



Clinical trial results:

A multiple treatment session, open label phase 2 clinical study of GSK2398852 administered following and together with GSK2315698 in cohorts of patients with cardiac amyloidosis

Summary

| | |
|--------------------------|-----------------|
| EudraCT number | 2016-000276-23 |
| Trial protocol | GB |
| Global end of trial date | 03 January 2019 |

Results information

| | |
|--------------------------------|-----------------|
| Result version number | v1 (current) |
| This version publication date | 12 October 2019 |
| First version publication date | 12 October 2019 |

Trial information

Trial identification

| | |
|-----------------------|--------|
| Sponsor protocol code | 201464 |
|-----------------------|--------|

Additional study identifiers

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

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | GlaxoSmithKline |
| Sponsor organisation address | 980 Great West Road, Brentford, Middlesex, United Kingdom, |
| Public contact | GSK Response Center, GlaxoSmithKline, 1 8664357343, GSKClinicalSupportHD@gsk.com |
| Scientific contact | GSK Response Center, GlaxoSmithKline, 1 8664357343, GSKClinicalSupportHD@gsk.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 | 15 August 2019 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 03 January 2019 |
| Was the trial ended prematurely? | Yes |

Notes:

General information about the trial

Main objective of the trial:

- Assessment of reduction in cardiac amyloid load after repeated administrations of Anti-SAP treatment as evaluated by CMR in all study groups
- Assessment of safety & tolerability of repeated administration of Anti-SAP treatment, including compatibility with chemotherapy treatment in Group 3

Protection of trial subjects:

Not applicable

Background therapy: -

Evidence for comparator: -

| | |
|---|--------------|
| Actual start date of recruitment | 10 July 2017 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | No |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|-------------------|
| Country: Number of subjects enrolled | United Kingdom: 6 |
| Country: Number of subjects enrolled | United States: 1 |
| Worldwide total number of subjects | 7 |
| EEA total number of subjects | 6 |

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) | 0 |
| From 65 to 84 years | 7 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

This was an open label, non-randomized, monthly repeat anti-serum amyloid p component (anti-SAP) treatment study in systemic amyloidosis participants with cardiac dysfunction caused by cardiac amyloidosis.

Pre-assignment

Screening details:

Twelve participants were screened; seven were enrolled in to study (six were enrolled in Group 1 and one in Group 2). No participant was enrolled in Group 3. The study was terminated by sponsor due to a change in the benefit:risk profile of GSK2315698+GSK2398852 (anti-SAP treatment).

Period 1

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

Arms

| | |
|------------------------------|---|
| Are arms mutually exclusive? | Yes |
| Arm title | Group 1: Cardiac TTR amyloidosis (ATTR-CM) participants |

Arm description:

Cardiac transthyretin (TTR) amyloidosis (transthyretin amyloid cardiomyopathy [ATTR-CM]) participants with mutant genotypes primarily associated with familial amyloidotic cardiomyopathy (FAC) and wild-type TTR were included. Participants received 6 anti-SAP treatments, consisting of carboxy pyrrolidine hexanoyl pyrrolidine carboxylate (CPHPC) followed by anti-SAP monoclonal antibody (mAb) at monthly intervals. During each anti-SAP treatment, participants received CPHPC intravenous (IV) infusion once daily for up to 72 hours. After 72 hours of CPHPC administration, participants were administered intravenous infusion of anti-SAP mAb over 6-8 hours each on Days 1 and 3. The starting dose level of anti-SAP mAb was 600 milligrams (mg) (divided into 2 infusions of 300 mg). In each treatment session, CPHPC was administered as subcutaneous (SC) injection for 11 days from the day of first dose of anti-SAP mAb.

| | |
|--|-----------------------|
| Arm type | Experimental |
| Investigational medicinal product name | CPHPC IV |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

During each anti-SAP treatments, participants received CPHPC IV infusion once daily for up to 72 hours prior to initial mAb dose.

| | |
|--|------------------------|
| Investigational medicinal product name | CPHPC SC |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

In each treatment session, CPHPC was administered as SC injection for 11 days from the day of first dose of anti-SAP mAb.

| | |
|--|---------------------------------------|
| Investigational medicinal product name | anti-SAP mAb |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Concentrate for solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Anti-SAP mAb was administered as an IV infusion over 2 days (Days 1 and 3) with 6-8 hour infusion per day. The starting dose level of anti-SAP mAb was 600 mg (divided into 2 infusions of 300 mg).

| | |
|------------------|--|
| Arm title | Group 2: Post-chemotherapy AL Amyloidosis participants |
|------------------|--|

Arm description:

Immunoglobulin light chain amyloidosis (AL) participants who attained either a very good partial response (VGPR), or complete response (CR), to systemic chemotherapy (including autologous stem cell transplantation) were included. Participants received 6 anti-SAP treatments, consisting of CPHPC followed by anti-SAP mAb at monthly intervals. During each anti-SAP treatment, participants received CPHPC IV infusion once daily for up to 72 hours. After 72 hours of CPHPC administration, participants were administered IV infusion of anti-SAP mAb over 6-8 hours each on Days 1 and 3. The starting dose level of anti-SAP mAb was 600 mg (divided into 2 infusions of 300 mg). In each treatment session, CPHPC was administered by as SC injection for 11 days from the day of first dose of anti-SAP mAb.

| | |
|--|-----------------------|
| Arm type | Experimental |
| Investigational medicinal product name | CPHPC IV |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

During each anti-SAP treatments, participants received CPHPC IV infusion once daily for up to 72 hours prior to initial mAb dose.

| | |
|--|---------------------------------------|
| Investigational medicinal product name | anti-SAP mAb |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Concentrate for solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Anti-SAP mAb was administered as an IV infusion over 2 days (Days 1 and 3) with 6-8 hour infusion per day. The starting dose level of anti-SAP mAb was 600 mg (divided into 2 infusions of 300 mg).

| | |
|--|------------------------|
| Investigational medicinal product name | CPHPC SC |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

In each treatment session, CPHPC was administered as SC injection for 11 days from the day of first dose of anti-SAP mAb.

| Number of subjects in period 1 | Group 1: Cardiac TTR amyloidosis (ATTR-CM) participants | Group 2: Post-chemotherapy AL Amyloidosis participants |
|---------------------------------------|---|--|
| Started | 6 | 1 |
| Completed | 6 | 0 |
| Not completed | 0 | 1 |
| Adverse event, non-fatal | - | 1 |

Baseline characteristics

Reporting groups

| | |
|-----------------------|---|
| Reporting group title | Group 1: Cardiac TTR amyloidosis (ATTR-CM) participants |
|-----------------------|---|

Reporting group description:

Cardiac transthyretin (TTR) amyloidosis (transthyretin amyloid cardiomyopathy [ATTR-CM]) participants with mutant genotypes primarily associated with familial amyloidotic cardiomyopathy (FAC) and wild-type TTR were included. Participants received 6 anti-SAP treatments, consisting of carboxy pyrrolidine hexanoyl pyrrolidine carboxylate (CPHPC) followed by anti-SAP monoclonal antibody (mAb) at monthly intervals. During each anti-SAP treatment, participants received CPHPC intravenous (IV) infusion once daily for up to 72 hours. After 72 hours of CPHPC administration, participants were administered intravenous infusion of anti-SAP mAb over 6-8 hours each on Days 1 and 3. The starting dose level of anti-SAP mAb was 600 milligrams (mg) (divided into 2 infusions of 300 mg). In each treatment session, CPHPC was administered as subcutaneous (SC) injection for 11 days from the day of first dose of anti-SAP mAb.

| | |
|-----------------------|--|
| Reporting group title | Group 2: Post-chemotherapy AL Amyloidosis participants |
|-----------------------|--|

Reporting group description:

Immunoglobulin light chain amyloidosis (AL) participants who attained either a very good partial response (VGPR), or complete response (CR), to systemic chemotherapy (including autologous stem cell transplantation) were included. Participants received 6 anti-SAP treatments, consisting of CPHPC followed by anti-SAP mAb at monthly intervals. During each anti-SAP treatment, participants received CPHPC IV infusion once daily for up to 72 hours. After 72 hours of CPHPC administration, participants were administered IV infusion of anti-SAP mAb over 6-8 hours each on Days 1 and 3. The starting dose level of anti-SAP mAb was 600 mg (divided into 2 infusions of 300 mg). In each treatment session, CPHPC was administered by as SC injection for 11 days from the day of first dose of anti-SAP mAb.

| Reporting group values | Group 1: Cardiac TTR amyloidosis (ATTR-CM) participants | Group 2: Post-chemotherapy AL Amyloidosis participants | Total |
|---|---|--|-------|
| Number of subjects | 6 | 1 | 7 |
| Age categorical | | | |
| Units: Subjects | | | |
| Total participants | 6 | 1 | 7 |
| Age Continuous | | | |
| '99' or '99999' indicates data was not available. | | | |
| Units: years | | | |
| arithmetic mean | 74.3 | 67.0 | |
| standard deviation | ± 3.27 | ± 99999 | - |
| Sex: Female, Male | | | |
| Units: Subjects | | | |
| Female | 0 | 0 | 0 |
| Male | 6 | 1 | 7 |
| Race/Ethnicity, Customized | | | |
| Units: Subjects | | | |
| White/Caucasian/European Heritage | 6 | 1 | 7 |

End points

End points reporting groups

| | |
|--|---|
| Reporting group title | Group 1: Cardiac TTR amyloidosis (ATTR-CM) participants |
| Reporting group description: | |
| Cardiac transthyretin (TTR) amyloidosis (transthyretin amyloid cardiomyopathy [ATTR-CM]) participants with mutant genotypes primarily associated with familial amyloidotic cardiomyopathy (FAC) and wild-type TTR were included. Participants received 6 anti-SAP treatments, consisting of carboxy pyrrolidine hexanoyl pyrrolidine carboxylate (CPHPC) followed by anti-SAP monoclonal antibody (mAb) at monthly intervals. During each anti-SAP treatment, participants received CPHPC intravenous (IV) infusion once daily for up to 72 hours. After 72 hours of CPHPC administration, participants were administered intravenous infusion of anti-SAP mAb over 6-8 hours each on Days 1 and 3. The starting dose level of anti-SAP mAb was 600 milligrams (mg) (divided into 2 infusions of 300 mg). In each treatment session, CPHPC was administered as subcutaneous (SC) injection for 11 days from the day of first dose of anti-SAP mAb. | |
| Reporting group title | Group 2: Post-chemotherapy AL Amyloidosis participants |
| Reporting group description: | |
| Immunoglobulin light chain amyloidosis (AL) participants who attained either a very good partial response (VGPR), or complete response (CR), to systemic chemotherapy (including autologous stem cell transplantation) were included. Participants received 6 anti-SAP treatments, consisting of CPHPC followed by anti-SAP mAb at monthly intervals. During each anti-SAP treatment, participants received CPHPC IV infusion once daily for up to 72 hours. After 72 hours of CPHPC administration, participants were administered IV infusion of anti-SAP mAb over 6-8 hours each on Days 1 and 3. The starting dose level of anti-SAP mAb was 600 mg (divided into 2 infusions of 300 mg). In each treatment session, CPHPC was administered by as SC injection for 11 days from the day of first dose of anti-SAP mAb. | |

Primary: Change from Baseline in left ventricular (LV) mass over time up to 8-week follow-up

| | |
|---|--|
| End point title | Change from Baseline in left ventricular (LV) mass over time up to 8-week follow-up ^[1] |
| End point description: | |
| Left ventricular mass was measured by Cardiac Magnetic Resonance (CMR) imaging to assess reduction in cardiac amyloid load after repeated administration of anti-SAP treatment. Each CMR imaging session took approximately 45-60 minutes, with a maximum scan time inside of the scanner of 90 minutes. Baseline was considered as the latest assessment prior to first administration of either study drug, i.e. CPHPC or anti-SAP mAb. Change from Baseline was calculated as post-dose visit value minus Baseline value. Safety Population comprised of all participants who received at least one dose of study treatment (any dose of CPHPC [GSK2315698] or anti-SAP mAb [GSK2398852]). Only those participants with data available at the specified time points were analyzed (represented by n= X in the category titles). 99999 indicates data is not available. 88888 indicates data is not available as standard deviation could not be calculated as only one participant was analyzed. | |
| End point type | Primary |
| End point timeframe: | |
| Baseline (Day -1) and Session 2 Day 24, Session 3 Day 24, Session 4 Day 24, Session 5 Day 24, 8 Weeks Follow-up | |

Notes:

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

Justification: There are no statistical data to report.

| | | | | |
|-----------------------------|---|--|--|--|
| End point values | Group 1: Cardiac TTR amyloidosis (ATTR-CM) participants | Group 2: Post-chemotherapy AL Amyloidosis participants | | |
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6 ^[2] | 1 ^[3] | | |

| | | | | |
|--------------------------------------|-------------------|-------------------|--|--|
| Units: Grams | | | | |
| arithmetic mean (standard deviation) | | | | |
| Session 2, Day 24, n=6,0 | 2.505 (± 19.9174) | 99999 (± 99999) | | |
| Session 3, Day 24, n=6,0 | 4.175 (± 22.9366) | 99999 (± 99999) | | |
| Session 4, Day 24, n=5,0 | 9.194 (± 14.4271) | 99999 (± 99999) | | |
| Session 5, Day 24, n=4,0 | 7.955 (± 19.4341) | 99999 (± 99999) | | |
| 8 Weeks Follow up, n=6,1 | 0.977 (± 12.1795) | -32.420 (± 88888) | | |

Notes:

[2] - Safety Population

[3] - Safety Population

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with any on-treatment adverse events (AEs)

| | |
|-----------------|--|
| End point title | Number of participants with any on-treatment adverse events (AEs) ^[4] |
|-----------------|--|

End point description:

AE is any untoward medical occurrence in a participant, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. Number of participants with any on-treatment AEs are presented.

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

End point timeframe:

Up to 56 days after the last dosing session (up to 265 days)

Notes:

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

Justification: There are no statistical data to report.

| End point values | Group 1: Cardiac TTR amyloidosis (ATTR-CM) participants | Group 2: Post-chemotherapy AL Amyloidosis participants | | |
|-----------------------------|---|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6 ^[5] | 1 ^[6] | | |
| Units: Participants | 6 | 1 | | |

Notes:

[5] - Safety Population

[6] - Safety Population

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with any serious adverse events (SAEs)

| | |
|-----------------|--|
| End point title | Number of participants with any serious adverse events |
|-----------------|--|

End point description:

AE is any untoward medical occurrence in a participant, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. Any untoward event

resulting in death, life threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, congenital anomaly/birth defect, events associated with liver injury and impaired liver function, or any other situation according to medical or scientific judgment were categorized as SAE. Number of participants with any SAEs during study are presented.

| | |
|---|---------|
| End point type | Primary |
| End point timeframe: | |
| Up to the end of study (Up to 369 days) | |

Notes:

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

Justification: There are no statistical data to report.

| End point values | Group 1: Cardiac TTR amyloidosis (ATTR-CM) participants | Group 2: Post- chemotherapy AL Amyloidosis participants | | |
|-----------------------------|---|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6 ^[8] | 1 ^[9] | | |
| Units: Participants | 2 | 1 | | |

Notes:

[8] - Safety Population

[9] - Safety Population

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with abnormal hematology values

| | |
|-----------------|--|
| End point title | Number of participants with abnormal hematology values ^[10] |
|-----------------|--|

End point description:

Blood samples were collected for assessment of hematology parameters, which included platelet count, hemoglobin, hematocrit, erythrocytes, reticulocyte count, Mean corpuscular volume (MCV), Mean corpuscular hemoglobin (MCH), Mean corpuscular hemoglobin concentration (MCHC), neutrophils, lymphocytes, monocytes, eosinophils, leukocytes and basophils. Abnormal laboratory results are categorized as high, low or normal with respect to their normal ranges. Data for worst case post Baseline is presented. Participants having both High and Low values from Normal Ranges at any post-baseline visits for any parameter was counted in both the High and Low categories.

| | |
|---|---------|
| End point type | Primary |
| End point timeframe: | |
| Up to the end of study (Up to 369 days) | |

Notes:

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

Justification: There are no statistical data to report.

| End point values | Group 1: Cardiac TTR amyloidosis (ATTR-CM) participants | Group 2: Post- chemotherapy AL Amyloidosis participants | | |
|-----------------------------|---|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6 ^[11] | 1 ^[12] | | |
| Units: Participants | | | | |
| Basophils, high | 2 | 0 | | |
| Basophils, normal | 4 | 1 | | |
| Basophils, low | 0 | 0 | | |

| | | | | |
|------------------------|---|---|--|--|
| Eosinophils, high | 3 | 0 | | |
| Eosinophils, normal | 3 | 1 | | |
| Eosinophils, low | 0 | 0 | | |
| Hematocrit, high | 0 | 0 | | |
| Hematocrit, normal | 1 | 0 | | |
| Hematocrit, low | 5 | 1 | | |
| Hemoglobin, high | 0 | 0 | | |
| Hemoglobin, normal | 0 | 0 | | |
| Hemoglobin, low | 6 | 1 | | |
| Lymphocytes, high | 1 | 0 | | |
| Lymphocytes, normal | 0 | 0 | | |
| Lymphocytes, low | 6 | 1 | | |
| MCH, high | 1 | 0 | | |
| MCH, normal | 3 | 1 | | |
| MCH, low | 3 | 0 | | |
| MCHC, high | 3 | 0 | | |
| MCHC, normal | 1 | 1 | | |
| MCHC, low | 2 | 0 | | |
| MCV, high | 1 | 0 | | |
| MCV, normal | 4 | 1 | | |
| MCV, low | 2 | 0 | | |
| Monocytes, high | 2 | 1 | | |
| Monocytes, normal | 4 | 0 | | |
| Monocytes, low | 0 | 0 | | |
| Neutrophils, high | 5 | 1 | | |
| Neutrophils, normal | 0 | 0 | | |
| Neutrophils, low | 4 | 0 | | |
| Platelet count, high | 1 | 0 | | |
| Platelet count, normal | 3 | 0 | | |
| Platelet count, low | 2 | 1 | | |
| Erythrocytes, high | 0 | 0 | | |
| Erythrocytes, normal | 0 | 0 | | |
| Erythrocytes, low | 6 | 1 | | |
| Reticulocytes, high | 1 | 0 | | |
| Reticulocytes, normal | 5 | 1 | | |
| Reticulocytes, low | 0 | 0 | | |
| Leukocytes, high | 2 | 1 | | |
| Leukocytes, normal | 3 | 0 | | |
| Leukocytes, low | 1 | 0 | | |

Notes:

[11] - Safety Population

[12] - Safety Population

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with abnormal clinical chemistry values

| | |
|-----------------|---|
| End point title | Number of participants with abnormal clinical chemistry |
|-----------------|---|

End point description:

Blood samples were collected for assessment of clinical chemistry parameters, which included aspartate aminotransferase (AST), alanine aminotransferase (ALT), alkaline phosphatase (ALP), lactate

dehydrogenase (LDH), urea, creatinine, glucose, chloride, creatinine kinase, potassium, sodium, calcium, total carbon dioxide (CO₂), urate, total and direct bilirubin, total protein and albumin. Abnormal laboratory results are categorized as high, low or normal with respect to their normal ranges. Data for worst case post Baseline is presented. Participants having both High and Low values from Normal Ranges at any post-baseline visits for any parameter was counted in both the High and Low categories.

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

End point timeframe:

Up to the end of study (Up to 369 days)

Notes:

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

Justification: There are no statistical data to report.

| End point values | Group 1: Cardiac TTR amyloidosis (ATTR-CM) participants | Group 2: Post- chemotherapy AL Amyloidosis participants | | |
|-----------------------------|---|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6 ^[14] | 1 ^[15] | | |
| Units: Participants | | | | |
| Glucose, high | 6 | 1 | | |
| Glucose, normal | 0 | 0 | | |
| Glucose, low | 0 | 0 | | |
| Albumin, high | 0 | 0 | | |
| Albumin, normal | 2 | 1 | | |
| Albumin, low | 4 | 0 | | |
| ALP, high | 5 | 0 | | |
| ALP, normal | 1 | 1 | | |
| ALP, low | 0 | 0 | | |
| ALT, high | 2 | 1 | | |
| ALT, normal | 4 | 0 | | |
| ALT, low | 0 | 0 | | |
| AST, high | 4 | 1 | | |
| AST, normal | 2 | 0 | | |
| AST, low | 0 | 0 | | |
| Direct Bilirubin, high | 4 | 1 | | |
| Direct Bilirubin, normal | 2 | 0 | | |
| Direct Bilirubin, low | 0 | 0 | | |
| Total Bilirubin, high | 4 | 0 | | |
| Total Bilirubin, normal | 2 | 1 | | |
| Total Bilirubin, low | 0 | 0 | | |
| Calcium, high | 0 | 0 | | |
| Calcium, normal | 4 | 0 | | |
| Calcium, low | 2 | 1 | | |
| Creatinine Kinase, high | 1 | 0 | | |
| Creatinine Kinase, normal | 3 | 1 | | |
| Creatinine Kinase, low | 2 | 0 | | |
| Chloride, high | 0 | 0 | | |
| Chloride, normal | 1 | 0 | | |
| Chloride, low | 5 | 1 | | |
| CO ₂ , high | 6 | 0 | | |
| CO ₂ , normal | 0 | 1 | | |
| CO ₂ , low | 4 | 0 | | |

| | | | | |
|--------------------|---|---|--|--|
| Creatinine, high | 4 | 0 | | |
| Creatinine, normal | 2 | 1 | | |
| Creatinine, low | 0 | 0 | | |
| Potassium, high | 2 | 0 | | |
| Potassium, normal | 3 | 1 | | |
| Potassium, low | 2 | 0 | | |
| LDH, high | 6 | 1 | | |
| LDH, normal | 0 | 0 | | |
| LDH, low | 0 | 0 | | |
| Protein, high | 0 | 0 | | |
| Protein, normal | 0 | 0 | | |
| Protein, low | 6 | 1 | | |
| Sodium, high | 1 | 0 | | |
| Sodium, normal | 5 | 1 | | |
| Sodium, low | 0 | 0 | | |
| Urate, high | 5 | 1 | | |
| Urate, normal | 1 | 0 | | |
| Urate, low | 0 | 0 | | |
| Urea, high | 6 | 1 | | |
| Urea, normal | 0 | 0 | | |
| Urea, low | 0 | 0 | | |

Notes:

[14] - Safety Population

[15] - Safety Population

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with abnormal urinalysis results

| | |
|-----------------|---|
| End point title | Number of participants with abnormal urinalysis results ^[16] |
|-----------------|---|

End point description:

Urine samples were collected to assess potential of hydrogen (pH), specific gravity, albumin excretion rate, creatinine excretion rate and protein excretion rate. Abnormal urinalysis results are categorized as high, low or normal with respect to their normal ranges. Data for worst case post Baseline is presented. Participants having both High and Low values from Normal Ranges at any post-baseline visits for any parameter was counted in both the High and Low categories. Only those participants with data available at the specified time points were analyzed (represented by n= X in the category titles). 99999 indicates data is not available.

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

End point timeframe:

Up to the end of study (Up to 369 days)

Notes:

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

Justification: There are no statistical data to report.

| End point values | Group 1: Cardiac TTR amyloidosis (ATTR-CM) participants | Group 2: Post- chemotherapy AL Amyloidosis participants | | |
|-----------------------------|---|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6 ^[17] | 1 ^[18] | | |
| Units: Participants | | | | |

| | | | | |
|--|---|-------|--|--|
| pH, high, n=6,1 | 0 | 0 | | |
| pH, normal, n=6,1 | 6 | 1 | | |
| pH, low, n=6,1 | 0 | 0 | | |
| Specific gravity, high, n=1,0 | 0 | 99999 | | |
| Specific gravity, normal, n=1,0 | 1 | 99999 | | |
| Specific gravity, low, n=1,0 | 0 | 99999 | | |
| Albumin excretion rate, high, n=6,1 | 0 | 0 | | |
| Albumin excretion rate, normal, n=6,1 | 6 | 1 | | |
| Albumin excretion rate, low, n=6,1 | 0 | 0 | | |
| Creatinine excretion rate, high, n=6,1 | 1 | 0 | | |
| Creatinine excretion rate, normal, n=6,1 | 1 | 1 | | |
| Creatinine excretion rate, low, n=6,1 | 5 | 0 | | |
| Protein excretion rate, high, n=6,1 | 4 | 1 | | |
| Protein excretion rate, normal, n=6,1 | 2 | 0 | | |
| Protein excretion rate, low, n=6,1 | 0 | 0 | | |

Notes:

[17] - Safety Population

[18] - Safety Population

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with abnormal urinalysis results for character parameters

| | |
|-----------------|--|
| End point title | Number of participants with abnormal urinalysis results for character parameters ^[19] |
|-----------------|--|

End point description:

Urine samples were collected to assess character parameters which included Cellular Casts, Erythrocytes, Glucose, Ketones, Leukocytes and Occult Blood. Number of participants with abnormal urinalysis results are presented. Data for worst case post Baseline is presented. Only those participants with data available at the specified time points were analyzed (represented by n= X in the category titles).

