1.9.2.1.2 **全ての有害事象：維持投与期間**［Source: Table 7.32］

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Table 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=91)				Tralokinumab Q4W (n=89)				Placebo (n=46)				Placebo (n=31)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
All AEs	62	(68.1)	209	445.39	56	(62.9)	154	344.88	32	(69.6)	99	493.34	15	(48.4)	36	238.60
感染症および寄生虫症	37	(40.7)	63	134.26	31	(34.8)	41	91.82	18	(39.1)	21	104.65	10	(32.3)	17	112.67
上気道感染	14	(15.4)	18	38.36	9	(10.1)	12	26.87	3	(6.5)	3	14.95	2	(6.5)	2	13.26
ウイルス性上気道感染	9	(9.9)	10	21.31	6	(6.7)	6	13.44	7	(15.2)	7	34.88	4	(12.9)	7	46.39
結膜炎	5	(5.5)	8	17.05	1	(1.1)	1	2.24	2	(4.3)	2	9.97	1	(3.2)	1	6.63
鼻咽頭炎	3	(3.3)	4	8.52	2	(2.2)	2	4.48								
気管支炎	1	(1.1)	1	2.13	3	(3.4)	3	6.72					1	(3.2)	1	6.63
口腔ヘルペス	1	(1.1)	2	4.26					1	(2.2)	1	4.98	2	(6.5)	2	13.26
インフルエンザ	2	(2.2)	2	4.26	1	(1.1)	1	2.24	1	(2.2)	1	4.98				
胃腸炎					3	(3.4)	3	6.72								
皮膚感染	2	(2.2)	2	4.26					1	(2.2)	1	4.98				
膿瘍									2	(4.3)	2	9.97				
感染性皮膚炎					1	(1.1)	2	4.48								

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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=91)				Tralokinumab Q4W (n=89)				Placebo (n=46)				Placebo (n=31)			
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	(1.1)	1	2.13									1	(3.2)	1	6.63
せつ	1	(1.1)	1	2.13	1	(1.1)	1	2.24								
下気道感染	1	(1.1)	1	2.13	1	(1.1)	1	2.24								
鼻炎	1	(1.1)	1	2.13					1	(2.2)	1	4.98				
尿路感染	1	(1.1)	1	2.13	1	(1.1)	1	2.24								
細菌性疾患キャリアー					1	(1.1)	1	2.24								
よう									1	(2.2)	1	4.98				
蜂巣炎													1	(3.2)	1	6.63
クラミジア感染					1	(1.1)	1	2.24								
細菌性結膜炎	1	(1.1)	1	2.13												
ウイルス性結膜炎					1	(1.1)	1	2.24								
毛包炎	1	(1.1)	1	2.13												
消化管感染	1	(1.1)	1	2.13												
歯肉炎	1	(1.1)	1	2.13												
単純ヘルペス					1	(1.1)	1	2.24								

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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=91)				Tralokinumab Q4W (n=89)				Placebo (n=46)				Placebo (n=31)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
麦粒腫	1	(1.1)	1	2.13												
伝染性軟属腫	1	(1.1)	1	2.13												
鼻ヘルペス													1	(3.2)	1	6.63
口腔カンジダ症	1	(1.1)	1	2.13												
乳頭腫ウイルス感染									1	(2.2)	1	4.98				
咽頭炎	1	(1.1)	1	2.13												
毛巣嚢胞					1	(1.1)	1	2.24								
肺炎					1	(1.1)	1	2.24								
歯髄炎					1	(1.1)	1	2.24								
副鼻腔炎	1	(1.1)	1	2.13												
癜風	1	(1.1)	1	2.13												
歯感染													1	(3.2)	1	6.63
膣感染					1	(1.1)	1	2.24								
ウイルス感染	1	(1.1)	1	2.13												
外陰膣真菌感染									1	(2.2)	1	4.98				

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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=91)				Tralokinumab Q4W (n=89)				Placebo (n=46)				Placebo (n=31)			
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	19	(20.9)	34	72.46	18	(20.2)	27	60.47	11	(23.9)	26	129.56	3	(9.7)	3	19.88
アトピー性皮膚炎	13	(14.3)	25	53.28	14	(15.7)	19	42.55	9	(19.6)	16	79.73	2	(6.5)	2	13.26
そう痒症	2	(2.2)	2	4.26	2	(2.2)	2	4.48	2	(4.3)	3	14.95				
皮膚疼痛					1	(1.1)	1	2.24	1	(2.2)	3	14.95				
ざ瘡					2	(2.2)	3	6.72								
皮膚嚢腫	1	(1.1)	1	2.13									1	(3.2)	1	6.63
蕁麻疹	2	(2.2)	2	4.26												
光線角化症					1	(1.1)	1	2.24								
脱毛症	1	(1.1)	1	2.13												
円形脱毛症	1	(1.1)	1	2.13												
接触皮膚炎	1	(1.1)	1	2.13												
皮膚乾燥									1	(2.2)	1	4.98				
異汗性湿疹									1	(2.2)	1	4.98				
過角化	1	(1.1)	1	2.13												
神経皮膚炎									1	(2.2)	1	4.98				
点状出血									1	(2.2)	1	4.98				

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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=91)				Tralokinumab Q4W (n=89)				Placebo (n=46)				Placebo (n=31)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
皮膚色素減少					1	(1.1)	1	2.24								
一般・全身障害および投与部位の状態	13	(14.3)	43	91.63	7	(7.9)	9	20.16	2	(4.3)	5	24.92	2	(6.5)	2	13.26
注射部位反応	4	(4.4)	12	25.57	4	(4.5)	4	8.96								
注射部位疼痛	3	(3.3)	7	14.92					1	(2.2)	4	19.93				
注射部位腫脹	2	(2.2)	8	17.05												
注射部位紅斑	3	(3.3)	4	8.52	2	(2.2)	2	4.48								
注射部位出血	1	(1.1)	3	6.39												
注射部位そう痒感	2	(2.2)	2	4.26	1	(1.1)	1	2.24								

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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=91)				Tralokinumab Q4W (n=89)				Placebo (n=46)				Placebo (n=31)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
無力症					1	(1.1)	1	2.24					1	(3.2)	1	6.63
発熱	1	(1.1)	1	2.13					1	(2.2)	1	4.98				
胸痛	1	(1.1)	1	2.13												
疲労	1	(1.1)	1	2.13												
インフルエンザ様疾患	1	(1.1)	1	2.13												
注射部位内出血													1	(3.2)	1	6.63
注射部位過敏反応					1	(1.1)	1	2.24								
注射部位浮腫	1	(1.1)	1	2.13												
注射部位発疹	1	(1.1)	1	2.13												
末梢腫脹	1	(1.1)	1	2.13												

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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=91)				Tralokinumab Q4W (n=89)				Placebo (n=46)				Placebo (n=31)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
呼吸器、胸郭および縦隔障害	7	(7.7)	7	14.92	12	(13.5)	13	29.11	4	(8.7)	6	29.90				
喘息	2	(2.2)	2	4.26	3	(3.4)	4	8.96	3	(6.5)	4	19.93				
咳嗽	2	(2.2)	2	4.26	2	(2.2)	2	4.48	1	(2.2)	2	9.97				
口腔咽頭痛	1	(1.1)	1	2.13	2	(2.2)	2	4.48								
鼻出血					2	(2.2)	2	4.48								
アレルギー性鼻炎	1	(1.1)	1	2.13	1	(1.1)	1	2.24								
副鼻腔うっ血					2	(2.2)	2	4.48								
鼻閉	1	(1.1)	1	2.13												
傷害、中毒および処置合併症	9	(9.9)	11	23.44	4	(4.5)	4	8.96	4	(8.7)	6	29.90	4	(12.9)	4	26.51

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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=91)				Tralokinumab Q4W (n=89)				Placebo (n=46)				Placebo (n=31)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
靭帯捻挫	3	(3.3)	4	8.52	1	(1.1)	1	2.24	1	(2.2)	1	4.98				
不適切な薬剤投与計画	1	(1.1)	1	2.13					1	(2.2)	1	4.98	1	(3.2)	1	6.63
四肢損傷	1	(1.1)	1	2.13	1	(1.1)	1	2.24					1	(3.2)	1	6.63
サンバーン	1	(1.1)	1	2.13	1	(1.1)	1	2.24	1	(2.2)	1	4.98				
転倒									2	(4.3)	2	9.97				
他の患者への薬剤誤投与	2	(2.2)	2	4.26												
関節脱臼					1	(1.1)	1	2.24								
肉離れ	1	(1.1)	1	2.13												
神経損傷									1	(2.2)	1	4.98				
滑膜断裂	1	(1.1)	1	2.13												
熱傷													1	(3.2)	1	6.63
歯牙破折													1	(3.2)	1	6.63
眼障害	4	(4.4)	5	10.66	9	(10.1)	9	20.16	6	(13.0)	12	59.80				
アレルギー性結膜炎	2	(2.2)	2	4.26	3	(3.4)	3	6.72	1	(2.2)	1	4.98				

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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=91)				Tralokinumab Q4W (n=89)				Placebo (n=46)				Placebo (n=31)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
眼乾燥	1	(1.1)	1	2.13					3	(6.5)	4	19.93				
眼瞼炎					2	(2.2)	2	4.48								
白内障					1	(1.1)	1	2.24								
網脈絡膜症	1	(1.1)	1	2.13												
眼瞼湿疹									1	(2.2)	1	4.98				
眼そう痒症									1	(2.2)	1	4.98				
眼瞼浮腫					1	(1.1)	1	2.24								
眼瞼そう痒症					1	(1.1)	1	2.24								
緑内障									1	(2.2)	1	4.98				
角膜炎	1	(1.1)	1	2.13												
角膜症									1	(2.2)	1	4.98				
涙液分泌低下									1	(2.2)	1	4.98				
マイボーム腺機能不全									1	(2.2)	1	4.98				
高眼圧症					1	(1.1)	1	2.24								
霧視									1	(2.2)	1	4.98				
臨床検査	5	(5.5)	7	14.92	7	(7.9)	11	24.63	2	(4.3)	4	19.93	1	(3.2)	6	39.77

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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=91)				Tralokinumab Q4W (n=89)				Placebo (n=46)				Placebo (n=31)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
アラニンアミノトランスフェラーゼ増加					2	(2.2)	3	6.72					1	(3.2)	3	19.88
血中トリグリセリド増加	1	(1.1)	1	2.13	1	(1.1)	2	4.48								
低比重リポ蛋白増加					2	(2.2)	2	4.48	1	(2.2)	1	4.98				
肝機能検査異常	1	(1.1)	1	2.13	1	(1.1)	1	2.24								
血中アルカリホスファターゼ減少													1	(3.2)	1	6.63
血中乳酸脱水素酵素増加									1	(2.2)	1	4.98				
血中カリウム増加													1	(3.2)	1	6.63
血圧低下					1	(1.1)	1	2.24								

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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=91)				Tralokinumab Q4W (n=89)				Placebo (n=46)				Placebo (n=31)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
血中尿素減少									1	(2.2)	1	4.98				
尿中血陽性	1	(1.1)	1	2.13												
好酸球数増加	1	(1.1)	1	2.13												
γ－グルタミルトランスフェラーゼ増加	1	(1.1)	1	2.13												
肝酵素上昇					1	(1.1)	1	2.24								
肝機能検査値上昇					1	(1.1)	1	2.24								
リンパ球数減少													1	(3.2)	1	6.63
好中球数増加	1	(1.1)	1	2.13												
尿中蛋白陽性	1	(1.1)	1	2.13												
トランスアミナーゼ上昇									1	(2.2)	1	4.98				

