1.8.2.1.3 全ての有害事象：全投与期間［Source: Table 7.62］

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Table 7.62: Table 300480: AEs by SOC and preferred term, entire treatment period: safety analysis set

	Tralokinumab Q2W (n=602)				Tralokinumab Q4W (n=76)				Tralokinumab Q2W + optional TCS (n=563)				Placebo (n=231)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
All AEs	468	(77.7)	1696	787.51	53	(69.7)	209	486.12	435	(77.3)	1630	466.47	181	(78.4)	613	685.92
感染症および寄生虫症	296	(49.2)	507	235.42	38	(50.0)	81	188.40	296	(52.6)	544	155.68	98	(42.4)	165	184.63
ウイルス性上気道感染	147	(24.4)	189	87.76	18	(23.7)	26	60.47	143	(25.4)	201	57.52	46	(19.9)	63	70.49
結膜炎	45	(7.5)	53	24.61	4	(5.3)	6	13.96	41	(7.3)	52	14.88	4	(1.7)	4	4.48
気管支炎	13	(2.2)	16	7.43	7	(9.2)	8	18.61	14	(2.5)	15	4.29	8	(3.5)	8	8.95
単純ヘルペス	12	(2.0)	15	6.96	1	(1.3)	1	2.33	18	(3.2)	23	6.58	1	(0.4)	2	2.24
インフルエンザ	22	(3.7)	23	10.68	3	(3.9)	3	6.98	7	(1.2)	7	2.00	6	(2.6)	6	6.71
毛包炎	11	(1.8)	12	5.57	3	(3.9)	3	6.98	12	(2.1)	13	3.72	3	(1.3)	4	4.48
口腔ヘルペス	7	(1.2)	8	3.71	3	(3.9)	3	6.98	16	(2.8)	17	4.86	4	(1.7)	10	11.19
鼻炎	13	(2.2)	17	7.89					9	(1.6)	10	2.86	5	(2.2)	5	5.59
上気道感染	10	(1.7)	10	4.64	2	(2.6)	3	6.98	13	(2.3)	14	4.01	4	(1.7)	4	4.48
咽頭炎	13	(2.2)	15	6.96	2	(2.6)	4	9.30	6	(1.1)	7	2.00	2	(0.9)	3	3.36
胃腸炎	10	(1.7)	10	4.64	2	(2.6)	2	4.65	12	(2.1)	12	3.43	5	(2.2)	5	5.59

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Table 300480: AEs by SOC and preferred term, entire treatment period: safety analysis set

	Tralokinumab Q2W (n=602)			Tralokinumab Q4W (n=76)			Tralokinumab Q2W + optional TCS (n=563)			Placebo (n=231)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
鼻咽頭炎	15 (2.5)	16	7.43	3 (3.9)	3	6.98	5 (0.9)	5	1.43	4 (1.7)	4	4.48
副鼻腔炎	5 (0.8)	5	2.32	1 (1.3)	1	2.33	9 (1.6)	11	3.15	2 (0.9)	2	2.24
扁桃炎	6 (1.0)	6	2.79	1 (1.3)	1	2.33	9 (1.6)	9	2.58	3 (1.3)	3	3.36
尿路感染	6 (1.0)	7	3.25				7 (1.2)	7	2.00	1 (0.4)	1	1.12
皮膚感染	7 (1.2)	8	3.71				5 (0.9)	5	1.43	3 (1.3)	3	3.36
蜂巣炎	4 (0.7)	4	1.86				7 (1.2)	7	2.00			
膀胱炎	4 (0.7)	4	1.86	1 (1.3)	1	2.33	5 (0.9)	6	1.72	4 (1.7)	5	5.59
中耳炎	5 (0.8)	6	2.79				4 (0.7)	4	1.14	2 (0.9)	2	2.24
麦粒腫	6 (1.0)	6	2.79				3 (0.5)	3	0.86			
膿痂疹	5 (0.8)	5	2.32				4 (0.7)	4	1.14	3 (1.3)	3	3.36
ヘルペス性状湿疹	3 (0.5)	3	1.39				4 (0.7)	5	1.43	2 (0.9)	2	2.24
せつ	2 (0.3)	2	0.93				5 (0.9)	6	1.72			
耳感染	4 (0.7)	4	1.86				3 (0.5)	3	0.86			
ウイルス性胃腸炎	3 (0.5)	3	1.39				3 (0.5)	4	1.14	1 (0.4)	1	1.12
帯状疱疹	1 (0.2)	1	0.46				5 (0.9)	6	1.72	1 (0.4)	1	1.12
歯膿瘍	4 (0.7)	5	2.32				2 (0.4)	2	0.57			
細菌性気管支炎	2 (0.3)	2	0.93				2 (0.4)	4	1.14			

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Table 300480: AEs by SOC and preferred term, entire treatment period: safety analysis set

	Tralokinumab Q2W (n=602)			Tralokinumab Q4W (n=76)			Tralokinumab Q2W + optional TCS (n=563)			Placebo (n=231)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
消化管感染							6 (1.1)	6	1.72	2 (0.9)	2	2.24
外耳炎	1 (0.2)	1	0.46	1 (1.3)	1	2.33	3 (0.5)	3	0.86			
膿瘍	2 (0.3)	3	1.39	1 (1.3)	1	2.33				1 (0.4)	1	1.12
細菌性結膜炎	2 (0.3)	2	0.93				2 (0.4)	2	0.57			
感染性皮膚炎	4 (0.7)	4	1.86							1 (0.4)	1	1.12
丹毒	1 (0.2)	1	0.46				3 (0.5)	3	0.86	1 (0.4)	2	2.24
ヘルペスウイルス感染							3 (0.5)	4	1.14			
喉頭炎	2 (0.3)	2	0.93	1 (1.3)	1	2.33	1 (0.2)	1	0.29	2 (0.9)	2	2.24
伝染性軟属腫	3 (0.5)	4	1.86									
爪真菌症				1 (1.3)	1	2.33	3 (0.5)	3	0.86			
爪囲炎	2 (0.3)	2	0.93	1 (1.3)	1	2.33	1 (0.2)	1	0.29			
歯周炎							4 (0.7)	4	1.14			
肺炎	1 (0.2)	1	0.46	3 (3.9)	3	6.98				1 (0.4)	1	1.12
歯髄炎	1 (0.2)	1	0.46				2 (0.4)	3	0.86			
ウイルス性気管支炎	1 (0.2)	1	0.46				2 (0.4)	2	0.57	1 (0.4)	1	1.12
歯肉炎	2 (0.3)	2	0.93				1 (0.2)	1	0.29			

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Table 300480: AEs by SOC and preferred term, entire treatment period: safety analysis set

System Organ Class (SOC) / Preferred term	Tralokinumab Q2W (n=602) N	(%)	E	R	Tralokinumab Q4W (n=76) N	(%)	E	R	Tralokinumab Q2W + optional TCS (n=563) N	(%)	E	R	Placebo (n=231) N	(%)	E	R
咽頭扁桃炎	1	(0.2)	1	0.46	1	(1.3)	1	2.33	1	(0.2)	1	0.29				
気道感染	1	(0.2)	2	0.93					1	(0.2)	1	0.29				
皮下組織膿瘍									2	(0.4)	3	0.86				
足部白癬									3	(0.5)	3	0.86	2	(0.9)	2	2.24
気管炎									2	(0.4)	3	0.86				
四肢膿瘍									2	(0.4)	2	0.57				
ウイルス性結膜炎	1	(0.2)	1	0.46					1	(0.2)	1	0.29				
精巣上体炎	1	(0.2)	1	0.46					1	(0.2)	1	0.29				
真菌感染									2	(0.4)	2	0.57				
手足口病	2	(0.3)	2	0.93												
口腔カンジダ症	1	(0.2)	1	0.46					1	(0.2)	1	0.29				
急性中耳炎									2	(0.4)	2	0.57				
レンサ球菌性咽頭炎	1	(0.2)	1	0.46					1	(0.2)	1	0.29				
膿疱性皮疹	1	(0.2)	1	0.46					1	(0.2)	1	0.29				
猩紅熱	1	(0.2)	1	0.46	1	(1.3)	1	2.33								
細菌性副鼻腔炎									2	(0.4)	2	0.57				

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Table 300480: AEs by SOC and preferred term, entire treatment period: safety analysis set

	Tralokinumab Q2W (n=602)			Tralokinumab Q4W (n=76)			Tralokinumab Q2W + optional TCS (n=563)			Placebo (n=231)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
外陰腟真菌感染	1 (0.2)	1	0.46				1 (0.2)	1	0.29			
頚部膿瘍				1 (1.3)	1	2.33						
ダニ皮膚炎										1 (0.4)	1	1.12
急性副鼻腔炎				1 (1.3)	1	2.33				1 (0.4)	1	1.12
無症候性細菌尿	1 (0.2)	1	0.46									
体部白癬							1 (0.2)	1	0.29			
乳房膿瘍				1 (1.3)	1	2.33						
カンピロバクター胃腸炎	1 (0.2)	1	0.46									
カンジダ感染							1 (0.2)	1	0.29			
クラミジア感染				1 (1.3)	1	2.33						
クロストリジウム・ディフィシレ大腸炎	1 (0.2)	1	0.46									
医療機器関連感染	1 (0.2)	1	0.46									
憩室炎	1 (0.2)	1	0.46									
膿痂疹性湿疹							1 (0.2)	1	0.29			
ウイルス性腸炎							1 (0.2)	1	0.29	1 (0.4)	1	1.12

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Table 300480: AEs by SOC and preferred term, entire treatment period: safety analysis set

	Tralokinumab Q2W (n=602)				Tralokinumab Q4W (n=76)				Tralokinumab Q2W + optional TCS (n=563)				Placebo (n=231)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
突発性発疹	1	(0.2)	1	0.46												
細菌性胃腸炎									1	(0.2)	1	0.29				
ノロウイルス性胃腸炎	1	(0.2)	1	0.46												
陰部単純ヘルペス									1	(0.2)	1	0.29				
細菌性性器感染									1	(0.2)	1	0.29				
肛径部膿瘍									1	(0.2)	1	0.29				
ヘリコバクター感染									1	(0.2)	1	0.29				
伝染性単核症									1	(0.2)	1	0.29				
ウイルス性角膜炎									1	(0.2)	1	0.29				
リーシュマニア症	1	(0.2)	1	0.46												
限局性感染									1	(0.2)	1	0.29				
リンパ管炎	1	(0.2)	1	0.46												
縦隔炎									1	(0.2)	1	0.29				
鼻ヘルペス	1	(0.2)	1	0.46												

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Table 300480: AEs by SOC and preferred term, entire treatment period: safety analysis set

	Tralokinumab Q2W (n=602)				Tralokinumab Q4W (n=76)				Tralokinumab Q2W + optional TCS (n=563)				Placebo (n=231)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
眼部単純ヘルペス													1	(0.4)	1	1.12
眼帯状疱疹	1	(0.2)	1	0.46												
真菌性外耳炎									1	(0.2)	1	0.29				
乳頭腫ウイルス感染									1	(0.2)	1	0.29				
細菌性咽頭炎									1	(0.2)	1	0.29				
シュードモナス感染									1	(0.2)	1	0.29				
腎盂腎炎									1	(0.2)	1	0.29	1	(0.4)	1	1.12
鼻喉頭炎					1	(1.3)	1	2.33								
皮膚細菌感染									1	(0.2)	1	0.29	1	(0.4)	1	1.12
皮膚カンジダ	1	(0.2)	1	0.46												
ブドウ球菌性膿痂疹	1	(0.2)	1	0.46												

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Table 300480: AEs by SOC and preferred term, entire treatment period: safety analysis set

	Tralokinumab Q2W (n=602)				Tralokinumab Q4W (n=76)				Tralokinumab Q2W + optional TCS (n=563)				Placebo (n=231)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
ブドウ球菌感染									1	(0.2)	1	0.29				
ブドウ球菌皮膚感染					1	(1.3)	1	2.33					1	(0.4)	1	1.12
股部白癬	1	(0.2)	1	0.46												
癜風	1	(0.2)	1	0.46									1	(0.4)	1	1.12
歯感染									1	(0.2)	1	0.29	1	(0.4)	1	1.12
泌尿生殖器トリコモナス症													1	(0.4)	1	1.12
腟感染									1	(0.2)	1	0.29				
ウイルス性咽頭炎									1	(0.2)	1	0.29				
ウイルス性鼻炎									1	(0.2)	1	0.29	1	(0.4)	2	2.24
創傷感染	1	(0.2)	1	0.46												
皮膚および皮下組織障害	227	(37.7)	359	166.70	22	(28.9)	41	95.36	173	(30.7)	316	90.43	111	(48.1)	196	219.31
アトピー性皮膚炎	163	(27.1)	216	100.30	14	(18.4)	22	51.17	124	(22.0)	203	58.09	92	(39.8)	152	170.08
そう痒症	33	(5.5)	43	19.97	4	(5.3)	5	11.63	20	(3.6)	27	7.73	13	(5.6)	18	20.14

