) | -0.4 (± 3.8) | -2.1 (± 6.2) | -0.3 (± 3.0) | -0.2 (± 6.9) |
| Week 24 (39, 39, 42, 43) | -0.9 (± 4.5) | -2.0 (± 6.5) | -0.6 (± 3.3) | -0.3 (± 7.3) |
| Week 28 (41, 40, 39, 38) | -1.2 (± 5.4) | -2.5 (± 5.9) | -1.1 (± 3.3) | -1.0 (± 6.6) |
| Week 32 (41, 41, 41, 41) | -0.4 (± 4.7) | -2.4 (± 5.5) | -0.6 (± 4.4) | -1.6 (± 6.3) |
| Week 40 (40, 41, 39, 43) | -1.2 (± 4.7) | -2.6 (± 5.4) | -1.9 (± 4.2) | -3.4 (± 6.7) |
| Week 48 (35, 40, 35, 41) | -1.2 (± 6.8) | -2.6 (± 7.2) | -1.6 (± 4.9) | -3.3 (± 6.2) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Aspartate Aminotransferase

| | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------|
| End point title | Mean change from baseline in Aspartate Aminotransferase |
| End point description: | |
| Aspartate Aminotransferase was measured in units per liter (U/L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points. | |
| End point type | Secondary |
| End point timeframe: | |
| From Baseline (Week 1) to Week 48 | |

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|--------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: U/L | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 (42, 45, 45, 43) | -0.5 (± 8.8) | 0.2 (± 8.0) | 4.3 (± 43.1) | 0.0 (± 7.2) |
| Week 4 (44, 44, 43, 46) | -0.1 (± 11.2) | 0.2 (± 7.4) | -1.1 (± 7.6) | -1.9 (± 8.0) |
| Week 8 (44, 43, 44, 44) | -0.1 (± 8.7) | -1.5 (± 6.2) | 0.5 (± 13.0) | -1.1 (± 8.1) |
| Week 12 (44, 44, 45, 44) | 5.1 (± 27.0) | 0.9 (± 6.2) | -1.8 (± 10.0) | -2.9 (± 7.1) |
| Week 16 (44, 44, 43, 45) | 0.4 (± 7.7) | 0.0 (± 6.3) | -2.3 (± 11.6) | -2.8 (± 8.4) |
| Week 20 (43, 43, 41, 44) | 4.1 (± 24.1) | 1.0 (± 11.5) | -0.7 (± 13.8) | -3.8 (± 8.1) |
| Week 24 (42, 43, 44, 44) | 0.6 (± 11.8) | 1.6 (± 10.4) | -1.8 (± 11.5) | -3.8 (± 8.4) |
| Week 28 (43, 42, 40, 42) | 0.0 (± 12.3) | 0.0 (± 10.2) | -1.5 (± 11.1) | -3.4 (± 9.1) |
| Week 32 (44, 44, 43, 44) | -0.3 (± 11.0) | 0.3 (± 6.8) | -0.7 (± 12.9) | -3.4 (± 9.2) |
| Week 40 (42, 42, 41, 44) | -0.6 (± 10.2) | 0.1 (± 9.1) | -0.3 (± 11.5) | -1.5 (± 9.8) |
| Week 48 (38, 42, 40, 43) | 1.1 (± 10.8) | 0.1 (± 13.1) | 1.4 (± 13.4) | -2.1 (± 8.6) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Alanine Aminotransferase

| | |
|-----------------|-------------------------------------------------------|
| End point title | Mean change from baseline in Alanine Aminotransferase |
|-----------------|-------------------------------------------------------|

End point description:

Alanine Aminotransferase was measured in units per liter (U/L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

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

End point timeframe:

From Baseline (Week 1) to Week 48

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|--------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: U/L | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 (42, 45, 45, 43) | 2.4 (± 14.1) | 2.6 (± 10.6) | 0.5 (± 11.1) | -0.1 (± 8.6) |
| Week 4 (44, 44, 43, 46) | 0.8 (± 9.9) | -0.5 (± 8.5) | 0.9 (± 7.4) | 0.3 (± 8.2) |
| Week 8 (44, 43, 44, 44) | 0.2 (± 10.2) | -0.8 (± 8.3) | 5.3 (± 28.8) | -0.6 (± 9.6) |
| Week 12 (44, 44, 45, 44) | 7.0 (± 21.3) | 0.8 (± 14.3) | -0.8 (± 8.1) | -0.1 (± 7.6) |
| Week 16 (44, 44, 43, 45) | 1.5 (± 13.3) | -0.4 (± 9.3) | 0.0 (± 10.3) | -1.1 (± 7.8) |
| Week 20 (43, 43, 42, 44) | 5.3 (± 23.6) | -0.2 (± 10.2) | 1.4 (± 10.8) | -3.7 (± 6.3) |
| Week 24 (42, 43, 44, 44) | 3.1 (± 20.9) | 0.5 (± 14.1) | 2.0 (± 12.0) | -2.8 (± 7.7) |
| Week 28 (43, 42, 40, 42) | 1.0 (± 13.9) | 0.7 (± 10.5) | -0.4 (± 9.3) | -2.7 (± 7.2) |
| Week 32 (44, 44, 43, 44) | 1.2 (± 13.4) | -0.5 (± 10.3) | 1.3 (± 10.8) | -3.2 (± 6.1) |
| Week 40 (42, 42, 41, 44) | -0.5 (± 13.4) | 2.6 (± 12.8) | 3.0 (± 12.9) | -0.7 (± 8.3) |
| Week 48 (38, 42, 40, 43) | 0.4 (± 11.5) | -1.2 (± 10.4) | 3.5 (± 17.0) | -1.1 (± 7.8) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Alkaline Phosphatase

| | |
|-----------------|---------------------------------------------------|
| End point title | Mean change from baseline in Alkaline Phosphatase |
|-----------------|---------------------------------------------------|

End point description:

Alkaline Phosphatase was measured in units per liter (U/L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

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

End point timeframe:

From Baseline (Week 1) to Week 48

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|--------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: U/L | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 (42, 45, 45, 44) | 1.8 (± 10.7) | 2.4 (± 10.6) | 1.5 (± 8.0) | -3.6 (± 10.1) |
| Week 4 (44, 44, 43, 46) | -1.7 (± 9.7) | 0.7 (± 9.2) | -0.7 (± 8.4) | -4.7 (± 9.4) |
| Week 8 (44, 43, 44, 44) | 1.7 (± 12.9) | 2.4 (± 12.7) | 1.8 (± 15.6) | -6.1 (± 11.0) |
| Week 12 (44, 44, 45, 44) | 2.2 (± 11.6) | 4.2 (± 16.4) | 1.9 (± 12.9) | -4.4 (± 11.8) |
| Week 16 (44, 45, 43, 45) | 3.1 (± 10.7) | 2.7 (± 13.0) | 0.0 (± 10.4) | -6.7 (± 12.8) |
| Week 20 (43, 45, 42, 44) | 3.9 (± 14.0) | 1.4 (± 11.8) | 1.4 (± 11.8) | -7.4 (± 11.2) |
| Week 24 (42, 43, 44, 44) | 4.7 (± 15.0) | 3.7 (± 14.0) | 2.8 (± 11.6) | -2.7 (± 14.0) |
| Week 28 (43, 43, 40, 43) | 2.8 (± 14.0) | 3.1 (± 14.2) | 1.9 (± 9.5) | -2.1 (± 13.5) |
| Week 32 (44, 44, 43, 45) | 3.8 (± 14.6) | 2.7 (± 16.0) | 3.2 (± 12.1) | 1.0 (± 15.9) |
| Week 40 (42, 42, 41, 44) | 2.4 (± 17.1) | 1.3 (± 13.1) | 2.7 (± 13.0) | -3.0 (± 18.0) |
| Week 48 (38, 42, 40, 43) | 2.6 (± 13.3) | 4.0 (± 16.8) | 5.5 (± 12.8) | -4.5 (± 18.8) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Gamma Glutamyl Transferase

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|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------|
| End point title | Mean change from baseline in Gamma Glutamyl Transferase |
| End point description: | |
| Gamma Glutamyl Transferase was measured in units per liter (U/L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points. | |
| End point type | Secondary |
| End point timeframe: | |
| From Baseline (Week 1) to Week 48 | |