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

End point timeframe:

Up to the end of study (Up to 369 days)

Notes:

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

Justification: There are no statistical data to report.

| End point values | Group 1: Cardiac TTR amyloidosis (ATTR-CM) participants | Group 2: Post-chemotherapy AL Amyloidosis participants | | |
|-----------------------------|---|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6 ^[20] | 1 ^[21] | | |
| Units: Participants | | | | |
| Cellular casts, n=5,1 | 0 | 0 | | |
| Erythrocytes , n=6,1 | 6 | 1 | | |
| Glucose, n=6,1 | 1 | 0 | | |
| Ketones, n=6,1 | 0 | 0 | | |
| Leukocytes, n=6,1 | 6 | 1 | | |
| Occult blood, n=6,1 | 2 | 1 | | |

Notes:

[20] - Safety Population

[21] - Safety Population

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with body temperature shifts from Baseline relative to potential clinical importance (PCI) criteria

| | |
|-----------------|--|
| End point title | Number of participants with body temperature shifts from Baseline relative to potential clinical importance (PCI) criteria ^[22] |
|-----------------|--|

End point description:

Vital signs including body temperature was measured after participants rested in semi-supine position for at least 5 minutes. Number of participants with shifts in body temperature from Baseline to worst case post Baseline relative to PCI criteria have been presented. PCI results were categorized as to high, to low and to normal/no change with reference to PCI criteria. PCI criteria for body temperature was: high: >37.5 degree Celsius; low: not applicable.

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

End point timeframe:

Up to the end of study (Up to 369 days)

Notes:

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

Justification: There are no statistical data to report.

| End point values | Group 1: Cardiac TTR amyloidosis (ATTR-CM) participants | Group 2: Post- chemotherapy AL Amyloidosis participants | | |
|-----------------------------|---|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6 ^[23] | 1 ^[24] | | |
| Units: Participants | | | | |
| To high | 2 | 0 | | |
| To normal/No change | 4 | 1 | | |
| To low | 0 | 0 | | |

Notes:

[23] - Safety Population

[24] - Safety Population

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with systolic blood pressure (SBP) and diastolic blood pressure (DBP) shifts from Baseline relative to PCI criteria

| | |
|-----------------|--|
| End point title | Number of participants with systolic blood pressure (SBP) and diastolic blood pressure (DBP) shifts from Baseline relative to PCI criteria ^[25] |
|-----------------|--|

End point description:

Vital signs including SBP and DBP were measured after participants rested in semi-supine position for at least 5 minutes. Number of participants with shifts in SBP and DBP from baseline to worst case post

baseline relative to PCI criteria have been presented. PCI results were categorized as to high, to low and to normal/no change with reference to PCI criteria. PCI criteria for SBP was: high: >180 millimeter of mercury (mmHg); low: <90 mmHg. PCI criteria for DBP was: high: >110 mmHg; low: <30 mmHg.

| | |
|---|---------|
| End point type | Primary |
| End point timeframe: | |
| Up to the end of study (Up to 369 days) | |

Notes:

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

Justification: There are no statistical data to report.

| End point values | Group 1: Cardiac TTR amyloidosis (ATTR-CM) participants | Group 2: Post- chemotherapy AL Amyloidosis participants | | |
|-----------------------------|---|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6 ^[26] | 1 ^[27] | | |
| Units: Participants | | | | |
| SBP, To high | 0 | 0 | | |
| SBP, To normal/No change | 1 | 1 | | |
| SBP, To low | 5 | 0 | | |
| DBP, To high | 0 | 0 | | |
| DBP, To normal/No change | 6 | 1 | | |
| DBP, To low | 0 | 0 | | |

Notes:

[26] - Safety Population

[27] - Safety Population

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with pulse rate shifts from Baseline relative to PCI criteria

| | |
|-----------------|--|
| End point title | Number of participants with pulse rate shifts from Baseline relative to PCI criteria ^[28] |
|-----------------|--|

End point description:

Vital signs including pulse rate were measured after participants rested in semi-supine position for at least 5 minutes. Number of participants with shifts in pulse rate from baseline to worst case post baseline relative to PCI criteria have been presented. PCI results were categorized as to high, to low and to normal/no change with reference to its PCI criteria. PCI criteria for pulse rate was: high: >140 beats per minute (bpm); low: <35 bpm.

| | |
|---|---------|
| End point type | Primary |
| End point timeframe: | |
| Up to the end of study (Up to 369 days) | |

Notes:

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

Justification: There are no statistical data to report.

| End point values | Group 1: Cardiac TTR amyloidosis (ATTR-CM) participants | Group 2: Post- chemotherapy AL Amyloidosis participants | | |
|-----------------------------|---|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6 ^[29] | 1 ^[30] | | |
| Units: Participants | | | | |
| To high | 0 | 0 | | |
| To normal/No change | 6 | 1 | | |
| To low | 0 | 0 | | |

Notes:

[29] - Safety Population

[30] - Safety Population

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with abnormal electrocardiogram (ECG) findings

| | |
|-----------------|---|
| End point title | Number of participants with abnormal electrocardiogram (ECG) findings ^[31] |
|-----------------|---|

End point description:

Twelve-lead ECGs were performed during the study using an automated ECG machine. The number of participants with worst case post-Baseline abnormal ECG findings were reported and categorized as abnormal-clinically significant and abnormal-not clinically significant.

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

End point timeframe:

Up to the end of study (Up to 369 days)

Notes:

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

Justification: There are no statistical data to report.

| End point values | Group 1: Cardiac TTR amyloidosis (ATTR-CM) participants | Group 2: Post- chemotherapy AL Amyloidosis participants | | |
|-------------------------------------|---|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6 ^[32] | 1 ^[33] | | |
| Units: Participants | | | | |
| Abnormal-Clinically significant | 0 | 0 | | |
| Abnormal-Not Clinically significant | 6 | 1 | | |

Notes:

[32] - Safety Population

[33] - Safety Population

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with abnormalities during cardiac monitoring

| | |
|-----------------|---|
| End point title | Number of participants with abnormalities during cardiac monitoring ^[34] |
|-----------------|---|

End point description:

Lead II telemetry and cardiac monitoring devices were used for electrical cardiac monitoring during the study. The number of participants with worst case post-Baseline abnormalities during cardiac monitoring as per investigator's assessment have been reported and categorized as Abnormal-clinically significant and Abnormal-not clinically significant. Only those participants with data available at the specified time point was analyzed.

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

End point timeframe:

Up to the end of study (Up to 369 days)

Notes:

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

Justification: There are no statistical data to report.

| End point values | Group 1: Cardiac TTR amyloidosis (ATTR-CM) participants | Group 2: Post- chemotherapy AL Amyloidosis participants | | |
|-------------------------------------|---|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 5 ^[35] | 1 ^[36] | | |
| Units: Participants | | | | |
| Abnormal-Clinically significant | 2 | 0 | | |
| Abnormal-Not Clinically significant | 3 | 1 | | |

Notes:

[35] - Safety Population

[36] - Safety Population

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants for which unscheduled echocardiography (ECHO) was performed for safety reasons

| | |
|-----------------|---|
| End point title | Number of participants for which unscheduled echocardiography (ECHO) was performed for safety reasons ^[37] |
|-----------------|---|

End point description:

Echocardiography was performed by a qualified echocardiographer or cardiologist during the study. Number of participants with unscheduled echocardiograms performed for safety reasons have been presented. Only those participants with data available at the specified time point was analyzed.

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

End point timeframe:

Up to the end of study (Up to 369 days)

Notes:

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

Justification: There are no statistical data to report.

| End point values | Group 1: Cardiac TTR amyloidosis (ATTR-CM) participants | Group 2: Post- chemotherapy AL Amyloidosis participants | | |
|-----------------------------|---|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 2 ^[38] | 0 ^[39] | | |
| Units: Participants | 2 | | | |

Notes:

[38] - Safety Population

[39] - Safety Population

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with skin rashes

| | |
|-----------------|---|
| End point title | Number of participants with skin rashes ^[40] |
|-----------------|---|

End point description:

Skin rash was an event of special interest. Only Rashes that were associated with study drug were categorised as Rash for Common Terminology Criteria for Adverse Events (CTCAE) and are presented. Number of participants with on-treatment skin rash AEs are presented.

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

End point timeframe:

Up to 56 days after the last dosing session (up to 265 days)

Notes:

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

Justification: There are no statistical data to report.

| End point values | Group 1: Cardiac TTR amyloidosis (ATTR-CM) participants | Group 2: Post- chemotherapy AL Amyloidosis participants | | |
|-----------------------------|---|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6 ^[41] | 1 ^[42] | | |
| Units: Participants | 4 | 0 | | |

Notes:

[41] - Safety Population

[42] - Safety Population

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with skin rashes classified using CTCAE

| | |
|-----------------|--|
| End point title | Number of participants with skin rashes classified using |
|-----------------|--|

End point description:

Skin rash was an event of special interest. All the events of rashes were graded for their severity using CTCAE version 4.0 . Grade 1: mild, Grade 2: moderate, Grade 3: severe, Grade 4: life threatening, Grade 5: death. Higher the grade, more severe the symptoms. Only Rashes that were associated with study drug were categorized as Rash for CTCAE and are presented here. Number of participants with skin rashes classified by their maximum grade are presented.

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

End point timeframe:

Up to 56 days after the last dosing session (up to 265 days)

Notes:

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

Justification: There are no statistical data to report.

| End point values | Group 1: Cardiac TTR amyloidosis (ATTR-CM) participants | Group 2: Post- chemotherapy AL Amyloidosis participants | | |
|-----------------------------|---|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 4 ^[44] | 0 ^[45] | | |
| Units: Participants | | | | |
| Grade 1 | 3 | | | |
| Grade 2 | 1 | | | |
| Grade 3 | 0 | | | |
| Grade 4 | 0 | | | |
| Grade 5 | 0 | | | |

Notes:

[44] - Safety Population

[45] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with abnormalities in histopathological examination of skin biopsies

| | |
|--|---|
| End point title | Number of participants with abnormalities in histopathological examination of skin biopsies |
| End point description: Skin biopsy samples were collected for histopathological examination only on any rash development (\geq Grade 1) as decided by clinical judgment of the Investigator and/or dermatologist. Number of participants with abnormalities in histopathological examination of skin biopsies are presented. | |
| End point type | Secondary |
| End point timeframe: Up to the end of study (Up to 369 days) | |

| End point values | Group 1: Cardiac TTR amyloidosis (ATTR-CM) participants | Group 2: Post- chemotherapy AL Amyloidosis participants | | |
|-----------------------------|---|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6 ^[46] | 1 ^[47] | | |
| Units: Participants | 2 | 0 | | |

Notes:

[46] - Safety Population

[47] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with abnormalities in immunohistochemical examination of skin biopsies

| | |
|--|---|
| End point title | Number of participants with abnormalities in immunohistochemical examination of skin biopsies |
| End point description: Skin biopsy samples were collected for immunohistochemical examination only on any rash development (\geq Grade 1) as decided by clinical judgment of the Investigator and/or dermatologist. Number of participants with abnormalities in immunohistochemical examination of skin biopsies are presented. | |
| End point type | Secondary |
| End point timeframe: Up to the end of study (Up to 369 days) | |

| End point values | Group 1: Cardiac TTR amyloidosis (ATTR-CM) participants | Group 2: Post- chemotherapy AL Amyloidosis participants | | |
|-----------------------------|---|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6 ^[48] | 1 ^[49] | | |
| Units: Participants | 2 | 1 | | |

Notes:

[48] - Safety Population

[49] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with abnormalities in histopathological examination of blood biomarkers

| | |
|---|--|
| End point title | Number of participants with abnormalities in histopathological examination of blood biomarkers |
| End point description: Blood samples were to be collected along with each skin biopsy sample for histopathological examination of blood biomarkers only on any rash development (\geq Grade 1) as decided by clinical judgment of the Investigator and/or dermatologist. Data was not collected due to project termination. | |
| End point type | Secondary |
| End point timeframe: Up to the end of study (Up to 369 days) | |

| End point values | Group 1: Cardiac TTR amyloidosis (ATTR-CM) participants | Group 2: Post- chemotherapy AL Amyloidosis participants | | |
|-----------------------------|---|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 0 ^[50] | 0 ^[51] | | |
| Units: Participants | | | | |

Notes:

[50] - Safety Population

[51] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with abnormalities in immunohistochemical examination of blood biomarkers

| | |
|---|--|
| End point title | Number of participants with abnormalities in immunohistochemical examination of blood biomarkers |
| End point description: Blood samples were to be collected along with each skin biopsy sample for immunohistochemical examination of blood biomarkers only on any rash development (\geq Grade 1) as decided by clinical judgment of the Investigator and/or dermatologist. Data was not collected due to project termination. | |
| End point type | Secondary |
| End point timeframe: Up to the end of study (Up to 369 days) | |

| End point values | Group 1: Cardiac TTR amyloidosis (ATTR-CM) participants | Group 2: Post- chemotherapy AL Amyloidosis participants | | |
|-----------------------------|---|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 0 ^[52] | 0 ^[53] | | |
| Units: Participants | | | | |

Notes:

[52] - Safety Population

[53] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Fluid Phase Complement Marker-Complement 3 (C3) over time

| | |
|---|---|
| End point title | Change from Baseline in Fluid Phase Complement Marker-Complement 3 (C3) over time |
| End point description: Blood samples were collected for assessment of Fluid Phase Complement Markers which included complement 3 (C3). Baseline was considered as the latest assessment prior to first administration of either study drug, i.e. CPHPC or anti-SAP mAb. Change from Baseline was calculated as post-dose visit value minus Baseline value. Only those participants with data available at the specified time points were analyzed (represented by n= X in the category titles).99999 indicates data is not available. 88888 indicates data is not available, as standard deviation could not be calculated as only one participant was analyzed. | |
| End point type | Secondary |
| End point timeframe: Baseline (Day -1) and Session 1 to 6: Day 1 (predose, 2,4,8 hours), Day 2, Day 3 (predose, 2,4,8 | |

| End point values | Group 1: Cardiac TTR amyloidosis (ATTR-CM) participants | Group 2: Post- chemotherapy AL Amyloidosis participants | | |
|--------------------------------------|---|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6 ^[54] | 1 ^[55] | | |
| Units: Grams per Liter (g/L) | | | | |
| arithmetic mean (standard deviation) | | | | |
| C3, Session 1, Day 1, predose, n=6,1 | -0.032 (± 0.1444) | -0.150 (± 88888) | | |
| C3, Session 1, Day 1, 2 hour, n=6,1 | -0.008 (± 0.1105) | -0.230 (± 88888) | | |
| C3, Session 1, Day 1, 4 hour, n=6,1 | 0.030 (± 0.0566) | -0.100 (± 88888) | | |
| C3, Session 1, Day 1, 8 hour, n=6,1 | 0.068 (± 0.2073) | -0.160 (± 88888) | | |
| C3, Session 1, Day 2, n=6,1 | -0.125 (± 0.1033) | -0.180 (± 88888) | | |
| C3, Session 1, Day 3, predose, n=6,1 | -0.198 (± 0.1607) | -0.200 (± 88888) | | |
| C3, Session 1, Day 3, 2 hour, n=6,0 | -0.188 (± 0.1572) | 99999 (± 99999) | | |
| C3, Session 1, Day 3, 4 hour, n=6,0 | -0.222 (± 0.1288) | 99999 (± 99999) | | |
| C3, Session 1, Day 3, 8 hour, n=6,0 | -0.155 (± 0.1590) | 99999 (± 99999) | | |
| C3, Session 1, Day 5, n=6,0 | -0.280 (± 0.1646) | 99999 (± 99999) | | |
| C3, Session 1, Day 6, n=6,0 | -0.338 (± 0.1969) | 99999 (± 99999) | | |
| C3, Session 2, Day 1, predose, n=6,0 | -0.067 (± 0.1999) | 99999 (± 99999) | | |
| C3, Session 2, Day 1, 2 hour, n=6,0 | -0.103 (± 0.1629) | 99999 (± 99999) | | |
| C3, Session 2, Day 1, 4 hour, n=6,0 | -0.075 (± 0.2017) | 99999 (± 99999) | | |
| C3, Session 2, Day 1, 8 hour, n=6,0 | -0.130 (± 0.1585) | 99999 (± 99999) | | |
| C3, Session 2, Day 2, n=6,0 | -0.153 (± 0.1485) | 99999 (± 99999) | | |
| C3, Session 2, Day 3, predose, n=6,0 | -0.263 (± 0.1385) | 99999 (± 99999) | | |
| C3, Session 2, Day 3, 2 hour, n=6,0 | -0.242 (± 0.1694) | 99999 (± 99999) | | |
| C3, Session 2, Day 3, 4 hour, n=6,0 | -0.243 (± 0.1994) | 99999 (± 99999) | | |
| C3, Session 2, Day 3, 8 hour, n=6,0 | -0.235 (± 0.1685) | 99999 (± 99999) | | |
| C3, Session 2, Day 5, n=6,0 | -0.280 (± 0.1716) | 99999 (± 99999) | | |
| C3, Session 2, Day 6, n=6,0 | -0.327 (± 0.2298) | 99999 (± 99999) | | |
| C3, Session 3, Day 1, predose, n=6,0 | -0.053 (± 0.1928) | 99999 (± 99999) | | |

| | | | | |
|--------------------------------------|-------------------|-----------------|--|--|
| C3, Session 3, Day 1, 2 hour, n=6,0 | -0.078 (± 0.2279) | 99999 (± 99999) | | |
| C3, Session 3, Day 1, 4 hour, n=6,0 | -0.058 (± 0.2299) | 99999 (± 99999) | | |
| C3, Session 3, Day 1, 8 hour, n=6,0 | -0.057 (± 0.1999) | 99999 (± 99999) | | |
| C3, Session 3, Day 2, n=5,0 | -0.084 (± 0.2792) | 99999 (± 99999) | | |
| C3, Session 3, Day 3, predose, n=6,0 | -0.215 (± 0.1576) | 99999 (± 99999) | | |
| C3, Session 3, Day 3, 2 hour, n=6,0 | -0.232 (± 0.1699) | 99999 (± 99999) | | |
| C3, Session 3, Day 3, 4 hour, n=6,0 | -0.200 (± 0.1808) | 99999 (± 99999) | | |
| C3, Session 3, Day 3, 8 hour, n=6,0 | -0.190 (± 0.2287) | 99999 (± 99999) | | |
| C3, Session 3, Day 5, n=6,0 | -0.290 (± 0.1719) | 99999 (± 99999) | | |
| C3, Session 3, Day 6, n=6,0 | -0.308 (± 0.2077) | 99999 (± 99999) | | |
| C3, Session 4, Day 1, predose, n=5,0 | -0.094 (± 0.2271) | 99999 (± 99999) | | |
| C3, Session 4, Day 1, 2 hour, n=5,0 | -0.088 (± 0.1993) | 99999 (± 99999) | | |
| C3, Session 4, Day 1, 4 hour, n=4,0 | -0.005 (± 0.1392) | 99999 (± 99999) | | |
| C3, Session 4, Day 1, 8 hour, n=5,0 | -0.124 (± 0.1747) | 99999 (± 99999) | | |
| C3, Session 4, Day 2, n=5,0 | -0.144 (± 0.1641) | 99999 (± 99999) | | |
| C3, Session 4, Day 3, predose, n=5,0 | -0.214 (± 0.2454) | 99999 (± 99999) | | |
| C3, Session 4, Day 3, 2 hour, n=5,0 | -0.204 (± 0.2306) | 99999 (± 99999) | | |
| C3, Session 4, Day 3, 4 hour, n=5,0 | -0.190 (± 0.2088) | 99999 (± 99999) | | |
| C3, Session 4, Day 3, 8 hour, n=5,0 | -0.188 (± 0.2305) | 99999 (± 99999) | | |
| C3, Session 4, Day 5, n=5,0 | -0.270 (± 0.1996) | 99999 (± 99999) | | |
| C3, Session 4, Day 6, n=5,0 | -0.302 (± 0.2251) | 99999 (± 99999) | | |
| C3, Session 5, Day 1, predose, n=4,0 | -0.173 (± 0.1863) | 99999 (± 99999) | | |
| C3, Session 5, Day 1, 2 hour, n=4,0 | -0.147 (± 0.2326) | 99999 (± 99999) | | |
| C3, Session 5, Day 1, 4 hour, n=4,0 | -0.125 (± 0.1741) | 99999 (± 99999) | | |
| C3, Session 5, Day 1, 8 hour, n=4,0 | -0.150 (± 0.1881) | 99999 (± 99999) | | |
| C3, Session 5, Day 2, n=4,0 | -0.178 (± 0.2340) | 99999 (± 99999) | | |
| C3, Session 5, Day 3, predose, n=4,0 | -0.248 (± 0.1919) | 99999 (± 99999) | | |
| C3, Session 5, Day 3, 2 hour, n=4,0 | -0.235 (± 0.1964) | 99999 (± 99999) | | |
| C3, Session 5, Day 3, 4 hour, n=4,0 | -0.280 (± 0.2045) | 99999 (± 99999) | | |
| C3, Session 5, Day 3, 8 hour, n=4,0 | -0.235 (± 0.2301) | 99999 (± 99999) | | |
| C3, Session 5, Day 5, n=4,0 | -0.258 (± 0.2035) | 99999 (± 99999) | | |

| | | | | |
|--------------------------------------|-------------------|-----------------|--|--|
| C3, Session 5, Day 6, n=4,0 | -0.288 (± 0.1941) | 99999 (± 99999) | | |
| C3, Session 6, Day 1, predose, n=4,0 | -0.152 (± 0.2144) | 99999 (± 99999) | | |
| C3, Session 6, Day 1, 2 hour, n=4,0 | -0.145 (± 0.1877) | 99999 (± 99999) | | |
| C3, Session 6, Day 1, 4 hour, n=4,0 | -0.145 (± 0.2528) | 99999 (± 99999) | | |
| C3, Session 6, Day 1, 8 hour, n=4,0 | -0.135 (± 0.2626) | 99999 (± 99999) | | |
| C3, Session 6, Day 2, n=4,0 | -0.203 (± 0.2090) | 99999 (± 99999) | | |
| C3, Session 6, Day 3, predose, n=4,0 | -0.215 (± 0.2319) | 99999 (± 99999) | | |
| C3, Session 6, Day 3, 2 hour, n=4,0 | -0.273 (± 0.2179) | 99999 (± 99999) | | |
| C3, Session 6, Day 3, 4 hour, n=4,0 | -0.235 (± 0.2243) | 99999 (± 99999) | | |
| C3, Session 6, Day 3, 8 hour, n=4,0 | -0.238 (± 0.2421) | 99999 (± 99999) | | |
| C3, Session 6, Day 5, n=4,0 | -0.288 (± 0.2269) | 99999 (± 99999) | | |
| C3, Session 6, Day 6, n=4,0 | -0.315 (± 0.2225) | 99999 (± 99999) | | |

Notes:

[54] - Safety Population

[55] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Fluid Phase Complement Marker-Complement 4 (C4) over time

| | |
|-----------------|---|
| End point title | Change from Baseline in Fluid Phase Complement Marker-Complement 4 (C4) over time |
|-----------------|---|

End point description:

Blood samples were collected for assessment of Fluid Phase Complement Markers which included complement 4 (C4). Baseline was considered as the latest assessment prior to first administration of either study drug, i.e. CPHPC or anti-SAP mAb. Change from Baseline was calculated as post-dose visit value minus Baseline value. Only those participants with data available at the specified time points were analyzed (represented by n= X in the category titles). 99999 indicates data is not available. 88888 indicates data is not available, as standard deviation could not be calculated as only one participant was analyzed.

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

End point timeframe:

Baseline (Day -1) and Day 2, Day 5, Day 6

| End point values | Group 1: Cardiac TTR amyloidosis (ATTR-CM) participants | Group 2: Post-chemotherapy AL Amyloidosis participants | | |
|------------------------------|---|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6 ^[56] | 1 ^[57] | | |
| Units: Grams per Liter (g/L) | | | | |

| arithmetic mean (standard deviation) | | | | |
|--------------------------------------|-------------------|-----------------|--|--|
| C4, Session 1, Day 2, n=6,1 | -0.015 (± 0.0373) | 0.000 (± 88888) | | |
| C4, Session 1, Day 5, n=6,0 | -0.013 (± 0.0393) | 99999 (± 99999) | | |
| C4, Session 1, Day 6, n=6,0 | -0.017 (± 0.0403) | 99999 (± 99999) | | |
| C4, Session 2, Day 2, n=6,0 | -0.027 (± 0.0423) | 99999 (± 99999) | | |
| C4, Session 2, Day 5, n=6,0 | -0.023 (± 0.0505) | 99999 (± 99999) | | |
| C4, Session 2, Day 6, n=6,0 | -0.030 (± 0.0540) | 99999 (± 99999) | | |
| C4, Session 3, Day 2, n=5,0 | -0.010 (± 0.0543) | 99999 (± 99999) | | |
| C4, Session 3, Day 5, n=6,0 | -0.042 (± 0.0449) | 99999 (± 99999) | | |
| C4, Session 3, Day 6, n=6,0 | -0.042 (± 0.0542) | 99999 (± 99999) | | |
| C4, Session 4, Day 2, n=5,0 | -0.022 (± 0.0531) | 99999 (± 99999) | | |
| C4, Session 4, Day 5, n=5,0 | -0.036 (± 0.0677) | 99999 (± 99999) | | |
| C4, Session 4, Day 6, n=5,0 | -0.042 (± 0.0507) | 99999 (± 99999) | | |
| C4, Session 5, Day 2, n=4,0 | -0.028 (± 0.0574) | 99999 (± 99999) | | |
| C4, Session 5, Day 5, n=4,0 | -0.033 (± 0.0574) | 99999 (± 99999) | | |
| C4, Session 5, Day 6, n=4,0 | -0.025 (± 0.0545) | 99999 (± 99999) | | |
| C4, Session 6, Day 2, n=4,0 | -0.043 (± 0.0544) | 99999 (± 99999) | | |
| C4, Session 6, Day 5, n=4,0 | -0.050 (± 0.0678) | 99999 (± 99999) | | |
| C4, Session 6, Day 6, n=4,0 | -0.045 (± 0.0666) | 99999 (± 99999) | | |

Notes:

[56] - Safety Population

[57] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Fluid Phase Complement Marker-Total Complement (CH50) over time

| | |
|-----------------|---|
| End point title | Change from Baseline in Fluid Phase Complement Marker-Total Complement (CH50) over time |
|-----------------|---|

End point description:

Blood samples were collected for assessment of Fluid Phase Complement Markers which included total complement (CH50). Baseline was considered as the latest assessment prior to first administration of either study drug, i.e. CPHPC or anti-SAP mAb. Change from Baseline was calculated as post-dose visit value minus Baseline value. Only those participants with data available at the specified time points were analyzed (represented by n= X in the category titles). 99999 indicates data is not available. 88888 indicates data is not available, as standard deviation could not be calculated as only one participant was analyzed.