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Table 300480: AEs by SOC and preferred term, entire treatment period: safety analysis set

	Tralokinumab Q2W (n=602)			Tralokinumab Q4W (n=76)			Tralokinumab Q2W + optional TCS (n=563)			Placebo (n=231)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
蕁麻疹	4 (0.7)	5	2.32	1 (1.3)	1	2.33	8 (1.4)	17	4.86	4 (1.7)	6	6.71
紅斑	9 (1.5)	14	6.50				4 (0.7)	6	1.72	2 (0.9)	2	2.24
脱毛症	11 (1.8)	13	6.04				4 (0.7)	4	1.14	1 (0.4)	1	1.12
皮膚乾燥	8 (1.3)	8	3.71				3 (0.5)	3	0.86	1 (0.4)	2	2.24
多汗症	8 (1.3)	9	4.18	1 (1.3)	1	2.33	1 (0.2)	1	0.29	2 (0.9)	2	2.24
ざ瘡	4 (0.7)	4	1.86				6 (1.1)	6	1.72	3 (1.3)	3	3.36
円形脱毛症	3 (0.5)	3	1.39	2 (2.6)	3	6.98	2 (0.4)	2	0.57			
接触皮膚炎	3 (0.5)	3	1.39				5 (0.9)	5	1.43	1 (0.4)	1	1.12
酒さ	1 (0.2)	1	0.46	1 (1.3)	1	2.33	3 (0.5)	3	0.86			
血管浮腫	2 (0.3)	3	1.39				1 (0.2)	1	0.29			
皮膚局面	1 (0.2)	2	0.93	1 (1.3)	1	2.33	1 (0.2)	1	0.29			
顔面腫脹	2 (0.3)	2	0.93	1 (1.3)	1	2.33	1 (0.2)	1	0.29			
光線角化症	3 (0.5)	3	1.39									
剥脱性皮膚炎	1 (0.2)	2	0.93				1 (0.2)	1	0.29			
びまん性脱毛症	2 (0.3)	2	0.93				1 (0.2)	1	0.29			
斑							1 (0.2)	3	0.86			
寝汗	2 (0.3)	2	0.93				1 (0.2)	1	0.29			
皮膚疼痛	2 (0.3)	3	1.39							1 (0.4)	1	1.12
丘疹	2 (0.3)	2	0.93				1 (0.2)	1	0.29			

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Table 300480: AEs by SOC and preferred term, entire treatment period: safety analysis set

System Organ Class (SOC) Preferred term	Tralokinumab Q2W (n=602) N (%)	E	R	Tralokinumab Q4W (n=76) N (%)	E	R	Tralokinumab Q2W + optional TCS (n=563) N (%)	E	R	Placebo (n=231) N (%)	E	R
慢性特発性蕁麻疹							2 (0.4)	2	0.57			
皮膚嚢腫				2 (2.6)	2	4.65				1 (0.4)	1	1.12
全身性剥脱性皮膚炎	2 (0.3)	2	0.93							1 (0.4)	1	1.12
嵌入爪	1 (0.2)	1	0.46				1 (0.2)	1	0.29			
間擦疹				1 (1.3)	1	2.33	1 (0.2)	1	0.29			
爪甲脱落症	1 (0.2)	1	0.46				1 (0.2)	1	0.29			
脂漏性皮膚炎	1 (0.2)	1	0.46				1 (0.2)	1	0.29			
皮膚灼熱感				1 (1.3)	1	2.33	1 (0.2)	1	0.29			
皮膚びらん	1 (0.2)	1	0.46				1 (0.2)	1	0.29			
皮膚剥脱	1 (0.2)	1	0.46				1 (0.2)	1	0.29	1 (0.4)	1	1.12
皮膚刺激							2 (0.4)	2	0.57			
皮膚線条	1 (0.2)	1	0.46				1 (0.2)	1	0.29			
皮膚潰瘍	1 (0.2)	1	0.46				1 (0.2)	1	0.29	1 (0.4)	1	1.12
日光皮膚炎							2 (0.4)	2	0.57			
嚢胞性ざ瘡	1 (0.2)	1	0.46									

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Table 300480: AEs by SOC and preferred term, entire treatment period: safety analysis set

System Organ Class (SOC) Preferred term	Tralokinumab Q2W (n=602) N (%)	E	R	Tralokinumab Q4W (n=76) N (%)	E	R	Tralokinumab Q2W + optional TCS (n=563) N (%)	E	R	Placebo (n=231) N (%)	E	R
褥瘡性潰瘍										1 (0.4)	1	1.12
皮膚炎							1 (0.2)	1	0.29			
ざ瘡様皮膚炎										1 (0.4)	1	1.12
皮膚筋炎							1 (0.2)	1	0.29			
皮膚症				1 (1.3)	1	2.33						
糖尿病性足病変	1 (0.2)	1	0.46									
異汗性湿疹										1 (0.4)	1	1.12
斑状出血	1 (0.2)	1	0.46									
湿疹										1 (0.4)	1	1.12
特発性蕁麻疹				1 (1.3)	1	2.33						
苔癬化							1 (0.2)	1	0.29			
網状皮斑	1 (0.2)	1	0.46									
機械性蕁麻疹							1 (0.2)	1	0.29			
稗粒腫							1 (0.2)	1	0.29			
爪破損							1 (0.2)	1	0.29			
爪甲剥離症							1 (0.2)	1	0.29			
脂肪織炎	1 (0.2)	1	0.46									
丘疹膿疱性酒さ							1 (0.2)	1	0.29			
光線性皮膚症							1 (0.2)	1	0.29			

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Table 300480: AEs by SOC and preferred term, entire treatment period: safety analysis set

System Organ Class (SOC) Preferred term	Tralokinumab Q2W (n=602) N (%)	E	R	Tralokinumab Q4W (n=76) N (%)	E	R	Tralokinumab Q2W + optional TCS (n=563) N (%)	E	R	Placebo (n=231) N (%)	E	R
光線過敏性反応							1 (0.2)	1	0.29			
粃糠疹	1 (0.2)	1	0.46									
ばら色粃糠疹	1 (0.2)	1	0.46									
痒疹							1 (0.2)	1	0.29			
全身性そう痒症							1 (0.2)	1	0.29			
発疹	1 (0.2)	1	0.46									
皮膚障害							1 (0.2)	1	0.29			
皮膚硬結	1 (0.2)	1	0.46									
うっ滞性皮膚炎	1 (0.2)	1	0.46									
コリン性蕁麻疹							1 (0.2)	1	0.29			
一般・全身障害および投与部位の状態	94 (15.6)	184	85.44	14 (18.4)	35	81.41	75 (13.3)	153	43.78	20 (8.7)	27	30.21

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Table 300480: AEs by SOC and preferred term, entire treatment period: safety analysis set

	Tralokinumab Q2W (n=602)				Tralokinumab Q4W (n=76)				Tralokinumab Q2W + optional TCS (n=563)				Placebo (n=231)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
注射部位反応	27	(4.5)	61	28.32	7	(9.2)	21	48.84	28	(5.0)	60	17.17	1	(0.4)	1	1.12
注射部位紅斑	8	(1.3)	19	8.82	3	(3.9)	3	6.98	11	(2.0)	30	8.59	2	(0.9)	2	2.24
発熱	12	(2.0)	14	6.50					9	(1.6)	9	2.58	3	(1.3)	6	6.71
注射部位腫脹	2	(0.3)	2	0.93	1	(1.3)	3	6.98	6	(1.1)	15	4.29				
疲労	15	(2.5)	16	7.43					3	(0.5)	3	0.86	1	(0.4)	1	1.12
注射部位疼痛	9	(1.5)	11	5.11					6	(1.1)	7	2.00	2	(0.9)	2	2.24
注射部位蕁麻疹	3	(0.5)	11	5.11	1	(1.3)	2	4.65	1	(0.2)	1	0.29				
無力症	4	(0.7)	4	1.86					2	(0.4)	3	0.86	4	(1.7)	4	4.48
注射部位そう痒感	3	(0.5)	5	2.32					2	(0.4)	2	0.57				
インフルエンザ様疾患	4	(0.7)	4	1.86					2	(0.4)	2	0.57	1	(0.4)	1	1.12
注射部位浮腫	3	(0.5)	4	1.86					1	(0.2)	1	0.29				
注射部位発疹	1	(0.2)	2	0.93	1	(1.3)	1	2.33	2	(0.4)	2	0.57				
末梢性浮腫	4	(0.7)	4	1.86					1	(0.2)	1	0.29	3	(1.3)	4	4.48

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Table 300480: AEs by SOC and preferred term, entire treatment period: safety analysis set

	Tralokinumab Q2W (n=602)			Tralokinumab Q4W (n=76)			Tralokinumab Q2W + optional TCS (n=563)			Placebo (n=231)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
倦怠感	1 (0.2)	1	0.46	1 (1.3)	2	4.65	1 (0.2)	1	0.29			
悪寒	2 (0.3)	2	0.93				1 (0.2)	1	0.29	1 (0.4)	1	1.12
注射部位内出血	1 (0.2)	1	0.46				2 (0.4)	2	0.57	1 (0.4)	1	1.12
注射部位湿疹	1 (0.2)	3	1.39									
注射部位血腫	2 (0.3)	2	0.93				1 (0.2)	1	0.29			
胸痛				1 (1.3)	1	2.33	1 (0.2)	1	0.29			
薬物不耐性	2 (0.3)	2	0.93							1 (0.4)	1	1.12
体温変動感	2 (0.3)	2	0.93									
局所腫脹	1 (0.2)	1	0.46				1 (0.2)	1	0.29			
疼痛	2 (0.3)	2	0.93									
末梢腫脹	1 (0.2)	1	0.46				1 (0.2)	1	0.29			
圧痛	1 (0.2)	1	0.46				1 (0.2)	1	0.29			
乾燥症	1 (0.2)	1	0.46	1 (1.3)	1	2.33						
胸部不快感							1 (0.2)	1	0.29			
嚢胞							1 (0.2)	1	0.29	1 (0.4)	1	1.12

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Table 300480: AEs by SOC and preferred term, entire treatment period: safety analysis set

System Organ Class (SOC) Preferred term	Tralokinumab Q2W (n=602) N (%)	E	R	Tralokinumab Q4W (n=76) N (%)	E	R	Tralokinumab Q2W + optional TCS (n=563) N (%)	E	R	Placebo (n=231) N (%)	E	R
不快感	1 (0.2)	1	0.46									
顔面浮腫							1 (0.2)	1	0.29			
顔面痛										1 (0.4)	1	1.12
異常感				1 (1.3)	1	2.33						
冷感	1 (0.2)	1	0.46							1 (0.4)	1	1.12
肉芽腫							1 (0.2)	1	0.29			
治癒不良							1 (0.2)	1	0.29			
硬結	1 (0.2)	1	0.46									
炎症	1 (0.2)	1	0.46									
注射部位出血							1 (0.2)	1	0.29			
注射部位過敏反応	1 (0.2)	1	0.46									
注射部位硬結	1 (0.2)	1	0.46									
注射部位炎症							1 (0.2)	1	0.29			
粘膜びらん							1 (0.2)	1	0.29			
温度変化不耐症	1 (0.2)	1	0.46									

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Table 300480: AEs by SOC and preferred term, entire treatment period: safety analysis set

	Tralokinumab Q2W (n=602)				Tralokinumab Q4W (n=76)				Tralokinumab Q2W + optional TCS (n=563)				Placebo (n=231)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
口渇	1	(0.2)	1	0.46												
筋骨格系および結合組織障害	62	(10.3)	71	32.97	7	(9.2)	8	18.61	59	(10.5)	74	21.18	24	(10.4)	27	30.21
背部痛	8	(1.3)	8	3.71	4	(5.3)	4	9.30	18	(3.2)	19	5.44	3	(1.3)	3	3.36
関節痛	12	(2.0)	12	5.57					7	(1.2)	7	2.00	4	(1.7)	4	4.48
腱炎	3	(0.5)	3	1.39					6	(1.1)	6	1.72	2	(0.9)	2	2.24
筋骨格痛	5	(0.8)	5	2.32					3	(0.5)	3	0.86	1	(0.4)	1	1.12
頚部痛	3	(0.5)	5	2.32					3	(0.5)	3	0.86	2	(0.9)	2	2.24
変形性関節症	1	(0.2)	1	0.46	1	(1.3)	1	2.33	4	(0.7)	6	1.72	1	(0.4)	1	1.12
滑液包炎	3	(0.5)	3	1.39	1	(1.3)	1	2.33	3	(0.5)	3	0.86	2	(0.9)	2	2.24
四肢痛	5	(0.8)	5	2.32					2	(0.4)	2	0.57	1	(0.4)	1	1.12
筋骨格系胸痛	3	(0.5)	3	1.39					2	(0.4)	2	0.57	1	(0.4)	1	1.12
関節炎	2	(0.3)	3	1.39					1	(0.2)	1	0.29				
椎間板突出	2	(0.3)	2	0.93	1	(1.3)	1	2.33	1	(0.2)	1	0.29				