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|--------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: U/L | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 (42, 45, 45, 43) | 0.3 (± 7.6) | 2.0 (± 11.5) | 8.8 (± 68.9) | -3.4 (± 24.3) |
| Week 4 (44, 44, 43, 46) | 2.1 (± 8.7) | -1.3 (± 8.8) | 2.7 (± 28.5) | -6.5 (± 35.5) |
| Week 8 (44, 43, 44, 44) | 3.5 (± 23.0) | 0.3 (± 10.5) | -2.8 (± 49.3) | -9.2 (± 43.3) |
| Week 12 (44, 44, 45, 44) | 4.1 (± 21.0) | 0.5 (± 13.4) | -5.1 (± 29.3) | -8.3 (± 46.1) |

| | | | | |
|--------------------------|--------------|--------------|---------------|----------------|
| Week 16 (44, 45, 43, 45) | 6.5 (± 20.2) | 2.1 (± 12.5) | -6.1 (± 45.0) | -10.6 (± 47.7) |
| Week 20 (43, 44, 42, 44) | 3.5 (± 14.1) | 0.2 (± 13.4) | -3.7 (± 50.3) | -8.5 (± 50.5) |
| Week 24 (42, 43, 44, 44) | 7.1 (± 22.0) | 4.0 (± 18.7) | -0.4 (± 53.1) | -9.5 (± 47.2) |
| Week 28 (43, 43, 40, 43) | 4.6 (± 25.7) | 2.2 (± 18.3) | -7.0 (± 46.8) | 0.0 (± 23.1) |
| Week 32 (44, 44, 43, 45) | 4.4 (± 28.6) | 1.5 (± 16.7) | -5.9 (± 44.5) | -8.2 (± 37.4) |
| Week 40 (42, 42, 41, 44) | 3.4 (± 41.3) | 5.7 (± 32.4) | 0.4 (± 10.1) | -9.1 (± 45.3) |
| Week 48 (38, 42, 40, 43) | 1.8 (± 11.4) | 5.3 (± 23.9) | 4.7 (± 21.6) | -9.8 (± 44.5) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Bilirubin

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|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|
| End point title | Mean change from baseline in Bilirubin |
| End point description: Bilirubin was measured in micromols per liter (µmol/L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points. | |
| End point type | Secondary |
| End point timeframe: From Baseline (Week 1) to Week 48 | |

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|--------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: µmol/L | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 (42, 45, 45, 43) | 0.35 (± 2.72) | -0.48 (± 2.71) | 0.28 (± 2.38) | -0.78 (± 3.13) |
| Week 4 (44, 44, 43, 46) | 0.07 (± 2.50) | -0.18 (± 2.09) | -0.05 (± 2.14) | -0.79 (± 2.80) |
| Week 8 (44, 43, 44, 44) | -0.09 (± 2.66) | -0.69 (± 2.22) | -0.19 (± 2.13) | -0.23 (± 2.80) |
| Week 12 (44, 44, 45, 44) | -0.04 (± 2.60) | -0.70 (± 2.74) | 0.37 (± 2.17) | -0.33 (± 3.28) |
| Week 16 (44, 45, 43, 45) | 0.06 (± 2.41) | -0.45 (± 2.43) | -0.20 (± 2.71) | -0.51 (± 3.64) |
| Week 20 (43, 43, 42, 44) | -0.54 (± 2.89) | -0.38 (± 2.51) | 0.51 (± 2.81) | -0.30 (± 3.03) |
| Week 24 (42, 43, 44, 44) | 0.08 (± 2.75) | -0.14 (± 2.86) | 0.54 (± 2.18) | -0.38 (± 3.57) |
| Week 28 (43, 42, 40, 42) | -0.10 (± 2.98) | -0.26 (± 3.23) | 0.79 (± 2.71) | -0.82 (± 2.61) |
| Week 32 (44, 44, 43, 44) | 0.09 (± 2.75) | -0.38 (± 2.61) | 0.93 (± 3.18) | -0.38 (± 3.61) |
| Week 40 (42, 42, 41, 44) | -0.26 (± 3.70) | 0.07 (± 3.18) | 1.03 (± 2.35) | -0.15 (± 2.64) |
| Week 48 (38, 42, 40, 43) | 0.69 (± 3.57) | -0.50 (± 3.12) | 0.79 (± 3.04) | -0.20 (± 2.52) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Direct Bilirubin

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|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| End point title | Mean change from baseline in Direct Bilirubin |
| End point description: Direct Bilirubin was measured in micromols per liter (µmol/L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points. | |
| End point type | Secondary |
| End point timeframe: From Baseline (Week 1) to Week 48 | |

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|--------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: µmol/L | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 (42, 45, 45, 43) | 0.03 (± 0.92) | -0.06 (± 0.92) | 0.09 (± 1.12) | -0.24 (± 1.10) |
| Week 4 (44, 44, 43, 46) | 0.10 (± 1.03) | 0.03 (± 0.75) | -0.04 (± 0.82) | -0.10 (± 0.93) |
| Week 8 (44, 43, 44, 44) | 0.03 (± 0.91) | -0.18 (± 0.55) | -0.17 (± 0.86) | 0.03 (± 1.10) |
| Week 12 (44, 44, 45, 44) | 0.15 (± 0.99) | -0.07 (± 0.95) | -0.01 (± 1.06) | -0.05 (± 1.30) |
| Week 16 (44, 45, 43, 45) | 0.18 (± 0.81) | -0.01 (± 0.66) | -0.07 (± 1.04) | -0.01 (± 1.40) |
| Week 20 (43, 43, 42, 44) | -0.04 (± 0.95) | 0.07 (± 0.91) | 0.02 (± 0.94) | 0.00 (± 1.19) |
| Week 24 (42, 43, 44, 44) | 0.05 (± 1.10) | 0.14 (± 0.95) | 0.08 (± 1.02) | -0.08 (± 1.25) |
| Week 28 (43, 42, 40, 42) | 0.06 (± 1.06) | -0.06 (± 1.00) | 0.11 (± 0.80) | -0.06 (± 1.15) |
| Week 32 (44, 44, 43, 44) | 0.12 (± 1.16) | 0.05 (± 0.90) | 0.21 (± 1.21) | -0.04 (± 1.36) |
| Week 40 (42, 42, 41, 44) | 0.07 (± 1.31) | 0.03 (± 0.76) | 0.23 (± 1.00) | 0.07 (± 1.05) |
| Week 48 (38, 42, 40, 43) | 0.31 (± 1.34) | -0.05 (± 1.01) | 0.20 (± 1.25) | 0.08 (± 0.98) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Lactate Dehydrogenase

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|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------|
| End point title | Mean change from baseline in Lactate Dehydrogenase |
| End point description: Lactate Dehydrogenase was measured in units per liter (U/L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points. | |
| End point type | Secondary |
| End point timeframe: From Baseline (Week 1) to Week 48 | |

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|--------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: U/L | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 (42, 45, 45, 44) | -3.3 (± 27.8) | -7.8 (± 21.2) | -5.9 (± 35.2) | -12.8 (± 24.8) |
| Week 4 (44, 44, 43, 46) | -3.0 (± 23.4) | -3.7 (± 37.0) | -5.6 (± 35.6) | -18.5 (± 34.1) |
| Week 8 (44, 43, 44, 44) | -5.7 (± 27.4) | -11.8 (± 31.5) | -9.2 (± 39.0) | -20.4 (± 37.4) |
| Week 12 (44, 44, 45, 44) | 3.0 (± 28.7) | -7.4 (± 34.6) | -11.1 (± 45.1) | -24.4 (± 39.0) |
| Week 16 (44, 44, 43, 45) | -2.2 (± 25.5) | -11.1 (± 29.9) | -10.6 (± 48.6) | -22.4 (± 43.3) |
| Week 20 (43, 45, 41, 44) | -0.7 (± 33.9) | -10.8 (± 37.0) | -9.9 (± 47.8) | -28.5 (± 32.1) |
| Week 24 (42, 43, 44, 44) | -4.5 (± 31.3) | -14.3 (± 31.5) | -14.6 (± 34.4) | -29.3 (± 32.2) |
| Week 28 (43, 43, 40, 43) | 0.0 (± 40.8) | -16.0 (± 40.9) | -13.2 (± 35.0) | -34.8 (± 36.9) |
| Week 32 (44, 44, 43, 45) | 5.0 (± 55.0) | -9.9 (± 43.4) | -8.1 (± 33.5) | -22.9 (± 40.6) |
| Week 40 (42, 42, 41, 44) | -1.6 (± 38.1) | -2.9 (± 41.1) | -8.0 (± 28.4) | -20.5 (± 40.1) |
| Week 48 (38, 42, 40, 43) | -8.8 (± 35.2) | -4.2 (± 54.3) | -1.5 (± 32.7) | -16.0 (± 36.3) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Creatinine

