1.8.2.1.7 治験薬との因果関係が否定できない有害事象：全投与期間［Source: Table 7.66］

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Table 7.66: Table 300520: Related 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	205	(34.1)	510	236.81	22	(28.9)	61	141.88	196	(34.8)	465	133.07	73	(31.6)	138	154.41
感染症および寄生虫症	82	(13.6)	104	48.29	10	(13.2)	15	34.89	96	(17.1)	145	41.50	22	(9.5)	30	33.57
結膜炎	23	(3.8)	26	12.07	3	(3.9)	4	9.30	29	(5.2)	36	10.30	2	(0.9)	2	2.24
ウイルス性上気道感染	15	(2.5)	16	7.43	3	(3.9)	4	9.30	20	(3.6)	24	6.87	3	(1.3)	5	5.59
単純ヘルペス	2	(0.3)	2	0.93	1	(1.3)	1	2.33	7	(1.2)	9	2.58	1	(0.4)	1	1.12
鼻咽頭炎	7	(1.2)	8	3.71	1	(1.3)	1	2.33	3	(0.5)	3	0.86	1	(0.4)	1	1.12
鼻炎	6	(1.0)	6	2.79					4	(0.7)	4	1.14				
気管支炎	4	(0.7)	4	1.86	1	(1.3)	1	2.33	4	(0.7)	4	1.14	2	(0.9)	2	2.24
毛包炎	3	(0.5)	3	1.39					5	(0.9)	5	1.43	1	(0.4)	1	1.12
咽頭炎	5	(0.8)	5	2.32	1	(1.3)	1	2.33	2	(0.4)	2	0.57	2	(0.9)	3	3.36
口腔ヘルペス	2	(0.3)	2	0.93	1	(1.3)	1	2.33	3	(0.5)	3	0.86	2	(0.9)	3	3.36
蜂巣炎	1	(0.2)	1	0.46					4	(0.7)	4	1.14				
帯状疱疹									4	(0.7)	5	1.43				
インフルエンザ	4	(0.7)	4	1.86					1	(0.2)	1	0.29	1	(0.4)	1	1.12

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Table 300520: Related 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
上気道感染	2 (0.3)	2	0.93	1 (1.3)	1	2.33	2 (0.4)	2	0.57	1 (0.4)	1	1.12
膿痂疹	3 (0.5)	3	1.39				1 (0.2)	1	0.29	1 (0.4)	1	1.12
副鼻腔炎	2 (0.3)	2	0.93				2 (0.4)	2	0.57			
ウイルス性胃腸炎							2 (0.4)	3	0.86	1 (0.4)	1	1.12
中耳炎	1 (0.2)	1	0.46				2 (0.4)	2	0.57			
扁桃炎				1 (1.3)	1	2.33	2 (0.4)	2	0.57	1 (0.4)	1	1.12
膿瘍	1 (0.2)	2	0.93									
膀胱炎							2 (0.4)	2	0.57			
耳感染	1 (0.2)	1	0.46				1 (0.2)	1	0.29			
ヘルペス性状湿疹	1 (0.2)	1	0.46				1 (0.2)	1	0.29	1 (0.4)	1	1.12
丹毒	1 (0.2)	1	0.46				1 (0.2)	1	0.29			
せつ							1 (0.2)	2	0.57			
消化管感染							2 (0.4)	2	0.57	1 (0.4)	1	1.12
歯肉炎	1 (0.2)	1	0.46				1 (0.2)	1	0.29			
麦粒腫	1 (0.2)	1	0.46				1 (0.2)	1	0.29			
外耳炎							2 (0.4)	2	0.57			
咽頭扁桃炎	1 (0.2)	1	0.46				1 (0.2)	1	0.29			

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Table 300520: Related 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
皮膚感染	1 (0.2)	2	0.93							1 (0.4)	1	1.12
尿路感染							2 (0.4)	2	0.57			
四肢膿瘍							1 (0.2)	1	0.29			
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			
クロストリジウム・ディフィシレ大腸炎	1 (0.2)	1	0.46									
ウイルス性結膜炎							1 (0.2)	1	0.29			
胃腸炎							1 (0.2)	1	0.29			
陰部単純ヘルペス							1 (0.2)	1	0.29			
ウイルス性角膜炎							1 (0.2)	1	0.29			
喉頭炎	1 (0.2)	1	0.46									
リーシュマニア症	1 (0.2)	1	0.46									
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 300520: Related AEs by SOC and preferred term, entire treatment period: safety analysis set

System Organ Class (SOC) Preferred term	Tralokinumab Q2W (n=602)				Tralokinumab Q4W (n=76)				Tralokinumab Q2W + optional TCS (n=563)				Placebo (n=231)			
	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
乳頭腫ウイルス感染									1	(0.2)	1	0.29				
レンサ球菌性咽頭炎									1	(0.2)	1	0.29				
肺炎	1	(0.2)	1	0.46									1	(0.4)	1	1.12
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
膿疱性皮疹	1	(0.2)	1	0.46												
皮膚細菌感染									1	(0.2)	1	0.29				
ブドウ球菌感染									1	(0.2)	1	0.29				
足部白癬									1	(0.2)	1	0.29	1	(0.4)	1	1.12
歯膿瘍									1	(0.2)	1	0.29				
歯感染													1	(0.4)	1	1.12
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				
外陰膣真菌感染	1	(0.2)	1	0.46												

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Table 300520: Related 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
皮膚および皮下組織障害	74	(12.3)	116	53.86	7	(9.2)	13	30.24	54	(9.6)	77	22.04	34	(14.7)	42	47.00
アトピー性皮膚炎	37	(6.1)	49	22.75	3	(3.9)	4	9.30	33	(5.9)	43	12.31	25	(10.8)	31	34.69
そう痒症	11	(1.8)	14	6.50	3	(3.9)	3	6.98	5	(0.9)	6	1.72	4	(1.7)	4	4.48
紅斑	5	(0.8)	8	3.71					3	(0.5)	5	1.43	1	(0.4)	1	1.12
脱毛症	7	(1.2)	9	4.18					3	(0.5)	3	0.86	1	(0.4)	1	1.12
皮膚乾燥	8	(1.3)	8	3.71					2	(0.4)	2	0.57	1	(0.4)	2	2.24
多汗症	6	(1.0)	7	3.25	1	(1.3)	1	2.33					1	(0.4)	1	1.12
円形脱毛症	2	(0.3)	2	0.93	1	(1.3)	2	4.65	1	(0.2)	1	0.29				
蕁麻疹									3	(0.5)	5	1.43	1	(0.4)	1	1.12
接触皮膚炎	2	(0.3)	2	0.93					2	(0.4)	2	0.57				
びまん性脱毛症	2	(0.3)	2	0.93												
寝汗	1	(0.2)	1	0.46					1	(0.2)	1	0.29				
爪甲脱落症	1	(0.2)	1	0.46					1	(0.2)	1	0.29				
皮膚疼痛	1	(0.2)	2	0.93												
酒さ	1	(0.2)	1	0.46					1	(0.2)	1	0.29				
皮膚局面	1	(0.2)	1	0.46	1	(1.3)	1	2.33								

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Table 300520: Related 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
顔面腫脹	1 (0.2)	1	0.46	1 (1.3)	1	2.33						
ざ瘡							1 (0.2)	1	0.29			
光線角化症	1 (0.2)	1	0.46									
血管浮腫							1 (0.2)	1	0.29			
慢性特発性蕁麻疹							1 (0.2)	1	0.29			
皮膚嚢腫										1 (0.4)	1	1.12
全身性剥脱性皮膚炎	1 (0.2)	1	0.46									
皮膚筋炎							1 (0.2)	1	0.29			
斑状出血	1 (0.2)	1	0.46									
嵌入爪	1 (0.2)	1	0.46									
網状皮斑	1 (0.2)	1	0.46									
爪破損							1 (0.2)	1	0.29			
丘疹							1 (0.2)	1	0.29			
ばら色粃糠疹	1 (0.2)	1	0.46									
発疹	1 (0.2)	1	0.46									
皮膚灼熱感				1 (1.3)	1	2.33						

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Table 300520: Related 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
皮膚びらん	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	63	(10.5)	142	65.94	10	(13.2)	30	69.78	55	(9.8)	131	37.49	11	(4.8)	15	16.78
注射部位反応	26	(4.3)	60	27.86	7	(9.2)	21	48.84	27	(4.8)	59	16.88	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
注射部位腫脹	2	(0.3)	2	0.93	1	(1.3)	3	6.98	6	(1.1)	15	4.29				
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				
疲労	8	(1.3)	8	3.71					3	(0.5)	3	0.86	1	(0.4)	1	1.12

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Table 300520: Related 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
注射部位そう痒感	3 (0.5)	5	2.32				2 (0.4)	2	0.57			
無力症	3 (0.5)	3	1.39				1 (0.2)	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			
発熱	3 (0.5)	3	1.39				1 (0.2)	1	0.29	2 (0.9)	5	5.59
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	1 (0.2)	1	0.46				1 (0.2)	1	0.29			
冷感	1 (0.2)	1	0.46							1 (0.4)	1	1.12
体温変動感	1 (0.2)	1	0.46									
炎症	1 (0.2)	1	0.46									
注射部位過敏反応	1 (0.2)	1	0.46									

