2) 被験者番号 54179060GVH3001-[redacted]

■ REASON FOR NARRATIVE SELECTION

Death

Treatment-emergent serious adverse events (SAEs)

■ Death

Date of First Exposure to Treatment	Date of Last Exposure to Treatment	Date/Time of Death	Cause of Death	Other Cause of Death
[redacted]	[redacted]	[redacted]	ADVERSE EVENT	-

■ Treatment-emergent serious adverse events (SAEs)

Dictionary-Derived Term	Reported Term for the Adverse Event	Start Date of Adverse Event End Date of Adverse Event	Study Day of Start of Adverse Event Adverse Event Duration (days)	Serious Event Standard Toxicity Grade	Causality Action Taken with Study Treatment	Concomitant or Additional Treatment Given Outcome of Adverse Event	Sequence Number
肺炎	PNEUMONIA	20[redacted] 20[redacted]	33 25	Y 3	PROBABLE DOSE NOT CHANGED	Y RECOVERED/RESOLVED	14
虫垂膿瘍	APPENDICEAL ABSCESS	20[redacted] 20[redacted]	220 22	Y 3	NOT RELATED DOSE NOT CHANGED	Y RECOVERED/RESOLVED	1

Note: Adverse Events are coded using MedDRA 22.1

■ Adverse events (AEs) leading to ibrutinib discontinuation

No Adverse events (AEs) leading to ibrutinib discontinuation reported

■ Other malignancies

No Other malignancies reported

■ Major hemorrhage

No Major hemorrhage reported

■ Demographics, Baseline Characteristics

- Country: JPN
- Race: Asian
- Age: 5[redacted]
- Sex: Male
- Baseline height (cm): [redacted]
- Baseline weight (kg): [redacted]
- Baseline karnofsky/Lansky performance status score: 80
- Overall severity of cGVHD: Severe
- cGVHD disease state: STEROID DEPENDENT DISEASE
- Month from initial diagnosis date: 14.1
- Number of prior cGVHD treatment regimens: 2
- First study drug intake: 20[redacted] (Study Day 1)
- Last study drug intake: 20[redacted] (Study Day 293)

■ Disposition Information

- End of treatment: Subject Discontinued from Treatment
- End of trial: Subject Discontinued from Study

■ Other Adverse Events

Dictionary-Derived Term	Reported Term for the Adverse Event	Start Date of Adverse Event End Date of Adverse Event	Study Day of Start of Adverse Event Adverse Event Duration (days)	Serious Event Standard Toxicity Grade	Causality Action Taken with Study Treatment	Concomitant or Additional Treatment Given Outcome of Adverse Event	Sequence Number
血小板数減少	PLATELET COUNT DECREASED	20[redacted] -	8 -	N 1	VERY LIKELY DOSE NOT CHANGED	N NOT RECOVERED/NOT RESOLVED	13
体調不良	PHYSICAL DECONDITIONING	20 20	24 1	N 1	NOT RELATED DOSE NOT CHANGED	N RECOVERED/RESOLVED	11
そう痒症	ITCHING	20 20	29 15	N 1	VERY LIKELY DOSE NOT CHANGED	N RECOVERED/RESOLVED	8
口内炎	STOMATITIS	20 20	29 34	N 1	NOT RELATED DOSE NOT CHANGED	N RECOVERED/RESOLVED	18
体調不良	PHYSICAL DECONDITIONING	20 20	31 3	N 1	NOT RELATED DOSE NOT CHANGED	N RECOVERED/RESOLVED	12
血中乳酸脱水素酵素増加	LDH INCREASED	20 -	113 -	N 1	VERY LIKELY DOSE NOT CHANGED	N NOT RECOVERED/NOT RESOLVED	9

Dictionary-Derived Term	Reported Term for the Adverse Event	Start Date of Adverse Event End Date of Adverse Event	Study Day of Start of Adverse Event Adverse Event Duration (days)	Serious Event Standard Toxicity Grade	Causality Action Taken with Study Treatment	Concomitant or Additional Treatment Given Outcome of Adverse Event	Sequence Number
蜂巣炎	CELLULITIS OF THUMB	20[redacted] 20	139 59	N 1	NOT RELATED DOSE NOT CHANGED	Y RECOVERED/RESOLVED	5
結膜充血	RIGHT BULBAR CONJUNCTIVE HYPERAEMIA	20 -	139 -	N 1	NOT RELATED DOSE NOT CHANGED	N NOT RECOVERED/NOT RESOLVED	17
緑内障	GLAUCOMA STEROID-INDUCED	20 -	167 -	N 1	NOT RELATED DOSE NOT CHANGED	Y NOT RECOVERED/NOT RESOLVED	7
口内炎	STOMATITIS	20 -	167 -	N 1	NOT RELATED DOSE NOT CHANGED	Y NOT RECOVERED/NOT RESOLVED	19
肺炎	PNEUMONIA	20 20	193 14	N 2	DOUBTFUL DOSE NOT CHANGED	Y RECOVERED/RESOLVED	15
処置による疼痛	POSTOPERATIVE PAIN	20 20	206 15	N 2	NOT RELATED DOSE NOT CHANGED	Y RECOVERED/RESOLVED	16
背部痛	WORSENING LOW BACK PAIN	20 20	209 27	N 2	NOT RELATED DOSE NOT CHANGED	Y RECOVERED/RESOLVED	21
虫垂膿瘍	APPENDICEAL ABSCESS	20 20	242 21	N 2	NOT RELATED DOSE NOT CHANGED	Y RECOVERED/RESOLVED	2
虫垂膿瘍	APPENDICEAL ABSCESS	20 20	286 8	N 3	NOT RELATED DOSE NOT CHANGED	Y RECOVERED/RESOLVED	3
虫垂膿瘍	APPENDICEAL ABSCESS	20 -	294 -	N 1	NOT RELATED NOT APPLICABLE	N NOT RECOVERED/NOT RESOLVED	4

Note: Adverse Events are coded using MedDRA 22.1

■ Medical History

Body System or Organ Class	Dictionary-Derived Term	Reported Term for the Medical History	End Relative to Reference Period	Toxicity Grade
Immune system disorders	Acute graft versus host disease	ACUTE GRAFT VERSUS HOST DISEASE	BEFORE	-
Eye disorders	Glaucoma	GLAUCOMA	BEFORE	-
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Leukaemic retinopathy	LEUKEMIC RETINOPATHY	BEFORE	-
Infections and infestations	Anal abscess	PERIANAL ABSCESS	BEFORE	-
Injury, poisoning and procedural complications	Radius fracture	RIGHT RADIAL FRACTURE	BEFORE	-
Skin and subcutaneous tissue disorders	Acute febrile neutrophilic dermatosis	SWEET DISEASE	BEFORE	-
Eye disorders	Cataract	CATARACT	ONGOING	1
Hepatobiliary disorders	Hepatic steatosis	FATTY LIVER	ONGOING	1
Gastrointestinal disorders	Haemorrhoids	HEMORRHOID	ONGOING	1
Vascular disorders	Hypertension	HYPERTENSION STEROID-INDUCED	ONGOING	1
Immune system disorders	Hypogammaglobulinaemia	HYPOGAMMMAGLOBULINEMIA	ONGOING	1
Musculoskeletal and connective tissue disorders	Back pain	LOW BACK PAIN	ONGOING	1
Metabolism and nutrition disorders	Diabetes mellitus	DIABETES	ONGOING	3

Note: Medical History are coded using MedDRA 22.1

■ Transplant History

Transplantation Date	Dictionary-Derived Term	Transplant Type	HLA matching and donor relation to recipient	Sex matching between donor and recipient	Stem Cell Source
20[redacted]	Acute myeloid leukaemia	Myeloablative	Matched unrelated	Matched	Bone Marrow

■ Disease History

Date of Initial Diagnosis	Initial Diagnosis
20[redacted]	CGVHD

■ Study Medication

Visit Name	Start Date of Treatment	End Date of Treatment	Study Day of Start of Treatment	Study Day of End of Treatment	Dose per Administration (mg)	Reason for Dose Skip	Reason for Dose Adjustment	AE Sequence Number(s)
WEEK 1 DAY 1	20[redacted]	20[redacted]	1	1	280.0	-	CYP3A INHIBITOR	-
WEEK 1 DAY 2	20[redacted]	20[redacted]	2	7	280.0	-	-	-
WEEK 2	20[redacted]	20[redacted]	8	23	280.0	-	-	-
WEEK 2	20[redacted]	20[redacted]	24	24	0.0	OTHER	-	-
WEEK 2	20[redacted]	20[redacted]	25	25	280.0	-	-	-
WEEK 2	20[redacted]	20[redacted]	26	26	0.0	OTHER	-	-
WEEK 2	20[redacted]	20[redacted]	27	28	280.0	-	-	-
WEEK 5	20[redacted]	20[redacted]	29	30	280.0	-	-	-
WEEK 5	20[redacted]	20[redacted]	31	33	0.0	OTHER	-	-
WEEK 5	20[redacted]	20[redacted]	34	56	280.0	-	-	-
WEEK 9	20[redacted]	20[redacted]	57	79	280.0	-	-	-
WEEK 13	20[redacted]	20[redacted]	80	112	280.0	-	-	-
WEEK 17	20[redacted]	20[redacted]	113	138	280.0	-	-	-
WEEK 21	20[redacted]	20[redacted]	139	166	280.0	-	-	-
WEEK 25	20[redacted]	20[redacted]	167	177	280.0	-	-	-
WEEK 25	20[redacted]	20[redacted]	178	178	0.0	OTHER	-	-
WEEK 25	20[redacted]	20[redacted]	179	192	280.0	-	-	-
WEEK 25	20[redacted]	20[redacted]	193	194	0.0	OTHER	-	-
WEEK 25	20[redacted]	20[redacted]	195	198	280.0	-	-	-
WEEK 25	20[redacted]	20[redacted]	199	213	0.0	OTHER	-	-
WEEK 25	20[redacted]	20[redacted]	214	214	0.0	OTHER	-	-
WEEK 25	20[redacted]	20[redacted]	215	220	280.0	-	-	-
WEEK 25	20[redacted]	20[redacted]	221	222	0.0	OTHER	-	-
WEEK 25	20[redacted]	20[redacted]	223	243	0.0	OTHER	-	-
WEEK 25	20[redacted]	20[redacted]	244	247	280.0	-	-	-
WEEK 25	20[redacted]	20[redacted]	248	248	0.0	OTHER	-	-
WEEK 25	20[redacted]	20[redacted]	249	250	280.0	-	-	-
WEEK 37	20[redacted]	20[redacted]	251	283	280.0	-	-	-

Visit Name	Start Date of Treatment	End Date of Treatment	Study Day of Start of Treatment	Study Day of End of Treatment	Dose per Administration (mg)	Reason for Dose Skip	Reason for Dose Adjustment	AE Sequence Number(s)
WEEK 37	20[redacted]	20[redacted]	284	285	0.0	OTHER	-	-
WEEK 37	20[redacted]	20[redacted]	286	293	280.0	-	-	-

■ Prior and Concomitant Medications

Standardized Medication Name Reported Name of Drug, Med, or Therapy	Start Date of Medication Study Day of Start of Medication	Started Before Informed Concent Date	End Date of Medication Study Day of End of Medication	Indication	Dose per Administration Dose Units	Dosing Frequency per Interval Route of Administration	AE Sequence Number(s)
PARACETAMOL (ACELIO)	20[redacted] 223	-	20[redacted] 223	ADVERSE EVENT	1000 mg	QD INTRAVENOUS	1
ACICLOVIR (ACICLOVIR)	- -	Y	- -	PROPHYLAXIS	200 ug	QD ORAL	-
BRIMONIDINE TARTRATE (AIPHAGAN OPHTHALMIC SOLUTION 0.1%)	20[redacted] 205	-	- -	ADVERSE EVENT	5 mL	BID OPHTHALMIC	7
ALFACALCIDOL (ALFACALCIDOL)	- -	Y	- -	PROPHYLAXIS	0.5 ug	QD ORAL	-
AMOXICILLIN TRIHYDRATE (AMOXICILLIN HYDRATE)	20[redacted] 197	-	20[redacted] 220	ADVERSE EVENT	1 TABLET	TID ORAL	1
AMPHOTERICIN B (AMPHOTERICIN)	20[redacted] 33	-	20[redacted] 40	ADVERSE EVENT	150 mg	ONCE INTRAVENOUS	1
AMOXICILLIN TRIHYDRATE; CLAVULANATE POTASSIUM (AUGMENTIN COMBINATION TABLETS)	20[redacted] 40	-	20[redacted] 45	ADVERSE EVENT	1 TABLET	TID ORAL	1
AMOXICILLIN TRIHYDRATE; CLAVULANATE POTASSIUM (AUGMENTIN COMBINATION TABLETS)	20[redacted] 197	-	20[redacted] 220	PROPHYLAXIS	1 TABLET	TID ORAL	-
AMOXICILLIN TRIHYDRATE; CLAVULANATE POTASSIUM (AUGMENTIN COMBINATION TABLETS)	20[redacted] 327	-	20[redacted] 329	ADVERSE EVENT	1 TABLET	TID ORAL	6
GUAIAZULENE (AZUNOL [GUAIAZULENE])	20[redacted] 321	-	- -	CGVHD	- OTHER	PRN TOPICAL	-
SULFAMETHOXAZOLE; TRIMETHOPRIM (BACTRAMIN)	- -	Y	- -	PROPHYLAXIS	0.5 TABLET	QD ORAL	-

Standardized Medication Name Reported Name of Drug, Med, or Therapy	Start Date of Medication Study Day of Start of Medication	Started Before Informed Concent Date	End Date of Medication Study Day of End of Medication	Indication	Dose per Administration Dose Units	Dosing Frequency per Interval Route of Administration	AE Sequence Number(s)
BIFIDOBACTERIUM NOS (BIFIDOBACTERIUM)	20[redacted] 197	-	20[redacted] 231	OTHER	10 g	TID ORAL	-
ENTEROCOCCUS FAECALIS (BIOFERMIN-R POWDER)	20[redacted] 177	-	20[redacted] 183	PROPHYLAXIS	- OTHER	TID ORAL	-
ASPARTATE CALCIUM (CALCIUM L-ASPARTATE HYDRATE)	- -	Y	- -	PROPHYLAXIS	200 mg	TID ORAL	-
PARACETAMOL (CALONAL TAB)	20[redacted] 196	-	20[redacted] 200	ADVERSE EVENT	400 mg	PRN ORAL	1
CEFAZOLIN SODIUM (CEFAZOLIN SODIUM)	20[redacted] 206	-	20[redacted] 207	ADVERSE EVENT	1 g	QD INTRAVENOUS	1
CEFEPIME HYDROCHLORIDE (CEFEPIME DIHYDROCHLORIDE HYDRATE)	20[redacted] 33	-	20[redacted] 40	ADVERSE EVENT	1 g	BID INTRAVENOUS	1
CEFDINIR (CEFZON [CEFDINIR] CAPSULES)	20[redacted] 177	-	20[redacted] 183	ADVERSE EVENT	100 mg	QD ORAL	5
DORZOLAMIDE HYDROCHLORIDE; TIMOLOL MALEATE (COSOPT OPHTHALMIC SOLUTION)	20[redacted] 235	-	- -	ADVERSE EVENT	5 mL	PRN OPHTHALMIC	7
LEVOFLOXACIN (CRAVIT TABLETS)	20[redacted] 220	-	20[redacted] 220	ADVERSE EVENT	500 mg	ONCE ORAL	1
LEVOFLOXACIN (CRAVIT TABLETS)	20[redacted] 221	-	20[redacted] 223	ADVERSE EVENT	500 mg	QD ORAL	1
LEVOFLOXACIN (CRAVIT TABLETS)	20[redacted] 286	-	20[redacted] 292	ADVERSE EVENT	500 mg	QD ORAL	3
DEXAMETHASONE (DEXALTIN ORAL OINTMENT)	20[redacted] 272	-	- -	ADVERSE EVENT	- OTHER	PRN TOPICAL	1
DIPHENHYDRAMINE (DIPHENHYDRAMINE)	20[redacted] 33	-	- -	CGVHD	20 g	PRN OTHER	-
DIQUAFOSOL TETRASODIUM (DIQUAS OPHTHALMIC SOLUTION 3%)	20[redacted] 233	-	- -	CGVHD	5 mL	PRN OPHTHALMIC	-
DORZOLAMIDE HYDROCHLORIDE; TIMOLOL MALEATE (DORMOLOL)	20[redacted] 205	-	- -	ADVERSE EVENT	1 mL	PRN OPHTHALMIC	7

Standardized Medication Name Reported Name of Drug, Med, or Therapy	Start Date of Medication Study Day of Start of Medication	Started Before Informed Concent Date	End Date of Medication Study Day of End of Medication	Indication	Dose per Administration Dose Units	Dosing Frequency per Interval Route of Administration	AE Sequence Number(s)
BACTERIA NOS; HYDROCORTISONE (EKSALB)	20[redacted] 167	-	- -	CGVHD	- OTHER	PRN TOPICAL	-
CEFCAPENE PIVOXIL HYDROCHLORIDE (FLOMOX [CEFCAPENE PIVOXIL HYDROCHLORIDE])	20[redacted] 207	-	20[redacted] 213	PROPHYLAXIS	100 mg	TID ORAL	-
INFLUENZA VACCINE (FLUBIK HA)	20[redacted] 139	-	20[redacted] 139	PROPHYLAXIS	0.5 mL	ONCE INTRAVENOUS	-
IMMUNOGLOBULIN HUMAN NORMAL (FREEZE-DRIED SULFONATED HUMAN NORMAL IMMUNOGLOBULIN)	20[redacted] 33	-	20[redacted] 34	MEDICAL HISTORY	5 g	ONCE INTRAVENOUS	-
FUSIDATE SODIUM (FUCIDIN LEO OINTMENT)	20[redacted] 184	-	20[redacted] 196	ADVERSE EVENT	1 FINGERTIP UNIT	PRN TOPICAL	5
MUCOPOLYSACCHARIDE POLYSULFURIC ACID ESTER (HIRUDOID SOFT OINTMENT)	20[redacted] 226	-	- -	CGVHD	- OTHER	PRN TOPICAL	-
INSULIN HUMAN (HUMULIN R)	20[redacted] 224	-	20[redacted] 224	MEDICAL HISTORY	10 U	QD SUBCUTANEOUS	-
INSULIN HUMAN (HUMULIN R)	20[redacted] 225	-	20[redacted] 225	MEDICAL HISTORY	6 U	QD SUBCUTANEOUS	-
INSULIN HUMAN (HUMULIN R)	20[redacted] 226	-	20[redacted] 226	MEDICAL HISTORY	2 U	QD SUBCUTANEOUS	-
INSULIN HUMAN (HUMULIN R)	20[redacted] 227	-	20[redacted] 227	MEDICAL HISTORY	10 U	QD SUBCUTANEOUS	-
INSULIN HUMAN (HUMULIN R)	20[redacted] 228	-	20[redacted] 228	MEDICAL HISTORY	8 U	QD SUBCUTANEOUS	-
INSULIN HUMAN (HUMULIN R)	20[redacted] 230	-	20[redacted] 230	MEDICAL HISTORY	10 U	QD SUBCUTANEOUS	-
INSULIN HUMAN (HUMULIN R)	20[redacted] 231	-	20[redacted] 231	MEDICAL HISTORY	14 U	QD SUBCUTANEOUS	-
INSULIN HUMAN (HUMULIN R)	20[redacted] 232	-	20[redacted] 233	MEDICAL HISTORY	18 U	QD SUBCUTANEOUS	-
INSULIN HUMAN (HUMULIN R)	20[redacted] 234	-	20[redacted] 234	MEDICAL HISTORY	16 U	QD SUBCUTANEOUS	-

Standardized Medication Name Reported Name of Drug, Med, or Therapy	Start Date of Medication Study Day of Start of Medication	Started Before Informed Concent Date	End Date of Medication Study Day of End of Medication	Indication	Dose per Administration Dose Units	Dosing Frequency per Interval Route of Administration	AE Sequence Number(s)
INSULIN HUMAN (HUMULIN R)	20[redacted] 235	-	20[redacted] 235	MEDICAL HISTORY	20 U	QD SUBCUTANEOUS	-
EMPAGLIFLOZIN (JARDIANCE TABLETS)	- -	Y	- -	MEDICAL HISTORY	10 mg	QD ORAL	-
KALLIDINOGENASE (KALLIDINOGENASE)	20[redacted] 205	-	20[redacted] 208	ADVERSE EVENT	50 IU	TID ORAL	7
CEFACLOR (KEFRAL)	20[redacted] 175	-	20[redacted] 177	ADVERSE EVENT	250 mg	TID ORAL	5
IMMUNOGLOBULIN G HUMAN (KENKETSU VENILON I)	20[redacted] 80	-	20[redacted] 80	MEDICAL HISTORY	5 g	ONCE INTRAVENOUS	-
IMMUNOGLOBULIN G HUMAN (KENKETSU VENILON I)	20[redacted] 197	-	20[redacted] 197	MEDICAL HISTORY	5 g	ONCE INTRAVENOUS	-
LANSOPRAZOLE (LANSOPRAZOLE)	20[redacted] 223	-	20[redacted] 231	PROPHYLAXIS	30 mg	QD INTRAVENOUS	-
LANSOPRAZOLE (LANSOPRAZOLEOD)	- -	Y	- -	PROPHYLAXIS	30 mg	QD ORAL	-
LEVOFLOXACIN (LEVOFLOXACIN HYDRATE)	20[redacted] 234	-	20[redacted] 259	ADVERSE EVENT	500 mg	QD ORAL	2
LEVOFLOXACIN (LEVOFLOXACIN HYDRATE)	20[redacted] 234	-	20[redacted] 259	ADVERSE EVENT	500 mg	QD ORAL	1
LEVOFLOXACIN (LEVOFLOXACIN IV INFUSION)	20[redacted] 232	-	20[redacted] 233	ADVERSE EVENT	500 mg	QD INTRAVENOUS	1
HYDROCORTISONE BUTYRATE (LOCOIDO CREAM 0.1%)	- -	Y	- -	CGVHD	- OTHER	PRN TOPICAL	-
LOXOPROFEN SODIUM (LOXONIN)	20[redacted] 207	-	20[redacted] 218	ADVERSE EVENT	60 mg	PRN ORAL	1
BIMATOPROST (LUMIGAN OPHTHALMIC SOLUTION 0.03%)	20[redacted] 205	-	- -	ADVERSE EVENT	2.5 mL	QD OPHTHALMIC	7
MAGNESIUM CITRATE (MAGCOROL P)	20[redacted] 238	-	20[redacted] 238	OTHER	50 g	ONCE ORAL	-
MEROPENEM (MEROPENEM FOR I.V. INFUSION BAG)	20[redacted] 223	-	20[redacted] 231	ADVERSE EVENT	0.5 g	QD INTRAVENOUS	1

Standardized Medication Name Reported Name of Drug, Med, or Therapy	Start Date of Medication Study Day of Start of Medication	Started Before Informed Concent Date	End Date of Medication Study Day of End of Medication	Indication	Dose per Administration Dose Units	Dosing Frequency per Interval Route of Administration	AE Sequence Number(s)
METFORMIN HYDROCHLORIDE (METGLUCO)	- -	Y	- -	MEDICAL HISTORY	500 mg	QD ORAL	-
CLOSTRIDIUM BUTYRICUM (MIYA-BM TABLETS)	20[redacted] 286	-	20[redacted] 292	PROPHYLAXIS	20 mg	TID ORAL	-
CLOSTRIDIUM BUTYRICUM (MIYA-BM TABLETS)	20[redacted] 327	-	20[redacted] 329	PROPHYLAXIS	20 mg	TID ORAL	-
KETOPROFEN (MOHRUS TAPE L)	20[redacted] 209	-	20[redacted] 235	ADVERSE EVENT	40 mg	QD TOPICAL	2
CARBOCISTEINE (MUCODYNE TABLETS)	20[redacted] 327	-	20[redacted] 329	ADVERSE EVENT	250 mg	TID ORAL	6
REBAMIPIDE (MUCOSTA OPHTHALMIC SUSPENSION UD2%)	- -	Y	- -	CGVHD	6 gtt	PRN OPHTHALMIC	-
MACROGOL; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE ANHYDROUS (NIFLEC)	20[redacted] 239	-	20[redacted] 239	OTHER	2 L	ONCE ORAL	-
INSULIN ASPART (NOVORAPID FLEXTOUCH)	- -	Y	- -	MEDICAL HISTORY	60 IU	QD SUBCUTANEOUS	-
HYALURONATE SODIUM (PURIFIED SODIUM HYALURONATE)	- -	Y	- -	CGVHD	6 gtt	CONTINUOUS OPHTHALMIC	-
FLUTICASONE FUROATE; VILANTEROL TRIFENATATE (RELVAR 200 ELLIPTA 30DOSES)	- -	Y	- -	CGVHD	2 PUFF	OCCASIONAL RESPIRATORY (INHALATION)	-
FLURBIPROFEN AXETIL (ROPION)	20[redacted] 206	-	20[redacted] 206	ADVERSE EVENT	50 mg	ONCE INTRAVENOUS	1
MONTELUKAST SODIUM (SINGULAIR)	- -	Y	- -	CGVHD	10 mg	QD ORAL	-
INSULIN DEGLUDEC (TRESIBA FLEXTOUCH)	- -	Y	- -	MEDICAL HISTORY	28 IU	QD SUBCUTANEOUS	-
IMMUNOGLOBULIN HUMAN NORMAL (VENOGLOBULIN IH)	20[redacted] 223	-	20[redacted] 223	MEDICAL HISTORY	5 g	ONCE INTRAVENOUS	-

Standardized Medication Name Reported Name of Drug, Med, or Therapy	Start Date of Medication Study Day of Start of Medication	Started Before Informed Concent Date	End Date of Medication Study Day of End of Medication	Indication	Dose per Administration Dose Units	Dosing Frequency per Interval Route of Administration	AE Sequence Number(s)
VORICONAZOLE (VFEND TABLETS)	- -	Y	20[redacted] 32	PROPHYLAXIS	50 mg	BID ORAL	-
VORICONAZOLE (VFEND TABLETS)	20[redacted] 41	-	- -	PROPHYLAXIS	50 mg	BID ORAL	-
CYANOCOBALAMIN; PYRIDOXINE HYDROCHLORIDE; THIAMINE DISULFIDE (VITAMEDIN FOR INTRAVENOUS INJECTION)	20[redacted] 223	-	20[redacted] 227	ADVERSE EVENT	1 VIAL	QD INTRAVENOUS	1
DICLOFENAC (VOLTAREN SUPPO)	20[redacted] 206	-	20[redacted] 207	ADVERSE EVENT	50 mg	PRN RECTAL	1
TRELAGLIPTIN SUCCINATE (ZAFATEK TABLETS)	- -	Y	- -	MEDICAL HISTORY	100 mg	QD ORAL	-
PIPERACILLIN SODIUM; TAZOBACTAM SODIUM (ZOSYN)	20[redacted] 197	-	20[redacted] 197	ADVERSE EVENT	4.5 g	QD INTRAVENOUS	1

■ Karnofsky/Lansky performance status score

Date of Finding Study Day of Finding	Visit Name	Result
20[redacted] -23	SCREENING	80
20[redacted] 1	WEEK 1 DAY 1	80
20[redacted] 29	WEEK 5	90
20[redacted] 57	WEEK 9	90
20[redacted] 80	WEEK 13	90
20[redacted] 113	WEEK 17	90
20[redacted] 139	WEEK 21	90

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Date of Finding Study Day of Finding	Visit Name	Result
20[redacted] 167	WEEK 25	90
20[redacted] 251	WEEK 37	90

■ Laboratory Data

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Alanine Aminotransferase (Enzyme U/L)	20[redacted] -9	SCREENING	44	0	34.99	HIGH	1
Alanine Aminotransferase (Enzyme U/L)	20[redacted] 1	WEEK 1 DAY 1	35	0	34.99	HIGH	1
Alanine Aminotransferase (Enzyme U/L)	20[redacted] 8	WEEK 2	31	0	34.99	NORMAL	0
Alanine Aminotransferase (Enzyme U/L)	20[redacted] 29	WEEK 5	42	0	34.99	HIGH	1
Alanine Aminotransferase (Enzyme U/L)	20[redacted] 57	WEEK 9	39	0	34.99	HIGH	1
Alanine Aminotransferase (Enzyme U/L)	20[redacted] 80	WEEK 13	47	0	34.99	HIGH	1
Alanine Aminotransferase (Enzyme U/L)	20[redacted] 113	WEEK 17	38	0	34.99	HIGH	1
Alanine Aminotransferase (Enzyme U/L)	20[redacted] 139	WEEK 21	30	0	34.99	NORMAL	0
Alanine Aminotransferase (Enzyme U/L)	20[redacted] 167	WEEK 25	23	0	34.99	NORMAL	0
Alanine Aminotransferase (Enzyme U/L)	20[redacted] 251	WEEK 37	16	0	34.99	NORMAL	0
Albumin (g/L)	20[redacted] -9	SCREENING	42	39	48	NORMAL	0
Albumin (g/L)	20[redacted] 1	WEEK 1 DAY 1	36	39	48	LOW	1
Albumin (g/L)	20[redacted] 8	WEEK 2	37	39	48	LOW	1

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Albumin (g/L)	20[redacted] 29	WEEK 5	36	39	48	LOW	1
Albumin (g/L)	20[redacted] 57	WEEK 9	37	39	48	LOW	1
Albumin (g/L)	20[redacted] 80	WEEK 13	39	39	48	NORMAL	0
Albumin (g/L)	20[redacted] 113	WEEK 17	37	39	48	LOW	1
Albumin (g/L)	20[redacted] 139	WEEK 21	40	39	48	NORMAL	0
Albumin (g/L)	20[redacted] 167	WEEK 25	39	39	48	NORMAL	0
Albumin (g/L)	20[redacted] 251	WEEK 37	35	39	48	LOW	1
Alkaline Phosphatase (Enzyme U/L)	20[redacted] -9	SCREENING	224	100	310	NORMAL	0
Alkaline Phosphatase (Enzyme U/L)	20[redacted] 1	WEEK 1 DAY 1	207	100	310	NORMAL	0
Alkaline Phosphatase (Enzyme U/L)	20[redacted] 8	WEEK 2	176	100	310	NORMAL	0
Alkaline Phosphatase (Enzyme U/L)	20[redacted] 29	WEEK 5	238	100	310	NORMAL	0
Alkaline Phosphatase (Enzyme U/L)	20[redacted] 57	WEEK 9	153	100	310	NORMAL	0
Alkaline Phosphatase (Enzyme U/L)	20[redacted] 80	WEEK 13	204	100	310	NORMAL	0
Alkaline Phosphatase (Enzyme U/L)	20[redacted] 113	WEEK 17	178	100	310	NORMAL	0
Alkaline Phosphatase (Enzyme U/L)	20[redacted] 139	WEEK 21	224	100	310	NORMAL	0
Alkaline Phosphatase (Enzyme U/L)	20[redacted] 167	WEEK 25	235	100	310	NORMAL	0
Alkaline Phosphatase (Enzyme U/L)	20[redacted] 251	WEEK 37	528	100	310	HIGH	1