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

End point timeframe:

Baseline (Day -1) and Session 1 to 6: Day 1 (predose, 2,4,8 hours), Day 2, Day 3 (predose, 2,4,8

| End point values | Group 1: Cardiac TTR amyloidosis (ATTR-CM) participants | Group 2: Post- chemotherapy AL Amyloidosis participants | | |
|--|---|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6 ^[58] | 1 ^[59] | | |
| Units: Units per milliliter | | | | |
| arithmetic mean (standard deviation) | | | | |
| CH50, Session 1, Day 1, predose, n=6,1 | -0.7 (± 1.37) | 0.0 (± 88888) | | |
| CH50, Session 1, Day 1, 2 hour, n=6,1 | -0.8 (± 1.33) | 0.0 (± 88888) | | |
| CH50, Session 1, Day 1, 4 hour, n=6,1 | 0.2 (± 0.41) | 0.0 (± 88888) | | |
| CH50, Session 1, Day 1, 8 hour, n=6,1 | -0.8 (± 1.60) | 0.0 (± 88888) | | |
| CH50, Session 1, Day 2, n=6,1 | -2.7 (± 3.20) | 0.0 (± 88888) | | |
| CH50, Session 1, Day 3, predose, n=6,1 | -3.3 (± 4.46) | 0.0 (± 88888) | | |
| CH50, Session 1, Day 3, 2 hour, n=6,0 | -3.3 (± 4.37) | 99999 (± 99999) | | |
| CH50, Session 1, Day 3, 4 hour, n=6,0 | -2.5 (± 3.78) | 99999 (± 99999) | | |
| CH50, Session 1, Day 3, 8 hour, n=6,0 | -2.2 (± 3.25) | 99999 (± 99999) | | |
| CH50, Session 1, Day 5, n=6,0 | -4.7 (± 5.01) | 99999 (± 99999) | | |
| CH50, Session 1, Day 6, n=6,0 | -7.3 (± 6.19) | 99999 (± 99999) | | |
| CH50, Session 2, Day 1, predose, n=6,0 | -1.7 (± 3.67) | 99999 (± 99999) | | |
| CH50, Session 2, Day 1, 2 hour, n=6,0 | -2.3 (± 4.84) | 99999 (± 99999) | | |
| CH50, Session 2, Day 1, 4 hour, n=6,0 | -2.3 (± 4.63) | 99999 (± 99999) | | |
| CH50, Session 2, Day 1, 8 hour, n=6,0 | -3.5 (± 7.84) | 99999 (± 99999) | | |
| CH50, Session 2, Day 2, n=6,0 | -4.3 (± 6.02) | 99999 (± 99999) | | |
| CH50, Session 2, Day 3, predose, n=6,0 | -4.5 (± 6.16) | 99999 (± 99999) | | |
| CH50, Session 2, Day 3, 2 hour, n=6,0 | -4.0 (± 5.55) | 99999 (± 99999) | | |
| CH50, Session 2, Day 3, 4 hour, n=6,0 | -3.8 (± 6.31) | 99999 (± 99999) | | |
| CH50, Session 2, Day 3, 8 hour, n=6,0 | -3.8 (± 3.92) | 99999 (± 99999) | | |
| CH50, Session 2, Day 5, n=6,0 | -5.2 (± 6.31) | 99999 (± 99999) | | |
| CH50, Session 2, Day 6, n=6,0 | -8.5 (± 9.61) | 99999 (± 99999) | | |
| CH50, Session 3, Day 1, predose, n=6,0 | -4.5 (± 7.94) | 99999 (± 99999) | | |
| CH50, Session 3, Day 1, 2 hour, n=6,0 | -4.2 (± 7.44) | 99999 (± 99999) | | |
| CH50, Session 3, Day 1, 4 hour, n=6,0 | -4.5 (± 7.79) | 99999 (± 99999) | | |
| CH50, Session 3, Day 1, 8 hour, n=6,0 | -4.8 (± 8.35) | 99999 (± 99999) | | |

| | | | | |
|--|----------------|-----------------|--|--|
| CH50, Session 3, Day 2, n=5,0 | -3.6 (± 8.68) | 99999 (± 99999) | | |
| CH50, Session 3, Day 3, predose, n=6,0 | -5.2 (± 8.86) | 99999 (± 99999) | | |
| CH50, Session 3, Day 3, 2 hour, n=6,0 | -5.2 (± 8.86) | 99999 (± 99999) | | |
| CH50, Session 3, Day 3, 4 hour, n=6,0 | -5.3 (± 8.57) | 99999 (± 99999) | | |
| CH50, Session 3, Day 3, 8 hour, n=6,0 | -6.8 (± 10.05) | 99999 (± 99999) | | |
| CH50, Session 3, Day 5, n=6,0 | -7.0 (± 10.28) | 99999 (± 99999) | | |
| CH50, Session 3, Day 6, n=6,0 | -8.2 (± 11.02) | 99999 (± 99999) | | |
| CH50, Session 4, Day 1, predose, n=5,0 | -3.0 (± 5.20) | 99999 (± 99999) | | |
| CH50, Session 4, Day 1, 2 hour, n=5,0 | -2.0 (± 3.94) | 99999 (± 99999) | | |
| CH50, Session 4, Day 1, 4 hour, n=5,0 | -1.6 (± 4.77) | 99999 (± 99999) | | |
| CH50, Session 4, Day 1, 8 hour, n=5,0 | -1.6 (± 3.21) | 99999 (± 99999) | | |
| CH50, Session 4, Day 2, n=5,0 | -1.6 (± 3.13) | 99999 (± 99999) | | |
| CH50, Session 4, Day 3, predose, n=5,0 | -5.0 (± 6.08) | 99999 (± 99999) | | |
| CH50, Session 4, Day 3, 2 hour, n=5,0 | -3.2 (± 4.09) | 99999 (± 99999) | | |
| CH50, Session 4, Day 3, 4 hour, n=5,0 | -3.0 (± 6.40) | 99999 (± 99999) | | |
| CH50, Session 4, Day 3, 8 hour, n=5,0 | -4.0 (± 6.04) | 99999 (± 99999) | | |
| CH50, Session 4, Day 5, n=5,0 | -5.6 (± 7.70) | 99999 (± 99999) | | |
| CH50, Session 4, Day 6, n=5,0 | -6.6 (± 7.83) | 99999 (± 99999) | | |
| CH50, Session 5, Day 1, predose, n=4,0 | -3.8 (± 5.91) | 99999 (± 99999) | | |
| CH50, Session 5, Day 1, 2 hour, n=4,0 | -3.0 (± 5.72) | 99999 (± 99999) | | |
| CH50, Session 5, Day 1, 4 hour, n=4,0 | -2.8 (± 6.29) | 99999 (± 99999) | | |
| CH50, Session 5, Day 1, 8 hour, n=4,0 | -3.0 (± 5.29) | 99999 (± 99999) | | |
| CH50, Session 5, Day 2, n=4,0 | -3.5 (± 5.32) | 99999 (± 99999) | | |
| CH50, Session 5, Day 3, predose, n=4,0 | -5.0 (± 5.77) | 99999 (± 99999) | | |
| CH50, Session 5, Day 3, 2 hour, n=4,0 | -4.8 (± 6.80) | 99999 (± 99999) | | |
| CH50, Session 5, Day 3, 4 hour, n=4,0 | -4.8 (± 6.70) | 99999 (± 99999) | | |
| CH50, Session 5, Day 3, 8 hour, n=4,0 | -4.8 (± 6.80) | 99999 (± 99999) | | |
| CH50, Session 5, Day 5, n=4,0 | -5.5 (± 7.72) | 99999 (± 99999) | | |
| CH50, Session 5, Day 6, n=4,0 | -5.3 (± 8.54) | 99999 (± 99999) | | |
| CH50, Session 6, Day 1, predose, n=4,0 | -2.3 (± 4.03) | 99999 (± 99999) | | |
| CH50, Session 6, Day 1, 2 hour, n=4,0 | -2.8 (± 6.90) | 99999 (± 99999) | | |

| | | | | |
|--|---------------|-----------------|--|--|
| CH50, Session 6, Day 1, 4 hour, n=4,0 | -3.3 (± 7.27) | 99999 (± 99999) | | |
| CH50, Session 6, Day 1, 8 hour, n=4,0 | -3.5 (± 6.66) | 99999 (± 99999) | | |
| CH50, Session 6, Day 2, n=4,0 | -4.3 (± 6.13) | 99999 (± 99999) | | |
| CH50, Session 6, Day 3, predose, n=4,0 | -5.0 (± 8.52) | 99999 (± 99999) | | |
| CH50, Session 6, Day 3, 2 hour, n=4,0 | -4.8 (± 8.54) | 99999 (± 99999) | | |
| CH50, Session 6, Day 3, 4 hour, n=4,0 | -4.3 (± 8.66) | 99999 (± 99999) | | |
| CH50, Session 6, Day 3, 8 hour, n=4,0 | -5.0 (± 8.52) | 99999 (± 99999) | | |
| CH50, Session 6, Day 5, n=4,0 | -5.3 (± 9.00) | 99999 (± 99999) | | |
| CH50, Session 6, Day 6, n=4,0 | -5.5 (± 9.47) | 99999 (± 99999) | | |

Notes:

[58] - Safety Population

[59] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in inflammatory biomarkers over time

| | |
|-----------------|---|
| End point title | Change from Baseline in inflammatory biomarkers over time |
|-----------------|---|

End point description:

Blood samples were collected for assessment of inflammatory biomarkers which included C-Reactive protein (CRP), high-sensitivity C-reactive protein (hsCRP), serum amyloid A protein (SAA). Baseline was considered as the latest assessment prior to first administration of either study drug, i.e. CPHPC or anti-SAP mAb. Change from Baseline was calculated as post-dose visit value minus Baseline value. Only those participants with data available at the specified time points were analyzed (represented by n= X in the category titles). 99999 indicates data is not available. 88888 indicates data is not available, as standard deviation could not be calculated as only one participant was analyzed.

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

End point timeframe:

Baseline (Day -1) and Session 1 to 6: Day 1 (predose, 2,4,8 hours), Day 2, Day 3 (predose, 2,4,8 hours), Day 5, Day 6

| End point values | Group 1: Cardiac TTR amyloidosis (ATTR-CM) participants | Group 2: Post-chemotherapy AL Amyloidosis participants | | |
|---------------------------------------|---|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6 ^[60] | 1 ^[61] | | |
| Units: Milligrams per Liter (mg/L) | | | | |
| arithmetic mean (standard deviation) | | | | |
| CRP, Session 1, Day 1, predose, n=5,1 | -0.12 (± 0.572) | -4.60 (± 88888) | | |
| CRP, Session 1, Day 1, 2 hour, n=5,1 | -0.26 (± 0.573) | -4.80 (± 88888) | | |
| CRP, Session 1, Day 1, 4 hour, n=4,1 | -0.28 (± 0.486) | -4.70 (± 88888) | | |

| | | | | |
|---------------------------------------|------------------|------------------|--|--|
| CRP, Session 1, Day 1, 8 hour, n=5,1 | -0.18 (± 0.634) | -4.60 (± 88888) | | |
| CRP, Session 1, Day 2, n=5,1 | 0.64 (± 1.701) | 44.70 (± 88888) | | |
| CRP, Session 1, Day 3, predose, n=5,1 | 14.08 (± 12.511) | 131.20 (± 88888) | | |
| CRP, Session 1, Day 3, 2 hour, n=5,0 | 14.52 (± 13.128) | 99999 (± 99999) | | |
| CRP, Session 1, Day 3, 4 hour, n=5,0 | 15.30 (± 13.119) | 99999 (± 99999) | | |
| CRP, Session 1, Day 3, 8 hour, n=5,0 | 17.64 (± 14.527) | 99999 (± 99999) | | |
| CRP, Session 1, Day 5, n=5,0 | 17.20 (± 14.772) | 99999 (± 99999) | | |
| CRP, Session 1, Day 6, n=5,0 | 19.52 (± 15.665) | 99999 (± 99999) | | |
| CRP, Session 2, Day 1, predose, n=5,0 | 2.24 (± 2.864) | 99999 (± 99999) | | |
| CRP, Session 2, Day 1, 2 hour, n=5,0 | 2.12 (± 2.613) | 99999 (± 99999) | | |
| CRP, Session 2, Day 1, 4 hour, n=5,0 | 2.18 (± 2.710) | 99999 (± 99999) | | |
| CRP, Session 2, Day 1, 8 hour, n=5,0 | 2.18 (± 2.658) | 99999 (± 99999) | | |
| CRP, Session 2, Day 2, n=4,0 | 2.00 (± 2.624) | 99999 (± 99999) | | |
| CRP, Session 2, Day 3, predose, n=5,0 | 27.42 (± 26.283) | 99999 (± 99999) | | |
| CRP, Session 2, Day 3, 2 hour, n=5,0 | 29.46 (± 27.415) | 99999 (± 99999) | | |
| CRP, Session 2, Day 3, 4 hour, n=5,0 | 30.90 (± 27.961) | 99999 (± 99999) | | |
| CRP, Session 2, Day 3, 8 hour, n=5,0 | 31.76 (± 27.897) | 99999 (± 99999) | | |
| CRP, Session 2, Day 5, n=4,0 | 28.33 (± 22.386) | 99999 (± 99999) | | |
| CRP, Session 2, Day 6, n=5,0 | 27.04 (± 18.632) | 99999 (± 99999) | | |
| CRP, Session 3, Day 1, predose, n=4,0 | 1.93 (± 2.343) | 99999 (± 99999) | | |
| CRP, Session 3, Day 1, 2 hour, n=4,0 | 2.05 (± 2.626) | 99999 (± 99999) | | |
| CRP, Session 3, Day 1, 4 hour, n=4,0 | 2.15 (± 2.891) | 99999 (± 99999) | | |
| CRP, Session 3, Day 1, 8 hour, n=4,0 | 2.15 (± 2.760) | 99999 (± 99999) | | |
| CRP, Session 3, Day 2, n=4,0 | 1.75 (± 2.161) | 99999 (± 99999) | | |
| CRP, Session 3, Day 3, predose, n=4,0 | 18.13 (± 15.476) | 99999 (± 99999) | | |
| CRP, Session 3, Day 3, 2 hour, n=4,0 | 19.40 (± 16.403) | 99999 (± 99999) | | |
| CRP, Session 3, Day 3, 4 hour, n=4,0 | 21.20 (± 17.827) | 99999 (± 99999) | | |
| CRP, Session 3, Day 3, 8 hour, n=4,0 | 22.63 (± 18.466) | 99999 (± 99999) | | |
| CRP, Session 3, Day 5, n=5,0 | 19.00 (± 15.625) | 99999 (± 99999) | | |
| CRP, Session 3, Day 6, n=4,0 | 24.10 (± 16.785) | 99999 (± 99999) | | |
| CRP, Session 4, Day 1, predose, n=4,0 | 2.33 (± 4.487) | 99999 (± 99999) | | |

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|---------------------------------------|-----------------------|----------------------|--|--|
| CRP, Session 4, Day 1, 2 hour, n=4,0 | 2.53 (\pm 4.762) | 99999 (\pm 99999) | | |
| CRP, Session 4, Day 1, 4 hour, n=4,0 | 2.45 (\pm 4.669) | 99999 (\pm 99999) | | |
| CRP, Session 4, Day 1, 8 hour, n=4,0 | 2.40 (\pm 4.455) | 99999 (\pm 99999) | | |
| CRP, Session 4, Day 2, n=4,0 | 2.23 (\pm 3.963) | 99999 (\pm 99999) | | |
| CRP, Session 4, Day 3, predose, n=4,0 | 12.45 (\pm 13.533) | 99999 (\pm 99999) | | |
| CRP, Session 4, Day 3, 2 hour, n=4,0 | 14.75 (\pm 16.539) | 99999 (\pm 99999) | | |
| CRP, Session 4, Day 3, 4 hour, n=4,0 | 16.75 (\pm 19.129) | 99999 (\pm 99999) | | |
| CRP, Session 4, Day 3, 8 hour, n=4,0 | 17.30 (\pm 17.830) | 99999 (\pm 99999) | | |
| CRP, Session 4, Day 5, n=4,0 | 18.43 (\pm 9.959) | 99999 (\pm 99999) | | |
| CRP, Session 4, Day 6, n=4,0 | 19.98 (\pm 11.277) | 99999 (\pm 99999) | | |
| CRP, Session 5, Day 1, predose, n=3,0 | 2.23 (\pm 3.439) | 99999 (\pm 99999) | | |
| CRP, Session 5, Day 1, 2 hour, n=3,0 | 2.13 (\pm 3.350) | 99999 (\pm 99999) | | |
| CRP, Session 5, Day 1, 4 hour, n=3,0 | 1.97 (\pm 3.147) | 99999 (\pm 99999) | | |
| CRP, Session 5, Day 1, 8 hour, n=3,0 | 2.10 (\pm 3.378) | 99999 (\pm 99999) | | |
| CRP, Session 5, Day 2, n=3,0 | 1.37 (\pm 2.811) | 99999 (\pm 99999) | | |
| CRP, Session 5, Day 3, predose, n=3,0 | 8.33 (\pm 11.517) | 99999 (\pm 99999) | | |
| CRP, Session 5, Day 3, 2 hour, n=3,0 | 9.87 (\pm 12.881) | 99999 (\pm 99999) | | |
| CRP, Session 5, Day 3, 4 hour, n=3,0 | 10.47 (\pm 12.874) | 99999 (\pm 99999) | | |
| CRP, Session 5, Day 3, 8 hour, n=3,0 | 12.90 (\pm 14.944) | 99999 (\pm 99999) | | |
| CRP, Session 5, Day 5, n=2,0 | 34.30 (\pm 40.588) | 99999 (\pm 99999) | | |
| CRP, Session 5, Day 6, n=2,0 | 35.20 (\pm 34.931) | 99999 (\pm 99999) | | |
| CRP, Session 6, Day 1, predose, n=3,0 | 4.00 (\pm 3.851) | 99999 (\pm 99999) | | |
| CRP, Session 6, Day 1, 2 hour, n=3,0 | 3.63 (\pm 3.711) | 99999 (\pm 99999) | | |
| CRP, Session 6, Day 1, 4 hour, n=3,0 | 3.70 (\pm 3.835) | 99999 (\pm 99999) | | |
| CRP, Session 6, Day 1, 8 hour, n=3,0 | 3.70 (\pm 3.874) | 99999 (\pm 99999) | | |
| CRP, Session 6, Day 2, n=3,0 | 2.63 (\pm 2.914) | 99999 (\pm 99999) | | |
| CRP, Session 6, Day 3, predose, n=3,0 | 9.17 (\pm 8.879) | 99999 (\pm 99999) | | |
| CRP, Session 6, Day 3, 2 hour, n=3,0 | 11.10 (\pm 10.887) | 99999 (\pm 99999) | | |
| CRP, Session 6, Day 3, 4 hour, n=3,0 | 12.70 (\pm 11.555) | 99999 (\pm 99999) | | |
| CRP, Session 6, Day 3, 8 hour, n=3,0 | 14.67 (\pm 12.580) | 99999 (\pm 99999) | | |
| CRP, Session 6, Day 5, n=3,0 | 14.10 (\pm 7.146) | 99999 (\pm 99999) | | |

| | | | | |
|---|------------------|------------------|--|--|
| CRP, Session 6, Day 6, n=3,0 | 17.33 (± 7.844) | 99999 (± 99999) | | |
| hsCRP, Session 1, Day 1, predose, n=5,1 | -0.08 (± 0.356) | -3.60 (± 88888) | | |
| hsCRP, Session 1, Day 1, 2 hour, n=5,1 | -0.08 (± 0.327) | -3.70 (± 88888) | | |
| hsCRP, Session 1, Day 1, 4 hour, n=4,1 | -0.20 (± 0.271) | -3.70 (± 88888) | | |
| hsCRP, Session 1, Day 1, 8 hour, n=5,1 | -0.10 (± 0.406) | -3.60 (± 88888) | | |
| hsCRP, Session 1, Day 2, n=5,1 | 0.56 (± 1.286) | 41.40 (± 88888) | | |
| hsCRP, Session 1, Day 3, predose, n=5,1 | 14.54 (± 13.149) | 135.20 (± 88888) | | |
| hsCRP, Session 1, Day 3, 2 hour, n=5,0 | 15.14 (± 13.363) | 99999 (± 99999) | | |
| hsCRP, Session 1, Day 3, 4 hour, n=5,0 | 15.84 (± 13.607) | 99999 (± 99999) | | |
| hsCRP, Session 1, Day 3, 8 hour, n=5,0 | 17.10 (± 14.294) | 99999 (± 99999) | | |
| hsCRP, Session 1, Day 5, n=5,0 | 16.70 (± 14.332) | 99999 (± 99999) | | |
| hsCRP, Session 1, Day 6, n=5,0 | 18.60 (± 14.778) | 99999 (± 99999) | | |
| hsCRP, Session 2, Day 1, predose, n=5,0 | 1.88 (± 2.539) | 99999 (± 99999) | | |
| hsCRP, Session 2, Day 1, 2 hour, n=5,0 | 1.78 (± 2.351) | 99999 (± 99999) | | |
| hsCRP, Session 2, Day 1, 4 hour, n=5,0 | 1.90 (± 2.478) | 99999 (± 99999) | | |
| hsCRP, Session 2, Day 1, 8 hour, n=5,0 | 1.78 (± 2.179) | 99999 (± 99999) | | |
| hsCRP, Session 2, Day 2, n=4,0 | 1.75 (± 2.266) | 99999 (± 99999) | | |
| hsCRP, Session 2, Day 3, predose, n=5,0 | 26.76 (± 26.122) | 99999 (± 99999) | | |
| hsCRP, Session 2, Day 3, 2 hour, n=5,0 | 29.28 (± 27.373) | 99999 (± 99999) | | |
| hsCRP, Session 2, Day 3, 4 hour, n=5,0 | 30.36 (± 27.018) | 99999 (± 99999) | | |
| hsCRP, Session 2, Day 3, 8 hour, n=5,0 | 31.10 (± 26.885) | 99999 (± 99999) | | |
| hsCRP, Session 2, Day 5, n=4,0 | 28.13 (± 21.919) | 99999 (± 99999) | | |
| hsCRP, Session 2, Day 6, n=5,0 | 27.20 (± 18.468) | 99999 (± 99999) | | |
| hsCRP, Session 3, Day 1, predose, n=4,0 | 1.60 (± 2.017) | 99999 (± 99999) | | |
| hsCRP, Session 3, Day 1, 2 hour, n=4,0 | 1.63 (± 2.175) | 99999 (± 99999) | | |
| hsCRP, Session 3, Day 1, 4 hour, n=4,0 | 1.70 (± 2.403) | 99999 (± 99999) | | |
| hsCRP, Session 3, Day 1, 8 hour, n=4,0 | 1.65 (± 2.161) | 99999 (± 99999) | | |
| hsCRP, Session 3, Day 2, n=4,0 | 1.25 (± 1.754) | 99999 (± 99999) | | |
| hsCRP, Session 3, Day 3, predose, n=4,0 | 17.88 (± 15.954) | 99999 (± 99999) | | |
| hsCRP, Session 3, Day 3, 2 hour, n=4,0 | 19.23 (± 16.675) | 99999 (± 99999) | | |
| hsCRP, Session 3, Day 3, 4 hour, n=4,0 | 20.58 (± 17.733) | 99999 (± 99999) | | |