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Table 300520: Related 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
注射部位硬結	1 (0.2)	1	0.46									
注射部位炎症							1 (0.2)	1	0.29			
局所腫脹							1 (0.2)	1	0.29			
倦怠感							1 (0.2)	1	0.29			
末梢性浮腫	1 (0.2)	1	0.46							1 (0.4)	1	1.12
疼痛	1 (0.2)	1	0.46									
末梢腫脹							1 (0.2)	1	0.29			
圧痛							1 (0.2)	1	0.29			
口渇	1 (0.2)	1	0.46									
乾燥症	1 (0.2)	1	0.46									
神経系障害	22 (3.7)	37	17.18	1 (1.3)	1	2.33	13 (2.3)	17	4.86	9 (3.9)	12	13.43
頭痛	13 (2.2)	27	12.54				6 (1.1)	8	2.29	4 (1.7)	6	6.71
片頭痛	3 (0.5)	3	1.39				1 (0.2)	1	0.29	1 (0.4)	1	1.12
灼熱感	2 (0.3)	2	0.93	1 (1.3)	1	2.33				1 (0.4)	2	2.24
味覚異常	1 (0.2)	1	0.46				1 (0.2)	1	0.29			

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Table 300520: Related 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
蟻走感									1	(0.2)	2	0.57				
神経痛									1	(0.2)	2	0.57				
浮動性めまい	1	(0.2)	1	0.46												
異常感覚	1	(0.2)	1	0.46												
知覚過敏	1	(0.2)	1	0.46												
記憶障害									1	(0.2)	1	0.29				
錯感覚	1	(0.2)	1	0.46												
失神寸前の状態									1	(0.2)	1	0.29				
失神									1	(0.2)	1	0.29	2	(0.9)	2	2.24
振戦													1	(0.4)	1	1.12
臨床検査	9	(1.5)	10	4.64					19	(3.4)	25	7.15	7	(3.0)	11	12.31
リンパ球数減少	3	(0.5)	4	1.86					6	(1.1)	8	2.29				
アスパラギン酸アミノトランスフェラーゼ増加													3	(1.3)	3	3.36
血中ビリルビン増加									3	(0.5)	3	0.86				

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Table 300520: Related 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
γーグルタミルトランスフェラーゼ増加							2 (0.4)	3	0.86	1 (0.4)	1	1.12
血中アルカリホスファターゼ増加							2 (0.4)	2	0.57			
好酸球数増加	1 (0.2)	1	0.46				1 (0.2)	1	0.29			
肝酵素上昇							2 (0.4)	2	0.57	2 (0.9)	2	2.24
肝機能検査値上昇	2 (0.3)	2	0.93							1 (0.4)	1	1.12
アラニンアミノトランスフェラーゼ増加	1 (0.2)	1	0.46							3 (1.3)	3	3.36
血中免疫グロブリンE増加							1 (0.2)	1	0.29			
血圧上昇	1 (0.2)	1	0.46									

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Table 300520: Related 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
血中トリグリセリド増加							1 (0.2)	1	0.29			
C－反応性蛋白増加	1 (0.2)	1	0.46									
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			
好中球数減少							1 (0.2)	1	0.29			
トランスアミナーゼ上昇							1 (0.2)	1	0.29			
体重増加										1 (0.4)	1	1.12
眼障害	16 (2.7)	19	8.82				9 (1.6)	13	3.72	6 (2.6)	6	6.71
アレルギー性結膜炎	5 (0.8)	5	2.32				2 (0.4)	2	0.57	3 (1.3)	3	3.36
眼乾燥	4 (0.7)	4	1.86				3 (0.5)	3	0.86	1 (0.4)	1	1.12
眼瞼炎	2 (0.3)	2	0.93				1 (0.2)	1	0.29			
角膜炎	1 (0.2)	1	0.46				2 (0.4)	2	0.57			

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Table 300520: Related 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
眼痛							1 (0.2)	2	0.57			
眼瞼浮腫	1 (0.2)	2	0.93									
潰瘍性角膜炎	1 (0.2)	1	0.46				1 (0.2)	1	0.29			
アトピー性角結膜炎	1 (0.2)	1	0.46									
霰粒腫	1 (0.2)	1	0.46									
角膜浸潤							1 (0.2)	1	0.29			
眼脂							1 (0.2)	1	0.29			
眼そう痒症	1 (0.2)	1	0.46									
円錐角膜	1 (0.2)	1	0.46									
強膜炎										1 (0.4)	1	1.12
霧視										1 (0.4)	1	1.12
胃腸障害	12 (2.0)	22	10.22	1 (1.3)	1	2.33	11 (2.0)	14	4.01	3 (1.3)	4	4.48
悪心	3 (0.5)	6	2.79				3 (0.5)	3	0.86	2 (0.9)	2	2.24
下痢	3 (0.5)	4	1.86	1 (1.3)	1	2.33	2 (0.4)	2	0.57	1 (0.4)	1	1.12
嘔吐	2 (0.3)	2	0.93				1 (0.2)	3	0.86			

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Table 300520: Related 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
上腹部痛	2 (0.3)	2	0.93				1 (0.2)	1	0.29			
硬便	1 (0.2)	2	0.93									
腹部膨満	1 (0.2)	1	0.46									
腹痛	1 (0.2)	1	0.46									
下腹部痛	1 (0.2)	1	0.46									
腹部症状	1 (0.2)	1	0.46									
便秘	1 (0.2)	1	0.46									
齲歯							1 (0.2)	1	0.29			
歯嚢胞	1 (0.2)	1	0.46									
腸炎							1 (0.2)	1	0.29			
胃潰瘍							1 (0.2)	1	0.29			
歯肉出血							1 (0.2)	1	0.29			
口腔粘膜水疱形成										1 (0.4)	1	1.12
口内炎							1 (0.2)	1	0.29			
血液およびリンパ系障害	11 (1.8)	15	6.96				5 (0.9)	6	1.72	2 (0.9)	2	2.24
好酸球増加症	8 (1.3)	9	4.18				4 (0.7)	5	1.43	1 (0.4)	1	1.12

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Table 300520: Related 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
白血球増加症	2 (0.3)	2	0.93									
リンパ節症	1 (0.2)	1	0.46				1 (0.2)	1	0.29	1 (0.4)	1	1.12
貧血	1 (0.2)	1	0.46									
リンパ球減少症	1 (0.2)	1	0.46									
好中球減少症	1 (0.2)	1	0.46									
呼吸器、胸郭および縦隔障害	9 (1.5)	11	5.11				6 (1.1)	8	2.29	3 (1.3)	3	3.36
咳嗽	2 (0.3)	3	1.39				1 (0.2)	1	0.29			
喘息	2 (0.3)	2	0.93				1 (0.2)	1	0.29	1 (0.4)	1	1.12
口腔咽頭痛	1 (0.2)	1	0.46				1 (0.2)	1	0.29	1 (0.4)	1	1.12
呼吸困難							1 (0.2)	1	0.29			
労作性呼吸困難	1 (0.2)	1	0.46									
鼻出血							1 (0.2)	1	0.29			
鼻閉	1 (0.2)	1	0.46									
湿性咳嗽							1 (0.2)	1	0.29			

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Table 300520: Related 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
鼻漏	1 (0.2)	1	0.46							1 (0.4)	1	1.12
副鼻腔うっ血	1 (0.2)	1	0.46									
くしゃみ	1 (0.2)	1	0.46									
上気道性喘鳴							1 (0.2)	1	0.29			
咽喉刺激感							1 (0.2)	1	0.29			
筋骨格系および結合組織障害	5 (0.8)	5	2.32				5 (0.9)	6	1.72	7 (3.0)	7	7.83
関節痛	1 (0.2)	1	0.46				1 (0.2)	1	0.29			
筋肉痛	1 (0.2)	1	0.46				1 (0.2)	1	0.29	1 (0.4)	1	1.12
頚部痛										2 (0.9)	2	2.24
関節障害							1 (0.2)	1	0.29			
背部痛							1 (0.2)	1	0.29			
滑液包炎							1 (0.2)	1	0.29	1 (0.4)	1	1.12
筋痙縮	1 (0.2)	1	0.46							1 (0.4)	1	1.12
筋緊張										1 (0.4)	1	1.12
筋攣縮							1 (0.2)	1	0.29			

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Table 300520: Related 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
筋骨格痛										1 (0.4)	1	1.12
四肢痛	1 (0.2)	1	0.46									
腱炎	1 (0.2)	1	0.46									
血管障害	5 (0.8)	5	2.32				5 (0.9)	5	1.43	1 (0.4)	1	1.12
高血圧	4 (0.7)	4	1.86				2 (0.4)	2	0.57	1 (0.4)	1	1.12
潮紅	1 (0.2)	1	0.46									
血腫							1 (0.2)	1	0.29			
低血圧							1 (0.2)	1	0.29			
静脈血栓症							1 (0.2)	1	0.29			
傷害、中毒および処置合併症	5 (0.8)	6	2.79				2 (0.4)	4	1.14			
処置によるめまい	4 (0.7)	5	2.32				1 (0.2)	2	0.57			
処置による頭痛	1 (0.2)	1	0.46				1 (0.2)	2	0.57			

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Table 300520: Related 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
精神障害	5 (0.8)	5	2.32				2 (0.4)	2	0.57	3 (1.3)	4	4.48
不眠症	3 (0.5)	3	1.39									
無感情										1 (0.4)	2	2.24
注意欠陥多動性障害							1 (0.2)	1	0.29			
うつ病	1 (0.2)	1	0.46							1 (0.4)	1	1.12
易刺激性							1 (0.2)	1	0.29			
睡眠障害	1 (0.2)	1	0.46							1 (0.4)	1	1.12
心臓障害	2 (0.3)	2	0.93	1 (1.3)	1	2.33	1 (0.2)	2	0.57			
動悸							1 (0.2)	2	0.57			
第一度房室ブロック	1 (0.2)	1	0.46									
右脚ブロック				1 (1.3)	1	2.33						
頻脈	1 (0.2)	1	0.46									