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|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|
| End point title | Mean change from baseline in Creatinine |
| End point description: Creatinine was measured in micromols per liter (µmol/L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points. | |
| End point type | Secondary |
| End point timeframe: From Baseline (Week 1) to Week 48 | |

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|--------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: µmol/L | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 (42, 45, 45, 44) | 0.9 (± 9.1) | -0.1 (± 8.0) | 1.5 (± 5.8) | 0.6 (± 7.2) |
| Week 4 (44, 44, 43, 46) | -0.8 (± 8.9) | -0.2 (± 9.3) | -0.6 (± 7.3) | -1.4 (± 8.2) |
| Week 8 (44, 43, 44, 44) | 0.5 (± 7.0) | 0.3 (± 7.6) | -0.5 (± 6.9) | 0.1 (± 8.4) |
| Week 12 (44, 44, 45, 44) | -0.3 (± 7.0) | 1.4 (± 7.5) | -0.4 (± 6.4) | -0.7 (± 8.2) |
| Week 16 (44, 45, 43, 45) | -0.1 (± 9.8) | 1.0 (± 8.2) | 0.7 (± 6.8) | -1.1 (± 9.4) |
| Week 20 (43, 45, 42, 44) | 0.7 (± 8.6) | 1.4 (± 10.2) | 0.8 (± 6.9) | -0.3 (± 7.7) |
| Week 24 (42, 43, 44, 44) | 0.0 (± 8.8) | 0.8 (± 8.8) | 0.3 (± 6.6) | 0.9 (± 9.7) |
| Week 28 (43, 43, 40, 43) | 2.5 (± 10.0) | 2.7 (± 10.0) | 1.0 (± 7.8) | -0.9 (± 7.8) |

| | | | | |
|--------------------------|--------------|-------------|-------------|--------------|
| Week 32 (44, 44, 43, 45) | 5.5 (± 35.7) | 0.5 (± 8.1) | 3.6 (± 7.8) | 1.6 (± 11.2) |
| Week 40 (42, 42, 41, 44) | 2.3 (± 9.5) | 2.2 (± 8.5) | 3.9 (± 6.0) | 3.0 (± 8.4) |
| Week 48 (38, 42, 40, 43) | 1.9 (± 10.6) | 0.7 (± 7.6) | 2.5 (± 5.2) | 2.9 (± 9.8) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Urea Nitrogen

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|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| End point title | Mean change from baseline in Urea Nitrogen |
| End point description: Urea Nitrogen was measured in millimoles per liter (mmol/L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points. | |
| End point type | Secondary |
| End point timeframe: From Baseline (Week 1) to Week 48 | |

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|--------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: mmol/L | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 (42, 45, 45, 43) | 0.28 (± 1.55) | -0.09 (± 1.23) | -0.05 (± 1.32) | -0.02 (± 1.31) |
| Week 4 (44, 44, 43, 46) | -0.07 (± 1.21) | -0.33 (± 1.52) | -0.14 (± 1.20) | 0.04 (± 1.19) |
| Week 8 (44, 43, 44, 44) | 0.06 (± 1.25) | -0.26 (± 1.22) | -0.19 (± 1.07) | 0.17 (± 1.59) |
| Week 12 (44, 44, 45, 44) | 0.03 (± 1.13) | -0.39 (± 1.31) | -0.29 (± 1.17) | -0.22 (± 1.15) |
| Week 16 (44, 45, 43, 45) | 0.19 (± 1.35) | -0.18 (± 1.40) | 0.19 (± 1.49) | -0.03 (± 1.41) |
| Week 20 (43, 44, 42, 44) | -0.18 (± 1.29) | -0.20 (± 1.33) | -0.25 (± 1.22) | -0.16 (± 1.08) |
| Week 24 (42, 43, 44, 44) | 0.08 (± 1.69) | -0.44 (± 1.38) | -0.13 (± 1.18) | -0.09 (± 1.50) |
| Week 28 (43, 43, 40, 43) | 0.13 (± 1.38) | 0.03 (± 1.61) | -0.23 (± 1.26) | -0.22 (± 1.14) |
| Week 32 (44, 44, 43, 45) | 0.40 (± 2.37) | -0.30 (± 1.65) | 0.21 (± 1.17) | 0.10 (± 1.43) |
| Week 40 (42, 42, 41, 44) | 0.29 (± 1.54) | 0.10 (± 1.73) | 0.21 (± 1.20) | 0.14 (± 1.43) |
| Week 48 (38, 42, 40, 43) | 0.05 (± 1.22) | -0.31 (± 1.54) | 0.23 (± 1.38) | -0.02 (± 1.56) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Sodium

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|----------------------------------------------------------------------------------------------------------------------------|-------------------------------------|
| End point title | Mean change from baseline in Sodium |
| End point description: Sodium was measured in millimoles per liter (mmol/L). The Safety Set (SS) consisted of all study | |

participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

| | |
|-----------------------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| From Baseline (Week 1) to Week 48 | |

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|--------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: mmol/L | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 (42, 45, 45, 44) | -0.1 (± 1.9) | -0.4 (± 2.4) | 0.1 (± 1.6) | 0.0 (± 2.2) |
| Week 4 (44, 44, 43, 46) | -0.3 (± 2.0) | -0.6 (± 2.1) | 0.3 (± 2.1) | -0.1 (± 2.4) |
| Week 8 (44, 43, 44, 44) | 0.1 (± 2.2) | -0.4 (± 2.4) | 0.3 (± 2.2) | 0.1 (± 2.3) |
| Week 12 (44, 44, 45, 44) | -0.3 (± 2.0) | -0.5 (± 2.0) | 0.2 (± 2.0) | 0.1 (± 2.3) |
| Week 16 (44, 45, 43, 45) | -0.4 (± 2.3) | -0.2 (± 1.9) | 0.0 (± 2.0) | -0.2 (± 2.3) |
| Week 20 (43, 45, 42, 44) | 0.3 (± 2.2) | -0.8 (± 2.2) | -0.1 (± 2.0) | -0.5 (± 2.4) |
| Week 24 (42, 43, 44, 44) | -0.1 (± 2.5) | -0.4 (± 2.2) | 0.0 (± 2.2) | -0.3 (± 2.1) |
| Week 28 (43, 43, 40, 43) | 0.0 (± 1.9) | -0.4 (± 2.4) | 0.2 (± 1.9) | 0.1 (± 2.3) |
| Week 32 (44, 44, 43, 45) | 0.0 (± 2.3) | -0.8 (± 3.2) | 0.1 (± 2.1) | 0.2 (± 2.2) |
| Week 40 (42, 42, 41, 44) | -0.1 (± 2.2) | -1.2 (± 2.2) | -0.1 (± 1.6) | -0.3 (± 2.4) |
| Week 48 (38, 42, 40, 43) | -0.4 (± 2.0) | -1.1 (± 2.6) | -0.5 (± 1.7) | 0.2 (± 2.3) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Potassium

| | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|
| End point title | Mean change from baseline in Potassium |
| End point description: | |
| Potassium was measured in millimoles per liter (mmol/L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points. | |
| End point type | Secondary |
| End point timeframe: | |
| From Baseline (Week 1) to Week 48 | |

