Table 100: R1500-CL-1719 Serious Adverse Events

Listing 16.2.7.2 Serious Adverse Events
Safety Analysis Set

Patient Group: New Evinacumab

Patient Number	Age/Sex/ Race	System Organ Class/ Preferred Term/ Verbatim Term	Start Date (Study Day)/ AE duration (days)/ AE Status	Infusion Related Reaction	Serious Event Type	Severity	Relationship to Evinacumab?/ Alirocumab?/ LMT(specify)	Relationship to Protocol Required Procedure?/ Study Conduct	Action Taken with Study Drug	Outcome
[redacted]	6[redacted]/M/WHITE	血管障害/ 末梢動脈狭窄/ SIGNIFICANT STENOSIS OF THE LEFT COMMON FEMORAL ARTERY (90%)	20[redacted] (611)/ 4/ T	N	Requires or Prolongs Hospitalization	Moderate	Not Related/ Not Related/ Not Related	Not Related/ Not Related	DOSE NOT CHANGED	RECOVERED/RESOLVED
[redacted]	4[redacted]/F/NOT REPORTED	生殖系および乳房障害/ 卵巣嚢胞破裂/ OVARIAN KYST RUPTUR	20[redacted] (152)/ 6/ T	N	Requires or Prolongs Hospitalization	Moderate	Not Related/ Not Related/ Not Related	Not Related/ Not Related	DOSE NOT CHANGED	RECOVERED/RESOLVED
	4[redacted]/F/NOT REPORTED	心臓障害/ 心房細動/ RECEDIVE ATRIAL FIBRILATION	20[redacted] (488)/ 3/ T	N	Requires or Prolongs Hospitalization	Moderate	Not Related/ Not Related/ Not Related	Not Related/ Not Related	DOSE NOT CHANGED	RECOVERED/RESOLVED

Abbreviations: Sex: M= male, F= female; Race: Wh-White, Bk-Black or African American, Ai-American Indian or Alaska Native, An-Asian, Nh-Native Hawaiian or Other Pacific Islander, Oth-Other.
MedDRA (Version 22.0) coding dictionary applied.
AE Status: Pre=pre-treatment;T=treatment emergent; Post=post-treatment; AE duration=(end date-onset date+1)
Study Day= Event Date - First Dosing Date, if Event Date was before First Dosing Date/Time, Study Day= Event Date - First Dosing Date + 1, if Event Date was on or after First Dosing Date/Time.

/sasdata/Data/Production/BDM/R1500/R1500-CL/R1500-CL-1719/Interim3/Analysis_CSR/Programs/TFL/Generated/l_1320_sae.sas ([redacted] 03OCT2022 16:18 SAS Linux 9.4)

Listing 16.2.7.2 Serious Adverse Events
Safety Analysis Set

Patient Group: New Evinacumab

Patient Number	Age/Sex/ Race	System Organ Class/ Preferred Term/ Verbatim Term	Start Date (Study Day)/ AE duration (days)/ AE Status	Infusion Related Reaction	Serious Event Type	Severity	Relationship to Evinacumab?/ Alirocumab?/ LMT(specify)	Relationship to Protocol Required Procedure?/ Study Conduct	Action Taken with Study Drug	Outcome
[redacted]	4[redacted]/F/NOT REPORTED	心臓障害/ 慢性心不全/ WORSENING NYHA IV DYSPNEA	20[redacted] (950)/ 26/ T	N	Requires or Prolongs Hospitalization	Severe	Not Related/ Not Related/ Not Related	Not Related/ Not Related	DRUG INTERRUPTED	RECOVERED/RESOLVED
[redacted]	1[redacted]/M/OTHER	傷害、中毒および処置合併症/ 血管偽動脈瘤/ FALSE ANEURYSM	20[redacted] (215)/ 4/ T	N	Requires or Prolongs Hospitalization	Severe	Not Related/ Not Related/ Not Related	Not Related/ Not Related	DOSE NOT CHANGED	RECOVERED/RESOLVED
	1[redacted]/M/OTHER	傷害、中毒および処置合併症/ 動静脈瘻部位合併症/ ARTERIOVENOUS FISTULAE INACCESSIBLE	20[redacted] (215)/ 4/ T	N	Requires or Prolongs Hospitalization	Severe	Not Related/ Not Related/ Not Related	Not Related/ Not Related	DOSE NOT CHANGED	RECOVERED/RESOLVED

Abbreviations: Sex: M= male, F= female; Race: Wh-White, Bk-Black or African American, Ai-American Indian or Alaska Native, An-Asian, Nh-Native Hawaiian or Other Pacific Islander, Oth-Other.
MedDRA (Version 22.0) coding dictionary applied.
AE Status: Pre=pre-treatment;T=treatment emergent; Post=post-treatment; AE duration=(end date-onset date+1)
Study Day= Event Date - First Dosing Date, if Event Date was before First Dosing Date/Time, Study Day= Event Date - First Dosing Date + 1, if Event Date was on or after First Dosing Date/Time.

/sasdata/Data/Production/BDM/R1500/R1500-CL/R1500-CL-1719/Interim3/Analysis_CSR/Programs/TFL/Generated/l_1320_sae.sas ([redacted] 03OCT2022 16:18 SAS Linux 9.4)

Listing 16.2.7.2 Serious Adverse Events
Safety Analysis Set

Patient Group: New Evinacumab

Patient Number	Age/Sex/ Race	System Organ Class/ Preferred Term/ Verbatim Term	Start Date (Study Day)/ AE duration (days)/ AE Status	Infusion Related Reaction	Serious Event Type	Severity	Relationship to Evinacumab?/ Alirocumab?/ LMT(specify)	Relationship to Protocol Required Procedure?/ Study Conduct	Action Taken with Study Drug	Outcome
[redacted]	1[redacted]/M/OTHER	感染症および寄生虫症/ 胃腸炎/ GASTROENTERITIS	20[redacted] (978)/ 3/ T	N	Requires or Prolongs Hospitalization	Moderate	Not Related/ Not Related/ Not Related	Not Related/ Not Related	DOSE NOT CHANGED	RECOVERED/RESOLVED
[redacted]	6[redacted]/F/WHITE	心臓障害/ 心臓弁膜疾患/ WORSENING CARDIAC VALVE DISEASE	20[redacted] (504)/ Ongoing/ T	N	Is Life Threatening	Moderate	Not Related/ Not Related/ Not Related	Not Related/ Not Related	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
[redacted]	5[redacted]/M/WHITE	感染症および寄生虫症/ 肺炎/ PNEUMONIA	20[redacted] (85)/ 4/ T	N	Requires or Prolongs Hospitalization	Severe	Not Related/ Not Related/ Not Related	Not Related/ Not Related	DOSE NOT CHANGED	RECOVERED/RESOLVED

Abbreviations: Sex: M= male, F= female; Race: Wh-White, Bk-Black or African American, Ai-American Indian or Alaska Native, An-Asian, Nh-Native Hawaiian or Other Pacific Islander, Oth-Other.
MedDRA (Version 22.0) coding dictionary applied.
AE Status: Pre=pre-treatment;T=treatment emergent; Post=post-treatment; AE duration=(end date-onset date+1)
Study Day= Event Date - First Dosing Date, if Event Date was before First Dosing Date/Time, Study Day= Event Date - First Dosing Date + 1, if Event Date was on or after First Dosing Date/Time.

/sasdata/Data/Production/BDM/R1500/R1500-CL/R1500-CL-1719/Interim3/Analysis_CSR/Programs/TFL/Generated/l_1320_sae.sas ([redacted] 03OCT2022 16:18 SAS Linux 9.4)

Listing 16.2.7.2 Serious Adverse Events
Safety Analysis Set

Patient Group: New Evinacumab

Patient Number	Age/Sex/ Race	System Organ Class/ Preferred Term/ Verbatim Term	Start Date (Study Day)/ AE duration (days)/ AE Status	Infusion Related Reaction	Serious Event Type	Severity	Relationship to Evinacumab?/ Alirocumab?/ LMT(specify)	Relationship to Protocol Required Procedure?/ Study Conduct	Action Taken with Study Drug	Outcome
[redacted]	5[redacted]/M/WHITE	心臓障害/ 心停止/ SUDDEN CARDIAC ARREST	20[redacted] (235)/ 1/ T	N	Results in Death	Severe	Not Related/ Not Related/ Not Related	Not Related/ Not Related	NOT APPLICABLE	FATAL

Abbreviations: Sex: M= male, F= female; Race: Wh-White, Bk-Black or African American, Ai-American Indian or Alaska Native, An-Asian, Nh-Native Hawaiian or Other Pacific Islander, Oth-Other.
MedDRA (Version 22.0) coding dictionary applied.
AE Status: Pre=pre-treatment;T=treatment emergent; Post=post-treatment; AE duration=(end date-onset date+1)
Study Day= Event Date - First Dosing Date, if Event Date was before First Dosing Date/Time, Study Day= Event Date - First Dosing Date + 1, if Event Date was on or after First Dosing Date/Time.