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Table 300480: AEs by SOC and preferred term, entire treatment period: safety analysis set

System Organ Class (SOC) Preferred term	Tralokinumab Q2W (n=602) N (%)	E	R	Tralokinumab Q4W (n=76) N (%)	E	R	Tralokinumab Q2W + optional TCS (n=563) N (%)	E	R	Placebo (n=231) N (%)	E	R
筋肉痛	3 (0.5)	3	1.39				1 (0.2)	1	0.29	2 (0.9)	2	2.24
関節腫脹	2 (0.3)	2	0.93				1 (0.2)	1	0.29			
脊椎痛	2 (0.3)	2	0.93				1 (0.2)	1	0.29			
腱鞘炎	1 (0.2)	1	0.46				2 (0.4)	2	0.57			
関節障害	1 (0.2)	1	0.46				1 (0.2)	1	0.29			
骨痛	2 (0.3)	2	0.93									
筋痙縮	1 (0.2)	1	0.46				1 (0.2)	1	0.29	1 (0.4)	1	1.12
筋硬化症	1 (0.2)	1	0.46				1 (0.2)	1	0.29			
脊椎炎	1 (0.2)	1	0.46				1 (0.2)	1	0.29			
滑液嚢腫	2 (0.3)	2	0.93							1 (0.4)	1	1.12
軟骨炎										1 (0.4)	1	1.12
外骨腫							1 (0.2)	1	0.29			
側腹部痛										1 (0.4)	1	1.12
椎間板圧迫	1 (0.2)	1	0.46									
四肢の変形	1 (0.2)	1	0.46									
腰部脊柱管狭窄症	1 (0.2)	1	0.46									
半月板変性							1 (0.2)	1	0.29			

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Table 300480: AEs by SOC and preferred term, entire treatment period: safety analysis set

	Tralokinumab Q2W (n=602)			Tralokinumab Q4W (n=76)			Tralokinumab Q2W + optional TCS (n=563)			Placebo (n=231)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
筋緊張	1 (0.2)	1	0.46							1 (0.4)	1	1.12
筋攣縮							1 (0.2)	1	0.29			
筋骨格硬直							1 (0.2)	1	0.29			
神経障害性関節症				1 (1.3)	1	2.33						
関節周囲炎							1 (0.2)	1	0.29			
リウマチ性多発筋痛										1 (0.4)	1	1.12
肩回旋筋腱板症候群							1 (0.2)	1	0.29			
シェーグレン症候群							1 (0.2)	1	0.29			
変形性脊椎症							1 (0.2)	1	0.29	1 (0.4)	1	1.12
腱不快感							1 (0.2)	1	0.29			
腱痛	1 (0.2)	1	0.46									
狭窄性腱鞘炎							1 (0.2)	1	0.29			
斜頸							1 (0.2)	1	0.29	1 (0.4)	1	1.12
弾発指							1 (0.2)	1	0.29			

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Table 300480: AEs by SOC and preferred term, entire treatment period: safety analysis set

System Organ Class (SOC) Preferred term	Tralokinumab Q2W (n=602) N (%)	E	R	Tralokinumab Q4W (n=76) N (%)	E	R	Tralokinumab Q2W + optional TCS (n=563) N (%)	E	R	Placebo (n=231) N (%)	E	R
胃腸障害	63 (10.5)	92	42.72	9 (11.8)	10	23.26	54 (9.6)	80	22.89	20 (8.7)	30	33.57
下痢	12 (2.0)	17	7.89	3 (3.9)	3	6.98	9 (1.6)	10	2.86	4 (1.7)	4	4.48
悪心	11 (1.8)	14	6.50				7 (1.2)	7	2.00	6 (2.6)	6	6.71
齲歯	4 (0.7)	6	2.79	2 (2.6)	2	4.65	9 (1.6)	9	2.58	4 (1.7)	5	5.59
嘔吐	8 (1.3)	8	3.71				5 (0.9)	7	2.00	2 (0.9)	2	2.24
上腹部痛	8 (1.3)	8	3.71	1 (1.3)	1	2.33	5 (0.9)	5	1.43	1 (0.4)	1	1.12
歯痛	6 (1.0)	6	2.79				4 (0.7)	4	1.14	2 (0.9)	2	2.24
腹痛	3 (0.5)	4	1.86				2 (0.4)	2	0.57	3 (1.3)	3	3.36
胃食道逆流性疾患	2 (0.3)	2	0.93				4 (0.7)	4	1.14	1 (0.4)	1	1.12
便秘	4 (0.7)	4	1.86	1 (1.3)	1	2.33				1 (0.4)	1	1.12
食中毒	3 (0.5)	3	1.39				2 (0.4)	2	0.57			
胃腸障害	1 (0.2)	2	0.93				2 (0.4)	2	0.57	1 (0.4)	1	1.12
腹部膨満	1 (0.2)	1	0.46				2 (0.4)	2	0.57			
消化不良	1 (0.2)	1	0.46				2 (0.4)	2	0.57			
鼓腸	1 (0.2)	2	0.93	1 (1.3)	1	2.33						

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Table 300480: AEs by SOC and preferred term, entire treatment period: safety analysis set

	Tralokinumab Q2W (n=602)			Tralokinumab Q4W (n=76)			Tralokinumab Q2W + optional TCS (n=563)			Placebo (n=231)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
胃炎	1 (0.2)	1	0.46				2 (0.4)	2	0.57			
痔核	1 (0.2)	1	0.46				2 (0.4)	2	0.57			
歯周病							3 (0.5)	3	0.86	1 (0.4)	1	1.12
アフタ性潰瘍	1 (0.2)	1	0.46				1 (0.2)	1	0.29			
大腸炎							2 (0.4)	2	0.57			
腸炎							2 (0.4)	2	0.57			
硬便	1 (0.2)	2	0.93									
大腸ポリープ	1 (0.2)	1	0.46				1 (0.2)	1	0.29			
嚥下痛	1 (0.2)	1	0.46				1 (0.2)	1	0.29			
口内炎							2 (0.4)	2	0.57			
下腹部痛	1 (0.2)	1	0.46									
腹部症状	1 (0.2)	1	0.46									
肛門出血							1 (0.2)	1	0.29			
潰瘍性大腸炎										1 (0.4)	1	1.12
歯嚢胞	1 (0.2)	1	0.46									
腸憩室				1 (1.3)	1	2.33						
胃潰瘍							1 (0.2)	1	0.29			

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Table 300480: AEs by SOC and preferred term, entire treatment period: safety analysis set

System Organ Class (SOC) Preferred term	Tralokinumab Q2W (n=602) N (%)	E	R	Tralokinumab Q4W (n=76) N (%)	E	R	Tralokinumab Q2W + optional TCS (n=563) N (%)	E	R	Placebo (n=231) N (%)	E	R
消化器痛							1 (0.2)	1	0.29			
歯肉出血							1 (0.2)	1	0.29			
歯肉嚢胞	1 (0.2)	1	0.46									
血便排泄	1 (0.2)	1	0.46									
嵌頓臍ヘルニア	1 (0.2)	1	0.46									
口腔嚢胞	1 (0.2)	1	0.46									
口腔粘膜水疱形成										1 (0.4)	1	1.12
直腸出血				1 (1.3)	1	2.33						
唾液腺粘液嚢胞										1 (0.4)	1	1.12
舌変色							1 (0.2)	1	0.29			
歯の障害							1 (0.2)	1	0.29			
埋伏歯							1 (0.2)	1	0.29			
歯の脱落							1 (0.2)	1	0.29			

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Table 300480: AEs by SOC and preferred term, entire treatment period: safety analysis set

	Tralokinumab Q2W (n=602)			Tralokinumab Q4W (n=76)			Tralokinumab Q2W + optional TCS (n=563)			Placebo (n=231)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
神経系障害	62 (10.3)	103	47.83	4 (5.3)	6	13.96	57 (10.1)	74	21.18	21 (9.1)	33	36.93
頭痛	32 (5.3)	62	28.79	2 (2.6)	2	4.65	22 (3.9)	29	8.30	13 (5.6)	22	24.62
片頭痛	6 (1.0)	6	2.79	1 (1.3)	1	2.33	5 (0.9)	6	1.72	1 (0.4)	1	1.12
浮動性めまい	6 (1.0)	7	3.25	1 (1.3)	1	2.33	4 (0.7)	4	1.14	1 (0.4)	1	1.12
失神	4 (0.7)	4	1.86	1 (1.3)	1	2.33	5 (0.9)	5	1.43	2 (0.9)	2	2.24
感覚鈍麻	3 (0.5)	4	1.86				2 (0.4)	2	0.57	1 (0.4)	1	1.12
錯感覚	4 (0.7)	4	1.86				2 (0.4)	2	0.57			
失神寸前の状態	1 (0.2)	1	0.46				4 (0.7)	4	1.14	1 (0.4)	1	1.12
手根管症候群	1 (0.2)	1	0.46				2 (0.4)	3	0.86			
坐骨神経痛	2 (0.3)	2	0.93				2 (0.4)	2	0.57			
灼熱感	2 (0.3)	2	0.93	1 (1.3)	1	2.33				1 (0.4)	2	2.24
神経痛							2 (0.4)	3	0.86			
味覚異常	1 (0.2)	1	0.46				1 (0.2)	1	0.29			
蟻走感							1 (0.2)	2	0.57			
記憶障害							2 (0.4)	2	0.57			
神経圧迫							2 (0.4)	2	0.57			

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Table 300480: AEs by SOC and preferred term, entire treatment period: safety analysis set

System Organ Class (SOC) / Preferred term	Tralokinumab Q2W (n=602) N	(%)	E	R	Tralokinumab Q4W (n=76) N	(%)	E	R	Tralokinumab Q2W + optional TCS (n=563) N	(%)	E	R	Placebo (n=231) N	(%)	E	R
健忘									1	(0.2)	1	0.29				
運動失調									1	(0.2)	1	0.29				
脱力発作									1	(0.2)	1	0.29				
頚髄神経根障害	1	(0.2)	1	0.46									1	(0.4)	1	1.12
複合性局所疼痛症候群									1	(0.2)	1	0.29				
意識レベルの低下	1	(0.2)	1	0.46												
注意力障害													1	(0.4)	1	1.12
異常感覚	1	(0.2)	1	0.46												
顔面麻痺									1	(0.2)	1	0.29				
知覚過敏	1	(0.2)	1	0.46												
高血圧性脳症	1	(0.2)	1	0.46												
ヘルペス後神経痛									1	(0.2)	1	0.29				
傾眠	1	(0.2)	1	0.46												
緊張性頭痛	1	(0.2)	1	0.46												

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Table 300480: AEs by SOC and preferred term, entire treatment period: safety analysis set

	Tralokinumab Q2W (n=602)			Tralokinumab Q4W (n=76)			Tralokinumab Q2W + optional TCS (n=563)			Placebo (n=231)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
振戦	1 (0.2)	1	0.46							1 (0.4)	1	1.12
三叉神経痛	1 (0.2)	1	0.46									
第6脳神経麻痺							1 (0.2)	1	0.29			
呼吸器、胸郭および縦隔障害	59 (9.8)	67	31.11	5 (6.6)	8	18.61	45 (8.0)	48	13.74	17 (7.4)	20	22.38
咳嗽	13 (2.2)	14	6.50	3 (3.9)	4	9.30	14 (2.5)	14	4.01	4 (1.7)	5	5.59
喘息	15 (2.5)	16	7.43	1 (1.3)	2	4.65	5 (0.9)	5	1.43	3 (1.3)	3	3.36
口腔咽頭痛	11 (1.8)	12	5.57				10 (1.8)	10	2.86	3 (1.3)	3	3.36
鼻出血	3 (0.5)	4	1.86				2 (0.4)	3	0.86	1 (0.4)	2	2.24
アレルギー性鼻炎	2 (0.3)	2	0.93				4 (0.7)	4	1.14	1 (0.4)	1	1.12
鼻閉	3 (0.5)	3	1.39				2 (0.4)	2	0.57			
呼吸困難	1 (0.2)	1	0.46				2 (0.4)	2	0.57			
鼻漏	2 (0.3)	2	0.93				1 (0.2)	1	0.29	1 (0.4)	1	1.12
アレルギー性咳嗽	2 (0.3)	2	0.93									
労作性呼吸困難	2 (0.3)	2	0.93									

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Table 300480: AEs by SOC and preferred term, entire treatment period: safety analysis set