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Table 300520: Related 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
代謝および栄養障害	3 (0.5)	3	1.39				1 (0.2)	1	0.29			
異常体重増加	1 (0.2)	1	0.46									
脂質異常症	1 (0.2)	1	0.46									
高コレステロール血症							1 (0.2)	1	0.29			
高カリウム血症	1 (0.2)	1	0.46									
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）							3 (0.5)	3	0.86			
浸潤性乳癌							2 (0.4)	2	0.57			
皮膚乳頭腫							1 (0.2)	1	0.29			

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Table 300520: Related 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
耳および迷路障害	2 (0.3)	2	0.93							1 (0.4)	1	1.12
耳痛	1 (0.2)	1	0.46									
回転性めまい	1 (0.2)	1	0.46							1 (0.4)	1	1.12
肝胆道系障害							2 (0.4)	4	1.14			
胆嚢炎							1 (0.2)	1	0.29			
脂肪肝							1 (0.2)	1	0.29			
肝炎							1 (0.2)	1	0.29			
黄疸眼							1 (0.2)	1	0.29			
腎および尿路障害	1 (0.2)	1	0.46				1 (0.2)	1	0.29			
腎結石症	1 (0.2)	1	0.46									
蛋白尿							1 (0.2)	1	0.29			

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Table 300520: Related 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									
皮様嚢腫	1 (0.2)	1	0.46									
内分泌障害	1 (0.2)	1	0.46									
自己免疫性甲状腺炎	1 (0.2)	1	0.46									
免疫系障害	1 (0.2)	3	1.39									
過敏症	1 (0.2)	2	0.93									
季節性アレルギー	1 (0.2)	1	0.46									

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Table 300520: Related 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
生殖系および乳房障害									1	(0.2)	1	0.29				
前立腺炎									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).

1.8.2.1.8 治験薬との因果関係が否定できない有害事象：追跡調査期間［Source: Table 7.118］

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Table 7.118: Table 300940: Related 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	6 (6.9)	6	36.84				12 (2.9)	18	20.78			
感染症および寄生虫症	2 (2.3)	2	12.28				6 (1.4)	6	6.93			
ウイルス性上気道感染							2 (0.5)	2	2.31			
結膜炎							1 (0.2)	1	1.15			
ヘルペス性状湿疹							1 (0.2)	1	1.15			
丹毒	1 (1.1)	1	6.14									
単純ヘルペス							1 (0.2)	1	1.15			
帯状疱疹							1 (0.2)	1	1.15			
副鼻腔炎	1 (1.1)	1	6.14									
臨床検査							4 (1.0)	4	4.62			
リンパ球数減少							2 (0.5)	2	2.31			

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Table 300940: Related 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
血中乳酸脱水素酵素増加							1 (0.2)	1	1.15			
体重減少							1 (0.2)	1	1.15			
皮膚および皮下組織障害	2 (2.3)	2	12.28				1 (0.2)	1	1.15			
アトピー性皮膚炎	2 (2.3)	2	12.28				1 (0.2)	1	1.15			
精神障害	1 (1.1)	1	6.14				1 (0.2)	1	1.15			
不安							1 (0.2)	1	1.15			
うつ病	1 (1.1)	1	6.14									
血液およびリンパ系障害							1 (0.2)	1	1.15			
リンパ節症							1 (0.2)	1	1.15			

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Table 300940: Related 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
眼障害	1 (1.1)	1	6.14									
アレルギー性結膜炎	1 (1.1)	1	6.14									
胃腸障害							1 (0.2)	3	3.46			
下痢							1 (0.2)	1	1.15			
悪心							1 (0.2)	1	1.15			
嘔吐							1 (0.2)	1	1.15			
代謝および栄養障害							1 (0.2)	1	1.15			
低カルシウム血症							1 (0.2)	1	1.15			

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Table 300940: Related 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
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.

1.8.2.1.9　日本人での全ての有害事象：初期投与期間［Source: Table J 7.2］

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Table J.7.2: Table 300020: AEs by SOC and preferred term, initial treatment period: safety analysis set

System Organ Class (SOC) Preferred term	Tralokinumab Q2W (n=96) N (%)	E	R	Placebo (n=31) N (%)	E	R
All AEs	79 (82.3)	189	657.50	27 (87.1)	74	776.49
Treatment comparison, p-value	0.3692					
皮膚および皮下組織障害	55 (57.3)	57	198.29	18 (58.1)	22	230.85
アトピー性皮膚炎	51 (53.1)	51	177.42	15 (48.4)	18	188.88
脱毛症	2 (2.1)	2	6.96			
ざ瘡				1 (3.2)	1	10.49
円形脱毛症	1 (1.0)	1	3.48			
皮膚嚢腫				1 (3.2)	1	10.49
接触皮膚炎	1 (1.0)	1	3.48			
湿疹				1 (3.2)	1	10.49
そう痒症				1 (3.2)	1	10.49
脂漏性皮膚炎	1 (1.0)	1	3.48			
蕁麻疹	1 (1.0)	1	3.48			
感染症および寄生虫症	35 (36.5)	48	166.98	11 (35.5)	18	188.88
ウイルス性上気道感染	11 (11.5)	13	45.22	2 (6.5)	2	20.99
毛包炎	3 (3.1)	3	10.44	2 (6.5)	3	31.48

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Table 300020: AEs by SOC and preferred term, initial treatment period: safety analysis set

System Organ Class (SOC) Preferred term	Tralokinumab Q2W (n=96) N (%)	E	R	Placebo (n=31) N (%)	E	R
咽頭炎	3 (3.1)	3	10.44	1 (3.2)	2	20.99
結膜炎	3 (3.1)	3	10.44	1 (3.2)	1	10.49
ヘルペス性状湿疹	3 (3.1)	3	10.44	1 (3.2)	1	10.49
インフルエンザ	3 (3.1)	3	10.44	1 (3.2)	1	10.49
胃腸炎	1 (1.0)	1	3.48	1 (3.2)	1	10.49
麦粒腫	2 (2.1)	2	6.96			
膿痂疹	2 (2.1)	2	6.96			
伝染性軟属腫	1 (1.0)	2	6.96			
口腔ヘルペス	1 (1.0)	1	3.48	1 (3.2)	1	10.49
上気道感染	2 (2.1)	2	6.96			
気管支炎				1 (3.2)	1	10.49
細菌性結膜炎	1 (1.0)	1	3.48			
感染性皮膚炎	1 (1.0)	1	3.48			
突発性発疹	1 (1.0)	1	3.48			
せつ	1 (1.0)	1	3.48			
手足口病	1 (1.0)	1	3.48			
単純ヘルペス	1 (1.0)	1	3.48			
帯状疱疹				1 (3.2)	1	10.49
鼻咽頭炎	1 (1.0)	1	3.48			
外耳炎	1 (1.0)	1	3.48			

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Table 300020: AEs by SOC and preferred term, initial treatment period: safety analysis set

System Organ Class (SOC) Preferred term	Tralokinumab Q2W (n=96) N (%)	E	R	Placebo (n=31) N (%)	E	R
爪囲炎	1 (1.0)	1	3.48			
肺炎				1 (3.2)	1	10.49
歯髄炎	1 (1.0)	1	3.48			
腎盂腎炎				1 (3.2)	1	10.49
皮膚細菌感染				1 (3.2)	1	10.49
足部白癬				1 (3.2)	1	10.49
眼障害	13 (13.5)	15	52.18	2 (6.5)	3	31.48
アレルギー性結膜炎	8 (8.3)	8	27.83			
眼瞼炎	3 (3.1)	3	10.44			
眼乾燥	2 (2.1)	2	6.96	1 (3.2)	1	10.49
眼精疲労				1 (3.2)	1	10.49
アトピー性角結膜炎	1 (1.0)	1	3.48			
眼充血	1 (1.0)	1	3.48			
強膜炎				1 (3.2)	1	10.49
胃腸障害	8 (8.3)	11	38.27	7 (22.6)	11	115.42
齲歯	2 (2.1)	4	13.92	4 (12.9)	5	52.47
下痢	1 (1.0)	1	3.48	2 (6.5)	2	20.99
悪心	2 (2.1)	2	6.96	1 (3.2)	1	10.49

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Table 300020: AEs by SOC and preferred term, initial treatment period: safety analysis set

	Tralokinumab Q2W (n=96)			Placebo (n=31)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R
上腹部痛	2 (2.1)	2	6.96			
便秘				1 (3.2)	1	10.49
胃腸障害				1 (3.2)	1	10.49
胃食道逆流性疾患	1 (1.0)	1	3.48			
歯周病				1 (3.2)	1	10.49
嘔吐	1 (1.0)	1	3.48			
一般・全身障害および投与部位の状態	12 (12.5)	20	69.58	1 (3.2)	4	41.97
注射部位反応	5 (5.2)	8	27.83			
発熱	3 (3.1)	3	10.44	1 (3.2)	4	41.97
注射部位紅斑	1 (1.0)	4	13.92			
硬結	1 (1.0)	1	3.48			
注射部位過敏反応	1 (1.0)	1	3.48			
局所腫脹	1 (1.0)	1	3.48			
倦怠感	1 (1.0)	1	3.48			
圧痛	1 (1.0)	1	3.48			
筋骨格系および結合組織障害	8 (8.3)	8	27.83	2 (6.5)	2	20.99
関節痛	3 (3.1)	3	10.44			
関節炎	1 (1.0)	1	3.48			