/sasdata/Data/Production/BDM/R1500/R1500-CL/R1500-CL-1719/Interim3/Analysis_CSR/Programs/TFL/Generated/l_1320_sae.sas ([redacted] 03OCT2022 16:18 SAS Linux 9.4)

Listing 16.2.7.2 Serious Adverse Events
Safety Analysis Set

Patient Group: Continue Evinacumab

Patient Number	Age/Sex/ Race	System Organ Class/ Preferred Term/ Verbatim Term	Start Date (Study Day)/ AE duration (days)/ AE Status	Infusion Related Reaction	Serious Event Type	Severity	Relationship to Evinacumab?/ Alirocumab?/ LMT(specify)	Relationship to Protocol Required Procedure?/ Study Conduct	Action Taken with Study Drug	Outcome
[redacted]	4[redacted]/M/WHITE	心臓障害/ 狭心症/ WORSENING CHRONIC STABLE ANGINA	20[redacted] (524)/ 179/ T	N	Requires or Prolongs Hospitalization	Severe	Not Related/ Not Related/ Not Related	Not Related/ Not Related	DOSE NOT CHANGED	RECOVERED/RESOLVED
[redacted]	4[redacted]/F/WHITE	血管障害/ 大動脈狭窄/ EXACERBATION OF AORTIC STENOSIS	20[redacted] (420)/ 47/ T	N	Requires or Prolongs Hospitalization Other Medically Important Serious Event	Moderate	Not Related/ Not Related/ Not Related	Not Related/ Not Related	DRUG INTERRUPTED	RECOVERED/RESOLVED

Abbreviations: Sex: M= male, F= female; Race: Wh-White, Bk-Black or African American, Ai-American Indian or Alaska Native, An-Asian, Nh-Native Hawaiian or Other Pacific Islander, Oth-Other.
MedDRA (Version 22.0) coding dictionary applied.
AE Status: Pre=pre-treatment;T=treatment emergent; Post=post-treatment; AE duration=(end date-onset date+1)
Study Day= Event Date - First Dosing Date, if Event Date was before First Dosing Date/Time, Study Day= Event Date - First Dosing Date + 1, if Event Date was on or after First Dosing Date/Time.

/sasdata/Data/Production/BDM/R1500/R1500-CL/R1500-CL-1719/Interim3/Analysis_CSR/Programs/TFL/Generated/l_1320_sae.sas ([redacted] 03OCT2022 16:18 SAS Linux 9.4)

Listing 16.2.7.2 Serious Adverse Events
Safety Analysis Set

Patient Group: Continue Evinacumab

Patient Number	Age/Sex/ Race	System Organ Class/ Preferred Term/ Verbatim Term	Start Date (Study Day)/ AE duration (days)/ AE Status	Infusion Related Reaction	Serious Event Type	Severity	Relationship to Evinacumab?/ Alirocumab?/ LMT(specify)	Relationship to Protocol Required Procedure?/ Study Conduct	Action Taken with Study Drug	Outcome
[redacted]	4[redacted]/F/WHITE	心臓障害/ 冠動脈疾患/ EXACERBATION OF CORONARY ARTERY DISEASE	20[redacted] (545)/ 44/ T	N	Requires or Prolongs Hospitalization Other Medically Important Serious Event	Severe	Not Related/ Not Related/ Not Related	Not Related/ Not Related	DRUG INTERRUPTED	RECOVERED/RESOLVED
[redacted]	3[redacted]/M/WHITE	血管障害/ 動脈硬化症/ WORSENING OF ATHEROSCLEROTIC ARTERY DISEASE	20[redacted] (439)/ 62/ T	N	Requires or Prolongs Hospitalization	Moderate	Not Related/ Not Related/ Not Related	Not Related/ Not Related	DOSE NOT CHANGED	RECOVERED/RESOLVED

Abbreviations: Sex: M= male, F= female; Race: Wh-White, Bk-Black or African American, Ai-American Indian or Alaska Native, An-Asian, Nh-Native Hawaiian or Other Pacific Islander, Oth-Other.
MedDRA (Version 22.0) coding dictionary applied.
AE Status: Pre=pre-treatment;T=treatment emergent; Post=post-treatment; AE duration=(end date-onset date+1)
Study Day= Event Date - First Dosing Date, if Event Date was before First Dosing Date/Time, Study Day= Event Date - First Dosing Date + 1, if Event Date was on or after First Dosing Date/Time.

/sasdata/Data/Production/BDM/R1500/R1500-CL/R1500-CL-1719/Interim3/Analysis_CSR/Programs/TFL/Generated/l_1320_sae.sas ([redacted] 03OCT2022 16:18 SAS Linux 9.4)

Listing 16.2.7.2 Serious Adverse Events
Safety Analysis Set

Patient Group: Continue Evinacumab

Patient Number	Age/Sex/ Race	System Organ Class/ Preferred Term/ Verbatim Term	Start Date (Study Day)/ AE duration (days)/ AE Status	Infusion Related Reaction	Serious Event Type	Severity	Relationship to Evinacumab?/ Alirocumab?/ LMT(specify)	Relationship to Protocol Required Procedure?/ Study Conduct	Action Taken with Study Drug	Outcome
[redacted]	5[redacted]/F/WHITE	心臓障害/ 冠動脈狭窄/ CORONARY ARTERY STENOSIS	20[redacted] (192)/ 12/ T	N	Requires or Prolongs Hospitalization	Moderate	Not Related/ Not Related/ Not Related	Not Related/ Not Related	NOT APPLICABLE	RECOVERED/RESOLVED
	5[redacted]/F/WHITE	胃腸障害/ 腸管虚血/ CHRONIC MESENTERIC ISCHEMIA	20[redacted] (233)/ 22/ T	N	Requires or Prolongs Hospitalization	Severe	Not Related/ Not Related/ Not Related	Not Related/ Not Related	NOT APPLICABLE	RECOVERED/RESOLVED
	5[redacted]/F/WHITE	心臓障害/ 心筋梗塞/ CARDIAC INFARCTION	20[redacted] (366)/ 2/ T	N	Results in Death	Severe	Not Related/ Not Related/ Not Related	Not Related/ Not Related	NOT APPLICABLE	FATAL

Abbreviations: Sex: M= male, F= female; Race: Wh-White, Bk-Black or African American, Ai-American Indian or Alaska Native, An-Asian, Nh-Native Hawaiian or Other Pacific Islander, Oth-Other.
MedDRA (Version 22.0) coding dictionary applied.
AE Status: Pre=pre-treatment;T=treatment emergent; Post=post-treatment; AE duration=(end date-onset date+1)
Study Day= Event Date - First Dosing Date, if Event Date was before First Dosing Date/Time, Study Day= Event Date - First Dosing Date + 1, if Event Date was on or after First Dosing Date/Time.

/sasdata/Data/Production/BDM/R1500/R1500-CL/R1500-CL-1719/Interim3/Analysis_CSR/Programs/TFL/Generated/l_1320_sae.sas ([redacted] 03OCT2022 16:18 SAS Linux 9.4)

Listing 16.2.7.2 Serious Adverse Events
Safety Analysis Set

Patient Group: Continue Evinacumab

Patient Number	Age/Sex/ Race	System Organ Class/ Preferred Term/ Verbatim Term	Start Date (Study Day)/ AE duration (days)/ AE Status	Infusion Related Reaction	Serious Event Type	Severity	Relationship to Evinacumab?/ Alirocumab?/ LMT(specify)	Relationship to Protocol Required Procedure?/ Study Conduct	Action Taken with Study Drug	Outcome
[redacted]	3[redacted]/F/OTHER	神経系障害/ 虚血性脳卒中/ RIGHT SYLVIAN ISCHEMIC STROKE	20[redacted] (448)/ 15/ T	N	Requires or Prolongs Hospitalization	Severe	Not Related/ Not Related/ Not Related	Not Related/ Not Related	DRUG INTERRUPTED	RECOVERED/RESOLVED
[redacted]	7[redacted]/F/WHITE	心臓障害/ 急性心筋梗塞/ NSTEMI	20[redacted] (473)/ 2/ T	Y	Requires or Prolongs Hospitalization	Severe	Not Related/ Not Related/ Not Related	Not Related/ Not Related	DOSE NOT CHANGED	RECOVERED/RESOLVED
[redacted]	2[redacted]/F/WHITE	心臓障害/ 大動脈弁上狭窄/ WORSENING OF SUPRAVALVAR AORTIC STENOSIS	20[redacted] (129)/ 7/ T	N	Requires or Prolongs Hospitalization	Severe	Not Related/ Not Related/ Not Related	Not Related/ Not Related	DOSE NOT CHANGED	RECOVERED/RESOLVED

Abbreviations: Sex: M= male, F= female; Race: Wh-White, Bk-Black or African American, Ai-American Indian or Alaska Native, An-Asian, Nh-Native Hawaiian or Other Pacific Islander, Oth-Other.
MedDRA (Version 22.0) coding dictionary applied.
AE Status: Pre=pre-treatment;T=treatment emergent; Post=post-treatment; AE duration=(end date-onset date+1)
Study Day= Event Date - First Dosing Date, if Event Date was before First Dosing Date/Time, Study Day= Event Date - First Dosing Date + 1, if Event Date was on or after First Dosing Date/Time.