	Tralokinumab Q2W (n=602)			Tralokinumab Q4W (n=76)			Tralokinumab Q2W + optional TCS (n=563)			Placebo (n=231)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
自然気胸	1 (0.2)	1	0.46	1 (1.3)	1	2.33						
湿性咳嗽							2 (0.4)	2	0.57			
副鼻腔うっ血	2 (0.3)	2	0.93									
上気道の炎症	1 (0.2)	1	0.46				1 (0.2)	1	0.29			
喘息クリーゼ	1 (0.2)	1	0.46									
慢性閉塞性肺疾患										1 (0.4)	1	1.12
肺気腫				1 (1.3)	1	2.33						
血胸							1 (0.2)	1	0.29			
鼻茸										1 (0.4)	1	1.12
鼻甲介肥大										1 (0.4)	1	1.12
肺うっ血	1 (0.2)	1	0.46							1 (0.4)	1	1.12
呼吸窮迫										1 (0.4)	1	1.12
睡眠時無呼吸症候群	1 (0.2)	1	0.46									
くしゃみ	1 (0.2)	1	0.46									

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Table 300480: AEs by SOC and preferred term, entire treatment period: safety analysis set

	Tralokinumab Q2W (n=602)				Tralokinumab Q4W (n=76)				Tralokinumab Q2W + optional TCS (n=563)				Placebo (n=231)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
上気道性喘鳴									1	(0.2)	1	0.29				
咽喉刺激感									1	(0.2)	1	0.29				
上気道咳症候群									1	(0.2)	1	0.29				
喘鳴	1	(0.2)	1	0.46												
傷害、中毒および処置合併症	47	(7.8)	59	27.40	6	(7.9)	7	16.28	51	(9.1)	62	17.74	21	(9.1)	25	27.97
他の患者への薬剤誤投与	8	(1.3)	13	6.04					2	(0.4)	2	0.57	3	(1.3)	3	3.36
靭帯捻挫	6	(1.0)	6	2.79					6	(1.1)	6	1.72	1	(0.4)	1	1.12
挫傷	2	(0.3)	2	0.93	2	(2.6)	2	4.65	4	(0.7)	4	1.14	1	(0.4)	1	1.12
裂傷	5	(0.8)	5	2.32	1	(1.3)	1	2.33	1	(0.2)	1	0.29	2	(0.9)	2	2.24
処置によるめまい	4	(0.7)	5	2.32					1	(0.2)	2	0.57				
転倒	4	(0.7)	4	1.86					2	(0.4)	2	0.57	2	(0.9)	2	2.24
靭帯断裂	3	(0.5)	3	1.39					2	(0.4)	3	0.86				

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Table 300480: AEs by SOC and preferred term, entire treatment period: safety analysis set

	Tralokinumab Q2W (n=602)			Tralokinumab Q4W (n=76)			Tralokinumab Q2W + optional TCS (n=563)			Placebo (n=231)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
四肢損傷	2 (0.3)	2	0.93	1 (1.3)	1	2.33	1 (0.2)	1	0.29	2 (0.9)	2	2.24
足骨折				1 (1.3)	1	2.33	2 (0.4)	2	0.57			
手骨折							3 (0.5)	3	0.86			
処置による頭痛	1 (0.2)	1	0.46				1 (0.2)	2	0.57			
肋骨骨折	1 (0.2)	1	0.46				2 (0.4)	2	0.57			
創傷	1 (0.2)	1	0.46				2 (0.4)	2	0.57			
アルコール中毒	1 (0.2)	1	0.46				1 (0.2)	1	0.29			
動物咬傷	2 (0.3)	2	0.93									
節足動物咬傷	1 (0.2)	1	0.46				1 (0.2)	1	0.29	1 (0.4)	1	1.12
上顎炎	1 (0.2)	1	0.46	1 (1.3)	1	2.33						
不適切な薬剤投与計画							2 (0.4)	2	0.57	2 (0.9)	2	2.24
損傷							2 (0.4)	2	0.57			
関節損傷							2 (0.4)	2	0.57			
肉離れ	1 (0.2)	1	0.46				1 (0.2)	1	0.29			
処置による疼痛	1 (0.2)	1	0.46				1 (0.2)	1	0.29			
事故							1 (0.2)	1	0.29			
節足動物刺傷							1 (0.2)	1	0.29			
耳介血腫							1 (0.2)	1	0.29			

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Table 300480: AEs by SOC and preferred term, entire treatment period: safety analysis set

System Organ Class (SOC) Preferred term	Tralokinumab Q2W (n=602) N (%)	E	R	Tralokinumab Q4W (n=76) N (%)	E	R	Tralokinumab Q2W + optional TCS (n=563) N (%)	E	R	Placebo (n=231) N (%)	E	R
自律神経異常反射							1 (0.2)	1	0.29			
骨挫傷	1 (0.2)	1	0.46									
骨亀裂							1 (0.2)	1	0.29			
化学熱傷							1 (0.2)	1	0.29			
皮膚化学熱傷							1 (0.2)	1	0.29			
胸部損傷							1 (0.2)	1	0.29			
脳振盪							1 (0.2)	1	0.29	1 (0.4)	1	1.12
擦過傷										1 (0.4)	1	1.12
腓骨骨折							1 (0.2)	1	0.29			
熱中症	1 (0.2)	1	0.46									
関節脱臼	1 (0.2)	1	0.46									
半月板損傷										1 (0.4)	1	1.12
多発骨折	1 (0.2)	1	0.46									
中毒							1 (0.2)	1	0.29			
処置後合併症	1 (0.2)	1	0.46									
処置後不快感							1 (0.2)	1	0.29			

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Table 300480: AEs by SOC and preferred term, entire treatment period: safety analysis set

	Tralokinumab Q2W (n=602)				Tralokinumab Q4W (n=76)				Tralokinumab Q2W + optional TCS (n=563)				Placebo (n=231)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
処置後血腫									1	(0.2)	1	0.29				
処置後出血									1	(0.2)	1	0.29				
外傷後頚部症候群									1	(0.2)	1	0.29				
交通事故									1	(0.2)	1	0.29	2	(0.9)	2	2.24
皮膚擦過傷									1	(0.2)	1	0.29	2	(0.9)	2	2.24
皮膚損傷									1	(0.2)	1	0.29				
スポーツ損傷													1	(0.4)	1	1.12
サンバーン	1	(0.2)	1	0.46									2	(0.9)	2	2.24
歯牙損傷	1	(0.2)	1	0.46												
外傷性骨折					1	(1.3)	1	2.33								
上肢骨折	1	(0.2)	1	0.46												
子宮頚管裂傷													1	(0.4)	1	1.12
創合併症									1	(0.2)	1	0.29				
手首関節骨折									1	(0.2)	1	0.29				

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Table 300480: AEs by SOC and preferred term, entire treatment period: safety analysis set

	Tralokinumab Q2W (n=602)			Tralokinumab Q4W (n=76)			Tralokinumab Q2W + optional TCS (n=563)			Placebo (n=231)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
誤薬投与	1 (0.2)	1	0.46									
眼障害	57 (9.5)	69	32.04	1 (1.3)	2	4.65	42 (7.5)	56	16.03	17 (7.4)	20	22.38
アレルギー性結膜炎	19 (3.2)	19	8.82	1 (1.3)	1	2.33	13 (2.3)	14	4.01	5 (2.2)	6	6.71
眼乾燥	8 (1.3)	8	3.71				9 (1.6)	9	2.58	2 (0.9)	2	2.24
角膜炎	3 (0.5)	3	1.39				5 (0.9)	5	1.43			
眼瞼炎	4 (0.7)	4	1.86				3 (0.5)	3	0.86	2 (0.9)	2	2.24
眼そう痒症	4 (0.7)	4	1.86				2 (0.4)	2	0.57	1 (0.4)	1	1.12
眼瞼湿疹	1 (0.2)	1	0.46				3 (0.5)	4	1.14	2 (0.9)	2	2.24
流涙増加	4 (0.7)	5	2.32									
アトピー性角結膜炎	3 (0.5)	3	1.39				1 (0.2)	1	0.29			
眼瞼浮腫	1 (0.2)	2	0.93				2 (0.4)	2	0.57			
白内障	2 (0.3)	2	0.93				1 (0.2)	1	0.29	1 (0.4)	1	1.12
角膜びらん	2 (0.3)	2	0.93				1 (0.2)	1	0.29	1 (0.4)	1	1.12
霧視	2 (0.3)	2	0.93				1 (0.2)	1	0.29	1 (0.4)	1	1.12

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Table 300480: AEs by SOC and preferred term, entire treatment period: safety analysis set

System Organ Class (SOC) Preferred term	Tralokinumab Q2W (n=602) N (%)	E	R	Tralokinumab Q4W (n=76) N (%)	E	R	Tralokinumab Q2W + optional TCS (n=563) N (%)	E	R	Placebo (n=231) N (%)	E	R
霰粒腫	1 (0.2)	2	0.93									
眼瞼外反							2 (0.4)	2	0.57			
眼痛							1 (0.2)	2	0.57			
緑内障							2 (0.4)	2	0.57	1 (0.4)	1	1.12
近視	1 (0.2)	2	0.93									
網膜浮腫	1 (0.2)	1	0.46				1 (0.2)	1	0.29			
潰瘍性角膜炎	1 (0.2)	1	0.46				1 (0.2)	1	0.29			
閉塞隅角緑内障							1 (0.2)	1	0.29			
眼精疲労										1 (0.4)	1	1.12
アレルギー性眼瞼炎	1 (0.2)	1	0.46									
一過性失明	1 (0.2)	1	0.46									
角膜浸潤							1 (0.2)	1	0.29			
角膜浮腫	1 (0.2)	1	0.46									
眼脂							1 (0.2)	1	0.29			
眼刺激	1 (0.2)	1	0.46									
眼部腫脹							1 (0.2)	1	0.29			
円錐角膜	1 (0.2)	1	0.46									
涙器障害										1 (0.4)	1	1.12
水晶体脱臼							1 (0.2)	1	0.29			

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Table 300480: AEs by SOC and preferred term, entire treatment period: safety analysis set

System Organ Class (SOC) Preferred term	Tralokinumab Q2W (n=602) N (%)	E	R	Tralokinumab Q4W (n=76) N (%)	E	R	Tralokinumab Q2W + optional TCS (n=563) N (%)	E	R	Placebo (n=231) N (%)	E	R
眼充血	1 (0.2)	1	0.46									
老視	1 (0.2)	1	0.46									
強膜炎										1 (0.4)	1	1.12
視力障害	1 (0.2)	1	0.46									
硝子体剥離				1 (1.3)	1	2.33						
臨床検査	24 (4.0)	27	12.54	1 (1.3)	1	2.33	38 (6.7)	49	14.02	13 (5.6)	18	20.14
リンパ球数減少	4 (0.7)	5	2.32				6 (1.1)	8	2.29	1 (0.4)	1	1.12
血中ビリルビン増加	1 (0.2)	1	0.46				6 (1.1)	6	1.72			
血中アルカリホスファターゼ増加	2 (0.3)	2	0.93				4 (0.7)	4	1.14			
血中トリグリセリド増加	2 (0.3)	2	0.93				3 (0.5)	3	0.86			
γ-グルタミルトランスフェラーゼ増加	1 (0.2)	1	0.46				3 (0.5)	4	1.14	1 (0.4)	1	1.12

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Table 300480: AEs by SOC and preferred term, entire treatment period: safety analysis set

System Organ Class (SOC) Preferred term	Tralokinumab Q2W (n=602) N (%)	E	R	Tralokinumab Q4W (n=76) N (%)	E	R	Tralokinumab Q2W + optional TCS (n=563) N (%)	E	R	Placebo (n=231) N (%)	E	R
肝機能検査値上昇	4 (0.7)	4	1.86				1 (0.2)	1	0.29	2 (0.9)	2	2.24
血圧上昇	1 (0.2)	2	0.93				2 (0.4)	2	0.57			
アラニンアミノトランスフェラーゼ増加	1 (0.2)	1	0.46				2 (0.4)	2	0.57	3 (1.3)	3	3.36
好酸球数増加	2 (0.3)	2	0.93				1 (0.2)	1	0.29			
肝酵素上昇							3 (0.5)	3	0.86	2 (0.9)	2	2.24
低比重リポ蛋白増加	1 (0.2)	1	0.46				2 (0.4)	2	0.57			
血中乳酸脱水素酵素増加	1 (0.2)	1	0.46				1 (0.2)	1	0.29	2 (0.9)	2	2.24
トランスアミナーゼ上昇							2 (0.4)	2	0.57			

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Table 300480: AEs by SOC and preferred term, entire treatment period: safety analysis set