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] -9	SCREENING	29	0	29.99	NORMAL	0
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] 1	WEEK 1 DAY 1	25	0	29.99	NORMAL	0
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] 8	WEEK 2	22	0	29.99	NORMAL	0
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] 29	WEEK 5	26	0	29.99	NORMAL	0
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] 57	WEEK 9	24	0	29.99	NORMAL	0
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] 80	WEEK 13	34	0	29.99	HIGH	1
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] 113	WEEK 17	39	0	29.99	HIGH	1
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] 139	WEEK 21	38	0	29.99	HIGH	1
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] 167	WEEK 25	21	0	29.99	NORMAL	0
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] 251	WEEK 37	19	0	29.99	NORMAL	0
Bilirubin (umol/L)	20[redacted] -9	SCREENING	8.55	3.42	18.81	NORMAL	0
Bilirubin (umol/L)	20[redacted] 1	WEEK 1 DAY 1	6.84	3.42	18.81	NORMAL	0
Bilirubin (umol/L)	20[redacted] 8	WEEK 2	10.26	3.42	18.81	NORMAL	0
Bilirubin (umol/L)	20[redacted] 29	WEEK 5	6.84	3.42	18.81	NORMAL	0
Bilirubin (umol/L)	20[redacted] 57	WEEK 9	8.55	3.42	18.81	NORMAL	0
Bilirubin (umol/L)	20[redacted] 80	WEEK 13	8.55	3.42	18.81	NORMAL	0
Bilirubin (umol/L)	20[redacted] 113	WEEK 17	8.55	3.42	18.81	NORMAL	0

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Bilirubin (umol/L)	20[redacted] 139	WEEK 21	6.84	3.42	18.81	NORMAL	0
Bilirubin (umol/L)	20[redacted] 167	WEEK 25	8.55	3.42	18.81	NORMAL	0
Bilirubin (umol/L)	20[redacted] 251	WEEK 37	6.84	3.42	18.81	NORMAL	0
Creatinine (umol/L)	20[redacted] -9	SCREENING	105.196	44.2	97.24	HIGH	1
Creatinine (umol/L)	20[redacted] 1	WEEK 1 DAY 1	107.848	44.2	97.24	HIGH	1
Creatinine (umol/L)	20[redacted] 8	WEEK 2	97.24	44.2	97.24	NORMAL	0
Creatinine (umol/L)	20[redacted] 29	WEEK 5	104.312	44.2	97.24	HIGH	1
Creatinine (umol/L)	20[redacted] 57	WEEK 9	107.848	44.2	97.24	HIGH	1
Creatinine (umol/L)	20[redacted] 80	WEEK 13	106.08	44.2	97.24	HIGH	1
Creatinine (umol/L)	20[redacted] 113	WEEK 17	106.08	44.2	97.24	HIGH	1
Creatinine (umol/L)	20[redacted] 139	WEEK 21	99.892	44.2	97.24	HIGH	1
Creatinine (umol/L)	20[redacted] 167	WEEK 25	103.428	44.2	97.24	HIGH	1
Creatinine (umol/L)	20[redacted] 251	WEEK 37	83.096	44.2	97.24	NORMAL	0
Deoxyribonucleic Acid	20[redacted] -9	SCREENING	NEGATIVE	-	-	-	-
Deoxyribonucleic Acid	20[redacted] 80	WEEK 13	NEGATIVE	-	-	-	-
Deoxyribonucleic Acid	20[redacted] 113	WEEK 17	NEGATIVE	-	-	-	-
Deoxyribonucleic Acid	20[redacted] 167	WEEK 25	NEGATIVE	-	-	-	-

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Deoxyribonucleic Acid	20[redacted] 251	WEEK 37	NEGATIVE	-	-	-	-
Eosinophils (10^9/L)	20[redacted] -9	SCREENING	0	0.04	0.32	LOW	-
Eosinophils (10^9/L)	20[redacted] 1	WEEK 1 DAY 1	0	0.04	0.32	LOW	-
Eosinophils (10^9/L)	20[redacted] 8	WEEK 2	0	0.04	0.32	LOW	-
Eosinophils (10^9/L)	20[redacted] 29	WEEK 5	0	0.04	0.32	LOW	-
Eosinophils (10^9/L)	20[redacted] 57	WEEK 9	0	0.04	0.32	LOW	-
Eosinophils (10^9/L)	20[redacted] 80	WEEK 13	0	0.04	0.32	LOW	-
Eosinophils (10^9/L)	20[redacted] 113	WEEK 17	0.065	0.04	0.32	NORMAL	-
Eosinophils (10^9/L)	20[redacted] 139	WEEK 21	0	0.04	0.32	LOW	-
Eosinophils (10^9/L)	20[redacted] 167	WEEK 25	0	0.04	0.32	LOW	-
Eosinophils (10^9/L)	20[redacted] 251	WEEK 37	0	0.04	0.32	LOW	-
Glucose (mmol/L)	20[redacted] -9	SCREENING	7.4383	3.8857	6.1061	HIGH	1
Glucose (mmol/L)	20[redacted] 1	WEEK 1 DAY 1	6.7167	3.8857	6.1061	HIGH	1
Glucose (mmol/L)	20[redacted] 8	WEEK 2	5.4955	3.8857	6.1061	NORMAL	0
Glucose (mmol/L)	20[redacted] 29	WEEK 5	11.324	3.8857	6.1061	HIGH	2
Glucose (mmol/L)	20[redacted] 57	WEEK 9	5.2735	3.8857	6.1061	NORMAL	0
Glucose (mmol/L)	20[redacted] 80	WEEK 13	8.16	3.8857	6.1061	HIGH	1

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Glucose (mmol/L)	20[redacted] 113	WEEK 17	5.551	3.8857	6.1061	NORMAL	0
Glucose (mmol/L)	20[redacted] 139	WEEK 21	4.2188	3.8857	6.1061	NORMAL	0
Glucose (mmol/L)	20[redacted] 167	WEEK 25	6.1061	3.8857	6.1061	NORMAL	0
Glucose (mmol/L)	20[redacted] 251	WEEK 37	4.6073	3.8857	6.1061	NORMAL	0
HIV Antibody	20[redacted] -23	SCREENING	NEGATIVE	-	-	-	-
Hemoglobin (g/L)	20[redacted] -9	SCREENING	146	135	175	NORMAL	0
Hemoglobin (g/L)	20[redacted] 1	WEEK 1 DAY 1	136	135	175	NORMAL	0
Hemoglobin (g/L)	20[redacted] 8	WEEK 2	135	135	175	NORMAL	0
Hemoglobin (g/L)	20[redacted] 29	WEEK 5	134	135	175	LOW	1
Hemoglobin (g/L)	20[redacted] 57	WEEK 9	121	135	175	LOW	1
Hemoglobin (g/L)	20[redacted] 80	WEEK 13	139	135	175	NORMAL	0
Hemoglobin (g/L)	20[redacted] 113	WEEK 17	130	135	175	LOW	1
Hemoglobin (g/L)	20[redacted] 139	WEEK 21	139	135	175	NORMAL	0
Hemoglobin (g/L)	20[redacted] 167	WEEK 25	142	135	175	NORMAL	0
Hemoglobin (g/L)	20[redacted] 251	WEEK 37	119	135	175	LOW	1
Hepatitis B Virus Core Antibody	20[redacted] -23	SCREENING	POSITIVE	-	-	-	-
Hepatitis B Virus Surface Antibody	20[redacted] -23	SCREENING	NEGATIVE	-	-	-	-

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Hepatitis B Virus Surface Antigen	20[redacted] -23	SCREENING	NEGATIVE	-	-	-	-
Hepatitis C Virus Antibody	20[redacted] -23	SCREENING	NEGATIVE	-	-	-	-
Immunoglobulin A (g/L)	20[redacted] -9	SCREENING	1.22	-	-	-	-
Immunoglobulin A (g/L)	20[redacted] 80	WEEK 13	0.94	-	-	-	-
Immunoglobulin A (g/L)	20[redacted] 167	WEEK 25	1.35	-	-	-	-
Immunoglobulin A (g/L)	20[redacted] 251	WEEK 37	1.49	-	-	-	-
Immunoglobulin G (g/L)	20[redacted] -9	SCREENING	3.9	-	-	-	-
Immunoglobulin G (g/L)	20[redacted] 80	WEEK 13	3.91	-	-	-	-
Immunoglobulin G (g/L)	20[redacted] 167	WEEK 25	4.22	-	-	-	-
Immunoglobulin G (g/L)	20[redacted] 251	WEEK 37	5.23	-	-	-	-
Immunoglobulin M (g/L)	20[redacted] -9	SCREENING	1.14	-	-	-	-
Immunoglobulin M (g/L)	20[redacted] 80	WEEK 13	0.39	-	-	-	-
Immunoglobulin M (g/L)	20[redacted] 167	WEEK 25	0.7	-	-	-	-
Immunoglobulin M (g/L)	20[redacted] 251	WEEK 37	1.68	-	-	-	-
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] -9	SCREENING	479	110	219	HIGH	-
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] 1	WEEK 1 DAY 1	473	110	219	HIGH	-
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] 8	WEEK 2	456	110	219	HIGH	-

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] 29	WEEK 5	525	110	219	HIGH	-
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] 57	WEEK 9	372	110	219	HIGH	-
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] 80	WEEK 13	572	110	219	HIGH	-
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] 113	WEEK 17	730	110	219	HIGH	-
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] 139	WEEK 21	780	110	219	HIGH	-
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] 167	WEEK 25	502	110	219	HIGH	-
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] 251	WEEK 37	252	110	219	HIGH	-
Leukocytes (10^9/L)	20[redacted] -9	SCREENING	12.9	4	8	HIGH	0
Leukocytes (10^9/L)	20[redacted] 1	WEEK 1 DAY 1	11.8	4	8	HIGH	0
Leukocytes (10^9/L)	20[redacted] 8	WEEK 2	13.1	4	8	HIGH	0
Leukocytes (10^9/L)	20[redacted] 29	WEEK 5	14.4	4	8	HIGH	0
Leukocytes (10^9/L)	20[redacted] 57	WEEK 9	13.7	4	8	HIGH	0
Leukocytes (10^9/L)	20[redacted] 80	WEEK 13	11.9	4	8	HIGH	0
Leukocytes (10^9/L)	20[redacted] 113	WEEK 17	12.9	4	8	HIGH	0
Leukocytes (10^9/L)	20[redacted] 139	WEEK 21	17.2	4	8	HIGH	0
Leukocytes (10^9/L)	20[redacted] 167	WEEK 25	12.9	4	8	HIGH	0
Leukocytes (10^9/L)	20[redacted] 251	WEEK 37	15.3	4	8	HIGH	0

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Lymphocytes (10^9/L)	20[redacted] -9	SCREENING	1.29	0.8	3.2	NORMAL	0
Lymphocytes (10^9/L)	20[redacted] 1	WEEK 1 DAY 1	2.655	0.8	3.2	NORMAL	0
Lymphocytes (10^9/L)	20[redacted] 8	WEEK 2	2.096	0.8	3.2	NORMAL	0
Lymphocytes (10^9/L)	20[redacted] 29	WEEK 5	2.016	0.8	3.2	NORMAL	0
Lymphocytes (10^9/L)	20[redacted] 57	WEEK 9	1.37	0.8	3.2	NORMAL	0
Lymphocytes (10^9/L)	20[redacted] 80	WEEK 13	2.559	0.8	3.2	NORMAL	0
Lymphocytes (10^9/L)	20[redacted] 113	WEEK 17	2.58	0.8	3.2	NORMAL	0
Lymphocytes (10^9/L)	20[redacted] 139	WEEK 21	0.516	0.8	3.2	LOW	2
Lymphocytes (10^9/L)	20[redacted] 167	WEEK 25	0.839	0.8	3.2	NORMAL	0
Lymphocytes (10^9/L)	20[redacted] 251	WEEK 37	0.383	0.8	3.2	LOW	3
Neutrophils (10^9/L)	20[redacted] -9	SCREENING	11.481	1.6	6.32	HIGH	0
Neutrophils (10^9/L)	20[redacted] 1	WEEK 1 DAY 1	8.614	1.6	6.32	HIGH	0
Neutrophils (10^9/L)	20[redacted] 8	WEEK 2	9.891	1.6	6.32	HIGH	0
Neutrophils (10^9/L)	20[redacted] 29	WEEK 5	11.304	1.6	6.32	HIGH	0
Neutrophils (10^9/L)	20[redacted] 57	WEEK 9	11.508	1.6	6.32	HIGH	0
Neutrophils (10^9/L)	20[redacted] 80	WEEK 13	8.449	1.6	6.32	HIGH	0
Neutrophils (10^9/L)	20[redacted] 113	WEEK 17	8.966	1.6	6.32	HIGH	0

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Neutrophils (10^9/L)	20[redacted] 139	WEEK 21	15.996	1.6	6.32	HIGH	0
Neutrophils (10^9/L)	20[redacted] 167	WEEK 25	11.61	1.6	6.32	HIGH	0
Neutrophils (10^9/L)	20[redacted] 251	WEEK 37	14.535	1.6	6.32	HIGH	0
Platelets (10^9/L)	20[redacted] -9	SCREENING	177	140	400	NORMAL	0
Platelets (10^9/L)	20[redacted] 1	WEEK 1 DAY 1	152	140	400	NORMAL	0
Platelets (10^9/L)	20[redacted] 8	WEEK 2	114	140	400	LOW	1
Platelets (10^9/L)	20[redacted] 29	WEEK 5	125	140	400	LOW	1
Platelets (10^9/L)	20[redacted] 57	WEEK 9	81	140	400	LOW	1
Platelets (10^9/L)	20[redacted] 80	WEEK 13	116	140	400	LOW	1
Platelets (10^9/L)	20[redacted] 113	WEEK 17	102	140	400	LOW	1
Platelets (10^9/L)	20[redacted] 139	WEEK 21	133	140	400	LOW	1
Platelets (10^9/L)	20[redacted] 167	WEEK 25	130	140	400	LOW	1
Platelets (10^9/L)	20[redacted] 251	WEEK 37	154	140	400	NORMAL	0
Potassium (mmol/L)	20[redacted] -9	SCREENING	4.6	3.5	4.8	NORMAL	0
Potassium (mmol/L)	20[redacted] 1	WEEK 1 DAY 1	3.8	3.5	4.8	NORMAL	0
Potassium (mmol/L)	20[redacted] 8	WEEK 2	4.2	3.5	4.8	NORMAL	0
Potassium (mmol/L)	20[redacted] 29	WEEK 5	4.7	3.5	4.8	NORMAL	0

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Potassium (mmol/L)	20[redacted] 57	WEEK 9	3.6	3.5	4.8	NORMAL	0
Potassium (mmol/L)	20[redacted] 80	WEEK 13	3.8	3.5	4.8	NORMAL	0
Potassium (mmol/L)	20[redacted] 113	WEEK 17	4	3.5	4.8	NORMAL	0
Potassium (mmol/L)	20[redacted] 139	WEEK 21	3.9	3.5	4.8	NORMAL	0
Potassium (mmol/L)	20[redacted] 167	WEEK 25	4	3.5	4.8	NORMAL	0
Potassium (mmol/L)	20[redacted] 251	WEEK 37	4	3.5	4.8	NORMAL	0
Protein (g/L)	20[redacted] -9	SCREENING	67	67	83	NORMAL	-
Protein (g/L)	20[redacted] 1	WEEK 1 DAY 1	58	67	83	LOW	-
Protein (g/L)	20[redacted] 8	WEEK 2	59	67	83	LOW	-
Protein (g/L)	20[redacted] 29	WEEK 5	61	67	83	LOW	-
Protein (g/L)	20[redacted] 57	WEEK 9	58	67	83	LOW	-
Protein (g/L)	20[redacted] 80	WEEK 13	61	67	83	LOW	-
Protein (g/L)	20[redacted] 113	WEEK 17	58	67	83	LOW	-
Protein (g/L)	20[redacted] 139	WEEK 21	65	67	83	LOW	-
Protein (g/L)	20[redacted] 167	WEEK 25	67	67	83	NORMAL	-
Protein (g/L)	20[redacted] 251	WEEK 37	63	67	83	LOW	-
Ribonucleic Acid	20[redacted] -9	SCREENING	NEGATIVE	-	-	-	-

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Sodium (mmol/L)	20[redacted] -9	SCREENING	146	136	145	HIGH	1
Sodium (mmol/L)	20[redacted] 1	WEEK 1 DAY 1	148	136	145	HIGH	1
Sodium (mmol/L)	20[redacted] 8	WEEK 2	148	136	145	HIGH	1
Sodium (mmol/L)	20[redacted] 29	WEEK 5	146	136	145	HIGH	1
Sodium (mmol/L)	20[redacted] 57	WEEK 9	147	136	145	HIGH	1
Sodium (mmol/L)	20[redacted] 80	WEEK 13	145	136	145	NORMAL	0
Sodium (mmol/L)	20[redacted] 113	WEEK 17	148	136	145	HIGH	1
Sodium (mmol/L)	20[redacted] 139	WEEK 21	146	136	145	HIGH	1
Sodium (mmol/L)	20[redacted] 167	WEEK 25	145	136	145	NORMAL	0
Sodium (mmol/L)	20[redacted] 251	WEEK 37	145	136	145	NORMAL	0
Urate (umol/L)	20[redacted] -9	SCREENING	392.568	237.92	416.36	NORMAL	0
Urate (umol/L)	20[redacted] 1	WEEK 1 DAY 1	404.464	237.92	416.36	NORMAL	0
Urate (umol/L)	20[redacted] 8	WEEK 2	422.308	237.92	416.36	HIGH	1
Urate (umol/L)	20[redacted] 29	WEEK 5	452.048	237.92	416.36	HIGH	1
Urate (umol/L)	20[redacted] 57	WEEK 9	416.36	237.92	416.36	NORMAL	0
Urate (umol/L)	20[redacted] 80	WEEK 13	475.84	237.92	416.36	HIGH	1
Urate (umol/L)	20[redacted] 113	WEEK 17	398.516	237.92	416.36	NORMAL	0

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Urate (umol/L)	20[redacted] 139	WEEK 21	463.944	237.92	416.36	HIGH	1
Urate (umol/L)	20[redacted] 167	WEEK 25	469.892	237.92	416.36	HIGH	1
Urate (umol/L)	20[redacted] 251	WEEK 37	368.776	237.92	416.36	NORMAL	0
Urea Nitrogen (mmol/L)	20[redacted] -9	SCREENING	9.639	2.856	7.14	HIGH	-
Urea Nitrogen (mmol/L)	20[redacted] 1	WEEK 1 DAY 1	10.353	2.856	7.14	HIGH	-
Urea Nitrogen (mmol/L)	20[redacted] 8	WEEK 2	10.71	2.856	7.14	HIGH	-
Urea Nitrogen (mmol/L)	20[redacted] 29	WEEK 5	8.568	2.856	7.14	HIGH	-
Urea Nitrogen (mmol/L)	20[redacted] 57	WEEK 9	11.424	2.856	7.14	HIGH	-
Urea Nitrogen (mmol/L)	20[redacted] 80	WEEK 13	12.138	2.856	7.14	HIGH	-
Urea Nitrogen (mmol/L)	20[redacted] 113	WEEK 17	9.639	2.856	7.14	HIGH	-
Urea Nitrogen (mmol/L)	20[redacted] 139	WEEK 21	12.495	2.856	7.14	HIGH	-
Urea Nitrogen (mmol/L)	20[redacted] 167	WEEK 25	12.495	2.856	7.14	HIGH	-
Urea Nitrogen (mmol/L)	20[redacted] 251	WEEK 37	9.282	2.856	7.14	HIGH	-

2.7.6.2.3.2　重篤な有害事象

(1) イブルチニブと関連性がある重篤な有害事象

1) 被験者番号 54179060GVH3001-[redacted]

■ REASON FOR NARRATIVE SELECTION

(101)

Treatment-emergent serious adverse events (SAEs)

■ Death

No Death reported

■ Treatment-emergent serious adverse events (SAEs)

Dictionary-Derived Term	Reported Term for the Adverse Event	Start Date of Adverse Event End Date of Adverse Event	Study Day of Start of Adverse Event Adverse Event Duration (days)	Serious Event Standard Toxicity Grade	Causality Action Taken with Study Treatment	Concomitant or Additional Treatment Given Outcome of Adverse Event	Sequence Number
蜂巣炎	CELLULITIS	20[redacted] 20[redacted]	277 17	Y 3	POSSIBLE DRUG INTERRUPTED	Y RECOVERED/RESOLVED	4
蜂巣炎	LEFT UPPER ARM CELLULITIS	20[redacted] 20[redacted]	359 8	Y 3	POSSIBLE DOSE NOT CHANGED	Y RECOVERED/RESOLVED	17
蜂巣炎	CELLULITIS AT RIGHT THIGH	20[redacted] 20[redacted]	440 10	Y 3	POSSIBLE DOSE NOT CHANGED	Y RECOVERED/RESOLVED	5

Note: Adverse Events are coded using MedDRA 22.1

■ Adverse events (AEs) leading to ibrutinib discontinuation

No Adverse events (AEs) leading to ibrutinib discontinuation reported

■ Other malignancies

No Other malignancies reported

■ Major hemorrhage

No Major hemorrhage reported

■ Demographics, Baseline Characteristics

- Country: JPN
- Race: Asian
- Age: 2[redacted]
- Sex: Female
- Baseline height (cm): [redacted]
- Baseline weight (kg): [redacted]
- Baseline karnofsky/Lansky performance status score: 70
- Overall severity of cGVHD: Severe
- cGVHD disease state: STEROID REFRACTORY DISEASE
- Month from initial diagnosis date: 33.0
- Number of prior cGVHD treatment regimens: 2
- First study drug intake: 20[redacted] (Study Day 1)
- Last study drug intake: 20[redacted] (Study Day 456)

■ Disposition Information

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□ End of treatment: Subject Ongoing on Treatment

□ End of trial: Subject Ongoing on Study

■ Other Adverse Events

Dictionary-Derived Term	Reported Term for the Adverse Event	Start Date of Adverse Event End Date of Adverse Event	Study Day of Start of Adverse Event Adverse Event Duration (days)	Serious Event Standard Toxicity Grade	Causality Action Taken with Study Treatment	Concomitant or Additional Treatment Given Outcome of Adverse Event	Sequence Number
関節痛	ARTHRALGIA	20[redacted] -	4 -	N 1	NOT RELATED DOSE NOT CHANGED	Y NOT RECOVERED/NOT RESOLVED	3
アラニンアミノトランスフェラーゼ増加	WORSENING OF ALANINE AMINOTRANSFERASE INCREASED	20[redacted] 20	29 21	N 2	POSSIBLE DOSE NOT CHANGED	Y RECOVERED/RESOLVED	22
アラニンアミノトランスフェラーゼ増加	WORSENING OF ALANINE AMINOTRANSFERASE INCREASED	20[redacted] 20	50 35	N 3	POSSIBLE DOSE NOT CHANGED	Y RECOVERED/RESOLVED	23
アラニンアミノトランスフェラーゼ増加	WORSENING OF ALANINE AMINOTRANSFERASE INCREASED	20[redacted] 20	85 55	N 2	POSSIBLE DOSE NOT CHANGED	Y RECOVERED/RESOLVED	24
ざ瘡	ACNE	20[redacted] 20	127 19	N 1	NOT RELATED DOSE NOT CHANGED	Y RECOVERED/RESOLVED	1
白内障	DETERIORATION OF CATARACT	20[redacted] -	169 -	N 2	NOT RELATED DOSE NOT CHANGED	Y NOT RECOVERED/NOT RESOLVED	9
アラニンアミノトランスフェラーゼ増加	WORSENING OF ALANINE AMINOTRANSFERASE INCREASED	20[redacted] 20	197 87	N 2	POSSIBLE DOSE NOT CHANGED	Y RECOVERED/RESOLVED	25
不安	ANXIETY	20[redacted] 20	267 85	N 1	NOT RELATED DOSE NOT CHANGED	Y RECOVERED/RESOLVED	2
γ－グルタミルトランスフェラーゼ増加	GGT INCREASED	20[redacted] 20	277 1	N 2	NOT RELATED DOSE NOT CHANGED	N RECOVERED/RESOLVED	10

Dictionary-Derived Term	Reported Term for the Adverse Event	Start Date of Adverse Event End Date of Adverse Event	Study Day of Start of Adverse Event Adverse Event Duration (days)	Serious Event Standard Toxicity Grade	Causality Action Taken with Study Treatment	Concomitant or Additional Treatment Given Outcome of Adverse Event	Sequence Number
低カルシウム血症	HYPOCALCEMIA	20[redacted] 20	277 13	N 1	NOT RELATED DOSE NOT CHANGED	N RECOVERED/RESOLVED	14
悪心	NAUSEA	20 20	277 1	N 2	NOT RELATED DOSE NOT CHANGED	Y RECOVERED/RESOLVED	19
γ－グルタミルトランスフェラーゼ増加	GGT INCREASED	20 20	278 8	N 1	NOT RELATED DOSE NOT CHANGED	N RECOVERED/RESOLVED	11
アラニンアミノトランスフェラーゼ増加	WORSENING OF ALANINE AMINOTRANSFERASE INCREASED	20 20	284 18	N 3	POSSIBLE DOSE NOT CHANGED	Y RECOVERED/RESOLVED	26
γ－グルタミルトランスフェラーゼ増加	GGT INCREASED	20 20	286 73	N 3	NOT RELATED DOSE NOT CHANGED	N RECOVERED/RESOLVED	12
低カルシウム血症	HYPOCALCEMIA	20 20	290 3	N 2	NOT RELATED DOSE NOT CHANGED	Y RECOVERED/RESOLVED	15
低カルシウム血症	HYPOCALCEMIA	20 -	293 -	N 1	NOT RELATED DOSE NOT CHANGED	Y NOT RECOVERED/NOT RESOLVED	16
アラニンアミノトランスフェラーゼ増加	WORSENING OF ALANINE AMINOTRANSFERASE INCREASED	20 20	302 8	N 2	POSSIBLE DOSE NOT CHANGED	Y RECOVERED/RESOLVED	27
うつ病	DEPRESSION	20 -	351 -	N 2	NOT RELATED DOSE NOT CHANGED	Y NOT RECOVERED/NOT RESOLVED	8
γ－グルタミルトランスフェラーゼ増加	GGT INCREASED	20 -	359 -	N 1	NOT RELATED DOSE NOT CHANGED	N NOT RECOVERED/NOT RESOLVED	13

Dictionary-Derived Term	Reported Term for the Adverse Event	Start Date of Adverse Event End Date of Adverse Event	Study Day of Start of Adverse Event Adverse Event Duration (days)	Serious Event Standard Toxicity Grade	Causality Action Taken with Study Treatment	Concomitant or Additional Treatment Given Outcome of Adverse Event	Sequence Number
蜂巣炎	LEFT UPPER ARM CELLULITIS	20[redacted] 20	367 90	N 2	POSSIBLE DOSE NOT CHANGED	Y RECOVERED/RESOLVED	18
下肢静止不能症候群	RESTLESS LEGS SYNDROME	20 20	367 69	N 2	NOT RELATED DOSE NOT CHANGED	Y RECOVERED/RESOLVED	20
歯牙破折	TOOTH FRACTURE	20 -	436 -	N 2	NOT RELATED DOSE NOT CHANGED	N NOT RECOVERED/NOT RESOLVED	21
齲歯	DENTAL CARIES	20 -	437 -	N 2	NOT RELATED DOSE NOT CHANGED	Y NOT RECOVERED/NOT RESOLVED	7
蜂巣炎	CELLULITIS AT RIGHT THIGH	20 -	450 -	N 2	POSSIBLE DOSE NOT CHANGED	Y NOT RECOVERED/NOT RESOLVED	6

Note: Adverse Events are coded using MedDRA 22.1

■ Medical History

Body System or Organ Class	Dictionary-Derived Term	Reported Term for the Medical History	End Relative to Reference Period	Toxicity Grade
Immune system disorders	Acute graft versus host disease	ACUTE GVHD	BEFORE	-
Investigations	Alanine aminotransferase increased	ALANINE AMINOTRANSFERASE INCREASED	ONGOING	1
Investigations	Aspartate aminotransferase increased	ASPARTATE AMINOTRANSFERASE INCREASED	ONGOING	1
Eye disorders	Cataract	CATARACT	ONGOING	1
Renal and urinary disorders	Chronic kidney disease	CHRONIC KIDNEY DISEASE	ONGOING	1
Metabolism and nutrition disorders	Hyperuricaemia	HYPERURICEMIA	ONGOING	1
Immune system disorders	Hypogammaglobulinaemia	HYPOGAMMAGLOBULINEMIA	ONGOING	1
Psychiatric disorders	Insomnia	INSOMNIA	ONGOING	1

Body System or Organ Class	Dictionary-Derived Term	Reported Term for the Medical History	End Relative to Reference Period	Toxicity Grade
Metabolism and nutrition disorders	Dyslipidaemia	DYSLIPIDEMIA	ONGOING	2
Vascular disorders	Hypertension	HYPERTENSION	ONGOING	2
Metabolism and nutrition disorders	Glucose tolerance impaired	GLUCOSE INTOLERANCE	ONGOING	3

Note: Medical History are coded using MedDRA 22.1

■ Transplant History

Transplantation Date	Dictionary-Derived Term	Transplant Type	HLA matching and donor relation to recipient	Sex matching between donor and recipient	Stem Cell Source
20[redacted]	Acute lymphocytic leukaemia	Myeloablative	Matched unrelated	Unmatched	Peripheral Stem Cells

■ Disease History

Date of Initial Diagnosis	Initial Diagnosis
20[redacted]	CGVHD

■ Study Medication

Visit Name	Start Date of Treatment	End Date of Treatment	Study Day of Start of Treatment	Study Day of End of Treatment	Dose per Administration (mg)	Reason for Dose Skip	Reason for Dose Adjustment	AE Sequence Number(s)
WEEK 1 DAY 1	20[redacted]	20[redacted]	1	1	420.0	-	-	-
WEEK 1 DAY 2	20	20	2	7	420.0	-	-	-
WEEK 2	20	20	8	28	420.0	-	-	-
WEEK 5	20	20	29	56	420.0	-	-	-
WEEK 9	20	20	57	84	420.0	-	-	-
WEEK 13	20	20	85	112	420.0	-	-	-
WEEK 17	20	20	113	138	420.0	-	-	-
WEEK 21	20	20	139	168	420.0	-	-	-
WEEK 25	20	20	169	252	420.0	-	-	-
WEEK 37	20	20	253	276	420.0	-	-	-
WEEK 37	20	20	277	292	0.0	ADVERSE EVENT	-	-

Visit Name	Start Date of Treatment	End Date of Treatment	Study Day of Start of Treatment	Study Day of End of Treatment	Dose per Administration (mg)	Reason for Dose Skip	Reason for Dose Adjustment	AE Sequence Number(s)
WEEK 37	20[redacted]	20[redacted]	293	336	420.0	-	-	-
WEEK 49	20[redacted]	20[redacted]	337	420	420.0	-	-	-
WEEK 61	20[redacted]	20[redacted]	421	456	420.0	-	-	-