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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=91)				Tralokinumab Q4W (n=89)				Placebo (n=46)				Placebo (n=31)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
筋骨格系および結合組織障害	8	(8.8)	14	29.83	4	(4.5)	5	11.20	2	(4.3)	2	9.97	1	(3.2)	1	6.63
関節痛	3	(3.3)	7	14.92	1	(1.1)	2	4.48								
背部痛	3	(3.3)	5	10.66	2	(2.2)	2	4.48								
肩回旋筋腱板症候群	1	(1.1)	1	2.13					1	(2.2)	1	4.98				
外骨腫					1	(1.1)	1	2.24								
関節腫脹									1	(2.2)	1	4.98				
筋骨格痛	1	(1.1)	1	2.13												
四肢痛													1	(3.2)	1	6.63
胃腸障害	4	(4.4)	4	8.52	4	(4.5)	4	8.96	3	(6.5)	5	24.92				
悪心					1	(1.1)	1	2.24	1	(2.2)	2	9.97				
便秘									2	(4.3)	2	9.97				

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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=91)				Tralokinumab Q4W (n=89)				Placebo (n=46)				Placebo (n=31)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
腹痛					1	(1.1)	1	2.24								
上腹部痛					1	(1.1)	1	2.24								
アフタ性潰瘍	1	(1.1)	1	2.13												
下痢									1	(2.2)	1	4.98				
痔核	1	(1.1)	1	2.13												
舌潰瘍					1	(1.1)	1	2.24								
歯痛	1	(1.1)	1	2.13												
嘔吐	1	(1.1)	1	2.13												
神経系障害	6	(6.6)	6	12.79	5	(5.6)	6	13.44								
頭痛	2	(2.2)	2	4.26	2	(2.2)	2	4.48								
浮動性めまい	1	(1.1)	1	2.13	1	(1.1)	1	2.24								
中枢神経系の炎症	1	(1.1)	1	2.13												
不全片麻痺					1	(1.1)	1	2.24								
嗜眠	1	(1.1)	1	2.13												
片頭痛	1	(1.1)	1	2.13												

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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=91)				Tralokinumab Q4W (n=89)				Placebo (n=46)				Placebo (n=31)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
副鼻腔炎に伴う頭痛					1	(1.1)	1	2.24								
失神					1	(1.1)	1	2.24								
免疫系障害	3	(3.3)	3	6.39	4	(4.5)	4	8.96	1	(2.2)	1	4.98				
季節性アレルギー	2	(2.2)	2	4.26	4	(4.5)	4	8.96								
動物アレルギー									1	(2.2)	1	4.98				
節足動物咬傷アレルギー	1	(1.1)	1	2.13												
精神障害	2	(2.2)	2	4.26	4	(4.5)	5	11.20	1	(2.2)	1	4.98	1	(3.2)	1	6.63
不安	1	(1.1)	1	2.13	1	(1.1)	1	2.24								
パニック発作					2	(2.2)	2	4.48								
抑うつ気分	1	(1.1)	1	2.13												
うつ病					1	(1.1)	1	2.24								
不眠症									1	(2.2)	1	4.98				
統合失調症					1	(1.1)	1	2.24								
睡眠障害													1	(3.2)	1	6.63

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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=91)				Tralokinumab Q4W (n=89)				Placebo (n=46)				Placebo (n=31)			
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	(1.1)	1	2.13	4	(4.5)	6	13.44	1	(2.2)	1	4.98	1	(3.2)	1	6.63
高カリウム血症					2	(2.2)	2	4.48								
痛風									1	(2.2)	1	4.98				
高コレステロール血症					1	(1.1)	1	2.24								
高脂血症	1	(1.1)	1	2.13												
高トリグリセリド血症					1	(1.1)	1	2.24								
低カルシウム血症													1	(3.2)	1	6.63
2型糖尿病					1	(1.1)	1	2.24								
ビタミンD欠乏					1	(1.1)	1	2.24								

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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=91)				Tralokinumab Q4W (n=89)				Placebo (n=46)				Placebo (n=31)			
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）	1	(1.1)	1	2.13	5	(5.6)	5	11.20								
皮膚乳頭腫					2	(2.2)	2	4.48								
肛門性器疣贅					1	(1.1)	1	2.24								
甲状腺の良性新生物	1	(1.1)	1	2.13												
乳頭様甲状腺癌					1	(1.1)	1	2.24								
皮膚有棘細胞癌					1	(1.1)	1	2.24								
血管障害	1	(1.1)	1	2.13	1	(1.1)	1	2.24	3	(6.5)	3	14.95				
高血圧	1	(1.1)	1	2.13	1	(1.1)	1	2.24	3	(6.5)	3	14.95				

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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=91)				Tralokinumab Q4W (n=89)				Placebo (n=46)				Placebo (n=31)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
血液およびリンパ系障害	1	(1.1)	1	2.13	2	(2.2)	3	6.72	1	(2.2)	1	4.98				
リンパ節症					2	(2.2)	3	6.72								
好酸球増加症	1	(1.1)	1	2.13					1	(2.2)	1	4.98				
生殖系および乳房障害	1	(1.1)	2	4.26					2	(4.3)	2	9.97				
月経困難症	1	(1.1)	2	4.26												
女性化乳房									1	(2.2)	1	4.98				
膣出血									1	(2.2)	1	4.98				
心臓障害									1	(2.2)	1	4.98	1	(3.2)	1	6.63
心房粗動													1	(3.2)	1	6.63
動悸									1	(2.2)	1	4.98				

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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=91)				Tralokinumab Q4W (n=89)				Placebo (n=46)				Placebo (n=31)			
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	(2.2)	2	4.26												
耳介腫脹	1	(1.1)	1	2.13												
乗物酔い	1	(1.1)	1	2.13												
肝胆道系障害	1	(1.1)	1	2.13	1	(1.1)	1	2.24								
高ビリルビン血症	1	(1.1)	1	2.13	1	(1.1)	1	2.24								
腎および尿路障害	1	(1.1)	1	2.13					1	(2.2)	1	4.98				
緊張性膀胱									1	(2.2)	1	4.98				
腎機能障害	1	(1.1)	1	2.13												
内分泌障害									1	(2.2)	1	4.98				
バセドウ病									1	(2.2)	1	4.98				

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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).

1.9.2.1.3 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=592)				Tralokinumab Q4W (n=89)				Tralokinumab Q2W + optional TCS (n=558)				Placebo (n=246)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
All AEs	383	(64.7)	1206	538.81	56	(62.9)	154	344.88	379	(67.9)	1240	393.05	172	(69.9)	543	587.03
感染症および寄生虫症	205	(34.6)	327	146.09	31	(34.8)	41	91.82	227	(40.7)	381	120.77	102	(41.5)	157	169.73
上気道感染	66	(11.1)	83	37.08	9	(10.1)	12	26.87	65	(11.6)	87	27.58	22	(8.9)	22	23.78
ウイルス性上気道感染	56	(9.5)	62	27.70	6	(6.7)	6	13.44	58	(10.4)	83	26.31	28	(11.4)	33	35.68
結膜炎	23	(3.9)	29	12.96	1	(1.1)	1	2.24	22	(3.9)	23	7.29	6	(2.4)	6	6.49
皮膚感染	14	(2.4)	15	6.70					11	(2.0)	13	4.12	12	(4.9)	12	12.97
胃腸炎	8	(1.4)	8	3.57	3	(3.4)	3	6.72	14	(2.5)	14	4.44	3	(1.2)	3	3.24
単純ヘルペス	8	(1.4)	10	4.47	1	(1.1)	1	2.24	7	(1.3)	11	3.49	2	(0.8)	2	2.16
尿路感染	6	(1.0)	7	3.13	1	(1.1)	1	2.24	7	(1.3)	8	2.54	1	(0.4)	1	1.08
鼻炎	4	(0.7)	5	2.23					9	(1.6)	10	3.17	2	(0.8)	3	3.24
感染性皮膚炎	5	(0.8)	5	2.23	1	(1.1)	2	4.48	5	(0.9)	6	1.90	5	(2.0)	7	7.57
帯状疱疹	4	(0.7)	4	1.79					8	(1.4)	8	2.54	1	(0.4)	1	1.08

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

	Tralokinumab Q2W (n=592)			Tralokinumab Q4W (n=89)			Tralokinumab Q2W + optional TCS (n=558)			Placebo (n=246)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
鼻咽頭炎	7 (1.2)	8	3.57	2 (2.2)	2	4.48	2 (0.4)	2	0.63	1 (0.4)	1	1.08
口腔ヘルペス	4 (0.7)	5	2.23				7 (1.3)	7	2.22	7 (2.8)	7	7.57
インフルエンザ	5 (0.8)	5	2.23	1 (1.1)	1	2.24	4 (0.7)	5	1.58	5 (2.0)	5	5.41
下気道感染	3 (0.5)	3	1.34	1 (1.1)	1	2.24	6 (1.1)	6	1.90	1 (0.4)	1	1.08
咽頭炎	5 (0.8)	5	2.23				5 (0.9)	5	1.58			
せつ	3 (0.5)	3	1.34	1 (1.1)	1	2.24	4 (0.7)	5	1.58			
ウイルス性胃腸炎	4 (0.7)	4	1.79				5 (0.9)	5	1.58	3 (1.2)	3	3.24
蜂巣炎	1 (0.2)	1	0.45				7 (1.3)	7	2.22	2 (0.8)	3	3.24
膿痂疹	3 (0.5)	5	2.23				3 (0.5)	3	0.95	2 (0.8)	2	2.16
気管支炎	1 (0.2)	1	0.45	3 (3.4)	3	6.72	3 (0.5)	3	0.95	1 (0.4)	1	1.08
毛包炎	7 (1.2)	7	3.13							2 (0.8)	2	2.16
副鼻腔炎	3 (0.5)	3	1.34				3 (0.5)	3	0.95			
ヘルペス性状湿疹	3 (0.5)	3	1.34				2 (0.4)	2	0.63	6 (2.4)	6	6.49
伝染性軟属腫	3 (0.5)	3	1.34				2 (0.4)	2	0.63			
レンサ球菌性咽頭炎	4 (0.7)	4	1.79				1 (0.2)	1	0.32	1 (0.4)	1	1.08
ウイルス感染	3 (0.5)	4	1.79				1 (0.2)	1	0.32			

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

	Tralokinumab Q2W (n=592)			Tralokinumab Q4W (n=89)			Tralokinumab Q2W + optional TCS (n=558)			Placebo (n=246)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
細菌性結膜炎	3 (0.5)	3	1.34				1 (0.2)	1	0.32	1 (0.4)	1	1.08
中耳炎	1 (0.2)	1	0.45				3 (0.5)	3	0.95	2 (0.8)	2	2.16
爪囲炎	1 (0.2)	1	0.45				2 (0.4)	3	0.95			
肺炎	1 (0.2)	1	0.45	1 (1.1)	1	2.24	2 (0.4)	2	0.63			
歯肉炎	3 (0.5)	3	1.34									
ヘリコバクター感染	1 (0.2)	1	0.45				2 (0.4)	2	0.63			
麦粒腫	2 (0.3)	2	0.89				1 (0.2)	1	0.32			
外耳炎	1 (0.2)	1	0.45				2 (0.4)	2	0.63			
ウイルス性気道感染							3 (0.5)	3	0.95			
ブドウ球菌皮膚感染	1 (0.2)	2	0.89				1 (0.2)	1	0.32	2 (0.8)	3	3.24
扁桃炎	1 (0.2)	1	0.45				2 (0.4)	2	0.63			
歯膿瘍	1 (0.2)	1	0.45				2 (0.4)	2	0.63			
急性副鼻腔炎	1 (0.2)	1	0.45				1 (0.2)	1	0.32			
細菌性疾患キャリアー				1 (1.1)	1	2.24	1 (0.2)	1	0.32			
カンジダ感染							2 (0.4)	2	0.63	1 (0.4)	2	2.16