System Organ Class (SOC) Preferred term	Tralokinumab Q2W (n=602) N (%)	E	R	Tralokinumab Q4W (n=76) N (%)	E	R	Tralokinumab Q2W + optional TCS (n=563) N (%)	E	R	Placebo (n=231) N (%)	E	R
アスパラギン酸アミノトランスフェラーゼ増加							1 (0.2)	1	0.29	3 (1.3)	3	3.36
血中免疫グロブリンE増加							1 (0.2)	1	0.29			
血圧低下							1 (0.2)	1	0.29			
血中尿素減少										1 (0.4)	1	1.12
C－反応性蛋白増加	1 (0.2)	1	0.46									
培養陽性							1 (0.2)	1	0.29			
心電図異常T波							1 (0.2)	1	0.29			
好酸球数減少							1 (0.2)	1	0.29			
ヘマトクリット増加										1 (0.4)	1	1.12
高比重リポ蛋白増加										1 (0.4)	1	1.12

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Table 300480: AEs by SOC and preferred term, entire treatment period: safety analysis set

	Tralokinumab Q2W (n=602)			Tralokinumab Q4W (n=76)			Tralokinumab Q2W + optional TCS (n=563)			Placebo (n=231)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
眼圧上昇							1 (0.2)	1	0.29			
眼圧検査	1 (0.2)	1	0.46									
脂質増加	1 (0.2)	1	0.46									
好中球数減少							1 (0.2)	1	0.29			
ブドウ球菌検査陽性				1 (1.3)	1	2.33						
腟内pH異常							1 (0.2)	1	0.29			
ビタミンB6減少							1 (0.2)	1	0.29			
体重減少	1 (0.2)	1	0.46									
体重増加	1 (0.2)	1	0.46							1 (0.4)	1	1.12
精神障害	23 (3.8)	25	11.61	1 (1.3)	1	2.33	17 (3.0)	20	5.72	10 (4.3)	11	12.31
不眠症	12 (2.0)	13	6.04				6 (1.1)	6	1.72	2 (0.9)	2	2.24
不安	4 (0.7)	4	1.86				3 (0.5)	4	1.14	3 (1.3)	3	3.36
睡眠障害	5 (0.8)	5	2.32				1 (0.2)	1	0.29	1 (0.4)	1	1.12
うつ病	1 (0.2)	1	0.46	1 (1.3)	1	2.33	1 (0.2)	1	0.29	1 (0.4)	1	1.12

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Table 300480: AEs by SOC and preferred term, entire treatment period: safety analysis set

	Tralokinumab Q2W (n=602)			Tralokinumab Q4W (n=76)			Tralokinumab Q2W + optional TCS (n=563)			Placebo (n=231)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
無感情										1 (0.4)	2	2.24
易刺激性							1 (0.2)	2	0.57			
アルコール離脱症候群							1 (0.2)	1	0.29			
注意欠陥多動性障害							1 (0.2)	1	0.29			
抑うつ気分	1 (0.2)	1	0.46							1 (0.4)	1	1.12
錯覚							1 (0.2)	1	0.29			
初期不眠症										1 (0.4)	1	1.12
精神障害							1 (0.2)	1	0.29			
パニック発作							1 (0.2)	1	0.29			
ストレス	1 (0.2)	1	0.46									
緊張							1 (0.2)	1	0.29			
血液およびリンパ系障害	21 (3.5)	32	14.86	1 (1.3)	1	2.33	12 (2.1)	14	4.01	7 (3.0)	8	8.95
リンパ節症	9 (1.5)	12	5.57				5 (0.9)	6	1.72	5 (2.2)	5	5.59
好酸球増加症	10 (1.7)	11	5.11				4 (0.7)	5	1.43	1 (0.4)	1	1.12

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Table 300480: AEs by SOC and preferred term, entire treatment period: safety analysis set

	Tralokinumab Q2W (n=602)				Tralokinumab Q4W (n=76)				Tralokinumab Q2W + optional TCS (n=563)				Placebo (n=231)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
リンパ球減少症	2	(0.3)	2	0.93					1	(0.2)	1	0.29	1	(0.4)	1	1.12
貧血	2	(0.3)	2	0.93												
白血球増加症	2	(0.3)	2	0.93												
白血球減少症	1	(0.2)	1	0.46	1	(1.3)	1	2.33								
慢性疾患の貧血									1	(0.2)	1	0.29				
鉄欠乏性貧血													1	(0.4)	1	1.12
リンパ節炎	1	(0.2)	1	0.46												
好中球減少症	1	(0.2)	1	0.46												
正色素性正球性貧血									1	(0.2)	1	0.29				
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)	15	(2.5)	18	8.36					18	(3.2)	20	5.72	4	(1.7)	4	4.48

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Table 300480: AEs by SOC and preferred term, entire treatment period: safety analysis set

	Tralokinumab Q2W (n=602)			Tralokinumab Q4W (n=76)			Tralokinumab Q2W + optional TCS (n=563)			Placebo (n=231)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
皮膚乳頭腫	8 (1.3)	8	3.71				9 (1.6)	9	2.58	1 (0.4)	1	1.12
肛門性器疣贅	3 (0.5)	3	1.39				2 (0.4)	2	0.57			
線維腫	1 (0.2)	2	0.93				2 (0.4)	2	0.57			
浸潤性乳癌							2 (0.4)	2	0.57			
メラノサイト性母斑	1 (0.2)	1	0.46				1 (0.2)	1	0.29			
皮膚有棘細胞癌	2 (0.3)	2	0.93									
棘細胞腫							1 (0.2)	1	0.29			
アクロコルドン										1 (0.4)	1	1.12
基底細胞癌	1 (0.2)	1	0.46									
乳房の良性新生物	1 (0.2)	1	0.46									
子宮頚部癌第0期										1 (0.4)	1	1.12
大腸腺腫							1 (0.2)	1	0.29			
化膿性肉芽腫							1 (0.2)	1	0.29	1 (0.4)	1	1.12
脂漏性角化症							1 (0.2)	1	0.29			

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Table 300480: AEs by SOC and preferred term, entire treatment period: safety analysis set

	Tralokinumab Q2W (n=602)			Tralokinumab Q4W (n=76)			Tralokinumab Q2W + optional TCS (n=563)			Placebo (n=231)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
血管障害	14 (2.3)	14	6.50	2 (2.6)	2	4.65	17 (3.0)	18	5.15	9 (3.9)	10	11.19
高血圧	12 (2.0)	12	5.57	2 (2.6)	2	4.65	7 (1.2)	7	2.00	6 (2.6)	6	6.71
血腫							3 (0.5)	3	0.86	1 (0.4)	1	1.12
ほてり							2 (0.4)	2	0.57			
進行性高血圧										1 (0.4)	1	1.12
深部静脈血栓症										1 (0.4)	1	1.12
潮紅	1 (0.2)	1	0.46							1 (0.4)	1	1.12
低血圧							1 (0.2)	1	0.29			
起立性低血圧							1 (0.2)	1	0.29			
末梢動脈狭窄	1 (0.2)	1	0.46									
血栓性静脈炎							1 (0.2)	1	0.29			
表在性血栓性静脈炎							1 (0.2)	1	0.29			
血管石灰化							1 (0.2)	1	0.29			
静脈血栓症							1 (0.2)	1	0.29			

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Table 300480: AEs by SOC and preferred term, entire treatment period: safety analysis set

	Tralokinumab Q2W (n=602)				Tralokinumab Q4W (n=76)				Tralokinumab Q2W + optional TCS (n=563)				Placebo (n=231)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
代謝および栄養障害	17	(2.8)	17	7.89	1	(1.3)	1	2.33	13	(2.3)	20	5.72	4	(1.7)	4	4.48
脂質異常症	3	(0.5)	3	1.39					2	(0.4)	2	0.57				
高カリウム血症	2	(0.3)	2	0.93					2	(0.4)	2	0.57				
高脂血症	3	(0.5)	3	1.39					1	(0.2)	1	0.29	1	(0.4)	1	1.12
ビタミンD欠乏	1	(0.2)	1	0.46					3	(0.5)	3	0.86				
食欲減退	2	(0.3)	2	0.93					1	(0.2)	1	0.29				
脱水	1	(0.2)	1	0.46					1	(0.2)	1	0.29				
高コレステロール血症									2	(0.4)	2	0.57				
高血糖	1	(0.2)	1	0.46					1	(0.2)	1	0.29				
高尿酸血症	1	(0.2)	1	0.46	1	(1.3)	1	2.33					1	(0.4)	1	1.12
異常体重増加	1	(0.2)	1	0.46												
耐糖能障害									1	(0.2)	1	0.29				
痛風									1	(0.2)	1	0.29				

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Table 300480: AEs by SOC and preferred term, entire treatment period: safety analysis set

	Tralokinumab Q2W (n=602)			Tralokinumab Q4W (n=76)			Tralokinumab Q2W + optional TCS (n=563)			Placebo (n=231)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
高トリグリセリド血症	1 (0.2)	1	0.46									
低カルシウム血症							1 (0.2)	1	0.29			
低カリウム血症							1 (0.2)	1	0.29			
低マグネシウム血症							1 (0.2)	1	0.29			
食欲亢進	1 (0.2)	1	0.46									
鉄欠乏							1 (0.2)	1	0.29			
肥満							1 (0.2)	1	0.29			
多飲症										1 (0.4)	1	1.12
ビタミンB12欠乏										1 (0.4)	1	1.12
心臓障害	8 (1.3)	14	6.50	2 (2.6)	2	4.65	14 (2.5)	19	5.44			
右脚ブロック				1 (1.3)	1	2.33	3 (0.5)	4	1.14			
動悸	2 (0.3)	2	0.93				2 (0.4)	3	0.86			
急性心筋梗塞							3 (0.5)	3	0.86			
頻脈	2 (0.3)	2	0.93				1 (0.2)	1	0.29			
狭心症				1 (1.3)	1	2.33	1 (0.2)	1	0.29			

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Table 300480: AEs by SOC and preferred term, entire treatment period: safety analysis set

System Organ Class (SOC) / Preferred term	Tralokinumab Q2W (n=602) N	(%)	E	R	Tralokinumab Q4W (n=76) N	(%)	E	R	Tralokinumab Q2W + optional TCS (n=563) N	(%)	E	R	Placebo (n=231) N	(%)	E	R
心不全									2	(0.4)	2	0.57				
冠動脈疾患	1	(0.2)	1	0.46					1	(0.2)	1	0.29				
心臓副伝導路	1	(0.2)	1	0.46												
急性左室不全	1	(0.2)	1	0.46												
大動脈弁狭窄									1	(0.2)	1	0.29				
上室性不整脈	1	(0.2)	1	0.46												
心房細動	1	(0.2)	1	0.46												
心房粗動									1	(0.2)	1	0.29				
第一度房室ブロック	1	(0.2)	1	0.46												
徐脈									1	(0.2)	1	0.29				
心血管障害									1	(0.2)	1	0.29				

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Table 300480: AEs by SOC and preferred term, entire treatment period: safety analysis set

	Tralokinumab Q2W (n=602)			Tralokinumab Q4W (n=76)			Tralokinumab Q2W + optional TCS (n=563)			Placebo (n=231)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
虚血性心筋症	1 (0.2)	1	0.46									
上室性期外収縮	1 (0.2)	1	0.46									
頻脈性不整脈	1 (0.2)	1	0.46									
発作性頻脈	1 (0.2)	1	0.46									
腎および尿路障害	6 (1.0)	7	3.25	2 (2.6)	2	4.65	12 (2.1)	13	3.72	3 (1.3)	5	5.59
血尿	1 (0.2)	1	0.46	1 (1.3)	1	2.33	5 (0.9)	6	1.72			
急性腎障害							2 (0.4)	2	0.57			
鹿角状結石	1 (0.2)	2	0.93									
ビリルビン尿							1 (0.2)	1	0.29			
排尿困難	1 (0.2)	1	0.46									
糖尿							1 (0.2)	1	0.29			
白血球尿										1 (0.4)	1	1.12
腎結石症	1 (0.2)	1	0.46							2 (0.9)	3	3.36
夜間頻尿							1 (0.2)	1	0.29			

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Table 300480: AEs by SOC and preferred term, entire treatment period: safety analysis set

	Tralokinumab Q2W (n=602)			Tralokinumab Q4W (n=76)			Tralokinumab Q2W + optional TCS (n=563)			Placebo (n=231)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
頻尿	1 (0.2)	1	0.46									
蛋白尿							1 (0.2)	1	0.29			
腎仙痛				1 (1.3)	1	2.33				1 (0.4)	1	1.12
腎臓痛							1 (0.2)	1	0.29			
尿管結石症	1 (0.2)	1	0.46									
生殖系および乳房障害	9 (1.5)	10	4.64				10 (1.8)	13	3.72	1 (0.4)	1	1.12
月経困難症	1 (0.2)	1	0.46				2 (0.4)	5	1.43			
不正子宮出血	2 (0.3)	3	1.39				1 (0.2)	1	0.29			
前立腺炎	1 (0.2)	1	0.46				1 (0.2)	1	0.29			
無月経	1 (0.2)	1	0.46									
良性前立腺肥大症	1 (0.2)	1	0.46									
子宮頚部上皮異形成							1 (0.2)	1	0.29			
子宮頚管ポリープ							1 (0.2)	1	0.29			
勃起不全	1 (0.2)	1	0.46									
乳汁漏出症	1 (0.2)	1	0.46									

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Table 300480: AEs by SOC and preferred term, entire treatment period: safety analysis set

System Organ Class (SOC) Preferred term	Tralokinumab Q2W (n=602) N (%)	E	R	Tralokinumab Q4W (n=76) N (%)	E	R	Tralokinumab Q2W + optional TCS (n=563) N (%)	E	R	Placebo (n=231) N (%)	E	R
閉経期症状	1 (0.2)	1	0.46									
月経障害							1 (0.2)	1	0.29	1 (0.4)	1	1.12
不規則月経							1 (0.2)	1	0.29			
卵巣嚢胞破裂							1 (0.2)	1	0.29			
腟出血							1 (0.2)	1	0.29			
免疫系障害	8 (1.3)	12	5.57	1 (1.3)	1	2.33	9 (1.6)	9	2.58	4 (1.7)	4	4.48
季節性アレルギー	6 (1.0)	7	3.25				5 (0.9)	5	1.43	4 (1.7)	4	4.48
食物アレルギー	1 (0.2)	2	0.93				2 (0.4)	2	0.57			
過敏症	1 (0.2)	2	0.93				1 (0.2)	1	0.29			
ダニアレルギー	1 (0.2)	1	0.46	1 (1.3)	1	2.33						
薬物過敏症							1 (0.2)	1	0.29			
耳および迷路障害	4 (0.7)	4	1.86				11 (2.0)	13	3.72	4 (1.7)	4	4.48

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Table 300480: AEs by SOC and preferred term, entire treatment period: safety analysis set

	Tralokinumab Q2W (n=602)			Tralokinumab Q4W (n=76)			Tralokinumab Q2W + optional TCS (n=563)			Placebo (n=231)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
回転性めまい	2 (0.3)	2	0.93				3 (0.5)	5	1.43	1 (0.4)	1	1.12
耳痛	2 (0.3)	2	0.93				3 (0.5)	3	0.86	1 (0.4)	1	1.12
耳垢分泌過多							2 (0.4)	2	0.57			
耳介仮性嚢胞							1 (0.2)	1	0.29			
片耳難聴							1 (0.2)	1	0.29			
耳部腫脹										1 (0.4)	1	1.12
耳鳴							1 (0.2)	1	0.29	1 (0.4)	1	1.12
肝胆道系障害	2 (0.3)	2	0.93				7 (1.2)	12	3.43			
脂肪肝							3 (0.5)	3	0.86			
高ビリルビン血症							2 (0.4)	3	0.86			
肝障害							1 (0.2)	3	0.86			
胆道仙痛	1 (0.2)	1	0.46									
胆嚢炎							1 (0.2)	1	0.29			
胆汁うっ滞	1 (0.2)	1	0.46									
肝炎							1 (0.2)	1	0.29			
黄疸眼							1 (0.2)	1	0.29			

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Table 300480: AEs by SOC and preferred term, entire treatment period: safety analysis set

	Tralokinumab Q2W (n=602)				Tralokinumab Q4W (n=76)				Tralokinumab Q2W + optional TCS (n=563)				Placebo (n=231)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
先天性、家族性および遺伝性障害	1	(0.2)	1	0.46					2	(0.4)	2	0.57				
皮様嚢腫	1	(0.2)	1	0.46					1	(0.2)	1	0.29				
ジルベール症候群									1	(0.2)	1	0.29				
内分泌障害	1	(0.2)	1	0.46									1	(0.4)	1	1.12
自己免疫性甲状腺炎	1	(0.2)	1	0.46												
ステロイド離脱症候群													1	(0.4)	1	1.12
社会環境	1	(0.2)	1	0.46												
義足使用者	1	(0.2)	1	0.46												

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Table 300480: AEs by SOC and preferred term, entire treatment period: safety analysis set

	Tralokinumab Q2W (n=602)				Tralokinumab Q4W (n=76)				Tralokinumab Q2W + optional TCS (n=563)				Placebo (n=231)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
外科および内科処置									1	(0.2)	1	0.29				
治療手技									1	(0.2)	1	0.29				

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AEs collected during the exposure time in the initial, maintenance and open-label periods are shown, assigned to latest treatment administered before onset of the AE. The same subject may contribute to more than one column.
Classification according to MedDRA 20.0.
Q2W: every 2 weeks, Q4W: every 4 weeks, TCS: topical corticosteroid, N: Number of subjects with one or more events, %: Percentage of subjects with one or more events, E: Number of adverse events, R: Rate (number of adverse events divided by patient years of exposure multiplied by 100).

1.8.2.1.4 全ての有害事象：追跡調査期間［Source: Table 7.117］

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Table 7.117: Table 300930: AEs by SOC and preferred term, follow-up period: safety follow-up analysis set

System Organ Class (SOC) Preferred term	Tralokinumab Q2W (n=87) N (%)	E	R	Tralokinumab Q4W (n=37) N (%)	E	R	Tralokinumab Q2W + optional TCS (n=417) N (%)	E	R	Placebo (n=54) N (%)	E	R
All AEs	19 (21.8)	26	159.63	1 (2.7)	1	13.34	57 (13.7)	89	102.72	6 (11.1)	10	101.80
感染症および寄生虫症	9 (10.3)	9	55.26	1 (2.7)	1	13.34	31 (7.4)	33	38.09	1 (1.9)	1	10.18
ウイルス性上気道感染	1 (1.1)	1	6.14	1 (2.7)	1	13.34	9 (2.2)	9	10.39	1 (1.9)	1	10.18
結膜炎							4 (1.0)	4	4.62			
単純ヘルペス							2 (0.5)	2	2.31			
帯状疱疹	1 (1.1)	1	6.14				1 (0.2)	1	1.15			
膿痂疹	1 (1.1)	1	6.14				1 (0.2)	1	1.15			
インフルエンザ							2 (0.5)	2	2.31			
副鼻腔炎	1 (1.1)	1	6.14				1 (0.2)	1	1.15			
尿路感染							2 (0.5)	2	2.31			
骨膿瘍							1 (0.2)	1	1.15			
気管支炎	1 (1.1)	1	6.14									
膀胱炎							1 (0.2)	1	1.15			

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Table 300930: AEs by SOC and preferred term, follow-up period: safety follow-up analysis set

	Tralokinumab Q2W (n=87)			Tralokinumab Q4W (n=37)			Tralokinumab Q2W + optional TCS (n=417)			Placebo (n=54)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
ヘルペス性状湿疹							1 (0.2)	1	1.15			
心内膜炎	1 (1.1)	1	6.14									
丹毒	1 (1.1)	1	6.14									
真菌感染							1 (0.2)	1	1.15			
細菌性角膜炎							1 (0.2)	1	1.15			
ウイルス性角膜炎	1 (1.1)	1	6.14									
喉頭炎							1 (0.2)	1	1.15			
鼻咽頭炎							1 (0.2)	1	1.15			
口腔ヘルペス							1 (0.2)	1	1.15			
肺炎							1 (0.2)	1	1.15			
マイコプラズマ性肺炎							1 (0.2)	1	1.15			
皮下組織膿瘍	1 (1.1)	1	6.14									
上気道感染							1 (0.2)	1	1.15			
皮膚および皮下組織障害	5 (5.7)	6	36.84				13 (3.1)	14	16.16	1 (1.9)	1	10.18

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Table 300930: AEs by SOC and preferred term, follow-up period: safety follow-up analysis set

System Organ Class (SOC) Preferred term	Tralokinumab Q2W (n=87) N (%)	E	R	Tralokinumab Q4W (n=37) N (%)	E	R	Tralokinumab Q2W + optional TCS (n=417) N (%)	E	R	Placebo (n=54) N (%)	E	R
アトピー性皮膚炎	4 (4.6)	5	30.70				9 (2.2)	10	11.54			
全身性剥脱性皮膚炎	1 (1.1)	1	6.14				1 (0.2)	1	1.15			
皮膚炎							1 (0.2)	1	1.15			
接触皮膚炎							1 (0.2)	1	1.15			
壊疽性膿皮症										1 (1.9)	1	10.18
蕁麻疹							1 (0.2)	1	1.15			
臨床検査	1 (1.1)	1	6.14				7 (1.7)	7	8.08	1 (1.9)	2	20.36
リンパ球数減少							2 (0.5)	2	2.31			
血中ビリルビン増加							1 (0.2)	1	1.15			
血中クレアチニン増加	1 (1.1)	1	6.14									
血中乳酸脱水素酵素増加							1 (0.2)	1	1.15			

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Table 300930: AEs by SOC and preferred term, follow-up period: safety follow-up analysis set

	Tralokinumab Q2W (n=87)				Tralokinumab Q4W (n=37)				Tralokinumab Q2W + optional TCS (n=417)				Placebo (n=54)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
血中トリグリセリド増加									1	(0.2)	1	1.15				
肝酵素上昇									1	(0.2)	1	1.15				
ブドウ球菌検査陽性													1	(1.9)	1	10.18
トロポニン増加													1	(1.9)	1	10.18
体重減少									1	(0.2)	1	1.15				
胃腸障害									5	(1.2)	7	8.08				
下痢									3	(0.7)	3	3.46				
腹痛									1	(0.2)	1	1.15				
鼠径ヘルニア									1	(0.2)	1	1.15				
悪心									1	(0.2)	1	1.15				
嘔吐									1	(0.2)	1	1.15				
精神障害	3	(3.4)	4	24.56					2	(0.5)	3	3.46				

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Table 300930: AEs by SOC and preferred term, follow-up period: safety follow-up analysis set

	Tralokinumab Q2W (n=87)			Tralokinumab Q4W (n=37)			Tralokinumab Q2W + optional TCS (n=417)			Placebo (n=54)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
不眠症	2 (2.3)	2	12.28				1 (0.2)	1	1.15			
うつ病	2 (2.3)	2	12.28									
不安							1 (0.2)	1	1.15			
神経症							1 (0.2)	1	1.15			
呼吸器、胸郭および縦隔障害							4 (1.0)	4	4.62	1 (1.9)	1	10.18
咳嗽							2 (0.5)	2	2.31			
喘息							1 (0.2)	1	1.15			
気管支痙攣							1 (0.2)	1	1.15			
肺障害										1 (1.9)	1	10.18
血液およびリンパ系障害	1 (1.1)	1	6.14				3 (0.7)	3	3.46			
リンパ節症							3 (0.7)	3	3.46			

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Table 300930: AEs by SOC and preferred term, follow-up period: safety follow-up analysis set

System Organ Class (SOC) Preferred term	Tralokinumab Q2W (n=87) N (%)	E	R	Tralokinumab Q4W (n=37) N (%)	E	R	Tralokinumab Q2W + optional TCS (n=417) N (%)	E	R	Placebo (n=54) N (%)	E	R
貧血	1 (1.1)	1	6.14									
眼障害	1 (1.1)	1	6.14				2 (0.5)	2	2.31			
アレルギー性結膜炎	1 (1.1)	1	6.14				1 (0.2)	1	1.15			
眼瞼下垂							1 (0.2)	1	1.15			
一般・全身障害および投与部位の状態	1 (1.1)	1	6.14				1 (0.2)	1	1.15	1 (1.9)	1	10.18
発熱										1 (1.9)	1	10.18
絞扼性ヘルニア	1 (1.1)	1	6.14									
血管穿刺部位内出血							1 (0.2)	1	1.15			

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Table 300930: AEs by SOC and preferred term, follow-up period: safety follow-up analysis set

System Organ Class (SOC) Preferred term	Tralokinumab Q2W (n=87) N (%) E R	Tralokinumab Q4W (n=37) N (%) E R	Tralokinumab Q2W + optional TCS (n=417) N (%) E R	Placebo (n=54) N (%) E R
傷害、中毒および処置合併症			3 (0.7) 3 3.46	
くも膜下出血			1 (0.2) 1 1.15	
腱断裂			1 (0.2) 1 1.15	
熱傷			1 (0.2) 1 1.15	
筋骨格系および結合組織障害			3 (0.7) 3 3.46	
椎間板突出			1 (0.2) 1 1.15	
筋痙縮			1 (0.2) 1 1.15	
腱痛			1 (0.2) 1 1.15	

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Table 300930: AEs by SOC and preferred term, follow-up period: safety follow-up analysis set