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Table 300020: AEs by SOC and preferred term, initial treatment period: safety analysis set

System Organ Class (SOC) Preferred term	Tralokinumab Q2W (n=96) N (%)	E	R	Placebo (n=31) N (%)	E	R
滑液包炎				1 (3.2)	1	10.49
椎間板突出	1 (1.0)	1	3.48			
腰部脊柱管狭窄症	1 (1.0)	1	3.48			
筋痙縮				1 (3.2)	1	10.49
変形性関節症	1 (1.0)	1	3.48			
滑液嚢腫	1 (1.0)	1	3.48			
傷害、中毒および処置合併症	6 (6.3)	7	24.35	1 (3.2)	1	10.49
挫傷	2 (2.1)	2	6.96			
靭帯捻挫	2 (2.1)	2	6.96			
関節脱臼	1 (1.0)	1	3.48			
裂傷	1 (1.0)	1	3.48			
サンバーン	1 (1.0)	1	3.48			
子宮頚管裂傷				1 (3.2)	1	10.49
神経系障害	4 (4.2)	5	17.39	3 (9.7)	4	41.97
頚髄神経根障害	1 (1.0)	1	3.48	1 (3.2)	1	10.49
頭痛	1 (1.0)	1	3.48	1 (3.2)	1	10.49
感覚鈍麻	1 (1.0)	1	3.48	1 (3.2)	1	10.49
意識レベルの低下	1 (1.0)	1	3.48			

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Table 300020: AEs by SOC and preferred term, initial treatment period: safety analysis set

System Organ Class (SOC) Preferred term	Tralokinumab Q2W (n=96) N (%)	E	R	Placebo (n=31) N (%)	E	R
浮動性めまい	1 (1.0)	1	3.48			
失神寸前の状態				1 (3.2)	1	10.49
呼吸器、胸郭および縦隔障害	7 (7.3)	9	31.31			
喘息	3 (3.1)	4	13.92			
口腔咽頭痛	2 (2.1)	3	10.44			
アレルギー性鼻炎	1 (1.0)	1	3.48			
上気道の炎症	1 (1.0)	1	3.48			
臨床検査	1 (1.0)	1	3.48	2 (6.5)	4	41.97
アラニンアミノトランスフェラーゼ増加				1 (3.2)	1	10.49
アスパラギン酸アミノトランスフェラーゼ増加				1 (3.2)	1	10.49
好酸球数増加	1 (1.0)	1	3.48			
γ－グルタミルトランスフェラーゼ増加				1 (3.2)	1	10.49
ヘマトクリット増加				1 (3.2)	1	10.49
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）	2 (2.1)	2	6.96	1 (3.2)	1	10.49
皮膚乳頭腫	2 (2.1)	2	6.96	1 (3.2)	1	10.49

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Table 300020: AEs by SOC and preferred term, initial treatment period: safety analysis set

System Organ Class (SOC) Preferred term	Tralokinumab Q2W (n=96) N (%)	E	R	Placebo (n=31) N (%)	E	R
精神障害	2 (2.1)	2	6.96	1 (3.2)	1	10.49
不眠症	2 (2.1)	2	6.96			
初期不眠症				1 (3.2)	1	10.49
血管障害	2 (2.1)	2	6.96	1 (3.2)	1	10.49
高血圧	2 (2.1)	2	6.96	1 (3.2)	1	10.49
血液およびリンパ系障害				1 (3.2)	1	10.49
リンパ節症				1 (3.2)	1	10.49
心臓障害	1 (1.0)	1	3.48			
心房細動	1 (1.0)	1	3.48			
内分泌障害				1 (3.2)	1	10.49
ステロイド離脱症候群				1 (3.2)	1	10.49
代謝および栄養障害	1 (1.0)	1	3.48			
脱水	1 (1.0)	1	3.48			

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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.

1.8.2.1.10　日本人での全ての有害事象：維持投与期間［Source: Table J 7.32］

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Table J.7.32: Table 300250: AEs by SOC and preferred term, maintenance treatment period: maintenance safety analysis set

	Week 16 Tralokinumab responders								Week 16 Placebo responders			
	Tralokinumab Q2W (n=11)				Tralokinumab Q4W (n=16)				Placebo (n=6)				Placebo (n=6)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
All AEs	9	(81.8)	25	384.50	10	(62.5)	39	393.32	6	(100)	12	338.52	5	(83.3)	7	242.66
皮膚および皮下組織障害	3	(27.3)	4	61.52	6	(37.5)	8	80.68	5	(83.3)	5	141.05	2	(33.3)	2	69.33
アトピー性皮膚炎	3	(27.3)	3	46.14	3	(18.8)	4	40.34	5	(83.3)	5	141.05	2	(33.3)	2	69.33
円形脱毛症					1	(6.3)	2	20.17								
皮膚嚢腫					1	(6.3)	1	10.09								
紅斑	1	(9.1)	1	15.38												
特発性蕁麻疹					1	(6.3)	1	10.09								
感染症および寄生虫症	4	(36.4)	8	123.04	6	(37.5)	13	131.11	2	(33.3)	2	56.42	1	(16.7)	3	104.00
ウイルス性上気道感染	2	(18.2)	2	30.76	1	(6.3)	1	10.09	2	(33.3)	2	56.42				
単純ヘルペス	2	(18.2)	2	30.76	1	(6.3)	1	10.09								

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Table 300250: AEs by SOC and preferred term, maintenance treatment period: maintenance safety analysis set

	Week 16 Tralokinumab responders										Week 16 Placebo responders			
	Tralokinumab Q2W (n=11)				Tralokinumab Q4W (n=16)				Placebo (n=6)				Placebo (n=6)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
毛包炎					2	(12.5)	2	20.17								
胃腸炎					1	(6.3)	1	10.09					1	(16.7)	1	34.67
鼻咽頭炎					2	(12.5)	2	20.17								
咽頭炎	1	(9.1)	2	30.76												
扁桃炎	1	(9.1)	1	15.38									1	(16.7)	1	34.67
気管支炎					1	(6.3)	1	10.09								
ウイルス性腸炎													1	(16.7)	1	34.67
インフルエンザ					1	(6.3)	1	10.09								
口腔ヘルペス					1	(6.3)	1	10.09								
外耳炎					1	(6.3)	1	10.09								
爪囲炎					1	(6.3)	1	10.09								
鼻喉頭炎					1	(6.3)	1	10.09								
股部白癬	1	(9.1)	1	15.38												
傷害、中毒および処置合併症	2	(18.2)	2	30.76	2	(12.5)	2	20.17	1	(16.7)	1	28.21	1	(16.7)	1	34.67
挫傷					1	(6.3)	1	10.09								

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Table 300250: AEs by SOC and preferred term, maintenance treatment period: maintenance safety analysis set

	Week 16 Tralokinumab responders								Week 16 Placebo responders			
	Tralokinumab Q2W (n=11)				Tralokinumab Q4W (n=16)				Placebo (n=6)				Placebo (n=6)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
上顎炎	1	(9.1)	1	15.38												
熱中症	1	(9.1)	1	15.38												
裂傷					1	(6.3)	1	10.09								
皮膚擦過傷									1	(16.7)	1	28.21				
スポーツ損傷													1	(16.7)	1	34.67
筋骨格系および結合組織障害	2	(18.2)	2	30.76	2	(12.5)	2	20.17	1	(16.7)	1	28.21				
背部痛	1	(9.1)	1	15.38	2	(12.5)	2	20.17								
四肢痛									1	(16.7)	1	28.21				
腱鞘炎	1	(9.1)	1	15.38												
眼障害	3	(27.3)	4	61.52					1	(16.7)	1	28.21				
アトピー性角結膜炎	2	(18.2)	2	30.76												

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Table 300250: AEs by SOC and preferred term, maintenance treatment period: maintenance safety analysis set

	Week 16 Tralokinumab responders								Week 16 Placebo responders			
	Tralokinumab Q2W (n=11)				Tralokinumab Q4W (n=16)				Placebo (n=6)				Placebo (n=6)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
アレルギー性結膜炎	1	(9.1)	1	15.38					1	(16.7)	1	28.21				
潰瘍性角膜炎	1	(9.1)	1	15.38												
一般・全身障害および投与部位の状態					3	(18.8)	11	110.94								
注射部位反応					2	(12.5)	10	100.85								
注射部位紅斑					1	(6.3)	1	10.09								
胃腸障害					1	(6.3)	1	10.09					1	(16.7)	1	34.67
齲歯					1	(6.3)	1	10.09								

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Table 300250: AEs by SOC and preferred term, maintenance treatment period: maintenance safety analysis set

	Week 16 Tralokinumab responders										Week 16 Placebo responders			
	Tralokinumab Q2W (n=11)				Tralokinumab Q4W (n=16)				Placebo (n=6)				Placebo (n=6)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
胃食道逆流性疾患													1	(16.7)	1	34.67
臨床検査	1	(9.1)	1	15.38					1	(16.7)	1	28.21				
アラニンアミノトランスフェラーゼ増加	1	(9.1)	1	15.38												
肝機能検査値上昇									1	(16.7)	1	28.21				
心臓障害					1	(6.3)	1	10.09								
右脚ブロック					1	(6.3)	1	10.09								
免疫系障害	1	(9.1)	1	15.38												
季節性アレルギー	1	(9.1)	1	15.38												

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Table 300250: AEs by SOC and preferred term, maintenance treatment period: maintenance safety analysis set

	Week 16 Tralokinumab responders								Week 16 Placebo responders			
	Tralokinumab Q2W (n=11)				Tralokinumab Q4W (n=16)				Placebo (n=6)				Placebo (n=6)			
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					1	(6.3)	1	10.09								
高尿酸血症					1	(6.3)	1	10.09								
神経系障害	1	(9.1)	2	30.76												
頭痛	1	(9.1)	2	30.76												
精神障害	1	(9.1)	1	15.38												
不眠症	1	(9.1)	1	15.38												
腎および尿路障害									1	(16.7)	1	28.21				
腎結石症									1	(16.7)	1	28.21				

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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).