■ Prior and Concomitant Medications

Standardized Medication Name Reported Name of Drug, Med, or Therapy	Start Date of Medication Study Day of Start of Medication	Started Before Informed Concent Date	End Date of Medication Study Day of End of Medication	Indication	Dose per Administration Dose Units	Dosing Frequency per Interval Route of Administration	AE Sequence Number(s)
PARACETAMOL (ACELIO)	20[redacted] 277	-	20[redacted] 280	ADVERSE EVENT	500 mg	PRN INTRAVENOUS	4
PARACETAMOL (ACELIO)	20[redacted] 440	-	20[redacted] 441	ADVERSE EVENT	500 mg	PRN INTRAVENOUS	5
PARACETAMOL (ACETAMINOPHEN)	20[redacted] 280	-	20[redacted] 283	ADVERSE EVENT	400 mg	PRN ORAL	4
PARACETAMOL (ACETAMINOPHEN)	20[redacted] 441	-	20[redacted] 445	ADVERSE EVENT	400 mg	PRN ORAL	5
ACICLOVIR (ACICLOVIR)	20[redacted] -	Y	20[redacted] 42	PROPHYLAXIS	800 mg	BID ORAL	-
ACICLOVIR (ACICLOVIR)	20[redacted] 43	-	- -	PROPHYLAXIS	200 mg	BID ORAL	-
RISEDRONATE SODIUM (ACTONEL)	- -	Y	20[redacted] 4	PROPHYLAXIS	75 mg	QM ORAL	-
ALFACALCIDOL (ALFACALCIDOL)	20[redacted] 290	-	- -	ADVERSE EVENT	1 ug	QD ORAL	1
ALFACALCIDOL (ALFACALCIDOL)	20[redacted] 290	-	- -	ADVERSE EVENT	1 ug	QD ORAL	1
AMLODIPINE (AMLODIPINE)	- -	Y	20[redacted] 278	MEDICAL HISTORY	5 mg	QD ORAL	-
AMLODIPINE (AMLODIPINE)	20[redacted] 297	-	- -	MEDICAL HISTORY	5 mg	QD ORAL	-
AMOXICILLIN (AMOXICILLIN)	20[redacted] 440	-	20[redacted] 440	ADVERSE EVENT	250 mg	ONCE ORAL	5

Standardized Medication Name Reported Name of Drug, Med, or Therapy	Start Date of Medication Study Day of Start of Medication	Started Before Informed Concent Date	End Date of Medication Study Day of End of Medication	Indication	Dose per Administration Dose Units	Dosing Frequency per Interval Route of Administration	AE Sequence Number(s)
HYDROXYZINE HYDROCHLORIDE (ATARAX-P)	- -	Y	- -	CGVHD	25 mg	BID ORAL	-
HYDROXYZINE HYDROCHLORIDE (ATARAX-P)	20[redacted] 279	-	20[redacted] 280	CGVHD	50 mg	PRN INTRAVENOUS	-
HYDROXYZINE HYDROCHLORIDE (ATARAX-P)	20[redacted] 442	-	- -	CGVHD	25 mg	PRN ORAL	-
AMOXICILLIN; CLAVULANIC ACID (AUGMENTIN)	20[redacted] 440	-	20[redacted] 440	ADVERSE EVENT	375 mg	ONCE ORAL	5
SODIUM GUALENATE HYDRATE (AZULENE(SODIUM GUALENATE HYDRATE))	20[redacted] 283	-	- -	PROPHYLAXIS	- OTHER	PRN OTHER	-
GUAIAZULENE (AZUNOL(DIMETHYL ISOPROPYLAZULENE))	20[redacted] 283	-	- -	PROPHYLAXIS	- OTHER	PRN TOPICAL	-
PENTAMIDINE ISETHIONATE (BENAMBAX)	20[redacted] 29	-	- -	PROPHYLAXIS	100 mg	EVERY 4 WEEKS RESPIRATORY (INHALATION)	-
PARACETAMOL (CALONAL)	20[redacted] 4	-	20[redacted] 277	ADVERSE EVENT	400 mg	PRN ORAL	3
CEFAZOLIN SODIUM (CEFAZOLIN NA)	20[redacted] 364	-	20[redacted] 364	ADVERSE EVENT	1 g	QD INTRAVENOUS	1
CEFAZOLIN SODIUM (CEFAZOLIN NA)	20[redacted] 365	-	20[redacted] 365	ADVERSE EVENT	1 g	TID INTRAVENOUS	1
CEFAZOLIN SODIUM (CEFAZOLIN NA)	20[redacted] 366	-	20[redacted] 366	ADVERSE EVENT	1 g	BID INTRAVENOUS	1
CEFEPIME (CEFEPIME)	20[redacted] 277	-	20[redacted] 277	ADVERSE EVENT	1 g	ONCE INTRAVENOUS	4
CEFEPIME (CEFEPIME)	20[redacted] 282	-	20[redacted] 282	ADVERSE EVENT	2 g	QD INTRAVENOUS	4
CEFEPIME (CEFEPIME)	20[redacted] 283	-	20[redacted] 292	ADVERSE EVENT	2 g	BID INTRAVENOUS	4
CEFEPIME (CEFEPIME)	20[redacted] 359	-	20[redacted] 363	ADVERSE EVENT	1 g	BID INTRAVENOUS	1

Standardized Medication Name Reported Name of Drug, Med, or Therapy	Start Date of Medication Study Day of Start of Medication	Started Before Informed Concent Date	End Date of Medication Study Day of End of Medication	Indication	Dose per Administration Dose Units	Dosing Frequency per Interval Route of Administration	AE Sequence Number(s)
CEFEPIME (CEFEPIME)	20[redacted] 364	-	20[redacted] 364	ADVERSE EVENT	1 g	QD INTRAVENOUS	1
CEFEPIME (CEFEPIME)	20[redacted] 440	-	20[redacted] 441	ADVERSE EVENT	1.5 g	BID INTRAVENOUS	5
CEFEPIME (CEFEPIME)	20[redacted] 442	-	20[redacted] 450	ADVERSE EVENT	2 g	BID INTRAVENOUS	5
CEFEPIME (CEFEPIME)	20[redacted] 442	-	20[redacted] 450	ADVERSE EVENT	2 g	BID INTRAVENOUS	6
CLOBETASOL PROPIONATE (CLOBETASOL PROPIONATE)	20[redacted] 267	-	- -	CGVHD	- OTHER	PRN TOPICAL	-
DEXAMETHASONE (DEXALTIN)	20[redacted] 323	-	- -	CGVHD	- OTHER	PRN TOPICAL	-
FEBUXOSTAT (FEBURIC)	20[redacted] 169	-	20[redacted] 434	MEDICAL HISTORY	10 mg	QD ORAL	-
FEBUXOSTAT (FEBURIC)	20[redacted] 435	-	- -	MEDICAL HISTORY	20 mg	QD ORAL	-
FLUCONAZOLE (FLUCONAZOLE)	- -	Y	20[redacted] 276	PROPHYLAXIS	400 mg	QD ORAL	-
FLUCONAZOLE (FLUCONAZOLE)	20[redacted] 277	-	- -	PROPHYLAXIS	200 mg	QD ORAL	-
GENTAMICIN SULFATE (GENTAMICIN SULFATE)	20[redacted] 127	-	20[redacted] 145	ADVERSE EVENT	- OTHER	PRN TOPICAL	1
HEPARINOID (HEPARINOID OIL-BASED CREAM)	- -	Y	- -	CGVHD	- OTHER	PRN TOPICAL	-
MUCOPOLYSACCHARIDE POLYSULFURIC ACID ESTER (HIRUDOID LOTION)	- -	Y	20[redacted] 84	CGVHD	- OTHER	PRN TOPICAL	-
INSULIN HUMAN (HUMULIN R)	20[redacted] 277	-	20[redacted] 286	MEDICAL HISTORY	4 U	BID SUBCUTANEOUS	-
INSULIN HUMAN (HUMULIN R)	20[redacted] 441	-	20[redacted] 441	MEDICAL HISTORY	12 U	ONCE SUBCUTANEOUS	-
INSULIN HUMAN (HUMULIN R)	20[redacted] 442	-	20[redacted] 442	MEDICAL HISTORY	8 U	BID SUBCUTANEOUS	-

Standardized Medication Name Reported Name of Drug, Med, or Therapy	Start Date of Medication Study Day of Start of Medication	Started Before Informed Concent Date	End Date of Medication Study Day of End of Medication	Indication	Dose per Administration Dose Units	Dosing Frequency per Interval Route of Administration	AE Sequence Number(s)
HYALURONATE SODIUM (HYALEIN)	- -	Y	- -	PROPHYLAXIS	- OTHER	PRN OPHTHALMIC	-
INFLUENZA VACCINE (INFLUENZA HA VACCINE)	20[redacted] 393	-	20[redacted] 393	PROPHYLAXIS	0.5 mL	ONCE SUBCUTANEOUS	-
PIRENOXINE (KARY UNI)	20[redacted] 43	-	20[redacted] 168	MEDICAL HISTORY	1 gtt	QID OPHTHALMIC	-
PIRENOXINE (KARY UNI)	20[redacted] 169	-	- -	ADVERSE EVENT	1 gtt	QID OPHTHALMIC	9
CEFALEXIN (L-KEFLEX)	20[redacted] 366	-	20[redacted] 366	ADVERSE EVENT	500 mg	QD ORAL	1
CEFALEXIN (L-KEFLEX)	20[redacted] 367	-	20[redacted] 382	ADVERSE EVENT	500 mg	TID ORAL	1
CEFALEXIN (L-KEFLEX)	20[redacted] 451	-	20[redacted] 451	ADVERSE EVENT	500 mg	QD ORAL	6
CEFALEXIN (L-KEFLEX)	20[redacted] 452	-	- -	ADVERSE EVENT	500 mg	BID ORAL	6
INSULIN GLARGINE (LANTUS)	20[redacted] 277	-	20[redacted] 285	MEDICAL HISTORY	- U	QD SUBCUTANEOUS	-
LATANOPROST (LATANOPROST)	20[redacted] 366	-	- -	PROPHYLAXIS	1 gtt	QD OPHTHALMIC	-
LEVOFLOXACIN (LEVOFLOXACIN)	- -	Y	20[redacted] 29	PROPHYLAXIS	500 mg	QD ORAL	-
HYDROCORTISONE BUTYRATE (LOCOID(HYDROCORTISONE BUTYRATE))	20[redacted] 71	-	- -	CGVHD	- OTHER	PRN TOPICAL	-
LORAZEPAM (LORAZEPAM)	20[redacted] 268	-	20[redacted] 350	ADVERSE EVENT	0.5 mg	PRN ORAL	2
LORAZEPAM (LORAZEPAM)	20[redacted] 351	-	20[redacted] 435	ADVERSE EVENT	1 mg	QD ORAL	8
LORAZEPAM (LORAZEPAM)	20[redacted] 421	-	- -	ADVERSE EVENT	0.5 mg	PRN ORAL	8
LORAZEPAM (LORAZEPAM)	20[redacted] 436	-	- -	ADVERSE EVENT	1 mg	BID ORAL	8

Standardized Medication Name Reported Name of Drug, Med, or Therapy	Start Date of Medication Study Day of Start of Medication	Started Before Informed Concent Date	End Date of Medication Study Day of End of Medication	Indication	Dose per Administration Dose Units	Dosing Frequency per Interval Route of Administration	AE Sequence Number(s)
OMEGA-3-ACID ETHYL ESTER (LOTRIGA)	20[redacted] 86	-	20[redacted] 276	MEDICAL HISTORY	2 g	QD ORAL	-
OMEGA-3-ACID ETHYL ESTER (LOTRIGA)	20[redacted] 297	-	- -	MEDICAL HISTORY	2 g	QD ORAL	-
MAGNESIUM OXIDE (MAGNESIUM OXIDE TABLETS)	- -	Y	20[redacted] 35	PROPHYLAXIS	660 mg	QD ORAL	-
MAGNESIUM OXIDE (MAGNESIUM OXIDE TABLETS)	20[redacted] 43	-	20[redacted] 276	PROPHYLAXIS	330 mg	QOD ORAL	-
MEROPENEM (MEROPENEM)	20[redacted] 277	-	20[redacted] 277	ADVERSE EVENT	1 g	BID INTRAVENOUS	4
MEROPENEM (MEROPENEM)	20[redacted] 278	-	20[redacted] 281	ADVERSE EVENT	1 g	TID INTRAVENOUS	4
MEROPENEM (MEROPENEM)	20[redacted] 282	-	20[redacted] 282	ADVERSE EVENT	1 g	BID INTRAVENOUS	4
MIRTAZAPINE (MIRTAZAPINE)	20[redacted] 351	-	- -	ADVERSE EVENT	15 mg	QD ORAL	8
MIRTAZAPINE (MIRTAZAPINE)	20[redacted] 351	-	- -	ADVERSE EVENT	15 mg	QD ORAL	2
CLOSTRIDIUM BUTYRICUM (MIYA-BM)	20[redacted] 113	-	20[redacted] 276	PROPHYLAXIS	1 g	TID ORAL	-
CLOSTRIDIUM BUTYRICUM (MIYA-BM)	20[redacted] 297	-	- -	PROPHYLAXIS	1 g	TID ORAL	-
CYSTEINE; GLYCINE; GLYCYRRHIZIC ACID (NEOPHAGEN(MONOAMMONIUM GLYCYRRHIZINAT GLYCINE L-CYSTEINE))	20[redacted] 284	-	20[redacted] 293	ADVERSE EVENT	100 mL	QD INTRAVENOUS	2
DIFLUCORTOLONE VALERATE (NERISONA UNIVERSAL CREAM)	20[redacted] 85	-	- -	CGVHD	- OTHER	PRN TOPICAL	-
ROTIGOTINE (NEUPRO PATCH)	20[redacted] 372	-	20[redacted] 421	ADVERSE EVENT	2.25 mg	QD TRANSDERMAL	2
ESOMEPRAZOLE MAGNESIUM (NEXIUM)	- -	Y	- -	PROPHYLAXIS	20 mg	QD ORAL	-

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Standardized Medication Name Reported Name of Drug, Med, or Therapy	Start Date of Medication Study Day of Start of Medication	Started Before Informed Concent Date	End Date of Medication Study Day of End of Medication	Indication	Dose per Administration Dose Units	Dosing Frequency per Interval Route of Administration	AE Sequence Number(s)
NOREPINEPHRINE (NORADRENALINE)	20[redacted] 277	-	20[redacted] 278	ADVERSE EVENT	- mg	QD INTRAVENOUS	4
INSULIN ASPART (NOVORAPID)	- -	Y	20[redacted] -2	MEDICAL HISTORY	- U	QOD SUBCUTANEOUS	-
INSULIN ASPART (NOVORAPID)	- -	Y	20[redacted] -1	MEDICAL HISTORY	- U	QOD SUBCUTANEOUS	-
INSULIN ASPART (NOVORAPID)	20[redacted] -1	-	20[redacted] 14	MEDICAL HISTORY	- U	QOD SUBCUTANEOUS	-
INSULIN ASPART (NOVORAPID)	20[redacted] 1	-	20[redacted] 15	MEDICAL HISTORY	- U	QOD SUBCUTANEOUS	-
INSULIN ASPART (NOVORAPID)	20[redacted] 15	-	20[redacted] 275	MEDICAL HISTORY	- U	QOD SUBCUTANEOUS	-
INSULIN ASPART (NOVORAPID)	20[redacted] 16	-	20[redacted] 276	MEDICAL HISTORY	- U	QOD SUBCUTANEOUS	-
INSULIN ASPART (NOVORAPID)	20[redacted] 286	-	20[redacted] 294	MEDICAL HISTORY	- U	TID SUBCUTANEOUS	-
INSULIN ASPART (NOVORAPID)	20[redacted] 295	-	20[redacted] 301	MEDICAL HISTORY	- U	TID SUBCUTANEOUS	-
INSULIN ASPART (NOVORAPID)	20[redacted] 302	-	20[redacted] 308	MEDICAL HISTORY	- U	QOD SUBCUTANEOUS	-
INSULIN ASPART (NOVORAPID)	20[redacted] 303	-	20[redacted] 307	MEDICAL HISTORY	- U	QOD SUBCUTANEOUS	-
INSULIN ASPART (NOVORAPID)	20[redacted] 309	-	20[redacted] 440	MEDICAL HISTORY	- U	TID SUBCUTANEOUS	-
INSULIN ASPART (NOVORAPID)	20[redacted] 441	-	20[redacted] 441	MEDICAL HISTORY	18 U	BID SUBCUTANEOUS	-
INSULIN ASPART (NOVORAPID)	20[redacted] 443	-	20[redacted] 443	MEDICAL HISTORY	14 U	BID SUBCUTANEOUS	-
INSULIN ASPART (NOVORAPID)	20[redacted] 444	-	- -	MEDICAL HISTORY	- U	TID SUBCUTANEOUS	-
PEMAFIBRATE (PARMODIA)	20[redacted] 127	-	20[redacted] 196	MEDICAL HISTORY	0.1 mg	BID ORAL	-

Standardized Medication Name Reported Name of Drug, Med, or Therapy	Start Date of Medication Study Day of Start of Medication	Started Before Informed Concent Date	End Date of Medication Study Day of End of Medication	Indication	Dose per Administration Dose Units	Dosing Frequency per Interval Route of Administration	AE Sequence Number(s)
PEMAFIBRATE (PARMODIA)	20[redacted] 197	-	20[redacted] 276	MEDICAL HISTORY	0.2 mg	BID ORAL	-
PEMAFIBRATE (PARMODIA)	20[redacted] 297	-	- -	MEDICAL HISTORY	0.2 mg	BID ORAL	-
ALL OTHER THERAPEUTIC PRODUCTS (PLUPECECTOMY)	20[redacted] 437	-	20[redacted] 437	ADVERSE EVENT	- -	- -	7
DEXCHLORPHENIRAMINE MALEATE (POLARAMINE)	20[redacted] 281	-	20[redacted] 291	CGVHD	5 mg	PRN INTRAVENOUS	-
DEXCHLORPHENIRAMINE MALEATE (POLARAMINE)	20[redacted] 361	-	20[redacted] 366	CGVHD	5 mg	PRN INTRAVENOUS	-
DEXCHLORPHENIRAMINE MALEATE (POLARAMINE)	20[redacted] 442	-	20[redacted] 450	CGVHD	5 mg	PRN INTRAVENOUS	-
DEXCHLORPHENIRAMINE MALEATE (POLARAMINE)	20[redacted] 450	-	- -	CGVHD	2 mg	PRN ORAL	-
IMMUNOGLOBULIN HUMAN NORMAL (POLYGLOBIN N 10%)	20[redacted] 29	-	- -	OTHER	10 g	PRN INTRAVENOUS	-
PNEUMOCOCCAL VACCINE CONJ 13V (CRM197) (PREVENAR13 SUSPENSION LIQUID FOR INJECTION)	20[redacted] 337	-	20[redacted] 337	PROPHYLAXIS	0.5 mL	ONCE SUBCUTANEOUS	-
PNEUMOCOCCAL VACCINE CONJ 13V (CRM197) (PREVENAR13 SUSPENSION LIQUID FOR INJECTION)	20[redacted] 393	-	20[redacted] 393	PROPHYLAXIS	0.5 mL	ONCE SUBCUTANEOUS	-
PNEUMOCOCCAL VACCINE CONJ 13V (CRM197) (PREVENAR13 SUSPENSION LIQUID FOR INJECTION)	20[redacted] 421	-	20[redacted] 421	PROPHYLAXIS	0.5 mL	ONCE SUBCUTANEOUS	-
METOCLOPRAMIDE HYDROCHLORIDE (PRIMPERAN)	20[redacted] 277	-	20[redacted] 277	ADVERSE EVENT	10 mg	ONCE INTRAVENOUS	1
WHITE SOFT PARAFFIN (PROPETO)	20[redacted] 71	-	- -	OTHER	- OTHER	PRN TOPICAL	-

Standardized Medication Name Reported Name of Drug, Med, or Therapy	Start Date of Medication Study Day of Start of Medication	Started Before Informed Concent Date	End Date of Medication Study Day of End of Medication	Indication	Dose per Administration Dose Units	Dosing Frequency per Interval Route of Administration	AE Sequence Number(s)
TACROLIMUS (PROTOPIC)	20[redacted] 267	-	- -	CGVHD	- OTHER	PRN TOPICAL	-
DIPHENHYDRAMINE (RESTAMIN)	20[redacted] 280	-	- -	CGVHD	- OTHER	PRN TOPICAL	-
BETAMETHASONE VALERATE (RINDERON-V LOTION)	20[redacted] 323	-	- -	CGVHD	- OTHER	PRN TOPICAL	-
BETAMETHASONE VALERATE (RINDERON-V OINTMENT)	20[redacted] 323	-	- -	CGVHD	- OTHER	PRN TOPICAL	-
RISEDRONATE SODIUM (RISEDORONATE NA)	20[redacted] 37	-	20[redacted] 275	PROPHYLAXIS	17.5 mg	EVERY WEEK ORAL	-
RISEDRONATE SODIUM (RISEDRONATE)	20[redacted] 297	-	- -	PROPHYLAXIS	17.5 mg	EVERY WEEK ORAL	-
CLONAZEPAM (RIVOTRIL)	20[redacted] 367	-	20[redacted] 371	ADVERSE EVENT	0.5 mg	PRN ORAL	2
RETINOL (SAHNE)	20[redacted] 139	-	- -	PROPHYLAXIS	- OTHER	PRN TOPICAL	-
BECLOMETASONE DIPROPIONATE (SALCOAT)	20[redacted] 372	-	- -	CGVHD	50 ug	QD TOPICAL	-
FLUOCINONIDE (TOPSYM)	- -	Y	20[redacted] 70	CGVHD	- OTHER	PRN TOPICAL	-
LINAGLIPTIN (TRAZENTA)	- -	Y	20[redacted] 276	MEDICAL HISTORY	5 mg	QD ORAL	-
LINAGLIPTIN (TRAZENTA)	20[redacted] 302	-	- -	MEDICAL HISTORY	5 mg	QD ORAL	-
TRAZODONE (TRAZODONE)	20[redacted] -1	-	20[redacted] 371	MEDICAL HISTORY	25 mg	PRN ORAL	-
TRAZODONE (TRAZODONE)	20[redacted] 442	-	- -	MEDICAL HISTORY	50 mg	QD ORAL	-
INSULIN DEGLUDEC (TRESIBA)	- -	Y	20[redacted] 183	MEDICAL HISTORY	20 U	QD SUBCUTANEOUS	-
INSULIN DEGLUDEC (TRESIBA)	20[redacted] 184	-	20[redacted] 276	MEDICAL HISTORY	16 U	QD SUBCUTANEOUS	-

Standardized Medication Name Reported Name of Drug, Med, or Therapy	Start Date of Medication Study Day of Start of Medication	Started Before Informed Concent Date	End Date of Medication Study Day of End of Medication	Indication	Dose per Administration Dose Units	Dosing Frequency per Interval Route of Administration	AE Sequence Number(s)
INSULIN DEGLUDEC (TRESIBA)	20[redacted] 286	-	20[redacted] 293	MEDICAL HISTORY	4 U	QD SUBCUTANEOUS	-
INSULIN DEGLUDEC (TRESIBA)	20[redacted] 294	-	20[redacted] 301	MEDICAL HISTORY	8 U	QD SUBCUTANEOUS	-
INSULIN DEGLUDEC (TRESIBA)	20[redacted] 302	-	20[redacted] 364	MEDICAL HISTORY	12 U	QD SUBCUTANEOUS	-
INSULIN DEGLUDEC (TRESIBA)	20[redacted] 365	-	- -	MEDICAL HISTORY	8 U	QD SUBCUTANEOUS	-
URSODEOXYCHOLIC ACID (URSODEOXYCHOLIC ACID)	20[redacted] 29	-	20[redacted] 276	ADVERSE EVENT	200 mg	TID ORAL	2
URSODEOXYCHOLIC ACID (URSODEOXYCHOLIC ACID)	20[redacted] 29	-	20[redacted] 276	ADVERSE EVENT	200 mg	TID ORAL	2
URSODEOXYCHOLIC ACID (URSODEOXYCHOLIC ACID)	20[redacted] 29	-	20[redacted] 276	ADVERSE EVENT	200 mg	TID ORAL	2
URSODEOXYCHOLIC ACID (URSODEOXYCHOLIC ACID)	20[redacted] 29	-	20[redacted] 276	ADVERSE EVENT	200 mg	TID ORAL	2
URSODEOXYCHOLIC ACID (URSODEOXYCHOLIC ACID)	20[redacted] 297	-	20[redacted] 309	ADVERSE EVENT	200 mg	TID ORAL	2
URSODEOXYCHOLIC ACID (URSODEOXYCHOLIC ACID)	20[redacted] 297	-	20[redacted] 309	ADVERSE EVENT	200 mg	TID ORAL	2
URSODEOXYCHOLIC ACID (URSODEOXYCHOLIC ACID)	20[redacted] 310	-	- -	MEDICAL HISTORY	200 mg	TID ORAL	-
SALBUTAMOL SULFATE (VENETLIN)	20[redacted] 29	-	- -	OTHER	0.3 mL	EVERY 4 WEEKS RESPIRATORY (INHALATION)	-
EPINEPHRINE; LIDOCAINE HYDROCHLORIDE (XYLOCAINE(EPINEPHRINE LIDOCAINE HYDROCHLORIDE)	20[redacted] 437	-	- -	ADVERSE EVENT	1.8 mL	PRN TOPICAL	7
ZOLPIDEM (ZOLPIDEM)	- -	Y	20[redacted] -2	MEDICAL HISTORY	10 mg	QD ORAL	-
ZOLPIDEM (ZOLPIDEM)	20[redacted] 3	-	- -	MEDICAL HISTORY	10 mg	QD ORAL	-

■ Karnofsky/Lansky performance status score

Date of Finding Study Day of Finding	Visit Name	Result
20[redacted] -19	SCREENING	70
20[redacted] 1	WEEK 1 DAY 1	70
20[redacted] 29	WEEK 5	70
20[redacted] 57	WEEK 9	70
20[redacted] 85	WEEK 13	70
20[redacted] 113	WEEK 17	70
20[redacted] 139	WEEK 21	70
20[redacted] 169	WEEK 25	80
20[redacted] 253	WEEK 37	70
20[redacted] 337	WEEK 49	70
20[redacted] 421	WEEK 61	70

■ Laboratory Data

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Alanine Aminotransferase (Enzyme U/L)	20[redacted] -19	SCREENING	96	5	40	HIGH	1
Alanine Aminotransferase (Enzyme U/L)	20[redacted] -2	WEEK 1 DAY 1	86	5	40	HIGH	1
Alanine Aminotransferase (Enzyme U/L)	20[redacted] 8	WEEK 2	62	5	40	HIGH	1

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Alanine Aminotransferase (Enzyme U/L)	20[redacted] 29	WEEK 5	132	5	40	HIGH	2
Alanine Aminotransferase (Enzyme U/L)	20[redacted] 50	WEEK 5 UNSCHEDULED 01	117	7	23	HIGH	3
Alanine Aminotransferase (Enzyme U/L)	20[redacted] 57	WEEK 9	133	7	23	HIGH	3
Alanine Aminotransferase (Enzyme U/L)	20[redacted] 85	WEEK 13	104	7	23	HIGH	2
Alanine Aminotransferase (Enzyme U/L)	20[redacted] 113	WEEK 17	102	7	23	HIGH	2
Alanine Aminotransferase (Enzyme U/L)	20[redacted] 139	WEEK 21	56	7	23	HIGH	1
Alanine Aminotransferase (Enzyme U/L)	20[redacted] 169	WEEK 25	64	7	23	HIGH	1
Alanine Aminotransferase (Enzyme U/L)	20[redacted] 197	WEEK 25 UNSCHEDULED 01	73	7	23	HIGH	2
Alanine Aminotransferase (Enzyme U/L)	20[redacted] 253	WEEK 37	75	7	23	HIGH	2
Alanine Aminotransferase (Enzyme U/L)	20[redacted] 284	WEEK 37 UNSCHEDULED 01	131	7	23	HIGH	3
Alanine Aminotransferase (Enzyme U/L)	20[redacted] 302	WEEK 37 UNSCHEDULED 02	95	7	23	HIGH	2
Alanine Aminotransferase (Enzyme U/L)	20[redacted] 309	WEEK 37 UNSCHEDULED 03	66	7	23	HIGH	1
Alanine Aminotransferase (Enzyme U/L)	20[redacted] 337	WEEK 49	62	7	23	HIGH	1
Alanine Aminotransferase (Enzyme U/L)	20[redacted] 421	WEEK 61	56	7	23	HIGH	1
Albumin (g/L)	20[redacted] -19	SCREENING	43	38	52	NORMAL	0
Albumin (g/L)	20[redacted] -2	WEEK 1 DAY 1	44	38	52	NORMAL	0
Albumin (g/L)	20[redacted] 8	WEEK 2	38	38	52	NORMAL	0

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Albumin (g/L)	20[redacted] 29	WEEK 5	43	38	52	NORMAL	0
Albumin (g/L)	20[redacted] 57	WEEK 9	43	41	51	NORMAL	0
Albumin (g/L)	20[redacted] 85	WEEK 13	43	41	51	NORMAL	0
Albumin (g/L)	20[redacted] 113	WEEK 17	43	41	51	NORMAL	0
Albumin (g/L)	20[redacted] 139	WEEK 21	44	41	51	NORMAL	0
Albumin (g/L)	20[redacted] 169	WEEK 25	45	41	51	NORMAL	0
Albumin (g/L)	20[redacted] 253	WEEK 37	43	41	51	NORMAL	0
Albumin (g/L)	20[redacted] 337	WEEK 49	43	41	51	NORMAL	0
Albumin (g/L)	20[redacted] 421	WEEK 61	44	41	51	NORMAL	0
Alkaline Phosphatase (Enzyme U/L)	20[redacted] -19	SCREENING	215	115	359	NORMAL	0
Alkaline Phosphatase (Enzyme U/L)	20[redacted] -2	WEEK 1 DAY 1	216	115	359	NORMAL	0
Alkaline Phosphatase (Enzyme U/L)	20[redacted] 8	WEEK 2	154	115	359	NORMAL	0
Alkaline Phosphatase (Enzyme U/L)	20[redacted] 29	WEEK 5	193	115	359	NORMAL	0
Alkaline Phosphatase (Enzyme U/L)	20[redacted] 57	WEEK 9	191	106	322	NORMAL	0
Alkaline Phosphatase (Enzyme U/L)	20[redacted] 85	WEEK 13	180	106	322	NORMAL	0
Alkaline Phosphatase (Enzyme U/L)	20[redacted] 113	WEEK 17	222	106	322	NORMAL	0
Alkaline Phosphatase (Enzyme U/L)	20[redacted] 139	WEEK 21	121	106	322	NORMAL	0

