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:

Immunoglobin 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:

Immunoglobin 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:

Immunoglobin 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		
CO2, high	6	0		
CO2, normal	0	1		
CO2, 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 (>= 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 (>= 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 (>= 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 (>= 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)		

CRP, Session 4, Day 1, 2 hour, n=4,0	2.53 (± 4.762)	99999 (± 99999)		
CRP, Session 4, Day 1, 4 hour, n=4,0	2.45 (± 4.669)	99999 (± 99999)		
CRP, Session 4, Day 1, 8 hour, n=4,0	2.40 (± 4.455)	99999 (± 99999)		
CRP, Session 4, Day 2, n=4,0	2.23 (± 3.963)	99999 (± 99999)		
CRP, Session 4, Day 3, predose, n=4,0	12.45 (± 13.533)	99999 (± 99999)		
CRP, Session 4, Day 3, 2 hour, n=4,0	14.75 (± 16.539)	99999 (± 99999)		
CRP, Session 4, Day 3, 4 hour, n=4,0	16.75 (± 19.129)	99999 (± 99999)		
CRP, Session 4, Day 3, 8 hour, n=4,0	17.30 (± 17.830)	99999 (± 99999)		
CRP, Session 4, Day 5, n=4,0	18.43 (± 9.959)	99999 (± 99999)		
CRP, Session 4, Day 6, n=4,0	19.98 (± 11.277)	99999 (± 99999)		
CRP, Session 5, Day 1, predose, n=3,0	2.23 (± 3.439)	99999 (± 99999)		
CRP, Session 5, Day 1, 2 hour, n=3,0	2.13 (± 3.350)	99999 (± 99999)		
CRP, Session 5, Day 1, 4 hour, n=3,0	1.97 (± 3.147)	99999 (± 99999)		
CRP, Session 5, Day 1, 8 hour, n=3,0	2.10 (± 3.378)	99999 (± 99999)		
CRP, Session 5, Day 2, n=3,0	1.37 (± 2.811)	99999 (± 99999)		
CRP, Session 5, Day 3, predose, n=3,0	8.33 (± 11.517)	99999 (± 99999)		
CRP, Session 5, Day 3, 2 hour, n=3,0	9.87 (± 12.881)	99999 (± 99999)		
CRP, Session 5, Day 3, 4 hour, n=3,0	10.47 (± 12.874)	99999 (± 99999)		
CRP, Session 5, Day 3, 8 hour, n=3,0	12.90 (± 14.944)	99999 (± 99999)		
CRP, Session 5, Day 5, n=2,0	34.30 (± 40.588)	99999 (± 99999)		
CRP, Session 5, Day 6, n=2,0	35.20 (± 34.931)	99999 (± 99999)		
CRP, Session 6, Day 1, predose, n=3,0	4.00 (± 3.851)	99999 (± 99999)		
CRP, Session 6, Day 1, 2 hour, n=3,0	3.63 (± 3.711)	99999 (± 99999)		
CRP, Session 6, Day 1, 4 hour, n=3,0	3.70 (± 3.835)	99999 (± 99999)		
CRP, Session 6, Day 1, 8 hour, n=3,0	3.70 (± 3.874)	99999 (± 99999)		
CRP, Session 6, Day 2, n=3,0	2.63 (± 2.914)	99999 (± 99999)		
CRP, Session 6, Day 3, predose, n=3,0	9.17 (± 8.879)	99999 (± 99999)		