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|--------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: mmol/L | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 (42, 45, 44, 44) | 0.04 (± 0.45) | 0.15 (± 0.40) | 0.00 (± 0.36) | -0.03 (± 0.37) |
| Week 4 (44, 44, 43, 46) | 0.06 (± 0.44) | 0.08 (± 0.35) | -0.07 (± 0.41) | -0.12 (± 0.40) |
| Week 8 (44, 43, 44, 44) | -0.04 (± 0.40) | 0.11 (± 0.38) | 0.00 (± 0.35) | -0.07 (± 0.40) |
| Week 12 (44, 44, 44, 44) | -0.01 (± 0.33) | 0.02 (± 0.31) | -0.07 (± 0.41) | -0.12 (± 0.34) |
| Week 16 (44, 44, 43, 45) | -0.01 (± 0.34) | 0.16 (± 0.33) | -0.09 (± 0.42) | -0.05 (± 0.33) |
| Week 20 (43, 45, 40, 43) | 0.04 (± 0.38) | 0.14 (± 0.33) | -0.04 (± 0.46) | -0.08 (± 0.37) |
| Week 24 (42, 43, 43, 43) | 0.06 (± 0.43) | 0.07 (± 0.39) | 0.03 (± 0.33) | -0.11 (± 0.37) |
| Week 28 (41, 43, 40, 43) | 0.09 (± 0.43) | 0.12 (± 0.47) | 0.06 (± 0.42) | 0.03 (± 0.45) |
| Week 32 (44, 44, 43, 45) | 0.03 (± 0.44) | 0.07 (± 0.44) | 0.10 (± 0.46) | -0.05 (± 0.38) |
| Week 40 (42, 41, 41, 44) | 0.06 (± 0.33) | 0.16 (± 0.51) | 0.16 (± 0.39) | -0.06 (± 0.37) |
| Week 48 (38, 42, 40, 43) | -0.01 (± 0.30) | 0.00 (± 0.30) | -0.02 (± 0.39) | -0.07 (± 0.40) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Calcium

| | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|
| End point title | Mean change from baseline in Calcium |
| End point description: | |
| Calcium was measured in millimoles per liter (mmol/L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points. | |
| End point type | Secondary |
| End point timeframe: | |
| From Baseline (Week 1) to Week 48 | |

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|--------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: mmol/L | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 (42, 45, 45, 44) | 0.008 (± 0.104) | -0.001 (± 0.103) | 0.004 (± 0.088) | -0.008 (± 0.092) |
| Week 4 (44, 44, 43, 46) | 0.007 (± 0.108) | -0.018 (± 0.099) | -0.018 (± 0.090) | -0.001 (± 0.086) |
| Week 8 (44, 43, 44, 44) | -0.006 (± 0.093) | -0.033 (± 0.117) | -0.014 (± 0.106) | -0.003 (± 0.089) |
| Week 12 (44, 44, 45, 44) | 0.006 (± 0.108) | -0.011 (± 0.121) | -0.013 (± 0.097) | -0.004 (± 0.111) |
| Week 16 (44, 45, 43, 45) | -0.025 (± 0.106) | -0.004 (± 0.088) | -0.013 (± 0.095) | -0.024 (± 0.119) |

| | | | | |
|--------------------------|------------------|------------------|------------------|------------------|
| Week 20 (43, 45, 42, 44) | -0.036 (± 0.116) | -0.020 (± 0.084) | -0.015 (± 0.108) | 0.005 (± 0.080) |
| Week 24 (42, 43, 44, 44) | -0.027 (± 0.106) | -0.026 (± 0.094) | -0.012 (± 0.095) | 0.007 (± 0.100) |
| Week 28 (43, 43, 40, 43) | -0.031 (± 0.121) | -0.039 (± 0.091) | -0.016 (± 0.113) | -0.014 (± 0.092) |
| Week 32 (44, 44, 43, 45) | 0.003 (± 0.098) | -0.043 (± 0.099) | 0.019 (± 0.107) | -0.001 (± 0.105) |
| Week 40 (42, 42, 41, 44) | -0.027 (± 0.114) | -0.022 (± 0.115) | 0.006 (± 0.115) | -0.012 (± 0.105) |
| Week 48 (38, 42, 40, 43) | -0.013 (± 0.096) | -0.037 (± 0.119) | -0.004 (± 0.104) | -0.017 (± 0.110) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Phosphate

| | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|
| End point title | Mean change from baseline in Phosphate |
| End point description: | |
| Phosphate was measured in millimoles per liter (mmol/L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points. | |
| End point type | Secondary |
| End point timeframe: | |
| From Baseline (Week 1) to Week 48 | |

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|--------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: mmol/L | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 (42, 45, 44, 43) | 0.044 (± 0.163) | 0.032 (± 0.192) | -0.047 (± 0.230) | 0.033 (± 0.168) |
| Week 4 (44, 44, 43, 46) | -0.004 (± 0.162) | -0.029 (± 0.185) | -0.070 (± 0.187) | 0.020 (± 0.163) |
| Week 8 (44, 43, 44, 44) | 0.006 (± 0.178) | -0.063 (± 0.225) | -0.028 (± 0.207) | 0.051 (± 0.187) |
| Week 12 (44, 44, 44, 44) | 0.029 (± 0.159) | -0.004 (± 0.149) | -0.015 (± 0.236) | 0.045 (± 0.183) |
| Week 16 (44, 44, 43, 45) | -0.010 (± 0.186) | 0.012 (± 0.182) | -0.025 (± 0.195) | 0.005 (± 0.178) |
| Week 20 (43, 43, 41, 43) | -0.030 (± 0.208) | -0.037 (± 0.244) | -0.031 (± 0.177) | 0.013 (± 0.187) |
| Week 24 (42, 43, 43, 43) | -0.013 (± 0.181) | -0.042 (± 0.160) | -0.040 (± 0.229) | 0.035 (± 0.200) |
| Week 28 (41, 42, 40, 42) | -0.024 (± 0.189) | 0.008 (± 0.238) | -0.031 (± 0.232) | 0.037 (± 0.184) |
| Week 32 (44, 44, 43, 44) | -0.002 (± 0.217) | -0.056 (± 0.223) | 0.015 (± 0.220) | 0.030 (± 0.190) |

| | | | | |
|--------------------------|-----------------|------------------|------------------|-----------------|
| Week 40 (42, 41, 41, 44) | 0.018 (± 0.207) | 0.009 (± 0.196) | -0.022 (± 0.208) | 0.034 (± 0.224) |
| Week 48 (38, 41, 40, 43) | 0.032 (± 0.183) | -0.012 (± 0.167) | -0.044 (± 0.214) | 0.035 (± 0.190) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Cholesterol

| | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|
| End point title | Mean change from baseline in Cholesterol |
| End point description: Cholesterol was measured in millimoles per liter (mmol/L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points. | |
| End point type | Secondary |
| End point timeframe: From Baseline (Week 1) to Week 48 | |

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|--------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: mmol/L | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 (42, 45, 45, 43) | 0.00 (± 0.49) | -0.07 (± 0.46) | -0.06 (± 0.51) | -0.19 (± 0.47) |
| Week 4 (44, 44, 43, 46) | -0.08 (± 0.49) | -0.03 (± 0.46) | -0.07 (± 0.68) | -0.07 (± 0.57) |
| Week 8 (44, 43, 44, 44) | -0.09 (± 0.57) | -0.07 (± 0.46) | -0.15 (± 0.81) | -0.17 (± 0.59) |
| Week 12 (44, 44, 45, 44) | -0.14 (± 0.72) | -0.16 (± 0.61) | -0.23 (± 0.68) | -0.10 (± 0.75) |
| Week 16 (44, 45, 43, 45) | -0.16 (± 0.80) | -0.16 (± 0.66) | -0.35 (± 0.80) | -0.27 (± 0.72) |
| Week 20 (43, 44, 42, 44) | -0.27 (± 0.77) | -0.22 (± 0.60) | -0.42 (± 0.81) | -0.23 (± 0.85) |
| Week 24 (42, 43, 44, 44) | -0.12 (± 0.87) | -0.17 (± 0.66) | -0.28 (± 0.96) | -0.16 (± 0.78) |
| Week 28 (43, 43, 40, 43) | -0.17 (± 0.89) | -0.37 (± 0.63) | -0.35 (± 0.97) | -0.29 (± 0.80) |
| Week 32 (44, 44, 43, 45) | -0.13 (± 0.86) | -0.22 (± 0.63) | -0.16 (± 0.83) | -0.15 (± 0.81) |
| Week 40 (42, 42, 41, 44) | -0.34 (± 0.87) | -0.25 (± 0.80) | -0.19 (± 0.77) | -0.13 (± 1.15) |
| Week 48 (38, 42, 40, 43) | -0.40 (± 0.80) | -0.36 (± 0.74) | -0.23 (± 0.97) | -0.18 (± 1.09) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Triglycerides

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|-----------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| End point title | Mean change from baseline in Triglycerides |
| End point description: Triglycerides was measured in millimoles per liter (mmol/L). The Safety Set (SS) consisted of all study | |

participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

| | |
|-----------------------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| From Baseline (Week 1) to Week 48 | |