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Alkaline Phosphatase (Enzyme U/L)	20[redacted] 169	WEEK 25	111	106	322	NORMAL	0
Alkaline Phosphatase (Enzyme U/L)	20[redacted] 253	WEEK 37	135	106	322	NORMAL	0
Alkaline Phosphatase (Enzyme U/L)	20[redacted] 337	WEEK 49	139	106	322	NORMAL	0
Alkaline Phosphatase (Enzyme U/L)	20[redacted] 421	WEEK 61	123	106	322	NORMAL	0
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] -19	SCREENING	42	10	40	HIGH	1
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] -2	WEEK 1 DAY 1	35	10	40	NORMAL	0
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] 8	WEEK 2	28	10	40	NORMAL	0
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] 29	WEEK 5	57	10	40	HIGH	1
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] 57	WEEK 9	47	13	30	HIGH	1
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] 85	WEEK 13	38	13	30	HIGH	1
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] 113	WEEK 17	40	13	30	HIGH	1
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] 139	WEEK 21	25	13	30	NORMAL	0
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] 169	WEEK 25	32	13	30	HIGH	1
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] 253	WEEK 37	32	13	30	HIGH	1
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] 337	WEEK 49	28	13	30	NORMAL	0
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] 421	WEEK 61	27	13	30	NORMAL	0
Bilirubin (umol/L)	20[redacted] -19	SCREENING	11.97	5.13	20.52	NORMAL	0

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Bilirubin (umol/L)	20[redacted] -2	WEEK 1 DAY 1	10.26	5.13	20.52	NORMAL	0
Bilirubin (umol/L)	20[redacted] 8	WEEK 2	10.26	5.13	20.52	NORMAL	0
Bilirubin (umol/L)	20[redacted] 29	WEEK 5	10.26	5.13	20.52	NORMAL	0
Bilirubin (umol/L)	20[redacted] 57	WEEK 9	10.26	6.84	25.65	NORMAL	0
Bilirubin (umol/L)	20[redacted] 85	WEEK 13	8.55	6.84	25.65	NORMAL	0
Bilirubin (umol/L)	20[redacted] 113	WEEK 17	10.26	6.84	25.65	NORMAL	0
Bilirubin (umol/L)	20[redacted] 139	WEEK 21	8.55	6.84	25.65	NORMAL	0
Bilirubin (umol/L)	20[redacted] 169	WEEK 25	10.26	6.84	25.65	NORMAL	0
Bilirubin (umol/L)	20[redacted] 253	WEEK 37	8.55	6.84	25.65	NORMAL	0
Bilirubin (umol/L)	20[redacted] 337	WEEK 49	8.55	6.84	25.65	NORMAL	0
Bilirubin (umol/L)	20[redacted] 421	WEEK 61	10.26	6.84	25.65	NORMAL	0
Creatinine (umol/L)	20[redacted] -19	SCREENING	71.604	44.2	70.72	HIGH	1
Creatinine (umol/L)	20[redacted] -2	WEEK 1 DAY 1	81.328	44.2	70.72	HIGH	1
Creatinine (umol/L)	20[redacted] 8	WEEK 2	87.516	44.2	70.72	HIGH	1
Creatinine (umol/L)	20[redacted] 29	WEEK 5	78.676	44.2	70.72	HIGH	1
Creatinine (umol/L)	20[redacted] 57	WEEK 9	87.516	40.664	69.836	HIGH	1
Creatinine (umol/L)	20[redacted] 85	WEEK 13	85.748	40.664	69.836	HIGH	1

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Creatinine (umol/L)	20[redacted] 113	WEEK 17	89.284	40.664	69.836	HIGH	1
Creatinine (umol/L)	20[redacted] 139	WEEK 21	99.008	40.664	69.836	HIGH	1
Creatinine (umol/L)	20[redacted] 169	WEEK 25	99.008	40.664	69.836	HIGH	1
Creatinine (umol/L)	20[redacted] 253	WEEK 37	97.24	40.664	69.836	HIGH	1
Creatinine (umol/L)	20[redacted] 337	WEEK 49	97.24	40.664	69.836	HIGH	1
Creatinine (umol/L)	20[redacted] 421	WEEK 61	89.284	40.664	69.836	HIGH	1
Eosinophils (10^9/L)	20[redacted] -19	SCREENING	0.057	0.033	0.684	NORMAL	-
Eosinophils (10^9/L)	20[redacted] -2	WEEK 1 DAY 1	0.113	0.033	0.684	NORMAL	-
Eosinophils (10^9/L)	20[redacted] 8	WEEK 2	0.42	0.033	0.684	NORMAL	-
Eosinophils (10^9/L)	20[redacted] 29	WEEK 5	0	0.033	0.684	LOW	-
Eosinophils (10^9/L)	20[redacted] 57	WEEK 9	0	0	0.731	NORMAL	-
Eosinophils (10^9/L)	20[redacted] 85	WEEK 13	0	0	0.731	NORMAL	-
Eosinophils (10^9/L)	20[redacted] 113	WEEK 17	0	0	0.731	NORMAL	-
Eosinophils (10^9/L)	20[redacted] 139	WEEK 21	0.765	0	0.731	HIGH	-
Eosinophils (10^9/L)	20[redacted] 169	WEEK 25	0	0	0.731	NORMAL	-
Eosinophils (10^9/L)	20[redacted] 253	WEEK 37	0.156	0	0.731	NORMAL	-
Eosinophils (10^9/L)	20[redacted] 337	WEEK 49	0.078	0	0.731	NORMAL	-

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Eosinophils (10^9/L)	20[redacted] 421	WEEK 61	0	0	0.731	NORMAL	-
Glucose (mmol/L)	20[redacted] -19	SCREENING	5.1069	3.8857	6.0506	NORMAL	0
Glucose (mmol/L)	20[redacted] -2	WEEK 1 DAY 1	9.2702	3.8857	6.0506	HIGH	2
Glucose (mmol/L)	20[redacted] 8	WEEK 2	4.3298	3.8857	6.0506	NORMAL	0
Glucose (mmol/L)	20[redacted] 29	WEEK 5	7.6604	3.8857	6.0506	HIGH	1
Glucose (mmol/L)	20[redacted] 57	WEEK 9	7.9934	4.0522	6.0506	HIGH	1
Glucose (mmol/L)	20[redacted] 85	WEEK 13	8.2155	4.0522	6.0506	HIGH	1
Glucose (mmol/L)	20[redacted] 113	WEEK 17	7.5494	4.0522	6.0506	HIGH	1
Glucose (mmol/L)	20[redacted] 139	WEEK 21	6.6057	4.0522	6.0506	HIGH	1
Glucose (mmol/L)	20[redacted] 169	WEEK 25	5.0514	4.0522	6.0506	NORMAL	0
Glucose (mmol/L)	20[redacted] 253	WEEK 37	6.1616	4.0522	6.0506	HIGH	1
Glucose (mmol/L)	20[redacted] 337	WEEK 49	5.1624	4.0522	6.0506	NORMAL	0
Glucose (mmol/L)	20[redacted] 421	WEEK 61	4.6073	4.0522	6.0506	NORMAL	0
HIV Antibody	20[redacted] -19	SCREENING	NEGATIVE	-	-	-	-
Hemoglobin (g/L)	20[redacted] -19	SCREENING	131	118	146	NORMAL	0
Hemoglobin (g/L)	20[redacted] -2	WEEK 1 DAY 1	134	118	146	NORMAL	0
Hemoglobin (g/L)	20[redacted] 8	WEEK 2	131	118	146	NORMAL	0

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Hemoglobin (g/L)	20[redacted] 29	WEEK 5	139	118	146	NORMAL	0
Hemoglobin (g/L)	20[redacted] 57	WEEK 9	140	116	148	NORMAL	0
Hemoglobin (g/L)	20[redacted] 85	WEEK 13	138	116	148	NORMAL	0
Hemoglobin (g/L)	20[redacted] 113	WEEK 17	145	116	148	NORMAL	0
Hemoglobin (g/L)	20[redacted] 139	WEEK 21	142	116	148	NORMAL	0
Hemoglobin (g/L)	20[redacted] 169	WEEK 25	137	116	148	NORMAL	0
Hemoglobin (g/L)	20[redacted] 253	WEEK 37	139	116	148	NORMAL	0
Hemoglobin (g/L)	20[redacted] 337	WEEK 49	133	116	148	NORMAL	0
Hemoglobin (g/L)	20[redacted] 421	WEEK 61	131	116	148	NORMAL	0
Hepatitis B Virus Core Antibody	20[redacted] -19	SCREENING	NEGATIVE	-	-	-	-
Hepatitis B Virus Surface Antibody	20[redacted] -19	SCREENING	NEGATIVE	-	-	-	-
Hepatitis B Virus Surface Antigen	20[redacted] -19	SCREENING	NEGATIVE	-	-	-	-
Hepatitis C Virus Antibody	20[redacted] -19	SCREENING	NEGATIVE	-	-	-	-
Immunoglobulin A (g/L)	20[redacted] -19	SCREENING	0.13	-	-	-	-
Immunoglobulin A (g/L)	20[redacted] 85	WEEK 13	0.14	-	-	-	-
Immunoglobulin A (g/L)	20[redacted] 169	WEEK 25	0.13	-	-	-	-
Immunoglobulin A (g/L)	20[redacted] 253	WEEK 37	0.12	-	-	-	-

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Immunoglobulin A (g/L)	20[redacted] 337	WEEK 49	0.14	-	-	-	-
Immunoglobulin A (g/L)	20[redacted] 421	WEEK 61	0.13	-	-	-	-
Immunoglobulin G (g/L)	20[redacted] -19	SCREENING	1.4	-	-	-	-
Immunoglobulin G (g/L)	20[redacted] 85	WEEK 13	4.83	-	-	-	-
Immunoglobulin G (g/L)	20[redacted] 169	WEEK 25	3.82	-	-	-	-
Immunoglobulin G (g/L)	20[redacted] 253	WEEK 37	4.52	-	-	-	-
Immunoglobulin G (g/L)	20[redacted] 337	WEEK 49	4.69	-	-	-	-
Immunoglobulin G (g/L)	20[redacted] 421	WEEK 61	4.47	-	-	-	-
Immunoglobulin M (g/L)	20[redacted] -19	SCREENING	0.09	-	-	-	-
Immunoglobulin M (g/L)	20[redacted] 85	WEEK 13	0.11	-	-	-	-
Immunoglobulin M (g/L)	20[redacted] 169	WEEK 25	0.08	-	-	-	-
Immunoglobulin M (g/L)	20[redacted] 253	WEEK 37	0.09	-	-	-	-
Immunoglobulin M (g/L)	20[redacted] 337	WEEK 49	0.08	-	-	-	-
Immunoglobulin M (g/L)	20[redacted] 421	WEEK 61	0.08	-	-	-	-
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] -19	SCREENING	554	115	245	HIGH	-
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] -2	WEEK 1 DAY 1	524	115	245	HIGH	-
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] 8	WEEK 2	410	115	245	HIGH	-

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] 29	WEEK 5	647	115	245	HIGH	-
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] 57	WEEK 9	568	124	222	HIGH	-
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] 85	WEEK 13	560	124	222	HIGH	-
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] 113	WEEK 17	535	124	222	HIGH	-
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] 139	WEEK 21	478	124	222	HIGH	-
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] 169	WEEK 25	488	124	222	HIGH	-
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] 253	WEEK 37	399	124	222	HIGH	-
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] 337	WEEK 49	338	124	222	HIGH	-
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] 421	WEEK 61	359	124	222	HIGH	-
Leukocytes (10^9/L)	20[redacted] -19	SCREENING	11.4	3.3	7.6	HIGH	0
Leukocytes (10^9/L)	20[redacted] -2	WEEK 1 DAY 1	11.3	3.3	7.6	HIGH	0
Leukocytes (10^9/L)	20[redacted] 8	WEEK 2	8.4	3.3	7.6	HIGH	0
Leukocytes (10^9/L)	20[redacted] 29	WEEK 5	13.9	3.3	7.6	HIGH	0
Leukocytes (10^9/L)	20[redacted] 57	WEEK 9	14	3.3	8.6	HIGH	0
Leukocytes (10^9/L)	20[redacted] 85	WEEK 13	12.7	3.3	8.6	HIGH	0
Leukocytes (10^9/L)	20[redacted] 113	WEEK 17	13.4	3.3	8.6	HIGH	0
Leukocytes (10^9/L)	20[redacted] 139	WEEK 21	15.3	3.3	8.6	HIGH	0

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Leukocytes (10^9/L)	20[redacted] 169	WEEK 25	13.5	3.3	8.6	HIGH	0
Leukocytes (10^9/L)	20[redacted] 253	WEEK 37	15.6	3.3	8.6	HIGH	0
Leukocytes (10^9/L)	20[redacted] 337	WEEK 49	15.6	3.3	8.6	HIGH	0
Leukocytes (10^9/L)	20[redacted] 421	WEEK 61	16	3.3	8.6	HIGH	0
Lymphocytes (10^9/L)	20[redacted] -19	SCREENING	5.187	0.66	4.18	HIGH	2
Lymphocytes (10^9/L)	20[redacted] -2	WEEK 1 DAY 1	5.198	0.66	4.18	HIGH	2
Lymphocytes (10^9/L)	20[redacted] 8	WEEK 2	3.654	0.66	4.18	NORMAL	0
Lymphocytes (10^9/L)	20[redacted] 29	WEEK 5	5.421	0.66	4.18	HIGH	2
Lymphocytes (10^9/L)	20[redacted] 57	WEEK 9	6.44	0.545	4.257	HIGH	2
Lymphocytes (10^9/L)	20[redacted] 85	WEEK 13	6.033	0.545	4.257	HIGH	2
Lymphocytes (10^9/L)	20[redacted] 113	WEEK 17	6.834	0.545	4.257	HIGH	2
Lymphocytes (10^9/L)	20[redacted] 139	WEEK 21	6.579	0.545	4.257	HIGH	2
Lymphocytes (10^9/L)	20[redacted] 169	WEEK 25	6.278	0.545	4.257	HIGH	2
Lymphocytes (10^9/L)	20[redacted] 253	WEEK 37	7.254	0.545	4.257	HIGH	2
Lymphocytes (10^9/L)	20[redacted] 337	WEEK 49	8.892	0.545	4.257	HIGH	2
Lymphocytes (10^9/L)	20[redacted] 421	WEEK 61	10.4	0.545	4.257	HIGH	2
Neutrophils (10^9/L)	20[redacted] -19	SCREENING	5.529	1.056	5.396	HIGH	0

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Neutrophils (10^9/L)	20[redacted] -2	WEEK 1 DAY 1	4.463	1.056	5.396	NORMAL	0
Neutrophils (10^9/L)	20[redacted] 8	WEEK 2	3.738	1.056	5.396	NORMAL	0
Neutrophils (10^9/L)	20[redacted] 29	WEEK 5	7.02	1.056	5.396	HIGH	0
Neutrophils (10^9/L)	20[redacted] 57	WEEK 9	5.74	1.271	6.923	NORMAL	0
Neutrophils (10^9/L)	20[redacted] 85	WEEK 13	5.652	1.271	6.923	NORMAL	0
Neutrophils (10^9/L)	20[redacted] 113	WEEK 17	5.36	1.271	6.923	NORMAL	0
Neutrophils (10^9/L)	20[redacted] 139	WEEK 21	7.344	1.271	6.923	HIGH	0
Neutrophils (10^9/L)	20[redacted] 169	WEEK 25	6.075	1.271	6.923	NORMAL	0
Neutrophils (10^9/L)	20[redacted] 253	WEEK 37	6.084	1.271	6.923	NORMAL	0
Neutrophils (10^9/L)	20[redacted] 337	WEEK 49	5.382	1.271	6.923	NORMAL	0
Neutrophils (10^9/L)	20[redacted] 421	WEEK 61	4.24	1.271	6.923	NORMAL	0
Platelets (10^9/L)	20[redacted] -19	SCREENING	132	141	315	LOW	1
Platelets (10^9/L)	20[redacted] -2	WEEK 1 DAY 1	137	141	315	LOW	1
Platelets (10^9/L)	20[redacted] 8	WEEK 2	151	141	315	NORMAL	0
Platelets (10^9/L)	20[redacted] 29	WEEK 5	194	141	315	NORMAL	0
Platelets (10^9/L)	20[redacted] 57	WEEK 9	190	158	348	NORMAL	0
Platelets (10^9/L)	20[redacted] 85	WEEK 13	199	158	348	NORMAL	0

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Platelets (10^9/L)	20[redacted] 113	WEEK 17	205	158	348	NORMAL	0
Platelets (10^9/L)	20[redacted] 139	WEEK 21	231	158	348	NORMAL	0
Platelets (10^9/L)	20[redacted] 169	WEEK 25	226	158	348	NORMAL	0
Platelets (10^9/L)	20[redacted] 253	WEEK 37	251	158	348	NORMAL	0
Platelets (10^9/L)	20[redacted] 337	WEEK 49	267	158	348	NORMAL	0
Platelets (10^9/L)	20[redacted] 421	WEEK 61	247	158	348	NORMAL	0
Potassium (mmol/L)	20[redacted] -19	SCREENING	3.7	3.6	5	NORMAL	0
Potassium (mmol/L)	20[redacted] -2	WEEK 1 DAY 1	3.4	3.6	5	LOW	2
Potassium (mmol/L)	20[redacted] 8	WEEK 2	3.7	3.6	5	NORMAL	0
Potassium (mmol/L)	20[redacted] 29	WEEK 5	3.8	3.6	5	NORMAL	0
Potassium (mmol/L)	20[redacted] 57	WEEK 9	3.7	3.6	4.8	NORMAL	0
Potassium (mmol/L)	20[redacted] 85	WEEK 13	3.7	3.6	4.8	NORMAL	0
Potassium (mmol/L)	20[redacted] 113	WEEK 17	4	3.6	4.8	NORMAL	0
Potassium (mmol/L)	20[redacted] 139	WEEK 21	4.2	3.6	4.8	NORMAL	0
Potassium (mmol/L)	20[redacted] 169	WEEK 25	4.1	3.6	4.8	NORMAL	0
Potassium (mmol/L)	20[redacted] 253	WEEK 37	4.4	3.6	4.8	NORMAL	0
Potassium (mmol/L)	20[redacted] 337	WEEK 49	4.1	3.6	4.8	NORMAL	0

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Potassium (mmol/L)	20[redacted] 421	WEEK 61	4	3.6	4.8	NORMAL	0
Protein (g/L)	20[redacted] -19	SCREENING	58	67	83	LOW	-
Protein (g/L)	20[redacted] -2	WEEK 1 DAY 1	60	67	83	LOW	-
Protein (g/L)	20[redacted] 8	WEEK 2	52	67	83	LOW	-
Protein (g/L)	20[redacted] 29	WEEK 5	58	67	83	LOW	-
Protein (g/L)	20[redacted] 57	WEEK 9	61	66	81	LOW	-
Protein (g/L)	20[redacted] 85	WEEK 13	62	66	81	LOW	-
Protein (g/L)	20[redacted] 113	WEEK 17	64	66	81	LOW	-
Protein (g/L)	20[redacted] 139	WEEK 21	64	66	81	LOW	-
Protein (g/L)	20[redacted] 169	WEEK 25	63	66	81	LOW	-
Protein (g/L)	20[redacted] 253	WEEK 37	62	66	81	LOW	-
Protein (g/L)	20[redacted] 337	WEEK 49	61	66	81	LOW	-
Protein (g/L)	20[redacted] 421	WEEK 61	61	66	81	LOW	-
Sodium (mmol/L)	20[redacted] -19	SCREENING	141	136	147	NORMAL	0
Sodium (mmol/L)	20[redacted] -2	WEEK 1 DAY 1	143	136	147	NORMAL	0
Sodium (mmol/L)	20[redacted] 8	WEEK 2	142	136	147	NORMAL	0
Sodium (mmol/L)	20[redacted] 29	WEEK 5	140	136	147	NORMAL	0

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Sodium (mmol/L)	20[redacted] 57	WEEK 9	140	138	145	NORMAL	0
Sodium (mmol/L)	20[redacted] 85	WEEK 13	139	138	145	NORMAL	0
Sodium (mmol/L)	20[redacted] 113	WEEK 17	140	138	145	NORMAL	0
Sodium (mmol/L)	20[redacted] 139	WEEK 21	139	138	145	NORMAL	0
Sodium (mmol/L)	20[redacted] 169	WEEK 25	140	138	145	NORMAL	0
Sodium (mmol/L)	20[redacted] 253	WEEK 37	140	138	145	NORMAL	0
Sodium (mmol/L)	20[redacted] 337	WEEK 49	140	138	145	NORMAL	0
Sodium (mmol/L)	20[redacted] 421	WEEK 61	141	138	145	NORMAL	0
Urate (umol/L)	20[redacted] -19	SCREENING	380.672	148.7	416.36	NORMAL	0
Urate (umol/L)	20[redacted] -2	WEEK 1 DAY 1	362.828	148.7	416.36	NORMAL	0
Urate (umol/L)	20[redacted] 8	WEEK 2	446.1	148.7	416.36	HIGH	1
Urate (umol/L)	20[redacted] 29	WEEK 5	428.256	148.7	416.36	HIGH	1
Urate (umol/L)	20[redacted] 57	WEEK 9	499.632	154.648	327.14	HIGH	1
Urate (umol/L)	20[redacted] 85	WEEK 13	457.996	154.648	327.14	HIGH	1
Urate (umol/L)	20[redacted] 113	WEEK 17	457.996	154.648	327.14	HIGH	1
Urate (umol/L)	20[redacted] 139	WEEK 21	571.008	154.648	327.14	HIGH	1
Urate (umol/L)	20[redacted] 169	WEEK 25	386.62	154.648	327.14	HIGH	1

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Urate (umol/L)	20[redacted] 253	WEEK 37	356.88	154.648	327.14	HIGH	1
Urate (umol/L)	20[redacted] 337	WEEK 49	398.516	154.648	327.14	HIGH	1
Urate (umol/L)	20[redacted] 421	WEEK 61	404.464	154.648	327.14	HIGH	1
Urea Nitrogen (mmol/L)	20[redacted] -19	SCREENING	7.497	2.856	7.854	NORMAL	-
Urea Nitrogen (mmol/L)	20[redacted] -2	WEEK 1 DAY 1	8.211	2.856	7.854	HIGH	-
Urea Nitrogen (mmol/L)	20[redacted] 8	WEEK 2	8.211	2.856	7.854	HIGH	-
Urea Nitrogen (mmol/L)	20[redacted] 29	WEEK 5	8.211	2.856	7.854	HIGH	-
Urea Nitrogen (mmol/L)	20[redacted] 57	WEEK 9	9.639	2.856	7.14	HIGH	-
Urea Nitrogen (mmol/L)	20[redacted] 85	WEEK 13	8.568	2.856	7.14	HIGH	-
Urea Nitrogen (mmol/L)	20[redacted] 113	WEEK 17	8.925	2.856	7.14	HIGH	-
Urea Nitrogen (mmol/L)	20[redacted] 139	WEEK 21	9.996	2.856	7.14	HIGH	-
Urea Nitrogen (mmol/L)	20[redacted] 169	WEEK 25	8.568	2.856	7.14	HIGH	-
Urea Nitrogen (mmol/L)	20[redacted] 253	WEEK 37	10.353	2.856	7.14	HIGH	-
Urea Nitrogen (mmol/L)	20[redacted] 337	WEEK 49	8.211	2.856	7.14	HIGH	-
Urea Nitrogen (mmol/L)	20[redacted] 421	WEEK 61	9.282	2.856	7.14	HIGH	-

2) 被験者番号 54179060GVH3001-[redacted]

■ REASON FOR NARRATIVE SELECTION

Treatment-emergent serious adverse events (SAEs)

■ Death

No Death reported

■ Treatment-emergent serious adverse events (SAEs)

Dictionary-Derived Term	Reported Term for the Adverse Event	Start Date of Adverse Event End Date of Adverse Event	Study Day of Start of Adverse Event Adverse Event Duration (days)	Serious Event Standard Toxicity Grade	Causality Action Taken with Study Treatment	Concomitant or Additional Treatment Given Outcome of Adverse Event	Sequence Number
蜂巣炎	LEFT KNEE CELLULITIS	20[redacted] 20[redacted]	301 12	Y 3	POSSIBLE DRUG INTERRUPTED	Y RECOVERED/RESOLVED	13
腎機能障害	RENAL IMPAIRMENT	20[redacted] -	335 -	Y 3	NOT RELATED DOSE NOT CHANGED	Y NOT RECOVERED/NOT RESOLVED	17

Note: Adverse Events are coded using MedDRA 22.1

■ Adverse events (AEs) leading to ibrutinib discontinuation

No Adverse events (AEs) leading to ibrutinib discontinuation reported

■ Other malignancies

No Other malignancies reported

■ Major hemorrhage

No Major hemorrhage reported

■ Demographics, Baseline Characteristics

- Country: JPN
- Race: Asian
- Age: 1[redacted]
- Sex: Male
- Baseline height (cm): [redacted]
- Baseline weight (kg): [redacted]
- Baseline karnofsky/Lansky performance status score: 80
- Overall severity of cGVHD: Moderate
- cGVHD disease state: STEROID DEPENDENT DISEASE
- Month from initial diagnosis date: 18.9
- Number of prior cGVHD treatment regimens: 2
- First study drug intake: 20[redacted] (Study Day 1)
- Last study drug intake: 20[redacted] (Study Day 356)

■ Disposition Information

□ End of treatment: Subject Discontinued from Treatment

□ End of trial: Subject Discontinued from Study

■ Other Adverse Events

Dictionary-Derived Term	Reported Term for the Adverse Event	Start Date of Adverse Event End Date of Adverse Event	Study Day of Start of Adverse Event Adverse Event Duration (days)	Serious Event Standard Toxicity Grade	Causality Action Taken with Study Treatment	Concomitant or Additional Treatment Given Outcome of Adverse Event	Sequence Number
上気道感染	ACUTE UPPER RESPIRATORY INFECTION	20[redacted] 20	11 17	N 2	NOT RELATED DOSE NOT CHANGED	Y RECOVERED/RESOLVED	3
高血圧症	HYPERTENSION	20 20	55 84	N 1	DOUBTFUL DOSE NOT CHANGED	N RECOVERED/RESOLVED	9
皮膚乾燥	DRY SKIN	20 -	62 -	N 1	NOT RELATED DOSE NOT CHANGED	Y NOT RECOVERED/NOT RESOLVED	8
羞明	PHOTOPHOBIA	20 20	65 26	N 2	NOT RELATED DOSE NOT CHANGED	N RECOVERED/RESOLVED	15
高血圧	HYPERTENSION	20 20	139 196	N 2	DOUBTFUL DOSE NOT CHANGED	Y RECOVERED/RESOLVED	10
細気管支炎	ACUTE BRONCHIOLITIS	20 20	147 49	N 2	POSSIBLE DOSE NOT CHANGED	Y RECOVERED/RESOLVED	1
体重増加	BODY WEIGHT GAIN	20 -	195 -	N 1	NOT RELATED DOSE NOT CHANGED	N NOT RECOVERED/NOT RESOLVED	4
血中クレアチニン増加	INCREASE OF SERUM CREATININE LEVEL	20 20	247 88	N 2	NOT RELATED DOSE NOT CHANGED	N RECOVERED/RESOLVED	12
膿痂疹	IMPETIGO	20 20	265 22	N 1	POSSIBLE DOSE NOT CHANGED	Y RECOVERED/RESOLVED	11

Dictionary-Derived Term	Reported Term for the Adverse Event	Start Date of Adverse Event End Date of Adverse Event	Study Day of Start of Adverse Event Adverse Event Duration (days)	Serious Event Standard Toxicity Grade	Causality Action Taken with Study Treatment	Concomitant or Additional Treatment Given Outcome of Adverse Event	Sequence Number
細気管支炎	ACUTE BRONCHIOLITIS	20[redacted] 20[redacted]	267 34	N 2	POSSIBLE DOSE NOT CHANGED	Y RECOVERED/RESOLVED	2
蜂巣炎	LEFT KNEE CELLULITIS	20[redacted] 20[redacted]	313 5	N 1	POSSIBLE DOSE NOT CHANGED	Y RECOVERED/RESOLVED	14
高血圧	WORSENING OF HYPERTENSION	20[redacted] -	335 -	N 3	DOUBTFUL DOSE NOT CHANGED	Y NOT RECOVERED/NOT RESOLVED	18
血小板数減少	DECREASE OF PLATELET COUNT	20[redacted] 20[redacted]	335 15	N 2	NOT RELATED DOSE NOT CHANGED	N RECOVERED/RESOLVED	6
浮動性めまい	DIZZINESS	20[redacted] 20[redacted]	348 1	N 2	NOT RELATED DOSE NOT CHANGED	N RECOVERED/RESOLVED	7

Note: Adverse Events are coded using MedDRA 22.1

■ Medical History

Body System or Organ Class	Dictionary-Derived Term	Reported Term for the Medical History	End Relative to Reference Period	Toxicity Grade
Eye disorders	Cataract	CATARACTS	ONGOING	1
Immune system disorders	Hypogammaglobulinaemia	HYPOGAMMMAGLOBULINEMIA	ONGOING	1

Note: Medical History are coded using MedDRA 22.1

■ Transplant History

Transplantation Date	Dictionary-Derived Term	Transplant Type	HLA matching and donor relation to recipient	Sex matching between donor and recipient	Stem Cell Source
20[redacted]	Acute myeloid leukaemia	Myeloablative	Matched related	Unmatched	Bone Marrow
20[redacted]	Acute myeloid leukaemia	Myeloablative	Matched related	Unmatched	Peripheral Stem Cells

■ Disease History

Date of Initial Diagnosis	Initial Diagnosis
20[redacted]	CGVHD

■ Study Medication

Visit Name	Start Date of Treatment	End Date of Treatment	Study Day of Start of Treatment	Study Day of End of Treatment	Dose per Administration (mg)	Reason for Dose Skip	Reason for Dose Adjustment	AE Sequence Number(s)
WEEK 1 DAY 1	20[redacted]	20[redacted]	1	1	280.0	-	CYP3A INHIBITOR	-
WEEK 1 DAY 2	20	20	2	7	280.0	-	-	-
WEEK 2	20	20	8	27	280.0	-	-	-
WEEK 5	20	20	28	55	280.0	-	-	-
WEEK 9	20	20	56	83	280.0	-	-	-
WEEK 13	20	20	84	111	280.0	-	-	-
WEEK 17	20	20	112	139	280.0	-	-	-
WEEK 21	20	20	140	167	280.0	-	-	-
WEEK 25	20	20	168	247	280.0	-	-	-
WEEK 37	20	20	248	302	280.0	-	-	-
WEEK 37	20	20	303	312	0.0	ADVERSE EVENT	-	-
WEEK 37	20	20	313	335	280.0	-	-	-
WEEK 49	20	20	336	356	280.0	-	-	-
WEEK 49	20	20	357	371	0.0	OTHER	-	-

