2.7.3.3 全試験を通しての結果の比較と解析

2.7.3.3.1 試験対象集団

2.7.3.3.1.1 人口統計学的及び他の基準値の特性の比較

第II相試験、第III相試験並びに長期投与試験の治療開始日の人口統計学的特性及びADの重症度を表 2.7.3-28に示した。

第III相試験と長期投与試験の患者の人口統計学的特性に明らかな違いはみられなかった。

患者の性別は、第II相試験では男性が52%、女性が48%と同じ割合であったが、第III相試験では男性が65.6%、女性が34.4%、長期投与試験ではそれぞれ63.6%、36.4%と男性患者が多かった。

患者の平均年齢は、第II相試験が33.0歳～35.7歳、第III相試験が39.3歳、長期投与試験が38.9歳であり、第III相試験及び長期投与試験の方が若干高かった。

患者の平均体重は、第II相試験では72.51 kg～76.01 kg、第III相試験では64.26 kg、長期投与試験では66.32 kgであった。第II相試験は日本人を含む国際共同試験であったが、第III相試験並びに長期投与試験は日本人のみを対象とした試験であったため、第II相試験と比較して、患者の体重が軽くなったものと考えた。また、患者の平均身長は、試験間で同様であった。

治療開始日のそう痒VASの平均値は、第II相試験が73.21～77.56、第III相試験が75.05、長期投与試験が78.39、EASI合計スコアの平均値は第II相試験が27.03～32.62、第III相試験が26.92、長期投与試験が29.04であり、試験間で同様であった。一方、治療開始日のsIGAスコアは、第II相試験では4以上が43.5%～63.0%であったのに対し、第III相試験では40.9%、長期投与試験では62.5%であり、第III相試験と比較して、長期投与試験では、ADの皮疹の重症度が高かった。

ADに対するTCSの併用状況は、第III相試験では併用ありが97.2%（209/215例）、長期投与試験では98.9%（87/88例）と同様であった。一方、TCIの併用状況は、第III相試験では併用ありが40.9%（88/215例）に対し、長期投与試験では48.9%（43/88例）であり、長期投与試験でTCIを併用していた患者が多かった。抗ヒスタミン薬又は抗アレルギー薬の併用状況は、第III相試験では併用ありが88.4%（190/215例）、長期投与試験では93.2%（82/88例）と同様であった。

アレルギー疾患の合併状況は、第III相試験では併用していた患者の割合が64.7%（139/215例）、長期投与試験では59.1%（52/88例）と同様であった。

2.7.3.3.1.2 試験から脱落した被験者の内訳

第II相試験では、264例（0.1 mg/kg Q4W群：53例、0.5 mg/kg Q4W群：54例、2.0 mg/kg Q4W群：52例、2.0 mg/kg Q8W群：52例、プラセボ群：53例）がランダム化され、治験薬を投与された。216例（0.1 mg/kg Q4W群：44例、0.5 mg/kg Q4W群：45例、2.0 mg/kg Q4W群：45例、2.0 mg/kg Q8W群：38例、プラセボ群：44例）がPartAを完了した。PartAでは、48例（0.1 mg/kg Q4W群：9例、0.5 mg/kg Q4W群：9例、2.0 mg/kg Q4W群：7例、2.0 mg/kg Q8W群：14例、プラセボ群：9例）が治験を中止した。PartBには191例（0.1 mg/kg Q4W群：54例、0.5 mg/kg Q4W群：50例、2.0 mg/kg Q4W群：52例、2.0 mg/kg Q8W群：35例）が移行し、131例（0.1 mg/kg Q4W群：39例、0.5 mg/kg Q4W群：35例、2.0 mg/kg Q4W群：38例、2.0 mg/kg Q8W群：19例）がPartBを完了した。PartBでは、60例（0.1 mg/kg Q4W群：15例、0.5 mg/kg Q4W群：15例、2.0 mg/kg Q4W群：14例、2.0 mg/kg Q8W群：16例）が治験を中止した。

PartAでは、2.0 mg/kg Q8W群（26.9%）で、他の群（13.5%～17.0%）と比較して、中止例が多かった。中止理由は、いずれの群も有害事象、被験者希望による中止が多かった（表2.7.6.2-5）

長期投与期間（PartA/B）では、PartAと同様、2.0 mg/kg Q8W群（45.7%）で、他の群（26.9%～

30.0%）と比較して、中止例が多かった。中止理由は、いずれの群も有害事象、効果不十分及び被験者希望による中止が多かった。

第III相試験では、215例（nemolizumab群：143例、プラセボ群：72例）がランダム化され、治験薬を投与された206例（95.8%）（nemolizumab群：139例（97.2%）、プラセボ群：67例（93.1%））がPartAを完了し、9例（4.2%）（nemolizumab群：4例（2.8%）、プラセボ群：5例（6.9%））が治験を中止した。PartAを完了した206例全例がPartBに移行した。194例（90.2%）が68週後の投与を完了し、21例（9.8%）が治験を中止した。

中止理由は、PartAでは選択・除外基準違反が最も多く、PartBでは被験者希望による中止が最も多かった（表2.7.6.3-3）。

長期投与試験では、88例（医療従事者群：44例、自己注射群：44例）が治験に組み入れられ、治験薬が投与された。78例（88.6%）（医療従事者群：41例（93.2%）、自己注射群：37例（84.1%））が52週後の投与を完了し、10例（11.4%）（医療従事者群：3例（6.8%）、自己注射群：7例（15.9%））が治験を中止した。

主な中止理由は、被験者希望による中止及び治験の継続が困難と思われる有害事象が発現したためであった（5.3.5.2-1Table14.1.1）。

2.7.3.3.2 全有効性試験の結果の比較検討

2.7.3.3.2.1 主要評価項目：そう痒VAS変化率

第II相試験及び第III相試験の投与開始12週後及び16週後のそう痒VAS変化率を表 2.7.3-14に示した。

Nemolizumabを単独投与した場合でも、TCS/TCI併用下でnemolizumabを投与した場合でも、そう痒VAS変化率は一貫して、nemolizumab群のプラセボ群に対する優越性が示された。各試験での経時推移では、プラセボ群に対して、nemolizumab群では投与開始1週後から改善傾向がみられ、投与開始12週後、投与開始16週後まで経時的に改善した（図 2.7.3-12、図 2.7.3-6）。

なお、長期投与試験（全体）のそう痒VAS変化率の平均値（SD）は投与開始12週後で–43.25%（26.93）、投与開始16週後で–47.48%（26.50）であり、第II相試験及び第III相試験と同様に改善した（表2.7.6.4-3）。

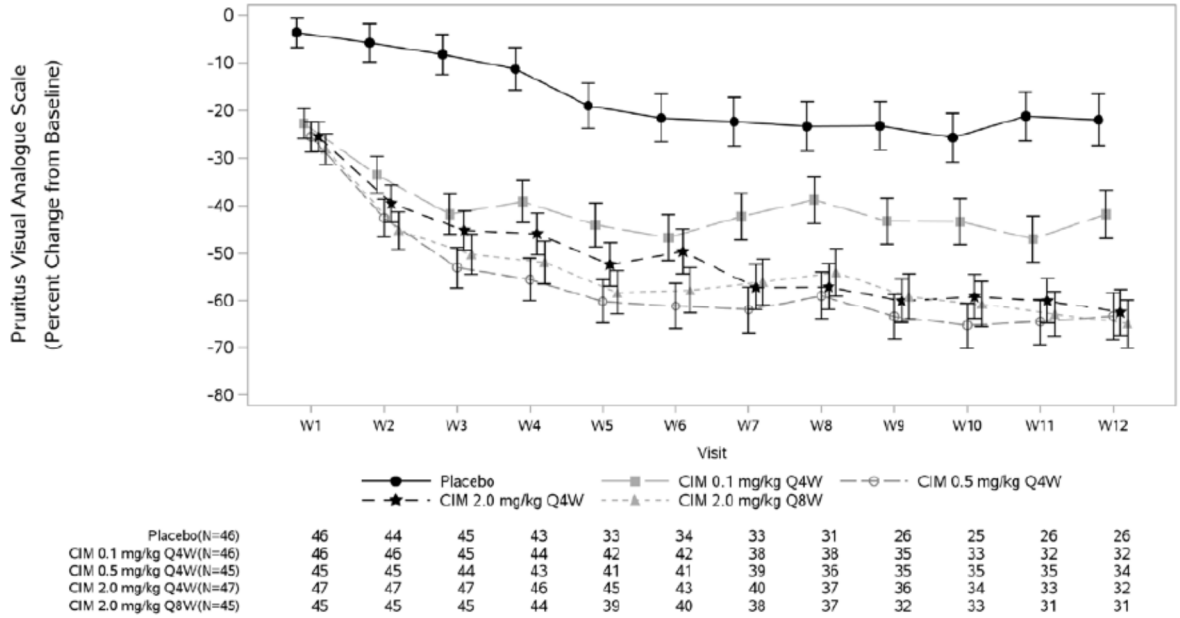
表 2.7.3-14 そう痒VAS変化率（PartA）

	第II相試験（CIM003JG）*（PPS）			第III相試験（M525101-01）（FAS）	
	0.5 mg/kg Q4W群（N=45）	2.0 mg/kg Q4W群（N=47）	プラセボ群（N=46）	nemolizumab群（N=143）	プラセボ群（N=72）
Baseline					
平均値（SD）	76.48（13.24）	75.97（11.13）	73.21（10.85）	74.92（10.48）	75.30（10.46）
投与開始12週後					
N	34	32	26	143	72
最小二乗平均値 SE 両側95%CI	–63.36 5.06 –73.33 , –53.38	–62.65 5.00 –72.51 , –52.79	–21.96 5.38 –32.56 , –11.36	–39.52 2.45 –44.36 , –34.68	–18.89 3.44 –25.67 , –12.11
プラセボ差 両側95%CI P値	–41.40 –55.96 , –26.83 < 0.0001	–40.69 –55.17 , –26.21 < 0.0001	—	–20.63 –28.96 , –12.30 < 0.0001	—
投与開始16週後					
N	—	—	—	143	72
最小二乗平均値 SE 両側95%CI	—	—	—	–42.84 2.57 –47.90 , –37.77	–21.39 3.61 –28.51 , –14.27
プラセボ差 両側95%CI P値	—	—	—	–21.45 –30.19 , –12.71 < 0.0001	—

*：MMRMによる探索的解析

5.3.5.1-1 Table14.2-7、5.3.5.1-2 Table14.2.1.1.3、Table14.2.3.2.1.1.1.1から改変

図 2.7.3-12 そう痒VAS変化率（平均値 ± SD）の経時推移図（第II相試験、PartA、PPS）



Placebo(N=46)	46	44	45	43	33	34	33	31	26	25	26	26
CIM 0.1 mg/kg Q4W(N=46)	46	46	45	44	42	42	38	38	35	33	32	32
CIM 0.5 mg/kg Q4W(N=45)	45	45	44	43	41	41	39	36	35	35	35	34
CIM 2.0 mg/kg Q4W(N=47)	47	47	47	46	45	43	40	37	36	34	33	32
CIM 2.0 mg/kg Q8W(N=45)	45	45	45	44	39	40	38	37	32	33	31	31

5.3.5.1-1 Figure14.2-9から引用

2.7.3.3.2.2 そう痒に関する評価項目

そう痒VAS、そう痒NRS及びかゆみスコアで、ADのそう痒に対するnemolizumabの有効性を評価した。Nemolizumabを単独投与した場合でも、TCS/TCI併用下でnemolizumabを投与した場合でも、一貫して、プラセボ群と比較して、ADのそう痒に対するnemolizumabの有効性が確認された。

(1) 投与開始4週後のそう痒VAS変化率

投与開始4週後のそう痒VAS変化率を表 2.7.3-15に示した。

投与開始4週後のそう痒VAS変化率は、プラセボ群と比較して、nemolizumab群の方が改善していた。なお、長期投与試験の投与開始4週後のそう痒VAS変化率の平均値（SD）は–32.17%（25.76）であり、第II相試験及び第III相試験と同様に改善した（表2.7.6.4-3）。

表 2.7.3-15 投与4週後のそう痒VAS変化率

	第II相試験（CIM003JG）*（PPS）			第III相試験（M525101-01）（FAS）	
	0.5 mg/kg Q4W群（N=45）	2.0 mg/kg Q4W群（N=47）	プラセボ群（N=46）	nemolizumab群（N=143）	プラセボ群（N=72）
投与開始4週後					
N	43	46	43	143	72
最小二乗平均値 SE 両側95%CI	–55.50 4.49 –64.35 , –46.65	–45.96 4.37 –54.58 , –37.34	–11.26 4.47 –20.07 , –2.45	–32.30 2.00 –36.24 , –28.36	–12.90 2.81 –18.45 , –7.35
プラセボ差 両側95%CI P値	—	—	—	–19.40 –26.20 , –12.60 < 0.0001	—

*：MMRMによる探索的解析

5.3.5.1-1 Table14.2-15、5.3.5.1-2 Table14.2.1.1.3から改変

(2) そう痒VAS（50%、75%改善）

そう痒VAS変化率が50%、75%改善した患者の割合を表 2.7.3-16に示した。

第II相試験、第III相試験ともに、そう痒VASが50%、75%改善した患者の割合は、プラセボ群と比較して、nemolizumab群で一貫して高かった。第III相試験では、投与開始16週後にそう痒VASが50%、75%改善した患者の割合は、プラセボ群と比較して、nemolizumab群で有意に高かった。また、そう痒VASが50%改善した患者の割合は、プラセボ群と比較して、投与開始1週後以降、一貫してnemolizumab群で高かった（表 2.7.3-38）。

長期投与試験は非盲検で実施しており、第III相試験とTCS/TCIの併用状況が異なるため、試験間で正確に比較はできないものの、投与開始16週後のそう痒VAS50%改善割合は、第III相試験と比較して高い傾向がみられ、75%改善割合は第III相試験と同様であった（表 2.7.3-31）。

表 2.7.3-16 そう痒VAS変化率が50%、75%改善した患者の割合

	第II相試験（CIM003JG）（PPS）			第III相試験（M525101-01）（FAS）		長期投与試験（M525101-02）（FAS）
	nemolizumab 0.5 mg/kg群（N=45）	nemolizumab 2.0 mg/kg群（N=47）	プラセボ群（N=46）	nemolizumab群（N=143）	プラセボ群（N=72）	nemolizumab群（N=88）
N	43	46	43	143	72	88
投与開始12週後：50%改善						
割合 例数	67.4% 29	58.7% 27	20.9% 9	33.6% 48	11.1% 8	40.9% 36
プラセボ差 両側95%CI P値	—	—	—	22.5 8.2 , 35.8 0.0002	—	—
75%改善						
割合 例数	48.8% 21	43.5% 20	11.6% 5	10.5% 15	4.2% 3	12.5% 11
プラセボ差 両側95%CI P値	—	—	—	6.3 –7.9 , 20.3 0.0895	—	—

5.3.5.1-1 Table11.17、5.3.5.1-2 Table14.2.3.3.1.1、5.3.5.2-1 Table14.2.2.1から改変

表 2.7.3-16 そう痒VAS変化率が50%、75%改善した患者の割合 （続き）

	第II相試験（CIM003JG）（PPS）			第III相試験（M525101-01）（FAS）		長期投与試験（M525101-02）（FAS）
	nemolizumab 0.5 mg/kg群（N=45）	nemolizumab 2.0 mg/kg群（N=47）	プラセボ群（N=46）	nemolizumab群（N=143）	プラセボ群（N=72）	nemolizumab群（N=88）
N	43	46	43	143	72	88
投与開始16週後：50%改善						
割合 例数	—	—	—	34.3% 49	13.9% 10	45.5% 40
プラセボ差 両側95%CI P値	—	—	—	20.4 6.1 , 33.8 0.0010	—	—
75%改善						
割合 例数	—	—	—	14.7% 21	4.2% 3	14.8% 13
プラセボ差 両側95%CI P値	—	—	—	10.5 –3.7 , 24.4 0.0144	—	—

5.3.5.1-1 Table11.17、5.3.5.1-2 Table14.2.3.3.1.1、5.3.5.2-1 Table14.2.2.1から改変

(3) そう痒NRS

投与開始16週後にそう痒NRSが4以上改善した患者の割合を表 2.7.3-17に示した。

第III相試験で、投与開始16週後にそう痒NRSが4以上改善した患者の割合は、プラセボ群と比較して、nemolizumab群で有意に高かった（$P = 0.0011$）。また、その割合は、投与開始1週後以降、プラセボ群と比較して、nemolizumab群で一貫して高かった（表 2.7.3-39）。また、投与開始16週後では、第III相試験よりも長期投与試験で改善割合が高かった。

表 2.7.3-17 投与開始16週後にそう痒NRSが4以上改善した患者の割合

	第III相試験（M525101-01）（FAS）		長期投与試験（M525101-02）（FAS）
	nemolizumab群（N=143）	プラセボ群（N=72）	nemolizumab群（N=88）
割合（例数）	32.2%（46）	12.5%（9）	44.3%（39）
プラセボ差（両側95%CI） P値	19.7%（5.4 , 33.2） 0.0011		—

5.3.5.1-2 Table14.2.3.3.3.1、5.3.5.2-1 Table14.2.2.3から改変

(4) かゆみスコア

投与開始16週後にかゆみスコアが1以下に達した患者の割合を表 2.7.3-18に示した。

第III相試験で、投与開始16週後にかゆみスコアが1以下となった患者の割合は、プラセボ群と比較して、nemolizumab群で有意に高かった（$P = 0.0144$）。また、投与開始16週後では、第III相試験と長期投与試験で同様の改善を示した。

表 2.7.3-18投与開始16週後にかゆみスコアが1以下に達した患者の割合

	第III相試験（M525101-01）（FAS）		長期投与試験（M525101-02）（FAS）
	nemolizumab群（N=143）	プラセボ群（N=72）	nemolizumab群（N=88）
割合（例数）	16.8%（24）	5.6%（4）	20.5%（18）
プラセボ差（両側95%CI） P値	11.2%（–3.0 , 25.1） 0.0144		–

5.3.5.1-2 Table14.2.3.3.2.1、5.3.5.2-1 Table14.2.2.2から改変

2.7.3.3.2.3 皮膚症状に関する評価項目

EASI合計スコア及びsIGAで、ADの皮膚症状に対するnemolizumabの有効性を評価した。Nemolizumabを単独投与した場合でも、TCS/TCI併用下でnemolizumabを投与した場合でも、一貫して、プラセボと比較して、ADの皮膚症状に対するnemolizumabの有効性が確認された。

(1) EASI合計スコア

第II相試験、第III相試験及び長期投与試験のEASI合計スコアの変化率を表 2.7.3-19に示した。第II相試験では、投与開始12週後に、nemolizumab群でプラセボよりも改善傾向を示し（表 2.7.3-5）、第III相試験では、投与開始16週後にプラセボ群との優越性が示された（表 2.7.3-7）。

第II相試験、第III相試験での経時推移では、プラセボ群に対して、nemolizumab群では投与1週後から改善傾向がみられ、投与開始12週後、投与開始16週後まで経時的に改善した（図 2.7.3-13、図 2.7.3-14）。

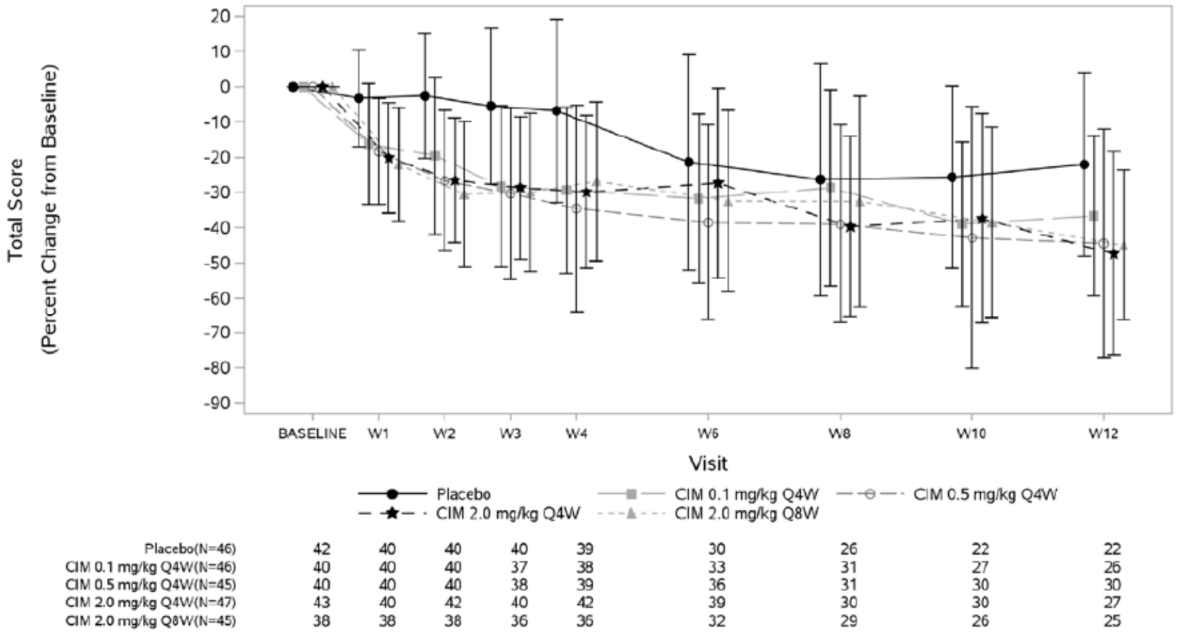
投与開始16週後では、第III相試験と長期投与試験で同様の改善を示した。長期投与試験では第III相試験と比較して、治療開始日のADの皮膚症状の重症度が高い傾向が認められたが（2.7.3.3.1.1 ）、投与開始16週後のnemolizumab群のEASIは同様の改善を示したことから、治療開始日のADの皮膚症状の重症度に関わらず、nemolizumabはADの皮膚症状を改善するものと考える。

表 2.7.3-19 EASI合計スコアの変化率

	第II相試験（CIM003JG）（PPS）			第III相試験（M525101-01）（FAS）		長期投与試験（M525101-02）（FAS）
	nemolizumab 0.5 mg/kg群（N=45）	nemolizumab 2.0 mg/kg群（N=47）	プラセボ群（N=46）	nemolizumab群（N=143）	プラセボ群（N=72）	nemolizumab群（N=88）
N	43	46	43	140	68	87
投与開始12週後						
平均値 SD	–44.57 48.21	–40.29 37.70	–20.89 47.63	–40.72 41.35	–30.72 41.26	–49.25 43.83
投与開始16週後						
平均値 SD	–	–	–	–45.97 38.35	–33.25 40.40	-48.71 46.22

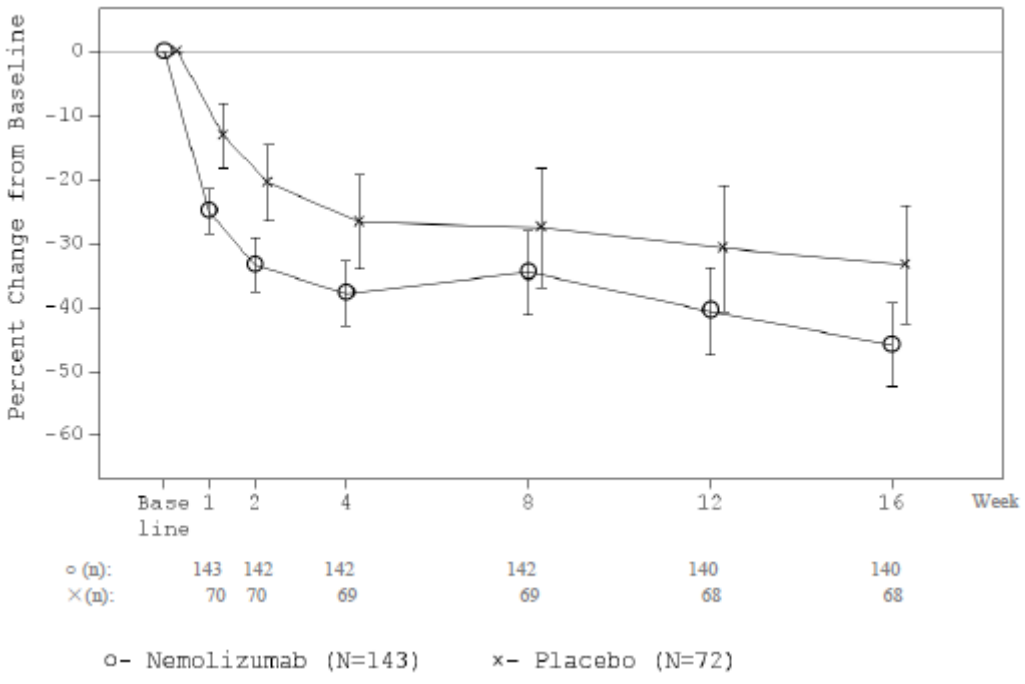
5.3.5.1-1 Table11.10、5.3.5.1-2 Table14.2.3.2.3.1.3、5.3.5.2-1 Table14.2.1.4から改変

図 2.7.3-13 EASI合計スコア変化率（平均値 ± SD）の経時推移図（第II相試験、PartA、PP）



5.3.5.1-1 Figure14.2-10から引用

図 2.7.3-14 EASI合計スコア変化率（最小二乗平均値 ± 両側95%CI）の経時推移図
（第III相試験、PartA、FAS）



5.3.5.1-2 Figure11-3から引用

(2) sIGA

第II相試験では、sIGAがベースラインより2段階以上改善した患者の割合並びにsIGAが0又は1以下となった患者の割合を求めた（表 2.7.3-20）。一方、第III相試験及び長期投与試験では、sIGAがベースラインより2段階以上改善かつ0又は1以下となった患者の割合を求めた（表 2.7.3-21）。

第II相試験で、投与開始12週後にsIGAが2段階以上改善した患者の割合は、プラセボ群と比較して、nemolizumab群で高かったが、第III相試験では群間差はみられなかった。また、投与開始16週後では、第III相試験と長期投与試験で同様の改善を示した。

表 2.7.3-20 投与開始12週後にsIGAがベースラインより2段階以上改善した患者の割合並びにsIGAが0又は1以下となった患者の割合

	第II相試験（CIM003JG）（PPS）			第II相試験（CIM003JG）（PPS）		
	nemolizumab 0.5 mg/kg群（N=45）	nemolizumab 2.0 mg/kg群（N=47）	プラセボ群（N=46）	nemolizumab 0.5 mg/kg群（N=45）	nemolizumab 2.0 mg/kg群（N=47）	プラセボ群（N=46）
N	43	46	43	43	46	43
評価項目	sIGAがベースラインより2段階以上改善			sIGAが0又は1以下		
割合	30.2%	21.7%	11.6%	20.9%	15.2%	4.7%
例数	13	10	5	9	7	2

5.3.5.1-1 Table14.2-111、Table14.2-322から改変

表 2.7.3-21 投与開始16週後にsIGAがベースラインより2段階以上改善かつ0又は1以下となった患者の割合

	第III相試験（M525101-01）（FAS）		長期投与試験（M525101-02）（FAS）
	nemolizumab群（N=143）	プラセボ群（N=72）	nemolizumab群（N=88）
N	143	72	88
割合 例数	5.6% 8	5.6% 4	8.0% 7
群間差 両側95%CI P値	0% –14.1 , 14.1 0.6293	—	—

5.3.5.1-2 Table14.2.3.3.5.1、5.3.5.2-1 Table14.2.2.5から改変

2.7.3.3.2.4 QOLに関する評価項目

ISI合計スコア、DLQI合計スコア及びWPAI-ADで、nemolizumabの患者QOLの改善効果を評価した。Nemolizumabを単独投与した場合でも、TCS/TCI併用下でnemolizumabを投与した場合でも、一貫して、プラセボと比較して、nemolizumabは患者QOLを改善した。

(1) ISI合計スコア（7以下）

第III相試験ではランダム化日、長期投与試験では治療開始日のISI合計スコアが8以上の患者を対象に、ISI合計スコアが7以下となった患者の割合を算出した。

第III相試験で、投与開始16週後にISI合計スコアが7以下となった患者の割合は、プラセボ群と比較して、nemolizumab群で有意に高かった（表 2.7.3-22）。また、投与開始16週後では、第III相試験と長期投与試験で同様の改善を示した。

表 2.7.3-22 ISI合計スコアが7以下となった被験者の割合

		第III相試験（M525101-01）（FAS）		長期投与試験（M525101-02）（FAS）
		nemolizumab群（N=108）	プラセボ群（N=56）	nemolizumab群（N=63）
投与開始16週後	%（例数）	54.6（59）	21.4（12）	49.2（31）
	群間差（両側95%CI） P値	33.2（17.3 , 48.1） <0.0001		—

5.3.5.1-2 Table14.2.2.4、5.3.5.2-1 Table14.2.2.6から改変

(2) DLQI合計スコア

DLQI合計スコアを表 2.7.3-23に示した。

治療開始日のDLQI合計スコアの平均値は、第III相試験と比較して、第II相試験で若干高かったが、試験内での群間差はなかった。第II相試験、第III相試験ともに、nemolizumab群のDLQI合計スコアは、プラセボ群より減少した。

表 2.7.3-23 DLQI合計スコア

	第II相試験（CIM003JG）（PPS）			第III相試験（M525101-01）（FAS）	
	nemolizumab 0.5 mg/kg群（N=45）	nemolizumab 2.0 mg/kg群（N=47）	プラセボ群（N=46）	nemolizumab群（N=143）	プラセボ群（N=72）
治療開始日					
平均値（SD）	14.3（6.3）	15.3（5.9）	15.1（6.1）	12.4（5.4）	12.1（5.4）
投与開始12週後					
平均値（SD）	7.6（7.5）	7.0（6.8）	10.3（6.8）	6.9（4.7）	9.7（6.1）
投与開始16週後					
平均値（SD）	—	—	—	6.6（4.9）	8.9（5.8）

5.3.5.1-1 Table14.2-222、5.3.5.1-2 Table14.2.3.2.6.1.1から改変

(3) WPAI-AD

第II相試験では、投与開始12週後のWPAI-ADのベースラインからの変化率は、すべての項目で、プラセボ群と比較して、memolizumab 0.5 mg/kg Q4W群で改善し、特に「work impairment」で、その改善が大きかった（表2.7.6.2-17）。

第III相試験では、投与開始16週後のWPAI-AD（Q7～Q10）のベースラインからの変化量は、「work time missed」では、プラセボ群とnemolizumab群で差はみられなかったが、それ以外の項目では、プラセボ群と比較して、nemolizumab群で改善がみられた（表2.7.6.3-10）。

2.7.3.3.3 部分集団における結果の比較

(1) 第II相試験

そう痒VAS変化率に対して、PPSを対象に部分集団で解析した。部分集団として、人口統計学的特性（性別、年齢、BMI、地域）、ベースラインのそう痒VAS、EASI、sIGA、SCORAD及びBSAを設定した。

投与開始12週後では、いずれの部分集団も一貫してnemolizumab群のそう痒VASが改善していた。また、部分集団間でも、そう痒VAS変化率に明らかな差はみられなかった（5.3.5.1-1Table11.70～Table11.72、Table14.2-167～Table14.2-173）。

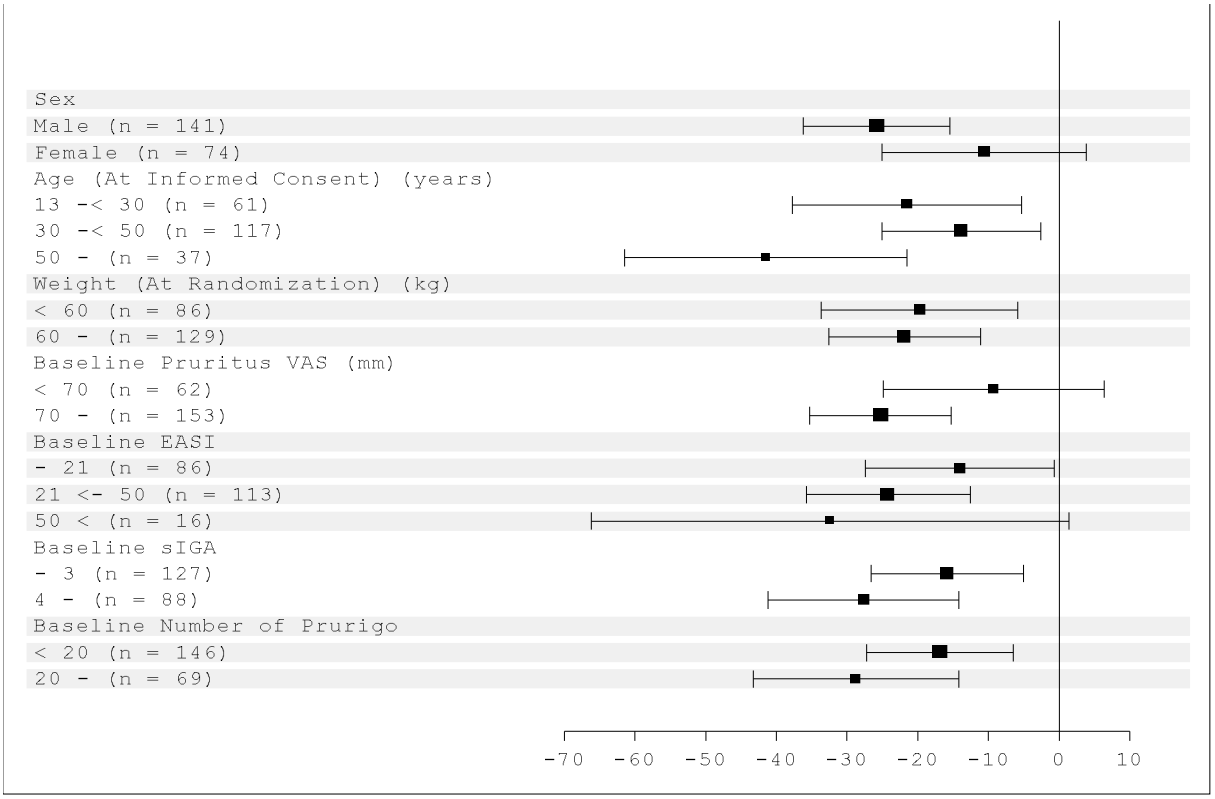
(2) 第III相試験

主要評価項目（投与開始16週後のそう痒VAS変化率）に対して、FASを対象に部分集団解析を実施した。層別因子として、人口統計学的データ（性別、年齢、体重）、ベースラインのそう痒VAS、EASI、sIGA及び痒疹数を設定した。最小二乗平均は層別因子を共変量としたANCOVAで推定した。投与開始16週後のデータが欠測の場合、LOCFで補完した。

投与開始16週後では、いずれの部分集団も一貫してそう痒VASは改善していた。特に、ベースラインそう痒VAS、EASI、IGAが大きい患者集団並びにベースラインの痒疹数が多い（20個以上）集団では、nemolizumab群でそう痒VASの改善が大きい傾向が認められた（図 2.7.3-15）。

部分集団解析の結果は、5.3.5.1-2Table14.2.4.1に示した。

図 2.7.3-15 投与開始16週後のそう痒VAS変化率に対する部分集団解析（第III相試験、PartA、FAS）



5.3.5.1-2 Figure11-7から引用、横軸：投与開始16週後のそう痒VAS変化率

(3) 長期投与試験

そう痒VASに対して、FASを対象に部分集団で解析した。部分集団として、人口統計学的データ（性別、年齢、体重）、ベースラインのそう痒VAS、EASI及びsIGAを設定した。

投与開始52週後では、いずれの部分集団も一貫してそう痒VASを改善していた。また、部分集団間でも、そう痒VASの変化率に明らかな差はみられなかった（5.3.5.2-1Table14.2.3.1～Table14.2.3.6）。

2.7.3.3.4 レスキュー治療

第II相試験では、投与4週後以降、そう痒VAS及び皮膚症状の改善が認められない場合、治験責任（分担）医師の判断で、2.7.3.1.2 臨床試験デザインで示したPartAではNICE ガイドライン[1)]で「potent」に分類される4種類のTCS、PartBでは「potent」又は「very potent」に分類される5種類のTCSでレスキュー治療することを認めた。また、日本及び米国では、NICE ガイドラインには含まれないが、各国で販売されているTCSのうち、日本ではstrongクラス以上、米国ではclass 1～3に分類される薬剤でレスキュー治療することを認めた。

なお、以下の基準すべてに該当する場合、「改善が認められない」と定義した。

- ベースライン時からsIGAスコアに変化が認められず、sIGAスコアが3以上
- ベースライン時のそう痒VASからの変化率が10%未満
- そう痒VASが50 mm以上

第III相試験では、ランダム化以降に、ADの皮疹の悪化の有害事象が認められた場合、治験責任（分担）医師の判断で、TCS（「日本皮膚科学会AD診療ガイドライン2016」で「very strong」以上）を併用することを可とした。

プラセボ対照期間（PartA）でレスキュー治療を受けた患者の割合を表 2.7.3-24、レスキュー治療を受けるまでの日数を図 2.7.3-16及び図 2.7.3-17に示した。

第II相試験でレスキュー治療を受けた患者の割合は、0.5 mg/kg Q4W群が24.4%（11/45例）、プラセボ群が39.1%（18/46例）であり、プラセボ群の割合が高かった。一方、第III相試験でレスキュー治療を受けた患者の割合は、nemolizumab群が17.5%（25/143例）、プラセボ群が18.1%（13/72例）であり、群間で差はみられなかった。

第II相試験では、治療開始日以降、nemolizumab群で段階的にレスキュー治療を受ける患者が増えたが、第III相試験では、投与8週後以降はレスキュー治療を受ける患者の割合が一定である傾向がみられた。また、第II相試験では、nemolizumab群と比較して、プラセボ群で投与5週後にレスキュー治療の割合が一気に増加する一方、第III相試験では、nemolizumab群とプラセボ群で同様の割合であった。

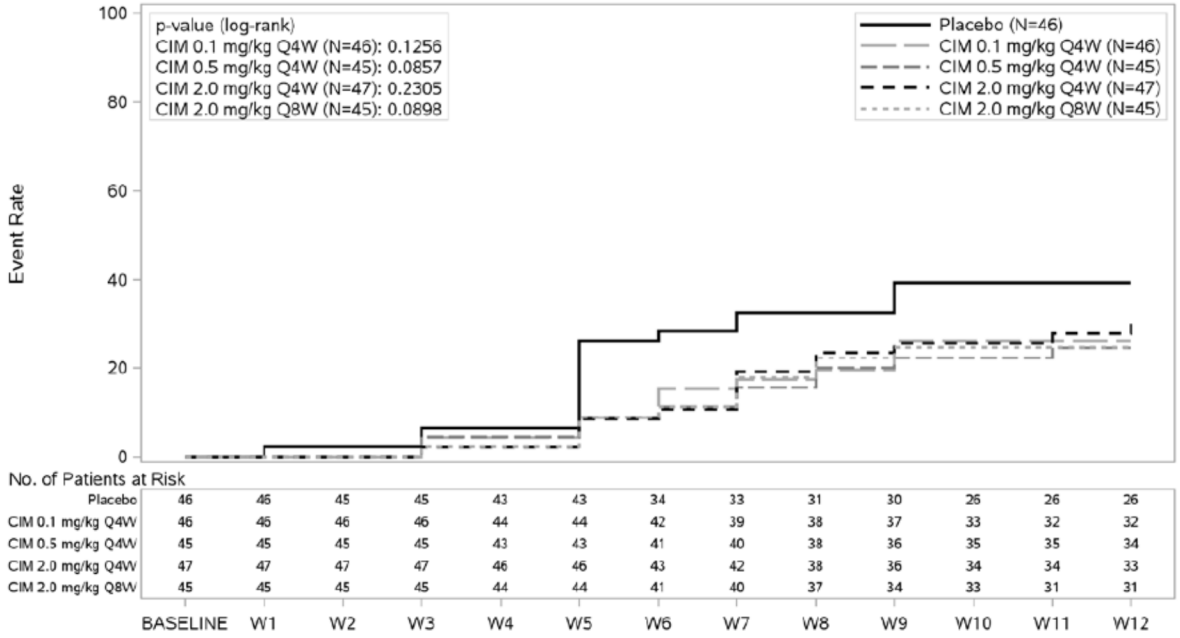
プラセボ対照期間（PartA）にレスキュー治療を受けた患者の割合及びレスキュー治療を受けるまでの日数共に、試験間で違いがみられた。この違いは、第II相試験では投与開始4週後まではレスキュー治療が禁止されていたこと、第II相試験ではnemolizumab単独治療、第III相試験ではTCS/TCI併用下でnemolizumabを投与した等、試験デザインの違いに起因するものと考える。

表 2.7.3-24 レスキュー治療を受けた患者の割合（PartA）

	第II相試験（CIM003JG）（PPS）		第III相試験（M525101-01）（FAS）	
	nemolizumab 0.5 mg/kg群（N=45）	プラセボ群（N=46）	nemolizumab群（N=143）	プラセボ群（N=72）
レスキュー治療あり	24.4%（11）	39.1%（18）	17.5%（25）	18.1%（13）

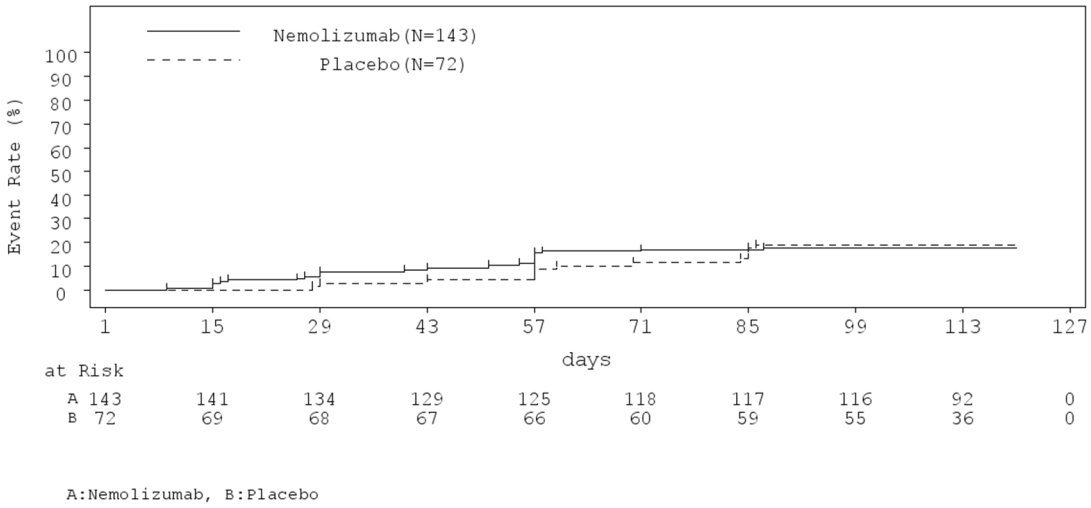
5.3.5.1-1 Table14.2-336、5.3.5.1-2 Table14.2.3.5.1から改変

図 2.7.3-16 レスキュー治療を受けるまでの日数（第II相試験、PartA、PPS）



5.3.5.1-1 Figure14.2-8から引用

図 2.7.3-17 レスキュー治療を受けるまでの日数（第III相試験、PartA、FAS）



5.3.5.1-2 Figure14.2.3.5.2から引用

2.7.3.3.5 長期投与時の有効性

各試験（第II相試験、第III相試験、長期投与試験）の長期投与時の有効性結果は、2.7.3.2.1 (2)2)、2.7.3.2.2 (2)2)及び2.7.3.2.3 (2)に示した。

第II相試験では、nemolizumabを長期投与することで、ADのそう痒及び皮膚症状は、経時的な改善が見られた。また、PartAでプラセボ投与された患者でも、投与開始12週（nemolizumabを初回投与）以降、速やかにADのそう痒及び皮膚症状を改善し、nemolizumabを長期投与することで、ADのそう痒及び皮膚症状は、経時的な改善が見られた。

第III相試験、長期投与試験でも、nemolizumab 60 mg/bodyをQ4Wで投与した際に、ADのそう痒及び皮膚症状の経時的な改善が、それぞれ投与開始68週後、投与開始52週後まで確認され、治験薬投与終了後もADのそう痒及び皮膚症状に対してnemolizumabの効果が維持された。

2.7.3.3.6 医療従事者群と自己注射群の有効性

長期投与試験で医療従事者群並びに自己注射群の有効性を比較した結果、両群の有効性は同様であった（2.7.3.2.3 (2)）。

2.7.3.4 推奨用法・用量に関する臨床情報の解析

2.7.3.4.1 推奨用法・用量

nemolizumabの国内AD患者に対する推奨用法・用量は、「通常、成人及び13歳以上の小児にはネモリズマブ（遺伝子組換え）として1回60 mgを4週間の間隔で皮下投与する。」とした。

2.7.3.4.2 推奨用法・用量の設定根拠

第III相試験では、既存治療では効果不十分な中等度以上のそう痒を伴う13歳以上のAD患者を対象に、TCS/TCI併用下でnemolizumab 60 mg/body又はプラセボを4週間隔で腹部へ皮下投与した。有

効性の主要評価項目は、投与開始16週後のそう痒VAS変化率とした。その結果、nemolizumab群はプラセボ群と比較して、そう痒VASを有意に改善した。また、nemolizumab群のそう痒VASの改善は投与翌日から認められ、プラセボ群と比較して、有意な改善であった。ADの皮膚症状及び患者QOLもnemolizumabを投与することで改善が認められ、臨床上問題となる安全性の懸念はなかった。また、第III相試験及び長期投与試験では、nemolizumabを4週間隔で長期投与した時の安全性及び有効性を確認した。その結果、第III相試験では投与開始68週後、長期投与試験では投与開始52週後まで、nemolizumab投与による安全性の問題はみられず、ADのそう痒、皮膚症状及び患者QOLを経時的に改善することが示された。更に、第III相試験では各因子（血清中nemolizumab濃度、C_{max}、AUC_{last}及びランダム化日の体重）と有効性評価項目（そう痒VAS、かゆみスコア、EASI）の関連を評価したが、各因子に関わらず、投与開始16週後では、nemolizumab 60 mg/body Q4Wの有効性が示された（2.7.3.2.2 (2)1)e)）。

以上より、本剤の推奨用量・用法は、1回60 mgを4週間の間隔で皮下投与するとした。

2.7.3.5 効果の持続、耐薬性

第II相試験、第III相試験及び長期投与試験のそう痒VAS及びEASI合計スコアの経時推移の結果より、第II相試験では投与開始64週後、第III相試験では投与開始68週後、長期投与試験では投与開始52週後まで、ADのそう痒、皮膚症状の経時的な改善がみられたことから、耐薬性はなく、本剤は長期投与できるものと考える。

2.7.3.5.1 免疫原性が有効性に与える影響

Shankarの定義（2.7.2.4.1）に基づき、抗薬物抗体（ADA）陽性患者を特定した。一部の患者でADA陽性と判定されたが、第II相試験の1例を除き、中和抗体は陰性であった。ADAが陽性と判定された患者のそう痒VAS及びEASIは改善しており、nemolizumabの効果は減弱していなかったことから、ADAは有効性に影響しないものと考える。以下に試験ごとの結果を示した。

(1) 第II相試験

0.1 mg/kg Q4W群では53例中4例、0.5 mg/kg Q4W群では54例中8例、2.0 mg/kg Q4W群では52例中1例、2.0 mg/kg Q8W群では52例中2例、placebo-2.0 mg/kg Q4W群では13例中1例でADAが陽性と判定された（5.3.5.1-1Listing16.2-44）。

これらの患者の大半が一過性の反応であり、いずれも中和抗体は陰性と判定された。0.1 mg/kg Q4W群の1例で、投与開始64週後及びフォローアップ時の中和抗体が陽性と判定された。当該被験者は、投与開始前もADAは陽性と判定されており、Titerは投与開始前及び投与後で変わらず、そう痒VAS及びEASIが悪化する傾向は認められなかった（5.3.5.1-1Listing16.2-15、Listing16.2-19）。

(2) 第III相試験

投与開始68週後までに、ADAが陽性と判定された患者は、nemolizumab群では143例中7例、placebo-nemolizumab群では67例中3例であった（5.3.5.1-2Table14.5.2）。

これらの患者の大半が一過性の反応であり、いずれも中和抗体は陰性と判定された。3例の被験者では、治験薬投与開始以降の複数の評価時点でADAが陽性と判定されたが、中和抗体は陰性と判定された。また、これらの患者でそう痒VASが悪化する傾向は認められなか

った（表 2.7.3-25）。

表 2.7.3-25 ADAが陽性と判定された患者のそう痒VASの変化率の経時推移（第III相試験）

被験者識別コード		Baseline	Week 16	Week 32	Week 44	Week 56	Week 68	FU
CA[redacted]	ADA	Positive	Negative	Negative	Negative	Negative	Negative	Positive
	そう痒VAS	–	1.6	11.8	–0.3	–2.5	–1.2	11.8
CA[redacted]	ADA	Negative	Negative	Positive	Negative	Negative	Negative	Negative
	そう痒VAS	–	–57.8	–74.1	–76.1	–79.5	–82.4	–74.8
CA[redacted]	ADA	Negative	Negative	Negative	Positive	Negative	Negative	Negative
	そう痒VAS	–	–22.9	–37.5	–37.5	–44.1	–44.5	–29.2
CA[redacted]*1	ADA	–	–	Negative	Positive	Positive	Negative	Negative
	そう痒VAS	–	–45.6	–58.0	–53.5	–49.7	–47.8	–36.0
CA[redacted]*1	ADA	–	–	Negative	Negative	Positive	Positive	Negative
	そう痒VAS	–	11.4	–74.0	–83.8	–86.5	–90.5	–88.2
CA[redacted]	ADA	Negative	Negative	Negative	Negative	Negative	Negative	Positive
	そう痒VAS	–	–61.4	–80.3	–69.9	–69.3	–72.3	–44.0
CA[redacted]*1	ADA	–	–	Negative	Negative	Negative	Positive	Negative
	そう痒VAS	–	–11.4	–26.5	6.0	–12.2	–0.2	17.9
CA[redacted]	ADA	Negative	Negative	Positive	Negative	Negative	Negative	Negative
	そう痒VAS	–	–57.7	–89.0	–96.3	–93.5	–91.0	–91.9
CA[redacted]	ADA	Negative	Negative	Positive	Positive	Negative	Positive	Positive
	そう痒VAS	–	–92.9	–93.9	–84.4	–83.6	–93.5	–95.1
CA[redacted]	ADA	Negative	Negative	Negative	Negative	Negative	Positive*2	Negative
	そう痒VAS	–	–82.1	–85.2	–79.1	–81.7	–81.0	–78.4

5.3.5.1-2 Listing16.2.5.2、Listing16.2.6.1.1から改変

FU：Follow Up、*1：Placebo-nemolizumab群、その他はnemolizumab群、*2：Titer=320倍（その他のTiterは10～40倍）

(3) 長期投与試験

投与開始52週後までに、ADAが陽性と判定された患者は、88例中11例（医療従事者群：9例、自己注射群：2例）であった（5.3.5.2-1Table14.5.2）。

これらの患者の大半が一過性の反応であり、いずれも中和抗体は陰性と判定された。4例の被験者では、治験薬投与以降の複数の評価時点でADAが陽性と判定されたが、中和抗体は陰性と判定された。また、これらの患者で、そう痒VASが悪化する傾向はみられなかった（表 2.7.3-26）。

表 2.7.3-26 ADAが陽性と判定された患者のそう痒VASの変化率の経時推移（長期投与試験）

被験者識別コード		Baseline	Week 16	Week 28	Week 40	Week 52	FU
CB[redacted]	ADA	Negative	Positive	Negative	Negative	Negative	Negative
	そう痒VAS	–	–24.3	–39.6	–73.9	–86.0	–82.0
CB[redacted]	ADA	Negative	Negative	Positive	Negative	Negative	Negative
	そう痒VAS	–	–89.4	–89.6	–91.0	–92.9	–82.6
CB[redacted]	ADA	Negative	Positive	Positive	Positive	Positive[*1]	Positive[*1]
	そう痒VAS	–	–40.1	–19.2	–28.8	–23.4	–6.3
CB[redacted]	ADA	Negative	Negative	Positive	Negative	Positive	Positive
	そう痒VAS	–	–80.7	–77.6	–87.5	–89.0	–76.7
CB[redacted]	ADA	Negative	Positive	Positive	Negative	Negative	Negative
	そう痒VAS	–	–63.8	–66.5	–36.8	–28.9	–38.2
CB[redacted]	ADA	Negative	Negative	Positive	Negative	Negative	Negative
	そう痒VAS	–	–88.7	–93.2	–98.2	–99.4	–95.9
CB[redacted]	ADA	Negative	Negative	Positive	Negative	Negative	Negative
	そう痒VAS	–	–30.8	–41.7	–45.5	–57.5	–36.0
CB[redacted]	ADA	Negative	Negative	Negative	Positive[*1]	Negative	Negative
	そう痒VAS	–	8.6	10.4	2.9	–2.2	–8.7
CB[redacted]	ADA	Negative	Negative	Negative	Positive	Positive	Negative
	そう痒VAS	–	–46.2	–43.8	–49.4	–49.7	–44.2
CB[redacted]	ADA	Negative	Positive	Negative	Negative	Negative	Negative
	そう痒VAS	–	–28.0	–42.2	–48.8	–58.5	–58.1
CB[redacted]	ADA	Negative	Negative	Negative	Negative	Negative	Positive
	そう痒VAS	–	–77.9	–85.7	–88.8	–95.6	–87.9

5.3.5.2-1Listing16.2.5.2、Listing16.2.6.1.1から改変

FU：Follow Up、[*1]：Titer=160倍（その他のTiterは10～40倍）

2.7.3.6 補遺

なし

2.7.3.7 付録

表 2.7.3-27 有効性の評価項目

	第II相試験（CIM003JG）	第III相試験（M525101-01）	長期投与試験（M525101-02）
主要評価項目	投与開始12週後のそう痒VASのベースラインからの変化率	投与開始16週後のそう痒VAS変化率	－
副次評価項目	・ベースラインと投与開始12週後及び規定評価時点の比較によるそう痒VAS、EASI、SCORAD、sIGA、BSA、そう痒VRS及び睡眠障害VASの改善度 ・EASI、SCORAD、そう痒VAS：投与開始12週後及び規定評価時点で、ベースラインからの変化率が25%、50%、75%に達した被験者の割合 ・sIGA、そう痒VRS：投与開始12週後及び規定評価時点で、ベースラインから2ポイント以上の改善が得られた被験者の割合 ・そう痒VAS、EASI、SCORAD：ベースラインから25%、50%及び75%の改善効果を認めるまでに要した時間 ・sIGA：ベースラインから2ポイントの改善効果を認めるまでに要した時間 ・レスキュー治療を受けるまでの時間 ・レスキュー治療を受けた被験者の割合	・投与開始4週後までのそう痒VAS変化率の経時推移 ・投与開始16週後のEASI変化率 ・DLQI合計スコアが4以下となった患者の割合 ・DLQI合計スコアが4以上改善した患者の割合 ・ISI合計スコアが7以下となった患者の割合	・そう痒VAS、かゆみスコア、そう痒NRS、EASI、mEASI 、sIGA、ISI、HADSの経時推移 ・そう痒VASが50%、75%、90%改善した患者の割合 ・かゆみスコアが1以下となった患者の割合 ・そう痒NRSが4以上改善した患者の割合 ・EASI合計スコアが50%、75%、90%を改善した患者の割合 ・sIGAスコアが2段階改善かつ1以下となった患者の割合 ・ISI合計スコアが7以下となった患者の割合

表 2.7.3-27 有効性の評価項目（続き）

	第II相試験（CIM003JG）	第III相試験（M525101-01）	長期投与試験（M525101-02）
その他の評価項目	・レスキュー治療に用いたTSCの使用頻度、使用期間及び使用量 ・アクティグラフによる睡眠の質 ・PROによるDLQI及びWPAI-AD（米国及び日本） ・写真撮影におるTLSS	・そう痒VASが50%、75%、90%改善した患者の割合 ・かゆみスコアが1以下に達した患者の割合 ・そう痒NRSが4以上改善した患者の割合 ・EASI合計スコアが50%、75%、90%改善した患者の割合 ・sIGAスコアが2段階改善かつ1以下となった患者の割合 ・POEM合計スコアが4以上改善した患者の割合 ・ISI合計スコアが6以上改善した患者の割合 ・POEM合計スコアが4以上改善した患者の割合 ・TCS及びTCIの使用量 ・レスキュー治療を受けるまでの日数 ・主要評価項目（そう痒VAS変化率）と副次評価項目（EASI合計スコアの変化率）との関連 ・主要評価項目（そう痒VAS変化率）とQOL（DLQI合計スコア、ISI合計スコア、WPAI-AD（Q8～Q10）、POEM合計スコア）の関連 ・ベースラインTARCと有効性（そう痒VAS変化率、EASI、EASI合計スコアの変化率）の関連	

表 2.7.3-28 治療開始日の患者の人口統計学的特性及び疾患重症度

項目		第II相試験（CIM003JG）（PPS）					第III相試験（M525101-01）（FAS）	長期投与試験（M525101-02）（FAS）
		nemolizumab				プラセボ群	ALL	ALL
		0.1 mg/kg Q4W群	0.5 mg/kg Q4W群	2.0 mg/kg Q4W群	2.0 mg/kg Q8W群			
例数		46	45	47	45	46	215	88
性別	男性, n,%	25（54.3%）	18（40.0%）	29（61.7%）	24（53.3%）	23（50.0%）	141（65.6%）	56（63.6%）
	女性, n,%	21（45.7%）	27（60.0%）	18（38.3%）	21（46.7%）	23（50.0%）	74（34.4%）	32（36.4%）
年齢（歳）	Mean（SD）	33.9（10.2）	33.0（11.5）	33.7（12.2）	34.6（13.3）	35.7（13.3）	39.3（13.4）	38.9（11.6）
	Min – Max	20 – 57	18 – 59	19 – 64	18 – 63	18 – 63	13 – 80	13 – 70
身長（cm）	Mean（SD）	170.19（10.52）	167.41（9.44）	170.04（8.84）	167.58（9.63）	167.81（8.84）	165.40（8.06）	165.83（7.68）
	Min – Max	149.6 – 190.5	151.0 – 190.5	151.6 – 190.0	144.0 – 188.0	149.9 – 190.0	143.5 – 188.8	145.0 – 181.3
体重（kg）	Mean（SD）	76.01（22.90）	73.40（19.98）	72.51（16.04）	72.63（20.96）	74.20（21.60）	64.26（12.09）	66.32（13.93）
	Min – Max	42.3 – 151.0	45.0 – 124.5	49.2 – 118.2	48.0 – 144.0	47.1 – 138.0	40.0 – 110.2	40.6 – 109.8
そう痒VAS（mm）	Mean（SD）	74.55（12.34）	76.48（13.24）	75.97（11.13）	77.56（12.25）	73.21（10.85）	75.05（10.45）	78.39（11.09）
	Min – Max	48.1 – 98.1	43.8 – 97.1	52.9 – 98.0	45.3 – 99.7	54.4 – 96.4	49.7 – 100.0	54.4 – 96.3
そう痒VAS	< 50	1（2.2%）	1（2.2%）	0	1（2.2%）	0	1（0.5%）	0
	50 – < 70	16（34.8%）	14（31.1%）	16（34.0%）	12（26.7%）	19（41.3%）	61（28.4%）	21（23.9%）
	70 –	29（63.0%）	30（66.7%）	31（66.0%）	32（71.1%）	27（58.7%）	153（71.2%）	67（76.1%）
EASI	Mean（SD）	32.62（15.51）	27.03（14.00）	28.16（11.92）	28.71（14.33）	27.88（14.01）	26.92（12.88）	29.04（14.74）
	Min – Max	10.4 – 72.0	10.0 – 72.0	10.4 – 57.9	10.3 – 65.1	10.8 – 72.0	10.0 – 65.3	6.3 – 72
sIGA	– 3	17（37.0%）	21（46.7%）	23（48.9%）	22（48.9%）	26（56.5%）	127（59.1%）	33（37.5%）
	4 –	29（63.0%）	24（53.3%）	24（51.1%）	23（51.1%）	20（43.5%）	88（40.9%）	55（62.5%）
AD 治療 TCS*	併用なし	–	–	–	–	–	6（2.8%）	1（1.1%）
	併用あり	–	–	–	–	–	209（97.2%）	87（98.9%）
AD 治療 TCI	併用なし	–	–	–	–	–	127（59.1%）	45（51.1%）
	併用あり	–	–	–	–	–	88（40.9%）	43（48.9%）
AD 治療 Oral Antihistamines or Antiallergics	併用なし	–	–	–	–	–	25（11.6%）	6（6.8%）
	併用あり	–	–	–	–	–	190（88.4%）	82（93.2%）
アレルギー疾患**の合併	合併なし	–	–	–	–	–	76（35.3%）	36（40.9%）
	合併あり	–	–	–	–	–	139（64.7%）	52（59.1%）

5.3.5.1-1 Table14.1-8、5.3.5.1-2 Table14.1.4.1、5.3.5.2-1 Table14.1.4.1から改変

*M525101-01：storong TCS、M525101-02：strong、very strong、strongest TCS、**季節性アレルギー、アレルギー性鼻炎、アレルギー性結膜炎、食物アレルギー及び喘息

表 2.7.3-29 PartAでプラセボが投与された患者の人口統計学的特性（第II相試験、ITT long population）

	Placebo - CIM0.1mg/kg (N=12)	Placebo - CIM0.5mg/kg (N=12)	Placebo - CIM2.0mg/kg (N=13)
Sex			
n	12	12	13
Male	8 (66.7%)	3 (25.0%)	6 (46.2%)
Female	4 (33.3%)	9 (75.0%)	7 (53.8%)
Age in years			
n	12	12	13
Mean	36.1	35.3	35.6
Std	14.4	13.4	14.0
Median	33.5	35.5	34.0
Min	18	19	20
Max	55	53	63
Age Category in years			
n	12	12	13
< 20	1 (8.3%)	2 (16.7%)	0
20 -< 30	4 (33.3%)	3 (25.0%)	5 (38.5%)
30 -< 40	2 (16.7%)	1 (8.3%)	4 (30.8%)
40 -< 50	1 (8.3%)	4 (33.3%)	1 (7.7%)
50 -< 60	4 (33.3%)	2 (16.7%)	2 (15.4%)
60 -	0	0	1 (7.7%)
Region			
n	12	12	13
US	1 (8.3%)	2 (16.7%)	3 (23.1%)
Europe	7 (58.3%)	7 (58.3%)	6 (46.2%)
Japan	4 (33.3%)	3 (25.0%)	4 (30.8%)
Country			
n	12	12	13
USA	1 (8.3%)	2 (16.7%)	3 (23.1%)
POL	3 (25.0%)	4 (33.3%)	4 (30.8%)
JPN	4 (33.3%)	3 (25.0%)	4 (30.8%)
DEU	4 (33.3%)	3 (25.0%)	2 (15.4%)
Ethnicity			
n	12	12	13
Not Hispanic or Latino	11 (91.7%)	12 (100.0%)	13 (100.0%)
Not Reported	1 (8.3%)	0	0
Race of Subject			
n	12	12	13
Asian	4 (33.3%)	3 (25.0%)	4 (30.8%)
Black or African American	0	0	1 (7.7%)
White	8 (66.7%)	9 (75.0%)	8 (61.5%)
Height in cm			
n	12	12	13
Mean	170.48	166.53	167.35
Std	8.76	7.48	9.30
Median	171.00	165.55	165.00
Min	156.0	152.0	154.7
Max	190.0	179.7	185.0

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5.3.5.1-1 Table14.1-27から引用

表 2.7.3-29 PartAでプラセボが投与された患者の人口統計学的特性（第II相試験、ITT long population）（続き）

	Placebo - CIM0.1mg/kg (N=12)	Placebo - CIM0.5mg/kg (N=12)	Placebo - CIM2.0mg/kg (N=13)
Weight in kg			
n	12	12	13
Mean	72.51	70.75	74.37
Std	20.99	17.42	23.96
Median	74.10	67.25	65.20
Min	48.0	47.1	49.0
Max	122.5	108.0	128.9
Weight Category in kg			
n	12	12	13
< 60	3 (25.0%)	2 (16.7%)	4 (30.8%)
60 -	9 (75.0%)	10 (83.3%)	9 (69.2%)
Body Mass Index (BMI) in kg/m**2			
n	12	12	13
Mean	24.73	25.43	26.43
Std	6.13	5.75	7.82
Median	22.47	23.72	24.01
Min	18.7	20.0	18.0
Max	39.9	39.2	43.2
Body Mass Index (BMI) Category in kg/m**2			
n	12	12	13
< 25	7 (58.3%)	7 (58.3%)	9 (69.2%)
25 -	5 (41.7%)	5 (41.7%)	4 (30.8%)
History of inadequate response to topical (TCS/TCI) therapy			
n	12	11	13
Inadequately controlled by TCS only	8 (66.7%)	9 (81.8%)	9 (69.2%)
Inadequately controlled by TCI only	0	0	1 (7.7%)
Inadequately controlled by TCS and TCI	4 (33.3%)	2 (18.2%)	3 (23.1%)
History of intolerance response to topical (TCS/TCI) therapy			
n	1	1	0
Intolerant or inability to TCS only	0	1 (100.0%)	0
Intolerant or inability to TCI only	1 (100.0%)	0	0
Intolerant or inability to TCS and TCI	0	0	0
Baseline Pruritus VAS in mm			
n	12	12	13
Mean	72.98	75.71	73.08
Std	8.31	13.45	11.40
Median	74.51	74.71	71.71
Min	58.7	58.9	54.4
Max	88.6	93.6	96.4
Baseline Pruritus VAS Category in mm			
n	12	12	13
50 -< 70	4 (33.3%)	6 (50.0%)	5 (38.5%)
70 -	8 (66.7%)	6 (50.0%)	8 (61.5%)

Program: /opt/BIOSTAT/prod/cdp70250/cim003/dmt01.sas
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5.3.5.1-1Table14.1-27から引用

表 2.7.3-29 PartAでプラセボが投与された患者の人口統計学的特性（第II相試験、ITT long population）（続き）

	Placebo - CIM0.1mg/kg (N=12)	Placebo - CIM0.5mg/kg (N=12)	Placebo - CIM2.0mg/kg (N=13)
Baseline EASI			
n	12	12	13
Mean	26.84	31.92	25.52
Std	12.24	20.43	9.82
Median	23.38	26.75	23.10
Min	10.8	12.2	12.5
Max	44.7	72.0	42.1
Baseline SCORAD			
n	10	11	13
Mean	66.99	67.74	62.96
Std	10.66	17.60	8.37
Median	68.58	61.00	65.08
Min	46.6	49.3	53.2
Max	79.9	96.8	74.3
Baseline BSA of AD involvement			
n	12	12	13
Mean	43.27	49.48	39.21
Std	21.67	32.32	22.19
Median	37.94	38.66	33.30
Min	15.4	10.5	8.5
Max	81.0	99.5	79.7
Baseline sIGA			
n	12	12	13
3	7 (58.3%)	6 (50.0%)	9 (69.2%)
4	5 (41.7%)	3 (25.0%)	4 (30.8%)
5	0	3 (25.0%)	0
Previous Disease			
n	12	12	13
YES	5 (41.7%)	8 (66.7%)	9 (69.2%)
NO	7 (58.3%)	4 (33.3%)	4 (30.8%)
Previous-Concomitant Disease			
n	12	12	13
YES	7 (58.3%)	10 (83.3%)	8 (61.5%)
NO	5 (41.7%)	2 (16.7%)	5 (38.5%)

Program: /opt/BIOSTAT/prod/cdp70250/cim003/dmt01.sas
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5.3.5.1-1 Table14.1-27から引用

表 2.7.3-30 そう痒VAS変化率（長期投与試験、FAS）

Visit	Prof*		Self**	
	N	平均値（SD）	N	平均値（SD）
投与開始1週後	44	–15.74（16.30）	44	–19.07（14.11）
投与開始2週後	44	–27.83（21.38）	44	–26.79（21.40）
投与開始4週後	44	–32.86（25.67）	44	–31.49（26.13）
投与開始6週後	44	–38.18（26.06）	44	–37.51（27.92）
投与開始8週後	44	–40.21（24.22）	44	–40.34（30.80）
投与開始12週後	43	–42.99（24.60）	44	–43.49（29.32）
投与開始16週後	43	–46.97（23.33）	44	–47.99（29.54）
投与開始20週後	42	–49.18（23.52）	43	–48.39（31.13）
投与開始24週後	41	–52.74（26.14）	42	–52.01（30.53）
投与開始28週後	41	–56.11（27.24）	41	–56.69（31.18）
投与開始32週後	41	–58.23（25.33）	41	–57.65（30.89）
投与開始36週後	41	–57.13（27.56）	39	–58.88（29.22）
投与開始40週後	41	–58.83（27.16）	38	–58.07（29.87）
投与開始44週後	41	–61.03（26.62）	38	–60.06（28.72）
投与開始48週後	41	–60.42（26.90）	37	–60.20（30.37）
投与開始52週後	41	–59.42（28.44）	37	–61.94（31.63）
フォローアップ1 a)	41	–58.46（28.70）	37	–59.56（29.75）
フォローアップ2 b)	41	–54.24（29.63）	37	–53.01（29.69）

*：Medical professional administration group
**：Self-injection group（投与8週後までは医療従事者が投与）
a)：最終投与から8週後
b)：最終投与から12週後
5.3.5.2-1 Table14.2.1.1から改変

表 2.7.3-31 そう痒VASが50%、75%、90%改善した患者の割合（長期投与試験、FAS）

改善割合	50%改善		75%改善		90%改善	
	Prof* n=44 % (n)	Self** n=44 % (n)	Prof n=44 % (n)	Self n=44 % (n)	Prof n=44 % (n)	Self n=44 % (n)
投与開始1週後	2.3 (1)	2.3 (1)	0	0	0	0
投与開始2週後	15.9 (7)	15.9 (7)	4.5 (2)	2.3 (1)	2.3 (1)	0
投与開始4週後	25.0 (11)	27.3 (12)	4.5 (2)	6.8 (3)	0	0
投与開始6週後	36.4 (16)	40.9 (18)	9.1 (4)	13.6 (6)	2.3 (1)	2.3 (1)
投与開始8週後	36.4 (16)	36.4 (16)	11.4 (5)	15.9 (7)	0	6.8 (3)
投与開始12週後	36.4 (16)	45.5 (20)	11.4 (5)	13.6 (6)	2.3 (1)	4.5 (2)
投与開始16週後	40.9 (18)	50.0 (22)	13.6 (6)	15.9 (7)	0	9.1 (4)
投与開始20週後	40.9 (18)	47.7 (21)	15.9 (7)	27.3 (12)	2.3 (1)	11.4 (5)
投与開始24週後	45.5 (20)	56.8 (25)	25.0 (11)	27.3 (12)	6.8 (3)	6.8 (3)
投与開始28週後	50.0 (22)	56.8 (25)	27.3 (12)	36.4 (16)	11.4 (5)	13.6 (6)
投与開始32週後	47.7 (21)	56.8 (25)	31.8 (14)	34.1 (15)	13.6 (6)	11.4 (5)
投与開始36週後	47.7 (21)	56.8 (25)	31.8 (14)	36.4 (16)	13.6 (6)	13.6 (6)
投与開始40週後	54.5 (24)	56.8 (25)	29.5 (13)	31.8 (14)	15.9 (7)	11.4 (5)
投与開始44週後	59.1 (26)	56.8 (25)	31.8 (14)	29.5 (13)	20.5 (9)	15.9 (7)
投与開始48週後	59.1 (26)	56.8 (25)	34.1 (15)	34.1 (15)	15.9 (7)	15.9 (7)
投与開始52週後	54.5 (24)	56.8 (25)	31.8 (14)	36.4 (16)	20.5 (9)	20.5 (9)
フォローアップ1 a)	56.8 (25)	52.3 (23)	27.3 (12)	29.5 (13)	15.9 (7)	20.5 (9)
フォローアップ2 b)	52.3 (23)	47.7 (21)	27.3 (12)	25.0 (11)	11.4 (5)	6.8 (3)

*：Medical professional administration group

**：Self-injection group（投与8週後までは医療従事者が投与）

a)：最終投与から8週後

b)：最終投与から12週後

5.3.5.2-1 Table14.2.2.1から改変

表 2.7.3-32 そう痒NRSが4以上改善した患者の割合（長期投与試験、FAS）

	Prof* n=44 %（n）	Self** n=44 %（n）
投与開始1週後	2.3（1）	2.3（1）
投与開始2週後	11.4（5）	15.9（7）
投与開始4週後	27.3（12）	22.7（10）
投与開始6週後	34.1（15）	31.8（14）
投与開始8週後	36.4（16）	31.8（14）
投与開始12週後	36.4（16）	40.9（18）
投与開始16週後	43.2（19）	45.5（20）
投与開始20週後	43.2（19）	45.5（20）
投与開始24週後	38.6（17）	47.7（21）
投与開始28週後	50.0（22）	52.3（23）
投与開始32週後	50.0（22）	56.8（25）
投与開始36週後	52.3（23）	54.5（24）
投与開始40週後	47.7（21）	50.0（22）
投与開始44週後	59.1（26）	50.0（22）
投与開始48週後	52.3（23）	61.4（27）
投与開始52週後	54.5（24）	56.8（25）
フォローアップ1 a)	56.8（25）	52.3（23）
フォローアップ2 b)	47.7（21）	47.7（21）

*：Medical professional administration group

**：Self-injection group（投与8週後までは医療従事者が投与）

a)：最終投与から8週後

b)：最終投与から12週後

5.3.5.2-1 Table14.2.2.3から改変

表 2.7.3-33 かゆみスコアが1以下となった患者の割合（長期投与試験、FAS）

	Prof* n=44 %（n）	Self** n=44 %（n）
投与開始1週後	0	0
投与開始2週後	4.5（2）	6.8（3）
投与開始4週後	6.8（3）	6.8（3）
投与開始6週後	11.4（5）	11.4（5）
投与開始8週後	15.9（7）	11.4（5）
投与開始12週後	11.4（5）	15.9（7）
投与開始16週後	18.2（8）	22.7（10）
投与開始20週後	31.8（14）	29.5（13）
投与開始24週後	31.8（14）	31.8（14）
投与開始28週後	36.4（16）	40.9（18）
投与開始32週後	36.4（16）	31.8（14）
投与開始36週後	38.6（17）	34.1（15）
投与開始40週後	34.1（15）	27.3（12）
投与開始44週後	38.6（17）	31.8（14）
投与開始48週後	36.4（16）	31.8（14）
投与開始52週後	36.4（16）	36.4（16）
フォローアップ1 [a)]	31.8（14）	34.1（15）
フォローアップ2 [b)]	27.3（12）	27.3（12）

*：Medical professional administration group

**：Self-injection group（投与開始8週後までは医療従事者が投与）

[a)]：最終投与から8週後

[b)]：最終投与から12週後

5.3.5.2-1 Table14.2.2.2から改変

表 2.7.3-34 EASI合計スコアの変化率（長期投与試験、FAS）

群	Prof* n=44 平均値（SD）	Self** n=44 平均値（SD）
投与開始1週後	–31.78（25.19）	–23.85（24.54）
投与開始2週後	–45.79（27.53）	–33.52（37.44）
投与開始4週後	–47.81（32.51）	–35.76（41.53）
投与開始8週後	–48.26（28.40）	–38.38（34.24）
投与開始12週後	–53.32（32.60）	–45.28（52.65）
投与開始16週後	–55.23（35.25）	–42.34（54.54）
投与開始20週後	–59.98（28.27）	–49.27（43.69）
投与開始24週後	–60.07（34.20）	–56.95（39.97）
投与開始28週後	–62.70（26.76）	–60.91（35.87）
投与開始32週後	–66.73（26.25）	–61.01（40.50）
投与開始36週後	–69.51（23.17）	–70.89（28.97）
投与開始40週後	–67.53（26.42）	–71.80（24.22）
投与開始44週後	–73.86（21.22）	–73.58（25.85）
投与開始48週後	–76.94（19.56）	–75.25（26.35）
投与開始52週後	–75.42（18.08）	–75.68（27.64）
フォローアップ [a)]	–72.76（23.12）	–66.28（35.21）

*：Medical professional administration group

**：Self-injection group（投与8週後までは医療従事者が投与）

a)：最終投与から12週後

5.3.5.2-1 Table14.2.1.4から改変

表 2.7.3-35 EASI合計スコアが50%、75%、90%改善した患者の割合（長期投与試験、FAS）

改善割合	50%改善		75%改善		90%改善	
群	Prof* n=44 %（n）	Self** n=44 %（n）	Prof n=44 %（n）	Self n=44 %（n）	Prof n=44 %（n）	Self n=44 %（n）
投与開始1週後	18.2（8）	15.9（7）	6.8（3）	4.5（2）	4.5（2）	0
投与開始2週後	45.5（20）	38.6（17）	15.9（7）	13.6（6）	4.5（2）	4.5（2）
投与開始4週後	40.9（18）	45.5（20）	22.7（10）	15.9（7）	9.1（4）	4.5（2）
投与開始8週後	47.7（21）	43.2（19）	22.7（10）	18.2（8）	6.8（3）	4.5（2）
投与開始12週後	56.8（25）	50.0（22）	29.5（13）	31.8（14）	11.4（5）	13.6（6）
投与開始16週後	65.9（29）	47.7（21）	34.1（15）	31.8（14）	11.4（5）	13.6（6）
投与開始20週後	61.4（27）	52.3（23）	34.1（15）	25.0（11）	11.4（5）	18.2（8）
投与開始24週後	68.2（30）	61.4（27）	36.4（16）	36.4（16）	18.2（8）	20.5（9）
投与開始28週後	61.4（27）	63.6（28）	36.4（16）	45.5（20）	13.6（6）	18.2（8）
投与開始32週後	77.3（34）	63.6（28）	40.9（18）	43.2（19）	20.5（9）	29.5（13）
投与開始36週後	81.8（36）	72.7（32）	43.2（19）	43.2（19）	20.5（9）	31.8（14）
投与開始40週後	75.0（33）	68.2（30）	38.6（17）	45.5（20）	22.7（10）	20.5（9）
投与開始44週後	79.5（35）	72.7（32）	56.8（25）	52.3（23）	29.5（13）	27.3（12）
投与開始48週後	81.8（36）	79.5（35）	59.1（26）	52.3（23）	29.5（13）	25.0（11）
投与開始52週後	86.4（38）	75.0（33）	50.0（22）	54.5（24）	25.0（11）	29.5（13）
フォローアップ a)	72.7（32）	68.2（30）	54.5（24）	50.0（22）	34.1（15）	15.9（7）

*：Medical professional administration group

**：Self-injection group（投与8週後までは医療従事者が投与）

a)：最終投与から12週後

5.3.5.2-1 Table14.2.2.4から改変

表 2.7.3-36 sIGAスコアが2段階改善かつ1以下となった患者の割合（長期投与試験、FAS）

群	Prof* n=44 %（n）	Self** n=44 %（n）
投与開始1週後	0	0
投与開始2週後	0	2.3（1）
投与開始4週後	2.3（1）	0
投与開始8週後	2.3（1）	4.5（2）
投与開始12週後	2.3（1）	6.8（3）
投与開始16週後	6.8（3）	9.1（4）
投与開始20週後	11.4（5）	9.1（4）
投与開始24週後	11.4（5）	11.4（5）
投与開始28週後	11.4（5）	15.9（7）
投与開始32週後	9.1（4）	20.5（9）
投与開始36週後	9.1（4）	15.9（7）
投与開始40週後	15.9（7）	9.1（4）
投与開始44週後	15.9（7）	15.9（7）
投与開始48週後	13.6（6）	20.5（9）
投与開始52週後	11.4（5）	13.6（6）
フォローアップ [a)]	13.6（6）	11.4（5）

*：Medical professional administration group

**：Self-injection group（投与8週後までは医療従事者が投与）

[a)]：最終投与から12週後

5.3.5.2-1 Table14.2.2.5から改変

表 2.7.3-37 ISIスコアが7以下となった患者の割合（長期投与試験、FAS）

群	Prof* n=35 %（n）	Self** n=28 %（n）
投与開始2週後	20.0（7）	35.7（10）
投与開始4週後	48.6（17）	32.1（9）
投与開始8週後	42.9（15）	46.4（13）
投与開始12週後	48.6（17）	53.6（15）
投与開始16週後	57.1（20）	39.3（11）
投与開始28週後	54.3（19）	50.0（14）
投与開始40週後	45.7（16）	50.0（14）
投与開始52週後	42.9（15）	50.0（14）
フォローアップ a)	51.4（18）	46.4（13）

*：Medical professional administration group

**：Self-injection group（投与8週後までは医療従事者が投与）

a)：最終投与から12週後

5.3.5.2-1 Table14.2.2.6から改変

表 2.7.3-38 そう痒VASが50%以上改善した患者の割合（第III相試験、FAS）

Parameter			n of	Comparison to Placebo			
Treatment			Imp.	Percent	95% CI [b]		
Visit	Total	n (%)	[a]	Difference	Lower	Upper	p-value [c]
50% Improvement							
Nemolizumab(N=143)							
Week 1	143	10 (7.0)	0	7.0	-7.2	21.0	0.0152
Week 4	143	34 (23.8)	7	19.6	5.4	33.2	0.0001
Week 8	143	45 (31.5)	17	23.1	8.9	36.5	<0.0001
Week 12	143	48 (33.6)	26	22.5	8.2	35.8	0.0002
Week 16	143	49 (34.3)	27	20.4	6.1	33.8	0.0010
Placebo(N=72)							
Week 1	72	0	0	-	-	-	-
Week 4	72	3 (4.2)	3	-	-	-	-
Week 8	72	6 (8.3)	6	-	-	-	-
Week 12	72	8 (11.1)	12	-	-	-	-
Week 16	72	10 (13.9)	17	-	-	-	-

Excluding the data after rescue therapy.
Missing values were imputed by not improvement.
Percentages are based on total subjects in each visit.
[a] Number of imputed values.
[b] Exact confidence interval.
[c] Fisher's exact test.