| | | | | |
|---|-----------------------|----------------------|--|--|
| hsCRP, Session 3, Day 3, 8 hour, n=4,0 | 22.10 (\pm 18.149) | 99999 (\pm 99999) | | |
| hsCRP, Session 3, Day 5, n=4,0 | 22.45 (\pm 15.042) | 99999 (\pm 99999) | | |
| hsCRP, Session 3, Day 6, n=4,0 | 23.73 (\pm 16.141) | 99999 (\pm 99999) | | |
| hsCRP, Session 4, Day 1, predose, n=4,0 | 2.28 (\pm 4.043) | 99999 (\pm 99999) | | |
| hsCRP, Session 4, Day 1, 2 hour, n=4,0 | 2.53 (\pm 4.610) | 99999 (\pm 99999) | | |
| hsCRP, Session 4, Day 1, 4 hour, n=4,0 | 2.53 (\pm 4.479) | 99999 (\pm 99999) | | |
| hsCRP, Session 4, Day 1, 8 hour, n=4,0 | 2.58 (\pm 4.528) | 99999 (\pm 99999) | | |
| hsCRP, Session 4, Day 2, n=4,0 | 2.20 (\pm 3.558) | 99999 (\pm 99999) | | |
| hsCRP, Session 4, Day 3, predose, n=4,0 | 12.33 (\pm 13.881) | 99999 (\pm 99999) | | |
| hsCRP, Session 4, Day 3, 2 hour, n=4,0 | 14.40 (\pm 16.324) | 99999 (\pm 99999) | | |
| hsCRP, Session 4, Day 3, 4 hour, n=4,0 | 16.00 (\pm 18.240) | 99999 (\pm 99999) | | |
| hsCRP, Session 4, Day 3, 8 hour, n=4,0 | 17.08 (\pm 17.972) | 99999 (\pm 99999) | | |
| hsCRP, Session 4, Day 5, n=4,0 | 19.60 (\pm 10.903) | 99999 (\pm 99999) | | |
| hsCRP, Session 4, Day 6, n=4,0 | 20.73 (\pm 11.391) | 99999 (\pm 99999) | | |
| hsCRP, Session 5, Day 1, predose, n=3,0 | 2.03 (\pm 3.349) | 99999 (\pm 99999) | | |
| hsCRP, Session 5, Day 1, 2 hour, n=3,0 | 1.97 (\pm 3.320) | 99999 (\pm 99999) | | |
| hsCRP, Session 5, Day 1, 4 hour, n=3,0 | 1.83 (\pm 3.175) | 99999 (\pm 99999) | | |
| hsCRP, Session 5, Day 1, 8 hour, n=3,0 | 1.87 (\pm 3.323) | 99999 (\pm 99999) | | |
| hsCRP, Session 5, Day 2, n=3,0 | 1.23 (\pm 2.574) | 99999 (\pm 99999) | | |
| hsCRP, Session 5, Day 3, predose, n=3,0 | 9.10 (\pm 13.182) | 99999 (\pm 99999) | | |
| hsCRP, Session 5, Day 3, 2 hour, n=3,0 | 10.43 (\pm 14.629) | 99999 (\pm 99999) | | |
| hsCRP, Session 5, Day 3, 4 hour, n=3,0 | 11.17 (\pm 14.865) | 99999 (\pm 99999) | | |
| hsCRP, Session 5, Day 3, 8 hour, n=3,0 | 12.67 (\pm 15.557) | 99999 (\pm 99999) | | |
| hsCRP, Session 5, Day 5, n=2,0 | 33.95 (\pm 40.941) | 99999 (\pm 99999) | | |
| hsCRP, Session 5, Day 6, n=2,0 | 34.80 (\pm 34.083) | 99999 (\pm 99999) | | |
| hsCRP, Session 6, Day 1, predose, n=3,0 | 3.77 (\pm 3.853) | 99999 (\pm 99999) | | |
| hsCRP, Session 6, Day 1, 2 hour, n=3,0 | 3.37 (\pm 3.523) | 99999 (\pm 99999) | | |
| hsCRP, Session 6, Day 1, 4 hour, n=3,0 | 3.50 (\pm 3.799) | 99999 (\pm 99999) | | |
| hsCRP, Session 6, Day 1, 8 hour, n=3,0 | 3.27 (\pm 3.584) | 99999 (\pm 99999) | | |
| hsCRP, Session 6, Day 2, n=3,0 | 2.33 (\pm 2.775) | 99999 (\pm 99999) | | |
| hsCRP, Session 6, Day 3, predose, n=3,0 | 8.97 (\pm 9.752) | 99999 (\pm 99999) | | |

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|--|-----------------------------|--------------------------|--|--|
| hsCRP, Session 6, Day 3, 2 hour, n=3,0 | 10.57 (\pm 11.075) | 99999 (\pm 99999) | | |
| hsCRP, Session 6, Day 3, 4 hour, n=3,0 | 12.60 (\pm 12.322) | 99999 (\pm 99999) | | |
| hsCRP, Session 6, Day 3, 8 hour, n=3,0 | 15.33 (\pm 14.276) | 99999 (\pm 99999) | | |
| hsCRP, Session 6, Day 5, n=3,0 | 14.43 (\pm 7.801) | 99999 (\pm 99999) | | |
| hsCRP, Session 6, Day 6, n=3,0 | 18.63 (\pm 8.607) | 99999 (\pm 99999) | | |
| SAA, Session 1, Day 1, predose, n=5,1 | 0.2164 (\pm 1.55486) | -22.3723 (\pm 88888) | | |
| SAA, Session 1, Day 1, 2 hour, n=5,1 | 0.1738 (\pm 1.13909) | -22.4187 (\pm 88888) | | |
| SAA, Session 1, Day 1, 4 hour, n=5,1 | 0.3902 (\pm 1.56253) | -21.7463 (\pm 88888) | | |
| SAA, Session 1, Day 1, 8 hour, n=5,1 | 0.2695 (\pm 1.57992) | -14.8767 (\pm 88888) | | |
| SAA, Session 1, Day 2, n=5,1 | 2.9247 (\pm 3.47577) | 322.2895 (\pm 88888) | | |
| SAA, Session 1, Day 3, predose, n=5,1 | 50.7137 (\pm 55.02969) | 1437.7667 (\pm 88888) | | |
| SAA, Session 1, Day 3, 2 hour, n=5,0 | 54.8466 (\pm 59.36005) | 99999 (\pm 99999) | | |
| SAA, Session 1, Day 3, 4 hour, n=5,0 | 54.9329 (\pm 55.92645) | 99999 (\pm 99999) | | |
| SAA, Session 1, Day 3, 8 hour, n=5,0 | 68.4699 (\pm 75.51138) | 99999 (\pm 99999) | | |
| SAA, Session 1, Day 5, n=5,0 | 54.6741 (\pm 69.66316) | 99999 (\pm 99999) | | |
| SAA, Session 1, Day 6, n=5,0 | 55.2882 (\pm 63.77870) | 99999 (\pm 99999) | | |
| SAA, Session 2, Day 1, predose, n=5,0 | 1.0277 (\pm 1.64965) | 99999 (\pm 99999) | | |
| SAA, Session 2, Day 1, 2 hour, n=5,0 | 0.9841 (\pm 2.22042) | 99999 (\pm 99999) | | |
| SAA, Session 2, Day 1, 4 hour, n=5,0 | 1.4543 (\pm 2.61184) | 99999 (\pm 99999) | | |
| SAA, Session 2, Day 1, 8 hour, n=5,0 | 1.0588 (\pm 1.52455) | 99999 (\pm 99999) | | |
| SAA, Session 2, Day 2, n=5,0 | 3.7244 (\pm 1.63856) | 99999 (\pm 99999) | | |
| SAA, Session 2, Day 3, predose, n=5,0 | 134.4489 (\pm 160.14208) | 99999 (\pm 99999) | | |
| SAA, Session 2, Day 3, 2 hour, n=5,0 | 145.2507 (\pm 171.92591) | 99999 (\pm 99999) | | |
| SAA, Session 2, Day 3, 4 hour, n=5,0 | 142.5438 (\pm 174.11156) | 99999 (\pm 99999) | | |
| SAA, Session 2, Day 3, 8 hour, n=5,0 | 100.8836 (\pm 184.35963) | 99999 (\pm 99999) | | |
| SAA, Session 2, Day 5, n=5,0 | 76.8593 (\pm 136.83379) | 99999 (\pm 99999) | | |
| SAA, Session 2, Day 6, n=5,0 | 101.0688 (\pm 105.88787) | 99999 (\pm 99999) | | |
| SAA, Session 3, Day 1, predose, n=4,0 | 0.2428 (\pm 1.13002) | 99999 (\pm 99999) | | |
| SAA, Session 3, Day 1, 2 hour, n=4,0 | 0.1863 (\pm 1.06333) | 99999 (\pm 99999) | | |
| SAA, Session 3, Day 1, 4 hour, n=4,0 | 0.0475 (\pm 1.00422) | 99999 (\pm 99999) | | |
| SAA, Session 3, Day 1, 8 hour, n=5,0 | 4.0339 (\pm 8.62955) | 99999 (\pm 99999) | | |

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|---------------------------------------|----------------------------|----------------------|--|--|
| SAA, Session 3, Day 2, n=4,0 | 6.4822 (\pm 11.14119) | 99999 (\pm 99999) | | |
| SAA, Session 3, Day 3, predose, n=5,0 | 54.7393 (\pm 82.22346) | 99999 (\pm 99999) | | |
| SAA, Session 3, Day 3, 2 hour, n=5,0 | 58.0526 (\pm 83.12677) | 99999 (\pm 99999) | | |
| SAA, Session 3, Day 3, 4 hour, n=5,0 | 64.1995 (\pm 93.61736) | 99999 (\pm 99999) | | |
| SAA, Session 3, Day 3, 8 hour, n=5,0 | 66.9605 (\pm 93.98658) | 99999 (\pm 99999) | | |
| SAA, Session 3, Day 5, n=5,0 | 58.6742 (\pm 50.93398) | 99999 (\pm 99999) | | |
| SAA, Session 3, Day 6, n=5,0 | 49.4029 (\pm 46.30012) | 99999 (\pm 99999) | | |
| SAA, Session 4, Day 1, predose, n=4,0 | -0.1305 (\pm 1.86822) | 99999 (\pm 99999) | | |
| SAA, Session 4, Day 1, 2 hour, n=4,0 | 0.0159 (\pm 1.91086) | 99999 (\pm 99999) | | |
| SAA, Session 4, Day 1, 4 hour, n=4,0 | -0.0013 (\pm 1.84104) | 99999 (\pm 99999) | | |
| SAA, Session 4, Day 1, 8 hour, n=4,0 | 0.1997 (\pm 1.70496) | 99999 (\pm 99999) | | |
| SAA, Session 4, Day 2, n=4,0 | 1.6015 (\pm 1.07082) | 99999 (\pm 99999) | | |
| SAA, Session 4, Day 3, predose, n=4,0 | 45.1067 (\pm 82.67535) | 99999 (\pm 99999) | | |
| SAA, Session 4, Day 3, 2 hour, n=4,0 | 51.0650 (\pm 94.33211) | 99999 (\pm 99999) | | |
| SAA, Session 4, Day 3, 4 hour, n=4,0 | 55.0009 (\pm 101.37965) | 99999 (\pm 99999) | | |
| SAA, Session 4, Day 3, 8 hour, n=4,0 | 55.7135 (\pm 101.39069) | 99999 (\pm 99999) | | |
| SAA, Session 4, Day 5, n=4,0 | 51.2002 (\pm 54.84780) | 99999 (\pm 99999) | | |
| SAA, Session 4, Day 6, n=4,0 | 41.2457 (\pm 38.77052) | 99999 (\pm 99999) | | |
| SAA, Session 5, Day 1, predose, n=3,0 | -0.1498 (\pm 1.04561) | 99999 (\pm 99999) | | |
| SAA, Session 5, Day 1, 2 hour, n=3,0 | -0.2399 (\pm 0.89843) | 99999 (\pm 99999) | | |
| SAA, Session 5, Day 1, 4 hour, n=3,0 | -0.1906 (\pm 0.94124) | 99999 (\pm 99999) | | |
| SAA, Session 5, Day 1, 8 hour, n=3,0 | -0.1771 (\pm 0.95814) | 99999 (\pm 99999) | | |
| SAA, Session 5, Day 2, n=3,0 | 0.1380 (\pm 0.61958) | 99999 (\pm 99999) | | |
| SAA, Session 5, Day 3, predose, n=3,0 | 10.8884 (\pm 17.72052) | 99999 (\pm 99999) | | |
| SAA, Session 5, Day 3, 2 hour, n=3,0 | 8.6783 (\pm 11.48176) | 99999 (\pm 99999) | | |
| SAA, Session 5, Day 3, 4 hour, n=3,0 | 9.2527 (\pm 11.23663) | 99999 (\pm 99999) | | |
| SAA, Session 5, Day 3, 8 hour, n=3,0 | 13.7941 (\pm 19.39827) | 99999 (\pm 99999) | | |
| SAA, Session 5, Day 5, n=3,0 | 66.2542 (\pm 107.98594) | 99999 (\pm 99999) | | |
| SAA, Session 5, Day 6, n=3,0 | 73.0823 (\pm 118.07036) | 99999 (\pm 99999) | | |
| SAA, Session 6, Day 1, predose, n=3,0 | 1.2964 (\pm 1.75482) | 99999 (\pm 99999) | | |
| SAA, Session 6, Day 1, 2 hour, n=3,0 | 1.0538 (\pm 1.74392) | 99999 (\pm 99999) | | |

| | | | | |
|---------------------------------------|----------------------|-----------------|--|--|
| SAA, Session 6, Day 1, 4 hour, n=3,0 | 1.3139 (± 2.18542) | 99999 (± 99999) | | |
| SAA, Session 6, Day 1, 8 hour, n=3,0 | 0.9078 (± 1.72500) | 99999 (± 99999) | | |
| SAA, Session 6, Day 2, n=3,0 | 1.2641 (± 0.89837) | 99999 (± 99999) | | |
| SAA, Session 6, Day 3, predose, n=3,0 | 7.4697 (± 5.41886) | 99999 (± 99999) | | |
| SAA, Session 6, Day 3, 2 hour, n=3,0 | 8.3574 (± 4.40865) | 99999 (± 99999) | | |
| SAA, Session 6, Day 3, 4 hour, n=3,0 | 11.0305 (± 8.80978) | 99999 (± 99999) | | |
| SAA, Session 6, Day 3, 8 hour, n=3,0 | 14.5333 (± 12.26460) | 99999 (± 99999) | | |
| SAA, Session 6, Day 5, n=3,0 | 25.2529 (± 27.55204) | 99999 (± 99999) | | |
| SAA, Session 6, Day 6, n=3,0 | 32.6318 (± 41.82856) | 99999 (± 99999) | | |

Notes:

[60] - Safety Population

[61] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum concentration (Cmax) of GSK2398852

| | |
|-----------------|--|
| End point title | Maximum concentration (Cmax) of GSK2398852 |
|-----------------|--|

End point description:

Blood samples were collected for evaluation of Pharmacokinetic (PK) parameters including Cmax at indicated time points. Geometric mean and geometric coefficient of variation of Cmax is presented. Only those participants with data available at the specified time points were analyzed (represented by n= X in the category titles). 99999 indicates data is not available. 88888 indicates data is not available, as standard deviation could not be calculated as only one participant was analyzed.

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

End point timeframe:

Session 1 to 6: Day 1 (Pre-dose, 6, 8, 12 hour), Day 2, Day 3 (Pre-dose and at 6 hour), Day 4, Day 7 and Day 11

| End point values | Group 1: Cardiac TTR amyloidosis (ATTR-CM) participants | Group 2: Post-chemotherapy AL Amyloidosis participants | | |
|---|---|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6 ^[62] | 1 ^[63] | | |
| Units: Micrograms per milliliter (ug/mL) | | | | |
| geometric mean (geometric coefficient of variation) | | | | |
| Session 1, n=6,1 | 86.94 (± 31.58) | 88.64 (± 88888) | | |
| Session 2, n=6,0 | 235.48 (± 25.22) | 99999 (± 99999) | | |
| Session 3, n=6,0 | 222.23 (± 44.40) | 99999 (± 99999) | | |

| | | | | |
|------------------|------------------|-----------------|--|--|
| Session 4, n=5,0 | 179.82 (± 33.87) | 99999 (± 99999) | | |
| Session 5, n=4,0 | 185.52 (± 34.06) | 99999 (± 99999) | | |
| Session 6, n=4,0 | 228.51 (± 49.73) | 99999 (± 99999) | | |

Notes:

[62] - Safety Population

[63] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Time associated with Cmax (Tmax) of GSK2398852

| | |
|-----------------|--|
| End point title | Time associated with Cmax (Tmax) of GSK2398852 |
|-----------------|--|

End point description:

Blood samples were collected for evaluation of PK parameters including Tmax at indicated time points. Median and full range of Tmax is presented. Only those participants with data available at the specified time points were analyzed (represented by n= X in the category titles). 99999 indicates data is not available.

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

End point timeframe:

Session 1 to 6: Day 1 (Pre-dose, 6, 8, 12 hour), Day 2, Day 3 (Pre-dose and at 6 hour), Day 4, Day 7 and Day 11

| End point values | Group 1: Cardiac TTR amyloidosis (ATTR-CM) participants | Group 2: Post-chemotherapy AL Amyloidosis participants | | |
|-------------------------------|---|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6 ^[64] | 1 ^[65] | | |
| Units: Hour | | | | |
| median (full range (min-max)) | | | | |
| Session 1, n=6,1 | 54.18 (53.9 to 54.9) | 6.1 (6.1 to 6.1) | | |
| Session 2, n=6,0 | 54.07 (53.3 to 54.7) | 99999 (-99999 to 99999) | | |
| Session 3, n=6,0 | 54.06 (12.1 to 55.8) | 99999 (-99999 to 99999) | | |
| Session 4, n=5,0 | 54.50 (53.9 to 56.1) | 99999 (-99999 to 99999) | | |
| Session 5, n=4,0 | 54.28 (6.1 to 56.1) | 99999 (-99999 to 99999) | | |
| Session 6, n=4,0 | 54.18 (53.9 to 56.0) | 99999 (-99999 to 99999) | | |

Notes:

[64] - Safety Population

[65] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Area under the plasma concentration-time curve from time zero to time t (AUC 0-t) of GSK2398852

| | |
|-----------------|---|
| End point title | Area under the plasma concentration-time curve from time zero to time t (AUC 0-t) of GSK2398852 |
|-----------------|---|

End point description:

Blood samples were collected for evaluation of PK parameters including AUC 0-t at indicated time points. Geometric mean and geometric coefficient of variation of AUC0-t is presented. Only those participants with data available at the specified time points were analyzed (represented by n= X in the category titles). 99999 indicates data is not available. 88888 indicates data is not available, as standard deviation could not be calculated as only one participant was analyzed.

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

End point timeframe:

Session 1 to 6: Day 1 (Pre-dose, 6, 8, 12 hour), Day 2, Day 3 (Pre-dose and at 6 hour), Day 4, Day 7 and Day 11

| End point values | Group 1: Cardiac TTR amyloidosis (ATTR-CM) participants | Group 2: Post-chemotherapy AL Amyloidosis participants | | |
|---|---|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6 ^[66] | 1 ^[67] | | |
| Units: Hour*micrograms per milliliter (h*ug/mL) | | | | |
| geometric mean (geometric coefficient of variation) | | | | |
| Session 1, n=6,1 | 5130.0 (± 46.72) | 2148.2 (± 88888) | | |
| Session 2, n=6,0 | 14610.1 (± 34.73) | 99999 (± 99999) | | |
| Session 3, n=6,0 | 13804.6 (± 50.34) | 99999 (± 99999) | | |
| Session 4, n=5,0 | 12970.9 (± 51.52) | 99999 (± 99999) | | |
| Session 5, n=4,0 | 15595.3 (± 51.13) | 99999 (± 99999) | | |
| Session 6, n=4,0 | 17126.7 (± 43.98) | 99999 (± 99999) | | |

Notes:

[66] - Safety Population

[67] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax of GSK2315698 for newly diagnosed Mayo stage II/IIIa AL Amyloidosis participants

| | |
|-----------------|---|
| End point title | Cmax of GSK2315698 for newly diagnosed Mayo stage II/IIIa AL Amyloidosis participants |
|-----------------|---|

End point description:

Blood samples were planned to be collected for evaluation of PK parameters including Cmax at indicated time points for GSK2315698 for newly diagnosed Mayo stage II/IIIa AL Amyloidosis participants. However, no participant was enrolled in 'Group 3: Newly diagnosed Mayo stage II/IIIa AL participants.' Safety Population. Data was not collected for this outcome due to blood samples were not collected to evaluate PK of GSK2315698 as no participant was enrolled in 'Group 3: Newly diagnosed Mayo stage

II/IIIa AL participants'.

| | |
|--|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Day 1: Pre-dose; Day 2 (pre-dose and 2 hours post-dose); Day 3: Pre-dose in each session (each session of 24 days) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Tmax of GSK2315698 for newly diagnosed Mayo stage II/IIIa AL Amyloidosis participants

| | |
|-----------------|---|
| End point title | Tmax of GSK2315698 for newly diagnosed Mayo stage II/IIIa AL Amyloidosis participants |
|-----------------|---|

End point description:

Blood samples were planned to be collected for evaluation of PK parameters including Tmax at indicated time points for GSK2315698 for newly diagnosed Mayo stage II/IIIa AL Amyloidosis participants. However, no participant was enrolled in 'Group 3: Newly diagnosed Mayo stage II/IIIa AL participants'. Data was not collected for this outcome due to blood samples were not collected to evaluate PK of GSK2315698 as no participant was enrolled in 'Group 3: Newly diagnosed Mayo stage II/IIIa AL participants'.

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

End point timeframe:

Day 1: Pre-dose; Day 2: pre-dose and 2 hours post-dose; Day 3: Pre-dose in each session (each session of 24 days)

Statistical analyses

No statistical analyses for this end point

Secondary: AUC 0-t of GSK2315698 for newly diagnosed Mayo stage II/IIIa AL Amyloidosis participants

| | |
|-----------------|--|
| End point title | AUC 0-t of GSK2315698 for newly diagnosed Mayo stage II/IIIa AL Amyloidosis participants |
|-----------------|--|

End point description:

Blood samples were planned to be collected for evaluation of PK parameters including AUC0-t at

indicated time points for GSK2315698 for newly diagnosed Mayo stage II/IIIa AL Amyloidosis participants. However, no participant was enrolled in 'Group 3: Newly diagnosed Mayo stage II/IIIa AL participants'. Safety Population. Data was not collected for this outcome due to blood samples were not collected to evaluate PK of GSK2315698 as no participant was enrolled in 'Group 3: Newly diagnosed Mayo stage II/IIIa AL participants'.

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

End point timeframe:

Day 1: Pre-dose; Day 2 (pre-dose and 2 hours post-dose); Day 3: Pre-dose in each session (each session of 24 days)

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Global Longitudinal Strain (GLS) by CMR

| | |
|-----------------|---|
| End point title | Change from Baseline in Global Longitudinal Strain (GLS) by CMR |
|-----------------|---|

End point description:

Global Longitudinal Strain was measured by CMR at indicated time points. GLS included feature tracking and tagging by CMR. Baseline was considered as the latest assessment prior to first administration of either study drug, i.e. CPHPC or anti-SAP mAb. Change from Baseline was calculated as post-dose visit value minus Baseline value. Only those participants with data available at the specified time points were analyzed (represented by n= X in the category titles). 99999 indicates data is not available. 88888 indicates data is not available, as standard deviation could not be calculated as only one participant was analyzed.

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

End point timeframe:

Baseline (Day -1) and Session 2 to 5: Day 24; 8 week follow-up; 6 months follow-up

| End point values | Group 1: Cardiac TTR amyloidosis (ATTR-CM) participants | Group 2: Post-chemotherapy AL Amyloidosis participants | | |
|--|---|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6 ^[68] | 1 ^[69] | | |
| Units: Percentage of myocardial shortening | | | | |
| arithmetic mean (standard deviation) | | | | |
| GLS Tagging, Session 2, Day 24, n=6,0 | 0.003 (± 0.2907) | 99999 (± 99999) | | |
| GLS Tagging, Session 3, Day 24, n=6,0 | 0.229 (± 0.5836) | 99999 (± 99999) | | |
| GLS Tagging, Session 4, Day 24, n=5,0 | 0.392 (± 0.4121) | 99999 (± 99999) | | |

| | | | | |
|--|-------------------|------------------|--|--|
| GLS Tagging, Session 5, Day 24, n=4,0 | 0.349 (± 0.9354) | 99999 (± 99999) | | |
| GLS Tagging, 8 Week follow-up, n=6,1 | 1.125 (± 1.6448) | -3.404 (± 88888) | | |
| GLS Tagging, 6 month follow-up, n=2,0 | -1.014 (± 0.3654) | 99999 (± 99999) | | |
| GLS Feature Tracking, Session 2, Day 24, n=6,0 | 1.729 (± 2.3613) | 99999 (± 99999) | | |
| GLS Feature Tracking, Session 3, Day 24, n=6,0 | 0.803 (± 2.3712) | 99999 (± 99999) | | |
| GLS Feature Tracking, Session 4, Day 24, n=5,0 | 1.326 (± 4.0639) | 99999 (± 99999) | | |
| GLS Feature Tracking, Session 5, Day 24, n=4,0 | 1.657 (± 2.1277) | 99999 (± 99999) | | |
| GLS Feature Tracking, 8 Week follow-up, n=6,1 | 0.639 (± 1.3678) | 3.951 (± 88888) | | |
| GLS Feature Tracking, 6 month follow-up, n=2,0 | 1.234 (± 4.6888) | 99999 (± 99999) | | |

Notes:

[68] - Safety Population

[69] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in GLS by ECHO

| | |
|-----------------|-------------------------------------|
| End point title | Change from Baseline in GLS by ECHO |
|-----------------|-------------------------------------|

End point description:

Global Longitudinal Strain was measured by ECHO at indicated time points. GLS included speckle tracking by ECHO. Baseline was considered as the latest assessment prior to first administration of either study drug, i.e. CPHPC or anti-SAP mAb. Change from Baseline was calculated as post-dose visit value minus Baseline value. Only those participants with data available at the specified time points were analyzed (represented by n= X in the category titles). 99999 indicates data is not available. 88888 indicates data is not available, as standard deviation could not be calculated as only one participant was analyzed.