1.8.2.1.11　日本人での全ての有害事象：非盲験期間［Source: Table J 7.62］

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

	Tralokinumab Q2W (n=96)				Tralokinumab Q4W (n=16)				Tralokinumab Q2W + optional TCS (n=89)				Placebo (n=37)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
All AEs	81	(84.4)	214	607.14	10	(62.5)	39	393.32	76	(85.4)	313	429.22	34	(91.9)	93	582.72
感染症および寄生虫症	37	(38.5)	56	158.88	6	(37.5)	13	131.11	53	(59.6)	112	153.59	14	(37.8)	23	144.11
ウイルス性上気道感染	13	(13.5)	15	42.56	1	(6.3)	1	10.09	31	(34.8)	43	58.97	4	(10.8)	4	25.06
単純ヘルペス	2	(2.1)	3	8.51	1	(6.3)	1	10.09	5	(5.6)	7	9.60				
毛包炎	3	(3.1)	3	8.51	2	(12.5)	2	20.17	5	(5.6)	5	6.86	2	(5.4)	3	18.80
咽頭炎	3	(3.1)	5	14.19					4	(4.5)	5	6.86	1	(2.7)	2	12.53
ヘルペス性状湿疹	3	(3.1)	3	8.51					3	(3.4)	4	5.49	1	(2.7)	1	6.27
結膜炎	3	(3.1)	3	8.51					2	(2.2)	3	4.11	1	(2.7)	1	6.27
胃腸炎	1	(1.0)	1	2.84	1	(6.3)	1	10.09	4	(4.5)	4	5.49	2	(5.4)	2	12.53
インフルエンザ	3	(3.1)	3	8.51	1	(6.3)	1	10.09	2	(2.2)	2	2.74	1	(2.7)	1	6.27
外耳炎	1	(1.0)	1	2.84	1	(6.3)	1	10.09	3	(3.4)	3	4.11				
せつ	1	(1.0)	1	2.84					2	(2.2)	3	4.11				
口腔ヘルペス	1	(1.0)	1	2.84	1	(6.3)	1	10.09	2	(2.2)	2	2.74	1	(2.7)	1	6.27
歯周炎									4	(4.5)	4	5.49				

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

	Tralokinumab Q2W (n=96)			Tralokinumab Q4W (n=16)			Tralokinumab Q2W + optional TCS (n=89)			Placebo (n=37)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
上気道感染	2 (2.1)	2	5.67				2 (2.2)	2	2.74			
蜂巣炎							3 (3.4)	3	4.11			
麦粒腫	2 (2.1)	2	5.67				1 (1.1)	1	1.37			
鼻咽頭炎	1 (1.0)	1	2.84	2 (12.5)	2	20.17						
歯髄炎	1 (1.0)	1	2.84				1 (1.1)	2	2.74			
皮膚感染							3 (3.4)	3	4.11			
気管支炎				1 (6.3)	1	10.09	1 (1.1)	1	1.37	1 (2.7)	1	6.27
帯状疱疹							1 (1.1)	2	2.74	1 (2.7)	1	6.27
膿痂疹	2 (2.1)	2	5.67									
伝染性軟属腫	1 (1.0)	2	5.67									
爪囲炎	1 (1.0)	1	2.84	1 (6.3)	1	10.09						
扁桃炎	1 (1.0)	1	2.84				1 (1.1)	1	1.37	1 (2.7)	1	6.27
四肢膿瘍							1 (1.1)	1	1.37			
細菌性結膜炎	1 (1.0)	1	2.84									
膀胱炎							1 (1.1)	1	1.37			
感染性皮膚炎	1 (1.0)	1	2.84									
ウイルス性腸炎							1 (1.1)	1	1.37	1 (2.7)	1	6.27

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

	Tralokinumab Q2W (n=96)				Tralokinumab Q4W (n=16)				Tralokinumab Q2W + optional TCS (n=89)				Placebo (n=37)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
精巣上体炎									1	(1.1)	1	1.37				
丹毒									1	(1.1)	1	1.37				
突発性発疹	1	(1.0)	1	2.84												
細菌性胃腸炎									1	(1.1)	1	1.37				
陰部単純ヘルペス									1	(1.1)	1	1.37				
歯肉炎									1	(1.1)	1	1.37				
手足口病	1	(1.0)	1	2.84												
真菌性外耳炎									1	(1.1)	1	1.37				
中耳炎									1	(1.1)	1	1.37				
肺炎													1	(2.7)	1	6.27
腎盂腎炎													1	(2.7)	1	6.27
鼻咽頭炎					1	(6.3)	1	10.09								
皮膚細菌感染									1	(1.1)	1	1.37	1	(2.7)	1	6.27
股部白癬	1	(1.0)	1	2.84												
足部白癬									1	(1.1)	1	1.37	1	(2.7)	1	6.27

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

	Tralokinumab Q2W (n=96)			Tralokinumab Q4W (n=16)			Tralokinumab Q2W + optional TCS (n=89)			Placebo (n=37)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
皮膚および皮下組織障害	57 (59.4)	61	173.06	6 (37.5)	8	80.68	30 (33.7)	44	60.34	25 (67.6)	29	181.71
アトピー性皮膚炎	53 (55.2)	54	153.20	3 (18.8)	4	40.34	20 (22.5)	22	30.17	22 (59.5)	25	156.65
ざ瘡							5 (5.6)	5	6.86	1 (2.7)	1	6.27
円形脱毛症	1 (1.0)	1	2.84	1 (6.3)	2	20.17	1 (1.1)	1	1.37			
蕁麻疹	1 (1.0)	1	2.84				3 (3.4)	3	4.11			
脱毛症	2 (2.1)	2	5.67				1 (1.1)	1	1.37			
接触皮膚炎	1 (1.0)	1	2.84				2 (2.2)	2	2.74			
脂漏性皮膚炎	1 (1.0)	1	2.84				1 (1.1)	1	1.37			
皮膚嚢腫				1 (6.3)	1	10.09				1 (2.7)	1	6.27
皮膚筋炎							1 (1.1)	1	1.37			
湿疹										1 (2.7)	1	6.27
紅斑	1 (1.0)	1	2.84									
特発性蕁麻疹				1 (6.3)	1	10.09						
嵌入爪							1 (1.1)	1	1.37			
間擦疹							1 (1.1)	1	1.37			

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

	Tralokinumab Q2W (n=96)				Tralokinumab Q4W (n=16)				Tralokinumab Q2W + optional TCS (n=89)				Placebo (n=37)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
寝汗									1	(1.1)	1	1.37				
爪甲剥離症									1	(1.1)	1	1.37				
そう痒症													1	(2.7)	1	6.27
皮膚障害									1	(1.1)	1	1.37				
皮膚刺激									1	(1.1)	1	1.37				
皮膚潰瘍									1	(1.1)	1	1.37				
日光皮膚炎									1	(1.1)	1	1.37				
一般・全身障害および投与部位の状態	12	(12.5)	20	56.74	3	(18.8)	11	110.94	13	(14.6)	44	60.34	1	(2.7)	4	25.06
注射部位反応	5	(5.2)	8	22.70	2	(12.5)	10	100.85	6	(6.7)	19	26.05				
注射部位紅斑	1	(1.0)	4	11.35	1	(6.3)	1	10.09	2	(2.2)	12	16.46				
注射部位腫脹									1	(1.1)	8	10.97				

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

	Tralokinumab Q2W (n=96)			Tralokinumab Q4W (n=16)			Tralokinumab Q2W + optional TCS (n=89)			Placebo (n=37)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
発熱	3 (3.1)	3	8.51				2 (2.2)	2	2.74	1 (2.7)	4	25.06
倦怠感	1 (1.0)	1	2.84				1 (1.1)	1	1.37			
肉芽腫							1 (1.1)	1	1.37			
硬結	1 (1.0)	1	2.84									
注射部位出血							1 (1.1)	1	1.37			
注射部位過敏反応	1 (1.0)	1	2.84									
局所腫脹	1 (1.0)	1	2.84									
圧痛	1 (1.0)	1	2.84									
眼障害	16 (16.7)	19	53.90				11 (12.4)	14	19.20	3 (8.1)	4	25.06
アレルギー性結膜炎	9 (9.4)	9	25.53				7 (7.9)	7	9.60	1 (2.7)	1	6.27
眼乾燥	2 (2.1)	2	5.67				3 (3.4)	3	4.11	1 (2.7)	1	6.27
アトピー性角結膜炎	3 (3.1)	3	8.51				1 (1.1)	1	1.37			
眼瞼炎	3 (3.1)	3	8.51									
角膜炎							2 (2.2)	2	2.74			