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|--------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: mmol/L | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 (42, 45, 45, 44) | -0.176 (± 1.593) | 0.046 (± 0.683) | 0.110 (± 0.855) | 0.183 (± 0.751) |
| Week 4 (44, 44, 43, 46) | -0.189 (± 1.212) | -0.004 (± 0.510) | -0.030 (± 0.471) | 0.084 (± 0.529) |
| Week 8 (44, 43, 44, 44) | -0.182 (± 1.554) | 0.076 (± 0.582) | -0.084 (± 0.498) | 0.046 (± 0.585) |
| Week 12 (44, 44, 45, 44) | -0.265 (± 1.445) | 0.088 (± 0.713) | 0.063 (± 0.578) | 0.009 (± 0.514) |
| Week 16 (44, 45, 43, 45) | -0.164 (± 1.345) | 0.099 (± 1.488) | 0.142 (± 0.580) | 0.112 (± 1.035) |
| Week 20 (43, 45, 42, 44) | -0.233 (± 1.391) | -0.104 (± 0.837) | 0.008 (± 0.622) | -0.060 (± 0.707) |
| Week 24 (42, 43, 44, 44) | -0.263 (± 1.515) | -0.045 (± 0.774) | -0.013 (± 0.608) | -0.030 (± 0.707) |
| Week 28 (43, 43, 40, 43) | -0.013 (± 1.559) | -0.125 (± 0.782) | -0.043 (± 0.423) | -0.036 (± 0.663) |
| Week 32 (44, 44, 43, 45) | -0.260 (± 1.418) | 0.045 (± 0.717) | 0.057 (± 0.532) | 0.112 (± 0.718) |
| Week 40 (42, 42, 41, 44) | -0.134 (± 1.175) | -0.159 (± 0.765) | 0.177 (± 0.821) | 0.022 (± 0.644) |
| Week 48 (38, 42, 40, 43) | -0.242 (± 1.516) | -0.149 (± 0.758) | 0.114 (± 0.507) | 0.054 (± 0.752) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Protein

| | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|
| End point title | Mean change from baseline in Protein |
| End point description: | |
| Protein was measured in grams per liter (g/L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points. | |
| End point type | Secondary |
| End point timeframe: | |
| From Baseline (Week 1) to Week 48 | |

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|--------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: g/L | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 (42, 45, 45, 44) | -0.2 (± 3.7) | -1.2 (± 4.0) | -1.0 (± 4.2) | -1.1 (± 3.8) |
| Week 4 (44, 44, 43, 46) | -1.5 (± 4.4) | -1.6 (± 4.2) | -1.5 (± 4.7) | -1.7 (± 4.4) |
| Week 8 (44, 43, 44, 44) | -1.1 (± 4.4) | -2.1 (± 4.1) | -1.8 (± 5.7) | -2.0 (± 3.9) |
| Week 12 (44, 44, 45, 44) | -0.8 (± 3.8) | -1.3 (± 4.7) | -1.4 (± 5.2) | -1.2 (± 5.8) |
| Week 16 (44, 45, 43, 45) | -1.2 (± 5.2) | -0.3 (± 4.1) | -2.3 (± 5.6) | -3.8 (± 5.0) |
| Week 20 (43, 45, 42, 44) | -2.7 (± 6.0) | -1.6 (± 4.6) | -2.6 (± 4.7) | -3.1 (± 5.4) |
| Week 24 (42, 43, 44, 44) | -2.2 (± 7.5) | -1.8 (± 4.6) | -1.8 (± 5.5) | -2.0 (± 4.7) |
| Week 28 (43, 43, 40, 43) | -3.1 (± 7.4) | -2.4 (± 4.6) | -2.5 (± 5.7) | -3.6 (± 6.4) |
| Week 32 (44, 44, 43, 45) | -1.4 (± 6.9) | -1.5 (± 5.7) | -0.8 (± 5.0) | -1.9 (± 6.4) |
| Week 40 (42, 42, 41, 44) | -2.2 (± 6.5) | -0.9 (± 5.0) | -1.8 (± 5.3) | -2.6 (± 6.1) |
| Week 48 (38, 42, 40, 43) | -2.3 (± 6.2) | -2.4 (± 5.9) | -0.9 (± 5.1) | -3.4 (± 6.4) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Albumin

| | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|
| End point title | Mean change from baseline in Albumin |
| End point description: | |
| Albumin was measured in grams per liter (g/L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points. | |
| End point type | Secondary |
| End point timeframe: | |
| From Baseline (Week 1) to Week 48 | |

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|--------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: g/L | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 (42, 45, 45, 44) | 0.1 (± 2.1) | -0.4 (± 2.4) | -0.5 (± 2.4) | -0.5 (± 1.9) |
| Week 4 (44, 44, 43, 46) | -0.5 (± 2.4) | -0.4 (± 2.3) | -0.2 (± 2.4) | -0.3 (± 1.9) |
| Week 8 (44, 43, 44, 44) | -0.3 (± 2.3) | -0.3 (± 2.5) | -0.3 (± 3.0) | 0.1 (± 2.2) |
| Week 12 (44, 44, 45, 44) | -0.1 (± 2.2) | 0.2 (± 2.7) | 0.2 (± 2.7) | 0.7 (± 3.0) |

| | | | | |
|--------------------------|--------------|--------------|-------------|--------------|
| Week 16 (44, 45, 43, 45) | 0.0 (± 2.5) | 1.0 (± 2.5) | 0.1 (± 2.9) | -0.2 (± 2.9) |
| Week 20 (43, 45, 42, 44) | -0.7 (± 2.7) | 0.1 (± 2.7) | 0.4 (± 2.4) | 0.4 (± 2.2) |
| Week 24 (42, 43, 44, 44) | -0.1 (± 2.9) | 0.0 (± 2.1) | 0.4 (± 2.4) | 1.2 (± 2.7) |
| Week 28 (43, 43, 40, 43) | -0.7 (± 3.0) | -0.4 (± 2.3) | 0.1 (± 2.9) | 0.1 (± 2.6) |
| Week 32 (44, 44, 43, 45) | 0.6 (± 2.8) | -0.1 (± 3.0) | 0.9 (± 3.2) | 0.7 (± 2.8) |
| Week 40 (42, 42, 41, 44) | 0.1 (± 2.8) | -0.1 (± 2.9) | 0.2 (± 2.6) | 0.3 (± 3.0) |
| Week 48 (38, 42, 40, 43) | 0.1 (± 2.8) | -0.7 (± 3.0) | 0.2 (± 3.0) | -0.8 (± 3.5) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Glucose

| | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|
| End point title | Mean change from baseline in Glucose |
| End point description: | |
| Glucose was measured in millimoles per liter (mmol/L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points. | |
| End point type | Secondary |
| End point timeframe: | |
| From Baseline (Week 1) to Week 48 | |

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|--------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: mmol/L | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 (42, 45, 44, 43) | 0.18 (± 0.75) | 0.26 (± 0.70) | 0.09 (± 0.78) | 0.13 (± 1.28) |
| Week 4 (44, 44, 43, 46) | 0.04 (± 0.71) | 0.03 (± 0.70) | -0.04 (± 0.90) | 0.11 (± 1.10) |
| Week 8 (44, 43, 44, 44) | 0.17 (± 0.66) | 0.12 (± 0.90) | 0.23 (± 0.95) | 0.12 (± 1.16) |
| Week 12 (44, 44, 43, 44) | -0.08 (± 0.69) | 0.08 (± 0.66) | -0.13 (± 0.79) | -0.15 (± 0.99) |
| Week 16 (44, 45, 43, 45) | 0.11 (± 0.77) | 0.06 (± 0.63) | 0.16 (± 0.92) | -0.18 (± 1.47) |
| Week 20 (43, 44, 42, 43) | 0.16 (± 0.85) | 0.20 (± 0.84) | 0.13 (± 0.83) | -0.08 (± 1.01) |
| Week 24 (42, 43, 43, 43) | -0.07 (± 0.85) | 0.05 (± 0.49) | -0.09 (± 0.73) | -0.22 (± 1.06) |
| Week 28 (39, 43, 40, 43) | 0.22 (± 1.01) | 0.09 (± 0.76) | -0.01 (± 0.74) | 0.07 (± 1.22) |
| Week 32 (44, 44, 42, 45) | -0.04 (± 0.72) | -0.07 (± 0.63) | -0.08 (± 0.65) | 0.06 (± 1.10) |
| Week 40 (41, 41, 41, 44) | -0.05 (± 0.62) | 0.08 (± 0.71) | -0.09 (± 0.68) | -0.08 (± 1.07) |
| Week 48 (38, 42, 40, 43) | -0.14 (± 0.78) | -0.11 (± 0.61) | -0.06 (± 0.64) | -0.14 (± 1.25) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Lipase, Pancreatic