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

End point timeframe:

Baseline (Day -1) and Session 1 to 6: Day 24; 8 week follow-up; 6 months follow-up

| End point values | Group 1: Cardiac TTR amyloidosis (ATTR-CM) participants | Group 2: Post-chemotherapy AL Amyloidosis participants | | |
|--|---|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6 ^[70] | 1 ^[71] | | |
| Units: Percentage of myocardial shortening | | | | |
| arithmetic mean (standard deviation) | | | | |
| GLS Speckle Tracking, Session 1, Day 24, n=6,1 | -3.55 (± 5.709) | -0.90 (± 88888) | | |
| GLS Speckle Tracking, Session 2, Day 24, n=6,0 | -0.58 (± 6.013) | 99999 (± 99999) | | |
| GLS Speckle Tracking, Session 3, Day 24, n=6,0 | -1.17 (± 7.487) | 99999 (± 99999) | | |

| | | | | |
|--|-----------------------|----------------------|--|--|
| GLS Speckle Tracking, Session 4, Day 24, n=5,0 | 1.26 (\pm 5.299) | 99999 (\pm 99999) | | |
| GLS Speckle Tracking, Session 5, Day 24, n=4,0 | 1.13 (\pm 9.044) | 99999 (\pm 99999) | | |
| GLS Speckle Tracking, Session 6, Day 24, n=4,0 | -2.08 (\pm 4.555) | 99999 (\pm 99999) | | |
| GLS Speckle Tracking, 8 Week follow-up, n=6,1 | -1.82 (\pm 10.013) | 1.60 (\pm 88888) | | |
| GLS Speckle Tracking, 6 month follow-up, n=4,0 | 0.40 (\pm 4.268) | 99999 (\pm 99999) | | |

Notes:

[70] - Safety Population

[71] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in LV twist over time

| | |
|-----------------|--|
| End point title | Change from Baseline in LV twist over time |
|-----------------|--|

End point description:

LV twist was measured by CMR at indicated time points. Baseline was considered as the latest assessment prior to first administration of either study drug, i.e. CPHPC or anti-SAP mAb. Change from Baseline was calculated as post-dose visit value minus Baseline value. Only those participants with data available at the specified time points were analyzed (represented by n= X in the category titles). 99999 indicates data is not available. 88888 indicates data is not available, as standard deviation could not be calculated as only one participant was analyzed.

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

End point timeframe:

Baseline (Day -1) and Session 2 to 5: Day 24; 8 week follow-up; 6 months follow-up

| End point values | Group 1: Cardiac TTR amyloidosis (ATTR-CM) participants | Group 2: Post-chemotherapy AL Amyloidosis participants | | |
|--------------------------------------|---|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6 ^[72] | 1 ^[73] | | |
| Units: Degree | | | | |
| arithmetic mean (standard deviation) | | | | |
| Session 2, Day 24, n=5,0 | 0.550 (\pm 1.6672) | 99999 (\pm 99999) | | |
| Session 3, Day 24, n=6,0 | 0.431 (\pm 2.4369) | 99999 (\pm 99999) | | |
| Session 4, Day 24, n=5,0 | -0.611 (\pm 1.8979) | 99999 (\pm 99999) | | |
| Session 5, Day 24, n=4,0 | -0.628 (\pm 1.2269) | 99999 (\pm 99999) | | |
| 8 Week follow-up, n=6,1 | -0.264 (\pm 2.0835) | 0.914 (\pm 88888) | | |
| 6 month follow-up, n=2,0 | -0.633 (\pm 0.3349) | 99999 (\pm 99999) | | |

Notes:

[72] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Stroke Volume (SV) by CMR

| | |
|-----------------|---|
| End point title | Change from Baseline in Stroke Volume (SV) by CMR |
|-----------------|---|

End point description:

Stroke volume is the amount of blood ejected by the left ventricle in one contraction. SV was measured by CMR at indicated time points. Baseline was considered as the latest assessment prior to first administration of either study drug, i.e. CPHPC or anti-SAP mAb. Change from Baseline was calculated as post-dose visit value minus Baseline value. Only those participants with data available at the specified time points were analyzed (represented by n= X in the category titles). 99999 indicates data is not available. 88888 indicates data is not available, as standard deviation could not be calculated as only one participant was analyzed.

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

End point timeframe:

Baseline (Day -1) and Session 2 to 5: Day 24; 8 week follow-up; 6 months follow-up

| End point values | Group 1: Cardiac TTR amyloidosis (ATTR-CM) participants | Group 2: Post-chemotherapy AL Amyloidosis participants | | |
|--------------------------------------|---|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6 ^[74] | 1 ^[75] | | |
| Units: Milliliter | | | | |
| arithmetic mean (standard deviation) | | | | |
| Session 2, Day 24, n=6,0 | -2.760 (± 7.8305) | 99999 (± 99999) | | |
| Session 3, Day 24, n=6,0 | -1.228 (± 24.3834) | 99999 (± 99999) | | |
| Session 4, Day 24, n=5,0 | -9.766 (± 9.7838) | 99999 (± 99999) | | |
| Session 5, Day 24, n=4,0 | -11.477 (± 14.4238) | 99999 (± 99999) | | |
| 8 Week follow-up, n=6,1 | 2.400 (± 19.1252) | -6.750 (± 88888) | | |
| 6 month follow-up, n=2,0 | -6.160 (± 12.0491) | 99999 (± 99999) | | |

Notes:

[74] - Safety Population

[75] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in SV by ECHO

| | |
|-----------------|------------------------------------|
| End point title | Change from Baseline in SV by ECHO |
|-----------------|------------------------------------|

End point description:

Stroke volume is the amount of blood ejected by the left ventricle in one contraction. SV was measured by ECHO at indicated time points. Baseline was considered as the latest assessment prior to first administration of either study drug, i.e. CPHPC or anti-SAP mAb. Change from Baseline was calculated as post-dose visit value minus Baseline value. Only those participants with data available at the specified time points were analyzed (represented by n= X in the category titles). 99999 indicates data is not available. 88888 indicates data is not available, as standard deviation could not be calculated as only one participant was analyzed.

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

End point timeframe:

Baseline (Day -1) and Session 1 to 6: Day 24; 8 week follow-up; 6 months follow-up

| End point values | Group 1: Cardiac TTR amyloidosis (ATTR-CM) participants | Group 2: Post- chemotherapy AL Amyloidosis participants | | |
|--------------------------------------|---|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6 ^[76] | 1 ^[77] | | |
| Units: Milliliter | | | | |
| arithmetic mean (standard deviation) | | | | |
| Session 1, Day 24, n=6,1 | 2.580 (± 5.4518) | -5.640 (± 88888) | | |
| Session 2, Day 24, n=6,0 | -1.885 (± 4.6569) | 99999 (± 99999) | | |
| Session 3, Day 24, n=6,0 | -1.398 (± 8.0106) | 99999 (± 99999) | | |
| Session 4, Day 24, n=5,0 | -7.484 (± 6.5228) | 99999 (± 99999) | | |
| Session 5, Day 24, n=4,0 | -9.043 (± 9.5173) | 99999 (± 99999) | | |
| Session 6, Day 24, n=4,0 | -5.095 (± 7.1431) | 99999 (± 99999) | | |
| 8 Week follow-up, n=6,1 | -4.343 (± 7.3457) | -6.490 (± 88888) | | |
| 6 month follow-up, n=4,0 | -4.275 (± 9.9743) | 99999 (± 99999) | | |

Notes:

[76] - Safety Population

[77] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in left ventricular ejection fraction (EF) by CMR

| | |
|-----------------|--|
| End point title | Change from Baseline in left ventricular ejection fraction (EF) by CMR |
|-----------------|--|

End point description:

Left ventricular ejection fraction is a measurement of the percentage of blood leaving the heart each time it contracts. EF was measured by CMR at indicated time points. Baseline was considered as the latest assessment prior to first administration of either study drug, i.e. CPHPC or anti-SAP mAb. Change from Baseline was calculated as post-dose visit value minus Baseline value. Only those participants with data available at the specified time points were analyzed (represented by n= X in the category titles).

99999 indicates data is not available. 88888 indicates data is not available, as standard deviation could not be calculated as only one participant was analyzed.

| | |
|--|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Baseline (Day -1) and Session 2 to 5: Day 24; 8 week follow-up; 6 months follow-up | |

| End point values | Group 1: Cardiac TTR amyloidosis (ATTR-CM) participants | Group 2: Post- chemotherapy AL Amyloidosis participants | | |
|--------------------------------------|---|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6 ^[78] | 1 ^[79] | | |
| Units: Percentage of ejected blood | | | | |
| arithmetic mean (standard deviation) | | | | |
| Session 2, Day 24, n=6,0 | 0.100 (± 3.9071) | 99999 (± 99999) | | |
| Session 3, Day 24, n=6,0 | 0.687 (± 11.7171) | 99999 (± 99999) | | |
| Session 4, Day 24, n=5,0 | -3.380 (± 5.4750) | 99999 (± 99999) | | |
| Session 5, Day 24, n=4,0 | -3.257 (± 7.9513) | 99999 (± 99999) | | |
| 8 Week follow-up, n=6,1 | -1.258 (± 7.9932) | -2.800 (± 88888) | | |
| 6 month follow-up, n=2,0 | 0.680 (± 8.7681) | 99999 (± 99999) | | |

Notes:

[78] - Safety Population

[79] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in left ventricular EF by ECHO

| | |
|---|---|
| End point title | Change from Baseline in left ventricular EF by ECHO |
| End point description: | |
| Left ventricular ejection fraction is a measurement of the percentage of blood leaving the heart each time it contracts. EF was measured by ECHO at indicated time points. Baseline was considered as the latest assessment prior to first administration of either study drug, i.e. CPHPC or anti-SAP mAb. Change from Baseline was calculated as post-dose visit value minus Baseline value. Only those participants with data available at the specified time points were analyzed (represented by n= X in the category titles). 99999 indicates data is not available. 88888 indicates data is not available, as standard deviation could not be calculated as only one participant was analyzed. | |
| End point type | Secondary |
| End point timeframe: | |
| Baseline (Day -1) and Session 1 to 6: Day 24; 8 week follow-up; 6 months follow-up | |

| End point values | Group 1: Cardiac TTR amyloidosis (ATTR-CM) participants | Group 2: Post- chemotherapy AL Amyloidosis participants | | |
|--------------------------------------|---|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6 ^[80] | 1 ^[81] | | |
| Units: Percentage of ejected blood | | | | |
| arithmetic mean (standard deviation) | | | | |
| Session 1, Day 24, n=6,1 | 2.10 (± 5.707) | -7.40 (± 88888) | | |
| Session 2, Day 24, n=6,0 | -0.38 (± 3.111) | 99999 (± 99999) | | |
| Session 3, Day 24, n=6,0 | -0.30 (± 3.318) | 99999 (± 99999) | | |
| Session 4, Day 24, n=5,0 | -2.74 (± 5.766) | 99999 (± 99999) | | |
| Session 5, Day 24, n=4,0 | -4.05 (± 7.832) | 99999 (± 99999) | | |
| Session 6, Day 24, n=4,0 | -3.53 (± 3.288) | 99999 (± 99999) | | |
| 8 Week follow-up, n=6,1 | -1.72 (± 8.471) | -3.20 (± 88888) | | |
| 6 month follow-up, n=4,0 | 1.20 (± 3.442) | 99999 (± 99999) | | |

Notes:

[80] - Safety Population

[81] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in left ventricle End Diastolic Volume (EDV) by CMR

| | |
|-----------------|--|
| End point title | Change from Baseline in left ventricle End Diastolic Volume (EDV) by CMR |
|-----------------|--|

End point description:

Left ventricle EDV is the volume of blood in the left ventricle at end load or filling in (diastole) or the amount of blood in the ventricles just before systole. EDV was measured by CMR at indicated time points. Baseline was considered as the latest assessment prior to first administration of either study drug, i.e. CPHPC or anti-SAP mAb. Change from Baseline was calculated as post-dose visit value minus Baseline value. Only those participants with data available at the specified time points were analyzed (represented by n= X in the category titles). 99999 indicates data is not available. 88888 indicates data is not available, as standard deviation could not be calculated as only one participant was analyzed.

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

End point timeframe:

Baseline (Day -1) and Session 2 to 5: Day 24; 8 week follow-up; 6 months follow-up

| End point values | Group 1: Cardiac TTR amyloidosis (ATTR-CM) participants | Group 2: Post- chemotherapy AL Amyloidosis participants | | |
|--------------------------------------|---|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6 ^[82] | 1 ^[83] | | |
| Units: Milliliter | | | | |
| arithmetic mean (standard deviation) | | | | |
| Session 2, Day 24, n=6,0 | -3.473 (± 11.2584) | 99999 (± 99999) | | |
| Session 3, Day 24, n=6,0 | 1.653 (± 7.3322) | 99999 (± 99999) | | |
| Session 4, Day 24, n=5,0 | -5.262 (± 5.3765) | 99999 (± 99999) | | |
| Session 5, Day 24, n=4,0 | -9.323 (± 11.5275) | 99999 (± 99999) | | |
| 8 Week follow-up, n=6,1 | 9.887 (± 19.3925) | -4.560 (± 88888) | | |
| 6 month follow-up, n=2,0 | -21.030 (± 8.0469) | 99999 (± 99999) | | |

Notes:

[82] - Safety Population

[83] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in left ventricle End Diastolic Volume (EDV) by ECHO

| | |
|-----------------|---|
| End point title | Change from Baseline in left ventricle End Diastolic Volume (EDV) by ECHO |
|-----------------|---|

End point description:

Left ventricle EDV is the volume of blood in the left ventricle at end load or filling in (diastole) or the amount of blood in the ventricles just before systole. EDV was measured by ECHO at indicated time points. Baseline was considered as the latest assessment prior to first administration of either study drug, i.e. CPHPC or anti-SAP mAb. Change from Baseline was calculated as post-dose visit value minus Baseline value. Only those participants with data available at the specified time points were analyzed (represented by n= X in the category titles). 99999 indicates data is not available. 88888 indicates data is not available, as standard deviation could not be calculated as only one participant was analyzed.

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

End point timeframe:

Baseline (Day -1) and Session 1 to 6: Day 24; 8 week follow-up; 6 months follow-up

| End point values | Group 1: Cardiac TTR amyloidosis (ATTR-CM) participants | Group 2: Post- chemotherapy AL Amyloidosis participants | | |
|--------------------------------------|---|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6 ^[84] | 1 ^[85] | | |
| Units: Milliliter | | | | |
| arithmetic mean (standard deviation) | | | | |
| Session 1, Day 24, n=6,1 | 0.050 (± 4.6276) | -1.790 (± 88888) | | |

| | | | | |
|--------------------------|---------------------|------------------|--|--|
| Session 2, Day 24, n=6,0 | -2.940 (± 10.2320) | 99999 (± 99999) | | |
| Session 3, Day 24, n=6,0 | -2.922 (± 14.0019) | 99999 (± 99999) | | |
| Session 4, Day 24, n=5,0 | -12.338 (± 10.2249) | 99999 (± 99999) | | |
| Session 5, Day 24, n=4,0 | -11.860 (± 14.5676) | 99999 (± 99999) | | |
| Session 6, Day 24, n=4,0 | -5.073 (± 11.3679) | 99999 (± 99999) | | |
| 8 Week follow-up, n=6,1 | -7.648 (± 4.4630) | -7.100 (± 88888) | | |
| 6 month follow-up, n=4,0 | -12.045 (± 20.2972) | 99999 (± 99999) | | |

Notes:

[84] - Safety Population

[85] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in ratio of mitral peak velocity of early filling to early diastolic mitral annual velocity (E/e' ratio)

| | |
|-----------------|---|
| End point title | Change from Baseline in ratio of mitral peak velocity of early filling to early diastolic mitral annual velocity (E/e' ratio) |
|-----------------|---|

End point description:

E/e' ratio was measured by ECHO at indicated time points. It had 2 separate measurements: lateral and septal. Baseline was considered as the latest assessment prior to first administration of either study drug, i.e. CPHPC or anti-SAP mAb. Change from Baseline was calculated as post-dose visit value minus Baseline value. Only those participants with data available at the specified time points were analyzed (represented by n= X in the category titles). 99999 indicates data is not available. 88888 indicates data is not available, as standard deviation could not be calculated as only one participant was analyzed.

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

End point timeframe:

Baseline (Day -1) and Session 1 to 6: Day 24; 8 week follow-up; 6 months follow-up

| End point values | Group 1: Cardiac TTR amyloidosis (ATTR-CM) participants | Group 2: Post-chemotherapy AL Amyloidosis participants | | |
|---|---|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6 ^[86] | 1 ^[87] | | |
| Units: Ratio | | | | |
| arithmetic mean (standard deviation) | | | | |
| E/e Lateral Ratio, Session 1, Day 24, n=6,1 | -1.55 (± 2.813) | -2.80 (± 88888) | | |
| E/e Lateral Ratio, Session 2, Day 24, n=6,0 | -0.77 (± 3.555) | 99999 (± 99999) | | |
| E/e Lateral Ratio, Session 3, Day 24, n=6,0 | 3.20 (± 2.197) | 99999 (± 99999) | | |
| E/e Lateral Ratio, Session 4, Day 24, n=5,0 | -0.64 (± 4.750) | 99999 (± 99999) | | |
| E/e Lateral Ratio, Session 5, Day 24, n=4,0 | 1.22 (± 5.134) | 99999 (± 99999) | | |

| | | | | |
|---|-----------------|-----------------|--|--|
| E/e Lateral Ratio, Session 6, Day 24, n=4,0 | 3.25 (± 2.300) | 99999 (± 99999) | | |
| E/e Lateral Ratio, 8 Week follow-up, n=6,1 | 0.05 (± 2.681) | 2.90 (± 88888) | | |
| E/e Lateral Ratio, 6 month follow-up, n=4,0 | -0.58 (± 4.442) | 99999 (± 99999) | | |
| E/e Septal Ratio, Session 1, Day 24, n=6,1 | 0.50 (± 2.995) | -2.00 (± 88888) | | |
| E/e Septal Ratio, Session 2, Day 24, n=6,0 | 0.52 (± 4.640) | 99999 (± 99999) | | |
| E/e Septal Ratio, Session 3, Day 24, n=6,0 | 5.33 (± 5.136) | 99999 (± 99999) | | |
| E/e Septal Ratio, Session 4, Day 24, n=5,0 | 2.96 (± 3.462) | 99999 (± 99999) | | |
| E/e Septal Ratio, Session 5, Day 24, n=4,0 | 4.48 (± 3.010) | 99999 (± 99999) | | |
| E/e Septal Ratio, Session 6, Day 24, n=4,0 | 6.23 (± 5.917) | 99999 (± 99999) | | |
| E/e Septal Ratio, 8 Week follow-up, n=6,0 | 2.83 (± 4.236) | 99999 (± 99999) | | |
| E/e Septal Ratio, 6 month follow-up, n=4,0 | 4.95 (± 1.708) | 99999 (± 99999) | | |

Notes:

[86] - Safety Population

[87] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in plasma cytokines over time

| | |
|-----------------|--|
| End point title | Change from Baseline in plasma cytokines over time |
|-----------------|--|

End point description:

Blood samples were collected for assessment of plasma cytokines biomarkers which included Tumor Necrosis Factor (TNF), Interleukin 1 beta (IL-1 beta), IL-6, IL-10, Interferon gamma (INF gamma), IL-12, IL-13, IL-2, IL-4 and IL-8. Baseline was considered as the latest assessment prior to first administration of either study drug, i.e. CPHPC or anti-SAP mAb. Change from Baseline was calculated as post-dose visit value minus Baseline value. Absolute values below the lower limit of quantification (LLQ) were imputed with half the LLQ and those above the upper limit of quantification (ULQ) were imputed with the ULQ. Only those participants with data available at the specified time points were analyzed (represented by n= X in the category titles). 99999 indicates data is not available. 88888 indicates data is not available, as standard deviation could not be calculated as only one participant was analyzed.

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

End point timeframe:

Baseline (Day -1) and Session 1: Day 1 (predose, 1,3,6 hours), Day 2, Day 3 (predose, 1,3,6 hours), Day 4, Day 5; Session 2 to 6: Day -2, Day 1 (predose, 1,3,6 hours), Day 2, Day 3 (predose, 1,3,6 hours), Day 4, Day 5

| End point values | Group 1: Cardiac TTR amyloidosis (ATTR-CM) participants | Group 2: Post-chemotherapy AL Amyloidosis participants | | |
|-----------------------------------|---|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6 ^[88] | 1 ^[89] | | |
| Units: Nanograms per liter (ng/L) | | | | |

| arithmetic mean (standard deviation) | | | | |
|---|------------------|-----------------|--|--|
| IL-1 beta, Session 1, Day 1, predose, n=6,1 | 0.000 (± 0.0000) | 0.000 (± 88888) | | |
| IL-1 beta, Session 1, Day 1, 1 hour, n=6,1 | 0.000 (± 0.0000) | 0.000 (± 88888) | | |
| IL-1 beta, Session 1, Day 1, 3 hour, n=6,1 | 0.000 (± 0.0000) | 0.000 (± 88888) | | |
| IL-1 beta, Session 1, Day 1, 6 hour, n=6,1 | 0.000 (± 0.0000) | 0.000 (± 88888) | | |
| IL-1 beta, Session 1, Day 2, n=6,1 | 0.000 (± 0.0000) | 0.000 (± 88888) | | |
| IL-1 beta, Session 1, Day 3, predose, n=6,1 | 0.000 (± 0.0000) | 0.000 (± 88888) | | |
| IL-1 beta, Session 1, Day 3, 1 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 1, Day 3, 3 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 1, Day 3, 6 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 1, Day 4, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 1, Day 5, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 2, Day -2, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 2, Day 1, predose, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 2, Day 1, 1 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 2, Day 1, 3 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 2, Day 1, 6 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 2, Day 2, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 2, Day 3, predose, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 2, Day 3, 1 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 2, Day 3, 3 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 2, Day 3, 6 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 2, Day 4, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 2, Day 5, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 3, Day -2, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 3, Day 1, predose, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 3, Day 1, 1 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 3, Day 1, 3 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 3, Day 1, 6 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 3, Day 2, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 3, Day 3, predose, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |

| | | | | |
|---|------------------|-----------------|--|--|
| IL-1 beta, Session 3, Day 3, 1 hour, n=6,0 | 0.293 (± 0.7185) | 99999 (± 99999) | | |
| IL-1 beta, Session 3, Day 3, 3 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 3, Day 3, 6 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 3, Day 4, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 3, Day 5, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 4, Day -2, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 4, Day 1, predose, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 4, Day 1, 1 hour, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 4, Day 1, 3 hour, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 4, Day 1, 6 hour, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 4, Day 2, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 4, Day 3, predose, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 4, Day 3, 1 hour, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 4, Day 3, 3 hour, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 4, Day 3, 6 hour, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 4, Day 4, n=5,0 | 0.504 (± 1.1270) | 99999 (± 99999) | | |
| IL-1 beta, Session 4, Day 5, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 5, Day -2, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 5, Day 1, predose, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 5, Day 1, 1 hour, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 5, Day 1, 3 hour, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 5, Day 1, 6 hour, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 5, Day 2, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 5, Day 3, predose, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 5, Day 3, 1 hour, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 5, Day 3, 3 hour, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 5, Day 3, 6 hour, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 5, Day 4, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 5, Day 5, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 6, Day -2, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 6, Day 1, predose, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |

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| IL-1 beta, Session 6, Day 1, 1 hour, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 6, Day 1, 3 hour, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 6, Day 1, 6 hour, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 6, Day 2, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 6, Day 3, predose, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 6, Day 3, 1 hour, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 6, Day 3, 3 hour, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 6, Day 3, 6 hour, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 6, Day 4, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-1 beta, Session 6, Day 5, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-6, Session 1, Day 1, predose, n=6,1 | 0.275 (± 0.4711) | 0.000 (± 88888) | | |
| IL-6, Session 1, Day 1, 1 hour, n=6,1 | -0.080 (± 0.7723) | 0.000 (± 88888) | | |
| IL-6, Session 1, Day 1, 3 hour, n=6,1 | -0.727 (± 1.2035) | 0.000 (± 88888) | | |
| IL-6, Session 1, Day 1, 6 hour, n=6,1 | -1.077 (± 1.2511) | 2.880 (± 88888) | | |
| IL-6, Session 1, Day 2, n=6,1 | 6.278 (± 6.3567) | 29.030 (± 88888) | | |
| IL-6, Session 1, Day 3, predose, n=6,1 | 7.688 (± 8.8639) | 16.980 (± 88888) | | |
| IL-6, Session 1, Day 3, 1 hour, n=6,0 | 6.857 (± 10.5934) | 99999 (± 99999) | | |
| IL-6, Session 1, Day 3, 3 hour, n=6,0 | 0.827 (± 3.5790) | 99999 (± 99999) | | |
| IL-6, Session 1, Day 3, 6 hour, n=6,0 | 0.932 (± 5.5637) | 99999 (± 99999) | | |
| IL-6, Session 1, Day 4, n=6,0 | 5.453 (± 3.6039) | 99999 (± 99999) | | |
| IL-6, Session 1, Day 5, n=6,0 | 3.245 (± 3.3934) | 99999 (± 99999) | | |
| IL-6, Session 2, Day -2, n=6,0 | 0.393 (± 0.5250) | 99999 (± 99999) | | |
| IL-6, Session 2, Day 1, predose, n=6,0 | 0.632 (± 1.2026) | 99999 (± 99999) | | |
| IL-6, Session 2, Day 1, 1 hour, n=6,0 | 0.025 (± 0.7117) | 99999 (± 99999) | | |
| IL-6, Session 2, Day 1, 3 hour, n=6,0 | -0.860 (± 1.0909) | 99999 (± 99999) | | |
| IL-6, Session 2, Day 1, 6 hour, n=6,0 | -0.282 (± 1.7148) | 99999 (± 99999) | | |
| IL-6, Session 2, Day 2, n=6,0 | 21.590 (± 27.1214) | 99999 (± 99999) | | |
| IL-6, Session 2, Day 3, predose, n=6,0 | 11.365 (± 11.4140) | 99999 (± 99999) | | |
| IL-6, Session 2, Day 3, 1 hour, n=6,0 | 7.517 (± 8.6084) | 99999 (± 99999) | | |
| IL-6, Session 2, Day 3, 3 hour, n=6,0 | 3.460 (± 5.0176) | 99999 (± 99999) | | |
| IL-6, Session 2, Day 3, 6 hour, n=6,0 | 0.723 (± 4.5392) | 99999 (± 99999) | | |

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| IL-6, Session 2, Day 4, n=6,0 | 4.580 (\pm 5.9326) | 99999 (\pm 99999) | | |
| IL-6, Session 2, Day 5, n=6,0 | 6.395 (\pm 5.2800) | 99999 (\pm 99999) | | |
| IL-6, Session 3, Day -2, n=5,0 | 0.148 (\pm 0.8211) | 99999 (\pm 99999) | | |
| IL-6, Session 3, Day 1, predose, n=6,0 | 0.782 (\pm 1.5023) | 99999 (\pm 99999) | | |
| IL-6, Session 3, Day 1, 1 hour, n=6,0 | 0.268 (\pm 1.4865) | 99999 (\pm 99999) | | |
| IL-6, Session 3, Day 1, 3 hour, n=6,0 | 0.062 (\pm 2.5899) | 99999 (\pm 99999) | | |
| IL-6, Session 3, Day 1, 6 hour, n=6,0 | -0.918 (\pm 1.2591) | 99999 (\pm 99999) | | |
| IL-6, Session 3, Day 2, n=5,0 | 17.608 (\pm 29.2558) | 99999 (\pm 99999) | | |
| IL-6, Session 3, Day 3, predose, n=6,0 | 11.872 (\pm 8.7413) | 99999 (\pm 99999) | | |
| IL-6, Session 3, Day 3, 1 hour, n=6,0 | 5.835 (\pm 3.8271) | 99999 (\pm 99999) | | |
| IL-6, Session 3, Day 3, 3 hour, n=6,0 | 1.742 (\pm 1.9174) | 99999 (\pm 99999) | | |
| IL-6, Session 3, Day 3, 6 hour, n=6,0 | 0.063 (\pm 2.2072) | 99999 (\pm 99999) | | |
| IL-6, Session 3, Day 4, n=6,0 | 4.667 (\pm 6.9875) | 99999 (\pm 99999) | | |
| IL-6, Session 3, Day 5, n=6,0 | 5.570 (\pm 2.6004) | 99999 (\pm 99999) | | |
| IL-6, Session 4, Day -2, n=5,0 | 0.892 (\pm 0.8423) | 99999 (\pm 99999) | | |
| IL-6, Session 4, Day 1, predose, n=5,0 | 1.486 (\pm 0.8702) | 99999 (\pm 99999) | | |
| IL-6, Session 4, Day 1, 1 hour, n=5,0 | 0.926 (\pm 0.7103) | 99999 (\pm 99999) | | |
| IL-6, Session 4, Day 1, 3 hour, n=5,0 | -0.026 (\pm 0.1599) | 99999 (\pm 99999) | | |
| IL-6, Session 4, Day 1, 6 hour, n=5,0 | -1.028 (\pm 1.3685) | 99999 (\pm 99999) | | |
| IL-6, Session 4, Day 2, n=5,0 | 5.720 (\pm 11.3851) | 99999 (\pm 99999) | | |
| IL-6, Session 4, Day 3, predose, n=5,0 | 10.924 (\pm 6.5370) | 99999 (\pm 99999) | | |
| IL-6, Session 4, Day 3, 1 hour, n=5,0 | 4.486 (\pm 2.0420) | 99999 (\pm 99999) | | |
| IL-6, Session 4, Day 3, 3 hour, n=5,0 | 1.446 (\pm 1.5368) | 99999 (\pm 99999) | | |
| IL-6, Session 4, Day 3, 6 hour, n=5,0 | -0.116 (\pm 1.7948) | 99999 (\pm 99999) | | |
| IL-6, Session 4, Day 4, n=5,0 | 5.756 (\pm 6.8645) | 99999 (\pm 99999) | | |
| IL-6, Session 4, Day 5, n=4,0 | 4.388 (\pm 3.7765) | 99999 (\pm 99999) | | |
| IL-6, Session 5, Day -2, n=4,0 | 0.027 (\pm 0.8164) | 99999 (\pm 99999) | | |
| IL-6, Session 5, Day 1, predose, n=4,0 | 0.865 (\pm 0.9927) | 99999 (\pm 99999) | | |
| IL-6, Session 5, Day 1, 1 hour, n=4,0 | -0.007 (\pm 1.3219) | 99999 (\pm 99999) | | |
| IL-6, Session 5, Day 1, 3 hour, n=4,0 | -0.423 (\pm 1.5816) | 99999 (\pm 99999) | | |
| IL-6, Session 5, Day 1, 6 hour, n=4,0 | -1.213 (\pm 1.5189) | 99999 (\pm 99999) | | |

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| IL-6, Session 5, Day 2, n=4,0 | 0.905 (± 4.0920) | 99999 (± 99999) | | |
| IL-6, Session 5, Day 3, predose, n=4,0 | 7.323 (± 4.8265) | 99999 (± 99999) | | |
| IL-6, Session 5, Day 3, 1 hour, n=4,0 | 4.240 (± 3.6214) | 99999 (± 99999) | | |
| IL-6, Session 5, Day 3, 3 hour, n=4,0 | -0.125 (± 0.7543) | 99999 (± 99999) | | |
| IL-6, Session 5, Day 3, 6 hour, n=4,0 | -1.390 (± 1.3301) | 99999 (± 99999) | | |
| IL-6, Session 5, Day 4, n=4,0 | 3.598 (± 5.7476) | 99999 (± 99999) | | |
| IL-6, Session 5, Day 5, n=4,0 | 6.533 (± 2.6812) | 99999 (± 99999) | | |
| IL-6, Session 6, Day -2, n=4,0 | 1.383 (± 1.8535) | 99999 (± 99999) | | |
| IL-6, Session 6, Day 1, predose, n=4,0 | 0.565 (± 1.4007) | 99999 (± 99999) | | |
| IL-6, Session 6, Day 1, 1 hour, n=4,0 | 0.077 (± 1.1200) | 99999 (± 99999) | | |
| IL-6, Session 6, Day 1, 3 hour, n=4,0 | -0.413 (± 1.4416) | 99999 (± 99999) | | |
| IL-6, Session 6, Day 1, 6 hour, n=4,0 | -1.165 (± 0.9786) | 99999 (± 99999) | | |
| IL-6, Session 6, Day 2, n=4,0 | 0.932 (± 4.0340) | 99999 (± 99999) | | |
| IL-6, Session 6, Day 3, predose, n=4,0 | 15.008 (± 13.0010) | 99999 (± 99999) | | |
| IL-6, Session 6, Day 3, 1 hour, n=4,0 | 10.083 (± 9.2076) | 99999 (± 99999) | | |
| IL-6, Session 6, Day 3, 3 hour, n=4,0 | 1.435 (± 1.7505) | 99999 (± 99999) | | |
| IL-6, Session 6, Day 3, 6 hour, n=4,0 | -1.005 (± 1.3522) | 99999 (± 99999) | | |
| IL-6, Session 6, Day 4, n=4,0 | 1.740 (± 3.2649) | 99999 (± 99999) | | |
| IL-6, Session 6, Day 5, n=4,0 | 7.190 (± 3.8811) | 99999 (± 99999) | | |
| IL-10, Session 1, Day 1, predose, n=6,1 | -0.067 (± 0.1633) | 0.000 (± 88888) | | |
| IL-10, Session 1, Day 1, 1 hour, n=6,1 | 0.105 (± 0.1663) | 8.580 (± 88888) | | |
| IL-10, Session 1, Day 1, 3 hour, n=6,1 | 0.763 (± 0.4804) | 5.260 (± 88888) | | |
| IL-10, Session 1, Day 1, 6 hour, n=6,1 | 1.710 (± 1.4719) | 6.020 (± 88888) | | |
| IL-10, Session 1, Day 2, n=6,1 | -0.005 (± 0.2436) | 1.150 (± 88888) | | |
| IL-10, Session 1, Day 3, predose, n=6,1 | 0.040 (± 0.3347) | 1.280 (± 88888) | | |
| IL-10, Session 1, Day 3, 1 hour, n=6,0 | 0.670 (± 1.0153) | 99999 (± 99999) | | |
| IL-10, Session 1, Day 3, 3 hour, n=6,0 | 0.065 (± 0.3896) | 99999 (± 99999) | | |
| IL-10, Session 1, Day 3, 6 hour, n=6,0 | 0.002 (± 0.0041) | 99999 (± 99999) | | |
| IL-10, Session 1, Day 4, n=6,0 | -0.067 (± 0.1633) | 99999 (± 99999) | | |
| IL-10, Session 1, Day 5, n=6,0 | -0.067 (± 0.1633) | 99999 (± 99999) | | |
| IL-10, Session 2, Day -2, n=6,0 | -0.067 (± 0.1633) | 99999 (± 99999) | | |

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| IL-10, Session 2, Day 1, predose, n=6,0 | 0.002 (± 0.0041) | 99999 (± 99999) | | |
| IL-10, Session 2, Day 1, 1 hour, n=6,0 | 0.612 (± 0.8293) | 99999 (± 99999) | | |
| IL-10, Session 2, Day 1, 3 hour, n=6,0 | 1.132 (± 1.1748) | 99999 (± 99999) | | |
| IL-10, Session 2, Day 1, 6 hour, n=6,0 | 0.785 (± 0.5189) | 99999 (± 99999) | | |
| IL-10, Session 2, Day 2, n=6,0 | 0.012 (± 0.2757) | 99999 (± 99999) | | |
| IL-10, Session 2, Day 3, predose, n=6,0 | 0.233 (± 0.5618) | 99999 (± 99999) | | |
| IL-10, Session 2, Day 3, 1 hour, n=6,0 | 0.775 (± 1.1274) | 99999 (± 99999) | | |
| IL-10, Session 2, Day 3, 3 hour, n=6,0 | 0.782 (± 0.8451) | 99999 (± 99999) | | |
| IL-10, Session 2, Day 3, 6 hour, n=6,0 | 0.015 (± 0.0367) | 99999 (± 99999) | | |
| IL-10, Session 2, Day 4, n=6,0 | -0.005 (± 0.0122) | 99999 (± 99999) | | |
| IL-10, Session 2, Day 5, n=6,0 | 0.110 (± 0.2122) | 99999 (± 99999) | | |
| IL-10, Session 3, Day -2, n=5,0 | 0.032 (± 0.3422) | 99999 (± 99999) | | |
| IL-10, Session 3, Day 1, predose, n=6,0 | -0.067 (± 0.1633) | 99999 (± 99999) | | |
| IL-10, Session 3, Day 1, 1 hour, n=6,0 | 0.228 (± 0.2328) | 99999 (± 99999) | | |
| IL-10, Session 3, Day 1, 3 hour, n=6,0 | 1.185 (± 1.1559) | 99999 (± 99999) | | |
| IL-10, Session 3, Day 1, 6 hour, n=6,0 | 0.495 (± 0.6641) | 99999 (± 99999) | | |
| IL-10, Session 3, Day 2, n=5,0 | -0.080 (± 0.1789) | 99999 (± 99999) | | |
| IL-10, Session 3, Day 3, predose, n=6,0 | -0.067 (± 0.1633) | 99999 (± 99999) | | |
| IL-10, Session 3, Day 3, 1 hour, n=6,0 | 0.450 (± 0.6048) | 99999 (± 99999) | | |
| IL-10, Session 3, Day 3, 3 hour, n=6,0 | 0.322 (± 0.5322) | 99999 (± 99999) | | |
| IL-10, Session 3, Day 3, 6 hour, n=6,0 | 0.092 (± 0.1542) | 99999 (± 99999) | | |
| IL-10, Session 3, Day 4, n=6,0 | -0.067 (± 0.1633) | 99999 (± 99999) | | |
| IL-10, Session 3, Day 5, n=6,0 | -0.067 (± 0.1633) | 99999 (± 99999) | | |
| IL-10, Session 4, Day -2, n=5,0 | -0.080 (± 0.1789) | 99999 (± 99999) | | |
| IL-10, Session 4, Day 1, predose, n=5,0 | -0.080 (± 0.1789) | 99999 (± 99999) | | |
| IL-10, Session 4, Day 1, 1 hour, n=5,0 | 0.758 (± 1.4466) | 99999 (± 99999) | | |
| IL-10, Session 4, Day 1, 3 hour, n=5,0 | 3.868 (± 6.3123) | 99999 (± 99999) | | |
| IL-10, Session 4, Day 1, 6 hour, n=5,0 | 0.868 (± 0.9281) | 99999 (± 99999) | | |
| IL-10, Session 4, Day 2, n=5,0 | -0.080 (± 0.1789) | 99999 (± 99999) | | |
| IL-10, Session 4, Day 3, predose, n=5,0 | 0.022 (± 0.0492) | 99999 (± 99999) | | |
| IL-10, Session 4, Day 3, 1 hour, n=5,0 | 0.808 (± 1.0592) | 99999 (± 99999) | | |

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| IL-10, Session 4, Day 3, 3 hour, n=5,0 | 0.598 (\pm 0.6549) | 99999 (\pm 99999) | | |
| IL-10, Session 4, Day 3, 6 hour, n=5,0 | 0.184 (\pm 0.4284) | 99999 (\pm 99999) | | |
| IL-10, Session 4, Day 4, n=5,0 | -0.080 (\pm 0.1789) | 99999 (\pm 99999) | | |
| IL-10, Session 4, Day 5, n=4,0 | -0.100 (\pm 0.2000) | 99999 (\pm 99999) | | |
| IL-10, Session 5, Day -2, n=4,0 | -0.100 (\pm 0.2000) | 99999 (\pm 99999) | | |
| IL-10, Session 5, Day 1, predose, n=4,0 | -0.100 (\pm 0.2000) | 99999 (\pm 99999) | | |
| IL-10, Session 5, Day 1, 1 hour, n=4,0 | 2.485 (\pm 4.8507) | 99999 (\pm 99999) | | |
| IL-10, Session 5, Day 1, 3 hour, n=4,0 | 3.828 (\pm 6.5828) | 99999 (\pm 99999) | | |
| IL-10, Session 5, Day 1, 6 hour, n=4,0 | 1.120 (\pm 1.5607) | 99999 (\pm 99999) | | |
| IL-10, Session 5, Day 2, n=4,0 | -0.100 (\pm 0.2000) | 99999 (\pm 99999) | | |
| IL-10, Session 5, Day 3, predose, n=4,0 | 0.393 (\pm 0.4774) | 99999 (\pm 99999) | | |
| IL-10, Session 5, Day 3, 1 hour, n=4,0 | 0.950 (\pm 0.9330) | 99999 (\pm 99999) | | |
| IL-10, Session 5, Day 3, 3 hour, n=4,0 | 1.060 (\pm 0.9783) | 99999 (\pm 99999) | | |
| IL-10, Session 5, Day 3, 6 hour, n=4,0 | 0.663 (\pm 0.6663) | 99999 (\pm 99999) | | |
| IL-10, Session 5, Day 4, n=4,0 | 0.210 (\pm 0.4267) | 99999 (\pm 99999) | | |
| IL-10, Session 5, Day 5, n=4,0 | 0.025 (\pm 0.0500) | 99999 (\pm 99999) | | |
| IL-10, Session 6, Day -2, n=4,0 | -0.100 (\pm 0.2000) | 99999 (\pm 99999) | | |
| IL-10, Session 6, Day 1, predose, n=4,0 | -0.100 (\pm 0.2000) | 99999 (\pm 99999) | | |
| IL-10, Session 6, Day 1, 1 hour, n=4,0 | 0.333 (\pm 0.9506) | 99999 (\pm 99999) | | |
| IL-10, Session 6, Day 1, 3 hour, n=4,0 | 1.738 (\pm 2.5365) | 99999 (\pm 99999) | | |
| IL-10, Session 6, Day 1, 6 hour, n=4,0 | 1.418 (\pm 1.7245) | 99999 (\pm 99999) | | |
| IL-10, Session 6, Day 2, n=4,0 | -0.100 (\pm 0.2000) | 99999 (\pm 99999) | | |
| IL-10, Session 6, Day 3, predose, n=4,0 | 0.015 (\pm 0.0300) | 99999 (\pm 99999) | | |
| IL-10, Session 6, Day 3, 1 hour, n=4,0 | 0.753 (\pm 1.4004) | 99999 (\pm 99999) | | |
| IL-10, Session 6, Day 3, 3 hour, n=4,0 | 0.675 (\pm 1.1466) | 99999 (\pm 99999) | | |
| IL-10, Session 6, Day 3, 6 hour, n=4,0 | 0.220 (\pm 0.2723) | 99999 (\pm 99999) | | |
| IL-10, Session 6, Day 4, n=4,0 | -0.100 (\pm 0.2000) | 99999 (\pm 99999) | | |
| IL-10, Session 6, Day 5, n=4,0 | 0.023 (\pm 0.0450) | 99999 (\pm 99999) | | |
| TNF, Session 1, Day 1, predose, n=6,1 | 0.055 (\pm 0.4378) | 0.320 (\pm 88888) | | |
| TNF, Session 1, Day 1, 1 hour, n=6,1 | 0.007 (\pm 0.7159) | 0.100 (\pm 88888) | | |
| TNF, Session 1, Day 1, 3 hour, n=6,1 | -0.180 (\pm 0.7430) | 0.880 (\pm 88888) | | |

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| TNF, Session 1, Day 1, 6 hour, n=6,1 | -0.132 (± 0.8145) | 2.300 (± 88888) | | |
| TNF, Session 1, Day 2, n=6,1 | 1.920 (± 1.5379) | 5.130 (± 88888) | | |
| TNF, Session 1, Day 3, predose, n=6,1 | 1.453 (± 1.3405) | 3.010 (± 88888) | | |
| TNF, Session 1, Day 3, 1 hour, n=6,0 | 1.240 (± 0.9968) | 99999 (± 99999) | | |
| TNF, Session 1, Day 3, 3 hour, n=6,0 | 0.797 (± 1.0229) | 99999 (± 99999) | | |
| TNF, Session 1, Day 3, 6 hour, n=6,0 | 0.460 (± 0.9373) | 99999 (± 99999) | | |
| TNF, Session 1, Day 4, n=6,0 | 1.088 (± 1.2874) | 99999 (± 99999) | | |
| TNF, Session 1, Day 5, n=6,0 | 1.577 (± 1.5915) | 99999 (± 99999) | | |
| TNF, Session 2, Day -2, n=6,0 | 0.167 (± 0.9735) | 99999 (± 99999) | | |
| TNF, Session 2, Day 1, predose, n=6,0 | 0.233 (± 0.8351) | 99999 (± 99999) | | |
| TNF, Session 2, Day 1, 1 hour, n=6,0 | 0.133 (± 1.0259) | 99999 (± 99999) | | |
| TNF, Session 2, Day 1, 3 hour, n=6,0 | 0.015 (± 1.0940) | 99999 (± 99999) | | |
| TNF, Session 2, Day 1, 6 hour, n=6,0 | -0.100 (± 1.2625) | 99999 (± 99999) | | |
| TNF, Session 2, Day 2, n=6,0 | 1.523 (± 1.6646) | 99999 (± 99999) | | |
| TNF, Session 2, Day 3, predose, n=6,0 | 2.143 (± 1.5642) | 99999 (± 99999) | | |
| TNF, Session 2, Day 3, 1 hour, n=6,0 | 1.682 (± 1.3855) | 99999 (± 99999) | | |
| TNF, Session 2, Day 3, 3 hour, n=6,0 | 1.133 (± 0.9970) | 99999 (± 99999) | | |
| TNF, Session 2, Day 3, 6 hour, n=6,0 | 0.503 (± 1.0718) | 99999 (± 99999) | | |
| TNF, Session 2, Day 4, n=6,0 | 1.397 (± 2.1712) | 99999 (± 99999) | | |
| TNF, Session 2, Day 5, n=6,0 | 1.968 (± 1.4560) | 99999 (± 99999) | | |
| TNF, Session 3, Day -2, n=5,0 | 0.098 (± 1.2163) | 99999 (± 99999) | | |
| TNF, Session 3, Day 1, predose, n=6,0 | 0.497 (± 0.9650) | 99999 (± 99999) | | |
| TNF, Session 3, Day 1, 1 hour, n=6,0 | -0.297 (± 0.9572) | 99999 (± 99999) | | |
| TNF, Session 3, Day 1, 3 hour, n=6,0 | -0.198 (± 0.9246) | 99999 (± 99999) | | |
| TNF, Session 3, Day 1, 6 hour, n=6,0 | -0.167 (± 1.2317) | 99999 (± 99999) | | |
| TNF, Session 3, Day 2, n=5,0 | 0.446 (± 1.1212) | 99999 (± 99999) | | |
| TNF, Session 3, Day 3, predose, n=6,0 | 1.267 (± 1.1583) | 99999 (± 99999) | | |
| TNF, Session 3, Day 3, 1 hour, n=6,0 | 0.513 (± 1.1234) | 99999 (± 99999) | | |
| TNF, Session 3, Day 3, 3 hour, n=6,0 | 0.128 (± 1.0706) | 99999 (± 99999) | | |
| TNF, Session 3, Day 3, 6 hour, n=6,0 | 0.233 (± 1.2605) | 99999 (± 99999) | | |
| TNF, Session 3, Day 4, n=6,0 | 0.585 (± 1.6017) | 99999 (± 99999) | | |

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| TNF, Session 3, Day 5, n=6,0 | 0.997 (± 1.3819) | 99999 (± 99999) | | |
| TNF, Session 4, Day -2, n=5,0 | -0.208 (± 0.5949) | 99999 (± 99999) | | |
| TNF, Session 4, Day 1, predose, n=5,0 | -0.214 (± 0.8527) | 99999 (± 99999) | | |
| TNF, Session 4, Day 1, 1 hour, n=5,0 | 0.160 (± 1.5494) | 99999 (± 99999) | | |
| TNF, Session 4, Day 1, 3 hour, n=5,0 | 0.218 (± 1.5011) | 99999 (± 99999) | | |
| TNF, Session 4, Day 1, 6 hour, n=5,0 | -0.412 (± 1.1373) | 99999 (± 99999) | | |
| TNF, Session 4, Day 2, n=5,0 | -0.122 (± 0.6977) | 99999 (± 99999) | | |
| TNF, Session 4, Day 3, predose, n=5,0 | 0.606 (± 0.5265) | 99999 (± 99999) | | |
| TNF, Session 4, Day 3, 1 hour, n=5,0 | 0.100 (± 0.5074) | 99999 (± 99999) | | |
| TNF, Session 4, Day 3, 3 hour, n=5,0 | 0.098 (± 0.7172) | 99999 (± 99999) | | |
| TNF, Session 4, Day 3, 6 hour, n=5,0 | -0.702 (± 0.5368) | 99999 (± 99999) | | |
| TNF, Session 4, Day 4, n=5,0 | -0.270 (± 0.7576) | 99999 (± 99999) | | |
| TNF, Session 4, Day 5, n=4,0 | 0.095 (± 0.4456) | 99999 (± 99999) | | |
| TNF, Session 5, Day -2, n=4,0 | -0.350 (± 0.5814) | 99999 (± 99999) | | |
| TNF, Session 5, Day 1, predose, n=4,0 | -0.320 (± 0.6703) | 99999 (± 99999) | | |
| TNF, Session 5, Day 1, 1 hour, n=4,0 | -0.130 (± 1.2227) | 99999 (± 99999) | | |
| TNF, Session 5, Day 1, 3 hour, n=4,0 | -0.055 (± 1.0728) | 99999 (± 99999) | | |
| TNF, Session 5, Day 1, 6 hour, n=4,0 | -0.513 (± 1.1003) | 99999 (± 99999) | | |
| TNF, Session 5, Day 2, n=4,0 | -0.498 (± 0.9752) | 99999 (± 99999) | | |
| TNF, Session 5, Day 3, predose, n=4,0 | 0.147 (± 0.8951) | 99999 (± 99999) | | |
| TNF, Session 5, Day 3, 1 hour, n=4,0 | -0.188 (± 0.7406) | 99999 (± 99999) | | |
| TNF, Session 5, Day 3, 3 hour, n=4,0 | -0.378 (± 0.9306) | 99999 (± 99999) | | |
| TNF, Session 5, Day 3, 6 hour, n=4,0 | -0.630 (± 0.7857) | 99999 (± 99999) | | |
| TNF, Session 5, Day 4, n=4,0 | -0.100 (± 1.0725) | 99999 (± 99999) | | |
| TNF, Session 5, Day 5, n=4,0 | 0.168 (± 0.3909) | 99999 (± 99999) | | |
| TNF, Session 6, Day -2, n=4,0 | -0.428 (± 1.3664) | 99999 (± 99999) | | |
| TNF, Session 6, Day 1, predose, n=4,0 | -0.238 (± 1.3158) | 99999 (± 99999) | | |
| TNF, Session 6, Day 1, 1 hour, n=4,0 | -0.303 (± 1.3853) | 99999 (± 99999) | | |
| TNF, Session 6, Day 1, 3 hour, n=4,0 | -0.145 (± 1.8684) | 99999 (± 99999) | | |
| TNF, Session 6, Day 1, 6 hour, n=4,0 | -0.500 (± 1.4020) | 99999 (± 99999) | | |
| TNF, Session 6, Day 2, n=4,0 | -0.000 (± 1.3253) | 99999 (± 99999) | | |