■ Prior and Concomitant Medications

Standardized Medication Name Reported Name of Drug, Med, or Therapy	Start Date of Medication Study Day of Start of Medication	Started Before Informed Concent Date	End Date of Medication Study Day of End of Medication	Indication	Dose per Administration Dose Units	Dosing Frequency per Interval Route of Administration	AE Sequence Number(s)
PARACETAMOL (ACELIO)	20[redacted] 303	-	20[redacted] 307	ADVERSE EVENT	1000 mg	PRN INTRAVENOUS	1
ACICLOVIR (ACICLOVIL)	20[redacted] 335	-	20[redacted] 349	PROPHYLAXIS	200 mg	BID ORAL	-

Standardized Medication Name Reported Name of Drug, Med, or Therapy	Start Date of Medication Study Day of Start of Medication	Started Before Informed Concent Date	End Date of Medication Study Day of End of Medication	Indication	Dose per Administration Dose Units	Dosing Frequency per Interval Route of Administration	AE Sequence Number(s)
ACICLOVIR (ACICLOVIR)	- -	Y	20[redacted] 334	PROPHYLAXIS	200 mg	TID OTHER	-
ALBUMIN HUMAN (ALBUMIN)	20[redacted] 303	-	20[redacted] 303	ADVERSE EVENT	100 mL	ONCE INTRAVENOUS	1
ALFACALCIDOL (ALFAROL)	20[redacted] 353	-	- -	ADVERSE EVENT	0.5 ug	QD ORAL	1
AMLODIPINE (AMLODIPINE)	20[redacted] 350	-	- -	ADVERSE EVENT	10 mg	BID ORAL	1
AMLODIPINE (AMLODIPINE TABLETS 5MG)	20[redacted] 195	-	20[redacted] 349	ADVERSE EVENT	5 mg	QD ORAL	1
AMLODIPINE (AMLODIPINE TABLETS 5MG)	20[redacted] 195	-	20[redacted] 349	ADVERSE EVENT	5 mg	QD ORAL	1
TIPEPIDINE HIBENZATE (ASVERIN [TIPEPIDINE HIBENZATE])	20[redacted] 180	-	20[redacted] 195	ADVERSE EVENT	20 mg	TID ORAL	1
HYDROXYZINE HYDROCHLORIDE (ATARAX-P)	20[redacted] 304	-	20[redacted] 304	ADVERSE EVENT	2 mL	ONCE INTRAVENOUS	1
HYDROXYZINE HYDROCHLORIDE (ATARAX-P)	20[redacted] 306	-	20[redacted] 306	ADVERSE EVENT	25 mg	ONCE INTRAVENOUS	1
AZITHROMYCIN (AZITHROMYCIN)	20[redacted] 279	-	20[redacted] 281	ADVERSE EVENT	500 mg	QD ORAL	2
ENTEROCOCCUS FAECALIS (BIOFERMIN-R)	20[redacted] 16	-	20[redacted] 20	ADVERSE EVENT	1 TABLET	TID ORAL	3
BROMHEXINE HYDROCHLORIDE (BISOLVON)	20[redacted] 180	-	20[redacted] 195	ADVERSE EVENT	4 mg	TID ORAL	1
PARACETAMOL (CALONAL)	20[redacted] 272	-	20[redacted] 276	ADVERSE EVENT	300 mg	TID ORAL	2
PARACETAMOL (CALONAL TABLETS)	20[redacted] 13	-	20[redacted] 16	ADVERSE EVENT	300 mg	TID ORAL	3
CARBOCISTEINE (CARBOCISTEINE TABLETS 250MG)	20[redacted] 167	-	20[redacted] 195	ADVERSE EVENT	500 mg	TID ORAL	1
CARBOCISTEINE (CARBOCISTEINE TABLETS 250MG)	20[redacted] 279	-	20[redacted] 299	ADVERSE EVENT	500 mg	TID ORAL	2

Standardized Medication Name Reported Name of Drug, Med, or Therapy	Start Date of Medication Study Day of Start of Medication	Started Before Informed Concent Date	End Date of Medication Study Day of End of Medication	Indication	Dose per Administration Dose Units	Dosing Frequency per Interval Route of Administration	AE Sequence Number(s)
CEFEPIME (CEFEPIME)	20[redacted] 307	-	20[redacted] 316	ADVERSE EVENT	1000 mg	BID INTRAVENOUS	1
CEFEPIME (CEFEPIME)	20[redacted] 307	-	20[redacted] 316	ADVERSE EVENT	1000 mg	BID INTRAVENOUS	1
CEFTRIAXONE SODIUM (CEFTRIAXONE NA)	20[redacted] 302	-	20[redacted] 302	ADVERSE EVENT	2000 mg	ONCE INTRAVENOUS	1
FUDOSTEINE (CLEANAL TABLETS)	20[redacted] 13	-	20[redacted] 16	ADVERSE EVENT	400 mg	TID ORAL	3
CLINDAMYCIN (CLINDAMYCIN)	20[redacted] 303	-	20[redacted] 304	ADVERSE EVENT	900 mg	PRN INTRAVENOUS	1
LEVOFLOXACIN (CRAVIT OPHTHALMIC SOLUTION1.5%)	20[redacted] 167	-	- -	CGVHD	1 gtt	TID OPHTHALMIC	-
SULFAMETHOXAZOLE; TRIMETHOPRIM (DAIPHEN TABLET)	- -	Y	20[redacted] 334	PROPHYLAXIS	1 TABLET	QOD ORAL	-
SULFAMETHOXAZOLE; TRIMETHOPRIM (DAIPHEN TABLET)	20[redacted] 335	-	20[redacted] 349	PROPHYLAXIS	1 TABLET	QOD ORAL	-
SULFAMETHOXAZOLE; TRIMETHOPRIM (DAIPHEN TABLETS)	- -	Y	20[redacted] 334	PROPHYLAXIS	2 TABLET	QOD ORAL	-
DIQUAFOSOL TETRASODIUM (DIQUAS OPHTHALMIC SOLUTION3%)	20[redacted] 139	-	- -	CGVHD	1 gtt	TID OPHTHALMIC	-
FEBUXOSTAT (FEBURIC)	20[redacted] 363	-	- -	ADVERSE EVENT	40 mg	QD ORAL	1
FEBUXOSTAT (FEBURIC TABLETS 10MG)	20[redacted] 351	-	20[redacted] 353	ADVERSE EVENT	10 mg	QD ORAL	1
FEBUXOSTAT (FEBURIC TABLETS 10MG)	20[redacted] 354	-	20[redacted] 362	ADVERSE EVENT	20 mg	QD ORAL	1
CEFCAPENE PIVOXIL HYDROCHLORIDE (FLOMOX [CEFCAPENE PIVOXIL HYDROCHLORIDE])	20[redacted] 16	-	20[redacted] 20	ADVERSE EVENT	100 mg	TID ORAL	3
FLUOROMETHOLONE (FLUMETHOLON OPHTHALMIC SUSPENSION0.1%)	20[redacted] 139	-	20[redacted] 166	CGVHD	1 gtt	TID OPHTHALMIC	-

Standardized Medication Name Reported Name of Drug, Med, or Therapy	Start Date of Medication Study Day of Start of Medication	Started Before Informed Concent Date	End Date of Medication Study Day of End of Medication	Indication	Dose per Administration Dose Units	Dosing Frequency per Interval Route of Administration	AE Sequence Number(s)
FUSIDATE SODIUM (FUCIDINLEO OINTMENT)	20[redacted] 279	-	20[redacted] 286	ADVERSE EVENT	1 FINGERTIP UNIT	BID TOPICAL	1
GLUCOSE INJECTION (GLUCOSE INJECTION)	20[redacted] 303	-	20[redacted] 304	ADVERSE EVENT	50 mg	QD INTRAVENOUS	1
HEPARINOID (HEPARINOID SPRAY0.3%)	20[redacted] 83	-	- -	ADVERSE EVENT	1 SPRAY	QD TOPICAL	8
MUCOPOLYSACCHARIDE POLYSULFURIC ACID ESTER (HIRUDOID FOAM)	20[redacted] 279	-	20[redacted] 286	ADVERSE EVENT	1 FINGERTIP UNIT	BID TOPICAL	1
CHLORPHENAMINE MALEATE; DIHYDROCODEINE PHOSPHATE; METHYLEPHEDRINE HYDROCHLORIDE-DL (HUSCODE)	20[redacted] 13	-	20[redacted] 16	ADVERSE EVENT	2 TABLET	TID ORAL	3
CHLORPHENAMINE MALEATE; DIHYDROCODEINE PHOSPHATE; METHYLEPHEDRINE HYDROCHLORIDE-DL (HUSCODE)	20[redacted] 272	-	20[redacted] 276	ADVERSE EVENT	2 TABLET	TID ORAL	2
CHLORPHENAMINE MALEATE; DIHYDROCODEINE PHOSPHATE; METHYLEPHEDRINE HYDROCHLORIDE-DL (HUSCODE)	20[redacted] 279	-	20[redacted] 299	ADVERSE EVENT	3 TABLET	TID ORAL	2
HYALURONATE SODIUM (HYALEIN MINI OPHTHALMIC SOLUTION 0.3%)	20[redacted] 139	-	- -	CGVHD	1 gtt	TID OPHTHALMIC	-
SODIUM CHLORIDE (ISOTONIC SODIUM CHLORIDE SOLUTION)	20[redacted] 303	-	20[redacted] 309	ADVERSE EVENT	500 mL	PRN INTRAVENOUS	1
POTASSIUM CHLORIDE (K-SUPPLY)	20[redacted] 352	-	20[redacted] 363	ADVERSE EVENT	600 mg	BID ORAL	1
KETOPROFEN (KETOPROFEN PAP)	20[redacted] 219	-	20[redacted] 226	ADVERSE EVENT	120 mg	QD TOPICAL	5
FUROSEMIDE (LASIX)	20[redacted] 359	-	- -	ADVERSE EVENT	20 mg	QD ORAL	1
LOXOPROFEN SODIUM (LOXOPROFEN SODIUM TABLETS 60MG)	20[redacted] 180	-	20[redacted] 195	ADVERSE EVENT	60 mg	PRN ORAL	1

Standardized Medication Name Reported Name of Drug, Med, or Therapy	Start Date of Medication Study Day of Start of Medication	Started Before Informed Concent Date	End Date of Medication Study Day of End of Medication	Indication	Dose per Administration Dose Units	Dosing Frequency per Interval Route of Administration	AE Sequence Number(s)
LOXOPROFEN SODIUM (LOXOPROFEN SODIUM TABLETS 60MG)	20[redacted] 279	-	20[redacted] 302	ADVERSE EVENT	60 mg	PRN ORAL	2
MAGNESIUM SULFATE (MAGNESIUM SULFATE CORRECTIVE INJECTION)	20[redacted] 303	-	20[redacted] 303	ADVERSE EVENT	20 mL	ONCE INTRAVENOUS	1
MEROPENEM (MEROPENEM)	20[redacted] 303	-	20[redacted] 306	ADVERSE EVENT	2000 mg	PRN INTRAVENOUS	1
PRAZOSIN HYDROCHLORIDE (MINIPRESS)	20[redacted] 355	-	20[redacted] 358	ADVERSE EVENT	1 mg	TID ORAL	1
METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA (MIRCERA)	20[redacted] 351	-	- -	ADVERSE EVENT	150 ug	PRN ORAL	1
REBAMIPIDE (MUCOSTA OPHTHALMIC SUSPENSION)	- -	Y	20[redacted] 139	CGVHD	1 gtt	TID OPHTHALMIC	-
NIFEDIPINE (NIFEDIPINE CR)	20[redacted] 358	-	- -	ADVERSE EVENT	10 mg	BID ORAL	1
OMEPRAZOLE (OMEPRAZOLE)	20[redacted] 303	-	20[redacted] 309	PROPHYLAXIS	20 mg	BID INTRAVENOUS	-
IMMUNOGLOBULIN HUMAN NORMAL (POLYGLOBIN)	20[redacted] 303	-	20[redacted] 303	ADVERSE EVENT	30 g	ONCE INTRAVENOUS	1
HYALURONATE SODIUM (PRIFIED SODIUM HYALURONATE)	- -	Y	20[redacted] 139	CGVHD	1 gtt	TID OPHTHALMIC	-
WHITE SOFT PARAFFIN (PROPETO)	20[redacted] 167	-	20[redacted] 169	ADVERSE EVENT	1 FINGERTIP UNIT	QD TOPICAL	8
BETAMETHASONE SODIUM PHOSPHATE (SANBETASON OPHTHALMIC AND OTORHINOLOGIC SOLUTION0.1%)	20[redacted] 167	-	- -	CGVHD	1 gtt	TID OPHTHALMIC	-
CALCIUM CHLORIDE DIHYDRATE; POTASSIUM CHLORIDE; SODIUM ACETATE TRIHYDRATE; SODIUM CHLORIDE (SOLACET F)	20[redacted] 302	-	20[redacted] 303	ADVERSE EVENT	500 mL	PRN INTRAVENOUS	1
FELBINAC (SUMILU STICK)	20[redacted] 219	-	20[redacted] 226	ADVERSE EVENT	1 FINGERTIP UNIT	QD TOPICAL	5

Standardized Medication Name Reported Name of Drug, Med, or Therapy	Start Date of Medication Study Day of Start of Medication	Started Before Informed Concent Date	End Date of Medication Study Day of End of Medication	Indication	Dose per Administration Dose Units	Dosing Frequency per Interval Route of Administration	AE Sequence Number(s)
TEICOPLANIN (TEICOPLANIN)	20[redacted] 307	-	20[redacted] 316	ADVERSE EVENT	400 mg	PRN INTRAVENOUS	1
TEICOPLANIN (TEICOPLANIN)	20[redacted] 307	-	20[redacted] 316	ADVERSE EVENT	400 mg	PRN INTRAVENOUS	1
TEPRENONE (TEPRENONE)	20[redacted] 180	-	20[redacted] 195	PROPHYLAXIS	50 mg	PRN ORAL	-
TEPRENONE (TEPRENONE)	20[redacted] 279	-	20[redacted] 302	PROPHYLAXIS	50 mg	PRN ORAL	-
TRANEXAMIC ACID (TRANEXAMIC ACID)	20[redacted] 272	-	20[redacted] 276	ADVERSE EVENT	250 mg	TID ORAL	2
VORICONAZOLE (VEEND)	20[redacted] 303	-	20[redacted] 316	ADVERSE EVENT	500 mL	PRN INTRAVENOUS	1
VORICONAZOLE (VFEND)	- -	Y	20[redacted] 63	PROPHYLAXIS	100 mg	BID ORAL	-
VORICONAZOLE (VFEND)	20[redacted] 64	-	20[redacted] 83	PROPHYLAXIS	250 mg	BID ORAL	-
VORICONAZOLE (VFEND)	20[redacted] 84	-	20[redacted] 334	PROPHYLAXIS	150 mg	BID ORAL	-
VORICONAZOLE (VFEND)	20[redacted] 335	-	20[redacted] 348	PROPHYLAXIS	100 mg	BID ORAL	-
VORICONAZOLE (VFEND)	20[redacted] 349	-	20[redacted] 357	PROPHYLAXIS	50 mg	QD ORAL	-
VORICONAZOLE (VFEND)	20[redacted] 363	-	- -	PROPHYLAXIS	150 mg	BID ORAL	-
AZITHROMYCIN (ZITHROMAC TABLETS)	20[redacted] 167	-	20[redacted] 169	ADVERSE EVENT	500 mg	QD ORAL	1
AZITHROMYCIN (ZITHROMAC TABLETS)	20[redacted] 180	-	20[redacted] 182	ADVERSE EVENT	500 mg	QD ORAL	1
LINEZOLID (ZYVOX)	20[redacted] 303	-	20[redacted] 306	ADVERSE EVENT	600 mg	PRN INTRAVENOUS	1

■ Karnofsky/Lansky performance status score

Date of Finding Study Day of Finding	Visit Name	Result
20[redacted]-17	SCREENING	80
20[redacted]1	WEEK 1 DAY 1	80
20[redacted]27	WEEK 5	80
20[redacted]55	WEEK 9	80
20[redacted]83	WEEK 13	80
20[redacted]111	WEEK 17	80
20[redacted]139	WEEK 21	80
20[redacted]167	WEEK 25	80
20[redacted]247	WEEK 37	80
20[redacted]335	WEEK 49	80
20[redacted]371	END OF TREATMENT	70

■ Laboratory Data

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Alanine Aminotransferase (Enzyme U/L)	20[redacted]-17	SCREENING	27	9	39	NORMAL	0
Alanine Aminotransferase (Enzyme U/L)	20[redacted]-1	WEEK 1 DAY 1	31	9	39	NORMAL	0
Alanine Aminotransferase (Enzyme U/L)	20[redacted]8	WEEK 2	30	9	39	NORMAL	0

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Alanine Aminotransferase (Enzyme U/L)	20[redacted] 27	WEEK 5	50	9	39	HIGH	1
Alanine Aminotransferase (Enzyme U/L)	20[redacted] 55	WEEK 9	41	9	39	HIGH	1
Alanine Aminotransferase (Enzyme U/L)	20[redacted] 83	WEEK 13	49	9	39	HIGH	1
Alanine Aminotransferase (Enzyme U/L)	20[redacted] 111	WEEK 17	38	9	39	NORMAL	0
Alanine Aminotransferase (Enzyme U/L)	20[redacted] 139	WEEK 21	41	9	39	HIGH	1
Alanine Aminotransferase (Enzyme U/L)	20[redacted] 167	WEEK 25	31	9	39	NORMAL	0
Alanine Aminotransferase (Enzyme U/L)	20[redacted] 247	WEEK 37	23	9	39	NORMAL	0
Alanine Aminotransferase (Enzyme U/L)	20[redacted] 335	WEEK 49	41	9	39	HIGH	1
Alanine Aminotransferase (Enzyme U/L)	20[redacted] 371	END OF TREATMENT	77	9	39	HIGH	1
Albumin (g/L)	20[redacted] -17	SCREENING	40	38	48	NORMAL	0
Albumin (g/L)	20[redacted] -1	WEEK 1 DAY 1	40	38	48	NORMAL	0
Albumin (g/L)	20[redacted] 8	WEEK 2	35	38	48	LOW	1
Albumin (g/L)	20[redacted] 27	WEEK 5	32	38	48	LOW	1
Albumin (g/L)	20[redacted] 55	WEEK 9	38	38	48	NORMAL	0
Albumin (g/L)	20[redacted] 83	WEEK 13	39	38	48	NORMAL	0
Albumin (g/L)	20[redacted] 111	WEEK 17	38	38	48	NORMAL	0
Albumin (g/L)	20[redacted] 139	WEEK 21	38	38	48	NORMAL	0

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Albumin (g/L)	20[redacted] 167	WEEK 25	34	38	48	LOW	1
Albumin (g/L)	20[redacted] 247	WEEK 37	36	38	48	LOW	1
Albumin (g/L)	20[redacted] 335	WEEK 49	35	38	48	LOW	1
Albumin (g/L)	20[redacted] 371	END OF TREATMENT	41	38	48	NORMAL	0
Alkaline Phosphatase (Enzyme U/L)	20[redacted] -17	SCREENING	194	160	500	NORMAL	0
Alkaline Phosphatase (Enzyme U/L)	20[redacted] -1	WEEK 1 DAY 1	169	160	500	NORMAL	0
Alkaline Phosphatase (Enzyme U/L)	20[redacted] 8	WEEK 2	119	160	500	LOW	0
Alkaline Phosphatase (Enzyme U/L)	20[redacted] 27	WEEK 5	233	160	500	NORMAL	0
Alkaline Phosphatase (Enzyme U/L)	20[redacted] 55	WEEK 9	162	160	500	NORMAL	0
Alkaline Phosphatase (Enzyme U/L)	20[redacted] 83	WEEK 13	162	160	500	NORMAL	0
Alkaline Phosphatase (Enzyme U/L)	20[redacted] 111	WEEK 17	179	160	500	NORMAL	0
Alkaline Phosphatase (Enzyme U/L)	20[redacted] 139	WEEK 21	191	160	500	NORMAL	0
Alkaline Phosphatase (Enzyme U/L)	20[redacted] 167	WEEK 25	240	160	500	NORMAL	0
Alkaline Phosphatase (Enzyme U/L)	20[redacted] 247	WEEK 37	271	160	500	NORMAL	0
Alkaline Phosphatase (Enzyme U/L)	20[redacted] 335	WEEK 49	321	160	500	NORMAL	0
Alkaline Phosphatase (Enzyme U/L)	20[redacted] 371	END OF TREATMENT	309	160	500	NORMAL	0
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] -17	SCREENING	15	14	31	NORMAL	0

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] -1	WEEK 1 DAY 1	19	14	31	NORMAL	0
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] 8	WEEK 2	20	14	31	NORMAL	0
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] 27	WEEK 5	27	14	31	NORMAL	0
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] 55	WEEK 9	20	14	31	NORMAL	0
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] 83	WEEK 13	28	14	31	NORMAL	0
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] 111	WEEK 17	21	14	31	NORMAL	0
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] 139	WEEK 21	20	14	31	NORMAL	0
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] 167	WEEK 25	19	14	31	NORMAL	0
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] 247	WEEK 37	23	14	31	NORMAL	0
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] 335	WEEK 49	35	14	31	HIGH	1
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] 371	END OF TREATMENT	36	14	31	HIGH	1
Bilirubin (umol/L)	20[redacted] -17	SCREENING	10.26	4.275	23.94	NORMAL	0
Bilirubin (umol/L)	20[redacted] -1	WEEK 1 DAY 1	9.405	4.275	23.94	NORMAL	0
Bilirubin (umol/L)	20[redacted] 8	WEEK 2	20.349	4.275	23.94	NORMAL	0
Bilirubin (umol/L)	20[redacted] 27	WEEK 5	8.721	4.275	23.94	NORMAL	0
Bilirubin (umol/L)	20[redacted] 55	WEEK 9	11.799	4.275	23.94	NORMAL	0
Bilirubin (umol/L)	20[redacted] 83	WEEK 13	7.695	4.275	23.94	NORMAL	0

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Bilirubin (umol/L)	20[redacted] 111	WEEK 17	8.892	4.275	23.94	NORMAL	0
Bilirubin (umol/L)	20[redacted] 139	WEEK 21	13.338	4.275	23.94	NORMAL	0
Bilirubin (umol/L)	20[redacted] 167	WEEK 25	10.431	4.275	23.94	NORMAL	0
Bilirubin (umol/L)	20[redacted] 247	WEEK 37	16.416	4.275	23.94	NORMAL	0
Bilirubin (umol/L)	20[redacted] 335	WEEK 49	22.743	4.275	23.94	NORMAL	0
Bilirubin (umol/L)	20[redacted] 371	END OF TREATMENT	9.576	4.275	23.94	NORMAL	0
Creatinine (umol/L)	20[redacted] -17	SCREENING	68.952	44.2	88.4	NORMAL	0
Creatinine (umol/L)	20[redacted] -1	WEEK 1 DAY 1	68.068	44.2	88.4	NORMAL	0
Creatinine (umol/L)	20[redacted] 8	WEEK 2	62.764	44.2	88.4	NORMAL	0
Creatinine (umol/L)	20[redacted] 27	WEEK 5	68.952	44.2	88.4	NORMAL	0
Creatinine (umol/L)	20[redacted] 55	WEEK 9	85.748	44.2	88.4	NORMAL	0
Creatinine (umol/L)	20[redacted] 83	WEEK 13	80.444	44.2	88.4	NORMAL	0
Creatinine (umol/L)	20[redacted] 111	WEEK 17	80.444	44.2	88.4	NORMAL	0
Creatinine (umol/L)	20[redacted] 139	WEEK 21	78.676	44.2	88.4	NORMAL	0
Creatinine (umol/L)	20[redacted] 167	WEEK 25	83.096	44.2	88.4	NORMAL	0
Creatinine (umol/L)	20[redacted] 247	WEEK 37	118.456	44.2	88.4	HIGH	2
Creatinine (umol/L)	20[redacted] 335	WEEK 49	241.332	44.2	88.4	HIGH	3

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Creatinine (umol/L)	20[redacted] 349	WEEK 49 UNSCHEDULED 01	368.628	44.2	88.4	HIGH	3
Creatinine (umol/L)	20[redacted] 371	END OF TREATMENT	558.688	44.2	88.4	HIGH	4
Eosinophils (10^9/L)	20[redacted] -17	SCREENING	0.09	0.04	0.32	NORMAL	-
Eosinophils (10^9/L)	20[redacted] -1	WEEK 1 DAY 1	0.02	0.04	0.32	LOW	-
Eosinophils (10^9/L)	20[redacted] 8	WEEK 2	0.48	0.04	0.32	HIGH	-
Eosinophils (10^9/L)	20[redacted] 27	WEEK 5	0.02	0.04	0.32	LOW	-
Eosinophils (10^9/L)	20[redacted] 55	WEEK 9	0.05	0.04	0.32	NORMAL	-
Eosinophils (10^9/L)	20[redacted] 83	WEEK 13	0.03	0.04	0.32	LOW	-
Eosinophils (10^9/L)	20[redacted] 111	WEEK 17	0.02	0.04	0.32	LOW	-
Eosinophils (10^9/L)	20[redacted] 139	WEEK 21	0.03	0.04	0.32	LOW	-
Eosinophils (10^9/L)	20[redacted] 167	WEEK 25	0.04	0.04	0.32	NORMAL	-
Eosinophils (10^9/L)	20[redacted] 247	WEEK 37	0.019	0.04	0.32	LOW	-
Eosinophils (10^9/L)	20[redacted] 335	WEEK 49	0.003	0.04	0.32	LOW	-
Eosinophils (10^9/L)	20[redacted] 371	END OF TREATMENT	0.02	0.04	0.32	LOW	-
Glucose (mmol/L)	20[redacted] -17	SCREENING	7.2718	4.0522	6.0506	HIGH	1
Glucose (mmol/L)	20[redacted] -1	WEEK 1 DAY 1	6.2726	4.0522	6.0506	HIGH	1
Glucose (mmol/L)	20[redacted] 8	WEEK 2	4.9404	4.0522	6.0506	NORMAL	0

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Glucose (mmol/L)	20[redacted] 27	WEEK 5	5.3845	4.0522	6.0506	NORMAL	0
Glucose (mmol/L)	20[redacted] 55	WEEK 9	5.1069	4.0522	6.0506	NORMAL	0
Glucose (mmol/L)	20[redacted] 83	WEEK 13	6.2726	4.0522	6.0506	HIGH	1
Glucose (mmol/L)	20[redacted] 111	WEEK 17	5.3845	4.0522	6.0506	NORMAL	0
Glucose (mmol/L)	20[redacted] 139	WEEK 21	6.7167	4.0522	6.0506	HIGH	1
Glucose (mmol/L)	20[redacted] 167	WEEK 25	7.2163	4.0522	6.0506	HIGH	1
Glucose (mmol/L)	20[redacted] 247	WEEK 37	6.4947	4.0522	6.0506	HIGH	1
Glucose (mmol/L)	20[redacted] 335	WEEK 49	5.8841	4.0522	6.0506	NORMAL	0
Glucose (mmol/L)	20[redacted] 371	END OF TREATMENT	6.7167	4.0522	6.0506	HIGH	1
HIV Antibody	20[redacted] -17	SCREENING	NEGATIVE	-	-	-	-
Hemoglobin (g/L)	20[redacted] -17	SCREENING	157	134	171	NORMAL	0
Hemoglobin (g/L)	20[redacted] -1	WEEK 1 DAY 1	161	134	171	NORMAL	0
Hemoglobin (g/L)	20[redacted] 8	WEEK 2	150	134	171	NORMAL	0
Hemoglobin (g/L)	20[redacted] 27	WEEK 5	158	134	171	NORMAL	0
Hemoglobin (g/L)	20[redacted] 55	WEEK 9	169	134	171	NORMAL	0
Hemoglobin (g/L)	20[redacted] 83	WEEK 13	167	134	171	NORMAL	0
Hemoglobin (g/L)	20[redacted] 111	WEEK 17	162	134	171	NORMAL	0

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Hemoglobin (g/L)	20[redacted] 139	WEEK 21	162	134	171	NORMAL	0
Hemoglobin (g/L)	20[redacted] 167	WEEK 25	154	134	171	NORMAL	0
Hemoglobin (g/L)	20[redacted] 247	WEEK 37	140	134	171	NORMAL	0
Hemoglobin (g/L)	20[redacted] 335	WEEK 49	106	134	171	LOW	1
Hemoglobin (g/L)	20[redacted] 371	END OF TREATMENT	120	134	171	LOW	1
Hepatitis B Virus Core Antibody	20[redacted] -17	SCREENING	NEGATIVE	-	-	-	-
Hepatitis B Virus Surface Antibody	20[redacted] -17	SCREENING	NEGATIVE	-	-	-	-
Hepatitis B Virus Surface Antigen	20[redacted] -17	SCREENING	NEGATIVE	-	-	-	-
Hepatitis C Virus Antibody	20[redacted] -17	SCREENING	NEGATIVE	-	-	-	-
Immunoglobulin A (g/L)	20[redacted] -17	SCREENING	2.94	-	-	-	-
Immunoglobulin A (g/L)	20[redacted] 83	WEEK 13	2.27	-	-	-	-
Immunoglobulin A (g/L)	20[redacted] 167	WEEK 25	3.28	-	-	-	-
Immunoglobulin A (g/L)	20[redacted] 247	WEEK 37	2.75	-	-	-	-
Immunoglobulin A (g/L)	20[redacted] 335	WEEK 49	1.87	-	-	-	-
Immunoglobulin A (g/L)	20[redacted] 371	END OF TREATMENT	1.64	-	-	-	-
Immunoglobulin G (g/L)	20[redacted] -17	SCREENING	6.04	-	-	-	-
Immunoglobulin G (g/L)	20[redacted] 83	WEEK 13	5.1	-	-	-	-

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Immunoglobulin G (g/L)	20[redacted] 167	WEEK 25	8.77	-	-	-	-
Immunoglobulin G (g/L)	20[redacted] 247	WEEK 37	5.67	-	-	-	-
Immunoglobulin G (g/L)	20[redacted] 335	WEEK 49	5.23	-	-	-	-
Immunoglobulin G (g/L)	20[redacted] 371	END OF TREATMENT	3.98	-	-	-	-
Immunoglobulin M (g/L)	20[redacted] -17	SCREENING	0.9	-	-	-	-
Immunoglobulin M (g/L)	20[redacted] 83	WEEK 13	0.34	-	-	-	-
Immunoglobulin M (g/L)	20[redacted] 167	WEEK 25	0.51	-	-	-	-
Immunoglobulin M (g/L)	20[redacted] 247	WEEK 37	0.23	-	-	-	-
Immunoglobulin M (g/L)	20[redacted] 335	WEEK 49	0.38	-	-	-	-
Immunoglobulin M (g/L)	20[redacted] 371	END OF TREATMENT	0.2	-	-	-	-
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] -17	SCREENING	167	120	250	NORMAL	-
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] -1	WEEK 1 DAY 1	249	120	250	NORMAL	-
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] 8	WEEK 2	233	120	250	NORMAL	-
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] 27	WEEK 5	228	120	250	NORMAL	-
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] 55	WEEK 9	253	120	250	HIGH	-
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] 83	WEEK 13	277	120	250	HIGH	-
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] 111	WEEK 17	323	120	250	HIGH	-