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|-----------------|-------------------------------------------------|
| End point title | Mean change from baseline in Lipase, Pancreatic |
|-----------------|-------------------------------------------------|

End point description:

Lipase, Pancreatic was measured in units per liter (U/L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

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

End point timeframe:

From Baseline (Week 1) to Week 48

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|--------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: U/L | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 (42, 45, 45, 44) | -1.1 (± 10.5) | 2.2 (± 11.9) | 0.1 (± 9.2) | -0.2 (± 7.5) |
| Week 4 (44, 44, 43, 46) | -2.1 (± 9.8) | 0.9 (± 9.1) | 0.1 (± 10.6) | -1.2 (± 10.0) |
| Week 8 (44, 43, 44, 44) | -3.1 (± 9.2) | 3.7 (± 11.8) | 2.0 (± 20.0) | -1.8 (± 10.3) |
| Week 12 (44, 44, 45, 44) | -0.5 (± 8.7) | 1.0 (± 11.1) | -0.7 (± 13.4) | -0.6 (± 9.6) |
| Week 16 (44, 45, 43, 45) | 0.4 (± 7.4) | 2.7 (± 8.4) | 0.5 (± 11.3) | -0.2 (± 11.8) |
| Week 20 (43, 45, 42, 44) | -0.6 (± 10.4) | 2.1 (± 8.0) | -0.9 (± 9.0) | -1.7 (± 9.3) |
| Week 24 (42, 43, 44, 44) | -0.5 (± 11.0) | -0.1 (± 9.1) | -0.1 (± 8.1) | 1.2 (± 11.8) |
| Week 28 (43, 43, 40, 43) | 1.6 (± 13.1) | 1.7 (± 10.5) | 0.5 (± 11.9) | 1.7 (± 14.1) |
| Week 32 (44, 44, 43, 45) | 1.1 (± 15.1) | 1.0 (± 11.0) | 1.2 (± 10.6) | 3.8 (± 21.6) |
| Week 40 (42, 42, 41, 44) | 1.2 (± 11.0) | 1.3 (± 7.0) | -0.3 (± 8.9) | 2.5 (± 8.9) |
| Week 48 (38, 42, 40, 43) | 1.4 (± 10.1) | 2.2 (± 10.0) | 0.3 (± 10.7) | 3.7 (± 10.2) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Creatine Kinase

| | |
|-----------------|----------------------------------------------|
| End point title | Mean change from baseline in Creatine Kinase |
|-----------------|----------------------------------------------|

End point description:

Creatine Kinase was measured in units per liter (U/L). The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points.

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

End point timeframe:

From Baseline (Week 1) to Week 48

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|--------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: U/L | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 (42, 45, 45, 43) | -3.0 (± 67.1) | -2.2 (± 55.6) | -2.2 (± 18.2) | 0.1 (± 46.5) |
| Week 4 (44, 44, 43, 46) | 29.6 (± 218.4) | -6.2 (± 54.8) | 3.2 (± 22.0) | -16.9 (± 56.5) |
| Week 8 (44, 43, 44, 44) | -4.9 (± 56.9) | -8.5 (± 52.7) | -1.5 (± 23.6) | -4.6 (± 122.1) |
| Week 12 (44, 44, 45, 44) | -6.3 (± 57.5) | -8.4 (± 85.8) | -3.0 (± 22.4) | -29.4 (± 80.7) |
| Week 16 (44, 45, 43, 45) | 0.9 (± 59.4) | -11.5 (± 105.1) | -7.5 (± 22.2) | -23.2 (± 106.3) |
| Week 20 (43, 43, 42, 44) | -8.2 (± 60.0) | 5.9 (± 149.1) | -3.5 (± 22.2) | -33.4 (± 95.3) |
| Week 24 (42, 43, 44, 44) | -6.4 (± 48.6) | -5.4 (± 123.7) | -2.6 (± 27.4) | -27.7 (± 98.9) |
| Week 28 (43, 42, 40, 43) | -1.5 (± 67.3) | -19.1 (± 131.5) | -0.7 (± 25.4) | -36.7 (± 103.8) |
| Week 32 (44, 44, 43, 45) | 2.0 (± 67.0) | -10.0 (± 167.0) | 34.0 (± 222.1) | -24.2 (± 91.2) |
| Week 40 (42, 42, 41, 44) | 9.9 (± 109.1) | -20.4 (± 131.4) | -2.7 (± 25.4) | -16.3 (± 106.4) |
| Week 48 (38, 42, 40, 43) | 7.8 (± 67.3) | -20.4 (± 138.3) | -3.6 (± 25.5) | -33.4 (± 106.5) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in pH

| | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|
| End point title | Mean change from baseline in pH |
| End point description: | |
| The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points. | |
| End point type | Secondary |
| End point timeframe: | |
| From Baseline (Week 1) to Week 48 | |

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|--------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: pH | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 (43, 43, 44, 43) | -0.01 (± 0.66) | 0.03 (± 0.62) | -0.07 (± 0.67) | 0.15 (± 0.78) |
| Week 4 (43, 43, 43, 43) | 0.10 (± 0.77) | 0.15 (± 0.52) | 0.06 (± 0.72) | 0.16 (± 0.74) |
| Week 8 (42, 44, 44, 42) | -0.12 (± 0.79) | 0.00 (± 0.62) | -0.08 (± 0.56) | -0.04 (± 0.65) |
| Week 12 (44, 43, 43, 42) | 0.00 (± 0.81) | 0.15 (± 0.69) | 0.03 (± 0.79) | 0.20 (± 0.83) |
| Week 16 (44, 45, 39, 45) | -0.02 (± 0.61) | 0.00 (± 0.51) | -0.09 (± 0.81) | 0.11 (± 0.69) |

| | | | | |
|--------------------------|----------------|----------------|----------------|----------------|
| Week 20 (42, 43, 41, 43) | -0.11 (± 0.75) | -0.01 (± 0.59) | 0.06 (± 0.58) | 0.07 (± 0.88) |
| Week 24 (43, 42, 44, 42) | 0.03 (± 0.85) | -0.01 (± 0.46) | -0.11 (± 0.81) | 0.02 (± 0.81) |
| Week 28 (44, 42, 42, 41) | -0.13 (± 0.84) | -0.06 (± 0.57) | -0.05 (± 0.73) | -0.01 (± 0.69) |
| Week 32 (44, 44, 42, 43) | -0.02 (± 0.75) | -0.03 (± 0.55) | -0.18 (± 0.66) | 0.09 (± 0.86) |
| Week 40 (42, 43, 41, 44) | -0.14 (± 0.81) | 0.19 (± 0.66) | -0.21 (± 0.81) | -0.07 (± 0.62) |
| Week 48 (38, 42, 40, 43) | -0.11 (± 0.66) | 0.06 (± 0.73) | -0.11 (± 0.74) | -0.08 (± 0.72) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Erythrocytes (/HPF)

| | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|
| End point title | Mean change from baseline in Erythrocytes (/HPF) |
| End point description: The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points. | |
| End point type | Secondary |
| End point timeframe: From Baseline (Week 1) to Week 48 | |

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|--------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: % of Erythrocytes per HPF | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 (43, 43, 44, 43) | -6.8 (± 53.7) | 0.1 (± 8.4) | 0.2 (± 2.4) | 0.9 (± 7.9) |
| Week 4 (43, 43, 43, 43) | -8.7 (± 52.6) | -0.8 (± 4.1) | 1.4 (± 10.5) | -0.6 (± 3.2) |
| Week 8 (42, 44, 44, 42) | -8.7 (± 53.5) | -0.3 (± 6.9) | 0.4 (± 6.1) | 0.0 (± 6.8) |
| Week 12 (44, 43, 43, 42) | -8.6 (± 52.6) | 1.3 (± 17.4) | -0.4 (± 2.4) | 17.4 (± 118.5) |
| Week 16 (43, 45, 39, 45) | -5.7 (± 48.0) | -1.3 (± 4.1) | -0.6 (± 2.6) | -0.5 (± 5.5) |
| Week 20 (42, 43, 41, 43) | -7.7 (± 53.7) | -1.0 (± 3.5) | -0.1 (± 3.9) | -0.6 (± 4.4) |
| Week 24 (43, 42, 44, 42) | -7.2 (± 53.5) | -1.2 (± 3.9) | -0.3 (± 2.3) | -0.9 (± 4.6) |
| Week 28 (44, 42, 42, 41) | -7.6 (± 51.3) | -1.3 (± 4.2) | -0.7 (± 2.9) | 3.0 (± 16.9) |
| Week 32 (44, 44, 42, 43) | -8.5 (± 52.5) | 4.9 (± 41.8) | 0.0 (± 3.9) | 0.1 (± 4.5) |
| Week 40 (42, 43, 41, 44) | -9.1 (± 53.2) | 3.5 (± 18.8) | -0.5 (± 3.5) | 0.4 (± 5.4) |
| Week 48 (38, 42, 40, 43) | -9.7 (± 56.3) | -0.4 (± 5.4) | 1.9 (± 15.5) | 0.1 (± 4.0) |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in Leukocytes (/HPF)

| | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
| End point title | Mean change from baseline in Leukocytes (/HPF) |
| End point description: The Safety Set (SS) consisted of all study participants who were randomized and received at least 1 dose (any amount) of study drug. Here, 'n' (Number analyzed) signifies participants who were evaluable at specified time points. | |
| End point type | Secondary |
| End point timeframe: From Baseline (Week 1) to Week 48 | |

| End point values | SOC + Placebo iv Q4W (SS) | SOC + DZP 6mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) |
|--------------------------------------|------------------------------|------------------------------------|-------------------------------------|-------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 45 | 45 | 45 | 47 |
| Units: % of Leukocytes per HPF | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 2 (43, 43, 44, 43) | -0.1 (± 11.4) | -1.4 (± 8.1) | -0.8 (± 2.9) | 2.9 (± 13.7) |
| Week 4 (43, 43, 43, 43) | -0.2 (± 9.0) | -0.6 (± 8.5) | -0.7 (± 4.5) | 3.0 (± 12.6) |
| Week 8 (42, 44, 44, 42) | -1.2 (± 10.4) | 4.8 (± 29.3) | -0.3 (± 6.8) | 3.0 (± 14.4) |
| Week 12 (44, 43, 43, 42) | -1.1 (± 11.3) | 4.4 (± 42.2) | -1.3 (± 4.2) | 2.7 (± 13.9) |
| Week 16 (43, 45, 39, 45) | 0.1 (± 9.6) | -1.6 (± 12.5) | -0.2 (± 9.6) | 1.8 (± 12.9) |
| Week 20 (42, 43, 41, 43) | -0.1 (± 10.1) | 3.7 (± 13.3) | 0.4 (± 9.8) | 1.7 (± 4.0) |
| Week 24 (43, 42, 44, 42) | -1.0 (± 10.9) | 10.7 (± 52.1) | -0.7 (± 4.5) | 0.4 (± 4.5) |
| Week 28 (44, 42, 42, 41) | -0.2 (± 9.6) | 2.4 (± 9.7) | -1.1 (± 4.4) | 2.0 (± 10.1) |
| Week 32 (44, 44, 42, 43) | -0.6 (± 10.8) | -0.5 (± 13.5) | -1.0 (± 5.4) | 4.1 (± 15.7) |
| Week 40 (42, 43, 41, 44) | -1.6 (± 10.4) | 2.2 (± 19.8) | 1.4 (± 7.7) | 6.8 (± 30.9) |
| Week 48 (38, 42, 40, 43) | -0.3 (± 8.9) | 10.8 (± 71.9) | -1.0 (± 4.0) | 0.8 (± 5.3) |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events were collected from Baseline (Week 1) until end of the study (Week 48)

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

Dictionary used

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

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

Reporting groups

| | |
|-----------------------|---------------------------|
| Reporting group title | SOC + Placebo iv Q4W (SS) |
|-----------------------|---------------------------|

Reporting group description:

This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive Placebo intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period. Participants formed the Safety Set (SS).

| | |
|-----------------------|-------------------------------|
| Reporting group title | SOC + DZP 45mg/kg iv Q4W (SS) |
|-----------------------|-------------------------------|

Reporting group description:

This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive dapirolizumab pegol (DZP) 45mg/kg intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period. Participants formed the SS.

| | |
|-----------------------|-------------------------------|
| Reporting group title | SOC + DZP 24mg/kg iv Q4W (SS) |
|-----------------------|-------------------------------|

Reporting group description:

This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive dapirolizumab pegol (DZP) 24mg/kg intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period. Participants formed the SS.

| | |
|-----------------------|------------------------------|
| Reporting group title | SOC + DZP 6mg/kg iv Q4W (SS) |
|-----------------------|------------------------------|

Reporting group description:

This arm consisted of participants who received stable standard-of-care (SOC) medications at study entry and were randomized to receive dapirolizumab pegol (DZP) 6mg/kg intravenous (iv) infusion every 4 weeks (Q4W) during the 24-week Double-Blind Treatment Period. Participants formed the SS.

| Serious adverse events | SOC + Placebo iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) |
|---------------------------------------------------|---------------------------|-------------------------------|-------------------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 6 / 45 (13.33%) | 5 / 47 (10.64%) | 6 / 45 (13.33%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Thoracic vertebral fracture | | | |
| subjects affected / exposed | 0 / 45 (0.00%) | 0 / 47 (0.00%) | 0 / 45 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vascular disorders | | | |

| | | | |
|-------------------------------------------------|----------------|----------------|----------------|
| Deep vein thrombosis | | | |
| subjects affected / exposed | 1 / 45 (2.22%) | 0 / 47 (0.00%) | 0 / 45 (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 |
| Cardiac disorders | | | |
| Coronary artery disease | | | |
| subjects affected / exposed | 0 / 45 (0.00%) | 0 / 47 (0.00%) | 1 / 45 (2.22%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pregnancy, puerperium and perinatal conditions | | | |
| Abortion spontaneous | | | |
| subjects affected / exposed | 0 / 45 (0.00%) | 0 / 47 (0.00%) | 0 / 45 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 0 / 45 (0.00%) | 0 / 47 (0.00%) | 1 / 45 (2.22%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Antiphospholipid syndrome | | | |
| subjects affected / exposed | 1 / 45 (2.22%) | 0 / 47 (0.00%) | 0 / 45 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Autoimmune haemolytic anaemia | | | |
| subjects affected / exposed | 0 / 45 (0.00%) | 0 / 47 (0.00%) | 0 / 45 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Haemorrhagic disorder | | | |
| subjects affected / exposed | 1 / 45 (2.22%) | 0 / 47 (0.00%) | 0 / 45 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Anastomotic ulcer perforation | | | |

| | | | |
|-------------------------------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 45 (0.00%) | 1 / 47 (2.13%) | 0 / 45 (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 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Pneumothorax | | | |
| subjects affected / exposed | 0 / 45 (0.00%) | 0 / 47 (0.00%) | 1 / 45 (2.22%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pulmonary embolism | | | |
| subjects affected / exposed | 1 / 45 (2.22%) | 0 / 47 (0.00%) | 0 / 45 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal and urinary disorders | | | |
| Lupus nephritis | | | |
| subjects affected / exposed | 0 / 45 (0.00%) | 1 / 47 (2.13%) | 0 / 45 (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 |
| Nephrosclerosis | | | |
| subjects affected / exposed | 0 / 45 (0.00%) | 0 / 47 (0.00%) | 0 / 45 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal tubular necrosis | | | |
| subjects affected / exposed | 0 / 45 (0.00%) | 0 / 47 (0.00%) | 0 / 45 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Systemic lupus erythematosus | | | |
| subjects affected / exposed | 1 / 45 (2.22%) | 1 / 47 (2.13%) | 0 / 45 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Cellulitis | | | |

| | | | |
|-------------------------------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 45 (0.00%) | 0 / 47 (0.00%) | 1 / 45 (2.22%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Herpes zoster | | | |
| subjects affected / exposed | 0 / 45 (0.00%) | 0 / 47 (0.00%) | 0 / 45 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Influenza | | | |
| subjects affected / exposed | 1 / 45 (2.22%) | 0 / 47 (0.00%) | 0 / 45 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pseudomonal bacteraemia | | | |
| subjects affected / exposed | 0 / 45 (0.00%) | 0 / 47 (0.00%) | 1 / 45 (2.22%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pyelonephritis | | | |
| subjects affected / exposed | 0 / 45 (0.00%) | 1 / 47 (2.13%) | 0 / 45 (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 |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 45 (0.00%) | 1 / 47 (2.13%) | 0 / 45 (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 |
| Appendicitis | | | |
| subjects affected / exposed | 0 / 45 (0.00%) | 0 / 47 (0.00%) | 1 / 45 (2.22%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---------------------------------------------------|---------------------------------|--|--|
| Serious adverse events | SOC + DZP 6mg/kg iv Q4W (SS) | | |
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 5 / 45 (11.11%) | | |
| number of deaths (all causes) | 0 | | |
| number of deaths resulting from adverse events | 0 | | |