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| TNF, Session 6, Day 3, predose, n=4,0 | 0.278 (± 1.9987) | 99999 (± 99999) | | |
| TNF, Session 6, Day 3, 1 hour, n=4,0 | -0.195 (± 1.6007) | 99999 (± 99999) | | |
| TNF, Session 6, Day 3, 3 hour, n=4,0 | -0.385 (± 1.4669) | 99999 (± 99999) | | |
| TNF, Session 6, Day 3, 6 hour, n=4,0 | -0.585 (± 1.3026) | 99999 (± 99999) | | |
| TNF, Session 6, Day 4, n=4,0 | -0.368 (± 1.1280) | 99999 (± 99999) | | |
| TNF, Session 6, Day 5, n=4,0 | 0.322 (± 1.2795) | 99999 (± 99999) | | |
| INF gamma, Session 1, Day 1, predose, n=6,1 | 0.075 (± 1.6224) | 1.860 (± 88888) | | |
| INF gamma, Session 1, Day 1, 1 hour, n=6,1 | -1.373 (± 2.1255) | 0.000 (± 88888) | | |
| INF gamma, Session 1, Day 1, 3 hour, n=6,1 | -3.298 (± 3.1409) | 0.000 (± 88888) | | |
| INF gamma, Session 1, Day 1, 6 hour, n=6,1 | -3.298 (± 3.1409) | 0.000 (± 88888) | | |
| INF gamma, Session 1, Day 2, n=6,1 | 1.713 (± 7.5955) | 1.930 (± 88888) | | |
| INF gamma, Session 1, Day 3, predose, n=6,1 | 17.122 (± 27.3980) | 0.000 (± 88888) | | |
| INF gamma, Session 1, Day 3, 1 hour, n=6,0 | 12.118 (± 22.0807) | 99999 (± 99999) | | |
| INF gamma, Session 1, Day 3, 3 hour, n=6,0 | 7.150 (± 18.4949) | 99999 (± 99999) | | |
| INF gamma, Session 1, Day 3, 6 hour, n=6,0 | 0.538 (± 8.5114) | 99999 (± 99999) | | |
| INF gamma, Session 1, Day 4, n=6,0 | 3.242 (± 12.2847) | 99999 (± 99999) | | |
| INF gamma, Session 1, Day 5, n=6,0 | 19.502 (± 38.3215) | 99999 (± 99999) | | |
| INF gamma, Session 2, Day -2, n=6,0 | -1.045 (± 3.4175) | 99999 (± 99999) | | |
| INF gamma, Session 2, Day 1, predose, n=6,0 | 0.452 (± 3.5018) | 99999 (± 99999) | | |
| INF gamma, Session 2, Day 1, 1 hour, n=6,0 | 0.145 (± 3.2180) | 99999 (± 99999) | | |
| INF gamma, Session 2, Day 1, 3 hour, n=6,0 | -1.833 (± 1.3991) | 99999 (± 99999) | | |
| INF gamma, Session 2, Day 1, 6 hour, n=6,0 | -3.072 (± 2.6378) | 99999 (± 99999) | | |
| INF gamma, Session 2, Day 2, n=6,0 | -2.660 (± 3.5043) | 99999 (± 99999) | | |
| INF gamma, Session 2, Day 3, predose, n=6,0 | -1.045 (± 2.2260) | 99999 (± 99999) | | |
| INF gamma, Session 2, Day 3, 1 hour, n=6,0 | -1.580 (± 2.5672) | 99999 (± 99999) | | |
| INF gamma, Session 2, Day 3, 3 hour, n=6,0 | -2.473 (± 2.5631) | 99999 (± 99999) | | |
| INF gamma, Session 2, Day 3, 6 hour, n=6,0 | -3.298 (± 3.1409) | 99999 (± 99999) | | |
| INF gamma, Session 2, Day 4, n=6,0 | -2.572 (± 3.4040) | 99999 (± 99999) | | |
| INF gamma, Session 2, Day 5, n=6,0 | -1.993 (± 2.8977) | 99999 (± 99999) | | |
| INF gamma, Session 3, Day -2, n=5,0 | -2.190 (± 3.9839) | 99999 (± 99999) | | |
| INF gamma, Session 3, Day 1, predose, n=6,0 | -1.035 (± 4.4739) | 99999 (± 99999) | | |

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| INF gamma, Session 3, Day 1, 1 hour, n=6,0 | -2.180 (\pm 3.8365) | 99999 (\pm 99999) | | |
| INF gamma, Session 3, Day 1, 3 hour, n=6,0 | -3.298 (\pm 3.1409) | 99999 (\pm 99999) | | |
| INF gamma, Session 3, Day 1, 6 hour, n=6,0 | -3.298 (\pm 3.1409) | 99999 (\pm 99999) | | |
| INF gamma, Session 3, Day 2, n=5,0 | -2.936 (\pm 3.7855) | 99999 (\pm 99999) | | |
| INF gamma, Session 3, Day 3, predose, n=6,0 | -2.948 (\pm 2.3737) | 99999 (\pm 99999) | | |
| INF gamma, Session 3, Day 3, 1 hour, n=6,0 | -3.298 (\pm 3.1409) | 99999 (\pm 99999) | | |
| INF gamma, Session 3, Day 3, 3 hour, n=6,0 | -3.298 (\pm 3.1409) | 99999 (\pm 99999) | | |
| INF gamma, Session 3, Day 3, 6 hour, n=6,0 | -3.298 (\pm 3.1409) | 99999 (\pm 99999) | | |
| INF gamma, Session 3, Day 4, n=6,0 | -3.048 (\pm 3.1886) | 99999 (\pm 99999) | | |
| INF gamma, Session 3, Day 5, n=6,0 | -2.752 (\pm 3.2989) | 99999 (\pm 99999) | | |
| INF gamma, Session 4, Day -2, n=5,0 | 0.298 (\pm 5.3631) | 99999 (\pm 99999) | | |
| INF gamma, Session 4, Day 1, predose, n=5,0 | -0.760 (\pm 4.2290) | 99999 (\pm 99999) | | |
| INF gamma, Session 4, Day 1, 1 hour, n=5,0 | -1.240 (\pm 4.3736) | 99999 (\pm 99999) | | |
| INF gamma, Session 4, Day 1, 3 hour, n=5,0 | -2.778 (\pm 3.9570) | 99999 (\pm 99999) | | |
| INF gamma, Session 4, Day 1, 6 hour, n=5,0 | -3.274 (\pm 3.5110) | 99999 (\pm 99999) | | |
| INF gamma, Session 4, Day 2, n=5,0 | -3.274 (\pm 3.5110) | 99999 (\pm 99999) | | |
| INF gamma, Session 4, Day 3, predose, n=5,0 | -2.836 (\pm 2.6051) | 99999 (\pm 99999) | | |
| INF gamma, Session 4, Day 3, 1 hour, n=5,0 | -3.274 (\pm 3.5110) | 99999 (\pm 99999) | | |
| INF gamma, Session 4, Day 3, 3 hour, n=5,0 | -3.274 (\pm 3.5110) | 99999 (\pm 99999) | | |
| INF gamma, Session 4, Day 3, 6 hour, n=5,0 | -3.274 (\pm 3.5110) | 99999 (\pm 99999) | | |
| INF gamma, Session 4, Day 4, n=5,0 | -3.274 (\pm 3.5110) | 99999 (\pm 99999) | | |
| INF gamma, Session 4, Day 5, n=4,0 | -2.910 (\pm 3.1667) | 99999 (\pm 99999) | | |
| INF gamma, Session 5, Day -2, n=4,0 | -0.930 (\pm 3.5480) | 99999 (\pm 99999) | | |
| INF gamma, Session 5, Day 1, predose, n=4,0 | -1.328 (\pm 2.1878) | 99999 (\pm 99999) | | |
| INF gamma, Session 5, Day 1, 1 hour, n=4,0 | -1.423 (\pm 1.9828) | 99999 (\pm 99999) | | |
| INF gamma, Session 5, Day 1, 3 hour, n=4,0 | -2.725 (\pm 2.8230) | 99999 (\pm 99999) | | |
| INF gamma, Session 5, Day 1, 6 hour, n=4,0 | -3.373 (\pm 4.0462) | 99999 (\pm 99999) | | |
| INF gamma, Session 5, Day 2, n=4,0 | -3.373 (\pm 4.0462) | 99999 (\pm 99999) | | |
| INF gamma, Session 5, Day 3, predose, n=4,0 | 0.753 (\pm 4.9155) | 99999 (\pm 99999) | | |
| INF gamma, Session 5, Day 3, 1 hour, n=4,0 | 0.203 (\pm 4.5195) | 99999 (\pm 99999) | | |
| INF gamma, Session 5, Day 3, 3 hour, n=4,0 | -1.388 (\pm 4.8505) | 99999 (\pm 99999) | | |

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| INF gamma, Session 5, Day 3, 6 hour, n=4,0 | -2.838 (\pm 4.4804) | 99999 (\pm 99999) | | |
| INF gamma, Session 5, Day 4, n=4,0 | -1.653 (\pm 6.0355) | 99999 (\pm 99999) | | |
| INF gamma, Session 5, Day 5, n=4,0 | -0.615 (\pm 2.9091) | 99999 (\pm 99999) | | |
| INF gamma, Session 6, Day -2, n=4,0 | -2.625 (\pm 4.4662) | 99999 (\pm 99999) | | |
| INF gamma, Session 6, Day 1, predose, n=4,0 | -2.668 (\pm 4.4299) | 99999 (\pm 99999) | | |
| INF gamma, Session 6, Day 1, 1 hour, n=4,0 | -2.823 (\pm 4.3091) | 99999 (\pm 99999) | | |
| INF gamma, Session 6, Day 1, 3 hour, n=4,0 | -3.373 (\pm 4.0462) | 99999 (\pm 99999) | | |
| INF gamma, Session 6, Day 1, 6 hour, n=4,0 | -3.373 (\pm 4.0462) | 99999 (\pm 99999) | | |
| INF gamma, Session 6, Day 2, n=4,0 | -3.373 (\pm 4.0462) | 99999 (\pm 99999) | | |
| INF gamma, Session 6, Day 3, predose, n=4,0 | -1.988 (\pm 5.0857) | 99999 (\pm 99999) | | |
| INF gamma, Session 6, Day 3, 1 hour, n=4,0 | -3.018 (\pm 4.1848) | 99999 (\pm 99999) | | |
| INF gamma, Session 6, Day 3, 3 hour, n=4,0 | -3.373 (\pm 4.0462) | 99999 (\pm 99999) | | |
| INF gamma, Session 6, Day 3, 6 hour, n=4,0 | -3.373 (\pm 4.0462) | 99999 (\pm 99999) | | |
| INF gamma, Session 6, Day 4, n=4,0 | -3.373 (\pm 4.0462) | 99999 (\pm 99999) | | |
| INF gamma, Session 6, Day 5, n=4,0 | -3.373 (\pm 4.0462) | 99999 (\pm 99999) | | |
| IL-12, Session 1, Day 1, predose, n=6,1 | 0.000 (\pm 0.0000) | 0.000 (\pm 88888) | | |
| IL-12, Session 1, Day 1, 1 hour, n=6,1 | 0.000 (\pm 0.0000) | 0.000 (\pm 88888) | | |
| IL-12, Session 1, Day 1, 3 hour, n=6,1 | 0.000 (\pm 0.0000) | 0.000 (\pm 88888) | | |
| IL-12, Session 1, Day 1, 6 hour, n=6,1 | 0.000 (\pm 0.0000) | 0.000 (\pm 88888) | | |
| IL-12, Session 1, Day 2, n=6,1 | 0.000 (\pm 0.0000) | 0.000 (\pm 88888) | | |
| IL-12, Session 1, Day 3, predose, n=6,1 | 0.000 (\pm 0.0000) | 0.000 (\pm 88888) | | |
| IL-12, Session 1, Day 3, 1 hour, n=6,0 | 0.000 (\pm 0.0000) | 99999 (\pm 99999) | | |
| IL-12, Session 1, Day 3, 3 hour, n=6,0 | 0.000 (\pm 0.0000) | 99999 (\pm 99999) | | |
| IL-12, Session 1, Day 3, 6 hour, n=6,0 | 0.000 (\pm 0.0000) | 99999 (\pm 99999) | | |
| IL-12, Session 1, Day 4, n=6,0 | 0.000 (\pm 0.0000) | 99999 (\pm 99999) | | |
| IL-12, Session 1, Day 5, n=6,0 | 0.000 (\pm 0.0000) | 99999 (\pm 99999) | | |
| IL-12, Session 2, Day -2, n=6,0 | 0.000 (\pm 0.0000) | 99999 (\pm 99999) | | |
| IL-12, Session 2, Day 1, predose, n=6,0 | 0.000 (\pm 0.0000) | 99999 (\pm 99999) | | |
| IL-12, Session 2, Day 1, 1 hour, n=6,0 | 0.000 (\pm 0.0000) | 99999 (\pm 99999) | | |
| IL-12, Session 2, Day 1, 3 hour, n=6,0 | 0.000 (\pm 0.0000) | 99999 (\pm 99999) | | |
| IL-12, Session 2, Day 1, 6 hour, n=6,0 | 0.000 (\pm 0.0000) | 99999 (\pm 99999) | | |

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| IL-12, Session 2, Day 2, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 2, Day 3, predose, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 2, Day 3, 1 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 2, Day 3, 3 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 2, Day 3, 6 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 2, Day 4, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 2, Day 5, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 3, Day -2, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 3, Day 1, predose, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 3, Day 1, 1 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 3, Day 1, 3 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 3, Day 1, 6 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 3, Day 2, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 3, Day 3, predose, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 3, Day 3, 1 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 3, Day 3, 3 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 3, Day 3, 6 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 3, Day 4, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 3, Day 5, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 4, Day -2, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 4, Day 1, predose, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 4, Day 1, 1 hour, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 4, Day 1, 3 hour, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 4, Day 1, 6 hour, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 4, Day 2, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 4, Day 3, predose, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 4, Day 3, 1 hour, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 4, Day 3, 3 hour, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 4, Day 3, 6 hour, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 4, Day 4, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 4, Day 5, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |

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|---|------------------|-----------------|--|--|
| IL-12, Session 5, Day -2, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 5, Day 1, predose, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 5, Day 1, 1 hour, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 5, Day 1, 3 hour, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 5, Day 1, 6 hour, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 5, Day 2, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 5, Day 3, predose, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 5, Day 3, 1 hour, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 5, Day 3, 3 hour, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 5, Day 3, 6 hour, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 5, Day 4, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 5, Day 5, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 6, Day -2, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 6, Day 1, predose, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 6, Day 1, 1 hour, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 6, Day 1, 3 hour, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 6, Day 1, 6 hour, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 6, Day 2, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 6, Day 3, predose, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 6, Day 3, 1 hour, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 6, Day 3, 3 hour, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 6, Day 3, 6 hour, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 6, Day 4, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-12, Session 6, Day 5, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 1, Day 1, predose, n=6,1 | 0.000 (± 0.0000) | 0.000 (± 88888) | | |
| IL-13, Session 1, Day 1, 1 hour, n=6,1 | 0.000 (± 0.0000) | 0.000 (± 88888) | | |
| IL-13, Session 1, Day 1, 3 hour, n=6,1 | 0.000 (± 0.0000) | 0.000 (± 88888) | | |
| IL-13, Session 1, Day 1, 6 hour, n=6,1 | 0.000 (± 0.0000) | 0.000 (± 88888) | | |
| IL-13, Session 1, Day 2, n=6,1 | 0.000 (± 0.0000) | 0.000 (± 88888) | | |
| IL-13, Session 1, Day 3, predose, n=6,1 | 0.000 (± 0.0000) | 0.000 (± 88888) | | |
| IL-13, Session 1, Day 3, 1 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |

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| IL-13, Session 1, Day 3, 3 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 1, Day 3, 6 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 1, Day 4, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 1, Day 5, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 2, Day -2, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 2, Day 1, predose, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 2, Day 1, 1 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 2, Day 1, 3 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 2, Day 1, 6 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 2, Day 2, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 2, Day 3, predose, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 2, Day 3, 1 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 2, Day 3, 3 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 2, Day 3, 6 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 2, Day 4, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 2, Day 5, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 3, Day -2, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 3, Day 1, predose, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 3, Day 1, 1 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 3, Day 1, 3 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 3, Day 1, 6 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 3, Day 2, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 3, Day 3, predose, n=6,0 | 0.333 (± 0.8165) | 99999 (± 99999) | | |
| IL-13, Session 3, Day 3, 1 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 3, Day 3, 3 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 3, Day 3, 6 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 3, Day 4, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 3, Day 5, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 4, Day -2, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 4, Day 1, predose, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 4, Day 1, 1 hour, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |

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| IL-13, Session 4, Day 1, 3 hour, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 4, Day 1, 6 hour, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 4, Day 2, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 4, Day 3, predose, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 4, Day 3, 1 hour, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 4, Day 3, 3 hour, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 4, Day 3, 6 hour, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 4, Day 4, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 4, Day 5, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 5, Day -2, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 5, Day 1, predose, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 5, Day 1, 1 hour, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 5, Day 1, 3 hour, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 5, Day 1, 6 hour, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 5, Day 2, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 5, Day 3, predose, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 5, Day 3, 1 hour, n=4,0 | 0.283 (± 0.5650) | 99999 (± 99999) | | |
| IL-13, Session 5, Day 3, 3 hour, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 5, Day 3, 6 hour, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 5, Day 4, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 5, Day 5, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 6, Day -2, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 6, Day 1, predose, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 6, Day 1, 1 hour, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 6, Day 1, 3 hour, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 6, Day 1, 6 hour, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 6, Day 2, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 6, Day 3, predose, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 6, Day 3, 3 hour, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 6, Day 3, 6 hour, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-13, Session 6, Day 4, n=4,0 | 0.488 (± 0.9750) | 99999 (± 99999) | | |

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| IL-13, Session 6, Day 5, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 1, Day 1, predose, n=6,1 | 0.000 (± 0.0000) | 0.000 (± 88888) | | |
| IL-2, Session 1, Day 1, 1 hour, n=6,1 | 0.000 (± 0.0000) | 0.000 (± 88888) | | |
| IL-2, Session 1, Day 1, 3 hour, n=6,1 | 0.000 (± 0.0000) | 0.000 (± 88888) | | |
| IL-2, Session 1, Day 1, 6 hour, n=6,1 | 0.000 (± 0.0000) | 0.000 (± 88888) | | |
| IL-2, Session 1, Day 2, n=6,1 | 0.000 (± 0.0000) | 0.000 (± 88888) | | |
| IL-2, Session 1, Day 3, predose, n=6,1 | 0.000 (± 0.0000) | 0.000 (± 88888) | | |
| IL-2, Session 1, Day 3, 1 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 1, Day 3, 3 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 1, Day 3, 6 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 1, Day 4, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 1, Day 5, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 2, Day -2, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 2, Day 1, predose, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 2, Day 1, 1 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 2, Day 1, 3 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 2, Day 1, 6 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 2, Day 2, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 2, Day 3, predose, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 2, Day 3, 1 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 2, Day 3, 3 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 2, Day 3, 6 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 2, Day 4, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 2, Day 5, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 3, Day -2, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 3, Day 1, predose, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 3, Day 1, 1 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 3, Day 1, 3 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 3, Day 1, 6 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 3, Day 2, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 3, Day 3, predose, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |

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| IL-2, Session 3, Day 3, 1 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 3, Day 3, 3 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 3, Day 3, 6 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 3, Day 4, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 3, Day 5, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 4, Day -2, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 4, Day 1, predose, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 4, Day 1, 1 hour, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 4, Day 1, 3 hour, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 4, Day 1, 6 hour, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 4, Day 2, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 4, Day 3, predose, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 4, Day 3, 1 hour, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 4, Day 3, 3 hour, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 4, Day 3, 6 hour, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 4, Day 4, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 4, Day 5, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 5, Day -2, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 5, Day 1, predose, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 5, Day 1, 1 hour, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 5, Day 1, 3 hour, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 5, Day 1, 6 hour, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 5, Day 2, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 5, Day 3, predose, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 5, Day 3, 1 hour, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 5, Day 3, 3 hour, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 5, Day 3, 6 hour, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 5, Day 4, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 5, Day 5, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 6, Day -2, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 6, Day 1, predose, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |

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|--|------------------|-----------------|--|--|
| IL-2, Session 6, Day 1, 1 hour, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 6, Day 1, 3 hour, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 6, Day 1, 6 hour, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 6, Day 2, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 6, Day 3, predose, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 6, Day 3, 1 hour, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 6, Day 3, 3 hour, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 6, Day 3, 6 hour, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 6, Day 4, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-2, Session 6, Day 5, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-4, Session 1, Day 1, predose, n=6,1 | 0.000 (± 0.0000) | 0.000 (± 88888) | | |
| IL-4, Session 1, Day 1, 1 hour, n=6,1 | 0.000 (± 0.0000) | 0.000 (± 88888) | | |
| IL-4, Session 1, Day 1, 3 hour, n=6,1 | 0.000 (± 0.0000) | 0.000 (± 88888) | | |
| IL-4, Session 1, Day 1, 6 hour, n=6,1 | 0.000 (± 0.0000) | 0.000 (± 88888) | | |
| IL-4, Session 1, Day 2, n=6,1 | 0.000 (± 0.0000) | 0.000 (± 88888) | | |
| IL-4, Session 1, Day 3, predose, n=6,1 | 0.000 (± 0.0000) | 0.000 (± 88888) | | |
| IL-4, Session 1, Day 3, 1 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-4, Session 1, Day 3, 3 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-4, Session 1, Day 3, 6 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-4, Session 1, Day 4, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-4, Session 1, Day 5, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-4, Session 2, Day -2, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-4, Session 2, Day 1, predose, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-4, Session 2, Day 1, 1 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-4, Session 2, Day 1, 3 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-4, Session 2, Day 1, 6 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-4, Session 2, Day 2, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-4, Session 2, Day 3, predose, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-4, Session 2, Day 3, 1 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-4, Session 2, Day 3, 3 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-4, Session 2, Day 3, 6 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |

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|--|------------------|-----------------|--|--|
| IL-4, Session 2, Day 4, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-4, Session 2, Day 5, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-4, Session 3, Day -2, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-4, Session 3, Day 1, predose, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-4, Session 3, Day 1, 1 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-4, Session 3, Day 1, 3 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-4, Session 3, Day 1, 6 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-4, Session 3, Day 2, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-4, Session 3, Day 3, predose, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-4, Session 3, Day 3, 1 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-4, Session 3, Day 3, 3 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-4, Session 3, Day 3, 6 hour, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-4, Session 3, Day 4, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-4, Session 3, Day 5, n=6,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-4, Session 4, Day -2, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-4, Session 4, Day 1, predose, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-4, Session 4, Day 1, 1 hour, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-4, Session 4, Day 1, 3 hour, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-4, Session 4, Day 1, 6 hour, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-4, Session 4, Day 2, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-4, Session 4, Day 3, predose, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-4, Session 4, Day 3, 1 hour, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-4, Session 4, Day 3, 3 hour, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-4, Session 4, Day 3, 6 hour, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-4, Session 4, Day 4, n=5,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-4, Session 4, Day 5, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-4, Session 5, Day -2, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-4, Session 5, Day 1, predose, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-4, Session 5, Day 1, 1 hour, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-4, Session 5, Day 1, 3 hour, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |
| IL-4, Session 5, Day 1, 6 hour, n=4,0 | 0.000 (± 0.0000) | 99999 (± 99999) | | |