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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=592) N (%)	E	R	Tralokinumab Q4W (n=89) N (%)	E	R	Tralokinumab Q2W + optional TCS (n=558) N (%)	E	R	Placebo (n=246) N (%)	E	R
よう										2 (0.8)	2	2.16
クラミジア感染	1 (0.2)	1	0.45	1 (1.1)	1	2.24						
膀胱炎							2 (0.4)	2	0.63			
皮膚真菌感染							1 (0.2)	2	0.63			
喉頭炎							2 (0.4)	2	0.63	3 (1.2)	3	3.24
口腔カンジダ症	2 (0.3)	2	0.89									
歯髄炎				1 (1.1)	1	2.24	1 (0.2)	1	0.32			
膿皮症	1 (0.2)	2	0.89									
歯感染							2 (0.4)	2	0.63	3 (1.2)	3	3.24
腟感染	1 (0.2)	1	0.45	1 (1.1)	1	2.24				1 (0.4)	1	1.08
外陰腟真菌感染	1 (0.2)	1	0.45				1 (0.2)	1	0.32	1 (0.4)	1	1.08
膿瘍							1 (0.2)	1	0.32	2 (0.8)	2	2.16
異型肺炎	1 (0.2)	1	0.45									
水疱性膿痂疹										1 (0.4)	1	1.08
ウイルス性結膜炎				1 (1.1)	1	2.24						
角膜感染							1 (0.2)	1	0.32			
耳感染										1 (0.4)	1	1.08
真菌性耳感染										1 (0.4)	1	1.08

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

	Tralokinumab Q2W (n=592)				Tralokinumab Q4W (n=89)				Tralokinumab Q2W + optional TCS (n=558)				Placebo (n=246)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
精巣上体炎	1	(0.2)	1	0.45												
細菌性眼感染									1	(0.2)	1	0.32				
眼瞼感染	1	(0.2)	1	0.45									1	(0.4)	1	1.08
細菌性胃腸炎									1	(0.2)	1	0.32				
クリプトスポリジウム性胃腸炎	1	(0.2)	1	0.45												
ノロウイルス性胃腸炎	1	(0.2)	1	0.45												
消化管感染	1	(0.2)	1	0.45												
陰部ヘルペス													1	(0.4)	1	1.08
歯肉膿瘍									1	(0.2)	1	0.32				
淋疾	1	(0.2)	1	0.45												
鼠径部膿瘍									1	(0.2)	1	0.32	1	(0.4)	1	1.08
手足口病									1	(0.2)	1	0.32				
ヘルペス性皮膚炎													1	(0.4)	1	1.08

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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=592) N (%)	E	R	Tralokinumab Q4W (n=89) N (%)	E	R	Tralokinumab Q2W + optional TCS (n=558) N (%)	E	R	Placebo (n=246) N (%)	E	R
ヘルペスウイルス感染							1 (0.2)	1	0.32			
感染性嚢腫							1 (0.2)	1	0.32			
ウイルス性角膜炎							1 (0.2)	1	0.32	1 (0.4)	1	1.08
肺感染							1 (0.2)	1	0.32			
リンパ管炎	1 (0.2)	1	0.45									
鼻ヘルペス										1 (0.4)	1	1.08
眼帯状疱疹							1 (0.2)	1	0.32			
乳頭腫ウイルス感染										1 (0.4)	1	1.08
軟骨膜炎							1 (0.2)	1	0.32			
会陰膿瘍							1 (0.2)	1	0.32			
扁桃周囲膿瘍							1 (0.2)	1	0.32			
毛巣嚢胞				1 (1.1)	1	2.24				1 (0.4)	2	2.16
術後創感染							1 (0.2)	1	0.32			
気道感染							1 (0.2)	1	0.32			

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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=592)				Tralokinumab Q4W (n=89)				Tralokinumab Q2W + optional TCS (n=558)				Placebo (n=246)			
	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
皮膚細菌感染	1	(0.2)	1	0.45									3	(1.2)	3	3.24
ブドウ球菌性菌血症									1	(0.2)	1	0.32				
ブドウ球菌感染									1	(0.2)	1	0.32				
股部白癬									1	(0.2)	1	0.32				
足部白癬									1	(0.2)	1	0.32				
癜風	1	(0.2)	1	0.45												
トリコフィトン感染症									1	(0.2)	1	0.32				
水痘帯状疱疹ウイルス感染									1	(0.2)	1	0.32				
創傷感染									1	(0.2)	1	0.32				
細菌性創感染									1	(0.2)	1	0.32				
皮膚および皮下組織障害	148	(25.0)	233	104.10	18	(20.2)	27	60.47	157	(28.1)	263	83.36	93	(37.8)	151	163.24

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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=592) N	(%)	E	R	Tralokinumab Q4W (n=89) N	(%)	E	R	Tralokinumab Q2W + optional TCS (n=558) N	(%)	E	R	Placebo (n=246) N	(%)	E	R
アトピー性皮膚炎	105	(17.7)	157	70.14	14	(15.7)	19	42.55	114	(20.4)	175	55.47	78	(31.7)	115	124.32
そう痒症	14	(2.4)	15	6.70	2	(2.2)	2	4.48	14	(2.5)	16	5.07	7	(2.8)	8	8.65
脱毛症	6	(1.0)	6	2.68					8	(1.4)	8	2.54	3	(1.2)	3	3.24
蕁麻疹	7	(1.2)	9	4.02					5	(0.9)	5	1.58	2	(0.8)	3	3.24
皮膚疼痛	5	(0.8)	5	2.23	1	(1.1)	1	2.24	4	(0.7)	5	1.58	1	(0.4)	3	3.24
ざ瘡	2	(0.3)	2	0.89	2	(2.2)	3	6.72	4	(0.7)	5	1.58				
光線角化症	2	(0.3)	2	0.89	1	(1.1)	1	2.24	4	(0.7)	4	1.27	1	(0.4)	1	1.08
円形脱毛症	3	(0.5)	3	1.34					3	(0.5)	3	0.95	2	(0.8)	2	2.16
接触皮膚炎	4	(0.7)	4	1.79					2	(0.4)	2	0.63	1	(0.4)	1	1.08
皮膚乾燥	1	(0.2)	2	0.89					4	(0.7)	4	1.27	1	(0.4)	1	1.08
神経皮膚炎	3	(0.5)	3	1.34					3	(0.5)	3	0.95	1	(0.4)	1	1.08
皮膚炎	2	(0.3)	2	0.89					2	(0.4)	3	0.95	1	(0.4)	1	1.08
多汗症	3	(0.5)	3	1.34					2	(0.4)	2	0.63				
皮膚嚢腫	2	(0.3)	2	0.89					2	(0.4)	2	0.63	1	(0.4)	1	1.08
光線過敏性反応	1	(0.2)	1	0.45					2	(0.4)	3	0.95				
皮膚剥脱	1	(0.2)	1	0.45					2	(0.4)	3	0.95				
発疹									2	(0.4)	3	0.95				
脂漏性皮膚炎	1	(0.2)	1	0.45					2	(0.4)	2	0.63				

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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=592) N (%)	E	R	Tralokinumab Q4W (n=89) N (%)	E	R	Tralokinumab Q2W + optional TCS (n=558) N (%)	E	R	Placebo (n=246) N (%)	E	R
血管浮腫	1 (0.2)	2	0.89									
剥脱性皮膚炎	1 (0.2)	1	0.45				1 (0.2)	1	0.32			
過角化	1 (0.2)	1	0.45				1 (0.2)	1	0.32			
寝汗										2 (0.8)	2	2.16
酒さ							2 (0.4)	2	0.63			
コリン性蕁麻疹	1 (0.2)	1	0.45				1 (0.2)	1	0.32			
水疱										1 (0.4)	1	1.08
頭部粃糠疹							1 (0.2)	1	0.32			
水疱性皮膚炎										1 (0.4)	1	1.08
薬疹							1 (0.2)	1	0.32	1 (0.4)	1	1.08
異汗性湿疹										1 (0.4)	1	1.08
貨幣状湿疹	1 (0.2)	1	0.45									
紅斑							1 (0.2)	1	0.32	1 (0.4)	1	1.08
毛髪成長異常										1 (0.4)	1	1.08
汗疹							1 (0.2)	1	0.32			
爪変色	1 (0.2)	1	0.45									
丘疹	1 (0.2)	1	0.45							1 (0.4)	1	1.08
点状出血										1 (0.4)	1	1.08

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

	Tralokinumab Q2W (n=592)				Tralokinumab Q4W (n=89)				Tralokinumab Q2W + optional TCS (n=558)				Placebo (n=246)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
多形日光疹									1	(0.2)	1	0.32				
炎症後色素沈着変化									1	(0.2)	1	0.32				
痒疹	1	(0.2)	1	0.45												
紅斑性皮疹	1	(0.2)	1	0.45												
斑状丘疹状皮疹													1	(0.4)	1	1.08
脂漏									1	(0.2)	1	0.32				
皮膚灼熱感	1	(0.2)	1	0.45												
皮膚変色	1	(0.2)	1	0.45												
皮膚障害	1	(0.2)	1	0.45												
皮膚色素過剰	1	(0.2)	1	0.45												
皮膚色素減少					1	(1.1)	1	2.24								
皮膚病変									1	(0.2)	1	0.32				
皮膚腫瘤									1	(0.2)	1	0.32				
皮膚潰瘍									1	(0.2)	1	0.32				

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

	Tralokinumab Q2W (n=592)				Tralokinumab Q4W (n=89)				Tralokinumab Q2W + optional TCS (n=558)				Placebo (n=246)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
裂毛	1	(0.2)	1	0.45												
一般・全身障害および投与部位の状態	77	(13.0)	189	84.44	7	(7.9)	9	20.16	47	(8.4)	142	45.01	26	(10.6)	50	54.05
注射部位疼痛	27	(4.6)	60	26.81					11	(2.0)	36	11.41	9	(3.7)	21	22.70
注射部位反応	19	(3.2)	38	16.98	4	(4.5)	4	8.96	12	(2.2)	40	12.68	2	(0.8)	7	7.57
注射部位紅斑	9	(1.5)	12	5.36	2	(2.2)	2	4.48	6	(1.1)	20	6.34				
注射部位出血	5	(0.8)	14	6.25					4	(0.7)	12	3.80	2	(0.8)	4	4.32
注射部位腫脹	7	(1.2)	17	7.60					3	(0.5)	5	1.58				
発熱	4	(0.7)	4	1.79					6	(1.1)	7	2.22	5	(2.0)	5	5.41
疲労	6	(1.0)	7	3.13					3	(0.5)	3	0.95	3	(1.2)	3	3.24

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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=592) N	(%)	E	R	Tralokinumab Q4W (n=89) N	(%)	E	R	Tralokinumab Q2W + optional TCS (n=558) N	(%)	E	R	Placebo (n=246) N	(%)	E	R
注射部位そう痒感	4	(0.7)	6	2.68	1	(1.1)	1	2.24	2	(0.4)	2	0.63	1	(0.4)	1	1.08
インフルエンザ様疾患	4	(0.7)	4	1.79					3	(0.5)	3	0.95	1	(0.4)	1	1.08
注射部位内出血	4	(0.7)	4	1.79					1	(0.2)	1	0.32	1	(0.4)	1	1.08
注射部位過敏反応	1	(0.2)	2	0.89	1	(1.1)	1	2.24	1	(0.2)	2	0.63				
注射部位浮腫	2	(0.3)	2	0.89					1	(0.2)	3	0.95				
胸痛	3	(0.5)	3	1.34									1	(0.4)	1	1.08
注射部位硬結	2	(0.3)	2	0.89					1	(0.2)	1	0.32				
末梢性浮腫	3	(0.5)	3	1.34									1	(0.4)	1	1.08
無力症					1	(1.1)	1	2.24	1	(0.2)	1	0.32	1	(0.4)	1	1.08
悪寒	2	(0.3)	2	0.89												
異物反応	1	(0.2)	1	0.45					1	(0.2)	1	0.32				
注射部位腫瘤	2	(0.3)	2	0.89												
倦怠感													2	(0.8)	2	2.16

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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=592) N (%)	E	R	Tralokinumab Q4W (n=89) N (%)	E	R	Tralokinumab Q2W + optional TCS (n=558) N (%)	E	R	Placebo (n=246) N (%)	E	R
小結節	1 (0.2)	1	0.45				1 (0.2)	1	0.32			
末梢腫脹	1 (0.2)	1	0.45				1 (0.2)	1	0.32			
医療機器関連眼合併症							1 (0.2)	1	0.32			
顔面浮腫										1 (0.4)	1	1.08
肉芽腫	1 (0.2)	1	0.45									
炎症							1 (0.2)	1	0.32			
注射部位発疹	1 (0.2)	1	0.45									
注射部位蕁麻疹							1 (0.2)	1	0.32			
疼痛	1 (0.2)	1	0.45							1 (0.4)	1	1.08
温度変化不耐症	1 (0.2)	1	0.45									
胃腸障害	42 (7.1)	51	22.79	4 (4.5)	4	8.96	43 (7.7)	64	20.29	17 (6.9)	22	23.78
悪心	6 (1.0)	7	3.13	1 (1.1)	1	2.24	8 (1.4)	19	6.02	4 (1.6)	6	6.49
下痢	9 (1.5)	9	4.02				14 (2.5)	14	4.44	4 (1.6)	4	4.32

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

	Tralokinumab Q2W (n=592)			Tralokinumab Q4W (n=89)			Tralokinumab Q2W + optional TCS (n=558)			Placebo (n=246)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
腹痛	6 (1.0)	6	2.68	1 (1.1)	1	2.24	7 (1.3)	8	2.54	2 (0.8)	2	2.16
嘔吐	4 (0.7)	4	1.79				3 (0.5)	3	0.95			
便秘	4 (0.7)	4	1.79				2 (0.4)	2	0.63	2 (0.8)	2	2.16
歯痛	2 (0.3)	2	0.89				2 (0.4)	3	0.95	2 (0.8)	2	2.16
胃食道逆流性疾患	1 (0.2)	1	0.45				3 (0.5)	3	0.95			
上腹部痛	1 (0.2)	1	0.45	1 (1.1)	1	2.24	1 (0.2)	1	0.32			
齲歯	1 (0.2)	1	0.45				2 (0.4)	2	0.63			
消化不良	2 (0.3)	2	0.89				1 (0.2)	1	0.32			
口の錯感覚	2 (0.3)	2	0.89									
腹部不快感	1 (0.2)	1	0.45							1 (0.4)	1	1.08
下腹部痛	1 (0.2)	1	0.45									
肛門そう痒症	1 (0.2)	1	0.45									
アフタ性潰瘍	1 (0.2)	1	0.45							1 (0.4)	1	1.08
セリアック病							1 (0.2)	1	0.32			
潰瘍性大腸炎	1 (0.2)	1	0.45									
十二指腸潰瘍	1 (0.2)	1	0.45									
排便回数増加	1 (0.2)	1	0.45									
胃炎							1 (0.2)	1	0.32			

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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=592) N (%)	E	R	Tralokinumab Q4W (n=89) N (%)	E	R	Tralokinumab Q2W + optional TCS (n=558) N (%)	E	R	Placebo (n=246) N (%)	E	R
歯肉出血										1 (0.4)	1	1.08
血便排泄							1 (0.2)	1	0.32			
痔核	1 (0.2)	1	0.45									
鼠径ヘルニア	1 (0.2)	1	0.45									
過敏性腸症候群	1 (0.2)	1	0.45							1 (0.4)	2	2.16
口唇浮腫	1 (0.2)	1	0.45									
口腔内潰瘍形成	1 (0.2)	1	0.45									
非感染性歯肉炎							1 (0.2)	1	0.32			
直腸出血							1 (0.2)	1	0.32			
過剰歯							1 (0.2)	1	0.32			
舌潰瘍				1 (1.1)	1	2.24						
歯の障害							1 (0.2)	1	0.32			
埋伏歯										1 (0.4)	1	1.08
臍ヘルニア							1 (0.2)	1	0.32			
眼障害	40 (6.8)	50	22.34	9 (10.1)	9	20.16	38 (6.8)	54	17.12	11 (4.5)	20	21.62
アレルギー性結膜炎	13 (2.2)	15	6.70	3 (3.4)	3	6.72	10 (1.8)	15	4.75	3 (1.2)	3	3.24

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

	Tralokinumab Q2W (n=592)			Tralokinumab Q4W (n=89)			Tralokinumab Q2W + optional TCS (n=558)			Placebo (n=246)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
眼瞼炎	7 (1.2)	7	3.13	2 (2.2)	2	4.48	3 (0.5)	3	0.95			
眼乾燥	4 (0.7)	4	1.79				5 (0.9)	5	1.58	4 (1.6)	5	5.41
白内障	1 (0.2)	1	0.45	1 (1.1)	1	2.24	4 (0.7)	5	1.58			
角膜炎	4 (0.7)	4	1.79				1 (0.2)	1	0.32			
流涙増加	4 (0.7)	4	1.79				1 (0.2)	1	0.32			
眼瞼湿疹	1 (0.2)	1	0.45				2 (0.4)	2	0.63	1 (0.4)	1	1.08
眼そう痒症	1 (0.2)	1	0.45				2 (0.4)	2	0.63	1 (0.4)	1	1.08
霧視	2 (0.3)	2	0.89				1 (0.2)	1	0.32	1 (0.4)	1	1.08
嚢下白内障										1 (0.4)	2	2.16
結膜充血							1 (0.2)	2	0.63			
眼瞼外反	2 (0.3)	2	0.89							1 (0.4)	1	1.08
眼刺激	1 (0.2)	1	0.45				1 (0.2)	1	0.32			
眼痛							2 (0.4)	2	0.63			
眼瞼刺激							2 (0.4)	2	0.63			
眼瞼浮腫				1 (1.1)	1	2.24	1 (0.2)	1	0.32			
羞明	2 (0.3)	2	0.89									
網膜剥離							1 (0.2)	2	0.63			
眼瞼痙攣							1 (0.2)	1	0.32			

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

	Tralokinumab Q2W (n=592)			Tralokinumab Q4W (n=89)			Tralokinumab Q2W + optional TCS (n=558)			Placebo (n=246)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
霰粒腫	1 (0.2)	1	0.45									
網脈絡膜症	1 (0.2)	1	0.45									
角膜浸潤							1 (0.2)	1	0.32			
眼瞼内反							1 (0.2)	1	0.32			
眼瞼そう痒症				1 (1.1)	1	2.24						
緑内障										1 (0.4)	1	1.08
虹彩炎							1 (0.2)	1	0.32			
円錐角膜	1 (0.2)	1	0.45									
角膜症										1 (0.4)	1	1.08
涙液分泌低下										1 (0.4)	1	1.08
水晶体脱臼							1 (0.2)	1	0.32			
マイボーム腺機能不全							1 (0.2)	1	0.32	1 (0.4)	1	1.08
近視	1 (0.2)	1	0.45									
眼充血							1 (0.2)	1	0.32			
高眼圧症				1 (1.1)	1	2.24						
後嚢部混濁							1 (0.2)	1	0.32			
潰瘍性角膜炎	1 (0.2)	1	0.45									

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

	Tralokinumab Q2W (n=592)				Tralokinumab Q4W (n=89)				Tralokinumab Q2W + optional TCS (n=558)				Placebo (n=246)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
視力障害									1	(0.2)	1	0.32				
硝子体浮遊物													1	(0.4)	1	1.08
眼球乾燥症	1	(0.2)	1	0.45									1	(0.4)	1	1.08
神経系障害	45	(7.6)	59	26.36	5	(5.6)	6	13.44	35	(6.3)	58	18.38	11	(4.5)	16	17.30
頭痛	16	(2.7)	22	9.83	2	(2.2)	2	4.48	14	(2.5)	17	5.39	6	(2.4)	7	7.57
浮動性めまい	6	(1.0)	7	3.13	1	(1.1)	1	2.24	6	(1.1)	6	1.90	2	(0.8)	3	3.24
片頭痛	5	(0.8)	8	3.57					4	(0.7)	6	1.90	1	(0.4)	1	1.08
味覚異常									1	(0.2)	8	2.54				
感覚鈍麻	6	(1.0)	6	2.68					2	(0.4)	2	0.63				
失神	4	(0.7)	5	2.23	1	(1.1)	1	2.24	1	(0.2)	1	0.32				
手根管症候群	1	(0.2)	1	0.45					5	(0.9)	5	1.58	1	(0.4)	1	1.08
錯感覚	4	(0.7)	4	1.79					1	(0.2)	1	0.32	1	(0.4)	1	1.08
嗜眠	2	(0.3)	2	0.89					1	(0.2)	1	0.32	1	(0.4)	1	1.08
失神寸前の状態	1	(0.2)	1	0.45					2	(0.4)	2	0.63				
神経圧迫	1	(0.2)	1	0.45					1	(0.2)	1	0.32				

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

	Tralokinumab Q2W (n=592)			Tralokinumab Q4W (n=89)			Tralokinumab Q2W + optional TCS (n=558)			Placebo (n=246)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
ヘルペス後神経痛							2 (0.4)	2	0.63			
副鼻腔炎に伴う頭痛				1 (1.1)	1	2.24	1 (0.2)	1	0.32			
傾眠							1 (0.2)	2	0.63	1 (0.4)	1	1.08
灼熱感	1 (0.2)	1	0.45									
中枢神経系の炎症	1 (0.2)	1	0.45									
不全片麻痺				1 (1.1)	1	2.24						
片麻痺性片頭痛										1 (0.4)	1	1.08
過眠症							1 (0.2)	1	0.32			
単神経炎							1 (0.2)	1	0.32			
神経学的症状							1 (0.2)	1	0.32			
筋骨格系および結合組織障害	41 (6.9)	57	25.47	4 (4.5)	5	11.20	39 (7.0)	51	16.17	16 (6.5)	19	20.54
関節痛	12 (2.0)	18	8.04	1 (1.1)	2	4.48	7 (1.3)	8	2.54	3 (1.2)	3	3.24

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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=592) N (%)	E	R	Tralokinumab Q4W (n=89) N (%)	E	R	Tralokinumab Q2W + optional TCS (n=558) N (%)	E	R	Placebo (n=246) N (%)	E	R
背部痛	7 (1.2)	10	4.47	2 (2.2)	2	4.48	9 (1.6)	11	3.49	1 (0.4)	1	1.08
筋骨格痛	4 (0.7)	6	2.68				6 (1.1)	6	1.90	1 (0.4)	1	1.08
滑液包炎	5 (0.8)	5	2.23				1 (0.2)	1	0.32	3 (1.2)	3	3.24
筋肉痛	1 (0.2)	1	0.45				4 (0.7)	5	1.58			
脊椎痛	1 (0.2)	1	0.45				1 (0.2)	3	0.95			
筋痙縮	1 (0.2)	2	0.89				1 (0.2)	1	0.32			
四肢痛	2 (0.3)	2	0.89				1 (0.2)	1	0.32	1 (0.4)	1	1.08
腱炎	1 (0.2)	1	0.45				2 (0.4)	2	0.63			
椎間板変性症							2 (0.4)	2	0.63			
筋骨格硬直	1 (0.2)	1	0.45				1 (0.2)	1	0.32	1 (0.4)	2	2.16
変形性関節症							2 (0.4)	2	0.63			
足底筋膜炎	1 (0.2)	1	0.45				1 (0.2)	1	0.32	2 (0.8)	2	2.16
斜頸	1 (0.2)	1	0.45				1 (0.2)	1	0.32			
関節炎	1 (0.2)	1	0.45									
肋軟骨炎							1 (0.2)	1	0.32			
外骨腫				1 (1.1)	1	2.24						
線維筋痛	1 (0.2)	1	0.45									
側腹部痛							1 (0.2)	1	0.32			

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

	Tralokinumab Q2W (n=592)			Tralokinumab Q4W (n=89)			Tralokinumab Q2W + optional TCS (n=558)			Placebo (n=246)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
関節滲出液							1 (0.2)	1	0.32			
関節硬直	1 (0.2)	1	0.45									
関節腫脹	1 (0.2)	1	0.45							3 (1.2)	4	4.32
筋力低下							1 (0.2)	1	0.32	1 (0.4)	1	1.08
骨溶解	1 (0.2)	1	0.45									
関節周囲炎	1 (0.2)	1	0.45									
肩回旋筋腱板症候群	1 (0.2)	1	0.45							1 (0.4)	1	1.08
強皮症							1 (0.2)	1	0.32			
腱痛	1 (0.2)	1	0.45									
弾発指							1 (0.2)	1	0.32			
呼吸器、胸郭および縦隔障害	36 (6.1)	48	21.45	12 (13.5)	13	29.11	35 (6.3)	42	13.31	13 (5.3)	15	16.22
喘息	8 (1.4)	15	6.70	3 (3.4)	4	8.96	9 (1.6)	9	2.85	8 (3.3)	9	9.73
咳嗽	9 (1.5)	10	4.47	2 (2.2)	2	4.48	8 (1.4)	9	2.85	2 (0.8)	3	3.24

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

	Tralokinumab Q2W (n=592)			Tralokinumab Q4W (n=89)			Tralokinumab Q2W + optional TCS (n=558)			Placebo (n=246)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
口腔咽頭痛	7 (1.2)	7	3.13	2 (2.2)	2	4.48	6 (1.1)	7	2.22	2 (0.8)	2	2.16
鼻閉	2 (0.3)	2	0.89				4 (0.7)	4	1.27			
副鼻腔うっ血	2 (0.3)	2	0.89	2 (2.2)	2	4.48	1 (0.2)	1	0.32			
鼻出血	1 (0.2)	1	0.45	2 (2.2)	2	4.48	1 (0.2)	1	0.32			
鼻漏	3 (0.5)	3	1.34				1 (0.2)	1	0.32			
湿性咳嗽	1 (0.2)	1	0.45				2 (0.4)	2	0.63			
アレルギー性鼻炎	1 (0.2)	1	0.45	1 (1.1)	1	2.24	1 (0.2)	1	0.32			
息詰まり	1 (0.2)	1	0.45				1 (0.2)	1	0.32			
呼吸困難	1 (0.2)	1	0.45				1 (0.2)	1	0.32	1 (0.4)	1	1.08
胞隔炎							1 (0.2)	1	0.32			
縦隔腫瘤	1 (0.2)	1	0.45									
鼻部不快感							1 (0.2)	1	0.32			
気胸							1 (0.2)	1	0.32			
肺塞栓症	1 (0.2)	1	0.45									
呼吸抑制	1 (0.2)	1	0.45									
くしゃみ							1 (0.2)	1	0.32			
喘息発作重積	1 (0.2)	1	0.45									
扁桃肥大							1 (0.2)	1	0.32			

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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=592) N (%)	E	R	Tralokinumab Q4W (n=89) N (%)	E	R	Tralokinumab Q2W + optional TCS (n=558) N (%)	E	R	Placebo (n=246) N (%)	E	R
臨床検査	29 (4.9)	36	16.08	7 (7.9)	11	24.63	33 (5.9)	46	14.58	16 (6.5)	34	36.76
アラニンアミノトランスフェラーゼ増加	2 (0.3)	2	0.89	2 (2.2)	3	6.72	5 (0.9)	5	1.58	1 (0.4)	3	3.24
アスパラギン酸アミノトランスフェラーゼ増加	2 (0.3)	2	0.89				6 (1.1)	6	1.90			
血中トリグリセリド増加	2 (0.3)	2	0.89	1 (1.1)	2	4.48	3 (0.5)	3	0.95	3 (1.2)	3	3.24
血中アルカリホスファターゼ増加	3 (0.5)	3	1.34				2 (0.4)	2	0.63			
好酸球数増加	3 (0.5)	3	1.34				2 (0.4)	2	0.63			
血圧上昇	1 (0.2)	1	0.45				3 (0.5)	3	0.95	1 (0.4)	2	2.16
γ-グルタミルトランスフェラーゼ増加	2 (0.3)	2	0.89				2 (0.4)	2	0.63	1 (0.4)	1	1.08

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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=592)			Tralokinumab Q4W (n=89)			Tralokinumab Q2W + optional TCS (n=558)			Placebo (n=246)		
	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
血中免疫グロブリンE増加	2 (0.3)	2	0.89				1 (0.2)	1	0.32	2 (0.8)	2	2.16
肝機能検査異常	1 (0.2)	1	0.45	1 (1.1)	1	2.24	1 (0.2)	1	0.32			
低比重リポ蛋白増加	1 (0.2)	1	0.45	2 (2.2)	2	4.48				2 (0.8)	2	2.16
尿中蛋白陽性	2 (0.3)	2	0.89				1 (0.2)	1	0.32			
血中ビリルビン増加							2 (0.4)	2	0.63	1 (0.4)	1	1.08
血中コレステロール増加	2 (0.3)	2	0.89							1 (0.4)	1	1.08
血中ブドウ糖増加	1 (0.2)	1	0.45				1 (0.2)	1	0.32	1 (0.4)	1	1.08
血中乳酸脱水素酵素増加							2 (0.4)	2	0.63	4 (1.6)	5	5.41
血圧低下	1 (0.2)	1	0.45	1 (1.1)	1	2.24						

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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=592)			Tralokinumab Q4W (n=89)			Tralokinumab Q2W + optional TCS (n=558)			Placebo (n=246)		
	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
体温上昇	1 (0.2)	1	0.45				1 (0.2)	1	0.32			
心電図T波逆転							2 (0.4)	2	0.63			
肝機能検査値上昇	1 (0.2)	1	0.45	1 (1.1)	1	2.24						
リンパ節触知							2 (0.4)	2	0.63			
好中球数増加	2 (0.3)	2	0.89							1 (0.4)	1	1.08
トランスアミナーゼ上昇	1 (0.2)	1	0.45				1 (0.2)	1	0.32	1 (0.4)	1	1.08
白血球数減少	1 (0.2)	1	0.45				1 (0.2)	1	0.32			
抱合ビリルビン増加										1 (0.4)	1	1.08
血中アルカリホスファターゼ減少										1 (0.4)	1	1.08
血中クレアチニン増加							1 (0.2)	1	0.32			

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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=592) N (%)	E	R	Tralokinumab Q4W (n=89) N (%)	E	R	Tralokinumab Q2W + optional TCS (n=558) N (%)	E	R	Placebo (n=246) N (%)	E	R
血中カリウム増加										1 (0.4)	1	1.08
収縮期血圧低下							1 (0.2)	1	0.32			
血中尿素減少										1 (0.4)	1	1.08
尿中血陽性	1 (0.2)	1	0.45									
尿中結晶陽性	1 (0.2)	1	0.45									
心電図異常P波							1 (0.2)	1	0.32			
心電図PR延長							1 (0.2)	1	0.32			
心音異常	1 (0.2)	1	0.45									
肝酵素上昇				1 (1.1)	1	2.24				1 (0.4)	1	1.08
免疫グロブリン増加							1 (0.2)	1	0.32			

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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=592) N (%)	E	R	Tralokinumab Q4W (n=89) N (%)	E	R	Tralokinumab Q2W + optional TCS (n=558) N (%)	E	R	Placebo (n=246) N (%)	E	R
眼圧上昇							1 (0.2)	1	0.32			
検査										1 (0.4)	1	1.08
リンパ球数減少							1 (0.2)	1	0.32	1 (0.4)	1	1.08
平均赤血球容積増加										1 (0.4)	1	1.08
好中球数減少	1 (0.2)	1	0.45									
レンサ球菌検査陽性							1 (0.2)	1	0.32			
体重減少										1 (0.4)	1	1.08
体重増加										1 (0.4)	1	1.08
白血球数増加	1 (0.2)	1	0.45							1 (0.4)	1	1.08

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

	Tralokinumab Q2W (n=592)			Tralokinumab Q4W (n=89)			Tralokinumab Q2W + optional TCS (n=558)			Placebo (n=246)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
傷害、中毒および処置合併症	25 (4.2)	30	13.40	4 (4.5)	4	8.96	32 (5.7)	41	13.00	14 (5.7)	16	17.30
靭帯捻挫	3 (0.5)	4	1.79	1 (1.1)	1	2.24	4 (0.7)	4	1.27	1 (0.4)	1	1.08
不適切な薬剤投与計画	1 (0.2)	1	0.45				5 (0.9)	5	1.58	2 (0.8)	2	2.16
関節脱臼	3 (0.5)	3	1.34	1 (1.1)	1	2.24	1 (0.2)	1	0.32			
挫傷	1 (0.2)	2	0.89				2 (0.4)	2	0.63			
転倒							3 (0.5)	3	0.95	2 (0.8)	2	2.16
関節損傷	3 (0.5)	3	1.34									
裂傷	1 (0.2)	1	0.45				2 (0.4)	2	0.63			
処置による疼痛	1 (0.2)	1	0.45				2 (0.4)	2	0.63			
他の患者への薬剤誤投与	3 (0.5)	3	1.34									
擦過傷	1 (0.2)	1	0.45				1 (0.2)	1	0.32			

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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=592) N (%)	E	R	Tralokinumab Q4W (n=89) N (%)	E	R	Tralokinumab Q2W + optional TCS (n=558) N (%)	E	R	Placebo (n=246) N (%)	E	R
顔面骨骨折							2 (0.4)	2	0.63			
損傷							2 (0.4)	2	0.63			
四肢損傷	1 (0.2)	1	0.45	1 (1.1)	1	2.24				1 (0.4)	1	1.08
肉離れ	1 (0.2)	1	0.45				1 (0.2)	1	0.32			
肋骨骨折							2 (0.4)	2	0.63			
交通事故							2 (0.4)	2	0.63	1 (0.4)	1	1.08
皮膚損傷							2 (0.4)	2	0.63			
サンバーン	1 (0.2)	1	0.45	1 (1.1)	1	2.24				2 (0.8)	2	2.16
足関節部骨折	1 (0.2)	1	0.45									
節足動物咬傷							1 (0.2)	1	0.32			
節足動物刺傷										1 (0.4)	1	1.08
剥離骨折							1 (0.2)	1	0.32			
頚椎骨折							1 (0.2)	1	0.32			
耳部損傷	1 (0.2)	1	0.45									
頭部損傷							1 (0.2)	1	0.32			
企図的過量投与	1 (0.2)	1	0.45									
筋損傷							1 (0.2)	1	0.32			

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

	Tralokinumab Q2W (n=592)				Tralokinumab Q4W (n=89)				Tralokinumab Q2W + optional TCS (n=558)				Placebo (n=246)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
神経損傷													1	(0.4)	1	1.08
処置後出血									1	(0.2)	1	0.32				
処置による悪心	1	(0.2)	1	0.45												
肺挫傷									1	(0.2)	1	0.32				
橈骨骨折									1	(0.2)	1	0.32	1	(0.4)	1	1.08
瘢痕													1	(0.4)	1	1.08
皮膚擦過傷	1	(0.2)	1	0.45												
軟部組織損傷	1	(0.2)	1	0.45												
滑膜断裂	1	(0.2)	1	0.45												
腱断裂									1	(0.2)	1	0.32				
熱傷													1	(0.4)	1	1.08
歯牙破折													1	(0.4)	1	1.08
歯牙損傷									1	(0.2)	1	0.32				
手首関節骨折	1	(0.2)	1	0.45									1	(0.4)	1	1.08
精神障害	25	(4.2)	28	12.51	4	(4.5)	5	11.20	10	(1.8)	13	4.12	6	(2.4)	6	6.49
不眠症	12	(2.0)	12	5.36					3	(0.5)	3	0.95	4	(1.6)	4	4.32
不安	5	(0.8)	5	2.23	1	(1.1)	1	2.24	2	(0.4)	2	0.63				

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

	Tralokinumab Q2W (n=592)			Tralokinumab Q4W (n=89)			Tralokinumab Q2W + optional TCS (n=558)			Placebo (n=246)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
うつ病	4 (0.7)	4	1.79	1 (1.1)	1	2.24	3 (0.5)	3	0.95			
抑うつ気分	1 (0.2)	1	0.45				3 (0.5)	4	1.27			
パニック発作				2 (2.2)	2	4.48						
睡眠障害	2 (0.3)	2	0.89							1 (0.4)	1	1.08
激越	1 (0.2)	1	0.45									
不安障害							1 (0.2)	1	0.32			
希死念慮を有するうつ病	1 (0.2)	1	0.45									
ギャンブル障害	1 (0.2)	1	0.45									
気分変化	1 (0.2)	1	0.45									
ニコチン依存										1 (0.4)	1	1.08
統合失調症				1 (1.1)	1	2.24						
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）	12 (2.0)	18	8.04	5 (5.6)	5	11.20	14 (2.5)	16	5.07	1 (0.4)	3	3.24
皮膚乳頭腫	4 (0.7)	5	2.23	2 (2.2)	2	4.48	4 (0.7)	4	1.27			