/sasdata/Data/Production/BDM/R1500/R1500-CL/R1500-CL-1719/Interim3/Analysis_CSR/Programs/TFL/Generated/l_1320_sae.sas ([redacted] 03OCT2022 16:18 SAS Linux 9.4)

Listing 16.2.7.2 Serious Adverse Events
Safety Analysis Set

Patient Group: Continue Evinacumab

Patient Number	Age/Sex/ Race	System Organ Class/ Preferred Term/ Verbatim Term	Start Date (Study Day)/ AE duration (days)/ AE Status	Infusion Related Reaction	Serious Event Type	Severity	Relationship to Evinacumab?/ Alirocumab?/ LMT(specify)	Relationship to Protocol Required Procedure?/ Study Conduct	Action Taken with Study Drug	Outcome
[redacted]	6[redacted]/M/ASIAN	眼障害/ 緑内障/ WORSENING OF GLAUCOMA	20[redacted] (21)/ 8/ T	N	Requires or Prolongs Hospitalization	Moderate	Not Related/ Not Related/ Not Related	Not Related/ Not Related	DOSE NOT CHANGED	RECOVERED/RESOLVED
	6[redacted]/M/ASIAN	眼障害/ 白内障/ WARSENING OF CATARACT	20[redacted] (651)/ 6/ T	N	Requires or Prolongs Hospitalization	Moderate	Not Related/ Not Related/ Not Related	Not Related/ Not Related	DOSE NOT CHANGED	RECOVERED/RESOLVED
	6[redacted]/M/ASIAN	心臓障害/ 狭心症/ ANGINA PECTORIS	20[redacted] (786)/ 4/ T	N	Requires or Prolongs Hospitalization	Moderate	Not Related/ Not Related/ Not Related	Not Related/ Not Related	DOSE NOT CHANGED	RECOVERED/RESOLVED

Abbreviations: Sex: M= male, F= female; Race: Wh-White, Bk-Black or African American, Ai-American Indian or Alaska Native, An-Asian, Nh-Native Hawaiian or Other Pacific Islander, Oth-Other.
MedDRA (Version 22.0) coding dictionary applied.
AE Status: Pre=pre-treatment;T=treatment emergent; Post=post-treatment; AE duration=(end date-onset date+1)
Study Day= Event Date - First Dosing Date, if Event Date was before First Dosing Date/Time, Study Day= Event Date - First Dosing Date + 1, if Event Date was on or after First Dosing Date/Time.

/sasdata/Data/Production/BDM/R1500/R1500-CL/R1500-CL-1719/Interim3/Analysis_CSR/Programs/TFL/Generated/l_1320_sae.sas ([redacted] 03OCT2022 16:18 SAS Linux 9.4)

Listing 16.2.7.2 Serious Adverse Events
Safety Analysis Set

Patient Group: Continue Evinacumab

Patient Number	Age/Sex/ Race	System Organ Class/ Preferred Term/ Verbatim Term	Start Date (Study Day)/ AE duration (days)/ AE Status	Infusion Related Reaction	Serious Event Type	Severity	Relationship to Evinacumab?/ Alirocumab?/ LMT(specify)	Relationship to Protocol Required Procedure?/ Study Conduct	Action Taken with Study Drug	Outcome
[redacted]	6[redacted]/F/ASIAN	傷害、中毒および処置合併症/ 頚椎骨折/ CEREVICAL SPINE FRACTURE	20[redacted](49)/ 249/ T	N	Requires or Prolongs Hospitalization	Moderate	Not Related/ Not Related/ Not Related	Not Related/ Not Related	DOSE NOT CHANGED	RECOVERED/RESOLVED
[redacted]	3[redacted]/M/ASIAN	傷害、中毒および処置合併症/ 肋骨骨折/ FRACTURES(RIGHT RIB)	20[redacted](740)/ 109/ T	N	Requires or Prolongs Hospitalization	Severe	Not Related/ Not Related/ Not Related	Not Related/ Not Related	DOSE NOT CHANGED	RECOVERED/RESOLVED
	3[redacted]/M/ASIAN	傷害、中毒および処置合併症/ 肩甲骨骨折/ FRACTURES(RIGHT SCAPULA)	20[redacted](740)/ 109/ T	N	Requires or Prolongs Hospitalization	Severe	Not Related/ Not Related/ Not Related	Not Related/ Not Related	DOSE NOT CHANGED	RECOVERED/RESOLVED

Abbreviations: Sex: M= male, F= female; Race: Wh-White, Bk-Black or African American, Ai-American Indian or Alaska Native, An-Asian, Nh-Native Hawaiian or Other Pacific Islander, Oth-Other.
MedDRA (Version 22.0) coding dictionary applied.
AE Status: Pre=pre-treatment;T=treatment emergent; Post=post-treatment; AE duration=(end date-onset date+1)
Study Day= Event Date - First Dosing Date, if Event Date was before First Dosing Date/Time, Study Day= Event Date - First Dosing Date + 1, if Event Date was on or after First Dosing Date/Time.

/sasdata/Data/Production/BDM/R1500/R1500-CL/R1500-CL-1719/Interim3/Analysis_CSR/Programs/TFL/Generated/l_1320_sae.sas ([redacted] 03OCT2022 16:18 SAS Linux 9.4)

Listing 16.2.7.2 Serious Adverse Events
Safety Analysis Set

Patient Group: Continue Evinacumab

Patient Number	Age/Sex/ Race	System Organ Class/ Preferred Term/ Verbatim Term	Start Date (Study Day)/ AE duration (days)/ AE Status	Infusion Related Reaction	Serious Event Type	Severity	Relationship to Evinacumab?/ Alirocumab?/ LMT(specify)	Relationship to Protocol Required Procedure?/ Study Conduct	Action Taken with Study Drug	Outcome
[redacted]	6[redacted]/M/ASIAN	心臓障害/ うっ血性心不全/ CONGESTIVE HEART FAILURE	20[redacted] (-57)/ Ongoing/ Pre	N	Requires or Prolongs Hospitalization	Severe	Not Related/ Not Related/ Not Related	Not Related/ Not Related	DOSE NOT CHANGED	RECOVERING/ RESOLVING
[redacted]	2[redacted]/F/WHITE	一般・全身障害および投与部位の状態/ 胸痛/ CHEST PAIN	20[redacted] (159)/ 123/ T	N	Requires or Prolongs Hospitalization	Moderate	Not Related/ Not Related/ Not Related	Not Related/ Not Related	DOSE NOT CHANGED	RECOVERED/RESOLVED
[redacted]	2[redacted]/F/WHITE	腎および尿路障害/ 腎梗塞/ SEGMENTAL INFARCTION OF UPPER POLE OF LEFT KIDNEY	20[redacted] (202)/ 3/ T	N	Requires or Prolongs Hospitalization	Severe	Not Related/ Not Related/ Not Related	Not Related/ Not Related	DOSE NOT CHANGED	RECOVERED/RESOLVED

Abbreviations: Sex: M= male, F= female; Race: Wh-White, Bk-Black or African American, Ai-American Indian or Alaska Native, An-Asian, Nh-Native Hawaiian or Other Pacific Islander, Oth-Other.
MedDRA (Version 22.0) coding dictionary applied.
AE Status: Pre=pre-treatment;T=treatment emergent; Post=post-treatment; AE duration=(end date-onset date+1)
Study Day= Event Date - First Dosing Date, if Event Date was before First Dosing Date/Time, Study Day= Event Date - First Dosing Date + 1, if Event Date was on or after First Dosing Date/Time.

/sasdata/Data/Production/BDM/R1500/R1500-CL/R1500-CL-1719/Interim3/Analysis_CSR/Programs/TFL/Generated/l_1320_sae.sas ([redacted] 03OCT2022 16:18 SAS Linux 9.4)

Listing 16.2.7.2 Serious Adverse Events
Safety Analysis Set

Patient Group: Continue Evinacumab

Patient Number	Age/Sex/ Race	System Organ Class/ Preferred Term/ Verbatim Term	Start Date (Study Day)/ AE duration (days)/ AE Status	Infusion Related Reaction	Serious Event Type	Severity	Relationship to Evinacumab?/ Alirocumab?/ LMT(specify)	Relationship to Protocol Required Procedure?/ Study Conduct	Action Taken with Study Drug	Outcome
[redacted]	3[redacted]/F/WHITE	心臓障害/ 大動脈弁疾患/ AORTIC VALVE DISEASE PROGRESSION	20[redacted] (307)/ 11/ T	N	Requires or Prolongs Hospitalization	Severe	Not Related/ Not Related/ Not Related	Not Related/ Not Related	DOSE NOT CHANGED	RECOVERED/RESOLVED
[redacted]	4[redacted]/F/WHITE	心臓障害/ 不安定狭心症/ UNSTABLE ANGINA	20[redacted] (15)/ 14/ T	N	Requires or Prolongs Hospitalization	Moderate	Not Related/ Not Related/ Not Related	Not Related/ Not Related	DOSE NOT CHANGED	RECOVERED/RESOLVED
	4[redacted]/F/WHITE	心臓障害/ 不安定狭心症/ UNSTABLE ANGINA	20[redacted] (167)/ 11/ T	N	Requires or Prolongs Hospitalization	Moderate	Not Related/ Not Related/ Not Related	Not Related/ Not Related	DOSE NOT CHANGED	RECOVERED/RESOLVED

Abbreviations: Sex: M= male, F= female; Race: Wh-White, Bk-Black or African American, Ai-American Indian or Alaska Native, An-Asian, Nh-Native Hawaiian or Other Pacific Islander, Oth-Other.
MedDRA (Version 22.0) coding dictionary applied.
AE Status: Pre=pre-treatment;T=treatment emergent; Post=post-treatment; AE duration=(end date-onset date+1)
Study Day= Event Date - First Dosing Date, if Event Date was before First Dosing Date/Time, Study Day= Event Date - First Dosing Date + 1, if Event Date was on or after First Dosing Date/Time.

/sasdata/Data/Production/BDM/R1500/R1500-CL/R1500-CL-1719/Interim3/Analysis_CSR/Programs/TFL/Generated/l_1320_sae.sas ([redacted] 03OCT2022 16:18 SAS Linux 9.4)

Listing 16.2.7.2 Serious Adverse Events
Safety Analysis Set

Patient Group: Continue Evinacumab

Patient Number	Age/Sex/ Race	System Organ Class/ Preferred Term/ Verbatim Term	Start Date (Study Day)/ AE duration (days)/ AE Status	Infusion Related Reaction	Serious Event Type	Severity	Relationship to Evinacumab?/ Alirocumab?/ LMT(specify)	Relationship to Protocol Required Procedure?/ Study Conduct	Action Taken with Study Drug	Outcome
[redacted]	3[redacted]/M/OTHER	心臓障害/ 不安定狭心症/ WORSENING OF UNSTABLE ANGINA	20[redacted] (94)/ 3/ T	N	Requires or Prolongs Hospitalization	Moderate	Not Related/ Not Related/ Not Related	Not Related/ Not Related	DOSE NOT CHANGED	RECOVERED/RESOLVED
	3[redacted]/M/OTHER	一般・全身障害および投与部位の状態/ 胸痛/ CHEST PAIN	20[redacted] (299)/ 3/ T	N	Requires or Prolongs Hospitalization	Moderate	Not Related/ Not Related/ Not Related	Not Related/ Not Related	DOSE NOT CHANGED	RECOVERED/RESOLVED
	3[redacted]/M/OTHER	一般・全身障害および投与部位の状態/ 胸痛/ CHEST PAIN	20[redacted] (598)/ 2/ T	N	Requires or Prolongs Hospitalization	Moderate	Not Related/ Not Related/ Not Related	Not Related/ Not Related	DOSE NOT CHANGED	RECOVERED/RESOLVED

Abbreviations: Sex: M= male, F= female; Race: Wh-White, Bk-Black or African American, Ai-American Indian or Alaska Native, An-Asian, Nh-Native Hawaiian or Other Pacific Islander, Oth-Other.
MedDRA (Version 22.0) coding dictionary applied.
AE Status: Pre=pre-treatment;T=treatment emergent; Post=post-treatment; AE duration=(end date-onset date+1)
Study Day= Event Date - First Dosing Date, if Event Date was before First Dosing Date/Time, Study Day= Event Date - First Dosing Date + 1, if Event Date was on or after First Dosing Date/Time.

/sasdata/Data/Production/BDM/R1500/R1500-CL/R1500-CL-1719/Interim3/Analysis_CSR/Programs/TFL/Generated/l_1320_sae.sas ([redacted] 03OCT2022 16:18 SAS Linux 9.4)

Listing 16.2.7.2 Serious Adverse Events
Safety Analysis Set

Patient Group: Continue Evinacumab

Patient Number	Age/Sex/ Race	System Organ Class/ Preferred Term/ Verbatim Term	Start Date (Study Day)/ AE duration (days)/ AE Status	Infusion Related Reaction	Serious Event Type	Severity	Relationship to Evinacumab?/ Alirocumab?/ LMT(specify)	Relationship to Protocol Required Procedure?/ Study Conduct	Action Taken with Study Drug	Outcome
[redacted]	2[redacted]/M/WHITE	免疫系障害/ 食物アレルギー/ WORSENING FOOD ALLERGY (SESAME)	20[redacted] (805)/ 2/ T	N	Other Medically Important Serious Event	Moderate	Not Related/ Not Related/ Not Related	Not Related/ Not Related	DOSE NOT CHANGED	RECOVERED/RESOLVED
[redacted]	3[redacted]/F/BLACK OR AFRICAN AMERICAN	感染症および寄生虫症/ 食道カンジダ症/ CANDIDA ESOPHAGITIS	20[redacted] (268)/ 5/ T	N	Requires or Prolongs Hospitalization	Severe	Not Related/ Not Related/ Not Related	Not Related/ Not Related	DOSE NOT CHANGED	RECOVERED/RESOLVED

Abbreviations: Sex: M= male, F= female; Race: Wh-White, Bk-Black or African American, Ai-American Indian or Alaska Native, An-Asian, Nh-Native Hawaiian or Other Pacific Islander, Oth-Other.
MedDRA (Version 22.0) coding dictionary applied.
AE Status: Pre=pre-treatment;T=treatment emergent; Post=post-treatment; AE duration=(end date-onset date+1)
Study Day= Event Date - First Dosing Date, if Event Date was before First Dosing Date/Time, Study Day= Event Date - First Dosing Date + 1, if Event Date was on or after First Dosing Date/Time.

/sasdata/Data/Production/BDM/R1500/R1500-CL/R1500-CL-1719/Interim3/Analysis_CSR/Programs/TFL/Generated/l_1320_sae.sas ([redacted] 03OCT2022 16:18 SAS Linux 9.4)

Listing 16.2.7.2 Serious Adverse Events
Safety Analysis Set

Patient Group: Continue Evinacumab

Patient Number	Age/Sex/ Race	System Organ Class/ Preferred Term/ Verbatim Term	Start Date (Study Day)/ AE duration (days)/ AE Status	Infusion Related Reaction	Serious Event Type	Severity	Relationship to Evinacumab?/ Alirocumab?/ LMT(specify)	Relationship to Protocol Required Procedure?/ Study Conduct	Action Taken with Study Drug	Outcome
[redacted]	6[redacted]/M/WHITE	心臓障害/ 大動脈弁疾患/ WORSENING OF AORTIC VALVE DISEASE	20[redacted] (146)/ 8/ T	N	Requires or Prolongs Hospitalization	Moderate	Not Related/ Not Related/ Not Related	Not Related/ Not Related	DOSE NOT CHANGED	RECOVERED/RESOLVED
	6[redacted]/M/WHITE	心臓障害/ 冠動脈疾患/ WORSENING OF CORONARY ARTERY DISEASE	20[redacted] (146)/ 8/ T	N	Requires or Prolongs Hospitalization	Mild	Not Related/ Not Related/ Not Related	Not Related/ Not Related	DOSE NOT CHANGED	RECOVERED/RESOLVED
	6[redacted]/M/WHITE	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 前立腺癌/ PROSTATE CANCER	20[redacted] (569)/ Ongoing/ T	N	Other Medically Important Serious Event	Mild	Not Related/ Not Related/ Not Related	Not Related/ Not Related	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED

Abbreviations: Sex: M= male, F= female; Race: Wh-White, Bk-Black or African American, Ai-American Indian or Alaska Native, An-Asian, Nh-Native Hawaiian or Other Pacific Islander, Oth-Other.
MedDRA (Version 22.0) coding dictionary applied.
AE Status: Pre=pre-treatment;T=treatment emergent; Post=post-treatment; AE duration=(end date-onset date+1)
Study Day= Event Date - First Dosing Date, if Event Date was before First Dosing Date/Time, Study Day= Event Date - First Dosing Date + 1, if Event Date was on or after First Dosing Date/Time.

/sasdata/Data/Production/BDM/R1500/R1500-CL/R1500-CL-1719/Interim3/Analysis_CSR/Programs/TFL/Generated/l_1320_sae.sas ([redacted]u 03OCT2022 16:18 SAS Linux 9.4)

Listing 16.2.7.2 Serious Adverse Events
Safety Analysis Set

Patient Group: Continue Evinacumab

Patient Number	Age/Sex/ Race	System Organ Class/ Preferred Term/ Verbatim Term	Start Date (Study Day)/ AE duration (days)/ AE Status	Infusion Related Reaction	Serious Event Type	Severity	Relationship to Evinacumab?/ Alirocumab?/ LMT(specify)	Relationship to Protocol Required Procedure?/ Study Conduct	Action Taken with Study Drug	Outcome
[redacted]	6[redacted]/F/BLACK OR AFRICAN AMERICAN	精神障害/ 精神状態変化/ ALTERED MENTAL STATUS	20[redacted] (308)/ 3/ T	N	Requires or Prolongs Hospitalization	Severe	Not Related/ Not Related/ Not Related	Not Related/ Not Related	DOSE NOT CHANGED	RECOVERED/RESOLVED

Abbreviations: Sex: M= male, F= female; Race: Wh-White, Bk-Black or African American, Ai-American Indian or Alaska Native, An-Asian, Nh-Native Hawaiian or Other Pacific Islander, Oth-Other.
MedDRA (Version 22.0) coding dictionary applied.
AE Status: Pre=pre-treatment;T=treatment emergent; Post=post-treatment; AE duration=(end date-onset date+1)
Study Day= Event Date - First Dosing Date, if Event Date was before First Dosing Date/Time, Study Day= Event Date - First Dosing Date + 1, if Event Date was on or after First Dosing Date/Time.

/sasdata/Data/Production/BDM/R1500/R1500-CL/R1500-CL-1719/Interim3/Analysis_CSR/Programs/TFL/Generated/l_1320_sae.sas ([redacted] 03OCT2022 16:18 SAS Linux 9.4)

Table 101: R1500-CL-17100 Serious Adverse Events

Regeneron Pharmaceuticals, Inc.
Protocol: R1500-CL-17100

Listing 16.2.7.2 Serious Adverse Events
Safety Analysis Set

Patient Group: Part B

Patient ID	Age(yrs)/ Gender/ Race/Last Trt Day	System Organ Class/ Preferred Term/ Verbatim Term	Start Date (Study Day)/ AE duration (days)/ AE Status	Infusion Related Reaction?	Serious Event Type	Grade/ Severity	Relationship to Evinacumab/ LMT(specify)	Relationship to Required Procedure/ Study Conduct	Action Taken with Study Drug[1]	Outcome[2]
[redacted]	1[redacted]/F/OTHER/386	感染症および寄生虫症/ 扁桃炎/ TONSILLITIS	20[redacted](95)/ 6/ T	No	Requires or Prolongs Hospitalization	Severe	Not Related/ Not Related	Not Related/ Not Related	DOSE NOT CHANGED	RECOVERED/ RESOLVED

Abbreviations: M= male, F= female.
MedDRA (Version 24.0) coding dictionary applied.
AE status:Pre= pre-treatment;T= treatment emergent; Post= post-treatment; AE duration= (end date-onset date+1).
Study Day= Event Date - First Dosing Date, if Event Date was before First Dosing Date/Time; Study Day= Event Date - First Dosing Date + 1, if Event Date was on or after First Dosing Date/Time.
[1] Action Taken with Study Drug: 1 = Dose Withdrawn Temporarily 2 = Dose Reduced 3 = Dose Withdrawn Permanently 4 = Dose Not Changed 5 = Not known 6 = Not Applicable.
[2] Outcome: 1 = Recovered/Resolved, 2 = Recovered/Resolved with SequelAE, 3 = Recovering/Resolving, 4 =Not Recovered/Not Resolved, 5 = Fatal, 6 = Unknown.

/sasdata/Data/Production/BDM/R1500/R1500-CL/R1500-CL-17100/sBLA/Analysis_CSR/Programs/TFL/Generated/l_1120_sae.sas ([redacted] 30AUG2022 16:12 SAS Linux 9.4)

Table 102: R1500-HV-1214 Serious Adverse Events (Group C)

Regeneron Pharmaceutical, Inc.
Protocol: R1500-HV-1214

Confidential

Listing 16.2.7.2.3 Serious Adverse Events - Subjects in Group C
Safety Analysis Set

Treatment: SC Regimen REGN1500 250 mg

Cohort	Subject ID	Age[a]/ Gender/ Race[b]	Period	System Organ Class/ Preferred Term/ AE Reported Term	Start Date (Study Day)/ Stop Date (Study Day)[c]	TEAE?	Ser-ious AE?	Grade/ Severity	Relation-ship to Study Drug	Action Taken with Study Drug	Outcome	Concomitant or Addi-tional Treatment
Cohort 1C	[redacted]	3[redacted]M/Asian	On-treatment	呼吸器、胸郭および縦隔障害/急性呼吸窮迫症候群/ ACUTE RESPIRATORY DISTRESS SYNDROME RELATED TO PANCREATITIS	20[redacted] (132)/ 20[redacted] (159)	Y	Y	Severe	Not Related	Not Applicable	Recovered/ Resolved	TRACHEOSTOMY PROCEDURE
			On-treatment	精神障害/アルコール離脱症候群 /ALCOHOL WITHDRAWAL FROM FORCED ABSTINENCE	20[redacted] (120)/ 20[redacted] (161)	Y	Y	Severe	Not Related	Not Applicable	Recovered/ Resolved	Medication
			On-treatment	胃腸障害/ アルコール性膵炎/ ALCOHOLIC PANCREATITIS	20[redacted] (120)/ 20[redacted] (161)	Y	Y	Severe	Not Related	Not Applicable	Recovered/ Resolved	Medication

Group C includes subjects with elevations of TG >1000 mg/dL on lipid lowering therapy (LLT).
a Age is calculated as an integer value indicating the number of full years passed since birth.
b Race: Wh-White; Bk-Black or African American; Ai-American Indian or Alaska Native; An-Asian; Nh-Native Hawaiian or Other Pacific Islander; Oth-Other.
MedDRA (Version 15.1) applied.

G:/DATA/Production/Early Clinical Studies/REGN1500/R1500_HV_1214/Final_Analysis_C/Analysis_CSR/Programs/TFL/Generated/L_SAEC.sas ([redacted] 04MAR2016 11:29 SAS Win 9.2)

Listing 16.2.7.2.3 Serious Adverse Events - Subjects in Group C
Safety Analysis Set

Treatment: IV Regimen REGN1500 20 mg/kg

Cohort	Subject ID	Age[a]/ Gender/ Race[b]	Period	System Organ Class/ Preferred Term/ AE Reported Term	Start Date (Study Day)/ Stop Date (Study Day)[c]	TEAE?	Ser-ious AE?	Grade/ Severity	Relation-ship to Study Drug	Action Taken with Study Drug	Outcome	Concomitant or Additional Treatment
Cohort 2C	[redacted]	4[redacted]M/Other: SUDANESE (AFRICAN-ARABIAN)	On-treatment	胃腸障害/急性膵炎/ ACUTE PANCREATITIS	20[redacted](76)/ 20[redacted](79)	Y	Y	Severe	Not Related	Not Applicable	Recovered/ Resolved	
			On-treatment	胃腸障害/膵炎/ PANCREATITIS	20[redacted](153)/ 20[redacted](155)	Y	Y	Severe	Not Related	Not Applicable	Recovered/ Resolved	
			On-treatment	胃腸障害/再発性膵炎/ RECURRENT PANCREATITIS	20[redacted](139)/ 20[redacted](141)	Y	Y	Severe	Not Related	Not Applicable	Recovered/ Resolved	
			On-treatment	神経系障害/ 一過性脳虚血発作/ TRANSIENT ISCHEMIC ATTACK	20[redacted](41)/ 20[redacted](42)	Y	Y	Severe	Not Related	Not Applicable	Recovered/ Resolved	Medication
	[redacted]	1[redacted]M/White	On-treatment	胃腸障害/再発性膵炎/ RECURRENT PANCREATITIS	20[redacted](70)/ 20[redacted](75)	Y	Y	Severe	Not Related	Not Applicable	Recovered/ Resolved	Medication

Group C includes subjects with elevations of TG >1000 mg/dL on lipid lowering therapy (LLT).
a Age is calculated as an integer value indicating the number of full years passed since birth.
b Race: Wh-White; Bk-Black or African American; Ai-American Indian or Alaska Native; An-Asian; Nh-Native Hawaiian or Other Pacific Islander; Oth-Other.
MedDRA (Version 15.1) applied.

G:/DATA/Production/Early Clinical Studies/REGN1500/R1500_HV_1214/Final_Analysis_C/Analysis_CSR/Programs/TFL/Generated/L_SAEC.sas ([redacted]04MAR2016 11:29 SAS Win 9.2)

Table 103: R1500-HTG-1522 Serious Adverse Events (Double-blind Treatment Period, First-step Analysis CSR)

Regeneron Pharmaceuticals, Inc.
Protocol: R1500-HTG-1522

Listing 16.2.7.2.1 Serious Adverse Events
Double-blind Safety Analysis Set - DBTP

Treatment Group as Treated/ Actual Cohort: Placebo IV Q4W/ Cohort 1

Patient Number	Age/Sex/Race/ Last Trt Day	System Organ Class/ Preferred Term/ Verbatim Term	Start Date (Study Day)/ AE duration (days)/ AE Status	Infusion Related Reaction	Serious Event Type	Severity	Relationship to IP?/ Infusion/ Study Conduct, specify	Action Taken with Study Drug	Outcome
[redacted]	6[redacted]M/WHITE/ 61	胃腸障害/ 急性膵炎/ ACUTE PANCREATITIS	20[redacted]54)/ 5/ T	N	Requires or Prolongs Hospitalization	Severe	Not Related/ Not Related/ N	DOSE NOT CHANGED	RECOVERED/RESOLVED

Abbreviations: M= male; F= female;
Study Day= Event Date (First Dosing Date, if Event Date was before First Dosing Date; Study Day= Event Date (First Dosing Date + 1, if Event Date was on or after First Dosing Date.
AE status:Pre=pre-treatment;T=treatment emergent; Post=post-treatment; AE duration=(end date-onset date+1)

/sasdata/Data/Production/BDM/R1500/R1500-HTG/R1500-HTG-1522/first_step/Analysis_CSR/Programs/TFL/Generated/l_8250_aeser_db.sas ([redacted]20APR2020 17:31 SAS Linux 9.4)

MedDRA (Version 22.0) coding dictionary applied.

Listing 16.2.7.2.1 Serious Adverse Events
Double-blind Safety Analysis Set - DBTP

Treatment Group as Treated/ Actual Cohort: Placebo IV Q4W/ Cohort 2

Patient Number	Age/Sex/Race/ Last Trt Day	System Organ Class/ Preferred Term/ Verbatim Term	Start Date (Study Day)/ AE duration (days)/ AE Status	Infusion Related Reaction	Serious Event Type	Severity	Relationship to IP?/ Infusion/ Study Conduct, specify	Action Taken with Study Drug	Outcome
[redacted]	6[redacted]M/WHITE/ 57	胃腸障害/ 腹痛/ ABDOMINAL PAIN	20[redacted]29)/ 2/ T	N	Requires or Prolongs Hospitalization	Moderate	Not Related/ Not Related/ N	NOT APPLICABLE	RECOVERED/RESOLVED

Abbreviations: M= male; F= female;
Study Day= Event Date (First Dosing Date, if Event Date was before First Dosing Date; Study Day= Event Date (First Dosing Date + 1, if Event Date was on or after First Dosing Date.
AE status:Pre=pre-treatment;T=treatment emergent; Post=post-treatment; AE duration=(end date-onset date+1)

/sasdata/Data/Production/BDM/R1500/R1500-HTG/R1500-HTG-1522/first_step/Analysis_CSR/Programs/TFL/Generated/l_8250_aeser_db.sas ([redacted]20APR2020 17:31 SAS Linux 9.4)

MedDRA (Version 22.0) coding dictionary applied.

Listing 16.2.7.2.1 Serious Adverse Events
Double-blind Safety Analysis Set - DBTP

Treatment Group as Treated/ Actual Cohort: Placebo IV Q4W/ Cohort 3

Patient Number	Age/Sex/Race/ Last Trt Day	System Organ Class/ Preferred Term/ Verbatim Term	Start Date (Study Day)/ AE duration (days)/ AE Status	Infusion Related Reaction	Serious Event Type	Severity	Relationship to IP?/ Infusion/ Study Conduct, specify	Action Taken with Study Drug	Outcome
[redacted]	2[redacted]F/OTHER/ 29	胃腸障害/ 急性膵炎/ ACUTE PANCREATITIS	20[redacted]65)/ 3/ T	N	Requires or Prolongs Hospitalization	Severe	Not Related/ Not Related/ N	DOSE NOT CHANGED	RECOVERED/RESOLVED

Abbreviations: M= male; F= female;
Study Day= Event Date (First Dosing Date, if Event Date was before First Dosing Date; Study Day= Event Date (First Dosing Date + 1, if Event Date was on or after First Dosing Date.
AE status:Pre=pre-treatment;T=treatment emergent; Post=post-treatment; AE duration=(end date-onset date+1)

MedDRA (Version 22.0) coding dictionary applied.

Regeneron Pharmaceuticals, Inc.
Protocol: R1500-HTG-1522

Listing 16.2.7.2.1 Serious Adverse Events
Double-blind Safety Analysis Set - DBTP

Treatment Group as Treated/ Actual Cohort: Evinacumab IV 15mg/kg Q4W/ Cohort 1

Patient Number	Age/Sex/Race/ Last Trt Day	System Organ Class/ Preferred Term/ Verbatim Term	Start Date (Study Day)/ AE duration (days)/ AE Status	Infusion Related Reaction	Serious Event Type	Severity	Relationship to IP?/ Infusion/ Study Conduct, specify	Action Taken with Study Drug	Outcome
[redacted]	5[redacted]M/WHITE/ 57	胃腸障害/ 急性膵炎/ ACUTE PANCREATITIS	20[redacted]86)/ 3/ T	N	Requires or Prolongs Hospitalization	Severe	Not Related/ Not Related/ N	DOSE NOT CHANGED	RECOVERED/RESOLVED

Abbreviations: M= male; F= female;
Study Day= Event Date (First Dosing Date, if Event Date was before First Dosing Date; Study Day= Event Date (First Dosing Date + 1, if Event Date was on or after First Dosing Date.
AE status:Pre=pre-treatment;T=treatment emergent; Post=post-treatment; AE duration=(end date-onset date+1)

/sasdata/Data/Production/BDM/R1500/R1500-HTG/R1500-HTG-1522/first_step/Analysis_CSR/Programs/TFL/Generated/l_8250_aeser_db.sas ([redacted]20APR2020 17:31 SAS Linux 9.4)

MedDRA (Version 22.0) coding dictionary applied.

Regeneron Pharmaceuticals, Inc.
Protocol: R1500-HTG-1522

Listing 16.2.7.2.1 Serious Adverse Events
Double-blind Safety Analysis Set - DBTP

Treatment Group as Treated/ Actual Cohort: Evinacumab IV 15mg/kg Q4W/ Cohort 3

Patient Number	Age/Sex/Race/ Last Trt Day	System Organ Class/ Preferred Term/ Verbatim Term	Start Date (Study Day)/ AE duration (days)/ AE Status	Infusion Related Reaction	Serious Event Type	Severity	Relationship to IP?/ Infusion/ Study Conduct, specify	Action Taken with Study Drug	Outcome
[redacted]	4[redacted]M/ASIAN/ 1	胃腸障害/ 急性膵炎/ ACUTE PANCREATITIS	20[redacted]4)/ 7/ T	N	Requires or Prolongs Hospitalization	Severe	Related/ Not Related/ N	DRUG WITHDRAWN	RECOVERED/RESOLVED
[redacted]	5[redacted]M/WHITE/ 59	胃腸障害/ 腹痛/ ABDOMINAL PAIN	20[redacted]53)/ 4/ T	N	Requires or Prolongs Hospitalization	Severe	Not Related/ Not Related/ N	DOSE NOT CHANGED	RECOVERED/RESOLVED
[redacted]	3[redacted]M/WHITE/ 63	胃腸障害/ 急性膵炎/ ACUTE ON CHRONIC PANCREATITIS	20[redacted]13)/ 5/ T	N	Requires or Prolongs Hospitalization	Severe	Not Related/ Not Related/ N	DOSE NOT CHANGED	RECOVERED/RESOLVED

Abbreviations: M= male; F= female;
Study Day= Event Date (First Dosing Date, if Event Date was before First Dosing Date; Study Day= Event Date (First Dosing Date + 1, if Event Date was on or after First Dosing Date.
AE status:Pre=pre-treatment;T=treatment emergent; Post=post-treatment; AE duration=(end date-onset date+1)

/sasdata/Data/Production/BDM/R1500/R1500-HTG/R1500-HTG-1522/first_step/Analysis_CSR/Programs/TFL/Generated/l_8250_aeser_db.sas ([redacted]20APR2020 17:31 SAS Linux 9.4)

MedDRA (Version 22.0) coding dictionary applied.

Table 104: R1500-HTG-1522 Serious Adverse Events (Single-blind Treatment Period, Final CSR)

Regeneron Pharmaceuticals, Inc.
Protocol: R1500-HTG-1522

Listing 16.2.7.2.2 Serious Adverse Events
Single-Blind Safety Analysis Set - SBTP

DB Treatment Group as Treated/ Actual Cohort: Placebo IV Q4W/ Cohort 2

Patient Number	Age/Sex/Race/ Last Trt Day	System Organ Class/ Preferred Term/ Verbatim Term	Start Date (Study Day)/ AE duration (days)/ AE Status	Infusion Related Reaction	Serious Event Type	Severity	Relationship to IP?/ Infusion/ Study Conduct, specify	Action Taken with Study Drug	Outcome
[redacted]	5[redacted]F/WHITE/ 64	胃腸障害/ 急性膵炎/ ACUTE PANCREATITIS	20[redacted]91)/ 9/ T	N	Requires or Prolongs Hospitalization	Severe	Not Related/ Not Related/ N	DOSE NOT CHANGED	RECOVERED/RESOLVED
[redacted]	3[redacted]F/OTHER/ 57	胃腸障害/ 急性膵炎/ ACUTE PANCREATITIS	20[redacted]112)/ 3/ T	N	Requires or Prolongs Hospitalization	Severe	Not Related/ Not Related/ N	DOSE NOT CHANGED	RECOVERED/RESOLVED

Abbreviations: M= male; F= female;
Study Day= Event Date (First Dosing Date, if Event Date was before First Dosing Date; Study Day= Event Date (First Dosing Date + 1, if Event Date was on or after First Dosing Date.
AE status:Pre=pre-treatment;T=treatment emergent; Post=post-treatment; AE duration=(end date-onset date+1)
/sasdata/Data/Production/BDM/R1500/R1500-HTG/R1500-HTG-1522/Final/Analysis_CSR/Programs/TFL/Generated/1_8251_aeser_sb.sas ([redacted]01APR2021 09:30 SAS Linux 9.4)

MedDRA (Version 22.0) coding dictionary applied.

Listing 16.2.7.2.2 Serious Adverse Events
Single-Blind Safety Analysis Set - SBTP

DB Treatment Group as Treated/ Actual Cohort: Placebo IV Q4W/ Cohort 3

Patient Number	Age/Sex/Race/ Last Trt Day	System Organ Class/ Preferred Term/ Verbatim Term	Start Date (Study Day)/ AE duration (days)/ AE Status	Infusion Related Reaction	Serious Event Type	Severity	Relationship to IP?/ Infusion/ Study Conduct, specify	Action Taken with Study Drug	Outcome
[redacted]	4[redacted]M/WHITE/ 59	胃腸障害/ 急性膵炎/ ACUTE PANCREATITIS	20[redacted]199)/ 21/ T	N	Requires or Prolongs Hospitalization	Severe	Not Related/ Not Related/ N	NOT APPLICABLE	RECOVERED/RESOLVED
	4[redacted]M/WHITE/ 59	胃腸障害/ イレウス/ ILEUS	20[redacted]209)/ 3/ T	N	Requires or Prolongs Hospitalization	Severe	Not Related/ Not Related/ N	NOT APPLICABLE	RECOVERED/RESOLVED
[redacted]	4[redacted]M/WHITE/ 57	胃腸障害/ 急性膵炎/ ACUTE PANCREATITIS	20[redacted]240)/ 10/ T	N	Requires or Prolongs Hospitalization	Severe	Not Related/ Not Related/ N	NOT APPLICABLE	RECOVERED/RESOLVED

Abbreviations: M= male; F= female;
Study Day= Event Date (First Dosing Date, if Event Date was before First Dosing Date; Study Day= Event Date (First Dosing Date + 1, if Event Date was on or after First Dosing Date.
AE status:Pre=pre-treatment;T=treatment emergent; Post=post-treatment; AE duration=(end date-onset date+1)

MedDRA (Version 22.0) coding dictionary applied.