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|--|-------------------------|-----------------------|--|--|
| IL-4, Session 5, Day 2, n=4,0 | 0.000 (\pm 0.0000) | 99999 (\pm 99999) | | |
| IL-4, Session 5, Day 3, predose, n=4,0 | 0.000 (\pm 0.0000) | 99999 (\pm 99999) | | |
| IL-4, Session 5, Day 3, 1 hour, n=4,0 | 0.000 (\pm 0.0000) | 99999 (\pm 99999) | | |
| IL-4, Session 5, Day 3, 3 hour, n=4,0 | 0.000 (\pm 0.0000) | 99999 (\pm 99999) | | |
| IL-4, Session 5, Day 3, 6 hour, n=4,0 | 0.000 (\pm 0.0000) | 99999 (\pm 99999) | | |
| IL-4, Session 5, Day 4, n=4,0 | 0.000 (\pm 0.0000) | 99999 (\pm 99999) | | |
| IL-4, Session 5, Day 5, n=4,0 | 0.000 (\pm 0.0000) | 99999 (\pm 99999) | | |
| IL-4, Session 6, Day -2, n=4,0 | 0.000 (\pm 0.0000) | 99999 (\pm 99999) | | |
| IL-4, Session 6, Day 1, predose, n=4,0 | 0.000 (\pm 0.0000) | 99999 (\pm 99999) | | |
| IL-4, Session 6, Day 1, 1 hour, n=4,0 | 0.000 (\pm 0.0000) | 99999 (\pm 99999) | | |
| IL-4, Session 6, Day 1, 3 hour, n=4,0 | 0.000 (\pm 0.0000) | 99999 (\pm 99999) | | |
| IL-4, Session 6, Day 1, 6 hour, n=4,0 | 0.000 (\pm 0.0000) | 99999 (\pm 99999) | | |
| IL-4, Session 6, Day 2, n=4,0 | 0.000 (\pm 0.0000) | 99999 (\pm 99999) | | |
| IL-4, Session 6, Day 3, predose, n=4,0 | 0.000 (\pm 0.0000) | 99999 (\pm 99999) | | |
| IL-4, Session 6, Day 3, 1 hour, n=4,0 | 0.000 (\pm 0.0000) | 99999 (\pm 99999) | | |
| IL-4, Session 6, Day 3, 3 hour, n=4,0 | 0.000 (\pm 0.0000) | 99999 (\pm 99999) | | |
| IL-4, Session 6, Day 3, 6 hour, n=4,0 | 0.000 (\pm 0.0000) | 99999 (\pm 99999) | | |
| IL-4, Session 6, Day 4, n=4,0 | 0.000 (\pm 0.0000) | 99999 (\pm 99999) | | |
| IL-4, Session 6, Day 5, n=4,0 | 0.000 (\pm 0.0000) | 99999 (\pm 99999) | | |
| IL-8, Session 1, Day 1, predose, n=6,1 | 4.377 (\pm 5.8881) | 1.140 (\pm 88888) | | |
| IL-8, Session 1, Day 1, 1 hour, n=6,1 | 4.887 (\pm 12.0436) | 0.450 (\pm 88888) | | |
| IL-8, Session 1, Day 1, 3 hour, n=6,1 | 1.097 (\pm 6.7834) | 0.480 (\pm 88888) | | |
| IL-8, Session 1, Day 1, 6 hour, n=6,1 | 4.400 (\pm 9.5000) | 8.350 (\pm 88888) | | |
| IL-8, Session 1, Day 2, n=6,1 | 10.977 (\pm 25.4607) | 12.720 (\pm 88888) | | |
| IL-8, Session 1, Day 3, predose, n=6,1 | 6.830 (\pm 10.6309) | 9.350 (\pm 88888) | | |
| IL-8, Session 1, Day 3, 1 hour, n=6,0 | 3.035 (\pm 6.9193) | 99999 (\pm 99999) | | |
| IL-8, Session 1, Day 3, 3 hour, n=6,0 | -0.788 (\pm 4.9840) | 99999 (\pm 99999) | | |
| IL-8, Session 1, Day 3, 6 hour, n=6,0 | -0.490 (\pm 7.3654) | 99999 (\pm 99999) | | |
| IL-8, Session 1, Day 4, n=6,0 | -0.542 (\pm 5.0480) | 99999 (\pm 99999) | | |
| IL-8, Session 1, Day 5, n=6,0 | 1.198 (\pm 3.0063) | 99999 (\pm 99999) | | |
| IL-8, Session 2, Day -2, n=6,0 | 7.848 (\pm 12.9271) | 99999 (\pm 99999) | | |

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|--|-------------------------|----------------------|--|--|
| IL-8, Session 2, Day 1, predose, n=6,0 | 4.920 (\pm 8.3853) | 99999 (\pm 99999) | | |
| IL-8, Session 2, Day 1, 1 hour, n=6,0 | 1.592 (\pm 6.9965) | 99999 (\pm 99999) | | |
| IL-8, Session 2, Day 1, 3 hour, n=6,0 | 0.275 (\pm 7.2669) | 99999 (\pm 99999) | | |
| IL-8, Session 2, Day 1, 6 hour, n=6,0 | 1.243 (\pm 6.1976) | 99999 (\pm 99999) | | |
| IL-8, Session 2, Day 2, n=6,0 | 5.468 (\pm 7.5652) | 99999 (\pm 99999) | | |
| IL-8, Session 2, Day 3, predose, n=6,0 | 8.322 (\pm 5.0082) | 99999 (\pm 99999) | | |
| IL-8, Session 2, Day 3, 1 hour, n=6,0 | 6.432 (\pm 10.6402) | 99999 (\pm 99999) | | |
| IL-8, Session 2, Day 3, 3 hour, n=6,0 | -1.107 (\pm 5.8160) | 99999 (\pm 99999) | | |
| IL-8, Session 2, Day 3, 6 hour, n=6,0 | -0.870 (\pm 4.6278) | 99999 (\pm 99999) | | |
| IL-8, Session 2, Day 4, n=6,0 | 1.667 (\pm 5.5170) | 99999 (\pm 99999) | | |
| IL-8, Session 2, Day 5, n=6,0 | 2.853 (\pm 5.4769) | 99999 (\pm 99999) | | |
| IL-8, Session 3, Day -2, n=5,0 | 12.742 (\pm 7.8571) | 99999 (\pm 99999) | | |
| IL-8, Session 3, Day 1, predose, n=6,0 | 7.635 (\pm 6.3602) | 99999 (\pm 99999) | | |
| IL-8, Session 3, Day 1, 1 hour, n=6,0 | 3.848 (\pm 5.5264) | 99999 (\pm 99999) | | |
| IL-8, Session 3, Day 1, 3 hour, n=6,0 | -0.517 (\pm 5.6983) | 99999 (\pm 99999) | | |
| IL-8, Session 3, Day 1, 6 hour, n=6,0 | 0.933 (\pm 8.0166) | 99999 (\pm 99999) | | |
| IL-8, Session 3, Day 2, n=5,0 | 3.024 (\pm 5.5819) | 99999 (\pm 99999) | | |
| IL-8, Session 3, Day 3, predose, n=6,0 | 14.440 (\pm 13.4971) | 99999 (\pm 99999) | | |
| IL-8, Session 3, Day 3, 1 hour, n=6,0 | 4.887 (\pm 5.2130) | 99999 (\pm 99999) | | |
| IL-8, Session 3, Day 3, 3 hour, n=6,0 | 0.088 (\pm 4.3970) | 99999 (\pm 99999) | | |
| IL-8, Session 3, Day 3, 6 hour, n=6,0 | 2.450 (\pm 6.2029) | 99999 (\pm 99999) | | |
| IL-8, Session 3, Day 4, n=6,0 | 3.680 (\pm 4.5662) | 99999 (\pm 99999) | | |
| IL-8, Session 3, Day 5, n=6,0 | 7.783 (\pm 3.9382) | 99999 (\pm 99999) | | |
| IL-8, Session 4, Day -2, n=5,0 | 15.686 (\pm 10.4436) | 99999 (\pm 99999) | | |
| IL-8, Session 4, Day 1, predose, n=5,0 | 9.910 (\pm 11.2178) | 99999 (\pm 99999) | | |
| IL-8, Session 4, Day 1, 1 hour, n=5,0 | 10.088 (\pm 13.7154) | 99999 (\pm 99999) | | |
| IL-8, Session 4, Day 1, 3 hour, n=5,0 | 5.242 (\pm 11.1547) | 99999 (\pm 99999) | | |
| IL-8, Session 4, Day 1, 6 hour, n=5,0 | 6.992 (\pm 12.0857) | 99999 (\pm 99999) | | |
| IL-8, Session 4, Day 2, n=5,0 | 4.282 (\pm 8.9442) | 99999 (\pm 99999) | | |
| IL-8, Session 4, Day 3, predose, n=5,0 | 15.072 (\pm 11.8360) | 99999 (\pm 99999) | | |
| IL-8, Session 4, Day 3, 1 hour, n=5,0 | 10.536 (\pm 8.8924) | 99999 (\pm 99999) | | |

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|--|-------------------------|----------------------|--|--|
| IL-8, Session 4, Day 3, 3 hour, n=5,0 | 1.474 (\pm 3.3523) | 99999 (\pm 99999) | | |
| IL-8, Session 4, Day 3, 6 hour, n=5,0 | 1.208 (\pm 3.6252) | 99999 (\pm 99999) | | |
| IL-8, Session 4, Day 4, n=5,0 | 7.118 (\pm 14.6164) | 99999 (\pm 99999) | | |
| IL-8, Session 4, Day 5, n=4,0 | -1.795 (\pm 4.8526) | 99999 (\pm 99999) | | |
| IL-8, Session 5, Day -2, n=4,0 | 21.055 (\pm 14.5161) | 99999 (\pm 99999) | | |
| IL-8, Session 5, Day 1, predose, n=4,0 | 18.213 (\pm 16.0292) | 99999 (\pm 99999) | | |
| IL-8, Session 5, Day 1, 1 hour, n=4,0 | 17.667 (\pm 15.2020) | 99999 (\pm 99999) | | |
| IL-8, Session 5, Day 1, 3 hour, n=4,0 | 12.463 (\pm 16.7548) | 99999 (\pm 99999) | | |
| IL-8, Session 5, Day 1, 6 hour, n=4,0 | 5.617 (\pm 8.7263) | 99999 (\pm 99999) | | |
| IL-8, Session 5, Day 2, n=4,0 | 5.463 (\pm 9.5943) | 99999 (\pm 99999) | | |
| IL-8, Session 5, Day 3, predose, n=4,0 | 16.915 (\pm 13.4207) | 99999 (\pm 99999) | | |
| IL-8, Session 5, Day 3, 1 hour, n=4,0 | 9.240 (\pm 11.0353) | 99999 (\pm 99999) | | |
| IL-8, Session 5, Day 3, 3 hour, n=4,0 | 5.902 (\pm 9.1992) | 99999 (\pm 99999) | | |
| IL-8, Session 5, Day 3, 6 hour, n=4,0 | 5.335 (\pm 7.4134) | 99999 (\pm 99999) | | |
| IL-8, Session 5, Day 4, n=4,0 | 7.610 (\pm 12.4139) | 99999 (\pm 99999) | | |
| IL-8, Session 5, Day 5, n=4,0 | 7.330 (\pm 14.2059) | 99999 (\pm 99999) | | |
| IL-8, Session 6, Day -2, n=4,0 | 12.908 (\pm 11.2540) | 99999 (\pm 99999) | | |
| IL-8, Session 6, Day 1, predose, n=4,0 | 17.575 (\pm 14.9713) | 99999 (\pm 99999) | | |
| IL-8, Session 6, Day 1, 1 hour, n=4,0 | 18.718 (\pm 14.2024) | 99999 (\pm 99999) | | |
| IL-8, Session 6, Day 1, 3 hour, n=4,0 | 13.823 (\pm 18.3486) | 99999 (\pm 99999) | | |
| IL-8, Session 6, Day 1, 6 hour, n=4,0 | 12.923 (\pm 15.0125) | 99999 (\pm 99999) | | |
| IL-8, Session 6, Day 2, n=4,0 | 13.338 (\pm 15.7070) | 99999 (\pm 99999) | | |
| IL-8, Session 6, Day 3, predose, n=4,0 | 25.338 (\pm 17.9965) | 99999 (\pm 99999) | | |
| IL-8, Session 6, Day 3, 1 hour, n=4,0 | 11.733 (\pm 12.1142) | 99999 (\pm 99999) | | |
| IL-8, Session 6, Day 3, 3 hour, n=4,0 | 6.853 (\pm 7.9858) | 99999 (\pm 99999) | | |
| IL-8, Session 6, Day 3, 6 hour, n=4,0 | 7.220 (\pm 9.8022) | 99999 (\pm 99999) | | |
| IL-8, Session 6, Day 4, n=4,0 | 13.500 (\pm 13.0942) | 99999 (\pm 99999) | | |
| IL-8, Session 6, Day 5, n=4,0 | 14.130 (\pm 9.1046) | 99999 (\pm 99999) | | |

Notes:

[88] - Safety Population

[89] - Safety Population

Statistical analyses

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Non-serious AEs were collected from start of study treatment (Week 0) up to 56 days after the last dosing session (up to 265 days). SAEs were collected from start of the study treatment (Week 0) up to the end of study (Up to 369 days).

Adverse event reporting additional description:

SAEs and non-serious AEs are reported for Safety Population for Group 1 and 2 only as no participant was enrolled in Group-3.

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

Dictionary used

| | |
|-----------------|--------|
| Dictionary name | MedDRA |
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| Dictionary version | 21.0 |
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Reporting groups

| | |
|-----------------------|--|
| Reporting group title | Group 2: Post-chemotherapy AL Amyloidosis participants |
|-----------------------|--|

Reporting group description:

Immunoglobulin light chain amyloidosis (AL) participants who attained either a very good partial response (VGPR), or complete response (CR), to systemic chemotherapy (including autologous stem cell transplantation) were included. Participants received 6 anti-SAP treatments, consisting of CPHPC followed by anti-SAP mAb at monthly intervals. During each anti-SAP treatment, participants received CPHPC IV infusion once daily for up to 72 hours. After 72 hours of CPHPC administration, participants were administered IV infusion of anti-SAP mAb over 6-8 hours each on Days 1 and 3. The starting dose level of anti-SAP mAb was 600 mg (divided into 2 infusions of 300 mg). In each treatment session, CPHPC was administered by as SC injection for 11 days from the day of first dose of anti-SAP mAb.

| | |
|-----------------------|---|
| Reporting group title | Group 1: Cardiac TTR amyloidosis (ATTR-CM) participants |
|-----------------------|---|

Reporting group description:

Cardiac transthyretin (TTR) amyloidosis (transthyretin amyloid cardiomyopathy [ATTR-CM]) participants with mutant genotypes primarily associated with familial amyloidotic cardiomyopathy (FAC) and wild-type TTR were included. Participants received 6 anti-SAP treatments, consisting of carboxy pyrrolidine hexanoyl pyrrolidine carboxylate (CPHPC) followed by anti-SAP monoclonal antibody (mAb) at monthly intervals. During each anti-SAP treatment, participants received CPHPC intravenous (IV) infusion once daily for up to 72 hours. After 72 hours of CPHPC administration, participants were administered intravenous infusion of anti-SAP mAb over 6-8 hours each on Days 1 and 3. The starting dose level of anti-SAP mAb was 600 milligrams (mg) (divided into 2 infusions of 300 mg). In each treatment session, CPHPC was administered as subcutaneous (SC) injection for 11 days from the day of first dose of anti-SAP mAb.

| Serious adverse events | Group 2: Post-chemotherapy AL Amyloidosis participants | Group 1: Cardiac TTR amyloidosis (ATTR-CM) participants | |
|---|--|---|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 1 / 1 (100.00%) | 2 / 6 (33.33%) | |
| number of deaths (all causes) | 0 | 0 | |
| number of deaths resulting from adverse events | | | |
| Vascular disorders | | | |
| Vasculitis | | | |
| subjects affected / exposed | 1 / 1 (100.00%) | 0 / 6 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|---------------|----------------|--|
| Cardiac disorders | | | |
| Cardiac failure | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 6 (16.67%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nervous system disorders | | | |
| Transient ischaemic attack | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 6 (16.67%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

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

| Non-serious adverse events | Group 2: Post-chemotherapy AL Amyloidosis participants | Group 1: Cardiac TTR amyloidosis (ATTR-CM) participants | |
|---|--|---|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 1 / 1 (100.00%) | 6 / 6 (100.00%) | |
| Vascular disorders | | | |
| Flushing | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 3 / 6 (50.00%) | |
| occurrences (all) | 0 | 12 | |
| Haemorrhage | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 6 (16.67%) | |
| occurrences (all) | 0 | 2 | |
| General disorders and administration site conditions | | | |
| Catheter site bruise | | | |
| subjects affected / exposed | 1 / 1 (100.00%) | 3 / 6 (50.00%) | |
| occurrences (all) | 1 | 6 | |
| Fatigue | | | |
| subjects affected / exposed | 1 / 1 (100.00%) | 3 / 6 (50.00%) | |
| occurrences (all) | 1 | 9 | |
| Injection site bruising | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 2 / 6 (33.33%) | |
| occurrences (all) | 0 | 2 | |
| Oedema peripheral | | | |

| | | | |
|--|-----------------|----------------|--|
| subjects affected / exposed | 0 / 1 (0.00%) | 2 / 6 (33.33%) | |
| occurrences (all) | 0 | 2 | |
| Catheter site dermatitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 6 (16.67%) | |
| occurrences (all) | 0 | 1 | |
| Catheter site erythema | | | |
| subjects affected / exposed | 1 / 1 (100.00%) | 0 / 6 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Catheter site related reaction | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 6 (16.67%) | |
| occurrences (all) | 0 | 1 | |
| Feeling cold | | | |
| subjects affected / exposed | 1 / 1 (100.00%) | 0 / 6 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Oedema | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 6 (16.67%) | |
| occurrences (all) | 0 | 1 | |
| Peripheral swelling | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 6 (16.67%) | |
| occurrences (all) | 0 | 1 | |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 6 (16.67%) | |
| occurrences (all) | 0 | 1 | |
| Secretion discharge | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 6 (16.67%) | |
| occurrences (all) | 0 | 2 | |
| Thirst | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 6 (16.67%) | |
| occurrences (all) | 0 | 2 | |
| Vessel puncture site bruise | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 6 (16.67%) | |
| occurrences (all) | 0 | 1 | |
| Reproductive system and breast disorders | | | |
| Nipple pain | | | |

| | | | |
|---|--------------------|---------------------|--|
| subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 1 / 6 (16.67%) 1 | |
| Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 3 / 6 (50.00%) 3 | |
| Dyspnoea subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 1 / 6 (16.67%) 1 | |
| Dyspnoea exertional subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 1 / 6 (16.67%) 1 | |
| Oropharyngeal pain subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 1 / 6 (16.67%) 1 | |
| Psychiatric disorders Insomnia subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 2 / 6 (33.33%) 2 | |
| Investigations Liver function test increased subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 1 / 6 (16.67%) 1 | |
| Urine output increased subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 1 / 6 (16.67%) 1 | |
| Injury, poisoning and procedural complications Skin laceration subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 2 / 6 (33.33%) 4 | |
| Arthropod bite subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 1 / 6 (16.67%) 1 | |
| Limb injury subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 1 / 6 (16.67%) 1 | |

| | | | |
|----------------------------------|-----------------|----------------|--|
| Nail injury | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 6 (16.67%) | |
| occurrences (all) | 0 | 1 | |
| Lip injury | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 6 (16.67%) | |
| occurrences (all) | 0 | 1 | |
| Thermal burn | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 6 (16.67%) | |
| occurrences (all) | 0 | 1 | |
| Cardiac disorders | | | |
| Ventricular tachycardia | | | |
| subjects affected / exposed | 1 / 1 (100.00%) | 2 / 6 (33.33%) | |
| occurrences (all) | 1 | 33 | |
| Cardiac failure | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 6 (16.67%) | |
| occurrences (all) | 0 | 1 | |
| Palpitations | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 6 (16.67%) | |
| occurrences (all) | 0 | 1 | |
| Ventricular extrasystoles | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 6 (16.67%) | |
| occurrences (all) | 0 | 1 | |
| Nervous system disorders | | | |
| Somnolence | | | |
| subjects affected / exposed | 1 / 1 (100.00%) | 2 / 6 (33.33%) | |
| occurrences (all) | 1 | 8 | |
| Dizziness | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 2 / 6 (33.33%) | |
| occurrences (all) | 0 | 3 | |
| Headache | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 2 / 6 (33.33%) | |
| occurrences (all) | 0 | 3 | |
| Ageusia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 6 (16.67%) | |
| occurrences (all) | 0 | 1 | |
| Depressed level of consciousness | | | |

| | | | |
|---|----------------------|---------------------|--|
| subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 1 / 6 (16.67%) 1 | |
| Paraesthesia subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 1 / 6 (16.67%) 1 | |
| Eye disorders Dry eye subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 1 / 6 (16.67%) 1 | |
| Ocular hyperaemia subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 1 / 6 (16.67%) 1 | |
| Gastrointestinal disorders Constipation subjects affected / exposed occurrences (all) | 1 / 1 (100.00%) 1 | 3 / 6 (50.00%) 5 | |
| Abdominal discomfort subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 1 / 6 (16.67%) 1 | |
| Dyspepsia subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 2 / 6 (33.33%) 2 | |
| Diarrhoea subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 1 / 6 (16.67%) 1 | |
| Dry mouth subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 1 / 6 (16.67%) 1 | |
| Skin and subcutaneous tissue disorders Rash erythematous subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 3 / 6 (50.00%) 3 | |
| Dermatitis contact subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 2 / 6 (33.33%) 6 | |
| Rash maculo-papular | | | |

| | | | |
|---------------------------------------|-----------------|----------------|--|
| subjects affected / exposed | 0 / 1 (0.00%) | 2 / 6 (33.33%) | |
| occurrences (all) | 0 | 3 | |
| Acne | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 6 (16.67%) | |
| occurrences (all) | 0 | 1 | |
| Dermal cyst | | | |
| subjects affected / exposed | 1 / 1 (100.00%) | 0 / 6 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Erythema | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 6 (16.67%) | |
| occurrences (all) | 0 | 1 | |
| Miliaria | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 6 (16.67%) | |
| occurrences (all) | 0 | 1 | |
| Palmar erythema | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 6 (16.67%) | |
| occurrences (all) | 0 | 2 | |
| Post inflammatory pigmentation change | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 6 (16.67%) | |
| occurrences (all) | 0 | 1 | |
| Pruritus generalised | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 6 (16.67%) | |
| occurrences (all) | 0 | 1 | |
| Pruritus | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 6 (16.67%) | |
| occurrences (all) | 0 | 1 | |
| Renal and urinary disorders | | | |
| Haematuria | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 6 (16.67%) | |
| occurrences (all) | 0 | 1 | |
| Dysuria | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 6 (16.67%) | |
| occurrences (all) | 0 | 1 | |
| Urinary retention | | | |

| | | | |
|---|-----------------|----------------|--|
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 6 (16.67%) | |
| occurrences (all) | 0 | 1 | |
| Musculoskeletal and connective tissue disorders | | | |
| Muscle spasms | | | |
| subjects affected / exposed | 1 / 1 (100.00%) | 1 / 6 (16.67%) | |
| occurrences (all) | 1 | 1 | |
| Back pain | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 6 (16.67%) | |
| occurrences (all) | 0 | 1 | |
| Joint stiffness | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 6 (16.67%) | |
| occurrences (all) | 0 | 2 | |
| Joint swelling | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 6 (16.67%) | |
| occurrences (all) | 0 | 1 | |
| Limb discomfort | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 6 (16.67%) | |
| occurrences (all) | 0 | 1 | |
| Musculoskeletal stiffness | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 6 (16.67%) | |
| occurrences (all) | 0 | 1 | |
| Myalgia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 6 (16.67%) | |
| occurrences (all) | 0 | 2 | |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 6 (16.67%) | |
| occurrences (all) | 0 | 3 | |
| Neck pain | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 6 (16.67%) | |
| occurrences (all) | 0 | 1 | |
| Arthralgia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 2 / 6 (33.33%) | |
| occurrences (all) | 0 | 8 | |
| Infections and infestations | | | |

| | | | |
|-----------------------------------|---------------|----------------|--|
| Nasopharyngitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 6 (16.67%) | |
| occurrences (all) | 0 | 1 | |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 6 (16.67%) | |
| occurrences (all) | 0 | 1 | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|---------------|--|
| 20 April 2017 | Amendment 1: Changes made to reflect regulatory input from the Food and Drug Administration (FDA). Other changes made to correct minor errors included in the original version. |
| 05 March 2018 | Amendment 2: Regulatory input from the FDA on clarifying requirements for recruitment. Define plasma SAP depletion target level of <3 milligrams per liter. Inclusion criterion for LV mass updated for Groups 2 and 3 to reflect the immunoglobulin light chain amyloidosis (AL) participants population. Reflect regulatory safety update information for Gadolinium contrast agents. Dermatology review timings adjusted for grade 3 rash incidences. Other changes made for clarity and to correct minor typographical errors. |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported