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略号一覧表

略号又は略称	名称及び内容
5-ASA	5-アミノサリチル酸（5-amino s salicylate）
AZA	アザチオプリン（azathioprine）
F_1	絶対的バイオアベイラビリティ（absolute bioavailability）
IgG1	免疫グロブリン G1（immunoglobulin G1）
LIV	バイアルに充填した液剤（liquid in vial）
6-MP	6-メルカプトプリン（6-mercaptopurine）
NONMEM	非線形混合効果モデル（non-linear mixed effect model）
PFS	プレフィルドシリンジ（prefilled syringe）
PPK	母集団薬物動態（population pharmacokinetics）
TNFα	腫瘍壊死因子 α（tumor necrosis factor α）

2.7.1　生物薬剤学試験及び関連する分析法

2.7.1.1　背景及び概観

ゴリムマブ（遺伝子組換え）は米国セントコア社（現 Janssen Biotech, Inc.）で開発されたヒト型抗ヒト腫瘍壊死因子 α（以下，TNFα）モノクローナル抗体である。ゴリムマブは，国内において「既存治療で効果不十分な関節リウマチ（関節の構造的損傷の防止を含む）」の適応症で 2011 年 7 月に承認されている。本承認申請は，「中等症から重症の潰瘍性大腸炎の寛解導入および維持（既存治療で効果不十分な場合に限る）」の効能・効果を追加するものである。

2.7.1.1.1　製剤開発過程

日本人及び外国人の健康成人及び潰瘍性大腸炎患者を対象とした国内，海外及び国際共同試験で用いた製剤一覧を表 2.7.1-1 に示す。国内，海外及び国際共同試験で用いられた製剤は，化学的に組成が明らかな培地（動物由来成分を含有しない化学的に合成された培地）を用いて培養した[redacted]細胞株から作成したゴリムマブの液剤（ゴリムマブ 100 mg/mL）であり，現在，国内で市販されているものと同一である。なお，皮下投与試験（CNTO148NAP1001 試験，C0524T17 試験，C0524T18 試験及び CNTO148UCO3001 試験）ではプレフィルドシリンジ（prefilled syringe，以下 PFS）に，静脈内投与試験（C0524T16 試験）ではバイアル（liquid in vial，以下 LIV）にゴリムマブを充填したものを用いた。LIV と PFS の組成は同一であり，容器のみが異なる製剤である。市販製剤の PFS 50 mg 製剤に加え，PFS 100 mg 製剤も市販予定である。なお，PFS 50 mg 製剤と PFS 100 mg 製剤の組成は同一である。

表 2.7.1-1 国内，海外及び国際共同試験で使用したゴリムマブ製剤

細胞株 （培地）	製剤剤型	治験実施 計画書番号 [資料番号]	開発 の相	国内/ 海外	投与方法	試験対象集団
[redacted] （化学的に組成が明らかな培地）	液剤 （PFS）	CNTO148NAP1001 【5.3.3.3.1】	I	海外	単回皮下投与	健康成人（日本人及び外国人）
		C0524T17 【 5.3.5.1.2 】	II/III	国際 共同	反復皮下投与	潰瘍性大腸炎患者（日本人及び外国人）
		C0524T18 【5.3.5.1.3-1】 【5.3.5.1.3-2】	III	国際 共同	反復皮下投与	潰瘍性大腸炎患者（日本人及び外国人）
		CNTO148UCO3001 【5.3.5.1.5】	III	国内	反復皮下投与	潰瘍性大腸炎患者（日本人）
	液剤 （LIV）	C0524T16 【5.3.5.1.1】	II/III	海外	単回静脈内投与	潰瘍性大腸炎患者（外国人）

2.7.1.1.2　生体試料分析法及び測定法バリデーションの概観

2.7.1.1.2.1　血清中ゴリムマブ濃度及び血清中抗ゴリムマブ抗体の測定方法

国内，海外及び国際共同試験で使用した血清中ゴリムマブ濃度及び抗ゴリムマブ中和抗体の測定には，それぞれ [redacted] 社製電気化学発光検出器を用いたサンドイッチ ECLIA 法【初回申請時 CTD 2.7.1.1.2.1 (4)】，及び WEHI 細胞を使用したバイオアッセイ法【初回申請時 CTD 2.7.1.1.2.3】を用いた。

C0524T16 試験，C0524T17 試験，C0524T18 試験及び CNTO148NAP1001 試験では血清中抗ゴリムマブ抗体の測定に酵素免疫測定法（以下，EIA）【初回申請 CTD 2.7.1.1.2.2】を用いたが，本測定法は血清検体中のゴリムマブの影響を受ける【初回申請時 CTD 2.7.1.1.2.2 (1)】。そこで，血清検体中のゴリムマブの影響を受けない新規の測定法（Drug-Tolerant EIA）を開発した。CNTO148UCO3001 試験では，開発した新規の測定法を用いて血清中抗ゴリムマブ抗体を測定した。また，C0524T16 試験，C0524T17 試験及び C0524T18 試験から得られた検体についても Drug-Tolerant EIA を使用して再測定し，両測定法間で結果を比較した【2.7.2.4.1.4】。

(1)　Drug-Tolerant EIA【評価資料 5.3.1.4.1】

血清中の抗ゴリムマブ抗体の検出には EIA を用いた。本測定法では，血清検体中のゴリムマブによる測定の妨害を防ぐため，検体を酸により前処理した。血清中の抗ゴリムマブ抗体の検出に用いた Drug-Tolerant EIA のバリデーション結果を表 2.7.1-2 に示す。

測定法のカットオフ値は，本剤の適応となりうる疾患患者由来の血清（潰瘍性大腸炎患者 25 例を含む）及び健康成人由来の血清を測定することにより 1.23 normalized value (NV)に確定した。本カットオフ値を用いた結果，測定感度は希釈していない検体における 2.5 ng/mL と設定された。

カニクイザルから単離したポリクローナル抗体をヒト血清に 10 ng/mL でプールした検体を低濃度の陽性対照とした。陽性対照を用いた測定内及び測定間精度の平均値はそれぞれ 6.2%および 23.1%であった。

250 ng/mL のカニクイザル陽性対照は 50,000 ng/mL までのゴリムマブ存在下でも検出され，1000 ng/mL のカニクイザル陽性対照は最大 100,000 ng/mL までのゴリムマブ存在下でも検出され

た。これらのゴリムマブ濃度は 0 週/2 週にゴリムマブ 200 mg/100 mg を皮下投与した後，ゴリムマブ 100 mg を 4 週間に 1 回皮下投与したときのトラフ濃度の中央値を上回っている。希釈可能性の検討の結果から，希釈系列のカットオフ値は 2.27 NV と設定した。

表 2.7.1-2 Drug-Tolerant EIA のバリデーション結果

報告書番号	CP[redacted]V-037, CP[redacted]V-037-A1, CP[redacted]V-037-A2, CP[redacted]V-037-A3 及び CP[redacted]V-037-A4
測定法の種類	EIA
測定結果の種類	Normalized OD 値
最小必要希釈度	6 倍希釈
感度	最大感度 2.5 ng/mL
精度	測定内精度：6.2%CV 測定間精度：23.1%CV
回収率	63.0～96.2%
安定性	凍結融解： 4℃での融解にて 5 サイクル，37℃での融解にて 1 サイクルまで安定 保存： -70℃，-20℃及び 4℃にて少なくとも 14 日間安定 25℃にて少なくとも 2 日間安定

(2) 従来の EIA 法と Drug-Tolerant EIA 法の比較【評価資料 5.3.1.4.2】

従来の EIA 法と Drug-Tolerant EIA 法を比較した。その結果，血清検体中抗ゴリムマブ抗体陽性／陰性の判定において，Drug-Tolerant EIA 法の方がより精度が高いことが示された。

2.7.1.2　個々の試験結果の要約

今回の承認申請にあたり，生物薬剤学に関する新たな試験は実施及び予定していない。

2.7.1.3　全試験を通しての結果の比較と解析

2.7.1.3.1　絶対的バイオアベイラビリティ

潰瘍性大腸炎患者にゴリムマブを単回静脈内（C0524T16 試験）又は反復皮下（C0524T17 試験及び C0524T18 試験）投与したときの血清中ゴリムマブ濃度データ（解析対象被験者数：1227 例，測定ポイント数：11280 ポイント）を用いて，非線形混合効果モデル（NONMEM）により，母集団薬物動態解析（PPK 解析）を実施した。その結果，ゴリムマブを潰瘍性大腸炎患者に皮下投与したときの絶対的バイオアベイラビリティ（F_1）は 52.2%であり【2.7.2.3.1.2】，外国人健康成人にゴリムマブを上腕部，腹部及び大腿部に単回皮下投与したときの絶対的バイオアベイラビリティ［49.71～54.79%（中央値）］【初回申請時 CTD 2.7.1.2.1】と同程度であった。

2.7.1.4　生物薬剤学試験の結論

潰瘍性大腸炎患者にゴリムマブを皮下投与したとき，PPK 解析で推定された絶対的バイオアベイラビリティ（F_1）は 52.2%であった。

参考文献

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略号一覧表

略号又は略称	名称及び内容
ALB	血清アルブミン（albumin）
ALK	アルカリホスファターゼ（alkaline phosphatase）
ALT	アラニン・アミノトランスフェラーゼ（alanine aminotransferase）
AST	アスパラギン酸アミノトランスフェラーゼ（aspartate aminotransferase）
$AUC_{0\text{-}49D}$	0時間から49日目までの血清中濃度－時間曲線下面積（area under the serum concentration – time curve from time 0 to Day 49）
AUC_{last}	0時間から最終定量可能時間までの血清中濃度－時間曲線下面積（area under the serum concentration – time curve from time 0 to the last quantifiable time）
AUC_{inf}	0時間から無限大時間までの血清中濃度－時間曲線下面積（area under the serum concentration – time curve from time 0 to infinity）
AZA	アザチオプリン（azathioprine）
BILI	総ビリルビン（total birilbin）
CI	信頼区間（confidence interval）
CL	全身クリアランス（total body clearance）
CL/F	血管外投与後のみかけの全身クリアランス（apparent total body clearance after extravascular administration）
C_{max}	最高血清中濃度（maximum serum concentration）
CrCL	クレアチニンクリアランス（creatinine clearance）
CRP	C-反応性たん白（C-reactive protein）
F_1	絶対的バイオアベイラビリティ（absolute bioavailability）
HGF	肝細胞増殖因子（hepatocyte growth factor）
IgG_1	免疫グロブリンG1（immunoglobulin G1）
K_a	吸収速度定数（absorption rate constant）
MMP-9	マトリックスメタロプロテアーゼ-9（matrix metalloproteinase-9）
6-MP	6-メルカプトプリン（6-mercaptopurine）
NONMEM	非線形混合効果モデル（non-linear mixed effect model）
PPK	母集団薬物動態（population pharmacokinetics）
Q	中枢コンパートメントと末梢コンパートメント間のクリアランス（clearance between central compartment and peripheral compartment）
SAA	血清アミロイドA（serum amylod A）
SD	標準偏差（standard deviation）
$T_{1/2}$	消失半減期（elimination half-life）
T_{max}	最高血清中濃度到達時間（time to reach the maximum serum concentration）
TNFα	腫瘍壊死因子α（tumor necrosis factor α）
TNFR1	腫瘍壊死因子レセプター1（tumor necrosis factor receptor 1）
V_2	中枢コンパートメントの分布容積（volume of distribution of the central compartment）
V_3	末梢コンパートメントの分布容積（volume of distribution of the peripheral compartment）
V_z/F	血管外投与後の最終相におけるみかけの分布容積（apparent volume of distribution at the terminal phase after extravascular administration）
WGT	体重（body weight）

2.7.2 臨床薬理試験

2.7.2.1 背景及び概観

ゴリムマブ（遺伝子組換え）は米国セントコア社（現 Janssen Biotech, Inc.）で開発されたヒト型抗ヒト腫瘍壊死因子α（TNFα）モノクローナル抗体である。ゴリムマブは，国内において「既存治療で効果不十分な関節リウマチ（関節の構造的損傷の防止を含む）」の適応症で 2011 年 7 月に承認されている。本承認申請は，「中等症から重症の潰瘍性大腸炎の寛解導入および維持（既存治療で効果不十分な場合に限る）」の効能・効果を追加するものである。

本項では，血清中ゴリムマブ濃度と有効性の相関及び有効性に対する抗ゴリムマブ抗体の影響の検討については，重大な逸脱が認められた施設（施設番号 6706，7257 及び 7407）を除いたデータを用いた。血清中ゴリムマブ濃度，免疫原性及び薬力学については上述の施設を含むすべてのデータを記載した。血清中ゴリムマブ濃度及び免疫原性について，当該施設を除外した解析結果については【5.3.5.1.4】に記載した。なお，施設番号 6706，7257 及び 7407 の被験者数は，C0524T17 試験で 25 例／1065 例及び C0524T18 試験で 29 例／1228 例と全体集団と比較して少数であるため，当該施設を除いた場合においても薬物動態成績及び免疫原性の結果への影響は限定的であり，臨床薬理に関する結論に違いはなかった。

2.7.2.1.1 臨床試験

ゴリムマブの薬物動態，薬力学及び免疫原性を検討した試験一覧を表 2.7.2-1 に示す。また，各臨床試験の要約を表 2.7.2-付録-1～表 2.7.2-付録-5 に示す。

ゴリムマブの薬物動態及び免疫原性について，中等症から重症の潰瘍性大腸炎患者を対象とした海外第 II/III 相試験 1 試験（C0524T16 試験，静脈内投与による寛解導入療法試験），国際共同第 II/III 相試験 1 試験（C0524T17 試験，皮下投与による寛解導入療法試験），国際共同第 III 相試験 1 試験（C0524T18 試験，寛解維持療法試験），及び国内第 III 相試験 1 試験（CNTO148UCO3001 試験），並びに日本人及び外国人（白人）健康成人を対象とした海外第 I 相試験 1 試験（CNTO148NAP1001 試験）で検討した。また，C0524T16 試験，C0524T17 試験及び C0524T18 試験で得られた血清中ゴリムマブ濃度データを用いて母集団薬物動態解析（PPK）を実施した。なお，C0524T16 試験及び C0524T17 試験に組み入れられた被験者が引き続き，C0524T18 試験に組み入れられた。

C0524T16 試験及び C0524T17 試験では，潰瘍性大腸炎患者におけるゴリムマブの薬力学についても検討した。

なお，関節リウマチの適応症による申請時に，ゴリムマブ 50 mg 又は 100 mg を日本人及び外国人健康成人に単回皮下投与したときのゴリムマブの薬物動態及び免疫原性を検討した（C0524T23 試験）【初回申請時 CTD 2.7.2.2.2 (1)】。

表 2.7.2-1 ゴリムマブの臨床薬理評価に用いた臨床試験一覧

実施地域	開発の相 (評価/参考)	治験実施計画書番号 [資料番号]	対象	試験目的（薬物動態，薬力学，免疫原性）
国際共同	第 II/III 相（評価）	C0524T17【5.3.5.1.2】	潰瘍性大腸炎患者（日本人及び外国人）	0 週/2 週にゴリムマブ 100 mg/50 mg，200 mg/100 mg 又は 400 mg/200 mg を皮下投与したときの薬物動態，薬力学及び免疫原性の検討
	第 III 相（評価）	C0524T18【5.3.5.1.3】	潰瘍性大腸炎患者（日本人及び外国人）	C0524T16 試験又は C0524T17 試験終了後（初回投与から 6 週後），ゴリムマブ 50 mg 又は 100 mg を 4 週ごとに皮下投与したときの薬物動態及び免疫原性の検討
海外	第 II/III 相（参考）	C0524T16【5.3.5.1.1】	潰瘍性大腸炎患者（外国人）	ゴリムマブ 1 mg/kg，2 mg/kg 又は 4 mg/kg を単回静脈内投与したときの薬物動態，薬力学及び免疫原性の検討
	第 I 相（評価）	CNTO148NAP1001【5.3.3.3.1】	健康成人（日本人及び外国人）	ゴリムマブ 200 mg 又は 400 mg を単回皮下投与したときの薬物動態及び免疫原性の検討
国内	第 III 相（評価）	CNTO148UCO3001【5.3.5.1.5】	潰瘍性大腸炎患者（日本人）	寛解導入療法として，0 週/2 週にゴリムマブ 200 mg/100 mg を皮下投与した後，寛解維持療法としてゴリムマブ 100 mg を 4 週ごとに皮下投与したときの薬物動態及び免疫原性の検討

2.7.2.2　個々の試験結果の要約

日本人及び外国人潰瘍性大腸炎患者（C0524T17 試験及び C0524T18 試験，反復皮下投与），外国人潰瘍性大腸炎患者（C0524T16 試験，単回静脈内投与），日本人潰瘍性大腸炎患者（CNTO148UCO3001 試験，反復皮下投与）並びに，日本人及び外国人健康成人（CNTO148NAP1001 試験，単回皮下投与）を対象とした臨床試験の要約を以下に示す。

2.7.2.2.1　日本人及び外国人潰瘍性大腸炎患者を対象とした臨床試験

2.7.2.2.1.1　寛解導入療法（C0524T17 試験）　【評価資料 5.3.5.1.2】

中等症から重症の活動期潰瘍性大腸炎患者を対象に，寛解導入療法として，ゴリムマブを反復皮下投与したときの血清中ゴリムマブの薬物動態，薬力学及び免疫原性を検討した。

本臨床試験はパート 1 及びパート 2 から構成され，パート 1 では潰瘍性大腸炎患者 169 例，パート 2 では潰瘍性大腸炎患者 896 例（うち日本人 72 例）の計 1065 例［年齢中央値 38.0 歳，体重中央値 72.00 kg（日本人被験者：年齢中央値 37.0 歳，体重中央値 58.00 kg）］が，以下の用法・用量群に割り付けられた。

- 0 週及び 2 週にプラセボ（プラセボ群）
- 0 週にゴリムマブ 100 mg 及び 2 週にゴリムマブ 50 mg（100 mg→50 mg 群）
- 0 週にゴリムマブ 200 mg 及び 2 週にゴリムマブ 100 mg（200 mg→100 mg 群）
- 0 週にゴリムマブ 400 mg 及び 2 週にゴリムマブ 200 mg（400 mg→200 mg 群）

(1) 薬物動態（血清中ゴリムマブ濃度）

1) 試験全体

潰瘍性大腸炎患者にゴリムマブを 0 週及び 2 週に 100 mg→50 mg，200 mg→100 mg 及び 400 mg→200 mg の用量で反復皮下投与したとき，投与 6 週までの血清中ゴリムマブ濃度の中央値は，用量におおむね比例して増加した【2.7.6.3 図 2.7.6.3-1】。投与 2 週の投与前の血清中ゴリムマブ濃度の中央値は，100 mg→50 mg 群，200 mg→100 mg 群及び 400 mg→200 mg 群でそれぞれ 2.34 μg/mL，6.27 μg/mL 及び 11.95 μg/mL，投与 6 週の血清中ゴリムマブ濃度の中央値はそれぞれ 0.78 μg/mL，1.78 μg/mL 及び 4.01 μg/mL であった（表 2.7.2-付録-1）。

2) 日本人

日本人潰瘍性大腸炎患者にゴリムマブを反復皮下投与したときの血清中ゴリムマブ濃度を表 2.7.2-付録-6 に示す。日本人潰瘍性大腸炎患者においても，投与 6 週までの血清中ゴリムマブ濃度の中央値は用量におおむね比例して増加した。投与 2 週の血清中ゴリムマブ濃度の中央値は，200 mg→100 mg 群及び 400 mg→200 mg 群でそれぞれ 6.68 μg/mL 及び 16.36 μg/mL，6 週の血清中ゴリムマブ濃度の中央値はそれぞれ 1.60 μg/mL 及び 3.63 μg/mL であった。

(2) 免疫原性

ゴリムマブを投与した 721 例中 3 例（0.4%，200 mg→100 mg 群及び 400 mg→200 mg 群でそれぞれ 1 例及び 2 例）で抗ゴリムマブ抗体陽性が認められたが，いずれの被験者も抗体価は 1:20 以下であった。抗ゴリムマブ抗体陽性であった 3 例中 2 例で抗ゴリムマブ抗体の中和能が認められなかった。残りの 1 例は評価できなかった。なお，日本人被験者（42 例）には，抗ゴリムマブ抗体陽性は認められなかった。

(3) 薬力学

薬力学の結果は 2.7.2.3.2.2 に記載した。

2.7.2.2.1.2 C0524T18 試験 評価資料【5.3.5.1.3-1】,【5.3.5.1.3-2】

C0524T16 試験及び C0524T17 試験を完了した中等症から重症の活動期潰瘍性大腸炎患者 1228 例（うち日本人 62 例）［年齢中央値 39.0 歳，体重中央値 72.00 kg］を対象に，寛解維持療法として，プラセボ又はゴリムマブを反復皮下投与したときの血清中ゴリムマブの薬物動態及び免疫原性を検討した。

本臨床試験では，静脈内投与による寛解導入試験（C0524T16 試験）及び皮下投与による寛解導入試験（C0524T17 試験）における投与 6 週の clinical response【2.7.3.1.3.2】の有無に基づき，以下の用法・用量群に割り付けられた。

【ゴリムマブによる寛解導入療法により clinical response が認められた被験者（以下，ランダム化された被験者）】

・ 4 週ごとにプラセボ（プラセボ群）

・ 4 週ごとにゴリムマブ 50 mg（ゴリムマブ 50 mg 群）

・ 4 週ごとにゴリムマブ 100 mg（ゴリムマブ 100 mg 群）

なお，52 週までに clinical response が消失した場合は，以下の用量に変更した。

・ プラセボ群：4 週ごとにゴリムマブ 100 mg

・ ゴリムマブ 50 mg 群：4 週ごとにゴリムマブ 50 mg 又は 100 mg（再度ランダムに割付け）

・ ゴリムマブ 100 mg 群：4 週ごとにゴリムマブ 100 mg 又は 200 mg（再度ランダムに割付け）
（ただし，治験実施計画書の変更により試験途中からは 100 mg のみ）

【プラセボによる寛解導入療法により clinical response が認められた被験者】

・ 4 週ごとにプラセボ

なお，52 週までに clinical response が消失した場合は，用量をゴリムマブ 100 mg に変更した。

【寛解導入療法により clinical response が認められなかった被験者】

・ 4 週ごとにゴリムマブ 100 mg

(1) 薬物動態（血清中ゴリムマブ濃度）

1) 試験全体

a) ランダム化された被験者

① ランダム化された被験者全体

ランダム化された被験者にプラセボ，ゴリムマブ 50 mg 及び 100 mg を反復皮下投与したときの血清中ゴリムマブ濃度を表 2.7.2-付録-2 に示す。

ランダム化された被験者にプラセボを 4 週ごとに反復皮下投与したとき，寛解維持 12 週の血清中ゴリムマブ濃度の中央値は定量下限未満（<0.039 μg/mL）であった。一方，50 mg 及び 100 mg を 4 週ごとに反復皮下投与したときの投与 12 週の血清中ゴリムマブのトラフ濃度の中央値はそれぞれ 0.71 μg/mL 及び 1.43 μg/mL であり，用量におおむね比例していた。同様に，寛解維持 8 週から 54 週までのゴリムマブ 100 mg 群の血清中ゴリムマブ濃度の中央値は，50 mg 群のおよそ 2 倍であり，寛解維持療法の期間を通して，血清中ゴリムマブ濃度は用量におおむね比例して増加することが示唆された。また，寛解維持 8 週から 52 週までの血清中ゴリムマブのトラフ濃度の中央値は，50 mg 群及び 100 mg 群でそれぞれ 0.69 μg/mL～0.83 μg/mL 及び 1.33 μg/mL～1.58 μg/mL であり，いずれの投与群もおおむね一定の濃度で推移していたことから，血清中ゴリムマブ濃度は，寛解維持 8 週（寛解導入開始から 14 週）までには定常状態に達していると考えられた。

なお，ランダム化された被験者の寛解維持開始時（寛解維持 0 週，寛解導入開始から 6 週）の血清中ゴリムマブ濃度の中央値は，プラセボ群， 50 mg 群及び 100 mg 群でそれぞれ 2.46 μg/mL，2.28 μg/mL 及び 2.50 μg/mL であり，投与群間で差は認められなかった。

寛解維持 52 週までに clinical response が消失し，用量を調節したときの血清中ゴリムマブ濃度は，用量の増加に伴い増加した。また，100 mg に用量調節後の血清中ゴリムマブ濃度の中央値は，プラセボ群及び 50 mg 群で同程度であった。血清中ゴリムマブ濃度は用量調節 8 週後には，定常状態に達した。

本臨床試験継続投与にてゴリムマブ 50 mg 及び 100 mg を 212 週まで反復皮下投与したときの血清中ゴリムマブ濃度を表 2.7.2-付録-8 に示す。

50 mg 及び 100 mg を 212 週まで反復皮下投与したときの血清中ゴリムマブのトラフ濃度の中央値も 54 週までに認められた血清中ゴリムマブのトラフ濃度の中央値と同程度の値で推移していた。また，最終投与 16 週後（228 週）の血清中ゴリムマブ濃度の中央値は，いずれの投与群でも定量下限未満であった。

② 皮下投与による寛解導入療法を受けた被験者

ランダム化された被験者に，寛解維持療法（C0524T18 試験）においてプラセボ，ゴリムマブ 50 mg 又は 100 mg を反復皮下投与したときの血清中ゴリムマブ濃度－時間推移を図 2.7.2-1 に示す。

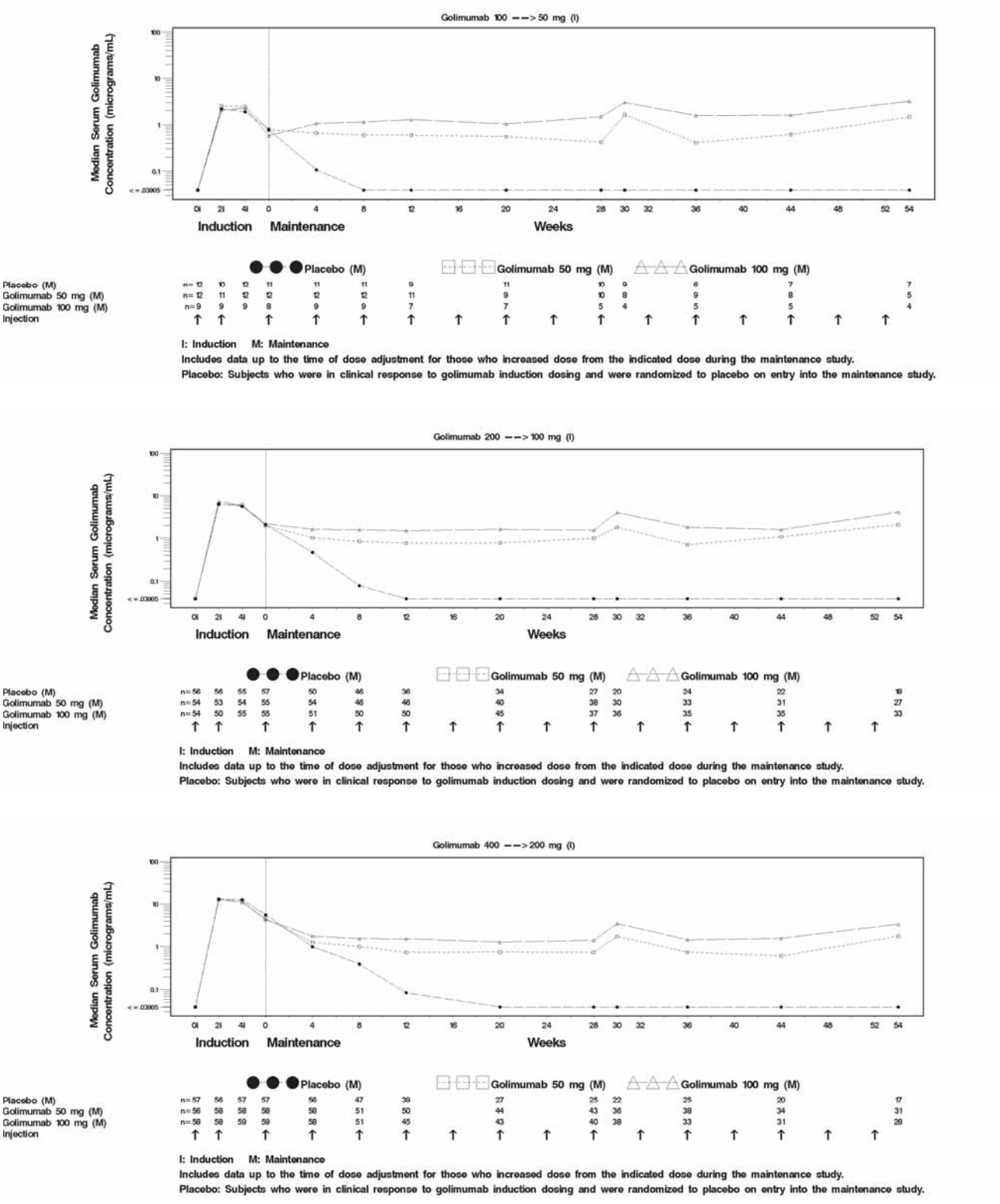


図 2.7.2-1 ゴリムマブの反復皮下投与による寛解導入療法後に寛解維持療法において
プラセボ又はゴリムマブを反復皮下投与したときの
寛解導入療法時の用量別の血清中ゴリムマブ濃度－時間推移
（ランダム化された被験者，中央値）

上段：100 mg → 50 mg 群，中段：200 mg → 100 mg 群，下段：400 mg → 200 mg 群

寛解維持開始時の血清中ゴリムマブ濃度は，寛解導入時の用量におおむね比例した（100 mg→50 mg，200 mg→100 mg 及び 400 mg→200 mg を投与した被験者でそれぞれ 0.58 μg/mL～0.79 μg/mL，2.00 μg/mL～2.20 μg/mL 及び 4.31 μg/mL～4.48 μg/mL）。プラセボを 4 週ごとに反復皮下投与したとき，寛解維持 8 週の血清中ゴリムマブのトラフ濃度の中央値は，寛解導入療法において 100 mg→50 mg を投与した被験者では定量下限未満， 200 mg→100 mg 及び 400 mg→200 mg を投与した被験者ではそれぞれ 0.08 μg/mL 及び 0.39 μg/mL であった。50 mg を 4 週ごとに反復皮下投与したとき，寛解維持 8 週の血清中ゴリムマブのトラフ濃度の中央値はそれぞれ，0.60 μg/mL，0.85 μg/mL 及び 1.01 μg/mL であった。100 mg を 4 週ごとに反復皮下投与したとき，寛解維持 8 週の血清中ゴリムマブのトラフ濃度の中央値はそれぞれ，1.14 μg/mL，1.60 μg/mL 及び 1.54 μg/mL であった。8 週以降の血清中ゴリムマブのトラフ濃度はおおむね一定の濃度で推移したことから（図 2.7.2-1），遅くとも寛解維持 8 週には定常状態に達していると考えられた。

③ 静脈内投与による寛解導入療法を受けた被験者

ゴリムマブの単回静脈内投与による寛解導入療法（C0524T16 試験）において clinical response が認められた被験者に，寛解維持療法（C0524T18 試験）にてプラセボ，ゴリムマブ 50 mg 又は 100 mg を反復皮下投与したときの血清中ゴリムマブ濃度を図 2.7.2-2 に示す。

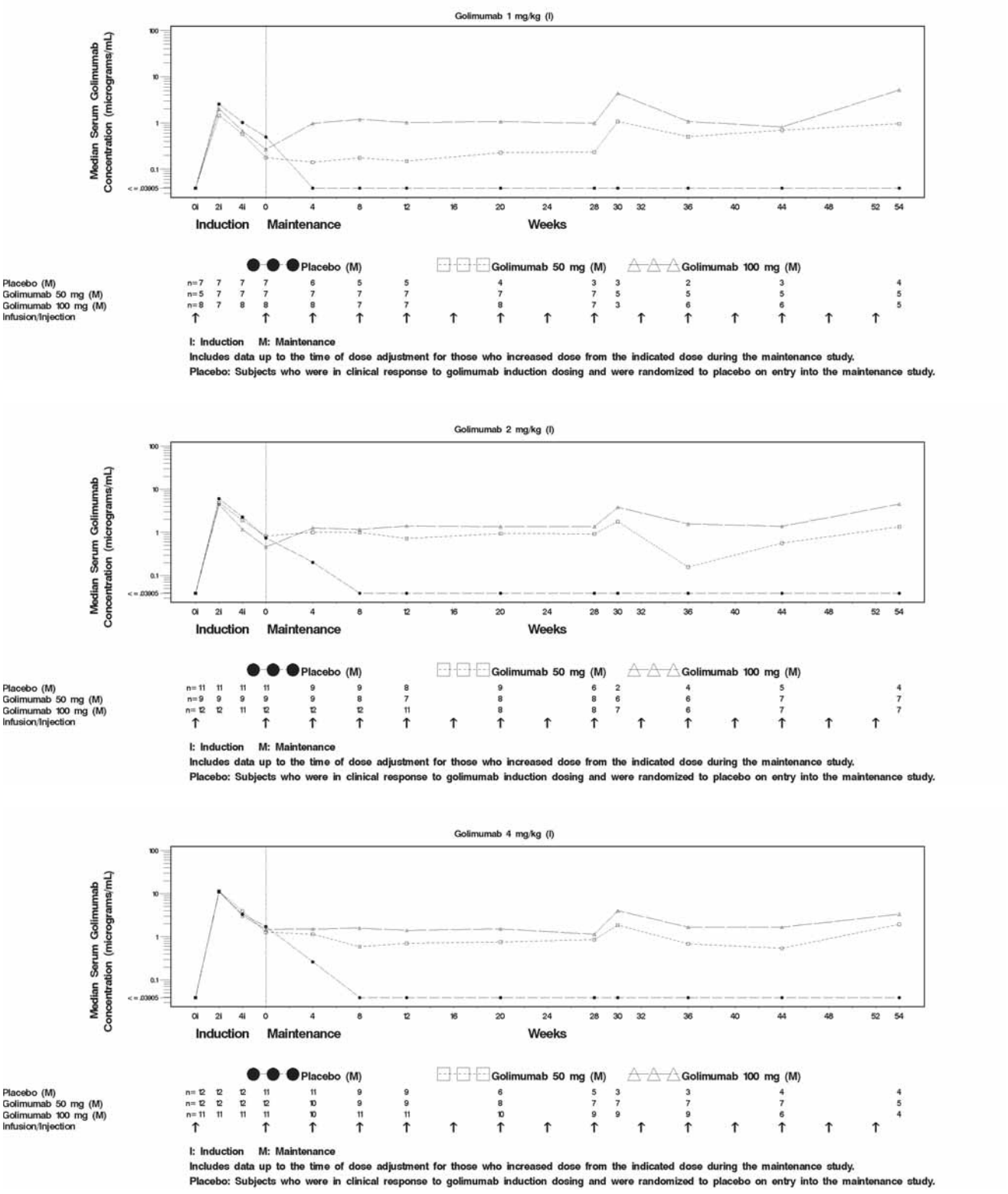


図 2.7.2-2 ゴリムマブの単回静脈内投与による寛解導入療法後に寛解維持療法において
プラセボ又はゴリムマブを反復皮下投与したときの寛解導入療法時の
用量別の血清中ゴリムマブ濃度－時間推移
（ランダム化された被験者，中央値）

上段：1 mg/kg 群，中段：2 mg/kg 群，下段：4 mg/kg 群

ゴリムマブの単回静脈内投与により寛解導入療法を実施した場合においても，寛解維持療法開始時の血清中ゴリムマブ濃度は，寛解導入の用量におおむね比例した（1 mg/kg，2 mg/kg 及び 4 mg/kg を投与した被験者でそれぞれ 0.18 μg/mL～0.50 μg/mL，0.46 μg/mL～0.82 μg/mL 及び 1.28 μg/mL～1.73 μg/mL）。プラセボを 4 週ごとに反復皮下投与したときの寛解維持 8 週の血清中ゴリムマブ濃度の中央値は，寛解導入療法において 1 mg/kg，2 mg/kg 及び 4 mg/kg のいずれの群においても定量下限未満であり，100 mg を 4 週ごとに反復皮下投与したときの寛解維持 8 週の血清中ゴリムマブのトラフ濃度の中央値は，それぞれ 1.20 μg/mL，1.17 μg/mL 及び 1.59 μg/mL であった。50 mg を 4 週ごとに反復皮下投与したときの寛解維持 8 週の血清中ゴリムマブのトラフ濃度の中央値は，それぞれ 0.18 μg/mL，1.00 μg/mL 及び 0.59 μg/mL であった。8 週以降の血清中ゴリムマブのトラフ濃度がおおむね一定の濃度で推移を示したことから（図 2.7.2-2），遅くとも寛解維持 8 週（寛解導入開始から 14 週）には定常状態に達していると考えられた。

b) 寛解導入療法により clinical response が認められなかった被験者

ゴリムマブによる寛解導入療法により clinical response が認められなかった被験者の寛解維持療法開始時の血清中ゴリムマブ濃度の中央値は，ランダム化された被験者と比較して低値であった。当該被験者に 100 mg を 4 週ごとに反復皮下投与したときの血清中ゴリムマブのトラフ濃度の中央値は，ランダム化された被験者に 100 mg を 4 週ごとに反復皮下投与したときと比較してやや低値を示した（表 2.7.2-付録-2）。

プラセボによる寛解導入療法により clinical response が認められなかった被験者に 100 mg を 4 週ごとに反復皮下投与したときの 8 週から 44 週の血清中ゴリムマブのトラフ濃度の中央値は，ランダム化された被験者に 100 mg を 4 週ごとに反復皮下投与したときの定常状態における血清中ゴリムマブのトラフ濃度の中央値と同程度であった（表 2.7.2-付録-2）。

2) 日本人

ランダム化された日本人被験者にプラセボ，ゴリムマブ 50 mg 又は 100 mg，あるいはランダム化された被験者を含む本臨床試験に登録された日本人被験者（以下，日本人全被験者）に 100 mg を 4 週ごとに反復皮下投与したときの血清中ゴリムマブ濃度を表 2.7.2-付録-7 に示す。

ランダム化された日本人被験者数は 12 例（プラセボ群 4 例，50 mg 群 3 例，100 mg 群 5 例）と少なかった。50 mg 又は 100 mg を 4 週ごとに反復皮下投与したときの血清中ゴリムマブのトラフ濃度の中央値は，8 週以降，用量の増加に伴い増加し，おおむね一定の濃度で推移した。また，ランダム化された日本人被験者にプラセボを 4 週ごとに反復皮下投与したときの 8 週の血清中ゴリムマブ濃度の中央値は 0.05 μg/mL と低値であり，12 週以降は，いずれの被験者も定量下限未満であった。

日本人全被験者に 100 mg を 4 週ごとに反復皮下投与したときの血清中ゴリムマブのトラフ濃度の中央値も同様に寛解維持 8 週以降，寛解維持 44 週までおおむね一定の濃度で推移したが，ランダム化された日本人被験者に 100 mg を 4 週ごとに反復皮下投与したときと比較して低値を示した。

(2) 免疫原性

寛解導入又は寛解維持療法でゴリムマブを投与した 1103 例の被験者において，抗ゴリムマブ抗体の評価が可能であった。寛解維持 54 週までに 1103 例中 32 例（2.9%）で抗ゴリムマブ抗体陽性が認められたが，大部分の被験者で抗体価は 1:640 未満であった。抗ゴリムマブ抗体陽性であった 32 例のうち中和能が評価可能であった 31 例中 21 例（67.7%）で中和能が認められた。

日本人被験者では，62 例中 2 例（3.2%）で抗ゴリムマブ抗体陽性が認められた。

本臨床試験の継続投与でゴリムマブを投与した 618 例（50 mg：94 例，100 mg：524 例）の被験者のうち，604 例（50 mg：90 例，100 mg：514 例）で抗ゴリムマブ抗体の評価が可能であった。50 mg 群では 90 例中 4 例（4.4%），100 mg 群では 514 例中 19 例（3.7%）で抗ゴリムマブ抗体陽性が認められた。抗ゴリムマブ抗体陽性であった 23 例のうち 22 例（50 mg：4 例，100 mg：18 例）で中和能が評価可能であった。50 mg 群及び 100 mg 群で中和能が認められたのは，それぞれ 3 例（75%）及び 15 例（83.3%）であった。

2.7.2.2.2 日本人潰瘍性大腸炎患者を対象とした臨床試験

2.7.2.2.2.1 CNTO148UCO3001 試験 【評価資料 5.3.5.1.5】

日本人の中等症から重症の活動期潰瘍性大腸炎患者 144 例を対象に，寛解導入療法としてゴリムマブを反復皮下投与した後寛解維持療法として，プラセボ又はゴリムマブを反復皮下投与したときの血清中ゴリムマブの薬物動態，薬力学及び免疫原性を検討した。

本試験の寛解導入期では，すべての被験者に，ゴリムマブを 0 週に 200 mg，2 週に 100 mg 皮下投与した。寛解維持期では，寛解導入療法により clinical response が認められた被験者（以下，ランダム化された被験者）を，100 mg 群又はプラセボ群に 1:1 の比でランダムに割り付け，治験薬を寛解維持 52 週まで 4 週ごとに皮下投与した。プラセボ群の被験者について，寛解維持 52 週までに clinical response が消失した場合，用量を変更し，100 mg を 4 週ごとに投与した。また，寛解導入療法により clinical response が認められなかった被験者には，100 mg を寛解維持 4 週まで 4 週ごとに皮下投与し，寛解維持 8 週までに疾患活動性の改善が認められた被験者には，引き続き，100 mg を寛解維持 52 週まで 4 週ごとに皮下投与した。

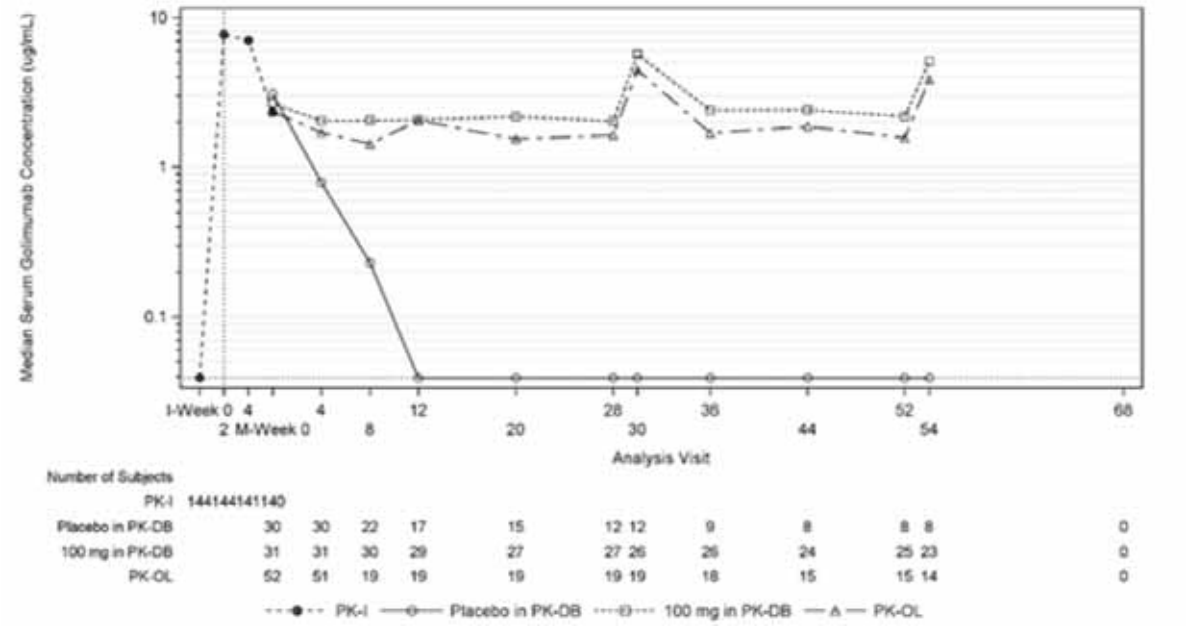
(1) 薬物動態（血清中ゴリムマブ濃度）

日本人潰瘍性大腸炎患者にゴリムマブを初回に 200 mg，2 週目に 100 mg を反復皮下投与した後，ランダム化された被験者を対象に 4 週ごとにプラセボ又は 100 mg を反復皮下投与したときの血清中ゴリムマブ濃度－時間推移を図 2.7.2-3 に示す。

寛解導入期に 0 週及び 2 週に 200 mg→100 mg の用量で反復皮下投与したとき，2 週，4 週及び 6 週の血清中ゴリムマブ濃度の中央値は，それぞれ 7.72 μg/mL，7.06 μg/mL 及び 2.33 μg/mL であった。ランダム化された被験者にプラセボを 4 週ごとに反復皮下投与したとき，12 週の血清中ゴリムマブ濃度の中央値は定量下限未満（＜0.039 μg/mL）であった。一方，ランダム化された被験者に 100 mg を 4 週ごとに反復皮下投与したとき，8 週から 54 週までの血清中ゴリムマブのトラフ濃度の中央値は 2.02 μg/mL～2.41 μg/mL であり，おおむね一定の濃度で推移していたことから，

血清中ゴリムマブ濃度は，寛解維持 8 週（寛解導入開始から 14 週）までには定常状態に達していると考えられた（表 2.7.2-付録-4）。

なお，ランダム化された被験者の寛解維持 0 週（寛解導入開始から 6 週）の血清中ゴリムマブ濃度の中央値は，プラセボ及びゴリムマブ群でそれぞれ 3.09 μg/mL 及び 2.67 μg/mL であり，投与群間で差は認められなかった。



PK-I: 寛解導入，PK-DB: ランダム化された被験者，PK-OL: 寛解導入で clinical response が認められなかった被験者

図 2.7.2-3 日本人潰瘍性大腸炎患者を対象にゴリムマブを反復皮下投与したときの血清中ゴリムマブ－時間推移（中央値）

参照元：CNTO148UCO3001 試験 54 週治験総括報告書 Figure 4

(2) 免疫原性

本臨床試験の寛解導入開始から寛解維持 68 週（寛解導入開始から 74 週）までの間での抗体陽性であった被験者の割合（抗ゴリムマブ抗体陽性率）を表 2.7.2-2 に示す。ゴリムマブを投与した 144 例の被験者において，抗ゴリムマブ抗体の評価が可能であった。寛解維持 52 週までにゴリムマブの投与を受けた 144 例中 13 例（9.0%）の被験者で抗ゴリムマブ抗体陽性が認められた。抗抗体陽性であった 13 例中 13 例で中和能が認められた。

表 2.7.2-2 寛解導入及び寛解維持療法（68 週まで）の抗ゴリムマブ抗体陽性率（CNTO148UCO3001 試験）

		寛解導入奏効例		寛解導入無効例	全体
		プラセボ群	100 mg 群		
評価可能被験者数		31	32	60	144
抗体陽性被験者数	寛解維持 54 週まで	4 (12.9%)	0 (0%)	1 (1.7%)	5 (3.5%)
	寛解維持 68 週まで	6 (19.4%)	3 (9.4%)	4 (6.7%)	13 (9.0%)

2.7.2.2.3 外国人潰瘍性大腸炎患者を対象とした臨床試験

2.7.2.2.3.1 C0524T16 試験 【参考資料 5.3.5.1.1】

外国人の中等症から重症の活動期潰瘍性大腸炎患者を対象に，寛解導入療法として，ゴリムマブを単回静脈内投与したときの血清中ゴリムマブの薬物動態，薬力学及び免疫原性を検討した。

本臨床試験はパート 1 及びパート 2 から構成され，パート 1 では 176 例，パート 2 では 115 例の計 291 例（年齢中央値 40.0 歳，体重中央値 70.0 kg）が，プラセボ群，1 mg/kg 群，2 mg/kg 群及び 4 mg/kg 群に割り付けられた。

(1) 薬物動態（血清中ゴリムマブ濃度）

潰瘍性大腸炎患者にゴリムマブを単回静脈内投与したとき，血清中ゴリムマブ濃度の中央値は用量におおむね比例して増加した【2.7.6.2 図 2.7.6.2-1】。6 週の血清中ゴリムマブ濃度の中央値は，1 mg/kg 群，2 mg/kg 群及び 4 mg/kg 群でそれぞれ 0.16 μg/mL，0.56 μg/mL 及び 1.40 μg/mL であった（表 2.7.2-付録-3）。

(2) 免疫原性

潰瘍性大腸炎患者にゴリムマブを単回静脈内投与したとき，最終安全性評価時点である 16 週までに，抗ゴリムマブ抗体陽性の被験者は認められなかった。

(3) 薬力学

薬力学の結果は 2.7.2.3.2.2 に記載した。

2.7.2.2.4 日本人及び外国人健康成人を対象とした臨床試験

2.7.2.2.4.1 CNTO148NAP1001 試験 【評価資料 5.3.3.3.1】

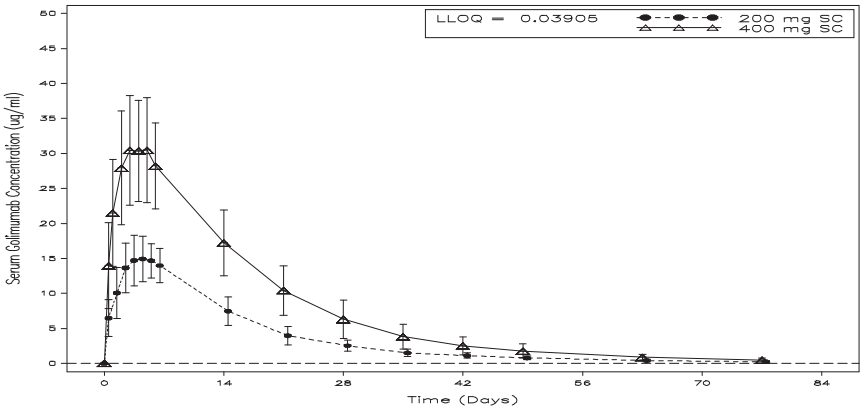
日本人及び外国人（白人）健康成人男性 49 例［日本人：25 例（年齢中央値 28 歳，体重中央値 65.30 kg），外国人 24 例（年齢中央値 30 歳，体重中央値 75.85 kg）］を対象に，ゴリムマブ 200 mg 又は 400 mg を単回皮下投与したときの血清中ゴリムマブの薬物動態及び免疫原性を検討した。

(1) 薬物動態

日本人及び外国人（白人）健康成人にゴリムマブ 200 mg 又は 400 mg を単回皮下投与したときの血清中ゴリムマブ濃度－時間推移を図 2.7.2-4 及び図 2.7.2-5 に，薬物動態パラメータを表 2.7.2-3 に示す。200 mg 又は 400 mg を単回皮下投与したとき，ゴリムマブは全身循環に緩やかに移行し，T_{max}（中央値）は日本人及び外国人ともに 3.5～5.0 日であった。C_{max} 及び AUC_{inf} の平均値は，日本人及び外国人ともに用量におおむね比例して増加した。

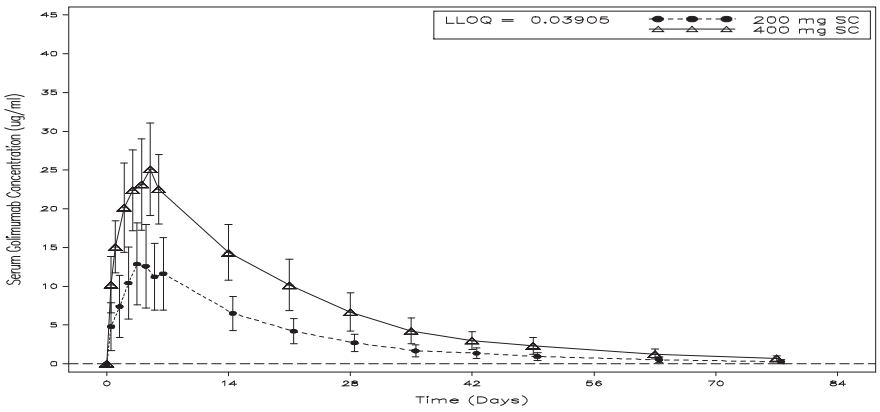
日本人での C_{max} 及び AUC_{inf} の平均値は白人と比較してやや高かったものの，分布範囲はおおむね外国人の分布範囲と重なっていた（図 2.7.2-7）。また，体重あたりのみかけのクリアランス

（CL/F）及び体重あたりのみかけの分布容積（V_z/F）の平均値は日本人及び外国人ともに，用量によらず一定であり，日本人と外国人はおおむね一致していた。$T_{1/2}$の平均値も日本人と外国人でおおむね同程度であった。



参照元：CNTO148NAP1001 総括報告書 Figure 3

図 2.7.2-4 日本人健康成人にゴリムマブを単回皮下投与したときの血清中ゴリムマブ濃度－時間推移（平均値±SD，200 mg：11 例，400 mg：10 例）



参照元：CNTO148NAP1001 総括報告書 Figure 4

図 2.7.2-5 外国人健康成人にゴリムマブを単回皮下投与したときの血清中ゴリムマブ濃度－時間推移（平均値±SD，各群 10 例）

表 2.7.2-3 日本人及び外国人健康成人にゴリムマブを単回皮下投与したときの血清中ゴリムマブの薬物動態パラメータ［平均値 (SD)］

	200 mg		400 mg	
	外国人	日本人	外国人	日本人
被験者数	10	11	10	10
C_{max} (μg/mL)	13.20 (5.42)	15.85 (2.98)	25.90 (5.87)	31.32 (8.01)
$AUC_{0\text{-}49D}$ (μg·day/mL)	225.69 (76.86)	253.28 (47.15)	487.09 (123.26)	560.91 (159.56)[c]
AUC_{last} (μg·day/mL)	238.64 (81.87)	262.27 (51.42)	519.94 (142.39)	588.17 (171.54)[c]
AUC_{inf} (μg·day/mL)	246.11 (86.16)	268.87 (51.79)	535.54 (146.79)	597.15 (175.58)[c]
T_{max} (day)[a]	3.50 (3.0, 4.0)	5.00 (3.0, 6.0)	5.00 (2.0, 6.0)	3.50 (3.0, 5.0)
$T_{1/2}$ (day)	13.15 (3.18)	12.27 (1.48)	13.65 (1.96)	12.10 (1.26)[c]
CL/F (mL/day)	910.53 (324.18)	768.09 (140.56)	789.46 (179.73)	718.51 (192.63)[c]
CL/F (mL/day/kg)[b]	12.46 (4.29)	11.47 (1.66)	10.55 (2.09)	11.11 (3.16)[c]
V_z/F (mL)	17256.65 (7522.98)	13529.89 (2796.50)	15309.61 (3321.93)	12454.98 (3342.77)[c]
V_z/F (mL/kg)[b]	234.19 (98.17)	202.87 (38.26)	204.55 (37.11)	191.62 (50.07)[c]

a) 中央値 （最小値，最大値）
b) 体重あたりの値
c) n = 9
参照元：CNTO148NAP1001 総括報告書 Table 4

(2) 免疫原性

血清検体が得られた 36 例（日本人 18 例，外国人 18 例）に，12 週までに抗ゴリムマブ抗体陽性の被験者は認められなかった。

2.7.2.3 全試験を通しての結果の比較と解析

2.7.2.3.1 薬物動態

2.7.2.3.1.1 潰瘍性大腸炎患者における薬物動態

潰瘍性大腸炎患者にゴリムマブを皮下又は静脈内投与したとき（C0524T16 試験，C0524T17 試験及び C0524T18 試験）の血清中ゴリムマブ濃度は用量におおむね比例して増加した。

寛解維持療法（C0524T18 試験）において，ゴリムマブの単回静脈内（C0524T16 試験）及び反復皮下投与（C0524T17 試験）による寛解導入療法により clinical response が認められた被験者（ランダム化された被験者）にゴリムマブ 50 mg 又は 100 mg，あるいは，寛解導入療法により clinical response が認められなかった被験者にゴリムマブ 100 mg を 4 週ごとに反復皮下投与したときの血清中ゴリムマブのトラフ濃度の中央値は 8 週から 44 週までおおむね一定の濃度で推移したことから，寛解維持 8 週（寛解導入開始から 14 週）までには血清中ゴリムマブ濃度は定常状態に達していると考えられた。また，国内試験（CNTO148UCO3001 試験）にて潰瘍性大腸炎患者にゴリムマブの皮下投与による寛解導入後にゴリムマブ 100 mg を 4 週ごとに反復皮下投与したときも同様に，寛解維持 8 週までには血清中ゴリムマブ濃度が定常状態に達していると考えられた。

2.7.2.3.1.2 母集団薬物動態解析 【評価資料 5.3.3.5.1】

C0524T16 試験，C0524T17 試験及び C0524T18 試験で得られた血清中ゴリムマブ濃度データ（1227 例 11280 ポイント）を用いて，非線形混合効果モデル（NONMEM）による PPK 解析を実施し，潰瘍性大腸炎患者におけるゴリムマブの PPK パラメータを推定した。更に，被験者の人

口統計学的特性及び他の内因性又は外因性要因がゴリムマブの薬物動態に及ぼす影響について検討した。検討した被験者の人口統計学的特性及び他の内因性又は外因性要因（共変量候補）を表2.7.2-4 に示す。なお，「抗ゴリムマブ抗体陽性又は陰性」を除く共変量候補はベースライン時の値を用いた。

表 2.7.2-4 PPK 解析で検討した被験者の人口統計学的特性及び他の内因性又は外因性要因

連続変数	カテゴリカル変数
年齢（AGE）	年齢群（加齢又は非加齢）（AGEC）
体重（WGT）	性別（SEX）
除脂肪体重（LBM）	人種
体表面積（BSA）	・白人又は非白人（RAC）
クレアチニンクリアランス（計算値，CrCL）	・アジア人又は非アジア人（RAC1）
アスパラギン酸アミノトランスフェラーゼ（AST）	・日本人又は外国人（非日本人）（RAC2）
アラニン・アミノトランスフェラーゼ（ALT）	併用薬使用の有無
アルカリホスファターゼ（ALK）	・6-MP 又は AZA（AZMP）
総ビリルビン（BILI）	・MTX（MTX）
血清アルブミン（ALB）	抗ゴリムマブ抗体陽性又は陰性（IRP）
白血球数（WBC）	喫煙の有無（SMOK）
Mayo スコア（BMYO）	
C-反応性たん白（CRP）	
罹患期間（DDUR）	

関節リウマチ患者を対象とした臨床試験成績を用いた PPK 解析では，構造モデル（structural model）として一次吸収過程を有する 1-コンパートメントモデルを選択したが【初回申請時 CTD 2.7.2.3.6】，今回の PPK 解析に単回静脈内投与試験（C0524T16 試験）の血清中ゴリムマブ濃度データを含めたことにより，血清中ゴリムマブ濃度データは 1-コンパートメントモデルよりも 2-コンパートメントモデルの方が良く当てはまったことから，一次吸収過程（皮下投与）を有する 2-コンパートメントモデル（図 2.7.2-6）を選択した。

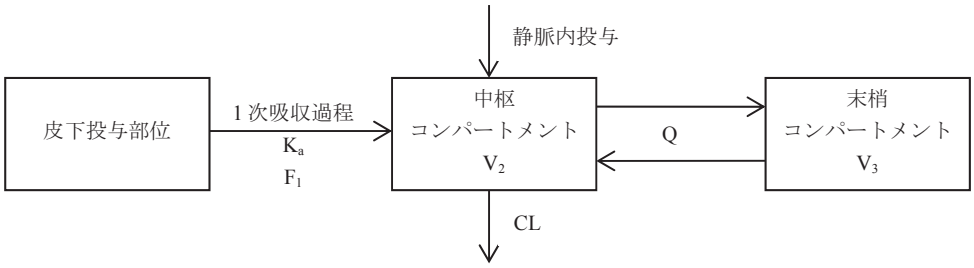


図 2.7.2-6 ゴリムマブの薬物動態に関する構造モデル

海外第 II/III 相試験（C0524T16 試験），国際共同第 II/III 相試験（C0524T17 試験）及び国際共同第 III 相試験（C0524T18 試験，54 週のデータ固定まで）で得られた血清中ゴリムマブ濃度データから，以下の最終モデルを構築した。

ゴリムマブの薬物動態に関する最終モデル

$$CL\ (L/day) = 0.544 \times \left(\frac{WGT}{70}\right)^{0.812} \times \left(\frac{ALB}{4.2}\right)^{-1.15} \times \left(\frac{ALK}{68}\right)^{0.069} \times \left(\frac{CRP}{4.8}\right)^{0.033} \times (1 + IRP \times 0.243)$$

$$V_2\ (L) = 3.43 \times \left(\frac{WGT}{70}\right)^{0.873}$$

$$V_3\ (L) = 2.27 \times \left(\frac{WGT}{70}\right)^{0.90}$$

$$Q\ (L/day) = 0.291 \times \left(\frac{WGT}{70}\right)^{1.22}$$

	推定値		個体間変動（BSV）[b]	
	母集団平均 (RSE%)	中央値 (95% CI)[a]	推定値 (RSE%)	中央値 (95% CI)[a]
CL (L/day)	0.544 (2.3)	0.538 (0.511 ~ 0.567)	26.7 (8.2)	25.7 (22.5 ~ 29.1)
WGT on CL	0.812 (6.4)	0.791 (0.694 ~ 0.890)		
ALB on CL	-1.150 (7.3)	-1.060 (-1.250 ~ -0.864)		
IRP on CL	0.243 (26.2)	0.262 (0.149 ~ 0.385)		
ALK on CL	0.069 (38.9)	0.085 (0.040 ~ 0.134)		
CRP on CL	0.033 (17.8)	0.030 (0.018 ~ 0.043)		
V_2 (L)	3.43 (4.0)	3.44 (3.29 ~ 3.58)	24.0 (12.4)	23.7 (11.3 ~ 33.8)
WGT on V_2	0.873 (13.4)	0.856 (0.663 ~ 1.050)		
V_3 (L)	2.27 (4.3)	2.31 (2.13 ~ 2.52)	35.4 (6.3)	35.2 (26.5 ~ 42.5)
WGT on V_3	0.900 (15.9)	0.907 (0.736 ~ 1.090)		
Q (L/day)	0.291 (6.9)	0.297 (0.257 ~ 0.355)	0.0 (fixed)	0.0 (fixed)
WGT on Q	1.220 (19.1)	1.240 (0.826 ~ 1.700)		
K_a (1/day)	0.213 (3.3)	0.213 (0.200 ~ 0.230)	44.6 (9.8)	43.9 (37.8 ~ 49.3)
F_1	0.522 (2.4)	0.527 (0.499 ~ 0.559)	47.4 (8.7)	48.8 (35.6 ~ 59.6)

a) 復元抽出による 1000 回のブートストラップの結果
b) 分散 $^{1/2}$*100 (%)により算出，個体間変動は F_1 を除き，指数誤差モデルとした（F_1 はロジット変換モデル）
WGT: 体重（kg），ALB: 血清アルブミン（g/dL），ALK: アルカリホスファターゼ（U/L），
CRP: C-反応性たん白（mg/L），IRP: 抗ゴリムマブ抗体陽性又は陰性（陽性=1）
誤差の推定値[平均値 (RSE%)]：比例誤差: 32.2 (0.4)%，絶対誤差: 0.040 (1.0) μg/mL
CL と V_2 の個体間変動の相関: 0.768，CL と V_3 の個体間変動の相関: -0.641
参照元：PPK 解析報告書 Table 1

全身クリアランス（CL）に対して統計学的に有意（p<0.001）な共変量は体重，血清アルブミン（ALB），アルカリホスファターゼ（ALK），C-反応性たん白（CRP）及び抗ゴリムマブ抗体陽性であった。また，体重は，中枢コンパートメントの分布容積（V_2），末梢コンパートメントの分布容積（V_3）及び中枢コンパートメントと末梢コンパートメント間のクリアランス（Q）に対しても統計学的に有意な共変量であった。これらの共変量のうち，体重，血清アルブミン及び抗ゴリムマブ抗体陽性はゴリムマブの薬物動態に対する影響が大きい共変量と考えられた。一方，「日本人又は非日本人」はいずれのパラメータに対しても統計的に有意な共変量ではなかった。

ゴリムマブを潰瘍性大腸炎患者に皮下投与したときの絶対的バイオアベイラビリティ（F_1）は 52.2%と推定された。

ゴリムマブを体重 70 kg の潰瘍性大腸炎患者に皮下投与したときの中枢コンパートメント（V_2）及び末梢コンパートメント（V_3）の分布容積はそれぞれ 3.43 L 及び 2.27 L（=49.0 mL/kg 及び 32.4 mL/kg）と推定され，定常状態における分布容積（=V_2+V_3）が 5.7 L（=81.4 mL/kg）と小さいことから，潰瘍性大腸炎患者においても，ゴリムマブは主として，循環血中に局在しており，血管外への分布が小さいことが示唆された。体重 70 kg の潰瘍性大腸炎患者における $T_{1/2}$ 及び CL はそれぞれ 10.5 日及び 0.544 L/day と推定された。

2.7.2.3.1.3 潰瘍性大腸炎患者と健康成人における薬物動態の比較

潰瘍性大腸炎患者にゴリムマブを皮下投与したときの絶対的バイオアベイラビリティ（F_1）は52.2%と推定された（2.7.2.3.1.2）。この値は，外国人健康成人にゴリムマブ 100 mg を皮下投与したときの絶対的バイオアベイラビリティ［52.09%（中央値）］【初回申請時 CTD 2.7.2.3.1】と同程度であった。潰瘍性大腸炎患者（体重 70 kg）における CL の推定値は 0.544 L/day（7.78 mL/day/kg）であった。絶対的バイオアベイラビリティの推定値が 52.2%であったことから，潰瘍性大腸炎患者（体重 70 kg）にゴリムマブを皮下投与したときの CL/F は 1.042 L/day（14.9 mL/day/kg）と算出された。一方，日本人及び外国人健康成人に 200 mg 又は 400 mg を単回皮下投与したとき（CNTO148NAP1001 試験）の CL/F の中央値は 10.75 mL/day/kg～11.76 mL/day/kg であった。また，日本人及び外国人健康成人に 50 mg 又は 100 mg を単回皮下投与したとき（C0524T23 試験）の CL/F の中央値は 12.28 mL/day/kg～15.20 mL/day/kg であった【初回申請時 CTD 2.7.2.3.3】。潰瘍性大腸炎患者（体重 70 kg）並びに日本人及び外国人健康成人にゴリムマブを皮下投与したときの $T_{1/2}$ はそれぞれ 10.5 日（推定値）及び 11.3 日～13.5 日（中央値）であった。

以上のことから，異なる解析方法（頻回採血によるノンコンパートメント解析及びスパース採血による PPK 解析）による比較ではあるが，潰瘍性大腸炎患者と健康成人にゴリムマブを皮下投与したときの薬物動態に大きな差はないと考えられた。

2.7.2.3.1.4 用量比例性

日本人及び外国人（白人）健康成人にゴリムマブ 50 mg 又は 100 mg（C0524T23 試験）【初回申請時 CTD 2.7.2.2.2 (1)】並びにゴリムマブ 200 mg 又は 400 mg（CNTO148NAP1001 試験）を単回皮下投与したときの薬物動態パラメータを表 2.7.2-5 に示す。

日本人及び外国人健康成人に 200 mg 又は 400 mg を単回皮下投与したときの C_{max} 及び AUC_{inf} はいずれも用量におおむね比例して増加した（CNTO148NAP1001 試験）。また，日本人及び外国人健康成人に 50 mg 又は 100 mg を単回皮下投与したときの C_{max} 及び AUC_{inf} も，用量におおむね比例して増加した（C0524T23 試験）【初回申請時 CTD 2.7.2.3.4】。

日本人及び外国人健康成人に 200 mg 又は 400 mg を単回皮下投与したときの V_z/F の中央値は 190.74 mL/kg～202.95 mL/kg，日本人及び外国人健康成人に 50 mg 又は 100 mg を単回皮下投与したときの V_z/F の中央値は 211.34 mL/kg～247.79 mL/kg であった。日本人及び外国人健康成人に 200 mg 又は 400 mg を単回皮下投与したときの CL/F の中央値は 10.75～11.76 mL/day/kg，日本人及び外国人健康成人に 50 mg 又は 100 mg を単回皮下投与したときの CL/F の中央値は 12.28 mL/day/kg～15.20 mL/day/kg であった。

表 2.7.2-5 健康成人にゴリムマブを単回皮下投与したときの薬物動態パラメータ

試験番号 被験者	用量		C_{max} (μg/mL)	AUC_{inf} (μg·day/mL)	CL/F (mL/day/kg)	V_z/F (mL/kg)
CNTO148NAP1001 試験						
白人健康成人	200 mg	例数	10	10	10	10
		平均値 (SD)	13.20 (5.424)	246.11 (86.155)	12.46 (4.288)	234.19 (98.168)
		中央値	12.44	222.01	11.71	202.95
日本人健康成人	200 mg	例数	11	11	11	11
		平均値 (SD)	15.85 (2.975)	268.87 (51.789)	11.47 (1.658)	202.87 (38.263)
		中央値	16.60	281.86	11.41	190.74
白人健康成人	400 mg	例数	10	10	10	10
		平均値 (SD)	25.90 (5.872)	535.54 (146.792)	10.55 (2.087)	204.55 (37.113)
		中央値	27.30	517.64	10.75	198.38
日本人健康成人	400 mg	例数	10	9	9	9
		平均値 (SD)	31.32 (8.011)	597.15 (175.583)	11.11 (3.157)	191.62 (50.072)
		中央値	30.68	540.70	11.76	194.01
C0524T23 試験						
白人健康成人	50 mg	例数	11	10	11	11
		平均値 (SD)	2.48 (0.77)	47.69 (17.49)	18.78 (12.90)	262.16 (81.98)
		中央値	2.52	43.94	15.20	239.56
日本人健康成人	50 mg	例数	12	12	12	12
		平均値 (SD)	2.82 (0.97)	53.25 (13.06)	15.21 (3.88)	256.73 (60.94)
		中央値	2.53	49.42	14.08	247.79
白人健康成人	100 mg	例数	12	12	12	12
		平均値 (SD)	7.21 (2.31)	129.72 (47.12)	12.04 (3.12)	224.18 (48.62)
		中央値	6.81	125.47	12.28	211.34
日本人健康成人	100 mg	例数	12	12	12	12
		平均値 (SD)	6.72 (2.35)	121.63 (33.89)	13.41 (3.74)	237.00 (57.98)
		中央値	5.90	110.64	12.96	221.98

参照元：C0524T23 試験 治験総括報告書　Table 14.2.2 及び CNTO148NAP1001 試験 治験総括報告書　Table 4

以上のことから，日本人及び外国人健康成人に 200 mg 又は 400 mg を単回皮下投与したときと，50 mg 又は 100 mg を単回皮下投与したときの成績は，異なる臨床試験での成績であり，ゴリムマブの測定方法も異なっていることから，直接比較することには注意が必要ではあるものの，日本人及び外国人健康成人にゴリムマブを皮下投与したときのゴリムマブの薬物動態は，50 mg～400 mg の用量範囲において，非線形性は認められなかった。

日本人及び外国人潰瘍性大腸炎患者にゴリムマブを皮下又は静脈内投与したとき（C0524T16 試験，C0524T17 試験及び C0524T18 試験）の血清中ゴリムマブ濃度は用量におおむね比例して増加した。

2.7.2.3.1.5　ゴリムマブの薬物動態に及ぼす内因性及び外因性要因

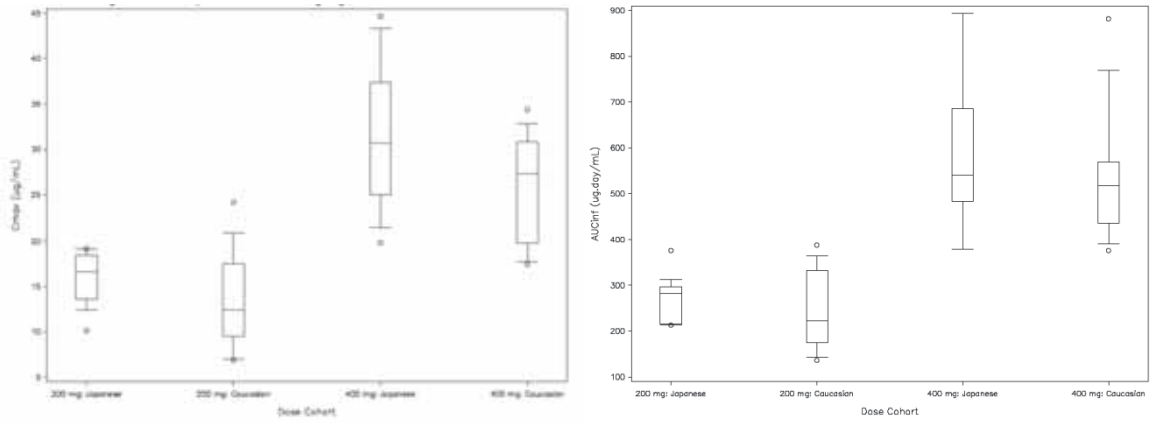
(1) 人種・民族差の影響

1) 日本人と外国人の比較

CNTO148NAP1001 試験にて日本人及び外国人（白人）健康成人にゴリムマブ 200 mg 又は 400 mg を単回皮下投与したときの血清中ゴリムマブ濃度－時間推移を図 2.7.2-4 及び図 2.7.2-5 に，薬物動態パラメータを表 2.7.2-3 に示す。

200 mg 又は 400 mg を単回皮下投与したとき，日本人での C_{max} 及び AUC_{inf} の平均値は外国人と比較してやや高かったものの，分布範囲はおおむね外国人の分布範囲と重なっていた（図 2.7.2-

7）。また，体重あたりの CL/F 及び体重あたりの V_z/F は，日本人と外国人はおおむね一致していた。$T_{1/2}$ の平均値も日本人と外国人でおおむね同程度であった。



参照元：CNTO148NAP1001 治験総括報告書 Attachment 2.8 及び Attachment 2.9

図 2.7.2-7 日本人及び外国人健康成人にゴリムマブを単回皮下投与したときの C_{max}（左図）及び AUC_{inf}（右図）の分布

C0524T23 試験にて日本人及び外国人健康成人に 50 mg 又は 100 mg を単回皮下投与したときのゴリムマブの薬物動態は日本人と外国人で同様と考えられた【初回申請時 CTD 2.7.2.3.7 (1)】。

ゴリムマブの皮下投与による寛解導入療法（C0524T17 試験）において，日本人及び外国人潰瘍性大腸炎患者にゴリムマブを反復皮下投与したとき，日本人の血清中ゴリムマブ濃度の中央値は，外国人と比較して同程度か若干高値を示す傾向が認められたが，6 週を除き，いずれの用量及び時点においても，日本人における血清中ゴリムマブ濃度の範囲は外国人における血清中ゴリムマブ濃度の範囲内であった（表 2.7.2-付録-6）。同様に，寛解維持療法（C0524T18 試験）において，日本人及び外国人潰瘍性大腸炎患者にゴリムマブを反復皮下投与したとき，8 週以降の日本人全被験者の血清中ゴリムマブ濃度の中央値は，外国人の全被験者と比較して同程度か若干高値を示す傾向が認められたが，ゴリムマブ 100 mg 群の 28 週を除き，いずれの用量及び時点においても，日本人における血清中ゴリムマブ濃度の範囲は外国人における血清中ゴリムマブ濃度の範囲内であった（表 2.7.2-付録-7 ）。

また，日本人潰瘍性大腸炎患者を対象とした試験（CNTO148UCO3001 試験）にて，日本人潰瘍性大腸炎患者にゴリムマブを反復皮下投与したときの血清中ゴリムマブ濃度の中央値は，C0524T17 試験及び C0524T18 試験における外国人と比較して同程度か若干高値を示す傾向が認められたものの，寛解導入 4 週を除き，血清中ゴリムマブ濃度の範囲は，C0524T17 試験及び C0524T18 試験における外国人の血清中ゴリムマブ濃度の範囲内であった（表 2.7.2-付録-6，表 2.7.2-付録-7 及び表 2.7.2-付録-4）。ゴリムマブの薬物動態には体重の影響が認められている（2.7.2.3.1.5(2)）。CNTO148UCO3001 試験の被験者 144 例、C0524T17 試験の日本人 72 例及び外国人 701 例の体重（中央値）はそれぞれ，60.75 kg，58.00 kg 及び 72.60 kg と，日本人潰瘍性大腸炎患者の体重は外国人と比較して低いことから，日本人と外国人の体重差が血清中ゴリムマブ濃度の差に影響している可能性が考えられる。

また，日本人及び外国人潰瘍性大腸炎患者の血清中ゴリムマブ濃度データ（1227 例 11280 ポイント）を用いた PPK 解析において，68 例の日本人データが含まれていたが，CL 及び V_2 に対して，日本人及び外国人（非日本人）は統計学的に有意な共変量ではなかった。

以上のことから，ゴリムマブの薬物動態には，日本人と外国人の間で大きな差はないと考えられた。

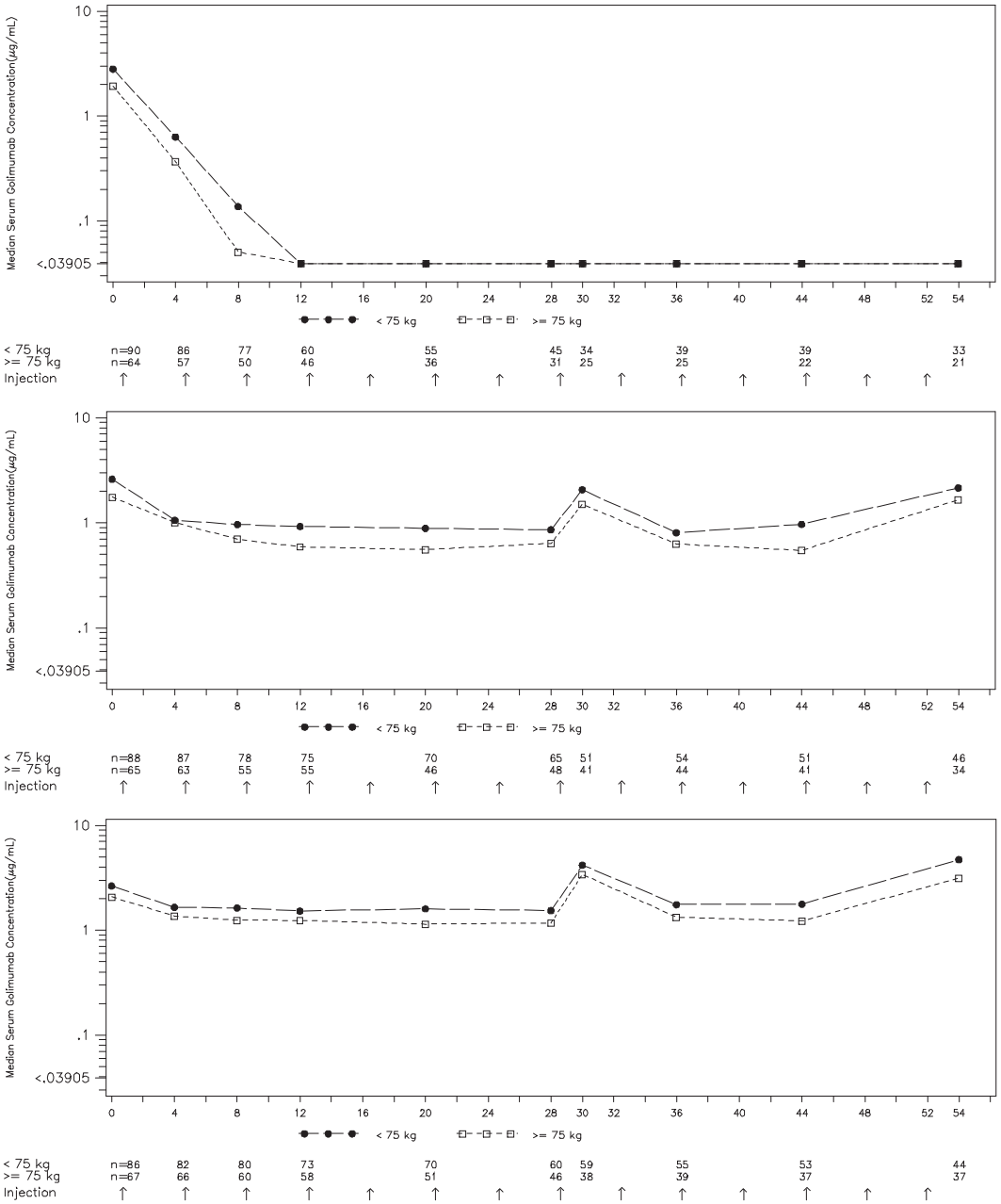
2) 全人種間での薬物動態の比較

日本人及び外国人潰瘍性大腸炎患者の血清中ゴリムマブ濃度データを用いた PPK 解析において，人種の影響（白人／非白人及びアジア人／非アジア人）について検討した。なお，血清中ゴリムマブ濃度データには，白人 1008 例（82.2%），アジア人 155 例（12.6%），黒人 24 例（2.0%）及びその他の人種 40 例（3.3%）のデータが含まれていた。

その結果，CL 及び V_2 に対して，人種は統計学的に有意な共変量ではなかったことから，ゴリムマブの薬物動態に対する人種の影響は小さいと考えられる。

(2) 体重の影響

寛解維持療法（C0524T18 試験）においてランダム化された被験者に，プラセボ，ゴリムマブ 50 mg 又は 100 mg を 4 週ごとに反復皮下投与したときの血清中ゴリムマブ濃度を，体重 75 kg 未満及び 75 kg 以上の部分集団に層別したときの血清中ゴリムマブ濃度の中央値を図 2.7.2-8 に示す。プラセボ，ゴリムマブ 50 mg 及び 100 mg を投与したときの血清中ゴリムマブ濃度の中央値は，体重 75 kg 以上の被験者群と比較して体重 75 kg 未満の被験者群の方が，若干高値を示した。



参照元：C0524T18 治験総括報告書 Attachment 2.6～Attachment 2.8

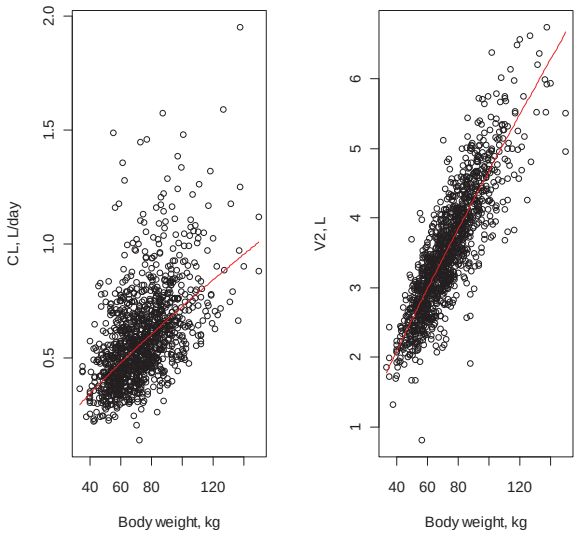
図 2.7.2-8 潰瘍性大腸炎患者にゴリムマブを反復皮下投与したときの体重（75 kg 以上及び 75 kg 未満）で層別したときの血清中ゴリムマブ濃度－時間推移（ランダム化された被験者，中央値）

上段：プラセボ群，中段：ゴリムマブ 50 mg 群，下段：ゴリムマブ 100 mg 群

日本人及び外国人潰瘍性大腸炎患者の血清中ゴリムマブ濃度データを用いた PPK 解析において，体重の影響を検討した。なお，PPK 解析に用いた被験者の体重の中央値（四分位範囲，範囲）は 71.9（60～84，33～150）kg であった。

その結果，CL，Q，V_2 及び V_3 に対して，体重は統計学的に有意な共変量であった。被験者の体重とベイズ推定による各被験者の CL 及び V_2 との相関を図 2.7.2-9 に示す。被験者の体重の四

分位範囲（60 kg～84 kg）における CL 及び V_2 の中央値からの変化の範囲は，それぞれ-11.8%～+16.0%及び-12.6%～+17.3%であった。



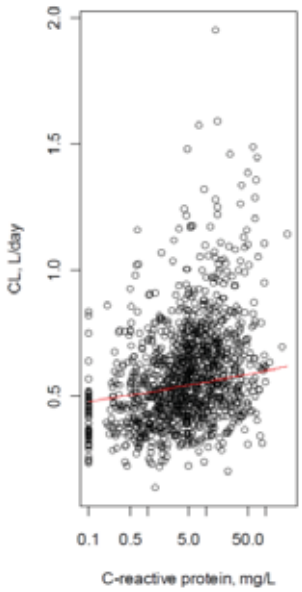
参照元：PPK 解析報告書 Attachment 22.1 及び Attachment 22.2

図 2.7.2-9 潰瘍性大腸炎患者における体重とゴリムマブの CL 及び V_2 の推定値との相関

(3) ベースライン時の疾患活動性

日本人及び外国人潰瘍性大腸炎患者の血清中ゴリムマブ濃度データを用いた PPK 解析において，CRP の影響について検討した。なお，PPK 解析に用いた被験者の CRP の中央値（範囲）は 4.8（0.1～240）mg/L であった。その結果，CL に対し，CRP は統計学的に有意な共変量であった。各被験者の CRP とベイズ推定による CL との相関を図 2.7.2-10 に示す。CL に対する CRP のべき乗項の値は 0.033 と小さく，被験者の CRP の四分位範囲（1.59 mg/L～12.8 mg/L）における CL の中央値からの変化の範囲は，-3.6%～+3.3%と限定的であった。V_2 に対する影響は認められなかった。

その他潰瘍性大腸炎の疾患活動性の影響の検討として，ベースラインの Mayo スコア及び罹患期間の影響についても検討したが，いずれも統計学的に有意な共変量ではなかった。



参照元：PPK 解析報告書 Attachment 26

図 2.7.2-10 潰瘍性大腸炎患者における CRP とゴリムマブの CL の推定値との相関

(4) 腎機能低下患者

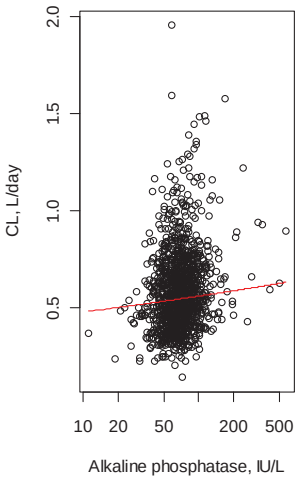
日本人及び外国人潰瘍性大腸炎患者の血清中ゴリムマブ濃度データを用いた PPK 解析において，大部分の被験者は腎機能正常患者であったものの，ベースライン時のクレアチニンクリアランス（CrCL）が 32.8 mL/min～270.5 mL/min の被験者のデータが含まれており，CrCL の影響を検討した。

その結果，CL 及び V_2 に対して，CrCL は統計学的に有意な共変量ではなかった。腎機能低下の影響を検討した臨床試験は実施していないが，ゴリムマブはヒト型免疫グロブリン G1（IgG_1）モノクローナル抗体であり，主として内因性 IgG_1 と同様に，低ペプチドと構成アミノ酸に分解されることから [1)]，ゴリムマブの薬物動態に対する腎機能の影響は小さいと考えられる。

(5) 肝機能低下患者

日本人及び外国人潰瘍性大腸炎患者の血清中ゴリムマブ濃度データを用いた PPK 解析において，肝機能［ベースライン時のアスパラギン酸アミノトランスフェラーゼ（AST），アラニン・アミノトランスフェラーゼ（ALT），ALK 及び総ビリルビン（BILI）］の影響を検討した。なお，大部分の被験者においてこれらの臨床検査値は基準値の範囲内であった。

PPK 解析の結果，CL に対して，ALK は，統計学的に有意な共変量であった。各被験者の ALK とベイズ推定による CL との相関を図 2.7.2-11 に示す。被験者の ALK の四分位範囲（57 IU/L～83 IU/L）における CL の中央値からの変化の範囲は，-1.2%～+1.4%と限定的であった。AST，ALT，ALK 及び BILI のいずれも CL 及び V_2 に対する影響は認められなかった。



参照元：PPK 解析報告書 Attachment 24.2

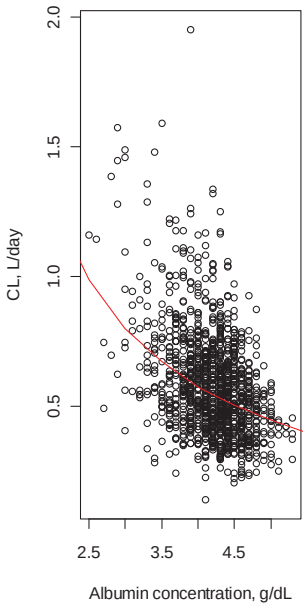
図 2.7.2-11 潰瘍性大腸炎患者における ALK とゴリムマブの CL の推定値との相関

(6) 血清アルブミンの影響

これまでに，他の抗体薬において，血清アルブミンが潰瘍性大腸炎患者における CL に影響を及ぼすことが報告されていることから[2),3)]，日本人及び外国人潰瘍性大腸炎患者の血清中ゴリムマブ濃度データを用いた PPK 解析において，ALB の影響を検討した。なお，PPK 解析に用いた被験者の ALB の中央値（四分位範囲，範囲）は 4.2（3.9～4.5，2.5～5.3）g/dL であった。

その結果，CL に対して，ALB は，統計学的に有意な共変量であった。各被験者の ALB とベイズ推定による CL との相関を図 2.7.2-12 に示す。被験者の ALB の四分位範囲（3.9 g/dL～4.5 g/dL）における CL の中央値からの変化の範囲は，+8.9～-7.6%であった。V_2 に対する影響は認められなかった。

血清アルブミン及び内因性の IgG は neonatal Fc receptor（FcRn）により，異化されずに生体内に滞留している。血清アルブミンが高値を示した被験者では FcRn が高発現している可能性が考えられ[2)]，ヒト型 IgG_1 モノクローナル抗体であるゴリムマブも，高発現した FcRn により異化を受けにくくなり，CL が低値を示した可能性が考えられた。



参照元：PPK 解析報告書 Attachment 24.1

図 2.7.2-12 潰瘍性大腸炎患者における ALB とゴリムマブの CL の推定値との相関

(7) その他の人口統計学的特性の影響

日本人及び外国人潰瘍性大腸炎患者の血清中ゴリムマブ濃度データを用いた PPK 解析の結果，年齢及び性別は，統計学的に有意な共変量ではなかった。

(8) 併用薬の影響

潰瘍性大腸炎の治療薬として，免疫抑制薬が広く使用されており，国内では 6-メルカプトプリン（6-MP）及びアザチオプリン（AZA），海外では更に MTX が使用されていることから，6-MP 又は AZA の併用及び MTX の併用の影響について検討した。なお，379 例（30.9%）の被験者が 6-MP 又は AZA を，16 例（1.3%）の被験者が MTX を併用していた。

寛解維持療法（C0524T18 試験）においてランダム化された被験者に，ゴリムマブ 50 mg 又は 100 mg を 4 週ごとに反復皮下投与したときの血清中ゴリムマブ濃度を，6-MP，AZA 又は MTX の併用の有無で層別解析したときの血清中ゴリムマブ濃度の中央値を図 2.7.2-13 に示す。ゴリムマブ 50 mg を投与したときの血清中ゴリムマブ濃度の中央値は，6-MP，AZA 又は MTX を併用していなかった被験者群と比較して，6-MP，AZA 又は MTX を併用していた被験者群の方が，やや高値を示した。ゴリムマブ 100 mg を投与したときの血清中ゴリムマブ濃度の中央値は，6-MP，AZA 又は MTX の併用の有無でほとんど差は認められなかった。50 mg 群において，6-MP，AZA 又は MTX を併用していなかった被験者群と比較して，6-MP，AZA 又は MTX を併用していた被験者群で血清中ゴリムマブ濃度がやや高値を示した原因については不明である。

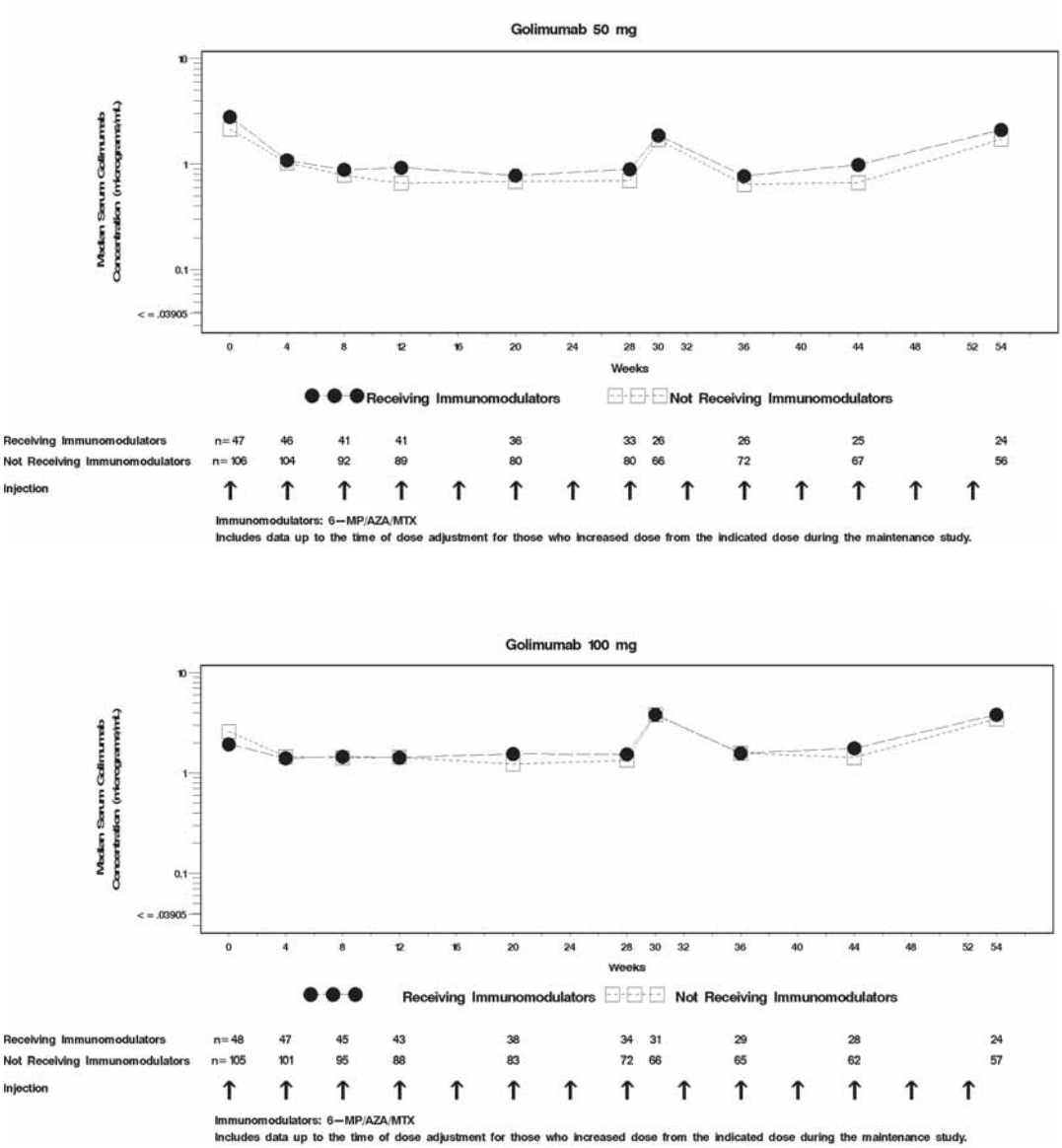


図 2.7.2-13 潰瘍性大腸炎患者にゴリムマブを反復皮下投与したときの 6-MP，AZA 又は MTX 併用の有無で層別したときの 血清中ゴリムマブ濃度－時間推移 （ランダム化された被験者，中央値）

上段：ゴリムマブ 50 mg 群，下段：ゴリムマブ 100 mg 群

日本人及び外国人潰瘍性大腸炎患者の血清中ゴリムマブ濃度データを用いた PPK 解析において，6-MP 又は AZA の併用及び MTX の併用の影響について検討した結果，6-MP 又は AZA の併用，並びに MTX の併用は，統計学的に有意な共変量ではなかった。

(9) 抗ゴリムマブ抗体の影響

寛解維持療法（C052T18 試験）においてランダム化された被験者に，プラセボ，ゴリムマブ 50 mg 及び 100 mg を 4 週ごとに反復皮下投与したときの血清中ゴリムマブ濃度を，抗ゴリムマブ抗体陽性及び陰性で層別したときの血清中ゴリムマブ濃度の中央値を図 2.7.2-14 に示す。

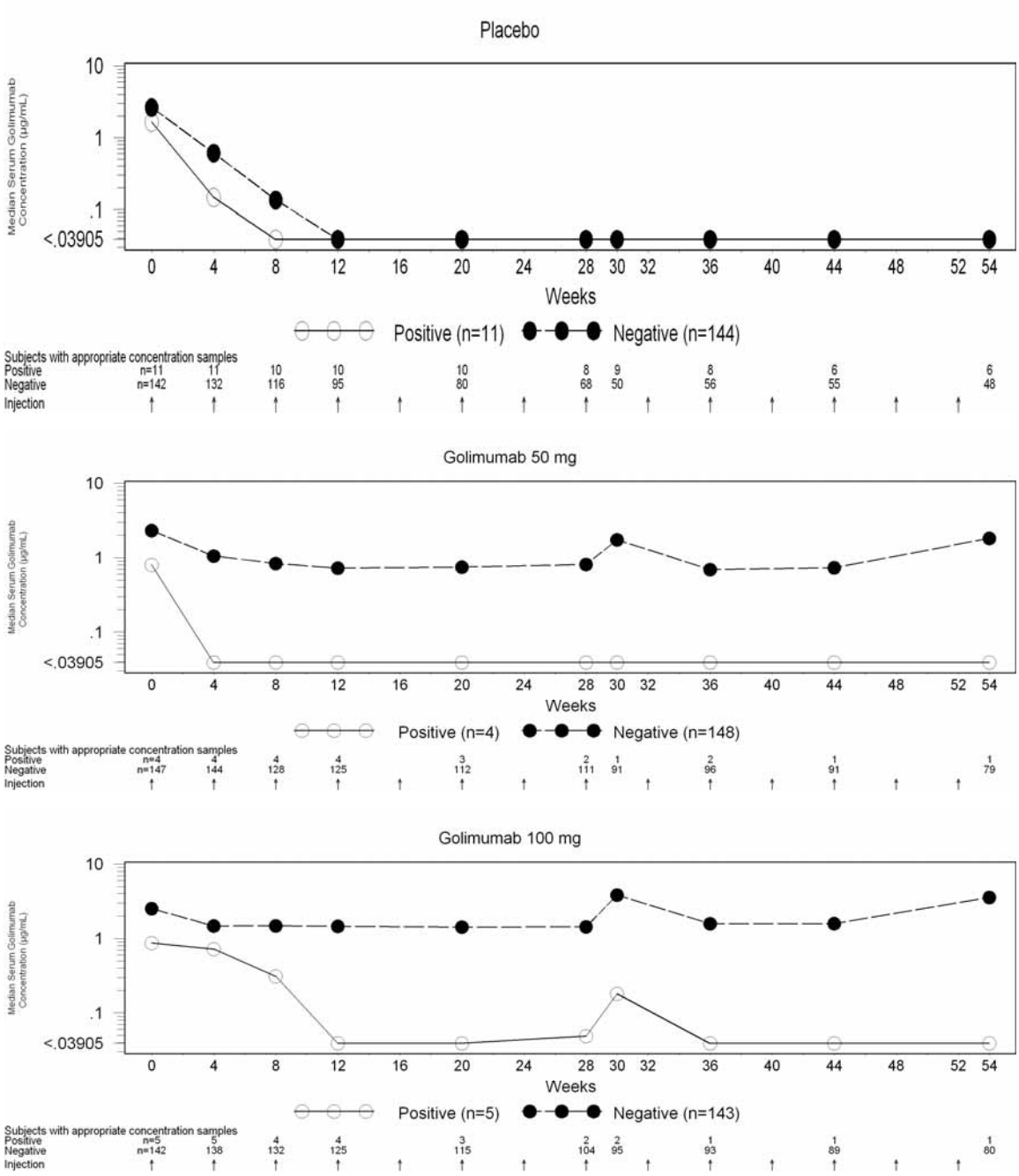


図 2.7.2-14 潰瘍性大腸炎患者にプラセボ又はゴリムマブを反復皮下投与したときの抗ゴリムマブ抗体発現の有無別で層別した血清中ゴリムマブ濃度－時間推移（ランダム化された被験者，中央値）

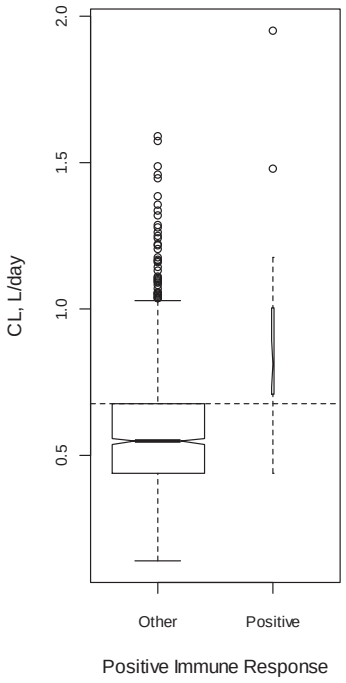
上段：プラセボ群，中段：ゴリムマブ 50 mg 群，下段：ゴリムマブ 100 mg 群

ゴリムマブ群において，抗体陽性の被験者群の血清中ゴリムマブ濃度の中央値は，抗体陰性の被験者群と比較して低値を示した。

潰瘍性大腸炎患者の血清中ゴリムマブ濃度データを用いた PPK 解析において，抗ゴリムマブ抗体の薬物動態に対する影響について検討した。

その結果，CL に対し，抗ゴリムマブ抗体は統計学的に有意な共変量であり，抗ゴリムマブ抗体陽性の被験者では，抗ゴリムマブ抗体陰性の被験者と比較して CL が 24.3%高値を示すと推定された（図 2.7.2-15）。

しかしながら，寛解維持療法でランダム化された被験者及び PPK 解析に用いた被験者において，抗ゴリムマブ抗体陽性であった被験者はそれぞれ 20 例及び 34 例と限られていたことから，血清中ゴリムマブ濃度に対する抗ゴリムマブ抗体の影響について明確な結論は見出せなかった。



参照元：PPK 解析報告書 Attachment 23

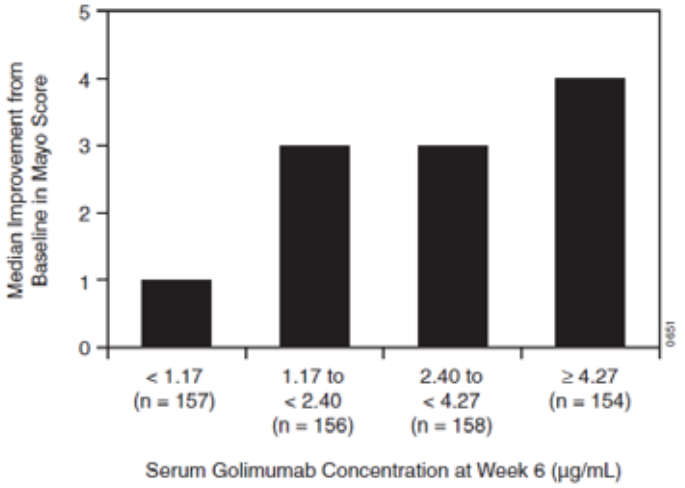
図 2.7.2-15 潰瘍性大腸炎患者における抗ゴリムマブ抗体陽性有無別のゴリムマブの CL の推定値

2.7.2.3.1.6 潰瘍性大腸炎患者における血清中ゴリムマブ濃度と有効性との相関

日本人又は外国人潰瘍性大腸炎患者を対象としたゴリムマブによる寛解導入療法（C0524T16 試験及び C0524T17 試験）並びに，寛解維持療法（C0524T18 試験）において，ゴリムマブを単回静脈内又は反復皮下投与したときの血清中ゴリムマブ濃度と有効性の相関を検討した。

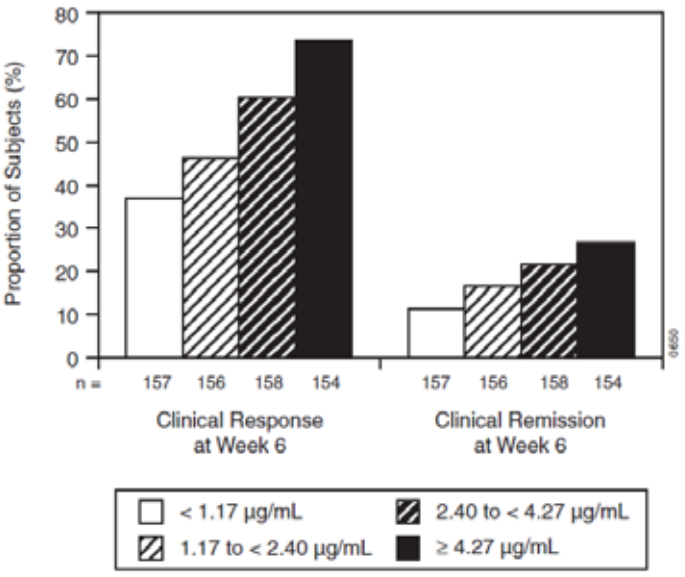
寛解導入療法（C0524T17 試験）において，ゴリムマブを反復皮下投与したときの 6 週の血清中ゴリムマブ濃度を統合し，四分位値（第 1 四分位：1.17 μg/mL，中央値：2.40 μg/mL，第 3 四分位：4.27 μg/mL）により層別したときの各部分集団における 6 週の Mayo スコアのベースラインからの改善量の中央値並びに clinical response 及び clinical remission が認められた被験者の割合をそれぞれ図 2.7.2-16 及び図 2.7.2-17 に示す。

血清中ゴリムマブ濃度が高値の群において，6 週の Mayo スコアのベースラインからの変化量の中央値並びに clinical response 及び clinical remission が認められた被験者の割合は高値を示した。



参照元: Re-analysis report for C0524T17 and C0524T18 54-Week
Appendix 2: Re-analyzed Tables and Figures in C0524T17 CSR Figure 16

図 2.7.2-16 ゴリムマブを反復皮下投与したときの 6 週の血清中ゴリムマブ濃度と Mayo スコアのベースラインからの変化量との相関
施設番号 6706，7257，7407 及び被験者番号 7078-00001 を除く



参照元: Re-analysis report for C0524T17 and C0524T18 54-Week
Appendix 2: Re-analyzed Tables and Figures in C0524T17 CSR Figure 17

図 2.7.2-17 ゴリムマブを反復皮下投与したときの 6 週の血清中ゴリムマブ濃度と clinical response 及び clinical remission との相関
施設番号 6706，7257，7407 及び被験者番号 7078-00001 を除く

寛解導入療法（C0524T17 試験）において，日本人潰瘍性大腸炎患者にゴリムマブを反復皮下投与したときの 6 週の血清中ゴリムマブ濃度を統合し，四分位値（第 1 四分位：1.25 μg/mL，中央値：2.38 μg/mL，第 3 四分位：3.84 μg/mL）により層別したときの各部分集団における 6 週の Mayo スコアのベースラインからの変化量の中央値並びに clinical response 及び clinical remission が認められた被験者の割合をそれぞれ表 2.7.2-6 に示す。

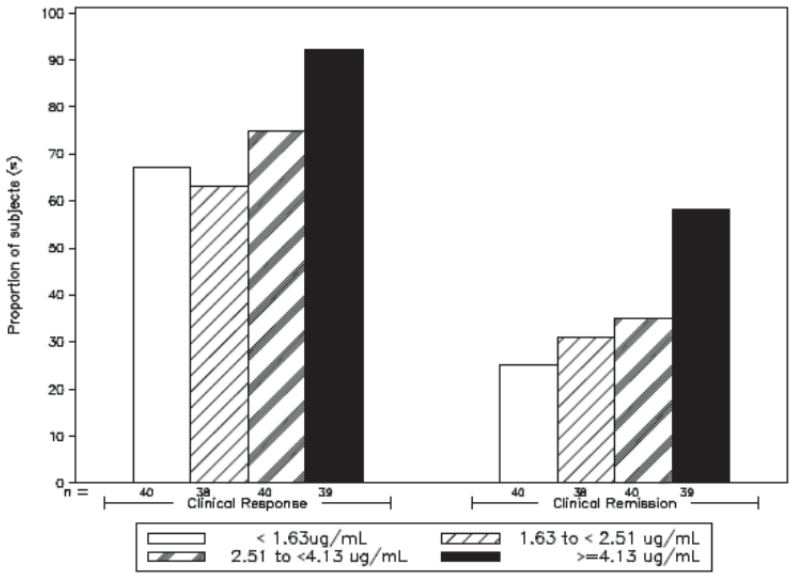
日本人被験者においても，血清中ゴリムマブ濃度が高値の群において，6 週の Mayo スコアのベースラインからの改善量の中央値並びに clinical response 及び clinical remission が認められた被験者の割合は高値を示したが，被験者数は限られていたため，明確な結論は見出せなかった。

表 2.7.2-6 日本人潰瘍性大腸炎患者にゴリムマブを反復皮下投与したときの 6 週の血清中ゴリムマブ濃度と有効性との相関

血清中ゴリムマブ濃度	Mayo スコアのベースラインからの改善量（中央値）	Clinical Response が認められた被験者の割合 (%)	Clinical Remission が認められた被験者の割合 (%)
< 1.25 μg/mL（n=10）	0.0	20.0	0.0
1.25 to < 2.38 μg/mL（n=10）	1.0	10.0	10.0
2.38 to < 3.84 μg/mL（n=10）	1.0	30.0	20.0
≥ 3.84 μg/mL（n=10）	4.0	60.0	20.0

ゴリムマブの静脈内投与による寛解導入療法（C0524T16 試験）において，外国人潰瘍性大腸炎患者にゴリムマブを静脈内投与したとき，4 週又は 6 週の血清中ゴリムマブ濃度が高かった被験者群の方が，わずかに 6 週の Mayo スコアのベースラインからの改善量及び clinical response が認められた被験者の割合が高かった。

寛解維持療法（C0524T18 試験）において，ランダム化された被験者にゴリムマブを反復皮下投与したときの 6 週の血清中ゴリムマブ濃度を統合し，四分位値（第 1 四分位：1.63 μg/mL，中央値：2.51 μg/mL，第 3 四分位：4.13 μg/mL）を用いて部分集団化したときの各部分集団における 54 週までの clinical response 及び 30 週と 54 週の clinical remission が認められた被験者の割合を図 2.7.2-18 に示す。

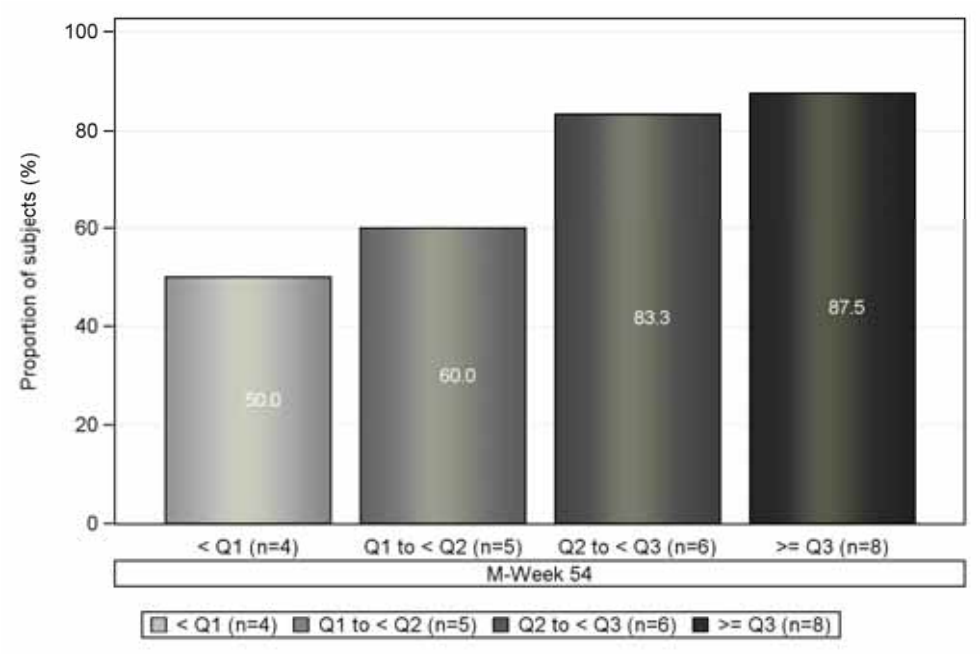


参照元: Re-analysis report for C0524T17 and C0524T18 54-Week
Appendix 3: Reanalyzed Tables and Figures in C0524T18 54-Week CSR Figure 14

図 2.7.2-18 ゴリムマブを反復皮下投与したときの 54 週の血清中ゴリムマブ濃度と 54 週までの clinical response 及び 30 週と 54 週の clinical remission との相関（6706，7257 及び 7407 を除く）

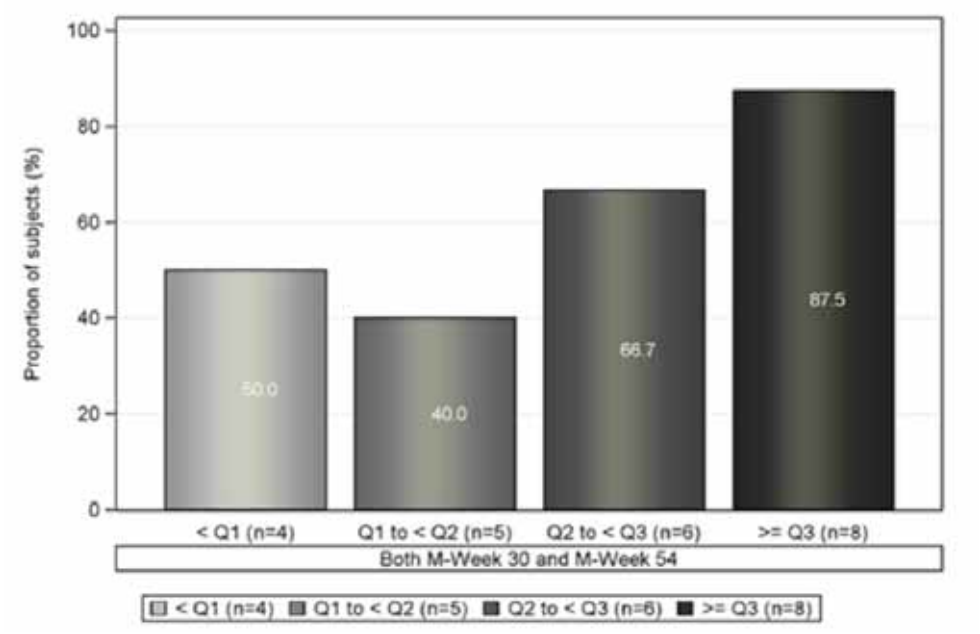
54 週までの clinical response 及び 30 週と 54 週の clinical remission が認められた被験者の割合のいずれも，血清中ゴリムマブ濃度が最も高かった被験者群において高値を示した。なお，C0524T18 試験では，ランダム化された日本人の被験者数が 12 例（プラセボ群 4 例，50 mg 群 3 例，100 mg 群 5 例）と限られていたため，日本人データのみによる検討は実施しなかった。

日本人潰瘍性大腸炎患者を対象にゴリムマブを反復皮下投与した試験（CNTO148UCO3001 試験）で，寛解導入として 200 mg→100 mg を皮下投与した後，6 週に clinical response が認められ，ランダム化された被験者に 100 mg を反復皮下投与したときの 54 週の血清中ゴリムマブ濃度を統合し，四分位値（第 1 四分位：3.26 μg/mL，中央値：4.81 μg/mL，第 3 四分位：6.04 μg/mL）により層別したときの各部分集団における 54 週までの clinical response 及び 30 週と 54 週の clinical remission が認められた被験者の割合を図 2.7.2-19 及び図 2.7.2-20 に示す。



Q1: 3.26 ug/mL, Q2: 4.81 ug/mL, Q3: 6.04 ug/mL
参照元：CNTO148UCO3001 試験治験総括報告書 Figure 6

図 2.7.2-19 ゴリムマブを反復皮下投与したときの 54 週（寛解維持期）の血清中ゴリムマブ濃度と 54 週までの clinical response との相関



Q1: 3.26 ug/mL, Q2: 4.81 ug/mL, Q3: 6.04 ug/mL
参照元：CNTO148UCO3001 試験治験総括報告書 Figure 7

図 2.7.2-20 ゴリムマブを反復皮下投与したときの 54 週（寛解維持期）の血清中ゴリムマブ濃度と 30 週と 54 週の clinical remission との相関

本臨床試験においても 54 週の血清中ゴリムマブ濃度が高値の群で，54 週まで clinical response 及び 30 週と 54 週の clinical remission が認められた被験者の割合が高かった。しかしながら，被験者数が限られていたことから，明確な結論は見出せなかった。

2.7.2.3.2 薬力学

2.7.2.3.2.1 QT/QTc 間隔に対する影響

ゴリムマブはヒト型 IgG_1 モノクローナル抗体であり，投与後，主として循環血中に局在し，血管外への分布が小さいと考えられることから（2.7.2.3.1.2），心筋細胞内への分布は制限されると考えられる。したがって，低分子化合物とは異なり，ゴリムマブが hERG チャネル機能を直接阻害する可能性は小さいことから，QT/QTc 評価を目的とした臨床試験は実施していない。

日本人及び外国人（白人）健康成人にゴリムマブ 200 mg 又は 400 mg を単回皮下投与したときの Fridericia 補正法による QTc（以下，QTcF）間隔を表 2.7.2-付録-9 に示す。

日本人及び外国人（白人）健康成人にゴリムマブ 200 mg 又は 400 mg を単回皮下投与したときの QTcF 間隔に臨床的に問題となる実測値又はベースラインからの変化は認められなかった。

また，日本人及び外国人潰瘍性大腸炎患者にゴリムマブを反復皮下又は単回静脈内投与したとき，QT/QTc 間隔延長が疑われる有害事象は認められなかった【2.7.4.2.1.1】。

2.7.2.3.2.2 潰瘍性大腸炎に関するバイオマーカー

【参考資料 5.3.5.4.1，参考資料 5.3.5.4.2】

寛解導入療法として，潰瘍性大腸炎患者にゴリムマブを単回静脈内（C0524T16 試験）及び反復皮下（C0524T17 試験）投与したときの血清検体及び直腸組織検体を採取し，疾患との関連性，ゴリムマブの影響及びゴリムマブの効果が認められた被験者群と認められなかった被験者群での相違の有無について検討した。

(1) 血清バイオマーカー

寛解導入療法として，潰瘍性大腸炎患者にゴリムマブを単回静脈内（C0524T16 試験）及び反復皮下（C0524T17 試験）投与したときの血清検体を用いて，以下のバイオマーカーについて検討した。

serum amyloid A protein (SAA)	plasminogen activator inhibitor-1 (PAI-1)
matrix metalloproteinase-9 (MMP-9)	hepatocyte growth factor (HGF)
soluble signaling proteins;	
soluble glycoprotein 130 (sgp130)	
soluble interleukin-6 receptor-1 (sIL-6R1)	
soluble interleukin-2 receptor-alpha (sIL-2Rα)	
soluble tumor necrosis factor receptor 1 (sTNFR1)	

C0524T16 試験で得られた血清検体を用いて，疾患との関連性の検討としてベースライン時のバイオマーカー濃度について，Mayo スコアとの相関を検討した。その結果，ベースライン時の HGF，MMP-9，SAA 及び TNFR1 濃度とベースライン時の Mayo スコアの間で弱い（$r<0.33$）な

がらも統計学的に有意な相関（p<0.05）が認められたことから，これらのバイオマーカーが疾患の重症度と関連していることが示唆された。また，ゴリムマブの影響の検討として，バイオマーカー濃度について投与前後で比較した。その結果，ゴリムマブ 4 mg/kg 群において，0 週に対して 2 週の MMP-9 濃度が有意に低下していたが，6 週まで維持されなかった。ベースライン時のバイオマーカー濃度について，6 週の clinical response の有無（clinical response が認められた被験者 25 例，clinical response が認められなかった被験者 24 例）で比較した。その結果，いずれのバイオマーカーも clinical response の有無との相関は認められなかった。また，clinical response が認められた被験者群と認められなかった被験者群で，2 週及び 6 週のバイオマーカー濃度の 0 週からの変化を比較した。その結果，clinical response が認められた被験者群では 0 週に対して 2 週及び 6 週の HGF 及び MMP-9 濃度が有意に低下していたのに対し，clinical response が認められなかった被験者群及びプラセボ群では有意な低下は認められなかった。

C0524T17 試験では，C0524T16 試験と同様に，ベースライン時の HGF，MMP-9，SAA 及び TNFR1 濃度とベースライン時の Mayo スコアで統計学的に有意な相関（p<0.05）が認められた。ゴリムマブ群において，0 週と比較して 6 週の MMP-9 濃度の低下が認められた。C0524T17 試験では，C0524T16 試験で認められたその他の相関は認められなかった。なお，C0524T17 試験での検討は C0524T16 試験よりも少数例であったことから（clinical response が認められた被験者 13 例，clinical response が認められなかった被験者 12 例），一部の検討において，C0524T16 試験と同様の結果が得られなかった可能性も考えられた。

両試験を通じたバイオマーカーの測定結果から，中等症から重症の潰瘍性大腸炎患者では，全身性の炎症症状及び組織リモデリングの兆候を有していることが示唆された。しかしながら，本試験では少数例での検討であったため，いずれのバイオマーカーでも Mayo スコアで示されるような疾患の重症度との相関を見出すことができなかった。いずれの試験においてもゴリムマブの投与により MMP-9 濃度の低下が認められたが，ゴリムマブの標的である TNFαは MMP-9 の発現調節及び活性化に関与していることから，ゴリムマブによる TNFαの阻害作用が直接的に MMP-9 濃度の低下に作用している可能性が考えられた。プラセボ群では MMP-9 濃度の低下が認められていないことからも，ゴリムマブ投与による MMP-9 濃度の低下はゴリムマブの影響であることを支持している。

(2) 直腸サンプルを用いた遺伝子発現解析

C0524T17 試験において，ベースライン時及び 6 週において直腸組織検体を採取し（87 例：プラセボ群 28 例，ゴリムマブ群 59 例），マイクロアレー解析を用いて mRNA の発現量を解析した。

6 週の遺伝子発現の 0 週からの変化をプラセボ群と各ゴリムマブ群で比較した。その結果，200 mg→100 mg 群では，遺伝子発現の有意な変化は認められなかったものの，400 mg→200 mg 群では，132 プローブで変化が認められた。また，ゴリムマブ群を併合して解析したとき，508 転写産物，390 遺伝子において影響が認められた（1.5 倍超の変化，false discovery rate adjusted p-value <0.05）。

Clinical response が認められた被験者群及び認められなかった被験者群の 6 週の遺伝子発現の 0 週からの変化を比較した。その結果，61 プローブで差が認められた。61 プローブ中 34 プローブ（56%）が，上記 508 転写産物と重なっていた。ゴリムマブにより clinical response が認められた被験者群では，14 遺伝子（AGT，BIRC3，CD86，CD163，CTSB，CXCL9，CXCL10，CXCL13，FADS1，FGR，ICAM1，KYNU，S100A8 及び SELP）で発現量の低下が認められた。発現量の低下が認められた遺伝子は好中球の活性化及び炎症に関与していることが知られている。CXCL9，CXCL10 及び CXCL13 は好中球ケモカイン，S100A8 は好中球に関連したものであった。
SLC26A2 及び CDHR1 は clinical response が認められた被験者群で発現量が増加していた。
Clinical response が認められなかった被験者群及びプラセボ群では 0 週と 6 週のサンプルで遺伝子発現に変化は認められなかった。

2.7.2.4 特別な試験

2.7.2.4.1 ゴリムマブに対する抗体（抗ゴリムマブ抗体）

2.7.2.4.1.1 抗ゴリムマブ抗体陽性率

寛解導入療法（C0524T16 試験又は C0524T17 試験）及び寛解維持療法（C0524T18 試験）において，寛解導入開始から寛解維持 54 週までの間での抗体陽性であった被験者の割合（抗ゴリムマブ抗体陽性率）を表 2.7.2-7 に示す。なお，プラセボ群において，52 週までに clinical response を消失し，ゴリムマブの投与を受けた被験者は 76 例であり，そのうち 4 例（5.3%）が抗ゴリムマブ抗体陽性であった。

表 2.7.2-7 寛解導入及び寛解維持療法（54 週まで）の抗ゴリムマブ抗体陽性率

寛解導入時の薬剤	プラセボ	ゴリムマブ				全体
寛解維持時の用量	100 mg	寛解維持療法に移行せず	プラセボ	50 mg	100 mg	
C0524T17→C0524T18						
投与被験者数	236	57	127	126	424	970
評価可能被験者数	224	45	127	126	424	946
抗体陽性被験者数	6 (2.7%)	2 (4.4%)	7 (5.5%)	3 (2.4%)	8 (1.9%)	26 (2.7%)
C0524T16 又は C0524T17→C0524T18						
投与被験者数	286	77	157	154	559	1233
評価可能被験者数	268	60	157	154	559	1198
抗体陽性被験者数	6 (2.2%)	2 (3.3%)	11 (7.0%)	4 (2.6%)	11 (2.0%)	34 (2.8%)

2.7.2.4.1.2 抗ゴリムマブ抗体陽性率に対する免疫抑制薬の影響

抗ゴリムマブ抗体陽性率に対する免疫抑制薬 6-MP，AZA 及び MTX 併用の影響について検討するため，6-MP，AZA 又は MTX 併用の有無別の抗ゴリムマブ抗体陽性率を表 2.7.2-8 に示す。

抗ゴリムマブ抗体陽性被験者は限られていたために，明確な結論は見出せなかったものの， 6-MP，AZA 又は MTX を併用していなかった被験者群では，寛解導入（C0524T16 試験又は C0524T17 試験）開始から寛解維持 54 週（C0524T18 試験）までに，抗ゴリムマブ抗体陽性被験者は 809 例中 28 例（3.5%）であったのに対し，6-MP，AZA 又は MTX を併用していた被験者群

では 389 例中 6 例（1.5%）と，6-MP，AZA 又は MTX を併用していたときの抗ゴリムマブ抗体陽性率が低値を示した。ゴリムマブの皮下投与による寛解導入（C0524T17 試験）開始から寛解維持 54 週（C0524T18 試験）までに，抗ゴリムマブ抗体陽性被験者は 638 例中 22 例（3.4%）であったのに対し，6-MP，AZA 又は MTX を併用していた被験者群では 308 例中 4 例（1.3%）であった。

表 2.7.2-8 抗ゴリムマブ抗体陽性率に対する免疫抑制薬 6-MP，AZA 及び MTX 併用の影響

寛解導入時の薬剤	プラセボ		ゴリムマブ								全体	
寛解維持時の用量	100 mg		寛解維持療法に移行せず		プラセボ		50 mg		100 mg			
免疫抑制薬併用の有無	なし	あり	なし	あり	なし	あり	なし	あり	なし	あり	なし	あり
C0524T17→C0524T18												
投与被験者数	162	74	36	21	80	47	88	38	290	134	656	314
評価可能被験者数	154	70	26	19	80	47	88	38	290	134	638	308
抗体陽性被験者数	6 (3.9%)	0 (0.0%)	0 (0.0%)	2 (10.5%)	7 (8.8%)	0 (0.0%)	2 (2.3%)	1 (2.6%)	7 (2.4%)	1 (0.7%)	22 (3.4%)	4 (1.3%)
C0524T16 又は C0524T17→C0524T18												
投与被験者数	192	94	52	25	104	53	107	47	380	179	835	398
評価可能被験者数	179	89	39	21	104	53	107	47	380	179	809	389
抗体陽性被験者数	6 (3.4%)	0 (0.0%)	0 (0.0%)	2 (9.5%)	10 (9.6%)	1 (1.9%)	3 (2.8%)	1 (2.1%)	9 (2.4%)	2 (1.1%)	28 (3.5%)	6 (1.5%)

2.7.2.4.1.3 有効性に対する抗ゴリムマブ抗体の影響

寛解維持療法（C0524T18 試験）においてランダム化された被験者に，プラセボ，ゴリムマブ 50 mg 及び 100 mg を 4 週ごとに反復皮下投与したときの 54 週までの clinical response について，抗ゴリムマブ抗体陽性及び陰性で層別したときの 54 週までの clinical response が認められた被験者の割合を表 2.7.2-9 に示す。

ランダム化された被験者にゴリムマブを 4 週ごとに反復皮下投与したときの 54 週までの clinical response が認められた被験者の割合は抗ゴリムマブ抗体陽性被験者群で，抗ゴリムマブ抗体陰性被験者群と比較して低値を示した。このことから，ゴリムマブを投与したとき，抗ゴリムマブ抗体陽性被験者群では，抗ゴリムマブ抗体陰性被験者群と比較して効果が低い傾向が示唆されたものの，抗ゴリムマブ抗体陽性被験者は限られていたために，明確な結論は見出せなかった。

表 2.7.2-9 潰瘍性大腸炎患者にプラセボ又はゴリムマブを反復皮下投与したときの抗ゴリムマブ抗体発現の有無別で層別した 54 週までの clinical response が認められた被験者数及び被験者割合（6706，7257 及び 7407 を除く）

	プラセボ [a,b)]	ゴリムマブ [a)]			全体
		50 mg	100 mg	全体	
ランダム化された被験者（6706，7257 及び 7407 を除く）	154	151	151	302	456
評価可能被験者 [c)]	153	149	145	294	447
抗ゴリムマブ抗体陽性被験者 [d,e)]	11 (7.2%)	4 (2.7%)	5 (3.4%)	9 (3.1%)	20 (4.5%)
54 週までの clinical response [f,g,h)]	5 (45.5%)	1 (25.0%)	1 (20.0%)	2 (22.2%)	7 (35.0%)
抗ゴリムマブ抗体陰性被験者 [d,i)]	142 (92.8%)	145 (97.3%)	140 (96.6%)	285 (96.9%)	427 (95.5%)
54 週までの clinical response [g,h,j)]	43 (30.3%)	70 (48.3%)	74 (52.9%)	144 (50.5%)	187 (43.8%)

a) 寛解維持開始時の投与群
b) 寛解導入において clinical response を示し，寛解維持療法においてプラセボを投与した被験者
c) 寛解維持療法において治験薬投与後，1 ポイント以上の検体が得られた被験者
d) 分母は評価可能被験者数
e) 寛解維持療法において，1 ポイント以上で抗ゴリムマブ抗体陽性の被験者
f) 分母は寛解維持療法において，1 ポイント以上で抗ゴリムマブ抗体陽性の被験者
g) 54 週までに，潰瘍性大腸炎治療において禁止された用量変更，造孔術，結腸切除，効果不十分による治験薬の用量調節及び投与中止を行った場合，clinical response が認められなかったとした。
h) 30 週及び 54 週の Mayo サブスコアが 4 つとも得られなかった場合，clinical response が認められなかったとした。
i) 寛解維持療法において抗ゴリムマブ抗体陽性の被験者を除く（血清中ゴリムマブ濃度が検出された被験者を含む）
j) 分母は寛解維持療法において，抗ゴリムマブ抗体陰性の被験者
参照元: Re-analysis report for C0524T17 and C0524T18 54-Week
Appendix 3: Re-analyzed Tables and Figures in C0524T18 54-Week CSR Attachment 3.81

日本人潰瘍性大腸炎患者を対象とした国内試験（CNTO148UCO3001）では，寛解導入後にゴリムマブ群にランダム化された被験者では，有効性の最終評価時点である寛解維持 54 週までに抗ゴリムマブ抗体陽性被験者は認められなかったため，本臨床試験では有効性に対する抗ゴリムマブ抗体の影響は評価できなかった。

2.7.2.4.1.4　抗ゴリムマブ抗体測定法の変更　【参考資料 5.3.1.4.3】

初回申請時に提出した血清中抗ゴリムマブ抗体測定法（旧測定法）は，血清検体中のゴリムマブの影響を受けるため，その影響を受けにくい新たな測定法（Drug-Tolerant EIA 法）を開発した【2.7.1.1.2.1】。Drug-Tolerant EIA 法にて C0524T16 試験，C0524T17 試験及び C0524T18 試験で得られた検体を測定したところ，ゴリムマブの投与を受けた 1195 例中 254 例（21.3%）の被験者が抗ゴリムマブ抗体陽性と判定された。一方で，旧測定法にて測定したところ，抗ゴリムマブ抗体陽性と判定された被験者は 34 例（2.8%）であった。抗ゴリムマブ抗体陽性率はおよそ 8 倍高くなっているものの，Drug-Tolerant EIA 法で新たに抗ゴリムマブ抗体陽性と判定された被験者の抗体価は概して低かった。抗体価により層別したところ，抗体価が低い（＜1:100）被験者群では薬物動態への影響はほとんど認められなかった。また，抗体価が高い（≧1:100）被験者群では，抗ゴリムマブ抗体陰性又は抗体価の低い被験者群と比較して血清中抗ゴリムマブ濃度は低値であった。また，有効性に関しては，C0524T18 試験でゴリムマブを投与され，Drug-Tolerant EIA 法にて抗ゴリムマブ抗体陽性と判定された被験者群では 54 週に clinical response を維持した被験者

の割合は 38.1%であり，抗ゴリムマブ抗体陰性と判定された被験者群（52.8%）より低かった。一方，C0524T18 試験でゴリムマブを投与され，旧測定法にて抗ゴリムマブ抗体陽性と判定された被験者群では 54 週に clinical response を維持した被験者の割合は 25%であり，抗ゴリムマブ抗体陰性と判定された被験者群（54.1%）より低く，旧測定法で得られた結果と Drug-Tolerant EIA 法を用いて判定した結果は一貫性を示している。血清中ゴリムマブ濃度と有効性に相関が認められていること（2.7.2.3.1.6）及び抗ゴリムマブ抗体陽性と判定された被験者のうち抗体価の低い被験者では薬物動態への影響は限定的であったことを考慮すると，抗体価の低い被験者において，抗ゴリムマブ抗体の発現は有効性に大きく影響しないものと考えられる。一方，抗体価の高い被験者の数は限られており，有効性に対する抗ゴリムマブ抗体の影響については結論を見出せなかった。

抗ゴリムマブ抗体陽性と判定された被験者のうち，抗体価の高い被験者のほとんどが旧測定法でも抗ゴリムマブ抗体陽性と判定されており，今回の測定法の変更で測定感度は高くなったものの，旧測定法から得られた結論を変更するものではなかった。

2.7.2.5 臨床薬理に関する結論

日本人及び外国人（白人）健康成人にゴリムマブ 200 mg 又は 400 mg 単回皮下投与したとき，ゴリムマブは緩徐に吸収され，血清中ゴリムマブは投与後 3.5～5.0 日に C_{max} に達した後，12.10～13.65 日の $T_{1/2}$ で消失した。また，みかけの分布容積が小さかったことから，ゴリムマブは投与後，主として循環血液中に局在することが示唆された。これらの結果は，日本人及び外国人（白人）健康成人にゴリムマブ 50 mg 又は 100 mg を単回皮下投与したときと同様であった。

日本人及び外国人健康成人にゴリムマブ 200 mg 又は 400 mg を単回皮下投与したときの C_{max} 及び AUC_{inf} はいずれも用量におおむね比例して増加した。また，CL/F 及び V_z/F は用量によらずおおむね一定であった。同様に，潰瘍性大腸炎患者に寛解導入療法として，ゴリムマブ 1 mg/kg，2 mg/kg，4 mg/kg を単回静脈内又はゴリムマブ 100 mg→50 mg，200 mg→100 mg，400 mg→200 mg を反復皮下投与したときの血清中ゴリムマブ濃度は，用量におおむね比例して増加した。寛解導入療法後に，寛解維持療法として，ゴリムマブ 50 mg 又は 100 mg を 4 週ごとに反復皮下投与したときの血清中ゴリムマブ濃度は用量におおむね比例して増加し，寛解維持開始 8 週までに定常状態に達した。

潰瘍性大腸炎患者にゴリムマブの皮下投与による寛解導入後に寛解維持療法としてゴリムマブを反復皮下投与したときの血清中ゴリムマブ濃度は，日本人と外国人の間で大きな差はなかった。潰瘍性大腸炎患者にゴリムマブを単回静脈内又は反復皮下投与したときの血清中ゴリムマブ濃度データを用いて PPK 解析を実施した結果，ゴリムマブを皮下投与したときの絶対的バイオアベイラビリティ及び $T_{1/2}$ はそれぞれ 52.2%及び 10.5 日と推定された。また，CL に対し，体重，アルブミン，ALK，CRP 及び抗ゴリムマブ抗体陽性が統計学的に有意な共変量であった。体重は，Q，V_2 及び V_3 に対しても，統計学的に有意な共変量であった。人種は統計学的に有意な共変量ではなかった。また，健康成人にゴリムマブを単回皮下投与したときのゴリムマブの薬物動態には，日本人と外国人の間で大きな差はなかった。

潰瘍性大腸炎患者にゴリムマブを反復皮下投与したときの clinical response 及び clinical remission が認められた被験者の割合は，いずれも，血清中ゴリムマブ濃度が高かった被験者群に

おいて，最も高値を示した。また，寛解導入療法において clinical response が認められなかった被験者群の血清中ゴリムマブ濃度は，clinical response が認められた被験者群と比較して低値であった。

潰瘍性大腸炎患者にゴリムマブを反復皮下投与したとき，寛解導入療法から寛解維持療法の 54 週までに 1198 例中 34 例（2.8%）で抗体陽性が認められた。抗ゴリムマブ抗体陽性被験者群での有効性は抗ゴリムマブ抗体陰性被験者群と比較して低い傾向が認められたが，抗ゴリムマブ抗体陽性被験者が限られていたため結論は見出せなかった。6-MP，AZA 又は MTX の併用により抗ゴリムマブ抗体陽性の被験者の割合が低下する傾向が認められた。日本人潰瘍性大腸炎患者に寛解導入としてゴリムマブを皮下投与したとき，寛解導入療法から寛解維持療法の 54 週までに 144 例中 13 例（9.0%）で抗体陽性が認められた。本臨床試験では抗ゴリムマブ抗体の発現による有効性への影響は検討できなかった。また，健康成人にゴリムマブを単回皮下投与したとき，投与後 12 週までに抗ゴリムマブ抗体陽性被験者は認められなかった。

2.7.2.6 付録

表 2.7.2-付録-1 潰瘍性大腸炎患者を対象とした臨床試験の要約（1）

試験番号 開発の相 （実施国） 施設数	試験の目的	試験デザイン	被験者の種類 被験者数 a) （男/女） 評価数 b) 平均体重（範囲）c) 平均年齢（範囲）d)		投与方法（用量, 投与経路） 100 mg→50 mg 皮下	 200 mg→100 mg 皮下	 400 mg→200 mg 皮下	試験報告書 添付場所
C0524T17 試験 第 II/III 相 （国際共同） 多施設	中等症から重症の活動期潰瘍性大腸炎患者を対象としたゴリムマブ皮下投与による寛解導入療法の安全性及び有効性の評価	多施設共同 ランダム化 プラセボ対照 二重盲検	潰瘍性大腸炎患者 1065 例 パート 1：169 例 パート 2：896 例 （596 例/469 例） 1064 例 73.54 (33.0, 149.7) kg 40.0 (18, 78) 歳	投与例数	71	331	332	[5.3.5.1.2]
				投与前				
				例数	67	323	327	
				平均値 (SD)	0.02 (0.029)	0.02 (0.013)	0.02 (0.048)	
				中央値	0.02	0.02	0.02	
				範囲	(0.0, 0.3)	(0.0, 0.2)	(0.0, 0.9)	
				2 週 投与前				
				例数	65	322	321	
				平均値 (SD)	2.61 (1.314)	6.40 (2.899)	12.61 (5.796)	
				中央値	2.34	6.27	11.95	
				範囲	(0.0, 6.5)	(0.2, 19.4)	(0.0, 38.0)	
				4 週				
				例数	65	308	311	
				平均値 (SD)	32.17 (237.636)	5.60 (2.767)	11.39 (5.684)	
				中央値	2.26	5.26	10.48	
				範囲	(0.4, 1918.5)	(0.0, 14.9)	(0.3, 34.8)	
				6 週				
				例数	60	292	285	
				平均値 (SD)	9.66 (67.345)	2.11 (1.477)	4.63 (3.197)	
				中央値	0.79	1.78	4.01	
				範囲	(0.0, 522.6)	(0.0, 8.9)	(0.0, 22.2)	

a)：ランダム化された被験者数，b)：ランダム化及び投与された被験者数，c)： ランダム化及び投与された被験者の平均値 (最小値, 最大値)，d)： ランダム化された被験者の平均値 (最小値, 最大値)

治験薬ロット番号

プラセボ：[redacted]

ゴリムマブ：[redacted]

表 2.7.2-付録-2 潰瘍性大腸炎患者を対象とした臨床試験の要約（2）

試験番号 開発の相 （実施国） 施設数	試験の目的	試験デザイン	被験者の種類 被験者数 a)（男/女） 評価数 b) 平均体重（範囲）c) 平均年齢（範囲）c)		投与方法（用量, 投与経路）						試験報告書 添付場所
					プラセボ 皮下	50 mg 皮下	100 mg 皮下				
							寛解導入 奏効例	寛解導入 プラセボ 無効例	寛解導入 ゴリムマブ 無効例	全体	
C0524T18 試験 第 III 相 （国際共同） 多施設	中等症から重症の活動期潰瘍性大腸炎患者を対象としたゴリムマブ皮下投与による寛解維持療法の安全性及び有効性の評価	多施設共同 ランダム化 プラセボ対照 二重盲検	潰瘍性大腸炎患者 1228 例 （700 例/528 例） 1228 例 73.54 (33.0, 150.0) kg 40.3 (18, 79) 歳	投与例数	156	154	154	230	405	789	[5.3.5.1.3]
				投与前							
				例数	154	153	153	227	396	776	
				平均値 (SD)	3.48 (3.280)	3.02 (2.726)	3.08 (2.811)	0.00 (0.003)	1.94 (1.897)	1.60 (2.150)	
				中央値	2.46	2.28	2.50	0.00	1.31	0.82	
				範囲	(0.0, 16.4)	(0.0, 13.2)	(0.0, 22.2)	(0.0, 0.0)	(0.0, 12.4)	(0.0, 22.2)	
				4 週 投与前							
				例数	143	150	148	218	361	727	
				平均値 (SD)	0.68 (0.732)	1.36 (1.508)	2.57 (9.518)	1.05 (0.670)	1.21 (1.024)	1.44 (4.396)	
				中央値	0.56	1.04	1.43	0.94	0.99	1.07	
				範囲	(0.0, 5.6)	(0.0, 13.9)	(0.0, 116.6)	(0.0, 4.3)	(0.0, 7.4)	(0.0, 116.6)	
				8 週 投与前							
				例数	127	133	140	188	312	640	
				平均値 (SD)	0.22 (0.279)	0.90 (0.661)	1.68 (1.052)	1.19 (0.864)	1.11 (0.821)	1.26 (0.916)	
				中央値	0.10	0.83	1.44	0.98	0.93	1.07	
				範囲	(0.0, 1.3)	(0.0, 3.9)	(0.0, 6.4)	(0.0, 6.0)	(0.0, 4.9)	(0.0, 6.4)	
				12 週 投与前							
				例数	106	130	131	169	290	590	
				平均値 (SD)	0.10 (0.246)	0.85 (0.633)	1.64 (1.141)	1.26 (0.890)	1.13 (0.862)	1.28 (0.957)	
				中央値	0.00	0.71	1.43	1.08	0.95	1.10	
				範囲	(0.0, 2.0)	(0.0, 3.1)	(0.0, 6.0)	(0.0, 5.3)	(0.0, 5.1)	(0.0, 6.0)	
				20 週 投与前							
				例数	91	116	121	145	240	506	
				平均値 (SD)	0.04 (0.217)	0.82 (0.645)	1.53 (0.985)	1.45 (1.237)	1.24 (1.084)	1.37 (1.113)	
				中央値	0.00	0.74	1.33	1.23	0.98	1.13	
				範囲	(0.0, 1.9)	(0.0, 3.2)	(0.0, 5.0)	(0.0, 8.8)	(0.0, 9.8)	(0.0, 9.8)	

a)：ランダム化された被験者数，b)：ランダム化及び投与された被験者数，c)： ランダム化された被験者の平均値 (最小値, 最大値)

表 2.7.2-付録-2 潰瘍性大腸炎患者を対象とした臨床試験の要約（2）（続き）

試験番号 開発の相 （実施国） 施設数	試験の目的	試験デザイン	被験者の種類 被験者数（男/女） 評価数 a)/登録数 b) 平均体重（範囲）c) 平均年齢（範囲）c)		投与方法（用量, 投与経路）						試験報告書 添付場所
					プラセボ 皮下	50 mg 皮下	100 mg 皮下				
							寛解導入 奏効例	寛解導入 プラセボ 無効例	寛解導入 ゴリムマブ 無効例	全体	
				28 週 投与前							
				例数	76	113	106	135	207	448	
				平均値 (SD)	0.03 (0.159)	0.78 (0.479)	1.70 (1.843)	1.40 (1.223)	1.26 (0.879)	1.41 (1.278)	
				中央値	0.00	0.79	1.41	1.09	1.12	1.15	
				範囲	(0.0, 1.3)	(0.0, 2.1)	(0.0, 17.8)	(0.0, 9.5)	(0.0, 5.5)	(0.0, 17.8)	
				30 週							
				例数	59	92	97	111	177	385	
				平均値 (SD)	0.04 (0.285)	1.92 (1.058)	4.27 (2.327)	3.96 (2.347)	3.57 (2.069)	3.86 (2.231)	
				中央値	0.00	1.73	3.81	3.63	3.36	3.55	
				範囲	(0.0, 2.2)	(0.0, 5.3)	(0.0, 10.7)	(0.0, 13.7)	(0.0, 12.0)	(0.0, 13.7)	
				36 週 投与前							
				例数	64	98	94	119	183	396	
				平均値 (SD)	0.05 (0.305)	0.78 (0.618)	1.90 (1.266)	1.68 (1.327)	1.31 (0.919)	1.56 (1.164)	
				中央値	0.00	0.69	1.58	1.42	1.15	1.33	
				範囲	(0.0, 2.2)	(0.0, 2.5)	(0.0, 6.5)	(0.0, 8.3)	(0.0, 4.1)	(0.0, 8.3)	
				44 週 投与前							
				例数	61	92	90	116	170	376	
				平均値 (SD)	0.10 (0.472)	0.89 (0.728)	1.77 (1.074)	1.57 (1.038)	1.35 (0.946)	1.52 (1.018)	
				中央値	0.00	0.73	1.58	1.32	1.22	1.34	
				範囲	(0.0, 3.2)	(0.0, 4.9)	(0.0, 4.8)	(0.0, 6.2)	(0.0, 4.6)	(0.0, 6.2)	
				54 週							
				例数	54	80	81	100	141	322	
				平均値 (SD)	0.00 (0.000)	2.09 (1.359)	4.10 (2.299)	4.05 (2.361)	3.34 (2.256)	3.75 (2.322)	
				中央値	0.00	1.81	3.52	3.56	2.77	3.18	
				範囲	(0.0, 0.0)	(0.0, 7.8)	(0.0, 11.6)	(0.0, 12.1)	(0.0, 15.2)	(0.0, 15.2)	

a)：ランダム化された被験者数，b)：ランダム化及び投与された被験者数，c)： ランダム化された被験者の平均値 (最小値, 最大値)

治験薬ロット番号

プラセボ：[redacted]

ゴリムマブ：[redacted]

表 2.7.2-付録-3 潰瘍性大腸炎患者を対象とした臨床試験の要約（3）

試験番号 開発の相 （実施国） 施設数	試験の目的	試験デザイン	被験者の種類 被験者数 a)（男/女） 評価数 b) 平均体重（範囲）c) 平均年齢（範囲）c)		投与方法（用量, 投与経路） 1 mg/kg 静脈内投与	 2 mg/kg 静脈内投与	 4 mg/kg 静脈内投与	試験報告書 添付場所
C0524T16 試験 第 II/III 相 （海外） 多施設	中等症から重症の活動期潰瘍性大腸炎患者を対象としたゴリムマブ静脈内投与による寛解導入療法の安全性及び有効性の評価	多施設共同 ランダム化 プラセボ対照 二重盲検	潰瘍性大腸炎患者 291 例 パート 1：176 例 パート 2：115 例 （174 例/117 例） 290 例 72.2 (35, 150) kg 41.0 (19, 79) 歳	投与例数	63	74	76	[5.3.5.1.1]
				投与前				
				例数	60	72	75	
				平均値 (SD)	0.54 (4.068)	0.05 (0.212)	0.02 (0.000)	
				中央値	0.02	0.02	0.02	
				範囲	(0.0, 31.5)	(0.0, 1.8)	(0.0, 0.0)	
				投与 1 時間後				
				例数	56	72	74	
				平均値 (SD)	21.58 (6.872)	48.20 (34.704)	81.87 (27.128)	
				中央値	21.28	42.16	77.54	
				範囲	(0.5, 33.1)	(26.0, 321.1)	(0.0, 216.7)	
				2 週				
				例数	56	71	71	
				平均値 (SD)	1.96 (0.930)	5.08 (2.417)	10.65 (3.987)	
				中央値	2.02	4.87	10.92	
				範囲	(0.0, 4.1)	(0.8, 11.6)	(3.1, 19.3)	
				4 週				
				例数	54	68	76	
				平均値 (SD)	0.62 (0.356)	1.73 (1.187)	3.79 (2.199)	
				中央値	0.69	1.51	3.57	
				範囲	(0.0, 1.4)	(0.0, 6.3)	(0.6, 10.6)	
				6 週				
				例数	48	64	68	
				平均値 (SD)	0.24 (0.233)	0.69 (0.633)	1.77 (1.468)	
				中央値	0.16	0.56	1.40	
				範囲	(0.0, 0.8)	(0.0, 3.2)	(0.1, 7.0)	

a)：ランダム化された被験者数，b)：ランダム化及び投与された被験者数，c)： ランダム化された被験者の平均値 (最小値, 最大値)

治験薬ロット番号

プラセボ：[redacted], [redacted]

ゴリムマブ：[redacted], [redacted]

表 2.7.2-付録-4 潰瘍性大腸炎患者を対象とした臨床試験の要約（4）

試験番号 開発の相 （実施国） 施設数	試験の目的	試験デザイン	被験者の種類 被験者数[a]（男/女） 平均体重（範囲）[b] 平均年齢（範囲）[b]		投与方法（用量, 投与経路） 200 mg→100 mg 皮下	
CNTO148UCO3001 試験 第 III 相 （日本） 多施設	中等症から重症の活動期潰瘍性大腸炎患者を対象としたゴリムマブ皮下投与による寛解維持療法の安全性及び有効性の評価	多施設共同 ランダム化 プラセボ対照 二重盲検	潰瘍性大腸炎患者 144 例 61.51（98 例/46 例） 61.2（42, 100）kg 42.4（18, 73）歳	投与例数	144	[5.3.5.1.5]
				投与前		
				例数	144	
				平均値 (SD)	0.00 (0.015)	
				中央値	0.00	
				範囲	(0.0; 0.2)	
				2 週　投与前		
				例数	144	
				平均値 (SD)	7.91 (2.984)	
				中央値	7.72	
				範囲	(1.0, 18.7)	
				4 週		
				例数	141	
				平均値 (SD)	7.21 (3.015)	
				中央値	7.06	
				範囲	(1.8, 16.9)	
				6 週　投与前		
				例数	140	
				平均値 (SD)	2.72 (1.578)	
				中央値	2.33	
				範囲	(0.4, 6.6)	

表 2.7.2-付録-4 潰瘍性大腸炎患者を対象とした臨床試験の要約（4）（続き）

試験番号 開発の相 （実施国） 施設数	試験の目的	試験デザイン	被験者の種類 被験者数 a)（男/女） 平均体重（範囲）b) 平均年齢（範囲）b)		投与方法（用量, 投与経路）		
						100 mg 皮下	
					プラセボ皮下	ランダム化された被験者	寛解導入無効例
				投与例数	30	31	52
				投与前			
				例数	30	31	52
				平均値 (SD)	3.42 (1.604)	2.92 (1.426)	2.68 (1.577)
				中央値	3.09	2.67	2.35
				範囲	(1.0; 6.3)	(0.4; 6.0)	(0.4, 6.6)
				4 週　投与前			
				例数	30	31	51
				平均値 (SD)	0.87 (0.517)	2.32 (1.083)	1.94 (1.244)
				中央値	0.79	2.04	1.70
				範囲	(0.0; 2.0)	(0.3; 5.2)	(0.3, 5.0)
				8 週　投与前			
				例数	22	30	19
				平均値 (SD)	0.26 (0.210)	2.16 (1.004)	1.65 (1.218)
				中央値	0.23	2.06	1.43
				範囲	(0.0; 0.8)	(0.3; 4.4)	(0.2, 4.9)
				12 週　投与前			
				例数	17	29	19
				平均値 (SD)	0.08 (0.102)	2.29 (1.180)	2.08 (1.197)
				中央値	0.00	2.07	2.05
				範囲	(0.0; 0.3)	(0.3; 5.3)	(0.3, 4.5)
				20 週　投与前			
				例数	15	27	19
				平均値 (SD)	0.00 (0.013)	2.20 (0.850)	1.70 (1.176)
				中央値	0.00	2.18	1.54
				範囲	(0.0; 0.0)	(0.7; 4.1)	(0.2, 4.7)
				28 週　投与前			
				例数	12	27	19
				平均値 (SD)	0.00 (0.000)	2.22 (0.868)	2.12 (1.548)
				中央値	0.00	2.02	1.64
				範囲	(0.0; 0.0)	(1.1; 4.2)	(0.2, 5.5)

表 2.7.2-付録-4 潰瘍性大腸炎患者を対象とした臨床試験の要約（4）（続き）

試験番号 開発の相 （実施国） 施設数	試験の目的	試験デザイン	被験者の種類 被験者数 a)（男/女） 平均体重（範囲）b) 平均年齢（範囲）b)		投与方法（用量, 投与経路）		
						100 mg 皮下	
					プラセボ皮下	ランダム化された被験者	寛解導入無効例
				30 週			
				例数	12	26	19
				平均値 (SD)	0.00 (0.014)	6.15 (2.663)	5.57 (3.413)
				中央値	0.00	5.68	4.48
				範囲	(0.0; 0.0)	(2.5; 13.7)	(1.2, 13.4)
				36 週　投与前			
				例数	9	26	18
				平均値 (SD)	0.00 (0.000)	2.50 (0.867)	2.40 (1.814)
				中央値	0.00	2.40	1.70
				範囲	(0.0; 0.0)	(1.1; 4.7)	(0.3, 6.2)
				44 週　投与前			
				例数	8	24	15
				平均値 (SD)	0.00 (0.000)	2.67 (1.166)	2.27 (1.785)
				中央値	0.00	2.41	1.87
				範囲	(0.0; 0.0)	(1.0; 5.3)	(0.5, 5.8)
				52 週　投与前			
				例数	8	25	15
				平均値 (SD)	0.00 (0.000)	2.47 (1.146)	2.12 (1.474)
				中央値	0.00	2.19	1.57
				範囲	(0.0; 0.0)	(0.8; 5.7)	(0.3, 5.3)
				54 週			
				例数	8	23	14
				平均値 (SD)	0.00 (0.000)	5.21 (2.071)	4.15 (2.617)
				中央値	0.00	5.09	3.86
				範囲	(0.0; 0.0)	(2.0; 9.1)	(1.3, 11.2)

a)：投与された被験者数，b)： 投与された被験者の平均値 (最小値, 最大値)

表 2.7.2-付録-4 潰瘍性大腸炎患者を対象とした臨床試験の要約（4）（続き）

試験番号 開発の相 （実施国） 施設数	試験の目的	試験デザイン	被験者の種類 被験者数 a)（男/女） 平均体重（範囲）b) 平均年齢（範囲）b)		投与方法（用量, 投与経路）		
						100 mg 皮下	
					プラセボ皮下	ランダム化された被験者	寛解導入無効例
			68 週				
				例数	11	26	56
				平均値 (SD)	0.00 (0.000)	0.08 (0.089)	0.05 (0.106)
				中央値	0.00	0.06	0.00
				範囲	(0.0; 0.0)	(0.0; 0.3)	(0.0, 0.4)

a)：投与された被験者数，b)： 投与された被験者の平均値 (最小値, 最大値)

表 2.7.2-付録-5 日本人及び外国人（白人）の健康成人における臨床試験の要約

試験番号 開発の相 （実施国） 施設数	試験の目的	試験デザイン	被験者の種類 被験者数（男/女） 評価数 a)/登録数 b) 平均体重（範囲）c) 平均年齢（範囲）c)	投与方法（剤型， 用量，投与経路） 人種， 年齢，体重（平均値）	薬物動態パラメータ 例数 平均値 (SD) 中央値						免疫原性 抗体陽性率 (%) (例数/評価数)	試験報告書 添付場所
					C_{max} (μg/mL)	T_{max} d) (day)	AUC_{inf} (μg·day/mL)	$T_{1/2}$ (day)	V_z/F (mL/kg)	CL/F (mL/day/kg)		
CNTO148NAP1001 第 I 相 （海外） 1 施設	日本人及び白人の健康成人男性にゴリムマブ 200 mg 及び 400 mg を単回皮下投与したときの薬物動態の評価，並びに，安全性，忍容性及び免疫原性の評価	単施設， ランダム化， 交互並行 プラセボ対照 二重盲検 単回投与	健康成人 49 例（49 例/0 例） 41 例/49 例	100 mg/mL 注射用液 200 mg, 皮下 日本人 29.6 歳，66.85 kg	11 15.85 (2.975) 16.60	11 5.00 (3.0, 6.0)	11 268.87 (51.789) 281.86	11 12.27 (1.479) 12.45	11 202.87 (38.263) 190.74	11 11.47 (1.658) 11.41	0.0 0 例/9 例	評価資料 [5.3.3.3.1]
			日本人（25 例） 66.68 kg （57.9, 79.9 kg） 28.4 歳 （21, 41 歳）	100 mg/mL 注射用液 400 mg, 皮下 日本人 27.9 歳，65.01 kg	10 31.32 (8.011) 30.68	10 3.50 (3.0, 5.0)	9 597.15 (175.583) 540.70	9 12.10 (1.258) 12.00	9 191.62 (50.072) 194.01	9 11.11 (3.157) 11.76	0.0 0 例/9 例	
			白人（24 例） 74.19 kg （56.1, 80.0 kg） 30.8 歳 （18, 45 歳）	100 mg/mL 注射用液 200 mg, 皮下 白人 33.2 歳，73.06 kg	10 13.20 (5.424) 12.44	10 3.50 (3.0, 4.0)	10 246.11 (86.155) 222.01	10 13.15 (3.178) 12.88	10 234.19 (98.168) 202.95	10 12.46 (4.288) 11.71	0.0 0 例/9 例	
				100 mg/mL 注射用液 400 mg, 皮下 白人 28.9 歳，74.51 kg	10 25.90 (5.872) 27.30	10 5.00 (2.0, 6.0)	10 535.54 (146.792) 517.64	10 13.65 (1.964) 13.52	10 204.55 (37.113) 198.38	10 10.55 (2.087) 10.75	0.0 0 例/9 例	

a)：薬物動態解析対象集団，b)：安全性解析対象集団，c)： 安全性解析対象集団の平均値（最小値，最大値），d)：例数，中央値，（最小値，最大値）

治験薬ロット番号

プラセボ：[redacted]

ゴリムマブ：[redacted]

表 2.7.2-付録-6 潰瘍性大腸炎患者にゴリムマブを反復皮下投与したときの
6 週までの血清中ゴリムマブ濃度 (μg/mL) （C0524T17 試験）

	200 mg → 100 mg		400 mg → 200 mg	
	日本人	外国人	日本人	外国人
投与被験者数	23	236	19	239
0 週　投与前				
例数	23	230	19	236
平均値 (SD)	0.02 (0.000)	0.02 (0.002)	0.02 (0.000)	0.02 (0.056)
中央値	0.02	0.02	0.02	0.02
範囲	(0.0, 0.0)	(0.0, 0.0)	(0.0, 0.0)	(0.0, 0.9)
2 週　投与前				
例数	22	229	19	230
平均値 (SD)	6.22 (2.298)	6.36 (2.832)	16.38 (8.182)	12.65 (5.533)
中央値	6.68	6.11	16.36	12.02
範囲	(2.4, 10.3)	(0.2, 19.4)	(5.5, 35.9)	(1.6, 38.0)
4 週				
例数	22	219	19	223
平均値 (SD)	5.59 (2.339)	5.53 (2.632)	13.60 (7.560)	11.42 (5.679)
中央値	5.63	5.22	13.07	10.57
範囲	(1.6, 11.7)	(0.0, 12.8)	(2.8, 32.8)	(0.3, 34.8)
6 週				
例数	21	202	19	206
平均値 (SD)	1.85 (1.020)	2.08 (1.414)	5.89 (5.414)	4.54 (3.006)
中央値	1.60	1.73	3.63	4.08
範囲	(0.3, 4.7)	(0.0, 6.7)	(0.9, 22.2)	(0.0, 16.4)

表 2.7.2-付録-7 潰瘍性大腸炎者にゴリムマブを反復皮下投与したときの血清中ゴリムマブ濃度（日本人）(μg/mL)（C0524T18 試験）

		血清中ゴリムマブ濃度（μg/mL）			
		ランダム化された被験者			全被験者
		プラセボ群	50 mg 群	100 mg 群	100 mg 群 [a)]
投与被験者数		4	3	5	51
0 週　投与前					
	例数	4	3	5	51
	平均値 (SD)	1.72 (1.169)	8.20 (4.360)	8.37 (7.945)	2.22 (3.903)
	中央値	1.94	8.91	4.83	1.11
	範囲	(0.3, 2.7)	(3.5, 12.2)	(2.3, 22.2)	(0.0, 22.2)
4 週　投与前					
	例数	4	3	5	48
	平均値 (SD)	0.37 (0.314)	4.21 (2.582)	2.68 (1.546)	1.47 (1.409)
	中央値	0.35	5.30	2.18	1.07
	範囲	(0.0, 0.8)	(1.3, 6.1)	(0.7, 4.6)	(0.3, 7.4)
8 週　投与前					
	例数	3	3	4	45
	平均値 (SD)	0.12 (0.163)	1.20 (0.432)	2.97 (1.462)	1.24 (0.902)
	中央値	0.05	1.04	2.69	1.04
	範囲	(0.0, 0.3)	(0.9, 1.7)	(1.7, 4.8)	(0.1, 4.8)
12 週　投与前					
	例数	2	2	4	45
	平均値 (SD)	0.00 (0.000)	0.89 (0.612)	2.18 (0.621)	1.12 (0.696)
	中央値	0.00	0.89	2.12	1.05
	範囲	(0.0, 0.0)	(0.5, 1.3)	(1.5, 3.0)	(0.1, 3.1)
20 週　投与前					
	例数	1	1	4	40
	平均値 (SD)	0.00	1.77	2.37 (1.072)	1.29 (0.792)
	中央値	0.00	1.77	2.62	1.15
	範囲	(0.0, 0.0)	(1.8, 1.8)	(1.0, 3.2)	(0.0, 3.2)
28 週　投与前					
	例数	1	0	4	37
	平均値 (SD)	0.00	NA	6.52 (7.650)	1.64 (2.845)
	中央値	0.00	NA	3.38	1.13
	範囲	(0.0, 0.0)	(NA, NA)	(1.5, 17.8)	(0.1, 17.8)
30 週					
	例数	1	0	4	31
	平均値 (SD)	0.00	NA	6.95 (3.038)	4.45 (2.310)
	中央値	0.00	NA	6.87	3.90
	範囲	(0.0, 0.0)	(NA, NA)	(3.5, 10.5)	(1.3, 10.5)
36 週　投与前					
	例数	1	0	4	29
	平均値 (SD)	0.00	NA	3.95 (2.180)	1.69 (1.433)
	中央値	0.00	NA	3.86	1.02
	範囲	(0.0, 0.0)	(NA, NA)	(1.5, 6.5)	(0.3, 6.5)
44 週　投与前					
	例数	1	0	4	27
	平均値 (SD)	0.00	NA	3.18 (1.447)	1.81 (1.270)
	中央値	0.00	NA	3.29	1.48
	範囲	(0.0, 0.0)	(NA, NA)	(1.3, 4.8)	(0.1, 4.8)
54 週					
	例数	1	0	4	26
	平均値 (SD)	0.00	NA	7.02 (4.235)	4.60 (2.984)
	中央値	0.00	NA	7.21	4.34
	範囲	(0.0, 0.0)	(NA, NA)	(2.1, 11.6)	(0.5, 11.6)

a) ランダム化された被験者，プラセボ又はゴリムマブによる寛解導入療法で clinical response が認められなかった被験者を含む
NA: 算出せず

表 2.7.2-付録-7 潰瘍性大腸炎患者にゴリムマブを反復皮下投与したときの血清中ゴリムマブ濃度（外国人）(μg/mL)（C0524T18 試験）（続き）

		血清中ゴリムマブ濃度（μg/mL）			
		ランダム化された被験者			全被験者
		プラセボ群	50 mg 群	100 mg 群	100 mg 群 [a]
投与被験者数		152	151	149	738
0 週　投与前					
	例数	150	150	148	725
	平均値 (SD)	3.53 (3.307)	2.91 (2.603)	2.90 (2.339)	1.55 (1.967)
	中央値	2.46	2.24	2.28	0.80
	範囲	(0.0, 16.4)	(0.0, 13.2)	(0.0, 12.5)	(0.0, 12.5)
4 週　投与前					
	例数	139	147	143	679
	平均値 (SD)	0.69 (0.739)	1.30 (1.435)	2.56 (9.681)	1.44 (4.534)
	中央値	0.58	1.03	1.43	1.07
	範囲	(0.0, 5.6)	(0.0, 13.9)	(0.0, 116.6)	(0.0, 116.6)
8 週　投与前					
	例数	124	130	136	595
	平均値 (SD)	0.22 (0.281)	0.90 (0.665)	1.64 (1.020)	1.26 (0.917)
	中央値	0.10	0.82	1.43	1.07
	範囲	(0.0, 1.3)	(0.0, 3.9)	(0.0, 6.4)	(0.0, 6.4)
12 週　投与前					
	例数	104	128	127	545
	平均値 (SD)	0.10 (0.248)	0.85 (0.636)	1.62 (1.151)	1.29 (0.975)
	中央値	0.00	0.71	1.41	1.10
	範囲	(0.0, 2.0)	(0.0, 3.1)	(0.0, 6.0)	(0.0, 6.0)
20 週　投与前					
	例数	90	115	117	466
	平均値 (SD)	0.04 (0.218)	0.81 (0.642)	1.50 (0.974)	1.37 (1.137)
	中央値	0.00	0.74	1.29	1.13
	範囲	(0.0, 1.9)	(0.0, 3.2)	(0.0, 5.0)	(0.0, 9.8)
28 週　投与前					
	例数	75	113	102	411
	平均値 (SD)	0.03 (0.160)	0.78 (0.479)	1.52 (0.916)	1.39 (1.032)
	中央値	0.00	0.79	1.37	1.16
	範囲	(0.0, 1.3)	(0.0, 2.1)	(0.0, 6.2)	(0.0, 9.5)
30 週					
	例数	58	92	93	354
	平均値 (SD)	0.04 (0.288)	1.92 (1.058)	4.15 (2.242)	3.81 (2.220)
	中央値	0.00	1.73	3.81	3.47
	範囲	(0.0, 2.2)	(0.0, 5.3)	(0.0, 10.7)	(0.0, 13.7)
36 週　投与前					
	例数	63	98	90	367
	平均値 (SD)	0.05 (0.307)	0.78 (0.618)	1.81 (1.148)	1.55 (1.142)
	中央値	0.00	0.69	1.56	1.34
	範囲	(0.0, 2.2)	(0.0, 2.5)	(0.0, 5.6)	(0.0, 8.3)
44 週　投与前					
	例数	60	92	86	349
	平均値 (SD)	0.10 (0.476)	0.89 (0.728)	1.71 (1.018)	1.49 (0.995)
	中央値	0.00	0.73	1.57	1.31
	範囲	(0.0, 3.2)	(0.0, 4.9)	(0.0, 4.7)	(0.0, 6.2)
54 週					
	例数	53	80	77	296
	平均値 (SD)	0.00 (0.000)	2.09 (1.359)	3.95 (2.093)	3.68 (2.245)
	中央値	0.00	1.81	3.49	3.12
	範囲	(0.0, 0.0)	(0.0, 7.8)	(0.0, 9.5)	(0.0, 15.2)

a) ランダム化された被験者，プラセボ又はゴリムマブによる寛解導入療法で clinical response が認められなかった被験者を含む

表 2.7.2-付録-8 C0524T18 試験継続投与にて潰瘍性大腸炎患者にゴリムマブを反復皮下投与したときの 228 週までの血清中ゴリムマブ濃度(μg/mL)

	0 週で割り付けられたゴリムマブ群	
	50 mg[a),b)]	100 mg[a),b)]
投与被験者数	93	91
54 週		
例数	73	77
平均値 (SD)	2.09 (1.395)	4.08 (2.364)
中央値	1.82	3.49
範囲	(0.0; 7.8)	(0.0; 11.6)
80 週，投与前		
例数	75	75
平均値 (SD)	1.18 (0.934)	2.27 (1.779)
中央値	0.98	1.71
範囲	(0.0; 5.9)	(0.0; 10.0)
104 週，投与前		
例数	66	69
平均値 (SD)	1.18 (0.797)	2.13 (1.486)
中央値	0.93	1.69
範囲	(0.0; 3.5)	(0.0; 7.7)
128 週，投与前		
例数	59	62
平均値 (SD)	1.20 (0.794)	1.95 (1.272)
中央値	0.91	1.59
範囲	(0.0; 3.5)	(0.0; 6.1)
152 週，投与前		
例数	57	56
平均値 (SD)	1.29 (1.144)	2.10 (1.954)
中央値	0.92	1.57
範囲	(0.0; 6.0)	(0.0; 12.5)
176 週，投与前		
例数	53	54
平均値 (SD)	1.19 (0.749)	2.04 (1.413)
中央値	1.01	1.63
範囲	(0.0; 3.7)	(0.0; 6.4)
200 週，投与前		
例数	48	47
平均値 (SD)	1.35 (1.560)	2.13 (1.585)
中央値	0.99	1.65
範囲	(0.0; 9.9)	(0.0; 7.5)
216 週		
例数	41	37
平均値 (SD)	1.07 (0.871)	2.11 (1.675)
中央値	0.85	1.59
範囲	(0.0; 4.6)	(0.0; 9.1)
228 週		
例数	31	27
平均値 (SD)	0.27 (1.022)	0.64 (2.039)
中央値	0.00	0.00
範囲	(0.0; 5.3)	(0.0; 10.1)

a) 用量を増量した被験者は増量の直前までのデータを含む
b) 54 週以前に用量を調節した被験者を除く

表 2.7.2-付録-9 日本人及び外国人（白人）健康成人にゴリムマブを単回皮下投与したときの QTcF 間隔（CNTO148NAP1001 試験）

	プラセボ			ゴリムマブ				
				200 mg		400 mg		全体
	日本人	白人	全体	日本人	白人	日本人	白人	
ベースライン								
例数	4	4	8	11	10	10	10	41
平均値 (SD)	405.7 (12.41)	408.4 (13.56)	407.0 (12.12)	413.7 (14.61)	405.9 (15.46)	401.6 (13.46)	402.7 (16.11)	406.2 (15.17)
中央値	404.5	411.1	406.2	411.2	404.6	403.7	407.2	405.7
範囲	(392, 422)	(390, 421)	(390, 422)	(396, 452)	(379, 433)	(378, 420)	(368, 422)	(368, 452)
4 日後								
実測値								
例数	4	4	8	11	10	10	10	41
平均値 (SD)	407.7 (12.51)	410.7 (16.70)	409.2 (13.75)	404.3 (13.73)	409.2 (21.33)	401.0 (14.08)	404.6 (8.10)	404.8 (14.74)
中央値	408.9	409.3	408.9	403.6	404.2	397.9	404.7	402.4
範囲	(391, 422)	(393, 432)	(391, 432)	(377, 433)	(374, 451)	(382, 425)	(393, 416)	(374, 451)
変化量 [a)]								
例数	4	4	8	11	10	10	10	41
平均値 (SD)	2.0 (17.90)	2.3 (26.21)	2.2 (20.78)	-9.5 (10.47)	3.3 (14.84)	-0.6 (8.10)	1.9 (13.22)	-1.4 (12.54)
中央値	2.1	-9.3	-8.8	-12.4	-2.2	4.3	-2.6	-2.7
範囲	(-15, 19)	(-13, 41)	(-15, 41)	(-24, 7)	(-11, 32)	(-16, 6)	(-17, 25)	(-24, 32)
7 日後								
実測値								
例数	4	4	8	11	10	10	10	41
平均値 (SD)	398.1 (13.90)	409.7 (12.95)	403.9 (13.91)	408.3 (11.92)	398.4 (15.22)	399.3 (12.94)	399.6 (9.94)	401.6 (12.84)
中央値	398.7	410.8	406.7	409.5	399.4	396.9	400.7	401.1
範囲	(382, 413)	(393, 424)	(382, 424)	(388, 431)	(377, 431)	(383, 422)	(379, 413)	(377, 431)
変化量 [a)]								
例数	4	4	8	11	10	10	10	41
平均値 (SD)	-7.6 (15.94)	1.3 (21.81)	-3.1 (18.32)	-5.4 (10.17)	-7.5 (7.30)	-2.3 (6.83)	-3.1 (9.37)	-4.6 (8.50)
中央値	-8.0	-7.9	-7.9	-4.1	-7.8	-2.5	-4.4	-4.0
範囲	(-25, 10)	(-13, 34)	(-25, 34)	(-21, 8)	(-19, 4)	(-13, 8)	(-20, 11)	(-21, 11)
78 日後								
実測値								
例数	4	4	8	9	9	9	9	36
平均値 (SD)	404.6 (5.41)	413.3 (25.15)	408.9 (17.48)	416.5 (15.74)	406.6 (22.70)	410.0 (13.19)	411.5 (24.21)	411.2 (19.00)
中央値	402.5	407.0	402.5	415.2	404.2	406.0	406.9	408.3
範囲	(401, 412)	(391, 448)	(391, 448)	(394, 445)	(374, 441)	(390, 432)	(384, 451)	(374, 451)
変化量 [a)]								
例数	4	4	8	9	9	9	9	36
平均値 (SD)	-1.1 (13.33)	5.0 (15.22)	1.9 (13.63)	0.4 (9.91)	-1.0 (10.65)	10.5 (15.12)	11.0 (21.79)	5.2 (15.52)
中央値	1.9	-0.9	-0.9	-1.8	-3.6	6.7	4.6	4.3
範囲	(-18, 10)	(-6, 27)	(-18, 27)	(-17, 13)	(-17, 17)	(-2, 49)	(-27, 45)	(-27, 49)

a) ベースラインからの変化量

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2） Fasanmade AA, et al. Population pharmacokinetic analysis of infliximab in patients with ulcerative colitis. Eur J Clin Pharmacol. 2009;65:1211-28.

3） Fasanmade AA. et al. Serum albumin concentration: a predictive factor of infliximab pharmacokinetics and clinical response in patients with ulcerative colitis. J Clin Pharmacol Ther. 2010;48(5):297-308.

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略号一覧表

略号又は略称	名称及び内容
5-ASA	5-aminosalicylate（5-アミノサリチル酸）
6-MP	6-mercaptopurine（6-メルカプトプリン）
ANCOVA	analysis of covariance（共分散分析）
ANOVA	analysis of variance（分散分析）
AZA	Azathioprine（アザチオプリン）
CMH	Cochran-Mantel-Haenszel
CRP	C-reactive protein（C 反応性蛋白）
CSR	clinical study report（治験総括報告書）
IBDQ	inflammatory bowel disease questionnaire（炎症性腸疾患調査票）
QOL	quality of life（生活の質）
SCE	Summary of Clinical Efficacy
TNFα	tumor necrosis factor-alpha（腫瘍壊死因子 α）
UC	ulcerative colitis（潰瘍性大腸炎）

2.7.3 臨床的有効性

2.7.3.1 背景及び概観

臨床的有効性の評価に用いた臨床試験を表 2.7.3-1 に示す。

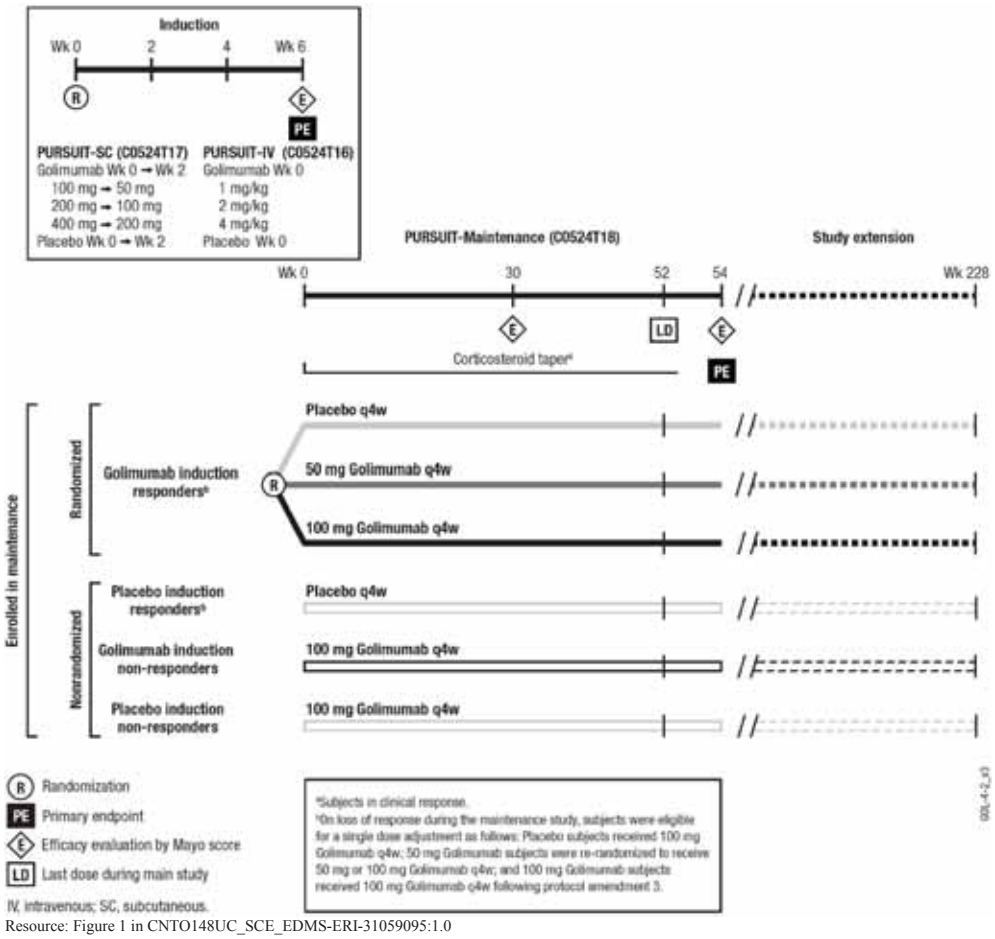
中等症から重症の活動期潰瘍性大腸炎（UC）患者にゴリムマブを皮下投与したときの有効性は，国際共同試験 2 試験［C0524T17 及び C0524T18 試験（T17 及び T18 試験）］及び国内臨床試験［CNTO148UCO3001 試験（UCO3001 試験）］の成績に基づいて評価した（評価資料）。中等症から重症の活動期 UC 患者にゴリムマブを単回静脈内投与した臨床試験［C0524T16 試験（T16 試験）］の成績は参考資料とした。

表 2.7.3-1 臨床的有効性評価に用いた臨床試験一覧

試験番号 開発の相 評価／参考資料番号	試験デザイン	投与量・投与方法	対象	有効性の主要評価項目	進捗状況 組入れ被験者数
T16 第 II/III 相 参考資料 【5.3.5.1.1】	国際共同 ランダム化 二重盲検 プラセボ対照	Part 1：投与量探索パート ゴリムマブ 1，2，4 mg/kg 又はプラセボを単回静脈内投与 Part 2：検証パート ゴリムマブ 2，4 mg/kg 又はプラセボを単回静脈内投与	UC 患者	6 週の clinical response	中止 291 例
T17 第 II/III 相 評価資料 【5.3.5.1.2】 【5.3.5.1.4】	国際共同[*1] ランダム化 二重盲検 プラセボ対照	Part 1：投与量探索パート 0 及び 2 週にゴリムマブ（100→50 mg，200→100 mg，400→200 mg）又はプラセボを皮下投与 Part 2：検証パート 0 及び 2 週にゴリムマブ（200→100 mg，400→200 mg）又はプラセボを皮下投与	UC 患者	6 週の clinical response	完了 1065 例 （72 例）[*2]
T18 第 III 相 評価資料 【5.3.5.1.3-1】 【5.3.5.1.3-2】 【5.3.5.1.4】	国際共同[*1] ランダム化 二重盲検 プラセボ対照	54 週まで（二重盲検／非盲検）： ゴリムマブ 50，100 mg 又はプラセボを 52 週まで 4 週ごとに皮下投与 54 週以降の継続試験： ゴリムマブ 50，100 mg 又はプラセボを 56 週から最長 212 週まで 4 週ごとに皮下投与	T16 又は T17 試験の被験者	54 週までの clinical response	完了 1228 例 （62 例）[*2]
UCO3001 第 III 相 評価資料 【5.3.5.1.5】	多施設共同 ランダム化 二重盲検 プラセボ対照	寛解導入期（非盲検）： 0 及び 2 週にゴリムマブ（200→100 mg）を皮下投与 寛解維持期（二重盲検／非盲検）： ゴリムマブ 100 mg 又はプラセボを 4 週ごとに皮下投与（最長 52 週）	日本人 UC 患者	54 週までの clinical response	完了 寛解導入期 144 例 寛解維持期 123 例

[*1]：日本が参加した国際共同試験，[*2]：日本人被験者数，xxx→yyy mg：0 週の投与量→2 週の投与量

T16 及び T17 試験は，それぞれゴリムマブを静脈内投与及び皮下投与する寛解導入試験であり，いずれもランダム化，二重盲検，プラセボ対照試験である。T18 試験は，ゴリムマブを皮下投与する寛解維持試験であり，T16 又は T17 試験において，6 週に clinical response が認められた被験者を対象としたランダム化，二重盲検，プラセボ対照試験である（図 2.7.3-1）。



Resource: Figure 1 in CNTO148UC_SCE_EDMS-ERI-31059095:1.0

図 2.7.3-1 国際共同試験（T16，T17 及び T18 試験）

T16 及び T17 試験では，いずれも Part 1 データの解析にて投与量を選択し，Part 2 にて有効性等を検証する計画であった。しかし，T16 試験 Part 1 の有効性は予測より低い結果であったこと，T16 試験 Part 1 と比べて T17 試験 Part 1 の結果が良好であったこと，単回静脈内投与では 6 週での効果を得るために必要な血清中濃度が十分に得られないと考えられたことから，T16 試験 Part 2 への被験者の登録を中止した（2.7.3.2.1(1)）。そのため，Part 2 検証パートを完了したのは T17 試験のみである。

日本は，T17 試験 Part 2（投与量選択後）及び T18 試験に参加した。T17 試験 Part 2（投与量選択後）の主要評価項目及び主な副次評価項目の日本人集団の結果は，いずれも試験全体より低かったが，試験全体の結果とおおむね一貫していた（2.7.3.3.3.1(1)）。一方，T18 試験で維持期 0 週にランダム化された日本人は 12 例と少数であったため，試験全体との比較が困難であった（2.7.3.3.3.1(2)）。そこで，日本人の活動期 UC 患者を対象とした UCO3001 試験を実施し，ゴリムマブ皮下投与による寛解維持療法の有効性を評価した。その結果，T18 試験と UCO3001 試験の有効性の結果は類似しており，日本人患者においてもゴリムマブによる寛解維持効果が期待できると判断した（2.7.3.3.2.2）。

有効性の主要解析対象集団は，T17 試験では投与量選択後の Part 2 でランダム化された被験者，T18 及び UCO3001 試験ではランダム化された被験者とした。

なお，FDA（Food and Drug Administration）への申請時には，有効性データから重大な逸脱が認められた 2 施設（施設番号 6706 及び 7257）の被験者を除外していたが，申請後に重大な逸脱

が新たに認められた（施設番号 7407）。主要評価項目及び主な副次評価項目について，当該施設（施設番号 7407）の被験者を除外した解析の結果は，2 施設の被験者を除外した解析結果と大きな違いはなく，結論は変わらなかった（【5.3.5.1.2】及び【5.3.5.1.3-1】の Correction report）。今回，日本での申請にあたって，主要評価項目及び主な副次評価項目以外の有効性評価項目についても当該施設（施設番号 7407）の被験者を除外して解析した。その結果は 2 施設の被験者を除外した解析結果と大きな違いはなく，結論は変わらないことを確認した【5.3.5.1.4】。そこで，今回提出する有効性については，重大な逸脱が認められた 3 施設（施設番号 6706，7257 及び 7407）の被験者を除外した結果を記載した。

2.7.3.1.1 試験デザイン

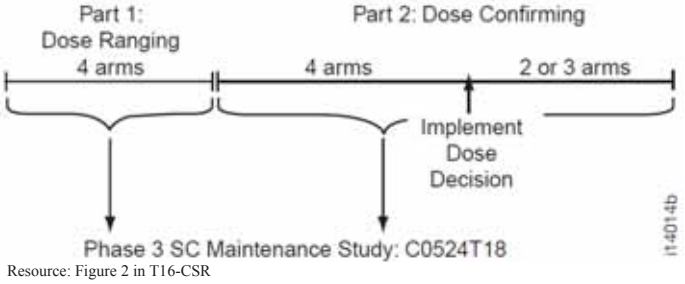
(1) T16 試験

【参考資料 5.3.5.1.1】

T16 試験は，中等症から重症の活動期 UC 患者にゴリムマブを単回静脈内投与したときの寛解導入療法の安全性及び有効性を評価する国際共同，ランダム化，二重盲検，プラセボ対照試験である。本試験では，ベースラインの Mayo スコアが 6～12 点かつ内視鏡検査サブスコアが 2 点以上で，生検により UC と確定診断された外来患者であり，経口 5-アミノサリチル酸（5-ASA），経口コルチコステロイド，アザチオプリン（AZA）若しくは 6-メルカプトプリン（6-MP）の効果が不十分であった患者，又はこれらの薬剤に対する忍容性が不良であった患者を対象とした。また，コルチコステロイドを漸減すると UC の症状が再燃する患者も対象とした。抗 TNFα 薬の投与歴を有する患者は，本試験の対象としなかった。目標被験者数は Part 1 が 176 例，Part 2 が約 500 例であった。

本試験のデザインを図 2.7.3-2 に示す。Part 1 にて投与量を探索し，Part 2 では Part 1 データの解析（中間解析）にて選択した投与量にて有効性等を検証する計画であった。Part 1 に組み入れる被験者を層別因子（実施施設）で調整して，ゴリムマブ 1，2，4 mg/kg 又はプラセボ群に 1:1:1:1 の比でランダムに割り付けた。また，Part 1 データの解析が完了し，Part 2 の投与量を選択するまで，Part 2 に組み入れる被験者は，Part 1 と同様に 4 群にランダムに割り付けた。Part 2 の投与量選択後，新たに Part 2 に組み入れる被験者を，プラセボを含む投与群に 1:1:1 の比でランダムに割り付けた。

本試験の 6 週の評価を完了した被験者は，T18 試験に参加することができた。T18 試験に参加しない被験者は，治験薬投与後 16 週まで後観察期として安全性を評価した。



Resource: Figure 2 in T16-CSR

図 2.7.3-2 T16 試験のデザイン

(2) T17 試験

【評価資料 5.3.5.1.2】【評価資料 5.3.5.1.4】

T17 試験は，中等症から重症の活動期 UC 患者にゴリムマブを皮下投与したときの寛解導入療法の安全性及び有効性を評価する国際共同，ランダム化，二重盲検，プラセボ対照試験である。本試験では，ベースラインの Mayo スコアが 6～12 点かつ内視鏡検査サブスコアが 2 点以上で，生検により UC と確定診断された外来患者であり，経口 5-ASA，経口コルチコステロイド，AZA 若しくは 6-MP の効果が不十分であった患者，又はこれらの薬剤に対する忍容性が不良であった患者を対象とした。また，コルチコステロイドを漸減すると UC の症状が再燃する患者も対象とした。抗 TNFα 薬の投与歴を有する患者は，本試験の対象としなかった。目標被験者数は Part 1 が 176 例，Part 2 が約 500 例であった。なお，主要解析対象集団の変更（Part 2 の投与量選択後の被験者に変更）による検出力確保，及び T16 試験 Part 2 の新たな被験者の登録中止による T18 試験の被験者数確保のため，Part 2 の目標被験者数を 875 例に変更した。

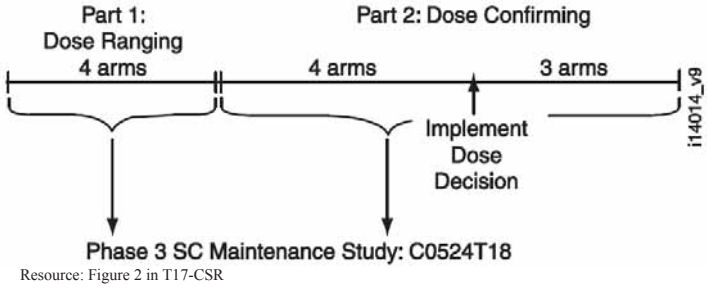
本試験のデザインを図 2.7.3-3 に示す。Part 1 にて投与量を探索し，Part 2 では Part 1 データの解析（中間解析）にて選択した投与量にて有効性等を検証した。Part 1 に組み入れる被験者を層別因子（実施施設）で調整して，下記 4 群に 1:1:1:1 の比でランダムに割り付けた。また，Part 1 データの解析が完了し，Part 2 の投与量を選択するまで，Part 2 に組み入れる被験者は，Part 1 と同様に下記 4 群にランダムに割り付けた。

- 100→50 mg 群：ゴリムマブを 0 週に 100 mg 及び 2 週に 50 mg 皮下投与
- 200→100 mg 群：ゴリムマブを 0 週に 200 mg 及び 2 週に 100 mg 皮下投与
- 400→200 mg 群：ゴリムマブを 0 週に 400 mg 及び 2 週に 200 mg 皮下投与
- プラセボ群：プラセボを 0 週及び 2 週に皮下投与

Part 2 の投与量選択後，新たに Part 2 に組み入れる被験者を，プラセボを含む投与群に 1:1:1 の比でランダムに割り付けた。

本試験の 6 週の評価を完了した被験者は，T18 試験に参加することができた。T18 試験に参加しない被験者は，治験薬最終投与後 16 週まで後観察期として安全性を評価した。

本試験 Part 2 の投与量選択後に，日本の治験実施施設は本試験に参加した。日本人の目標被験者数は，日本人集団及び試験全体の有効性（主要有効性評価項目）の一貫性を評価するために，50 例以上とした。



Resource: Figure 2 in T17-CSR

図 2.7.3-3 T17 試験のデザイン

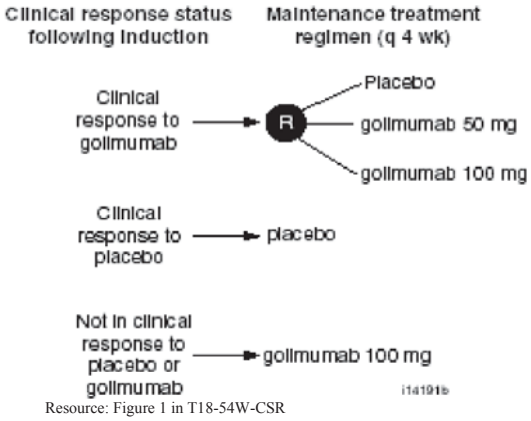
(3) T18 試験

【評価資料 5.3.5.1.3-1】【評価資料 5.3.5.1.3-2】【評価資料 5.3.5.1.4】

T18 試験は，T16 又は T17 試験のゴリムマブ群で clinical response が認められた被験者（ゴリムマブ寛解導入 responder）にゴリムマブを皮下投与したときの寛解維持療法の安全性及び有効性を評価する国際共同，ランダム化，二重盲検，プラセボ対照試験，及び 54 週の評価を完了した被験者に 56 週から最長 212 週までゴリムマブ又はプラセボを皮下投与する継続投与試験である。

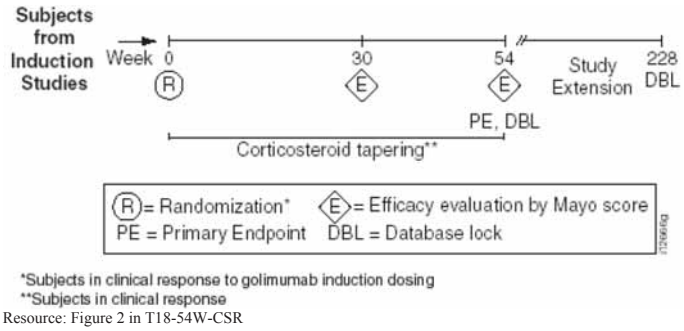
T16 又は T17 試験のプラセボ群で clinical response が認められた被験者（プラセボ寛解導入 responder），及びゴリムマブ群及びプラセボ群で clinical response が認められなかった被験者（ゴリムマブ寛解導入 nonresponder 及びプラセボ寛解導入 nonresponder）も対象としたが，ランダム化せず，有効性の主要解析集団に含めなかった。目標被験者数は，ランダム化する被験者として 384 例，全体として最大 1350 例であった。

本試験のデザインを図 2.7.3-4 及び図 2.7.3-5 に示す。



Resource: Figure 1 in T18-54W-CSR

図 2.7.3-4 T18 試験のデザイン



Resource: Figure 2 in T18-54W-CSR

図 2.7.3-5 T18 試験のデザイン（ランダム化された被験者）

T16 又は T17 試験のゴリムマブ寛解導入 responder を，層別因子（実施施設，T18 試験 0 週時の clinical remission の有無及びコルチコステロイド使用の有無，並びに寛解導入期のゴリムマブの投与量及び投与経路）で調整して，ゴリムマブ 50，100 mg 又はプラセボ群に 1:1:1 の比でランダムに割り付け，治験薬を 52 週まで 4 週ごとに皮下投与した。ゴリムマブ寛解導入 responder がコルチコステロイドを併用していた場合，維持期 0 週から漸減した（prednisone 換算で 20 mg/day 超の場合：5 mg/week で漸減，prednisone 換算で 20 mg/day 以下の場合：2.5 mg/week で漸減）。

プラセボ寛解導入 responder には，プラセボを 52 週まで 4 週ごとに皮下投与した。

ゴリムマブ寛解導入 responder 及びプラセボ寛解導入 responder が 52 週までに clinical response を消失した場合，投与量を 1 回のみ調節できることとした（図 2.7.3-6）。投与量調節後の初回投与から 16 週までに疾患活動性の改善が認められなかったと治験担当医師が判断した場合，治験薬の投与を中止した。

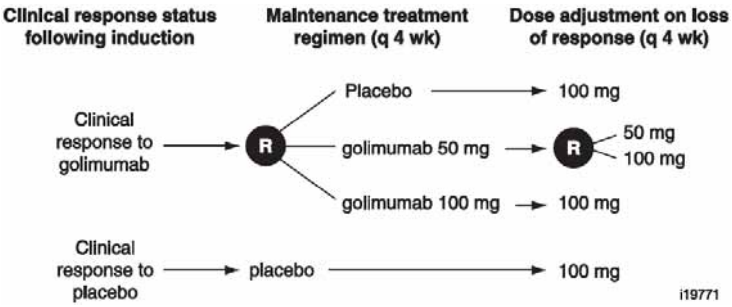
ゴリムマブ寛解導入 responder に対する投与量調節

- 50 mg 群：ゴリムマブ 50 又は 100 mg にランダムに割り付け，4 週ごとに投与
- 100 mg 群：ゴリムマブ 100 mg を 4 週ごとに投与（治験実施計画書 3 版発行までは，100 又は 200 mg に再度ランダムに割り付け，4 週ごとに投与する計画であった。3 版発行までに 200 mg に割り付けられた被験者の投与量を 100 mg に減量した。[#]）
- プラセボ群：ゴリムマブ 100 mg を 4 週ごとに投与

#200 mg への増量を中止した理由：ゴリムマブの第 IIb 相及び第 III 相臨床試験から得られた悪性腫瘍に関するデータレビューの結果，リンパ腫の確定診断例又は疑診断例が 7 例認められ，その大部分はリウマチ性関節炎（RA）に長期罹患していた患者であった。いずれもゴリムマブ 100 mg が皮下投与されていた。重症の RA 患者におけるリンパ増殖性の癌リスクが一般人口での頻度に比べて数倍高いことが，複数の疫学研究より示されている。第 IIb 相及び第 III 相臨床試験のゴリムマブ併合群のリンパ腫発現率（変更当時）は，他の抗 TNFα 抗体における発現率と同程度であった（100 人年あたりの発現率：ゴリムマブ 0.11，インフリキシマブ 0.10，アダリムマブ 0.11）。UC 患者を対象とした臨床試験において，変更当時ではリンパ腫発現は報告されていない。しかし，ゴリムマブの他の適応症での検討結果を考慮して，3 版発行以降はゴリムマブ 200 mg への増量は不可とし，現在ゴリムマブ 200 mg を投与している被験者は，100 mg に減量することとした。