Listing 16.2.7.2.2 Serious Adverse Events
Single-Blind Safety Analysis Set - SBTP

DB Treatment Group as Treated/ Actual Cohort: Placebo IV Q4W/ Cohort 3

Patient Number	Age/Sex/Race/ Last Trt Day	System Organ Class/ Preferred Term/ Verbatim Term	Start Date (Study Day)/ AE duration (days)/ AE Status	Infusion Related Reaction	Serious Event Type	Severity	Relationship to IP?/ Infusion/ Study Conduct, specify	Action Taken with Study Drug	Outcome
[redacted]	4[redacted]M/WHITE/ 57	呼吸器、胸郭および縦隔障害/ 急性呼吸不全/ ACUTE RESPIRATORY FAILURE	20[redacted]243)/ 3/ T	N	Requires or Prolongs Hospitalization	Severe	Not Related/ Not Related/ N	NOT APPLICABLE	RECOVERED/RESOLVED

Abbreviations: M= male; F= female;
Study Day= Event Date (First Dosing Date, if Event Date was before First Dosing Date; Study Day= Event Date (First Dosing Date + 1, if Event Date was on or after First Dosing Date.
AE status:Pre=pre-treatment;T=treatment emergent; Post=post-treatment; AE duration=(end date-onset date+1)

/sasdata/Data/Production/BDM/R1500/R1500-HTG/R1500-HTG-1522/Final/Analysis_CSR/Programs/TFL/Generated/l_8251_aeser_sb.sas ([redacted]01APR2021 09:30 SAS Linux 9.4)

MedDRA (Version 22.0) coding dictionary applied.

Listing 16.2.7.2.2 Serious Adverse Events
Single-Blind Safety Analysis Set - SBTP

DB Treatment Group as Treated/ Actual Cohort: Evinacumab IV 15mg/kg Q4W/ Cohort 1

Patient Number	Age/Sex/Race/ Last Trt Day	System Organ Class/ Preferred Term/ Verbatim Term	Start Date (Study Day)/ AE duration (days)/ AE Status	Infusion Related Reaction	Serious Event Type	Severity	Relationship to IP?/ Infusion/ Study Conduct, specify	Action Taken with Study Drug	Outcome
[redacted]	5[redacted]M/WHITE/ 57	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 前立腺癌/ PROSTATE ADENOCARCINOMA	20[redacted]238)/ 232/ T	N	Other Medically Important Serious Event	Moderate	Not Related/ Not Related/ N	DOSE NOT CHANGED	RECOVERED/RESOLVED
[redacted]	5[redacted]F/WHITE/ 57	胃腸障害/ 急性膵炎/ ACUTE PANCREATITIS	20[redacted]93)/ 3/ T	N	Requires or Prolongs Hospitalization	Moderate	Not Related/ Not Related/ N	DOSE NOT CHANGED	RECOVERED/RESOLVED
	5[redacted]F/WHITE/ 57	胃腸障害/ 急性膵炎/ ACUTE PANCREATITIS	20[redacted]141)/ 3/ T	N	Requires or Prolongs Hospitalization	Severe	Not Related/ Not Related/ N	DOSE NOT CHANGED	RECOVERED/RESOLVED

Abbreviations: M= male; F= female;
Study Day= Event Date (First Dosing Date, if Event Date was before First Dosing Date; Study Day= Event Date (First Dosing Date + 1, if Event Date was on or after First Dosing Date.
AE status:Pre=pre-treatment;T=treatment emergent; Post=post-treatment; AE duration=(end date-onset date+1)

MedDRA (Version 22.0) coding dictionary applied.

Listing 16.2.7.2.2 Serious Adverse Events
Single-Blind Safety Analysis Set - SBTP

DB Treatment Group as Treated/ Actual Cohort: Evinacumab IV 15mg/kg Q4W/ Cohort 1

Patient Number	Age/Sex/Race/ Last Trt Day	System Organ Class/ Preferred Term/ Verbatim Term	Start Date (Study Day)/ AE duration (days)/ AE Status	Infusion Related Reaction	Serious Event Type	Severity	Relationship to IP?/ Infusion/ Study Conduct, specify	Action Taken with Study Drug	Outcome
[redacted]	5[redacted]F/WHITE/ 57	胃腸障害/ 急性膵炎/ ACUTE PANCREATITIS	20[redacted]261)/ 7/ T	N	Requires or Prolongs Hospitalization	Severe	Not Related/ Not Related/ N	NOT APPLICABLE	RECOVERED/RESOLVED
[redacted]	6[redacted]F/WHITE/ 64	胃腸障害/ 急性膵炎/ ACUTE PANCREATITIS	20[redacted]245)/ 7/ T	N	Requires or Prolongs Hospitalization	Severe	Not Related/ Not Related/ N	NOT APPLICABLE	RECOVERED/RESOLVED

Abbreviations: M= male; F= female;
Study Day= Event Date (First Dosing Date, if Event Date was before First Dosing Date; Study Day= Event Date (First Dosing Date + 1, if Event Date was on or after First Dosing Date.
AE status:Pre=pre-treatment;T=treatment emergent; Post=post-treatment; AE duration=(end date-onset date+1)

MedDRA (Version 22.0) coding dictionary applied.

Regeneron Pharmaceuticals, Inc.
Protocol: R1500-HTG-1522

Listing 16.2.7.2.2 Serious Adverse Events
Single-Blind Safety Analysis Set - SBTP

DB Treatment Group as Treated/ Actual Cohort: Evinacumab IV 15mg/kg Q4W/ Cohort 2

Patient Number	Age/Sex/Race/ Last Trt Day	System Organ Class/ Preferred Term/ Verbatim Term	Start Date (Study Day)/ AE duration (days)/ AE Status	Infusion Related Reaction	Serious Event Type	Severity	Relationship to IP?/ Infusion/ Study Conduct, specify	Action Taken with Study Drug	Outcome
[redacted]	5[redacted]F/BLACK OR AFRICAN AMERICAN/ 57	胃腸障害/ 急性膵炎/ ACUTE PANCREATITIS	20[redacted]190)/ 5/ T	N	Requires or Prolongs Hospitalization	Severe	Not Related/ Not Related/ N	NOT APPLICABLE	RECOVERED/RESOLVED
	5[redacted]F/BLACK OR AFRICAN AMERICAN/ 57	胃腸障害/ 上腹部痛/ RIGHT UPPER QUADRANT ABDOMINAL PAIN, CHRONIC	20[redacted]214)/ 2/ T	N	Requires or Prolongs Hospitalization	Severe	Not Related/ Not Related/ N	NOT APPLICABLE	RECOVERED/RESOLVED

Abbreviations: M= male; F= female;
Study Day= Event Date (First Dosing Date, if Event Date was before First Dosing Date; Study Day= Event Date (First Dosing Date + 1, if Event Date was on or after First Dosing Date.
AE status:Pre=pre-treatment;T=treatment emergent; Post=post-treatment; AE duration=(end date-onset date+1)

/sasdata/Data/Production/BDM/R1500/R1500-HTG/R1500-HTG-1522/Final/Analysis_CSR/Programs/TFL/Generated/l_8251_aeser_sb.sas ([redacted]01APR2021 09:30 SAS Linux 9.4)

MedDRA (Version 22.0) coding dictionary applied.

Listing 16.2.7.2.2 Serious Adverse Events
Single-Blind Safety Analysis Set - SBTP

DB Treatment Group as Treated/ Actual Cohort: Evinacumab IV 15mg/kg Q4W/ Cohort 2

Patient Number	Age/Sex/Race/ Last Trt Day	System Organ Class/ Preferred Term/ Verbatim Term	Start Date (Study Day)/ AE duration (days)/ AE Status	Infusion Related Reaction	Serious Event Type	Severity	Relationship to IP?/ Infusion/ Study Conduct, specify	Action Taken with Study Drug	Outcome
[redacted]	5[redacted]F/BLACK OR AFRICAN AMERICAN/ 57	胃腸障害/ 急性膵炎/ ACUTE PANCREATITIS	20[redacted]272)/ 6/ T	N	Requires or Prolongs Hospitalization	Severe	Not Related/ Not Related/ N	NOT APPLICABLE	RECOVERED/RESOLVED
[redacted]	3[redacted]M/WHITE/ 57	胃腸障害/ 急性膵炎/ ACUTE PANCREATITIS	20[redacted]185)/ 7/ T	N	Requires or Prolongs Hospitalization	Severe	Not Related/ Not Related/ N	NOT APPLICABLE	RECOVERED/RESOLVED
	3[redacted]M/WHITE/ 57	肝胆道系障害/ 肝損傷/ ACUTE LIVER INJURY	20[redacted]196)/ 58/ T	Y	Requires or Prolongs Hospitalization	Severe	Not Related/ Not Related/ N	NOT APPLICABLE	RECOVERED/RESOLVED

Abbreviations: M= male; F= female;
Study Day= Event Date (First Dosing Date, if Event Date was before First Dosing Date; Study Day= Event Date (First Dosing Date + 1, if Event Date was on or after First Dosing Date.
AE status:Pre=pre-treatment;T=treatment emergent; Post=post-treatment; AE duration=(end date-onset date+1)

MedDRA (Version 22.0) coding dictionary applied.