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

	Tralokinumab Q2W (n=592)			Tralokinumab Q4W (n=89)			Tralokinumab Q2W + optional TCS (n=558)			Placebo (n=246)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
皮膚有棘細胞癌	4 (0.7)	8	3.57	1 (1.1)	1	2.24	2 (0.4)	2	0.63	1 (0.4)	3	3.24
肛門性器疣贅				1 (1.1)	1	2.24	1 (0.2)	1	0.32			
基底細胞癌	1 (0.2)	1	0.45				1 (0.2)	1	0.32			
眼瞼乳頭腫							1 (0.2)	2	0.63			
ボーエン病							2 (0.4)	2	0.63			
血管肉腫	1 (0.2)	1	0.45									
骨の良性新生物	1 (0.2)	1	0.45									
良性新生物							1 (0.2)	1	0.32			
甲状腺の良性新生物	1 (0.2)	1	0.45									
脂肪腫							1 (0.2)	1	0.32			
メラノサイト性母斑							1 (0.2)	1	0.32			
乳頭様甲状腺癌				1 (1.1)	1	2.24						
脂漏性角化症							1 (0.2)	1	0.32			
子宮平滑筋腫	1 (0.2)	1	0.45									

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

	Tralokinumab Q2W (n=592)			Tralokinumab Q4W (n=89)			Tralokinumab Q2W + optional TCS (n=558)			Placebo (n=246)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
血液およびリンパ系障害	16 (2.7)	20	8.94	2 (2.2)	3	6.72	9 (1.6)	11	3.49	6 (2.4)	6	6.49
リンパ節症	10 (1.7)	14	6.25	2 (2.2)	3	6.72	3 (0.5)	3	0.95	2 (0.8)	2	2.16
好酸球増加症	5 (0.8)	5	2.23				3 (0.5)	3	0.95	2 (0.8)	2	2.16
好中球減少症							2 (0.4)	2	0.63			
良性民族性好中球減少症							1 (0.2)	1	0.32			
白血球増加症	1 (0.2)	1	0.45									
白血球減少症							1 (0.2)	1	0.32	1 (0.4)	1	1.08
リンパ節炎							1 (0.2)	1	0.32			
リンパ球減少症										1 (0.4)	1	1.08
免疫系障害	12 (2.0)	13	5.81	4 (4.5)	4	8.96	11 (2.0)	12	3.80	5 (2.0)	5	5.41
季節性アレルギー	8 (1.4)	8	3.57	4 (4.5)	4	8.96	5 (0.9)	5	1.58	3 (1.2)	3	3.24
アナフィラキシー反応	1 (0.2)	1	0.45				2 (0.4)	2	0.63			
食物アレルギー	1 (0.2)	1	0.45				1 (0.2)	1	0.32	1 (0.4)	1	1.08

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

	Tralokinumab Q2W (n=592)			Tralokinumab Q4W (n=89)			Tralokinumab Q2W + optional TCS (n=558)			Placebo (n=246)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
賦形剤アレルギー反応							1 (0.2)	1	0.32			
動物アレルギー										1 (0.4)	1	1.08
節足動物咬傷アレルギー	1 (0.2)	1	0.45									
植物アレルギー							1 (0.2)	1	0.32			
薬物過敏症							1 (0.2)	1	0.32			
過敏症	1 (0.2)	1	0.45									
香料過敏症	1 (0.2)	1	0.45									
ゴム過敏症							1 (0.2)	1	0.32			
代謝および栄養障害	11 (1.9)	11	4.91	4 (4.5)	6	13.44	10 (1.8)	13	4.12	3 (1.2)	3	3.24
痛風	2 (0.3)	2	0.89				1 (0.2)	2	0.63	1 (0.4)	1	1.08
高カリウム血症				2 (2.2)	2	4.48	1 (0.2)	2	0.63			
2型糖尿病	1 (0.2)	1	0.45	1 (1.1)	1	2.24	2 (0.4)	2	0.63			

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

	Tralokinumab Q2W (n=592)			Tralokinumab Q4W (n=89)			Tralokinumab Q2W + optional TCS (n=558)			Placebo (n=246)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
高カルシウム血症							3 (0.5)	3	0.95			
高コレステロール血症	1 (0.2)	1	0.45	1 (1.1)	1	2.24	1 (0.2)	1	0.32			
高トリグリセリド血症	2 (0.3)	2	0.89	1 (1.1)	1	2.24						
高脂血症	2 (0.3)	2	0.89									
ビタミンD欠乏	1 (0.2)	1	0.45	1 (1.1)	1	2.24						
食欲減退							1 (0.2)	1	0.32	1 (0.4)	1	1.08
脂質異常症							1 (0.2)	1	0.32			
高血糖	1 (0.2)	1	0.45									
低カルシウム血症										1 (0.4)	1	1.08
低血糖							1 (0.2)	1	0.32			
低カリウム血症	1 (0.2)	1	0.45									
血管障害	9 (1.5)	9	4.02	1 (1.1)	1	2.24	9 (1.6)	9	2.85	6 (2.4)	6	6.49
高血圧	9 (1.5)	9	4.02	1 (1.1)	1	2.24	6 (1.1)	6	1.90	4 (1.6)	4	4.32
大腿動脈解離							1 (0.2)	1	0.32			
ほてり							1 (0.2)	1	0.32			
低血圧										1 (0.4)	1	1.08

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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=592) N (%)	E	R	Tralokinumab Q4W (n=89) N (%)	E	R	Tralokinumab Q2W + optional TCS (n=558) N (%)	E	R	Placebo (n=246) N (%)	E	R
静脈炎										1 (0.4)	1	1.08
レイノー現象							1 (0.2)	1	0.32			
生殖系および乳房障害	8 (1.4)	11	4.91				6 (1.1)	7	2.22	5 (2.0)	5	5.41
卵巣嚢胞	2 (0.3)	2	0.89				1 (0.2)	2	0.63			
乳房腫瘤	1 (0.2)	1	0.45				1 (0.2)	1	0.32	1 (0.4)	1	1.08
月経困難症	1 (0.2)	2	0.89									
無月経	1 (0.2)	1	0.45									
亀頭包皮炎	1 (0.2)	1	0.45									
良性前立腺肥大症							1 (0.2)	1	0.32			
乳房痛							1 (0.2)	1	0.32			
乳房圧痛							1 (0.2)	1	0.32			
女性化乳房	1 (0.2)	1	0.45							1 (0.4)	1	1.08
不正子宮出血										1 (0.4)	1	1.08
乳頭痛	1 (0.2)	1	0.45									
希発月経	1 (0.2)	1	0.45							1 (0.4)	1	1.08

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

	Tralokinumab Q2W (n=592)			Tralokinumab Q4W (n=89)			Tralokinumab Q2W + optional TCS (n=558)			Placebo (n=246)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
子宮出血	1 (0.2)	1	0.45									
腟出血							1 (0.2)	1	0.32	1 (0.4)	1	1.08
肝胆道系障害	4 (0.7)	4	1.79	1 (1.1)	1	2.24	4 (0.7)	4	1.27	1 (0.4)	1	1.08
高ビリルビン血症	2 (0.3)	2	0.89	1 (1.1)	1	2.24	1 (0.2)	1	0.32			
胆汁性消化不良							1 (0.2)	1	0.32			
胆石症							1 (0.2)	1	0.32			
脂肪肝							1 (0.2)	1	0.32			
高トランスアミナーゼ血症	1 (0.2)	1	0.45									
非アルコール性脂肪肝										1 (0.4)	1	1.08
黄疸眼	1 (0.2)	1	0.45									
腎および尿路障害	6 (1.0)	6	2.68				2 (0.4)	3	0.95	1 (0.4)	1	1.08
血尿	2 (0.3)	2	0.89									
頻尿	1 (0.2)	1	0.45				1 (0.2)	1	0.32			

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

	Tralokinumab Q2W (n=592)			Tralokinumab Q4W (n=89)			Tralokinumab Q2W + optional TCS (n=558)			Placebo (n=246)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
腎機能障害	1 (0.2)	1	0.45				1 (0.2)	1	0.32			
排尿困難							1 (0.2)	1	0.32			
緊張性膀胱										1 (0.4)	1	1.08
ケトン尿	1 (0.2)	1	0.45									
尿臭異常	1 (0.2)	1	0.45									
耳および迷路障害	5 (0.8)	5	2.23				2 (0.4)	2	0.63	2 (0.8)	2	2.16
耳介腫脹	1 (0.2)	1	0.45									
後天性外耳変形										1 (0.4)	1	1.08
耳痛	1 (0.2)	1	0.45									
耳管閉塞							1 (0.2)	1	0.32			
外耳痛	1 (0.2)	1	0.45									
聴力低下							1 (0.2)	1	0.32			
乗物酔い	1 (0.2)	1	0.45									
耳鳴	1 (0.2)	1	0.45							1 (0.4)	1	1.08

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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=592) N (%)	E	R	Tralokinumab Q4W (n=89) N (%)	E	R	Tralokinumab Q2W + optional TCS (n=558) N (%)	E	R	Placebo (n=246) N (%)	E	R
心臓障害	1 (0.2)	1	0.45				5 (0.9)	5	1.58	4 (1.6)	4	4.32
不整脈	1 (0.2)	1	0.45									
心房細動							1 (0.2)	1	0.32			
心房粗動										1 (0.4)	1	1.08
右脚ブロック							1 (0.2)	1	0.32			
冠動脈疾患							1 (0.2)	1	0.32			
動悸										1 (0.4)	1	1.08
心膜炎										1 (0.4)	1	1.08
洞性頻脈							1 (0.2)	1	0.32			
頻脈							1 (0.2)	1	0.32	1 (0.4)	1	1.08
先天性、家族性および遺伝性障害							1 (0.2)	1	0.32			
鰓性嚢胞							1 (0.2)	1	0.32			

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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=592) N (%)	E	R	Tralokinumab Q4W (n=89) N (%)	E	R	Tralokinumab Q2W + optional TCS (n=558) N (%)	E	R	Placebo (n=246) N (%)	E	R
内分泌障害										1 (0.4)	1	1.08
バセドウ病										1 (0.4)	1	1.08
製品の問題							1 (0.2)	1	0.32			
医療機器位置異常							1 (0.2)	1	0.32			
外科および内科処置							1 (0.2)	1	0.32			
卵巣嚢腫摘出術							1 (0.2)	1	0.32			

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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).