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] 139	WEEK 21	333	120	250	HIGH	-
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] 167	WEEK 25	332	120	250	HIGH	-
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] 247	WEEK 37	730	120	250	HIGH	-
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] 335	WEEK 49	981	120	250	HIGH	-
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] 371	END OF TREATMENT	474	120	250	HIGH	-
Leukocytes (10^9/L)	20[redacted] -17	SCREENING	9.82	3.8	9.5	HIGH	0
Leukocytes (10^9/L)	20[redacted] -1	WEEK 1 DAY 1	8.37	3.8	9.5	NORMAL	0
Leukocytes (10^9/L)	20[redacted] 8	WEEK 2	6	3.8	9.5	NORMAL	0
Leukocytes (10^9/L)	20[redacted] 27	WEEK 5	10.73	3.8	9.5	HIGH	0
Leukocytes (10^9/L)	20[redacted] 55	WEEK 9	10.58	3.8	9.5	HIGH	0
Leukocytes (10^9/L)	20[redacted] 83	WEEK 13	6.72	3.8	9.5	NORMAL	0
Leukocytes (10^9/L)	20[redacted] 111	WEEK 17	9.61	3.8	9.5	HIGH	0
Leukocytes (10^9/L)	20[redacted] 139	WEEK 21	9.34	3.8	9.5	NORMAL	0
Leukocytes (10^9/L)	20[redacted] 167	WEEK 25	10.12	3.8	9.5	HIGH	0
Leukocytes (10^9/L)	20[redacted] 247	WEEK 37	9.4	3.8	9.5	NORMAL	0
Leukocytes (10^9/L)	20[redacted] 335	WEEK 49	15.36	3.8	9.5	HIGH	0
Leukocytes (10^9/L)	20[redacted] 371	END OF TREATMENT	11.93	3.8	9.5	HIGH	0

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Lymphocytes (10^9/L)	20[redacted] -17	SCREENING	1.17	0.8	3.2	NORMAL	0
Lymphocytes (10^9/L)	20[redacted] -1	WEEK 1 DAY 1	1.4	0.8	3.2	NORMAL	0
Lymphocytes (10^9/L)	20[redacted] 8	WEEK 2	1.8	0.8	3.2	NORMAL	0
Lymphocytes (10^9/L)	20[redacted] 27	WEEK 5	1.19	0.8	3.2	NORMAL	0
Lymphocytes (10^9/L)	20[redacted] 55	WEEK 9	1.51	0.8	3.2	NORMAL	0
Lymphocytes (10^9/L)	20[redacted] 83	WEEK 13	1.6	0.8	3.2	NORMAL	0
Lymphocytes (10^9/L)	20[redacted] 111	WEEK 17	2.06	0.8	3.2	NORMAL	0
Lymphocytes (10^9/L)	20[redacted] 139	WEEK 21	1.73	0.8	3.2	NORMAL	0
Lymphocytes (10^9/L)	20[redacted] 167	WEEK 25	1.62	0.8	3.2	NORMAL	0
Lymphocytes (10^9/L)	20[redacted] 247	WEEK 37	1.37	0.8	3.2	NORMAL	0
Lymphocytes (10^9/L)	20[redacted] 335	WEEK 49	1.8	0.8	3.2	NORMAL	0
Lymphocytes (10^9/L)	20[redacted] 371	END OF TREATMENT	0.94	0.8	3.2	NORMAL	0
Neutrophils (10^9/L)	20[redacted] -17	SCREENING	8.2	1.6	6.32	HIGH	0
Neutrophils (10^9/L)	20[redacted] -1	WEEK 1 DAY 1	6.49	1.6	6.32	HIGH	0
Neutrophils (10^9/L)	20[redacted] 8	WEEK 2	3.64	1.6	6.32	NORMAL	0
Neutrophils (10^9/L)	20[redacted] 27	WEEK 5	8.9	1.6	6.32	HIGH	0
Neutrophils (10^9/L)	20[redacted] 55	WEEK 9	8.24	1.6	6.32	HIGH	0

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Neutrophils (10^9/L)	20[redacted] 83	WEEK 13	4.41	1.6	6.32	NORMAL	0
Neutrophils (10^9/L)	20[redacted] 111	WEEK 17	6.67	1.6	6.32	HIGH	0
Neutrophils (10^9/L)	20[redacted] 139	WEEK 21	6.86	1.6	6.32	HIGH	0
Neutrophils (10^9/L)	20[redacted] 167	WEEK 25	7.95	1.6	6.32	HIGH	0
Neutrophils (10^9/L)	20[redacted] 247	WEEK 37	7.33	1.6	6.32	HIGH	0
Neutrophils (10^9/L)	20[redacted] 335	WEEK 49	12.67	1.6	6.32	HIGH	0
Neutrophils (10^9/L)	20[redacted] 371	END OF TREATMENT	10.39	1.6	6.32	HIGH	0
Platelets (10^9/L)	20[redacted] -17	SCREENING	281	160	370	NORMAL	0
Platelets (10^9/L)	20[redacted] -1	WEEK 1 DAY 1	246	160	370	NORMAL	0
Platelets (10^9/L)	20[redacted] 8	WEEK 2	157	160	370	LOW	1
Platelets (10^9/L)	20[redacted] 27	WEEK 5	285	160	370	NORMAL	0
Platelets (10^9/L)	20[redacted] 55	WEEK 9	205	160	370	NORMAL	0
Platelets (10^9/L)	20[redacted] 83	WEEK 13	182	160	370	NORMAL	0
Platelets (10^9/L)	20[redacted] 111	WEEK 17	176	160	370	NORMAL	0
Platelets (10^9/L)	20[redacted] 139	WEEK 21	174	160	370	NORMAL	0
Platelets (10^9/L)	20[redacted] 167	WEEK 25	214	160	370	NORMAL	0
Platelets (10^9/L)	20[redacted] 247	WEEK 37	137	160	370	LOW	1

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Platelets (10^9/L)	20[redacted] 335	WEEK 49	60	160	370	LOW	2
Platelets (10^9/L)	20[redacted] 371	END OF TREATMENT	397	160	370	HIGH	0
Potassium (mmol/L)	20[redacted] -17	SCREENING	4.1	3.7	4.7	NORMAL	0
Potassium (mmol/L)	20[redacted] -1	WEEK 1 DAY 1	4.2	3.7	4.7	NORMAL	0
Potassium (mmol/L)	20[redacted] 8	WEEK 2	3	3.7	4.7	LOW	2
Potassium (mmol/L)	20[redacted] 27	WEEK 5	4.1	3.7	4.7	NORMAL	0
Potassium (mmol/L)	20[redacted] 55	WEEK 9	4.2	3.7	4.7	NORMAL	0
Potassium (mmol/L)	20[redacted] 83	WEEK 13	4.2	3.7	4.7	NORMAL	0
Potassium (mmol/L)	20[redacted] 111	WEEK 17	4	3.7	4.7	NORMAL	0
Potassium (mmol/L)	20[redacted] 139	WEEK 21	4	3.7	4.7	NORMAL	0
Potassium (mmol/L)	20[redacted] 167	WEEK 25	3.9	3.7	4.7	NORMAL	0
Potassium (mmol/L)	20[redacted] 247	WEEK 37	4.2	3.7	4.7	NORMAL	0
Potassium (mmol/L)	20[redacted] 335	WEEK 49	3.8	3.7	4.7	NORMAL	0
Potassium (mmol/L)	20[redacted] 371	END OF TREATMENT	4.4	3.7	4.7	NORMAL	0
Protein (g/L)	20[redacted] -17	SCREENING	65	63	78	NORMAL	-
Protein (g/L)	20[redacted] -1	WEEK 1 DAY 1	65	63	78	NORMAL	-
Protein (g/L)	20[redacted] 8	WEEK 2	55	63	78	LOW	-

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Protein (g/L)	20[redacted] 27	WEEK 5	60	63	78	LOW	-
Protein (g/L)	20[redacted] 55	WEEK 9	61	63	78	LOW	-
Protein (g/L)	20[redacted] 83	WEEK 13	61	63	78	LOW	-
Protein (g/L)	20[redacted] 111	WEEK 17	60	63	78	LOW	-
Protein (g/L)	20[redacted] 139	WEEK 21	61	63	78	LOW	-
Protein (g/L)	20[redacted] 167	WEEK 25	65	63	78	NORMAL	-
Protein (g/L)	20[redacted] 247	WEEK 37	64	63	78	NORMAL	-
Protein (g/L)	20[redacted] 335	WEEK 49	58	63	78	LOW	-
Protein (g/L)	20[redacted] 371	END OF TREATMENT	63	63	78	NORMAL	-
Sodium (mmol/L)	20[redacted] -17	SCREENING	140	138	144	NORMAL	0
Sodium (mmol/L)	20[redacted] -1	WEEK 1 DAY 1	140	138	144	NORMAL	0
Sodium (mmol/L)	20[redacted] 8	WEEK 2	141	138	144	NORMAL	0
Sodium (mmol/L)	20[redacted] 27	WEEK 5	140	138	144	NORMAL	0
Sodium (mmol/L)	20[redacted] 55	WEEK 9	141	138	144	NORMAL	0
Sodium (mmol/L)	20[redacted] 83	WEEK 13	140	138	144	NORMAL	0
Sodium (mmol/L)	20[redacted] 111	WEEK 17	141	138	144	NORMAL	0
Sodium (mmol/L)	20[redacted] 139	WEEK 21	140	138	144	NORMAL	0

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Sodium (mmol/L)	20[redacted] 167	WEEK 25	138	138	144	NORMAL	0
Sodium (mmol/L)	20[redacted] 247	WEEK 37	140	138	144	NORMAL	0
Sodium (mmol/L)	20[redacted] 335	WEEK 49	138	138	144	NORMAL	0
Sodium (mmol/L)	20[redacted] 371	END OF TREATMENT	136	138	144	LOW	1
Urate (umol/L)	20[redacted] -17	SCREENING	333.088	231.972	463.944	NORMAL	0
Urate (umol/L)	20[redacted] -1	WEEK 1 DAY 1	297.4	231.972	463.944	NORMAL	0
Urate (umol/L)	20[redacted] 8	WEEK 2	321.192	231.972	463.944	NORMAL	0
Urate (umol/L)	20[redacted] 27	WEEK 5	362.828	231.972	463.944	NORMAL	0
Urate (umol/L)	20[redacted] 55	WEEK 9	339.036	231.972	463.944	NORMAL	0
Urate (umol/L)	20[redacted] 83	WEEK 13	350.932	231.972	463.944	NORMAL	0
Urate (umol/L)	20[redacted] 111	WEEK 17	321.192	231.972	463.944	NORMAL	0
Urate (umol/L)	20[redacted] 139	WEEK 21	344.984	231.972	463.944	NORMAL	0
Urate (umol/L)	20[redacted] 167	WEEK 25	362.828	231.972	463.944	NORMAL	0
Urate (umol/L)	20[redacted] 247	WEEK 37	380.672	231.972	463.944	NORMAL	0
Urate (umol/L)	20[redacted] 335	WEEK 49	452.048	231.972	463.944	NORMAL	0
Urate (umol/L)	20[redacted] 371	END OF TREATMENT	428.256	231.972	463.944	NORMAL	0
Urea Nitrogen (mmol/L)	20[redacted] -17	SCREENING	4.7838	2.4276	6.6402	NORMAL	-

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Urea Nitrogen (mmol/L)	20[redacted] -1	WEEK 1 DAY 1	5.4264	2.4276	6.6402	NORMAL	-
Urea Nitrogen (mmol/L)	20[redacted] 8	WEEK 2	5.0337	2.4276	6.6402	NORMAL	-
Urea Nitrogen (mmol/L)	20[redacted] 27	WEEK 5	5.5335	2.4276	6.6402	NORMAL	-
Urea Nitrogen (mmol/L)	20[redacted] 55	WEEK 9	5.2479	2.4276	6.6402	NORMAL	-
Urea Nitrogen (mmol/L)	20[redacted] 83	WEEK 13	4.3911	2.4276	6.6402	NORMAL	-
Urea Nitrogen (mmol/L)	20[redacted] 111	WEEK 17	4.3554	2.4276	6.6402	NORMAL	-
Urea Nitrogen (mmol/L)	20[redacted] 139	WEEK 21	5.2479	2.4276	6.6402	NORMAL	-
Urea Nitrogen (mmol/L)	20[redacted] 167	WEEK 25	3.9627	2.4276	6.6402	NORMAL	-
Urea Nitrogen (mmol/L)	20[redacted] 247	WEEK 37	9.639	2.4276	6.6402	HIGH	-
Urea Nitrogen (mmol/L)	20[redacted] 335	WEEK 49	10.9599	2.4276	6.6402	HIGH	-
Urea Nitrogen (mmol/L)	20[redacted] 349	WEEK 49 UNSCHEDULED 01	16.8861	2.4276	6.6402	HIGH	-
Urea Nitrogen (mmol/L)	20[redacted] 371	END OF TREATMENT	24.1689	2.4276	6.6402	HIGH	-

3) 被験者番号 54179060GVH3001-[redacted]

■ REASON FOR NARRATIVE SELECTION

Treatment-emergent serious adverse events (SAEs)

Major hemorrhage

■ Death

No Death reported

■ Treatment-emergent serious adverse events (SAEs)

Dictionary-Derived Term	Reported Term for the Adverse Event	Start Date of Adverse Event End Date of Adverse Event	Study Day of Start of Adverse Event Adverse Event Duration (days)	Serious Event Standard Toxicity Grade	Causality Action Taken with Study Treatment	Concomitant or Additional Treatment Given Outcome of Adverse Event	Sequence Number
蜂巣炎	CELLULITIS(RIGHT LOWER LIMB)	20[redacted] 20[redacted]	249 17	Y 3	PROBABLE DOSE NOT CHANGED	Y RECOVERED/RESOLVED	8
肝障害	LIVER DISORDER	20[redacted] 20[redacted]	279 8	Y 3	DOUBTFUL DOSE NOT CHANGED	Y RECOVERED/RESOLVED	33

Note: Adverse Events are coded using MedDRA 22.1

■ Adverse events (AEs) leading to ibrutinib discontinuation

No Adverse events (AEs) leading to ibrutinib discontinuation reported

■ Other malignancies

No Other malignancies reported

■ Major hemorrhage

Dictionary-Derived Term	Reported Term for the Adverse Event	Start Date of Adverse Event End Date of Adverse Event	Study Day of Start of Adverse Event Adverse Event Duration (days)	Serious Event Standard Toxicity Grade	Causality Action Taken with Study Treatment	Concomitant or Additional Treatment Given Outcome of Adverse Event	Sequence Number
外傷性出血	TRAUMATIC BLEEDING(LEFT AND RIGHT KNEE INJURY)	20[redacted] 20[redacted]	387 15	N 3	POSSIBLE DOSE NOT CHANGED	Y RECOVERED/RESOLVED	49

Note: Adverse Events are coded using MedDRA 22.1

■ Demographics, Baseline Characteristics

- Country: JPN
- Race: Asian
- Age: 3[redacted]
- Sex: Male
- Baseline height (cm): [redacted]
- Baseline weight (kg): [redacted]
- Baseline karnofsky/Lansky performance status score: 80
- Overall severity of cGVHD: Severe
- cGVHD disease state: STEROID DEPENDENT DISEASE
- Month from initial diagnosis date: -
- Number of prior cGVHD treatment regimens: 1
- First study drug intake: 20[redacted] (Study Day 1)
- Last study drug intake: 20[redacted] (Study Day 422)

■ Disposition Information

- End of treatment: Subject Ongoing on Treatment
- End of trial: Subject Ongoing on Study

■ Other Adverse Events

Dictionary-Derived Term	Reported Term for the Adverse Event	Start Date of Adverse Event / End Date of Adverse Event	Study Day of Start of Adverse Event / Adverse Event Duration (days)	Serious Event / Standard Toxicity Grade	Causality / Action Taken with Study Treatment	Concomitant or Additional Treatment Given / Outcome of Adverse Event	Sequence Number
関節痛	WORSENING ARTHRALGIA(LUMBAR,KNEE)	20[redacted] 20[redacted]	6 56	N 2	DOUBTFUL DOSE NOT CHANGED	Y RECOVERED/RESOLVED	51
脂質代謝障害	LIPID METABOLISM DISORDER	20[redacted] -	29 -	N 1	DOUBTFUL DOSE NOT CHANGED	Y NOT RECOVERED/NOT RESOLVED	32
悪心	NAUSEA	20[redacted] 20[redacted]	36 51	N 1	DOUBTFUL DOSE NOT CHANGED	Y RECOVERED/RESOLVED	37
血中β－Ｄ－グルカン増加	BLOOD BETA-D-GLUCAN INCREASED	20[redacted] 20[redacted]	58 57	N 2	PROBABLE DOSE NOT CHANGED	Y RECOVERED/RESOLVED	5
高血圧	HYPERTENSION	20[redacted] 20[redacted]	58 190	N 2	POSSIBLE DOSE NOT CHANGED	N RECOVERED/RESOLVED	25
上咽頭炎	COLD	20[redacted] 20[redacted]	92 13	N 1	PROBABLE DOSE NOT CHANGED	Y RECOVERED/RESOLVED	12
上咽頭炎	COLD	20[redacted] 20[redacted]	110 61	N 1	PROBABLE DOSE NOT CHANGED	Y RECOVERED/RESOLVED	13

Dictionary-Derived Term	Reported Term for the Adverse Event	Start Date of Adverse Event End Date of Adverse Event	Study Day of Start of Adverse Event Adverse Event Duration (days)	Serious Event Standard Toxicity Grade	Causality Action Taken with Study Treatment	Concomitant or Additional Treatment Given Outcome of Adverse Event	Sequence Number
末梢性浮腫	EDEMA LOWER LIMB	20[redacted] 20	110 67	N 1	POSSIBLE DOSE NOT CHANGED	Y RECOVERED/RESOLVED	17
体重増加	WEIGHT GAIN	20 20	114 154	N 2	POSSIBLE DOSE NOT CHANGED	Y RECOVERED/RESOLVED	50
ドライアイ	DRY EYE	20 20	133 37	N 2	POSSIBLE DOSE NOT CHANGED	Y RECOVERED/RESOLVED	15
骨壊死	IDIOPATHIC FEMORAL HEAD NECROSIS	20 -	157 -	N 2	DOUBTFUL DOSE NOT CHANGED	Y NOT RECOVERED/NOT RESOLVED	27
ドライアイ	DRY EYE	20 -	170 -	N 1	POSSIBLE DOSE NOT CHANGED	Y NOT RECOVERED/NOT RESOLVED	16
末梢性浮腫	EDEMA LOWER LIMB	20 -	177 -	N 2	POSSIBLE DOSE NOT CHANGED	Y NOT RECOVERED/NOT RESOLVED	18
血中β－Ｄ－グルカン増加	BLOOD BETA-D-GLUCAN INCREASED	20 20	247 35	N 2	PROBABLE DOSE NOT CHANGED	Y RECOVERED/RESOLVED	6
転倒	FALL	20 20	248 1	N 2	NOT RELATED DOSE NOT CHANGED	N RECOVERED/RESOLVED	21
皮膚裂傷	RIGHT KNEE LACERATION	20 20	248 8	N 2	NOT RELATED DOSE NOT CHANGED	N RECOVERED/RESOLVED	46
低血圧	HYPOTENSION	20 20	250 5	N 2	NOT RELATED DOSE NOT CHANGED	N RECOVERED/RESOLVED	26
悪心	NAUSEA	20[redacted] -	250 -	N 1	NOT RELATED DOSE NOT CHANGED	Y NOT RECOVERED/NOT RESOLVED	38

Dictionary-Derived Term	Reported Term for the Adverse Event	Start Date of Adverse Event End Date of Adverse Event	Study Day of Start of Adverse Event Adverse Event Duration (days)	Serious Event Standard Toxicity Grade	Causality Action Taken with Study Treatment	Concomitant or Additional Treatment Given Outcome of Adverse Event	Sequence Number
血中クレアチニン増加	WORSENING CREATININE INCREASED	20[redacted] 20[redacted]	253 7	N 2	POSSIBLE DOSE NOT CHANGED	N RECOVERED/RESOLVED	53
血小板数減少	PLATELET COUNT DECREASED	20[redacted] 20[redacted]	253 29	N 3	POSSIBLE DOSE NOT CHANGED	Y RECOVERED/RESOLVED	44
貧血	ANEMIA	20[redacted] 20[redacted]	254 39	N 3	POSSIBLE DOSE NOT CHANGED	Y RECOVERED/RESOLVED	4
胸水	PLEURAL EFFUSION	20[redacted] 20[redacted]	254 4	N 2	POSSIBLE DOSE NOT CHANGED	Y RECOVERED/RESOLVED	45
アミラーゼ増加	AMYLASE INCREASED	20[redacted] 20[redacted]	257 2	N 1	NOT RELATED DOSE NOT CHANGED	N RECOVERED/RESOLVED	1
アミラーゼ増加	AMYLASE INCREASED	20[redacted] 20[redacted]	259 7	N 3	NOT RELATED DOSE NOT CHANGED	N RECOVERED/RESOLVED	2
アミラーゼ増加	AMYLASE INCREASED	20[redacted] 20[redacted]	266 27	N 4	NOT RELATED DOSE NOT CHANGED	N RECOVERED/RESOLVED	3
蜂巣炎	CELLULITIS(RIGHT LOWER LIMB)	20[redacted] 20[redacted]	266 26	N 2	PROBABLE DOSE NOT CHANGED	Y RECOVERED/RESOLVED	9
リパーゼ増加	LIPASE INCREASED	20[redacted] 20[redacted]	266 13	N 4	NOT RELATED DOSE NOT CHANGED	N RECOVERED/RESOLVED	30
好中球数減少	NEUTROPHIL COUNT DECREASED	20[redacted] 20[redacted]	275 4	N 3	POSSIBLE DOSE NOT CHANGED	N RECOVERED/RESOLVED	39
頭痛	HEADACHE	20[redacted] 20[redacted]	278 6	N 2	DOUBTFUL DOSE NOT CHANGED	Y RECOVERED/RESOLVED	24

Dictionary-Derived Term	Reported Term for the Adverse Event	Start Date of Adverse Event End Date of Adverse Event	Study Day of Start of Adverse Event Adverse Event Duration (days)	Serious Event Standard Toxicity Grade	Causality Action Taken with Study Treatment	Concomitant or Additional Treatment Given Outcome of Adverse Event	Sequence Number
リパーゼ増加	LIPASE INCREASED	20[redacted] 20[redacted]	279 66	N 3	NOT RELATED DOSE NOT CHANGED	N RECOVERED/RESOLVED	31
好中球数減少	NEUTROPHIL COUNT DECREASED	20[redacted] 20[redacted]	279 6	N 4	POSSIBLE DOSE NOT CHANGED	Y RECOVERED/RESOLVED	40
好中球数減少	NEUTROPHIL COUNT DECREASED	20[redacted] 20[redacted]	285 4	N 3	POSSIBLE DOSE NOT CHANGED	Y RECOVERED/RESOLVED	41
薬疹	DRUG ERUPTION	20[redacted] 20[redacted]	287 38	N 2	DOUBTFUL DOSE NOT CHANGED	N RECOVERED/RESOLVED	14
感覚鈍麻	NUMBNESS	20[redacted] -	287 -	N 2	DOUBTFUL DOSE NOT CHANGED	Y NOT RECOVERED/NOT RESOLVED	43
肝障害	LIVER DISORDER	20[redacted] 20[redacted]	287 14	N 2	DOUBTFUL DOSE NOT CHANGED	Y RECOVERED/RESOLVED	34
好中球数減少	NEUTROPHIL COUNT DECREASED	20[redacted] 20[redacted]	289 4	N 4	POSSIBLE DOSE NOT CHANGED	Y RECOVERED/RESOLVED	42
蜂巣炎	CELLULITIS(RIGHT LOWER LIMB)	20[redacted] 20[redacted]	292 40	N 1	PROBABLE DOSE NOT CHANGED	Y RECOVERED/RESOLVED	10
便秘	WORSENING CONSTIPATION	20[redacted] -	293 -	N 2	DOUBTFUL DOSE NOT CHANGED	Y NOT RECOVERED/NOT RESOLVED	52
肝障害	LIVER DISORDER	20[redacted] 20[redacted]	301 31	N 1	DOUBTFUL DOSE NOT CHANGED	Y RECOVERED/RESOLVED	35
蜂巣炎	CELLULITIS(LEFT LOWER LIMB)	20[redacted] 20[redacted]	306 40	N 2	PROBABLE DOSE NOT CHANGED	Y RECOVERED/RESOLVED	7

Dictionary-Derived Term	Reported Term for the Adverse Event	Start Date of Adverse Event End Date of Adverse Event	Study Day of Start of Adverse Event Adverse Event Duration (days)	Serious Event Standard Toxicity Grade	Causality Action Taken with Study Treatment	Concomitant or Additional Treatment Given Outcome of Adverse Event	Sequence Number
リパーゼ増加	INCREASED LIPASE	20[redacted] -	345 -	N 2	NOT RELATED DOSE NOT CHANGED	N NOT RECOVERED/NOT RESOLVED	28
蜂巣炎	CELLULITIS(WHOLE BODY)	20 -	366 -	N 2	PROBABLE DOSE NOT CHANGED	Y NOT RECOVERED/NOT RESOLVED	11
肝障害	LIVER DISORDER	20 20	366 8	N 2	DOUBTFUL DOSE NOT CHANGED	Y RECOVERED/RESOLVED	36
転倒	FALL	20 20	377 1	N 2	NOT RELATED DOSE NOT CHANGED	N RECOVERED/RESOLVED	22
皮膚裂傷	RIGHT KNEE LACERATION	20 -	377 -	N 2	NOT RELATED DOSE NOT CHANGED	N NOT RECOVERED/NOT RESOLVED	47
転倒	FALL	20 20	379 1	N 2	NOT RELATED DOSE NOT CHANGED	N RECOVERED/RESOLVED	23
皮膚裂傷	LEFT KNEE LACERATION	20 -	379 -	N 1	NOT RELATED DOSE NOT CHANGED	N NOT RECOVERED/NOT RESOLVED	29

Note: Adverse Events are coded using MedDRA 22.1

■ Medical History

Body System or Organ Class	Dictionary-Derived Term	Reported Term for the Medical History	End Relative to Reference Period	Toxicity Grade
Immune system disorders	Acute graft versus host disease	ACUTE GRAFT VERSUS HOST DISEASE	BEFORE	-
Infections and infestations	Cellulitis	CELLULITIS	BEFORE	-
Infections and infestations	Pneumonia	LEFT LOWER LOBE PNEUMONIA	BEFORE	-
Infections and infestations	Otitis media	LEFT OTITIS MEDIA SEROUS	BEFORE	-
Musculoskeletal and connective tissue disorders	Arthralgia	ARTHRALGIA	ONGOING	1
Gastrointestinal disorders	Constipation	CONSTIPATION	ONGOING	1

Body System or Organ Class	Dictionary-Derived Term	Reported Term for the Medical History	End Relative to Reference Period	Toxicity Grade
Investigations	Blood creatinine increased	CREATININE INCREASED	ONGOING	1
Gastrointestinal disorders	Haemorrhoids	HEMORRHOID	ONGOING	1
Hepatobiliary disorders	Alcoholic liver disease	HEPATOPATHY ALCOHOLIC	ONGOING	1
Metabolism and nutrition disorders	Hyperuricaemia	HYPERURICEMIA	ONGOING	1
Metabolism and nutrition disorders	Hypomagnesaemia	HYPOMAGNESEMIA	ONGOING	1
Psychiatric disorders	Insomnia	INSOMNIA	ONGOING	1
Cardiac disorders	Atrial fibrillation	ATRIAL FIBRILLATION	ONGOING	2
Eye disorders	Cataract	CATARACT	ONGOING	2

Note: Medical History are coded using MedDRA 22.1

■ Transplant History

Transplantation Date	Dictionary-Derived Term	Transplant Type	HLA matching and donor relation to recipient	Sex matching between donor and recipient	Stem Cell Source
20[redacted]	Acute lymphocytic leukaemia	Myeloablative	Matched unrelated	Matched	Bone Marrow

■ Disease History

Date of Initial Diagnosis	Initial Diagnosis
20[redacted]	CGVHD

■ Study Medication

Visit Name	Start Date of Treatment	End Date of Treatment	Study Day of Start of Treatment	Study Day of End of Treatment	Dose per Administration (mg)	Reason for Dose Skip	Reason for Dose Adjustment	AE Sequence Number(s)
WEEK 1 DAY 1	20[redacted]	20[redacted]	1	1	420.0	-	-	-
WEEK 1 DAY 2	20[redacted]	20[redacted]	2	7	420.0	-	-	-
WEEK 2	20[redacted]	20[redacted]	8	28	420.0	-	-	-
WEEK 5	20[redacted]	20[redacted]	29	57	420.0	-	-	-
WEEK 9	20[redacted]	20[redacted]	58	85	420.0	-	-	-
WEEK 13	20[redacted]	20[redacted]	86	113	420.0	-	-	-
WEEK 17	20[redacted]	20[redacted]	114	141	420.0	-	-	-
WEEK 21	20[redacted]	20[redacted]	142	169	420.0	-	-	-
WEEK 25	20[redacted]	20[redacted]	170	246	420.0	-	-	-

Visit Name	Start Date of Treatment	End Date of Treatment	Study Day of Start of Treatment	Study Day of End of Treatment	Dose per Administration (mg)	Reason for Dose Skip	Reason for Dose Adjustment	AE Sequence Number(s)
WEEK 37	20[redacted]	20[redacted]	247	249	420.0	-	-	-
WEEK 37	20	20	250	250	0.0	OTHER	-	-
WEEK 37	20	20	251	253	420.0	-	-	-
WEEK 37	20	20	254	261	0.0	OTHER	-	-
WEEK 37	20	20	262	298	420.0	-	-	-
WEEK 37	20	20	299	299	0.0	OTHER	-	-
WEEK 37	20	20	300	316	420.0	-	-	-
WEEK 37	20	20	317	317	0.0	OTHER	-	-
WEEK 37	20	20	318	330	420.0	-	-	-
WEEK 49	20	20	331	422	420.0	-	-	-