5.3.5.1-2 Table14.2.3.3.1.1から改変

表 2.7.3-39 そう痒NRSが4以上改善した患者の割合（第III相試験、FAS）

Parameter			n of	Comparison to Placebo			
Treatment			Imp.	Percent	95% CI [b]		
Visit	Total	n (%)	[a]	Difference	Lower	Upper	p-value [c]
4 or More Point Improvement							
Nemolizumab(N=143)							
Week 1	143	8 (5.6)	0	5.6	-8.6	19.6	0.0358
Week 4	143	28 (19.6)	7	18.2	4.0	31.8	<0.0001
Week 8	143	41 (28.7)	17	23.1	8.9	36.5	<0.0001
Week 12	143	41 (28.7)	26	18.9	4.7	32.5	0.0009
Week 16	143	46 (32.2)	27	19.7	5.4	33.2	0.0011
Placebo(N=72)							
Week 1	72	0	0	-	-	-	-
Week 4	72	1 (1.4)	3	-	-	-	-
Week 8	72	4 (5.6)	6	-	-	-	-
Week 12	72	7 (9.7)	12	-	-	-	-
Week 16	72	9 (12.5)	17	-	-	-	-

Excluding the data after rescue therapy.
Missing values were imputed by not improvement.
Percentages are based on total subjects in each visit.
Analysis Population: FAS (Subjects with 4 or More in Baseline Pruritus NRS).
[a] Number of imputed values.
[b] Exact confidence interval.
[c] Fisher's exact test.

5.3.5.1-2 Table14.2.3.3.3.1から改変

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ミチーガ皮下注用60 mgシリンジ

第2部（モジュール2）
CTDの概要（サマリー）

2.7.4 臨床的安全性

マルホ株式会社

略号一覧

略号及び用語	省略していない表現／定義
AD	Atopic dermatitis：アトピー性皮膚炎
ADA	Anti drug antibody：抗薬物抗体
A/G	Albumin/Globulin ratio：アルブミン/グロブリン比
ALB	Albumin：アルブミン
ALP	Alkaline phosphatase：アルカリホスファターゼ
ALT	Alanine aminotransferase：アラニンアミノトランスフェラーゼ
AST	Aspartate aminotransferase：アスパラギン酸アミノトランスフェラーゼ
AUC	Area under the serum concentration-time curve：血清中濃度-時間曲線下面積
C_{max}	Maximum concentration in serum：最高血清中濃度
CPK	Creatine phosphokinase：クレアチンホスホキナーゼ
CREA	Creatinine：クレアチニン
CRP	C reactive protein ：C反応性蛋白
D-Bil	Direct bilirubin：直接ビリルビン
EASI	Eczema Area and Severity Index
GLU	Glucose：血糖
γ-GT	γ-Glutamyl transpeptidase：γ-グルタミルトランスペプチターゼ
Hb	Hemoglobin：ヘモグロビン（量）
HDL-C	High-density lipoprotein cholesterol：高密度リポタンパク質コレステロール
Ht	Hematocrit：ヘマトクリット（値）
IGA	Investigator’s global assessment
LDH	Lactate dehydrogenase：乳酸脱水素酵素
LDL-C	Low density lipoprotein cholesterol：低密度リポタンパク質コレステロール
MALT	Mucosa associated lymphoid tissue：粘膜関連リンパ組織
MCH	Mean corpuscular hemoglobin：平均赤血球ヘモグロビン量
MCHC	Mean corpuscular hemoglobin concentration：平均赤血球ヘモグロビン濃度
MCV	Mean corpuscular volume：平均赤血球容積
MedDRA/J	Medical Dictionary for Regulatory Activities/Japanese edition
Nemolizumab（CIM331）	中外製薬株式会社で創製されたヒト化抗ヒトIL-31RA モノクローナル抗体
Plt	Platelet：血小板
PT	Preferred term：基本語
Q4W	Every 4 weeks：4週ごとに
Q8W	Every 8 weeks：8週ごとに
RBC	Red blood cell：赤血球（数）
SOC	System organ class：器官別大分類
TARC	Thymus and activation-regulated chemokine
T-Bil	Total-bilirubin:：総ビリルビン

略号及び用語	省略していない表現／定義
TC	Total cholesterol：総コレステロール
TCI	Topical calcineurin inhibitor：外用カルシニューリン阻害剤
TCS	Topical corticosteroid：ステロイド外用薬
TEAE	Treatment emergent adverse event：治験薬投与後に発現した有害事象
TG	Triglyceride：トリグリセリド
TP	Total protein：総蛋白
UA	Ureatic acid：尿酸
UN	Urea nitrogen：尿素窒素
WBC	White blood cell：白血球（数）

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2.7.4 臨床的安全性

2.7.4.1 医薬品への曝露

2.7.4.1.1 総括的安全性評価計画及び安全性試験の記述

2.7.4.1.1.1 安全性評価の対象とした臨床試験

Nemolizumabのアトピー性皮膚炎（以下、AD）に対する安全性は、日本で実施した第I相試験（CIM001JP）、日本を含む国際共同第II相試験（CIM003JG）、日本で実施した第III相試験（M525101-01）及び長期投与試験（M525101-02）の4試験で評価した。これらの試験の要約を表 2.7.4-1に示した。

安全性評価のための主要な臨床パッケージは、第II相試験（0.1 mg/kg群を除く）、第III相試験及び長期投与試験で構成している。第II相試験及び第III相試験は、プラセボ対照、ランダム化、二重盲検、並行群間、多施設共同試験で実施した。第II相試験、第III相試験ともに、プラセボ対照期間（PartA）の後、nemolizumabを長期投与する期間（PartB、52週間）へ移行するデザインとした。PartAではnemolizumabの有効性及び安全性をプラセボ対照で比較し、PartBでは、PartAでプラセボを投与した被験者も全例nemolizumabを投与し、nemolizumabを長期投与した時の安全性及び有効性を確認した。PartBでは最終投与から12週間のフォローアップ期間を設定した。また、第II相試験のPartAではnemolizumabを単独投与した時の安全性を評価し、第III相試験ではstrongクラスのステロイド外用薬（以下、TCS）及び/又は外用カルシニューリン阻害剤（以下、TCI）を併用下でnemolizumabを投与した際の安全性を評価した。長期投与試験は非盲検、多施設共同試験でTCS、TCI併用下で実施し、申請用量60 mgを52週間投与し、最終投与から12週間のフォローアップ期間を設定した。また、腹部以外への投与や自己注射する群を設定した。

本項では、第II相試験、第III相試験及び長期投与試験を併合した安全性解析を中心とした結果を記載し、第I相試験の安全性の結果は2.7.6.1、その他の試験の個々の試験の安全性の結果の詳細は2.7.6.2、2.7.6.3、2.7.6.4に記載した。

表 2.7.4-1 安全性評価に用いた試験の概要

相 資料区分 試験番号 実施国	試験デザイン	治験薬 投与方法 投与期間	対象 被験者数：登録数（完了数）	安全性に関する評価項目	報告書の添付場所（2.7.6の番号）
第I相 評価 CIM001JP 日本	ランダム化 二重盲検 プラセボ対照 個体間用量漸増試験	PartA： nemolizumab（0.003、0.01、0.03、0.1、0.3、1.0、3.0 mg/kg）、プラセボを腹部に単回皮下投与 PartB及びC： nemolizumab（0.3、1.0、3.0 mg/kg）、プラセボを腹部に単回皮下投与	PartA：日本人健康成人 PartB：白人健康成人 PartC：日本人AD患者 PartA：56例（56例） 各群：6例 プラセボ群：14例 PartB：24例（24例） 各群：6例 プラセボ群：6例 PartC：36例（35例） 各群：9例 プラセボ群：9例	有害事象 臨床検査 バイタルサイン 心電図	5.3.3.1-1 (2.7.6.1)
第II相 評価 CIM003JG 英国 ドイツ ポーランド 米国 日本	PartA： ランダム化 二重盲検 プラセボ対照 並行群間比較 多施設共同 用量反応 PartB： ランダム化 二重盲検 並行群間比較 多施設共同 長期投与試験	PartA： nemolizumab（0.1、0.5、2.0 mg/kg）、プラセボを4週間に1回（Q4W）腹部に皮下投与 nemolizumab（2.0 mg/kg）を8週間に1回（Q8W）腹部に皮下投与 12週間 PartB： nemolizumab（0.1、0.5、2.0 mg/kg）をQ4Wで腹部に皮下投与、又はnemolizumab（2.0 mg/kg）をQ8Wで腹部に皮下投与 52週間	外用治療に対して効果不十分若しくは忍容性のない中等症及び重症のAD患者 PartA：264例（216例） nemolizumab 0.1 mg/kgQ4W群：53例（44例） 0.5 mg/kgQ4W群：54例（45例） 2.0 mg/kgQ4W群：52例（45例） 2.0 mg/kgQ8W群：52例（38例） プラセボ群：53例（44例） PartB： nemolizumab/nemolizumab 0.1 mg/kgQ4W群：41例（31例） 0.5 mg/kgQ4W群：38例（28例） 2.0 mg/kgQ4W群：39例（30例） 2.0 mg/kgQ8W群：35例（19例） プラセボ/nemolizumab 0.1 mg/kgQ4W群：13例（8例） 0.5 mg/kgQ4W群：12例（7例） 2.0 mg/kgQ4W群：13例（8例）	有害事象 臨床検査 バイタルサイン 心電図	5.3.5.1-1 (2.7.6.2)

相 資料区分 試験番号 実施国	試験デザイン	治験薬 投与方法 投与期間	対象 被験者数：登録数（完了数）	安全性に関する評価項目	報告書の添付場所（2.7.6の番号）
第III相 評価 M525101-01 日本	PartA： ランダム化 二重盲検 プラセボ対照 並行群間比較 優越性 多施設共同 検証試験 PartB： 非盲検 多施設共同 長期投与試験	PartA： nemolizumab（60 mg/body）又はプラセボをQ4Wで腹部に皮下投与 16週間 PartB： nemolizumab（60 mg/body）をQ4Wで腹部に皮下投与 52週間	既存治療を実施したにも関わらず中等度以上のそう痒（かゆみスコアが3以上）を有する日本人AD患者 PartA：215例（206例） nemolizumab群：143例（139例） プラセボ群：72例（67例） PartB：206例（194例） nemolizumab/nemolizumab群：139例（130例） プラセボ/nemolizumab群：67例（64例）	有害事象 臨床検査 バイタルサイン 心電図	5.3.5.1-2 (2.7.6.3)
第III相 評価 M525101-02 日本	非対照 多施設共同 長期投与試験	nemolizumab（60 mg/body）をQ4Wで皮下投与 医療従事者投与群：上腕部、腹部、大腿部 自己注射群：上腕部（投与開始から8週後まで）、腹部、大腿部 52週間	既存治療を実施したにも関わらず中等度以上のそう痒（かゆみスコアが3以上）を有する日本人AD患者 医療従事者投与群:44例(41例) 自己注射群：44例（37例）	有害事象 臨床検査 バイタルサイン 心電図	5.3.5.2-1 (2.7.6.4)

2.7.4.1.1.2 安全性評価項目及びその定義

Nemolizumabの安全性は、有害事象、臨床検査、バイタルサイン及び心電図に基づき評価した。

2.7.4.1.1.2.1 有害事象

(1) 有害事象の定義

治験責任医師又は治験分担医師は、有害事象の発現状況を調査し、治験薬との因果関係及び重症度を表 2.7.4-2及び表 2.7.4-3の規準に従って評価した。有害事象は、第II相試験では治験薬投与後発現したものを、第III相試験及び長期投与試験では同意取得後発現したものを対象に収集した。ただし、第II相試験でも、同意取得後に治験実施計画書で規定した介入により発現した重篤な有害事象は収集した。また、第II相試験、第III相試験及び長期投与試験では、治験薬の投与中止を必要とした有害事象の他に、表 2.7.4-4に示す有害事象を注目すべき有害事象と規定し、治験責任（分担）医師に注意喚起した。併合解析では、第III相試験及び長期投与試験の規定に基づき、注目すべき有害事象を集計した。集計に際して、注射関連反応、喘息、アトピー性皮膚炎の悪化、血中クレアチンホスホキナーゼ上昇及び治験薬からの感染病原体感染は、それぞれの試験で特定された有害事象を対象とした。また、皮膚

感染症及び皮膚以外の感染症は、それぞれ5.3.5.3-1添付資料2及び添付資料3に示したPTに該当する有害事象を抽出した。

表 2.7.4-2 治験薬との因果関係の判定

治験薬との関連性	治験薬との関連性の判定基準	適用試験
関連なし	当該事象が明らかに治験薬以外の原因（疾患、環境等）によって引き起こされたと考えられる場合。	第I相試験
わずかにあり	当該事象が以下の事項に該当する場合。（ただし、(1)、(2)の該当は必須とする） (1) 治験薬投与との時間的関連性がみられない。 (2) 被験者の臨床症状、被験者の受けた他の治療形態、居住及び職場環境により容易に発現することが考えられる。 (3) 治験薬で既に知られているような反応パターン（有害事象、非臨床試験結果等）ではない。 (4) 治験薬を再投与しても症状の再発・悪化がみられない。	
可能性あり	当該事象が以下の事項に該当し、治験薬投与との関連性はありそうにないが，完全に否定することができないと判断された場合。（ただし、(1)、(2)の該当は必須とする） (1) 治験薬投与との時間的関連性がみられる。 (2) 被験者の臨床症状，被験者の受けた他の治療形態，居住及び職場環境により発現することが考えられる。 (3) 治験薬で既に知られているような反応パターン（有害事象、非臨床試験結果等）である。	
多分あり	当該事象が以下の事項に該当し，治験薬投与との関連性があると高い確率で考えられる場合。（ただし、(1)～(3)の該当は必須とする） (1) 治験薬投与との時間的関連性がみられる。 (2) 被験者の臨床症状、被験者の受けた他の治療形態、居住及び職場環境により発現することが考えられない。 (3) 治験薬の投与中止・減量により症状の消失・軽減がみられる。 (4) 治験薬で既に知られているような反応パターン（有害事象、非臨床試験結果等）である。 (5) 治験薬の再投与で症状の再発がみられる。	

治験薬との関連性	治験薬との関連性の判定基準	適用試験
あり/なし	治験責任医師は、以下に示す患者に関する情報及び有害事象を取り巻く環境に基づき、治験薬との因果関係を「あり」又は「なし」と判定した。 • 治験薬投与と有害事象発現との時間的関連性 • 有害事象の推移、特に用量の減少、治験薬投与の中止又は治験薬投与に再投与（可能であれば）の影響 • 治験薬又は類似療法との関連性が知られている有害事象 • 対象疾患との関連性が知られている有害事象 • 有害事象の発現を増加させることが知られている併用薬の使用 • 患者に有害事象のリスク因子が存在するか • 有害事象の発症に関連することが知られている無治療関連因子の存在	第II相試験
否定できる	有害事象と治験薬投与との時間的関係から、因果関係がありそうにないと考えられる。または、他の要因によって、観察された事象を説明することができる。	第III相試験 長期投与試験
否定できない	有害事象と治験薬投与との時間的関係から、因果関係が推定され、かつ他の要因によって、観察された事象を説明することができない。	

表 2.7.4-3 有害事象の重症度の判定基準

重症度	重症度の判定基準	
	第I相試験	第II相試験/第III相試験/長期投与試験
軽　度	被験者の通常の活動に支障をきたさない程度のもの。	不快感はあるが、通常の日常生活には支障をきたさない程度のもの
中等度	被験者の通常の活動に支障をきたす程度のもの。	不快感が日常生活を制限するか、あるいは通常の日常生活に影響するほどに大きい
高　度	被験者の通常の活動を完全に妨げ, 処置又は治験薬の投与中止が避けられないもの。	仕事あるいは通常の日常生活を行えない

表 2.7.4-4 注目すべき有害事象

注目すべき有害事象	第II相試験	第III相試験	長期投与試験
注射関連反応（注射部位の局所反応及び全身性の注射反応を含む）	○	○	○
喘息	—	○	○
アトピー性皮膚炎の悪化	—	○	○
皮膚感染症	—	○	○
皮膚以外の感染症	—	○*	○*
血中クレアチンホスホキナーゼ上昇（基準値の2.5倍以上）	○	○	○
ビリルビン上昇又は黄疸を伴うALT又はASTの上昇	○	—	—
白内障	○	—	—
カポジ水痘様発疹症	○	—	—
円形脱毛症	○	—	—

注目すべき有害事象	第II相試験	第III相試験	長期投与試験
感覚異常	○	—	—
AD以外のアレルギー疾患（喘息、アレルギー性鼻炎、アレルギー性結膜炎、食物アレルギー等）	○	—	—
治験薬からの感染病原体感染の疑い	○	○	○

－：未設定
*20[redacted]年[redacted]月[redacted]日改訂の治験実施計画書で追加

(2) 併合解析

有害事象の発現状況は、第II相試験、第III相試験及び長期投与試験を対象に以下の3つの安全性統合データセット（プール1～3）を用いて併合解析した。併合解析では、治験薬投与後に発現した有害事象を集計対象とした。第II相試験の結果、0.1 mg/kg、0.5 mg/kg又は2.0 mg/kgのnemolizumabをQ4Wで投与したときのそう痒VAS変化率は、0.5 mg/kg以上の用量でプラトーに達していると考えられたため本剤の申請用量は60 mgとした。なお、この申請用量60 mgは、体重が30 kg～120 kgの患者に投与したときに有効性が期待できる0.5 mg/kg～2.0 mg/kgの投与量となるように設定したことから、第II相試験の0.1 mg/kgを投与された被験者は併合解析対象集団から除外した。

1) 安全性統合データセット1（プール1）

第II相試験、第III相試験及び長期投与試験で、nemolizumabを0.5 mg/kg Q4W以上の曝露を受けた被験者で発現した有害事象を評価するためのデータセットであり、表 2.7.4-5に示す投与群から構成されている。

表 2.7.4-5 安全性統合データセット1（プール1）を構成する投与群

Nemolizumab-Total群	Nemolizumab群、プラセボ-Nemolizumab群を統合 ・Nemolizumab群を構成する投与群は以下の通り。 第II相試験：0.5 mg/kg Q4W、2 mg/kg Q4W、2 mg/kg Q8W 第III相試験：60 mg Q4W 長期投与試験：60 mg Q4W ・プラセボ-Nemolizumab群を構成する投与群は以下の通り。 第II相試験：プラセボ-0.5 mg/kg Q4W（Part Aでプラセボ、Part Bで0.5 mg/kg Q4Wの曝露を受けた群）、プラセボ-2.0 mg/kg Q4W（Part Aでプラセボ、Part Bで2.0 mg/kg Q4Wの曝露を受けた群） 第III相試験：プラセボ-60 mg Q4W（Part Aでプラセボ、Part Bで60 mg Q4Wの曝露を受けた群）

2) 安全性統合データセット2（プール2）

第II相試験及び第III相試験で、nemolizumabを0.5 mg/kg Q4W以上の曝露を受けた被験者のプラセボ対照期間（PartA）に発現した有害事象を評価するためのデータセットであり、表 2.7.4-6に示す投与群から構成されている。

表 2.7.4-6 安全性統合データセット2（プール2）を構成する投与群

Nemolizumab群	第II相試験：0.5 mg/kg Q4W、2 mg/kg Q4W、2 mg/kg Q8W 第III相試験：60 mg Q4W
プラセボ-Nemolizumab群	第II相試験：プラセボ、プラセボ-0.5 mg/kg Q4W（Part Aでプラセボ、Part Bで0.5 mg/kg Q4Wの曝露を受けた群）、プラセボ-2.0 mg/kg Q4W（Part Aでプラセボ、Part Bで2.0 mg/kg Q4Wの曝露を受けた群） 第III相試験：プラセボ-60 mg Q4W（Part Aでプラセボ、Part Bで60 mg Q4Wの曝露を受けた群）

3) 安全性統合データセット3（プール3）

申請用量である60 mgを投与された被験者に発現した有害事象を評価するためのデータセットであり、表 2.7.4-7に示す投与群から構成されている。

表 2.7.4-7 安全性統合データセット（プール3）を構成する投与群

Nemolizumab群	第III相試験：60 mg Q4W 長期投与試験：60 mg Q4W
プラセボ-Nemolizumab群	第III相試験：プラセボ-60 mg Q4W（Part Aでプラセボ、Part Bで60 mg Q4Wの曝露を受けた群）

2.7.4.1.1.2.2 臨床検査値及びバイタルサイン

臨床検査値及びバイタルサインは表 2.7.4-8に示す基準のいずれかに該当したときは有害事象とした。臨床検査に関する有害事象の評価は安全性統合データセットで評価した。

治験薬投与開始後の臨床検査値及びバイタルサインは併合せず、個々の試験で評価した。

表 2.7.4-8 臨床検査に関する有害事象の判定基準

	第II相試験	第III相試験	長期投与試験
臨床症状を伴う場合	○	○	○
治験薬投与の変更に至った場合	○	○	○
医学的処置（併用薬又は併用療法の変更含む）に至った場合	○	○	○
治験責任（分担）医師によって臨床的に重要であると判断された場合	○	○	○

	第II相試験	第III相試験	長期投与試験
総ビリルビンが基準値上限の2倍を超えるかつ、ALT又はASTが基準値上限の3倍を超えた場合	－	○	○
総ビリルビンの上昇を伴うALT又はASTの上昇	○	－	－
黄疸を伴いALT又はASTが基準値上限の3倍を超えた場合	－	○	○
黄疸を伴うALT又はASTの上昇	○	－	－
CPKが基準値上限の2.5倍以上となった場合	○	○	○

－：未設定

2.7.4.1.1.2.3 心電図

第I相試験、第II相試験、第III相試験及び長期投与試験で、12誘導心電図を測定した。治験責任医師又は治験分担医師が、臨床的に問題があると判断した心電図異常を有害事象とした。

心電図パラメータは、投与別に要約統計量を算出した。また、QTcB及びQTcFの測定値及び投与開始前からの変化量は、カテゴリ別の集計を実施した。QTc間隔の延長及び投与開始前からの延長に関する基準は、表 2.7.4-9に示した。

治験薬投与開始後の心電図は併合せず、個々の試験で評価した。

表 2.7.4-9 QTc間隔の延長及び投与開始前からの延長に関する基準

QTc間隔の延長	投与開始前方の延長
450 msec以下	30 msec以下
450 msec超480 msec以下	30 msec超60 msec以下
480 msec超500 msec以下	60 msec超
500 msec超	

2.7.4.1.2 全般的な曝露状況

2.7.4.1.2.1 曝露状況

(1) プラセボ対照期間（プール2）

プラセボ対照期間の治験薬投与回数は、第II相試験では4週間間隔で3回、第III相試験では4週間隔で4回と規定した。プラセボ対照期間中に投与された治験薬の回数は、表 2.7.4-10に示すように、投与回数が3回又は4回の被験者が約90%を占めた。

表 2.7.4-10 治験薬の投与回数別の被験者数（プール2）

	Overall (N=413) n (%)
Number of Doses Received	
1	22 (5.3)
2	22 (5.3)
3	166 (40.2)
4	203 (49.2)

5.3.5.3-1 Table 5.2.3から引用

(2) 全治療期間（プール1）

全治療期間の投与期間は、初回投与から最終投与までの期間とした。治験薬の最終投与日は、第II相試験では60週後、第III相試験では64週後、長期投与試験では48週後と規定した。全治療期間の投与期間は、表 2.7.4-11に示した。

全治療期間nemolizumabを投与された被験者のうち、投与期間が6カ月を経過した（24週超）被験者は314例、1年を経過した（48週超）被験者は268例であった。プラセボ対照期間はプラセボ群でnemolizumabに移行した被験者では、nemolizumab初回投与から6カ月を経過したのは86例、1年を経過したのは58例であった。

表 2.7.4-11 治験薬の投与日数（プール1）

	Nemolizumab (N=389) n (%)	Placebo-Nemolizumab [b] (N=92) n (%)
Treatment Duration for Nemolizumab (days) [a]		
n	389	92
Mean	331.5	309.5
SD	148.7	73.6
Min	1	1
Median	420.0	337.0
Max	458	345
- 12 Weeks	55 (14.1)	3 (3.3)
12 <- 24 Weeks	20 (5.1)	3 (3.3)
24 <- 36 Weeks	15 (3.9)	5 (5.4)
36 <- 48 Weeks	31 (8.0)	23 (25.0)
48 <- 60 Weeks	74 (19.0)	58 (63.0)
60 Weeks <	194 (49.9)	0

[a] Date of last dose - date of first dose + 1.
[b] Part B only
5.3.5.3-1 Table 5.2.2から引用

2.7.4.1.3 治験対象集団の人口統計学的特性及びその他の特性

Nemolizumabの安全性評価の主要な試験である第II相試験では18歳以上65歳未満、第III相試験及び長期投与試験では13歳以上の、既存治療を実施したにも関わらず中等度以上のそう痒（かゆみスコアが3以上）を有するAD患者を対象に安全性を評価した。

各試験の被験者は、表2.7.3-2に示す選択基準及び除外基準に基づき組み入れた。治験対象集団の人口統計学的特性及びその他の特性を表 2.7.4-12に示した。プラセボ対照期間からnemolizumabを投与された被験者（nemolizuab群）とプラセボ対照期間ではプラセボを投与された後、nemolizumabを投与された被験者（プラセボ-nemolizumab群）は、性別比、年齢、身長、体重及び人種に偏りはみられなかった。また、投与開始前のそう痒VAS、EASI、sIGA，アレルギー性疾患を合併した被験者の割合に差はみられなかった。

表 2.7.4-12 人口統計学的特性及びその他の特性（プール1）

	Nemolizumab (N=389) n (%)	Placebo-Nemolizumab (N=92) n (%)	Nemolizumab-Total (N=481) n (%)
Sex			
Male	231 (59.4)	53 (57.6)	284 (59.0)
Female	158 (40.6)	39 (42.4)	197 (41.0)
Age (At Informed Consent) (years)			
n	389	92	481
Mean (SD)	37.1 (12.7)	39.1 (13.2)	37.5 (12.8)
Median	37.0	40.0	38.0
Min, Max	13, 73	13, 70	13, 73
Height (At Randomization) (cm) [a]			
n	389	92	481
Mean (SD)	166.81 (8.59)	165.50 (7.87)	166.56 (8.47)
Median	167.00	166.00	166.60
Min, Max	143.5, 190.5	147.1, 185.0	143.5, 190.5
Weight (At Randomization) (kg) [b]			
n	389	92	481
Mean (SD)	67.74 (15.67)	67.12 (15.32)	67.62 (15.59)
Median	64.20	64.20	64.20
Min, Max	40.0, 144.0	42.3, 128.9	40.0, 144.0
Race			
Asian	279 (71.7)	74 (80.4)	353 (73.4)
Other	110 (28.3)	18 (19.6)	128 (26.6)
Baseline Pruritus VAS			
n	386	92	478
Mean (SD)	76.40 (11.28)	75.01 (11.12)	76.14 (11.25)
Median	77.23	75.00	76.54
Min, Max	43.8, 100.0	53.3, 100.0	43.8, 100.0
Baseline EASI			
n	389	92	481
Mean (SD)	28.308 (13.918)	27.089 (13.039)	28.075 (13.750)
Median	24.800	23.325	24.500
Min, Max	6.30, 72.00	10.00, 72.00	6.30, 72.00
Baseline sIGA			
- 3	188 (48.3)	55 (59.8)	243 (50.5)
4 -	201 (51.7)	37 (40.2)	238 (49.5)
Allergic Disease (Seasonal Allergy, Allergic Rhinitis, Allergic Conjunctivitis, Food Allergy and Asthma)			
No	233 (59.9)	50 (54.3)	283 (58.8)
Yes	156 (40.1)	42 (45.7)	198 (41.2)

[a] In the case of M525101-02, height at treatment start is used.
[b] In the case of M525101-02, weight at treatment start is used.
5.3.5.3-1 Table 5.2.1.1より改変

2.7.4.2 有害事象

2.7.4.2.1 有害事象の解析

(1) 有害事象の概要

1) プラセボ対照期間（プール2）

有害事象の概要を表 2.7.4-13に示した。有害事象の発現割合は、nemolizumab群で71.4%（215/301例）、プラセボ群で70.5%（79/112例）と、同程度であった。重症度が高度の有害事象の発現割合は、nemolizumab群が4.7%（14/301例）、プラセボ群が0.9%（1/112例）であり、nemolizumab群で高かった。また、中等度の有害事象の発現割合はそれぞれ27.6%

（83/301例）及び、24.1%（27/112例）と同程度であった。

因果関係が否定されなかった有害事象の発現割合は、nemolizumab群で35.5%（107/301例）、プラセボ群で19.6%（22/112例）であり、nemolizumab群で高かった。重症度が高度の因果関係が否定されなかった有害事象の発現割合は、それぞれ、2.3%（7/301例）及び0%であり、中等度の因果関係が否定されなかった有害事象の発現割合も、それぞれ12.6%（38/301例）、及び4.5%（5/112例）であり、nemolizumab群で高かった。

重篤な有害事象の発現割合は、nemolizumab群で3.3%（10/301例）、プラセボ群で2.7%（3/112例）で同程度であったが、その内、因果関係が否定されなかった有害事象は、それぞれ1.7%（5/301例）及び0%で、すべてnemolizumab群であった。

表 2.7.4-13 有害事象の概要（プール2）

	All TEAEs		TEAEs Related to Study Treatment	
	Nemolizumab (N=301) n (%) E [a]	Placebo-Nemolizumab (N=112) n (%) E [a]	Nemolizumab (N=301) n (%) E [a]	Placebo-Nemolizumab (N=112) n (%) E [a]
TEAEs	215 (71.4) 505	79 (70.5) 177	107 (35.5) 198	22 (19.6) 39
Severe TEAEs	14 (4.7) 20	1 (0.9) 1	7 (2.3) 10	0
Moderate TEAEs	83 (27.6) 120	27 (24.1) 43	38 (12.6) 51	5 (4.5) 9
Mild TEAEs	175 (58.1) 365	68 (60.7) 133	84 (27.9) 137	17 (15.2) 30
Serious TEAEs	10 (3.3) 12	3 (2.7) 3	5 (1.7) 7	0
TEAEs Leading to Death	0	0	0	0
Other Serious TEAEs	10 (3.3) 12	3 (2.7) 3	5 (1.7) 7	0

[a] E=Number of Treatment-Emergent Adverse Events
5.3.5.3-1 Table 5.2.4.1.2から改変

重症度が高度又は中等度の有害事象を表 2.7.4-39に示した。

重症度が高度又は中等度の有害事象の発現割合は、nemolizumab群では29.6%（89/301例）、プラセボ群では25.0%（28/112例）で同程度であり、因果関係が否定されなかった高度又は中等度の有害事象の発現割合は、それぞれ14.0%（42/301例）及び4.5%（5/112例）であり、nemolizumab群で高かった。

Nemolizumab群でみられた中等度又は高度で、発現割合が1.0%以上の有害事象は、アトピー性皮膚炎（13.6%、41/301例）、末梢性浮腫（2.3%、7/301例）、血中クレアチンホスホキナーゼ増加（2.0%、6/301例）、サイトカイン異常（2.0%、6/301例）、インフルエンザ（1.0%、3/301例）、咽頭炎（1.0%、3/301例）、細菌重複感染（1.0%、3/301例）、剥脱性皮膚炎（1.0%、3/301例）であり、その内、因果関係が否定されなかった有害事象は、アトピー性皮膚炎（7.3%、22/301例）、末梢性浮腫（1.0%、3/301例）、血中クレアチンホスホキナーゼ増加（0.7%、2/301例）、サイトカイン異常（2.0%、6/301例）、細菌重複感染（0.3%、

1/301例）、剥脱性皮膚炎（0.7%、2/301例）であった。一方、プラセボ群でみられた高度又は中等度で、発現割合が1.0%以上の有害事象は、アトピー性皮膚炎（10.7%、12/112例）、上気道感染（2.7%、3/112例）、インフルエンザ（1.8%、2/112例）、接触皮膚炎（1.8%、2/112例）であり、その内、因果関係が否定されなかった有害事象は、アトピー性皮膚炎（2.7%、3/112例）、上気道感染（0.9%、1/112例）であった。

2) 全治療期間（プール1）

有害事象の概要を表 2.7.4-14に示した。有害事象の発現割合は、91.3%（439/481例）であり、重症度が高度又は中等度の有害事象の発現割合は、それぞれ、7.5%（36/481例）及び43.7%（210/481例）であった。因果関係が否定されなかった有害事象の発現割合は、50.7%（244/481例）であり、重症度が高度又は中等度の因果関係が否定されなかった有害事象の発現割合は、それぞれ3.1%（15/481例）及び19.1%（92/481例）であった。

重篤な有害事象の発現割合は、10.0%（48/481例）であり、因果関係が否定されなかった重篤な有害事象の発現割合は、3.5%（17/481例）であった。

表 2.7.4-14 有害事象の概要（プール1）

	All TEAEs	TEAEs Related to Study Treatment
	Nemolizumab -Total (N=481) n (%) E [a]	Nemolizumab -Total (N=481) n (%) E [a]
TEAEs	439 (91.3) 2184	244 (50.7) 618
Severe TEAEs	36 (7.5) 52	15 (3.1) 22
Moderate TEAEs	210 (43.7) 440	92 (19.1) 146
Mild TEAEs	393 (81.7) 1692	202 (42.0) 450
Serious TEAEs	48 (10.0) 60	17 (3.5) 20
TEAEs Leading to Death	0	0
Other Serious TEAEs	48 (10.0) 60	17 (3.5) 20

[a] E=Number of Treatment-Emergent Adverse Events

5.3.5.3-1 Table 5.2.4.1.1から改変

重症度が高度又は中等度の有害事象を表 2.7.4-41に示した。重症度が高度又は中等度の有害事象の発現割合は、45.9%（221/481例）であり、その内、因果関係が否定されなかった有害事象の発現割合は21.0%（101/481例）であった。高度又は中等度で、発現割合が1.0%以上の有害事象は、アトピー性皮膚炎16.6%（80/481例）、上咽頭炎3.3%（16/481例）、

インフルエンザ2.7%（13/481例）、末梢性浮腫及び蜂巣炎各1.9%（9/481例）、上気道感染及び血中クレアチンホスホキナーゼ増加各1.7%（8/481例）、頭痛及び接触皮膚炎各1.5%（7/481例）、カポジ水痘様発疹、サイトカイン異常及び中毒性皮疹各1.2%（6/481例）、発熱、気管支炎、膀胱炎、咽頭炎、関節痛、背部痛及び剥脱性皮膚炎各1.0%（5/481例）であり、その内、因果関係が否定されなかった有害事象は、アトピー性皮膚炎8.5%（41/481例）、蜂巣炎1.5%（7/481例）、サイトカイン異常及び中毒性皮疹各1.2%（6/481例）、末梢性浮腫、カポジ水痘様発疹及び剥脱性皮膚炎各0.8%（4/481例）、上気道感染及び頭痛各0.6%（3/481例）、上咽頭炎、血中クレアチンホスホキナーゼ増加、関節痛及び背部痛各0.4%（2/481例）、気管支炎、膀胱炎、インフルエンザ、咽頭炎及び接触皮膚炎各0.2%（1/481例）であった。

2.7.4.2.1.1 比較的よくみられる有害事象

比較的よくみられる有害事象は、いずれかの投与群で発現割合が2%以上の有害事象とした。

(1) プラセボ対照期間（プール2）

比較的よくみられた有害事象の器官別・症状別の発現状況を表 2.7.4-15に示した。

1) 有害事象の投与群間比較

プラセボ投与期間中でみられた有害事象の発現割合は、nemolizumab群で71.4%（215/301例）、プラセボ群で70.5%（79/112例）と同程度であった。

Nemolizumab群で比較的よくみられた有害事象は、アトピー性皮膚炎20.9%（63/301例）、上咽頭炎12.3%（37/301例）、末梢性浮腫4.7%（14/301例）、血中クレアチンホスホキナーゼ増加4.7%（14/301例）、サイトカイン異常3.3%（10/301例）、頭痛3.3%（10/301例）、上気道感染3.0%（9/301例）、発熱2.3%（7/301例）であった。

プラセボ群で比較的よくみられた有害事象は、アトピー性皮膚炎18.8%（21/112例）、上咽頭炎16.1%（18/112例）、上気道感染4.5%（5/112例）、毛包炎2.7%（3/112例）、血中クレアチンホスホキナーゼ増加2.7%（3/112例）、ざ瘡2.7%（3/112例）であった。

2) 因果関係が否定されなかった有害事象の投与群間比較

プラセボ投与期間中でみられた因果関係が否定されなかった有害事象の発現割合は、nemolizumab群で35.5%（107/301例）、プラセボ群で19.6%（22/112例）であった。

Nemolizumab群で比較的よくみられた因果関係が否定されなかった有害事象は、アトピー性皮膚炎12.3%（37/301例）、サイトカイン異常3.3%（10/301例）、末梢性浮腫2.3%（7/301例）であった。

プラセボ群で比較的よくみられた因果関係が否定されなかった有害事象は、アトピー性皮膚炎4.5%（5/112例）であった。

表 2.7.4-15 器官別・症状別有害事象発現割合一覧（いずれかの投与群で発現割合2%以上）（プール2）

	All TEAEs		TEAEs Related to Study Treatment	
System Organ Class Preferred Term	Nemolizumab (N=301) n (%)	Placebo-Nemolizumab (N=112) n (%)	Nemolizumab (N=301) n (%)	Placebo-Nemolizumab (N=112) n (%)
一般・全身障害および投与部位の状態				
末梢性浮腫	14 (4.7)	0	7 (2.3)	0
発熱	7 (2.3)	2 (1.8)	3 (1.0)	0
感染症および寄生虫症				
毛包炎	2 (0.7)	3 (2.7)	0	1 (0.9)
上咽頭炎	37 (12.3)	18 (16.1)	4 (1.3)	1 (0.9)
上気道感染	9 (3.0)	5 (4.5)	5 (1.7)	1 (0.9)
臨床検査				
血中クレアチンホスホキナーゼ増加	14 (4.7)	3 (2.7)	3 (1.0)	0
サイトカイン異常	10 (3.3)	0	10 (3.3)	0
神経系障害				
頭痛	10 (3.3)	1 (0.9)	3 (1.0)	0
皮膚および皮下組織障害				
ざ瘡	2 (0.7)	3 (2.7)	0	0
アトピー性皮膚炎	63 (20.9)	21 (18.8)	37 (12.3)	5 (4.5)

TEAE occurred in equal to or more than 2% in any treatment group is presented.
Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.4.2.2から引用

(2) 全治療期間（プール1）

比較的よくみられた有害事象の器官別・症状別の発現状況を表 2.7.4-43に示した。

1) 有害事象

全治療期間でみられた有害事象の発現割合は、91.3%（439/481例）であった。

比較的よくみられた有害事象で最も発現割合が高いものは、上咽頭炎33.3%（160/481例）であり、次いでアトピー性皮膚炎27.2%（131/481例）、血中クレアチンホスホキナーゼ増加10.2%（49/481例）、頭痛7.5%（36/481例）、接触皮膚炎6.7%（32/481例）、インフルエンザ6.4%（31/481例）、蕁麻疹6.0%（29/481例）、ざ瘡5.6%（27/481例）、蜂巣炎5.2%（25/481例）であった。その他の比較的よくみられた有害事象の発現割合は5.0%未満であった。

2) 因果関係が否定されなかった有害事象

全治療期間でみられた因果関係が否定されなかった有害事象の発現割合は、50.7%（244/481例）であった。比較的よくみられた因果関係が否定されなかった有害事象は、アトピー性皮膚炎15.0%（72/481例）、蜂巣炎及び上咽頭炎各3.3%（16/481例）、サイトカイン異常2.7%（13/481例）、蕁麻疹2.5%（12/481例）、末梢性浮腫2.3%（11/481例）であった。

2.7.4.2.1.2 長期投与における安全性

(1) Nemolizumab投与期間の発現状況（プール1）

期間別の有害事象の発現割合を表 2.7.4-44に、期間別の因果関係が否定されなかった有害事象の発現割合を表 2.7.4-45に示した。

投与期間ごとの有害事象は、初めて有害事象が発現した時点を対象に、初回投与日以降85日目以前、86日目以降169日目以前、170日目以降253日目以前、254日目以降337日目以前、338日目以降421日目以前及び422日目以降 に分けて、期間別の有害事象発現割合を集計した。プラセボ-nemolizumab群では、プラセボ投与時にみられた有害事象は集計に含めず、プラセボ投与終了後に最初にnemolizumabを投与した日を初回投与日と置き換えて集計した。

1) Nemolizumab群

投与開始から85日までの有害事象の発現割合は67.4%（262/389例）と最も高く、86日目以降169日目以前が15.5%（53/343例）、170日目以降253日目以前が5.3%（17/318例）、254日目以降337日目以前が3.0%（9/304例）、338日目以降421日目以前が1.7%（5/290例）及び422日目以降が0.5%（1/211例）と投与開始から85日までに比べて低値であった。また、因果関係が否定されなかった有害事象の発現割合も同様に、投与開始から85日までが33.9%（132/389例）と最も高く、それ以降は10.5%（36/343例）、3.5%（11/318例）、3.0%（9/304例）、1.4%（4/290例）及び2.8%（6/211例）と低値であった。

重篤な有害事象の発現割合は、投与開始から85日までが3.1%（12/389例）と最も高く、それ以降は、1.2%（4/343例）、1.9%（6/318例）、1.0%（3/304例）、2.1%（6/290例）及び0.5%（1/211例）であった。また、因果関係が否定されなかった重篤な有害事象の発現割合は、投与開始から85日までが1.5%（6/389例）と最も高く、それ以降は0.3%（1/343例）、0.6%（2/318例）、0%、0.3%（1/290例）及び0.5%（1/211例）であった。

治験薬の投与中止又は中断に至った有害事象の発現割合は、投与開始から85日までが6.4%（25/389例）と最も高く、それ以降は3.2%（11/343例）、2.8%（9/318例）、0.3%（1/304例）、0.3%（1/290例）及び0%であった。また、因果関係が否定されなかった治験薬の投与中止又は中断に至った有害事象の発現割合は、投与開始から85日までが4.9%（19/389例）と最も高く、それ以降は2.0%（7/343例）、1.9%（6/318例）、0%、0%及び0%であった。

注目すべき有害事象で発現割合が高かったアトピー性皮膚炎の悪化、皮膚以外の感染症及び皮膚感染症の発現割合は、投与開始から85日までが19.3%（75/389例）、23.4%（91/389例）及び10.8%（42/389例）と最も高く、それ以降の発現割合は低値を示した。また、因果関係が否定されなかった注目すべき有害事象で発現割合が高かったアトピー性皮膚炎の悪化、皮膚以外の感染症及び皮膚感染症の発現割合は、投与開始から85日までが11.8%（46/389例）、6.4%（25/389例）及び4.1%（16/389例）と最も高く、それ以降の発現割合は低値を示した。

2) プラセボ-nemolizumab群

プラセボ-nemolizumab群では投与期間が422日目以降の被験者はいなかった。投与開始から85日までの有害事象の発現割合は55.4%（51/92例）と最も高く、それ以降は、20.2%（18/89例）、10.5%（9/86例）、4.9%（4/82例）及び2.6%（2/78例）と、最初の期間に比べて低値であった。また、因果関係が否定されなかった有害事象の発現割合も同様に、投与開始から85日までが22.8%（21/92例）と最も高く、それ以降は12.4%（11/89例）、7.0%

（6/86例）、3.7%（3/82例）及び0%と低値であった。

重篤な有害事象の発現割合は、投与開始から85日までが4.3%（4/92例）と最も高く、86日目以降169日目以前が2.2%（2/89例）、170日目以降253日目以前が1.2%（1/86例）、254日目以降337日目以前が0%、338日目以降421日目以前が0%であった。また、因果関係が否定されなかった重篤な有害事象の発現割合は、投与開始から85日までが2.2%（2/92例）と最も高く、それ以降は0%、1.2%（1/86例）、0%及び0%であった。

治験薬の投与中止又は中断に至った有害事象の発現割合は、投与開始から85日までが7.6%（7/92例）と最も高く、それ以降は1.1%（1/89例）、2.3%（2/86例）、2.4%（2/82例）及び0%と低値であった。また、因果関係が否定されなかった治験薬の投与中止又は中断に至った有害事象の発現割合は、投与開始から85日までが5.4%（5/92例）と最も高く、それ以降は1.1%（1/89例）、2.3%（2/86例）、1.2%（1/82例）及び0%と低値であった。

注目すべき有害事象で発現割合が高いアトピー性皮膚炎の悪化、皮膚以外の感染症及び皮膚感染症の発現割合は、投与開始から85日までが14.1%（13/92例）、16.3%（15/92例）及び7.6%（7/92例）と最も高く、それ以降の発現割合は低値を示した。また、因果関係が否定されなかった注目すべき有害事象で発現割合が高かったアトピー性皮膚炎の悪化及び皮膚感染症の発現割合は、投与開始から85日までが7.6%（7/92例）、5.4%（5/92例）と最も高く、それ以降の発現割合は低値を示した。皮膚以外の感染症は、投与開始から85日までが3.3%（3/92例）、86日目以降169日目以前が3.4%（3/89例）であり、それ以降は2.3%（2/86例）、1.2%（1/82例）及び0%であった。

(2) 投与開始から85日目までの発現状況（プール2）

投与開始から85日までの有害事象の発現割合が、nemolizumab群で全体の67.4%（262/389例）、プラセボ-nemolizumab群で55.4%（51/92例）を占めたことから、初めて有害事象が発現した時点を対象に、初回投与日以降28日目以前、29日目以降56日目以前、57日目以降84日目以前、85日目以降112日目以前に分けて、期間別の有害事象発現割合を集計した。

期間別の有害事象の発現割合を表 2.7.4-46に、期間別の因果関係が否定されなかった有害事象の発現割合を表 2.7.4-47に示した。

1) Nemolizumab群

有害事象の発現割合は、投与開始から28日までが42.2%（127/301例）と最も高く、29日目以降56日目以前が18.9%（55/291例）、57日目以降84日目以前が8.6%（24/278例）、85日目以降112日目以前が3.3%（8/240例）と投与開始から28日目までに比べて低値であった。また、因果関係が否定されなかった有害事象の発現割合も同様に、投与開始から28日までが16.3%（49/301例）と最も高く、それ以降は13.1%（38/291例）、4.3%（12/278例）及び2.9%（7/240例）と投与開始から28日目までに比べて低値であった。

重篤な有害事象の発現割合は、投与開始から28日までが1.7%（5/301例）と最も高く、それ以降は0.7%（2/291例）、1.1%（3/278例）及び0%であった。また、因果関係が否定されなかった重篤な有害事象の発現割合は、投与開始から28日までが0.7%（2/301例）、それ以降は0.3%（1/291例）、0.7%（2/278例）及び0%であった。

治験薬の投与中止又は中断に至った有害事象の発現割合は、投与開始から28日までが3.3%（10/301例）と最も高く、それ以降は、2.4%（7/291例）0.7%（2/278例）及び0%（0/240例）であった。また、因果関係が否定されなかった治験薬の投与中止又は中断に至った

有害事象の発現割合は、投与開始から28日までが2.3%（7/301例）と最も高く、それ以降は1.4%（4/291例）、0.7%（2/278例）及び0%であった。

注目すべき有害事象で発現割合が高かったアトピー性皮膚炎の悪化、皮膚以外の感染症及び皮膚感染の発現割合は、投与開始から28日までが8.6%（26/301例）、13.3%（40/301例）及び4.7%（14/301例）と最も高く、それ以降の発現割合は低値を示した。また、因果関係が否定されなかった注目すべき有害事象で発現割合が高かったアトピー性皮膚炎の悪化の発現割合は、投与開始から28日までが4.3%（13/301例）、29日目以降56日目以前が4.5%（13/291例）であり、それ以降の発現割合は低値を示した。皮膚感染症及び皮膚以外の感染症の発現割合は、投与開始から28日までが1.0%（3/301例）、3.7%（11/301例）と最も高く、それ以降の発現割合は低値を示した。

2) プラセボ-nemolizumab群

有害事象の発現割合は、投与開始から28日までが38.4%（43/112例）と最も高く、29日目以降56日目以前が15.0%（16/107例）、57日目以降84日目以前が15.5%（16/103例）、85日目以降112日目以前が3.2%（3/93例）と投与開始から28日目までに比べて低値であった。また、因果関係が否定されなかった有害事象の発現割合も同様に、投与開始から28日までが11.6%（13/112例）と最も高く、それ以降は1.9%（2/107例）、2.9%（3/103例）及び2.2%（2/93例）と投与開始から28日目までに比べて低値であった。

重篤な有害事象の発現割合は、投与開始から28日までが0.9%（1/112例）であり、それ以降は、0%、1.0%（1/103例）及び1.1%（1/93例）であった。これら重篤な有害事象はすべて因果関係が否定された。

治験薬の投与中止又は中断に至った有害事象の発現割合は、投与開始から28日までが0%であり、それ以降は、0%、1.0%（1/103例）及び1.1%（1/93例）であった。これら治験薬の投与中止又は中断に至った有害事象はすべて因果関係が否定された。

注目すべき有害事象で発現割合が高かったアトピー性皮膚炎の悪化、皮膚以外の感染症及び皮膚感染の発現割合は、投与開始から28日までが6.3%（7/112例）、10.7%（12/112例）及び4.5%（5/112例）と最も高く、それ以降の発現割合は投与開始から28日までに比べて低値を示した。また、因果関係が否定されなかった注目すべき有害事象のうち、アトピー性皮膚炎の悪化、皮膚感染症及び皮膚以外の感染症の発現割合は、投与開始から28日までが1.8%（2/112例）、1.8%（2/112例）及び1.8%（2/112例）であり、それ以降の発現割合は投与開始から28日までに比べて低値を示した。

2.7.4.2.1.3 死亡

第I相試験、第II相試験、第III相試験及び長期投与試験では、nemolizumabを投与した被験者で死亡例はみられなかった。

2.7.4.2.1.4 その他の重篤な有害事象

全治療期間（プール1）でみられた重篤な有害事象の発現割合は、10.0%（48/481例）であり、因果関係が否定されなかった重篤な有害事象は、3.5%（17/481例）であった。重篤な有害事象のPT別、因果関係別一覧は表 2.7.4-48に、重篤な有害事象の被験者ごとの一覧を表 2.7.4-49に示した。

重篤な有害事象として報告された有害事象の多くは、1例のみの発現であった。複数例で発現し

た重篤な有害事象は、アトピー性皮膚炎（5例）、蜂巣炎（3例）、菌血症、膀胱癌、剥脱性皮膚炎、感染及び視神経炎（各2例）であった。また、因果関係が否定されなかった重篤な有害事象は、菌血症、蜂巣炎及び剥脱性皮膚炎（各2例）、円形脱毛症、白内障、アトピー性皮膚炎、憩室炎、膿痂疹、リンパ節症、メニエール病、視神経炎、肺炎、腎盂腎炎、皮膚感染、ウイルス感染、カポジ水痘様発疹及び節外性辺縁帯B細胞性リンパ腫（MALT型）（各1例）であった。

なお、第I相試験では、重篤な有害事象はみられなかった。第II相試験のnemolizumab 0.1 mg/kg群では、膿皮症、非アルコール性脂肪性肝炎、心房細動（各1例）がみられたが、いずれも因果関係は否定された。

＜治験終了後の重篤な有害事象＞

因果関係が否定できない非重篤な有害事象として報告された眼部単純ヘルペス（1例）は、治験終了後に加療入院となり、重篤な有害事象として当局報告された。

2.7.4.2.1.5 その他の重要な有害事象

その他の重要な有害事象は、治験薬投与の中止（減量又は休薬）に至った有害事象及び第III試験及び長期投与試験で設定した注目すべき有害事象を対象に評価した。

2.7.4.2.1.5.1 治験薬投与の中止、減量又は休薬に至った有害事象

(1) プラセボ対照期間（プール2）

その他重要な有害事象のPT別、因果関係別一覧を表 2.7.4-50に示した。

1) 有害事象

治験薬の投与中止に至った有害事象の発現割合は、nemolizumab群で4.3%（13/301例）、プラセボ-nemolizumab群で0%であった。その多くは、1例のみの発現であった。複数例で発現した有害事象は、nemolizumab群で、アトピー性皮膚炎（9例）、皮膚感染（2例）であった。

治験薬の休薬に至った有害事象の発現割合は、nemolizumab群で2.0%（6/301例）、プラセボ-nemolizumab群で1.8%（2/112例）であった。すべて1例のみの発現であった。

治験薬の減量に至った有害事象はなかった。

2) 因果関係が否定されなかった有害事象

治験薬の投与中止に至った因果関係が否定されなかった有害事象の発現割合は、nemolizumab群で3.3%（10/301例）、プラセボ-nemolizumab群で0%であった。その多くは、1例のみの発現であった。複数例で発現した有害事象は、nemolizumab群で、アトピー性皮膚炎（6例）であった。

治験薬の休薬に至った因果関係が否定されなかった有害事象の発現割合は、nemolizumab群で1.0%（3/301例）、プラセボ-nemolizumab群で0%であった。全て1例のみの発現であった。

治験薬の減量に至った因果関係が否定されなかった有害事象はなかった。

(2) 全治療期間（プール1）

その他重要な有害事象のPT別、因果関係別一覧を表 2.7.4-51に示した。また、治験薬の投

与中止又は休薬、減量に至った有害事象の被験者ごとの一覧を表 2.7.4-52に示した。

1) 有害事象

治験薬の投与中止に至った有害事象の発現割合は、6.0%（29/481例）であった。その多くは、1例のみの発現であった。複数例で発現した有害事象は、アトピー性皮膚炎（14例）、中毒性皮疹（4例）、末梢性浮腫及び皮膚感染（各2例）であった。

治験薬の休薬に至った有害事象は、7.1%（34/481例）であった。その多くは、1例のみの発現であった。複数例で発現した有害事象は、アトピー性皮膚炎（5例）、蜂巣炎、膿痂疹、悪心、上気道の炎症、カポジ水痘様発疹及び中毒性皮疹（各2例）であった。

治験薬の減量に至った有害事象はなかった。

2) 因果関係が否定されなかった有害事象

治験薬の投与中止に至った因果関係が否定されなかった有害事象の発現割合は、4.4%（21/481例）であった。その多くは、1例のみの発現であった。複数例で発現した有害事象は、アトピー性皮膚炎（11例）、中毒性皮疹（4例）、末梢性浮腫（2例）であった。

治験薬の休薬に至った因果関係が否定されなかった有害事象は、4.4%（21/481例）であった。その多くは、1例のみの発現であった。複数例で発現した有害事象は、アトピー性皮膚炎（3例）、蜂巣炎、膿痂疹、上気道の炎症、カポジ水痘様発疹及び中毒性皮疹（各2例）であった。

治験薬の減量に至った因果関係が否定されなかった有害事象はなかった。

2.7.4.2.1.5.2 注目すべき有害事象

プラセボ対照期間（プール2）における注目すべき有害事象の発現状況を表 2.7.4-16に、全治療期間（プール1）における注目すべき有害事象の発現状況を表 2.7.4-17に示した。また、プラセボ対照期間（プール2）における注目すべき有害事象のPT別発現状況を表 2.7.4-50に、全治療期間（プール1）における注目すべき有害事象のPT別発現状況を表 2.7.4-51に示した。

表 2.7.4-16 注目すべき有害事象の発現状況（プール2）

	All TEAEs		TEAEs Related to Study Treatment	
	Nemolizumab (N=301) n (%) E [a]	Placebo-Nemolizumab (N=112) n (%) E [a]	Nemolizumab (N=301) n (%) E [a]	Placebo-Nemolizumab (N=112) n (%) E [a]
TEAEs	215 (71.4) 505	79 (70.5) 177	107 (35.5) 198	22 (19.6) 39
Other Significant TEAEs				
TEAEs Leading to Discontinuation (including Dose Interruption and Reduction) of Study Treatment	19 (6.3) 27	2 (1.8) 2	13 (4.3) 17	0
Discontinuation	13 (4.3) 20	0	10 (3.3) 13	0
Dose Interruption	6 (2.0) 7	2 (1.8) 2	3 (1.0) 4	0
Dose Reduction	0	0	0	0
TEAEs Special Interest				
Injection-Related Reaction	20 (6.6) 30	3 (2.7) 3	15 (5.0) 25	1 (0.9) 1
Asthma	1 (0.3) 1	1 (0.9) 2	1 (0.3) 1	1 (0.9) 2
Worsening of AD	64 (21.3) 73	21 (18.8) 22	37 (12.3) 40	5 (4.5) 5
Skin Infections	32 (10.6) 32	12 (10.7) 12	8 (2.7) 8	5 (4.5) 5
Non-skin Infections	78 (25.9) 98	34 (30.4) 38	25 (8.3) 28	4 (3.6) 5
Elevated CPK	13 (4.3) 13	3 (2.7) 3	3 (1.0) 3	0

[a] E=Number of Treatment-Emergent Adverse Events
5.3.5.3-1 Table 5.2.4.1.2より改変

表 2.7.4-17 注目すべき有害事象の発現状況（プール1）

	All TEAEs	TEAEs Related to Study Treatment
	Nemolizumab -Total (N=481) n (%) E [a]	Nemolizumab -Total (N=481) n (%) E [a]
TEAEs	439 (91.3) 2184	244 (50.7) 618
Other Significant TEAEs		
TEAEs Leading to Discontinuation (including Dose Interruption and Reduction) of Study Treatment	61 (12.7) 83	41 (8.5) 54
Discontinuation	29 (6.0) 44	21 (4.4) 30
Dose Interruption	34 (7.1) 39	21 (4.4) 24
Dose Reduction	0	0
TEAEs Special Interest		
Injection-Related Reaction	32 (6.7) 54	27 (5.6) 48
Asthma	12 (2.5) 13	4 (0.8) 5
Worsening of AD	133 (27.7) 172	73 (15.2) 89
Skin Infections	133 (27.7) 208	52 (10.8) 78
Non-skin Infections	264 (54.9) 526	58 (12.1) 95
Elevated CPK	49 (10.2) 57	6 (1.2) 6

[a] E=Number of Treatment-Emergent Adverse Events
5.3.5.3-1 Table 5.2.4.1.1より改変

(1) 注射関連反応（注射部位の局所反応及び全身性の注射反応を含む）

注射関連反応（注射部位の局所反応及び全身性の注射反応を含む）の被験者ごとの有害事象の一覧を表 2.7.4-53に示した。

1) プラセボ対照期間（プール2）

a) 有害事象

注射関連反応に関する有害事象の発現割合は、nemolizumab群で6.6%（20/301例）、プラセボ-nemolizumab群で2.7%（3/112例）であった。3例以上で発現した有害事象は、nemolizumab群で、注射部位反応（5例）、注射部位内出血、倦怠感（各3例）であった。

b) 因果関係が否定されなかった有害事象

注射関連反応に関する有害事象の発現割合は、nemolizumab群で5.0%（15/301例）、プラセボ-nemolizumab群で0.9%（1/112例）であった。3例以上で発現した有害事象は、

nemolizumab群で、注射部位反応（5例）であった。

2) 全治療期間（プール1）

a) 有害事象

注射関連反応に関する有害事象の発現割合は、6.7%（32/481例）であった。3例以上で発現した有害事象は、注射部位反応（7例）、注射部位内出血及び倦怠感（各4例）であった。

b) 因果関係が否定されなかった有害事象

注射関連反応に関する有害事象の発現割合は、5.6%（27/481例）であった。3例以上で発現した有害事象は、注射部位反応（7例）、注射部位内出血及び倦怠感（各3例）であった。

(2) 喘息

喘息の被験者ごとの有害事象の一覧を表 2.7.4-54に示した。

1) プラセボ対照期間（プール2）

a) 有害事象

喘息に関連する有害事象の発現割合は、nemolizumab群で0.3%（1/301例）、プラセボ-nemolizumab群で0.9%（1/112例）であった。内訳は、nemolizumab群で咳嗽（1例）、プラセボ-nemolizumab群で咳嗽（1例）、労作性呼吸困難（1例）であった。

b) 因果関係が否定されなかった有害事象

喘息に関連する有害事象の発現割合は、nemolizumab群で0.3%（1/301例）、プラセボ-nemolizumab群で0.9%（1/112例）であった。内訳は、nemolizumab群で咳嗽（1例）、プラセボ-nemolizumab群で咳嗽（1例）、労作性呼吸困難（1例）であった。

2) 全治療期間（プール1）

a) 有害事象

喘息に関連する有害事象の発現割合は、2.5%（12/481例）であった。3例以上で発現した有害事象は、喘息（9例）であった。

b) 因果関係が否定されなかった有害事象

喘息に関連する有害事象の発現割合は、0.8%（4/481例）であった。3例以上で発現した有害事象はなかった。

(3) アトピー性皮膚炎の悪化

アトピー性皮膚炎の悪化の被験者ごとの有害事象の一覧を表 2.7.4-55に示した。

1) プラセボ対照期間（プール2）

a) 有害事象

アトピー性皮膚炎の悪化に関連する有害事象の発現割合は、nemolizumab群で21.3%（64/301例）、プラセボ-nemolizumab群で18.8%（21/112例）であった。内訳は、nemolizumab群でアトピー性皮膚炎（63例）、剥脱性皮膚炎（1例）で、プラセボ-nemolizumab群では、アトピー性皮膚炎（21例）であった。

b) 因果関係が否定されなかった有害事象

アトピー性皮膚炎の悪化に関連する有害事象の発現割合は、nemolizumab群で12.3%（37/301例）、プラセボ-nemolizumab群で4.5%（5/112例）であった。内訳は、すべてアトピー性皮膚炎であった。

2) 全治療期間（プール1）

a) 有害事象

アトピー性皮膚炎の悪化に関連する有害事象の発現割合は、27.7%（133/481例）であった。内訳は、アトピー性皮膚炎（131例）、剥脱性皮膚炎（2例）であった。

b) 因果関係が否定されなかった有害事象

アトピー性皮膚炎の悪化に関連する有害事象の発現割合は、15.2%（73/481例）であった。内訳は、アトピー性皮膚炎（72例）、剥脱性皮膚炎（1例）であった。

(4) 皮膚感染症

皮膚感染症の被験者ごとの有害事象の一覧を表 2.7.4-56に示した。

1) プラセボ対照期間（プール2）

a) 有害事象

皮膚感染症に関連する有害事象の発現割合は、nemolizumab群で10.6%（32/301例）、プラセボ-nemolizumab群で10.7%（12/112例）であった。3例以上で発現した有害事象は、nemolizumab群で、蜂巣炎、外耳炎（各4例）、プラセボ-nemolizumab群で毛包炎（3例）であった。

b) 因果関係が否定されなかった有害事象

皮膚感染症に関連する有害事象の発現割合は、nemolizumab群で2.7%（8/301例）、プラセボ-nemolizumab群で4.5%（5/112例）であった。3例以上で発現した有害事象はなかった。

2) 全治療期間（プール1）

a) 有害事象

皮膚感染症に関連する有害事象の発現割合は、27.7%（133/481例）であった。3例以上で発現した有害事象は、蜂巣炎（25例）、毛包炎及び膿痂疹（各17例）、外耳炎（15例）、カポジ水痘様発疹（11例）、帯状疱疹（10例）、単純ヘルペス（9例）、皮膚乳頭腫（8例）、爪囲炎、皮膚感染、足部白癬及び口腔ヘルペス（各7例）、皮膚細菌感染（5例）、せつ（4例）、体部白癬、丹毒及び眼部単純ヘルペス（各3例）であった。

b) 因果関係が否定されなかった有害事象

皮膚感染症に関連する有害事象の発現割合は、10.8%（52/481例）であった。3例以上で発現した有害事象は、蜂巣炎（16例）、膿痂疹（8例）、帯状疱疹及びカポジ水痘様発疹（各6例）、単純ヘルペス及び皮膚乳頭腫（各4例）、毛包炎及び皮膚感染（各3例）であった。

(5) 皮膚以外の感染症

皮膚以外の感染症の被験者ごとの有害事象の一覧を表 2.7.4-57に示した。

1) プラセボ対照期間（プール2）

a) 有害事象

皮膚以外の感染症に関連する有害事象の発現割合は、nemolizumab群で25.9%（78/301例）、プラセボ-nemolizumab群で30.4%（34/112例）であった。3例以上で発現した有害事象は、nemolizumab群で、上咽頭炎（37例）、上気道感染（9例）、インフルエンザ（4例）、咽頭炎（4例）、細菌重複感染（4例）、プラセボ-nemolizumab群で、上咽頭炎（18例）、上気道感染（5例）であった。

b) 因果関係が否定されなかった有害事象

皮膚以外の感染症に関連する有害事象の発現割合は、nemolizumab群で8.3%（25/301例）、プラセボ-nemolizumab群で3.6%（4/112例）であった。3例以上で発現した有害事象は、nemolizumab群で、上気道感染（5例）、上咽頭炎（4例）であった。

2) 全治療期間（プール1）

a) 有害事象

皮膚以外の感染症に関連する有害事象の発現割合は、54.9%（264/481例）であった。3例以上で発現した有害事象は、上咽頭炎（160例）、インフルエンザ（31例）、胃腸炎（22例）、咽頭炎（21例）、上気道感染（16例）、気管支炎（13例）、膀胱炎（12例）、結膜炎（9例）、副鼻腔炎（8例）、感染（7例）、ウイルス性上気道感染（6例）、ウイルス性胃腸炎、歯髄炎、扁桃炎及び細菌重複感染（各5例）、尿路感染及び歯感染（各4例）、中耳炎及び感染性腸炎（各3例）であった。

b) 因果関係が否定されなかった有害事象

皮膚以外の感染症に関連する有害事象の発現割合は、12.1%（58/481例）であった。3例以上で発現した有害事象は、上咽頭炎（16例）、上気道感染（9例）、結膜炎、胃腸炎及び咽頭炎（各4例）、膀胱炎、感染及びインフルエンザ（各3例）であった。

(6) CPK上昇

CPK上昇の被験者ごとの有害事象の一覧を表 2.7.4-58に示した。

1) プラセボ対照期間（プール2）

a) 有害事象

CPK上昇に関連する有害事象の発現割合は、nemolizumab群で4.3%（13/301例）、プラセボ-nemolizumab群で2.7%（3/112例）であった。内訳は、すべて血中クレアチンホスホキナーゼ増加であった。

b) 因果関係が否定されなかった有害事象

CPK上昇に関連する有害事象の発現割合は、nemolizumab群で1.0%（3/301例）、プラセボ-nemolizumab群で0%（0/112例）であった。内訳は、すべて血中クレアチンホスホキナーゼ増加であった。

2) 全治療期間（プール1）

a) 有害事象

CPK上昇に関連する有害事象の発現割合は、10.2%（49/481例）であった。内訳は、血中クレアチンホスホキナーゼ増加（47例）、筋肉痛（2例）であった。

b) 因果関係が否定されなかった有害事象

CPK上昇に関連する有害事象の発現割合は、1.2%（6/481例）であった。内訳は、すべて血中クレアチンホスホキナーゼ増加であった。

(7) 治験薬からの感染病原体感染の疑い

各試験で治験薬からの感染病原体感染の疑いと特定された有害事象はなかったため、集計していない。

2.7.4.2.1.6 その他の皮膚症状

Nemolizumab投与群でTARCの一過性の上昇が認められており、TARCにTh2サイトカインの二次誘導及び遊走の働きがあることから、皮膚の炎症症状に着目した。アトピー性皮膚炎の悪化以外に注目した皮膚関連の有害事象を「その他の皮膚症状」として集計した。集計では、PTで、異汗性湿疹、貨幣状湿疹、紅斑、湿疹、水疱、中毒性皮疹、剥脱性皮膚炎、皮膚びらん、皮膚炎、皮膚剥脱に該当する有害事象を抽出した。

(1) プラセボ対照期間（プール2）

その他皮膚症状の有害事象発現割合を表 2.7.4-18に示した。

有害事象の発現割合は、nemolizumab群で4.3%（13/301例）、プラセボ-nemolizumab群で2.7%（3/112例）であった。因果関係が否定されなかった有害事象の発現割合は、nemolizumab群で3.0%（9/301例）、プラセボ-nemolizumab群で0%であった。

表 2.7.4-18 その他皮膚症状の有害事象一覧（プール2）

	All TEAEs		TEAEs Related to Study Treatment	
Preferred Term	Nemolizumab (N=301) n (%)	Placebo-Nemolizumab (N=112) n (%)	Nemolizumab (N=301) n (%)	Placebo-Nemolizumab (N=112) n (%)
Other Cutaneous Disorders	13 (4.3)	3 (2.7)	9 (3.0)	0
皮膚炎	1 (0.3)	0	1 (0.3)	0
剥脱性皮膚炎	3 (1.0)	0	2 (0.7)	0
異汗性湿疹	4 (1.3)	0	2 (0.7)	0
湿疹	0	1 (0.9)	0	0
紅斑	2 (0.7)	1 (0.9)	1 (0.3)	0
皮膚びらん	0	1 (0.9)	0	0
皮膚剥脱	2 (0.7)	0	2 (0.7)	0
中毒性皮疹	2 (0.7)	0	2 (0.7)	0

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.9.2.2から引用

(2) 全治療期間（プール1）

その他皮膚症状の有害事象発現割合を表 2.7.4-19に示した。

有害事象の発現割合は、11.2%（54/481例）であった。因果関係が否定されなかった有害事象の発現割合は、7.3%（35/481例）であった。

表 2.7.4-19 その他皮膚症状の有害事象一覧（プール1）

	All TEAEs	TEAEs Related to Study Treatment
	Nemolizumab -Total (N=481)	Nemolizumab -Total (N=481)
Preferred Term	n (%)	n (%)
Other Cutaneous Disorders	54 (11.2)	35 (7.3)
水疱	1 (0.2)	1 (0.2)
皮膚炎	5 (1.0)	4 (0.8)
剥脱性皮膚炎*	5 (1.0)	4 (0.8)
異汗性湿疹	13 (2.7)	4 (0.8)
湿疹	10 (2.1)	5 (1.0)
貨幣状湿疹	1 (0.2)	0
紅斑	10 (2.1)	9 (1.9)
皮膚びらん	2 (0.4)	0
皮膚剥脱	4 (0.8)	3 (0.6)
中毒性皮疹	8 (1.7)	8 (1.7)

*その他の皮膚症状に関する有害事象の集計は、あらかじめ規定したPTに基づき抽出したため、治験責任医師がAD悪化として報告した2例を含む。
Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.9.1.2から引用

2.7.4.2.1.7 器官別又は症候群別有害事象の解析

(1) プラセボ対照期間（プール2）

器官別大分類（以下、SOC）ごとの有害事象発現割合を表 2.7.4-20に示した。

SOCごとの有害事象の発現割合は、nemolizumab群で「感染症および寄生虫症」33.6%（101/301例）、「皮膚および皮下組織障害」29.2%（88/301例）、「一般・全身障害および投与部位の状態」14.0%（42/301例）の順で、プラセボ-nemolizumab群では、「感染症および寄生虫症」37.5%（42/112例）、「皮膚および皮下組織障害」28.6%（32/112例）、「筋骨格系および結合組織障害」10.7%（12/112例）の順で高かった。

因果関係が否定されなかったSOCごとの有害事象の発現割合は、nemolizumab群で「皮膚および皮下組織障害」16.6%（50/301例）、「感染症および寄生虫症」10.3%（31/301例）、「一般・全身障害および投与部位の状態」8.3%（25/301例）の順で、プラセボ-nemolizumab群では、「感染症および寄生虫症」8.0%（9/112例）、「皮膚および皮下組織障害」6.3%（7/112例）、「臨床検査」2.7%（3/112例）の順で高かった。

表 2.7.4-20 器官別有害事象発現割合一覧（プール2）

System Organ Class	All TEAEs		TEAEs Related to Study Treatment	
	Nemolizumab (N=301) n (%)	Placebo-Nemolizumab (N=112) n (%)	Nemolizumab (N=301) n (%)	Placebo-Nemolizumab (N=112) n (%)
TEAEs	215 (71.4)	79 (70.5)	107 (35.5)	22 (19.6)
血液およびリンパ系障害	3 (1.0)	2 (1.8)	1 (0.3)	2 (1.8)
心臓障害	5 (1.7)	1 (0.9)	1 (0.3)	0
耳および迷路障害	1 (0.3)	1 (0.9)	1 (0.3)	1 (0.9)
内分泌障害	1 (0.3)	1 (0.9)	0	0
眼障害	6 (2.0)	5 (4.5)	1 (0.3)	0
胃腸障害	22 (7.3)	7 (6.3)	2 (0.7)	1 (0.9)
一般・全身障害および投与部位の状態	42 (14.0)	4 (3.6)	25 (8.3)	1 (0.9)
肝胆道系障害	2 (0.7)	0	1 (0.3)	0
免疫系障害	2 (0.7)	2 (1.8)	0	1 (0.9)
感染症および寄生虫症	101 (33.6)	42 (37.5)	31 (10.3)	9 (8.0)
傷害、中毒および処置合併症	14 (4.7)	4 (3.6)	0	0
臨床検査	35 (11.6)	7 (6.3)	20 (6.6)	3 (2.7)
代謝および栄養障害	5 (1.7)	2 (1.8)	2 (0.7)	2 (1.8)
筋骨格系および結合組織障害	18 (6.0)	12 (10.7)	6 (2.0)	1 (0.9)
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 (0.3)	2 (1.8)	0	0
神経系障害	20 (6.6)	8 (7.1)	4 (1.3)	0
精神障害	4 (1.3)	3 (2.7)	2 (0.7)	1 (0.9)
腎および尿路障害	3 (1.0)	0	3 (1.0)	0
生殖系および乳房障害	2 (0.7)	2 (1.8)	0	1 (0.9)
呼吸器、胸郭および縦隔障害	13 (4.3)	3 (2.7)	5 (1.7)	1 (0.9)
皮膚および皮下組織障害	88 (29.2)	32 (28.6)	50 (16.6)	7 (6.3)
血管障害	3 (1.0)	1 (0.9)	1 (0.3)	0

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.6.2.2から引用

(2) 全治療期間（プール1）

器官別大分類（以下、SOC）ごとの有害事象発現割合を表 2.7.4-21に示した。

SOCごとの有害事象の発現割合は、「感染症および寄生虫症」66.3%（319/481例）、「皮膚および皮下組織障害」51.1%（246/481例）、「胃腸障害」21.6%（104/481例）の順で高かった。

因果関係が否定されなかったSOCごとの有害事象の発現割合は、「皮膚および皮下組織障害」25.4%（122/481例）、「感染症および寄生虫症」20.6%（99/481例）、「一般・全身障害および投与部位の状態」9.1%（44/481例）の順で高かった。

表 2.7.4-21 器官別有害事象発現割合一覧（プール1）

	All TEAEs	TEAEs Related to Study Treatment
	Nemolizumab -Total (N=481)	Nemolizumab -Total (N=481)
System Organ Class	n (%)	n (%)
TEAEs	439 (91.3)	244 (50.7)
血液およびリンパ系障害	14 (2.9)	4 (0.8)
心臓障害	14 (2.9)	4 (0.8)
耳および迷路障害	14 (2.9)	8 (1.7)
内分泌障害	4 (0.8)	0
眼障害	39 (8.1)	11 (2.3)
胃腸障害	104 (21.6)	21 (4.4)
一般・全身障害および投与部位の状態	73 (15.2)	44 (9.1)
肝胆道系障害	6 (1.2)	1 (0.2)
免疫系障害	8 (1.7)	1 (0.2)
感染症および寄生虫症	319 (66.3)	99 (20.6)
傷害、中毒および処置合併症	62 (12.9)	1 (0.2)
臨床検査	97 (20.2)	40 (8.3)
代謝および栄養障害	16 (3.3)	4 (0.8)
筋骨格系および結合組織障害	70 (14.6)	11 (2.3)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	15 (3.1)	6 (1.2)
神経系障害	74 (15.4)	15 (3.1)
精神障害	11 (2.3)	5 (1.0)
腎および尿路障害	8 (1.7)	3 (0.6)
生殖系および乳房障害	11 (2.3)	4 (0.8)
呼吸器、胸郭および縦隔障害	77 (16.0)	18 (3.7)
皮膚および皮下組織障害	246 (51.1)	122 (25.4)
外科および内科処置	2 (0.4)	0
血管障害	12 (2.5)	3 (0.6)
製品の問題	1 (0.2)	1 (0.2)

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.6.1.2から引用

2.7.4.2.2 個別有害事象の文章による説明

第II相試験でみられたその他の重篤な有害事象は、2.7.6.2及び5.3.5.1-1で叙述した。また、第III相試験及び長期投与試験でみられたその他の重篤な有害事象は、2.7.6.3、5.3.5.1-2及び2.7.6.4及び5.3.5.2-1にも叙述した。

2.7.4.3 臨床検査値の評価

第II相試験、第III相試験及び長期投与試験で実施した臨床検査項目を表 2.7.4-22に示した。

表 2.7.4-22 試験で実施した臨床検査項目

検査項目	内容
血液学検査	Hb、Ht、Plt、RBC、WBC、白血球分画、MCV、MCH、MCHC
血液生化学検査	Na、K、Cl、GLU*1、UN、CREA、Ca、T-Bil、D-Bil、TP、ALB、ALT（GPT）、AST（GOT）、ALP、P、LDH、CPK、UA、TC、LDL-C、HDL-C、TG、A/G比、γ-GT、CRP*2
免疫学的検査	TARC
尿検査	蛋白、潜血、尿糖、ウロビリノーゲン

*1：第II相試験のみで実施、 *2：第II相試験では高感度CRP

臨床検査値の異常変動に関する有害事象は、安全性統合データセットでの集計から評価した。試験を通しての臨床検査値の推移は、個々の試験の結果から評価した。

(1) 臨床検査の異常変動

1) プラセボ対照期間（プール2）

SOCが「臨床検査」に該当する有害事象発現割合を表 2.7.4-23に示した。

SOCが「臨床検査」に該当する有害事象の発現割合は、nemolizumab群で11.6%（35/301例）、プラセボ-nemolizumab群で6.3%（7/112例）であった。3例以上で発現した有害事象は、nemolizumab群で血中クレアチンホスホキナーゼ増加（14例）、サイトカイン異常（10例）、血中尿酸増加、C-反応性蛋白増加、好酸球数増加（各3例）、プラセボ-nemolizumab群で血中クレアチンホスホキナーゼ増加（3例）であった。

因果関係が否定されなかったSOCが「臨床検査」に該当する有害事象の発現割合は、nemolizumab群で6.6%（20/301例）、プラセボ-nemolizumab群で2.7%（3/112例）であった。3例以上で発現した有害事象は、nemolizumab群でサイトカイン異常（10例）、血中クレアチンホスホキナーゼ増加、好酸球数増加（各3例）であった。

表 2.7.4-23 SOC「臨床検査」の有害事象の発現割合（プール2）

	All TEAEs		TEAEs Related to Study Treatment	
System Organ Class Preferred Term	Nemolizumab (N=301) n (%)	Placebo-Nemolizumab (N=112) n (%)	Nemolizumab (N=301) n (%)	Placebo-Nemolizumab (N=112) n (%)
臨床検査	35 (11.6)	7 (6.3)	20 (6.6)	3 (2.7)
アスパラギン酸アミノトランスフェラーゼ増加	1 (0.3)	0	0	0
血中クレアチンホスホキナーゼ増加	14 (4.7)	3 (2.7)	3 (1.0)	0
血中トリグリセリド増加	1 (0.3)	0	0	0
血中尿酸増加	3 (1.0)	0	1 (0.3)	0
C-反応性蛋白増加	3 (1.0)	1 (0.9)	2 (0.7)	0
心電図ＱＴ延長	1 (0.3)	0	0	0
好酸球数増加	3 (1.0)	0	3 (1.0)	0
フィブリンＤダイマー増加	2 (0.7)	0	2 (0.7)	0
眼圧上昇	1 (0.3)	1 (0.9)	0	1 (0.9)
好中球数減少	1 (0.3)	0	1 (0.3)	0
体重増加	2 (0.7)	1 (0.9)	1 (0.3)	1 (0.9)
心電図異常Ｔ波	0	1 (0.9)	0	1 (0.9)
心電図Ｔ波振幅増加	1 (0.3)	0	0	0
尿中蛋白陽性	1 (0.3)	0	1 (0.3)	0
頚動脈脈拍増加	1 (0.3)	0	0	0
肝酵素上昇	1 (0.3)	0	0	0
サイトカイン異常	10 (3.3)	0	10 (3.3)	0

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.2.2.2 より改変

2) 全治療期間（プール1）

SOCが「臨床検査」に該当する有害事象発現割合を表 2.7.4-24に示した。

SOCが「臨床検査」に該当する有害事象の発現割合は、20.2%（97/481例）であった。3例以上で発現した有害事象は、血中クレアチンホスホキナーゼ増加（49例）、サイトカイン異常（14例）、好酸球数増加及び体重増加（各8例）、C-反応性蛋白増加（7例）、アスパラギン酸アミノトランスフェラーゼ増加及び血中尿酸増加（各4例）、血中トリグリセリド増加及び体重減少（3例）であった。

因果関係が否定されなかったSOCが「臨床検査」に該当する有害事象の発現割合は、8.3%（40/481例）であった。3例以上で発現した有害事象は、サイトカイン異常（13例）、好酸球数増加（8例）、血中クレアチンホスホキナーゼ増加（7例）、体重増加（4例）、C-反応性蛋白増加（3例）であった。

表 2.7.4-24 SOC「臨床検査」の有害事象の発現割合（プール1）

System Organ Class Preferred Term	All TEAEs Nemolizumab -Total (N=481) n (%)	TEAEs Related to Study Treatment Nemolizumab -Total (N=481) n (%)
臨床検査	97 (20.2)	40 (8.3)
アラニンアミノトランスフェラーゼ増加	2 (0.4)	2 (0.4)
アスパラギン酸アミノトランスフェラーゼ増加	4 (0.8)	1 (0.2)
血中ビリルビン増加	1 (0.2)	0
血中クレアチンホスホキナーゼ増加	49 (10.2)	7 (1.5)
血中フィブリノゲン増加	1 (0.2)	0
血中カリウム増加	1 (0.2)	0
血圧上昇	1 (0.2)	0
血中トリグリセリド増加	3 (0.6)	0
血中尿酸増加	4 (0.8)	1 (0.2)
Ｃ－反応性蛋白増加	7 (1.5)	3 (0.6)
心電図異常	1 (0.2)	1 (0.2)
心電図ＱＴ延長	2 (0.4)	1 (0.2)
好酸球数増加	8 (1.7)	8 (1.7)
フィブリンＤダイマー増加	2 (0.4)	2 (0.4)
尿中血陽性	1 (0.2)	0
眼圧上昇	2 (0.4)	1 (0.2)
脂質増加	1 (0.2)	0
好中球数減少	1 (0.2)	1 (0.2)
体重減少	3 (0.6)	0
体重増加	8 (1.7)	4 (0.8)
白血球数減少	2 (0.4)	0
白血球数増加	1 (0.2)	0
骨密度減少	1 (0.2)	0
心電図異常Ｔ波	2 (0.4)	2 (0.4)
心電図Ｔ波振幅増加	1 (0.2)	0
尿中蛋白陽性	1 (0.2)	1 (0.2)
頚動脈脈拍増加	1 (0.2)	0
肝酵素上昇	2 (0.4)	0
検査	1 (0.2)	0
サイトカイン異常	14 (2.9)	13 (2.7)
肝機能検査値上昇	1 (0.2)	1 (0.2)

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.2.1.2 より改変

(2) 試験期間を通しての臨床検査値の推移

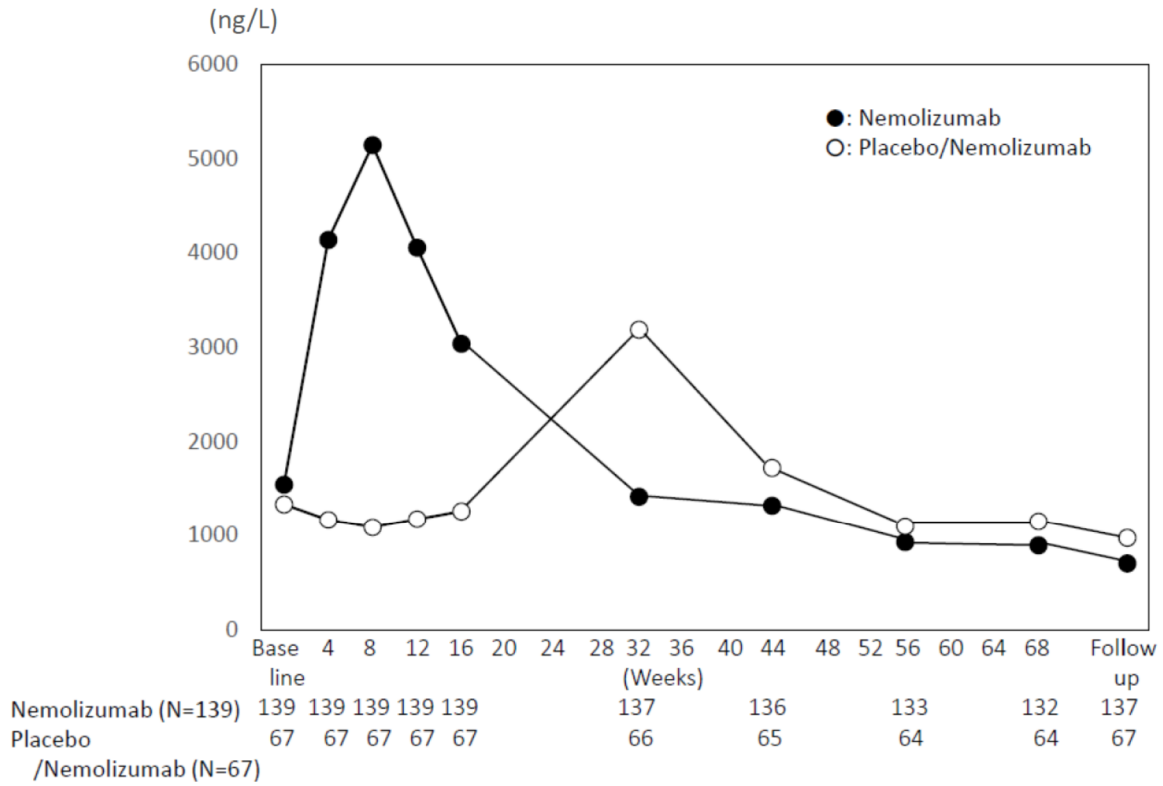
第III相試験の結果、TARC及びLDHを除き、試験期間を通して変化はみられなかった。TARC及びLDHはいずれもAD病勢を反映するバイオマーカーであり、好酸球数を含めて、試験期間の推移を以下に示した。

1) TARC

第III相試験のTARCの中央値の経時推移を図 2.7.4-1に示した。Nemolizumab群では、投与開始4週後から8週後にかけてTARC濃度は上昇し、その後は経時的に低下し、投与開始32週後以降はベースライン時よりも低い値で推移した。プラセボ群ではTARC濃度の一過性の上昇はみられなかったが、投与開始16週後にnemolizumabの投与を開始すると、投与開始32週後（nemolizumab投与開始16週後）にはTARC濃度が上昇した。その後は経時的に低下し、投与開始56週後(nemolizumab投与開始40週後)以降はベースライン時に近い値で推移した。

長期投与試験及び第II相試験も同様に、nemolizumab投与後にTARC濃度の一過性の上昇がみられた（表 2.7.4-25）。

図 2.7.4-1 TARC（中央値）の経時的推移（第III相試験）



5.3.5.1-2 Table 14.3.3.1.1.3.2より作図

表 2.7.4-25 TARCの経時的推移（長期投与試験及び第II相試験）

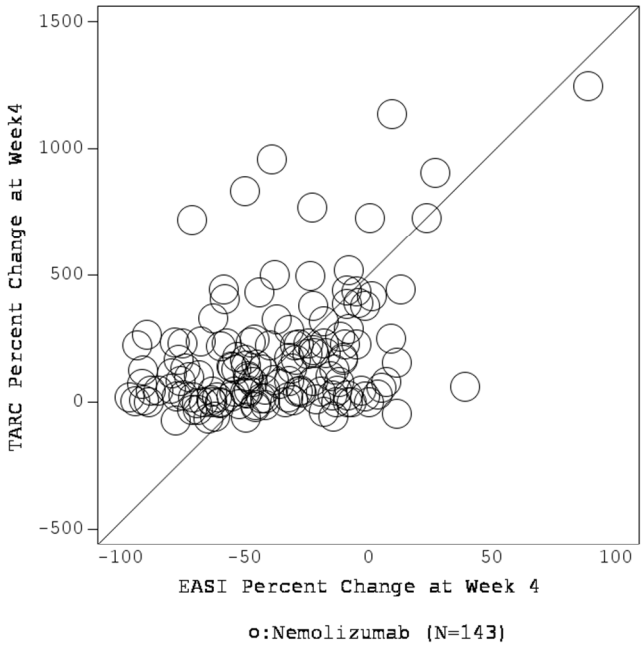
	Baseline	Week 4	Week 8	Week 12	Week 16	Week 28	Week 40	Week 52
60 mg Q4W（長期投与試験）								
例数	88	88	88	87	88	82	79	78
中央値	1894	4377	5844	4489	3750	2173	2093	1625
最小値, 最大値	284, 30000	378, 30000	332, 30000	336, 30000	287, 30000	215, 30000	365, 30000	180, 27134
0.1 mg/kg Q4W（第II相試験）								
例数	53	50	48	44	39	38	34	31
中央値	2113	5122	4390	2873	2218	1164	1246	1031
最小値, 最大値	265, 40182	278, 69532	93, 41646	202, 30207	154, 39511	130, 49660	255, 13643	166, 25182
0.5 mg/kg Q4W（第II相試験）								
例数	54	52	45	46	38	31	30	27
中央値	1899	2678	1703	1730	1255	1215	891	988
最小値, 最大値	290, 18344	258, 58528	283, 46450	308, 61152	274, 20432	312, 14169	303, 9884	250, 4420
2.0 mg/kg Q4W（第II相試験）								
例数	52	50	47	46	38	34	32	31
中央値	1760	2388	1888	2917	1309	1533	1205	882
最小値, 最大値	127, 44528	200, 100000	122, 86403	196, 68753	106, 19783	271, 22753	325, 45523	237, 20941
2.0 mg/kg Q8W（第II相試験）								
例数	52	46	42	37	33	27	22	19
中央値	2089	4169	3445	1994	1379	859	745	602
最小値, 最大値	261, 88440	418, 75573	471, 38480	270, 40114	336, 27830	234, 7611	178, 17503	311, 5153

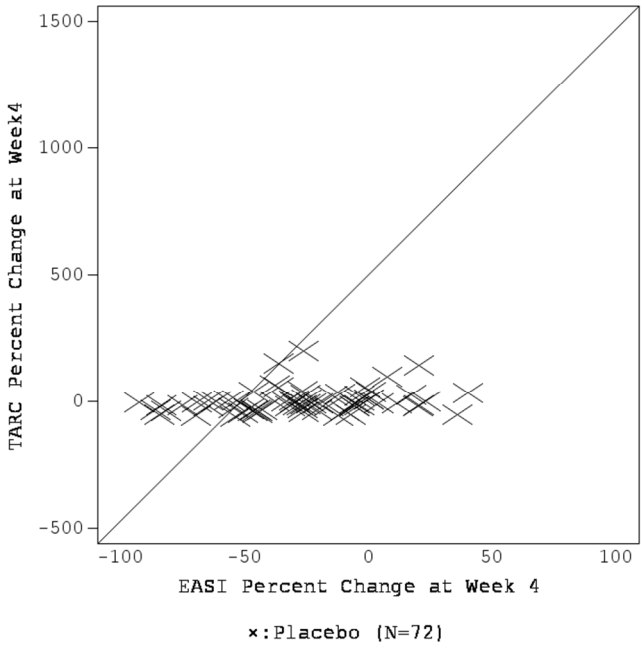
（単位: ng/L）

5.3.5.2-1 Table 14.3.9.3及び5.3.5.1-1 Table 14.4-90より改変

血清中のTARC値は、ADの短期病勢のマーカーとして用いられていることから、nemolizumab投与後にみられたTARC値上昇に伴って病状が変化しているかを確認するため、TARC値の変化率と、皮疹の面積及び重症度に基づき算出されるEASIの変化率の相関性を検討した。第III相試験のTARC値の変化率とEASI変化率の、投与開始4週後の散布図を図 2.7.4-2に、投与開始8週後の散布図を図 2.7.4-3に示した。Nemolizumab群及びプラセボ群ともに、TARC値とEASIの間に線形性はみられず、相関性はみられなかった。

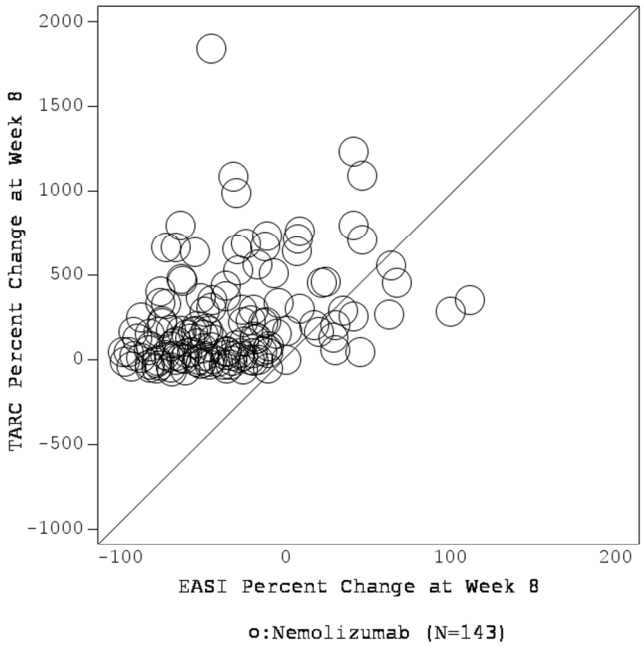
図 2.7.4-2 TARC値とEASIの相関性（投与開始4週後）

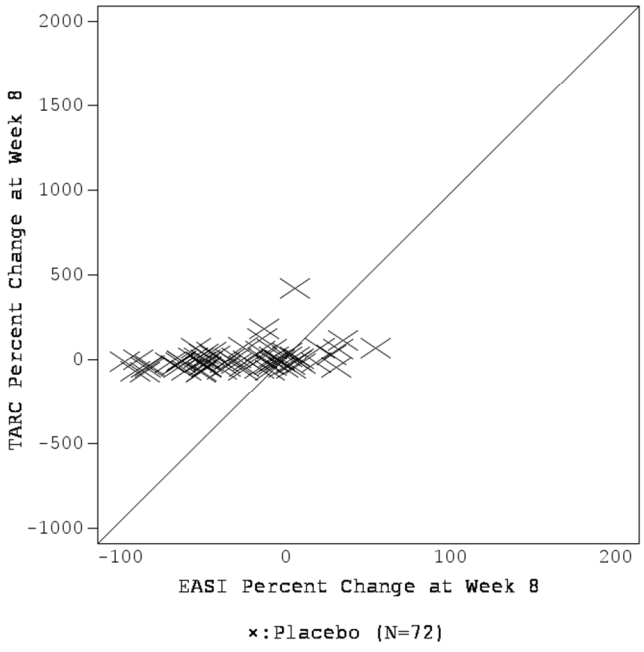




5.3.5.1-2 Figure 14.3.3.1.4.4.2より引用

図 2.7.4-3 TARC値とEASIの相関性（投与開始8週後）



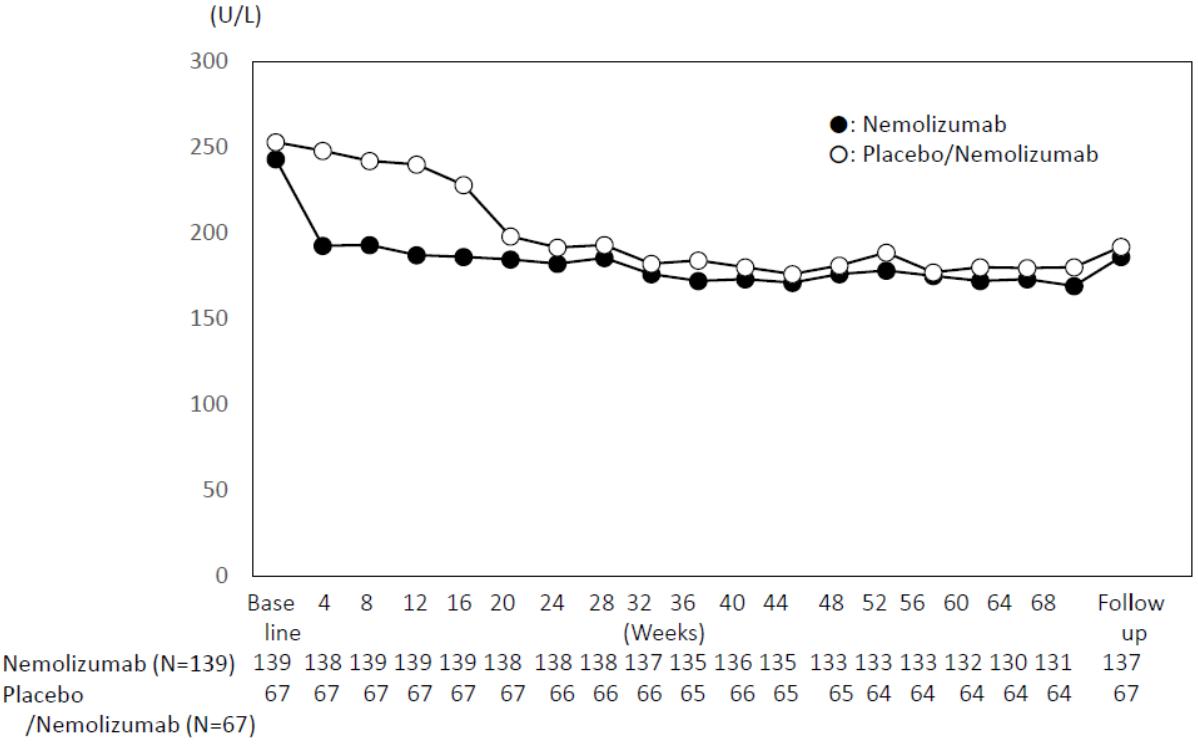


5.3.5.1-2 Figure 14.3.3.1.4.4.3より引用

2) LDH

第III相試験のLDHの推移を図 2.7.4-4に示した。Nemolizumab群では投与開始4週後からLDHの低下がみられ、その後は維持された。一方、プラセボ群では投与開始16週後までは変化がみられず、投与開始20週後(nemolizumab投与開始から4週後)からLDHの低下がみられた。長期投与試験では、投与開始前の中央値（標準偏差）は254.0（72.2）U/Lであったが、投与開始4週後には195.5（42.7）U/Lに低下した。なお、第III相試験及び長期投与試験でのLDHの施設基準値は、男性：120～245 U/L、女性：120～245 U/Lである。一方、第II相試験では、第III相試験及び長期投与試験のような変化はみられなかった。

図 2.7.4-4 LDH（中央値）の経時的推移（第III相試験）



5.3.5.1-2 Table 14.3.3.1.1.2.2より作図

3) 好酸球数

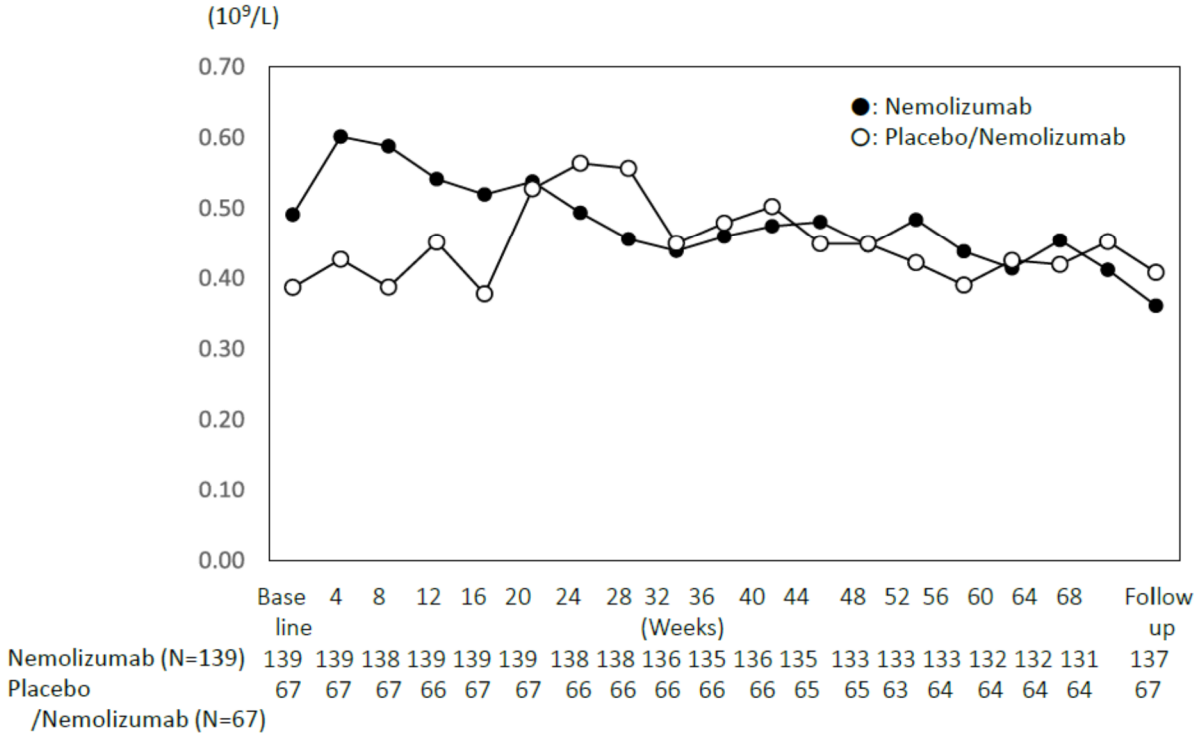
第III相試験の好酸球数の経時推移を図 2.7.4-5及び表 2.7.4-26に示した。nemolizumab群の好酸球数の中央値は、投与開始前が0.49 × 10^9個/Lであり、その後は0.44～0.60 × 10^9個/Lの範囲で推移し、nemolizumabの投与による変動はみられなかった。placebo-nemolizumab群の推移は、nemolizumab投与前（投与開始16週後まで）が0.38～0.45 × 10^9個/L、nemolizumab投与後（投与開始20～28週後）が0.53～0.56 × 10^9個/L、その後は0.42～0.48 × 10^9個/Lで推移した。placebo-nemolizumab群の投与開始前の好酸球数の標準偏差は0.34 × 10^9個/Lと大きく、nemolizumab投与による好酸球数の明確な変動はなかったと考える。

長期投与試験の好酸球数の中央値は、0.50～0.59 × 10^9個/Lの範囲で推移し、nemolizumabの投与による変動はみられなかった（表 2.7.4-27）。

第II相試験の好酸球数の推移は、第III相試験及び長期投与試験と同様、nemolizumabの

投与による明確な変動はみられなかった。

図 2.7.4-5 好酸球数（中央値）の経時推移（第III相試験）



5.3.5.1-2 Table 14.3.3.1.1.1.2より作図

表 2.7.4-26 好酸球数の経時推移（第III相試験）

	BL	W 4	W8	W12	W16	W20	W24	W28	W32	W36	W44	W52
Nemolizumab群												
例数	139	139	138	139	139	139	138	138	136	135	135	133
中央値	0.49	0.60	0.59	0.54	0.52	0.54	0.49	0.46	0.44	0.46	0.48	0.48
最小値	0.06	0.05	0.08	0.07	0.07	0.10	0.09	0.09	0.07	0.10	0.07	0.00
最大値	4.99	4.38	3.45	4.90	2.67	2.01	2.67	2.81	2.52	2.98	3.29	2.68
Placebo-nemolizumab群												
例数	67	67	67	66	67	67	66	66	66	66	65	63
中央値	0.39	0.43	0.39	0.45	0.38	0.53	0.56	0.56	0.45	0.48	0.45	0.42
最小値	0.08	0.10	0.09	0.04	0.10	0.07	0.11	0.07	0.08	0.05	0.08	0.08
最大値	1.51	1.50	1.87	2.44	1.43	1.97	1.65	1.49	2.98	2.30	1.11	1.69

（単位: 10^9個/L）

5.3.5.1-2 Table 14.3.3.1.1.1.2より改変

表 2.7.4-27 好酸球数の経時推移（長期投与試験）

	BL	W 4	W8	W12	W16	W20	W24	W28	W32	W36	W44	W52
例数	88	88	88	87	88	85	83	82	82	80	79	78
中央値	0.54	0.59	0.59	0.55	0.56	0.57	0.54	0.50	0.52	0.54	0.55	0.50
最小値	0.10	0.14	0.09	0.08	0.13	0.03	0.08	0.06	0.07	0.10	0.12	0.11
最大値	3.03	4.06	5.32	5.63	6.28	5.91	5.44	6.16	5.80	6.77	7.29	7.28

（単位: 10^9個/L）

5.3.5.2-1 Table 14.3.9.1より改変

表 2.7.4-28 好酸球数の経時推移（第II相試験）

	BL	W 4	W8	W12	W16	W20	W24	W28	W32	W36	W44	W52
0.1 mg/kg Q4W（第II相試験）												
例数	53	50	47	45	40	37	37	38	35	35	32	30
中央値	0.49	0.69	0.68	0.58	0.64	0.52	0.50	0.67	0.60	0.56	0.43	0.50
最小値	0.05	0.04	0.06	0.02	0.04	0.01	0.02	0.03	0.08	0.06	0.03	0.08
最大値	4.72	9.66	4.21	3.96	5.28	4.10	3.24	3.92	3.47	2.90	3.67	3.68
0.5 mg/kg Q4W（第II相試験）												
例数	54	53	45	46	38	35	32	31	30	30	30	27
中央値	0.39	0.41	0.38	0.38	0.32	0.43	0.39	0.38	0.37	0.37	0.33	0.45
最小値	0.05	0.02	0.07	0.03	0.08	0.04	0.06	0.03	0.05	0.04	0.03	0.04
最大値	2.49	4.46	2.46	2.13	1.51	1.81	0.98	1.76	2.41	2.27	1.95	0.99
2.0 mg/kg Q4W（第II相試験）												
例数	52	50	45	46	38	35	37	33	34	33	31	32
中央値	0.41	0.55	0.46	0.57	0.43	0.42	0.38	0.32	0.33	0.27	0.30	0.31
最小値	0.04	0.08	0.07	0.08	0.11	0.07	0.04	0.10	0.09	0.05	0.07	0.01
最大値	2.08	3.45	4.01	4.17	2.19	2.31	1.92	2.22	2.44	3.40	5.15	5.45
2.0 mg/kg Q8W（第II相試験）												
例数	52	46	43	36	33	30	29	27	25	23	19	19
中央値	0.45	0.53	0.68	0.58	0.68	0.50	0.46	0.35	0.44	0.37	0.39	0.44
最小値	0.00	0.06	0.06	0.05	0.03	0.04	0.07	0.02	0.07	0.07	0.07	0.01
最大値	2.09	4.07	3.23	2.44	2.68	2.09	2.84	1.11	1.32	1.40	1.49	1.81
P-0.1 mg/kg Q4W（第II相試験）												
例数	-	-	-	13	12	11	11	11	11	9	9	8
中央値	-	-	-	0.62	0.91	0.96	0.75	0.43	0.65	0.62	0.86	0.70
最小値	-	-	-	0.10	0.08	0.03	0.11	0.10	0.17	0.11	0.09	0.07
最大値	-	-	-	1.79	2.48	2.81	1.70	2.41	2.23	2.30	2.61	2.50
P-0.5 mg/kg Q4W（第II相試験）												
例数	-	-	-	12	12	11	12	12	10	10	9	7
中央値	-	-	-	0.26	0.30	0.34	0.48	0.34	0.28	0.41	0.41	0.27
最小値	-	-	-	0.06	0.06	0.01	0.09	0.06	0.10	0.06	0.02	0.04
最大値	-	-	-	0.92	2.21	1.19	2.02	2.46	3.15	0.77	1.62	1.91
P-2.0 mg/kg Q4W（第II相試験）												
例数	-	-	-	12	11	13	12	11	11	11	11	8
中央値	-	-	-	0.43	0.64	0.53	0.46	0.40	0.41	0.41	0.31	0.35
最小値	-	-	-	0.16	0.17	0.25	0.08	0.07	0.22	0.18	0.21	0.22
最大値	-	-	-	0.89	1.14	1.83	1.50	1.40	1.48	1.00	0.93	0.94

（単位: 10^9個/L）

5.3.5.1-1 Table 14.4-76及びTable 14.4-79より改変

2.7.4.4 バイタルサイン、身体的所見及び安全性に関連する他の観察項目

2.7.4.4.1 バイタルサイン

第II相試験では、血圧、脈拍数，呼吸数及び体温を測定した。各nemolizumab群及びプラセボ群の平均値は同様の値を示し、治験薬の投与により臨床的に問題となるような変動はみられなかった。

第III相試験では、血圧、脈拍数及び体温を測定した。Nemolizumab群及びプラセボ群の平均値は同様の値を示し、治験薬の投与により臨床的に問題となる変動はみられなかった。

長期投与試験では、血圧、脈拍数及び体温を測定したところ、治験薬の投与により臨床的に問題となるような変動はみられなかった。

2.7.4.4.2 心電図

臨床的に問題となる心電図異常は，いずれの試験でもみられなかった。また、表 2.7.4-29、表 2.7.4-30及び表 2.7.4-31に示すように、nemolizumab投与によるQTc間隔の延長はみられなかった。

表 2.7.4-29 Nemolizumab投与後のQTcFの変化量（第II相試験）

	0.1 mg/kg Q4W (N=53)	0.5 mg/kg Q4W (N=54)	2.0 mg/kg Q4W (N=52)	2.0 mg/kg Q8W (N=52)
Week 4				
n	52	52	52	51
- 30 msec	49 (94.2%)	50 (96.2%)	51 (98.1%)	48 (94.1%)
30 <- 60 msec	1 (1.9%)	2 (3.8%)	0	3 (5.9%)
60 msec <	2 (3.8%)	0	1 (1.9%)	0
Week 8				
n	49	46	46	41
- 30 msec	44 (89.8%)	45 (97.8%)	43 (93.5%)	36 (87.8%)
30 <- 60 msec	5 (10.2%)	1 (2.2%)	2 (4.3%)	5 (12.2%)
60 msec <	0	0	1 (2.2%)	0
Week 12				
n	45	45	43	38
- 30 msec	40 (88.9%)	44 (97.8%)	42 (97.7%)	32 (84.2%)
30 <- 60 msec	5 (11.1%)	0	0	4 (10.5%)
60 msec <	0	1 (2.2%)	1 (2.3%)	2 (5.3%)
Week 16				
n	40	38	36	33
- 30 msec	39 (97.5%)	37 (97.4%)	35 (97.2%)	32 (97.0%)
30 <- 60 msec	0	1 (2.6%)	1 (2.8%)	0
60 msec <	1 (2.5%)	0	0	1 (3.0%)
Week 20				
n	38	35	36	31
- 30 msec	34 (89.5%)	32 (91.4%)	35 (97.2%)	27 (87.1%)
30 <- 60 msec	3 (7.9%)	3 (8.6%)	1 (2.8%)	4 (12.9%)
60 msec <	1 (2.6%)	0	0	0
Week 24				
n	37	31	37	28
- 30 msec	34 (91.9%)	28 (90.3%)	35 (94.6%)	23 (82.1%)
30 <- 60 msec	2 (5.4%)	3 (9.7%)	0	2 (7.1%)
60 msec <	1 (2.7%)	0	2 (5.4%)	3 (10.7%)
Week 64				
n	30	29	27	19
- 30 msec	25 (83.3%)	26 (89.7%)	27 (100.0%)	18 (94.7%)
30 <- 60 msec	2 (6.7%)	1 (3.4%)	0	1 (5.3%)
60 msec <	3 (10.0%)	2 (6.9%)	0	0
Follow-Up				
n	48	46	43	38
- 30 msec	43 (89.6%)	45 (97.8%)	41 (95.3%)	36 (94.7%)
30 <- 60 msec	2 (4.2%)	0	2 (4.7%)	2 (5.3%)
60 msec <	3 (6.3%)	1 (2.2%)	0	0

5.3.5.1-1 Table 14.4-111より改変

表 2.7.4-30 Nemolizumab投与後のQTcF変化量（第III相試験）

Parameter	Treatment Visit	Total	- 450	450<- 480	480<- 500	500 <	Change from Baseline - 30	30<- 60	60<
QTcF Interval, Aggregate (msec)	Nemolizumab (N=139)								
	Baseline	139	138 (99.3)	1 (0.7)	0	0	-	-	-
	Week 4	139	138 (99.3)	1 (0.7)	0	0	137 (98.6)	2 (1.4)	0
	Week 16	139	136 (97.8)	2 (1.4)	1 (0.7)	0	135 (97.1)	4 (2.9)	0
	Week 20	139	137 (98.6)	2 (1.4)	0	0	137 (98.6)	2 (1.4)	0
	Week 32	137	136 (99.3)	1 (0.7)	0	0	130 (94.9)	7 (5.1)	0
	Week 44	136	136 (100)	0	0	0	133 (97.8)	3 (2.2)	0
	Week 56	133	132 (99.2)	1 (0.8)	0	0	130 (97.7)	3 (2.3)	0
	Week 68	132	131 (99.2)	1 (0.8)	0	0	129 (97.7)	3 (2.3)	0
	FU	137	137 (100)	0	0	0	134 (97.8)	3 (2.2)	0
	Placebo/Nemolizumab (N=67)								
	Baseline	67	66 (98.5)	1 (1.5)	0	0	-	-	-
	Week 4	67	65 (97.0)	2 (3.0)	0	0	65 (97.0)	2 (3.0)	0
	Week 16	67	67 (100)	0	0	0	67 (100)	0	0
	Week 20	67	67 (100)	0	0	0	66 (98.5)	1 (1.5)	0
	Week 32	66	66 (100)	0	0	0	62 (93.9)	3 (4.5)	1 (1.5)
	Week 44	65	65 (100)	0	0	0	63 (96.9)	1 (1.5)	1 (1.5)
	Week 56	64	63 (98.4)	1 (1.6)	0	0	60 (93.8)	4 (6.3)	0
	Week 68	64	64 (100)	0	0	0	62 (96.9)	2 (3.1)	0
	FU	67	66 (98.5)	1 (1.5)	0	0	65 (97.0)	2 (3.0)	0

Percentages are based on total subjects in each visit.
5.3.5.1-2 Table 14.3.4.3.2.2より改変

表 2.7.4-31 Nemolizumab投与後のQTcF変化量（長期投与試験）

Parameter	Treatment Visit	Change from Baseline - 450	450<- 480	480<- 500	500<	- 30	30<- 60	60<	Total
QTcF Interval, Aggregate (msec)	Overall (N=88)								
	Baseline	88 (100)	0	0	0	-	-	-	88
	Week 4	87 (98.9)	1 (1.1)	0	0	88 (100)	0	0	88
	Week 16	88 (100)	0	0	0	87 (98.9)	1 (1.1)	0	88
	Week 28	83 (100)	0	0	0	82 (98.8)	1 (1.2)	0	83
	Week 40	80 (100)	0	0	0	79 (98.8)	1 (1.3)	0	80
	Week 52	77 (98.7)	1 (1.3)	0	0	78 (100)	0	0	78
	FU	85 (98.8)	1 (1.2)	0	0	85 (98.8)	1 (1.2)	0	86

Percentages are based on total subjects in each visit.
5.3.5.2-1 Table 14.3.12.2より改変

2.7.4.4.3 免疫原性

2.7.4.4.3.1 抗薬物抗体と有害事象の関連

申請用量を投与した被験者で抗薬物抗体（以下、ADA）が陽性と判定された被験者の割合は、第III相試験では4.8%（10/210例）、長期投与試験では12.5%（11/88例）であった。これら被験者で、ADAが陽性と判断された測定日より前の測定日以降、陽性と判断された測定日の次の測定日までに発現した有害事象を表 2.7.4-32に示した。ADAが陽性と判断された前後で有害事象が発現した被験者は、14例30件であった。このうち、感染性腸炎、アトピー性皮膚炎（2例）、感染性腸炎及び靭帯捻挫（各1例）は中等度であったが、他はすべて軽度であった。また、転帰は、未回復の過敏性腸症候群及び腹部不快感（各1例）を除き、回復又は軽快であった。

Nemolizumab 60 mgを投与した被験者のうちADAが陽性と判定された被験者で発現した有害事象は、いずれも非重篤で、治験薬は継続して投与されており、ADAが安全性に影響を及ぼす懸念はないものと考える。

表 2.7.4-32 抗薬物抗体が陽性と判断された被験者で発現した有害事象

被験者	陽性反応日	陽性と判断された前後で発現した有害事象（重症度、転帰）
CA[redacted]	FU	白血球数減少（軽度、回復）、ざ瘡（軽度、回復） カポジ水痘様発疹（軽度、回復）
CA[redacted]	32週	膿疱性皮疹（軽度、回復）、膿疱性皮疹（軽度、回復） 発熱（軽度、回復）
CA[redacted]	44週	アトピー性皮膚炎（軽度、回復） 過敏性腸症候群（軽度、未回復）
CA[redacted]	44週、56週	喘息（軽度、回復） 血中クレアチンホスホキナーゼ増加（軽度、回復）
CA[redacted]	56週、68週	なし
CA[redacted]	FU	円形脱毛症（軽度、軽快）
CA[redacted]	68週	血中クレアチンホスホキナーゼ増加（軽度、回復） 上咽頭炎（軽度、回復）
CA[redacted]	32週	なし
CA[redacted]	32週、44週 68週、FU	下痢（軽度、回復）、感染性腸炎（中等度、回復） アトピー性皮膚炎（中等度、回復）、鼻出血（軽度、回復） 接触皮膚炎（軽度、回復）
CA[redacted]	68週	なし
CB[redacted]	16週	湿疹（軽度、回復）、靭帯捻挫（中等度、回復）
CB[redacted]	28週	なし
CB[redacted]	16週、28週 40週、52週 FU	排尿困難（軽度、回復）、マラセチア感染（軽度、回復）
CB[redacted]	28週、52週 FU	上咽頭炎（軽度、回復）
CB[redacted]	16週、28週	アトピー性皮膚炎（中等度、回復）、外耳炎（軽度、回復）、骨亀裂（軽度、回復）
CB[redacted]	28週	なし
CB[redacted]	28週	咳嗽（軽度、回復）
CB[redacted]	40週	齲歯（軽度、回復）
CB[redacted]	40週、52週	なし
CB[redacted]	16週	腹部不快感（軽度、未回復）、上咽頭炎（軽度、回復）
CB[redacted]	FU	なし

FU：フォローアップ

5.3.5.1-2 Listing 16.2.5.2及びListing 16.2.7、5.3.5.2-1 Listing 16.2.5.2及びListing 16.2.7より改変

2.7.4.5 特別な患者集団及び状況下における安全性

2.7.4.5.1 内因性要因

部分集団解析は、比較的よくみられる有害事象を対象に、性別、年齢区分別（13歳以上18歳未満、18歳以上65歳未満、65歳以上）、アレルギー性疾患の合併症の有無に基づき発現割合を集計し

た。また、プラセボ対象期間中に発現した重要な有害事象を対象に、投与開始時のTARC値[1)]（500 ng/L未満、500 ng/L以上 2000 ng/L未満、2000 ng/L以上 5000 ng/L未満、5000 ng/L以上）に基づき、発現割合を集計した。

(1) 性別

性別の有害事象の発現割合を表 2.7.4-65に示した。有害事象の発現割合は、男性が92.3%（262/284例）、女性が89.8%（177/197例）であった。また、因果関係が否定されない有害事象の発現割合は、男性が52.1%（148/284例）、女性が48.7%（96/197例）であり、治験薬との因果関係にかかわらず、有害事象の発現割合に男女差はみられなかった。

比較的よくみられた有害事象のうち、男性の発現割合が女性の2倍以上の有害事象は、血中クレアチンホスホキナーゼ増加、サイトカイン異常、咳嗽及び異汗性湿疹であった。一方、女性の発現割合が男性の2倍以上の有害事象は、気管支炎、膀胱炎、帯状疱疹、膿痂疹、上気道感染、挫傷、関節痛、頭痛、喘息、接触皮膚炎、紅斑及び蕁麻疹であった。

(2) 年齢

年齢別の有害事象の発現割合を表 2.7.4-66に示した。有害事象の発現割合は、13歳以上18歳未満が100%（13/13例）、18歳以上65歳未満が91.1%（419/460例）、65歳以上が87.5%（7/8例）であった。また、因果関係が否定されなかった有害事象の発現割合は、13歳以上18歳未満が61.5%（8/13例）、18歳以上65歳未満が50.7%（233/460例）、65歳以上が37.5%（3/8例）であった。被験者のほとんどが18歳以上65歳未満の区分に偏っていた。18歳未満及び65歳以上の被験者数が少なく、年齢間で意味のある比較を行うための十分な例数ではないため、年齢区分での比較は行わなかった。

(3) アレルギー性疾患の合併

アレルギー性疾患（季節性アレルギー、アレルギー性鼻炎、アレルギー性結膜炎、食物アレルギー、喘息）の合併別の有害事象の発現割合を表 2.7.4-67に示した。有害事象の発現割合は、合併なしが88.3%（250/283例）、合併ありが95.5%（189/198例）であった。また、因果関係が否定されなかった有害事象の発現割合は、合併なしが46.3%（131/283例）、合併ありが57.1%（113/198例）であり、治験薬との因果関係にかかわらず、合併ありの発現割合がわずかに高かった。

比較的よくみられた有害事象のうち、合併ありの発現割合が合併なしの2倍以上の有害事象は、アレルギー性結膜炎、齲歯、発熱、蜂巣炎、胃腸炎、インフルエンザ、カポジ水痘様発疹、サイトカイン異常、背部痛、喘息、上気道の炎症、ざ瘡、紅斑及び蕁麻疹であった。一方、合併なしの発現割合が合併ありの2倍以上の有害事象は、末梢性浮腫、膀胱炎及び上気道感染であった。

(4) ベースライン時のTARC

TARCは、ADの病態のバイオマーカーと位置づけられているため、ベースラインTARC別（500 ng/L未満、500 ng/L以上2000 ng/L未満、2000 ng/L以上5000 ng/L未満、5000 ng/L以上）での重要な有害事象の発現状況について評価した。ベースラインTARC別、投与群別に、プラセボ対照期間中にみられた重要な有害事象の一覧を表 2.7.4-33に、因果関係が否定されなかったこれら一覧を表 2.7.4-34に示した。

Nemolizumab群でみられた治験薬の投与中止又は休薬に至った有害事象の発現割合は、治験薬との因果関係にかかわらず、TARC濃度の最も高い区分で有害事象の発現割合も高かった。なお、プラセボ群で治験薬の投与中止又は休薬に至った有害事象は2例のみであり、TARC濃度に依存した発現割合の変化は確認できなかった。

注目すべき有害事象の内、発現割合の高いアトピー性皮膚炎の悪化、皮膚感染症及び皮膚以外の感染症について、TARC濃度の区分別の発現割合を評価した。

Nemolizumab群でみられたアトピー性皮膚炎の悪化の発現割合は、2000 ng/L未満に比べて、2000 ng/L以上で高くなる傾向を示したが、因果関係が否定されないアトピー性皮膚炎の悪化の発現割合は、TARC濃度に依存した変化はみられなかった。なお、プラセボ群でみられたアトピー性皮膚炎の悪化の発現割合は、治験薬との因果関係にかかわらず、TARC濃度に依存した変化はみられなかった。

Nemolizumab群でみられた皮膚感染症の発現割合は、2000 ng/L未満に比べて、2000 ng/L以上で高くなる傾向を示し、因果関係が否定されなかった皮膚感染症の発現割合は、TARC濃度に依存して増加する傾向を示した。一方、プラセボ群でみられた皮膚感染症の発現割合は、TARC濃度に依存した変化はみられず、因果関係が否定された有害事象の発現割合は、500 ng/L未満が最も高かった。

Nemolizumab群でみられた皮膚以外の感染症の発現割合は、治験薬との因果関係にかかわらず、TARC濃度に依存した変化はみられなかった。また、プラセボ群でみられた皮膚以外の感染症の発現割合は、nemolizumab群と同様、TARC濃度に依存した変化はみられなかった。

アトピー性皮膚炎の悪化、皮膚感染症及び皮膚以外の感染症のベースラインTARC別発現率は、nemolizumab群とプラセボ群の群間で、大きな差はなかった。

表 2.7.4-33 ベースラインTARC別の重要な有害事象の発現割合（プール2）

	Nemolizumab (N=301)				Placebo-Nemolizumab (N=112)			
	< 500 ng/L	500 -< 2000 ng/L	2000 - < 5000 ng/L	5000 - ng/L	< 500 ng/L	500 -< 2000 ng/L	2000 - < 5000 ng/L	5000 - ng/L
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Number of Subjects in Each Category	42	122	67	70	16	57	22	17
Significant TEAEs								
TEAEs Leading to Discontinuation (including Dose Interruption and Reduction) of Study Treatment	0	6 (4.9)	3 (4.5)	10 (14.3)	1 (6.3)	1 (1.8)	0	0
Discontinuation	0	5 (4.1)	1 (1.5)	7 (10.0)	0	0	0	0
Dose Interruption	0	1 (0.8)	2 (3.0)	3 (4.3)	1 (6.3)	1 (1.8)	0	0
Dose Reduction	0	0	0	0	0	0	0	0
TEAEs Special Interest								
Injection-Related Reaction	6 (14.3)	9 (7.4)	3 (4.5)	2 (2.9)	3 (18.8)	0	0	0
Asthma	1 (2.4)	0	0	0	0	1 (1.8)	0	0
Worsening of AD	6 (14.3)	20 (16.4)	20 (29.9)	18 (25.7)	2 (12.5)	10 (17.5)	6 (27.3)	3 (17.6)
Skin Infections	3 (7.1)	9 (7.4)	10 (14.9)	10 (14.3)	2 (12.5)	6 (10.5)	3 (13.6)	1 (5.9)
Non-skin Infections	12 (28.6)	27 (22.1)	17 (25.4)	22 (31.4)	6 (37.5)	12 (21.1)	11 (50.0)	5 (29.4)
Elevated CPK	2 (4.8)	6 (4.9)	3 (4.5)	2 (2.9)	1 (6.3)	2 (3.5)	0	0

5.3.5.3-1 Table 5.2.4.12.1から引用

表 2.7.4-34 ベースラインTARC別の因果関係が否定されなかった重要な有害事象の発現割合（プール2）

	Nemolizumab (N=301)				Placebo-Nemolizumab (N=112)			
	< 500 ng/L	500 -< 2000 ng/L	2000 - < 5000 ng/L	5000 - ng/L	< 500 ng/L	500 -< 2000 ng/L	2000 - < 5000 ng/L	5000 - ng/L
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Number of Subjects in Each Category	42	122	67	70	16	57	22	17
Significant TEAEs								
TEAEs Leading to Discontinuation (including Dose Interruption and Reduction) of Study Treatment	0	3 (2.5)	2 (3.0)	8 (11.4)	0	0	0	0
Discontinuation	0	3 (2.5)	1 (1.5)	6 (8.6)	0	0	0	0
Dose Interruption	0	0	1 (1.5)	2 (2.9)	0	0	0	0
Dose Reduction	0	0	0	0	0	0	0	0
TEAEs Special Interest								
Injection-Related Reaction	6 (14.3)	5 (4.1)	2 (3.0)	2 (2.9)	1 (6.3)	0	0	0
Asthma	1 (2.4)	0	0	0	0	1 (1.8)	0	0
Worsening of AD	5 (11.9)	12 (9.8)	12 (17.9)	8 (11.4)	0	4 (7.0)	0	1 (5.9)
Skin Infections	0	2 (1.6)	2 (3.0)	4 (5.7)	2 (12.5)	2 (3.5)	1 (4.5)	0
Non-skin Infections	6 (14.3)	8 (6.6)	4 (6.0)	7 (10.0)	1 (6.3)	2 (3.5)	0	1 (5.9)
Elevated CPK	2 (4.8)	0	1 (1.5)	0	0	0	0	0

5.3.5.3-1 Table 5.2.4.12.2から引用

2.7.4.5.2 自己注射における安全性

長期投与試験では、投与開始12週後よりnemolizumabを被験者自身が投与する自己注射群を設定した。長期投与試験の期間別の有害事象の発現割合を表 2.7.4-70に、このうち因果関係が否定されなかった有害事象の発現割合を表 2.7.4-71に示した。

有害事象の発現割合は、85日まででは、医療従事者が投与する群（以下、医療従事者群）、自己注射群それぞれで、56.8%（25/44例）、63.6%（28/44例）であり、86日から169日まででは、それぞれ13.6%（6/44例）、25.0%（11/44例）であり、自己注射群で高い値を示した。一方、170日から253日まででは、それぞれで、12.2%（5/41例）、0%（0/42例）であり、医療従事者群で高い値を示した。254日から337日まででは、それぞれで、4.9%（2/41例）、2.5%（1/40例）で同程度であった。338日以降は、いずれの群も0%であった。

因果関係が否定されなかった有害事象の発現割合は、85日まででは、医療従事群、自己注射群それぞれで、43.2%（19/44例）、27.3% （12/44例）であり、医療従事者群で高い値を示した。86日から169日まででは、それぞれ6.8%（3/44例）、20.5%（9/44例）であり、自己注射群で高い値を示した。170日から253日まででは、それぞれ、4.9%（2/41例）、2.4%（1/42例）で、254日から337日まででは、それぞれ4.9%（2/41例）、2.5%（1/40例）であり、医療従事者群、自己注射群で同程度であった。

また、注目すべき有害事象の発現例数は、皮膚以外の感染症が48例（医療従事者群：21例、自己注射群：27例）、皮膚感染症が25例（11例、14例）、アトピー性皮膚炎の悪化が23例（10例、13例）、血中クレアチンホスホキナーゼ上昇が5例（2例、3例）、注射関連の反応が3例（3例、0例）及び喘息が2例（2例及び0例）であった。このうち、86日以降の発現例数は、皮膚以外の感染症が33例（15例、18例）、皮膚感染症が11例（6例、5例）、アトピー性皮膚炎の悪化が9例（2例、7例）、血中クレアチンホスホキナーゼ上昇が4例（2例、2例）、注射関連の反応が1例（1例、0例）及び喘息が1例（1例、0例）であり、投与方法と有害事象の発現に明確な関係性はなかった。

2.7.4.5.3 曝露と安全性

申請用量は、60 mgの固定用量であることを踏まえ、第III相試験及び長期投与試験でnemolizumabを投与された被験者を対象に、投与開始16週後の血清中nemolizumab濃度、C_{max}及びAUC_{last}の四分位別に、重要な有害事象を集計した。

(1) 投与開始16週後の血清中nemolizumab濃度

血清中nemolizumab濃度の四分位の重要な有害事象の発現割合を表 2.7.4-72に示した。治験薬の投与中止（中断）に至った有害事象の発現割合は、25%点以下が15.5%（9/58例）、25%点超50%点以下が8.6%（5/58例）、50%点超75%点以下が12.1%（7/58例）及び75%点超が8.8%（5/57例）であった。また、因果関係が否定されなかった治験薬の投与中止（中断）に至った有害事象発現割合は、それぞれ10.3%（6/58例）、8.6%（5/58例）、8.6%（5/58例）及び7.0%（4/57例）であり、因果関係を問わず、血清中nemolizumab濃度に依存した有害事象の発現の増加はみられなかった。

注射関連反応の発現割合は、治験薬との因果関係に関わらず、75%超が最も高い値を示したが、他の注目すべき有害事象では、血清中nemolizumab濃度に依存した有害事象の発現の増加はみられなかった。

(2) C_{max}

C_{max}の四分位の重要な有害事象の発現割合を表 2.7.4-73に示した。治験薬の投与中止（中断）に至った有害事象の発現割合は、25%点以下が11.7%（7/60例）、25%点超50%点以下が9.8%（6/61例）、50%点超75%点以下が14.5%（8/55例）及び75%点超が9.1%（5/55例）であった。また、因果関係が否定されなかった治験薬の投与中止（中断）に至った有害事象発現割合は、それぞれ11.7%（7/60例）、9.8%（6/61例）、9.1%（5/55例）及び3.6%（2/55例）であり、因果関係を問わず、C_{max}依存した有害事象の発現の増加はみられなかった。

注射関連反応では、治験薬との因果関係に関わらず、75%超が最も高い値を示した。また、皮膚感染症では、治験薬との因果関係に関わらず、C_{max}に依存して有害事象の発現が増加する傾向がみられた。他の注目すべき有害事象では、血清中nemolizumab濃度に依存した有害事象の発現の増加はみられなかった。

(3) AUC_{last}

AUC_{last}の四分位の重要な有害事象の発現割合を表 2.7.4-74に示した。治験薬の投与中止（中断）に至った有害事象の発現割合は、25%点以下が8.6%（5/58例）、25%点超50%点以下が15.5%（9/58例）、50%点超75%点以下が12.1%（7/58例）及び75%点超が8.8%（5/57例）であった。また、因果関係が否定されなかった治験薬の投与中止（中断）に至った有害事象発

現割合は、それぞれ8.6%（5/58例）、12.1%（7/58例）、10.3%（6/58例）及び3.5%（2/57例）であり、因果関係を問わず、AUC_{last}に依存した有害事象の発現の増加はみられなかった

注射関連反応では、治験薬との因果関係に関わらず、AUC_{last}に依存して有害事象の発現が増加する傾向がみられた。また、アトピー性皮膚炎の悪化では、治験薬との因果関係に関わらず、25%点以下の発現割合が他の区分に比べて低かった。他の注目すべき有害事象では、AUC_{last}に依存した有害事象の発現の増加はみられなかった。

2.7.4.5.4 薬物相互作用

Nemolizumabはインターロイキン31受容体Aに対するヒト化モノクローナル抗体であり、nemolizumabがP450代謝酵素を介して他の薬剤と相互作用することはないと考えられることから、薬物相互作用に関する非臨床試験及び臨床試験は実施していない（2.7.2.3.4）。

2.7.4.5.5 妊娠及び授乳時の使用

第II相試験、第III相試験及び長期投与試験の除外基準では、妊婦、授乳婦、妊娠している可能性のある患者及び治験期間中に避妊する意志のない女性患者を設定した。

第III相試験及び長期投与試験では、妊娠症例はみられなかったが、第II相試験では、nemolizumab 2.0 mg/kg Q8W群で1名の被験者が妊娠した。この被験者は、nemolizumab最終投与後に妊娠が判明した。

2.7.4.5.6 過量投与

第II相試験、第III相試験及び長期投与試験では、過量投与された被験者はみられなかった。

第I相試験では、日本人の健康成人男性及びAD患者に対して、申請用量を上回る3 mg/kgを単回皮下投与した。健康成人男性でみられた有害事象は、感染性腸炎（2例）、鼻咽頭炎、急性扁桃炎、帯状疱疹、C-反応性蛋白増加、血中クレアチンホスホキナーゼ増加及び血中フィブリノゲン増加（各1例）であり、いずれも治験薬との因果関係は否定された。また、AD患者でみられた有害事象は、アトピー性皮膚炎（5例）、接触性皮膚炎、蕁麻疹、毛包炎、咽頭炎、単純ヘルペス、胃腸炎、筋痙縮、咳嗽、喘息及び眼瞼浮腫（各1例）であり、このうち、因果関係が否定されなかった有害事象は、蕁麻疹、単純ヘルペス、胃腸炎及び喘息であり、重症度はいずれも軽度であった。AD患者に60 mg/bodyをQ4Wで投与した際のC_{max}が、第III相試験及び長期投与試験でそれぞれ、5.74 µg/mL及び5.12 µg/mLであったのに対し、AD患者に3 mg/kgを単回皮下投与した際のC_{max}は19.4 µg/mLと高値を示したが、臨床症状では申請用量である60 mg/bodyに比べて明らかな安全性シグナルはみられなかった。

2.7.4.5.7 薬物乱用

薬物乱用に関する非臨床試験及び臨床試験は実施していない。

2.7.4.5.8 離脱症状及び反跳現象

離脱症状及び反跳現象に関する非臨床試験及び臨床試験は実施していない。

2.7.4.5.9 自動車運転及び機械操作に対する影響又は精神機能の障害

自動車運転及び機械操作に対する影響又は精神機能の障害を評価するための臨床試験は実施していない。ヒト化モノクローナル改変IgG2抗体であるnemolizumabは、分子量約144 kDaであることから、多量に血液脳関門を通過する可能性は低い[2)]。

第II相試験、第III相試験及び長期投与試験でみられた有害事象のうち、自動車の運転能力や機械操作能力、精神機能に影響があると考えられる「耳および迷路障害」、「眼障害」、「神経系障害」及び「精神障害」に関する有害事象の発現割合は、それぞれ2.9%（14/481例）、8.1%（39/481例）、15.4%（74/481例）及び2.3%（11/481例）にみられた。このうち、治験薬との因果関係が否定されなかった有害事象は、1.7%（8/481例）、2.3%（11/481例）、3.1%（15/481例）及び1.0%（5/481例）であった。治験薬との因果関係が否定されなかった有害事象のうち、複数例でみられたものは、頭痛（9例）、アレルギー性結膜炎（5例）、回転性めまい（3例）、アレルギー性眼瞼炎、浮動性めまい及び傾眠（各2例）であり、重症度が中等度又は高度の有害事象は、頭痛（3例）及び回転性めまい（2例）であり、自動車の運転能力や機械操作能力、精神機能の障害に関連すると考えられる有害事象の発現頻度はいずれも低かった。

2.7.4.5.10 市販後データ

Nemolizumabが承認された国はない。

2.7.4.6 付録

表 2.7.4-35 Number of Doses Received during PartA
Safety Analysis Set（pool2）

	Overall (N=413) n (%)
Number of Doses Received	
1	22 (5.3)
2	22 (5.3)
3	166 (40.2)
4	203 (49.2)

5.3.5.3-1 Table 5.2.3から引用

表 2.7.4-36 Treatment Duration for Nemolizumab
Safety Analysis Set（pool1）

	Nemolizumab (N=389) n (%)	Placebo-Nemolizumab [b] (N=92) n (%)
Treatment Duration for Nemolizumab (days) [a]		
n	389	92
Mean	331.5	309.5
SD	148.7	73.6
Min	1	1
Median	420.0	337.0
Max	458	345
- 12 Weeks	55 (14.1)	3 (3.3)
12 <- 24 Weeks	20 (5.1)	3 (3.3)
24 <- 36 Weeks	15 (3.9)	5 (5.4)
36 <- 48 Weeks	31 (8.0)	23 (25.0)
48 <- 60 Weeks	74 (19.0)	58 (63.0)
60 Weeks <	194 (49.9)	0

[a] Date of last dose - date of first dose + 1.
[b] Part B only
5.3.5.3-1 Table 5.2.2から引用

表 2.7.4-37 Demographics and Other Baseline Characteristics
Safety Analysis Set（pool1）

	Placebo-Nemolizumab (N=389) n (%)	Nemolizumab-Nemolizumab (N=92) n (%)	Nemolizumab-Total (N=481) n (%)
Sex			
Male	231 (59.4)	53 (57.6)	284 (59.0)
Female	158 (40.6)	39 (42.4)	197 (41.0)
Age (At Informed Consent) (years)			
n	389	92	481
Mean	37.1	39.1	37.5
SD	12.7	13.2	12.8
Min	13	13	13
Median	37.0	40.0	38.0
Max	73	70	73
Height (At Randomization) (cm) [a]			
n	389	92	481
Mean	166.81	165.50	166.56
SD	8.59	7.87	8.47
Min	143.5	147.1	143.5
Median	167.00	166.00	166.60
Max	190.5	185.0	190.5
Weight (At Randomization) (kg) [b]			
n	389	92	481
Mean	67.74	67.12	67.62
SD	15.67	15.32	15.59
Min	40.0	42.3	40.0
Median	64.20	64.20	64.20
Max	144.0	128.9	144.0
Race			
Asian	279 (71.7)	74 (80.4)	353 (73.4)
Other	110 (28.3)	18 (19.6)	128 (26.6)
Baseline Pruritus VAS			
n	386	92	478
Mean	76.40	75.01	76.14
SD	11.28	11.12	11.25
Min	43.8	53.3	43.8
Median	77.23	75.00	76.54
Max	100.0	100.0	100.0
Baseline EASI			
n	389	92	481
Mean	28.308	27.089	28.075
SD	13.918	13.039	13.750
Min	6.30	10.00	6.30
Median	24.800	23.325	24.500
Max	72.00	72.00	72.00

[a] In the case of M525101-02, height at treatment start is used.
[b] In the case of M525101-02, weight at treatment start is used.
5.3.5.3-1 Table 5.2.1から引用

	Nemolizumab (N=389) n (%)	Placebo-Nemolizumab (N=92) n (%)	Nemolizumab-Total (N=481) n (%)
Baseline sIGA			
- 3	188 (48.3)	55 (59.8)	243 (50.5)
4 -	201 (51.7)	37 (40.2)	238 (49.5)
Allergic Disease (Seasonal Allergy, Allergic Rhinitis, Allergic Conjunctivitis, Food Allergy and Asthma)			
No	233 (59.9)	50 (54.3)	283 (58.8)
Yes	156 (40.1)	42 (45.7)	198 (41.2)

[a] In the case of M525101-02, height at treatment start is used.
[b] In the case of M525101-02, weight at treatment start is used.

5.3.5.3-1 Table 5.2.1から引用

表 2.7.4-38 Overview of Treatment-Emergent Adverse Events during PartA Safety Analysis Set（pool2）

	All TEAEs		TEAEs Related to Study Treatment	
	Nemolizumab (N=301) n (%) E [a]	Placebo-Nemolizumab (N=112) n (%) E [a]	Nemolizumab (N=301) n (%) E [a]	Placebo-Nemolizumab (N=112) n (%) E [a]
TEAEs	215 (71.4) 505	79 (70.5) 177	107 (35.5) 198	22 (19.6) 39
Severe TEAEs	14 (4.7) 20	1 (0.9) 1	7 (2.3) 10	0
Moderate TEAEs	83 (27.6) 120	27 (24.1) 43	38 (12.6) 51	5 (4.5) 9
Mild TEAEs	175 (58.1) 365	68 (60.7) 133	84 (27.9) 137	17 (15.2) 30
Serious TEAEs	10 (3.3) 12	3 (2.7) 3	5 (1.7) 7	0
TEAEs Leading to Death	0	0	0	0
Other Serious TEAEs	10 (3.3) 12	3 (2.7) 3	5 (1.7) 7	0
Other Significant TEAEs				
TEAEs Leading to Discontinuation (including Dose Interruption and Reduction) of Study Treatment	19 (6.3) 27	2 (1.8) 2	13 (4.3) 17	0
Discontinuation	13 (4.3) 20	0	10 (3.3) 13	0
Dose Interruption	6 (2.0) 7	2 (1.8) 2	3 (1.0) 4	0
Dose Reduction	0	0	0	0
TEAEs Special Interest				
Injection-Related Reaction	20 (6.6) 30	3 (2.7) 3	15 (5.0) 25	1 (0.9) 1
Asthma	1 (0.3) 1	1 (0.9) 2	1 (0.3) 1	1 (0.9) 2
Worsening of AD	64 (21.3) 73	21 (18.8) 22	37 (12.3) 40	5 (4.5) 5
Skin Infections	32 (10.6) 32	12 (10.7) 12	8 (2.7) 8	5 (4.5) 5
Non-skin Infections	78 (25.9) 98	34 (30.4) 38	25 (8.3) 28	4 (3.6) 5
Elevated CPK	13 (4.3) 13	3 (2.7) 3	3 (1.0) 3	0

[a] E=Number of Treatment-Emergent Adverse Events

5.3.5.3-1 Table 5.2.4.1.2から引用

表 2.7.4-39 Summary of Treatment-Emergent Adverse Events (Moderate or Severe) Occurred during PartA by System Organ Class and Preferred Term (Japanese)
Safety Analysis Set（pool2）

	All TEAEs		TEAEs Related to Study Treatment	
System Organ Class Preferred Term	Nemolizumab (N=301) n (%)	Placebo-Nemolizumab (N=112) n (%)	Nemolizumab (N=301) n (%)	Placebo-Nemolizumab (N=112) n (%)
Overall	89 (29.6)	28 (25.0)	42 (14.0)	5 (4.5)
血液およびリンパ系障害	1 (0.3)	0	1 (0.3)	0
リンパ節症	1 (0.3)	0	1 (0.3)	0
血小板増加症	1 (0.3)	0	0	0
心臓障害	2 (0.7)	1 (0.9)	1 (0.3)	0
上室性不整脈	1 (0.3)	0	1 (0.3)	0
心房細動	0	1 (0.9)	0	0
動悸	1 (0.3)	0	0	0
耳および迷路障害	1 (0.3)	0	1 (0.3)	0
メニエール病	1 (0.3)	0	1 (0.3)	0
内分泌障害	1 (0.3)	0	0	0
甲状腺機能低下症	1 (0.3)	0	0	0
眼障害	1 (0.3)	1 (0.9)	0	0
網膜剥離	0	1 (0.9)	0	0
結膜充血	1 (0.3)	0	0	0
胃腸障害	4 (1.3)	0	0	0
上腹部痛	1 (0.3)	0	0	0
口内乾燥	1 (0.3)	0	0	0
急性膵炎	1 (0.3)	0	0	0
嘔吐	1 (0.3)	0	0	0
一般・全身障害および投与部位の状態	12 (4.0)	0	4 (1.3)	0
悪寒	1 (0.3)	0	0	0
注射部位反応	1 (0.3)	0	1 (0.3)	0
浮腫	1 (0.3)	0	1 (0.3)	0
末梢性浮腫	7 (2.3)	0	3 (1.0)	0
発熱	2 (0.7)	0	0	0
末梢腫脹	1 (0.3)	0	0	0
免疫系障害	1 (0.3)	1 (0.9)	0	1 (0.9)
過敏症	1 (0.3)	0	0	0
季節性アレルギー	0	1 (0.9)	0	1 (0.9)

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.3.2.2から引用

	All TEAEs		TEAEs Related to Study Treatment	
System Organ Class Preferred Term	Nemolizumab (N=301) n (%)	Placebo-Nemolizumab (N=112) n (%)	Nemolizumab (N=301) n (%)	Placebo-Nemolizumab (N=112) n (%)
感染症および寄生虫症	24 (8.0)	12 (10.7)	7 (2.3)	3 (2.7)
菌血症	1 (0.3)	0	1 (0.3)	0
気管支炎	0	1 (0.9)	0	0
蜂巣炎	0	1 (0.9)	0	1 (0.9)
膀胱炎	0	1 (0.9)	0	0
丹毒	1 (0.3)	0	0	0
眼感染	0	1 (0.9)	0	0
毛包炎	1 (0.3)	0	0	0
胃腸炎	0	1 (0.9)	0	0
ウイルス性胃腸炎	0	1 (0.9)	0	0
帯状疱疹	1 (0.3)	0	0	0
感染	1 (0.3)	0	0	0
インフルエンザ	3 (1.0)	2 (1.8)	0	0
外耳炎	2 (0.7)	0	0	0
中耳炎	0	1 (0.9)	0	1 (0.9)
咽頭炎	3 (1.0)	0	0	0
皮膚感染	2 (0.7)	0	1 (0.3)	0
上気道感染	1 (0.3)	3 (2.7)	1 (0.3)	1 (0.9)
歯感染	1 (0.3)	0	1 (0.3)	0
皮膚細菌感染	1 (0.3)	0	0	0
細菌性上気道感染	1 (0.3)	0	1 (0.3)	0
白癬感染	1 (0.3)	0	0	0
男性外性器蜂巣炎	1 (0.3)	0	1 (0.3)	0
細菌重複感染	3 (1.0)	0	1 (0.3)	0
口腔ヘルペス	1 (0.3)	0	1 (0.3)	0
傷害、中毒および処置合併症	2 (0.7)	1 (0.9)	0	0
顔面骨骨折	1 (0.3)	0	0	0
転倒	0	1 (0.9)	0	0
挫傷	1 (0.3)	0	0	0
歯の脱臼	1 (0.3)	0	0	0

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.3.2.2から引用

System Organ Class Preferred Term	All TEAEs Nemolizumab (N=301) n (%)	All TEAEs Placebo-Nemolizumab (N=112) n (%)	TEAEs Related to Study Treatment Nemolizumab (N=301) n (%)	TEAEs Related to Study Treatment Placebo-Nemolizumab (N=112) n (%)
臨床検査	14 (4.7)	1 (0.9)	9 (3.0)	0
血中クレアチンホスホキナーゼ増加	6 (2.0)	1 (0.9)	2 (0.7)	0
Ｃ－反応性蛋白増加	1 (0.3)	0	0	0
体重増加	1 (0.3)	0	1 (0.3)	0
サイトカイン異常	6 (2.0)	0	6 (2.0)	0
筋骨格系および結合組織障害	3 (1.0)	4 (3.6)	2 (0.7)	0
関節痛	1 (0.3)	0	1 (0.3)	0
背部痛	1 (0.3)	0	1 (0.3)	0
骨端離開	1 (0.3)	0	0	0
筋骨格痛	0	1 (0.9)	0	0
四肢痛	0	1 (0.9)	0	0
回帰性リウマチ	1 (0.3)	0	0	0
肩回旋筋腱板症候群	0	1 (0.9)	0	0
変形性脊椎症	0	1 (0.9)	0	0
滑液嚢腫	0	1 (0.9)	0	0
神経系障害	6 (2.0)	1 (0.9)	1 (0.3)	0
浮動性めまい	1 (0.3)	0	0	0
頭痛	2 (0.7)	0	1 (0.3)	0
片頭痛	0	1 (0.9)	0	0
神経痛	1 (0.3)	0	0	0
緊張性頭痛	1 (0.3)	0	0	0
パーキンソン病	1 (0.3)	0	0	0
精神障害	2 (0.7)	0	0	0
うつ病	1 (0.3)	0	0	0
不眠症	1 (0.3)	0	0	0
生殖系および乳房障害	0	1 (0.9)	0	1 (0.9)
外陰腟そう痒症	0	1 (0.9)	0	1 (0.9)
皮膚および皮下組織障害	49 (16.3)	15 (13.4)	27 (9.0)	3 (2.7)
円形脱毛症	1 (0.3)	0	1 (0.3)	0
頭部粃糠疹	0	1 (0.9)	0	0

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.3.2.2から引用

System Organ Class Preferred Term	All TEAEs Nemolizumab (N=301) n (%)	All TEAEs Placebo-Nemolizumab (N=112) n (%)	TEAEs Related to Study Treatment Nemolizumab (N=301) n (%)	TEAEs Related to Study Treatment Placebo-Nemolizumab (N=112) n (%)
皮膚および皮下組織障害 (Cont.)				
皮膚炎	1 (0.3)	0	1 (0.3)	0
アトピー性皮膚炎	41 (13.6)	12 (10.7)	22 (7.3)	3 (2.7)
接触皮膚炎	2 (0.7)	2 (1.8)	0	0
剥脱性皮膚炎	3 (1.0)	0	2 (0.7)	0
薬疹	1 (0.3)	0	0	0
異汗性湿疹	1 (0.3)	0	1 (0.3)	0
湿疹	0	1 (0.9)	0	0
全身性皮疹	1 (0.3)	0	1 (0.3)	0
皮膚障害	1 (0.3)	0	0	0
うっ滞性皮膚炎	1 (0.3)	0	1 (0.3)	0
湿潤性湿疹	1 (0.3)	0	0	0
中毒性皮疹	1 (0.3)	0	1 (0.3)	0
血管障害	1 (0.3)	0	1 (0.3)	0
高血圧	1 (0.3)	0	1 (0.3)	0

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.3.2.2から引用

表 2.7.4-40 Overview of Treatment-Emergent Adverse Events
Safety Analysis Set（pool1）

	All TEAEs	TEAEs Related to Study Treatment
	Nemolizumab -Total (N=481) n (%) E [a]	Nemolizumab -Total (N=481) n (%) E [a]
TEAEs	439 (91.3) 2184	244 (50.7) 618
Severe TEAEs	36 (7.5) 52	15 (3.1) 22
Moderate TEAEs	210 (43.7) 440	92 (19.1) 146
Mild TEAEs	393 (81.7) 1692	202 (42.0) 450
Serious TEAEs	48 (10.0) 60	17 (3.5) 20
TEAEs Leading to Death	0	0
Other Serious TEAEs	48 (10.0) 60	17 (3.5) 20
Other Significant TEAEs		
TEAEs Leading to Discontinuation (including Dose Interruption and Reduction) of Study Treatment	61 (12.7) 83	41 (8.5) 54
Discontinuation	29 (6.0) 44	21 (4.4) 30
Dose Interruption	34 (7.1) 39	21 (4.4) 24
Dose Reduction	0	0
TEAEs Special Interest		
Injection-Related Reaction	32 (6.7) 54	27 (5.6) 48
Asthma	12 (2.5) 13	4 (0.8) 5
Worsening of AD	133 (27.7) 172	73 (15.2) 89
Skin Infections	133 (27.7) 208	52 (10.8) 78
Non-skin Infections	264 (54.9) 526	58 (12.1) 95
Elevated CPK	49 (10.2) 57	6 (1.2) 6

[a] E=Number of Treatment-Emergent Adverse Events

5.3.5.3-1 Table 5.2.4.1.1から引用

表 2.7.4-41 Summary of Treatment-Emergent Adverse Events (Moderate or Severe) by System Organ Class and Preferred Term (Japanese) Safety Analysis Set（pool1）

	All TEAEs	TEAEs Related to Study Treatment
System Organ Class Preferred Term	Nemolizumab -Total (N=481) n (%)	Nemolizumab -Total (N=481) n (%)
Overall	221 (45.9)	101 (21.0)
血液およびリンパ系障害	2 (0.4)	1 (0.2)
リンパ節炎	1 (0.2)	0
リンパ節症	1 (0.2)	1 (0.2)
血小板増加症	1 (0.2)	0
心臓障害	4 (0.8)	1 (0.2)
上室性不整脈	1 (0.2)	1 (0.2)
心房細動	1 (0.2)	0
冠動脈狭窄	1 (0.2)	0
動悸	1 (0.2)	0
耳および迷路障害	4 (0.8)	4 (0.8)
メニエール病	1 (0.2)	1 (0.2)
回転性めまい	2 (0.4)	2 (0.4)
突発性難聴	1 (0.2)	1 (0.2)
内分泌障害	1 (0.2)	0
甲状腺機能低下症	1 (0.2)	0
眼障害	8 (1.7)	2 (0.4)
眼精疲労	2 (0.4)	0
白内障	1 (0.2)	0
アレルギー性結膜炎	1 (0.2)	0
眼乾燥	1 (0.2)	0
緑内障	1 (0.2)	1 (0.2)
網膜剥離	1 (0.2)	0
網膜裂孔	1 (0.2)	0
結膜充血	1 (0.2)	0
アトピー性角結膜炎	1 (0.2)	1 (0.2)
胃腸障害	16 (3.3)	2 (0.4)
下腹部痛	1 (0.2)	1 (0.2)
上腹部痛	3 (0.6)	0
口唇炎	1 (0.2)	0
便秘	1 (0.2)	0
齲歯	1 (0.2)	0
下痢	2 (0.4)	0

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.3.1.2から引用

System Organ Class Preferred Term	All TEAEs Nemolizumab -Total (N=481) n (%)	TEAEs Related to Study Treatment Nemolizumab -Total (N=481) n (%)
胃腸障害 (Cont.)		
口内乾燥	1 (0.2)	0
消化不良	1 (0.2)	0
胃食道逆流性疾患	1 (0.2)	0
痔核	1 (0.2)	0
悪心	3 (0.6)	0
急性膵炎	1 (0.2)	0
口内炎	1 (0.2)	1 (0.2)
歯痛	1 (0.2)	0
嘔吐	3 (0.6)	0
一般・全身障害および投与部位の状態	18 (3.7)	5 (1.0)
悪寒	1 (0.2)	0
注射部位反応	1 (0.2)	1 (0.2)
浮腫	1 (0.2)	1 (0.2)
末梢性浮腫	9 (1.9)	4 (0.8)
疼痛	1 (0.2)	1 (0.2)
発熱	5 (1.0)	0
末梢腫脹	1 (0.2)	0
非心臓性胸痛	1 (0.2)	0
免疫系障害	4 (0.8)	1 (0.2)
アナフィラキシー反応	1 (0.2)	0
食物アレルギー	1 (0.2)	0
過敏症	1 (0.2)	0
季節性アレルギー	1 (0.2)	1 (0.2)
感染症および寄生虫症	103 (21.4)	34 (7.1)
細菌性膿瘍	1 (0.2)	0
菌血症	2 (0.4)	2 (0.4)
気管支炎	5 (1.0)	1 (0.2)
蜂巣炎	9 (1.9)	7 (1.5)
結膜炎	1 (0.2)	1 (0.2)
膀胱炎	5 (1.0)	1 (0.2)
憩室炎	1 (0.2)	1 (0.2)
精巣上体炎	1 (0.2)	1 (0.2)
丹毒	2 (0.4)	1 (0.2)

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.3.1.2から引用

System Organ Class Preferred Term	All TEAEs Nemolizumab -Total (N=481) n (%)	TEAEs Related to Study Treatment Nemolizumab -Total (N=481) n (%)
感染症および寄生虫症 (Cont.)		
眼感染	1 (0.2)	0
毛包炎	1 (0.2)	0
胃腸炎	3 (0.6)	0
ウイルス性胃腸炎	2 (0.4)	0
手足口病	1 (0.2)	1 (0.2)
帯状疱疹	3 (0.6)	0
膿痂疹	4 (0.8)	2 (0.4)
感染	3 (0.6)	1 (0.2)
インフルエンザ	13 (2.7)	1 (0.2)
ムンプス	1 (0.2)	0
上咽頭炎	16 (3.3)	2 (0.4)
外耳炎	4 (0.8)	0
中耳炎	1 (0.2)	1 (0.2)
咽頭炎	5 (1.0)	1 (0.2)
肺炎	2 (0.4)	1 (0.2)
歯髄炎	2 (0.4)	0
腎盂腎炎	1 (0.2)	1 (0.2)
副鼻腔炎	2 (0.4)	0
皮膚感染	4 (0.8)	2 (0.4)
歯膿瘍	1 (0.2)	0
上気道感染	8 (1.7)	3 (0.6)
尿路感染	1 (0.2)	0
ウイルス感染	1 (0.2)	1 (0.2)
歯感染	3 (0.6)	1 (0.2)
膿痂疹性湿疹	1 (0.2)	0
カポジ水痘様発疹	6 (1.2)	4 (0.8)
皮膚細菌感染	3 (0.6)	0
細菌性上気道感染	1 (0.2)	1 (0.2)
感染性腸炎	2 (0.4)	1 (0.2)
白癬感染	1 (0.2)	0
鼓膜炎	1 (0.2)	0
男性外性器蜂巣炎	2 (0.4)	1 (0.2)
ブドウ球菌皮膚感染	1 (0.2)	0

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.3.1.2から引用

System Organ Class Preferred Term	All TEAEs Nemolizumab -Total (N=481) n (%)	TEAEs Related to Study Treatment Nemolizumab -Total (N=481) n (%)
感染症および寄生虫症 (Cont.)		
細菌重複感染	3 (0.6)	1 (0.2)
口腔ヘルペス	2 (0.4)	1 (0.2)
ウイルス性消化管感染	1 (0.2)	0
眼部単純ヘルペス	2 (0.4)	2 (0.4)
水痘帯状疱疹ウイルス感染	1 (0.2)	1 (0.2)
咬傷感染	1 (0.2)	0
傷害、中毒および処置合併症	13 (2.7)	0
顔面骨骨折	1 (0.2)	0
転倒	1 (0.2)	0
足骨折	1 (0.2)	0
関節脱臼	2 (0.4)	0
靱帯捻挫	2 (0.4)	0
肋骨骨折	1 (0.2)	0
挫傷	3 (0.6)	0
靱帯損傷	1 (0.2)	0
胸部損傷	1 (0.2)	0
上肢骨折	1 (0.2)	0
処置による疼痛	2 (0.4)	0
靱帯断裂	1 (0.2)	0
筋挫傷	1 (0.2)	0
歯の脱臼	1 (0.2)	0
臨床検査	20 (4.2)	12 (2.5)
アラニンアミノトランスフェラーゼ増加	1 (0.2)	1 (0.2)
アスパラギン酸アミノトランスフェラーゼ増加	1 (0.2)	0
血中クレアチンホスホキナーゼ増加	8 (1.7)	2 (0.4)
血中トリグリセリド増加	1 (0.2)	0
Ｃ－反応性蛋白増加	1 (0.2)	0
心電図ＱＴ延長	1 (0.2)	1 (0.2)
好酸球数増加	1 (0.2)	1 (0.2)
体重増加	2 (0.4)	1 (0.2)
骨密度減少	1 (0.2)	0
サイトカイン異常	6 (1.2)	6 (1.2)
代謝および栄養障害	3 (0.6)	0

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.3.1.2から引用

System Organ Class Preferred Term	All TEAEs Nemolizumab -Total (N=481) n (%)	TEAEs Related to Study Treatment Nemolizumab -Total (N=481) n (%)
代謝および栄養障害 (Cont.)		
ビタミンD欠乏	1 (0.2)	0
食欲減退	1 (0.2)	0
２型糖尿病	1 (0.2)	0
筋骨格系および結合組織障害	20 (4.2)	5 (1.0)
関節痛	5 (1.0)	2 (0.4)
背部痛	5 (1.0)	2 (0.4)
滑液包炎	1 (0.2)	0
ピロリン酸カルシウム結晶性軟骨石灰化症	1 (0.2)	0
骨端離開	1 (0.2)	0
筋骨格痛	1 (0.2)	0
四肢痛	1 (0.2)	1 (0.2)
回帰性リウマチ	1 (0.2)	0
関節周囲炎	2 (0.4)	0
肩回旋筋腱板症候群	2 (0.4)	0
変形性脊椎症	1 (0.2)	0
滑液嚢腫	1 (0.2)	0
椎間板突出	1 (0.2)	0
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 (0.6)	0
アクロコルドン	1 (0.2)	0
膀胱癌	2 (0.4)	0
肺腺癌第３期	1 (0.2)	0
神経系障害	20 (4.2)	4 (0.8)
浮動性めまい	3 (0.6)	0
全身性強直性間代性発作	1 (0.2)	0
頭痛	7 (1.5)	3 (0.6)
意識消失	1 (0.2)	0
メージ症候群	1 (0.2)	0
片頭痛	1 (0.2)	0
神経痛	1 (0.2)	0
末梢性ニューロパチー	1 (0.2)	1 (0.2)
視神経炎	2 (0.4)	1 (0.2)
傾眠	2 (0.4)	0
失神	1 (0.2)	0

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.3.1.2から引用

System Organ Class Preferred Term	All TEAEs Nemolizumab -Total (N=481) n (%)	TEAEs Related to Study Treatment Nemolizumab -Total (N=481) n (%)
神経系障害 (Cont.)		
緊張性頭痛	1 (0.2)	0
パーキンソン病	1 (0.2)	0
精神障害	4 (0.8)	2 (0.4)
双極１型障害	1 (0.2)	1 (0.2)
うつ病	2 (0.4)	1 (0.2)
不眠症	2 (0.4)	1 (0.2)
腎および尿路障害	2 (0.4)	0
尿路結石	1 (0.2)	0
腎仙痛	1 (0.2)	0
尿管結石症	1 (0.2)	0
生殖系および乳房障害	3 (0.6)	2 (0.4)
月経困難症	1 (0.2)	0
子宮内膜増殖症	1 (0.2)	1 (0.2)
外陰腟そう痒症	1 (0.2)	1 (0.2)
呼吸器、胸郭および縦隔障害	12 (2.5)	3 (0.6)
喘息	2 (0.4)	1 (0.2)
慢性閉塞性肺疾患	1 (0.2)	0
咳嗽	2 (0.4)	1 (0.2)
鼻中隔弯曲	1 (0.2)	0
アレルギー性鼻炎	1 (0.2)	0
睡眠時無呼吸症候群	1 (0.2)	0
喘鳴	1 (0.2)	0
上気道の炎症	3 (0.6)	0
気管支反応性亢進	1 (0.2)	1 (0.2)
皮膚および皮下組織障害	104 (21.6)	55 (11.4)
脱毛症	1 (0.2)	1 (0.2)
円形脱毛症	1 (0.2)	1 (0.2)
頭部粃糠疹	2 (0.4)	0
皮膚炎	4 (0.8)	3 (0.6)
アトピー性皮膚炎	80 (16.6)	41 (8.5)
接触皮膚炎	7 (1.5)	1 (0.2)
剥脱性皮膚炎	5 (1.0)	4 (0.8)
薬疹	1 (0.2)	0

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.3.1.2から引用

System Organ Class Preferred Term	All TEAEs Nemolizumab -Total (N=481) n (%)	TEAEs Related to Study Treatment Nemolizumab -Total (N=481) n (%)
皮膚および皮下組織障害 (Cont.)		
皮膚乾燥	1 (0.2)	0
異汗性湿疹	4 (0.8)	2 (0.4)
湿疹	2 (0.4)	0
ばら色粃糠疹	1 (0.2)	1 (0.2)
発疹	1 (0.2)	0
全身性皮疹	1 (0.2)	1 (0.2)
皮膚障害	1 (0.2)	0
皮膚病変	1 (0.2)	0
うっ滞性皮膚炎	1 (0.2)	1 (0.2)
蕁麻疹	2 (0.4)	0
湿潤性湿疹	1 (0.2)	0
中毒性皮疹	6 (1.2)	6 (1.2)
手皮膚炎	1 (0.2)	0
びまん性脱毛症	1 (0.2)	1 (0.2)
外科および内科処置	1 (0.2)	0
智歯抜歯	1 (0.2)	0
血管障害	2 (0.4)	1 (0.2)
高血圧	2 (0.4)	1 (0.2)
製品の問題	1 (0.2)	1 (0.2)
医療機器破損	1 (0.2)	1 (0.2)

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.3.1.2から引用

表 2.7.4-42 Common Treatment-Emergent Adverse Events Occurred during PartA (>- 2% in Any Treatment Group) (Japanese)
Safety Analysis Set（pool2）

	All TEAEs		TEAEs Related to Study Treatment	
System Organ Class Preferred Term	Nemolizumab (N=301) n (%)	Placebo-Nemolizumab (N=112) n (%)	Nemolizumab (N=301) n (%)	Placebo-Nemolizumab (N=112) n (%)
一般・全身障害および投与部位の状態				
末梢性浮腫	14 (4.7)	0	7 (2.3)	0
発熱	7 (2.3)	2 (1.8)	3 (1.0)	0
感染症および寄生虫症				
毛包炎	2 (0.7)	3 (2.7)	0	1 (0.9)
上咽頭炎	37 (12.3)	18 (16.1)	4 (1.3)	1 (0.9)
上気道感染	9 (3.0)	5 (4.5)	5 (1.7)	1 (0.9)
臨床検査				
血中クレアチンホスホキナーゼ増加	14 (4.7)	3 (2.7)	3 (1.0)	0
サイトカイン異常	10 (3.3)	0	10 (3.3)	0
神経系障害				
頭痛	10 (3.3)	1 (0.9)	3 (1.0)	0
皮膚および皮下組織障害				
ざ瘡	2 (0.7)	3 (2.7)	0	0
アトピー性皮膚炎	63 (20.9)	21 (18.8)	37 (12.3)	5 (4.5)

TEAE occurred in equal to or more than 2% in any treatment group is presented.
Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.4.2.2から引用

表 2.7.4-43 Common Treatment-Emergent Adverse Events (>- 2% in Treatment Group) (Japanese) Safety Analysis Set（pool1）

System Organ Class Preferred Term	All TEAEs Nemolizumab -Total (N=481) n (%)	TEAEs Related to Study Treatment Nemolizumab -Total (N=481) n (%)
眼障害		
アレルギー性結膜炎	13 (2.7)	5 (1.0)
胃腸障害		
齲歯	20 (4.2)	2 (0.4)
下痢	18 (3.7)	2 (0.4)
一般・全身障害および投与部位の状態		
末梢性浮腫	21 (4.4)	11 (2.3)
発熱	17 (3.5)	4 (0.8)
感染症および寄生虫症		
気管支炎	13 (2.7)	2 (0.4)
蜂巣炎	25 (5.2)	16 (3.3)
膀胱炎	12 (2.5)	3 (0.6)
毛包炎	17 (3.5)	3 (0.6)
胃腸炎	22 (4.6)	4 (0.8)
帯状疱疹	10 (2.1)	6 (1.2)
膿痂疹	17 (3.5)	8 (1.7)
インフルエンザ	31 (6.4)	3 (0.6)
上咽頭炎	160 (33.3)	16 (3.3)
外耳炎	15 (3.1)	1 (0.2)
咽頭炎	21 (4.4)	4 (0.8)
上気道感染	16 (3.3)	9 (1.9)
カポジ水痘様発疹	11 (2.3)	6 (1.2)
傷害、中毒および処置合併症		
挫傷	17 (3.5)	1 (0.2)
臨床検査		
血中クレアチンホスホキナーゼ増加	49 (10.2)	7 (1.5)
サイトカイン異常	14 (2.9)	13 (2.7)
筋骨格系および結合組織障害		
関節痛	15 (3.1)	5 (1.0)
背部痛	16 (3.3)	2 (0.4)
神経系障害		

TEAE occurred in equal to or more than 2% in treatment group is presented.
Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.4.1.2から引用

System Organ Class Preferred Term	All TEAEs Nemolizumab -Total (N=481) n (%)	TEAEs Related to Study Treatment Nemolizumab -Total (N=481) n (%)
神経系障害 (Cont.)		
頭痛	36 (7.5)	9 (1.9)
呼吸器、胸郭および縦隔障害		
喘息	10 (2.1)	2 (0.4)
咳嗽	17 (3.5)	5 (1.0)
上気道の炎症	22 (4.6)	5 (1.0)
皮膚および皮下組織障害		
ざ瘡	27 (5.6)	5 (1.0)
アトピー性皮膚炎	131 (27.2)	72 (15.0)
接触皮膚炎	32 (6.7)	2 (0.4)
異汗性湿疹	13 (2.7)	4 (0.8)
湿疹	10 (2.1)	5 (1.0)
紅斑	10 (2.1)	9 (1.9)
蕁麻疹	29 (6.0)	12 (2.5)

TEAE occurred in equal to or more than 2% in treatment group is presented.
Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.4.1.2から引用

表 2.7.4-44 Treatment-Emergent Adverse Events Occurred after First Dosing Nemolizumab by Time Period (Japanese)

Safety Analysis Set（pool1）

	Nemolizumab (N=389)								Placebo-Nemolizumab (N=92)							
	Any Period	- 85 days	86 - 169 days	170 - 253 days	254 - 337 days	338 - 421 days	422 - days	FU	Any Period	- 85 days	86 - 169 days	170 - 253 days	254 - 337 days	338 - 421 days	422 - days	FU
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Number of Subjects in Each Period	389	389	343	318	304	290	211	357	92	92	89	86	82	78	0	88
TEAEs	351 (90.2)	262 (67.4)	53 (15.5)	17 (5.3)	9 (3.0)	5 (1.7)	1 (0.5)	4 (1.1)	84 (91.3)	51 (55.4)	18 (20.2)	9 (10.5)	4 (4.9)	2 (2.6)	0	0
Serious TEAEs																
TEAEs Leading to Death	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Other Serious TEAEs	38 (9.8)	12 (3.1)	4 (1.2)	6 (1.9)	3 (1.0)	6 (2.1)	1 (0.5)	6 (1.7)	7 (7.6)	4 (4.3)	2 (2.2)	1 (1.2)	0	0	0	0
Other Significant TEAEs																
TEAEs Leading to Discontinuation (including Dose Interruption and Reduction) of Study Treatment	47 (12.1)	25 (6.4)	11 (3.2)	9 (2.8)	1 (0.3)	1 (0.3)	0	0	12 (13.0)	7 (7.6)	1 (1.1)	2 (2.3)	2 (2.4)	0	0	0
Discontinuation	25 (6.4)	17 (4.4)	3 (0.9)	5 (1.6)	0	0	0	0	4 (4.3)	2 (2.2)	0	2 (2.3)	0	0	0	0
Dose Interruption	22 (5.7)	8 (2.1)	8 (2.3)	4 (1.3)	1 (0.3)	1 (0.3)	0	0	10 (10.9)	5 (5.4)	1 (1.1)	2 (2.3)	2 (2.4)	0	0	0
Dose Reduction	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Percentages are based on number of subjects in each time period.
Multiple occurrences of an event for one subject are counted only once as earliest onset.
TEAE occurred in equal to or more than 2% in any treatment group is presented.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.5.1.2から引用

	Nemolizumab (N=389)								Placebo-Nemolizumab (N=92)							
	Any Period	- 85 days	86 - 169 days	170 - 253 days	254 - 337 days	338 - 421 days	422 - days	FU	Any Period	- 85 days	86 - 169 days	170 - 253 days	254 - 337 days	338 - 421 days	422 - days	FU
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
TEAEs Special Interest																
Injection-Related Reaction	29 (7.5)	22 (5.7)	3 (0.9)	0	2 (0.7)	2 (0.7)	0	0	3 (3.3)	1 (1.1)	0	2 (2.3)	0	0	0	0
Asthma	9 (2.3)	2 (0.5)	1 (0.3)	3 (0.9)	1 (0.3)	2 (0.7)	0	0	3 (3.3)	1 (1.1)	1 (1.1)	1 (1.2)	0	0	0	0
Worsening of AD	102 (26.2)	75 (19.3)	13 (3.8)	6 (1.9)	3 (1.0)	2 (0.7)	1 (0.5)	2 (0.6)	17 (18.5)	13 (14.1)	2 (2.2)	0	0	1 (1.3)	0	1 (1.1)
Skin Infections	109 (28.0)	42 (10.8)	25 (7.3)	15 (4.7)	9 (3.0)	7 (2.4)	5 (2.4)	6 (1.7)	19 (20.7)	7 (7.6)	3 (3.4)	3 (3.5)	3 (3.7)	1 (1.3)	0	2 (2.3)
Non-skin Infections	206 (53.0)	91 (23.4)	35 (10.2)	36 (11.3)	22 (7.2)	13 (4.5)	4 (1.9)	5 (1.4)	45 (48.9)	15 (16.3)	9 (10.1)	8 (9.3)	8 (9.8)	4 (5.1)	0	1 (1.1)
Elevated CPK	37 (9.5)	12 (3.1)	6 (1.7)	6 (1.9)	3 (1.0)	3 (1.0)	1 (0.5)	6 (1.7)	11 (12.0)	1 (1.1)	4 (4.5)	1 (1.2)	3 (3.7)	2 (2.6)	0	0

Percentages are based on number of subjects in each time period.
Multiple occurrences of an event for one subject are counted only once as earliest onset.
TEAE occurred in equal to or more than 2% in any treatment group is presented.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.5.1.2から引用

System Organ Class	Nemolizumab (N=389)								Placebo-Nemolizumab (N=92)							
	Any Period	- 85 days	86 - 169 days	170 - 253 days	254 - 337 days	338 - 421 days	422 - days	FU	Any Period	- 85 days	86 - 169 days	170 - 253 days	254 - 337 days	338 - 421 days	422 - days	FU
Preferred Term	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
血液およびリンパ系障害																
リンパ節炎	3 (0.8)	0	1 (0.3)	0	1 (0.3)	0	0	1 (0.3)	2 (2.2)	1 (1.1)	0	0	1 (1.2)	0	0	0
眼障害																
アレルギー性結膜炎	9 (2.3)	1 (0.3)	1 (0.3)	0	3 (1.0)	3 (1.0)	0	1 (0.3)	3 (3.3)	0	0	1 (1.2)	1 (1.2)	0	0	1 (1.1)
眼瞼浮腫	2 (0.5)	2 (0.5)	0	0	0	0	0	0	2 (2.2)	2 (2.2)	0	0	0	0	0	0
胃腸障害																
腹痛	8 (2.1)	2 (0.5)	1 (0.3)	1 (0.3)	1 (0.3)	1 (0.3)	2 (0.9)	0	1 (1.1)	0	0	0	1 (1.2)	0	0	0
上腹部痛	6 (1.5)	3 (0.8)	1 (0.3)	2 (0.6)	0	0	0	0	3 (3.3)	0	0	2 (2.3)	1 (1.2)	0	0	0
慢性胃炎	0	0	0	0	0	0	0	0	2 (2.2)	0	1 (1.1)	1 (1.2)	0	0	0	0
便秘	6 (1.5)	2 (0.5)	1 (0.3)	0	2 (0.7)	1 (0.3)	0	0	2 (2.2)	0	1 (1.1)	1 (1.2)	0	0	0	0
齲歯	13 (3.3)	2 (0.5)	6 (1.7)	1 (0.3)	2 (0.7)	1 (0.3)	0	1 (0.3)	7 (7.6)	1 (1.1)	0	3 (3.5)	2 (2.4)	1 (1.3)	0	0
下痢	13 (3.3)	5 (1.3)	0	3 (0.9)	3 (1.0)	1 (0.3)	1 (0.5)	0	4 (4.3)	0	2 (2.2)	0	1 (1.2)	1 (1.3)	0	0
胃食道逆流性疾患	8 (2.1)	1 (0.3)	2 (0.6)	1 (0.3)	2 (0.7)	2 (0.7)	0	0	1 (1.1)	0	0	0	1 (1.2)	0	0	0

Percentages are based on number of subjects in each time period.
Multiple occurrences of an event for one subject are counted only once as earliest onset.
TEAE occurred in equal to or more than 2% in any treatment group is presented.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.5.1.2から引用

System Organ Class	Nemolizumab (N=389)								Placebo-Nemolizumab (N=92)							
	Any Period	- 85 days	86 - 169 days	170 - 253 days	254 - 337 days	338 - 421 days	422 - days	FU	Any Period	- 85 days	86 - 169 days	170 - 253 days	254 - 337 days	338 - 421 days	422 - days	FU
Preferred Term	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
胃腸障害 (Cont.)																
痔核	1 (0.3)	0	1 (0.3)	0	0	0	0	0	2 (2.2)	0	1 (1.1)	1 (1.2)	0	0	0	0
口内炎	3 (0.8)	1 (0.3)	0	1 (0.3)	1 (0.3)	0	0	0	3 (3.3)	0	0	2 (2.3)	0	1 (1.3)	0	0
一般・全身障害および投与部位の状態																
倦怠感	8 (2.1)	5 (1.3)	3 (0.9)	0	0	0	0	0	1 (1.1)	0	1 (1.1)	0	0	0	0	0
末梢性浮腫	18 (4.6)	15 (3.9)	3 (0.9)	0	0	0	0	0	3 (3.3)	1 (1.1)	1 (1.1)	0	1 (1.2)	0	0	0
発熱	13 (3.3)	7 (1.8)	2 (0.6)	2 (0.6)	1 (0.3)	1 (0.3)	0	0	3 (3.3)	0	0	1 (1.2)	1 (1.2)	1 (1.3)	0	0
肝胆道系障害																
肝機能異常	2 (0.5)	2 (0.5)	0	0	0	0	0	0	2 (2.2)	0	1 (1.1)	0	0	0	0	1 (1.1)
感染症および寄生虫症																
気管支炎	11 (2.8)	1 (0.3)	4 (1.2)	1 (0.3)	2 (0.7)	1 (0.3)	0	2 (0.6)	2 (2.2)	1 (1.1)	0	0	1 (1.2)	0	0	0
蜂巣炎	20 (5.1)	6 (1.5)	7 (2.0)	2 (0.6)	1 (0.3)	0	2 (0.9)	2 (0.6)	3 (3.3)	2 (2.2)	0	1 (1.2)	0	0	0	0
結膜炎	6 (1.5)	1 (0.3)	2 (0.6)	2 (0.6)	0	0	0	1 (0.3)	3 (3.3)	2 (2.2)	1 (1.1)	0	0	0	0	0
膀胱炎	9 (2.3)	0	2 (0.6)	3 (0.9)	3 (1.0)	0	0	1 (0.3)	2 (2.2)	0	0	0	1 (1.2)	0	0	1 (1.1)

Percentages are based on number of subjects in each time period.
Multiple occurrences of an event for one subject are counted only once as earliest onset.
TEAE occurred in equal to or more than 2% in any treatment group is presented.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.5.1.2から引用

System Organ Class / Preferred Term	Nemolizumab (N=389) Any Period n (%)	- 85 days n (%)	86 - 169 days n (%)	170 - 253 days n (%)	254 - 337 days n (%)	338 - 421 days n (%)	422 - days n (%)	FU n (%)	Placebo-Nemolizumab (N=92) Any Period n (%)	- 85 days n (%)	86 - 169 days n (%)	170 - 253 days n (%)	254 - 337 days n (%)	338 - 421 days n (%)	422 - days n (%)	FU n (%)
感染症および寄生虫症 (Cont.)																
毛包炎	13 (3.3)	3 (0.8)	1 (0.3)	4 (1.3)	1 (0.3)	1 (0.3)	1 (0.5)	2 (0.6)	3 (3.3)	1 (1.1)	0	1 (1.2)	1 (1.2)	0	0	0
胃腸炎	14 (3.6)	1 (0.3)	2 (0.6)	2 (0.6)	4 (1.3)	3 (1.0)	0	2 (0.6)	7 (7.6)	2 (2.2)	0	0	3 (3.7)	2 (2.6)	0	0
単純ヘルペス	9 (2.3)	2 (0.5)	1 (0.3)	3 (0.9)	1 (0.3)	2 (0.7)	0	0	0	0	0	0	0	0	0	0
帯状疱疹	9 (2.3)	2 (0.5)	3 (0.9)	2 (0.6)	2 (0.7)	0	0	0	1 (1.1)	0	1 (1.1)	0	0	0	0	0
膿痂疹	13 (3.3)	1 (0.3)	7 (2.0)	2 (0.6)	0	2 (0.7)	0	1 (0.3)	4 (4.3)	1 (1.1)	1 (1.1)	1 (1.2)	1 (1.2)	0	0	0
インフルエンザ	26 (6.7)	4 (1.0)	2 (0.6)	9 (2.8)	7 (2.3)	4 (1.4)	0	0	3 (3.3)	0	0	1 (1.2)	2 (2.4)	0	0	0
上咽頭炎	122 (31.4)	46 (11.8)	25 (7.3)	19 (6.0)	15 (4.9)	10 (3.4)	3 (1.4)	4 (1.1)	27 (29.3)	6 (6.5)	7 (7.9)	7 (8.1)	4 (4.9)	3 (3.8)	0	0
外耳炎	11 (2.8)	4 (1.0)	2 (0.6)	2 (0.6)	3 (1.0)	0	0	0	4 (4.3)	1 (1.1)	1 (1.1)	0	1 (1.2)	0	0	1 (1.1)
咽頭炎	20 (5.1)	6 (1.5)	3 (0.9)	4 (1.3)	3 (1.0)	2 (0.7)	0	2 (0.6)	1 (1.1)	0	1 (1.1)	0	0	0	0	0
上気道感染	14 (3.6)	9 (2.3)	2 (0.6)	2 (0.6)	0	1 (0.3)	0	0	1 (1.1)	0	1 (1.1)	0	0	0	0	0
カポジ水痘様発疹	10 (2.6)	5 (1.3)	1 (0.3)	2 (0.6)	0	0	0	2 (0.6)	1 (1.1)	1 (1.1)	0	0	0	0	0	0
傷害、中毒および処置合併症																
上顆炎	1 (0.3)	0	0	1 (0.3)	0	0	0	0	2 (2.2)	0	0	2 (2.3)	0	0	0	0

Percentages are based on number of subjects in each time period.
Multiple occurrences of an event for one subject are counted only once as earliest onset.
TEAE occurred in equal to or more than 2% in any treatment group is presented.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.5.1.2から引用

System Organ Class Preferred Term	Nemolizumab (N=389) Any Period n (%)	 - 85 days n (%)	 86 - 169 days n (%)	 170 - 253 days n (%)	 254 - 337 days n (%)	 338 - 421 days n (%)	 422 - days n (%)	 FU n (%)	Placebo-Nemolizumab (N=92) Any Period n (%)	 - 85 days n (%)	 86 - 169 days n (%)	 170 - 253 days n (%)	 254 - 337 days n (%)	 338 - 421 days n (%)	 422 - days n (%)	 FU n (%)
傷害、中毒および処置合併症 (Cont.)																
挫傷	9 (2.3)	6 (1.5)	0	1 (0.3)	0	2 (0.7)	0	0	8 (8.7)	3 (3.3)	3 (3.4)	2 (2.3)	0	0	0	0
創傷	2 (0.5)	0	1 (0.3)	0	0	1 (0.3)	0	0	3 (3.3)	1 (1.1)	0	1 (1.2)	0	1 (1.3)	0	0
臨床検査																
血中クレアチンホスホキナーゼ増加	38 (9.8)	12 (3.1)	7 (2.0)	7 (2.2)	3 (1.0)	3 (1.0)	0	6 (1.7)	10 (10.9)	1 (1.1)	4 (4.5)	1 (1.2)	2 (2.4)	2 (2.6)	0	0
好酸球数増加	6 (1.5)	3 (0.8)	1 (0.3)	1 (0.3)	1 (0.3)	0	0	0	2 (2.2)	1 (1.1)	0	0	1 (1.2)	0	0	0
体重減少	1 (0.3)	0	0	1 (0.3)	0	0	0	0	2 (2.2)	0	0	0	1 (1.2)	0	0	1 (1.1)
体重増加	5 (1.3)	2 (0.5)	1 (0.3)	1 (0.3)	1 (0.3)	0	0	0	2 (2.2)	1 (1.1)	1 (1.1)	0	0	0	0	0
サイトカイン異常	12 (3.1)	11 (2.8)	1 (0.3)	0	0	0	0	0	2 (2.2)	1 (1.1)	0	1 (1.2)	0	0	0	0
筋骨格系および結合組織障害																
関節痛	12 (3.1)	5 (1.3)	2 (0.6)	1 (0.3)	3 (1.0)	1 (0.3)	0	0	2 (2.2)	0	1 (1.1)	0	1 (1.2)	0	0	0
背部痛	11 (2.8)	1 (0.3)	5 (1.5)	1 (0.3)	2 (0.7)	0	2 (0.9)	0	5 (5.4)	0	1 (1.1)	3 (3.5)	1 (1.2)	0	0	0
変形性関節症	2 (0.5)	0	0	1 (0.3)	1 (0.3)	0	0	0	2 (2.2)	0	0	1 (1.2)	1 (1.2)	0	0	0
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）																

Percentages are based on number of subjects in each time period.
Multiple occurrences of an event for one subject are counted only once as earliest onset.
TEAE occurred in equal to or more than 2% in any treatment group is presented.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.5.1.2から引用

System Organ Class / Preferred Term	Nemolizumab (N=389) Any Period n (%)	- 85 days n (%)	86 - 169 days n (%)	170 - 253 days n (%)	254 - 337 days n (%)	338 - 421 days n (%)	422 - days n (%)	FU n (%)	Placebo-Nemolizumab (N=92) Any Period n (%)	- 85 days n (%)	86 - 169 days n (%)	170 - 253 days n (%)	254 - 337 days n (%)	338 - 421 days n (%)	422 - days n (%)	FU n (%)
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） (Cont.)																
皮膚乳頭腫	5 (1.3)	0	1 (0.3)	2 (0.6)	1 (0.3)	0	0	1 (0.3)	2 (2.2)	0	0	0	2 (2.4)	0	0	0
神経系障害																
浮動性めまい	8 (2.1)	2 (0.5)	3 (0.9)	0	1 (0.3)	0	1 (0.5)	1 (0.3)	0	0	0	0	0	0	0	0
頭痛	31 (8.0)	12 (3.1)	8 (2.3)	2 (0.6)	3 (1.0)	3 (1.0)	1 (0.5)	2 (0.6)	5 (5.4)	3 (3.3)	0	1 (1.2)	1 (1.2)	0	0	0
呼吸器、胸郭および縦隔障害																
喘息	8 (2.1)	1 (0.3)	1 (0.3)	2 (0.6)	1 (0.3)	2 (0.7)	0	1 (0.3)	2 (2.2)	1 (1.1)	1 (1.1)	0	0	0	0	0
咳嗽	16 (4.1)	8 (2.1)	5 (1.5)	0	2 (0.7)	0	1 (0.5)	0	1 (1.1)	0	0	0	0	0	0	1 (1.1)
アレルギー性鼻炎	6 (1.5)	0	0	2 (0.6)	3 (1.0)	0	1 (0.5)	0	2 (2.2)	0	1 (1.1)	1 (1.2)	0	0	0	0
上気道の炎症	17 (4.4)	4 (1.0)	4 (1.2)	3 (0.9)	3 (1.0)	1 (0.3)	1 (0.5)	1 (0.3)	3 (3.3)	1 (1.1)	0	0	2 (2.4)	0	0	0
口腔咽頭痛	5 (1.3)	3 (0.8)	0	1 (0.3)	1 (0.3)	0	0	0	3 (3.3)	0	2 (2.2)	0	0	0	0	1 (1.1)
皮膚および皮下組織障害																
ざ瘡	18 (4.6)	0	4 (1.2)	3 (0.9)	7 (2.3)	4 (1.4)	0	0	6 (6.5)	2 (2.2)	0	0	2 (2.4)	1 (1.3)	0	1 (1.1)
皮膚嚢腫	5 (1.3)	1 (0.3)	1 (0.3)	1 (0.3)	1 (0.3)	0	0	1 (0.3)	3 (3.3)	1 (1.1)	1 (1.1)	1 (1.2)	0	0	0	0

Percentages are based on number of subjects in each time period.
Multiple occurrences of an event for one subject are counted only once as earliest onset.
TEAE occurred in equal to or more than 2% in any treatment group is presented.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.5.1.2から引用

System Organ Class	Nemolizumab (N=389)								Placebo-Nemolizumab (N=92)							
	Any Period	- 85 days	86 - 169 days	170 - 253 days	254 - 337 days	338 - 421 days	422 - days	FU	Any Period	- 85 days	86 - 169 days	170 - 253 days	254 - 337 days	338 - 421 days	422 - days	FU
Preferred Term	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
皮膚および皮下組織障害 (Cont.)																
アトピー性皮膚炎	101 (26.0)	74 (19.0)	13 (3.8)	6 (1.9)	3 (1.0)	2 (0.7)	1 (0.5)	2 (0.6)	16 (17.4)	12 (13.0)	2 (2.2)	0	0	1 (1.3)	0	1 (1.1)
接触皮膚炎	24 (6.2)	8 (2.1)	8 (2.3)	5 (1.6)	1 (0.3)	1 (0.3)	0	1 (0.3)	6 (6.5)	0	2 (2.2)	3 (3.5)	1 (1.2)	0	0	0
異汗性湿疹	10 (2.6)	4 (1.0)	2 (0.6)	1 (0.3)	1 (0.3)	0	0	2 (0.6)	3 (3.3)	1 (1.1)	0	1 (1.2)	1 (1.2)	0	0	0
湿疹	7 (1.8)	1 (0.3)	2 (0.6)	4 (1.3)	0	0	0	0	3 (3.3)	1 (1.1)	0	1 (1.2)	1 (1.2)	0	0	0
紅斑	8 (2.1)	4 (1.0)	0	2 (0.6)	1 (0.3)	1 (0.3)	0	0	2 (2.2)	0	2 (2.2)	0	0	0	0	0
蕁麻疹	26 (6.7)	8 (2.1)	3 (0.9)	2 (0.6)	3 (1.0)	5 (1.7)	2 (0.9)	3 (0.8)	3 (3.3)	2 (2.2)	0	0	0	1 (1.3)	0	0
中毒性皮疹	6 (1.5)	5 (1.3)	1 (0.3)	0	0	0	0	0	2 (2.2)	2 (2.2)	0	0	0	0	0	0
手皮膚炎	1 (0.3)	0	0	0	0	1 (0.3)	0	0	2 (2.2)	0	0	2 (2.3)	0	0	0	0

Percentages are based on number of subjects in each time period.
Multiple occurrences of an event for one subject are counted only once as earliest onset.
TEAE occurred in equal to or more than 2% in any treatment group is presented.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.5.1.2から引用

表 2.7.4-45 Treatment-Emergent Adverse Events Related to Study Drug Occurred after First Dosing Nemolizumab by Time Period (Japanese)

Safety Analysis Set（pool1）

	Nemolizumab (N=389)								Placebo-Nemolizumab (N=92)							
	Any Period	- 85 days	86 - 169 days	170 - 253 days	254 - 337 days	338 - 421 days	422 - days	FU	Any Period	- 85 days	86 - 169 days	170 - 253 days	254 - 337 days	338 - 421 days	422 - days	FU
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Number of Subjects in Each Period	389	389	343	318	304	290	211	357	92	92	89	86	82	78	0	88
TEAEs	199 (51.2)	132 (33.9)	36 (10.5)	11 (3.5)	9 (3.0)	4 (1.4)	6 (2.8)	1 (0.3)	42 (45.7)	21 (22.8)	11 (12.4)	6 (7.0)	3 (3.7)	0	0	1 (1.1)
Serious TEAEs																
TEAEs Leading to Death	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Other Serious TEAEs	14 (3.6)	6 (1.5)	1 (0.3)	2 (0.6)	0	1 (0.3)	1 (0.5)	3 (0.8)	3 (3.3)	2 (2.2)	0	1 (1.2)	0	0	0	0
Other Significant TEAEs																
TEAEs Leading to Discontinuation (including Dose Interruption and Reduction) of Study Treatment	32 (8.2)	19 (4.9)	7 (2.0)	6 (1.9)	0	0	0	0	9 (9.8)	5 (5.4)	1 (1.1)	2 (2.3)	1 (1.2)	0	0	0
Discontinuation	18 (4.6)	14 (3.6)	1 (0.3)	3 (0.9)	0	0	0	0	3 (3.3)	1 (1.1)	0	2 (2.3)	0	0	0	0
Dose Interruption	14 (3.6)	5 (1.3)	6 (1.7)	3 (0.9)	0	0	0	0	7 (7.6)	4 (4.3)	1 (1.1)	1 (1.2)	1 (1.2)	0	0	0
Dose Reduction	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Percentages are based on number of subjects in each time period.
Multiple occurrences of an event for one subject are counted only once as earliest onset.
TEAE occurred in equal to or more than 2% in any treatment group is presented.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.5.2.2から引用

	Nemolizumab (N=389)								Placebo-Nemolizumab (N=92)							
	Any Period	- 85 days	86 - 169 days	170 - 253 days	254 - 337 days	338 - 421 days	422 - days	FU	Any Period	- 85 days	86 - 169 days	170 - 253 days	254 - 337 days	338 - 421 days	422 - days	FU
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
TEAEs Special Interest																
Injection-Related Reaction	24 (6.2)	17 (4.4)	3 (0.9)	0	2 (0.7)	2 (0.7)	0	0	3 (3.3)	1 (1.1)	0	2 (2.3)	0	0	0	0
Asthma	2 (0.5)	1 (0.3)	1 (0.3)	0	0	0	0	0	2 (2.2)	0	1 (1.1)	1 (1.2)	0	0	0	0
Worsening of AD	62 (15.9)	46 (11.8)	11 (3.2)	2 (0.6)	1 (0.3)	2 (0.7)	0	0	8 (8.7)	7 (7.6)	1 (1.1)	0	0	0	0	0
Skin Infections	41 (10.5)	16 (4.1)	11 (3.2)	4 (1.3)	5 (1.6)	0	4 (1.9)	1 (0.3)	9 (9.8)	5 (5.4)	1 (1.1)	1 (1.2)	1 (1.2)	0	0	1 (1.1)
Non-skin Infections	48 (12.3)	25 (6.4)	9 (2.6)	7 (2.2)	2 (0.7)	3 (1.0)	1 (0.5)	1 (0.3)	9 (9.8)	3 (3.3)	3 (3.4)	2 (2.3)	1 (1.2)	0	0	0
Elevated CPK	4 (1.0)	2 (0.5)	1 (0.3)	0	0	1 (0.3)	0	0	2 (2.2)	0	1 (1.1)	0	1 (1.2)	0	0	0

Percentages are based on number of subjects in each time period.
Multiple occurrences of an event for one subject are counted only once as earliest onset.
TEAE occurred in equal to or more than 2% in any treatment group is presented.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.5.2.2から引用

System Organ Class / Preferred Term	Nemolizumab (N=389) Any Period n (%)	- 85 days n (%)	86 - 169 days n (%)	170 - 253 days n (%)	254 - 337 days n (%)	338 - 421 days n (%)	422 - days n (%)	FU n (%)	Placebo-Nemolizumab (N=92) Any Period n (%)	- 85 days n (%)	86 - 169 days n (%)	170 - 253 days n (%)	254 - 337 days n (%)	338 - 421 days n (%)	422 - days n (%)	FU n (%)
一般・全身障害および投与部位の状態																
末梢性浮腫	11 (2.8)	8 (2.1)	3 (0.9)	0	0	0	0	0	0	0	0	0	0	0	0	0
感染症および寄生虫症																
蜂巣炎	12 (3.1)	4 (1.0)	5 (1.5)	1 (0.3)	0	0	1 (0.5)	1 (0.3)	2 (2.2)	2 (2.2)	0	0	0	0	0	0
結膜炎	2 (0.5)	0	1 (0.3)	1 (0.3)	0	0	0	0	2 (2.2)	1 (1.1)	1 (1.1)	0	0	0	0	0
膿痂疹	5 (1.3)	1 (0.3)	2 (0.6)	1 (0.3)	0	0	0	1 (0.3)	3 (3.3)	1 (1.1)	0	1 (1.2)	1 (1.2)	0	0	0
上咽頭炎	12 (3.1)	4 (1.0)	4 (1.2)	0	1 (0.3)	3 (1.0)	0	0	4 (4.3)	1 (1.1)	2 (2.2)	0	0	1 (1.3)	0	0
上気道感染	8 (2.1)	5 (1.3)	2 (0.6)	1 (0.3)	0	0	0	0	1 (1.1)	0	1 (1.1)	0	0	0	0	0
臨床検査																
血中クレアチンホスホキナーゼ増加	5 (1.3)	2 (0.5)	1 (0.3)	1 (0.3)	0	1 (0.3)	0	0	2 (2.2)	0	1 (1.1)	0	1 (1.2)	0	0	0
好酸球数増加	6 (1.5)	3 (0.8)	1 (0.3)	1 (0.3)	1 (0.3)	0	0	0	2 (2.2)	1 (1.1)	0	0	1 (1.2)	0	0	0
サイトカイン異常	12 (3.1)	11 (2.8)	1 (0.3)	0	0	0	0	0	1 (1.1)	1 (1.1)	0	0	0	0	0	0
神経系障害																

Percentages are based on number of subjects in each time period.
Multiple occurrences of an event for one subject are counted only once as earliest onset.
TEAE occurred in equal to or more than 2% in any treatment group is presented.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.5.2.2から引用

System Organ Class	Nemolizumab (N=389)								Placebo-Nemolizumab (N=92)							
	Any Period	- 85 days	86 - 169 days	170 - 253 days	254 - 337 days	338 - 421 days	422 - days	FU	Any Period	- 85 days	86 - 169 days	170 - 253 days	254 - 337 days	338 - 421 days	422 - days	FU
Preferred Term	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
神経系障害 (Cont.)																
頭痛	8 (2.1)	3 (0.8)	3 (0.9)	0	1 (0.3)	0	0	1 (0.3)	1 (1.1)	1 (1.1)	0	0	0	0	0	0
皮膚および皮下組織障害																
ざ瘡	3 (0.8)	0	0	1 (0.3)	1 (0.3)	1 (0.3)	0	0	2 (2.2)	1 (1.1)	0	0	1 (1.2)	0	0	0
アトピー性皮膚炎	62 (15.9)	46 (11.8)	11 (3.2)	2 (0.6)	1 (0.3)	2 (0.7)	0	0	7 (7.6)	6 (6.5)	1 (1.1)	0	0	0	0	0
紅斑	7 (1.8)	3 (0.8)	0	2 (0.6)	1 (0.3)	1 (0.3)	0	0	2 (2.2)	0	2 (2.2)	0	0	0	0	0
蕁麻疹	10 (2.6)	5 (1.3)	1 (0.3)	1 (0.3)	0	1 (0.3)	0	2 (0.6)	2 (2.2)	2 (2.2)	0	0	0	0	0	0
中毒性皮疹	6 (1.5)	5 (1.3)	1 (0.3)	0	0	0	0	0	2 (2.2)	2 (2.2)	0	0	0	0	0	0

Percentages are based on number of subjects in each time period.
Multiple occurrences of an event for one subject are counted only once as earliest onset.
TEAE occurred in equal to or more than 2% in any treatment group is presented.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.5.2.2から引用

表 2.7.4-46 Treatment-Emergent Adverse Events Occurred during PartA by Time Period (Japanese)

Safety Analysis Set（pool2）

	Nemolizumab (N=301)					Placebo-Nemolizumab (N=112)				
	Any Period n (%)	- 28 days n (%)	29 - 56 days n (%)	57 - 84 days n (%)	85 - 112 days n (%)	Any Period n (%)	- 28 days n (%)	29 - 56 days n (%)	57 - 84 days n (%)	85 - 112 days n (%)
Number of Subjects in Each Period	301	301	291	278	240	112	112	107	103	93
TEAEs	215 (71.4)	127 (42.2)	55 (18.9)	24 (8.6)	8 (3.3)	79 (70.5)	43 (38.4)	16 (15.0)	16 (15.5)	3 (3.2)
Serious TEAEs										
TEAEs Leading to Death	0	0	0	0	0	0	0	0	0	0
Other Serious TEAEs	10 (3.3)	5 (1.7)	2 (0.7)	3 (1.1)	0	3 (2.7)	1 (0.9)	0	1 (1.0)	1 (1.1)
Other Significant TEAEs										
TEAEs Leading to Discontinuation (including Dose Interruption and Reduction) of Study Treatment	19 (6.3)	10 (3.3)	7 (2.4)	2 (0.7)	0	2 (1.8)	0	0	1 (1.0)	1 (1.1)
Discontinuation	13 (4.3)	7 (2.3)	5 (1.7)	1 (0.4)	0	0	0	0	0	0
Dose Interruption	6 (2.0)	3 (1.0)	2 (0.7)	1 (0.4)	0	2 (1.8)	0	0	1 (1.0)	1 (1.1)
Dose Reduction	0	0	0	0	0	0	0	0	0	0

Percentages are based on number of subjects in each time period.
Multiple occurrences of an event for one subject are counted only once as earliest onset.
TEAE occurred in equal to or more than 2% in any treatment group is presented.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.5.3.2から引用

	Nemolizumab (N=301)					Placebo-Nemolizumab (N=112)				
	Any Period n (%)	- 28 days n (%)	29 - 56 days n (%)	57 - 84 days n (%)	85 - 112 days n (%)	Any Period n (%)	- 28 days n (%)	29 - 56 days n (%)	57 - 84 days n (%)	85 - 112 days n (%)
TEAEs Special Interest										
Injection-Related Reaction	20 (6.6)	14 (4.7)	3 (1.0)	3 (1.1)	0	3 (2.7)	2 (1.8)	1 (0.9)	0	0
Asthma	1 (0.3)	1 (0.3)	0	0	0	1 (0.9)	1 (0.9)	0	0	0
Worsening of AD	64 (21.3)	26 (8.6)	21 (7.2)	13 (4.7)	4 (1.7)	21 (18.8)	7 (6.3)	6 (5.6)	5 (4.9)	3 (3.2)
Skin Infections	32 (10.6)	14 (4.7)	10 (3.4)	3 (1.1)	4 (1.7)	12 (10.7)	5 (4.5)	3 (2.8)	3 (2.9)	1 (1.1)
Non-skin Infections	78 (25.9)	40 (13.3)	15 (5.2)	18 (6.5)	5 (2.1)	34 (30.4)	12 (10.7)	10 (9.3)	8 (7.8)	4 (4.3)
Elevated CPK	13 (4.3)	6 (2.0)	2 (0.7)	2 (0.7)	2 (0.8)	3 (2.7)	3 (2.7)	0	0	0

Percentages are based on number of subjects in each time period.
Multiple occurrences of an event for one subject are counted only once as earliest onset.
TEAE occurred in equal to or more than 2% in any treatment group is presented.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.5.3.2から引用

System Organ Class Preferred Term	Nemolizumab (N=301) Any Period n (%)	 - 28 days n (%)	 29 - 56 days n (%)	 57 - 84 days n (%)	 85 - 112 days n (%)	Placebo-Nemolizumab (N=112) Any Period n (%)	 - 28 days n (%)	 29 - 56 days n (%)	 57 - 84 days n (%)	 85 - 112 days n (%)
一般・全身障害および投与部位の状態										
末梢性浮腫	14 (4.7)	7 (2.3)	6 (2.1)	0	1 (0.4)	0	0	0	0	0
発熱	7 (2.3)	4 (1.3)	1 (0.3)	2 (0.7)	0	2 (1.8)	0	0	1 (1.0)	0
感染症および寄生虫症										
毛包炎	2 (0.7)	1 (0.3)	1 (0.3)	0	0	3 (2.7)	1 (0.9)	2 (1.9)	0	0
上咽頭炎	37 (12.3)	21 (7.0)	8 (2.7)	5 (1.8)	3 (1.3)	18 (16.1)	4 (3.6)	5 (4.7)	6 (5.8)	3 (3.2)
上気道感染	9 (3.0)	4 (1.3)	0	5 (1.8)	0	5 (4.5)	2 (1.8)	2 (1.9)	1 (1.0)	0
臨床検査										
血中クレアチンホスホキナーゼ増加	14 (4.7)	6 (2.0)	2 (0.7)	2 (0.7)	3 (1.3)	3 (2.7)	3 (2.7)	0	0	0
サイトカイン異常	10 (3.3)	0	10 (3.4)	0	0	0	0	0	0	0
神経系障害										
頭痛	10 (3.3)	7 (2.3)	2 (0.7)	1 (0.4)	0	1 (0.9)	1 (0.9)	0	0	0
皮膚および皮下組織障害										

Percentages are based on number of subjects in each time period.
Multiple occurrences of an event for one subject are counted only once as earliest onset.
TEAE occurred in equal to or more than 2% in any treatment group is presented.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.5.3.2から引用

System Organ Class Preferred Term	Nemolizumab (N=301) Any Period n (%)	 - 28 days n (%)	 29 - 56 days n (%)	 57 - 84 days n (%)	 85 - 112 days n (%)	Placebo-Nemolizumab (N=112) Any Period n (%)	 - 28 days n (%)	 29 - 56 days n (%)	 57 - 84 days n (%)	 85 - 112 days n (%)
皮膚および皮下組織障害（Cont.）										
ざ瘡	2 (0.7)	0	0	0	1 (0.4)	3 (2.7)	0	0	1 (1.0)	0
アトピー性皮膚炎	63 (20.9)	25 (8.3)	21 (7.2)	13 (4.7)	4 (1.7)	21 (18.8)	7 (6.3)	6 (5.6)	5 (4.9)	3 (3.2)

Percentages are based on number of subjects in each time period.
Multiple occurrences of an event for one subject are counted only once as earliest onset.
TEAE occurred in equal to or more than 2% in any treatment group is presented.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.5.3.2から引用

表 2.7.4-47 Treatment-Emergent Adverse Events Related to Study Drug Occurred during PartA by Time Period (Japanese)

Safety Analysis Set（pool2）

	Nemolizumab (N=301)					Placebo-Nemolizumab (N=112)				
	Any Period n (%)	- 28 days n (%)	29 - 56 days n (%)	57 - 84 days n (%)	85 - 112 days n (%)	Any Period n (%)	- 28 days n (%)	29 - 56 days n (%)	57 - 84 days n (%)	85 - 112 days n (%)
Number of Subjects in Each Period	301	301	291	278	240	112	112	107	103	93
TEAEs	107 (35.5)	49 (16.3)	38 (13.1)	12 (4.3)	7 (2.9)	22 (19.6)	13 (11.6)	2 (1.9)	3 (2.9)	2 (2.2)
Serious TEAEs										
TEAEs Leading to Death	0	0	0	0	0	0	0	0	0	0
Other Serious TEAEs	5 (1.7)	2 (0.7)	1 (0.3)	2 (0.7)	0	0	0	0	0	0
Other Significant TEAEs										
TEAEs Leading to Discontinuation (including Dose Interruption and Reduction) of Study Treatment	13 (4.3)	7 (2.3)	4 (1.4)	2 (0.7)	0	0	0	0	0	0
Discontinuation	10 (3.3)	5 (1.7)	3 (1.0)	2 (0.7)	0	0	0	0	0	0
Dose Interruption	3 (1.0)	2 (0.7)	1 (0.3)	0	0	0	0	0	0	0
Dose Reduction	0	0	0	0	0	0	0	0	0	0

Percentages are based on number of subjects in each time period.
Multiple occurrences of an event for one subject are counted only once as earliest onset.
TEAE occurred in equal to or more than 2% in any treatment group is presented.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.5.4.2から引用

	Nemolizumab (N=301)					Placebo-Nemolizumab (N=112)				
	Any Period n (%)	- 28 days n (%)	29 - 56 days n (%)	57 - 84 days n (%)	85 - 112 days n (%)	Any Period n (%)	- 28 days n (%)	29 - 56 days n (%)	57 - 84 days n (%)	85 - 112 days n (%)
TEAEs Special Interest										
Injection-Related Reaction	15 (5.0)	11 (3.7)	2 (0.7)	2 (0.7)	0	1 (0.9)	1 (0.9)	0	0	0
Asthma	1 (0.3)	1 (0.3)	0	0	0	1 (0.9)	1 (0.9)	0	0	0
Worsening of AD	37 (12.3)	13 (4.3)	13 (4.5)	8 (2.9)	3 (1.3)	5 (4.5)	2 (1.8)	1 (0.9)	1 (1.0)	1 (1.1)
Skin Infections	8 (2.7)	3 (1.0)	2 (0.7)	2 (0.7)	1 (0.4)	5 (4.5)	2 (1.8)	1 (0.9)	2 (1.9)	0
Non-skin Infections	25 (8.3)	11 (3.7)	4 (1.4)	8 (2.9)	2 (0.8)	4 (3.6)	2 (1.8)	1 (0.9)	1 (1.0)	0
Elevated CPK	3 (1.0)	2 (0.7)	0	0	1 (0.4)	0	0	0	0	0

Percentages are based on number of subjects in each time period.
Multiple occurrences of an event for one subject are counted only once as earliest onset.
TEAE occurred in equal to or more than 2% in any treatment group is presented.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.5.4.2から引用

	Nemolizumab (N=301)					Placebo-Nemolizumab (N=112)				
System Organ Class	Any Period	- 28 days	29 - 56 days	57 - 84 days	85 - 112 days	Any Period	- 28 days	29 - 56 days	57 - 84 days	85 - 112 days
Preferred Term	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
一般・全身障害および投与部位の状態										
末梢性浮腫	7 (2.3)	2 (0.7)	5 (1.7)	0	0	0	0	0	0	0
臨床検査										
サイトカイン異常	10 (3.3)	0	10 (3.4)	0	0	0	0	0	0	0
皮膚および皮下組織障害										
アトピー性皮膚炎	37 (12.3)	13 (4.3)	13 (4.5)	8 (2.9)	3 (1.3)	5 (4.5)	2 (1.8)	1 (0.9)	1 (1.0)	1 (1.1)

Percentages are based on number of subjects in each time period.
Multiple occurrences of an event for one subject are counted only once as earliest onset.
TEAE occurred in equal to or more than 2% in any treatment group is presented.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.5.4.2から引用

表 2.7.4-48 Serious Treatment-Emergent Adverse Events by Preferred Term (Japanese)
Safety Analysis Set（pool1）

	All TEAEs	TEAEs Related to Study Treatment
	Nemolizumab -Total (N=481)	Nemolizumab -Total (N=481)
Preferred Term	n (%)	n (%)
Serious TEAEs	48 (10.0)	17 (3.5)
円形脱毛症	1 (0.2)	1 (0.2)
狭心症	1 (0.2)	0
眼精疲労	1 (0.2)	0
心房細動	1 (0.2)	0
菌血症	2 (0.4)	2 (0.4)
膀胱癌	2 (0.4)	0
白内障	1 (0.2)	1 (0.2)
蜂巣炎	3 (0.6)	2 (0.4)
ピロリン酸カルシウム結晶性軟骨石灰化症	1 (0.2)	0
冠動脈狭窄	1 (0.2)	0
アトピー性皮膚炎	5 (1.0)	1 (0.2)
剥脱性皮膚炎	2 (0.4)	2 (0.4)
憩室炎	1 (0.2)	1 (0.2)
全身性強直性間代性発作	1 (0.2)	0
痔核	1 (0.2)	0
単純ヘルペス	1 (0.2)	0
帯状疱疹	1 (0.2)	0
膿痂疹	1 (0.2)	1 (0.2)
感染	2 (0.4)	0
関節脱臼	1 (0.2)	0
意識消失	1 (0.2)	0
肺腺癌第３期	1 (0.2)	0
リンパ節症	1 (0.2)	1 (0.2)
メニエール病	1 (0.2)	1 (0.2)
鼻中隔弯曲	1 (0.2)	0
視神経炎	2 (0.4)	1 (0.2)
急性膵炎	1 (0.2)	0
肺炎	1 (0.2)	1 (0.2)
原発性アルドステロン症	1 (0.2)	0
腎盂腎炎	1 (0.2)	1 (0.2)
発疹	1 (0.2)	0
網膜剥離	1 (0.2)	0

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.8.1.2から引用

	All TEAEs	TEAEs Related to Study Treatment
	Nemolizumab -Total (N=481)	Nemolizumab -Total (N=481)
Preferred Term	n (%)	n (%)
皮膚感染	1 (0.2)	1 (0.2)
蕁麻疹	1 (0.2)	0
ウイルス感染	1 (0.2)	1 (0.2)
智歯抜歯	1 (0.2)	0
椎間板突出	1 (0.2)	0
カポジ水痘様発疹	1 (0.2)	1 (0.2)
皮膚細菌感染	1 (0.2)	0
副腎腫瘤	1 (0.2)	0
上肢骨折	1 (0.2)	0
食欲減退	1 (0.2)	0
パーキンソン病	1 (0.2)	0
節外性辺縁帯Ｂ細胞リンパ腫（ＭＡＬＴ型）	1 (0.2)	1 (0.2)
検査	1 (0.2)	0
白内障手術	1 (0.2)	0
男性外性器蜂巣炎	1 (0.2)	0

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.8.1.2から引用

表 2.7.4-49 Listing of Other Serious Treatment-Emergent Adverse Events (Japanese)

Safety Analysis Set（pool1）

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(0.5mg/kgQ4W) CIM003JG [redacted]	F 5[redacted] WHITE	アトピー性皮膚炎	127	SAFETY-FU	3	NOT RELATED	MODERATE	Yes	5	1
Nemolizumab(0.5mg/kgQ4W) CIM003JG [redacted]	F 2[redacted] WHITE	蕁麻疹	378	TREATMENT	2	NOT RELATED	MODERATE	Yes	1	1
Nemolizumab(0.5mg/kgQ4W) CIM003JG [redacted]	F 2[redacted] BLACK OR AFRICAN AMERICAN	発疹	344	TREATMENT	65	NOT RELATED	MODERATE	Yes	3	1
Nemolizumab(2mg/kgQ4W) CIM003JG [redacted]	F 4[redacted] ASIAN	アトピー性皮膚炎	10	TREATMENT	18	NOT RELATED	SEVERE	Yes	4	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.2.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(2mg/kgQ4W)	M	アトピー性皮膚炎	59	TREATMENT	9	RELATED	SEVERE	Yes	4	1
CIM003JG	4[redacted]	皮膚感染	59	TREATMENT	9	RELATED	SEVERE	Yes	4	1
[redacted]	WHITE									
Nemolizumab(2mg/kgQ4W)	F	リンパ節症	75	TREATMENT	61	RELATED	MODERATE	Yes	4	1
CIM003JG	3[redacted]									
[redacted]	WHITE									
Nemolizumab(2mg/kgQ4W)	M	関節脱臼	107	TREATMENT	79	NOT RELATED	SEVERE	Yes	1	1
CIM003JG	6[redacted]	上肢骨折	107	TREATMENT	79	NOT RELATED	SEVERE	Yes	1	1
[redacted]	WHITE									
Nemolizumab(2mg/kgQ8W)	M	全身性強直性間代性発作	169	TREATMENT	8	NOT RELATED	SEVERE	Yes	4	1
CIM003JG	4[redacted]									
[redacted]	WHITE									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.2.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(2mg/kgQ8W) CIM003JG [redacted]	M 3[redacted] WHITE	冠動脈狭窄	298	TREATMENT	8	NOT RELATED	SEVERE	Yes	1	1
Nemolizumab(2mg/kgQ8W) CIM003JG [redacted]	F 2[redacted] WHITE	腎盂腎炎	114	TREATMENT	10	RELATED	MODERATE	Yes	1	1
Nemolizumab(2mg/kgQ8W) CIM003JG [redacted]	F 5[redacted] WHITE	パーキンソン病	21	TREATMENT		NOT RELATED	MODERATE	Yes	1	3
Nemolizumab(2mg/kgQ8W) CIM003JG [redacted]	M 4[redacted] ASIAN	白内障	449	TREATMENT		RELATED	MILD	Yes	5	3

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.2.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(2mg/kgQ8W)	F	帯状疱疹	36	TREATMENT	50	NOT RELATED	SEVERE	Yes	1	1
CIM003JG	5[redacted]									
[redacted]	ASIAN									
Nemolizumab(2mg/kgQ8W)	M	剥脱性皮膚炎	1	TREATMENT	27	RELATED	SEVERE	Yes	4	1
CIM003JG	5[redacted]	単純ヘルペス	10	TREATMENT	10	NOT RELATED	MILD	Yes	5	1
[redacted]	WHITE									
Nemolizumab(2mg/kgQ8W)	M	アトピー性皮膚炎	77	SAFETY-FU	5	NOT RELATED	MODERATE	Yes	5	1
CIM003JG	2[redacted]	感染	77	SAFETY-FU	5	NOT RELATED	MODERATE	Yes	5	1
[redacted]	WHITE									
Nemolizumab(2mg/kgQ8W)	F	感染	18	TREATMENT	123	NOT RELATED	SEVERE	Yes	3	1
CIM003JG	2[redacted]	アトピー性皮膚炎	106	TREATMENT	35	NOT RELATED	SEVERE	Yes	3	1
[redacted]	WHITE									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.2.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 1[redacted] ASIAN	菌血症	20	DOUBLE BLIND TREATMENT	73	RELATED	MODERATE	Yes	1	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 2[redacted] ASIAN	智歯抜歯	500	FOLLOW-UP	2	NOT RELATED	MODERATE	Yes	5	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	F 5[redacted] ASIAN	視神経炎	339	OPEN LABEL TREATMENT	92	NOT RELATED	MODERATE	Yes	1	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	F 5[redacted] ASIAN	カポジ水痘様発疹 菌血症	184 188	OPEN LABEL TREATMENT OPEN LABEL TREATMENT	16 15	RELATED RELATED	MODERATE MODERATE	Yes Yes	3 3	1 1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.2.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	M	肺炎	375	OPEN LABEL TREATMENT	16	RELATED	MODERATE	Yes	1	1
M525101-01	5[redacted]									
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	M	急性膵炎	74	DOUBLE BLIND TREATMENT	126	NOT RELATED	SEVERE	Yes	3	1
M525101-01	6[redacted]	急性膵炎	479	FOLLOW-UP	20	NOT RELATED	SEVERE	Yes	5	1
CA[redacted]	ASIAN	検査	512	FOLLOW-UP	9	NOT RELATED	MILD	Yes	5	1
Nemolizumab(60mg/body)	M	膀胱癌	194	OPEN LABEL TREATMENT	47	NOT RELATED	SEVERE	Yes	4	1
M525101-01	6[redacted]									
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	F	食欲減退	174	OPEN LABEL TREATMENT	92	NOT RELATED	SEVERE	Yes	1	1
M525101-01	3[redacted]									
CA[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.2.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 3[redacted] ASIAN	男性外性器蜂巣炎	390	OPEN LABEL TREATMENT	11	NOT RELATED	MODERATE	Yes	1	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 4[redacted] ASIAN	円形脱毛症 メニエール病	42 105	DOUBLE BLIND TREATMENT DOUBLE BLIND TREATMENT		RELATED RELATED	MODERATE SEVERE	Yes Yes	4 4	3 3
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 2[redacted] ASIAN	眼精疲労	413	OPEN LABEL TREATMENT		NOT RELATED	MODERATE	Yes	1	2
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 6[redacted] ASIAN	意識消失	276	OPEN LABEL TREATMENT	2	NOT RELATED	SEVERE	Yes	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.2.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 4[redacted] ASIAN	胆管結石	-12	SCREENING	12	NOT RELATED	SEVERE	Yes	1	1
Nemolizumab(60mg/body) M525101-02 CB[redacted]	M 2[redacted] ASIAN	鼻中隔弯曲	77	TREATMENT	6	NOT RELATED	MODERATE	Yes	1	1
Nemolizumab(60mg/body) M525101-02 CB[redacted]	M 2[redacted] ASIAN	椎間板突出	204	TREATMENT		NOT RELATED	MODERATE	Yes	1	2
Nemolizumab(60mg/body) M525101-02 CB[redacted]	M 4[redacted] ASIAN	原発性アルドステロン症	96	TREATMENT	5	NOT RELATED	MILD	Yes	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.2.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body) M525101-02 CB[redacted]	M 3[redacted] ASIAN	蜂巣炎	152	FOLLOW-UP	18	RELATED	SEVERE	Yes	5	1
Nemolizumab(60mg/body) M525101-02 CB[redacted]	M 5[redacted] ASIAN	蜂巣炎	179	TREATMENT	61	NOT RELATED	MODERATE	Yes	4	1
Nemolizumab(60mg/body) M525101-02 CB[redacted]	M 2[redacted] ASIAN	ウイルス感染	419	FOLLOW-UP		RELATED	SEVERE	Yes	5	2
Nemolizumab(60mg/body) M525101-02 CB[redacted]	M 6[redacted] ASIAN	節外性辺縁帯Ｂ細胞リンパ腫（ＭＡＬＴ型）	246	TREATMENT		RELATED	MILD	Yes	4	3

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.2.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body) M525101-02 CB[redacted]	F 3[redacted] ASIAN	皮膚細菌感染	265	TREATMENT	38	NOT RELATED	MODERATE	Yes	1	1
Nemolizumab(60mg/body) M525101-02 CB[redacted]	M 3[redacted] ASIAN	視神経炎	74	TREATMENT		RELATED	SEVERE	Yes	4	3
Nemolizumab(60mg/body) M525101-02 CB[redacted]	M 4[redacted] ASIAN	膿痂疹	408	FOLLOW-UP		RELATED	MODERATE	Yes	5	2
Placebo-Nemolizumab(Placebo-2mg/kgQ4W) CIM003JG [redacted]	F 2[redacted] ASIAN	網膜剥離	13	TREATMENT		NOT RELATED	SEVERE	Yes	1	2

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.2.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Placebo-Nemolizumab(Placebo-2mg/kgQ4W) CIM003JG [redacted]	F 5[redacted] WHITE	憩室炎	295	TREATMENT	12	RELATED	SEVERE	Yes	1	1
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	F 4[redacted] ASIAN	剥脱性皮膚炎	160	OPEN LABEL TREATMENT	9	RELATED	MODERATE	Yes	1	1
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 4[redacted] ASIAN	副腎腫瘤	57	DOUBLE BLIND TREATMENT		NOT RELATED	MILD	Yes	1	3
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 5[redacted] ASIAN	白内障手術 白内障手術	246 337	OPEN LABEL TREATMENT OPEN LABEL TREATMENT	8 8	NOT RELATED NOT RELATED	MILD MILD	Yes Yes	1 1	1 1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.2.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 4[redacted] ASIAN	蜂巣炎	170	OPEN LABEL TREATMENT	52	RELATED	SEVERE	Yes	3	1
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 6[redacted] ASIAN	肺腺癌第３期 膀胱癌	170 176	OPEN LABEL TREATMENT OPEN LABEL TREATMENT	 	NOT RELATED NOT RELATED	SEVERE SEVERE	Yes Yes	4 5	3 3
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 3[redacted] ASIAN	心房細動	100	DOUBLE BLIND TREATMENT	53	NOT RELATED	MODERATE	Yes	3	1
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 4[redacted] ASIAN	出血性腸炎	-25	SCREENING	16	NOT RELATED	SEVERE	Yes	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.2.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 4[redacted] ASIAN	痔核	197	OPEN LABEL TREATMENT	111	NOT RELATED	MODERATE	Yes	1	1
Placebo-Nemolizumab(Placebo-60mg/body)	M	ピロリン酸カルシウム結晶性軟骨石灰化症	162	OPEN LABEL TREATMENT	36	NOT RELATED	SEVERE	Yes	1	1
M525101-01 CA[redacted]	6[redacted] ASIAN	狭心症	172	OPEN LABEL TREATMENT		NOT RELATED	MILD	Yes	1	3

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.2.2から引用

表 2.7.4-50 Significant Treatment-Emergent Adverse Events Occurred during PartA by Preferred Term (Japanese)
Safety Analysis Set（pool2）

Kind of Significant Preferred Term	All TEAEs		TEAEs Related to Study Treatment	
	Nemolizumab (N=301) n (%)	Placebo-Nemolizumab (N=112) n (%)	Nemolizumab (N=301) n (%)	Placebo-Nemolizumab (N=112) n (%)
Significant TEAEs	166 (55.1)	58 (51.8)	80 (26.6)	13 (11.6)
TEAEs Leading to Discontinuation of Study Treatment	13 (4.3)	0	10 (3.3)	0
円形脱毛症	1 (0.3)	0	1 (0.3)	0
アトピー性皮膚炎	9 (3.0)	0	6 (2.0)	0
剥脱性皮膚炎	1 (0.3)	0	1 (0.3)	0
丹毒	1 (0.3)	0	0	0
リンパ節症	1 (0.3)	0	1 (0.3)	0
メニエール病	1 (0.3)	0	1 (0.3)	0
末梢性浮腫	1 (0.3)	0	1 (0.3)	0
回帰性リウマチ	1 (0.3)	0	0	0
落ち着きのなさ	1 (0.3)	0	1 (0.3)	0
洞性頻脈	1 (0.3)	0	0	0
皮膚感染	2 (0.7)	0	1 (0.3)	0
TEAEs Leading to Dose Interruption of Study Treatment	6 (2.0)	2 (1.8)	3 (1.0)	0
心房細動	0	1 (0.9)	0	0
蜂巣炎	1 (0.3)	0	1 (0.3)	0
アトピー性皮膚炎	1 (0.3)	1 (0.9)	1 (0.3)	0
頭痛	1 (0.3)	0	0	0
感染	1 (0.3)	0	0	0
急性膵炎	1 (0.3)	0	0	0
全身性皮疹	1 (0.3)	0	1 (0.3)	0
中毒性皮疹	1 (0.3)	0	1 (0.3)	0
TEAEs Leading to Dose Reduction of Study Treatment	0	0	0	0
Injection-Related Reaction	20 (6.6)	3 (2.7)	15 (5.0)	1 (0.9)
剥脱性皮膚炎	1 (0.3)	0	1 (0.3)	0
浮動性めまい	1 (0.3)	0	1 (0.3)	0
紅斑	1 (0.3)	0	0	0
顔面浮腫	1 (0.3)	0	1 (0.3)	0
頭痛	1 (0.3)	0	1 (0.3)	0
感覚鈍麻	1 (0.3)	0	1 (0.3)	0
注射部位内出血	3 (1.0)	0	2 (0.7)	0
注射部位血腫	1 (0.3)	1 (0.9)	1 (0.3)	0
注射部位疼痛	1 (0.3)	0	1 (0.3)	0

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.7.2.2から引用

Kind of Significant Preferred Term	All TEAEs		TEAEs Related to Study Treatment	
	Nemolizumab (N=301) n (%)	Placebo-Nemolizumab (N=112) n (%)	Nemolizumab (N=301) n (%)	Placebo-Nemolizumab (N=112) n (%)
Injection-Related Reaction (Cont.)				
注射部位そう痒感	1 (0.3)	0	1 (0.3)	0
注射部位反応	5 (1.7)	0	5 (1.7)	0
倦怠感	3 (1.0)	1 (0.9)	2 (0.7)	1 (0.9)
紫斑	1 (0.3)	0	0	0
頚動脈脈拍増加	1 (0.3)	0	0	0
注射に伴う反応	0	1 (0.9)	0	0
Asthma	1 (0.3)	1 (0.9)	1 (0.3)	1 (0.9)
咳嗽	1 (0.3)	1 (0.9)	1 (0.3)	1 (0.9)
労作性呼吸困難	0	1 (0.9)	0	1 (0.9)
Worsening of AD	64 (21.3)	21 (18.8)	37 (12.3)	5 (4.5)
アトピー性皮膚炎	63 (20.9)	21 (18.8)	37 (12.3)	5 (4.5)
剥脱性皮膚炎	1 (0.3)	0	0	0
Skin Infections	32 (10.6)	12 (10.7)	8 (2.7)	5 (4.5)
蜂巣炎	4 (1.3)	2 (1.8)	2 (0.7)	2 (1.8)
丹毒	1 (0.3)	0	0	0
毛包炎	2 (0.7)	3 (2.7)	0	1 (0.9)
せつ	1 (0.3)	0	0	0
単純ヘルペス	2 (0.7)	0	2 (0.7)	0
ヘルペスウイルス感染	1 (0.3)	0	0	0
帯状疱疹	1 (0.3)	0	0	0
麦粒腫	1 (0.3)	1 (0.9)	0	1 (0.9)
膿痂疹	2 (0.7)	0	1 (0.3)	0
外耳炎	4 (1.3)	0	0	0
爪囲炎	0	2 (1.8)	0	0
膿疱性皮疹	1 (0.3)	0	0	0
皮膚感染	2 (0.7)	0	1 (0.3)	0
皮膚乳頭腫	0	2 (1.8)	0	0
足部白癬	1 (0.3)	1 (0.9)	0	1 (0.9)
膿痂疹性湿疹	1 (0.3)	0	0	0
カポジ水痘様発疹	1 (0.3)	0	0	0
皮膚細菌感染	2 (0.7)	0	0	0
白癬感染	1 (0.3)	0	0	0
男性外性器蜂巣炎	1 (0.3)	0	1 (0.3)	0

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.7.2.2から引用

Kind of Significant Preferred Term	All TEAEs		TEAEs Related to Study Treatment	
	Nemolizumab (N=301) n (%)	Placebo-Nemolizumab (N=112) n (%)	Nemolizumab (N=301) n (%)	Placebo-Nemolizumab (N=112) n (%)
Skin Infections (Cont.)				
口腔ヘルペス	1 (0.3)	0	1 (0.3)	0
眼部単純ヘルペス	1 (0.3)	0	0	0
鼻ヘルペス	1 (0.3)	1 (0.9)	0	0
Non-skin Infections	78 (25.9)	34 (30.4)	25 (8.3)	4 (3.6)
菌血症	1 (0.3)	0	1 (0.3)	0
気管支炎	1 (0.3)	1 (0.9)	1 (0.3)	0
結膜炎	2 (0.7)	0	0	0
膀胱炎	0	1 (0.9)	0	0
眼感染	0	1 (0.9)	0	0
胃腸炎	2 (0.7)	1 (0.9)	2 (0.7)	0
ウイルス性胃腸炎	0	1 (0.9)	0	0
感染	2 (0.7)	0	0	0
伝染性単核症	0	1 (0.9)	0	0
インフルエンザ	4 (1.3)	2 (1.8)	1 (0.3)	0
上咽頭炎	37 (12.3)	18 (16.1)	4 (1.3)	1 (0.9)
中耳炎	1 (0.3)	2 (1.8)	0	1 (0.9)
耳下腺炎	0	1 (0.9)	0	0
咽頭炎	4 (1.3)	1 (0.9)	1 (0.3)	0
歯髄炎	2 (0.7)	0	1 (0.3)	0
鼻炎	1 (0.3)	0	0	0
副鼻腔炎	2 (0.7)	0	2 (0.7)	0
レンサ球菌性扁桃炎	1 (0.3)	0	0	0
上気道感染	9 (3.0)	5 (4.5)	5 (1.7)	1 (0.9)
ウイルス性上気道感染	2 (0.7)	0	2 (0.7)	0
外陰部腟カンジダ症	1 (0.3)	0	0	0
歯感染	2 (0.7)	0	1 (0.3)	0
四肢膿瘍	0	1 (0.9)	0	1 (0.9)
アデノイド咽頭炎	1 (0.3)	0	0	0
ウイルス性気管支炎	1 (0.3)	0	1 (0.3)	0
細菌性上気道感染	1 (0.3)	0	1 (0.3)	0
感染性腸炎	1 (0.3)	0	1 (0.3)	0
鼓膜炎	1 (0.3)	0	0	0
ウイルス性気道感染	1 (0.3)	0	0	0

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.7.2.2から引用

Kind of Significant Preferred Term	All TEAEs		TEAEs Related to Study Treatment	
	Nemolizumab (N=301) n (%)	Placebo-Nemolizumab (N=112) n (%)	Nemolizumab (N=301) n (%)	Placebo-Nemolizumab (N=112) n (%)
Non-skin Infections (Cont.)				
細菌性扁桃炎	1 (0.3)	0	0	0
細菌重複感染	4 (1.3)	1 (0.9)	1 (0.3)	0
処置後感染	1 (0.3)	0	0	0
カンジダ感染	1 (0.3)	0	1 (0.3)	0
細菌性外陰腟炎	1 (0.3)	0	1 (0.3)	0
Elevated CPK	13 (4.3)	3 (2.7)	3 (1.0)	0
血中クレアチンホスホキナーゼ増加	13 (4.3)	3 (2.7)	3 (1.0)	0

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.7.2.2から引用

表 2.7.4-51 Significant Treatment-Emergent Adverse Events by Preferred Term (Japanese)
Safety Analysis Set（pool1）

Kind of Significant Preferred Term	All TEAEs Nemolizumab -Total (N=481) n (%)	TEAEs Related to Study Treatment Nemolizumab -Total (N=481) n (%)
Significant TEAEs	381 (79.2)	182 (37.8)
TEAEs Leading to Discontinuation of Study Treatment	29 (6.0)	21 (4.4)
円形脱毛症	1 (0.2)	1 (0.2)
関節痛	1 (0.2)	1 (0.2)
膀胱癌	1 (0.2)	0
蜂巣炎	1 (0.2)	0
アトピー性皮膚炎	14 (2.9)	11 (2.3)
接触皮膚炎	1 (0.2)	1 (0.2)
剥脱性皮膚炎	1 (0.2)	1 (0.2)
丹毒	1 (0.2)	0
全身性強直性間代性発作	1 (0.2)	0
膿痂疹	1 (0.2)	0
肺腺癌第３期	1 (0.2)	0
リンパ節症	1 (0.2)	1 (0.2)
メニエール病	1 (0.2)	1 (0.2)
末梢性ニューロパチー	1 (0.2)	1 (0.2)
末梢性浮腫	2 (0.4)	2 (0.4)
視神経炎	1 (0.2)	1 (0.2)
回帰性リウマチ	1 (0.2)	0
落ち着きのなさ	1 (0.2)	1 (0.2)
洞性頻脈	1 (0.2)	0
皮膚感染	2 (0.4)	1 (0.2)
カポジ水痘様発疹	1 (0.2)	0
中毒性皮疹	4 (0.8)	4 (0.8)
節外性辺縁帯Ｂ細胞リンパ腫（ＭＡＬＴ型）	1 (0.2)	1 (0.2)
気管支反応性亢進	1 (0.2)	1 (0.2)
アトピー性角結膜炎	1 (0.2)	1 (0.2)
TEAEs Leading to Dose Interruption of Study Treatment	34 (7.1)	21 (4.4)
円形脱毛症	1 (0.2)	1 (0.2)
喘息	1 (0.2)	1 (0.2)
心房細動	1 (0.2)	0
菌血症	1 (0.2)	1 (0.2)
蜂巣炎	2 (0.4)	2 (0.4)

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.7.1.2から引用

Kind of Significant Preferred Term	All TEAEs Nemolizumab -Total (N=481) n (%)	TEAEs Related to Study Treatment Nemolizumab -Total (N=481) n (%)
TEAEs Leading to Dose Interruption of Study Treatment (Cont.)		
アトピー性皮膚炎	5 (1.0)	3 (0.6)
接触皮膚炎	1 (0.2)	0
湿疹	1 (0.2)	1 (0.2)
精巣上体炎	1 (0.2)	1 (0.2)
頭痛	1 (0.2)	0
単純ヘルペス	1 (0.2)	1 (0.2)
帯状疱疹	1 (0.2)	1 (0.2)
膿痂疹	2 (0.4)	2 (0.4)
感染	1 (0.2)	0
ムンプス	1 (0.2)	0
悪心	2 (0.4)	0
急性膵炎	1 (0.2)	0
マイコプラズマ性肺炎	1 (0.2)	1 (0.2)
発熱	1 (0.2)	0
発疹	1 (0.2)	0
全身性皮疹	1 (0.2)	1 (0.2)
上気道感染	1 (0.2)	0
嘔吐	1 (0.2)	0
喘鳴	1 (0.2)	0
上気道の炎症	2 (0.4)	2 (0.4)
カポジ水痘様発疹	2 (0.4)	2 (0.4)
中毒性皮疹	2 (0.4)	2 (0.4)
びまん性脱毛症	1 (0.2)	1 (0.2)
水痘帯状疱疹ウイルス感染	1 (0.2)	1 (0.2)
TEAEs Leading to Dose Reduction of Study Treatment	0	0
Injection-Related Reaction	32 (6.7)	27 (5.6)
腹部不快感	1 (0.2)	1 (0.2)
下腹部痛	1 (0.2)	1 (0.2)
剥脱性皮膚炎	1 (0.2)	1 (0.2)
浮動性めまい	1 (0.2)	1 (0.2)
紅斑	1 (0.2)	0
顔面浮腫	1 (0.2)	1 (0.2)
頭痛	2 (0.4)	2 (0.4)

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.7.1.2から引用

Kind of Significant Preferred Term	All TEAEs Nemolizumab -Total (N=481) n (%)	TEAEs Related to Study Treatment Nemolizumab -Total (N=481) n (%)
Injection-Related Reaction (Cont.)		
感覚鈍麻	1 (0.2)	1 (0.2)
注射部位内出血	4 (0.8)	3 (0.6)
注射部位紅斑	1 (0.2)	1 (0.2)
注射部位血腫	1 (0.2)	1 (0.2)
注射部位出血	1 (0.2)	1 (0.2)
注射部位疼痛	2 (0.4)	2 (0.4)
注射部位そう痒感	1 (0.2)	1 (0.2)
注射部位反応	7 (1.5)	7 (1.5)
倦怠感	4 (0.8)	3 (0.6)
紫斑	2 (0.4)	1 (0.2)
傾眠	2 (0.4)	2 (0.4)
注射部位腫脹	2 (0.4)	2 (0.4)
頚動脈脈拍増加	1 (0.2)	0
注射部位不快感	1 (0.2)	1 (0.2)
注射に伴う反応	1 (0.2)	0
Asthma	12 (2.5)	4 (0.8)
喘息	9 (1.9)	2 (0.4)
咳嗽	1 (0.2)	1 (0.2)
喘鳴	1 (0.2)	0
気管支反応性亢進	1 (0.2)	1 (0.2)
Worsening of AD	133 (27.7)	73 (15.2)
アトピー性皮膚炎	131 (27.2)	72 (15.0)
剥脱性皮膚炎	2 (0.4)	1 (0.2)
Skin Infections	133 (27.7)	52 (10.8)
膿疱性ざ瘡	1 (0.2)	1 (0.2)
口角口唇炎	1 (0.2)	0
体部白癬	3 (0.6)	1 (0.2)
蜂巣炎	25 (5.2)	16 (3.3)
爪の皮膚糸状菌症	1 (0.2)	0
丹毒	3 (0.6)	2 (0.4)
毛包炎	17 (3.5)	3 (0.6)
せつ	4 (0.8)	1 (0.2)
手足口病	1 (0.2)	1 (0.2)

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.7.1.2から引用

Kind of Significant Preferred Term	All TEAEs Nemolizumab -Total (N=481) n (%)	TEAEs Related to Study Treatment Nemolizumab -Total (N=481) n (%)
Skin Infections (Cont.)		
単純ヘルペス	9 (1.9)	4 (0.8)
ヘルペスウイルス感染	2 (0.4)	0
帯状疱疹	10 (2.1)	6 (1.2)
麦粒腫	2 (0.4)	1 (0.2)
膿痂疹	17 (3.5)	8 (1.7)
伝染性軟属腫	2 (0.4)	1 (0.2)
外耳炎	15 (3.1)	1 (0.2)
爪囲炎	7 (1.5)	1 (0.2)
膿疱性皮疹	1 (0.2)	0
皮膚感染	7 (1.5)	3 (0.6)
皮膚乳頭腫	8 (1.7)	4 (0.8)
足部白癬	7 (1.5)	2 (0.4)
膿痂疹性湿疹	2 (0.4)	0
カポジ水痘様発疹	11 (2.3)	6 (1.2)
皮膚細菌感染	5 (1.0)	0
マラセチア感染	2 (0.4)	0
皮膚カンジダ	1 (0.2)	1 (0.2)
癜風	2 (0.4)	1 (0.2)
白癬感染	1 (0.2)	0
男性外性器蜂巣炎	2 (0.4)	1 (0.2)
細菌性外耳炎	1 (0.2)	0
ブドウ球菌皮膚感染	2 (0.4)	0
口腔ヘルペス	7 (1.5)	2 (0.4)
感染性皮膚嚢腫	2 (0.4)	1 (0.2)
眼部単純ヘルペス	3 (0.6)	2 (0.4)
鼻ヘルペス	2 (0.4)	0
Non-skin Infections	264 (54.9)	58 (12.1)
細菌性膿瘍	1 (0.2)	0
急性副鼻腔炎	1 (0.2)	0
菌血症	2 (0.4)	2 (0.4)
気管支炎	13 (2.7)	2 (0.4)
結膜炎	9 (1.9)	4 (0.8)
膀胱炎	12 (2.5)	3 (0.6)

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.7.1.2から引用

Kind of Significant Preferred Term	All TEAEs Nemolizumab -Total (N=481) n (%)	TEAEs Related to Study Treatment Nemolizumab -Total (N=481) n (%)
Non-skin Infections (Cont.)		
サイトメガロウイルス肝炎	1 (0.2)	1 (0.2)
憩室炎	1 (0.2)	1 (0.2)
精巣上体炎	1 (0.2)	1 (0.2)
眼感染	1 (0.2)	0
食中毒	1 (0.2)	0
胃腸炎	22 (4.6)	4 (0.8)
ウイルス性胃腸炎	5 (1.0)	0
感染	7 (1.5)	3 (0.6)
伝染性単核症	1 (0.2)	0
インフルエンザ	31 (6.4)	3 (0.6)
リンパ管炎	1 (0.2)	0
ムンプス	1 (0.2)	0
上咽頭炎	160 (33.3)	16 (3.3)
中耳炎	3 (0.6)	1 (0.2)
耳下腺炎	1 (0.2)	0
歯冠周囲炎	2 (0.4)	2 (0.4)
歯周炎	2 (0.4)	0
咽頭炎	21 (4.4)	4 (0.8)
肺炎	2 (0.4)	1 (0.2)
マイコプラズマ性肺炎	1 (0.2)	1 (0.2)
歯髄炎	5 (1.0)	1 (0.2)
腎盂腎炎	1 (0.2)	1 (0.2)
鼻炎	2 (0.4)	1 (0.2)
副鼻腔炎	8 (1.7)	2 (0.4)
扁桃炎	5 (1.0)	2 (0.4)
レンサ球菌性扁桃炎	1 (0.2)	0
歯膿瘍	1 (0.2)	0
上気道感染	16 (3.3)	9 (1.9)
尿道炎	1 (0.2)	0
尿路感染	4 (0.8)	0
ウイルス感染	2 (0.4)	1 (0.2)
ウイルス性上気道感染	6 (1.2)	2 (0.4)
外陰部腟カンジダ症	1 (0.2)	0

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.7.1.2から引用

Kind of Significant Preferred Term	All TEAEs Nemolizumab -Total (N=481) n (%)	TEAEs Related to Study Treatment Nemolizumab -Total (N=481) n (%)
Non-skin Infections (Cont.)		
歯感染	4 (0.8)	1 (0.2)
四肢膿瘍	1 (0.2)	1 (0.2)
アデノイド咽頭炎	1 (0.2)	0
ウイルス性気管支炎	1 (0.2)	1 (0.2)
ヘリコバクター感染	2 (0.4)	1 (0.2)
ヘリコバクター性胃炎	2 (0.4)	0
細菌性上気道感染	1 (0.2)	1 (0.2)
ブドウ球菌感染	1 (0.2)	0
感染性腸炎	3 (0.6)	2 (0.4)
鼓膜炎	2 (0.4)	0
レンサ球菌感染	1 (0.2)	0
ウイルス性気道感染	1 (0.2)	0
外陰腟真菌感染	1 (0.2)	0
細菌性リンパ節炎	1 (0.2)	0
細菌性扁桃炎	1 (0.2)	0
細菌重複感染	5 (1.0)	2 (0.4)
処置後感染	1 (0.2)	0
ウイルス性消化管感染	1 (0.2)	0
カンジダ感染	2 (0.4)	1 (0.2)
水痘帯状疱疹ウイルス感染	1 (0.2)	1 (0.2)
咬傷感染	1 (0.2)	0
細菌性外陰腟炎	1 (0.2)	1 (0.2)
Elevated CPK	49 (10.2)	6 (1.2)
血中クレアチンホスホキナーゼ増加	47 (9.8)	6 (1.2)
筋肉痛	2 (0.4)	0

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.7.1.2から引用

表 2.7.4-52 Listing of Treatment-Emergent Adverse Events Leading to Discontinuation (including Dose Interruption and Reduction) of Study Treatment (Japanese)
Safety Analysis Set（pool1）

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(0.5mg/kgQ4W)	M	蜂巣炎	28	TREATMENT	23	RELATED	MILD	No	3	1
CIM003JG	3[redacted]									
[redacted]	ASIAN									
Nemolizumab(0.5mg/kgQ4W)	M	アトピー性皮膚炎	9	TREATMENT		RELATED	SEVERE	No	4	3
CIM003JG	4[redacted]									
[redacted]	ASIAN									
Nemolizumab(0.5mg/kgQ4W)	M	アトピー性皮膚炎	27	TREATMENT		RELATED	MODERATE	No	4	3
CIM003JG	4[redacted]	皮膚感染	27	TREATMENT	66	NOT RELATED	MODERATE	No	4	1
[redacted]	ASIAN									
Nemolizumab(0.5mg/kgQ4W)	F	帯状疱疹	166	TREATMENT	27	RELATED	MILD	No	3	1
CIM003JG	4[redacted]									
[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(0.5mg/kgQ4W)	F	上気道感染	130	TREATMENT	8	NOT RELATED	MILD	No	3	1
CIM003JG	1[redacted]									
[redacted]	WHITE									
Nemolizumab(0.5mg/kgQ4W)	F	アトピー性皮膚炎	32	TREATMENT		RELATED	MODERATE	No	4	3
CIM003JG	4[redacted]	落ち着きのなさ	32	TREATMENT	2	RELATED	MILD	No	4	1
[redacted]	WHITE									
Nemolizumab(0.5mg/kgQ4W)	M	精巣上体炎	114	TREATMENT	10	RELATED	MODERATE	No	3	1
CIM003JG	2[redacted]									
[redacted]	WHITE									
Nemolizumab(0.5mg/kgQ4W)	F	発疹	344	TREATMENT	65	NOT RELATED	MODERATE	Yes	3	1
CIM003JG	2[redacted]									
[redacted]	BLACK OR AFRICAN AMERICAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(2mg/kgQ4W)	F	丹毒	24	TREATMENT	9	NOT RELATED	MODERATE	No	4	1
CIM003JG	4[redacted]									
[redacted]	WHITE									
Nemolizumab(2mg/kgQ4W)	F	アトピー性皮膚炎	10	TREATMENT	18	NOT RELATED	SEVERE	Yes	4	1
CIM003JG	4[redacted]									
[redacted]	ASIAN									
Nemolizumab(2mg/kgQ4W)	M	アトピー性皮膚炎	59	TREATMENT	9	RELATED	SEVERE	Yes	4	1
CIM003JG	4[redacted]	皮膚感染	59	TREATMENT	9	RELATED	SEVERE	Yes	4	1
[redacted]	WHITE									
Nemolizumab(2mg/kgQ4W)	F	回帰性リウマチ	29	TREATMENT	107	NOT RELATED	MODERATE	No	4	1
CIM003JG	3[redacted]	アトピー性皮膚炎	75	TREATMENT	61	NOT RELATED	MODERATE	No	4	1
[redacted]	WHITE	リンパ節症	75	TREATMENT	61	RELATED	MODERATE	Yes	4	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(2mg/kgQ4W) CIM003JG [redacted]	F 3[redacted] WHITE	全身性皮疹	32	TREATMENT	19	RELATED	MODERATE	No	3	1
Nemolizumab(2mg/kgQ4W) CIM003JG [redacted]	M 5[redacted]	アトピー性角結膜炎	199	TREATMENT		RELATED	MODERATE	No	4	3
Nemolizumab(2mg/kgQ8W) CIM003JG [redacted]	M 4[redacted] WHITE	全身性強直性間代性発作	169	TREATMENT	8	NOT RELATED	SEVERE	Yes	4	1
Nemolizumab(2mg/kgQ8W) CIM003JG [redacted]	M 5[redacted] ASIAN	アトピー性皮膚炎	45	TREATMENT	97	NOT RELATED	MODERATE	No	4	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(2mg/kgQ8W)	M	カポジ水痘様発疹	172	TREATMENT	33	NOT RELATED	MODERATE	No	4	1
CIM003JG	2[redacted]									
[redacted]	ASIAN									
Nemolizumab(2mg/kgQ8W)	M	アトピー性皮膚炎	19	TREATMENT		RELATED	MODERATE	No	4	2
CIM003JG	5[redacted]									
[redacted]	WHITE									
Nemolizumab(2mg/kgQ8W)	M	剥脱性皮膚炎	1	TREATMENT	27	RELATED	SEVERE	Yes	4	1
CIM003JG	5[redacted]	洞性頻脈	8	TREATMENT	78	NOT RELATED	MILD	No	4	1
[redacted]	WHITE									
Nemolizumab(2mg/kgQ8W)	F	感染	18	TREATMENT	123	NOT RELATED	SEVERE	Yes	3	1
CIM003JG	2[redacted]	アトピー性皮膚炎	106	TREATMENT	35	NOT RELATED	SEVERE	Yes	3	1
[redacted]	WHITE									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(2mg/kgQ8W)	F	膿痂疹	98	TREATMENT	14	NOT RELATED	SEVERE	No	4	1
CIM003JG	2[redacted]									
[redacted]	WHITE									
Nemolizumab(60mg/body)	F	悪心	208	OPEN LABEL TREATMENT	76	NOT RELATED	MODERATE	No	3	1
M525101-01	2[redacted]	発熱	226	OPEN LABEL TREATMENT	2	NOT RELATED	MILD	No	3	1
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	F	ムンプス	299	OPEN LABEL TREATMENT	40	NOT RELATED	MODERATE	No	3	1
M525101-01	1[redacted]									
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	F	カポジ水痘様発疹	184	OPEN LABEL TREATMENT	16	RELATED	MODERATE	Yes	3	1
M525101-01	5[redacted]	菌血症	188	OPEN LABEL TREATMENT	15	RELATED	MODERATE	Yes	3	1
CA[redacted]	ASIAN	単純ヘルペス	392	OPEN LABEL TREATMENT	10	RELATED	MILD	No	3	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 6[redacted] ASIAN	末梢性浮腫	13	DOUBLE BLIND TREATMENT	66	RELATED	MODERATE	No	4	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 6[redacted] ASIAN	急性膵炎	74	DOUBLE BLIND TREATMENT	126	NOT RELATED	SEVERE	Yes	3	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 6[redacted] ASIAN	膀胱癌	194	OPEN LABEL TREATMENT	47	NOT RELATED	SEVERE	Yes	4	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	F 2[redacted] ASIAN	喘息	153	OPEN LABEL TREATMENT	45	RELATED	MILD	No	3	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.

5.3.5.3-1 Listing 5.2.4.10.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 5[redacted] ASIAN	アトピー性皮膚炎	140	OPEN LABEL TREATMENT		RELATED	MODERATE	No	3	3
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 4[redacted] ASIAN	円形脱毛症 メニエール病	42 105	DOUBLE BLIND TREATMENT DOUBLE BLIND TREATMENT		RELATED RELATED	MODERATE SEVERE	Yes Yes	4 4	3 3
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 4[redacted] ASIAN	頭痛	37	DOUBLE BLIND TREATMENT	114	NOT RELATED	MODERATE	No	3	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 2[redacted] ASIAN	円形脱毛症	162	OPEN LABEL TREATMENT	270	RELATED	MILD	No	3	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.

5.3.5.3-1 Listing 5.2.4.10.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 1[redacted] ASIAN	アトピー性皮膚炎	45	DOUBLE BLIND TREATMENT	189	RELATED	MODERATE	No	4	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 2[redacted] ASIAN	上気道の炎症	194	OPEN LABEL TREATMENT	14	RELATED	MILD	No	3	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 2[redacted] ASIAN	上気道の炎症	140	OPEN LABEL TREATMENT	26	RELATED	MILD	No	3	1
Nemolizumab(60mg/body)	M	中毒性皮疹	26	DOUBLE BLIND TREATMENT	46	RELATED	MODERATE	No	3	1
M525101-01 CA[redacted]	6[redacted] ASIAN	アトピー性皮膚炎	69	DOUBLE BLIND TREATMENT	17	RELATED	MODERATE	No	3	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	M	接触皮膚炎	106	TREATMENT	64	NOT RELATED	MODERATE	No	3	1
M525101-02	3[redacted]									
CB[redacted]	ASIAN									
Nemolizumab(60mg/body)	M	アトピー性皮膚炎	108	TREATMENT		RELATED	MODERATE	No	4	3
M525101-02	5[redacted]	蜂巣炎	179	TREATMENT	61	NOT RELATED	MODERATE	Yes	4	1
CB[redacted]	ASIAN	蜂巣炎	214	TREATMENT	26	NOT RELATED	MODERATE	No	4	1
Nemolizumab(60mg/body)	M	アトピー性皮膚炎	27	TREATMENT		RELATED	MILD	No	4	3
M525101-02	4[redacted]	中毒性皮疹	27	TREATMENT		RELATED	MILD	No	4	2
CB[redacted]	ASIAN									
Nemolizumab(60mg/body)	F	中毒性皮疹	6	TREATMENT		RELATED	MODERATE	No	4	2
M525101-02	5[redacted]	アトピー性皮膚炎	6	TREATMENT	143	RELATED	MODERATE	No	4	1
CB[redacted]	ASIAN	関節痛	36	TREATMENT		RELATED	SEVERE	No	4	3
		末梢性ニューロパチー	103	TREATMENT		RELATED	SEVERE	No	4	3
		末梢性浮腫	103	TREATMENT	46	RELATED	MODERATE	No	4	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body) M525101-02 CB[redacted]	M 5[redacted] ASIAN	アトピー性皮膚炎 中毒性皮疹	44 44	TREATMENT TREATMENT		RELATED RELATED	MILD MODERATE	No No	4 4	3 3
Nemolizumab(60mg/body) M525101-02 CB[redacted]	M 5[redacted] ASIAN	カポジ水痘様発疹	54	TREATMENT	11	RELATED	MODERATE	No	3	1
Nemolizumab(60mg/body) M525101-02 CB[redacted]	F 5[redacted] ASIAN	びまん性脱毛症	58	TREATMENT	84	RELATED	MODERATE	No	3	1
Nemolizumab(60mg/body) M525101-02 CB[redacted]	M 6[redacted] ASIAN	節外性辺縁帯Ｂ細胞リンパ腫（ＭＡＬＴ型）	246	TREATMENT		RELATED	MILD	Yes	4	3

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body) M525101-02 CB[redacted]	F 3[redacted] ASIAN	アトピー性皮膚炎	225	TREATMENT		RELATED	MODERATE	No	4	3
Nemolizumab(60mg/body) M525101-02 CB[redacted]	F 4[redacted] ASIAN	膿痂疹	173	TREATMENT	51	RELATED	MILD	No	3	1
Nemolizumab(60mg/body) M525101-02 CB[redacted]	M 3[redacted] ASIAN	視神経炎	74	TREATMENT		RELATED	SEVERE	Yes	4	3
Placebo-Nemolizumab(Placebo-0.5mg/kgQ4W) CIM003JG [redacted]	F 4[redacted] WHITE	悪心	421	TREATMENT	2	NOT RELATED	MILD	No	3	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Placebo-Nemolizumab(Placebo-0.5mg/kgQ4W)	F	アトピー性皮膚炎	124	TREATMENT	69	RELATED	SEVERE	No	3	1
CIM003JG	3[redacted]									
[redacted]	WHITE									
Placebo-Nemolizumab(Placebo-2mg/kgQ4W)	M	嘔吐	128	TREATMENT	41	NOT RELATED	MILD	No	3	1
CIM003JG	2[redacted]									
[redacted]	WHITE									
Placebo-Nemolizumab(Placebo-2mg/kgQ4W)	F	水痘帯状疱疹ウイルス感染	336	TREATMENT	11	RELATED	MODERATE	No	3	4
CIM003JG	3[redacted]									
[redacted]	BLACK OR AFRICAN AMERICAN									
Placebo-Nemolizumab(Placebo-2mg/kgQ4W)	F	気管支反応性亢進	336	TREATMENT		RELATED	MODERATE	No	4	3
CIM003JG	5[redacted]	喘鳴	336	TREATMENT	2	NOT RELATED	MODERATE	No	3	1
[redacted]	WHITE									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 4[redacted] ASIAN	湿疹	173	OPEN LABEL TREATMENT	29	RELATED	MILD	No	3	1
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 3[redacted] ASIAN	中毒性皮疹	180	OPEN LABEL TREATMENT		RELATED	MODERATE	No	4	3
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	F 3[redacted] ASIAN	中毒性皮疹	150	OPEN LABEL TREATMENT		RELATED	MODERATE	No	3	2
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	F 5[redacted] ASIAN	アトピー性皮膚炎	70	DOUBLE BLIND TREATMENT	100	NOT RELATED	MILD	No	3	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 4[redacted] ASIAN	蜂巣炎	170	OPEN LABEL TREATMENT	52	RELATED	SEVERE	Yes	3	1
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	F 3[redacted] ASIAN	マイコプラズマ性肺炎 接触皮膚炎	226 293	OPEN LABEL TREATMENT OPEN LABEL TREATMENT	55	RELATED RELATED	MILD MILD	No No	3 4	1 3
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 6[redacted] ASIAN	肺腺癌第３期	170	OPEN LABEL TREATMENT		NOT RELATED	SEVERE	Yes	4	3
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 3[redacted] ASIAN	心房細動	100	DOUBLE BLIND TREATMENT	53	NOT RELATED	MODERATE	Yes	3	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	F 4[redacted] ASIAN	膿痂疹	367	OPEN LABEL TREATMENT	90	RELATED	MILD	No	3	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.3.2から引用

表 2.7.4-53 Listing of Other Significant Treatment-Emergent Adverse Events (Injection-Related Reaction) (Japanese)

Safety Analysis Set（pool1）

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(0.5mg/kgQ4W) CIM003JG [redacted]	F 2[redacted] WHITE	注射部位血腫	58	TREATMENT	5	RELATED	MILD	No	1	1
Nemolizumab(0.5mg/kgQ4W) CIM003JG [redacted]	F 4[redacted] WHITE	紅斑	32	TREATMENT	1	NOT RELATED	MILD	No	1	1
Nemolizumab(0.5mg/kgQ4W) CIM003JG [redacted]	F 2[redacted] BLACK OR AFRICAN AMERICAN	注射部位反応	32	TREATMENT	26	RELATED	MILD	No	1	1
Nemolizumab(0.5mg/kgQ4W) CIM003JG [redacted]	F 2[redacted] WHITE	注射部位内出血	58	TREATMENT	5	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.1.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(0.5mg/kgQ4W)	F	注射部位出血	255	TREATMENT	8	RELATED	MILD	No	1	1
CIM003JG	2[redacted]									
[redacted]	BLACK OR AFRICAN AMERICAN									
Nemolizumab(2mg/kgQ4W)	F	注射部位疼痛	1	TREATMENT	1	RELATED	MILD	No	1	1
CIM003JG	2[redacted]									
[redacted]	WHITE									
Nemolizumab(2mg/kgQ4W)	F	注射部位反応	1	TREATMENT	3	RELATED	MODERATE	No	1	1
CIM003JG	5[redacted]	注射部位反応	33	TREATMENT	2	RELATED	MILD	No	1	1
[redacted]	WHITE									
Nemolizumab(2mg/kgQ8W)	F	注射部位反応	29	TREATMENT	2	RELATED	MILD	No	1	1
CIM003JG	2[redacted]									
[redacted]	WHITE									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.1.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(2mg/kgQ8W) CIM003JG [redacted]	M 2[redacted] ASIAN	注射部位反応	281	TREATMENT	4	RELATED	MILD	No	1	1
Nemolizumab(2mg/kgQ8W) CIM003JG [redacted]	M 5[redacted] WHITE	剥脱性皮膚炎	1	TREATMENT	27	RELATED	SEVERE	Yes	4	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	F 2[redacted] ASIAN	浮動性めまい	2	DOUBLE BLIND TREATMENT	2	RELATED	MILD	No	1	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	F 4[redacted] ASIAN	紫斑	394	OPEN LABEL TREATMENT	8	RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.1.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	M	注射部位腫脹	372	OPEN LABEL TREATMENT	3	RELATED	MILD	No	1	1
M525101-01	2[redacted]									
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	F	頭痛	1	DOUBLE BLIND TREATMENT	3	RELATED	MILD	No	1	1
M525101-01	1[redacted]	顔面浮腫	1	DOUBLE BLIND TREATMENT	4	RELATED	MILD	No	1	1
CA[redacted]	ASIAN	頭痛	57	DOUBLE BLIND TREATMENT	4	RELATED	MILD	No	1	1
		感覚鈍麻	57	DOUBLE BLIND TREATMENT	4	RELATED	MILD	No	1	1
Nemolizumab(60mg/body)	M	紫斑	1	DOUBLE BLIND TREATMENT	29	NOT RELATED	MILD	No	1	1
M525101-01	4[redacted]									
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	F	倦怠感	2	DOUBLE BLIND TREATMENT	3	RELATED	MILD	No	1	1
M525101-01	4[redacted]	倦怠感	29	DOUBLE BLIND TREATMENT	3	RELATED	MILD	No	1	1
CA[redacted]	ASIAN	倦怠感	87	DOUBLE BLIND TREATMENT	3	RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.1.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body) M525101-01 CA[redacted]	F 3[redacted] ASIAN	注射部位内出血	83	DOUBLE BLIND TREATMENT	28	RELATED	MILD	No	1	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	F 4[redacted] ASIAN	倦怠感	2	DOUBLE BLIND TREATMENT	2	RELATED	MILD	No	1	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 1[redacted] ASIAN	傾眠	141	OPEN LABEL TREATMENT	2	RELATED	MILD	No	1	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	F 4[redacted] ASIAN	頚動脈脈拍増加	1	DOUBLE BLIND TREATMENT	1	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.1.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 2[redacted] ASIAN	注射部位そう痒感	1	DOUBLE BLIND TREATMENT	391	RELATED	MILD	No	1	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 2[redacted] ASIAN	注射部位腫脹	253	OPEN LABEL TREATMENT	2	RELATED	MILD	No	1	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 2[redacted] ASIAN	注射部位腫脹	336	OPEN LABEL TREATMENT	2	RELATED	MILD	No	1	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 4[redacted] ASIAN	注射部位内出血	1	DOUBLE BLIND TREATMENT	15	RELATED	MILD	No	1	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 3[redacted] ASIAN	注射部位内出血	148	OPEN LABEL TREATMENT	15	RELATED	MILD	No	1	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 4[redacted] ASIAN	倦怠感	2	DOUBLE BLIND TREATMENT	4	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.1.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	M	注射部位反応	1	DOUBLE BLIND TREATMENT	1	RELATED	MILD	No	1	1
M525101-01	3[redacted]	注射部位反応	29	DOUBLE BLIND TREATMENT	1	RELATED	MILD	No	1	1
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	M	注射部位反応	1	DOUBLE BLIND TREATMENT	1	RELATED	MILD	No	1	1
M525101-01	2[redacted]	注射部位反応	29	DOUBLE BLIND TREATMENT	1	RELATED	MILD	No	1	1
CA[redacted]	ASIAN	注射部位反応	57	DOUBLE BLIND TREATMENT	1	RELATED	MILD	No	1	1
		注射部位反応	85	DOUBLE BLIND TREATMENT	1	RELATED	MILD	No	1	1
		注射部位反応	113	OPEN LABEL TREATMENT	1	RELATED	MILD	No	1	1
		注射部位反応	143	OPEN LABEL TREATMENT	1	RELATED	MILD	No	1	1
Nemolizumab(60mg/body)	F	注射部位紅斑	86	TREATMENT	8	RELATED	MILD	No	1	1
M525101-02	2[redacted]	注射部位紅斑	113	TREATMENT	8	RELATED	MILD	No	1	1
CB[redacted]	ASIAN	注射部位紅斑	141	TREATMENT	8	RELATED	MILD	No	1	1
		注射部位紅斑	169	TREATMENT	3	RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.1.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body) M525101-02 CB[redacted]	F 3[redacted] ASIAN	腹部不快感	1	TREATMENT	20	RELATED	MILD	No	1	1
		下腹部痛	2	TREATMENT	12	RELATED	MILD	No	1	1
		注射部位不快感	29	TREATMENT	2	RELATED	MILD	No	1	1
Nemolizumab(60mg/body) M525101-02 CB[redacted]	F 4[redacted] ASIAN	傾眠	1	TREATMENT	257	RELATED	MILD	No	1	1
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	F 4[redacted] ASIAN	注射部位反応	282	OPEN LABEL TREATMENT	4	RELATED	MILD	No	1	1
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 2[redacted] ASIAN	倦怠感	2	DOUBLE BLIND TREATMENT	119	RELATED	MILD	No	1	1
		頭痛	135	OPEN LABEL TREATMENT	317	RELATED	MILD	No	1	1
		倦怠感	253	OPEN LABEL TREATMENT	199	RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.1.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Placebo-Nemolizumab(Placebo-60mg/body)	F	注射に伴う反応	2	DOUBLE BLIND TREATMENT	1	NOT RELATED	MILD	No	1	1
M525101-01	3[redacted]	注射部位疼痛	282	OPEN LABEL TREATMENT	2	RELATED	MILD	No	1	1
CA[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.1.2から引用

表 2.7.4-54 Listing of Other Significant Treatment-Emergent Adverse Events (Asthma) (Japanese)

Safety Analysis Set（pool1）

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(0.5mg/kgQ4W) CIM003JG [redacted]	F 5[redacted] WHITE	咳嗽	7	TREATMENT		RELATED	MILD	No	1	3
Nemolizumab(2mg/kgQ4W) CIM003JG [redacted]	M 2[redacted] WHITE	喘息	267	TREATMENT	22	NOT RELATED	MILD	No	1	1
Nemolizumab(2mg/kgQ8W) CIM003JG [redacted]	F 2[redacted] BLACK OR AFRICAN AMERICAN	喘鳴	242	TREATMENT		NOT RELATED	MILD	No	1	3
Nemolizumab(60mg/body) M525101-01 CA[redacted]	F 2[redacted] ASIAN	喘息	377	OPEN LABEL TREATMENT	57	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.2.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 4[redacted] ASIAN	喘息	179	OPEN LABEL TREATMENT	164	NOT RELATED	MILD	No	1	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	F 4[redacted] ASIAN	喘息	369	OPEN LABEL TREATMENT	25	NOT RELATED	MILD	No	1	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	F 2[redacted] ASIAN	喘息 喘息	153 372	OPEN LABEL TREATMENT OPEN LABEL TREATMENT	45 29	RELATED RELATED	MILD MODERATE	No No	3 1	1 1
Nemolizumab(60mg/body) M525101-02 CB[redacted]	M 5[redacted] ASIAN	喘息	183	TREATMENT		NOT RELATED	MILD	No	1	2

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.2.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body) M525101-02 CB[redacted]	F 3[redacted] ASIAN	喘息	12	TREATMENT	403	NOT RELATED	MODERATE	No	1	1
Placebo-Nemolizumab(Placebo-0.5mg/kgQ4W) CIM003JG [redacted]	F 4[redacted] ASIAN	喘息	167	TREATMENT		NOT RELATED	MILD	No	1	3
Placebo-Nemolizumab(Placebo-2mg/kgQ4W) CIM003JG [redacted]	F 5[redacted] WHITE	気管支反応性亢進	336	TREATMENT		RELATED	MODERATE	No	4	3
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 4[redacted] ASIAN	喘息	238	OPEN LABEL TREATMENT	111	RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.2.2から引用

表 2.7.4-55 Listing of Other Significant Treatment-Emergent Adverse Events (Worsening of AD) (Japanese)
Safety Analysis Set（pool1）

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Nemolizumab(0.5mg/kgQ4W) CIM003JG [redacted]	F 5[redacted] WHITE	アトピー性皮膚炎	127	SAFETY-FU	3	NOT RELATED	MODERATE	Yes	5	1	
Nemolizumab(0.5mg/kgQ4W) CIM003JG [redacted]	M 4[redacted] ASIAN	アトピー性皮膚炎	9	TREATMENT		RELATED	SEVERE	No	4	3	1 DISEASE UNDER STUDY: NOT APPLICABLE, 2 PAST/CONCURRENT ILLNESS: NOT APPLICABLE, 3 PREVIOUS/CONCOMITANT MEDICATIONS: : NOT APPLICABLE, THERE IS NO SUSPECTED CAUSAL FACTORS OTHER THAN THE ADMINISTRATION OF IP. THEREFORE, IP WOULD BE RELATED TO EXACERBATION OF ATOPIC DERMATITIS.
Nemolizumab(0.5mg/kgQ4W) CIM003JG [redacted]	M 4[redacted] ASIAN	アトピー性皮膚炎	27	TREATMENT		RELATED	MODERATE	No	4	3	WASHOUT OF MEDICINES FOR AD THERAPY BEFORE RANDOMIZATION IS LIKELY TO BE CAUSATIVE.

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Nemolizumab(0.5mg/kgQ4W) CIM003JG [redacted]	M 2 OTHER	アトピー性皮膚炎	72	TREATMENT	12	NOT RELATED	MODERATE	No	1	1	
Nemolizumab(0.5mg/kgQ4W) CIM003JG [redacted]	F 3 WHITE	アトピー性皮膚炎	34	TREATMENT	15	NOT RELATED	MILD	No	1	1	
Nemolizumab(0.5mg/kgQ4W) CIM003JG [redacted]	F 1 WHITE	アトピー性皮膚炎	91	TREATMENT	3	NOT RELATED	MILD	No	1	1	
		アトピー性皮膚炎	224	TREATMENT	1	NOT RELATED	MILD	No	1	1	

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Nemolizumab(0.5mg/kgQ4W) CIM003JG [redacted]	M 2[redacted] WHITE	アトピー性皮膚炎	450	TREATMENT	39	NOT RELATED	MODERATE	No	5	1	
Nemolizumab(0.5mg/kgQ4W) CIM003JG [redacted]	F 2[redacted] WHITE	アトピー性皮膚炎	9	TREATMENT	4	NOT RELATED	MILD	No	1	1	PATIENT REPORTED A RASH ON NECKLINE THAT DISAPPERAED ON IT'S OWN
Nemolizumab(0.5mg/kgQ4W) CIM003JG [redacted]	F 4[redacted] WHITE	アトピー性皮膚炎 アトピー性皮膚炎	2 32	TREATMENT TREATMENT	6	NOT RELATED RELATED	MILD MODERATE	No No	1 4	1 3	REFERS TO THE SKIN OF THE NECK, FACE AND D COLLETAGE INCLUDING HEAD, NECK, TORSO AND LIMBS. SEVERE DRYNESS DESPITE GREASING SUSPECTED CAUSES: 1 - NO 2 - NO 3 - NO

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Nemolizumab(0.5mg/kgQ4W) CIM003JG [redacted]	F 2[redacted] WHITE	アトピー性皮膚炎	38	TREATMENT	51	NOT RELATED	MODERATE	No	1	1	EXACERBATION OF SKIN INFLAMMATION PROCESS
Nemolizumab(0.5mg/kgQ4W) CIM003JG [redacted]	F 2[redacted] WHITE	アトピー性皮膚炎	31	TREATMENT	83	RELATED	MILD	No	1	1	INFILTRATION OF SEROUS FLUID ON THE BACK. AE IS RELATED TO AD BUT IT IS NOT A NATURAL COURSE OF THE DISEASE.
Nemolizumab(0.5mg/kgQ4W)	M	アトピー性皮膚炎	15	TREATMENT	16	NOT RELATED	MILD	No	1	1	EVENT IS RELATED TO WORSENING OF ATOPIC DERMATITIS PER INVESTIGATOR
CIM003JG [redacted]	5[redacted] WHITE	アトピー性皮膚炎	178	TREATMENT	38	NOT RELATED	MILD	No	1	1	AREA OF IMPETIGINIZED ECZEMA IS NOT IN IP ADMINISTRATION LOCATION. IP ADMINISTERED IN ABDOMEN. AE AREA IS RIGHT ANTERIOR UPPER THIGH.

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Nemolizumab(0.5mg/kgQ4W) CIM003JG [redacted]	M 2[redacted] BLACK OR AFRICAN AMERICAN	アトピー性皮膚炎	85	TREATMENT		NOT RELATED	MODERATE	No	1	3	
Nemolizumab(2mg/kgQ4W) CIM003JG [redacted]	F 2[redacted] WHITE	アトピー性皮膚炎	341	TREATMENT		RELATED	MODERATE	No	1	3	
Nemolizumab(2mg/kgQ4W) CIM003JG [redacted]	M 3[redacted] WHITE	アトピー性皮膚炎 アトピー性皮膚炎	34 88	TREATMENT TREATMENT	42 21	NOT RELATED RELATED	SEVERE SEVERE	No No	1 1	1 1	

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Nemolizumab(2mg/kgQ4W) CIM003JG [redacted]	M 4[redacted] ASIAN	アトピー性皮膚炎	14	TREATMENT	50	NOT RELATED	MODERATE	No	1	1	
Nemolizumab(2mg/kgQ4W) CIM003JG [redacted]	F 4[redacted] ASIAN	アトピー性皮膚炎	10	TREATMENT	18	NOT RELATED	SEVERE	Yes	4	1	WASHOUT OF MEDICINES RELATED AD THERAPY BEFORE RANDOMIZATION IS RELATED TO THE EVENT.
Nemolizumab(2mg/kgQ4W) CIM003JG [redacted]	M 3[redacted] ASIAN	アトピー性皮膚炎	55	TREATMENT	31	NOT RELATED	MODERATE	No	1	1	

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Nemolizumab(2mg/kgQ4W)	M	アトピー性皮膚炎	17	TREATMENT	12	NOT RELATED	SEVERE	No	1	1	
CIM003JG	2[redacted]	アトピー性皮膚炎	35	TREATMENT	107	RELATED	SEVERE	No	1	1	
[redacted]	ASIAN										

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Nemolizumab(2mg/kgQ4W)	M	アトピー性皮膚炎	59	TREATMENT	9	RELATED	SEVERE	Yes	4	1	*Day 63 PATIENT CAME TO THE SITE BECAUSE OF THE SIGNIFICANT DETERIORATION OF SKIN CONDITION, SHIVERS AND INCREASED BODY TEMPERATURE (37,8 C). ABOVE-MENTIONED SYMPTOMS HAS BEEN REMAINING FOR FOURDAYS (*Day 59). ON *Day 62 THE PATIENT WAS CONSULTED BY GP WHO PRESCRIBED THE PATIENT DALACIN C (CLINDAMYCINUM). DURING TODAY S VISIT AT THE SITE PI PERFORMED PHYSICAL EXAMINATION THERE WERE NO ABNORMALITIES DETECTED EXCEPT FOR SKIN MODIFICATIONS. AFTER PERFORMING DERMATOLOGICAL EXAMINATION, GENERALIZED INFLAMMATION OF THE SKIN HAS BEEN STATED WITH FEATURES OF BACTERIAL SUPERINFECTION (EXUDATION, YELLOW SCABS). THE PATIENT HAS BEEN URGENTLY DIRECTED TO THE DERMATOLOGICAL HOSPITAL ON ACCOUNT OF ERYTHRODERMA APPEARANCE. ON *Day 63 PATIENT STARTED HOSPITALIZATION. PATIENT DISCHARGED FROM HOSPITAL *Day 67 .
CIM003JG [redacted]	4[redacted] WHITE										

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Nemolizumab(2mg/kgQ4W) CIM003JG [redacted]	F 2[redacted] WHITE	アトピー性皮膚炎	43	TREATMENT	15	NOT RELATED	MODERATE	No	1	1	
Nemolizumab(2mg/kgQ4W) CIM003JG [redacted]	F 2[redacted] WHITE	アトピー性皮膚炎	76	TREATMENT	43	NOT RELATED	MODERATE	No	1	1	
Nemolizumab(2mg/kgQ4W) CIM003JG [redacted]	F 3[redacted] WHITE	アトピー性皮膚炎	75	TREATMENT	61	NOT RELATED	MODERATE	No	4	1	REASON OF AE IS UNKNOWN

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Nemolizumab(2mg/kgQ4W) CIM003JG [redacted]	M 2[redacted] WHITE	アトピー性皮膚炎	65	TREATMENT	13	RELATED	MILD	No	1	1	
Nemolizumab(2mg/kgQ4W) CIM003JG [redacted]	M 6[redacted] WHITE	アトピー性皮膚炎	378	TREATMENT	23	NOT RELATED	MODERATE	No	1	1	
Nemolizumab(2mg/kgQ4W) CIM003JG [redacted]	F 2[redacted] WHITE	アトピー性皮膚炎	50	TREATMENT	100	RELATED	MILD	No	1	1	IT IS CONNECTED WITH AD BUT IT IS NOT A NORMAL COURSE OF THE DISEASE.

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Nemolizumab(2mg/kgQ4W) CIM003JG [redacted]	M 2[redacted] WHITE	アトピー性皮膚炎	238	TREATMENT	23	NOT RELATED	MILD	No	1	1	
Nemolizumab(2mg/kgQ8W) CIM003JG [redacted]	M 1[redacted] WHITE	アトピー性皮膚炎	52	TREATMENT	17	NOT RELATED	MODERATE	No	1	1	
Nemolizumab(2mg/kgQ8W) CIM003JG [redacted]	M 2[redacted] WHITE	アトピー性皮膚炎	43	TREATMENT		RELATED	MODERATE	No	1	3	

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Nemolizumab(2mg/kgQ8W) CIM003JG [redacted]	M 5[redacted] ASIAN	アトピー性皮膚炎	45	TREATMENT	97	NOT RELATED	MODERATE	No	4	1	THE SUSPECTED CAUSES IS NOTHING.
Nemolizumab(2mg/kgQ8W) CIM003JG [redacted]	F 3[redacted] ASIAN	アトピー性皮膚炎	17 43	TREATMENT TREATMENT	6	NOT RELATED NOT RELATED	MODERATE MODERATE	No No	1 1	1 3	FOLLOW UP IS UNNECESSARY. THIS EVENT IS NOT RELATED TO STUDY DRUG.
Nemolizumab(2mg/kgQ8W) CIM003JG [redacted]	M 5[redacted] WHITE	アトピー性皮膚炎	19	TREATMENT		RELATED	MODERATE	No	4	2	DISCONTINUATION OF THE STUDY WAS PROVOCED NEW SKIN LESIONS OF DISEASE UNDER STUDY

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Nemolizumab(2mg/kgQ8W) CIM003JG [redacted]	F 2[redacted] WHITE	アトピー性皮膚炎	16	TREATMENT		NOT RELATED	MODERATE	No	1	2	
Nemolizumab(2mg/kgQ8W) CIM003JG [redacted]	M 2[redacted] WHITE	アトピー性皮膚炎	5	TREATMENT	2	NOT RELATED	MILD	No	1	1	SEVERE ERYTHEMA OF THE SKIN ON WHOLE BODY. ONE DAY LATER ERYTHEMA DISAPPEARED AE TERM RELATES TO UNANTICIPATED SYMPTOMS/ DETERIORATION OF ATOPIC DERMATITIS
Nemolizumab(2mg/kgQ8W) CIM003JG [redacted]	M 2[redacted] WHITE	アトピー性皮膚炎	77	SAFETY-FU	5	NOT RELATED	MODERATE	Yes	5	1	

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Nemolizumab(2mg/kgQ8W)	F	アトピー性皮膚炎	66	TREATMENT	154	RELATED	MODERATE	No	1	1	
CIM003JG [redacted]	4[redacted] WHITE	アトピー性皮膚炎	246	TREATMENT	32	NOT RELATED	MODERATE	No	5	1	
Nemolizumab(2mg/kgQ8W)	F	アトピー性皮膚炎	16	TREATMENT	16	NOT RELATED	MODERATE	No	1	1	SUBJECT REPORTED AT VISIT 6 THAT SHE RECENTLY WENT TO URGENT CARE FOR A SKIN FLARE - UP. A METHYLPREDNISOLONE INJECTION WAS GIVEN IN CLINIC AND ALSO A WEEK OF ORAL METHYLPREDNISOLONE WAS PRESCRIBED.
CIM003JG [redacted]	3[redacted] WHITE										
Nemolizumab(2mg/kgQ8W)	F	アトピー性皮膚炎	106	TREATMENT	35	NOT RELATED	SEVERE	Yes	3	1	SUBJECT WENT INTO THE HOSPITAL ON [redacted]/[redacted]/[redacted] DUE TO WORSENING ATOPIC DERMATITIS
CIM003JG [redacted]	2[redacted] WHITE										

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment / Study No / Subject ID	Sex / Age (years) / Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Nemolizumab(60 mg/body)	M	アトピー性皮膚炎	33	DOUBLE BLIND TREATMENT	79	NOT RELATED	MILD	No	1	1	上気道炎に引き続きアトピー性皮膚炎が悪化した可能性がある。
M525101-01	1[redacted]	アトピー性皮膚炎	228	OPEN LABEL TREATMENT	103	NOT RELATED	MILD	No	1	1	アトピー性皮膚炎の悪化要因(サッカー)があったため治験薬との因果関係は否定した。
CA[redacted]	ASIAN										
Nemolizumab(60 mg/body)	F	アトピー性皮膚炎	87	DOUBLE BLIND TREATMENT	29	RELATED	MODERATE	No	1	1	
M525101-01	2[redacted]										
CA[redacted]	ASIAN										

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Nemolizumab(60 mg/body)	F	アトピー性皮膚炎	51	DOUBLE BLIND TREATMENT	36	RELATED	MODERATE	No	1	1	皮疹の拡大又は新生：あり、紅斑や丘疹の新生：あり、浸潤性紅斑または浮腫性紅斑の新生あるいは増加：あり、皮疹部の浸出液の増大：なし、皮疹部の落屑の増悪：なし、非皮疹部のける乾燥の増大：なし、治験参加前直近1年に実施していたおもなAD治療：全身性ステロイド薬、StrongestクラスのTCS、Very StrongクラスのTCS、Strongクラス以下のTCS、保湿・保護剤、検査結果：なし
M525101-01	2[redacted]	アトピー性皮膚炎	98	DOUBLE BLIND TREATMENT	74	RELATED	MODERATE	No	1	1	皮疹の拡大又は新生：あり、紅斑や丘疹の新生：あり、浸潤性紅斑または浮腫性紅斑の新生あるいは増加：あり、皮疹部の浸出液の増大：なし、皮疹部の落屑の増悪：なし、非皮疹部のける乾燥の増大：なし、治験参加前直近1年に実施していたおもなAD治療：全身性ステロイド薬、StrongestクラスのTCS、Very StrongクラスのTCS、Strongクラス以下のTCS、保湿・保護剤、検査結果：なしAE No.1のAD悪化と同様の症状が発現した。尚、AE No.1はこれまで出現のなかった部位に紅斑や丘疹の新生があり、面積が広がった
CA[redacted]	ASIAN										

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Nemolizumab(60 mg/body) M525101-01 CA[redacted]	F 2[redacted] ASIAN	アトピー性皮膚炎	141	OPEN LABEL TREATMENT	57	RELATED	MILD	No	1	1	
Nemolizumab(60 mg/body) M525101-01 CA[redacted]	F 3[redacted] ASIAN	アトピー性皮膚炎	98	DOUBLE BLIND TREATMENT	16	NOT RELATED	MODERATE	No	1	1	不安定で急な気候の変化によるものと考えられる
		アトピー性皮膚炎	121	OPEN LABEL TREATMENT	28	NOT RELATED	MILD	No	1	1	季節による増悪
Nemolizumab(60 mg/body) M525101-01 CA[redacted]	F 5[redacted] ASIAN	アトピー性皮膚炎	202	OPEN LABEL TREATMENT		NOT RELATED	MILD	No	1	3	治験開始前より同様の悪化はみられたから

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Nemolizumab(60 mg/body) M525101-01 CA[redacted]	M 5[redacted] ASIAN	アトピー性皮膚炎	260	OPEN LABEL TREATMENT	85	NOT RELATED	MILD	No	1	1	尋常性疣贅の多発に伴い、外用を中止したため、悪化した。
Nemolizumab(60 mg/body) M525101-01 CA[redacted]	F 4[redacted] ASIAN	アトピー性皮膚炎	17	DOUBLE BLIND TREATMENT	39	RELATED	MILD	No	1	1	
Nemolizumab(60 mg/body) M525101-01 CA[redacted]	F 3[redacted] ASIAN	アトピー性皮膚炎	179	OPEN LABEL TREATMENT	40	NOT RELATED	MILD	No	1	1	治験薬投与開始以前より前様の皮疹を繰り返している為。

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Nemolizumab(60 mg/body)	M	アトピー性皮膚炎	15	DOUBLE BLIND TREATMENT	99	RELATED	MILD	No	1	1	
M525101-01	2[redacted]	アトピー性皮膚炎	337	OPEN LABEL TREATMENT	85	RELATED	MILD	No	1	1	
CA[redacted]	ASIAN										
Nemolizumab(60 mg/body)	F	アトピー性皮膚炎	30	DOUBLE BLIND TREATMENT	195	RELATED	MILD	No	1	1	顔、四肢、体幹の紅色丘疹の増加
M525101-01	1[redacted]										
CA[redacted]	ASIAN										
Nemolizumab(60 mg/body)	F	アトピー性皮膚炎	2	DOUBLE BLIND TREATMENT	448	RELATED	MILD	No	1	1	
M525101-01	3[redacted]	アトピー性皮膚炎	71	DOUBLE BLIND TREATMENT	352	RELATED	MODERATE	No	1	1	
CA[redacted]	ASIAN										

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Nemolizumab(60 mg/body)	F	アトピー性皮膚炎	34	DOUBLE BLIND TREATMENT	37	RELATED	MODERATE	No	1	1	
M525101-01	4[redacted]	アトピー性皮膚炎	169	OPEN LABEL TREATMENT	365	RELATED	MILD	No	1	1	
CA[redacted]	ASIAN	アトピー性皮膚炎	267	OPEN LABEL TREATMENT	267	RELATED	MILD	No	1	1	
Nemolizumab(60 mg/body)	M	アトピー性皮膚炎	17	DOUBLE BLIND TREATMENT		NOT RELATED	MODERATE	No	1	3	治験wash outの影響による(PartA終了時）転帰は未回復だが今後の診療にてフォローを続けるため治験での追跡は終了する（最終確認時）
M525101-01 CA[redacted]	6[redacted] ASIAN										
Nemolizumab(60 mg/body)	M	アトピー性皮膚炎	58	DOUBLE BLIND TREATMENT	56	RELATED	MODERATE	No	1	1	
M525101-01 CA[redacted]	4[redacted] ASIAN										

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Nemolizumab(60 mg/body) M525101-01 CA[redacted]	M 4[redacted] ASIAN	アトピー性皮膚炎	14	DOUBLE BLIND TREATMENT	101	RELATED	MODERATE	No	1	1	
Nemolizumab(60 mg/body) M525101-01 CA[redacted]	M 4[redacted] ASIAN	アトピー性皮膚炎	29	DOUBLE BLIND TREATMENT	85	NOT RELATED	SEVERE	No	1	1	元々のアトピー症状が日常生活を契機に増悪している（連日の暑さにより汗などの刺激など）
Nemolizumab(60 mg/body) M525101-01 CA[redacted]	M 2[redacted] ASIAN	アトピー性皮膚炎	55	DOUBLE BLIND TREATMENT	142	RELATED	MILD	No	1	1	

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment / Study No / Subject ID	Sex / Age (years) / Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Nemolizumab(60 mg/body)	M	アトピー性皮膚炎	12	DOUBLE BLIND TREATMENT	74	NOT RELATED	MILD	No	1	1	冬期乾燥などの環境変化による原疾患の悪化であると考えられるため
M525101-01	4[redacted]	アトピー性皮膚炎	12	DOUBLE BLIND TREATMENT	74	NOT RELATED	MILD	No	1	1	冬期乾燥などの環境変化による原疾患の悪化であると考えられる
CA[redacted]	ASIAN										
Nemolizumab(60 mg/body)	F	アトピー性皮膚炎	57	DOUBLE BLIND TREATMENT	253	NOT RELATED	MODERATE	No	1	1	投与回数を重ねた後出現しているため治験中のADに対する治療制限の影響が考えられ治験薬による事象の助長はないため
M525101-01	4[redacted]										
CA[redacted]	ASIAN										
Nemolizumab(60 mg/body)	M	アトピー性皮膚炎	57	DOUBLE BLIND TREATMENT	148	NOT RELATED	MILD	No	1	1	投与回数を重ねた後発現したため。新しい整髪剤の使用後であったため。
M525101-01	4[redacted]	アトピー性皮膚炎	68	DOUBLE BLIND TREATMENT	137	RELATED	MILD	No	1	1	
CA[redacted]	ASIAN										

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Nemolizumab(60 mg/body) M525101-01 CA[redacted]	M 5[redacted] ASIAN	アトピー性皮膚炎	140	OPEN LABEL TREATMENT		RELATED	MODERATE	No	3	3	
Nemolizumab(60 mg/body) M525101-01 CA[redacted]	M 2[redacted] ASIAN	アトピー性皮膚炎	15	DOUBLE BLIND TREATMENT	99	RELATED	MODERATE	No	1	1	症状の特徴が変化。点状の丘疹が多発。

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Nemolizumab(60 mg/body)	M	アトピー性皮膚炎	83	DOUBLE BLIND TREATMENT		NOT RELATED	MILD	No	1	2	AE＃3、皮疹の拡大又は新生：なし、これまで紅斑や丘疹のない部位における紅斑や丘疹の新生：該当せず、紅斑（湿潤性/浮腫性）の新生あるいは増加：なし、浸出液の増大：なし、落屑の増悪：あり、乾燥の増悪：なし、治験参加前の直近1年に実施していた主なAD治療：Strongクラス以下のTCS、保湿・保護剤、検査結果：なし因果関係が「否定できる」理由：投与から時間を経過して発現しており、投与時との因果関係がはっきりしないため
M525101-01 CA[redacted]	4[redacted] ASIAN										

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Nemolizumab(60 mg/body)	M	アトピー性皮膚炎	20	DOUBLE BLIND TREATMENT	171	RELATED	MODERATE	No	1	1	因果関係は否定できないが、投与継続により、痒み、皮疹が今後改善する可能性もあるために本人と相談して継続することにした。アトピー性皮膚炎は病勢に合った治療継続中においても、増悪することはよくみられるが、今回の皮疹悪化に関しては、他に誘因はなく、本剤による影響も悪化の一因として否定できないと考えられる。
M525101-01 CA[redacted]	2[redacted] ASIAN										

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Nemolizumab(60 mg/body) M525101-01 CA[redacted]	M 1[redacted] ASIAN	アトピー性皮膚炎	31	DOUBLE BLIND TREATMENT	27	NOT RELATED	MODERATE	No	1	1	掻痒が著明に軽減したため外用剤の塗布量が減った。結果、塗布量が不足したためADの悪化を認めた。治験薬2/15リチャレンジ後再発なし。

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Nemolizumab(60 mg/body)	M	アトピー性皮膚炎	16	DOUBLE BLIND TREATMENT	133	RELATED	MILD	No	1	1	プレドニン眼軟膏処方AE#2　皮疹の拡大又は新生：あり、これまで紅斑や丘疹のない部位における紅斑や丘疹の新生：あり、紅斑（浸潤性/浮腫性）の新生あるいは増加：あり、浸出液の増大：なし、落屑の増悪：なし、乾燥の増悪：なし、治験参加前の直近１年に実施していた主なAD治療：Strongクラス以下のTCS、TCI、保湿・保護剤、検査結果：なし
M525101-01 CA[redacted]	2[redacted] ASIAN										

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Nemolizumab(60 mg/body)	M	アトピー性皮膚炎	14	DOUBLE BLIND TREATMENT	44	RELATED	MILD	No	1	1	マイザー軟膏処方AE#3　皮疹の拡大又は新生：あり、これまで紅斑や丘疹のない部位における紅斑や丘疹の新生：あり、紅斑（浸潤性/浮腫性）の新生あるいは増加：あり、浸出液の増大：なし、落屑の増悪：なし、乾燥の増悪：なし、治験参加前の直近１年に実施していた主なAD治療：Very StrongクラスのTCS、保湿・保護剤、検査結果：なし
M525101-01	4[redacted]	アトピー性皮膚炎	88	FOLLOW-UP	12	RELATED	MILD	No	5	1	リンデロンＶＧ軟膏処方AE#4　皮疹の拡大又は新生：あり、これまで紅斑や丘疹のない部位における紅斑や丘疹の新生：あり、紅斑（浸潤性/浮腫性）の新生あるいは増加：あり、浸出液の増大：なし、落層の増悪：なし、乾燥の増悪：なし、治験参加前の直近１年に実施していた主なAD治療：Very StrongクラスのTCS、保湿・保護剤、検査結果：なし
CA[redacted]	ASIAN										

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Nemolizumab(60 mg/body)	M	アトピー性皮膚炎	309	OPEN LABEL TREATMENT	92	RELATED	MILD	No	1	1	AE#4 皮疹の拡大又は新生：あり、これまで紅斑や丘疹のない部位における紅斑や丘疹の新生：あり、紅斑（浸潤性/浮腫性）の新生あるいは増加：あり、浸出液の増大：なし、落屑の増悪：なし、乾燥の増悪：なし、治験参加前の直近１年に実施していた主なAD治療：Very StrongクラスのTCS、Strongクラス以下のTCS、保湿・保護剤、検査結果：なし
M525101-01 CA[redacted]	2[redacted] ASIAN										

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Nemolizumab(60 mg/body) M525101-01 CA[redacted]	F 4[redacted] ASIAN	アトピー性皮膚炎	7	DOUBLE BLIND TREATMENT	135	RELATED	MILD	No	1	1	
Nemolizumab(60 mg/body) M525101-01 CA[redacted]	M 2[redacted] ASIAN	アトピー性皮膚炎	57 204 308	DOUBLE BLIND TREATMENT OPEN LABEL TREATMENT OPEN LABEL TREATMENT	231 22 64	RELATED RELATED RELATED	MODERATE MODERATE MODERATE	No No No	1 1 1	1 1 1	
Nemolizumab(60 mg/body) M525101-01 CA[redacted]	M 5[redacted] ASIAN	アトピー性皮膚炎	37 267 503	DOUBLE BLIND TREATMENT OPEN LABEL TREATMENT FOLLOW-UP	218 71	RELATED RELATED NOT RELATED	MODERATE MILD MILD	No No No	1 1 5	1 1 3	治験薬の投与中止約8週頃から出現、増強しており治験薬投与による変化ではない。しかし治験薬の投与初期にみられていた紅斑と同様であり、治験薬の投与中止によって誘発された症状であることは否定できない。

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Nemolizumab(60 mg/body)	F	アトピー性皮膚炎	29	DOUBLE BLIND TREATMENT	281	RELATED	MILD	No	1	1	治験薬投与4週間目頃に、それまでみられていなかった程度・範囲である頭皮・顔面の皮膚炎の増強・新生がみられた。
M525101-01 CA[redacted]	3[redacted] ASIAN	アトピー性皮膚炎	85	DOUBLE BLIND TREATMENT	225	RELATED	MILD	No	1	1	
Nemolizumab(60 mg/body)	M	アトピー性皮膚炎	45	DOUBLE BLIND TREATMENT	189	RELATED	MODERATE	No	4	1	
M525101-01 CA[redacted]	1[redacted] ASIAN	アトピー性皮膚炎	163	OPEN LABEL TREATMENT		RELATED	MILD	No	1	3	
Nemolizumab(60 mg/body)	M	アトピー性皮膚炎	57	DOUBLE BLIND TREATMENT	111	RELATED	MODERATE	No	1	1	
M525101-01 CA[redacted]	2[redacted] ASIAN										

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Nemolizumab(60 mg/body) M525101-01 CA[redacted]	M 3[redacted] ASIAN	アトピー性皮膚炎	29	DOUBLE BLIND TREATMENT	512	RELATED	MILD	No	1	1	
Nemolizumab(60 mg/body) M525101-01 CA[redacted]	M 1[redacted] ASIAN	アトピー性皮膚炎	198	OPEN LABEL TREATMENT	168	NOT RELATED	MODERATE	No	1	1	感染性腸炎と同時期の悪化で、感染に伴う悪化や体調不良に伴う外用不足が原因と考えられるため
Nemolizumab(60 mg/body) M525101-01 CA[redacted]	M 4[redacted] ASIAN	アトピー性皮膚炎	15	DOUBLE BLIND TREATMENT	68	RELATED	MILD	No	1	1	

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment / Study No / Subject ID	Sex / Age (years) / Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Nemolizumab(60 mg/body)	F	剥脱性皮膚炎	13	DOUBLE BLIND TREATMENT	13	NOT RELATED	MODERATE	No	1	1	インフルエンザ罹患後に悪化した。
M525101-01	4[redacted]										
CA[redacted]	ASIAN										
Nemolizumab(60 mg/body)	M	アトピー性皮膚炎	91	DOUBLE BLIND TREATMENT	443	RELATED	MILD	No	1	1	
M525101-01	2[redacted]										
CA[redacted]	ASIAN										
Nemolizumab(60 mg/body)	M	アトピー性皮膚炎	69	DOUBLE BLIND TREATMENT	17	RELATED	MODERATE	No	3	1	
M525101-01	6[redacted]										
CA[redacted]	ASIAN										

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Nemolizumab(60 mg/body) M525101-02 CB[redacted]	M 1[redacted] ASIAN	アトピー性皮膚炎	148	TREATMENT	22	RELATED	MILD	No	1	1	
Nemolizumab(60 mg/body) M525101-02 CB[redacted]	F 1[redacted] ASIAN	アトピー性皮膚炎	28	TREATMENT	8	RELATED	MODERATE	No	1	1	
Nemolizumab(60 mg/body) M525101-02 CB[redacted]	M 2[redacted] ASIAN	アトピー性皮膚炎	140	TREATMENT	57	RELATED	MODERATE	No	1	1	

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Nemolizumab(60 mg/body) M525101-02 CB[redacted]	M 4[redacted] ASIAN	アトピー性皮膚炎	141	TREATMENT	36	RELATED	MILD	No	1	1	
Nemolizumab(60 mg/body) M525101-02 CB[redacted]	M 5[redacted] ASIAN	アトピー性皮膚炎	108	TREATMENT		RELATED	MODERATE	No	4	3	
Nemolizumab(60 mg/body) M525101-02 CB[redacted]	M 4[redacted] ASIAN	アトピー性皮膚炎	27	TREATMENT		RELATED	MILD	No	4	3	

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Nemolizumab(60 mg/body) M525101-02 CB[redacted]	F 5[redacted] ASIAN	アトピー性皮膚炎	6	TREATMENT	143	RELATED	MODERATE	No	4	1	
Nemolizumab(60 mg/body) M525101-02 CB[redacted]	M 3[redacted] ASIAN	アトピー性皮膚炎	27	TREATMENT	58	RELATED	MODERATE	No	1	1	
Nemolizumab(60 mg/body) M525101-02 CB[redacted]	F 4[redacted] ASIAN	アトピー性皮膚炎	50	TREATMENT	35	RELATED	MILD	No	1	1	

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Nemolizumab(60 mg/body) M525101-02 CB[redacted]	M 5[redacted] ASIAN	アトピー性皮膚炎	44	TREATMENT		RELATED	MILD	No	4	3	
Nemolizumab(60 mg/body) M525101-02 CB[redacted]	M 5[redacted] ASIAN	アトピー性皮膚炎	196	TREATMENT	30	RELATED	MODERATE	No	1	1	
Nemolizumab(60 mg/body) M525101-02 CB[redacted]	F 5[redacted] ASIAN	アトピー性皮膚炎	43	TREATMENT	99	RELATED	MODERATE	No	1	1	
Nemolizumab(60 mg/body) M525101-02 CB[redacted]	M 5[redacted] ASIAN	アトピー性皮膚炎	162	TREATMENT		NOT RELATED	MILD	No	1	3	投与終了後も症状に変化が認められなかったため

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Nemolizumab(60 mg/body) M525101-02 CB[redacted]	M 4[redacted] ASIAN	アトピー性皮膚炎	113	TREATMENT		RELATED	MODERATE	No	1	3	20[redacted].[redacted].[redacted]から背部にも発現
Nemolizumab(60 mg/body) M525101-02 CB[redacted]	F 3[redacted] ASIAN	アトピー性皮膚炎	225	TREATMENT		RELATED	MODERATE	No	4	3	a、b、cに該当。「発現要因を治験薬以外で特定できない、境界明瞭な浮腫性の紅斑に類する所見を伴う有害事象」への該当の有無：なし
Nemolizumab(60 mg/body) M525101-02 CB[redacted]	F 4[redacted] ASIAN	アトピー性皮膚炎	36	TREATMENT	22	RELATED	MODERATE	No	1	1	

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Nemolizumab(60 mg/body)	M	アトピー性皮膚炎	55	TREATMENT	59	RELATED	MILD	No	1	1	TARC値の上昇が大きいわりに皮疹の増悪はそれほどでもない
M525101-02	5[redacted]	アトピー性皮膚炎	284	TREATMENT	82	RELATED	MILD	No	1	1	
CB[redacted]	ASIAN										
Nemolizumab(60 mg/body)	F	アトピー性皮膚炎	29	TREATMENT	82	NOT RELATED	MILD	No	1	1	治験薬を継続しているが、皮疹の増悪は認めておらず経過から否定出来る。
M525101-02	3[redacted]	アトピー性皮膚炎	346	TREATMENT		RELATED	MILD	No	5	3	
CB[redacted]	ASIAN										
Nemolizumab(60 mg/body)	F	アトピー性皮膚炎	281	TREATMENT	33	NOT RELATED	MILD	No	1	1	機械的刺激によるもの
M525101-02	1[redacted]	アトピー性皮膚炎	365	TREATMENT		NOT RELATED	MILD	No	5	3	機械的刺激によるもの
CB[redacted]	ASIAN	アトピー性皮膚炎	419	FOLLOW-UP		NOT RELATED	MILD	No	5	3	治験終了に伴い痒み増強したため。掻破の刺激によるAD悪化のため。

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Nemolizumab(60 mg/body) M525101-02 CB[redacted]	M 1[redacted] ASIAN	アトピー性皮膚炎	68	TREATMENT	155	NOT RELATED	MILD	No	1	1	掻把の刺激による増悪と考えられるため。
Nemolizumab(60 mg/body) M525101-02 CB[redacted]	M 3[redacted] ASIAN	アトピー性皮膚炎	52	TREATMENT	120	RELATED	MILD	No	1	1	
Nemolizumab(60 mg/body) M525101-02 CB[redacted]	M 4[redacted] ASIAN	アトピー性皮膚炎	85	TREATMENT	143	RELATED	MODERATE	No	1	1	

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Nemolizumab(60 mg/body) M525101-02 CB[redacted]	F 4[redacted] ASIAN	アトピー性皮膚炎	163	TREATMENT	32	RELATED	MILD	No	1	1	AE＃3、皮疹の拡大又は新生：あり、これまで紅斑や丘疹のない部位における紅斑や丘疹の新生：なし、紅斑（湿潤性/浮腫性）の新生あるいは増加：あり、浸出液の増大：なし、落屑の増悪：なし、乾燥の増悪：あり、治験参加前の直近1年に実施していた主なAD治療：Very StrongクラスのTCS、TCI、保湿・保護剤、検査結果：なし
Nemolizumab(60 mg/body) M525101-02 CB[redacted]	M 3[redacted] ASIAN	アトピー性皮膚炎	13	TREATMENT	409	RELATED	MILD	No	1	1	
Placebo-Nemolizumab(Placebo-0.5mg/kgQ4W) CIM003JG [redacted]	F 2[redacted] WHITE	アトピー性皮膚炎	24	TREATMENT	384	NOT RELATED	MODERATE	No	1	1	

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Placebo-Nemolizumab(Placebo-0.5mg/kgQ4W) CIM003JG [redacted]	F 4[redacted] ASIAN	アトピー性皮膚炎	1	TREATMENT	113	NOT RELATED	MODERATE	No	1	1	ACRINOL DID NOT INFLUENCE EVALUATION FOR ITCHY SCORE.
Placebo-Nemolizumab(Placebo-0.5mg/kgQ4W) CIM003JG [redacted]	M 4[redacted] ASIAN	アトピー性皮膚炎	134	TREATMENT	113	NOT RELATED	MODERATE	No	1	1	
Placebo-Nemolizumab(Placebo-0.5mg/kgQ4W) CIM003JG [redacted]	F 3[redacted] WHITE	アトピー性皮膚炎	427	TREATMENT	51	NOT RELATED	MODERATE	No	5	1	
Placebo-Nemolizumab(Placebo-0.5mg/kgQ4W) CIM003JG [redacted]	F 4[redacted] ASIAN	アトピー性皮膚炎	124	TREATMENT	69	RELATED	SEVERE	No	3	1	THE AE HAS OCCURRED 7 DAYS AFTER LAST INJECTION.

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Placebo-Nemolizumab(Placebo-2mg/kgQ4W)	F	アトピー性皮膚炎	24	TREATMENT	21	NOT RELATED	MODERATE	No	1	1	
CIM003JG [redacted]	5[redacted] WHITE										
Placebo-Nemolizumab(Placebo-2mg/kgQ4W)	M	アトピー性皮膚炎	42	TREATMENT	6	NOT RELATED	MILD	No	1	1	
CIM003JG [redacted]	2[redacted] WHITE										
Placebo-Nemolizumab(Placebo-2mg/kgQ4W)	F	アトピー性皮膚炎	3	TREATMENT	13	NOT RELATED	MILD	No	1	1	
CIM003JG	4[redacted]	アトピー性皮膚炎	31	TREATMENT	11	NOT RELATED	MILD	No	1	1	
[redacted]	WHITE	アトピー性皮膚炎	91	TREATMENT	21	NOT RELATED	MODERATE	No	1	1	
		アトピー性皮膚炎	143	TREATMENT	12	NOT RELATED	MODERATE	No	1	1	

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Placebo-Nemolizumab(Placebo-2mg/kgQ4W) CIM003JG [redacted]	F 3[redacted] BLACK OR AFRICAN AMERICAN	アトピー性皮膚炎	40	TREATMENT	81	RELATED	MODERATE	No	1	1	
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 5[redacted] ASIAN	アトピー性皮膚炎	60	DOUBLE BLIND TREATMENT	145	NOT RELATED	MILD	No	1	1	日常生活でアトピー性皮膚炎が悪化する要因があったと患者が述べてたため
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 2[redacted] ASIAN	アトピー性皮膚炎	200	OPEN LABEL TREATMENT		NOT RELATED	MILD	No	1	3	セルフケア不足と職業的なものに起因すると考えられる

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	F 4[redacted] ASIAN	剥脱性皮膚炎	160	OPEN LABEL TREATMENT	9	RELATED	MODERATE	Yes	1	1	
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	F 4[redacted] ASIAN	アトピー性皮膚炎	137	OPEN LABEL TREATMENT	117	NOT RELATED	MODERATE	No	1	1	気候の変化による高湿度、発汗過多が生じたことによるアトピー性皮膚炎の悪化
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	F 4[redacted] ASIAN	アトピー性皮膚炎	85	DOUBLE BLIND TREATMENT	78	NOT RELATED	MODERATE	No	1	1	急な気候変動によるアトピー性皮膚炎の悪化と思われる

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	F 3[redacted] ASIAN	アトピー性皮膚炎	72	DOUBLE BLIND TREATMENT	71	NOT RELATED	MILD	No	1	1	季節性の悪化と考えられる
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 3[redacted] ASIAN	アトピー性皮膚炎	176	OPEN LABEL TREATMENT	107	RELATED	MILD	No	1	1	
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 4[redacted] ASIAN	アトピー性皮膚炎	141	OPEN LABEL TREATMENT	57	RELATED	MILD	No	1	1	

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 6[redacted] ASIAN	アトピー性皮膚炎	29	DOUBLE BLIND TREATMENT	57	NOT RELATED	MODERATE	No	1	1	薬剤投与と症状悪化の時間的な相関が乏しいため
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	F 5[redacted] ASIAN	アトピー性皮膚炎	70	DOUBLE BLIND TREATMENT	100	NOT RELATED	MILD	No	3	1	例年同時期に症状が悪化する傾向にあり、また、今まで経験する以上に症状が悪化している。予想される薬剤の半減期から、今回悪化した時期には薬剤の影響が軽減されている時期と判断したため。
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 2[redacted] ASIAN	アトピー性皮膚炎	67	DOUBLE BLIND TREATMENT	75	NOT RELATED	MILD	No	1	1	汗による皮疹の悪化と考える。

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 6[redacted] ASIAN	アトピー性皮膚炎	28	DOUBLE BLIND TREATMENT	142	RELATED	MILD	No	1	1	
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	F 4[redacted] ASIAN	アトピー性皮膚炎 アトピー性皮膚炎	85 169	DOUBLE BLIND TREATMENT OPEN LABEL TREATMENT	141 57	NOT RELATED NOT RELATED	MODERATE MILD	No No	1 1	1 1	投与回数を重ねた後出現しているため治験中のADに対する治療制限の影響が考えられ治験薬による事象の助長はないため 投与回数を重ねた後出現しているため治験中のADに対する治療制限の影響が考えられ治験薬による事象の助長はないため
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 4[redacted] ASIAN	アトピー性皮膚炎 アトピー性皮膚炎	104 225	DOUBLE BLIND TREATMENT OPEN LABEL TREATMENT	66 86	RELATED RELATED	MODERATE MODERATE	No No	1 1	1 1	

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 5[redacted] ASIAN	アトピー性皮膚炎	36	DOUBLE BLIND TREATMENT	134	NOT RELATED	MILD	No	1	1	悪化した部位が顔と両前腕のみで体幹はむしろ改善していた。花粉が増悪の因子の一つとして考えられる。
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	F 4[redacted] ASIAN	アトピー性皮膚炎	169	OPEN LABEL TREATMENT	139	NOT RELATED	MODERATE	No	1	1	症状の特徴が変化している。全身に紅斑が拡大。治験薬使用中に症状が改善。季節的な要因と考える。
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	F 4[redacted] ASIAN	アトピー性皮膚炎	141	OPEN LABEL TREATMENT	140	NOT RELATED	MODERATE	No	1	1	c)症状の特徴が変化治験薬投与中に症状が軽快した。

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment / Study No / Subject ID	Sex / Age (years) / Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Placebo-Nemolizumab(Placebo-60mg/body)	M	アトピー性皮膚炎	5	DOUBLE BLIND TREATMENT	53	NOT RELATED	MODERATE	No	1	1	当該患者の、寛解、日光曝露による増悪の変動の範囲内。ランダム化後に、釣りに行き日光曝露があったことを聴取。
M525101-01	4[redacted]	アトピー性皮膚炎	136	OPEN LABEL TREATMENT	10	RELATED	MILD	No	1	1	
CA[redacted]	ASIAN	アトピー性皮膚炎	165	OPEN LABEL TREATMENT	19	RELATED	MODERATE	No	1	1	

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Placebo-Nemolizumab(Placebo-60mg/body)	M	アトピー性皮膚炎	49	DOUBLE BLIND TREATMENT	65	NOT RELATED	MODERATE	No	1	1	マイザー軟膏処方。マイザー軟膏外用のみで改善しているため。AE#1 皮疹の拡大又は新生：あり、これまで紅斑や丘疹のない部位における紅斑や丘疹の新生：あり、紅斑（浸潤性/浮腫性）の新生あるいは増加：あり、浸出液の増大：なし、落屑の増悪：なし、乾燥の増悪：なし、治験参加前の直近１年に実施していた主なAD治療：StrongestクラスのTCS、Very StrongクラスのTCS、StrongクラスのTCS、TCI、保湿・保護剤、検査結果：なし
M525101-01	2[redacted]	アトピー性皮膚炎	162	OPEN LABEL TREATMENT	92	RELATED	MILD	No	1	1	AE#2 皮疹の拡大又は新生：あり、これまで紅斑や丘疹のない部位における紅斑や丘疹の新生：あり、紅斑（浸潤性/浮腫性）の新生あるいは増加：あり、浸出液の増大：なし、落屑の増悪：なし、乾燥の増悪：なし、治験参加前の直近１年に実施していた主なAD治療：StrongestクラスのTCS、Very StrongクラスのTCS、StrongクラスのTCS、TCI、保湿・保護剤、検査結果：なし
CA[redacted]	ASIAN										

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 4[redacted] ASIAN	アトピー性皮膚炎	33	DOUBLE BLIND TREATMENT	515	NOT RELATED	MODERATE	No	1	1	アトピー素因による手指湿疹の悪化
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	F 4[redacted] ASIAN	アトピー性皮膚炎 アトピー性皮膚炎	144 186	OPEN LABEL TREATMENT OPEN LABEL TREATMENT	110 40	RELATED RELATED	MODERATE MODERATE	No No	1 1	1 1	
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 1[redacted] ASIAN	アトピー性皮膚炎	491	FOLLOW-UP		NOT RELATED	MODERATE	No	5	3	治験薬の投与中止、約5週間後頃から出現、増悪しており治験薬投与による変化ではない。しかし治験薬投与前にみられていた元来の皮疹の再燃であり、投与中止によって誘発された症状であることは否定できない。

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]	Comment
Placebo-Nemolizumab(Placebo-60mg/body)	F	アトピー性皮膚炎	76	DOUBLE BLIND TREATMENT		RELATED	MODERATE	No	1	2	
M525101-01	3[redacted]										
CA[redacted]	ASIAN										

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.3.2から引用

表 2.7.4-56 Listing of Other Significant Treatment-Emergent Adverse Events (Skin Infections) (Japanese)
Safety Analysis Set（pool1）

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(0.5mg/kgQ4W) CIM003JG [redacted]	F 2[redacted] WHITE	マラセチア感染	249	TREATMENT	8	NOT RELATED	MILD	No	1	1
Nemolizumab(0.5mg/kgQ4W) CIM003JG [redacted]	F 1[redacted] WHITE	皮膚感染	134	TREATMENT	12	NOT RELATED	MODERATE	No	1	1
Nemolizumab(0.5mg/kgQ4W) CIM003JG [redacted]	M 2[redacted] ASIAN	皮膚細菌感染	39	TREATMENT	75	NOT RELATED	MODERATE	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.4.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(0.5mg/kgQ4W) CIM003JG [redacted]	F 3[redacted] ASIAN	帯状疱疹	106	TREATMENT	41	RELATED	MILD	No	1	1
Nemolizumab(0.5mg/kgQ4W) CIM003JG [redacted]	M 3[redacted] ASIAN	蜂巣炎	28	TREATMENT	23	RELATED	MILD	No	3	1
Nemolizumab(0.5mg/kgQ4W) CIM003JG [redacted]	F 5[redacted] ASIAN	膿痂疹	394	TREATMENT	80	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.4.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(0.5mg/kgQ4W)	M	皮膚感染	27	TREATMENT	66	NOT RELATED	MODERATE	No	4	1
CIM003JG	4[redacted]									
[redacted]	ASIAN									
Nemolizumab(0.5mg/kgQ4W)	F	帯状疱疹	166	TREATMENT	27	RELATED	MILD	No	3	1
CIM003JG	4[redacted]	外耳炎	303	TREATMENT	5	NOT RELATED	MODERATE	No	1	1
[redacted]	ASIAN									
Nemolizumab(0.5mg/kgQ4W)	M	膿痂疹	379	TREATMENT	25	NOT RELATED	MILD	No	1	1
CIM003JG	2[redacted]									
[redacted]	OTHER									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.4.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(0.5mg/kgQ4W)	M	膿痂疹	141	TREATMENT		NOT RELATED	MILD	No	1	3
CIM003JG	2[redacted]									
[redacted]	ASIAN									
Nemolizumab(0.5mg/kgQ4W)	F	ヘルペスウイルス感染	20	TREATMENT	8	NOT RELATED	MILD	No	1	1
CIM003JG	3[redacted]									
[redacted]	WHITE									
Nemolizumab(0.5mg/kgQ4W)	F	単純ヘルペス	411	TREATMENT	26	NOT RELATED	MILD	No	1	1
CIM003JG	2[redacted]	単純ヘルペス	514	SAFETY-FU		NOT RELATED	MILD	No	5	2
[redacted]	WHITE									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.4.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(0.5mg/kgQ4W) CIM003JG [redacted]	M 4[redacted] WHITE	皮膚細菌感染	15	TREATMENT	29	NOT RELATED	MILD	No	1	1
Nemolizumab(0.5mg/kgQ4W) CIM003JG [redacted]	M 2[redacted] WHITE	蜂巣炎	13	TREATMENT	10	RELATED	MILD	No	1	1
Nemolizumab(0.5mg/kgQ4W) CIM003JG [redacted]	M 5[redacted] WHITE	膿痂疹性湿疹	15	TREATMENT	8	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.4.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(0.5mg/kgQ4W) CIM003JG [redacted]	M 5[redacted] WHITE	カポジ水痘様発疹	153	SAFETY-FU	12	NOT RELATED	MODERATE	No	1	1
Nemolizumab(2mg/kgQ4W) CIM003JG [redacted]	F 2[redacted] WHITE	単純ヘルペス	249	TREATMENT	9	NOT RELATED	MILD	No	1	1
Nemolizumab(2mg/kgQ4W) CIM003JG [redacted]	F 4[redacted] WHITE	丹毒	24	TREATMENT	9	NOT RELATED	MODERATE	No	4	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.4.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(2mg/kgQ4W)	M	外耳炎	37	TREATMENT		NOT RELATED	MODERATE	No	1	3
CIM003JG	2[redacted]									
[redacted]	ASIAN									
Nemolizumab(2mg/kgQ4W)	M	せつ	80	TREATMENT	34	NOT RELATED	MILD	No	1	1
CIM003JG	3[redacted]	爪の皮膚糸状菌症	113	TREATMENT		NOT RELATED	MILD	No	1	3
[redacted]	ASIAN	足部白癬	113	TREATMENT		NOT RELATED	MILD	No	1	3
		単純ヘルペス	225	TREATMENT	11	NOT RELATED	MILD	No	1	1
		体部白癬	273	TREATMENT	41	NOT RELATED	MILD	No	1	1
Nemolizumab(2mg/kgQ4W)	M	皮膚感染	59	TREATMENT	9	RELATED	SEVERE	Yes	4	1
CIM003JG	4[redacted]									
[redacted]	WHITE									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.4.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(2mg/kgQ4W)	F	口腔ヘルペス	31	TREATMENT	19	RELATED	MODERATE	No	1	1
CIM003JG	3[redacted]									
[redacted]	WHITE									
Nemolizumab(2mg/kgQ4W)	F	ブドウ球菌皮膚感染	165	TREATMENT	24	NOT RELATED	MILD	No	1	1
CIM003JG	2[redacted]	毛包炎	336	TREATMENT	9	NOT RELATED	MILD	No	1	1
[redacted]	WHITE									
Nemolizumab(2mg/kgQ4W)	M	足部白癬	1	TREATMENT		NOT RELATED	MILD	No	1	2
CIM003JG	5[redacted]									
[redacted]	AMERICAN INDIAN OR ALASKA NATIVE									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.4.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(2mg/kgQ8W) CIM003JG [redacted]	F 2[redacted] WHITE	口腔ヘルペス	255	TREATMENT	8	NOT RELATED	MODERATE	No	1	1
Nemolizumab(2mg/kgQ8W) CIM003JG [redacted]	F 5[redacted] WHITE	口腔ヘルペス	110	TREATMENT	3	NOT RELATED	MILD	No	1	1
Nemolizumab(2mg/kgQ8W) CIM003JG [redacted]	M 2[redacted] ASIAN	カポジ水痘様発疹	8	TREATMENT	8	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.4.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(2mg/kgQ8W)	M	カポジ水痘様発疹	172	TREATMENT	33	NOT RELATED	MODERATE	No	4	1
CIM003JG	2[redacted]	毛包炎	204	SAFETY-FU	8	NOT RELATED	MILD	No	5	1
[redacted]	ASIAN									
Nemolizumab(2mg/kgQ8W)	F	外耳炎	18	TREATMENT	41	NOT RELATED	MODERATE	No	1	1
CIM003JG	3[redacted]									
[redacted]	ASIAN									
Nemolizumab(2mg/kgQ8W)	F	帯状疱疹	36	TREATMENT	50	NOT RELATED	SEVERE	Yes	1	1
CIM003JG	5[redacted]	毛包炎	183	TREATMENT	18	NOT RELATED	MILD	No	1	1
[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.4.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(2mg/kgQ8W)	F	膿痂疹	225	TREATMENT	85	NOT RELATED	MILD	No	1	1
CIM003JG	3[redacted]	癜風	281	TREATMENT	113	NOT RELATED	MILD	No	1	1
[redacted]	ASIAN	感染性皮膚嚢腫	309	TREATMENT	30	NOT RELATED	MILD	No	1	1
		体部白癬	477	SAFETY-FU	29	NOT RELATED	MILD	No	5	4
Nemolizumab(2mg/kgQ8W)	M	単純ヘルペス	10	TREATMENT	10	NOT RELATED	MILD	Yes	5	1
CIM003JG	5[redacted]									
[redacted]	WHITE									
Nemolizumab(2mg/kgQ8W)	F	ブドウ球菌皮膚感染	361	TREATMENT	24	NOT RELATED	MODERATE	No	1	1
CIM003JG	4[redacted]	ブドウ球菌皮膚感染	399	TREATMENT	97	NOT RELATED	MODERATE	No	1	1
[redacted]	WHITE	皮膚細菌感染	464	SAFETY-FU	16	NOT RELATED	MODERATE	No	5	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.4.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(2mg/kgQ8W) CIM003JG [redacted]	F 4[redacted] WHITE	麦粒腫	27	TREATMENT	2	NOT RELATED	MILD	No	1	1
Nemolizumab(2mg/kgQ8W) CIM003JG [redacted]	M 2[redacted] ASIAN	白癬感染	49	TREATMENT	37	NOT RELATED	MODERATE	No	1	1
Nemolizumab(2mg/kgQ8W) CIM003JG [redacted]	F 2[redacted] WHITE	膿痂疹	98	TREATMENT	14	NOT RELATED	SEVERE	No	4	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.4.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(2mg/kgQ8W)	F	毛包炎	35	TREATMENT	46	NOT RELATED	MODERATE	No	1	1
CIM003JG	2[redacted]	膿痂疹	125	TREATMENT	153	NOT RELATED	MODERATE	No	1	1
[redacted]	BLACK OR AFRICAN AMERICAN									
Nemolizumab(60mg/body)	F	足部白癬	442	OPEN LABEL TREATMENT	81	NOT RELATED	MILD	No	1	1
M525101-01	2[redacted]									
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	F	カポジ水痘様発疹	506	FOLLOW-UP	8	NOT RELATED	MILD	No	5	1
M525101-01	2[redacted]									
CA[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.4.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 2[redacted] ASIAN	毛包炎	141	OPEN LABEL TREATMENT	29	NOT RELATED	MILD	No	1	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	F 1[redacted] ASIAN	毛包炎	219	OPEN LABEL TREATMENT	36	NOT RELATED	MILD	No	1	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 4[redacted] ASIAN	皮膚感染	437	OPEN LABEL TREATMENT	15	RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.4.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	F	単純ヘルペス	99	DOUBLE BLIND TREATMENT	68	RELATED	MILD	No	1	1
M525101-01	5[redacted]									
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	M	蜂巣炎	-21	SCREENING	3	NOT RELATED	MILD	No	1	1
M525101-01	3[redacted]	蜂巣炎	99	DOUBLE BLIND TREATMENT	3	NOT RELATED	MILD	No	1	1
CA[redacted]	ASIAN	蜂巣炎	222	OPEN LABEL TREATMENT	6	NOT RELATED	MILD	No	1	1
		蜂巣炎	287	OPEN LABEL TREATMENT	3	NOT RELATED	MILD	No	1	1
		蜂巣炎	393	OPEN LABEL TREATMENT	5	NOT RELATED	MILD	No	1	1
		蜂巣炎	399	OPEN LABEL TREATMENT	4	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.4.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	M	せつ	162	OPEN LABEL TREATMENT	11	RELATED	MILD	No	1	1
M525101-01	4[redacted]									
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	M	蜂巣炎	-21	SCREENING	8	NOT RELATED	MILD	No	1	1
M525101-01	2[redacted]	蜂巣炎	-11	SCREENING	4	NOT RELATED	MILD	No	1	1
CA[redacted]	ASIAN	蜂巣炎	218	OPEN LABEL TREATMENT	8	RELATED	MILD	No	1	1
		単純ヘルペス	331	OPEN LABEL TREATMENT	24	RELATED	MILD	No	1	1
		皮膚カンジダ	370	OPEN LABEL TREATMENT	18	RELATED	MILD	No	1	1
Nemolizumab(60mg/body)	F	皮膚乳頭腫	157	OPEN LABEL TREATMENT		RELATED	MILD	No	1	2
M525101-01	4[redacted]									
CA[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.4.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	M	蜂巣炎	446	OPEN LABEL TREATMENT	11	RELATED	MILD	No	5	1
M525101-01	1[redacted]									
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	M	帯状疱疹	304	OPEN LABEL TREATMENT	6	RELATED	MILD	No	1	1
M525101-01	2[redacted]									
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	M	膿疱性皮疹	113	DOUBLE BLIND TREATMENT	36	NOT RELATED	MILD	No	1	1
M525101-01	2[redacted]	膿疱性皮疹	148	OPEN LABEL TREATMENT	22	NOT RELATED	MILD	No	1	1
CA[redacted]	ASIAN	膿疱性皮疹	533	FOLLOW-UP		NOT RELATED	MILD	No	5	3

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.4.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	M	皮膚乳頭腫	246	OPEN LABEL TREATMENT	99	RELATED	MILD	No	1	1
M525101-01	5[redacted]	足部白癬	442	OPEN LABEL TREATMENT		NOT RELATED	MILD	No	1	2
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	F	爪囲炎	345	OPEN LABEL TREATMENT	32	NOT RELATED	MILD	No	1	1
M525101-01	1[redacted]									
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	F	皮膚乳頭腫	534	FOLLOW-UP	1	NOT RELATED	MILD	No	5	1
M525101-01	3[redacted]									
CA[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.4.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	F	カポジ水痘様発疹	184	OPEN LABEL TREATMENT	16	RELATED	MODERATE	Yes	3	1
M525101-01	5[redacted]	単純ヘルペス	392	OPEN LABEL TREATMENT	10	RELATED	MILD	No	3	1
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	M	男性外性器蜂巣炎	17	DOUBLE BLIND TREATMENT	13	RELATED	MODERATE	No	1	1
M525101-01	5[redacted]	蜂巣炎	165	OPEN LABEL TREATMENT	16	RELATED	MILD	No	1	1
CA[redacted]	ASIAN	毛包炎	446	OPEN LABEL TREATMENT	11	RELATED	MILD	No	1	1
		毛包炎	477	OPEN LABEL TREATMENT	57	RELATED	MILD	No	5	1
Nemolizumab(60mg/body)	F	帯状疱疹	235	OPEN LABEL TREATMENT	19	RELATED	MILD	No	1	1
M525101-01	4[redacted]									
CA[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.4.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	M	外耳炎	29	DOUBLE BLIND TREATMENT	85	NOT RELATED	MILD	No	1	1
M525101-01	4[redacted]									
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	M	口腔ヘルペス	-29	SCREENING	3	NOT RELATED	MILD	No	1	1
M525101-01	5[redacted]	口腔ヘルペス	384	OPEN LABEL TREATMENT	13	NOT RELATED	MILD	No	1	1
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	M	蜂巣炎	479	OPEN LABEL TREATMENT	17	NOT RELATED	MODERATE	No	5	1
M525101-01	4[redacted]									
CA[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.4.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	F	膿痂疹	57	DOUBLE BLIND TREATMENT	169	RELATED	MILD	No	1	1
M525101-01	4[redacted]									
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	M	蜂巣炎	52	DOUBLE BLIND TREATMENT	34	NOT RELATED	MILD	No	1	1
M525101-01	6[redacted]									
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	M	外耳炎	309	OPEN LABEL TREATMENT	169	NOT RELATED	MILD	No	1	1
M525101-01	3[redacted]	毛包炎	365	OPEN LABEL TREATMENT	29	NOT RELATED	MILD	No	1	1
CA[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.4.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	M	口腔ヘルペス	442	OPEN LABEL TREATMENT	15	RELATED	MILD	No	1	1
M525101-01	4[redacted]									
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	M	男性外性器蜂巣炎	390	OPEN LABEL TREATMENT	11	NOT RELATED	MODERATE	Yes	1	1
M525101-01	3[redacted]	癜風	422	OPEN LABEL TREATMENT	35	RELATED	MILD	No	1	1
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	F	毛包炎	223	OPEN LABEL TREATMENT	10	NOT RELATED	MILD	No	1	1
M525101-01	4[redacted]	せつ	313	OPEN LABEL TREATMENT	29	NOT RELATED	MILD	No	1	1
CA[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.4.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	M	膿痂疹	126	OPEN LABEL TREATMENT		NOT RELATED	MILD	No	1	3
M525101-01	2[redacted]									
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	M	外耳炎	177	OPEN LABEL TREATMENT	7	NOT RELATED	MILD	No	1	1
M525101-01	2[redacted]									
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	F	膿痂疹	104	DOUBLE BLIND TREATMENT		NOT RELATED	MILD	No	1	3
M525101-01	3[redacted]	膿痂疹	241	OPEN LABEL TREATMENT		NOT RELATED	MILD	No	1	3
CA[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.4.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	M	口腔ヘルペス	223	OPEN LABEL TREATMENT	13	NOT RELATED	MILD	No	1	1
M525101-01	4[redacted]									
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	F	帯状疱疹	222	OPEN LABEL TREATMENT	4	NOT RELATED	MILD	No	1	1
M525101-01	3[redacted]	外耳炎	262	OPEN LABEL TREATMENT		NOT RELATED	MILD	No	1	3
CA[redacted]	ASIAN	細菌性外耳炎	279	OPEN LABEL TREATMENT		NOT RELATED	MILD	No	1	3
Nemolizumab(60mg/body)	M	カポジ水痘様発疹	142	OPEN LABEL TREATMENT	12	RELATED	MILD	No	1	1
M525101-01	4[redacted]									
CA[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.4.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body) M525101-01 CA[redacted]	F 4[redacted] ASIAN	毛包炎	-3	SCREENING	142	NOT RELATED	MILD	No	1	1
Nemolizumab(60mg/body)	M	毛包炎	9	DOUBLE BLIND TREATMENT	21	NOT RELATED	MILD	No	1	1
M525101-01 CA[redacted]	2[redacted] ASIAN	毛包炎	477	OPEN LABEL TREATMENT	11	NOT RELATED	MILD	No	5	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 4[redacted] ASIAN	爪囲炎	508	FOLLOW-UP		NOT RELATED	MILD	No	5	3

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.4.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body) M525101-01 CA[redacted]	F 4[redacted] ASIAN	眼部単純ヘルペス	55	DOUBLE BLIND TREATMENT	5	NOT RELATED	MILD	No	1	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 2[redacted] ASIAN	蜂巣炎	148	OPEN LABEL TREATMENT	11	RELATED	MILD	No	1	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	F 3[redacted] ASIAN	せつ	293	OPEN LABEL TREATMENT	45	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.4.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	M	ヘルペスウイルス感染	271	OPEN LABEL TREATMENT	18	NOT RELATED	MILD	No	1	1
M525101-01 CA[redacted]	3[redacted] ASIAN									
Nemolizumab(60mg/body)	M	蜂巣炎	123	OPEN LABEL TREATMENT	22	RELATED	SEVERE	No	1	1
M525101-01 CA[redacted]	3[redacted] ASIAN									
Nemolizumab(60mg/body)	M	麦粒腫	-23	SCREENING	24	NOT RELATED	MILD	No	1	1
M525101-01 CA[redacted]	4[redacted] ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.4.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	F	鼻ヘルペス	13	DOUBLE BLIND TREATMENT	13	NOT RELATED	MILD	No	1	1
M525101-01	4[redacted]	足部白癬	143	OPEN LABEL TREATMENT	139	NOT RELATED	MILD	No	1	1
CA[redacted]	ASIAN	口角口唇炎	163	OPEN LABEL TREATMENT	14	NOT RELATED	MILD	No	1	1
Nemolizumab(60mg/body)	M	外耳炎	109	DOUBLE BLIND TREATMENT	11	NOT RELATED	MILD	No	1	1
M525101-01	2[redacted]									
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	M	単純ヘルペス	36	DOUBLE BLIND TREATMENT	22	RELATED	MILD	No	1	1
M525101-01	6[redacted]									
CA[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.4.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body) M525101-02 CB[redacted]	M 4[redacted] ASIAN	蜂巣炎	55	TREATMENT	8	RELATED	MODERATE	No	1	1
		足部白癬	58	TREATMENT		RELATED	MILD	No	1	2
Nemolizumab(60mg/body) M525101-02 CB[redacted]	F 4[redacted] ASIAN	カポジ水痘様発疹	12	TREATMENT	16	NOT RELATED	MILD	No	1	1
		蜂巣炎	254	TREATMENT	26	NOT RELATED	MILD	No	1	1
Nemolizumab(60mg/body) M525101-02 CB[redacted]	M 3[redacted] ASIAN	マラセチア感染	278	TREATMENT	141	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.4.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body) M525101-02 CB[redacted]	F 4[redacted] ASIAN	蜂巣炎	-18	SCREENING	8	NOT RELATED	MODERATE	No	1	1
Nemolizumab(60mg/body) M525101-02 CB[redacted]	F 1[redacted] ASIAN	外耳炎	138	TREATMENT	34	NOT RELATED	MILD	No	1	1
Nemolizumab(60mg/body) M525101-02 CB[redacted]	M 4[redacted] ASIAN	帯状疱疹	6	TREATMENT	10	RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.4.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	M	カポジ水痘様発疹	58	TREATMENT	7	RELATED	MODERATE	No	1	1
M525101-02	3[redacted]	蜂巣炎	152	FOLLOW-UP	18	RELATED	SEVERE	Yes	5	1
CB[redacted]	ASIAN									
Nemolizumab(60mg/body)	M	毛包炎	5	TREATMENT	7	NOT RELATED	MILD	No	1	1
M525101-02	5[redacted]	皮膚感染	134	TREATMENT	17	NOT RELATED	MILD	No	1	1
CB[redacted]	ASIAN	蜂巣炎	179	TREATMENT	61	NOT RELATED	MODERATE	Yes	4	1
		蜂巣炎	214	TREATMENT	26	NOT RELATED	MODERATE	No	4	1
		蜂巣炎	265	FOLLOW-UP	17	NOT RELATED	MILD	No	5	1
Nemolizumab(60mg/body)	M	蜂巣炎	373	FOLLOW-UP	5	NOT RELATED	MILD	No	5	1
M525101-02	4[redacted]									
CB[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.4.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	F	蜂巣炎	74	TREATMENT	30	RELATED	MILD	No	1	1
M525101-02	4[redacted]	蜂巣炎	273	TREATMENT	72	RELATED	MODERATE	No	1	1
CB[redacted]	ASIAN									
Nemolizumab(60mg/body)	M	カポジ水痘様発疹	54	TREATMENT	11	RELATED	MODERATE	No	3	1
M525101-02	5[redacted]									
CB[redacted]	ASIAN									
Nemolizumab(60mg/body)	F	帯状疱疹	129	TREATMENT	34	NOT RELATED	MODERATE	No	1	1
M525101-02	5[redacted]	蜂巣炎	138	TREATMENT	4	NOT RELATED	MILD	No	1	1
CB[redacted]	ASIAN	皮膚乳頭腫	186	TREATMENT		NOT RELATED	MILD	No	1	2

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.4.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body) M525101-02 CB[redacted]	M 4[redacted] ASIAN	カポジ水痘様発疹	79	TREATMENT	14	RELATED	MILD	No	1	1
Nemolizumab(60mg/body) M525101-02 CB[redacted]	F 3[redacted] ASIAN	膿痂疹	141	TREATMENT	15	RELATED	MODERATE	No	1	1
Nemolizumab(60mg/body) M525101-02 CB[redacted]	M 3[redacted] ASIAN	丹毒 伝染性軟属腫	64 381	TREATMENT FOLLOW-UP	8	RELATED RELATED	MILD MILD	No No	1 5	1 3

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.4.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	M	爪囲炎	-14	SCREENING	29	NOT RELATED	MILD	No	1	1
M525101-02	5[redacted]									
CB[redacted]	ASIAN									
Nemolizumab(60mg/body)	M	膿痂疹	106	TREATMENT	29	RELATED	MILD	No	1	1
M525101-02	4[redacted]									
CB[redacted]	ASIAN									
Nemolizumab(60mg/body)	F	皮膚感染	36	TREATMENT	22	RELATED	MODERATE	No	1	1
M525101-02	4[redacted]	蜂巣炎	91	TREATMENT	23	RELATED	MODERATE	No	1	1
CB[redacted]	ASIAN	蜂巣炎	146	TREATMENT	17	RELATED	MILD	No	1	1
		爪囲炎	173	TREATMENT	13	RELATED	MILD	No	1	1
		膿痂疹	173	TREATMENT	51	RELATED	MILD	No	3	1
		膿痂疹	270	TREATMENT	159	RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.4.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	M	単純ヘルペス	218	TREATMENT	8	NOT RELATED	MILD	No	1	1
M525101-02	7[redacted]	伝染性軟属腫	233	TREATMENT		NOT RELATED	MILD	No	1	3
CB[redacted]	ASIAN	感染性皮膚嚢腫	255	TREATMENT	25	RELATED	MILD	No	1	1
		毛包炎	375	FOLLOW-UP	20	NOT RELATED	MILD	No	5	1
Nemolizumab(60mg/body)	M	帯状疱疹	258	TREATMENT	23	RELATED	MILD	No	1	1
M525101-02	4[redacted]									
CB[redacted]	ASIAN									
Nemolizumab(60mg/body)	M	口腔ヘルペス	73	TREATMENT	2	NOT RELATED	MILD	No	1	1
M525101-02	2[redacted]									
CB[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.4.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	M	眼部単純ヘルペス	393	FOLLOW-UP		RELATED	MODERATE	No	5	3
M525101-02	5[redacted]									
CB[redacted]	ASIAN									
Nemolizumab(60mg/body)	F	蜂巣炎	18	TREATMENT	11	NOT RELATED	MILD	No	1	1
M525101-02	3[redacted]	皮膚細菌感染	265	TREATMENT	38	NOT RELATED	MODERATE	Yes	1	1
CB[redacted]	ASIAN	皮膚細菌感染	309	TREATMENT	12	NOT RELATED	MILD	No	1	1
Nemolizumab(60mg/body)	F	皮膚感染	149	TREATMENT	54	NOT RELATED	MILD	No	1	1
M525101-02	1[redacted]	外耳炎	241	TREATMENT	5	NOT RELATED	MILD	No	1	1
CB[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.4.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	M	外耳炎	3	TREATMENT	8	NOT RELATED	MODERATE	No	1	1
M525101-02	1[redacted]									
CB[redacted]	ASIAN									
Nemolizumab(60mg/body)	M	毛包炎	234	TREATMENT	52	NOT RELATED	MILD	No	1	1
M525101-02	3[redacted]	眼部単純ヘルペス	319	TREATMENT		RELATED	MODERATE	No	1	2
CB[redacted]	ASIAN									
Nemolizumab(60mg/body)	M	皮膚乳頭腫	309	TREATMENT		RELATED	MILD	No	1	3
M525101-02	4[redacted]	膿痂疹	408	FOLLOW-UP		RELATED	MODERATE	Yes	5	2
CB[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.4.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body) M525101-02 CB[redacted]	M 1[redacted] ASIAN	膿疱性ざ瘡	85	TREATMENT	57	RELATED	MILD	No	1	1
Nemolizumab(60mg/body) M525101-02 CB[redacted]	M 5[redacted] ASIAN	蜂巣炎	105 274	TREATMENT TREATMENT	36 8	RELATED RELATED	MILD MILD	No No	1 1	1 1
Nemolizumab(60mg/body) M525101-02 CB[redacted]	F 4[redacted] ASIAN	爪囲炎	307	TREATMENT	31	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.4.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Placebo-Nemolizumab(Placebo-0.5mg/kgQ4W)	F	皮膚細菌感染	154	TREATMENT	14	NOT RELATED	MILD	No	1	1
CIM003JG	2[redacted]	外耳炎	416	TREATMENT	6	NOT RELATED	MILD	No	1	1
[redacted]	WHITE									
Placebo-Nemolizumab(Placebo-0.5mg/kgQ4W)	F	膿痂疹	216	TREATMENT	3	NOT RELATED	MILD	No	1	1
CIM003JG	4[redacted]	外耳炎	218	TREATMENT	29	NOT RELATED	MILD	No	1	1
[redacted]	ASIAN	膿痂疹	246	SAFETY-FU	41	NOT RELATED	MILD	No	1	1
Placebo-Nemolizumab(Placebo-2mg/kgQ4W)	M	皮膚乳頭腫	104	TREATMENT		NOT RELATED	MILD	No	1	3
CIM003JG	2[redacted]									
[redacted]	WHITE									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.4.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Placebo-Nemolizumab(Placebo-2mg/kgQ4W) CIM003JG [redacted]	F 5[redacted] WHITE	帯状疱疹	189	TREATMENT	13	NOT RELATED	MODERATE	No	1	1
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 4[redacted] ASIAN	毛包炎 外耳炎	4 177	DOUBLE BLIND TREATMENT OPEN LABEL TREATMENT	12 10	RELATED RELATED	MILD MILD	No No	1 1	1 1
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 4[redacted] ASIAN	膿痂疹	393	OPEN LABEL TREATMENT	14	RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.4.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Placebo-Nemolizumab(Placebo-60mg/body)	F	麦粒腫	67	DOUBLE BLIND TREATMENT	52	RELATED	MILD	No	1	1
M525101-01	4[redacted]	丹毒	126	OPEN LABEL TREATMENT	16	RELATED	MODERATE	No	1	1
CA[redacted]	ASIAN	カポジ水痘様発疹	134	OPEN LABEL TREATMENT	8	RELATED	MODERATE	No	1	1
		膿痂疹	148	OPEN LABEL TREATMENT	21	RELATED	MILD	No	1	1
		カポジ水痘様発疹	227	OPEN LABEL TREATMENT	18	RELATED	MODERATE	No	1	1
		膿痂疹	338	OPEN LABEL TREATMENT	33	RELATED	MILD	No	1	1
Placebo-Nemolizumab(Placebo-60mg/body)	F	毛包炎	162	OPEN LABEL TREATMENT	28	RELATED	MILD	No	1	1
M525101-01	5[redacted]									
CA[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.4.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 4[redacted] ASIAN	毛包炎	358	OPEN LABEL TREATMENT	36	NOT RELATED	MILD	No	1	1
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 6[redacted] ASIAN	体部白癬	532	FOLLOW-UP		RELATED	MILD	No	5	3
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	F 5[redacted] ASIAN	外耳炎	494	FOLLOW-UP	4	NOT RELATED	MILD	No	5	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.4.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 4[redacted] ASIAN	蜂巣炎	170	OPEN LABEL TREATMENT	52	RELATED	SEVERE	Yes	3	1
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	F 3[redacted] ASIAN	爪囲炎	21	DOUBLE BLIND TREATMENT	64	NOT RELATED	MILD	No	1	1
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 4[redacted] ASIAN	蜂巣炎	32	DOUBLE BLIND TREATMENT	54	RELATED	MODERATE	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.4.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	F 4[redacted] ASIAN	蜂巣炎	319	OPEN LABEL TREATMENT	4	NOT RELATED	MILD	No	1	1
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 3[redacted] ASIAN	毛包炎	467	OPEN LABEL TREATMENT	15	NOT RELATED	MILD	No	5	1
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	F 4[redacted] ASIAN	爪囲炎	64	DOUBLE BLIND TREATMENT	32	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.4.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 4[redacted] ASIAN	爪囲炎	181	OPEN LABEL TREATMENT	33	NOT RELATED	MILD	No	1	1
Placebo-Nemolizumab(Placebo-60mg/body)	F	足部白癬	25	DOUBLE BLIND TREATMENT	61	RELATED	MILD	No	1	1
M525101-01	4[redacted]	膿痂疹	340	OPEN LABEL TREATMENT	19	RELATED	MILD	No	1	1
CA[redacted]	ASIAN	膿痂疹	367	OPEN LABEL TREATMENT	90	RELATED	MILD	No	3	1
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	F 4[redacted] ASIAN	蜂巣炎	169	OPEN LABEL TREATMENT	12	RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.4.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Placebo-Nemolizumab(Placebo-60mg/body)	M	皮膚乳頭腫	449	OPEN LABEL TREATMENT		NOT RELATED	MILD	No	1	3
M525101-01	1[redacted]									
CA[redacted]	ASIAN									
Placebo-Nemolizumab(Placebo-60mg/body)	M	鼻ヘルペス	26	DOUBLE BLIND TREATMENT	18	NOT RELATED	MILD	No	1	1
M525101-01	4[redacted]									
CA[redacted]	ASIAN									
Placebo-Nemolizumab(Placebo-60mg/body)	M	蜂巣炎	80	DOUBLE BLIND TREATMENT	6	RELATED	MILD	No	1	1
M525101-01	4[redacted]	膿痂疹性湿疹	478	OPEN LABEL TREATMENT		NOT RELATED	MODERATE	No	5	3
CA[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.4.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Placebo-Nemolizumab(Placebo-60mg/body)	F	手足口病	239	OPEN LABEL TREATMENT	8	RELATED	MODERATE	No	1	1
M525101-01	3[redacted]	皮膚乳頭腫	386	OPEN LABEL TREATMENT	29	RELATED	MILD	No	1	1
CA[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.4.2から引用

表 2.7.4-57 Listing of Other Significant Treatment-Emergent Adverse Events (Non-skin Infections) (Japanese)

Safety Analysis Set（pool1）

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(0.5mg/kgQ4W)	F	上咽頭炎	67	TREATMENT	9	NOT RELATED	MILD	No	1	1
CIM003JG	2[redacted]	上咽頭炎	214	TREATMENT	8	NOT RELATED	MILD	No	1	1
[redacted]	WHITE	上咽頭炎	250	TREATMENT	32	NOT RELATED	MILD	No	1	1
		上咽頭炎	348	TREATMENT	20	NOT RELATED	MILD	No	1	1
		上咽頭炎	413	TREATMENT	42	NOT RELATED	MILD	No	1	1
		上咽頭炎	502	SAFETY-FU		NOT RELATED	MILD	No	1	3
Nemolizumab(0.5mg/kgQ4W)	F	上咽頭炎	27	TREATMENT	12	NOT RELATED	MILD	No	1	1
CIM003JG	1[redacted]	細菌重複感染	57	TREATMENT	15	NOT RELATED	MODERATE	No	1	1
[redacted]	WHITE	上咽頭炎	65	TREATMENT	11	NOT RELATED	MILD	No	1	1
		上咽頭炎	412	TREATMENT	9	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(0.5mg/kgQ4W)	M	上咽頭炎	118	TREATMENT	8	RELATED	MILD	No	1	1
CIM003JG	4[redacted]	膀胱炎	191	TREATMENT	7	NOT RELATED	MODERATE	No	1	1
[redacted]	WHITE	上咽頭炎	440	TREATMENT	12	RELATED	MILD	No	5	1
		上咽頭炎	474	SAFETY-FU	5	RELATED	MODERATE	No	5	1
Nemolizumab(0.5mg/kgQ4W)	F	咬傷感染	97	TREATMENT	8	NOT RELATED	MODERATE	No	1	1
CIM003JG	2[redacted]	膀胱炎	301	TREATMENT	5	NOT RELATED	MODERATE	No	1	1
[redacted]	WHITE									
Nemolizumab(0.5mg/kgQ4W)	M	上咽頭炎	69	TREATMENT	7	RELATED	MILD	No	1	1
CIM003JG	3[redacted]									
[redacted]	WHITE									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(0.5mg/kgQ4W)	F	副鼻腔炎	12	TREATMENT	25	RELATED	MILD	No	1	1
CIM003JG	2[redacted]									
[redacted]	WHITE									
Nemolizumab(0.5mg/kgQ4W)	F	扁桃炎	223	TREATMENT	71	RELATED	MILD	No	1	1
CIM003JG	3[redacted]	インフルエンザ	275	TREATMENT	4	NOT RELATED	MILD	No	1	1
[redacted]	ASIAN	上咽頭炎	309	TREATMENT	9	NOT RELATED	MILD	No	1	1
Nemolizumab(0.5mg/kgQ4W)	M	上咽頭炎	22	TREATMENT	9	NOT RELATED	MILD	No	1	1
CIM003JG	3[redacted]									
[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(0.5mg/kgQ4W)	F	上咽頭炎	38	TREATMENT	17	NOT RELATED	MILD	No	1	1
CIM003JG	4[redacted]	上咽頭炎	74	TREATMENT	11	NOT RELATED	MILD	No	1	1
[redacted]	ASIAN	上咽頭炎	237	TREATMENT	2	NOT RELATED	MILD	No	1	1
		上咽頭炎	279	TREATMENT	5	NOT RELATED	MILD	No	1	1
		上咽頭炎	390	TREATMENT	7	NOT RELATED	MILD	No	1	1
		上咽頭炎	413	TREATMENT	24	NOT RELATED	MILD	No	1	1
Nemolizumab(0.5mg/kgQ4W)	M	上咽頭炎	448	TREATMENT	5	NOT RELATED	MODERATE	No	5	1
CIM003JG	2[redacted]									
[redacted]	OTHER									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(0.5mg/kgQ4W)	M	鼓膜炎	26	TREATMENT	18	NOT RELATED	MILD	No	1	1
CIM003JG	2[redacted]									
[redacted]	ASIAN									
Nemolizumab(0.5mg/kgQ4W)	F	ウイルス性気道感染	4	TREATMENT	12	NOT RELATED	MILD	No	1	1
CIM003JG	2[redacted]	上咽頭炎	19	TREATMENT	11	NOT RELATED	MILD	No	1	1
[redacted]	WHITE									
Nemolizumab(0.5mg/kgQ4W)	F	上咽頭炎	439	TREATMENT	4	NOT RELATED	MODERATE	No	1	1
CIM003JG	2[redacted]									
[redacted]	WHITE									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(0.5mg/kgQ4W)	F	上気道感染	101	TREATMENT	6	RELATED	MILD	No	1	1
CIM003JG	3[redacted]	ウイルス性上気道感染	386	TREATMENT	6	NOT RELATED	MILD	No	1	1
[redacted]	WHITE	ウイルス性上気道感染	415	TREATMENT	15	NOT RELATED	MILD	No	1	1
Nemolizumab(0.5mg/kgQ4W)	F	上気道感染	81	TREATMENT	4	NOT RELATED	MILD	No	1	1
CIM003JG	1[redacted]	上気道感染	104	TREATMENT	19	RELATED	MILD	No	1	1
[redacted]	WHITE	副鼻腔炎	111	TREATMENT		NOT RELATED	MODERATE	No	1	2
		上気道感染	130	TREATMENT	8	NOT RELATED	MILD	No	3	1
		上気道感染	148	TREATMENT	8	NOT RELATED	MILD	No	1	1
		上気道感染	171	TREATMENT	30	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(0.5mg/kgQ4W)	M	咽頭炎	193	TREATMENT	8	NOT RELATED	MILD	No	1	1
CIM003JG	2[redacted]									
[redacted]	WHITE									
Nemolizumab(0.5mg/kgQ4W)	F	気管支炎	133	TREATMENT	9	NOT RELATED	MODERATE	No	1	1
CIM003JG	2[redacted]	尿路感染	508	SAFETY-FU	8	NOT RELATED	MILD	No	5	1
[redacted]	WHITE									
Nemolizumab(0.5mg/kgQ4W)	F	上咽頭炎	19	TREATMENT	3	NOT RELATED	MILD	No	1	1
CIM003JG	1[redacted]	膀胱炎	136	TREATMENT	6	NOT RELATED	MILD	No	1	1
[redacted]	WHITE	歯感染	193	TREATMENT	7	NOT RELATED	MODERATE	No	1	1
		上咽頭炎	248	TREATMENT	3	NOT RELATED	MILD	No	1	1
		歯髄炎	335	TREATMENT	6	NOT RELATED	MILD	No	1	1
		上咽頭炎	421	TREATMENT	7	NOT RELATED	MILD	No	1	1
		上咽頭炎	448	TREATMENT	4	NOT RELATED	MILD	No	5	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(0.5mg/kgQ4W)	F	尿路感染	98	TREATMENT	50	NOT RELATED	MILD	No	1	1
CIM003JG	5[redacted]									
[redacted]	WHITE									
Nemolizumab(0.5mg/kgQ4W)	F	咽頭炎	301	TREATMENT	6	NOT RELATED	MILD	No	1	1
CIM003JG	2[redacted]	上咽頭炎	333	TREATMENT	4	NOT RELATED	MILD	No	1	1
[redacted]	WHITE									
Nemolizumab(0.5mg/kgQ4W)	M	上咽頭炎	114	TREATMENT	8	NOT RELATED	MILD	No	1	1
CIM003JG	4[redacted]									
[redacted]	WHITE									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(0.5mg/kgQ4W)	M	副鼻腔炎	25	TREATMENT	12	RELATED	MILD	No	1	1
CIM003JG	2[redacted]	精巣上体炎	114	TREATMENT	10	RELATED	MODERATE	No	3	1
[redacted]	WHITE									
Nemolizumab(0.5mg/kgQ4W)	M	処置後感染	78	TREATMENT	20	NOT RELATED	MILD	No	1	1
CIM003JG	5[redacted]									
[redacted]	WHITE									
Nemolizumab(0.5mg/kgQ4W)	F	気管支炎	296	TREATMENT	11	NOT RELATED	MODERATE	No	1	1
CIM003JG	2[redacted]									
[redacted]	WHITE									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(0.5mg/kgQ4W)	F	ウイルス性胃腸炎	158	TREATMENT	2	NOT RELATED	MILD	No	1	1
CIM003JG	5[redacted]	上気道感染	195	TREATMENT	16	NOT RELATED	SEVERE	No	1	1
[redacted]	BLACK AFRICAN AMERICAN	OR 上気道感染	396	TREATMENT	15	NOT RELATED	MODERATE	No	1	1
Nemolizumab(0.5mg/kgQ4W)	F	咽頭炎	29	TREATMENT	5	NOT RELATED	MODERATE	No	1	1
CIM003JG	2[redacted]	上咽頭炎	347	TREATMENT	5	NOT RELATED	MODERATE	No	1	1
[redacted]	WHITE									
Nemolizumab(2mg/kgQ4W)	M	上咽頭炎	250	TREATMENT	8	NOT RELATED	MILD	No	1	1
CIM003JG	4[redacted]									
[redacted]	WHITE									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(2mg/kgQ4W)	F	上咽頭炎	16	TREATMENT	3	NOT RELATED	MILD	No	1	1
CIM003JG	2[redacted]	上咽頭炎	65	TREATMENT	4	NOT RELATED	MILD	No	1	1
[redacted]	WHITE	上咽頭炎	79	TREATMENT	34	NOT RELATED	MILD	No	1	1
		副鼻腔炎	195	TREATMENT	14	NOT RELATED	MILD	No	1	1
		上咽頭炎	291	TREATMENT	8	NOT RELATED	MILD	No	1	1
		上咽頭炎	359	TREATMENT	9	NOT RELATED	MILD	No	1	1
		上咽頭炎	498	SAFETY-FU	7	NOT RELATED	MILD	No	5	1
Nemolizumab(2mg/kgQ4W)	F	上咽頭炎	13	TREATMENT	11	NOT RELATED	MILD	No	1	1
CIM003JG	4[redacted]									
[redacted]	WHITE									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(2mg/kgQ4W)	M	上咽頭炎	140	TREATMENT	8	NOT RELATED	MILD	No	1	1
CIM003JG	2[redacted]									
[redacted]	WHITE									
Nemolizumab(2mg/kgQ4W)	F	上咽頭炎	22	TREATMENT	39	NOT RELATED	MILD	No	1	1
CIM003JG	3[redacted]	胃腸炎	268	TREATMENT	3	NOT RELATED	SEVERE	No	1	1
[redacted]	WHITE	膀胱炎	569	SAFETY-FU	14	NOT RELATED	MODERATE	No	5	1
Nemolizumab(2mg/kgQ4W)	M	上咽頭炎	24	TREATMENT	5	NOT RELATED	MILD	No	1	1
CIM003JG	2[redacted]	細菌重複感染	43	TREATMENT	5	NOT RELATED	MODERATE	No	1	1
[redacted]	WHITE	細菌重複感染	114	TREATMENT	15	NOT RELATED	SEVERE	No	1	1
		上咽頭炎	122	TREATMENT	8	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(2mg/kgQ4W)	F	上咽頭炎	106	TREATMENT	4	RELATED	MILD	No	1	1
CIM003JG	2[redacted]	上咽頭炎	380	TREATMENT	7	RELATED	MILD	No	1	1
[redacted]	WHITE	上咽頭炎	393	TREATMENT	20	RELATED	MODERATE	No	1	1
		気管支炎	403	TREATMENT	10	RELATED	MODERATE	No	1	1
		歯髄炎	472	SAFETY-FU	29	NOT RELATED	MODERATE	No	1	1
Nemolizumab(2mg/kgQ4W)	M	歯感染	350	TREATMENT	51	NOT RELATED	MODERATE	No	1	1
CIM003JG	3[redacted]									
[redacted]	WHITE									
Nemolizumab(2mg/kgQ4W)	M	上咽頭炎	166	TREATMENT	14	NOT RELATED	MILD	No	1	1
CIM003JG	3[redacted]	上咽頭炎	199	TREATMENT	21	NOT RELATED	MODERATE	No	1	1
[redacted]	ASIAN	急性副鼻腔炎	281	TREATMENT	11	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(2mg/kgQ4W)	M	上咽頭炎	86	TREATMENT	7	NOT RELATED	MILD	No	1	1
CIM003JG	2[redacted]	胃腸炎	125	TREATMENT	10	NOT RELATED	MILD	No	1	1
[redacted]	ASIAN	上咽頭炎	471	SAFETY-FU	12	NOT RELATED	MILD	No	5	1
Nemolizumab(2mg/kgQ4W)	M	ウイルス性気管支炎	25	TREATMENT	9	RELATED	MILD	No	1	1
CIM003JG	4[redacted]									
[redacted]	ASIAN									
Nemolizumab(2mg/kgQ4W)	F	上咽頭炎	4	TREATMENT	19	RELATED	MILD	No	1	1
CIM003JG	4[redacted]									
[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(2mg/kgQ4W)	F	上咽頭炎	420	TREATMENT	6	NOT RELATED	MILD	No	1	1
CIM003JG	4[redacted]	尿路感染	428	TREATMENT	54	NOT RELATED	MILD	No	5	1
[redacted]	ASIAN									
Nemolizumab(2mg/kgQ4W)	M	上気道感染	5	TREATMENT	7	RELATED	MODERATE	No	1	1
CIM003JG	4[redacted]									
[redacted]	WHITE									
Nemolizumab(2mg/kgQ4W)	F	咽頭炎	6	TREATMENT	3	NOT RELATED	MODERATE	No	1	1
CIM003JG	2[redacted]									
[redacted]	WHITE									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(2mg/kgQ4W)	M	上咽頭炎	324	TREATMENT	5	NOT RELATED	MODERATE	No	1	1
CIM003JG	2[redacted]									
[redacted]	WHITE									
Nemolizumab(2mg/kgQ4W)	F	上気道感染	71	TREATMENT	3	RELATED	MILD	No	1	1
CIM003JG	2[redacted]	上気道感染	101	TREATMENT	13	RELATED	MILD	No	1	1
[redacted]	WHITE	インフルエンザ	200	TREATMENT	5	RELATED	MODERATE	No	1	1
Nemolizumab(2mg/kgQ4W)	M	ウイルス性上気道感染	332	TREATMENT	9	NOT RELATED	MILD	No	1	1
CIM003JG	3[redacted]	ウイルス性上気道感染	485	SAFETY-FU	8	NOT RELATED	MILD	No	5	1
[redacted]	WHITE									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(2mg/kgQ4W)	M	細菌性上気道感染	60	TREATMENT	8	RELATED	MODERATE	No	1	1
CIM003JG	6[redacted]	カンジダ感染	275	TREATMENT	9	NOT RELATED	MILD	No	1	1
[redacted]	WHITE									
Nemolizumab(2mg/kgQ4W)	M	上気道感染	6	TREATMENT	7	RELATED	MILD	No	1	1
CIM003JG	1[redacted]	咽頭炎	207	TREATMENT	6	RELATED	MODERATE	No	1	1
[redacted]	WHITE	上気道感染	278	TREATMENT	7	RELATED	MILD	No	1	1
		上気道感染	351	TREATMENT	10	NOT RELATED	MODERATE	No	1	1
Nemolizumab(2mg/kgQ4W)	F	ウイルス感染	253	TREATMENT	14	NOT RELATED	MILD	No	1	1
CIM003JG	2[redacted]	咽頭炎	303	TREATMENT	51	NOT RELATED	MILD	No	1	1
[redacted]	WHITE	上咽頭炎	365	TREATMENT	2	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(2mg/kgQ4W)	F	上咽頭炎	140	TREATMENT	5	NOT RELATED	MILD	No	1	1
CIM003JG	3[redacted]									
[redacted]	WHITE									
Nemolizumab(2mg/kgQ4W)	M	上気道感染	18	TREATMENT	11	RELATED	MILD	No	1	1
CIM003JG	2[redacted]									
[redacted]	WHITE									
Nemolizumab(2mg/kgQ4W)	F	上咽頭炎	-11	RUN-IN	4	NOT RELATED	MILD	No	5	1
CIM003JG	2[redacted]	外陰部腟カンジダ症	20	TREATMENT	3	NOT RELATED	MILD	No	1	1
[redacted]	WHITE	上気道感染	134	TREATMENT	7	NOT RELATED	MILD	No	1	1
		上気道感染	336	TREATMENT	8	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(2mg/kgQ4W) CIM003JG [redacted]	M 4[redacted] ASIAN	レンサ球菌性扁桃炎	54	TREATMENT		NOT RELATED	MILD	No	1	2
Nemolizumab(2mg/kgQ4W) CIM003JG [redacted]	M 5[redacted] [redacted]	上咽頭炎	451	SAFETY-FU	9	NOT RELATED	MILD	No	5	1
Nemolizumab(2mg/kgQ4W) CIM003JG [redacted]	M 6[redacted] WHITE	インフルエンザ 気管支炎	201 486	TREATMENT SAFETY-FU	23 6	NOT RELATED NOT RELATED	MODERATE MODERATE	No No	1 5	1 1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(2mg/kgQ8W)	M	上咽頭炎	53	TREATMENT	5	NOT RELATED	MILD	No	1	1
CIM003JG	2[redacted]	上咽頭炎	75	TREATMENT	9	NOT RELATED	MILD	No	1	1
[redacted]	WHITE	上咽頭炎	347	TREATMENT	5	NOT RELATED	MILD	No	1	1
Nemolizumab(2mg/kgQ8W)	M	上咽頭炎	32	TREATMENT	3	RELATED	MILD	No	1	1
CIM003JG	4[redacted]									
[redacted]	WHITE									
Nemolizumab(2mg/kgQ8W)	M	上咽頭炎	4	TREATMENT	18	NOT RELATED	MILD	No	1	1
CIM003JG	1[redacted]	上咽頭炎	57	TREATMENT	14	NOT RELATED	MILD	No	1	1
[redacted]	WHITE									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(2mg/kgQ8W)	M	上咽頭炎	196	TREATMENT	5	NOT RELATED	MODERATE	No	1	1
CIM003JG	3[redacted]	上咽頭炎	209	TREATMENT	5	NOT RELATED	MODERATE	No	1	1
[redacted]	WHITE									
Nemolizumab(2mg/kgQ8W)	M	細菌重複感染	13	TREATMENT	17	NOT RELATED	MILD	No	1	1
CIM003JG	5[redacted]	歯髄炎	67	TREATMENT	5	RELATED	MILD	No	1	1
[redacted]	WHITE	細菌重複感染	112	TREATMENT	49	RELATED	MILD	No	1	1
		上咽頭炎	139	TREATMENT	22	RELATED	MILD	No	1	1
Nemolizumab(2mg/kgQ8W)	M	上咽頭炎	23	TREATMENT	7	RELATED	MILD	No	1	1
CIM003JG	2[redacted]	上咽頭炎	47	TREATMENT	5	RELATED	MILD	No	1	1
[redacted]	WHITE	歯感染	57	TREATMENT	8	RELATED	MODERATE	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(2mg/kgQ8W)	M	細菌重複感染	34	TREATMENT	84	RELATED	MODERATE	No	1	1
CIM003JG	3[redacted]									
[redacted]	WHITE									
Nemolizumab(2mg/kgQ8W)	F	腎盂腎炎	114	TREATMENT	10	RELATED	MODERATE	Yes	1	1
CIM003JG	2[redacted]	ウイルス性胃腸炎	227	TREATMENT	5	NOT RELATED	MODERATE	No	1	1
[redacted]	WHITE	上咽頭炎	303	TREATMENT	2	NOT RELATED	MILD	No	1	1
		膀胱炎	326	TREATMENT	4	RELATED	MODERATE	No	1	1
		上咽頭炎	364	TREATMENT	8	RELATED	MILD	No	1	1
		胃腸炎	365	TREATMENT	1	RELATED	MILD	No	1	1
		腎盂腎炎	478	SAFETY-FU	7	RELATED	MODERATE	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(2mg/kgQ8W)	F	歯感染	38	TREATMENT	6	NOT RELATED	MILD	No	1	1
CIM003JG	5[redacted]	歯髄炎	76	TREATMENT	33	NOT RELATED	MILD	No	1	1
[redacted]	WHITE	歯髄炎	198	TREATMENT	140	NOT RELATED	MODERATE	No	1	1
Nemolizumab(2mg/kgQ8W)	M	上咽頭炎	42	TREATMENT	3	NOT RELATED	MILD	No	1	1
CIM003JG	4[redacted]									
[redacted]	ASIAN									
Nemolizumab(2mg/kgQ8W)	M	上咽頭炎	129	TREATMENT	15	NOT RELATED	MILD	No	1	1
CIM003JG	2[redacted]	上咽頭炎	280	TREATMENT	3	NOT RELATED	MILD	No	1	1
[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(2mg/kgQ8W)	F	上咽頭炎	136	TREATMENT	1	NOT RELATED	MILD	No	1	1
CIM003JG	5[redacted]									
[redacted]	ASIAN									
Nemolizumab(2mg/kgQ8W)	F	アデノイド咽頭炎	66	TREATMENT	20	NOT RELATED	MILD	No	1	1
CIM003JG	3[redacted]	扁桃炎	373	TREATMENT	54	NOT RELATED	MILD	No	1	1
[redacted]	ASIAN									
Nemolizumab(2mg/kgQ8W)	M	ウイルス性上気道感染	53	TREATMENT	7	RELATED	MILD	No	1	1
CIM003JG	2[redacted]	ウイルス性上気道感染	109	TREATMENT	10	RELATED	MILD	No	1	1
[redacted]	WHITE	ウイルス性上気道感染	216	TREATMENT	9	RELATED	MILD	No	1	1
		ウイルス性上気道感染	267	TREATMENT	22	NOT RELATED	MILD	No	1	1
		ウイルス性上気道感染	361	TREATMENT	12	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(2mg/kgQ8W)	F	上気道感染	187	TREATMENT	7	RELATED	MODERATE	No	1	1
CIM003JG	2[redacted]									
[redacted]	WHITE									
Nemolizumab(2mg/kgQ8W)	M	上気道感染	5	TREATMENT	6	NOT RELATED	MILD	No	1	1
CIM003JG	4[redacted]									
[redacted]	WHITE									
Nemolizumab(2mg/kgQ8W)	F	上気道感染	57	TREATMENT	18	RELATED	MILD	No	1	1
CIM003JG	2[redacted]	ウイルス性上気道感染	336	TREATMENT	7	NOT RELATED	MILD	No	1	1
[redacted]	WHITE									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(2mg/kgQ8W)	M	鼻炎	82	TREATMENT	60	NOT RELATED	MILD	No	1	1
CIM003JG	3[redacted]									
[redacted]	WHITE									
Nemolizumab(2mg/kgQ8W)	M	感染	77	SAFETY-FU	5	NOT RELATED	MODERATE	Yes	5	1
CIM003JG	2[redacted]									
[redacted]	WHITE									
Nemolizumab(2mg/kgQ8W)	M	上咽頭炎	10	TREATMENT	34	NOT RELATED	MILD	No	1	1
CIM003JG	5[redacted]	上咽頭炎	244	TREATMENT	8	NOT RELATED	MILD	No	1	1
[redacted]	WHITE	ブドウ球菌感染	393	TREATMENT	15	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(2mg/kgQ8W)	M	上咽頭炎	21	TREATMENT	13	NOT RELATED	MILD	No	1	1
CIM003JG	4[redacted]	上咽頭炎	71	TREATMENT	8	NOT RELATED	MILD	No	1	1
[redacted]	BLACK OR AFRICAN AMERICAN	副鼻腔炎	253	TREATMENT	6	NOT RELATED	MILD	No	1	1
Nemolizumab(2mg/kgQ8W)	F	上気道感染	72	TREATMENT	11	NOT RELATED	MILD	No	1	1
CIM003JG	4[redacted]									
[redacted]	WHITE									
Nemolizumab(2mg/kgQ8W)	F	カンジダ感染	68	TREATMENT		RELATED	MILD	No	1	3
CIM003JG	4[redacted]									
[redacted]	WHITE									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(2mg/kgQ8W)	F	咽頭炎	25	TREATMENT	4	NOT RELATED	MODERATE	No	1	1
CIM003JG	6[redacted]	尿路感染	193	TREATMENT	9	NOT RELATED	MODERATE	No	1	1
[redacted]	BLACK OR AFRICAN AMERICAN									
Nemolizumab(2mg/kgQ8W)	F	感染	18	TREATMENT	123	NOT RELATED	SEVERE	Yes	3	1
CIM003JG	2[redacted]									
[redacted]	WHITE									
Nemolizumab(2mg/kgQ8W)	F	中耳炎	53	TREATMENT	7	NOT RELATED	MILD	No	1	1
CIM003JG	2[redacted]									
[redacted]	WHITE									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(2mg/kgQ8W)	F	上気道感染	68	TREATMENT	11	NOT RELATED	MILD	No	1	1
CIM003JG	2[redacted]	外陰腟真菌感染	235	TREATMENT	6	NOT RELATED	MILD	No	1	1
[redacted]	BLACK OR AFRICAN AMERICAN	上気道感染	398	SAFETY-FU		NOT RELATED	MODERATE	No	5	3
Nemolizumab(60mg/body)	M	インフルエンザ	-19	SCREENING	5	NOT RELATED	MILD	No	1	1
M525101-01	1[redacted]	上咽頭炎	54	DOUBLE BLIND TREATMENT	8	NOT RELATED	MILD	No	1	1
CA[redacted]	ASIAN	結膜炎	93	DOUBLE BLIND TREATMENT	7	NOT RELATED	MILD	No	1	1
		胃腸炎	361	OPEN LABEL TREATMENT	5	NOT RELATED	MILD	No	1	1
Nemolizumab(60mg/body)	F	上咽頭炎	311	OPEN LABEL TREATMENT	13	NOT RELATED	MODERATE	No	1	1
M525101-01	2[redacted]									
CA[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 3[redacted] ASIAN	上咽頭炎	5	DOUBLE BLIND TREATMENT	25	NOT RELATED	MILD	No	1	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	F 2[redacted] ASIAN	上咽頭炎 扁桃炎	50 177	DOUBLE BLIND TREATMENT OPEN LABEL TREATMENT	14 18	NOT RELATED NOT RELATED	MILD MILD	No No	1 1	1 1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	F 2[redacted] ASIAN	膀胱炎	330	OPEN LABEL TREATMENT	3	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body) M525101-01 CA[redacted]	F 1[redacted] ASIAN	ムンプス	299	OPEN LABEL TREATMENT	40	NOT RELATED	MODERATE	No	3	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	F 2[redacted] ASIAN	咽頭炎	511	FOLLOW-UP		NOT RELATED	MODERATE	No	5	3
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 2[redacted] ASIAN	咽頭炎	420	OPEN LABEL TREATMENT	9	RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	M	上咽頭炎	76	DOUBLE BLIND TREATMENT	9	NOT RELATED	MILD	No	1	1
M525101-01	5[redacted]	上咽頭炎	224	OPEN LABEL TREATMENT	5	NOT RELATED	MILD	No	1	1
CA[redacted]	ASIAN	ヘリコバクター性胃炎	387	OPEN LABEL TREATMENT		NOT RELATED	MILD	No	1	2
Nemolizumab(60mg/body)	M	上咽頭炎	404	OPEN LABEL TREATMENT	15	NOT RELATED	MILD	No	1	1
M525101-01	6[redacted]									
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	F	上咽頭炎	12	DOUBLE BLIND TREATMENT	6	NOT RELATED	MILD	No	1	1
M525101-01	3[redacted]	インフルエンザ	296	OPEN LABEL TREATMENT	9	NOT RELATED	MILD	No	1	1
CA[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 4[redacted] ASIAN	上咽頭炎	13	DOUBLE BLIND TREATMENT	7	NOT RELATED	MILD	No	1	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	F 5[redacted] ASIAN	上咽頭炎	-7	SCREENING	7	NOT RELATED	MILD	No	1	1
		ウイルス性胃腸炎	394	OPEN LABEL TREATMENT	5	NOT RELATED	MILD	No	1	1
		インフルエンザ	416	OPEN LABEL TREATMENT	6	NOT RELATED	MILD	No	1	1
		歯髄炎	438	OPEN LABEL TREATMENT	2	NOT RELATED	MILD	No	1	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 3[redacted] ASIAN	上咽頭炎	357	OPEN LABEL TREATMENT	4	RELATED	MILD	No	1	1
		上咽頭炎	462	OPEN LABEL TREATMENT	9	RELATED	MILD	No	5	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	F	インフルエンザ	79	DOUBLE BLIND TREATMENT	4	RELATED	MILD	No	1	1
M525101-01	5[redacted]	結膜炎	203	OPEN LABEL TREATMENT		RELATED	MILD	No	1	2
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	M	インフルエンザ	326	OPEN LABEL TREATMENT	4	RELATED	MILD	No	1	1
M525101-01	2[redacted]	胃腸炎	481	FOLLOW-UP	6	NOT RELATED	MILD	No	5	1
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	F	気管支炎	96	DOUBLE BLIND TREATMENT	10	RELATED	MILD	No	1	1
M525101-01	4[redacted]	上咽頭炎	334	OPEN LABEL TREATMENT	4	RELATED	MILD	No	1	1
CA[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	M	上咽頭炎	-6	SCREENING	5	NOT RELATED	MILD	No	1	1
M525101-01	1[redacted]	菌血症	20	DOUBLE BLIND TREATMENT	73	RELATED	MODERATE	Yes	1	1
CA[redacted]	ASIAN	胃腸炎	84	DOUBLE BLIND TREATMENT	3	RELATED	MILD	No	1	1
Nemolizumab(60mg/body)	F	上咽頭炎	224	OPEN LABEL TREATMENT	5	NOT RELATED	MILD	No	1	1
M525101-01	4[redacted]	上咽頭炎	260	OPEN LABEL TREATMENT	19	NOT RELATED	MILD	No	1	1
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	F	上咽頭炎	91	DOUBLE BLIND TREATMENT	9	NOT RELATED	MILD	No	1	1
M525101-01	1[redacted]	インフルエンザ	391	OPEN LABEL TREATMENT	6	NOT RELATED	MILD	No	1	1
CA[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body) M525101-01 CA[redacted]	F 3[redacted] ASIAN	細菌性外陰膣炎	27	DOUBLE BLIND TREATMENT	15	RELATED	MILD	No	1	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	F 5[redacted] ASIAN	膀胱炎	170	OPEN LABEL TREATMENT	84	RELATED	MILD	No	1	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	F 5[redacted] ASIAN	菌血症	188	OPEN LABEL TREATMENT	15	RELATED	MODERATE	Yes	3	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 5[redacted] ASIAN	肺炎	375	OPEN LABEL TREATMENT	16	RELATED	MODERATE	Yes	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body) M525101-01 CA[redacted]	F 4[redacted] ASIAN	上咽頭炎	-12	SCREENING	7	NOT RELATED	MILD	No	1	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	F 3[redacted] ASIAN	上咽頭炎	474	OPEN LABEL TREATMENT	3	NOT RELATED	MILD	No	5	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	F 3[redacted] ASIAN	胃腸炎	279	OPEN LABEL TREATMENT	2	NOT RELATED	MILD	No	1	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 4[redacted] ASIAN	咽頭炎	171	OPEN LABEL TREATMENT	11	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 4[redacted] ASIAN	上咽頭炎	35	DOUBLE BLIND TREATMENT	8	NOT RELATED	MILD	No	1	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 4[redacted] ASIAN	インフルエンザ	279	OPEN LABEL TREATMENT	10	NOT RELATED	MILD	No	1	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 4[redacted] ASIAN	ヘリコバクター感染	470	OPEN LABEL TREATMENT		RELATED	MILD	No	5	3
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 4[redacted] ASIAN	胃腸炎	172	OPEN LABEL TREATMENT	4	NOT RELATED	MODERATE	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	M	インフルエンザ	68	DOUBLE BLIND TREATMENT	10	NOT RELATED	MODERATE	No	1	1
M525101-01	5[redacted]	上咽頭炎	370	OPEN LABEL TREATMENT	16	NOT RELATED	MILD	No	1	1
CA[redacted]	ASIAN	胃腸炎	475	FOLLOW-UP	15	NOT RELATED	MILD	No	5	1
Nemolizumab(60mg/body)	F	上咽頭炎	20	DOUBLE BLIND TREATMENT	12	NOT RELATED	MILD	No	1	1
M525101-01	1[redacted]	上咽頭炎	259	OPEN LABEL TREATMENT	4	NOT RELATED	MILD	No	1	1
CA[redacted]	ASIAN	上咽頭炎	341	OPEN LABEL TREATMENT	5	NOT RELATED	MILD	No	1	1
		上咽頭炎	408	OPEN LABEL TREATMENT	32	NOT RELATED	MILD	No	1	1
Nemolizumab(60mg/body)	F	上咽頭炎	85	DOUBLE BLIND TREATMENT	8	NOT RELATED	MILD	No	1	1
M525101-01	4[redacted]	上咽頭炎	316	OPEN LABEL TREATMENT	11	NOT RELATED	MILD	No	1	1
CA[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	M	上咽頭炎	-21	SCREENING	13	NOT RELATED	MILD	No	1	1
M525101-01	4[redacted]	上咽頭炎	135	OPEN LABEL TREATMENT	26	NOT RELATED	MODERATE	No	1	1
CA[redacted]	ASIAN	気管支炎	192	OPEN LABEL TREATMENT	23	NOT RELATED	MILD	No	1	1
		歯周炎	303	OPEN LABEL TREATMENT	9	NOT RELATED	MILD	No	1	1
Nemolizumab(60mg/body)	F	上咽頭炎	44	DOUBLE BLIND TREATMENT	14	NOT RELATED	MILD	No	1	1
M525101-01	4[redacted]	上咽頭炎	226	OPEN LABEL TREATMENT	4	NOT RELATED	MILD	No	1	1
CA[redacted]	ASIAN	上咽頭炎	369	OPEN LABEL TREATMENT	9	NOT RELATED	MILD	No	1	1
		上咽頭炎	462	OPEN LABEL TREATMENT	4	NOT RELATED	MILD	No	5	1
		上咽頭炎	532	FOLLOW-UP		NOT RELATED	MILD	No	5	3

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	F	上咽頭炎	78	DOUBLE BLIND TREATMENT	13	NOT RELATED	MILD	No	1	1
M525101-01	3[redacted]	上咽頭炎	95	DOUBLE BLIND TREATMENT	3	NOT RELATED	MILD	No	1	1
CA[redacted]	ASIAN	上咽頭炎	133	OPEN LABEL TREATMENT	12	NOT RELATED	MILD	No	1	1
		上咽頭炎	173	OPEN LABEL TREATMENT	14	NOT RELATED	MILD	No	1	1
		上咽頭炎	227	OPEN LABEL TREATMENT	6	NOT RELATED	MILD	No	1	1
		上咽頭炎	459	OPEN LABEL TREATMENT	4	NOT RELATED	MILD	No	5	1
		上咽頭炎	496	FOLLOW-UP	13	NOT RELATED	MILD	No	5	1
Nemolizumab(60mg/body)	F	上咽頭炎	203	OPEN LABEL TREATMENT	3	NOT RELATED	MILD	No	1	1
M525101-01	4[redacted]									
CA[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body) M525101-01 CA[redacted]	F 4[redacted] ASIAN	感染性腸炎	8	DOUBLE BLIND TREATMENT	8	RELATED	MILD	No	1	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	F 4[redacted] ASIAN	上咽頭炎	8	DOUBLE BLIND TREATMENT	27	NOT RELATED	MILD	No	1	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	F 4[redacted] ASIAN	上咽頭炎	330	OPEN LABEL TREATMENT	9	NOT RELATED	MILD	No	1	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 6[redacted] ASIAN	尿道炎	234	FOLLOW-UP	6	NOT RELATED	MILD	No	5	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	M	上気道感染	362	OPEN LABEL TREATMENT	30	NOT RELATED	MODERATE	No	1	1
M525101-01	4[redacted]									
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	F	ヘリコバクター感染	209	OPEN LABEL TREATMENT	57	NOT RELATED	MILD	No	1	1
M525101-01	3[redacted]	副鼻腔炎	520	FOLLOW-UP		NOT RELATED	MILD	No	5	3
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	F	膀胱炎	189	OPEN LABEL TREATMENT	3	NOT RELATED	MILD	No	1	1
M525101-01	2[redacted]	上咽頭炎	307	OPEN LABEL TREATMENT	9	NOT RELATED	MILD	No	1	1
CA[redacted]	ASIAN	上咽頭炎	361	OPEN LABEL TREATMENT	11	NOT RELATED	MILD	No	1	1
		上咽頭炎	408	OPEN LABEL TREATMENT	3	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	M	結膜炎	147	OPEN LABEL TREATMENT		RELATED	MILD	No	1	3
M525101-01	2[redacted]									
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	M	インフルエンザ	-19	SCREENING	5	NOT RELATED	MILD	No	1	1
M525101-01	5[redacted]	感染	5	DOUBLE BLIND TREATMENT	25	NOT RELATED	MILD	No	1	1
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	F	上咽頭炎	13	DOUBLE BLIND TREATMENT	12	NOT RELATED	MILD	No	1	1
M525101-01	3[redacted]	上咽頭炎	75	DOUBLE BLIND TREATMENT	12	NOT RELATED	MILD	No	1	1
CA[redacted]	ASIAN	上咽頭炎	238	OPEN LABEL TREATMENT	21	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	M	インフルエンザ	411	OPEN LABEL TREATMENT	10	NOT RELATED	MILD	No	1	1
M525101-01	5[redacted]									
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	M	咽頭炎	357	OPEN LABEL TREATMENT		NOT RELATED	MILD	No	1	3
M525101-01	4[redacted]	胃腸炎	357	OPEN LABEL TREATMENT	62	NOT RELATED	MILD	No	1	1
CA[redacted]	ASIAN	上咽頭炎	517	FOLLOW-UP		NOT RELATED	MILD	No	5	3
Nemolizumab(60mg/body)	M	上咽頭炎	207	OPEN LABEL TREATMENT	8	NOT RELATED	MILD	No	1	1
M525101-01	1[redacted]	上咽頭炎	239	OPEN LABEL TREATMENT	5	NOT RELATED	MILD	No	1	1
CA[redacted]	ASIAN	上咽頭炎	290	OPEN LABEL TREATMENT	24	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 2[redacted] ASIAN	結膜炎	224	OPEN LABEL TREATMENT	29	NOT RELATED	MILD	No	1	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	F 3[redacted] ASIAN	インフルエンザ	285	OPEN LABEL TREATMENT	6	NOT RELATED	MILD	No	1	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 2[redacted] ASIAN	上咽頭炎	135	OPEN LABEL TREATMENT	9	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.

5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	F	上咽頭炎	-29	SCREENING	4	NOT RELATED	MILD	No	1	1
M525101-01	2[redacted]									
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	F	上咽頭炎	238	OPEN LABEL TREATMENT	9	NOT RELATED	MILD	No	1	1
M525101-01	3[redacted]	上咽頭炎	399	OPEN LABEL TREATMENT	8	NOT RELATED	MILD	No	1	1
CA[redacted]	ASIAN	上咽頭炎	427	OPEN LABEL TREATMENT	24	NOT RELATED	MILD	No	1	1
Nemolizumab(60mg/body)	M	上咽頭炎	102	DOUBLE BLIND TREATMENT	5	NOT RELATED	MILD	No	1	1
M525101-01	2[redacted]	上咽頭炎	330	OPEN LABEL TREATMENT	3	NOT RELATED	MILD	No	1	1
CA[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 4[redacted] ASIAN	気管支炎	-35	SCREENING	7	NOT RELATED	MILD	No	1	1
Nemolizumab(60mg/body)	M	上咽頭炎	261	OPEN LABEL TREATMENT	7	NOT RELATED	MILD	No	1	1
M525101-01	2[redacted]	インフルエンザ	380	OPEN LABEL TREATMENT	9	NOT RELATED	MODERATE	No	1	1
CA[redacted]	ASIAN	上咽頭炎	441	OPEN LABEL TREATMENT	8	NOT RELATED	MILD	No	1	1
		上咽頭炎	500	FOLLOW-UP	14	NOT RELATED	MILD	No	5	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 3[redacted] ASIAN	上咽頭炎	198	OPEN LABEL TREATMENT	2	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	F	上咽頭炎	198	OPEN LABEL TREATMENT	81	NOT RELATED	MILD	No	1	1
M525101-01	4[redacted]	細菌性リンパ節炎	244	OPEN LABEL TREATMENT	5	NOT RELATED	MILD	No	1	1
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	M	上咽頭炎	269	OPEN LABEL TREATMENT	4	NOT RELATED	MILD	No	1	1
M525101-01	2[redacted]									
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	M	上咽頭炎	-19	SCREENING	20	NOT RELATED	MILD	No	1	1
M525101-01	4[redacted]	上咽頭炎	312	OPEN LABEL TREATMENT	3	NOT RELATED	MILD	No	1	1
CA[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	M	咽頭炎	-1	SCREENING	9	NOT RELATED	MILD	No	1	1
M525101-01	1[redacted]	上咽頭炎	13	DOUBLE BLIND TREATMENT	9	NOT RELATED	MILD	No	1	1
CA[redacted]	ASIAN	咽頭炎	167	OPEN LABEL TREATMENT	3	NOT RELATED	MILD	No	1	1
		上咽頭炎	372	OPEN LABEL TREATMENT	4	NOT RELATED	MILD	No	1	1
Nemolizumab(60mg/body)	M	上咽頭炎	188	OPEN LABEL TREATMENT	42	NOT RELATED	MILD	No	1	1
M525101-01	3[redacted]									
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	M	咽頭炎	200	OPEN LABEL TREATMENT	15	RELATED	MILD	No	1	1
M525101-01	2[redacted]									
CA[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 4[redacted] ASIAN	上咽頭炎	13	DOUBLE BLIND TREATMENT	6	NOT RELATED	MILD	No	1	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 2[redacted] ASIAN	感染	201	OPEN LABEL TREATMENT	11	RELATED	MILD	No	1	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	F 4[redacted] ASIAN	上咽頭炎	295	OPEN LABEL TREATMENT	11	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.