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

	Tralokinumab Q2W (n=96)				Tralokinumab Q4W (n=16)				Tralokinumab Q2W + optional TCS (n=89)				Placebo (n=37)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
眼精疲労													1	(2.7)	1	6.27
眼脂									1	(1.1)	1	1.37				
眼充血	1	(1.0)	1	2.84												
強膜炎													1	(2.7)	1	6.27
潰瘍性角膜炎	1	(1.0)	1	2.84												
胃腸障害	8	(8.3)	11	31.21	1	(6.3)	1	10.09	16	(18.0)	21	28.80	8	(21.6)	12	75.19
齲歯	2	(2.1)	4	11.35	1	(6.3)	1	10.09	5	(5.6)	5	6.86	4	(10.8)	5	31.33
悪心	2	(2.1)	2	5.67					2	(2.2)	2	2.74	1	(2.7)	1	6.27
胃食道逆流性疾患	1	(1.0)	1	2.84					2	(2.2)	2	2.74	1	(2.7)	1	6.27
歯周病									3	(3.4)	3	4.11	1	(2.7)	1	6.27
上腹部痛	2	(2.1)	2	5.67												
腸炎									2	(2.2)	2	2.74				
痔核									2	(2.2)	2	2.74				
口内炎									2	(2.2)	2	2.74				
大腸炎									1	(1.1)	1	1.37				
便秘													1	(2.7)	1	6.27

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

	Tralokinumab Q2W (n=96)			Tralokinumab Q4W (n=16)			Tralokinumab Q2W + optional TCS (n=89)			Placebo (n=37)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
下痢	1 (1.0)	1	2.84							2 (5.4)	2	12.53
胃潰瘍							1 (1.1)	1	1.37			
胃腸障害										1 (2.7)	1	6.27
歯痛							1 (1.1)	1	1.37			
嘔吐	1 (1.0)	1	2.84									
筋骨格系および結合組織障害	10 (10.4)	10	28.37	2 (12.5)	2	20.17	13 (14.6)	16	21.94	3 (8.1)	3	18.80
背部痛	1 (1.0)	1	2.84	2 (12.5)	2	20.17	5 (5.6)	5	6.86			
関節痛	3 (3.1)	3	8.51				1 (1.1)	1	1.37			
関節炎	1 (1.0)	1	2.84				1 (1.1)	1	1.37			
四肢痛							2 (2.2)	2	2.74	1 (2.7)	1	6.27
腱鞘炎	1 (1.0)	1	2.84				1 (1.1)	1	1.37			
滑液包炎										1 (2.7)	1	6.27
椎間板突出	1 (1.0)	1	2.84									

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

	Tralokinumab Q2W (n=96)			Tralokinumab Q4W (n=16)			Tralokinumab Q2W + optional TCS (n=89)			Placebo (n=37)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
腰部脊柱管狭窄症	1 (1.0)	1	2.84									
筋痙縮							1 (1.1)	1	1.37	1 (2.7)	1	6.27
頚部痛							1 (1.1)	1	1.37			
変形性関節症	1 (1.0)	1	2.84									
関節周囲炎							1 (1.1)	1	1.37			
変形性脊椎症							1 (1.1)	1	1.37			
滑液嚢腫	1 (1.0)	1	2.84									
腱炎							1 (1.1)	1	1.37			
狭窄性腱鞘炎							1 (1.1)	1	1.37			
傷害、中毒および処置合併症	8 (8.3)	9	25.53	2 (12.5)	2	20.17	9 (10.1)	10	13.71	3 (8.1)	3	18.80
挫傷	2 (2.1)	2	5.67	1 (6.3)	1	10.09	2 (2.2)	2	2.74			
靭帯捻挫	2 (2.1)	2	5.67				1 (1.1)	1	1.37			

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

	Tralokinumab Q2W (n=96)			Tralokinumab Q4W (n=16)			Tralokinumab Q2W + optional TCS (n=89)			Placebo (n=37)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
裂傷	1 (1.0)	1	2.84	1 (6.3)	1	10.09						
アルコール中毒							1 (1.1)	1	1.37			
節足動物刺傷							1 (1.1)	1	1.37			
自律神経異常反射							1 (1.1)	1	1.37			
上顎炎	1 (1.0)	1	2.84									
熱中症	1 (1.0)	1	2.84									
関節脱臼	1 (1.0)	1	2.84									
肋骨骨折							1 (1.1)	1	1.37			
皮膚擦過傷										1 (2.7)	1	6.27
スポーツ損傷										1 (2.7)	1	6.27
サンバーン	1 (1.0)	1	2.84									
子宮頸管裂傷										1 (2.7)	1	6.27
創傷							1 (1.1)	1	1.37			
創合併症							1 (1.1)	1	1.37			
手首関節骨折							1 (1.1)	1	1.37			

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

	Tralokinumab Q2W (n=96)			Tralokinumab Q4W (n=16)			Tralokinumab Q2W + optional TCS (n=89)			Placebo (n=37)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
神経系障害	5 (5.2)	7	19.86				8 (9.0)	9	12.34	3 (8.1)	4	25.06
頭痛	2 (2.1)	3	8.51				2 (2.2)	3	4.11	1 (2.7)	1	6.27
感覚鈍麻	1 (1.0)	1	2.84				1 (1.1)	1	1.37	1 (2.7)	1	6.27
失神寸前の状態							2 (2.2)	2	2.74	1 (2.7)	1	6.27
脱力発作							1 (1.1)	1	1.37			
頚髄神経根障害	1 (1.0)	1	2.84							1 (2.7)	1	6.27
意識レベルの低下	1 (1.0)	1	2.84									
浮動性めまい	1 (1.0)	1	2.84									
片頭痛							1 (1.1)	1	1.37			
第6脳神経麻痺							1 (1.1)	1	1.37			

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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=96) N (%)	E	R	Tralokinumab Q4W (n=16) N (%)	E	R	Tralokinumab Q2W + optional TCS (n=89) N (%)	E	R	Placebo (n=37) N (%)	E	R
呼吸器、胸郭および縦隔障害	7 (7.3)	9	25.53				5 (5.6)	5	6.86			
喘息	3 (3.1)	4	11.35									
口腔咽頭痛	2 (2.1)	3	8.51				1 (1.1)	1	1.37			
アレルギー性鼻炎	1 (1.0)	1	2.84				1 (1.1)	1	1.37			
上気道の炎症	1 (1.0)	1	2.84				1 (1.1)	1	1.37			
咳嗽							1 (1.1)	1	1.37			
呼吸困難							1 (1.1)	1	1.37			
臨床検査	2 (2.1)	2	5.67				8 (9.0)	13	17.83	3 (8.1)	5	31.33
アラニンアミノトランスフェラーゼ増加	1 (1.0)	1	2.84				1 (1.1)	1	1.37	1 (2.7)	1	6.27

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

	Tralokinumab Q2W (n=96)			Tralokinumab Q4W (n=16)			Tralokinumab Q2W + optional TCS (n=89)			Placebo (n=37)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
血中アルカリホスファターゼ増加							2 (2.2)	2	2.74			
血中ビリルビン増加							2 (2.2)	2	2.74			
好酸球数増加	1 (1.0)	1	2.84				1 (1.1)	1	1.37			
アスパラギン酸アミノトランスフェラーゼ増加							1 (1.1)	1	1.37	1 (2.7)	1	6.27
血中免疫グロブリンE増加							1 (1.1)	1	1.37			
血圧上昇							1 (1.1)	1	1.37			
血中トリグリセリド増加							1 (1.1)	1	1.37			
心電図異常T波							1 (1.1)	1	1.37			

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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=96) N (%)	E	R	Tralokinumab Q4W (n=16) N (%)	E	R	Tralokinumab Q2W + optional TCS (n=89) N (%)	E	R	Placebo (n=37) N (%)	E	R
γ-グルタミルトランスフェラーゼ増加							1 (1.1)	1	1.37	1 (2.7)	1	6.27
ヘマトクリット増加										1 (2.7)	1	6.27
肝機能検査値上昇										1 (2.7)	1	6.27
好中球数減少							1 (1.1)	1	1.37			
精神障害	3 (3.1)	3	8.51				6 (6.7)	7	9.60	1 (2.7)	1	6.27
不眠症	3 (3.1)	3	8.51				5 (5.6)	5	6.86			
易刺激性							1 (1.1)	2	2.74			
初期不眠症										1 (2.7)	1	6.27

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

	Tralokinumab Q2W (n=96)			Tralokinumab Q4W (n=16)			Tralokinumab Q2W + optional TCS (n=89)			Placebo (n=37)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
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）	2 (2.1)	2	5.67				6 (6.7)	8	10.97	1 (2.7)	1	6.27
皮膚乳頭腫	2 (2.1)	2	5.67				4 (4.5)	4	5.49	1 (2.7)	1	6.27
大腸腺腫							1 (1.1)	1	1.37			
線維腫							1 (1.1)	1	1.37			
浸潤性乳癌							1 (1.1)	1	1.37			
脂漏性角化症							1 (1.1)	1	1.37			
肝胆道系障害							4 (4.5)	7	9.60			
高ビリルビン血症							2 (2.2)	3	4.11			
肝障害							1 (1.1)	3	4.11			
脂肪肝							1 (1.1)	1	1.37			

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

	Tralokinumab Q2W (n=96)			Tralokinumab Q4W (n=16)			Tralokinumab Q2W + optional TCS (n=89)			Placebo (n=37)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
血管障害	2 (2.1)	2	5.67				2 (2.2)	2	2.74	1 (2.7)	1	6.27
ほてり							2 (2.2)	2	2.74			
高血圧	2 (2.1)	2	5.67							1 (2.7)	1	6.27
心臓障害	1 (1.0)	1	2.84	1 (6.3)	1	10.09						
心房細動	1 (1.0)	1	2.84									
右脚ブロック				1 (6.3)	1	10.09						
代謝および栄養障害	1 (1.0)	1	2.84	1 (6.3)	1	10.09						
脱水	1 (1.0)	1	2.84									
高尿酸血症				1 (6.3)	1	10.09						
血液およびリンパ系障害										1 (2.7)	1	6.27

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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=96) N (%)	E	R	Tralokinumab Q4W (n=16) N (%)	E	R	Tralokinumab Q2W + optional TCS (n=89) N (%)	E	R	Placebo (n=37) N (%)	E	R
リンパ節症										1 (2.7)	1	6.27
内分泌障害										1 (2.7)	1	6.27
ステロイド離脱症候群										1 (2.7)	1	6.27
免疫系障害	1 (1.0)	1	2.84									
季節性アレルギー	1 (1.0)	1	2.84									
腎および尿路障害										1 (2.7)	1	6.27
腎結石症										1 (2.7)	1	6.27
生殖系および乳房障害							1 (1.1)	1	1.37			

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

	Tralokinumab Q2W (n=96)				Tralokinumab Q4W (n=16)				Tralokinumab Q2W + optional TCS (n=89)				Placebo (n=37)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
不規則月経									1	(1.1)	1	1.37				

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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).