Listing 16.2.7.2.2 Serious Adverse Events
Single-Blind Safety Analysis Set - SBTP

DB Treatment Group as Treated/ Actual Cohort: Evinacumab IV 15mg/kg Q4W/ Cohort 3

Patient Number	Age/Sex/Race/ Last Trt Day	System Organ Class/ Preferred Term/ Verbatim Term	Start Date (Study Day)/ AE duration (days)/ AE Status	Infusion Related Reaction	Serious Event Type	Severity	Relationship to IP?/ Infusion/ Study Conduct, specify	Action Taken with Study Drug	Outcome
[redacted]	5[redacted]M/WHITE/ 58	神経系障害/ 虚血性脳卒中/ ISCHAEMIC STROKE	20[redacted]142)/ 2/ T	N	Requires or Prolongs Hospitalization	Severe	Not Related/ Not Related/ N	DOSE NOT CHANGED	RECOVERED/RESOLVED
[redacted]	4[redacted]F/WHITE/ 57	感染症および寄生虫症/ クロストリジウム・ディフィシレ感染/ CLOSTRIDIUM DIFFICILE (CDIFF) INFECTION	20[redacted]256)/ 38/ T	N	Requires or Prolongs Hospitalization	Severe	Not Related/ Not Related/ N	NOT APPLICABLE	RECOVERED/RESOLVED
	4[redacted]F/WHITE/ 57	代謝および栄養障害/ 高トリグリセリド血症/ WORSENING OF HYPERTRIGLYCERIDEMIA	20[redacted]256)/ 5/ T	N	Requires or Prolongs Hospitalization	Severe	Not Related/ Not Related/ N	NOT APPLICABLE	RECOVERED/RESOLVED

Abbreviations: M= male; F= female;
Study Day= Event Date (First Dosing Date, if Event Date was before First Dosing Date; Study Day= Event Date (First Dosing Date + 1, if Event Date was on or after First Dosing Date.
AE status:Pre=pre-treatment;T=treatment emergent; Post=post-treatment; AE duration=(end date-onset date+1)

/sasdata/Data/Production/BDM/R1500/R1500-HTG/R1500-HTG-1522/Final/Analysis_CSR/Programs/TFL/Generated/l_8251_aeser_sb.sas ([redacted]01APR2021 09:30 SAS Linux 9.4)

MedDRA (Version 22.0) coding dictionary applied.

Listing 16.2.7.2.2 Serious Adverse Events
Single-Blind Safety Analysis Set - SBTP

DB Treatment Group as Treated/ Actual Cohort: Evinacumab IV 15mg/kg Q4W/ Cohort 3

Patient Number	Age/Sex/Race/ Last Trt Day	System Organ Class/ Preferred Term/ Verbatim Term	Start Date (Study Day)/ AE duration (days)/ AE Status	Infusion Related Reaction	Serious Event Type	Severity	Relationship to IP?/ Infusion/ Study Conduct, specify	Action Taken with Study Drug	Outcome
[redacted]	5[redacted]M/WHITE/ 59	胃腸障害/ 急性膵炎/ ACUTE PANCREATITIS	20[redacted]224)/ 16/ T	N	Requires or Prolongs Hospitalization	Severe	Not Related/ Not Related/ N	NOT APPLICABLE	RECOVERED/RESOLVED
[redacted]	4[redacted]F/WHITE/ 54	代謝および栄養障害/ 代謝性アシドーシス/ METABOLIC ACIDOSIS	20[redacted]219)/ 3/ T	N	Requires or Prolongs Hospitalization	Moderate	Not Related/ Not Related/ N	NOT APPLICABLE	RECOVERED/RESOLVED
	4[redacted]F/WHITE/ 54	胃腸障害/ 急性膵炎/ ACUTE PANCREATITIS	20[redacted]261)/ 9/ T	N	Requires or Prolongs Hospitalization	Severe	Not Related/ Not Related/ N	NOT APPLICABLE	RECOVERED/RESOLVED

Abbreviations: M= male; F= female;
Study Day= Event Date (First Dosing Date, if Event Date was before First Dosing Date; Study Day= Event Date (First Dosing Date + 1, if Event Date was on or after First Dosing Date.
AE status:Pre=pre-treatment;T=treatment emergent; Post=post-treatment; AE duration=(end date-onset date+1)

MedDRA (Version 22.0) coding dictionary applied.

Listing 16.2.7.2.2 Serious Adverse Events
Single-Blind Safety Analysis Set - SBTP

DB Treatment Group as Treated/ Actual Cohort: Evinacumab IV 15mg/kg Q4W/ Cohort 3

Patient Number	Age/Sex/Race/ Last Trt Day	System Organ Class/ Preferred Term/ Verbatim Term	Start Date (Study Day)/ AE duration (days)/ AE Status	Infusion Related Reaction	Serious Event Type	Severity	Relationship to IP?/ Infusion/ Study Conduct, specify	Action Taken with Study Drug	Outcome
[redacted]	2[redacted]F/ASIAN/ 57	胃腸障害/ 急性膵炎/ ACUTE PANCREATITIS	20[redacted]92)/ 7/ T	N	Requires or Prolongs Hospitalization	Severe	Not Related/ Not Related/ N	DRUG INTERRUPTED	RECOVERED/RESOLVED
	2[redacted]F/ASIAN/ 57	胃腸障害/ 急性膵炎/ ACUTE PANCREATITIS	20[redacted]168)/ 10/ T	N	Requires or Prolongs Hospitalization	Moderate	Not Related/ Not Related/ N	NOT APPLICABLE	RECOVERED/RESOLVED
	2[redacted]F/ASIAN/ 57	感染症および寄生虫症/ ウイルス感染/ VIRAL SYNDROME (UNKNOWN)	20[redacted]260)/ 4/ T	N	Requires or Prolongs Hospitalization	Moderate	Not Related/ Not Related/ N	NOT APPLICABLE	RECOVERED/RESOLVED

Abbreviations: M= male; F= female;
Study Day= Event Date (First Dosing Date, if Event Date was before First Dosing Date; Study Day= Event Date (First Dosing Date + 1, if Event Date was on or after First Dosing Date.
AE status:Pre=pre-treatment;T=treatment emergent; Post=post-treatment; AE duration=(end date-onset date+1)

/sasdata/Data/Production/BDM/R1500/R1500-HTG/R1500-HTG-1522/Final/Analysis_CSR/Programs/TFL/Generated/l_8251_aeser_sb.sas ([redacted]01APR2021 09:30 SAS Linux 9.4)

MedDRA (Version 22.0) coding dictionary applied.

Listing 16.2.7.2.2 Serious Adverse Events
Single-Blind Safety Analysis Set - SBTP

DB Treatment Group as Treated/ Actual Cohort: Evinacumab IV 15mg/kg Q4W/ Cohort 3

Patient Number	Age/Sex/Race/ Last Trt Day	System Organ Class/ Preferred Term/ Verbatim Term	Start Date (Study Day)/ AE duration (days)/ AE Status	Infusion Related Reaction	Serious Event Type	Severity	Relationship to IP?/ Infusion/ Study Conduct, specify	Action Taken with Study Drug	Outcome
[redacted]	2[redacted]F/ASIAN/ 57	胃腸障害/ 急性膵炎/ ACUTE PANCREATITIS	20[redacted]296)/ 16/ T	N	Requires or Prolongs Hospitalization	Moderate	Not Related/ Not Related/ N	NOT APPLICABLE	RECOVERED/RESOLVED
[redacted]	3[redacted]M/WHITE/ 63	胃腸障害/ 急性膵炎/ ACUTE PANCREATITIS	20[redacted]140)/ 4/ T	N	Requires or Prolongs Hospitalization	Severe	Not Related/ Not Related/ N	DOSE NOT CHANGED	RECOVERED/RESOLVED
	3[redacted]M/WHITE/ 63	胃腸障害/ 急性膵炎/ ACUTE ON CHRONIC PANCREATITIS	20[redacted]213)/ 6/ T	N	Requires or Prolongs Hospitalization	Severe	Not Related/ Not Related/ N	NOT APPLICABLE	RECOVERED/RESOLVED

Abbreviations: M= male; F= female;
Study Day= Event Date (First Dosing Date, if Event Date was before First Dosing Date; Study Day= Event Date (First Dosing Date + 1, if Event Date was on or after First Dosing Date.
AE status:Pre=pre-treatment;T=treatment emergent; Post=post-treatment; AE duration=(end date-onset date+1)

/sasdata/Data/Production/BDM/R1500/R1500-HTG/R1500-HTG-1522/Final/Analysis_CSR/Programs/TFL/Generated/l_8251_aeser_sb.sas ([redacted]01APR2021 09:30 SAS Linux 9.4)

MedDRA (Version 22.0) coding dictionary applied.