5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	F	上咽頭炎	378	OPEN LABEL TREATMENT	8	NOT RELATED	MILD	No	1	1
M525101-01	4[redacted]									
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	M	上咽頭炎	249	OPEN LABEL TREATMENT	33	NOT RELATED	MILD	No	1	1
M525101-01	4[redacted]	上咽頭炎	432	OPEN LABEL TREATMENT	5	NOT RELATED	MILD	No	1	1
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	M	インフルエンザ	288	OPEN LABEL TREATMENT	5	NOT RELATED	MODERATE	No	1	1
M525101-01	3[redacted]	上咽頭炎	505	FOLLOW-UP	7	NOT RELATED	MODERATE	No	5	1
CA[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	M	上咽頭炎	283	OPEN LABEL TREATMENT	2	NOT RELATED	MILD	No	1	1
M525101-01	2[redacted]									
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	F	胃腸炎	-5	SCREENING	6	NOT RELATED	MILD	No	1	1
M525101-01	3[redacted]									
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	M	インフルエンザ	1	SCREENING	9	NOT RELATED	MILD	No	1	1
M525101-01	1[redacted]									
CA[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	M	気管支炎	278	OPEN LABEL TREATMENT	6	NOT RELATED	MILD	No	1	1
M525101-01	3[redacted]	上咽頭炎	299	OPEN LABEL TREATMENT	3	NOT RELATED	MILD	No	1	1
CA[redacted]	ASIAN	上咽頭炎	352	OPEN LABEL TREATMENT	8	NOT RELATED	MILD	No	1	1
Nemolizumab(60mg/body)	F	上咽頭炎	-27	SCREENING	35	NOT RELATED	MILD	No	1	1
M525101-01	3[redacted]	上咽頭炎	57	DOUBLE BLIND TREATMENT	3	NOT RELATED	MILD	No	1	1
CA[redacted]	ASIAN	咽頭炎	152	OPEN LABEL TREATMENT	9	NOT RELATED	MILD	No	1	1
		上咽頭炎	226	OPEN LABEL TREATMENT	6	NOT RELATED	MILD	No	1	1
		上咽頭炎	267	OPEN LABEL TREATMENT	29	NOT RELATED	MILD	No	1	1
		上咽頭炎	400	OPEN LABEL TREATMENT	13	NOT RELATED	MILD	No	1	1
		上咽頭炎	485	FOLLOW-UP	8	NOT RELATED	MILD	No	5	1
		上咽頭炎	508	FOLLOW-UP	11	NOT RELATED	MILD	No	5	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	M	咽頭炎	32	DOUBLE BLIND TREATMENT	4	RELATED	MILD	No	1	1
M525101-01	3[redacted]	扁桃炎	291	OPEN LABEL TREATMENT	4	RELATED	MILD	No	1	1
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	M	胃腸炎	99	DOUBLE BLIND TREATMENT	4	RELATED	MILD	No	1	1
M525101-01	2[redacted]	上咽頭炎	342	OPEN LABEL TREATMENT	4	RELATED	MILD	No	1	1
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	M	上咽頭炎	348	OPEN LABEL TREATMENT	2	NOT RELATED	MILD	No	1	1
M525101-01	7[redacted]	上咽頭炎	455	OPEN LABEL TREATMENT	2	NOT RELATED	MILD	No	5	1
CA[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	M	上咽頭炎	-14	SCREENING	3	NOT RELATED	MILD	No	1	1
M525101-01	4[redacted]	インフルエンザ	18	DOUBLE BLIND TREATMENT	12	NOT RELATED	MODERATE	No	1	1
CA[redacted]	ASIAN	上咽頭炎	153	OPEN LABEL TREATMENT	11	RELATED	MILD	No	1	1
		上咽頭炎	175	OPEN LABEL TREATMENT	23	NOT RELATED	MILD	No	1	1
		上咽頭炎	270	OPEN LABEL TREATMENT	11	NOT RELATED	MILD	No	1	1
		上咽頭炎	328	FOLLOW-UP	8	NOT RELATED	MILD	No	5	1
Nemolizumab(60mg/body)	M	感染性腸炎	197	OPEN LABEL TREATMENT	6	NOT RELATED	MODERATE	No	1	1
M525101-01	1[redacted]									
CA[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	M	細菌性扁桃炎	12	DOUBLE BLIND TREATMENT	18	NOT RELATED	MILD	No	1	1
M525101-01	4[redacted]	上咽頭炎	232	OPEN LABEL TREATMENT	22	NOT RELATED	MODERATE	No	1	1
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	M	上咽頭炎	136	OPEN LABEL TREATMENT	6	NOT RELATED	MILD	No	1	1
M525101-01	4[redacted]	上咽頭炎	201	OPEN LABEL TREATMENT	29	NOT RELATED	MILD	No	1	1
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	F	インフルエンザ	10	DOUBLE BLIND TREATMENT	7	NOT RELATED	MODERATE	No	1	1
M525101-01	4[redacted]	結膜炎	20	DOUBLE BLIND TREATMENT	6	NOT RELATED	MILD	No	1	1
CA[redacted]	ASIAN	胃腸炎	182	OPEN LABEL TREATMENT	6	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 2[redacted] ASIAN	ウイルス性上気道感染	63	DOUBLE BLIND TREATMENT	16	RELATED	MILD	No	1	1
Nemolizumab(60mg/body) M525101-02 CB[redacted]	F 3[redacted] ASIAN	歯冠周囲炎	242	TREATMENT	9	RELATED	MILD	No	1	1
Nemolizumab(60mg/body) M525101-02 CB[redacted]	M 4[redacted] ASIAN	歯冠周囲炎	257	TREATMENT	46	RELATED	MILD	No	1	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	2[redacted] ASIAN	インフルエンザ	314	OPEN LABEL TREATMENT	3	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body) M525101-02 CB[redacted]	M 1[redacted] ASIAN	インフルエンザ	168	TREATMENT	9	NOT RELATED	MODERATE	No	1	1
Nemolizumab(60mg/body) M525101-02 CB[redacted]	M 1[redacted] ASIAN	上咽頭炎	105	TREATMENT	16	NOT RELATED	MILD	No	1	1
Nemolizumab(60mg/body) M525101-02 CB[redacted]	F 4[redacted] ASIAN	インフルエンザ	193	TREATMENT	9	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	F	ヘリコバクター性胃炎	82	TREATMENT	141	NOT RELATED	MILD	No	1	1
M525101-02	4[redacted]									
CB[redacted]	ASIAN									
Nemolizumab(60mg/body)	F	胃腸炎	295	TREATMENT	4	NOT RELATED	MILD	No	1	1
M525101-02	3[redacted]									
CB[redacted]	ASIAN									
Nemolizumab(60mg/body)	F	咽頭炎	111	TREATMENT	11	NOT RELATED	MILD	No	1	1
M525101-02	4[redacted]	上咽頭炎	138	TREATMENT	15	NOT RELATED	MILD	No	1	1
CB[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	F	上咽頭炎	108	TREATMENT	2	NOT RELATED	MILD	No	1	1
M525101-02	4[redacted]	上咽頭炎	135	TREATMENT	5	NOT RELATED	MILD	No	1	1
CB[redacted]	ASIAN	インフルエンザ	236	TREATMENT	5	NOT RELATED	MILD	No	1	1
		上咽頭炎	340	TREATMENT	2	NOT RELATED	MILD	No	1	1
Nemolizumab(60mg/body)	F	インフルエンザ	231	TREATMENT	7	NOT RELATED	MILD	No	1	1
M525101-02	3[redacted]									
CB[redacted]	ASIAN									
Nemolizumab(60mg/body)	F	上咽頭炎	116	TREATMENT	5	NOT RELATED	MILD	No	1	1
M525101-02	4[redacted]	インフルエンザ	203	TREATMENT	5	NOT RELATED	MILD	No	1	1
CB[redacted]	ASIAN	上咽頭炎	308	TREATMENT	11	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	M	上咽頭炎	11	TREATMENT	34	NOT RELATED	MILD	No	1	1
M525101-02	5[redacted]	咽頭炎	45	TREATMENT	12	NOT RELATED	MILD	No	1	1
CB[redacted]	ASIAN	リンパ管炎	120	TREATMENT	31	NOT RELATED	MILD	No	1	1
Nemolizumab(60mg/body)	M	上咽頭炎	35	TREATMENT	4	NOT RELATED	MILD	No	1	1
M525101-02	4[redacted]									
CB[redacted]	ASIAN									
Nemolizumab(60mg/body)	M	上咽頭炎	80	TREATMENT	6	NOT RELATED	MILD	No	1	1
M525101-02	3[redacted]									
CB[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	F	上咽頭炎	12	TREATMENT	3	NOT RELATED	MILD	No	1	1
M525101-02	4[redacted]	咽頭炎	384	FOLLOW-UP	4	NOT RELATED	MILD	No	5	1
CB[redacted]	ASIAN	結膜炎	407	FOLLOW-UP		NOT RELATED	MILD	No	5	3
Nemolizumab(60mg/body)	M	上咽頭炎	161	FOLLOW-UP		NOT RELATED	MILD	No	5	3
M525101-02	5[redacted]									
CB[redacted]	ASIAN									
Nemolizumab(60mg/body)	M	上咽頭炎	246	TREATMENT	4	NOT RELATED	MILD	No	1	1
M525101-02	4[redacted]									
CB[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	F	膀胱炎	161	TREATMENT	24	NOT RELATED	MILD	No	1	1
M525101-02	4[redacted]	膀胱炎	229	TREATMENT	13	NOT RELATED	MILD	No	1	1
CB[redacted]	ASIAN									
Nemolizumab(60mg/body)	M	感染性腸炎	247	TREATMENT	29	RELATED	MODERATE	No	1	1
M525101-02	3[redacted]									
CB[redacted]	ASIAN									
Nemolizumab(60mg/body)	M	上咽頭炎	52	TREATMENT	12	NOT RELATED	MILD	No	1	1
M525101-02	2[redacted]	上咽頭炎	145	TREATMENT	10	NOT RELATED	MILD	No	1	1
CB[redacted]	ASIAN	上咽頭炎	218	TREATMENT	9	NOT RELATED	MILD	No	1	1
		ウイルス感染	419	FOLLOW-UP		RELATED	SEVERE	Yes	5	2

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	M	上咽頭炎	194	TREATMENT	6	NOT RELATED	MILD	No	1	1
M525101-02	2[redacted]									
CB[redacted]	ASIAN									
Nemolizumab(60mg/body)	M	上咽頭炎	71	TREATMENT	11	NOT RELATED	MILD	No	1	1
M525101-02	4[redacted]	上咽頭炎	275	TREATMENT	2	NOT RELATED	MILD	No	1	1
CB[redacted]	ASIAN	上咽頭炎	362	TREATMENT	5	NOT RELATED	MILD	No	5	1
Nemolizumab(60mg/body)	F	感染	1	SCREENING	29	NOT RELATED	MILD	No	1	1
M525101-02	5[redacted]	上咽頭炎	259	TREATMENT	8	NOT RELATED	MILD	No	1	1
CB[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	M	上咽頭炎	79	TREATMENT	18	NOT RELATED	MILD	No	1	1
M525101-02	4[redacted]	インフルエンザ	165	TREATMENT	6	NOT RELATED	MODERATE	No	1	1
CB[redacted]	ASIAN	上咽頭炎	258	TREATMENT	7	NOT RELATED	MILD	No	1	1
Nemolizumab(60mg/body)	F	インフルエンザ	229	TREATMENT	7	NOT RELATED	MILD	No	1	1
M525101-02	2[redacted]									
CB[redacted]	ASIAN									
Nemolizumab(60mg/body)	M	上咽頭炎	41	TREATMENT	4	NOT RELATED	MILD	No	1	1
M525101-02	6[redacted]	上咽頭炎	153	TREATMENT	8	NOT RELATED	MILD	No	1	1
CB[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	F	気管支炎	38	TREATMENT	20	NOT RELATED	MILD	No	1	1
M525101-02	3[redacted]									
CB[redacted]	ASIAN									
Nemolizumab(60mg/body)	M	上咽頭炎	168	TREATMENT	13	NOT RELATED	MILD	No	1	1
M525101-02	3[redacted]	上咽頭炎	247	TREATMENT	11	NOT RELATED	MILD	No	1	1
CB[redacted]	ASIAN									
Nemolizumab(60mg/body)	M	インフルエンザ	205	TREATMENT	7	NOT RELATED	MILD	No	1	1
M525101-02	2[redacted]									
CB[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	F	気管支炎	94	TREATMENT	42	NOT RELATED	MILD	No	1	1
M525101-02	4[redacted]	気管支炎	268	TREATMENT	24	NOT RELATED	MILD	No	1	1
CB[redacted]	ASIAN									
Nemolizumab(60mg/body)	M	咽頭炎	54	TREATMENT	9	NOT RELATED	MILD	No	1	1
M525101-02	2[redacted]	咽頭炎	80	TREATMENT	13	NOT RELATED	MILD	No	1	1
CB[redacted]	ASIAN									
Nemolizumab(60mg/body)	M	気管支炎	126	TREATMENT	16	NOT RELATED	MILD	No	1	1
M525101-02	4[redacted]	上咽頭炎	205	TREATMENT	8	NOT RELATED	MILD	No	1	1
CB[redacted]	ASIAN	上咽頭炎	333	TREATMENT	4	NOT RELATED	MILD	No	5	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body) M525101-02 CB[redacted]	F 3[redacted] ASIAN	上咽頭炎 胃腸炎	108 275	TREATMENT TREATMENT	9 8	NOT RELATED NOT RELATED	MILD MILD	No No	1 1	1 1
Nemolizumab(60mg/body) M525101-02 CB[redacted]	M 2[redacted] ASIAN	上咽頭炎	349	TREATMENT	10	NOT RELATED	MILD	No	5	1
Nemolizumab(60mg/body) M525101-02 CB[redacted]	M 4[redacted] ASIAN	上咽頭炎	183	TREATMENT	78	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	F	上咽頭炎	188	TREATMENT	9	NOT RELATED	MILD	No	1	1
M525101-02	3[redacted]									
CB[redacted]	ASIAN									
Nemolizumab(60mg/body)	M	上咽頭炎	186	TREATMENT	10	NOT RELATED	MILD	No	1	1
M525101-02	6[redacted]	気管支炎	409	FOLLOW-UP	4	NOT RELATED	MILD	No	5	1
CB[redacted]	ASIAN									
Nemolizumab(60mg/body)	F	レンサ球菌感染	282	TREATMENT	21	NOT RELATED	MILD	No	1	1
M525101-02	3[redacted]	レンサ球菌感染	327	TREATMENT	11	NOT RELATED	MILD	No	1	1
CB[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	F	上咽頭炎	148	TREATMENT	28	NOT RELATED	MILD	No	1	1
M525101-02	1[redacted]	副鼻腔炎	148	TREATMENT	28	NOT RELATED	MILD	No	1	1
CB[redacted]	ASIAN	上咽頭炎	216	TREATMENT	16	NOT RELATED	MILD	No	1	1
		咽頭炎	270	TREATMENT	6	NOT RELATED	MILD	No	1	1
Nemolizumab(60mg/body)	M	鼓膜炎	3	TREATMENT	8	NOT RELATED	MODERATE	No	1	1
M525101-02	1[redacted]	インフルエンザ	173	TREATMENT	8	NOT RELATED	MODERATE	No	1	1
CB[redacted]	ASIAN									
Nemolizumab(60mg/body)	M	上咽頭炎	82	TREATMENT	11	NOT RELATED	MILD	No	1	1
M525101-02	4[redacted]									
CB[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body) M525101-02 CB[redacted]	M 5[redacted] ASIAN	上咽頭炎	23	TREATMENT	63	NOT RELATED	MILD	No	1	1
Nemolizumab(60mg/body) M525101-02 CB[redacted]	M 3[redacted] ASIAN	上咽頭炎	10	TREATMENT	6	NOT RELATED	MILD	No	1	1
Nemolizumab(60mg/body) M525101-02 CB[redacted]	F 4[redacted] ASIAN	上咽頭炎	241	TREATMENT	8	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	M	感染	48	TREATMENT	38	RELATED	MODERATE	No	1	1
M525101-02	3[redacted]	上咽頭炎	237	TREATMENT	7	NOT RELATED	MODERATE	No	1	1
CB[redacted]	ASIAN									
Nemolizumab(60mg/body)	F	上咽頭炎	129	TREATMENT	4	NOT RELATED	MILD	No	1	1
M525101-02	4[redacted]	上咽頭炎	346	TREATMENT	11	NOT RELATED	MILD	No	5	1
CB[redacted]	ASIAN									
Nemolizumab(60mg/body)	F	感染	22	TREATMENT	63	RELATED	MILD	No	1	1
M525101-02	4[redacted]	上咽頭炎	163	TREATMENT	2	NOT RELATED	MILD	No	1	1
CB[redacted]	ASIAN	上咽頭炎	200	TREATMENT	3	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Placebo-Nemolizumab(Placebo-0.5mg/kgQ4W)	F	細菌重複感染	57	TREATMENT	8	NOT RELATED	MILD	No	1	1
CIM003JG	4[redacted]	気管支炎	162	TREATMENT	13	NOT RELATED	MODERATE	No	1	1
[redacted]	WHITE	上咽頭炎	249	TREATMENT	20	NOT RELATED	MODERATE	No	1	1
Placebo-Nemolizumab(Placebo-0.5mg/kgQ4W)	F	膀胱炎	4	TREATMENT	7	NOT RELATED	MODERATE	No	1	1
CIM003JG	2[redacted]									
[redacted]	WHITE									
Placebo-Nemolizumab(Placebo-0.5mg/kgQ4W)	F	上咽頭炎	24	TREATMENT	42	NOT RELATED	MILD	No	1	1
CIM003JG	2[redacted]	細菌性膿瘍	126	TREATMENT	6	NOT RELATED	MODERATE	No	1	1
[redacted]	WHITE	上咽頭炎	273	TREATMENT	9	NOT RELATED	MILD	No	1	1
		上咽頭炎	444	TREATMENT	6	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Placebo-Nemolizumab(Placebo-0.5mg/kgQ4W)	F	上咽頭炎	165	TREATMENT	10	NOT RELATED	MILD	No	1	1
CIM003JG	4[redacted]									
[redacted]	ASIAN									
Placebo-Nemolizumab(Placebo-0.5mg/kgQ4W)	F	上気道感染	8	TREATMENT	6	NOT RELATED	MODERATE	No	1	1
CIM003JG	3[redacted]									
[redacted]	WHITE									
Placebo-Nemolizumab(Placebo-2mg/kgQ4W)	F	上咽頭炎	37	TREATMENT	11	NOT RELATED	MILD	No	1	1
CIM003JG	5[redacted]	眼感染	48	TREATMENT	6	NOT RELATED	MODERATE	No	1	1
[redacted]	WHITE	結膜炎	99	TREATMENT	11	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Placebo-Nemolizumab(Placebo-2mg/kgQ4W)	M	上咽頭炎	385	TREATMENT	4	NOT RELATED	MILD	No	1	1
CIM003JG	3[redacted]									
[redacted]	WHITE									
Placebo-Nemolizumab(Placebo-2mg/kgQ4W)	M	上咽頭炎	84	TREATMENT	7	NOT RELATED	MILD	No	1	1
CIM003JG	3[redacted]									
[redacted]	ASIAN									
Placebo-Nemolizumab(Placebo-2mg/kgQ4W)	F	上咽頭炎	124	TREATMENT	29	NOT RELATED	MILD	No	1	1
CIM003JG	2[redacted]	上咽頭炎	283	TREATMENT	5	NOT RELATED	MILD	No	1	1
[redacted]	ASIAN	胃腸炎	406	TREATMENT	8	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Placebo-Nemolizumab(Placebo-2mg/kgQ4W)	M	ウイルス性消化管感染	138	TREATMENT	5	NOT RELATED	MODERATE	No	1	1
CIM003JG	3[redacted]									
[redacted]	WHITE									
Placebo-Nemolizumab(Placebo-2mg/kgQ4W)	M	上咽頭炎	443	TREATMENT	6	NOT RELATED	MODERATE	No	1	1
CIM003JG	2[redacted]									
[redacted]	WHITE									
Placebo-Nemolizumab(Placebo-2mg/kgQ4W)	F	副鼻腔炎	131	TREATMENT	9	NOT RELATED	MODERATE	No	1	1
CIM003JG	4[redacted]	上咽頭炎	447	TREATMENT	3	NOT RELATED	MODERATE	No	1	1
[redacted]	WHITE									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Placebo-Nemolizumab(Placebo-2mg/kgQ4W)	F	上咽頭炎	82	TREATMENT	7	NOT RELATED	MILD	No	1	1
CIM003JG	2[redacted]									
[redacted]	WHITE									
Placebo-Nemolizumab(Placebo-2mg/kgQ4W)	M	上咽頭炎	67	TREATMENT	4	NOT RELATED	MILD	No	1	1
CIM003JG	2[redacted]									
[redacted]	WHITE									
Placebo-Nemolizumab(Placebo-2mg/kgQ4W)	F	上気道感染	26	TREATMENT	7	RELATED	MODERATE	No	1	1
CIM003JG	3[redacted]	上気道感染	84	TREATMENT	12	RELATED	MODERATE	No	1	1
[redacted]	BLACK AFRICAN AMERICAN	OR 上気道感染	193	TREATMENT	11	RELATED	MODERATE	No	1	1
		水痘帯状疱疹ウイルス感染	336	TREATMENT	11	RELATED	MODERATE	No	3	4
		ウイルス性上気道感染	368	TREATMENT	5	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Placebo-Nemolizumab(Placebo-2mg/kgQ4W)	F	中耳炎	38	TREATMENT	10	RELATED	MODERATE	No	1	1
CIM003JG	5[redacted]	中耳炎	189	TREATMENT	13	NOT RELATED	MILD	No	1	1
[redacted]	WHITE	憩室炎	295	TREATMENT	12	RELATED	SEVERE	Yes	1	1
		肺炎	399	SAFETY-FU		NOT RELATED	MODERATE	No	5	3
Placebo-Nemolizumab(Placebo-60mg/body)	M	歯周炎	370	OPEN LABEL TREATMENT	15	NOT RELATED	MILD	No	1	1
M525101-01	5[redacted]									
CA[redacted]	ASIAN									
Placebo-Nemolizumab(Placebo-60mg/body)	F	上咽頭炎	363	OPEN LABEL TREATMENT	3	NOT RELATED	MILD	No	1	1
M525101-01	2[redacted]									
CA[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 3[redacted] ASIAN	上咽頭炎	1	DOUBLE BLIND TREATMENT	14	NOT RELATED	MILD	No	1	1
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 1[redacted] ASIAN	胃腸炎 ウイルス性胃腸炎	115 211	OPEN LABEL TREATMENT OPEN LABEL TREATMENT	41 27	RELATED NOT RELATED	MILD MILD	No No	1 1	1 1
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	F 4[redacted] ASIAN	結膜炎	126	OPEN LABEL TREATMENT	31	RELATED	MODERATE	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Placebo-Nemolizumab(Placebo-60mg/body)	F	インフルエンザ	42	DOUBLE BLIND TREATMENT	22	NOT RELATED	MODERATE	No	1	1
M525101-01	4[redacted]	上咽頭炎	306	OPEN LABEL TREATMENT	2	NOT RELATED	MILD	No	1	1
CA[redacted]	ASIAN	上咽頭炎	396	OPEN LABEL TREATMENT	4	NOT RELATED	MILD	No	1	1
Placebo-Nemolizumab(Placebo-60mg/body)	F	咽頭炎	225	OPEN LABEL TREATMENT	8	NOT RELATED	MILD	No	1	1
M525101-01	3[redacted]									
CA[redacted]	ASIAN									
Placebo-Nemolizumab(Placebo-60mg/body)	F	上咽頭炎	413	OPEN LABEL TREATMENT	15	NOT RELATED	MILD	No	1	1
M525101-01	5[redacted]									
CA[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	F 3[redacted] ASIAN	上咽頭炎	29	DOUBLE BLIND TREATMENT	47	NOT RELATED	MILD	No	1	1
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	F 4[redacted] ASIAN	上咽頭炎 インフルエンザ	358 377	OPEN LABEL TREATMENT OPEN LABEL TREATMENT	8 3	NOT RELATED NOT RELATED	MILD MODERATE	No No	1 1	1 1
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 4[redacted] ASIAN	上咽頭炎 上咽頭炎 上咽頭炎	43 148 442	DOUBLE BLIND TREATMENT OPEN LABEL TREATMENT OPEN LABEL TREATMENT	4 8 7	NOT RELATED NOT RELATED NOT RELATED	MILD MILD MILD	No No No	1 1 1	1 1 1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Placebo-Nemolizumab(Placebo-60mg/body)	M	上咽頭炎	231	OPEN LABEL TREATMENT	4	NOT RELATED	MILD	No	1	1
M525101-01	4[redacted]	上咽頭炎	398	OPEN LABEL TREATMENT	10	NOT RELATED	MILD	No	1	1
CA[redacted]	ASIAN	胃腸炎	417	OPEN LABEL TREATMENT	9	NOT RELATED	MILD	No	1	1
Placebo-Nemolizumab(Placebo-60mg/body)	F	上咽頭炎	46	DOUBLE BLIND TREATMENT	3	NOT RELATED	MILD	No	1	1
M525101-01 CA[redacted]	4[redacted] ASIAN									
Placebo-Nemolizumab(Placebo-60mg/body)	F	上咽頭炎	85	DOUBLE BLIND TREATMENT	6	NOT RELATED	MILD	No	1	1
M525101-01	4[redacted]	インフルエンザ	279	OPEN LABEL TREATMENT	7	NOT RELATED	MILD	No	1	1
CA[redacted]	ASIAN	上咽頭炎	392	OPEN LABEL TREATMENT	3	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Placebo-Nemolizumab(Placebo-60mg/body)	M	上咽頭炎	70	DOUBLE BLIND TREATMENT	2	NOT RELATED	MILD	No	1	1
M525101-01	2[redacted]	上咽頭炎	299	OPEN LABEL TREATMENT	3	NOT RELATED	MILD	No	1	1
CA[redacted]	ASIAN									
Placebo-Nemolizumab(Placebo-60mg/body)	M	胃腸炎	127	OPEN LABEL TREATMENT	8	NOT RELATED	MILD	No	1	1
M525101-01	2[redacted]	胃腸炎	308	OPEN LABEL TREATMENT	5	NOT RELATED	MILD	No	1	1
CA[redacted]	ASIAN	胃腸炎	334	OPEN LABEL TREATMENT	8	NOT RELATED	MILD	No	1	1
Placebo-Nemolizumab(Placebo-60mg/body)	M	インフルエンザ	86	DOUBLE BLIND TREATMENT	21	NOT RELATED	MODERATE	No	1	1
M525101-01	6[redacted]									
CA[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	F 5[redacted] ASIAN	膀胱炎	512	FOLLOW-UP	3	NOT RELATED	MILD	No	5	1
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 4[redacted] ASIAN	胃腸炎	55	DOUBLE BLIND TREATMENT	3	NOT RELATED	MODERATE	No	1	1
Placebo-Nemolizumab(Placebo-60mg/body)	F	上咽頭炎	150	OPEN LABEL TREATMENT	9	RELATED	MILD	No	1	1
M525101-01	3[redacted]	結膜炎	210	OPEN LABEL TREATMENT		RELATED	MILD	No	1	3
CA[redacted]	ASIAN	マイコプラズマ性肺炎	226	OPEN LABEL TREATMENT	55	RELATED	MILD	No	3	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Placebo-Nemolizumab(Placebo-60mg/body)	M	上咽頭炎	78	DOUBLE BLIND TREATMENT	10	RELATED	MILD	No	1	1
M525101-01	6[redacted]	上咽頭炎	276	OPEN LABEL TREATMENT	4	RELATED	MILD	No	1	1
CA[redacted]	ASIAN	上咽頭炎	295	OPEN LABEL TREATMENT	3	RELATED	MILD	No	1	1
		上咽頭炎	363	OPEN LABEL TREATMENT	4	NOT RELATED	MILD	No	1	1
Placebo-Nemolizumab(Placebo-60mg/body)	F	感染	-7	SCREENING	15	NOT RELATED	MILD	No	1	1
M525101-01	4[redacted]	中耳炎	16	DOUBLE BLIND TREATMENT	21	NOT RELATED	MILD	No	1	1
CA[redacted]	ASIAN	伝染性単核症	99	DOUBLE BLIND TREATMENT	11	NOT RELATED	MILD	No	1	1
		感染	411	OPEN LABEL TREATMENT	91	NOT RELATED	MILD	No	1	1
Placebo-Nemolizumab(Placebo-60mg/body)	M	胃腸炎	457	OPEN LABEL TREATMENT	4	NOT RELATED	MILD	No	5	1
M525101-01	2[redacted]									
CA[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Placebo-Nemolizumab(Placebo-60mg/body)	F	上咽頭炎	247	OPEN LABEL TREATMENT	15	RELATED	MILD	No	1	1
M525101-01	4[redacted]									
CA[redacted]	ASIAN									
Placebo-Nemolizumab(Placebo-60mg/body)	M	上咽頭炎	358	OPEN LABEL TREATMENT	4	NOT RELATED	MILD	No	1	1
M525101-01	2[redacted]									
CA[redacted]	ASIAN									
Placebo-Nemolizumab(Placebo-60mg/body)	F	ウイルス性胃腸炎	7	DOUBLE BLIND TREATMENT	9	NOT RELATED	MODERATE	No	1	1
M525101-01	3[redacted]	上咽頭炎	189	OPEN LABEL TREATMENT	5	NOT RELATED	MILD	No	1	1
CA[redacted]	ASIAN	上咽頭炎	280	OPEN LABEL TREATMENT	5	NOT RELATED	MILD	No	1	1
		上咽頭炎	407	OPEN LABEL TREATMENT	3	NOT RELATED	MILD	No	1	1
		膀胱炎	448	OPEN LABEL TREATMENT	8	RELATED	MILD	No	1	1
		上咽頭炎	454	OPEN LABEL TREATMENT	19	RELATED	MILD	No	5	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 6[redacted] ASIAN	上咽頭炎	108	DOUBLE BLIND TREATMENT	9	NOT RELATED	MILD	No	1	1
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	F 4[redacted] ASIAN	上咽頭炎 気管支炎	49 377	DOUBLE BLIND TREATMENT OPEN LABEL TREATMENT	13 17	NOT RELATED NOT RELATED	MILD MILD	No No	1 1	1 1
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 1[redacted] ASIAN	インフルエンザ	415	OPEN LABEL TREATMENT	5	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 4[redacted] ASIAN	食中毒	152	OPEN LABEL TREATMENT	1	NOT RELATED	MILD	No	1	1
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 3[redacted] ASIAN	上咽頭炎	407	OPEN LABEL TREATMENT	13	NOT RELATED	MILD	No	1	1
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 3[redacted] ASIAN	上咽頭炎	10	DOUBLE BLIND TREATMENT	3	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.

5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Placebo-Nemolizumab(Placebo-60mg/body)	M	上咽頭炎	-20	SCREENING	18	NOT RELATED	MILD	No	1	1
M525101-01	4[redacted]	上咽頭炎	111	DOUBLE BLIND TREATMENT	7	NOT RELATED	MILD	No	1	1
CA[redacted]	ASIAN	胃腸炎	482	OPEN LABEL TREATMENT	8	NOT RELATED	MILD	No	5	1
Placebo-Nemolizumab(Placebo-60mg/body)	F	上咽頭炎	265	OPEN LABEL TREATMENT	4	NOT RELATED	MILD	No	1	1
M525101-01	4[redacted]	歯膿瘍	430	OPEN LABEL TREATMENT	39	NOT RELATED	MODERATE	No	1	1
CA[redacted]	ASIAN									
Placebo-Nemolizumab(Placebo-60mg/body)	M	上咽頭炎	224	OPEN LABEL TREATMENT	4	NOT RELATED	MILD	No	1	1
M525101-01	2[redacted]									
CA[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 4[redacted] ASIAN	胃腸炎	408	OPEN LABEL TREATMENT	5	NOT RELATED	MILD	No	1	1
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	F 4[redacted] ASIAN	上咽頭炎	465	OPEN LABEL TREATMENT	5	NOT RELATED	MILD	No	5	1
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 1[redacted] ASIAN	上咽頭炎 扁桃炎	130 512	OPEN LABEL TREATMENT FOLLOW-UP	7	NOT RELATED NOT RELATED	MILD MILD	No No	1 5	1 3

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 4[redacted] ASIAN	耳下腺炎	19	DOUBLE BLIND TREATMENT	25	NOT RELATED	MILD	No	1	1
		上咽頭炎	250	OPEN LABEL TREATMENT	5	NOT RELATED	MILD	No	1	1
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 4[redacted] ASIAN	サイトメガロウイルス肝炎	314	OPEN LABEL TREATMENT		RELATED	MILD	No	1	2
		鼻炎	433	OPEN LABEL TREATMENT	46	RELATED	MILD	No	1	1
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	F 3[redacted] ASIAN	インフルエンザ	-46	SCREENING	8	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 6[redacted] ASIAN	上咽頭炎	345	OPEN LABEL TREATMENT	21	NOT RELATED	MILD	No	1	1
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 2[redacted] ASIAN	四肢膿瘍	9	DOUBLE BLIND TREATMENT	17	RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.5.2から引用

表 2.7.4-58 Listing of Other Significant Treatment-Emergent Adverse Events (Elevated CPK) (Japanese)

Safety Analysis Set（pool1）

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(0.5mg/kgQ4W)	F	血中クレアチンホスホキナーゼ増加	7	TREATMENT	8	NOT RELATED	MILD	No	1	1
CIM003JG	1[redacted]	血中クレアチンホスホキナーゼ増加	364	TREATMENT	4	NOT RELATED	MILD	No	1	1
[redacted]	WHITE									
Nemolizumab(0.5mg/kgQ4W)	M	血中クレアチンホスホキナーゼ増加	84	TREATMENT	29	NOT RELATED	MODERATE	No	1	1
CIM003JG	2[redacted]	血中クレアチンホスホキナーゼ増加	141	TREATMENT	30	NOT RELATED	MILD	No	1	1
[redacted]	WHITE	血中クレアチンホスホキナーゼ増加	310	TREATMENT	56	NOT RELATED	MILD	No	1	1
		血中クレアチンホスホキナーゼ増加	457	SAFETY-FU	34	NOT RELATED	MILD	No	5	1
Nemolizumab(0.5mg/kgQ4W)	F	血中クレアチンホスホキナーゼ増加	137	TREATMENT	32	NOT RELATED	MILD	No	1	1
CIM003JG	2[redacted]									
[redacted]	WHITE									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.6.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(2mg/kgQ4W)	F	血中クレアチンホスホキナーゼ増加	364	TREATMENT	27	NOT RELATED	MILD	No	1	1
CIM003JG [redacted]	2[redacted] WHITE									
Nemolizumab(2mg/kgQ4W)	M	血中クレアチンホスホキナーゼ増加	337	TREATMENT	10	NOT RELATED	MILD	No	1	1
CIM003JG [redacted]	2[redacted] WHITE									
Nemolizumab(2mg/kgQ4W)	M	血中クレアチンホスホキナーゼ増加	227	TREATMENT	30	NOT RELATED	MILD	No	1	1
CIM003JG [redacted]	2[redacted] WHITE									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.6.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(2mg/kgQ4W)	M	血中クレアチンホスホキナーゼ増加	9	TREATMENT	14	RELATED	MODERATE	No	1	1
CIM003JG [redacted]	3[redacted] WHITE									
Nemolizumab(2mg/kgQ4W)	M	血中クレアチンホスホキナーゼ増加	15	TREATMENT	8	NOT RELATED	MODERATE	No	1	1
CIM003JG [redacted]	3[redacted] ASIAN									
Nemolizumab(2mg/kgQ4W)	F	血中クレアチンホスホキナーゼ増加	86	TREATMENT	5	RELATED	MILD	No	1	1
CIM003JG	2[redacted]	血中クレアチンホスホキナーゼ増加	202	TREATMENT	52	NOT RELATED	MILD	No	1	1
[redacted]	WHITE	血中クレアチンホスホキナーゼ増加	366	TREATMENT	33	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.6.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(2mg/kgQ4W)	M	血中クレアチンホスホキナーゼ増加	167	TREATMENT	35	NOT RELATED	MILD	No	1	1
CIM003JG	3[redacted]									
[redacted]	WHITE									
Nemolizumab(2mg/kgQ4W)	M	血中クレアチンホスホキナーゼ増加	27	TREATMENT	15	NOT RELATED	MILD	No	1	1
CIM003JG	2[redacted]	血中クレアチンホスホキナーゼ増加	392	TREATMENT	31	NOT RELATED	MILD	No	1	1
[redacted]	WHITE									
Nemolizumab(2mg/kgQ8W)	M	血中クレアチンホスホキナーゼ増加	66	TREATMENT		NOT RELATED	MILD	No	5	6
CIM003JG	2[redacted]									
[redacted]	WHITE									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.6.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(2mg/kgQ8W)	F	血中クレアチンホスホキナーゼ増加	225	TREATMENT	6	NOT RELATED	MILD	No	1	1
CIM003JG [redacted]	2[redacted] WHITE									
Nemolizumab(2mg/kgQ8W)	M	血中クレアチンホスホキナーゼ増加	28	TREATMENT	16	RELATED	MODERATE	No	1	1
CIM003JG [redacted]	5[redacted] WHITE									
Nemolizumab(2mg/kgQ8W)	F	血中クレアチンホスホキナーゼ増加	232	SAFETY-FU		NOT RELATED	MODERATE	No	5	3
CIM003JG [redacted]	2[redacted] WHITE									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.6.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(2mg/kgQ8W)	M	血中クレアチンホスホキナーゼ増加	14	TREATMENT	14	NOT RELATED	SEVERE	No	1	1
CIM003JG [redacted]	2[redacted] ASIAN									
Nemolizumab(2mg/kgQ8W)	F	血中クレアチンホスホキナーゼ増加	174	SAFETY-FU		NOT RELATED	MODERATE	No	5	3
CIM003JG [redacted]	2[redacted] WHITE									
Nemolizumab(60mg/body)	M	血中クレアチンホスホキナーゼ増加	365	OPEN LABEL TREATMENT	29	NOT RELATED	MILD	No	1	1
M525101-01 CA[redacted]	1[redacted] ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.6.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 2[redacted] ASIAN	血中クレアチンホスホキナーゼ増加	533	FOLLOW-UP		NOT RELATED	MILD	No	5	3
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 5[redacted] ASIAN	血中クレアチンホスホキナーゼ増加	225	OPEN LABEL TREATMENT	29	NOT RELATED	MILD	No	1	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 4[redacted] ASIAN	血中クレアチンホスホキナーゼ増加	114	DOUBLE BLIND TREATMENT	29	NOT RELATED	MODERATE	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.6.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	M	血中クレアチンホスホキナーゼ増加	281	OPEN LABEL TREATMENT	29	NOT RELATED	MILD	No	1	1
M525101-01	4[redacted]									
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	M	血中クレアチンホスホキナーゼ増加	197	OPEN LABEL TREATMENT	29	NOT RELATED	MILD	No	1	1
M525101-01	4[redacted]	血中クレアチンホスホキナーゼ増加	372	OPEN LABEL TREATMENT	22	NOT RELATED	MILD	No	1	1
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	M	血中クレアチンホスホキナーゼ増加	421	OPEN LABEL TREATMENT	106	RELATED	MILD	No	1	1
M525101-01	3[redacted]									
CA[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.6.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body)	M	血中クレアチンホスホキナーゼ増加	29	DOUBLE BLIND TREATMENT	29	NOT RELATED	MILD	No	1	1
M525101-01	1[redacted]									
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	M	血中クレアチンホスホキナーゼ増加	533	FOLLOW-UP		NOT RELATED	MILD	No	5	3
M525101-01	2[redacted]									
CA[redacted]	ASIAN									
Nemolizumab(60mg/body)	M	筋肉痛	422	OPEN LABEL TREATMENT	15	NOT RELATED	MILD	No	1	1
M525101-01	2[redacted]									
CA[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.6.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 4[redacted] ASIAN	血中クレアチンホスホキナーゼ増加	542	FOLLOW-UP		NOT RELATED	MILD	No	5	3
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 3[redacted] ASIAN	血中クレアチンホスホキナーゼ増加	169	OPEN LABEL TREATMENT	29	NOT RELATED	MILD	No	1	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 2[redacted] ASIAN	血中クレアチンホスホキナーゼ増加	29	DOUBLE BLIND TREATMENT	29	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.6.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 2[redacted] ASIAN	血中クレアチンホスホキナーゼ増加	203	OPEN LABEL TREATMENT	29	NOT RELATED	MILD	No	1	1
Nemolizumab(60mg/body) M525101-01 CA[redacted]	M 4[redacted] ASIAN	血中クレアチンホスホキナーゼ増加	85	DOUBLE BLIND TREATMENT	29	NOT RELATED	MILD	No	1	1
Nemolizumab(60mg/body) M525101-02 CB[redacted]	M 4[redacted] ASIAN	血中クレアチンホスホキナーゼ増加	111	TREATMENT	32	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.6.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body) M525101-02 CB[redacted]	M 1[redacted] ASIAN	血中クレアチンホスホキナーゼ増加	281	TREATMENT	22	NOT RELATED	MILD	No	1	1
Nemolizumab(60mg/body) M525101-02 CB[redacted]	M 2[redacted] ASIAN	血中クレアチンホスホキナーゼ増加	190	TREATMENT	36	NOT RELATED	MILD	No	1	1
Nemolizumab(60mg/body) M525101-02 CB[redacted]	M 3[redacted] ASIAN	血中クレアチンホスホキナーゼ増加	26	TREATMENT	13	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.6.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Nemolizumab(60mg/body) M525101-02 CB[redacted]	M 5[redacted] ASIAN	血中クレアチンホスホキナーゼ増加	414	FOLLOW-UP		NOT RELATED	MILD	No	5	3
Placebo-Nemolizumab(Placebo-0.5mg/kgQ4W) CIM003JG [redacted]	M 1[redacted] WHITE	血中クレアチンホスホキナーゼ増加	400	TREATMENT	29	NOT RELATED	MILD	No	1	1
Placebo-Nemolizumab(Placebo-2mg/kgQ4W) CIM003JG [redacted]	M 2[redacted] ASIAN	血中クレアチンホスホキナーゼ増加	252	TREATMENT	8	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.6.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Placebo-Nemolizumab(Placebo-2mg/kgQ4W)	F	血中クレアチンホスホキナーゼ増加	446	TREATMENT	9	NOT RELATED	MILD	No	5	1
CIM003JG	2[redacted]									
[redacted]	ASIAN									
Placebo-Nemolizumab(Placebo-60mg/body)	M	血中クレアチンホスホキナーゼ増加	197	OPEN LABEL TREATMENT	25	RELATED	MILD	No	1	1
M525101-01	4[redacted]									
CA[redacted]	ASIAN									
Placebo-Nemolizumab(Placebo-60mg/body)	M	筋肉痛	364	OPEN LABEL TREATMENT	37	NOT RELATED	MILD	No	1	1
M525101-01	1[redacted]									
CA[redacted]	ASIAN									

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.6.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	F 4[redacted] ASIAN	血中クレアチンホスホキナーゼ増加	253	OPEN LABEL TREATMENT	29	NOT RELATED	MILD	No	1	1
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 4[redacted] ASIAN	血中クレアチンホスホキナーゼ増加	280	OPEN LABEL TREATMENT	57	NOT RELATED	MILD	No	1	1
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 2[redacted] ASIAN	血中クレアチンホスホキナーゼ増加	134	OPEN LABEL TREATMENT	36	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.6.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 5[redacted] ASIAN	血中クレアチンホスホキナーゼ増加	344	OPEN LABEL TREATMENT	50	NOT RELATED	MILD	No	1	1
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 3[redacted] ASIAN	血中クレアチンホスホキナーゼ増加	386	OPEN LABEL TREATMENT	31	RELATED	MILD	No	1	1
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 4[redacted] ASIAN	血中クレアチンホスホキナーゼ増加	447	OPEN LABEL TREATMENT	32	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.6.2から引用

Treatment Study No Subject ID	Sex Age (years) Race	Preferred Term	Onset day [a]	Timing	Duration (days) [b]	Relationship to Study Drug	Severity	Serious	Action Taken with Study Drug [c]	Outcome [d]
Placebo-Nemolizumab(Placebo-60mg/body) M525101-01 CA[redacted]	M 2[redacted] ASIAN	血中クレアチンホスホキナーゼ増加	28	DOUBLE BLIND TREATMENT	5	NOT RELATED	MILD	No	1	1

[a] Date of onset - date of first dose + 1.
[b] End date - start date + 1.
[c] Action taken with study drug: 1 = Dose Not Changed, 2 = Dose Reduced, 3 = Drug Interrupted, 4 = Drug Withdrawn, 5 = Not Applicable, 6 = Unknown.
[d] Outcome: 1 = Recovered/Resolved, 2 = Recovering/Resolving, 3 = Not Recovered/Not Resolved, 4 = Recovered/Resolved with Sequelae, 5 = Fatal, 6 = Unknown.
5.3.5.3-1 Listing 5.2.4.10.4.6.2から引用

表 2.7.4-59 Other Cutaneous Disorders of Treatment-Emergent Adverse Events Occurred during PartA by Preferred Term (Japanese)
Safety Analysis Set（pool2）

	All TEAEs		TEAEs Related to Study Treatment	
Preferred Term	Nemolizumab (N=301) n (%)	Placebo-Nemolizumab (N=112) n (%)	Nemolizumab (N=301) n (%)	Placebo-Nemolizumab (N=112) n (%)
Other Cutaneous Disorders	13 (4.3)	3 (2.7)	9 (3.0)	0
皮膚炎	1 (0.3)	0	1 (0.3)	0
剥脱性皮膚炎	3 (1.0)	0	2 (0.7)	0
異汗性湿疹	4 (1.3)	0	2 (0.7)	0
湿疹	0	1 (0.9)	0	0
紅斑	2 (0.7)	1 (0.9)	1 (0.3)	0
皮膚びらん	0	1 (0.9)	0	0
皮膚剥脱	2 (0.7)	0	2 (0.7)	0
中毒性皮疹	2 (0.7)	0	2 (0.7)	0

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.9.2.2から引用

表 2.7.4-60 Other Cutaneous Disorders of Treatment-Emergent Adverse Events by Preferred Term (Japanese)
Safety Analysis Set（pool1）

	All TEAEs	TEAEs Related to Study Treatment
	Nemolizumab -Total (N=481)	Nemolizumab -Total (N=481)
Preferred Term	n (%)	n (%)
Other Cutaneous Disorders	54 (11.2)	35 (7.3)
水疱	1 (0.2)	1 (0.2)
皮膚炎	5 (1.0)	4 (0.8)
剥脱性皮膚炎	5 (1.0)	4 (0.8)
異汗性湿疹	13 (2.7)	4 (0.8)
湿疹	10 (2.1)	5 (1.0)
貨幣状湿疹	1 (0.2)	0
紅斑	10 (2.1)	9 (1.9)
皮膚びらん	2 (0.4)	0
皮膚剥脱	4 (0.8)	3 (0.6)
中毒性皮疹	8 (1.7)	8 (1.7)

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.9.1.2から引用

表 2.7.4-61 Summary of Treatment-Emergent Adverse Events Occurred during PartA by System Organ Class (Japanese) Safety Analysis Set（pool2）

	All TEAEs		TEAEs Related to Study Treatment	
System Organ Class	Nemolizumab (N=301) n (%)	Placebo-Nemolizumab (N=112) n (%)	Nemolizumab (N=301) n (%)	Placebo-Nemolizumab (N=112) n (%)
TEAEs	215 (71.4)	79 (70.5)	107 (35.5)	22 (19.6)
血液およびリンパ系障害	3 (1.0)	2 (1.8)	1 (0.3)	2 (1.8)
心臓障害	5 (1.7)	1 (0.9)	1 (0.3)	0
耳および迷路障害	1 (0.3)	1 (0.9)	1 (0.3)	1 (0.9)
内分泌障害	1 (0.3)	1 (0.9)	0	0
眼障害	6 (2.0)	5 (4.5)	1 (0.3)	0
胃腸障害	22 (7.3)	7 (6.3)	2 (0.7)	1 (0.9)
一般・全身障害および投与部位の状態	42 (14.0)	4 (3.6)	25 (8.3)	1 (0.9)
肝胆道系障害	2 (0.7)	0	1 (0.3)	0
免疫系障害	2 (0.7)	2 (1.8)	0	1 (0.9)
感染症および寄生虫症	101 (33.6)	42 (37.5)	31 (10.3)	9 (8.0)
傷害、中毒および処置合併症	14 (4.7)	4 (3.6)	0	0
臨床検査	35 (11.6)	7 (6.3)	20 (6.6)	3 (2.7)
代謝および栄養障害	5 (1.7)	2 (1.8)	2 (0.7)	2 (1.8)
筋骨格系および結合組織障害	18 (6.0)	12 (10.7)	6 (2.0)	1 (0.9)
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 (0.3)	2 (1.8)	0	0
神経系障害	20 (6.6)	8 (7.1)	4 (1.3)	0
精神障害	4 (1.3)	3 (2.7)	2 (0.7)	1 (0.9)
腎および尿路障害	3 (1.0)	0	3 (1.0)	0
生殖系および乳房障害	2 (0.7)	2 (1.8)	0	1 (0.9)
呼吸器、胸郭および縦隔障害	13 (4.3)	3 (2.7)	5 (1.7)	1 (0.9)
皮膚および皮下組織障害	88 (29.2)	32 (28.6)	50 (16.6)	7 (6.3)
血管障害	3 (1.0)	1 (0.9)	1 (0.3)	0

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.6.2.2から引用

表 2.7.4-62 Summary of Treatment-Emergent Adverse Events by System Organ Class (Japanese) Safety Analysis Set（pool1）

	All TEAEs	TEAEs Related to Study Treatment
	Nemolizumab -Total (N=481)	Nemolizumab -Total (N=481)
System Organ Class	n (%)	n (%)
TEAEs	439 (91.3)	244 (50.7)
血液およびリンパ系障害	14 (2.9)	4 (0.8)
心臓障害	14 (2.9)	4 (0.8)
耳および迷路障害	14 (2.9)	8 (1.7)
内分泌障害	4 (0.8)	0
眼障害	39 (8.1)	11 (2.3)
胃腸障害	104 (21.6)	21 (4.4)
一般・全身障害および投与部位の状態	73 (15.2)	44 (9.1)
肝胆道系障害	6 (1.2)	1 (0.2)
免疫系障害	8 (1.7)	1 (0.2)
感染症および寄生虫症	319 (66.3)	99 (20.6)
傷害、中毒および処置合併症	62 (12.9)	1 (0.2)
臨床検査	97 (20.2)	40 (8.3)
代謝および栄養障害	16 (3.3)	4 (0.8)
筋骨格系および結合組織障害	70 (14.6)	11 (2.3)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	15 (3.1)	6 (1.2)
神経系障害	74 (15.4)	15 (3.1)
精神障害	11 (2.3)	5 (1.0)
腎および尿路障害	8 (1.7)	3 (0.6)
生殖系および乳房障害	11 (2.3)	4 (0.8)
呼吸器、胸郭および縦隔障害	77 (16.0)	18 (3.7)
皮膚および皮下組織障害	246 (51.1)	122 (25.4)
外科および内科処置	2 (0.4)	0
血管障害	12 (2.5)	3 (0.6)
製品の問題	1 (0.2)	1 (0.2)

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.6.1.2から引用

表 2.7.4-63 Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term Occurred during PartA (Japanese) Safety Analysis Set（pool2）

	All TEAEs		TEAEs Related to Study Treatment	
System Organ Class Preferred Term	Nemolizumab (N=301) n (%)	Placebo-Nemolizumab (N=112) n (%)	Nemolizumab (N=301) n (%)	Placebo-Nemolizumab (N=112) n (%)
Overall	215 (71.4)	79 (70.5)	107 (35.5)	22 (19.6)
血液およびリンパ系障害	3 (1.0)	2 (1.8)	1 (0.3)	2 (1.8)
貧血	1 (0.3)	0	0	0
リンパ節症	3 (1.0)	2 (1.8)	1 (0.3)	2 (1.8)
血小板増加症	1 (0.3)	0	0	0
心臓障害	5 (1.7)	1 (0.9)	1 (0.3)	0
上室性不整脈	1 (0.3)	0	1 (0.3)	0
心房細動	0	1 (0.9)	0	0
左脚ブロック	0	1 (0.9)	0	0
動悸	2 (0.7)	0	0	0
洞性頻脈	1 (0.3)	0	0	0
頻脈	1 (0.3)	0	0	0
耳および迷路障害	1 (0.3)	1 (0.9)	1 (0.3)	1 (0.9)
難聴	0	1 (0.9)	0	1 (0.9)
メニエール病	1 (0.3)	0	1 (0.3)	0
内分泌障害	1 (0.3)	1 (0.9)	0	0
甲状腺機能低下症	1 (0.3)	0	0	0
副腎腫瘤	0	1 (0.9)	0	0
眼障害	6 (2.0)	5 (4.5)	1 (0.3)	0
眼瞼炎	0	1 (0.9)	0	0
白内障	1 (0.3)	0	0	0
アレルギー性結膜炎	1 (0.3)	1 (0.9)	1 (0.3)	0
眼瞼浮腫	2 (0.7)	1 (0.9)	0	0
流涙増加	1 (0.3)	0	0	0
光視症	1 (0.3)	0	0	0
網膜剥離	0	1 (0.9)	0	0
硝子体剥離	0	1 (0.9)	0	0
結膜充血	1 (0.3)	0	0	0
胃腸障害	22 (7.3)	7 (6.3)	2 (0.7)	1 (0.9)
腹部不快感	1 (0.3)	2 (1.8)	0	0
腹痛	2 (0.7)	0	0	0
上腹部痛	2 (0.7)	0	0	0
便秘	1 (0.3)	2 (1.8)	0	1 (0.9)

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.2.2.2 から引用

System Organ Class Preferred Term	All TEAEs Nemolizumab (N=301) n (%)	All TEAEs Placebo-Nemolizumab (N=112) n (%)	TEAEs Related to Study Treatment Nemolizumab (N=301) n (%)	TEAEs Related to Study Treatment Placebo-Nemolizumab (N=112) n (%)
胃腸障害 (Cont.)				
齲歯	3 (1.0)	0	0	0
下痢	5 (1.7)	2 (1.8)	1 (0.3)	0
口内乾燥	1 (0.3)	0	0	0
消化不良	2 (0.7)	0	1 (0.3)	0
腸炎	1 (0.3)	0	0	0
胃炎	1 (0.3)	0	0	0
メレナ	0	1 (0.9)	0	0
急性膵炎	1 (0.3)	0	0	0
口唇色素沈着	1 (0.3)	0	0	0
口内炎	1 (0.3)	0	0	0
歯痛	1 (0.3)	0	0	0
嘔吐	2 (0.7)	0	0	0
弛緩歯	0	1 (0.9)	0	0
一般・全身障害および投与部位の状態	42 (14.0)	4 (3.6)	25 (8.3)	1 (0.9)
無力症	1 (0.3)	0	1 (0.3)	0
胸部不快感	1 (0.3)	0	0	0
悪寒	2 (0.7)	0	0	0
不快感	1 (0.3)	0	1 (0.3)	0
顔面浮腫	1 (0.3)	0	1 (0.3)	0
疲労	2 (0.7)	0	0	0
冷感	1 (0.3)	0	0	0
肉芽腫	1 (0.3)	0	1 (0.3)	0
注射部位内出血	3 (1.0)	0	2 (0.7)	0
注射部位血腫	1 (0.3)	1 (0.9)	1 (0.3)	0
注射部位疼痛	1 (0.3)	0	1 (0.3)	0
注射部位そう痒感	1 (0.3)	0	1 (0.3)	0
注射部位反応	5 (1.7)	0	5 (1.7)	0
倦怠感	4 (1.3)	1 (0.9)	3 (1.0)	1 (0.9)
浮腫	1 (0.3)	0	1 (0.3)	0
末梢性浮腫	14 (4.7)	0	7 (2.3)	0
発熱	7 (2.3)	2 (1.8)	3 (1.0)	0
末梢腫脹	1 (0.3)	0	0	0
医療機器関連損傷	1 (0.3)	0	0	0

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.2.2.2 から引用

System Organ Class Preferred Term	All TEAEs Nemolizumab (N=301) n (%)	All TEAEs Placebo-Nemolizumab (N=112) n (%)	TEAEs Related to Study Treatment Nemolizumab (N=301) n (%)	TEAEs Related to Study Treatment Placebo-Nemolizumab (N=112) n (%)
肝胆道系障害	2 (0.7)	0	1 (0.3)	0
肝機能異常	2 (0.7)	0	1 (0.3)	0
免疫系障害	2 (0.7)	2 (1.8)	0	1 (0.9)
過敏症	2 (0.7)	0	0	0
季節性アレルギー	0	2 (1.8)	0	1 (0.9)
感染症および寄生虫症	101 (33.6)	42 (37.5)	31 (10.3)	9 (8.0)
菌血症	1 (0.3)	0	1 (0.3)	0
気管支炎	1 (0.3)	1 (0.9)	1 (0.3)	0
蜂巣炎	4 (1.3)	2 (1.8)	2 (0.7)	2 (1.8)
結膜炎	2 (0.7)	0	0	0
膀胱炎	0	1 (0.9)	0	0
丹毒	1 (0.3)	0	0	0
眼感染	0	1 (0.9)	0	0
毛包炎	2 (0.7)	3 (2.7)	0	1 (0.9)
せつ	1 (0.3)	0	0	0
胃腸炎	2 (0.7)	1 (0.9)	2 (0.7)	0
ウイルス性胃腸炎	0	1 (0.9)	0	0
単純ヘルペス	2 (0.7)	0	2 (0.7)	0
ヘルペスウイルス感染	1 (0.3)	0	0	0
帯状疱疹	1 (0.3)	0	0	0
麦粒腫	1 (0.3)	1 (0.9)	0	1 (0.9)
膿痂疹	2 (0.7)	0	1 (0.3)	0
感染	2 (0.7)	0	0	0
伝染性単核症	0	1 (0.9)	0	0
インフルエンザ	4 (1.3)	2 (1.8)	1 (0.3)	0
上咽頭炎	37 (12.3)	18 (16.1)	4 (1.3)	1 (0.9)
外耳炎	4 (1.3)	0	0	0
中耳炎	1 (0.3)	2 (1.8)	0	1 (0.9)
爪囲炎	0	2 (1.8)	0	0
耳下腺炎	0	1 (0.9)	0	0
咽頭炎	4 (1.3)	1 (0.9)	1 (0.3)	0
歯髄炎	2 (0.7)	0	1 (0.3)	0
膿疱性皮疹	1 (0.3)	0	0	0

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.2.2.2 から引用

System Organ Class Preferred Term	All TEAEs Nemolizumab (N=301) n (%)	All TEAEs Placebo-Nemolizumab (N=112) n (%)	TEAEs Related to Study Treatment Nemolizumab (N=301) n (%)	TEAEs Related to Study Treatment Placebo-Nemolizumab (N=112) n (%)
感染症および寄生虫症 (Cont.)				
鼻炎	1 (0.3)	0	0	0
副鼻腔炎	2 (0.7)	0	2 (0.7)	0
皮膚感染	2 (0.7)	0	1 (0.3)	0
足部白癬	1 (0.3)	1 (0.9)	0	1 (0.9)
レンサ球菌性扁桃炎	1 (0.3)	0	0	0
上気道感染	9 (3.0)	5 (4.5)	5 (1.7)	1 (0.9)
ウイルス性上気道感染	2 (0.7)	0	2 (0.7)	0
外陰部腟カンジダ症	1 (0.3)	0	0	0
歯感染	2 (0.7)	0	1 (0.3)	0
四肢膿瘍	0	1 (0.9)	0	1 (0.9)
アデノイド咽頭炎	1 (0.3)	0	0	0
膿痂疹性湿疹	1 (0.3)	0	0	0
カポジ水痘様発疹	1 (0.3)	0	0	0
皮膚細菌感染	2 (0.7)	0	0	0
ウイルス性気管支炎	1 (0.3)	0	1 (0.3)	0
細菌性上気道感染	1 (0.3)	0	1 (0.3)	0
感染性腸炎	1 (0.3)	0	1 (0.3)	0
白癬感染	1 (0.3)	0	0	0
鼓膜炎	1 (0.3)	0	0	0
ウイルス性気道感染	1 (0.3)	0	0	0
男性外性器蜂巣炎	1 (0.3)	0	1 (0.3)	0
細菌性扁桃炎	1 (0.3)	0	0	0
細菌重複感染	4 (1.3)	1 (0.9)	1 (0.3)	0
口腔ヘルペス	1 (0.3)	0	1 (0.3)	0
処置後感染	1 (0.3)	0	0	0
眼部単純ヘルペス	1 (0.3)	0	0	0
カンジダ感染	1 (0.3)	0	1 (0.3)	0
鼻ヘルペス	1 (0.3)	1 (0.9)	0	0
細菌性外陰腟炎	1 (0.3)	0	1 (0.3)	0
傷害、中毒および処置合併症	14 (4.7)	4 (3.6)	0	0
顔面骨骨折	1 (0.3)	0	0	0
転倒	1 (0.3)	1 (0.9)	0	0
靭帯捻挫	2 (0.7)	0	0	0

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.2.2.2 から引用

System Organ Class Preferred Term	All TEAEs Nemolizumab (N=301) n (%)	All TEAEs Placebo-Nemolizumab (N=112) n (%)	TEAEs Related to Study Treatment Nemolizumab (N=301) n (%)	TEAEs Related to Study Treatment Placebo-Nemolizumab (N=112) n (%)
傷害、中毒および処置合併症 (Cont.)				
処置部位反応	1 (0.3)	0	0	0
擦過傷	2 (0.7)	1 (0.9)	0	0
挫傷	5 (1.7)	2 (1.8)	0	0
創傷	1 (0.3)	0	0	0
挫滅	1 (0.3)	0	0	0
歯牙破折	1 (0.3)	0	0	0
処置による疼痛	1 (0.3)	0	0	0
皮膚擦過傷	1 (0.3)	0	0	0
注射に伴う反応	0	1 (0.9)	0	0
歯の脱臼	1 (0.3)	0	0	0
臨床検査	35 (11.6)	7 (6.3)	20 (6.6)	3 (2.7)
アスパラギン酸アミノトランスフェラーゼ増加	1 (0.3)	0	0	0
血中クレアチンホスホキナーゼ増加	14 (4.7)	3 (2.7)	3 (1.0)	0
血中トリグリセリド増加	1 (0.3)	0	0	0
血中尿酸増加	3 (1.0)	0	1 (0.3)	0
Ｃ－反応性蛋白増加	3 (1.0)	1 (0.9)	2 (0.7)	0
心電図ＱＴ延長	1 (0.3)	0	0	0
好酸球数増加	3 (1.0)	0	3 (1.0)	0
フィブリンDダイマー増加	2 (0.7)	0	2 (0.7)	0
眼圧上昇	1 (0.3)	1 (0.9)	0	1 (0.9)
好中球数減少	1 (0.3)	0	1 (0.3)	0
体重増加	2 (0.7)	1 (0.9)	1 (0.3)	1 (0.9)
心電図異常Ｔ波	0	1 (0.9)	0	1 (0.9)
心電図Ｔ波振幅増加	1 (0.3)	0	0	0
尿中蛋白陽性	1 (0.3)	0	1 (0.3)	0
頚動脈脈拍増加	1 (0.3)	0	0	0
肝酵素上昇	1 (0.3)	0	0	0
サイトカイン異常	10 (3.3)	0	10 (3.3)	0
代謝および栄養障害	5 (1.7)	2 (1.8)	2 (0.7)	2 (1.8)
痛風	1 (0.3)	0	0	0
高尿酸血症	2 (0.7)	1 (0.9)	2 (0.7)	1 (0.9)
低リン酸血症	1 (0.3)	1 (0.9)	0	1 (0.9)
ビタミン欠乏症	1 (0.3)	0	0	0

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.2.2.2 から引用

System Organ Class Preferred Term	All TEAEs Nemolizumab (N=301) n (%)	All TEAEs Placebo-Nemolizumab (N=112) n (%)	TEAEs Related to Study Treatment Nemolizumab (N=301) n (%)	TEAEs Related to Study Treatment Placebo-Nemolizumab (N=112) n (%)
筋骨格系および結合組織障害	18 (6.0)	12 (10.7)	6 (2.0)	1 (0.9)
関節痛	4 (1.3)	1 (0.9)	2 (0.7)	1 (0.9)
背部痛	3 (1.0)	1 (0.9)	1 (0.3)	0
骨痛	0	1 (0.9)	0	0
滑液包炎	0	2 (1.8)	0	0
骨端離開	1 (0.3)	0	0	0
側腹部痛	1 (0.3)	0	0	0
出血性関節症	1 (0.3)	0	0	0
関節腫脹	0	1 (0.9)	0	1 (0.9)
筋痙縮	2 (0.7)	0	0	0
筋骨格痛	1 (0.3)	2 (1.8)	0	0
筋肉痛	2 (0.7)	0	1 (0.3)	0
ミオパチー	1 (0.3)	0	1 (0.3)	0
頚部痛	1 (0.3)	0	1 (0.3)	0
四肢痛	1 (0.3)	1 (0.9)	1 (0.3)	0
回帰性リウマチ	1 (0.3)	0	0	0
肩回旋筋腱板症候群	0	1 (0.9)	0	0
変形性脊椎症	0	2 (1.8)	0	0
滑液嚢腫	0	1 (0.9)	0	0
椎間板突出	1 (0.3)	0	0	0
筋骨格系胸痛	1 (0.3)	0	0	0
筋骨格硬直	0	2 (1.8)	0	1 (0.9)
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 (0.3)	2 (1.8)	0	0
メラノサイト性母斑	1 (0.3)	0	0	0
皮膚乳頭腫	0	2 (1.8)	0	0
神経系障害	20 (6.6)	8 (7.1)	4 (1.3)	0
浮動性めまい	2 (0.7)	0	1 (0.3)	0
頭痛	10 (3.3)	1 (0.9)	3 (1.0)	0
感覚鈍麻	1 (0.3)	2 (1.8)	1 (0.3)	0
意識消失	1 (0.3)	0	0	0
片頭痛	1 (0.3)	1 (0.9)	0	0
神経痛	1 (0.3)	0	0	0
錯感覚	1 (0.3)	0	0	0

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.2.2.2 から引用

System Organ Class Preferred Term	All TEAEs Nemolizumab (N=301) n (%)	All TEAEs Placebo-Nemolizumab (N=112) n (%)	TEAEs Related to Study Treatment Nemolizumab (N=301) n (%)	TEAEs Related to Study Treatment Placebo-Nemolizumab (N=112) n (%)
神経系障害（Cont.）				
失神寸前の状態	1 (0.3)	0	0	0
坐骨神経痛	0	1 (0.9)	0	0
傾眠	1 (0.3)	0	0	0
緊張性頭痛	1 (0.3)	1 (0.9)	0	0
三叉神経痛	0	1 (0.9)	0	0
腰髄神経根障害	0	1 (0.9)	0	0
パーキンソン病	1 (0.3)	0	0	0
精神障害	4 (1.3)	3 (2.7)	2 (0.7)	1 (0.9)
無感情	1 (0.3)	0	1 (0.3)	0
うつ病	1 (0.3)	0	0	0
不眠症	1 (0.3)	1 (0.9)	0	0
リビドー減退	0	1 (0.9)	0	1 (0.9)
落ち着きのなさ	1 (0.3)	0	1 (0.3)	0
睡眠障害	0	1 (0.9)	0	0
腎および尿路障害	3 (1.0)	0	3 (1.0)	0
蛋白尿	3 (1.0)	0	3 (1.0)	0
生殖系および乳房障害	2 (0.7)	2 (1.8)	0	1 (0.9)
月経過多	1 (0.3)	0	0	0
腟出血	0	1 (0.9)	0	0
精索静脈瘤	1 (0.3)	0	0	0
外陰腟そう痒症	0	1 (0.9)	0	1 (0.9)
呼吸器、胸郭および縦隔障害	13 (4.3)	3 (2.7)	5 (1.7)	1 (0.9)
咳嗽	3 (1.0)	1 (0.9)	2 (0.7)	1 (0.9)
発声障害	1 (0.3)	0	1 (0.3)	0
呼吸困難	1 (0.3)	0	0	0
労作性呼吸困難	0	1 (0.9)	0	1 (0.9)
起坐呼吸	1 (0.3)	0	1 (0.3)	0
咽喉刺激感	1 (0.3)	0	0	0
上気道の炎症	4 (1.3)	2 (1.8)	1 (0.3)	0
口腔咽頭痛	2 (0.7)	0	0	0
皮膚および皮下組織障害	88 (29.2)	32 (28.6)	50 (16.6)	7 (6.3)
ざ瘡	2 (0.7)	3 (2.7)	0	0
脱毛症	1 (0.3)	0	1 (0.3)	0

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.2.2.2 から引用

System Organ Class Preferred Term	All TEAEs Nemolizumab (N=301) n (%)	All TEAEs Placebo-Nemolizumab (N=112) n (%)	TEAEs Related to Study Treatment Nemolizumab (N=301) n (%)	TEAEs Related to Study Treatment Placebo-Nemolizumab (N=112) n (%)
皮膚および皮下組織障害 (Cont.)				
円形脱毛症	2 (0.7)	2 (1.8)	2 (0.7)	1 (0.9)
頭部粃糠疹	0	1 (0.9)	0	0
皮膚嚢腫	1 (0.3)	1 (0.9)	0	0
皮膚炎	1 (0.3)	0	1 (0.3)	0
ざ瘡様皮膚炎	0	1 (0.9)	0	1 (0.9)
アトピー性皮膚炎	63 (20.9)	21 (18.8)	37 (12.3)	5 (4.5)
接触皮膚炎	5 (1.7)	2 (1.8)	0	0
剥脱性皮膚炎	3 (1.0)	0	2 (0.7)	0
薬疹	1 (0.3)	0	0	0
異汗性湿疹	4 (1.3)	0	2 (0.7)	0
湿疹	0	1 (0.9)	0	0
紅斑	2 (0.7)	1 (0.9)	1 (0.3)	0
過角化	1 (0.3)	1 (0.9)	0	0
爪甲剥離症	0	1 (0.9)	0	0
紫斑	1 (0.3)	0	0	0
全身性皮疹	1 (0.3)	0	1 (0.3)	0
丘疹性皮疹	1 (0.3)	1 (0.9)	1 (0.3)	1 (0.9)
脂漏性皮膚炎	1 (0.3)	0	0	0
皮膚障害	1 (0.3)	0	0	0
皮膚びらん	0	1 (0.9)	0	0
皮膚剥脱	2 (0.7)	0	2 (0.7)	0
皮膚亀裂	0	1 (0.9)	0	0
皮膚刺激	1 (0.3)	0	0	0
うっ滞性皮膚炎	1 (0.3)	0	1 (0.3)	0
蕁麻疹	6 (2.0)	0	4 (1.3)	0
湿潤性湿疹	1 (0.3)	0	0	0
中毒性皮疹	2 (0.7)	0	2 (0.7)	0
色素沈着障害	0	1 (0.9)	0	0
アンドロゲン性脱毛症	1 (0.3)	0	0	0
血管障害	3 (1.0)	1 (0.9)	1 (0.3)	0
高血圧	3 (1.0)	1 (0.9)	1 (0.3)	0

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.2.2.2 から引用

表 2.7.4-64 Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Japanese)
Safety Analysis Set（pool1）

System Organ Class Preferred Term	All TEAEs Nemolizumab -Total (N=481) n (%)	TEAEs Related to Study Treatment Nemolizumab -Total (N=481) n (%)
Overall	439 (91.3)	244 (50.7)
血液およびリンパ系障害	14 (2.9)	4 (0.8)
貧血	1 (0.2)	0
リンパ節炎	5 (1.0)	1 (0.2)
リンパ節症	8 (1.7)	3 (0.6)
リンパ球減少症	1 (0.2)	0
血小板増加症	1 (0.2)	0
心臓障害	14 (2.9)	4 (0.8)
狭心症	1 (0.2)	0
大動脈弁閉鎖不全症	1 (0.2)	0
上室性不整脈	1 (0.2)	1 (0.2)
心房細動	1 (0.2)	0
第一度房室ブロック	1 (0.2)	1 (0.2)
左脚ブロック	1 (0.2)	0
冠動脈狭窄	1 (0.2)	0
僧帽弁閉鎖不全症	1 (0.2)	0
動悸	5 (1.0)	2 (0.4)
洞性頻脈	1 (0.2)	0
頻脈	1 (0.2)	0
心室性期外収縮	1 (0.2)	0
耳および迷路障害	14 (2.9)	8 (1.7)
難聴	1 (0.2)	1 (0.2)
耳管開放	2 (0.4)	1 (0.2)
メニエール病	2 (0.4)	1 (0.2)
耳鳴	3 (0.6)	0
回転性めまい	4 (0.8)	3 (0.6)
突発性難聴	1 (0.2)	1 (0.2)
外耳の炎症	1 (0.2)	1 (0.2)
内分泌障害	4 (0.8)	0
高プロラクチン血症	1 (0.2)	0
甲状腺機能低下症	1 (0.2)	0
原発性アルドステロン症	1 (0.2)	0
副腎腫瘤	1 (0.2)	0

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.2.1.2 から引用

System Organ Class Preferred Term	All TEAEs Nemolizumab -Total (N=481) n (%)	TEAEs Related to Study Treatment Nemolizumab -Total (N=481) n (%)
眼障害	39 (8.1)	11 (2.3)
眼精疲労	3 (0.6)	0
眼瞼炎	2 (0.4)	0
アレルギー性眼瞼炎	2 (0.4)	2 (0.4)
白内障	4 (0.8)	1 (0.2)
結膜嚢胞	1 (0.2)	0
結膜出血	1 (0.2)	0
アレルギー性結膜炎	13 (2.7)	5 (1.0)
眼乾燥	5 (1.0)	0
眼瞼紅斑	1 (0.2)	1 (0.2)
眼脂	2 (0.4)	1 (0.2)
眼の炎症	1 (0.2)	0
眼瞼浮腫	4 (0.8)	0
緑内障	1 (0.2)	1 (0.2)
角膜炎	1 (0.2)	0
流涙増加	1 (0.2)	0
光視症	1 (0.2)	0
網膜剥離	1 (0.2)	0
網膜裂孔	1 (0.2)	0
視力障害	1 (0.2)	0
硝子体剥離	1 (0.2)	0
結膜充血	1 (0.2)	0
アトピー性角結膜炎	1 (0.2)	1 (0.2)
胃腸障害	104 (21.6)	21 (4.4)
腹部不快感	7 (1.5)	1 (0.2)
腹痛	9 (1.9)	2 (0.4)
下腹部痛	2 (0.4)	2 (0.4)
上腹部痛	9 (1.9)	2 (0.4)
口唇炎	1 (0.2)	0
慢性胃炎	2 (0.4)	0
便秘	9 (1.9)	2 (0.4)
齲歯	20 (4.2)	2 (0.4)
歯組織の壊死	1 (0.2)	0

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.2.1.2 から引用

System Organ Class Preferred Term	All TEAEs Nemolizumab -Total (N=481) n (%)	TEAEs Related to Study Treatment Nemolizumab -Total (N=481) n (%)
胃腸障害 (Cont.)		
下痢	18 (3.7)	2 (0.4)
口内乾燥	1 (0.2)	0
十二指腸潰瘍	2 (0.4)	1 (0.2)
消化不良	3 (0.6)	1 (0.2)
腸炎	1 (0.2)	0
食中毒	1 (0.2)	0
胃ポリープ	3 (0.6)	2 (0.4)
胃炎	6 (1.2)	0
胃食道逆流性疾患	9 (1.9)	2 (0.4)
胃腸障害	1 (0.2)	1 (0.2)
消化器痛	1 (0.2)	0
痔核	3 (0.6)	0
過敏性腸症候群	2 (0.4)	1 (0.2)
メレナ	2 (0.4)	1 (0.2)
悪心	8 (1.7)	1 (0.2)
急性膵炎	1 (0.2)	0
歯周病	1 (0.2)	0
口唇色素沈着	2 (0.4)	0
口内炎	6 (1.2)	2 (0.4)
歯痛	5 (1.0)	0
嘔吐	7 (1.5)	0
大腸ポリープ	1 (0.2)	0
弛緩歯	1 (0.2)	0
軟便	1 (0.2)	0
一般・全身障害および投与部位の状態	73 (15.2)	44 (9.1)
無力症	1 (0.2)	1 (0.2)
胸部不快感	1 (0.2)	0
胸痛	1 (0.2)	1 (0.2)
悪寒	2 (0.4)	0
不快感	1 (0.2)	1 (0.2)
顔面浮腫	1 (0.2)	1 (0.2)
疲労	3 (0.6)	1 (0.2)
異常感	1 (0.2)	1 (0.2)

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.2.1.2 から引用

System Organ Class Preferred Term	All TEAEs Nemolizumab -Total (N=481) n (%)	TEAEs Related to Study Treatment Nemolizumab -Total (N=481) n (%)
一般・全身障害および投与部位の状態 (Cont.)		
冷感	1 (0.2)	0
肉芽腫	1 (0.2)	1 (0.2)
注射部位内出血	4 (0.8)	3 (0.6)
注射部位紅斑	2 (0.4)	2 (0.4)
注射部位血腫	1 (0.2)	1 (0.2)
注射部位出血	1 (0.2)	1 (0.2)
注射部位疼痛	2 (0.4)	2 (0.4)
注射部位そう痒感	1 (0.2)	1 (0.2)
注射部位反応	7 (1.5)	7 (1.5)
倦怠感	9 (1.9)	6 (1.2)
浮腫	1 (0.2)	1 (0.2)
末梢性浮腫	21 (4.4)	11 (2.3)
疼痛	4 (0.8)	2 (0.4)
発熱	17 (3.5)	4 (0.8)
末梢腫脹	3 (0.6)	1 (0.2)
注射部位腫脹	2 (0.4)	2 (0.4)
注射部位不快感	1 (0.2)	1 (0.2)
非心臓性胸痛	1 (0.2)	0
医療機器関連損傷	1 (0.2)	0
肝胆道系障害	6 (1.2)	1 (0.2)
肝機能異常	4 (0.8)	1 (0.2)
脂肪肝	1 (0.2)	0
肝障害	1 (0.2)	0
免疫系障害	8 (1.7)	1 (0.2)
アナフィラキシー反応	1 (0.2)	0
食物アレルギー	2 (0.4)	0
過敏症	2 (0.4)	0
季節性アレルギー	3 (0.6)	1 (0.2)
ダニアレルギー	1 (0.2)	0
感染症および寄生虫症	319 (66.3)	99 (20.6)
細菌性膿瘍	1 (0.2)	0
膿疱性ざ瘡	1 (0.2)	1 (0.2)
急性副鼻腔炎	1 (0.2)	0

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.2.1.2 から引用

System Organ Class Preferred Term	All TEAEs Nemolizumab -Total (N=481) n (%)	TEAEs Related to Study Treatment Nemolizumab -Total (N=481) n (%)
感染症および寄生虫症 (Cont.)		
口角口唇炎	1 (0.2)	0
菌血症	2 (0.4)	2 (0.4)
体部白癬	3 (0.6)	1 (0.2)
気管支炎	13 (2.7)	2 (0.4)
蜂巣炎	25 (5.2)	16 (3.3)
結膜炎	9 (1.9)	4 (0.8)
膀胱炎	12 (2.5)	3 (0.6)
サイトメガロウイルス肝炎	1 (0.2)	1 (0.2)
爪の皮膚糸状菌症	1 (0.2)	0
憩室炎	1 (0.2)	1 (0.2)
精巣上体炎	1 (0.2)	1 (0.2)
丹毒	3 (0.6)	2 (0.4)
眼感染	1 (0.2)	0
毛包炎	17 (3.5)	3 (0.6)
せつ	4 (0.8)	1 (0.2)
胃腸炎	22 (4.6)	4 (0.8)
ウイルス性胃腸炎	5 (1.0)	0
手足口病	1 (0.2)	1 (0.2)
単純ヘルペス	9 (1.9)	4 (0.8)
ヘルペスウイルス感染	2 (0.4)	0
帯状疱疹	10 (2.1)	6 (1.2)
麦粒腫	2 (0.4)	1 (0.2)
膿痂疹	17 (3.5)	8 (1.7)
感染	7 (1.5)	3 (0.6)
伝染性単核症	1 (0.2)	0
インフルエンザ	31 (6.4)	3 (0.6)
リンパ管炎	1 (0.2)	0
伝染性軟属腫	2 (0.4)	1 (0.2)
ムンプス	1 (0.2)	0
上咽頭炎	160 (33.3)	16 (3.3)
外耳炎	15 (3.1)	1 (0.2)
中耳炎	3 (0.6)	1 (0.2)
爪囲炎	7 (1.5)	1 (0.2)

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.2.1.2 から引用

System Organ Class Preferred Term	All TEAEs Nemolizumab -Total (N=481) n (%)	TEAEs Related to Study Treatment Nemolizumab -Total (N=481) n (%)
感染症および寄生虫症 (Cont.)		
耳下腺炎	1 (0.2)	0
歯冠周囲炎	2 (0.4)	2 (0.4)
歯周炎	2 (0.4)	0
咽頭炎	21 (4.4)	4 (0.8)
肺炎	2 (0.4)	1 (0.2)
マイコプラズマ性肺炎	1 (0.2)	1 (0.2)
歯髄炎	5 (1.0)	1 (0.2)
腎盂腎炎	1 (0.2)	1 (0.2)
膿疱性皮疹	1 (0.2)	0
鼻炎	2 (0.4)	1 (0.2)
副鼻腔炎	8 (1.7)	2 (0.4)
皮膚感染	7 (1.5)	3 (0.6)
足部白癬	7 (1.5)	2 (0.4)
扁桃炎	5 (1.0)	2 (0.4)
レンサ球菌性扁桃炎	1 (0.2)	0
歯膿瘍	1 (0.2)	0
上気道感染	16 (3.3)	9 (1.9)
尿道炎	1 (0.2)	0
尿路感染	4 (0.8)	0
ウイルス感染	2 (0.4)	1 (0.2)
ウイルス性上気道感染	6 (1.2)	2 (0.4)
外陰部腟カンジダ症	1 (0.2)	0
歯感染	4 (0.8)	1 (0.2)
四肢膿瘍	1 (0.2)	1 (0.2)
アデノイド咽頭炎	1 (0.2)	0
膿痂疹性湿疹	2 (0.4)	0
カポジ水痘様発疹	11 (2.3)	6 (1.2)
皮膚細菌感染	5 (1.0)	0
ウイルス性気管支炎	1 (0.2)	1 (0.2)
マラセチア感染	2 (0.4)	0
皮膚カンジダ	1 (0.2)	1 (0.2)
ヘリコバクター感染	2 (0.4)	1 (0.2)
ヘリコバクター性胃炎	2 (0.4)	0