	Tralokinumab Q2W (n=87)			Tralokinumab Q4W (n=37)			Tralokinumab Q2W + optional TCS (n=417)			Placebo (n=54)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
神経系障害	1 (1.1)	1	6.14				1 (0.2)	1	1.15	1 (1.9)	1	10.18
脳梗塞										1 (1.9)	1	10.18
頭痛	1 (1.1)	1	6.14									
失神							1 (0.2)	1	1.15			
心臓障害							1 (0.2)	1	1.15	1 (1.9)	2	20.36
急性心筋梗塞										1 (1.9)	1	10.18
急性心不全							1 (0.2)	1	1.15			
頻脈										1 (1.9)	1	10.18
内分泌障害	1 (1.1)	1	6.14				1 (0.2)	1	1.15			
グルココルチコイド欠乏症	1 (1.1)	1	6.14									
甲状腺機能亢進症							1 (0.2)	1	1.15			

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Table 300930: AEs by SOC and preferred term, follow-up period: safety follow-up analysis set

System Organ Class (SOC) Preferred term	Tralokinumab Q2W (n=87) N (%)	E	R	Tralokinumab Q4W (n=37) N (%)	E	R	Tralokinumab Q2W + optional TCS (n=417) N (%)	E	R	Placebo (n=54) N (%)	E	R
免疫系障害							2 (0.5)	2	2.31			
薬物過敏症							1 (0.2)	1	1.15			
ダニアレルギー							1 (0.2)	1	1.15			
代謝および栄養障害	1 (1.1)	1	6.14				1 (0.2)	1	1.15			
痛風	1 (1.1)	1	6.14									
低カルシウム血症							1 (0.2)	1	1.15			
腎および尿路障害							1 (0.2)	1	1.15	1 (1.9)	1	10.18
急性腎障害										1 (1.9)	1	10.18
膀胱不快感							1 (0.2)	1	1.15			

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Table 300930: AEs by SOC and preferred term, follow-up period: safety follow-up analysis set

System Organ Class (SOC) Preferred term	Tralokinumab Q2W (n=87) N (%)	E	R	Tralokinumab Q4W (n=37) N (%)	E	R	Tralokinumab Q2W + optional TCS (n=417) N (%)	E	R	Placebo (n=54) N (%)	E	R
肝胆道系障害							1 (0.2)	1	1.15			
肝機能異常							1 (0.2)	1	1.15			
生殖系および乳房障害							1 (0.2)	1	1.15			
閉経期症状							1 (0.2)	1	1.15			

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Classification according to MedDRA 20.0.
Q2W: every 2 weeks, Q4W: every 4 weeks, TCS: topical corticosteroid, N: Number of subjects with one or more events, %: Percentage of subjects with one or more events, E: Number of adverse events, R: Rate (number of adverse events divided by patient years of follow-up multiplied by 100).
Table shows AEs collected after end of exposure, defined as Week 52[Week 68] visit (if available), otherwise early termination visit (if available), otherwise last visit excluding safety follow-up visit and nominal Week 16 visit after permanent discontinuation of IMP.

1.8.2.1.5 治験薬との因果関係が否定できない有害事象：初期投与期間［Source: Table 7.4］

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Table 7.4: Table 300040: Related AEs by SOC and preferred term, initial treatment period: safety analysis set

System Organ Class (SOC) Preferred term	Tralokinumab Q2W (n=602) N (%)	E	R	Placebo (n=196) N (%)	E	R
All AEs	187 (31.1)	417	234.85	58 (29.6)	118	206.55
Treatment comparison, p-value	0.2598					
皮膚および皮下組織障害	69 (11.5)	104	58.57	28 (14.3)	36	63.02
アトピー性皮膚炎	33 (5.5)	43	24.22	20 (10.2)	26	45.51
そう痒症	10 (1.7)	13	7.32	3 (1.5)	3	5.25
脱毛症	7 (1.2)	9	5.07	1 (0.5)	1	1.75
皮膚乾燥	8 (1.3)	8	4.51	1 (0.5)	2	3.50
紅斑	4 (0.7)	7	3.94	1 (0.5)	1	1.75
多汗症	5 (0.8)	6	3.38	1 (0.5)	1	1.75
円形脱毛症	2 (0.3)	2	1.13			
接触皮膚炎	2 (0.3)	2	1.13			
びまん性脱毛症	2 (0.3)	2	1.13			
皮膚疼痛	1 (0.2)	2	1.13			
皮膚嚢腫				1 (0.5)	1	1.75
全身性剥脱性皮膚炎	1 (0.2)	1	0.56			
斑状出血	1 (0.2)	1	0.56			
嵌入爪	1 (0.2)	1	0.56			

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Table 300040: Related AEs by SOC and preferred term, initial treatment period: safety analysis set

System Organ Class (SOC) Preferred term	Tralokinumab Q2W (n=602) N (%)	E	R	Placebo (n=196) N (%)	E	R
網状皮斑	1 (0.2)	1	0.56			
寝汗	1 (0.2)	1	0.56			
爪甲脱落症	1 (0.2)	1	0.56			
ばら色粃糠疹	1 (0.2)	1	0.56			
皮膚びらん	1 (0.2)	1	0.56			
皮膚局面	1 (0.2)	1	0.56			
顔面腫脹	1 (0.2)	1	0.56			
蕁麻疹				1 (0.5)	1	1.75
感染症および寄生虫症	73 (12.1)	92	51.81	18 (9.2)	25	43.76
結膜炎	22 (3.7)	25	14.08	2 (1.0)	2	3.50
ウイルス性上気道感染	12 (2.0)	13	7.32	3 (1.5)	5	8.75
鼻咽頭炎	7 (1.2)	8	4.51			
咽頭炎	5 (0.8)	5	2.82	1 (0.5)	2	3.50
鼻炎	5 (0.8)	5	2.82			
気管支炎	3 (0.5)	3	1.69	1 (0.5)	1	1.75
膿痂疹	3 (0.5)	3	1.69	1 (0.5)	1	1.75
インフルエンザ	3 (0.5)	3	1.69	1 (0.5)	1	1.75
口腔ヘルペス	1 (0.2)	1	0.56	2 (1.0)	3	5.25
毛包炎	2 (0.3)	2	1.13	1 (0.5)	1	1.75

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Table 300040: Related AEs by SOC and preferred term, initial treatment period: safety analysis set

System Organ Class (SOC) Preferred term	Tralokinumab Q2W (n=602) N (%)	E	R	Placebo (n=196) N (%)	E	R
単純ヘルペス	2 (0.3)	2	1.13	1 (0.5)	1	1.75
皮膚感染	1 (0.2)	2	1.13	1 (0.5)	1	1.75
上気道感染	2 (0.3)	2	1.13	1 (0.5)	1	1.75
膿瘍	1 (0.2)	2	1.13			
ヘルペス性状湿疹	1 (0.2)	1	0.56	1 (0.5)	1	1.75
肺炎	1 (0.2)	1	0.56	1 (0.5)	1	1.75
副鼻腔炎	2 (0.3)	2	1.13			
カンピロバクター胃腸炎	1 (0.2)	1	0.56			
蜂巣炎	1 (0.2)	1	0.56			
耳感染	1 (0.2)	1	0.56			
丹毒	1 (0.2)	1	0.56			
ウイルス性胃腸炎				1 (0.5)	1	1.75
消化管感染				1 (0.5)	1	1.75
歯肉炎	1 (0.2)	1	0.56			
麦粒腫	1 (0.2)	1	0.56			
喉頭炎	1 (0.2)	1	0.56			
リーシュマニア症	1 (0.2)	1	0.56			
リンパ管炎	1 (0.2)	1	0.56			
中耳炎	1 (0.2)	1	0.56			
腎盂腎炎				1 (0.5)	1	1.75

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Table 300040: Related AEs by SOC and preferred term, initial treatment period: safety analysis set

System Organ Class (SOC) Preferred term	Tralokinumab Q2W (n=602) N (%)	E	R	Placebo (n=196) N (%)	E	R
膿疱性皮疹	1 (0.2)	1	0.56			
足部白癬				1 (0.5)	1	1.75
外陰膣真菌感染	1 (0.2)	1	0.56			
一般・全身障害および投与部位の状態	54 (9.0)	96	54.07	10 (5.1)	14	24.51
注射部位反応	23 (3.8)	47	26.47			
注射部位紅斑	5 (0.8)	9	5.07	2 (1.0)	2	3.50
注射部位疼痛	7 (1.2)	9	5.07	2 (1.0)	2	3.50
疲労	8 (1.3)	8	4.51	1 (0.5)	1	1.75
発熱	3 (0.5)	3	1.69	2 (1.0)	5	8.75
無力症	3 (0.5)	3	1.69	1 (0.5)	1	1.75
冷感	1 (0.2)	1	0.56	1 (0.5)	1	1.75
注射部位内出血	1 (0.2)	1	0.56	1 (0.5)	1	1.75
注射部位浮腫	2 (0.3)	2	1.13			
注射部位そう痒感	1 (0.2)	2	1.13			
注射部位蕁麻疹	2 (0.3)	2	1.13			
末梢性浮腫	1 (0.2)	1	0.56	1 (0.5)	1	1.75
体温変動感	1 (0.2)	1	0.56			
炎症	1 (0.2)	1	0.56			
注射部位過敏反応	1 (0.2)	1	0.56			

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Table 300040: Related AEs by SOC and preferred term, initial treatment period: safety analysis set

System Organ Class (SOC) Preferred term	Tralokinumab Q2W (n=602) N (%)	E	R	Placebo (n=196) N (%)	E	R
注射部位硬結	1 (0.2)	1	0.56			
注射部位腫脹	1 (0.2)	1	0.56			
疼痛	1 (0.2)	1	0.56			
口渇	1 (0.2)	1	0.56			
乾燥症	1 (0.2)	1	0.56			
神経系障害	20 (3.3)	29	16.33	7 (3.6)	10	17.50
頭痛	13 (2.2)	21	11.83	4 (2.0)	6	10.50
灼熱感	1 (0.2)	1	0.56	1 (0.5)	2	3.50
片頭痛	3 (0.5)	3	1.69			
失神				2 (1.0)	2	3.50
浮動性めまい	1 (0.2)	1	0.56			
味覚異常	1 (0.2)	1	0.56			
知覚過敏	1 (0.2)	1	0.56			
錯感覚	1 (0.2)	1	0.56			
眼障害	12 (2.0)	14	7.88	4 (2.0)	4	7.00
眼乾燥	4 (0.7)	4	2.25	1 (0.5)	1	1.75
アレルギー性結膜炎	2 (0.3)	2	1.13	1 (0.5)	1	1.75
眼瞼炎	2 (0.3)	2	1.13			

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Table 300040: Related AEs by SOC and preferred term, initial treatment period: safety analysis set

System Organ Class (SOC) Preferred term	Tralokinumab Q2W (n=602) N (%)	E	R	Placebo (n=196) N (%)	E	R
眼瞼浮腫	1 (0.2)	2	1.13			
アトピー性角結膜炎	1 (0.2)	1	0.56			
霰粒腫	1 (0.2)	1	0.56			
眼そう痒症	1 (0.2)	1	0.56			
角膜炎	1 (0.2)	1	0.56			
強膜炎				1 (0.5)	1	1.75
霧視				1 (0.5)	1	1.75
胃腸障害	12 (2.0)	22	12.39	3 (1.5)	4	7.00
悪心	3 (0.5)	6	3.38	2 (1.0)	2	3.50
下痢	3 (0.5)	4	2.25	1 (0.5)	1	1.75
上腹部痛	2 (0.3)	2	1.13			
硬便	1 (0.2)	2	1.13			
嘔吐	2 (0.3)	2	1.13			
腹部膨満	1 (0.2)	1	0.56			
腹痛	1 (0.2)	1	0.56			
下腹部痛	1 (0.2)	1	0.56			
腹部症状	1 (0.2)	1	0.56			
便秘	1 (0.2)	1	0.56			
歯嚢胞	1 (0.2)	1	0.56			

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Table 300040: Related AEs by SOC and preferred term, initial treatment period: safety analysis set

System Organ Class (SOC) Preferred term	Tralokinumab Q2W (n=602) N (%)	E	R	Placebo (n=196) N (%)	E	R
口腔粘膜水疱形成				1 (0.5)	1	1.75
臨床検査	8 (1.3)	9	5.07	5 (2.6)	9	15.75
リンパ球数減少	3 (0.5)	4	2.25			
アラニンアミノトランスフェラーゼ増加				3 (1.5)	3	5.25
アスパラギン酸アミノトランスフェラーゼ増加				3 (1.5)	3	5.25
肝機能検査値上昇	2 (0.3)	2	1.13			
血圧上昇	1 (0.2)	1	0.56			
C－反応性蛋白増加	1 (0.2)	1	0.56			
好酸球数増加	1 (0.2)	1	0.56			
γ－グルタミルトランスフェラーゼ増加				1 (0.5)	1	1.75
肝酵素上昇				1 (0.5)	1	1.75
体重増加				1 (0.5)	1	1.75
血液およびリンパ系障害	9 (1.5)	13	7.32	2 (1.0)	2	3.50
好酸球増加症	7 (1.2)	8	4.51	1 (0.5)	1	1.75
白血球増加症	2 (0.3)	2	1.13			
貧血	1 (0.2)	1	0.56			
リンパ節症				1 (0.5)	1	1.75
リンパ球減少症	1 (0.2)	1	0.56			