■ Prior and Concomitant Medications

Standardized Medication Name Reported Name of Drug, Med, or Therapy	Start Date of Medication Study Day of Start of Medication	Started Before Informed Concent Date	End Date of Medication Study Day of End of Medication	Indication	Dose per Administration Dose Units	Dosing Frequency per Interval Route of Administration	AE Sequence Number(s)
ACICLOVIR (ACICLOVIR TABLETS)	20[redacted] -15	-	- -	PROPHYLAXIS	200 mg	QD ORAL	-
NADIFLOXACIN (ACUATIM OINTMENT)	20[redacted] 15	-	20[redacted] 29	CGVHD	- APPLICATION	PRN TOPICAL	-
NIFEDIPINE (ADALAT-L10)	20[redacted] 278	-	20[redacted] 278	ADVERSE EVENT	10 mg	QD ORAL	2
AMBROXOL (AMBROXOL HYDROCHLORIDE)	20[redacted] 115	-	20[redacted] 170	ADVERSE EVENT	15 mg	TID ORAL	1
LUBIPROSTONE (AMITIZA)	20[redacted] 301	-	- -	ADVERSE EVENT	2 CAPSULE	BID ORAL	5
ARTIFICIAL TEARS [UMBRELLA TERM] (ARTIFICIAL TEARS(UNKNOWN))	20[redacted] 133	-	20[redacted] 169	ADVERSE EVENT	- gtt	PRN TOPICAL	1
AMOXICILLIN TRIHYDRATE; CLAVULANATE POTASSIUM (AUGMENTIN COMBINATION)	20[redacted] 58	-	20[redacted] 71	PROPHYLAXIS	4 TABLET	QID ORAL	-

Standardized Medication Name Reported Name of Drug, Med, or Therapy	Start Date of Medication Study Day of Start of Medication	Started Before Informed Concent Date	End Date of Medication Study Day of End of Medication	Indication	Dose per Administration Dose Units	Dosing Frequency per Interval Route of Administration	AE Sequence Number(s)
AMOXICILLIN TRIHYDRATE; CLAVULANATE POTASSIUM (AUGMENTIN COMBINATION)	20[redacted] 142	-	20[redacted] 159	ADVERSE EVENT	3 TABLET	TID ORAL	1
AMOXICILLIN TRIHYDRATE; CLAVULANATE POTASSIUM (AUGMENTIN COMBINATION TABLETS)	20[redacted] 96	-	20[redacted] 103	ADVERSE EVENT	3 TABLET	TID ORAL	1
AMOXICILLIN TRIHYDRATE; CLAVULANATE POTASSIUM (AUGMENTIN COMBINATION TABLETS)	20[redacted] 316	-	20[redacted] 345	ADVERSE EVENT	4 TABLET	QID ORAL	7
AMOXICILLIN TRIHYDRATE; CLAVULANATE POTASSIUM (AUGMENTIN COMBINATION TABLETS)	20[redacted] 345	-	20[redacted] 359	PROPHYLAXIS	4 TABLET	QID ORAL	-
AMOXICILLIN TRIHYDRATE; CLAVULANATE POTASSIUM (AUGMENTIN COMBINATION TABLETS)	20[redacted] 366	-	- -	ADVERSE EVENT	4 TABLET	QID ORAL	1
BACITRACIN; NEOMYCIN (BARAMYCIN OINTMENT)	20[redacted] 268	-	20[redacted] 331	ADVERSE EVENT	- APPLICATION	PRN TOPICAL	9
BACITRACIN; NEOMYCIN (BARAMYCIN OINTMENT)	20[redacted] 268	-	20[redacted] 331	ADVERSE EVENT	- APPLICATION	PRN TOPICAL	1
BACITRACIN; NEOMYCIN (BARAMYCIN OINTMENT)	20[redacted] 306	-	20[redacted] 306	ADVERSE EVENT	- APPLICATION	ONCE TOPICAL	2
BACITRACIN; NEOMYCIN (BARAMYCIN OINTMENT)	20[redacted] 332	-	- -	CGVHD	- APPLICATION	PRN TOPICAL	-
MUCOPOLYSACCHARIDE POLYSULFURIC ACID ESTER (BESOFTEN LOTION)	20[redacted] -646	Y	- -	CGVHD	- APPLICATION	PRN TOPICAL	-
ALL OTHER NON-THERAPEUTIC PRODUCTS (BONE MARROW ASPIRATION)	20[redacted] 281	-	20[redacted] 281	OTHER	- -	- -	-
EPINEPHRINE (BOSMIN)	20[redacted] 306	-	20[redacted] 306	ADVERSE EVENT	- APPLICATION	ONCE TRANSDERMAL	2
BROTIZOLAM (BROTIZOLAM)	20[redacted] 61	-	- -	MEDICAL HISTORY	0.25 mg	PRN ORAL	-

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Standardized Medication Name Reported Name of Drug, Med, or Therapy	Start Date of Medication Study Day of Start of Medication	Started Before Informed Concent Date	End Date of Medication Study Day of End of Medication	Indication	Dose per Administration Dose Units	Dosing Frequency per Interval Route of Administration	AE Sequence Number(s)
CALCIUM; MAGNESIUM (CALCIUM,MAGNESIUM)	20[redacted] -561	Y	20[redacted] 1	MEDICAL HISTORY	8 TABLET	TID ORAL	-
PARACETAMOL (CALONAL)	20[redacted] 143	-	20[redacted] 159	ADVERSE EVENT	4 TABLET	BID ORAL	1
PARACETAMOL (CALONAL)	20[redacted] 171	-	- -	ADVERSE EVENT	4 TABLET	PRN ORAL	2
PARACETAMOL (CALONAL TAB)	20[redacted] 6	-	20[redacted] 60	ADVERSE EVENT	4 TABLET	PRN ORAL	5
PARACETAMOL (CALONAL TAB)	20[redacted] 92	-	20[redacted] 104	ADVERSE EVENT	4 TABLET	PRN ORAL	1
PARACETAMOL (CALONAL TAB)	20[redacted] 110	-	20[redacted] 142	ADVERSE EVENT	4 TABLET	PRN ORAL	1
CASPOFUNGIN ACETATE (CANCIDAS FOR INTRAVENOUS DRIP INFUSION)	20[redacted] 251	-	20[redacted] 251	ADVERSE EVENT	70 mg	QD INTRAVENOUS	6
CASPOFUNGIN ACETATE (CANCIDAS FOR INTRAVENOUS DRIP INFUSION)	20[redacted] 252	-	20[redacted] 279	ADVERSE EVENT	50 mg	QD INTRAVENOUS	6
CEFEPIME HYDROCHLORIDE (CEFEPIME DIHYDROCHLORIDE)	20[redacted] 285	-	20[redacted] 289	ADVERSE EVENT	2 g	BID INTRAVENOUS	9
CEFEPIME HYDROCHLORIDE (CEFEPIME DIHYDROCHLORIDE FOR INTRAVENOUS)	20[redacted] 250	-	20[redacted] 250	ADVERSE EVENT	2 g	BID INTRAVENOUS	8
CIBENZOLINE SUCCINATE (CIBENOL TABLETS)	20[redacted] -	Y	20[redacted] 114	MEDICAL HISTORY	50 mg	TID ORAL	-
CLOBETASONE BUTYRATE (CLOBETASONE BUTYRATE OINTMENT 0.05%)	20[redacted] 268	-	- -	CGVHD	- APPLICATION	PRN TOPICAL	-
DAPTOMYCIN (CUBICIN)	20[redacted] 252	-	20[redacted] 253	ADVERSE EVENT	450 mg	QD INTRAVENOUS	8
DAPTOMYCIN (CUBICIN)	20[redacted] 267	-	20[redacted] 279	ADVERSE EVENT	450 mg	QD INTRAVENOUS	9
DIFLORASONE DIACETATE (DIFLAL OINTMENT)	20[redacted] -646	Y	20[redacted] 86	CGVHD	- APPLICATION	PRN TOPICAL	-
DOMPERIDONE (DOMPERIDONE)	20[redacted] 61	-	20[redacted] 86	ADVERSE EVENT	10 mg	PRN ORAL	3

Standardized Medication Name Reported Name of Drug, Med, or Therapy	Start Date of Medication Study Day of Start of Medication	Started Before Informed Concent Date	End Date of Medication Study Day of End of Medication	Indication	Dose per Administration Dose Units	Dosing Frequency per Interval Route of Administration	AE Sequence Number(s)
ALL OTHER NON-THERAPEUTIC PRODUCTS (EXPLORATORY INCISION SUTURE)	20[redacted] 275	-	20[redacted] 275	ADVERSE EVENT	- -	- -	9
FEBUXOSTAT (FEBURIC TABLETS)	20[redacted] -1	-	20[redacted] 257	MEDICAL HISTORY	10 mg	QD ORAL	-
FEBUXOSTAT (FEBURIC TABLETS)	20[redacted] 258	-	20[redacted] 281	MEDICAL HISTORY	20 mg	QD ORAL	-
FEBUXOSTAT (FEBURIC TABLETS)	20[redacted] 324	-	- -	MEDICAL HISTORY	20 mg	QD ORAL	-
FENTANYL (FENTANYL INJECTION)	20[redacted] 280	-	20[redacted] 282	ADVERSE EVENT	8 mL	QD INTRAVENOUS	2
FEXOFENADINE HYDROCHLORIDE (FEXOFENADINE HYDROCHLORIDE)	20[redacted] 87	-	20[redacted] 259	CGVHD	1 TABLET	PRN ORAL	-
FEXOFENADINE HYDROCHLORIDE (FEXOFENADINE HYDROCHLORIDE)	20[redacted] 260	-	- -	CGVHD	1 TABLET	BID ORAL	-
FILGRASTIM (FILGRASTIM BS)	20[redacted] 289	-	20[redacted] 291	ADVERSE EVENT	75 ug	QD INTRAVENOUS	4
FILGRASTIM (FILGRASTIM BS INJECTION SYRINGE)	20[redacted] 279	-	20[redacted] 286	ADVERSE EVENT	75 ug	QD INTRAVENOUS	4
FILGRASTIM (FILGRASTIM BS INJECTION SYRINGE)	20[redacted] 279	-	20[redacted] 286	ADVERSE EVENT	75 ug	QD INTRAVENOUS	4
FLUNITRAZEPAM (FLUNITRAZEPAM)	20[redacted] 2	-	- -	MEDICAL HISTORY	1 mg	PRN ORAL	-
FUROSEMIDE (FUROSEMIDE)	20[redacted] 114	-	20[redacted] 142	ADVERSE EVENT	10 mg	QD ORAL	5
FUROSEMIDE (FUROSEMIDE)	20[redacted] 114	-	20[redacted] 142	ADVERSE EVENT	10 mg	QD ORAL	1
FUROSEMIDE (FUROSEMIDE)	20[redacted] 170	-	20[redacted] 176	ADVERSE EVENT	10 mg	QD ORAL	5
FUROSEMIDE (FUROSEMIDE)	20[redacted] 170	-	20[redacted] 176	ADVERSE EVENT	10 mg	QD ORAL	1
FUROSEMIDE (FUROSEMIDE)	20[redacted] 177	-	20[redacted] 246	ADVERSE EVENT	20 mg	QD ORAL	5

Standardized Medication Name Reported Name of Drug, Med, or Therapy	Start Date of Medication Study Day of Start of Medication	Started Before Informed Concent Date	End Date of Medication Study Day of End of Medication	Indication	Dose per Administration Dose Units	Dosing Frequency per Interval Route of Administration	AE Sequence Number(s)
FUROSEMIDE (FUROSEMIDE)	20[redacted] 177	-	20[redacted] 246	ADVERSE EVENT	20 mg	QD ORAL	1
FUROSEMIDE (FUROSEMIDE)	20[redacted] 247	-	20[redacted] 253	ADVERSE EVENT	10 mg	QD ORAL	5
FUROSEMIDE (FUROSEMIDE)	20[redacted] 247	-	20[redacted] 253	ADVERSE EVENT	10 mg	QD ORAL	1
FUROSEMIDE (FUROSEMIDE)	20[redacted] 254	-	20[redacted] 254	ADVERSE EVENT	2 mL	QD INTRAVENOUS	5
FUROSEMIDE (FUROSEMIDE)	20[redacted] 254	-	20[redacted] 254	ADVERSE EVENT	2 mL	QD INTRAVENOUS	4
FUROSEMIDE (FUROSEMIDE)	20[redacted] 254	-	20[redacted] 254	ADVERSE EVENT	2 mL	QD INTRAVENOUS	1
FUROSEMIDE (FUROSEMIDE)	20[redacted] 261	-	20[redacted] 267	ADVERSE EVENT	20 mg	QD ORAL	5
FUROSEMIDE (FUROSEMIDE)	20[redacted] 261	-	20[redacted] 267	ADVERSE EVENT	20 mg	QD ORAL	1
FUROSEMIDE (FUROSEMIDE)	20[redacted] 268	-	20[redacted] 400	ADVERSE EVENT	20 mg	QD ORAL	1
GARENOXACIN MESILATE (GENINAX TABLETS)	20[redacted] 159	-	20[redacted] 159	ADVERSE EVENT	2 TABLET	QD ORAL	1
GARENOXACIN MESILATE (GENINAX TABLETS)	20[redacted] 160	-	20[redacted] 170	ADVERSE EVENT	1 TABLET	QD ORAL	1
GARENOXACIN MESILATE (GENINAX TABLETS)	20[redacted] 306	-	20[redacted] 316	ADVERSE EVENT	2 TABLET	BID ORAL	7
GENTAMICIN SULFATE (GENTACIN)	20[redacted] 15	-	- -	CGVHD	- APPLICATION	PRN TOPICAL	-
DL-METHIONINE; GLYCINE; GLYCYRRHIZIC ACID, AMMONIUM SALT (GLYCYRON TABLETS(MONOAMMONIUM GLYCYRRHIZINZTE,GLYCINE,AMINOACETIC ACID,DL-METHIONINE)	20[redacted] 366	-	20[redacted] 373	ADVERSE EVENT	2 TABLET	TID ORAL	3
HEPARINOID (HEPARINOID)	20[redacted] -1	-	- -	CGVHD	- APPLICATION	PRN TOPICAL	-

Standardized Medication Name Reported Name of Drug, Med, or Therapy	Start Date of Medication Study Day of Start of Medication	Started Before Informed Concent Date	End Date of Medication Study Day of End of Medication	Indication	Dose per Administration Dose Units	Dosing Frequency per Interval Route of Administration	AE Sequence Number(s)
HEPARINOID (HEPARINOID CREAM)	20[redacted] 268	-	- -	CGVHD	- APPLICATION	PRN TOPICAL	-
LEVOFLOXACIN (LEVOFLOXACIN TABLETS)	20[redacted] -133	Y	20[redacted] 16	PROPHYLAXIS	500 mg	QD ORAL	-
LEVOFLOXACIN (LEVOFLOXACIN TABLETS)	20[redacted] 281	-	20[redacted] 285	PROPHYLAXIS	500 mg	QD ORAL	-
PREDNISOLONE VALEROACETATE (LIDOMEX KOWA LOTION 0.3%)	20[redacted] 345	-	- -	CGVHD	- APPLICATION	PRN TOPICAL	-
HYDROCORTISONE BUTYRATE (LOCOID OINTMENT)	20[redacted] -646	Y	- -	CGVHD	- APPLICATION	PRN TOPICAL	-
LOXOPROFEN SODIUM (LOXONIN PAP)	20[redacted] -20	Y	20[redacted] 60	MEDICAL HISTORY	100 mg	QD TRANSDERMAL	-
LOXOPROFEN SODIUM (LOXONIN PAP)	20[redacted] 177	-	20[redacted] 372	ADVERSE EVENT	100 mg	QD TRANSDERMAL	2
LOXOPROFEN (LOXOPROFEN)	20[redacted] 29	-	20[redacted] 60	ADVERSE EVENT	1 TABLET	PRN ORAL	5
LOXOPROFEN (LOXOPROFEN)	20[redacted] 157	-	20[redacted] 254	ADVERSE EVENT	1 TABLET	PRN ORAL	2
LOXOPROFEN (LOXOPROFEN)	20[redacted] 278	-	- -	ADVERSE EVENT	1 TABLET	PRN ORAL	2
LOXOPROFEN SODIUM (LOXOPROFEN NA PAP)	20[redacted] 373	-	- -	ADVERSE EVENT	100 mg	PRN TRANSDERMAL	2
ALL OTHER NON-THERAPEUTIC PRODUCTS (LUMBAR PUNCTURE)	20[redacted] 280	-	20[redacted] 280	OTHER	- -	- -	-
PREGABALIN (LYRICA OD TABLETS)	20[redacted] 301	-	20[redacted] 365	ADVERSE EVENT	75 mg	BID ORAL	4
PREGABALIN (LYRICA OD TABLETS)	20[redacted] 366	-	- -	ADVERSE EVENT	50 mg	BID ORAL	4
MAGNESIUM OXIDE (MAGMITT TAB)	20[redacted] -20	Y	20[redacted] 1	MEDICAL HISTORY	660 mg	PRN ORAL	-
MAGNESIUM OXIDE (MAGNESIUM OXIDE)	20[redacted] 2	-	- -	MEDICAL HISTORY	2 TABLET	PRN ORAL	-

Standardized Medication Name Reported Name of Drug, Med, or Therapy	Start Date of Medication Study Day of Start of Medication	Started Before Informed Concent Date	End Date of Medication Study Day of End of Medication	Indication	Dose per Administration Dose Units	Dosing Frequency per Interval Route of Administration	AE Sequence Number(s)
DEXTROMETHORPHAN HYDROBROMIDE (MEDICON(DEXTROMETHORPHAN HYDROBROMIDE HYDRATE))	20[redacted] 96	-	20[redacted] 103	ADVERSE EVENT	30 mg	TID ORAL	1
DEXTROMETHORPHAN HYDROBROMIDE (MEDICON[DEXTROMETHORPHAN HYDROBROMIDE HYDRATE])	20[redacted] 115	-	20[redacted] 170	ADVERSE EVENT	30 ug	TID ORAL	1
MEROPENEM (MEROPENEM FOR INJECTION)	20[redacted] 253	-	20[redacted] 266	ADVERSE EVENT	1 g	BID INTRAVENOUS	9
MEROPENEM (MEROPENEM FOR INJECTION)	20[redacted] 253	-	20[redacted] 266	ADVERSE EVENT	1 g	BID INTRAVENOUS	8
MEROPENEM (MEROPENEM FOR INJECTION)	20[redacted] 366	-	20[redacted] 366	ADVERSE EVENT	2 g	QD INTRAVENOUS	1
CLOBETASOL PROPIONATE (MYALONE[CLOBETASOL PROPIONATE])	20[redacted] 87	-	- -	CGVHD	- APPLICATION	PRN TOPICAL	-
CYSTEINE; GLYCINE; GLYCYRRHIZIC ACID (NEOPHAGEN I.V.INJECTION (MONOAMMONIUM GLYCYRRHIZINATE,GLYCINE,L-CYSTEINE))	20[redacted] 366	-	20[redacted] 366	ADVERSE EVENT	100 mL	QD INTRAVENOUS	3
CYSTEINE; GLYCINE; GLYCYRRHIZIC ACID (NEOPHAGEN I.V.INJECTION(MONOAMMONIUM GLYCYRRHIZINATE, GLYCINE, L-CYSTEINE))	20[redacted] 279	-	20[redacted] 293	ADVERSE EVENT	100 mL	QD INTRAVENOUS	3
CYSTEINE; GLYCINE; GLYCYRRHIZIC ACID (NEOPHAGEN I.V.INJECTION(MONOAMMONIUM GLYCYRRHIZINATE, GLYCINE, L-CYSTEINE))	20[redacted] 279	-	20[redacted] 293	ADVERSE EVENT	100 mL	QD INTRAVENOUS	3
PROCHLORPERAZINE MESILATE (NOVAMIN(PROCHLORPERAZINE MALEATE))	20[redacted] 250	-	- -	ADVERSE EVENT	1 TABLET	PRN ORAL	3
OXYCODONE HYDROCHLORIDE (OXINORM(OXYCODONE HYDROCHLORIDE HYDRATE))	20[redacted] 250	-	20[redacted] 283	ADVERSE EVENT	5 g	PRN ORAL	9
OXYCODONE HYDROCHLORIDE (OXINORM(OXYCODONE HYDROCHLORIDE HYDRATE))	20[redacted] 250	-	20[redacted] 283	ADVERSE EVENT	5 g	PRN ORAL	8
OXYCODONE HYDROCHLORIDE (OXINORM(OXYCODONE HYDROCHLORIDE HYDRATE))	20[redacted] 284	-	20[redacted] 293	ADVERSE EVENT	2.5 mg	PRN ORAL	2

Standardized Medication Name Reported Name of Drug, Med, or Therapy	Start Date of Medication Study Day of Start of Medication	Started Before Informed Concent Date	End Date of Medication Study Day of End of Medication	Indication	Dose per Administration Dose Units	Dosing Frequency per Interval Route of Administration	AE Sequence Number(s)
OXYCODONE (OXYCODONE EXTENDED RELEASE TABLETS)	20[redacted] 250	-	20[redacted] 250	ADVERSE EVENT	2 TABLET	ONCE ORAL	8
OXYCODONE (OXYCODONE EXTENDED RELEASE TABLETS)	20[redacted] 251	-	20[redacted] 264	ADVERSE EVENT	1 TABLET	PRN ORAL	8
OXYCODONE (OXYCODONE EXTENDED RELEASE TABLETS)	20[redacted] 284	-	20[redacted] 293	ADVERSE EVENT	2 TABLET	BID ORAL	2
SODIUM PICOSULFATE (PICOSULFATE NA ORAL SOLUTION 0.75%)	20[redacted] 293	-	- -	ADVERSE EVENT	- gtt	PRN ORAL	5
PLATELETS, CONCENTRATED (PLATELET CONCENTRATE,LEUKOCYTES REDUCED,NISSEKI)	20[redacted] 253	-	20[redacted] 280	ADVERSE EVENT	- U	PRN INTRAVENOUS	4
HYDROCORTISONE (POSTERISAN FORTE[HYDROCORTISONE])	20[redacted] 114	-	- -	MEDICAL HISTORY	- OTHER	PRN TOPICAL	-
RED BLOOD CELLS (RED BLOOD CELLS, REDUCED,NISSEKI)	20[redacted] 387	-	20[redacted] 387	ADVERSE EVENT	2 U	ONCE INTRAVENOUS	4
RED BLOOD CELLS, CONCENTRATED (RED BLOOD CELLS,LEUKOCYTES REDUCED,NISSEKI)	20[redacted] 254	-	20[redacted] 289	ADVERSE EVENT	2 U	PRN INTRAVENOUS	4
ALL OTHER NON-THERAPEUTIC PRODUCTS (RIGHT LEG EXPLORATORY INCISION)	20[redacted] 253	-	20[redacted] 253	ADVERSE EVENT	- -	- -	8
BETAMETHASONE VALERATE; GENTAMICIN SULFATE (RINDERON-VG)	20[redacted] 114	-	- -	CGVHD	- OTHER	PRN TOPICAL	-
ALLANTOIN; ASPARTIC ACID; NAPHAZOLINE HYDROCHLORIDE; ZINC SULFATE (ROHTO V)	20[redacted] 133	-	20[redacted] 169	ADVERSE EVENT	- gtt	PRN TOPICAL	1
ROSUVASTATIN (ROSUVASTATIN OD)	20[redacted] 30	-	20[redacted] 281	ADVERSE EVENT	0.5 TABLET	QD ORAL	3
RETINOL (SAHNE)	20[redacted] -120	Y	- -	CGVHD	- APPLICATION	PRN TOPICAL	-
TOLVAPTAN (SAMSCA)	20[redacted] 247	-	20[redacted] 253	ADVERSE EVENT	7.5 mg	QD ORAL	5

Standardized Medication Name Reported Name of Drug, Med, or Therapy	Start Date of Medication Study Day of Start of Medication	Started Before Informed Concent Date	End Date of Medication Study Day of End of Medication	Indication	Dose per Administration Dose Units	Dosing Frequency per Interval Route of Administration	AE Sequence Number(s)
TOLVAPTAN (SAMSCA)	20[redacted] 247	-	20[redacted] 253	ADVERSE EVENT	7.5 mg	QD ORAL	1
TOLVAPTAN (SAMSCA)	20[redacted] 274	-	20[redacted] 315	ADVERSE EVENT	7.5 mg	QD ORAL	1
TOLVAPTAN (SAMSCA)	20[redacted] 316	-	- -	ADVERSE EVENT	15 mg	QD ORAL	1
ATOVAQUONE (SAMTIREL ORAL SUSPENSION15%)	20[redacted] 61	-	20[redacted] 81	ADVERSE EVENT	5 mL	BID ORAL	5
ATOVAQUONE (SAMTIREL ORAL SUSPENSION15%)	20[redacted] 87	-	20[redacted] 114	ADVERSE EVENT	5 mL	BID ORAL	5
ATOVAQUONE (SAMTIREL ORAL SUSPENSION15%)	20[redacted] 115	-	20[redacted] 246	PROPHYLAXIS	5 mL	BID ORAL	-
ATOVAQUONE (SAMTIREL ORAL SUSPENSION15%)	20[redacted] 247	-	20[redacted] 281	ADVERSE EVENT	5 mL	BID ORAL	6
SENNOSIDE A+B (SENNOSIDE TAB)	20[redacted] 293	-	- -	ADVERSE EVENT	12 mg	PRN ORAL	5
GLYCYRRHIZA SPP. ROOT; PAEONIA LACTIFLORA ROOT (SHAKUYAKUKANZOTO)	20[redacted] 177	-	20[redacted] 280	CGVHD	2.5 g	PRN ORAL	-
CAMPHOR; ENOXOLONE; LEVOMENTHOL; METHYL SALICYLATE (STICKZENOL A)	20[redacted] 272	-	- -	PROPHYLAXIS	- APPLICATION	PRN TOPICAL	-
VONOPRAZAN FUMARATE (TAKECAB TABLETS)	20[redacted] -533	Y	- -	PROPHYLAXIS	10 mg	QD ORAL	-
BEPOTASTINE BESILATE (TALION TABLETS)	20[redacted] 96	-	- -	CGVHD	10 mg	BID ORAL	-
HYALURONATE SODIUM (TEARBALANCE OPHTHALMIC SOLUTION 0.1% [PURIFIED SODIUM HYALURONATE])	20[redacted] 142	-	- -	ADVERSE EVENT	- gtt	PRN TOPICAL	1
HYALURONATE SODIUM (TEARBALANCE OPHTHALMIC SOLUTION 0.1% [PURIFIED SODIUM HYALURONATE])	20[redacted] 142	-	- -	ADVERSE EVENT	- gtt	PRN TOPICAL	1

Standardized Medication Name Reported Name of Drug, Med, or Therapy	Start Date of Medication Study Day of Start of Medication	Started Before Informed Concent Date	End Date of Medication Study Day of End of Medication	Indication	Dose per Administration Dose Units	Dosing Frequency per Interval Route of Administration	AE Sequence Number(s)
PARACETAMOL; TRAMADOL HYDROCHLORIDE (TOARASET COMBINATION TABLETS)	20[redacted] 157	-	20[redacted] 279	ADVERSE EVENT	2 TABLET	QID ORAL	2
PARACETAMOL; TRAMADOL HYDROCHLORIDE (TOARASET COMBINATION TABLETS)	20[redacted] 283	-	20[redacted] 283	ADVERSE EVENT	2 TABLET	QID ORAL	2
PARACETAMOL; TRAMADOL HYDROCHLORIDE (TOARASET COMBINATION TABLETS(TRAMADOL HYDROCHLORIDE, ACETAMINOPHEN))	20[redacted] 293	-	- -	ADVERSE EVENT	4 TABLET	QID ORAL	2
PARACETAMOL; TRAMADOL HYDROCHLORIDE (TRAMCET COMBINATION TABLETS)	20[redacted] 7	-	20[redacted] 60	ADVERSE EVENT	1 TABLET	QID ORAL	5
HERBAL PREPARATION (TSUMURA KAMPO HOCHUEKKITO EXTRACT GRANULES)	20[redacted] -62	Y	20[redacted] 281	PROPHYLAXIS	2.5 g	TID ORAL	-
URSODEOXYCHOLIC ACID (URSODEOXYCHOLIC ACID)	20[redacted] 17	-	20[redacted] 29	MEDICAL HISTORY	100 mg	TID ORAL	-
URSODEOXYCHOLIC ACID (URSODEOXYCHOLIC ACID TABLETS)	20[redacted] -442	Y	20[redacted] 16	MEDICAL HISTORY	200 mg	TID ORAL	-
URSODEOXYCHOLIC ACID (URSODEOXYCHOLIC ACID TABLETS)	20[redacted] 280	-	20[redacted] 331	ADVERSE EVENT	100 mg	TID ORAL	3
URSODEOXYCHOLIC ACID (URSODEOXYCHOLIC ACID TABLETS)	20[redacted] 280	-	20[redacted] 331	ADVERSE EVENT	100 mg	TID ORAL	3
URSODEOXYCHOLIC ACID (URSODEOXYCHOLIC ACID TABLETS)	20[redacted] 280	-	20[redacted] 331	ADVERSE EVENT	100 mg	TID ORAL	3
URSODEOXYCHOLIC ACID (URSODEOXYCHOLIC ACID TABLETS)	20[redacted] 332	-	20[redacted] 365	PROPHYLAXIS	100 mg	TID ORAL	-
URSODEOXYCHOLIC ACID (URSODEOXYCHOLIC ACID TABLETS)	20[redacted] 366	-	20[redacted] 373	ADVERSE EVENT	100 mg	TID ORAL	3
URSODEOXYCHOLIC ACID (URSODEOXYCHOLIC ACID TABLETS)	20[redacted] 374	-	- -	PROPHYLAXIS	100 mg	TID ORAL	-
IMMUNOGLOBULIN HUMAN NORMAL (VENOGLOBULIN IH 10% I.V)	20[redacted] 280	-	20[redacted] 280	PROPHYLAXIS	20 mg	QD INTRAVENOUS	-
WHITE SOFT PARAFFIN (WHITE PETROLATUM)	20[redacted] -120	Y	- -	CGVHD	- APPLICATION	PRN TOPICAL	-

Standardized Medication Name Reported Name of Drug, Med, or Therapy	Start Date of Medication Study Day of Start of Medication	Started Before Informed Concent Date	End Date of Medication Study Day of End of Medication	Indication	Dose per Administration Dose Units	Dosing Frequency per Interval Route of Administration	AE Sequence Number(s)
LEVOCETIRIZINE DIHYDROCHLORIDE (XYZAL TABLETS)	20[redacted] -1	-	20[redacted] 86	CGVHD	1 TABLET	PRN ORAL	-
PIPERACILLIN SODIUM; TAZOBACTAM SODIUM (ZOSYN)	20[redacted] 267	-	20[redacted] 279	ADVERSE EVENT	4.5 g	TID INTRAVENOUS	9
LINEZOLID (ZYVOX INJECTION)	20[redacted] 254	-	20[redacted] 266	ADVERSE EVENT	300 mL	BID INTRAVENOUS	9
LINEZOLID (ZYVOX INJECTION)	20[redacted] 254	-	20[redacted] 266	ADVERSE EVENT	300 mL	BID INTRAVENOUS	8
LINEZOLID (ZYVOX TABLETS)	20[redacted] 366	-	20[redacted] 380	ADVERSE EVENT	600 mg	BID ORAL	1