1.8.2.1.12　日本人での全ての有害事象：追跡調査期間［Source: Table J 7.117］

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Table J.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=14) N (%)	E	R	Tralokinumab Q4W (n=6) N (%)	E	R	Tralokinumab Q2W + optional TCS (n=43) N (%)	E	R	Placebo (n=5) N (%)	E	R
All AEs	4 (28.6)	5	155.43	1 (16.7)	1	111.36	8 (18.6)	15	188.21			
感染症および寄生虫症	3 (21.4)	3	93.26	1 (16.7)	1	111.36	4 (9.3)	4	50.19			
骨膿瘍							1 (2.3)	1	12.55			
気管支炎	1 (7.1)	1	31.09									
丹毒	1 (7.1)	1	31.09									
単純ヘルペス							1 (2.3)	1	12.55			
インフルエンザ							1 (2.3)	1	12.55			
口腔ヘルペス							1 (2.3)	1	12.55			
皮下組織膿瘍	1 (7.1)	1	31.09									
ウイルス性上気道感染				1 (16.7)	1	111.36						

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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=14) N (%)	E	R	Tralokinumab Q4W (n=6) N (%)	E	R	Tralokinumab Q2W + optional TCS (n=43) N (%)	E	R	Placebo (n=5) N (%)	E	R
皮膚および皮下組織障害	2 (14.3)	2	62.17				2 (4.7)	2	25.09			
アトピー性皮膚炎	2 (14.3)	2	62.17				2 (4.7)	2	25.09			
眼障害							1 (2.3)	1	12.55			
アレルギー性結膜炎							1 (2.3)	1	12.55			
一般・全身障害および投与部位の状態							1 (2.3)	1	12.55			
血管穿刺部位内出血							1 (2.3)	1	12.55			

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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=14) N (%)	E	R	Tralokinumab Q4W (n=6) N (%)	E	R	Tralokinumab Q2W + optional TCS (n=43) N (%)	E	R	Placebo (n=5) N (%)	E	R
肝胆道系障害							1 (2.3)	1	12.55			
肝機能異常							1 (2.3)	1	12.55			
傷害、中毒および処置合併症							1 (2.3)	1	12.55			
熱傷							1 (2.3)	1	12.55			
臨床検査							1 (2.3)	1	12.55			
肝酵素上昇							1 (2.3)	1	12.55			
精神障害							1 (2.3)	2	25.09			
不眠症							1 (2.3)	1	12.55			

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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=14) N (%)	E	R	Tralokinumab Q4W (n=6) N (%)	E	R	Tralokinumab Q2W + optional TCS (n=43) N (%)	E	R	Placebo (n=5) N (%)	E	R
神経症							1 (2.3)	1	12.55			
生殖系および乳房障害							1 (2.3)	1	12.55			
閉経期症状							1 (2.3)	1	12.55			
呼吸器、胸郭および縦隔障害							1 (2.3)	1	12.55			
喘息							1 (2.3)	1	12.55			

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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.

1.8.2.1.13　日本人での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 J 7.4］

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Table J.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=96) N (%)	E	R	Placebo (n=31) N (%)	E	R
All AEs	32 (33.3)	47	163.50	15 (48.4)	28	293.81
Treatment comparison, p-value	0.0168					
皮膚および皮下組織障害	18 (18.8)	18	62.62	9 (29.0)	11	115.42
アトピー性皮膚炎	15 (15.6)	15	52.18	8 (25.8)	10	104.93
脱毛症	1 (1.0)	1	3.48			
円形脱毛症	1 (1.0)	1	3.48			
皮膚嚢腫				1 (3.2)	1	10.49
接触皮膚炎	1 (1.0)	1	3.48			
感染症および寄生虫症	8 (8.3)	8	27.83	4 (12.9)	7	73.45
結膜炎	3 (3.1)	3	10.44	1 (3.2)	1	10.49
咽頭炎	1 (1.0)	1	3.48	1 (3.2)	2	20.99
ヘルペス性状湿疹	1 (1.0)	1	3.48	1 (3.2)	1	10.49
膿痂疹	1 (1.0)	1	3.48			
鼻咽頭炎	1 (1.0)	1	3.48			
口腔ヘルペス				1 (3.2)	1	10.49
肺炎				1 (3.2)	1	10.49

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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=96) N (%)	E	R	Placebo (n=31) N (%)	E	R
腎盂腎炎				1 (3.2)	1	10.49
上気道感染	1 (1.0)	1	3.48			
一般・全身障害および投与部位の状態	9 (9.4)	15	52.18	1 (3.2)	4	41.97
注射部位反応	5 (5.2)	8	27.83			
発熱	2 (2.1)	2	6.96	1 (3.2)	4	41.97
注射部位紅斑	1 (1.0)	4	13.92			
注射部位過敏反応	1 (1.0)	1	3.48			
眼障害	3 (3.1)	3	10.44	1 (3.2)	1	10.49
眼瞼炎	2 (2.1)	2	6.96			
アトピー性角結膜炎	1 (1.0)	1	3.48			
強膜炎				1 (3.2)	1	10.49
臨床検査	1 (1.0)	1	3.48	1 (3.2)	3	31.48
アラニンアミノトランスフェラーゼ増加				1 (3.2)	1	10.49
アスパラギン酸アミノトランスフェラーゼ増加				1 (3.2)	1	10.49
好酸球数増加	1 (1.0)	1	3.48			
γ-グルタミルトランスフェラーゼ増加				1 (3.2)	1	10.49

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

	Tralokinumab Q2W (n=96)			Placebo (n=31)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R
胃腸障害				1 (3.2)	1	10.49
下痢				1 (3.2)	1	10.49
筋骨格系および結合組織障害				1 (3.2)	1	10.49
筋痙縮				1 (3.2)	1	10.49
精神障害	1 (1.0)	1	3.48			
不眠症	1 (1.0)	1	3.48			
呼吸器、胸郭および縦隔障害	1 (1.0)	1	3.48			
喘息	1 (1.0)	1	3.48			

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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.

1.8.2.1.14　日本人での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 J 7.33］

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Table J.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=11)				Tralokinumab Q4W (n=16)				Placebo (n=6)				Placebo (n=6)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
All AEs	4	(36.4)	6	92.28	5	(31.3)	16	161.36	4	(66.7)	4	112.84	3	(50.0)	3	104.00
皮膚および皮下組織障害	2	(18.2)	3	46.14	1	(6.3)	2	20.17	3	(50.0)	3	84.63	2	(33.3)	2	69.33
アトピー性皮膚炎	2	(18.2)	2	30.76					3	(50.0)	3	84.63	2	(33.3)	2	69.33
円形脱毛症					1	(6.3)	2	20.17								
紅斑	1	(9.1)	1	15.38												
眼障害	2	(18.2)	2	30.76					1	(16.7)	1	28.21				
アレルギー性結膜炎	1	(9.1)	1	15.38					1	(16.7)	1	28.21				
潰瘍性角膜炎	1	(9.1)	1	15.38												

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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=11)				Tralokinumab Q4W (n=16)				Placebo (n=6)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
一般・全身障害および投与部位の状態					3	(18.8)	11	110.94				
注射部位反応					2	(12.5)	10	100.85				
注射部位紅斑					1	(6.3)	1	10.09				
感染症および寄生虫症					1	(6.3)	2	20.17				
単純ヘルペス					1	(6.3)	1	10.09				
口腔ヘルペス					1	(6.3)	1	10.09				
心臓障害					1	(6.3)	1	10.09				

	Week 16 Placebo responders			
	Placebo (n=6)			
System Organ Class (SOC) Preferred term	N	(%)	E	R
扁桃炎	1	(16.7)	1	34.67

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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=11)				Tralokinumab Q4W (n=16)				Placebo (n=6)				Placebo (n=6)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
右脚ブロック					1	(6.3)	1	10.09								
臨床検査	1	(9.1)	1	15.38												
アラニンアミノトランスフェラーゼ増加	1	(9.1)	1	15.38												

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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).