| | | | |
|-------------------------------------------------|----------------|--|--|
| Injury, poisoning and procedural complications | | | |
| Thoracic vertebral fracture | | | |
| subjects affected / exposed | 1 / 45 (2.22%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Vascular disorders | | | |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 0 / 45 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cardiac disorders | | | |
| Coronary artery disease | | | |
| subjects affected / exposed | 0 / 45 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pregnancy, puerperium and perinatal conditions | | | |
| Abortion spontaneous | | | |
| subjects affected / exposed | 1 / 45 (2.22%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 0 / 45 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Antiphospholipid syndrome | | | |
| subjects affected / exposed | 0 / 45 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Autoimmune haemolytic anaemia | | | |
| subjects affected / exposed | 1 / 45 (2.22%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Haemorrhagic disorder | | | |

| | | | |
|-------------------------------------------------|----------------|--|--|
| subjects affected / exposed | 0 / 45 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gastrointestinal disorders | | | |
| Anastomotic ulcer perforation | | | |
| subjects affected / exposed | 0 / 45 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Pneumothorax | | | |
| subjects affected / exposed | 0 / 45 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pulmonary embolism | | | |
| subjects affected / exposed | 0 / 45 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Renal and urinary disorders | | | |
| Lupus nephritis | | | |
| subjects affected / exposed | 0 / 45 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Nephrosclerosis | | | |
| subjects affected / exposed | 1 / 45 (2.22%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Renal tubular necrosis | | | |
| subjects affected / exposed | 1 / 45 (2.22%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Musculoskeletal and connective tissue disorders | | | |
| Systemic lupus erythematosus | | | |

| | | | |
|-------------------------------------------------|----------------|--|--|
| subjects affected / exposed | 0 / 45 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Infections and infestations | | | |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 45 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Herpes zoster | | | |
| subjects affected / exposed | 1 / 45 (2.22%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Influenza | | | |
| subjects affected / exposed | 0 / 45 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pseudomonal bacteraemia | | | |
| subjects affected / exposed | 0 / 45 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pyelonephritis | | | |
| subjects affected / exposed | 0 / 45 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 45 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Appendicitis | | | |
| subjects affected / exposed | 0 / 45 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

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

| Non-serious adverse events | SOC + Placebo iv Q4W (SS) | SOC + DZP 45mg/kg iv Q4W (SS) | SOC + DZP 24mg/kg iv Q4W (SS) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|
| Total subjects affected by non-serious adverse events subjects affected / exposed | 22 / 45 (48.89%) | 25 / 47 (53.19%) | 24 / 45 (53.33%) |
| Investigations Hepatic enzyme increased subjects affected / exposed occurrences (all) | 3 / 45 (6.67%) 3 | 0 / 47 (0.00%) 0 | 0 / 45 (0.00%) 0 |
| Vascular disorders Hypertension subjects affected / exposed occurrences (all) | 1 / 45 (2.22%) 1 | 2 / 47 (4.26%) 2 | 3 / 45 (6.67%) 4 |
| Nervous system disorders Headache subjects affected / exposed occurrences (all) Migraine subjects affected / exposed occurrences (all) | 6 / 45 (13.33%) 6 0 / 45 (0.00%) 0 | 3 / 47 (6.38%) 3 3 / 47 (6.38%) 3 | 4 / 45 (8.89%) 6 1 / 45 (2.22%) 1 |
| Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all) Nausea subjects affected / exposed occurrences (all) Dyspepsia subjects affected / exposed occurrences (all) Abdominal pain upper subjects affected / exposed occurrences (all) | 3 / 45 (6.67%) 3 2 / 45 (4.44%) 2 5 / 45 (11.11%) 5 3 / 45 (6.67%) 3 | 3 / 47 (6.38%) 3 2 / 47 (4.26%) 2 0 / 47 (0.00%) 0 0 / 47 (0.00%) 0 | 4 / 45 (8.89%) 4 3 / 45 (6.67%) 3 0 / 45 (0.00%) 0 0 / 45 (0.00%) 0 |
| Psychiatric disorders Anxiety | | | |

| | | | |
|------------------------------------------------------------------------------------------------------------------|---------------------|----------------------|----------------------|
| subjects affected / exposed occurrences (all) | 2 / 45 (4.44%) 2 | 0 / 47 (0.00%) 0 | 3 / 45 (6.67%) 3 |
| Musculoskeletal and connective tissue disorders Back pain subjects affected / exposed occurrences (all) | 2 / 45 (4.44%) 3 | 2 / 47 (4.26%) 2 | 0 / 45 (0.00%) 0 |
| Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all) | 2 / 45 (4.44%) 2 | 5 / 47 (10.64%) 5 | 6 / 45 (13.33%) 7 |
| Upper respiratory tract infection subjects affected / exposed occurrences (all) | 4 / 45 (8.89%) 5 | 7 / 47 (14.89%) 9 | 3 / 45 (6.67%) 5 |
| Pharyngitis subjects affected / exposed occurrences (all) | 3 / 45 (6.67%) 3 | 5 / 47 (10.64%) 6 | 4 / 45 (8.89%) 6 |
| Urinary tract infection subjects affected / exposed occurrences (all) | 2 / 45 (4.44%) 3 | 2 / 47 (4.26%) 2 | 4 / 45 (8.89%) 4 |
| Bronchitis subjects affected / exposed occurrences (all) | 0 / 45 (0.00%) 0 | 3 / 47 (6.38%) 3 | 2 / 45 (4.44%) 2 |
| Influenza subjects affected / exposed occurrences (all) | 1 / 45 (2.22%) 1 | 3 / 47 (6.38%) 3 | 3 / 45 (6.67%) 3 |

| | | | |
|------------------------------------------------------------------------------------------------|---------------------------------|--|--|
| Non-serious adverse events | SOC + DZP 6mg/kg iv Q4W (SS) | | |
| Total subjects affected by non-serious adverse events subjects affected / exposed | 26 / 45 (57.78%) | | |
| Investigations Hepatic enzyme increased subjects affected / exposed occurrences (all) | 0 / 45 (0.00%) 0 | | |
| Vascular disorders Hypertension | | | |

| | | | |
|--------------------------------------------------|-----------------------|--|--|
| subjects affected / exposed occurrences (all) | 3 / 45 (6.67%) 3 | | |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed occurrences (all) | 6 / 45 (13.33%) 14 | | |
| Migraine | | | |
| subjects affected / exposed occurrences (all) | 0 / 45 (0.00%) 0 | | |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed occurrences (all) | 4 / 45 (8.89%) 4 | | |
| Nausea | | | |
| subjects affected / exposed occurrences (all) | 1 / 45 (2.22%) 1 | | |
| Dyspepsia | | | |
| subjects affected / exposed occurrences (all) | 1 / 45 (2.22%) 2 | | |
| Abdominal pain upper | | | |
| subjects affected / exposed occurrences (all) | 0 / 45 (0.00%) 0 | | |
| Psychiatric disorders | | | |
| Anxiety | | | |
| subjects affected / exposed occurrences (all) | 1 / 45 (2.22%) 1 | | |
| Musculoskeletal and connective tissue disorders | | | |
| Back pain | | | |
| subjects affected / exposed occurrences (all) | 5 / 45 (11.11%) 6 | | |
| Infections and infestations | | | |
| Nasopharyngitis | | | |
| subjects affected / exposed occurrences (all) | 5 / 45 (11.11%) 7 | | |
| Upper respiratory tract infection | | | |

| | | | |
|-----------------------------|-----------------|--|--|
| subjects affected / exposed | 5 / 45 (11.11%) | | |
| occurrences (all) | 5 | | |
| Pharyngitis | | | |
| subjects affected / exposed | 4 / 45 (8.89%) | | |
| occurrences (all) | 5 | | |
| Urinary tract infection | | | |
| subjects affected / exposed | 7 / 45 (15.56%) | | |
| occurrences (all) | 7 | | |
| Bronchitis | | | |
| subjects affected / exposed | 3 / 45 (6.67%) | | |
| occurrences (all) | 5 | | |
| Influenza | | | |
| subjects affected / exposed | 3 / 45 (6.67%) | | |
| occurrences (all) | 3 | | |

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

None reported