1.9.2.1.4 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

	Tralokinumab Q2W (n=83)			Tralokinumab Q4W (n=50)			Tralokinumab Q2W + optional TCS (n=454)			Placebo (n=54)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
All AEs	9 (10.8)	17	110.43	5 (10.0)	5	52.61	63 (13.9)	82	76.96	2 (3.7)	2	17.46
感染症および寄生虫症	3 (3.6)	3	19.49				23 (5.1)	25	23.46	2 (3.7)	2	17.46
上気道感染	1 (1.2)	1	6.50				5 (1.1)	6	5.63			
結膜炎							3 (0.7)	3	2.82			
気管支炎	1 (1.2)	1	6.50				1 (0.2)	1	0.94			
感染性皮膚炎							2 (0.4)	2	1.88			
咽頭炎							2 (0.4)	2	1.88			
膿瘍							1 (0.2)	1	0.94			
耳感染							1 (0.2)	1	0.94			
ヘルペス性状湿疹							1 (0.2)	1	0.94			
毛包炎							1 (0.2)	1	0.94			
単純ヘルペス										1 (1.9)	1	8.73
帯状疱疹							1 (0.2)	1	0.94			
膿痂疹							1 (0.2)	1	0.94			
寄生虫感染							1 (0.2)	1	0.94			

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

	Tralokinumab Q2W (n=83)			Tralokinumab Q4W (n=50)			Tralokinumab Q2W + optional TCS (n=454)			Placebo (n=54)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
伝染性軟属腫							1 (0.2)	1	0.94			
鼻咽頭炎							1 (0.2)	1	0.94			
口腔ヘルペス							1 (0.2)	1	0.94			
ブドウ球菌性膿痂							1 (0.2)	1	0.94			
ブドウ球菌皮膚感染	1 (1.2)	1	6.50									
ウイルス性上気道感染										1 (1.9)	1	8.73
皮膚および皮下組織障害	1 (1.2)	1	6.50	2 (4.0)	2	21.05	22 (4.8)	22	20.65			
アトピー性皮膚炎	1 (1.2)	1	6.50	2 (4.0)	2	21.05	12 (2.6)	12	11.26			
ざ瘡							3 (0.7)	3	2.82			
脱毛症							2 (0.4)	2	1.88			
蕁麻疹							2 (0.4)	2	1.88			

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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=83) N (%)	E	R	Tralokinumab Q4W (n=50) N (%)	E	R	Tralokinumab Q2W + optional TCS (n=454) N (%)	E	R	Placebo (n=54) N (%)	E	R
紅斑							1 (0.2)	1	0.94			
そう痒症							1 (0.2)	1	0.94			
皮膚病変							1 (0.2)	1	0.94			
傷害、中毒および処置合併症	2 (2.4)	2	12.99	2 (4.0)	2	21.05	6 (1.3)	6	5.63			
足骨折				1 (2.0)	1	10.52						
手骨折	1 (1.2)	1	6.50									
靱帯捻挫							1 (0.2)	1	0.94			
半月板損傷							1 (0.2)	1	0.94			
筋断裂							1 (0.2)	1	0.94			
肉離れ	1 (1.2)	1	6.50									
処置後合併症				1 (2.0)	1	10.52						
処置による疼痛							1 (0.2)	1	0.94			
腱断裂							1 (0.2)	1	0.94			
手首関節骨折							1 (0.2)	1	0.94			

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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=83) N (%)	E	R	Tralokinumab Q4W (n=50) N (%)	E	R	Tralokinumab Q2W + optional TCS (n=454) N (%)	E	R	Placebo (n=54) N (%)	E	R
筋骨格系および結合組織障害	2 (2.4)	2	12.99				5 (1.1)	5	4.69			
四肢痛	1 (1.2)	1	6.50				2 (0.4)	2	1.88			
肩径部痛							1 (0.2)	1	0.94			
筋肉痛							1 (0.2)	1	0.94			
頚部腫瘤							1 (0.2)	1	0.94			
変形性関節症	1 (1.2)	1	6.50									
眼障害	1 (1.2)	3	19.49				5 (1.1)	5	4.69			
アトピー性角結膜炎							1 (0.2)	1	0.94			
白内障							1 (0.2)	1	0.94			
アレルギー性結膜炎							1 (0.2)	1	0.94			
眼乾燥							1 (0.2)	1	0.94			

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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=83) N (%)	E	R	Tralokinumab Q4W (n=50) N (%)	E	R	Tralokinumab Q2W + optional TCS (n=454) N (%)	E	R	Placebo (n=54) N (%)	E	R
眼そう痒症	1 (1.2)	1	6.50									
流涙増加	1 (1.2)	1	6.50									
眼充血	1 (1.2)	1	6.50									
網膜裂孔							1 (0.2)	1	0.94			
胃腸障害	1 (1.2)	1	6.50				4 (0.9)	4	3.75			
上腹部痛							1 (0.2)	1	0.94			
便秘	1 (1.2)	1	6.50									
胃穿孔							1 (0.2)	1	0.94			
悪心							1 (0.2)	1	0.94			
嘔吐							1 (0.2)	1	0.94			
臨床検査	2 (2.4)	2	12.99				3 (0.7)	3	2.82			
血中コレステロール増加							1 (0.2)	1	0.94			
肝機能検査値上昇	1 (1.2)	1	6.50									

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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=83) N (%)	E	R	Tralokinumab Q4W (n=50) N (%)	E	R	Tralokinumab Q2W + optional TCS (n=454) N (%)	E	R	Placebo (n=54) N (%)	E	R
好中球数増加	1 (1.2)	1	6.50									
ビタミンD減少							1 (0.2)	1	0.94			
白血球数減少							1 (0.2)	1	0.94			
代謝および栄養障害							4 (0.9)	4	3.75			
痛風							1 (0.2)	1	0.94			
低ナトリウム血症							1 (0.2)	1	0.94			
2型糖尿病							1 (0.2)	1	0.94			
ビタミンD欠乏							1 (0.2)	1	0.94			

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

	Tralokinumab Q2W (n=83)			Tralokinumab Q4W (n=50)			Tralokinumab Q2W + optional TCS (n=454)			Placebo (n=54)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R	N (%)	E	R	N (%)	E	R
呼吸器、胸郭および縦隔障害	1 (1.2)	1	6.50	1 (2.0)	1	10.52	1 (0.2)	1	0.94			
喘息				1 (2.0)	1	10.52						
口腔咽頭痛							1 (0.2)	1	0.94			
喘息発作重積	1 (1.2)	1	6.50									
精神障害	1 (1.2)	1	6.50				1 (0.2)	1	0.94			
異常な夢							1 (0.2)	1	0.94			
不安	1 (1.2)	1	6.50									
腎および尿路障害							2 (0.4)	2	1.88			
蛋白尿							2 (0.4)	2	1.88			

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

	Tralokinumab Q2W (n=83)				Tralokinumab Q4W (n=50)				Tralokinumab Q2W + optional TCS (n=454)				Placebo (n=54)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
血液およびリンパ系障害	1	(1.2)	1	6.50												
リンパ節炎	1	(1.2)	1	6.50												
心臓障害									1	(0.2)	1	0.94				
心房頻脈									1	(0.2)	1	0.94				
耳および迷路障害									1	(0.2)	1	0.94				
耳閉									1	(0.2)	1	0.94				
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	(0.2)	1	0.94				

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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=83) N (%) E R	Tralokinumab Q4W (n=50) N (%) E R	Tralokinumab Q2W + optional TCS (n=454) N (%) E R	Placebo (n=54) N (%) E R
皮膚乳頭腫			1 (0.2) 1 0.94	
神経系障害			1 (0.2) 1 0.94	
手根管症候群			1 (0.2) 1 0.94	

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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 visit (if available), otherwise latest of date of early termination visit (if available) or date of onset of latest AE leading to withdrawal of trial product, otherwise last visit excluding safety follow-up visit and nominal Week 16 visit after permanent discontinuation of IMP.

1.9.2.1.5 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=592) N (%)	E	R	Placebo (n=200) N (%)	E	R
All AEs	150 (25.3)	343	193.89	61 (30.5)	144	251.11
Treatment comparison, p-value	0.0374					
感染症および寄生虫症	52 (8.8)	71	40.14	31 (15.5)	46	80.22
上気道感染	14 (2.4)	16	9.04	8 (4.0)	8	13.95
結膜炎	10 (1.7)	13	7.35	2 (1.0)	2	3.49
皮膚感染	6 (1.0)	7	3.96	7 (3.5)	7	12.21
ウイルス性上気道感染	6 (1.0)	7	3.96	5 (2.5)	5	8.72
単純ヘルペス	4 (0.7)	4	2.26	2 (1.0)	2	3.49
帯状疱疹	3 (0.5)	3	1.70	1 (0.5)	1	1.74
インフルエンザ	1 (0.2)	1	0.57	3 (1.5)	3	5.23
皮膚細菌感染	1 (0.2)	1	0.57	2 (1.0)	2	3.49
尿路感染	2 (0.3)	2	1.13	1 (0.5)	1	1.74
カンジダ感染				1 (0.5)	2	3.49
蜂巣炎	1 (0.2)	1	0.57	1 (0.5)	1	1.74
細菌性結膜炎	1 (0.2)	1	0.57	1 (0.5)	1	1.74
ヘルペス性状湿疹				2 (1.0)	2	3.49
眼瞼感染	1 (0.2)	1	0.57	1 (0.5)	1	1.74

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

	Tralokinumab Q2W (n=592)			Placebo (n=200)		
System Organ Class (SOC) Preferred term	N (%)	E	R	N (%)	E	R
鼻咽頭炎	1 (0.2)	1	0.57	1 (0.5)	1	1.74
口腔ヘルペス	1 (0.2)	1	0.57	1 (0.5)	1	1.74
咽頭炎	2 (0.3)	2	1.13			
異型肺炎	1 (0.2)	1	0.57			
よう				1 (0.5)	1	1.74
感染性皮膚炎	1 (0.2)	1	0.57			
せつ	1 (0.2)	1	0.57			
胃腸炎				1 (0.5)	1	1.74
陰部ヘルペス				1 (0.5)	1	1.74
歯肉炎	1 (0.2)	1	0.57			
鼡径部膿瘍				1 (0.5)	1	1.74
ウイルス性角膜炎				1 (0.5)	1	1.74
下気道感染	1 (0.2)	1	0.57			
爪囲炎	1 (0.2)	1	0.57			
肺炎	1 (0.2)	1	0.57			
歯膿瘍	1 (0.2)	1	0.57			
歯感染				1 (0.5)	1	1.74
ウイルス感染	1 (0.2)	1	0.57			
外陰腟真菌感染	1 (0.2)	1	0.57			

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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=592) N (%)	E	R	Placebo (n=200) N (%)	E	R
一般・全身障害および投与部位の状態	53 (9.0)	129	72.92	17 (8.5)	37	64.52
注射部位疼痛	24 (4.1)	52	29.39	8 (4.0)	17	29.65
注射部位反応	15 (2.5)	26	14.70	2 (1.0)	7	12.21
注射部位出血	5 (0.8)	11	6.22	2 (1.0)	4	6.98
注射部位腫脹	7 (1.2)	9	5.09			
注射部位紅斑	7 (1.2)	8	4.52			
注射部位そう痒感	2 (0.3)	4	2.26	1 (0.5)	1	1.74
疲労	2 (0.3)	3	1.70	1 (0.5)	1	1.74
注射部位内出血	4 (0.7)	4	2.26			
インフルエンザ様疾患	2 (0.3)	2	1.13	1 (0.5)	1	1.74
発熱				3 (1.5)	3	5.23
注射部位過敏反応	1 (0.2)	2	1.13			
注射部位硬結	2 (0.3)	2	1.13			
注射部位腫瘤	2 (0.3)	2	1.13			
末梢性浮腫	1 (0.2)	1	0.57	1 (0.5)	1	1.74
胸痛				1 (0.5)	1	1.74
悪寒	1 (0.2)	1	0.57			
注射部位浮腫	1 (0.2)	1	0.57			
倦怠感				1 (0.5)	1	1.74

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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=592) N (%)	E	R	Placebo (n=200) N (%)	E	R
疼痛	1 (0.2)	1	0.57			
皮膚および皮下組織障害	37 (6.3)	47	26.57	19 (9.5)	25	43.60
アトピー性皮膚炎	27 (4.6)	30	16.96	15 (7.5)	21	36.62
そう痒症	3 (0.5)	3	1.70	1 (0.5)	1	1.74
蕁麻疹	2 (0.3)	4	2.26			
脱毛症	1 (0.2)	1	0.57	1 (0.5)	1	1.74
丘疹	1 (0.2)	1	0.57	1 (0.5)	1	1.74
ざ瘡	1 (0.2)	1	0.57			
剥脱性皮膚炎	1 (0.2)	1	0.57			
毛髪成長異常				1 (0.5)	1	1.74
爪変色	1 (0.2)	1	0.57			
神経皮膚炎	1 (0.2)	1	0.57			
皮膚疼痛	1 (0.2)	1	0.57			
皮膚灼熱感	1 (0.2)	1	0.57			
皮膚変色	1 (0.2)	1	0.57			
皮膚剥脱	1 (0.2)	1	0.57			
眼障害	21 (3.5)	26	14.70	3 (1.5)	4	6.98
アレルギー性結膜炎	8 (1.4)	8	4.52	2 (1.0)	2	3.49