1.8.2.1.15　日本人での治験薬と因果関係が否定できない有害事象：非盲験期間［Source: Table J 7.66］

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Table J.7.66: Table 300520: Related AEs by SOC and preferred term, entire treatment period: safety analysis set

	Tralokinumab Q2W (n=96)			Tralokinumab Q4W (n=16)			Tralokinumab Q2W + optional TCS (n=89)			Placebo (n=37)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
All AEs	34 (35.4)	53	150.37	5 (31.3)	16	161.36	37 (41.6)	103	141.24	22 (59.5)	35	219.30
皮膚および皮下組織障害	19 (19.8)	21	59.58	1 (6.3)	2	20.17	13 (14.6)	18	24.68	14 (37.8)	16	100.25
アトピー性皮膚炎	16 (16.7)	17	48.23				10 (11.2)	12	16.46	13 (35.1)	15	93.99
円形脱毛症	1 (1.0)	1	2.84	1 (6.3)	2	20.17						
接触皮膚炎	1 (1.0)	1	2.84				2 (2.2)	2	2.74			
ざ瘡							1 (1.1)	1	1.37			
脱毛症	1 (1.0)	1	2.84									
皮膚嚢腫										1 (2.7)	1	6.27
皮膚筋炎							1 (1.1)	1	1.37			
紅斑	1 (1.0)	1	2.84									
寝汗							1 (1.1)	1	1.37			
蕁麻疹							1 (1.1)	1	1.37			

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Table 300520: Related AEs by SOC and preferred term, entire treatment period: safety analysis set

	Tralokinumab Q2W (n=96)			Tralokinumab Q4W (n=16)			Tralokinumab Q2W + optional TCS (n=89)			Placebo (n=37)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
感染症および寄生虫症	8 (8.3)	8	22.70	1 (6.3)	2	20.17	17 (19.1)	25	34.28	5 (13.5)	8	50.13
結膜炎	3 (3.1)	3	8.51				2 (2.2)	3	4.11	1 (2.7)	1	6.27
ウイルス性上気道感染							4 (4.5)	4	5.49			
毛包炎							2 (2.2)	2	2.74			
せつ							1 (1.1)	2	2.74			
単純ヘルペス				1 (6.3)	1	10.09	1 (1.1)	1	1.37			
帯状疱疹							1 (1.1)	2	2.74			
外耳炎							2 (2.2)	2	2.74			
四肢膿瘍							1 (1.1)	1	1.37			
蜂巣炎							1 (1.1)	1	1.37			
膀胱炎							1 (1.1)	1	1.37			
ヘルペス性状湿疹	1 (1.0)	1	2.84							1 (2.7)	1	6.27
胃腸炎							1 (1.1)	1	1.37			
陰部単純ヘルペス							1 (1.1)	1	1.37			

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Table 300520: Related AEs by SOC and preferred term, entire treatment period: safety analysis set

	Tralokinumab Q2W (n=96)			Tralokinumab Q4W (n=16)			Tralokinumab Q2W + optional TCS (n=89)			Placebo (n=37)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
歯肉炎							1 (1.1)	1	1.37			
膿痂疹	1 (1.0)	1	2.84									
鼻咽頭炎	1 (1.0)	1	2.84									
口腔ヘルペス				1 (6.3)	1	10.09				1 (2.7)	1	6.27
中耳炎							1 (1.1)	1	1.37			
咽頭炎	1 (1.0)	1	2.84							1 (2.7)	2	12.53
肺炎										1 (2.7)	1	6.27
腎盂腎炎										1 (2.7)	1	6.27
皮膚細菌感染							1 (1.1)	1	1.37			
足部白癬							1 (1.1)	1	1.37			
扁桃炎										1 (2.7)	1	6.27
上気道感染	1 (1.0)	1	2.84									

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Table 300520: Related AEs by SOC and preferred term, entire treatment period: safety analysis set

	Tralokinumab Q2W (n=96)			Tralokinumab Q4W (n=16)			Tralokinumab Q2W + optional TCS (n=89)			Placebo (n=37)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
一般・全身障害および投与部位の状態	9 (9.4)	15	42.56	3 (18.8)	11	110.94	9 (10.1)	40	54.85	1 (2.7)	4	25.06
注射部位反応	5 (5.2)	8	22.70	2 (12.5)	10	100.85	6 (6.7)	19	26.05			
注射部位紅斑	1 (1.0)	4	11.35	1 (6.3)	1	10.09	2 (2.2)	12	16.46			
注射部位腫脹							1 (1.1)	8	10.97			
発熱	2 (2.1)	2	5.67							1 (2.7)	4	25.06
注射部位過敏反応	1 (1.0)	1	2.84									
倦怠感							1 (1.1)	1	1.37			
眼障害	5 (5.2)	5	14.19				5 (5.6)	5	6.86	2 (5.4)	2	12.53

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Table 300520: Related AEs by SOC and preferred term, entire treatment period: safety analysis set

	Tralokinumab Q2W (n=96)			Tralokinumab Q4W (n=16)			Tralokinumab Q2W + optional TCS (n=89)			Placebo (n=37)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
アレルギー性結膜炎	1 (1.0)	1	2.84				2 (2.2)	2	2.74	1 (2.7)	1	6.27
眼瞼炎	2 (2.1)	2	5.67									
アトピー性角結膜炎	1 (1.0)	1	2.84									
眼乾燥							1 (1.1)	1	1.37			
眼脂							1 (1.1)	1	1.37			
角膜炎							1 (1.1)	1	1.37			
強膜炎										1 (2.7)	1	6.27
潰瘍性角膜炎	1 (1.0)	1	2.84									
臨床検査	2 (2.1)	2	5.67				6 (6.7)	7	9.60	1 (2.7)	3	18.80
血中アルカリホスファターゼ増加							2 (2.2)	2	2.74			
好酸球数増加	1 (1.0)	1	2.84				1 (1.1)	1	1.37			

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Table 300520: Related AEs by SOC and preferred term, entire treatment period: safety analysis set

System Organ Class (SOC) Preferred term	Tralokinumab Q2W (n=96) N (%)	E	R	Tralokinumab Q4W (n=16) N (%)	E	R	Tralokinumab Q2W + optional TCS (n=89) N (%)	E	R	Placebo (n=37) N (%)	E	R
アラニンアミノトランスフェラーゼ増加	1 (1.0)	1	2.84							1 (2.7)	1	6.27
アスパラギン酸アミノトランスフェラーゼ増加										1 (2.7)	1	6.27
血中ビリルビン増加							1 (1.1)	1	1.37			
血中免疫グロブリンE増加							1 (1.1)	1	1.37			
心電図異常T波							1 (1.1)	1	1.37			
γ-グルタミルトランスフェラーゼ増加										1 (2.7)	1	6.27
好中球数減少							1 (1.1)	1	1.37			

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Table 300520: Related AEs by SOC and preferred term, entire treatment period: safety analysis set

System Organ Class (SOC) Preferred term	Tralokinumab Q2W (n=96) N (%)	E	R	Tralokinumab Q4W (n=16) N (%)	E	R	Tralokinumab Q2W + optional TCS (n=89) N (%)	E	R	Placebo (n=37) N (%)	E	R
胃腸障害							4 (4.5)	4	5.49	1 (2.7)	1	6.27
下痢										1 (2.7)	1	6.27
腸炎							1 (1.1)	1	1.37			
胃潰瘍							1 (1.1)	1	1.37			
悪心							1 (1.1)	1	1.37			
口内炎							1 (1.1)	1	1.37			
精神障害	1 (1.0)	1	2.84				1 (1.1)	1	1.37			
不眠症	1 (1.0)	1	2.84									
易刺激性							1 (1.1)	1	1.37			
心臓障害				1 (6.3)	1	10.09						
右脚ブロック				1 (6.3)	1	10.09						

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Table 300520: Related AEs by SOC and preferred term, entire treatment period: safety analysis set

System Organ Class (SOC) Preferred term	Tralokinumab Q2W (n=96) N (%)	E	R	Tralokinumab Q4W (n=16) N (%)	E	R	Tralokinumab Q2W + optional TCS (n=89) N (%)	E	R	Placebo (n=37) N (%)	E	R
筋骨格系および結合組織障害							1 (1.1)	1	1.37	1 (2.7)	1	6.27
背部痛							1 (1.1)	1	1.37			
筋痙縮										1 (2.7)	1	6.27
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）							1 (1.1)	1	1.37			
浸潤性乳癌							1 (1.1)	1	1.37			

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Table 300520: Related AEs by SOC and preferred term, entire treatment period: safety analysis set

	Tralokinumab Q2W (n=96)				Tralokinumab Q4W (n=16)				Tralokinumab Q2W + optional TCS (n=89)				Placebo (n=37)			
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	1.37				
片頭痛									1	(1.1)	1	1.37				
呼吸器、胸郭および縦隔障害	1	(1.0)	1	2.84												
喘息	1	(1.0)	1	2.84												

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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).

1.8.2.1.16　日本人での治験薬との因果関係が否定できない有害事象：追跡調査期間

［Source: Table J 7.118］

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Table J.7.118: Table 300940: Related AEs by SOC and preferred term, follow-up period: safety follow-up analysis set

	Tralokinumab Q2W (n=14)			Tralokinumab Q4W (n=6)			Tralokinumab Q2W + optional TCS (n=43)			Placebo (n=5)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
All AEs	2 (14.3)	2	62.17				1 (2.3)	1	12.55			
感染症および寄生虫症	1 (7.1)	1	31.09									
丹毒	1 (7.1)	1	31.09									
生殖系および乳房障害							1 (2.3)	1	12.55			
閉経期症状							1 (2.3)	1	12.55			
皮膚および皮下組織障害	1 (7.1)	1	31.09									
アトピー性皮膚炎	1 (7.1)	1	31.09									

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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.