CRP, Session 6, Day 3, 2 hour, n=3,0	11.10 (± 10.887)	99999 (± 99999)		
CRP, Session 6, Day 3, 4 hour, n=3,0	12.70 (± 11.555)	99999 (± 99999)		
CRP, Session 6, Day 3, 8 hour, n=3,0	14.67 (± 12.580)	99999 (± 99999)		
CRP, Session 6, Day 5, n=3,0	14.10 (± 7.146)	99999 (± 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 (± 18.149)	99999 (± 99999)		
hsCRP, Session 3, Day 5, n=4,0	22.45 (± 15.042)	99999 (± 99999)		
hsCRP, Session 3, Day 6, n=4,0	23.73 (± 16.141)	99999 (± 99999)		
hsCRP, Session 4, Day 1, predose, n=4,0	2.28 (± 4.043)	99999 (± 99999)		
hsCRP, Session 4, Day 1, 2 hour, n=4,0	2.53 (± 4.610)	99999 (± 99999)		
hsCRP, Session 4, Day 1, 4 hour, n=4,0	2.53 (± 4.479)	99999 (± 99999)		
hsCRP, Session 4, Day 1, 8 hour, n=4,0	2.58 (± 4.528)	99999 (± 99999)		
hsCRP, Session 4, Day 2, n=4,0	2.20 (± 3.558)	99999 (± 99999)		
hsCRP, Session 4, Day 3, predose, n=4,0	12.33 (± 13.881)	99999 (± 99999)		
hsCRP, Session 4, Day 3, 2 hour, n=4,0	14.40 (± 16.324)	99999 (± 99999)		
hsCRP, Session 4, Day 3, 4 hour, n=4,0	16.00 (± 18.240)	99999 (± 99999)		
hsCRP, Session 4, Day 3, 8 hour, n=4,0	17.08 (± 17.972)	99999 (± 99999)		
hsCRP, Session 4, Day 5, n=4,0	19.60 (± 10.903)	99999 (± 99999)		
hsCRP, Session 4, Day 6, n=4,0	20.73 (± 11.391)	99999 (± 99999)		
hsCRP, Session 5, Day 1, predose, n=3,0	2.03 (± 3.349)	99999 (± 99999)		
hsCRP, Session 5, Day 1, 2 hour, n=3,0	1.97 (± 3.320)	99999 (± 99999)		
hsCRP, Session 5, Day 1, 4 hour, n=3,0	1.83 (± 3.175)	99999 (± 99999)		
hsCRP, Session 5, Day 1, 8 hour, n=3,0	1.87 (± 3.323)	99999 (± 99999)		
hsCRP, Session 5, Day 2, n=3,0	1.23 (± 2.574)	99999 (± 99999)		
hsCRP, Session 5, Day 3, predose, n=3,0	9.10 (± 13.182)	99999 (± 99999)		
hsCRP, Session 5, Day 3, 2 hour, n=3,0	10.43 (± 14.629)	99999 (± 99999)		
hsCRP, Session 5, Day 3, 4 hour, n=3,0	11.17 (± 14.865)	99999 (± 99999)		
hsCRP, Session 5, Day 3, 8 hour, n=3,0	12.67 (± 15.557)	99999 (± 99999)		
hsCRP, Session 5, Day 5, n=2,0	33.95 (± 40.941)	99999 (± 99999)		
hsCRP, Session 5, Day 6, n=2,0	34.80 (± 34.083)	99999 (± 99999)		
hsCRP, Session 6, Day 1, predose, n=3,0	3.77 (± 3.853)	99999 (± 99999)		
hsCRP, Session 6, Day 1, 2 hour, n=3,0	3.37 (± 3.523)	99999 (± 99999)		
hsCRP, Session 6, Day 1, 4 hour, n=3,0	3.50 (± 3.799)	99999 (± 99999)		
hsCRP, Session 6, Day 1, 8 hour, n=3,0	3.27 (± 3.584)	99999 (± 99999)		
hsCRP, Session 6, Day 2, n=3,0	2.33 (± 2.775)	99999 (± 99999)		
hsCRP, Session 6, Day 3, predose, n=3,0	8.97 (± 9.752)	99999 (± 99999)		