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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=592) N (%)	E	R	Placebo (n=200) N (%)	E	R
眼瞼炎	4 (0.7)	4	2.26			
流涙増加	4 (0.7)	4	2.26			
眼乾燥	1 (0.2)	1	0.57	1 (0.5)	1	1.74
角膜炎	2 (0.3)	2	1.13			
眼瞼外反	1 (0.2)	1	0.57			
眼刺激	1 (0.2)	1	0.57			
眼そう痒症	1 (0.2)	1	0.57			
円錐角膜	1 (0.2)	1	0.57			
羞明	1 (0.2)	1	0.57			
潰瘍性角膜炎	1 (0.2)	1	0.57			
霧視	1 (0.2)	1	0.57			
眼球乾燥症				1 (0.5)	1	1.74
神経系障害	14 (2.4)	15	8.48	4 (2.0)	4	6.98
頭痛	4 (0.7)	4	2.26	2 (1.0)	2	3.49
浮動性めまい	2 (0.3)	3	1.70			
片頭痛	2 (0.3)	2	1.13			
錯感覚	1 (0.2)	1	0.57	1 (0.5)	1	1.74
灼熱感	1 (0.2)	1	0.57			
手根管症候群	1 (0.2)	1	0.57			

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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=592) N (%)	E	R	Placebo (n=200) N (%)	E	R
嗜眠	1 (0.2)	1	0.57			
失神寸前の状態	1 (0.2)	1	0.57			
傾眠				1 (0.5)	1	1.74
失神	1 (0.2)	1	0.57			
胃腸障害	13 (2.2)	15	8.48	3 (1.5)	5	8.72
下痢	5 (0.8)	5	2.83	1 (0.5)	1	1.74
悪心	3 (0.5)	3	1.70	1 (0.5)	2	3.49
過敏性腸症候群				1 (0.5)	2	3.49
腹痛	1 (0.2)	1	0.57			
胃食道逆流性疾患	1 (0.2)	1	0.57			
鼠径ヘルニア	1 (0.2)	1	0.57			
口唇浮腫	1 (0.2)	1	0.57			
口腔内潰瘍形成	1 (0.2)	1	0.57			
口の錯感覚	1 (0.2)	1	0.57			
嘔吐	1 (0.2)	1	0.57			
臨床検査	12 (2.0)	15	8.48	4 (2.0)	8	13.95
血中アルカリホスファターゼ増加	3 (0.5)	3	1.70			
血中免疫グロブリンE増加	1 (0.2)	1	0.57	1 (0.5)	1	1.74

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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=592) N (%)	E	R	Placebo (n=200) N (%)	E	R
血中乳酸脱水素酵素増加				1 (0.5)	2	3.49
血圧上昇				1 (0.5)	2	3.49
アラニンアミノトランスフェラーゼ増加	1 (0.2)	1	0.57			
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	0.57			
抱合ビリルビン増加				1 (0.5)	1	1.74
血中ビリルビン増加				1 (0.5)	1	1.74
血中コレステロール増加	1 (0.2)	1	0.57			
血中ブドウ糖増加	1 (0.2)	1	0.57			
血中トリグリセリド増加	1 (0.2)	1	0.57			
体温上昇	1 (0.2)	1	0.57			
好酸球数増加	1 (0.2)	1	0.57			
γ－グルタミルトランスフェラーゼ増加	1 (0.2)	1	0.57			
肝機能検査値上昇	1 (0.2)	1	0.57			
好中球数減少	1 (0.2)	1	0.57			
体重増加				1 (0.5)	1	1.74
白血球数減少	1 (0.2)	1	0.57			
血液およびリンパ系障害	6 (1.0)	6	3.39	3 (1.5)	3	5.23
好酸球増加症	4 (0.7)	4	2.26			
リンパ節症	2 (0.3)	2	1.13	1 (0.5)	1	1.74

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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=592) N (%)	E	R	Placebo (n=200) N (%)	E	R
白血球減少症				1 (0.5)	1	1.74
リンパ球減少症				1 (0.5)	1	1.74
筋骨格系および結合組織障害	4 (0.7)	6	3.39	4 (2.0)	5	8.72
関節痛	2 (0.3)	2	1.13			
関節腫脹				1 (0.5)	2	3.49
足底筋膜炎				2 (1.0)	2	3.49
背部痛	1 (0.2)	1	0.57			
関節硬直	1 (0.2)	1	0.57			
筋力低下				1 (0.5)	1	1.74
筋骨格硬直	1 (0.2)	1	0.57			
関節周囲炎	1 (0.2)	1	0.57			
呼吸器、胸郭および縦隔障害	3 (0.5)	3	1.70	3 (1.5)	3	5.23
口腔咽頭痛	1 (0.2)	1	0.57	1 (0.5)	1	1.74
喘息				1 (0.5)	1	1.74
咳嗽	1 (0.2)	1	0.57			
呼吸困難				1 (0.5)	1	1.74
鼻漏	1 (0.2)	1	0.57			

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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=592) N (%)	E	R	Placebo (n=200) N (%)	E	R
精神障害	5 (0.8)	7	3.96			
睡眠障害	2 (0.3)	2	1.13			
激越	1 (0.2)	1	0.57			
不安	1 (0.2)	1	0.57			
うつ病	1 (0.2)	1	0.57			
不眠症	1 (0.2)	1	0.57			
気分変化	1 (0.2)	1	0.57			
傷害、中毒および処置合併症	1 (0.2)	1	0.57	1 (0.5)	1	1.74
処置による悪心	1 (0.2)	1	0.57			
瘢痕				1 (0.5)	1	1.74
生殖系および乳房障害	2 (0.3)	2	1.13			
女性化乳房	1 (0.2)	1	0.57			
乳頭痛	1 (0.2)	1	0.57			
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）				1 (0.5)	3	5.23
皮膚有棘細胞癌				1 (0.5)	3	5.23

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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.

1.9.2.1.6 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=91)				Tralokinumab Q4W (n=89)				Placebo (n=46)				Placebo (n=31)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
All AEs	26	(28.6)	76	161.96	19	(21.3)	36	80.62	11	(23.9)	20	99.67	6	(19.4)	12	79.53
感染症および寄生虫症	14	(15.4)	21	44.75	4	(4.5)	5	11.20	4	(8.7)	4	19.93	3	(9.7)	5	33.14
結膜炎	3	(3.3)	5	10.66												
上気道感染	4	(4.4)	4	8.52	1	(1.1)	1	2.24								
ウイルス性上気道感染	4	(4.4)	4	8.52					1	(2.2)	1	4.98				
口腔ヘルペス	1	(1.1)	2	4.26					1	(2.2)	1	4.98	1	(3.2)	1	6.63
気管支炎					1	(1.1)	1	2.24					1	(3.2)	1	6.63
ヘルペス性状湿疹	1	(1.1)	1	2.13									1	(3.2)	1	6.63
下気道感染	1	(1.1)	1	2.13	1	(1.1)	1	2.24								
皮膚感染	1	(1.1)	1	2.13					1	(2.2)	1	4.98				
蜂巣炎													1	(3.2)	1	6.63
毛包炎	1	(1.1)	1	2.13												

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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=91)				Tralokinumab Q4W (n=89)				Placebo (n=46)				Placebo (n=31)			
System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
せつ					1	(1.1)	1	2.24								
伝染性軟属腫	1	(1.1)	1	2.13												
鼻ヘルペス													1	(3.2)	1	6.63
鼻炎									1	(2.2)	1	4.98				
癜風	1	(1.1)	1	2.13												
腟感染					1	(1.1)	1	2.24								
一般・全身障害および投与部位の状態	10	(11.0)	39	83.11	6	(6.7)	8	17.92	1	(2.2)	4	19.93	1	(3.2)	1	6.63
注射部位反応	4	(4.4)	12	25.57	4	(4.5)	4	8.96								
注射部位疼痛	3	(3.3)	7	14.92					1	(2.2)	4	19.93				
注射部位腫脹	2	(2.2)	8	17.05												

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System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
注射部位紅斑	3	(3.3)	4	8.52	2	(2.2)	2	4.48								
注射部位出血	1	(1.1)	3	6.39												
注射部位そう痒感	2	(2.2)	2	4.26	1	(1.1)	1	2.24								
注射部位内出血													1	(3.2)	1	6.63
注射部位過敏反応					1	(1.1)	1	2.24								
注射部位浮腫	1	(1.1)	1	2.13												
注射部位発疹	1	(1.1)	1	2.13												
末梢腫脹	1	(1.1)	1	2.13												
皮膚および皮下組織障害	5	(5.5)	6	12.79	3	(3.4)	4	8.96	2	(4.3)	3	14.95	1	(3.2)	1	6.63
アトピー性皮膚炎	4	(4.4)	5	10.66	3	(3.4)	3	6.72	1	(2.2)	1	4.98	1	(3.2)	1	6.63

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System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
ざ瘡					1	(1.1)	1	2.24								
神経皮膚炎									1	(2.2)	1	4.98				
点状出血									1	(2.2)	1	4.98				
蕁麻疹	1	(1.1)	1	2.13												
臨床検査	3	(3.3)	4	8.52	4	(4.5)	6	13.44	2	(4.3)	4	19.93	1	(3.2)	5	33.14
アラニンアミノトランスフェラーゼ増加					2	(2.2)	3	6.72					1	(3.2)	2	13.26
肝機能検査異常	1	(1.1)	1	2.13	1	(1.1)	1	2.24								
低比重リポ蛋白増加					1	(1.1)	1	2.24	1	(2.2)	1	4.98				
血中アルカリホスファターゼ減少													1	(3.2)	1	6.63
血中乳酸脱水素酵素増加									1	(2.2)	1	4.98				

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System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
血中カリウム増加													1	(3.2)	1	6.63
血中尿素減少									1	(2.2)	1	4.98				
好酸球数増加	1	(1.1)	1	2.13												
肝機能検査値上昇					1	(1.1)	1	2.24								
リンパ球数減少													1	(3.2)	1	6.63
好中球数増加	1	(1.1)	1	2.13												
尿中蛋白陽性	1	(1.1)	1	2.13												
トランスアミナーゼ上昇									1	(2.2)	1	4.98				
眼障害	2	(2.2)	3	6.39	3	(3.4)	3	6.72	2	(4.3)	2	9.97				
アレルギー性結膜炎	1	(1.1)	1	2.13	1	(1.1)	1	2.24								
眼乾燥	1	(1.1)	1	2.13					1	(2.2)	1	4.98				

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System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
眼瞼炎					1	(1.1)	1	2.24								
眼瞼湿疹									1	(2.2)	1	4.98				
眼瞼浮腫					1	(1.1)	1	2.24								
角膜炎	1	(1.1)	1	2.13												
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	2.13	2	(2.2)	2	4.48								
肛門性器疣贅					1	(1.1)	1	2.24								
甲状腺の良性新生物	1	(1.1)	1	2.13												
皮膚有棘細胞癌					1	(1.1)	1	2.24								
血液およびリンパ系障害	1	(1.1)	1	2.13					1	(2.2)	1	4.98				

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System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
好酸球増加症	1	(1.1)	1	2.13					1	(2.2)	1	4.98				
呼吸器、胸郭および縦隔障害					2	(2.2)	2	4.48								
喘息					1	(1.1)	1	2.24								
口腔咽頭痛					1	(1.1)	1	2.24								
胃腸障害					1	(1.1)	1	2.24								
舌潰瘍					1	(1.1)	1	2.24								

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System Organ Class (SOC) Preferred term	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R	N	(%)	E	R
筋骨格系および結合組織障害					1	(1.1)	2	4.48								
関節痛					1	(1.1)	2	4.48								
神経系障害					1	(1.1)	1	2.24								
頭痛					1	(1.1)	1	2.24								
精神障害					1	(1.1)	2	4.48								
不安					1	(1.1)	1	2.24								
パニック発作					1	(1.1)	1	2.24								

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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	(1.1)	1	2.13												
腎機能障害	1	(1.1)	1	2.13												
生殖系および乳房障害									1	(2.2)	1	4.98				
女性化乳房									1	(2.2)	1	4.98				
血管障害									1	(2.2)	1	4.98				
高血圧									1	(2.2)	1	4.98				

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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).