■ Karnofsky/Lansky performance status score

Date of Finding Study Day of Finding	Visit Name	Result
20[redacted] -1	SCREENING	80
20[redacted] 1	WEEK 1 DAY 1	80
20[redacted] 29	WEEK 5	80
20[redacted] 58	WEEK 9	80
20[redacted] 86	WEEK 13	90
20[redacted] 114	WEEK 17	90
20[redacted] 142	WEEK 21	80
20[redacted] 170	WEEK 25	80
20[redacted] 247	WEEK 37	80

Date of Finding Study Day of Finding	Visit Name	Result
20[redacted] 331	WEEK 49	90

■ Laboratory Data

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Alanine Aminotransferase (Enzyme U/L)	20[redacted] -1	SCREENING	16	10	42	NORMAL	0
Alanine Aminotransferase (Enzyme U/L)	20[redacted] 8	WEEK 2	17	10	42	NORMAL	0
Alanine Aminotransferase (Enzyme U/L)	20[redacted] 29	WEEK 5	16	10	42	NORMAL	0
Alanine Aminotransferase (Enzyme U/L)	20[redacted] 58	WEEK 9	17	10	42	NORMAL	0
Alanine Aminotransferase (Enzyme U/L)	20[redacted] 86	WEEK 13	22	10	42	NORMAL	0
Alanine Aminotransferase (Enzyme U/L)	20[redacted] 114	WEEK 17	25	10	42	NORMAL	0
Alanine Aminotransferase (Enzyme U/L)	20[redacted] 142	WEEK 21	28	10	42	NORMAL	0
Alanine Aminotransferase (Enzyme U/L)	20[redacted] 170	WEEK 25	16	10	42	NORMAL	0
Alanine Aminotransferase (Enzyme U/L)	20[redacted] 247	WEEK 37	16	10	42	NORMAL	0
Alanine Aminotransferase (Enzyme U/L)	20[redacted] 279	WEEK 37 UNSCHEDULED 07	591	10	42	HIGH	3
Alanine Aminotransferase (Enzyme U/L)	20[redacted] 287	WEEK 37 UNSCHEDULED 10	160	10	42	HIGH	2
Alanine Aminotransferase (Enzyme U/L)	20[redacted] 292	WEEK 37 UNSCHEDULED 12	127	10	42	HIGH	2
Alanine Aminotransferase (Enzyme U/L)	20[redacted] 301	WEEK 37 UNSCHEDULED 13	45	10	42	HIGH	1
Alanine Aminotransferase (Enzyme U/L)	20[redacted] 331	WEEK 49	19	10	42	NORMAL	0

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Alanine Aminotransferase (Enzyme U/L)	20[redacted] 366	WEEK 49 UNSCHEDULED 01	128	10	42	HIGH	2
Alanine Aminotransferase (Enzyme U/L)	20[redacted] 373	WEEK 49 UNSCHEDULED 02	19	10	42	NORMAL	0
Albumin (g/L)	20[redacted] -1	SCREENING	40	41	51	LOW	1
Albumin (g/L)	20[redacted] 8	WEEK 2	41	41	51	NORMAL	0
Albumin (g/L)	20[redacted] 29	WEEK 5	36	41	51	LOW	1
Albumin (g/L)	20[redacted] 58	WEEK 9	39	41	51	LOW	1
Albumin (g/L)	20[redacted] 86	WEEK 13	38	41	51	LOW	1
Albumin (g/L)	20[redacted] 114	WEEK 17	37	41	51	LOW	1
Albumin (g/L)	20[redacted] 142	WEEK 21	38	41	51	LOW	1
Albumin (g/L)	20[redacted] 170	WEEK 25	34	41	51	LOW	1
Albumin (g/L)	20[redacted] 247	WEEK 37	35	41	51	LOW	1
Albumin (g/L)	20[redacted] 331	WEEK 49	38	41	51	LOW	1
Albumin (g/L)	20[redacted] 366	WEEK 49 UNSCHEDULED 01	30	41	51	LOW	1
Albumin (g/L)	20[redacted] 373	WEEK 49 UNSCHEDULED 02	31	41	51	LOW	1
Alkaline Phosphatase (Enzyme U/L)	20[redacted] -1	SCREENING	195	106	322	NORMAL	0
Alkaline Phosphatase (Enzyme U/L)	20[redacted] 8	WEEK 2	178	106	322	NORMAL	0
Alkaline Phosphatase (Enzyme U/L)	20[redacted] 29	WEEK 5	177	106	322	NORMAL	0

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Alkaline Phosphatase (Enzyme U/L)	20[redacted] 58	WEEK 9	173	106	322	NORMAL	0
Alkaline Phosphatase (Enzyme U/L)	20[redacted] 86	WEEK 13	152	106	322	NORMAL	0
Alkaline Phosphatase (Enzyme U/L)	20[redacted] 114	WEEK 17	144	106	322	NORMAL	0
Alkaline Phosphatase (Enzyme U/L)	20[redacted] 142	WEEK 21	224	106	322	NORMAL	0
Alkaline Phosphatase (Enzyme U/L)	20[redacted] 170	WEEK 25	183	106	322	NORMAL	0
Alkaline Phosphatase (Enzyme U/L)	20[redacted] 247	WEEK 37	206	106	322	NORMAL	0
Alkaline Phosphatase (Enzyme U/L)	20[redacted] 331	WEEK 49	573	106	322	HIGH	1
Alkaline Phosphatase (Enzyme U/L)	20[redacted] 366	WEEK 49 UNSCHEDULED 01	1267	106	322	HIGH	2
Alkaline Phosphatase (Enzyme U/L)	20[redacted] 373	WEEK 49 UNSCHEDULED 02	692	106	322	HIGH	1
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] -1	SCREENING	14	13	30	NORMAL	0
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] 8	WEEK 2	15	13	30	NORMAL	0
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] 29	WEEK 5	13	13	30	NORMAL	0
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] 58	WEEK 9	15	13	30	NORMAL	0
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] 86	WEEK 13	19	13	30	NORMAL	0
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] 114	WEEK 17	17	13	30	NORMAL	0
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] 142	WEEK 21	20	13	30	NORMAL	0
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] 170	WEEK 25	14	13	30	NORMAL	0

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] 247	WEEK 37	18	13	30	NORMAL	0
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] 279	WEEK 37 UNSCHEDULED 07	473	13	30	HIGH	3
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] 287	WEEK 37 UNSCHEDULED 10	74	13	30	HIGH	1
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] 292	WEEK 37 UNSCHEDULED 12	39	13	30	HIGH	1
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] 301	WEEK 37 UNSCHEDULED 13	21	13	30	NORMAL	0
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] 331	WEEK 49	17	13	30	NORMAL	0
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] 366	WEEK 49 UNSCHEDULED 01	65	13	30	HIGH	1
Aspartate Aminotransferase (Enzyme U/L)	20[redacted] 373	WEEK 49 UNSCHEDULED 02	15	13	30	NORMAL	0
Bilirubin (umol/L)	20[redacted] -1	SCREENING	8.55	6.84	25.65	NORMAL	0
Bilirubin (umol/L)	20[redacted] 8	WEEK 2	8.55	6.84	25.65	NORMAL	0
Bilirubin (umol/L)	20[redacted] 29	WEEK 5	8.55	6.84	25.65	NORMAL	0
Bilirubin (umol/L)	20[redacted] 58	WEEK 9	10.26	6.84	25.65	NORMAL	0
Bilirubin (umol/L)	20[redacted] 86	WEEK 13	10.26	6.84	25.65	NORMAL	0
Bilirubin (umol/L)	20[redacted] 114	WEEK 17	8.55	6.84	25.65	NORMAL	0
Bilirubin (umol/L)	20[redacted] 142	WEEK 21	10.26	6.84	25.65	NORMAL	0
Bilirubin (umol/L)	20[redacted] 170	WEEK 25	8.55	6.84	25.65	NORMAL	0
Bilirubin (umol/L)	20[redacted] 247	WEEK 37	8.55	6.84	25.65	NORMAL	0

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Bilirubin (umol/L)	20[redacted] 331	WEEK 49	10.26	6.84	25.65	NORMAL	0
Bilirubin (umol/L)	20[redacted] 366	WEEK 49 UNSCHEDULED 01	10.26	6.84	25.65	NORMAL	0
Bilirubin (umol/L)	20[redacted] 373	WEEK 49 UNSCHEDULED 02	8.55	6.84	25.65	NORMAL	0
Creatinine (umol/L)	20[redacted] -1	SCREENING	108.732	57.46	94.588	HIGH	1
Creatinine (umol/L)	20[redacted] 8	WEEK 2	114.92	57.46	94.588	HIGH	1
Creatinine (umol/L)	20[redacted] 29	WEEK 5	122.876	57.46	94.588	HIGH	1
Creatinine (umol/L)	20[redacted] 58	WEEK 9	121.108	57.46	94.588	HIGH	1
Creatinine (umol/L)	20[redacted] 86	WEEK 13	107.848	57.46	94.588	HIGH	1
Creatinine (umol/L)	20[redacted] 114	WEEK 17	116.688	57.46	94.588	HIGH	1
Creatinine (umol/L)	20[redacted] 142	WEEK 21	116.688	57.46	94.588	HIGH	1
Creatinine (umol/L)	20[redacted] 170	WEEK 25	118.456	57.46	94.588	HIGH	1
Creatinine (umol/L)	20[redacted] 247	WEEK 37	104.312	57.46	94.588	HIGH	1
Creatinine (umol/L)	20[redacted] 253	WEEK 37 UNSCHEDULED 02	239.564	57.46	94.588	HIGH	2
Creatinine (umol/L)	20[redacted] 259	WEEK 37 UNSCHEDULED 04	90.168	57.46	94.588	NORMAL	0
Creatinine (umol/L)	20[redacted] 331	WEEK 49	91.052	57.46	94.588	NORMAL	0
Creatinine (umol/L)	20[redacted] 366	WEEK 49 UNSCHEDULED 01	106.08	57.46	94.588	HIGH	1
Creatinine (umol/L)	20[redacted] 373	WEEK 49 UNSCHEDULED 02	100.776	57.46	94.588	HIGH	1

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Eosinophils (10^9/L)	20[redacted] -1	SCREENING	0	0	0.516	NORMAL	-
Eosinophils (10^9/L)	20[redacted] 8	WEEK 2	0	0	0.516	NORMAL	-
Eosinophils (10^9/L)	20[redacted] 29	WEEK 5	0	0	0.516	NORMAL	-
Eosinophils (10^9/L)	20[redacted] 58	WEEK 9	0.067	0	0.516	NORMAL	-
Eosinophils (10^9/L)	20[redacted] 86	WEEK 13	0.048	0	0.516	NORMAL	-
Eosinophils (10^9/L)	20[redacted] 114	WEEK 17	0	0	0.516	NORMAL	-
Eosinophils (10^9/L)	20[redacted] 142	WEEK 21	0	0	0.516	NORMAL	-
Eosinophils (10^9/L)	20[redacted] 170	WEEK 25	0	0	0.516	NORMAL	-
Eosinophils (10^9/L)	20[redacted] 247	WEEK 37	0.058	0	0.516	NORMAL	-
Eosinophils (10^9/L)	20[redacted] 275	WEEK 37 UNSCHEDULED 06	0.168	0	0.516	NORMAL	-
Eosinophils (10^9/L)	20[redacted] 331	WEEK 49	0	0	0.516	NORMAL	-
Eosinophils (10^9/L)	20[redacted] 387	WEEK 49 UNSCHEDULED 03	0.33	0	0.516	NORMAL	-
Glucose (mmol/L)	20[redacted] -1	SCREENING	4.5518	4.0522	6.0506	NORMAL	0
Glucose (mmol/L)	20[redacted] 8	WEEK 2	6.1616	4.0522	6.0506	HIGH	1
Glucose (mmol/L)	20[redacted] 29	WEEK 5	5.7175	4.0522	6.0506	NORMAL	0
Glucose (mmol/L)	20[redacted] 58	WEEK 9	4.7184	4.0522	6.0506	NORMAL	0
Glucose (mmol/L)	20[redacted] 86	WEEK 13	4.6628	4.0522	6.0506	NORMAL	0

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Glucose (mmol/L)	20[redacted] 114	WEEK 17	5.7175	4.0522	6.0506	NORMAL	0
Glucose (mmol/L)	20[redacted] 142	WEEK 21	3.9967	4.0522	6.0506	LOW	1
Glucose (mmol/L)	20[redacted] 170	WEEK 25	5.329	4.0522	6.0506	NORMAL	0
Glucose (mmol/L)	20[redacted] 247	WEEK 37	5.2179	4.0522	6.0506	NORMAL	0
Glucose (mmol/L)	20[redacted] 331	WEEK 49	5.2735	4.0522	6.0506	NORMAL	0
Glucose (mmol/L)	20[redacted] 366	WEEK 49 UNSCHEDULED 01	5.2735	4.0522	6.0506	NORMAL	0
HIV Antibody	20[redacted] -15	SCREENING	NEGATIVE	-	-	-	-
Hemoglobin (g/L)	20[redacted] -1	SCREENING	89	137	168	LOW	2
Hemoglobin (g/L)	20[redacted] 8	WEEK 2	93	137	168	LOW	2
Hemoglobin (g/L)	20[redacted] 29	WEEK 5	93	137	168	LOW	2
Hemoglobin (g/L)	20[redacted] 58	WEEK 9	97	137	168	LOW	2
Hemoglobin (g/L)	20[redacted] 86	WEEK 13	103	137	168	LOW	1
Hemoglobin (g/L)	20[redacted] 114	WEEK 17	97	137	168	LOW	2
Hemoglobin (g/L)	20[redacted] 142	WEEK 21	101	137	168	LOW	1
Hemoglobin (g/L)	20[redacted] 170	WEEK 25	86	137	168	LOW	2
Hemoglobin (g/L)	20[redacted] 247	WEEK 37	92	137	168	LOW	2
Hemoglobin (g/L)	20[redacted] 254	WEEK 37 UNSCHEDULED 03	71	137	168	LOW	3

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Hemoglobin (g/L)	20[redacted] 275	WEEK 37 UNSCHEDULED 06	85	137	168	LOW	2
Hemoglobin (g/L)	20[redacted] 292	WEEK 37 UNSCHEDULED 12	89	137	168	LOW	2
Hemoglobin (g/L)	20[redacted] 331	WEEK 49	91	137	168	LOW	2
Hemoglobin (g/L)	20[redacted] 387	WEEK 49 UNSCHEDULED 03	60	137	168	LOW	3
Hepatitis B Virus Core Antibody	20[redacted] -15	SCREENING	NEGATIVE	-	-	-	-
Hepatitis B Virus Surface Antibody	20[redacted] -15	SCREENING	NEGATIVE	-	-	-	-
Hepatitis B Virus Surface Antigen	20[redacted] -15	SCREENING	NEGATIVE	-	-	-	-
Hepatitis C Virus Antibody	20[redacted] -15	SCREENING	NEGATIVE	-	-	-	-
Immunoglobulin A (g/L)	20[redacted] -1	SCREENING	1.56	-	-	-	-
Immunoglobulin A (g/L)	20[redacted] 86	WEEK 13	2.38	-	-	-	-
Immunoglobulin A (g/L)	20[redacted] 170	WEEK 25	3.15	-	-	-	-
Immunoglobulin A (g/L)	20[redacted] 247	WEEK 37	3.11	-	-	-	-
Immunoglobulin A (g/L)	20[redacted] 331	WEEK 49	1.18	-	-	-	-
Immunoglobulin G (g/L)	20[redacted] -1	SCREENING	5.3	-	-	-	-
Immunoglobulin G (g/L)	20[redacted] 86	WEEK 13	4.82	-	-	-	-
Immunoglobulin G (g/L)	20[redacted] 170	WEEK 25	5.3	-	-	-	-
Immunoglobulin G (g/L)	20[redacted] 247	WEEK 37	4.45	-	-	-	-

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Immunoglobulin G (g/L)	20[redacted] 331	WEEK 49	3.49	-	-	-	-
Immunoglobulin M (g/L)	20[redacted] -1	SCREENING	0.59	-	-	-	-
Immunoglobulin M (g/L)	20[redacted] 86	WEEK 13	0.42	-	-	-	-
Immunoglobulin M (g/L)	20[redacted] 170	WEEK 25	0.21	-	-	-	-
Immunoglobulin M (g/L)	20[redacted] 247	WEEK 37	0.25	-	-	-	-
Immunoglobulin M (g/L)	20[redacted] 331	WEEK 49	0.11	-	-	-	-
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] -1	SCREENING	625	124	222	HIGH	-
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] 8	WEEK 2	520	124	222	HIGH	-
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] 29	WEEK 5	517	124	222	HIGH	-
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] 58	WEEK 9	536	124	222	HIGH	-
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] 86	WEEK 13	491	124	222	HIGH	-
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] 114	WEEK 17	477	124	222	HIGH	-
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] 142	WEEK 21	480	124	222	HIGH	-
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] 170	WEEK 25	446	124	222	HIGH	-
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] 247	WEEK 37	485	124	222	HIGH	-
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] 279	WEEK 37 UNSCHEDULED 07	866	124	222	HIGH	-
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] 287	WEEK 37 UNSCHEDULED 10	232	124	222	HIGH	-

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] 292	WEEK 37 UNSCHEDULED 12	457	124	222	HIGH	-
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] 301	WEEK 37 UNSCHEDULED 13	385	124	222	HIGH	-
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] 331	WEEK 49	393	124	222	HIGH	-
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] 366	WEEK 49 UNSCHEDULED 01	462	124	222	HIGH	-
Lactate Dehydrogenase (Enzyme U/L)	20[redacted] 373	WEEK 49 UNSCHEDULED 02	391	124	222	HIGH	-
Leukocytes (10^9/L)	20[redacted] -1	SCREENING	5.3	3.3	8.6	NORMAL	0
Leukocytes (10^9/L)	20[redacted] 8	WEEK 2	4.7	3.3	8.6	NORMAL	0
Leukocytes (10^9/L)	20[redacted] 29	WEEK 5	6.3	3.3	8.6	NORMAL	0
Leukocytes (10^9/L)	20[redacted] 58	WEEK 9	6.7	3.3	8.6	NORMAL	0
Leukocytes (10^9/L)	20[redacted] 86	WEEK 13	4.8	3.3	8.6	NORMAL	0
Leukocytes (10^9/L)	20[redacted] 114	WEEK 17	7.1	3.3	8.6	NORMAL	0
Leukocytes (10^9/L)	20[redacted] 142	WEEK 21	6.8	3.3	8.6	NORMAL	0
Leukocytes (10^9/L)	20[redacted] 170	WEEK 25	5.7	3.3	8.6	NORMAL	0
Leukocytes (10^9/L)	20[redacted] 247	WEEK 37	5.8	3.3	8.6	NORMAL	0
Leukocytes (10^9/L)	20[redacted] 275	WEEK 37 UNSCHEDULED 06	2.4	3.3	8.6	LOW	2
Leukocytes (10^9/L)	20[redacted] 331	WEEK 49	17	3.3	8.6	HIGH	0
Leukocytes (10^9/L)	20[redacted] 387	WEEK 49 UNSCHEDULED 03	16.5	3.3	8.6	HIGH	0

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Lymphocytes (10^9/L)	20[redacted] -1	SCREENING	0.848	0.99	4.3	LOW	1
Lymphocytes (10^9/L)	20[redacted] 8	WEEK 2	1.598	0.99	4.3	NORMAL	0
Lymphocytes (10^9/L)	20[redacted] 29	WEEK 5	1.512	0.99	4.3	NORMAL	0
Lymphocytes (10^9/L)	20[redacted] 58	WEEK 9	2.613	0.99	4.3	NORMAL	0
Lymphocytes (10^9/L)	20[redacted] 86	WEEK 13	1.92	0.99	4.3	NORMAL	0
Lymphocytes (10^9/L)	20[redacted] 114	WEEK 17	2.769	0.99	4.3	NORMAL	0
Lymphocytes (10^9/L)	20[redacted] 142	WEEK 21	1.564	0.99	4.3	NORMAL	0
Lymphocytes (10^9/L)	20[redacted] 170	WEEK 25	0.684	0.99	4.3	LOW	2
Lymphocytes (10^9/L)	20[redacted] 247	WEEK 37	0.754	0.99	4.3	LOW	2
Lymphocytes (10^9/L)	20[redacted] 275	WEEK 37 UNSCHEDULED 06	1.344	0.99	4.3	NORMAL	0
Lymphocytes (10^9/L)	20[redacted] 331	WEEK 49	4.25	0.99	4.3	NORMAL	0
Lymphocytes (10^9/L)	20[redacted] 387	WEEK 49 UNSCHEDULED 03	6.105	0.99	4.3	HIGH	2
Neutrophils (10^9/L)	20[redacted] -1	SCREENING	3.922	1.32	6.45	NORMAL	0
Neutrophils (10^9/L)	20[redacted] 8	WEEK 2	2.679	1.32	6.45	NORMAL	0
Neutrophils (10^9/L)	20[redacted] 29	WEEK 5	4.032	1.32	6.45	NORMAL	0
Neutrophils (10^9/L)	20[redacted] 58	WEEK 9	3.216	1.32	6.45	NORMAL	0
Neutrophils (10^9/L)	20[redacted] 86	WEEK 13	1.872	1.32	6.45	NORMAL	0

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Neutrophils (10^9/L)	20[redacted] 114	WEEK 17	3.479	1.32	6.45	NORMAL	0
Neutrophils (10^9/L)	20[redacted] 142	WEEK 21	4.624	1.32	6.45	NORMAL	0
Neutrophils (10^9/L)	20[redacted] 170	WEEK 25	4.56	1.32	6.45	NORMAL	0
Neutrophils (10^9/L)	20[redacted] 247	WEEK 37	4.698	1.32	6.45	NORMAL	0
Neutrophils (10^9/L)	20[redacted] 275	WEEK 37 UNSCHEDULED 06	0.84	1.32	6.45	LOW	3
Neutrophils (10^9/L)	20[redacted] 279	WEEK 37 UNSCHEDULED 07	0.141	1.32	6.45	LOW	4
Neutrophils (10^9/L)	20[redacted] 285	WEEK 37 UNSCHEDULED 09	0.636	1.32	6.45	LOW	3
Neutrophils (10^9/L)	20[redacted] 289	WEEK 37 UNSCHEDULED 11	0.456	1.32	6.45	LOW	4
Neutrophils (10^9/L)	20[redacted] 292	WEEK 37 UNSCHEDULED 12	12.243	1.32	6.45	HIGH	0
Neutrophils (10^9/L)	20[redacted] 331	WEEK 49	11.22	1.32	6.45	HIGH	0
Neutrophils (10^9/L)	20[redacted] 387	WEEK 49 UNSCHEDULED 03	8.415	1.32	6.45	HIGH	0
Platelets (10^9/L)	20[redacted] -1	SCREENING	44	158	348	LOW	3
Platelets (10^9/L)	20[redacted] 8	WEEK 2	38	158	348	LOW	3
Platelets (10^9/L)	20[redacted] 29	WEEK 5	56	158	348	LOW	2
Platelets (10^9/L)	20[redacted] 58	WEEK 9	59	158	348	LOW	2
Platelets (10^9/L)	20[redacted] 86	WEEK 13	77	158	348	LOW	1
Platelets (10^9/L)	20[redacted] 114	WEEK 17	78	158	348	LOW	1

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Platelets (10^9/L)	20[redacted] 142	WEEK 21	95	158	348	LOW	1
Platelets (10^9/L)	20[redacted] 170	WEEK 25	74	158	348	LOW	2
Platelets (10^9/L)	20[redacted] 247	WEEK 37	110	158	348	LOW	1
Platelets (10^9/L)	20[redacted] 253	WEEK 37 UNSCHEDULED 02	35	158	348	LOW	3
Platelets (10^9/L)	20[redacted] 275	WEEK 37 UNSCHEDULED 06	72	158	348	LOW	2
Platelets (10^9/L)	20[redacted] 281	WEEK 37 UNSCHEDULED 08	65	158	348	LOW	2
Platelets (10^9/L)	20[redacted] 331	WEEK 49	95	158	348	LOW	1
Platelets (10^9/L)	20[redacted] 387	WEEK 49 UNSCHEDULED 03	102	158	348	LOW	1
Potassium (mmol/L)	20[redacted] -1	SCREENING	4.9	3.6	4.8	HIGH	1
Potassium (mmol/L)	20[redacted] 8	WEEK 2	4.5	3.6	4.8	NORMAL	0
Potassium (mmol/L)	20[redacted] 29	WEEK 5	3.5	3.6	4.8	LOW	2
Potassium (mmol/L)	20[redacted] 58	WEEK 9	4.5	3.6	4.8	NORMAL	0
Potassium (mmol/L)	20[redacted] 86	WEEK 13	4.4	3.6	4.8	NORMAL	0
Potassium (mmol/L)	20[redacted] 114	WEEK 17	4.2	3.6	4.8	NORMAL	0
Potassium (mmol/L)	20[redacted] 142	WEEK 21	4.7	3.6	4.8	NORMAL	0
Potassium (mmol/L)	20[redacted] 170	WEEK 25	4.7	3.6	4.8	NORMAL	0
Potassium (mmol/L)	20[redacted] 247	WEEK 37	4.4	3.6	4.8	NORMAL	0

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Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Potassium (mmol/L)	20[redacted] 331	WEEK 49	4.2	3.6	4.8	NORMAL	0
Potassium (mmol/L)	20[redacted] 366	WEEK 49 UNSCHEDULED 01	4.1	3.6	4.8	NORMAL	0
Potassium (mmol/L)	20[redacted] 373	WEEK 49 UNSCHEDULED 02	3.5	3.6	4.8	LOW	2
Protein (g/L)	20[redacted] -1	SCREENING	62	66	81	LOW	-
Protein (g/L)	20[redacted] 8	WEEK 2	65	66	81	LOW	-
Protein (g/L)	20[redacted] 29	WEEK 5	63	66	81	LOW	-
Protein (g/L)	20[redacted] 58	WEEK 9	66	66	81	NORMAL	-
Protein (g/L)	20[redacted] 86	WEEK 13	61	66	81	LOW	-
Protein (g/L)	20[redacted] 114	WEEK 17	59	66	81	LOW	-
Protein (g/L)	20[redacted] 142	WEEK 21	67	66	81	NORMAL	-
Protein (g/L)	20[redacted] 170	WEEK 25	61	66	81	LOW	-
Protein (g/L)	20[redacted] 247	WEEK 37	62	66	81	LOW	-
Protein (g/L)	20[redacted] 331	WEEK 49	59	66	81	LOW	-
Protein (g/L)	20[redacted] 366	WEEK 49 UNSCHEDULED 01	59	66	81	LOW	-
Protein (g/L)	20[redacted] 373	WEEK 49 UNSCHEDULED 02	54	66	81	LOW	-
Sodium (mmol/L)	20[redacted] -1	SCREENING	141	138	145	NORMAL	0
Sodium (mmol/L)	20[redacted] 8	WEEK 2	140	138	145	NORMAL	0

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Sodium (mmol/L)	20[redacted] 29	WEEK 5	142	138	145	NORMAL	0
Sodium (mmol/L)	20[redacted] 58	WEEK 9	141	138	145	NORMAL	0
Sodium (mmol/L)	20[redacted] 86	WEEK 13	142	138	145	NORMAL	0
Sodium (mmol/L)	20[redacted] 114	WEEK 17	140	138	145	NORMAL	0
Sodium (mmol/L)	20[redacted] 142	WEEK 21	140	138	145	NORMAL	0
Sodium (mmol/L)	20[redacted] 170	WEEK 25	139	138	145	NORMAL	0
Sodium (mmol/L)	20[redacted] 247	WEEK 37	139	138	145	NORMAL	0
Sodium (mmol/L)	20[redacted] 331	WEEK 49	140	138	145	NORMAL	0
Sodium (mmol/L)	20[redacted] 366	WEEK 49 UNSCHEDULED 01	140	138	145	NORMAL	0
Sodium (mmol/L)	20[redacted] 373	WEEK 49 UNSCHEDULED 02	143	138	145	NORMAL	0
Urate (umol/L)	20[redacted] -1	SCREENING	487.736	220.076	463.944	HIGH	1
Urate (umol/L)	20[redacted] 8	WEEK 2	440.152	220.076	463.944	NORMAL	0
Urate (umol/L)	20[redacted] 29	WEEK 5	374.724	220.076	463.944	NORMAL	0
Urate (umol/L)	20[redacted] 58	WEEK 9	422.308	220.076	463.944	NORMAL	0
Urate (umol/L)	20[redacted] 86	WEEK 13	368.776	220.076	463.944	NORMAL	0
Urate (umol/L)	20[redacted] 114	WEEK 17	434.204	220.076	463.944	NORMAL	0
Urate (umol/L)	20[redacted] 142	WEEK 21	368.776	220.076	463.944	NORMAL	0

Parameter	Date of Specimen Collection Study Day of Specimen Collection	Visit Name	Result	LLN	ULN	Reference Range Indicator	Analysis Toxicity Grade
Urate (umol/L)	20[redacted] 170	WEEK 25	410.412	220.076	463.944	NORMAL	0
Urate (umol/L)	20[redacted] 247	WEEK 37	452.048	220.076	463.944	NORMAL	0
Urate (umol/L)	20[redacted] 331	WEEK 49	398.516	220.076	463.944	NORMAL	0
Urate (umol/L)	20[redacted] 366	WEEK 49 UNSCHEDULED 01	452.048	220.076	463.944	NORMAL	0
Urate (umol/L)	20[redacted] 373	WEEK 49 UNSCHEDULED 02	487.736	220.076	463.944	HIGH	1
Urea Nitrogen (mmol/L)	20[redacted] -1	SCREENING	14.637	2.856	7.14	HIGH	-
Urea Nitrogen (mmol/L)	20[redacted] 8	WEEK 2	12.495	2.856	7.14	HIGH	-
Urea Nitrogen (mmol/L)	20[redacted] 29	WEEK 5	12.495	2.856	7.14	HIGH	-
Urea Nitrogen (mmol/L)	20[redacted] 58	WEEK 9	10.353	2.856	7.14	HIGH	-
Urea Nitrogen (mmol/L)	20[redacted] 86	WEEK 13	11.781	2.856	7.14	HIGH	-
Urea Nitrogen (mmol/L)	20[redacted] 114	WEEK 17	11.781	2.856	7.14	HIGH	-
Urea Nitrogen (mmol/L)	20[redacted] 142	WEEK 21	9.996	2.856	7.14	HIGH	-
Urea Nitrogen (mmol/L)	20[redacted] 170	WEEK 25	14.28	2.856	7.14	HIGH	-
Urea Nitrogen (mmol/L)	20[redacted] 247	WEEK 37	11.424	2.856	7.14	HIGH	-
Urea Nitrogen (mmol/L)	20[redacted] 331	WEEK 49	11.067	2.856	7.14	HIGH	-
Urea Nitrogen (mmol/L)	20[redacted] 366	WEEK 49 UNSCHEDULED 01	9.639	2.856	7.14	HIGH	-
Urea Nitrogen (mmol/L)	20[redacted] 373	WEEK 49 UNSCHEDULED 02	9.996	2.856	7.14	HIGH	-