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

SAA, Session 3, Day 2, n=4,0	6.4822 (± 11.14119)	99999 (± 99999)		
SAA, Session 3, Day 3, predose, n=5,0	54.7393 (± 82.22346)	99999 (± 99999)		
SAA, Session 3, Day 3, 2 hour, n=5,0	58.0526 (± 83.12677)	99999 (± 99999)		
SAA, Session 3, Day 3, 4 hour, n=5,0	64.1995 (± 93.61736)	99999 (± 99999)		
SAA, Session 3, Day 3, 8 hour, n=5,0	66.9605 (± 93.98658)	99999 (± 99999)		
SAA, Session 3, Day 5, n=5,0	58.6742 (± 50.93398)	99999 (± 99999)		
SAA, Session 3, Day 6, n=5,0	49.4029 (± 46.30012)	99999 (± 99999)		
SAA, Session 4, Day 1, predose, n=4,0	-0.1305 (± 1.86822)	99999 (± 99999)		
SAA, Session 4, Day 1, 2 hour, n=4,0	0.0159 (± 1.91086)	99999 (± 99999)		
SAA, Session 4, Day 1, 4 hour, n=4,0	-0.0013 (± 1.84104)	99999 (± 99999)		
SAA, Session 4, Day 1, 8 hour, n=4,0	0.1997 (± 1.70496)	99999 (± 99999)		
SAA, Session 4, Day 2, n=4,0	1.6015 (± 1.07082)	99999 (± 99999)		
SAA, Session 4, Day 3, predose, n=4,0	45.1067 (± 82.67535)	99999 (± 99999)		
SAA, Session 4, Day 3, 2 hour, n=4,0	51.0650 (± 94.33211)	99999 (± 99999)		
SAA, Session 4, Day 3, 4 hour, n=4,0	55.0009 (± 101.37965)	99999 (± 99999)		
SAA, Session 4, Day 3, 8 hour, n=4,0	55.7135 (± 101.39069)	99999 (± 99999)		
SAA, Session 4, Day 5, n=4,0	51.2002 (± 54.84780)	99999 (± 99999)		
SAA, Session 4, Day 6, n=4,0	41.2457 (± 38.77052)	99999 (± 99999)		
SAA, Session 5, Day 1, predose, n=3,0	-0.1498 (± 1.04561)	99999 (± 99999)		
SAA, Session 5, Day 1, 2 hour, n=3,0	-0.2399 (± 0.89843)	99999 (± 99999)		
SAA, Session 5, Day 1, 4 hour, n=3,0	-0.1906 (± 0.94124)	99999 (± 99999)		
SAA, Session 5, Day 1, 8 hour, n=3,0	-0.1771 (± 0.95814)	99999 (± 99999)		
SAA, Session 5, Day 2, n=3,0	0.1380 (± 0.61958)	99999 (± 99999)		
SAA, Session 5, Day 3, predose, n=3,0	10.8884 (± 17.72052)	99999 (± 99999)		
SAA, Session 5, Day 3, 2 hour, n=3,0	8.6783 (± 11.48176)	99999 (± 99999)		
SAA, Session 5, Day 3, 4 hour, n=3,0	9.2527 (± 11.23663)	99999 (± 99999)		
SAA, Session 5, Day 3, 8 hour, n=3,0	13.7941 (± 19.39827)	99999 (± 99999)		
SAA, Session 5, Day 5, n=3,0	66.2542 (± 107.98594)	99999 (± 99999)		
SAA, Session 5, Day 6, n=3,0	73.0823 (± 118.07036)	99999 (± 99999)		
SAA, Session 6, Day 1, predose, n=3,0	1.2964 (± 1.75482)	99999 (± 99999)		
SAA, Session 6, Day 1, 2 hour, n=3,0	1.0538 (± 1.74392)	99999 (± 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 (± 5.299)	99999 (± 99999)		
GLS Speckle Tracking, Session 5, Day 24, n=4,0	1.13 (± 9.044)	99999 (± 99999)		
GLS Speckle Tracking, Session 6, Day 24, n=4,0	-2.08 (± 4.555)	99999 (± 99999)		
GLS Speckle Tracking, 8 Week follow-up, n=6,1	-1.82 (± 10.013)	1.60 (± 88888)		
GLS Speckle Tracking, 6 month follow-up, n=4,0	0.40 (± 4.268)	99999 (± 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 (± 1.6672)	99999 (± 99999)		
Session 3, Day 24, n=6,0	0.431 (± 2.4369)	99999 (± 99999)		
Session 4, Day 24, n=5,0	-0.611 (± 1.8979)	99999 (± 99999)		
Session 5, Day 24, n=4,0	-0.628 (± 1.2269)	99999 (± 99999)		
8 Week follow-up, n=6,1	-0.264 (± 2.0835)	0.914 (± 88888)		
6 month follow-up, n=2,0	-0.633 (± 0.3349)	99999 (± 99999)		

Notes:

[72] - Safety Population

[73] - 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)		

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)		

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

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)		

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)		

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

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)		

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)		

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)		

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

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

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)		

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)		

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)		

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)		

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)		

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)		

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)		

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)		

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

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

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

Notes:

[88] - Safety Population

[89] - Safety Population

Statistical analyses

No statistical analyses for this end point

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
Dictionary version	21.0

Reporting groups

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

Reporting group description:

Immunoglobin 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	0 / 1 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 1 (0.00%)	3 / 6 (50.00%)	
occurrences (all)	0	3	
Dyspnoea			
subjects affected / exposed	0 / 1 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Dyspnoea exertional			
subjects affected / exposed	0 / 1 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Oropharyngeal pain			
subjects affected / exposed	0 / 1 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 1 (0.00%)	2 / 6 (33.33%)	
occurrences (all)	0	2	
Investigations			
Liver function test increased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Urine output increased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Injury, poisoning and procedural complications			
Skin laceration			
subjects affected / exposed	0 / 1 (0.00%)	2 / 6 (33.33%)	
occurrences (all)	0	4	
Arthropod bite			
subjects affected / exposed	0 / 1 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Limb injury			
subjects affected / exposed	0 / 1 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	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	0 / 1 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Paraesthesia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 1 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Ocular hyperaemia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	1 / 1 (100.00%)	3 / 6 (50.00%)	
occurrences (all)	1	5	
Abdominal discomfort			
subjects affected / exposed	0 / 1 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Dyspepsia			
subjects affected / exposed	0 / 1 (0.00%)	2 / 6 (33.33%)	
occurrences (all)	0	2	
Diarrhoea			
subjects affected / exposed	0 / 1 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Dry mouth			
subjects affected / exposed	0 / 1 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Skin and subcutaneous tissue disorders			
Rash erythematous			
subjects affected / exposed	0 / 1 (0.00%)	3 / 6 (50.00%)	
occurrences (all)	0	3	
Dermatitis contact			
subjects affected / exposed	0 / 1 (0.00%)	2 / 6 (33.33%)	
occurrences (all)	0	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 immunoglobin 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