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Table 300040: Related AEs by SOC and preferred term, initial treatment period: safety analysis set

System Organ Class (SOC) Preferred term	Tralokinumab Q2W (n=602) N (%)	E	R	Placebo (n=196) N (%)	E	R
好中球減少症	1 (0.2)	1	0.56			
筋骨格系および結合組織障害	4 (0.7)	4	2.25	7 (3.6)	7	12.25
筋肉痛	1 (0.2)	1	0.56	1 (0.5)	1	1.75
頚部痛				2 (1.0)	2	3.50
関節痛	1 (0.2)	1	0.56			
滑液包炎				1 (0.5)	1	1.75
筋痙縮				1 (0.5)	1	1.75
筋緊張				1 (0.5)	1	1.75
筋骨格痛				1 (0.5)	1	1.75
四肢痛	1 (0.2)	1	0.56			
腱炎	1 (0.2)	1	0.56			
呼吸器、胸郭および縦隔障害	8 (1.3)	10	5.63	2 (1.0)	2	3.50
喘息	2 (0.3)	2	1.13	1 (0.5)	1	1.75
咳嗽	2 (0.3)	3	1.69			
労作性呼吸困難	1 (0.2)	1	0.56			
鼻閉	1 (0.2)	1	0.56			
口腔咽頭痛	1 (0.2)	1	0.56			
鼻漏				1 (0.5)	1	1.75

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Table 300040: Related AEs by SOC and preferred term, initial treatment period: safety analysis set

System Organ Class (SOC) Preferred term	Tralokinumab Q2W (n=602) N (%)	E	R	Placebo (n=196) N (%)	E	R
副鼻腔うっ血	1 (0.2)	1	0.56			
くしゃみ	1 (0.2)	1	0.56			
精神障害	4 (0.7)	4	2.25	2 (1.0)	3	5.25
不眠症	3 (0.5)	3	1.69			
無感情				1 (0.5)	2	3.50
睡眠障害	1 (0.2)	1	0.56	1 (0.5)	1	1.75
血管障害	5 (0.8)	5	2.82	1 (0.5)	1	1.75
高血圧	4 (0.7)	4	2.25	1 (0.5)	1	1.75
潮紅	1 (0.2)	1	0.56			
傷害、中毒および処置合併症	5 (0.8)	6	3.38			
処置によるめまい	4 (0.7)	5	2.82			
処置による頭痛	1 (0.2)	1	0.56			
耳および迷路障害	2 (0.3)	2	1.13	1 (0.5)	1	1.75
回転性めまい	1 (0.2)	1	0.56	1 (0.5)	1	1.75
耳痛	1 (0.2)	1	0.56			

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Table 300040: Related AEs by SOC and preferred term, initial treatment period: safety analysis set

System Organ Class (SOC) Preferred term	Tralokinumab Q2W (n=602) N (%)	E	R	Placebo (n=196) N (%)	E	R
代謝および栄養障害	3 (0.5)	3	1.69			
異常体重増加	1 (0.2)	1	0.56			
脂質異常症	1 (0.2)	1	0.56			
高カリウム血症	1 (0.2)	1	0.56			
心臓障害	2 (0.3)	2	1.13			
第一度房室ブロック	1 (0.2)	1	0.56			
頻脈	1 (0.2)	1	0.56			
先天性、家族性および遺伝性障害	1 (0.2)	1	0.56			
皮様嚢腫	1 (0.2)	1	0.56			
内分泌障害	1 (0.2)	1	0.56			
自己免疫性甲状腺炎	1 (0.2)	1	0.56			

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AEs collected during the exposure time in the initial treatment period are shown. Classification according to MedDRA 20.0.
Q2W: every 2 weeks, N: Number of subjects with one or more events, %: Percentage of subjects with one or more events, E: Number of adverse events, R: Rate (number of adverse events divided by patient years of exposure multiplied by 100).
Treatment comparison, p-value: Chi-square test comparing the percentage of subjects with AEs between treatment groups.

1.8.2.1.6 治験薬との因果関係が否定できない有害事象：維持投与期間［Source: Table 7.33］

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Table 7.33: Table 300260: Related AEs by SOC and preferred term, maintenance treatment period: maintenance safety analysis set

	Week 16 Tralokinumab responders								Week 16 Placebo responders			
	Tralokinumab Q2W (n=68)				Tralokinumab Q4W (n=76)				Placebo (n=35)				Placebo (n=29)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
All AEs	33	(48.5)	93	246.03	22	(28.9)	61	141.88	10	(28.6)	14	77.08	6	(20.7)	6	42.62
感染症および寄生虫症	10	(14.7)	12	31.75	10	(13.2)	15	34.89	3	(8.6)	3	16.52	2	(6.9)	2	14.21
ウイルス性上気道感染	3	(4.4)	3	7.94	3	(3.9)	4	9.30								
結膜炎	1	(1.5)	1	2.65	3	(3.9)	4	9.30								
気管支炎	1	(1.5)	1	2.65	1	(1.3)	1	2.33	1	(2.9)	1	5.51				
鼻咽頭炎					1	(1.3)	1	2.33	1	(2.9)	1	5.51				
口腔ヘルペス	1	(1.5)	1	2.65	1	(1.3)	1	2.33								
咽頭炎					1	(1.3)	1	2.33	1	(2.9)	1	5.51				
扁桃炎					1	(1.3)	1	2.33					1	(3.4)	1	7.10
クロストリジウム・ディフィシレ大腸炎	1	(1.5)	1	2.65												
毛包炎	1	(1.5)	1	2.65												
単純ヘルペス					1	(1.3)	1	2.33								
インフルエンザ	1	(1.5)	1	2.65												

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Table 300260: Related AEs by SOC and preferred term, maintenance treatment period: maintenance safety analysis set

	Week 16 Tralokinumab responders								Week 16 Placebo responders			
	Tralokinumab Q2W (n=68)				Tralokinumab Q4W (n=76)				Placebo (n=35)				Placebo (n=29)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
鼻ヘルペス	1	(1.5)	1	2.65												
咽頭扁桃炎	1	(1.5)	1	2.65												
鼻炎	1	(1.5)	1	2.65												
歯感染													1	(3.4)	1	7.10
上気道感染					1	(1.3)	1	2.33								
一般・全身障害および投与部位の状態	11	(16.2)	46	121.69	10	(13.2)	30	69.78	1	(2.9)	1	5.51				
注射部位反応	5	(7.4)	13	34.39	7	(9.2)	21	48.84	1	(2.9)	1	5.51				
注射部位紅斑	3	(4.4)	10	26.45	3	(3.9)	3	6.98								
注射部位蕁麻疹	1	(1.5)	9	23.81	1	(1.3)	2	4.65								

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Table 300260: Related AEs by SOC and preferred term, maintenance treatment period: maintenance safety analysis set

	Week 16 Tralokinumab responders								Week 16 Placebo responders			
	Tralokinumab Q2W (n=68)				Tralokinumab Q4W (n=76)				Placebo (n=35)				Placebo (n=29)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
注射部位腫脹	1	(1.5)	1	2.65	1	(1.3)	3	6.98								
注射部位湿疹	1	(1.5)	3	7.94												
注射部位そう痒感	2	(2.9)	3	7.94												
注射部位発疹	1	(1.5)	2	5.29	1	(1.3)	1	2.33								
注射部位浮腫	1	(1.5)	2	5.29												
注射部位疼痛	2	(2.9)	2	5.29												
注射部位血腫	1	(1.5)	1	2.65												
皮膚および皮下組織障害	9	(13.2)	12	31.75	7	(9.2)	13	30.24	4	(11.4)	4	22.02	2	(6.9)	2	14.21
アトピー性皮膚炎	6	(8.8)	6	15.87	3	(3.9)	4	9.30	3	(8.6)	3	16.52	2	(6.9)	2	14.21
そう痒症	1	(1.5)	1	2.65	3	(3.9)	3	6.98	1	(2.9)	1	5.51				
円形脱毛症					1	(1.3)	2	4.65								

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Table 300260: Related AEs by SOC and preferred term, maintenance treatment period: maintenance safety analysis set

	Week 16 Tralokinumab responders								Week 16 Placebo responders			
	Tralokinumab Q2W (n=68)				Tralokinumab Q4W (n=76)				Placebo (n=35)				Placebo (n=29)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
多汗症	1	(1.5)	1	2.65	1	(1.3)	1	2.33								
光線角化症	1	(1.5)	1	2.65												
紅斑	1	(1.5)	1	2.65												
発疹	1	(1.5)	1	2.65												
酒さ	1	(1.5)	1	2.65												
皮膚灼熱感					1	(1.3)	1	2.33								
皮膚局面					1	(1.3)	1	2.33								
顔面腫脹					1	(1.3)	1	2.33								
眼障害	4	(5.9)	5	13.23					2	(5.7)	2	11.01				
アレルギー性結膜炎	3	(4.4)	3	7.94					2	(5.7)	2	11.01				
円錐角膜	1	(1.5)	1	2.65												
潰瘍性角膜炎	1	(1.5)	1	2.65												
神経系障害	3	(4.4)	8	21.16	1	(1.3)	1	2.33	1	(2.9)	1	5.51	1	(3.4)	1	7.10
頭痛	1	(1.5)	6	15.87												

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Table 300260: Related AEs by SOC and preferred term, maintenance treatment period: maintenance safety analysis set

	Week 16 Tralokinumab responders										Week 16 Placebo responders			
	Tralokinumab Q2W (n=68)				Tralokinumab Q4W (n=76)				Placebo (n=35)				Placebo (n=29)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
灼熱感	1	(1.5)	1	2.65	1	(1.3)	1	2.33								
異常感覚	1	(1.5)	1	2.65												
片頭痛									1	(2.9)	1	5.51				
振戦													1	(3.4)	1	7.10
臨床検査	1	(1.5)	1	2.65					1	(2.9)	1	5.51	1	(3.4)	1	7.10
アラニンアミノトランスフェラーゼ増加	1	(1.5)	1	2.65												
肝酵素上昇													1	(3.4)	1	7.10
肝機能検査値上昇									1	(2.9)	1	5.51				
血液およびリンパ系障害	2	(2.9)	2	5.29												
好酸球増加症	1	(1.5)	1	2.65												
リンパ節症	1	(1.5)	1	2.65												

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Table 300260: Related AEs by SOC and preferred term, maintenance treatment period: maintenance safety analysis set

	Week 16 Tralokinumab responders								Week 16 Placebo responders			
	Tralokinumab Q2W (n=68)				Tralokinumab Q4W (n=76)				Placebo (n=35)				Placebo (n=29)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
精神障害	1	(1.5)	1	2.65					1	(2.9)	1	5.51				
うつ病	1	(1.5)	1	2.65					1	(2.9)	1	5.51				
呼吸器、胸郭および縦隔障害	1	(1.5)	1	2.65					1	(2.9)	1	5.51				
口腔咽頭痛									1	(2.9)	1	5.51				
鼻漏	1	(1.5)	1	2.65												
心臓障害					1	(1.3)	1	2.33								
右脚ブロック					1	(1.3)	1	2.33								

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Table 300260: Related AEs by SOC and preferred term, maintenance treatment period: maintenance safety analysis set

	Week 16 Tralokinumab responders								Week 16 Placebo responders			
	Tralokinumab Q2W (n=68)				Tralokinumab Q4W (n=76)				Placebo (n=35)				Placebo (n=29)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
胃腸障害					1	(1.3)	1	2.33								
下痢					1	(1.3)	1	2.33								
免疫系障害	1	(1.5)	3	7.94												
過敏症	1	(1.5)	2	5.29												
季節性アレルギー	1	(1.5)	1	2.65												
筋骨格系および結合組織障害	1	(1.5)	1	2.65												
筋痙縮	1	(1.5)	1	2.65												

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Table 300260: Related AEs by SOC and preferred term, maintenance treatment period: maintenance safety analysis set

	Week 16 Tralokinumab responders								Week 16 Placebo responders			
	Tralokinumab Q2W (n=68)				Tralokinumab Q4W (n=76)				Placebo (n=35)				Placebo (n=29)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
腎および尿路障害	1	(1.5)	1	2.65												
腎結石症	1	(1.5)	1	2.65												

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AEs collected during the exposure time in the maintenance treatment period are shown. Classification according to MedDRA 20.0.
Q2W: every 2 weeks, Q4W: every 4 weeks, N: Number of subjects with one or more events, %: Percentage of subjects with one or more events, E: Number of adverse events, R: Rate (number of adverse events divided by patient years of exposure multiplied by 100).