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.2.1.2 から引用

System Organ Class Preferred Term	All TEAEs Nemolizumab -Total (N=481) n (%)	TEAEs Related to Study Treatment Nemolizumab -Total (N=481) n (%)
感染症および寄生虫症 (Cont.)		
癜風	2 (0.4)	1 (0.2)
細菌性上気道感染	1 (0.2)	1 (0.2)
ブドウ球菌感染	1 (0.2)	0
感染性腸炎	3 (0.6)	2 (0.4)
白癬感染	1 (0.2)	0
鼓膜炎	2 (0.4)	0
レンサ球菌感染	1 (0.2)	0
ウイルス性気道感染	1 (0.2)	0
外陰腟真菌感染	1 (0.2)	0
男性外性器蜂巣炎	2 (0.4)	1 (0.2)
細菌性外耳炎	1 (0.2)	0
細菌性リンパ節炎	1 (0.2)	0
細菌性扁桃炎	1 (0.2)	0
ブドウ球菌皮膚感染	2 (0.4)	0
細菌重複感染	5 (1.0)	2 (0.4)
口腔ヘルペス	7 (1.5)	2 (0.4)
処置後感染	1 (0.2)	0
ウイルス性消化管感染	1 (0.2)	0
感染性皮膚嚢腫	2 (0.4)	1 (0.2)
眼部単純ヘルペス	3 (0.6)	2 (0.4)
カンジダ感染	2 (0.4)	1 (0.2)
鼻ヘルペス	2 (0.4)	0
水痘帯状疱疹ウイルス感染	1 (0.2)	1 (0.2)
咬傷感染	1 (0.2)	0
細菌性外陰腟炎	1 (0.2)	1 (0.2)
傷害、中毒および処置合併症	62 (12.9)	1 (0.2)
節足動物刺傷	4 (0.8)	0
第２度熱傷	1 (0.2)	0
凍瘡	1 (0.2)	0
鎖骨骨折	1 (0.2)	0
上顆炎	3 (0.6)	0
顔面骨骨折	1 (0.2)	0
転倒	2 (0.4)	0

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.2.1.2 から引用

System Organ Class Preferred Term	All TEAEs Nemolizumab -Total (N=481) n (%)	TEAEs Related to Study Treatment Nemolizumab -Total (N=481) n (%)
傷害、中毒および処置合併症 (Cont.)		
足骨折	1 (0.2)	0
損傷	2 (0.4)	0
関節脱臼	2 (0.4)	0
靭帯捻挫	7 (1.5)	0
処置部位反応	1 (0.2)	0
肋骨骨折	1 (0.2)	0
脊椎骨折	1 (0.2)	0
刺創	1 (0.2)	0
脛骨骨折	1 (0.2)	0
外傷性血腫	1 (0.2)	0
外傷性潰瘍	1 (0.2)	0
擦過傷	7 (1.5)	0
肉離れ	3 (0.6)	0
挫傷	17 (3.5)	1 (0.2)
創傷	5 (1.0)	0
熱傷	4 (0.8)	0
挫滅	1 (0.2)	0
靭帯損傷	1 (0.2)	0
胸部損傷	1 (0.2)	0
上肢骨折	1 (0.2)	0
歯牙破折	3 (0.6)	0
骨亀裂	1 (0.2)	0
処置による疼痛	4 (0.8)	0
皮膚擦過傷	1 (0.2)	0
靭帯断裂	1 (0.2)	0
骨挫傷	1 (0.2)	0
処置後腫脹	1 (0.2)	0
熱中症	1 (0.2)	0
爪損傷	1 (0.2)	0
筋挫傷	1 (0.2)	0
注射に伴う反応	1 (0.2)	0
四肢骨折	1 (0.2)	0
歯の脱臼	1 (0.2)	0

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.2.1.2 から引用

System Organ Class Preferred Term	All TEAEs Nemolizumab -Total (N=481) n (%)	TEAEs Related to Study Treatment Nemolizumab -Total (N=481) n (%)
臨床検査	97 (20.2)	40 (8.3)
アラニンアミノトランスフェラーゼ増加	2 (0.4)	2 (0.4)
アスパラギン酸アミノトランスフェラーゼ増加	4 (0.8)	1 (0.2)
血中ビリルビン増加	1 (0.2)	0
血中クレアチンホスホキナーゼ増加	49 (10.2)	7 (1.5)
血中フィブリノゲン増加	1 (0.2)	0
血中カリウム増加	1 (0.2)	0
血圧上昇	1 (0.2)	0
血中トリグリセリド増加	3 (0.6)	0
血中尿酸増加	4 (0.8)	1 (0.2)
Ｃ－反応性蛋白増加	7 (1.5)	3 (0.6)
心電図異常	1 (0.2)	1 (0.2)
心電図ＱＴ延長	2 (0.4)	1 (0.2)
好酸球数増加	8 (1.7)	8 (1.7)
フィブリンＤダイマー増加	2 (0.4)	2 (0.4)
尿中血陽性	1 (0.2)	0
眼圧上昇	2 (0.4)	1 (0.2)
脂質増加	1 (0.2)	0
好中球数減少	1 (0.2)	1 (0.2)
体重減少	3 (0.6)	0
体重増加	8 (1.7)	4 (0.8)
白血球数減少	2 (0.4)	0
白血球数増加	1 (0.2)	0
骨密度減少	1 (0.2)	0
心電図異常Ｔ波	2 (0.4)	2 (0.4)
心電図Ｔ波振幅増加	1 (0.2)	0
尿中蛋白陽性	1 (0.2)	1 (0.2)
頚動脈脈拍増加	1 (0.2)	0
肝酵素上昇	2 (0.4)	0
検査	1 (0.2)	0
サイトカイン異常	14 (2.9)	13 (2.7)
肝機能検査値上昇	1 (0.2)	1 (0.2)
代謝および栄養障害	16 (3.3)	4 (0.8)

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.2.1.2 から引用

System Organ Class Preferred Term	All TEAEs Nemolizumab -Total (N=481) n (%)	TEAEs Related to Study Treatment Nemolizumab -Total (N=481) n (%)
代謝および栄養障害 (Cont.)		
痛風	3 (0.6)	0
高尿酸血症	3 (0.6)	3 (0.6)
低リン酸血症	2 (0.4)	1 (0.2)
ビタミン欠乏症	1 (0.2)	0
鉄欠乏	1 (0.2)	0
ビタミンD欠乏	1 (0.2)	0
亜鉛欠乏	2 (0.4)	0
脂質異常症	1 (0.2)	0
食欲減退	1 (0.2)	0
２型糖尿病	1 (0.2)	0
筋骨格系および結合組織障害	70 (14.6)	11 (2.3)
関節痛	15 (3.1)	5 (1.0)
背部痛	16 (3.3)	2 (0.4)
滑液包炎	2 (0.4)	0
ピロリン酸カルシウム結晶性軟骨石灰化症	1 (0.2)	0
骨端離開	1 (0.2)	0
外骨腫	1 (0.2)	0
筋膜炎	1 (0.2)	0
側腹部痛	1 (0.2)	0
出血性関節症	1 (0.2)	0
関節拘縮	1 (0.2)	0
関節腫脹	1 (0.2)	1 (0.2)
腰部脊柱管狭窄症	1 (0.2)	0
筋痙縮	2 (0.4)	0
筋力低下	1 (0.2)	0
筋骨格痛	3 (0.6)	0
筋肉痛	5 (1.0)	1 (0.2)
ミオパチー	1 (0.2)	1 (0.2)
頚部痛	2 (0.4)	2 (0.4)
変形性関節症	4 (0.8)	0
四肢痛	4 (0.8)	2 (0.4)
回帰性リウマチ	1 (0.2)	0
関節周囲炎	5 (1.0)	0

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.2.1.2 から引用

System Organ Class Preferred Term	All TEAEs Nemolizumab -Total (N=481) n (%)	TEAEs Related to Study Treatment Nemolizumab -Total (N=481) n (%)
筋骨格系および結合組織障害 (Cont.)		
肩回旋筋腱板症候群	4 (0.8)	0
シェーグレン症候群	1 (0.2)	0
変形性脊椎症	2 (0.4)	0
滑液嚢腫	2 (0.4)	0
顎関節症候群	1 (0.2)	0
腱炎	1 (0.2)	0
腱鞘炎	2 (0.4)	0
関節周囲障害	1 (0.2)	0
椎間板突出	5 (1.0)	0
筋骨格系胸痛	1 (0.2)	0
筋骨格硬直	1 (0.2)	1 (0.2)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	15 (3.1)	6 (1.2)
アクロコルドン	1 (0.2)	0
膀胱癌	2 (0.4)	0
肺腺癌第３期	1 (0.2)	0
メラノサイト性母斑	1 (0.2)	0
化膿性肉芽腫	1 (0.2)	0
皮膚乳頭腫	8 (1.7)	4 (0.8)
線維性組織球腫	1 (0.2)	1 (0.2)
節外性辺縁帯Ｂ細胞リンパ腫（ＭＡＬＴ型）	1 (0.2)	1 (0.2)
神経系障害	74 (15.4)	15 (3.1)
自律神経失調	1 (0.2)	0
頚腕症候群	1 (0.2)	0
浮動性めまい	8 (1.7)	2 (0.4)
全身性強直性間代性発作	1 (0.2)	0
頭痛	36 (7.5)	9 (1.9)
感覚鈍麻	5 (1.0)	1 (0.2)
意識消失	2 (0.4)	0
メージ症候群	1 (0.2)	0
片頭痛	3 (0.6)	1 (0.2)
神経痛	2 (0.4)	0
末梢性ニューロパチー	2 (0.4)	1 (0.2)
視神経炎	2 (0.4)	1 (0.2)

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.2.1.2 から引用

System Organ Class Preferred Term	All TEAEs Nemolizumab -Total (N=481) n (%)	TEAEs Related to Study Treatment Nemolizumab -Total (N=481) n (%)
神経系障害 (Cont.)		
錯感覚	2 (0.4)	1 (0.2)
ヘルペス後神経痛	1 (0.2)	0
失神寸前の状態	1 (0.2)	0
坐骨神経痛	3 (0.6)	0
傾眠	6 (1.2)	2 (0.4)
失神	1 (0.2)	0
緊張性頭痛	3 (0.6)	0
三叉神経痛	1 (0.2)	0
頚髄神経根障害	2 (0.4)	0
腰髄神経根障害	1 (0.2)	0
パーキンソン病	1 (0.2)	0
精神障害	11 (2.3)	5 (1.0)
無感情	1 (0.2)	1 (0.2)
双極１型障害	1 (0.2)	1 (0.2)
閉所恐怖症	1 (0.2)	0
うつ病	3 (0.6)	1 (0.2)
不眠症	3 (0.6)	1 (0.2)
リビドー減退	1 (0.2)	1 (0.2)
落ち着きのなさ	1 (0.2)	1 (0.2)
睡眠障害	1 (0.2)	0
腎および尿路障害	8 (1.7)	3 (0.6)
尿路結石	1 (0.2)	0
排尿困難	1 (0.2)	0
血尿	1 (0.2)	0
蛋白尿	3 (0.6)	3 (0.6)
腎仙痛	1 (0.2)	0
尿閉	1 (0.2)	0
尿管結石症	1 (0.2)	0
生殖系および乳房障害	11 (2.3)	4 (0.8)
月経困難症	2 (0.4)	0
子宮内膜増殖症	1 (0.2)	1 (0.2)
子宮内膜症	1 (0.2)	1 (0.2)
月経過多	1 (0.2)	0

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.2.1.2 から引用

System Organ Class Preferred Term	All TEAEs Nemolizumab -Total (N=481) n (%)	TEAEs Related to Study Treatment Nemolizumab -Total (N=481) n (%)
生殖系および乳房障害 (Cont.)		
不規則月経	2 (0.4)	1 (0.2)
月経前症候群	1 (0.2)	0
腟出血	1 (0.2)	0
精索静脈瘤	1 (0.2)	0
外陰腟そう痒症	1 (0.2)	1 (0.2)
呼吸器、胸郭および縦隔障害	77 (16.0)	18 (3.7)
喘息	10 (2.1)	2 (0.4)
無気肺	1 (0.2)	0
慢性閉塞性肺疾患	1 (0.2)	0
咳嗽	17 (3.5)	5 (1.0)
発声障害	1 (0.2)	1 (0.2)
呼吸困難	3 (0.6)	1 (0.2)
肺気腫	1 (0.2)	0
鼻出血	1 (0.2)	0
過換気	1 (0.2)	0
喉頭痛	1 (0.2)	0
鼻閉	1 (0.2)	0
鼻中隔弯曲	2 (0.4)	0
起坐呼吸	1 (0.2)	1 (0.2)
アレルギー性鼻炎	8 (1.7)	1 (0.2)
睡眠時無呼吸症候群	1 (0.2)	0
咽喉刺激感	1 (0.2)	0
喘鳴	2 (0.4)	0
上気道の炎症	22 (4.6)	5 (1.0)
アレルギー性咽頭炎	1 (0.2)	0
気管支反応性亢進	1 (0.2)	1 (0.2)
口腔咽頭不快感	1 (0.2)	0
口腔咽頭痛	8 (1.7)	2 (0.4)
皮膚および皮下組織障害	246 (51.1)	122 (25.4)
ざ瘡	27 (5.6)	5 (1.0)
脱毛症	5 (1.0)	5 (1.0)
円形脱毛症	7 (1.5)	6 (1.2)
血管浮腫	1 (0.2)	0

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.2.1.2 から引用

System Organ Class Preferred Term	All TEAEs Nemolizumab -Total (N=481) n (%)	TEAEs Related to Study Treatment Nemolizumab -Total (N=481) n (%)
皮膚および皮下組織障害 (Cont.)		
水疱	1 (0.2)	1 (0.2)
頭部粃糠疹	2 (0.4)	0
皮膚嚢腫	9 (1.9)	1 (0.2)
皮膚炎	5 (1.0)	4 (0.8)
ざ瘡様皮膚炎	2 (0.4)	1 (0.2)
アトピー性皮膚炎	131 (27.2)	72 (15.0)
接触皮膚炎	32 (6.7)	2 (0.4)
剥脱性皮膚炎	5 (1.0)	4 (0.8)
皮膚筋炎	1 (0.2)	0
薬疹	1 (0.2)	0
皮膚乾燥	1 (0.2)	0
異汗性湿疹	13 (2.7)	4 (0.8)
湿疹	10 (2.1)	5 (1.0)
貨幣状湿疹	1 (0.2)	0
紅斑	10 (2.1)	9 (1.9)
過角化	7 (1.5)	0
嵌入爪	2 (0.4)	0
間擦疹	1 (0.2)	0
稗粒腫	2 (0.4)	0
爪肥厚	1 (0.2)	0
爪甲剥離症	3 (0.6)	0
光線過敏性反応	2 (0.4)	1 (0.2)
ばら色粃糠疹	2 (0.4)	1 (0.2)
紫斑	5 (1.0)	2 (0.4)
発疹	1 (0.2)	0
全身性皮疹	1 (0.2)	1 (0.2)
丘疹性皮疹	2 (0.4)	2 (0.4)
脂漏性皮膚炎	2 (0.4)	0
皮膚障害	1 (0.2)	0
皮膚びらん	2 (0.4)	0
皮膚剥脱	4 (0.8)	3 (0.6)
皮膚亀裂	3 (0.6)	0
皮膚刺激	1 (0.2)	0

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.2.1.2 から引用

System Organ Class Preferred Term	All TEAEs Nemolizumab -Total (N=481) n (%)	TEAEs Related to Study Treatment Nemolizumab -Total (N=481) n (%)
皮膚および皮下組織障害 (Cont.)		
皮膚病変	1 (0.2)	0
皮膚線条	1 (0.2)	1 (0.2)
日光皮膚炎	1 (0.2)	0
うっ滞性皮膚炎	1 (0.2)	1 (0.2)
蕁麻疹	29 (6.0)	12 (2.5)
爪甲脱落症	1 (0.2)	0
湿潤性湿疹	1 (0.2)	0
中毒性皮疹	8 (1.7)	8 (1.7)
爪色素沈着	1 (0.2)	1 (0.2)
手皮膚炎	3 (0.6)	0
色素沈着障害	1 (0.2)	0
爪痛	1 (0.2)	0
爪萎縮	1 (0.2)	0
アンドロゲン性脱毛症	1 (0.2)	0
びまん性脱毛症	2 (0.4)	2 (0.4)
外科および内科処置	2 (0.4)	0
智歯抜歯	1 (0.2)	0
白内障手術	1 (0.2)	0
血管障害	12 (2.5)	3 (0.6)
高血圧	9 (1.9)	2 (0.4)
起立性低血圧	1 (0.2)	0
レイノー現象	1 (0.2)	0
表在性血栓性静脈炎	1 (0.2)	1 (0.2)
製品の問題	1 (0.2)	1 (0.2)
医療機器破損	1 (0.2)	1 (0.2)

Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.2.1.2 から引用

表 2.7.4-65 Subgroup Analysis, Treatment-Emergent Adverse Events by Sex (>- 2% in Group) (Japanese)
Safety Analysis Set（pool1）

System Organ Class Preferred Term	Sex	All TEAEs Nemolizumab-Total (N=481) n (%)	TEAEs Related to Study Drug Nemolizumab-Total (N=481) n (%)
Number of Subjects in Each Category	Male	284	284
	Female	197	197
Overall	Male	262 (92.3)	148 (52.1)
	Female	177 (89.8)	96 (48.7)
眼障害			
アレルギー性結膜炎	Male	6 (2.1)	4 (1.4)
	Female	7 (3.6)	1 (0.5)
胃腸障害			
齲歯	Male	12 (4.2)	1 (0.4)
	Female	8 (4.1)	1 (0.5)
下痢	Male	11 (3.9)	1 (0.4)
	Female	7 (3.6)	1 (0.5)
一般・全身障害および投与部位の状態			
末梢性浮腫	Male	9 (3.2)	5 (1.8)
	Female	12 (6.1)	6 (3.0)
発熱	Male	10 (3.5)	2 (0.7)
	Female	7 (3.6)	2 (1.0)
感染症および寄生虫症			
気管支炎	Male	5 (1.8)	0
	Female	8 (4.1)	2 (1.0)
蜂巣炎	Male	18 (6.3)	13 (4.6)
	Female	7 (3.6)	3 (1.5)
膀胱炎	Male	1 (0.4)	0
	Female	11 (5.6)	3 (1.5)

TEAE occurred in equal to or more than 2% in any treatment group is presented.
Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.11.1.2から引用

System Organ Class Preferred Term	Sex	All TEAEs Nemolizumab-Total (N=481) n (%)	TEAEs Related to Study Drug Nemolizumab-Total (N=481) n (%)
感染症および寄生虫症 (Cont.)			
毛包炎	Male	11 (3.9)	2 (0.7)
	Female	6 (3.0)	1 (0.5)
胃腸炎	Male	15 (5.3)	3 (1.1)
	Female	7 (3.6)	1 (0.5)
帯状疱疹	Male	3 (1.1)	3 (1.1)
	Female	7 (3.6)	3 (1.5)
膿痂疹	Male	6 (2.1)	3 (1.1)
	Female	11 (5.6)	5 (2.5)
インフルエンザ	Male	15 (5.3)	1 (0.4)
	Female	16 (8.1)	2 (1.0)
上咽頭炎	Male	89 (31.3)	9 (3.2)
	Female	71 (36.0)	7 (3.6)
外耳炎	Male	7 (2.5)	1 (0.4)
	Female	8 (4.1)	0
咽頭炎	Male	10 (3.5)	4 (1.4)
	Female	11 (5.6)	0
上気道感染	Male	5 (1.8)	3 (1.1)
	Female	11 (5.6)	6 (3.0)
カポジ水痘様発疹	Male	7 (2.5)	4 (1.4)
	Female	4 (2.0)	2 (1.0)
傷害、中毒および処置合併症			
挫傷	Male	5 (1.8)	1 (0.4)
	Female	12 (6.1)	0
臨床検査			

TEAE occurred in equal to or more than 2% in any treatment group is presented.
Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.11.1.2から引用

System Organ Class Preferred Term	Sex	All TEAEs Nemolizumab-Total (N=481) n (%)	TEAEs Related to Study Drug Nemolizumab-Total (N=481) n (%)
臨床検査 (Cont.)			
血中クレアチンホスホキナーゼ増加	Male	38 (13.4)	5 (1.8)
	Female	11 (5.6)	2 (1.0)
サイトカイン異常	Male	11 (3.9)	10 (3.5)
	Female	3 (1.5)	3 (1.5)
筋骨格系および結合組織障害			
関節痛	Male	2 (0.7)	0
	Female	13 (6.6)	5 (2.5)
背部痛	Male	7 (2.5)	1 (0.4)
	Female	9 (4.6)	1 (0.5)
神経系障害			
頭痛	Male	13 (4.6)	3 (1.1)
	Female	23 (11.7)	6 (3.0)
呼吸器、胸郭および縦隔障害			
喘息	Male	4 (1.4)	1 (0.4)
	Female	6 (3.0)	1 (0.5)
咳嗽	Male	13 (4.6)	4 (1.4)
	Female	4 (2.0)	1 (0.5)
上気道の炎症	Male	13 (4.6)	3 (1.1)
	Female	9 (4.6)	2 (1.0)
皮膚および皮下組織障害			
ざ瘡	Male	14 (4.9)	2 (0.7)
	Female	13 (6.6)	3 (1.5)
アトピー性皮膚炎	Male	76 (26.8)	46 (16.2)
	Female	55 (27.9)	26 (13.2)

TEAE occurred in equal to or more than 2% in any treatment group is presented.
Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.11.1.2から引用

System Organ Class Preferred Term	Sex	All TEAEs Nemolizumab-Total (N=481) n (%)	TEAEs Related to Study Drug Nemolizumab-Total (N=481) n (%)
皮膚および皮下組織障害 (Cont.)			
接触皮膚炎	Male	12 (4.2)	1 (0.4)
	Female	20 (10.2)	1 (0.5)
異汗性湿疹	Male	10 (3.5)	3 (1.1)
	Female	3 (1.5)	1 (0.5)
湿疹	Male	7 (2.5)	4 (1.4)
	Female	3 (1.5)	1 (0.5)
紅斑	Male	2 (0.7)	2 (0.7)
	Female	8 (4.1)	7 (3.6)
蕁麻疹	Male	12 (4.2)	4 (1.4)
	Female	17 (8.6)	8 (4.1)

TEAE occurred in equal to or more than 2% in any treatment group is presented.
Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.11.1.2から引用

表 2.7.4-66 Subgroup Analysis, Treatment-Emergent Adverse Events by Age (>- 2% in Group) (Japanese)
Safety Analysis Set（pool1）

System Organ Class Preferred Term	Age (At Informed Consent) (years)	All TEAEs Nemolizumab-Total (N=481) n (%)	TEAEs Related to Study Drug Nemolizumab-Total (N=481) n (%)
Number of Subjects in Each Category	13 -< 18	13	13
	18 -< 65	460	460
	65 -	8	8
Overall	13 -< 18	13 (100)	8 (61.5)
	18 -< 65	419 (91.1)	233 (50.7)
	65 -	7 (87.5)	3 (37.5)
眼障害			
アレルギー性結膜炎	13 -< 18	0	0
	18 -< 65	13 (2.8)	5 (1.1)
	65 -	0	0
胃腸障害			
齲歯	13 -< 18	0	0
	18 -< 65	18 (3.9)	2 (0.4)
	65 -	2 (25.0)	0
下痢	13 -< 18	1 (7.7)	0
	18 -< 65	17 (3.7)	2 (0.4)
	65 -	0	0
一般・全身障害および投与部位の状態			
末梢性浮腫	13 -< 18	0	0
	18 -< 65	21 (4.6)	11 (2.4)
	65 -	0	0
発熱	13 -< 18	1 (7.7)	1 (7.7)
	18 -< 65	16 (3.5)	3 (0.7)
	65 -	0	0
感染症および寄生虫症			

TEAE occurred in equal to or more than 2% in any treatment group is presented.
Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.11.2.2から引用

System Organ Class Preferred Term	Age (At Informed Consent) (years)	All TEAEs Nemolizumab-Total (N=481) n (%)	TEAEs Related to Study Drug Nemolizumab-Total (N=481) n (%)
感染症および寄生虫症 (Cont.)			
気管支炎	13 -< 18	0	0
	18 -< 65	13 (2.8)	2 (0.4)
	65 -	0	0
蜂巣炎	13 -< 18	1 (7.7)	1 (7.7)
	18 -< 65	23 (5.0)	15 (3.3)
	65 -	1 (12.5)	0
膀胱炎	13 -< 18	0	0
	18 -< 65	12 (2.6)	3 (0.7)
	65 -	0	0
毛包炎	13 -< 18	1 (7.7)	0
	18 -< 65	15 (3.3)	3 (0.7)
	65 -	1 (12.5)	0
胃腸炎	13 -< 18	3 (23.1)	2 (15.4)
	18 -< 65	19 (4.1)	2 (0.4)
	65 -	0	0
帯状疱疹	13 -< 18	0	0
	18 -< 65	10 (2.2)	6 (1.3)
	65 -	0	0
膿痂疹	13 -< 18	0	0
	18 -< 65	17 (3.7)	8 (1.7)
	65 -	0	0
インフルエンザ	13 -< 18	3 (23.1)	0
	18 -< 65	28 (6.1)	3 (0.7)
	65 -	0	0

TEAE occurred in equal to or more than 2% in any treatment group is presented.
Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.11.2.2から引用

System Organ Class Preferred Term	Age (At Informed Consent) (years)	All TEAEs Nemolizumab-Total (N=481) n (%)	TEAEs Related to Study Drug Nemolizumab-Total (N=481) n (%)
感染症および寄生虫症 (Cont.)			
上咽頭炎	13 -< 18	6 (46.2)	0
	18 -< 65	152 (33.0)	16 (3.5)
	65 -	2 (25.0)	0
外耳炎	13 -< 18	1 (7.7)	0
	18 -< 65	14 (3.0)	1 (0.2)
	65 -	0	0
咽頭炎	13 -< 18	1 (7.7)	0
	18 -< 65	20 (4.3)	4 (0.9)
	65 -	0	0
上気道感染	13 -< 18	0	0
	18 -< 65	16 (3.5)	9 (2.0)
	65 -	0	0
カポジ水痘様発疹	13 -< 18	0	0
	18 -< 65	11 (2.4)	6 (1.3)
	65 -	0	0
傷害、中毒および処置合併症			
挫傷	13 -< 18	1 (7.7)	1 (7.7)
	18 -< 65	15 (3.3)	0
	65 -	1 (12.5)	0
臨床検査			
血中クレアチンホスホキナーゼ増加	13 -< 18	3 (23.1)	0
	18 -< 65	46 (10.0)	7 (1.5)
	65 -	0	0
サイトカイン異常	13 -< 18	1 (7.7)	1 (7.7)
	18 -< 65	13 (2.8)	12 (2.6)
	65 -	0	0
筋骨格系および結合組織障害			

TEAE occurred in equal to or more than 2% in any treatment group is presented.
Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.11.2.2から引用

System Organ Class Preferred Term	Age (At Informed Consent) (years)	All TEAEs Nemolizumab-Total (N=481) n (%)	TEAEs Related to Study Drug Nemolizumab-Total (N=481) n (%)
筋骨格系および結合組織障害 (Cont.)			
関節痛	13 -< 18	0	0
	18 -< 65	15 (3.3)	5 (1.1)
	65 -	0	0
背部痛	13 -< 18	0	0
	18 -< 65	16 (3.5)	2 (0.4)
	65 -	0	0
神経系障害			
頭痛	13 -< 18	1 (7.7)	1 (7.7)
	18 -< 65	35 (7.6)	8 (1.7)
	65 -	0	0
呼吸器、胸郭および縦隔障害			
喘息	13 -< 18	0	0
	18 -< 65	10 (2.2)	2 (0.4)
	65 -	0	0
咳嗽	13 -< 18	1 (7.7)	1 (7.7)
	18 -< 65	16 (3.5)	4 (0.9)
	65 -	0	0
上気道の炎症	13 -< 18	4 (30.8)	1 (7.7)
	18 -< 65	18 (3.9)	4 (0.9)
	65 -	0	0
皮膚および皮下組織障害			
ざ瘡	13 -< 18	4 (30.8)	1 (7.7)
	18 -< 65	23 (5.0)	4 (0.9)
	65 -	0	0

TEAE occurred in equal to or more than 2% in any treatment group is presented.
Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.11.2.2から引用

System Organ Class Preferred Term	Age (At Informed Consent) (years)	All TEAEs Nemolizumab-Total (N=481) n (%)	TEAEs Related to Study Drug Nemolizumab-Total (N=481) n (%)
皮膚および皮下組織障害（Cont.）			
アトピー性皮膚炎	13 -< 18	7 (53.8)	3 (23.1)
	18 -< 65	124 (27.0)	69 (15.0)
	65 -	0	0
接触皮膚炎	13 -< 18	0	0
	18 -< 65	32 (7.0)	2 (0.4)
	65 -	0	0
異汗性湿疹	13 -< 18	0	0
	18 -< 65	12 (2.6)	4 (0.9)
	65 -	1 (12.5)	0
湿疹	13 -< 18	1 (7.7)	1 (7.7)
	18 -< 65	9 (2.0)	4 (0.9)
	65 -	0	0
紅斑	13 -< 18	1 (7.7)	1 (7.7)
	18 -< 65	9 (2.0)	8 (1.7)
	65 -	0	0
蕁麻疹	13 -< 18	3 (23.1)	2 (15.4)
	18 -< 65	26 (5.7)	10 (2.2)
	65 -	0	0

TEAE occurred in equal to or more than 2% in any treatment group is presented.
Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.11.2.2から引用

表 2.7.4-67 Subgroup Analysis, Treatment-Emergent Adverse Events by Allergic Disease (>- 2% in Group) (Japanese)
Safety Analysis Set（pool1）

System Organ Class Preferred Term	Allergic Disease [a]	All TEAEs Nemolizumab-Total (N=481) n (%)	TEAEs Related to Study Drug Nemolizumab-Total (N=481) n (%)
Number of Subjects in Each Category	No	283	283
	Yes	198	198
Overall	No	250 (88.3)	131 (46.3)
	Yes	189 (95.5)	113 (57.1)
眼障害			
アレルギー性結膜炎	No	5 (1.8)	1 (0.4)
	Yes	8 (4.0)	4 (2.0)
胃腸障害			
齲歯	No	8 (2.8)	1 (0.4)
	Yes	12 (6.1)	1 (0.5)
下痢	No	9 (3.2)	1 (0.4)
	Yes	9 (4.5)	1 (0.5)
一般・全身障害および投与部位の状態			
末梢性浮腫	No	17 (6.0)	8 (2.8)
	Yes	4 (2.0)	3 (1.5)
発熱	No	6 (2.1)	2 (0.7)
	Yes	11 (5.6)	2 (1.0)
感染症および寄生虫症			
気管支炎	No	6 (2.1)	1 (0.4)
	Yes	7 (3.5)	1 (0.5)
蜂巣炎	No	8 (2.8)	7 (2.5)
	Yes	17 (8.6)	9 (4.5)
膀胱炎	No	9 (3.2)	2 (0.7)
	Yes	3 (1.5)	1 (0.5)

[a] Seasonal Allergy, Allergic Rhinitis, Allergic Conjunctivitis, Food Allergy and Asthma
TEAE occurred in equal to or more than 2% in any treatment group is presented.
Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.11.3.2から引用

System Organ Class Preferred Term	Allergic Disease [a]	All TEAEs Nemolizumab-Total (N=481) n (%)	TEAEs Related to Study Drug Nemolizumab-Total (N=481) n (%)
感染症および寄生虫症 (Cont.)			
毛包炎	No	8 (2.8)	0
	Yes	9 (4.5)	3 (1.5)
胃腸炎	No	8 (2.8)	2 (0.7)
	Yes	14 (7.1)	2 (1.0)
帯状疱疹	No	7 (2.5)	5 (1.8)
	Yes	3 (1.5)	1 (0.5)
膿痂疹	No	10 (3.5)	3 (1.1)
	Yes	7 (3.5)	5 (2.5)
インフルエンザ	No	7 (2.5)	2 (0.7)
	Yes	24 (12.1)	1 (0.5)
上咽頭炎	No	79 (27.9)	9 (3.2)
	Yes	81 (40.9)	7 (3.5)
外耳炎	No	7 (2.5)	0
	Yes	8 (4.0)	1 (0.5)
咽頭炎	No	11 (3.9)	3 (1.1)
	Yes	10 (5.1)	1 (0.5)
上気道感染	No	14 (4.9)	8 (2.8)
	Yes	2 (1.0)	1 (0.5)
カポジ水痘様発疹	No	4 (1.4)	1 (0.4)
	Yes	7 (3.5)	5 (2.5)
傷害、中毒および処置合併症			
挫傷	No	9 (3.2)	0
	Yes	8 (4.0)	1 (0.5)
臨床検査			

[a] Seasonal Allergy, Allergic Rhinitis, Allergic Conjunctivitis, Food Allergy and Asthma
TEAE occurred in equal to or more than 2% in any treatment group is presented.
Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.11.3.2から引用

System Organ Class Preferred Term	Allergic Disease [a]	All TEAEs Nemolizumab-Total (N=481) n (%)	TEAEs Related to Study Drug Nemolizumab-Total (N=481) n (%)
臨床検査 (Cont.)			
血中クレアチンホスホキナーゼ増加	No	26 (9.2)	4 (1.4)
	Yes	23 (11.6)	3 (1.5)
サイトカイン異常	No	3 (1.1)	3 (1.1)
	Yes	11 (5.6)	10 (5.1)
筋骨格系および結合組織障害			
関節痛	No	9 (3.2)	3 (1.1)
	Yes	6 (3.0)	2 (1.0)
背部痛	No	6 (2.1)	1 (0.4)
	Yes	10 (5.1)	1 (0.5)
神経系障害			
頭痛	No	19 (6.7)	5 (1.8)
	Yes	17 (8.6)	4 (2.0)
呼吸器、胸郭および縦隔障害			
喘息	No	3 (1.1)	0
	Yes	7 (3.5)	2 (1.0)
咳嗽	No	10 (3.5)	3 (1.1)
	Yes	7 (3.5)	2 (1.0)
上気道の炎症	No	4 (1.4)	2 (0.7)
	Yes	18 (9.1)	3 (1.5)
皮膚および皮下組織障害			
ざ瘡	No	6 (2.1)	0
	Yes	21 (10.6)	5 (2.5)
アトピー性皮膚炎	No	77 (27.2)	35 (12.4)
	Yes	54 (27.3)	37 (18.7)

[a] Seasonal Allergy, Allergic Rhinitis, Allergic Conjunctivitis, Food Allergy and Asthma
TEAE occurred in equal to or more than 2% in any treatment group is presented.
Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.11.3.2から引用

System Organ Class Preferred Term	Allergic Disease [a]	All TEAEs Nemolizumab-Total (N=481) n (%)	TEAEs Related to Study Drug Nemolizumab-Total (N=481) n (%)
皮膚および皮下組織障害 (Cont.)			
接触皮膚炎	No	16 (5.7)	0
	Yes	16 (8.1)	2 (1.0)
異汗性湿疹	No	7 (2.5)	3 (1.1)
	Yes	6 (3.0)	1 (0.5)
湿疹	No	6 (2.1)	3 (1.1)
	Yes	4 (2.0)	2 (1.0)
紅斑	No	4 (1.4)	3 (1.1)
	Yes	6 (3.0)	6 (3.0)
蕁麻疹	No	9 (3.2)	5 (1.8)
	Yes	20 (10.1)	7 (3.5)

[a] Seasonal Allergy, Allergic Rhinitis, Allergic Conjunctivitis, Food Allergy and Asthma
TEAE occurred in equal to or more than 2% in any treatment group is presented.
Multiple occurrences of an event for one subject are counted only once.
MedDRA/J version 20.1 is used for coding.
5.3.5.3-1 Table 5.2.4.11.3.2から引用

表 2.7.4-68 Significant Treatment-Emergent Adverse Events Occurred during PartA
by Baseline TARC
Safety Analysis Set（pool2）

	Nemolizumab (N=301)				Placebo-Nemolizumab (N=112)			
	< 500 ng/L	500 -< 2000 ng/L	2000 - < 5000 ng/L	5000 - ng/L	< 500 ng/L	500 -< 2000 ng/L	2000 - < 5000 ng/L	5000 - ng/L
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Number of Subjects in Each Category	42	122	67	70	16	57	22	17
Significant TEAEs								
TEAEs Leading to Discontinuation (including Dose Interruption and Reduction) of Study Treatment	0	6 (4.9)	3 (4.5)	10 (14.3)	1 (6.3)	1 (1.8)	0	0
Discontinuation	0	5 (4.1)	1 (1.5)	7 (10.0)	0	0	0	0
Dose Interruption	0	1 (0.8)	2 (3.0)	3 (4.3)	1 (6.3)	1 (1.8)	0	0
Dose Reduction	0	0	0	0	0	0	0	0
TEAEs Special Interest								
Injection-Related Reaction	6 (14.3)	9 (7.4)	3 (4.5)	2 (2.9)	3 (18.8)	0	0	0
Asthma	1 (2.4)	0	0	0	0	1 (1.8)	0	0
Worsening of AD	6 (14.3)	20 (16.4)	20 (29.9)	18 (25.7)	2 (12.5)	10 (17.5)	6 (27.3)	3 (17.6)
Skin Infections	3 (7.1)	9 (7.4)	10 (14.9)	10 (14.3)	2 (12.5)	6 (10.5)	3 (13.6)	1 (5.9)
Non-skin Infections	12 (28.6)	27 (22.1)	17 (25.4)	22 (31.4)	6 (37.5)	12 (21.1)	11 (50.0)	5 (29.4)
Elevated CPK	2 (4.8)	6 (4.9)	3 (4.5)	2 (2.9)	1 (6.3)	2 (3.5)	0	0

5.3.5.3-1 Table 5.2.4.12.1から引用

表 2.7.4-69 Significant Treatment-Emergent Adverse Events Related to Study Drug Occurred during PartA by Baseline TARC
Safety Analysis Set（pool2）

	Nemolizumab (N=301)				Placebo-Nemolizumab (N=112)			
	< 500 ng/L	500 -< 2000 ng/L	2000 - < 5000 ng/L	5000 - ng/L	< 500 ng/L	500 -< 2000 ng/L	2000 - < 5000 ng/L	5000 - ng/L
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Number of Subjects in Each Category	42	122	67	70	16	57	22	17
Significant TEAEs								
TEAEs Leading to Discontinuation (including Dose Interruption and Reduction) of Study Treatment	0	3 (2.5)	2 (3.0)	8 (11.4)	0	0	0	0
Discontinuation	0	3 (2.5)	1 (1.5)	6 (8.6)	0	0	0	0
Dose Interruption	0	0	1 (1.5)	2 (2.9)	0	0	0	0
Dose Reduction	0	0	0	0	0	0	0	0
TEAEs Special Interest								
Injection-Related Reaction	6 (14.3)	5 (4.1)	2 (3.0)	2 (2.9)	1 (6.3)	0	0	0
Asthma	1 (2.4)	0	0	0	0	1 (1.8)	0	0
Worsening of AD	5 (11.9)	12 (9.8)	12 (17.9)	8 (11.4)	0	4 (7.0)	0	1 (5.9)
Skin Infections	0	2 (1.6)	2 (3.0)	4 (5.7)	2 (12.5)	2 (3.5)	1 (4.5)	0
Non-skin Infections	6 (14.3)	8 (6.6)	4 (6.0)	7 (10.0)	1 (6.3)	2 (3.5)	0	1 (5.9)
Elevated CPK	2 (4.8)	0	1 (1.5)	0	0	0	0	0

5.3.5.3-1 Table 5.2.4.12.2から引用

表 2.7.4-70 Treatment-Emergent Adverse Events by Time Period (Japanese)
Safety Analysis Set

System Organ Class / Preferred Term	Overall (N=88)							Prof[a] (N=44)							Self[b] (N=44)						
	Any Period	- 85 days	86 - 169 days	170 - 253 days	254 - 337 days	338 - days	FU	Any Period	- 85 days	86 - 169 days	170 - 253 days	254 - 337 days	338 - days	FU	Any Period	- 85 days	86 - 169 days	170 - 253 days	254 - 337 days	338 - days	FU
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Number of Subjects in Each Period	88	88	88	83	81	78	86	44	44	44	41	41	41	43	44	44	44	42	40	37	43
TEAEs	79 (89.8)	53 (60.2)	17 (19.3)	5 (6.0)	3 (3.7)	0	1 (1.2)	38 (86.4)	25 (56.8)	6 (13.6)	5 (12.2)	2 (4.9)	0	0	41 (93.2)	28 (63.6)	11 (25.0)	0	1 (2.5)	0	1 (2.3)
Serious TEAEs	10 (11.4)	2 (2.3)	1 (1.1)	3 (3.6)	1 (1.2)	0	3 (3.5)	3 (6.8)	2 (4.5)	0	0	0	0	1 (2.3)	7 (15.9)	0	1 (2.3)	3 (7.1)	1 (2.5)	0	2 (4.7)
TEAEs Leading to Death	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Other Serious TEAEs	10 (11.4)	2 (2.3)	1 (1.1)	3 (3.6)	1 (1.2)	0	3 (3.5)	3 (6.8)	2 (4.5)	0	0	0	0	1 (2.3)	7 (15.9)	0	1 (2.3)	3 (7.1)	1 (2.5)	0	2 (4.7)

Percentages are based on number of subjects in each time period.
Multiple occurrences of an event for one subject are counted only once as earliest onset.
TEAE occurred in equal to or more than 3 subjects is presented.
MedDRA/J version 20.1 is used for coding.
[a] Medical professional administration group
[b] Self-injection group
5.3.5.2-1 Table 14.3.4.1.2から引用

System Organ Class / Preferred Term	Overall (N=88) Any Period n (%)	Overall - 85 days n (%)	Overall 86 - 169 days n (%)	Overall 170 - 253 days n (%)	Overall 254 - 337 days n (%)	Overall 338 - days n (%)	Overall FU n (%)	Prof[a] (N=44) Any Period n (%)	Prof[a] - 85 days n (%)	Prof[a] 86 - 169 days n (%)	Prof[a] 170 - 253 days n (%)	Prof[a] 254 - 337 days n (%)	Prof[a] 338 - days n (%)	Prof[a] FU n (%)	Self[b] (N=44) Any Period n (%)	Self[b] - 85 days n (%)	Self[b] 86 - 169 days n (%)	Self[b] 170 - 253 days n (%)	Self[b] 254 - 337 days n (%)	Self[b] 338 - days n (%)	Self[b] FU n (%)
Other Significant TEAEs																					
TEAEs Leading to Discontinuation (including Dose Interruption and Reduction) of Study Treatment	11 (12.5)	6 (6.8)	2 (2.3)	3 (3.6)	0	0	0	4 (9.1)	4 (9.1)	0	0	0	0	0	7 (15.9)	2 (4.5)	2 (4.5)	3 (7.1)	0	0	0
Discontinuation	7 (8.0)	4 (4.5)	1 (1.1)	2 (2.4)	0	0	0	2 (4.5)	2 (4.5)	0	0	0	0	0	5 (11.4)	2 (4.5)	1 (2.3)	2 (4.8)	0	0	0
Dose Interruption	4 (4.5)	2 (2.3)	1 (1.1)	1 (1.2)	0	0	0	2 (4.5)	2 (4.5)	0	0	0	0	0	2 (4.5)	0	1 (2.3)	1 (2.4)	0	0	0
Dose Reduction	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Percentages are based on number of subjects in each time period.
Multiple occurrences of an event for one subject are counted only once as earliest onset.
TEAE occurred in equal to or more than 3 subjects is presented.
MedDRA/J version 20.1 is used for coding.
[a] Medical professional administration group
[b] Self-injection group
5.3.5.2-1 Table 14.3.4.1.2から引用

System Organ Class / Preferred Term	Overall (N=88)							Prof[a] (N=44)							Self[b] (N=44)						
	Any Period	- 85 days	86 - 169 days	170 - 253 days	254 - 337 days	338 - days	FU	Any Period	- 85 days	86 - 169 days	170 - 253 days	254 - 337 days	338 - days	FU	Any Period	- 85 days	86 - 169 days	170 - 253 days	254 - 337 days	338 - days	FU
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
TEAEs Special Interest																					
Injection-Related Reaction	3 (3.4)	2 (2.3)	1 (1.1)	0	0	0	0	3 (6.8)	2 (4.5)	1 (2.3)	0	0	0	0	0	0	0	0	0	0	0
Asthma	2 (2.3)	1 (1.1)	0	1 (1.2)	0	0	0	2 (4.5)	1 (2.3)	0	1 (2.4)	0	0	0	0	0	0	0	0	0	0
Worsening of AD	23 (26.1)	14 (15.9)	6 (6.8)	2 (2.4)	1 (1.2)	0	0	10 (22.7)	8 (18.2)	1 (2.3)	1 (2.4)	0	0	0	13 (29.5)	6 (13.6)	5 (11.4)	1 (2.4)	1 (2.5)	0	0
Skin Infections	25 (28.4)	14 (15.9)	5 (5.7)	2 (2.4)	3 (3.7)	0	1 (1.2)	11 (25.0)	5 (11.4)	3 (6.8)	0	3 (7.3)	0	0	14 (31.8)	9 (20.5)	2 (4.5)	2 (4.8)	0	0	1 (2.3)
Non-skin Infections	48 (54.5)	15 (17.0)	14 (15.9)	13 (15.7)	4 (4.9)	1 (1.3)	1 (1.2)	21 (47.7)	6 (13.6)	7 (15.9)	7 (17.1)	1 (2.4)	0	0	27 (61.4)	9 (20.5)	7 (15.9)	6 (14.3)	3 (7.5)	1 (2.7)	1 (2.3)
Elevated CPK	5 (5.7)	1 (1.1)	1 (1.1)	1 (1.2)	1 (1.2)	0	1 (1.2)	2 (4.5)	0	0	1 (2.4)	0	0	1 (2.3)	3 (6.8)	1 (2.3)	1 (2.3)	0	1 (2.5)	0	0
Suspected Transmission of an Infectious Agent by the Study Drug	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Percentages are based on number of subjects in each time period.
Multiple occurrences of an event for one subject are counted only once as earliest onset.
TEAE occurred in equal to or more than 3 subjects is presented.
MedDRA/J version 20.1 is used for coding.
[a] Medical professional administration group
[b] Self-injection group
5.3.5.2-1 Table 14.3.4.1.2から引用

System Organ Class / Preferred Term	Overall (N=88) Any Period n (%)	Overall (N=88) - 85 days n (%)	Overall (N=88) 86 - 169 days n (%)	Overall (N=88) 170 - 253 days n (%)	Overall (N=88) 254 - 337 days n (%)	Overall (N=88) 338 - days n (%)	Overall (N=88) FU n (%)	Prof[a] (N=44) Any Period n (%)	Prof[a] (N=44) - 85 days n (%)	Prof[a] (N=44) 86 - 169 days n (%)	Prof[a] (N=44) 170 - 253 days n (%)	Prof[a] (N=44) 254 - 337 days n (%)	Prof[a] (N=44) 338 - days n (%)	Prof[a] (N=44) FU n (%)	Self[b] (N=44) Any Period n (%)	Self[b] (N=44) - 85 days n (%)	Self[b] (N=44) 86 - 169 days n (%)	Self[b] (N=44) 170 - 253 days n (%)	Self[b] (N=44) 254 - 337 days n (%)	Self[b] (N=44) 338 - days n (%)	Self[b] (N=44) FU n (%)
耳および迷路障害																					
回転性めまい	3 (3.4)	1 (1.1)	1 (1.1)	1 (1.2)	0	0	0	2 (4.5)	1 (2.3)	1 (2.3)	0	0	0	0	1 (2.3)	0	0	1 (2.4)	0	0	0
胃腸障害																					
齲歯	3 (3.4)	0	1 (1.1)	0	2 (2.5)	0	0	2 (4.5)	0	1 (2.3)	0	1 (2.4)	0	0	1 (2.3)	0	0	0	1 (2.5)	0	0
胃食道逆流性疾患	3 (3.4)	1 (1.1)	1 (1.1)	0	1 (1.2)	0	0	0	0	0	0	0	0	0	3 (6.8)	1 (2.3)	1 (2.3)	0	1 (2.5)	0	0
一般・全身障害および投与部位の状態																					
疼痛	3 (3.4)	0	1 (1.1)	1 (1.2)	0	0	1 (1.2)	1 (2.3)	0	0	0	0	0	1 (2.3)	2 (4.5)	0	1 (2.3)	1 (2.4)	0	0	0
感染症および寄生虫症																					

Percentages are based on number of subjects in each time period.
Multiple occurrences of an event for one subject are counted only once as earliest onset.
TEAE occurred in equal to or more than 3 subjects is presented.
MedDRA/J version 20.1 is used for coding.
[a] Medical professional administration group
[b] Self-injection group
5.3.5.2-1 Table 14.3.4.1.2から引用

System Organ Class / Preferred Term	Overall (N=88) Any Period n (%)	Overall (N=88) - 85 days n (%)	Overall (N=88) 86 - 169 days n (%)	Overall (N=88) 170 - 253 days n (%)	Overall (N=88) 254 - 337 days n (%)	Overall (N=88) 338 - days n (%)	Overall (N=88) FU n (%)	Prof[a] (N=44) Any Period n (%)	Prof[a] (N=44) - 85 days n (%)	Prof[a] (N=44) 86 - 169 days n (%)	Prof[a] (N=44) 170 - 253 days n (%)	Prof[a] (N=44) 254 - 337 days n (%)	Prof[a] (N=44) 338 - days n (%)	Prof[a] (N=44) FU n (%)	Self[b] (N=44) Any Period n (%)	Self[b] (N=44) - 85 days n (%)	Self[b] (N=44) 86 - 169 days n (%)	Self[b] (N=44) 170 - 253 days n (%)	Self[b] (N=44) 254 - 337 days n (%)	Self[b] (N=44) 338 - days n (%)	Self[b] (N=44) FU n (%)
感染症および寄生虫症 (Cont.)																					
気管支炎	4 (4.5)	1 (1.1)	2 (2.3)	0	0	0	1 (1.2)	0	0	0	0	0	0	0	4 (9.1)	1 (2.3)	2 (4.5)	0	0	0	1 (2.3)
蜂巣炎	10 (11.4)	3 (3.4)	3 (3.4)	1 (1.2)	1 (1.2)	0	2 (2.3)	3 (6.8)	1 (2.3)	2 (4.5)	0	0	0	0	7 (15.9)	2 (4.5)	1 (2.3)	1 (2.4)	1 (2.5)	0	2 (4.7)
毛包炎	3 (3.4)	1 (1.1)	0	1 (1.2)	0	0	1 (1.2)	0	0	0	0	0	0	0	3 (6.8)	1 (2.3)	0	1 (2.4)	0	0	1 (2.3)
帯状疱疹	3 (3.4)	1 (1.1)	1 (1.1)	0	1 (1.2)	0	0	2 (4.5)	0	1 (2.3)	0	1 (2.4)	0	0	1 (2.3)	1 (2.3)	0	0	0	0	0
膿痂疹	4 (4.5)	0	2 (2.3)	1 (1.2)	0	0	1 (1.2)	2 (4.5)	0	1 (2.3)	0	0	0	1 (2.3)	2 (4.5)	0	1 (2.3)	1 (2.4)	0	0	0
インフルエンザ	9 (10.2)	0	2 (2.3)	7 (8.4)	0	0	0	6 (13.6)	0	0	6 (14.6)	0	0	0	3 (6.8)	0	2 (4.5)	1 (2.4)	0	0	0
上咽頭炎	31 (35.2)	11 (12.5)	9 (10.2)	8 (9.6)	1 (1.2)	1 (1.3)	1 (1.2)	14 (31.8)	4 (9.1)	6 (13.6)	3 (7.3)	1 (2.4)	0	0	17 (38.6)	7 (15.9)	3 (6.8)	5 (11.9)	0	1 (2.7)	1 (2.3)

Percentages are based on number of subjects in each time period.
Multiple occurrences of an event for one subject are counted only once as earliest onset.
TEAE occurred in equal to or more than 3 subjects is presented.
MedDRA/J version 20.1 is used for coding.
[a] Medical professional administration group
[b] Self-injection group
5.3.5.2-1 Table 14.3.4.1.2から引用

System Organ Class / Preferred Term	Overall (N=88) Any Period n (%)	Overall (N=88) - 85 days n (%)	Overall (N=88) 86 - 169 days n (%)	Overall (N=88) 170 - 253 days n (%)	Overall (N=88) 254 - 337 days n (%)	Overall (N=88) 338 - days n (%)	Overall (N=88) FU n (%)	Prof[a] (N=44) Any Period n (%)	Prof[a] (N=44) - 85 days n (%)	Prof[a] (N=44) 86 - 169 days n (%)	Prof[a] (N=44) 170 - 253 days n (%)	Prof[a] (N=44) 254 - 337 days n (%)	Prof[a] (N=44) 338 - days n (%)	Prof[a] (N=44) FU n (%)	Self[b] (N=44) Any Period n (%)	Self[b] (N=44) - 85 days n (%)	Self[b] (N=44) 86 - 169 days n (%)	Self[b] (N=44) 170 - 253 days n (%)	Self[b] (N=44) 254 - 337 days n (%)	Self[b] (N=44) 338 - days n (%)	Self[b] (N=44) FU n (%)
感染症および寄生虫症 (Cont.)																					
外耳炎	3 (3.4)	1 (1.1)	1 (1.1)	1 (1.2)	0	0	0	2 (4.5)	1 (2.3)	1 (2.3)	0	0	0	0	1 (2.3)	0	0	1 (2.4)	0	0	0
咽頭炎	5 (5.7)	2 (2.3)	1 (1.1)	0	1 (1.2)	0	1 (1.2)	2 (4.5)	1 (2.3)	0	0	0	0	1 (2.3)	3 (6.8)	1 (2.3)	1 (2.3)	0	1 (2.5)	0	0
皮膚感染	3 (3.4)	1 (1.1)	2 (2.3)	0	0	0	0	0	0	0	0	0	0	0	3 (6.8)	1 (2.3)	2 (4.5)	0	0	0	0
カポジ水痘様発疹	4 (4.5)	4 (4.5)	0	0	0	0	0	1 (2.3)	1 (2.3)	0	0	0	0	0	3 (6.8)	3 (6.8)	0	0	0	0	0
臨床検査																					
血中クレアチンホスホキナーゼ増加	5 (5.7)	1 (1.1)	1 (1.1)	1 (1.2)	1 (1.2)	0	1 (1.2)	2 (4.5)	0	0	1 (2.4)	0	0	1 (2.3)	3 (6.8)	1 (2.3)	1 (2.3)	0	1 (2.5)	0	0
筋骨格系および結合組織障害																					

Percentages are based on number of subjects in each time period.
Multiple occurrences of an event for one subject are counted only once as earliest onset.
TEAE occurred in equal to or more than 3 subjects is presented.
MedDRA/J version 20.1 is used for coding.
[a] Medical professional administration group
[b] Self-injection group
5.3.5.2-1 Table 14.3.4.1.2から引用

System Organ Class / Preferred Term	Overall (N=88) Any Period n (%)	Overall (N=88) - 85 days n (%)	Overall (N=88) 86 - 169 days n (%)	Overall (N=88) 170 - 253 days n (%)	Overall (N=88) 254 - 337 days n (%)	Overall (N=88) 338 - days n (%)	Overall (N=88) FU n (%)	Prof[a] (N=44) Any Period n (%)	Prof[a] (N=44) - 85 days n (%)	Prof[a] (N=44) 86 - 169 days n (%)	Prof[a] (N=44) 170 - 253 days n (%)	Prof[a] (N=44) 254 - 337 days n (%)	Prof[a] (N=44) 338 - days n (%)	Prof[a] (N=44) FU n (%)	Self[b] (N=44) Any Period n (%)	Self[b] (N=44) - 85 days n (%)	Self[b] (N=44) 86 - 169 days n (%)	Self[b] (N=44) 170 - 253 days n (%)	Self[b] (N=44) 254 - 337 days n (%)	Self[b] (N=44) 338 - days n (%)	Self[b] (N=44) FU n (%)
筋骨格系および結合組織障害 (Cont.)																					
関節痛	3 (3.4)	2 (2.3)	1 (1.1)	0	0	0	0	1 (2.3)	1 (2.3)	0	0	0	0	0	2 (4.5)	1 (2.3)	1 (2.3)	0	0	0	0
神経系障害																					
頭痛	8 (9.1)	2 (2.3)	4 (4.5)	0	1 (1.2)	0	1 (1.2)	3 (6.8)	0	2 (4.5)	0	0	0	1 (2.3)	5 (11.4)	2 (4.5)	2 (4.5)	0	1 (2.5)	0	0
呼吸器、胸郭および縦隔障害																					
咳嗽	8 (9.1)	5 (5.7)	1 (1.1)	0	2 (2.5)	0	0	5 (11.4)	3 (6.8)	1 (2.3)	0	1 (2.4)	0	0	3 (6.8)	2 (4.5)	0	0	1 (2.5)	0	0
上気道の炎症	4 (4.5)	1 (1.1)	1 (1.1)	0	1 (1.2)	0	1 (1.2)	2 (4.5)	1 (2.3)	0	0	1 (2.4)	0	0	2 (4.5)	0	1 (2.3)	0	0	0	1 (2.3)
皮膚および皮下組織障害																					

Percentages are based on number of subjects in each time period.
Multiple occurrences of an event for one subject are counted only once as earliest onset.
TEAE occurred in equal to or more than 3 subjects is presented.
MedDRA/J version 20.1 is used for coding.
[a] Medical professional administration group
[b] Self-injection group
5.3.5.2-1 Table 14.3.4.1.2から引用

System Organ Class / Preferred Term	Overall (N=88) Any Period n (%)	Overall (N=88) - 85 days n (%)	Overall (N=88) 86 - 169 days n (%)	Overall (N=88) 170 - 253 days n (%)	Overall (N=88) 254 - 337 days n (%)	Overall (N=88) 338 - days n (%)	Overall (N=88) FU n (%)	Prof[a] (N=44) Any Period n (%)	Prof[a] (N=44) - 85 days n (%)	Prof[a] (N=44) 86 - 169 days n (%)	Prof[a] (N=44) 170 - 253 days n (%)	Prof[a] (N=44) 254 - 337 days n (%)	Prof[a] (N=44) 338 - days n (%)	Prof[a] (N=44) FU n (%)	Self[b] (N=44) Any Period n (%)	Self[b] (N=44) - 85 days n (%)	Self[b] (N=44) 86 - 169 days n (%)	Self[b] (N=44) 170 - 253 days n (%)	Self[b] (N=44) 254 - 337 days n (%)	Self[b] (N=44) 338 - days n (%)	Self[b] (N=44) FU n (%)
皮膚および皮下組織障害 (Cont.)																					
皮膚嚢腫	3 (3.4)	0	0	1 (1.2)	1 (1.2)	0	1 (1.2)	0	0	0	0	0	0	0	3 (6.8)	0	0	1 (2.4)	1 (2.5)	0	1 (2.3)
皮膚炎	3 (3.4)	1 (1.1)	1 (1.1)	0	0	1 (1.3)	0	1 (2.3)	0	0	0	0	1 (2.4)	0	2 (4.5)	1 (2.3)	1 (2.3)	0	0	0	0
アトピー性皮膚炎	23 (26.1)	14 (15.9)	6 (6.8)	2 (2.4)	1 (1.2)	0	0	10 (22.7)	8 (18.2)	1 (2.3)	1 (2.4)	0	0	0	13 (29.5)	6 (13.6)	5 (11.4)	1 (2.4)	1 (2.5)	0	0
接触皮膚炎	11 (12.5)	3 (3.4)	3 (3.4)	3 (3.6)	1 (1.2)	0	1 (1.2)	6 (13.6)	2 (4.5)	2 (4.5)	1 (2.4)	0	0	1 (2.3)	5 (11.4)	1 (2.3)	1 (2.3)	2 (4.8)	1 (2.5)	0	0
蕁麻疹	4 (4.5)	2 (2.3)	0	0	1 (1.2)	0	1 (1.2)	2 (4.5)	1 (2.3)	0	0	0	0	1 (2.3)	2 (4.5)	1 (2.3)	0	0	1 (2.5)	0	0
中毒性皮疹	4 (4.5)	3 (3.4)	1 (1.1)	0	0	0	0	1 (2.3)	1 (2.3)	0	0	0	0	0	3 (6.8)	2 (4.5)	1 (2.3)	0	0	0	0

Percentages are based on number of subjects in each time period.
Multiple occurrences of an event for one subject are counted only once as earliest onset.
TEAE occurred in equal to or more than 3 subjects is presented.
MedDRA/J version 20.1 is used for coding.
[a] Medical professional administration group
[b] Self-injection group
5.3.5.2-1 Table 14.3.4.1.2から引用

表 2.7.4-71 Treatment-Emergent Adverse Events Related to Study Drug by Time Period (Japanese)
Safety Analysis Set

System Organ Class / Preferred Term	Overall (N=88) Any Period n (%)	Overall (N=88) - 85 days n (%)	Overall (N=88) 86 - 169 days n (%)	Overall (N=88) 170 - 253 days n (%)	Overall (N=88) 254 - 337 days n (%)	Overall (N=88) 338 - days n (%)	Overall (N=88) FU n (%)	Prof[a] (N=44) Any Period n (%)	Prof[a] (N=44) - 85 days n (%)	Prof[a] (N=44) 86 - 169 days n (%)	Prof[a] (N=44) 170 - 253 days n (%)	Prof[a] (N=44) 254 - 337 days n (%)	Prof[a] (N=44) 338 - days n (%)	Prof[a] (N=44) FU n (%)	Self[b] (N=44) Any Period n (%)	Self[b] (N=44) - 85 days n (%)	Self[b] (N=44) 86 - 169 days n (%)	Self[b] (N=44) 170 - 253 days n (%)	Self[b] (N=44) 254 - 337 days n (%)	Self[b] (N=44) 338 - days n (%)	Self[b] (N=44) FU n (%)
Number of Subjects in Each Period	88	88	88	83	81	78	86	44	44	44	41	41	41	43	44	44	44	42	40	37	43
TEAEs	50 (56.8)	31 (35.2)	12 (13.6)	3 (3.6)	3 (3.7)	1 (1.3)	0	26 (59.1)	19 (43.2)	3 (6.8)	2 (4.9)	2 (4.9)	0	0	24 (54.5)	12 (27.3)	9 (20.5)	1 (2.4)	1 (2.5)	1 (2.7)	0
Serious TEAEs	5 (5.7)	1 (1.1)	0	1 (1.2)	0	0	3 (3.5)	2 (4.5)	1 (2.3)	0	0	0	0	1 (2.3)	3 (6.8)	0	0	1 (2.4)	0	0	2 (4.7)
TEAEs Leading to Death	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Other Serious TEAEs	5 (5.7)	1 (1.1)	0	1 (1.2)	0	0	3 (3.5)	2 (4.5)	1 (2.3)	0	0	0	0	1 (2.3)	3 (6.8)	0	0	1 (2.4)	0	0	2 (4.7)

Percentages are based on number of subjects in each time period.
Multiple occurrences of an event for one subject are counted only once as earliest onset.
TEAE occurred in equal to or more than 3 subjects is presented.
MedDRA/J version 20.1 is used for coding.
[a] Medical professional administration group
[b] Self-injection group
5.3.5.2-1 Table 14.3.4.1.4から引用

System Organ Class / Preferred Term	Overall (N=88) Any Period n (%)	Overall (N=88) - 85 days n (%)	Overall (N=88) 86 - 169 days n (%)	Overall (N=88) 170 - 253 days n (%)	Overall (N=88) 254 - 337 days n (%)	Overall (N=88) 338 - days n (%)	Overall (N=88) FU n (%)	Prof[a] (N=44) Any Period n (%)	Prof[a] (N=44) - 85 days n (%)	Prof[a] (N=44) 86 - 169 days n (%)	Prof[a] (N=44) 170 - 253 days n (%)	Prof[a] (N=44) 254 - 337 days n (%)	Prof[a] (N=44) 338 - days n (%)	Prof[a] (N=44) FU n (%)	Self[b] (N=44) Any Period n (%)	Self[b] (N=44) - 85 days n (%)	Self[b] (N=44) 86 - 169 days n (%)	Self[b] (N=44) 170 - 253 days n (%)	Self[b] (N=44) 254 - 337 days n (%)	Self[b] (N=44) 338 - days n (%)	Self[b] (N=44) FU n (%)
Other Significant TEAEs																					
TEAEs Leading to Discontinuation (including Dose Interruption and Reduction) of Study Treatment	10 (11.4)	6 (6.8)	1 (1.1)	3 (3.6)	0	0	0	4 (9.1)	4 (9.1)	0	0	0	0	0	6 (13.6)	2 (4.5)	1 (2.3)	3 (7.1)	0	0	0
Discontinuation	7 (8.0)	4 (4.5)	1 (1.1)	2 (2.4)	0	0	0	2 (4.5)	2 (4.5)	0	0	0	0	0	5 (11.4)	2 (4.5)	1 (2.3)	2 (4.8)	0	0	0
Dose Interruption	3 (3.4)	2 (2.3)	0	1 (1.2)	0	0	0	2 (4.5)	2 (4.5)	0	0	0	0	0	1 (2.3)	0	0	1 (2.4)	0	0	0
Dose Reduction	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Percentages are based on number of subjects in each time period.
Multiple occurrences of an event for one subject are counted only once as earliest onset.
TEAE occurred in equal to or more than 3 subjects is presented.
MedDRA/J version 20.1 is used for coding.
[a] Medical professional administration group
[b] Self-injection group
5.3.5.2-1 Table 14.3.4.1.4から引用

System Organ Class / Preferred Term	Overall (N=88) Any Period n (%)	Overall (N=88) - 85 days n (%)	Overall (N=88) 86 - 169 days n (%)	Overall (N=88) 170 - 253 days n (%)	Overall (N=88) 254 - 337 days n (%)	Overall (N=88) 338 - days n (%)	Overall (N=88) FU n (%)	Prof[a] (N=44) Any Period n (%)	Prof[a] (N=44) - 85 days n (%)	Prof[a] (N=44) 86 - 169 days n (%)	Prof[a] (N=44) 170 - 253 days n (%)	Prof[a] (N=44) 254 - 337 days n (%)	Prof[a] (N=44) 338 - days n (%)	Prof[a] (N=44) FU n (%)	Self[b] (N=44) Any Period n (%)	Self[b] (N=44) - 85 days n (%)	Self[b] (N=44) 86 - 169 days n (%)	Self[b] (N=44) 170 - 253 days n (%)	Self[b] (N=44) 254 - 337 days n (%)	Self[b] (N=44) 338 - days n (%)	Self[b] (N=44) FU n (%)
TEAEs Special Interest																					
Injection-Related Reaction	3 (3.4)	2 (2.3)	1 (1.1)	0	0	0	0	3 (6.8)	2 (4.5)	1 (2.3)	0	0	0	0	0	0	0	0	0	0	0
Asthma	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Worsening of AD	21 (23.9)	12 (13.6)	6 (6.8)	2 (2.4)	0	1 (1.3)	0	9 (20.5)	7 (15.9)	1 (2.3)	1 (2.4)	0	0	0	12 (27.3)	5 (11.4)	5 (11.4)	1 (2.4)	0	1 (2.7)	0
Skin Infections	16 (18.2)	10 (11.4)	3 (3.4)	0	3 (3.7)	0	0	9 (20.5)	5 (11.4)	2 (4.5)	0	2 (4.9)	0	0	7 (15.9)	5 (11.4)	1 (2.3)	0	1 (2.5)	0	0
Non-skin Infections	3 (3.4)	0	0	2 (2.4)	1 (1.2)	0	0	1 (2.3)	0	0	1 (2.4)	0	0	0	2 (4.5)	0	0	1 (2.4)	1 (2.5)	0	0
Elevated CPK	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Suspected Transmission of an Infectious Agent by the Study Drug	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Percentages are based on number of subjects in each time period.
Multiple occurrences of an event for one subject are counted only once as earliest onset.
TEAE occurred in equal to or more than 3 subjects is presented.
MedDRA/J version 20.1 is used for coding.
[a] Medical professional administration group
[b] Self-injection group
5.3.5.2-1 Table 14.3.4.1.4から引用

System Organ Class / Preferred Term	Overall (N=88) Any Period n (%)	Overall (N=88) - 85 days n (%)	Overall (N=88) 86 - 169 days n (%)	Overall (N=88) 170 - 253 days n (%)	Overall (N=88) 254 - 337 days n (%)	Overall (N=88) 338 - days n (%)	Overall (N=88) FU n (%)	Prof[a] (N=44) Any Period n (%)	Prof[a] (N=44) - 85 days n (%)	Prof[a] (N=44) 86 - 169 days n (%)	Prof[a] (N=44) 170 - 253 days n (%)	Prof[a] (N=44) 254 - 337 days n (%)	Prof[a] (N=44) 338 - days n (%)	Prof[a] (N=44) FU n (%)	Self[b] (N=44) Any Period n (%)	Self[b] (N=44) - 85 days n (%)	Self[b] (N=44) 86 - 169 days n (%)	Self[b] (N=44) 170 - 253 days n (%)	Self[b] (N=44) 254 - 337 days n (%)	Self[b] (N=44) 338 - days n (%)	Self[b] (N=44) FU n (%)
感染症および寄生虫症																					
蜂巣炎	5 (5.7)	2 (2.3)	2 (2.3)	0	0	0	1 (1.2)	2 (4.5)	1 (2.3)	1 (2.3)	0	0	0	0	3 (6.8)	1 (2.3)	1 (2.3)	0	0	0	1 (2.3)
膿痂疹	4 (4.5)	0	2 (2.3)	1 (1.2)	0	0	1 (1.2)	2 (4.5)	0	1 (2.3)	0	0	0	1 (2.3)	2 (4.5)	0	1 (2.3)	1 (2.4)	0	0	0
カポジ水痘様発疹	3 (3.4)	3 (3.4)	0	0	0	0	0	1 (2.3)	1 (2.3)	0	0	0	0	0	2 (4.5)	2 (4.5)	0	0	0	0	0
神経系障害																					
頭痛	4 (4.5)	0	3 (3.4)	0	0	0	1 (1.2)	3 (6.8)	0	2 (4.5)	0	0	0	1 (2.3)	1 (2.3)	0	1 (2.3)	0	0	0	0
呼吸器、胸郭および縦隔障害																					
咳嗽	3 (3.4)	2 (2.3)	0	0	1 (1.2)	0	0	3 (6.8)	2 (4.5)	0	0	1 (2.4)	0	0	0	0	0	0	0	0	0

Percentages are based on number of subjects in each time period.
Multiple occurrences of an event for one subject are counted only once as earliest onset.
TEAE occurred in equal to or more than 3 subjects is presented.
MedDRA/J version 20.1 is used for coding.
[a] Medical professional administration group
[b] Self-injection group
5.3.5.2-1 Table 14.3.4.1.4から引用

System Organ Class / Preferred Term	Overall (N=88)							Prof[a] (N=44)							Self[b] (N=44)						
	Any Period	- 85 days	86 - 169 days	170 - 253 days	254 - 337 days	338 - days	FU	Any Period	- 85 days	86 - 169 days	170 - 253 days	254 - 337 days	338 - days	FU	Any Period	- 85 days	86 - 169 days	170 - 253 days	254 - 337 days	338 - days	FU
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
皮膚および皮下組織障害																					
アトピー性皮膚炎	21 (23.9)	12 (13.6)	6 (6.8)	2 (2.4)	0	1 (1.3)	0	9 (20.5)	7 (15.9)	1 (2.3)	1 (2.4)	0	0	0	12 (27.3)	5 (11.4)	5 (11.4)	1 (2.4)	0	1 (2.7)	0
中毒性皮疹	4 (4.5)	3 (3.4)	1 (1.1)	0	0	0	0	1 (2.3)	1 (2.3)	0	0	0	0	0	3 (6.8)	2 (4.5)	1 (2.3)	0	0	0	0

Percentages are based on number of subjects in each time period.
Multiple occurrences of an event for one subject are counted only once as earliest onset.
TEAE occurred in equal to or more than 3 subjects is presented.
MedDRA/J version 20.1 is used for coding.
[a] Medical professional administration group
[b] Self-injection group
5.3.5.2-1 Table 14.3.4.1.4から引用

表 2.7.4-72 Significant Treatment-Emergent Adverse Events by Serum Nemolizumab Concentration at Week 16
Safety Analysis Set（pool3）

	All TEAEs				TEAEs Related to Study Drug			
	Nemolizumab (N=231)				Nemolizumab (N=231)			
	- 2240 ng/mL n (%)	2240 <- 3440 ng/mL n (%)	3440 <- 4340 ng/mL n (%)	4340 < ng/mL n (%)	- 2240 ng/mL n (%)	2240 <- 3440 ng/mL n (%)	3440 <- 4340 ng/mL n (%)	4340 < ng/mL n (%)
Number of Subjects in Each Category	58	58	58	57	58	58	58	57
Significant TEAEs								
TEAEs Leading to Discontinuation (including Dose Interruption and Reduction) of Study Treatment	9 (15.5)	5 (8.6)	7 (12.1)	5 (8.8)	6 (10.3)	5 (8.6)	5 (8.6)	4 (7.0)
Discontinuation	5 (8.6)	2 (3.4)	1 (1.7)	3 (5.3)	5 (8.6)	2 (3.4)	0	3 (5.3)
Dose Interruption	4 (6.9)	3 (5.2)	6 (10.3)	2 (3.5)	1 (1.7)	3 (5.2)	5 (8.6)	1 (1.8)
Dose Reduction	0	0	0	0	0	0	0	0
TEAEs Special Interest								
Injection-Related Reaction	3 (5.2)	3 (5.2)	4 (6.9)	9 (15.8)	2 (3.4)	2 (3.4)	3 (5.2)	9 (15.8)
Asthma	1 (1.7)	1 (1.7)	3 (5.2)	1 (1.8)	0	0	1 (1.7)	0
Worsening of AD	20 (34.5)	14 (24.1)	13 (22.4)	17 (29.8)	13 (22.4)	13 (22.4)	10 (17.2)	13 (22.8)
Skin Infections	22 (37.9)	20 (34.5)	12 (20.7)	18 (31.6)	11 (19.0)	11 (19.0)	7 (12.1)	6 (10.5)
Non-skin Infections	35 (60.3)	25 (43.1)	34 (58.6)	32 (56.1)	6 (10.3)	6 (10.3)	7 (12.1)	5 (8.8)
Elevated CPK	5 (8.6)	6 (10.3)	7 (12.1)	2 (3.5)	1 (1.7)	0	0	0

5.3.5.3-1 Table 5.3.1から引用

表 2.7.4-73 Significant Treatment-Emergent Adverse Events by C_{max}
Safety Analysis Set（pool3）

	All TEAEs				TEAEs Related to Study Drug			
	Nemolizumab (N=231)				Nemolizumab (N=231)			
	- 4.3 ug/mL n (%)	4.3 <- 5.5 ug/mL n (%)	5.5 <- 6.6 ug/mL n (%)	6.6 < ug/mL n (%)	- 4.3 ug/mL n (%)	4.3 <- 5.5 ug/mL n (%)	5.5 <- 6.6 ug/mL n (%)	6.6 < ug/mL n (%)
Number of Subjects in Each Category	60	61	55	55	60	61	55	55
Significant TEAEs								
TEAEs Leading to Discontinuation (including Dose Interruption and Reduction) of Study Treatment	7 (11.7)	6 (9.8)	8 (14.5)	5 (9.1)	7 (11.7)	6 (9.8)	5 (9.1)	2 (3.6)
Discontinuation	3 (5.0)	5 (8.2)	1 (1.8)	2 (3.6)	3 (5.0)	5 (8.2)	1 (1.8)	1 (1.8)
Dose Interruption	4 (6.7)	1 (1.6)	7 (12.7)	3 (5.5)	4 (6.7)	1 (1.6)	4 (7.3)	1 (1.8)
Dose Reduction	0	0	0	0	0	0	0	0
TEAEs Special Interest								
Injection-Related Reaction	3 (5.0)	4 (6.6)	5 (9.1)	7 (12.7)	2 (3.3)	4 (6.6)	3 (5.5)	7 (12.7)
Asthma	1 (1.7)	1 (1.6)	1 (1.8)	3 (5.5)	0	0	1 (1.8)	0
Worsening of AD	12 (20.0)	14 (23.0)	24 (43.6)	14 (25.5)	10 (16.7)	11 (18.0)	18 (32.7)	10 (18.2)
Skin Infections	14 (23.3)	16 (26.2)	21 (38.2)	21 (38.2)	8 (13.3)	7 (11.5)	11 (20.0)	9 (16.4)
Non-skin Infections	28 (46.7)	40 (65.6)	25 (45.5)	33 (60.0)	4 (6.7)	9 (14.8)	5 (9.1)	6 (10.9)
Elevated CPK	5 (8.3)	7 (11.5)	4 (7.3)	4 (7.3)	1 (1.7)	0	0	0

5.3.5.3-1 Table 5.3.2から引用

表 2.7.4-74 Significant Treatment-Emergent Adverse Events byAUC_{last}
Safety Analysis Set（pool3）

	All TEAEs				TEAEs Related to Study Drug			
	Nemolizumab (N=231)				Nemolizumab (N=231)			
	- 73.9 day*ug/mL n (%)	73.9 <- 95.6 day*ug/mL n (%)	95.6 <- 119.9 day*ug/mL n (%)	119.9 < day*ug/mL n (%)	- 73.9 day*ug/mL n (%)	73.9 <- 95.6 day*ug/mL n (%)	95.6 <- 119.9 day*ug/mL n (%)	119.9 < day*ug/mL n (%)
Number of Subjects in Each Category	58	58	58	57	58	58	58	57
Significant TEAEs								
TEAEs Leading to Discontinuation (including Dose Interruption and Reduction) of Study Treatment	5 (8.6)	9 (15.5)	7 (12.1)	5 (8.8)	5 (8.6)	7 (12.1)	6 (10.3)	2 (3.5)
Discontinuation	1 (1.7)	6 (10.3)	3 (5.2)	1 (1.8)	1 (1.7)	6 (10.3)	3 (5.2)	0
Dose Interruption	4 (6.9)	3 (5.2)	4 (6.9)	4 (7.0)	4 (6.9)	1 (1.7)	3 (5.2)	2 (3.5)
Dose Reduction	0	0	0	0	0	0	0	0
TEAEs Special Interest								
Injection-Related Reaction	2 (3.4)	3 (5.2)	7 (12.1)	7 (12.3)	1 (1.7)	3 (5.2)	5 (8.6)	7 (12.3)
Asthma	1 (1.7)	1 (1.7)	2 (3.4)	2 (3.5)	0	0	1 (1.7)	0
Worsening of AD	10 (17.2)	17 (29.3)	18 (31.0)	19 (33.3)	8 (13.8)	13 (22.4)	13 (22.4)	15 (26.3)
Skin Infections	18 (31.0)	14 (24.1)	18 (31.0)	22 (38.6)	9 (15.5)	8 (13.8)	11 (19.0)	7 (12.3)
Non-skin Infections	27 (46.6)	34 (58.6)	34 (58.6)	31 (54.4)	5 (8.6)	6 (10.3)	8 (13.8)	5 (8.8)
Elevated CPK	5 (8.6)	6 (10.3)	6 (10.3)	3 (5.3)	1 (1.7)	0	0	0

5.3.5.3-1 Table 5.3.3から引用

2.7.4.7 参考文献

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