プラセボ寛解導入 responder に対する投与量調節

- ゴリムマブ 100 mg を 4 週ごとに投与



Resource: Figure 3 in T18-54W-CSR

図 2.7.3-6 投与量の調節（T18 試験）

ゴリムマブ寛解導入 nonresponder 及びプラセボ寛解導入 nonresponder には，ゴリムマブ 100 mg を 12 週まで 4 週ごとに皮下投与し，16 週に疾患活動性の改善が認められた被験者は，引き続き，ゴリムマブ 100 mg を 52 週まで 4 週ごとに皮下投与した。16 週までに疾患活動性の改善が認められない被験者には，その後の治験薬投与を中止し，治験薬最終投与後 16 週まで後観察期として安全性を評価した。

54 週の評価を完了し，治験薬を継続投与することにより効果が得られると治験担当医師が判断した被験者には，52 週と同じ治験薬・投与量を 56 週から最大 212 週まで継続投与した。54 週の解析完了までは盲検性を保持した。盲検解除後，プラセボを投与されていた被験者については試験を中止した。疾患活動性が悪化したと治験担当医師が判断した場合，投与量を 1 回のみ調節できることとした。投与量調節後の初回投与から 16 週までに疾患活動性の改善が認められなかっ

たと治験担当医師が判断した場合，治験薬の投与を中止した。治験薬最終投与後 16 週まで後観察期として安全性を評価した。

(4) UCO3001 試験

【評価資料 5.3.5.1.5】

UCO3001 試験は，日本人の中等症から重症の活動期 UC 患者にゴリムマブを皮下投与したときの寛解維持療法の安全性及び有効性を評価する多施設共同，ランダム化，二重盲検，プラセボ対照試験である。本試験では，ベースラインの Mayo スコアが 6～12 点かつ内視鏡検査サブスコアが 2 点以上で，生検により UC と確定診断された外来患者であり，経口 5-ASA，経口コルチコステロイド，AZA 若しくは 6-MP の効果が不十分であった患者，又はこれらの薬剤に対する忍容性が不良であった患者を対象とした。また，コルチコステロイドを漸減すると UC の症状が再燃する患者も対象とした。抗 TNFα 薬の投与歴を有する患者は，本試験の対象としなかった。目標被験者数は，ランダム化する被験者として 60 例であった。

本試験のデザインを図 2.7.3-7 及び図 2.7.3-8 に示す。

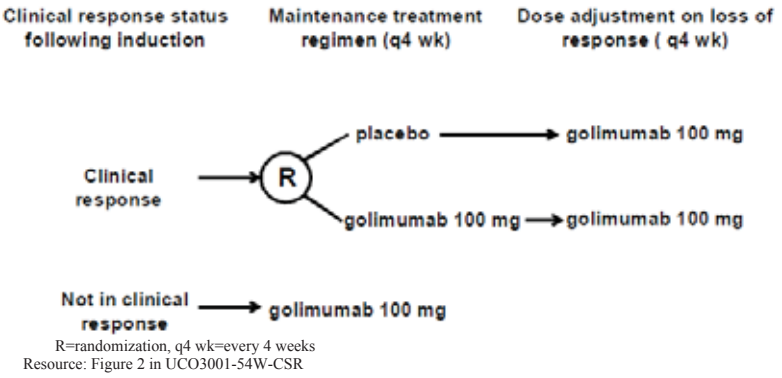


図 2.7.3-7 UCO3001 試験のデザイン及び投与量の調節

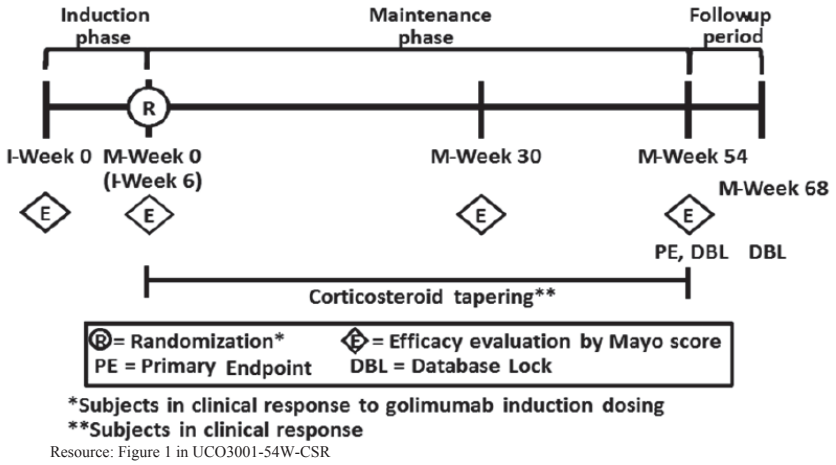


図 2.7.3-8 UCO3001 試験のデザイン（維持期 0 週にランダム化された被験者）

寛解導入期では，すべての被験者に，ゴリムマブを 0 週に 200 mg，2 週に 100 mg を皮下投与した。

寛解維持期では，ゴリムマブ寛解導入 responder を，層別因子（維持期 0 週の clinical remission の有無及びコルチコステロイド使用の有無）で調整して，ゴリムマブ 100 mg 又はプラセボ群に

1:1 の比でランダムに割り付け，治験薬を維持期 0 週から 52 週まで 4 週ごとに皮下投与した。ゴリムマブ寛解導入 responder がコルチコステロイドを併用していた場合，維持期 0 週から漸減した（prednisone 換算で 20 mg/day 超の場合：5 mg/week で漸減，prednisone 換算で 20 mg/day 以下の場合：2.5 mg/week で漸減）。維持期プラセボ群が維持期 52 週までに clinical response を消失した場合，投与量を 1 回のみ変更できることとし，ゴリムマブ 100 mg を 4 週ごとに投与した（図 2.7.3-7）。維持期ゴリムマブ群が維持期 52 週までに clinical response を消失した場合，投与量は変更せず，引き続き，ゴリムマブ 100 mg を 4 週ごとに投与した。投与量調節後の初回投与から 12 週までに疾患活動性の改善（clinical response）が認められなかった場合，治験薬の投与を中止し，治験薬最終投与後 16 週まで後観察期として安全性を評価した。

ゴリムマブ寛解導入 nonresponder には，ゴリムマブ 100 mg を維持期 52 週まで 4 週ごとに皮下投与した。維持期 8 週までに疾患活動性の改善（clinical response）が認められない場合，維持期 8 週以降の治験薬投与を中止し，治験薬最終投与後 16 週まで後観察期として安全性を評価した。

2.7.3.1.2 試験対象集団

T16，T17 及び UCO3001 試験の対象は，いずれも中等症から重症の活動期 UC 患者であり，ベースラインの Mayo スコアが 6～12 点かつ内視鏡検査サブスコアが 2 点以上で，生検により UC と確定診断された外来患者であり，経口 5-ASA，経口コルチコステロイド，AZA 若しくは 6-MP の効果が不十分であった患者，又はこれらの薬剤に対する忍容性が不良であった患者であった。また，コルチコステロイドを漸減すると UC の症状が再燃する患者も対象とした。ただし，いずれの試験でも，抗 TNFα 薬の投与歴を有する患者は対象としなかった。

T18 試験は，T16 又は T17 試験を完了した被験者を対象とした。

2.7.3.1.3 有効性評価項目

2.7.3.1.3.1 有効性評価に使用したスコア

(1) Mayo スコア

Mayo スコアは，UC の疾患活動性を評価するための尺度であり，4 項目（排便回数，直腸出血，内視鏡検査の所見及び医師による全般評価）のサブスコア（0～3 点／項目）の合計値である（0～12 点）。3～5 点は軽症，6～10 点は中等症，11～12 点は重症の疾患活動性と定義される。

Partial Mayo スコアは，内視鏡検査の所見を除いた 3 項目のサブスコアの合計値である。

＜排便回数サブスコア＞

0 点：被験者の通常の排便回数

1 点：通常の排便回数よりも 1～2 回多い

2 点：通常の排便回数よりも 3～4 回多い

3 点：通常の排便回数よりも 5 回以上多い

＜直腸出血サブスコア＞

0 点：血液は認められない

1 点：半分未満の排便で，便に線状の血液が認められる

2 点：ほとんどの排便で，便に明らかな血液が認められる

3 点：血液のみ排出される

＜内視鏡検査サブスコア＞

0 点：異常なし又は非活動性疾患

1 点：軽症（紅斑，血管パターンの減少又は軽度の脆弱化）

2 点：中等症（顕著な紅斑，血管パターンの消失，脆弱化又はびらん）

3 点：重症（特発性出血又は潰瘍形成）

内視鏡検査として，S 状結腸鏡検査又は大腸内視鏡検査を実施し，内視鏡検査サブスコアは，評価訓練を受けた治験担当医師又はスタッフが評価した。

＜医師による全般評価＞

0 点：異常なし，1 点：軽症，2 点：中等症，3 点：重症

1) clinical response の定義

Mayo スコアが導入期 0 週から 30%以上かつ 3 点以上減少し，さらに直腸出血サブスコアが導入期 0 週から 1 点以上減少するか，若しくは 0 又は 1 の場合，clinical response が認められたと定義した。

2) clinical remission の定義

Mayo スコアが 2 点以下になり，サブスコアがいずれも 0 又は 1 の場合，clinical remission が認められたと定義した。

3) mucosal healing の定義

Mayo スコアの内視鏡検査サブスコアが 0 又は 1 になった場合，mucosal healing が認められたと定義した。

(2) 炎症性腸疾患調査票（IBDQ）

IBDQ は，炎症性腸疾患患者に対する 32 項目の調査票であり，4 つのカテゴリーのスコアにより生活の質（QOL）を評価する：腸の状態（軟便，腹痛），全身状態（疲労，睡眠パターンの変化），社会面（仕事への出勤率，社会行事のキャンセルを要する度合い），情緒面（怒り，気分の落ち込み，いらだち）。スコアの合計は 32～224 であり，高スコアほど，QOL が良好である。

2.7.3.1.3.2 有効性評価項目

評価資料である T17，T18 及び UCO3001 試験の主な有効性評価項目を表 2.7.3-2 に示す。

表 2.7.3-2 主な有効性評価項目

	T17 試験 Part2 寛解導入	T18 試験 寛解維持	UCO3001 試験 寛解維持
clinical response at Week 6	◎		
clinical remission at Week 6	○		
mucosal healing at Week 6	○		
mean change from baseline in the IBDQ at Week 6	○		
>20 points improvement from baseline in the IBDQ at Week 6	△		
clinical response through Week 54		◎	◎
clinical remission at both Week 30 and Week 54		○	○
mucosal healing at both Week 30 and Week 54		○	○
clinical remission at both Week 30 and Week 54 among subjects in remission at Week 0		○	△
clinical remission and elimination of corticosteroid use at Week 54 among subjects receiving corticosteroid at Week 0		○	△
>20 points improvement from Week 0 of induction in the IBDQ through Week 54		△	▽

◎：主要評価項目，○：主な副次評価項目，△：その他の評価項目，▽：追加解析項目

2.7.3.1.4 統計解析

2.7.3.1.4.1 各試験に共通する統計解析

記述統計量（平均値，中央値，標準偏差，四分位範囲，最小値及び最大値など）を用いて，連続変数を集計した。T17 及び T18 試験では，カテゴリカルデータに適した解析法［カイ二乗検定，Cochran-Mantel-Haenszel（CMH）検定等］を用いて，clinical remission が認められた被験者の割合等，特定の評価項目に達した被験者の割合を群間比較した。該当被験者数が極めて少ない場合，Fisher 直接確率検定を用いて群間比較した。連続応答パラメータは，特に断りがない限り，分散分析／共分散分析（ANOVA/ANCOVA）を用いて群間比較した。正規性が仮定できない場合は，van der Waerden 正規スコアに基づく ANOVA 又は ANCOVA を用いた。

有効性は，実際の投与量ではなく，割り付けられた投与群に従って解析した。

特に明記しない限り，有意水準両側 5%にて群間比較した。

以下に示す treatment failure の取扱い基準及び欠測値の取扱い基準は，特に明記しない限り，すべての有効性解析に適用した。

(1) Treatment failure の取扱い基準

以下の事象が認められた被験者は，発現時以降 treatment failure として取り扱った。

- 結腸切除術（部分切除又は全摘）又は造瘻術の実施
- 効果不十分による治験薬投与中止
- 投与量の調節（T18 及び UCO3001 試験で適用）
- UC に対する併用薬の変更

2 値変数の評価項目では，あらかじめ規定した解析時点より前に treatment failure となった被験者の当該評価項目は未達成とみなした。連続変数の評価項目では，treatment failure となった被験者の導入期 0 週の値で treatment failure となった時点及びそれ以降の時点の値を補完した。

Treatment failure の取扱い基準は，他のデータの取扱いに関する基準よりも優先して適用した。

(2) 欠測値の取扱い基準

2 値変数の評価項目が欠測の場合，該当する項目は欠測とした。連続変数の評価項目が欠測の場合，該当する項目を利用可能な最終値で補完した。

Mayo スコアは，4 つの Mayo サブスコアがいずれも欠測の場合，該当する来院時のスコアは欠測とし，clinical response 及び clinical remission も未達成とした。

2.7.3.1.4.2 主要評価項目及び主な副次評価項目の統計解析

(1) T17 試験 Part 2（投与量選択後）

1) 主要評価項目（6 週に clinical response が認められた被験者の割合）

固定順序法にて，まず，400→200 mg 群とプラセボ群と比較し，この検定で統計学的に有意な差が認められた場合のみ，200→100 mg 群をプラセボ群と比較した。200→100 mg 群の検定結果にかかわらず，400→200 mg 群の検定で統計学的に有意な差が認められた場合，ゴリムマブの有効性が認められたと判断した。

2) 主な副次評価項目

主要評価項目の 400→200 mg 群の検定で統計学的に有意な差が認められた場合のみ，次の主な副次評価項目の検定を実施した。

主な副次評価項目の検定順序を以下に示す。

1. 6 週に clinical remission が認められた被験者の割合
2. 6 週に mucosal healing が認められた被験者の割合
3. 6 週の IBDQ のベースラインからの平均変化量

(2) T18 試験

1) 主要評価項目（54 週まで clinical response が維持された被験者の割合）

固定順序法にて，まず，100 mg 群とプラセボ群を比較し，この検定で統計学的に有意な差が認められた場合のみ，50 mg 群とプラセボ群を比較した。50 mg 群の検定結果にかかわらず，100 mg 群の検定で統計学的に有意な差が認められた場合，ゴリムマブの有効性が認められたと判断した。

2) 主な副次評価項目

主要評価項目の 100 mg 群の検定で統計学的に有意な差が認められた場合のみ，主な副次評価項目を検定した。

固定順序法にて，まず，100 mg 群とプラセボ群を比較し，この検定で統計学的に有意な差が認められた場合のみ，50 mg 群の検定結果にかかわらず，次の主な副次評価項目の 100 mg 群の検定を実施した。主な副次評価項目の 100 mg 群の検定で統計学的に有意な差が認められ，かつ前の評価項目の 50 mg 群の検定で統計学的に有意な差が認められた場合のみ，該当する主な副次評価項目の 50 mg 群の検定を実施した。

主な副次評価項目の検定順序を以下に示す。

1. 30 及び 54 週ともに clinical remission が認められた被験者の割合
2. 30 及び 54 週ともに mucosal healing が認められた被験者の割合
3. 0 週に clinical remission が認められていた被験者のうち，30 及び 54 週ともに clinical remission が認められた被験者の割合
4. 0 週にコルチコステロイドを併用していた被験者のうち，54 週に clinical remission が認められ，かつコルチコステロイドを併用していなかった被験者の割合

(3) UCO3001 試験

1) 主要評価項目

UCO3001 試験では，54 週まで clinical response が維持された被験者の割合の群間差及び 95%信頼区間（95%CI）を算出し，事前に定義した基準［群間差≥8.5%：T18 試験で 54 週まで clinical response が維持された被験者の割合の 100 mg 群及びプラセボ群の差 19.2%の 95%CI（8.5;29.9）の下限値］を達成した場合，ゴリムマブの有効性が認められたと判断した。

2) 主な副次評価項目

副次評価項目においては，特別な統計解析は実施しなかった。

2.7.3.2 個々の試験結果の要約

有効性評価に用いた臨床試験について，人口統計学的特性，ベースラインの疾患特性，有効性の主要評価項目／主な副次評価項目の結果を以下に示す。また，T16 試験については，Part 1 の結果，T17 試験については，Part 1 及び Part 2（投与量選択後）の結果を示す。なお，被験者の曝露状況は【2.7.4.1】に示す。

2.7.3.2.1 T16 試験

【参考資料 5.3.5.1.1】

本試験には 291 例が組み入れられた（1 mg/kg 群 62 例，2 mg/kg 群 75 例，4 mg/kg 群 77 例及びプラセボ群 77 例）。本試験は Part 2 実施中に新たな被験者の登録を中止したため，本項では Part 1 の結果のみを示す。

(1) Part 1

本試験の Part 1 には，176 例が 4 群にランダムに割り付けられた（1 mg/kg 群 44 例，2 mg/kg 群 44 例，4 mg/kg 群 44 例及びプラセボ群 44 例）。

被験者の 61.4%が男性，76.7%が白人であり，年齢の中央値（範囲）は 41.0（19～79）歳，体重の中央値（範囲）は 70.0（35～134）kg であった。UC 罹病期間の中央値（範囲）は 4.28（0.2～37.4）年，Mayo スコアの中央値（範囲）は 8.0（6～12）点，全大腸炎型の被験者の割合は 43.2%，CRP の中央値（範囲）は 4.99（0.1～116.0）mg/L であった。人口統計学的特性及びベースラインの疾患特性は，群間でおおむね類似していた。

6 週の Mayo スコアのベースラインからの変化量（中央値）は，1 mg/kg 群：−2.0，2 mg/kg 群：−2.0，4 mg/kg 群：−1.5 及びプラセボ群：−1.0 であり，ゴリムマブ群の減少量はいずれも小さく，同程度であった。6 週の Mayo スコアのベースラインからの変化量（平均値）は，1 mg/kg 群：−2.0，2 mg/kg 群：−2.3，4 mg/kg 群：−1.8 及びプラセボ群：−1.3 であった。

6 週に clinical response が認められた被験者の割合は，1 mg/kg 群 41.9%（18/43 例），2 mg/kg 群 40.9%（18/44 例），4 mg/kg 群 29.5%（13/44 例）及びプラセボ群 24.4%（10/41 例），6 週に clinical remission が認められた被験者の割合は，1 mg/kg 群 9.3%（4/43 例），2 mg/kg 群 18.2%（8/44 例），4 mg/kg 群 6.8%（3/44 例）及びプラセボ群 9.8%（4/41 例），6 週に mucosal healing が認められた被験者の割合は，1 mg/kg 群 34.9%（15/43 例），2 mg/kg 群 29.5%（13/44 例），4 mg/kg 群 29.5%（13/44 例）及びプラセボ群 24.4%（10/41 例）であった。いずれのゴリムマブ群でも，プラセボ群と比べて統計学的な有意差は認められなかった。

T16 試験 Part 1 の結果，Part 2 のゴリムマブの投与量として 2 及び 4 mg/kg を選択した。しかし，T17 試験 Part 1 の結果も含めて検討した結果，T16 試験 Part 1 では，Mayo スコアのベースラインからの変化量を含む有効性評価項目に用量相関が認められず，予測した有効性より低い結果であったこと，T16 試験 Part 1 と比べて T17 試験 Part 1 の結果が良好であったこと，単回静脈内投与では 6 週での効果を得るために必要な血清中濃度が十分に得られないと考えられたことから，Part 2 への被験者の登録を中止した。

(2) 有効性及び薬物動態

血清中ゴリムマブ濃度の四分位を用いて Part 1 及び Part 2 の被験者を部分集団化し，有効性との相関を検討した。その結果，血清中ゴリムマブ濃度の増加に伴う 6 週の Mayo スコアの改善は

認められず，単回静脈内投与では，6 週での効果を得るために必要な血清中濃度が十分に得られないと考えられた。

(3) 有効性及び免疫原性

ゴリムマブが投与され，適切な検体が得られた 206 例のうち，16 週までに抗ゴリムマブ抗体が検出された被験者は認められなかった。

2.7.3.2.2 T17 試験

【評価資料 5.3.5.1.2】【評価資料 5.3.5.1.4】

本試験では 1065 例が組み入れられた（100→50 mg 群 72 例，200→100 mg 群 331 例，400→200 mg 群 331 例及びプラセボ群 331 例）。

(1) Part 1

本試験の Part 1 には，169 例が 4 群にランダムに割り付けられた（100→50 mg 群 42 例，200→100 mg 群 42 例，400→200 mg 群 43 例及びプラセボ群 42 例）。

被験者の 58.6%が男性，88.8%が白人であり，年齢の中央値（範囲）は 38.0（18～67）歳，体重の中央値（範囲）は 74.50（44.0～136.4）kg であった。UC 罹病期間の中央値（範囲）は 4.43（0.1～37.5）年，Mayo スコアの中央値（範囲）は 8.0（6～12）点，全大腸炎型の被験者の割合は 42.6%，CRP の中央値（範囲）は 5.74（0.1～102.0）mg/L であった。下記事項を除いて，人口統計学的特性及び疾患特性は，群間でおおむね類似していた。

- ゴリムマブ群の年齢がプラセボ群より高い：100→50 mg 群 39.5（21～63）歳，200→100 mg 群 43.0（18～61）歳，400→200 mg 群 38.0（19～67）歳及びプラセボ群 34.5（20～65）歳
- ゴリムマブ群の UC 罹病期間がプラセボ群より長い：100→50 mg 群 6.41（0.1～37.5）年，200→100 mg 群 5.72（0.3～24.2）年，400→200 mg 群 4.16（0.4～23.7）年及びプラセボ群 2.96（0.3～18.5）年
- 100→50 mg 群の CRP が他の群より低値：100→50 mg 群 3.63（0.3～31.9）mg/L，200→100 mg 群 6.81（0.2～60.8）mg/L，400→200 mg 群 6.62（0.1～89.1）mg/L 及びプラセボ群 6.36（0.6～102.0）mg/L

6 週の Mayo スコアのベースラインからの変化量（中央値）は，100→50 mg 群：−3.0，200→100 mg 群：−2.0，400→200 mg 群：−3.0 及びプラセボ群：−1.0 であった。6 週の Mayo スコアのベースラインからの変化量（平均値）は，100→50 mg 群：−2.7，200→100 mg 群：−2.6，400→200 mg 群：−3.1 及びプラセボ群：−1.8 であり，400→200 mg 群のみに，プラセボ群と比べて統計学的に有意な差が認められた（p=0.0453，ANOVA）。

ゴリムマブ群の 6 週に clinical response が認められた被験者の割合は，100→50 mg 群 56.1%（23/41 例），200→100 mg 群 43.9%（18/41 例）及び 400→200 mg 群 53.7%（22/41 例）であり，100→50 mg 群及び 400→200 mg 群では，プラセボ群 31.7%（13/41 例）と比べて，いずれも統計学的に有意な差が認められた（それぞれ p=0.0261 及び p=0.0445，カイ二乗検定）。ゴリムマブ群の 6 週に clinical remission が認められた被験者の割合は，100→50 mg 群 17.1%（7/41 例），200→100 mg 群 17.1%（7/41 例）及び 400→200 mg 群 24.4%（10/41 例）であり，プラセボ群 9.8%

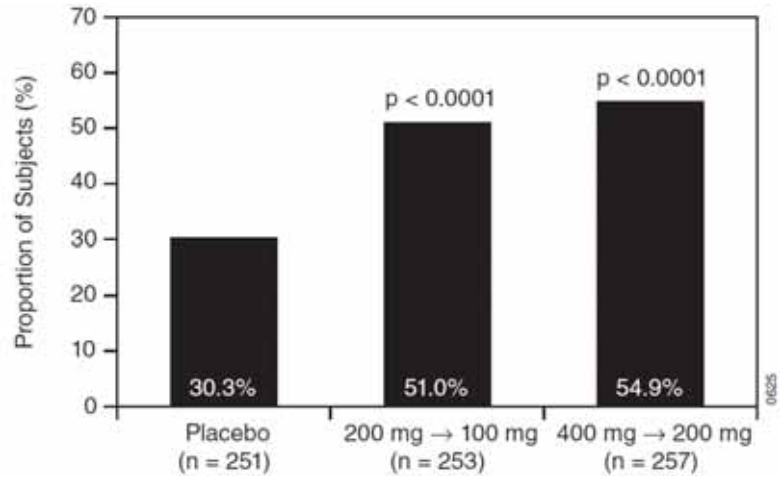
（4/41 例）と比べて統計学的に有意な差は認められなかったものの，いずれもより高い値であった。ゴリムマブ群の 6 週に mucosal healing が認められた被験者の割合は，100→50 mg 群 46.3%（19/41 例），200→100 mg 群 34.1%（14/41 例）及び 400→200 mg 群 46.3%（19/41 例）であり，100→50 mg 群及び 400→200 mg 群では，プラセボ群 24.4%（10/41 例）と比べて，いずれも統計学的に有意な差が認められた（いずれも p=0.0376，カイ二乗検定）。

(2) Part 2（投与量選択後）

投与量選択後の本試験の Part 2 では，774 例が 3 群にランダムに割り付けられた（200→100 mg 群 258 例，400→200 mg 群 258 例及びプラセボ群 258 例）。

被験者の 54.8%が男性，80.4%が白人であり，年齢の中央値（範囲）は 38.0（18～78）歳，体重の中央値（範囲）は 71.00（33.0～149.7）kg であった。UC 罹病期間の中央値（範囲）は 4.30（0.1～48.3）年，Mayo スコアの中央値（範囲）は 8.0（5～12）点，全大腸炎型の被験者の割合は 42.4%，CRP の中央値（範囲）は 4.76（0.1～240.0）mg/L であった。人口統計学的特性及びベースラインの疾患特性は，群間でおおむね類似していた。

主要評価項目である 6 週に clinical response が認められた被験者の割合は，200→100 mg 群 51.0%（129/253 例）及び 400→200 mg 群 54.9%（141/257 例）であり，プラセボ群 30.3%（76/251 例）と比べて，いずれも統計学的に有意な差が認められた（いずれも p<0.0001，カイ二乗検定，図 2.7.3-9）。



Source: Figure 5 of T17 in Re-analysis report for C0524T17 and C0524T18 54-Week

図 2.7.3-9 6 週に clinical response が認められた被験者の割合

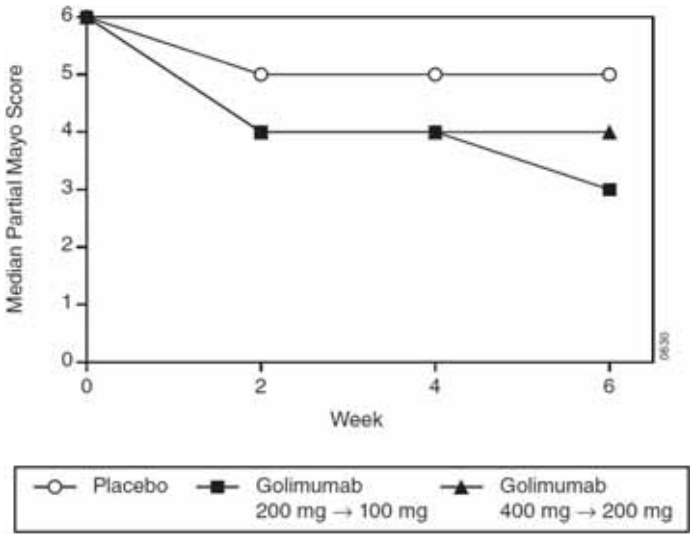
（T17 試験，Part 2 投与量選択後）

主な副次評価項目である 6 週に clinical remission が認められた被験者の割合，6 週に mucosal healing が認められた被験者の割合及び 6 週の IBDQ のベースラインからの平均変化量，並びにその他の副次評価項目である 6 週の IBDQ がベースラインより 21 以上改善した被験者の割合についても，200→100 mg 群及び 400→200 mg 群では，プラセボ群と比べて，いずれも統計学的に有意な差が認められた。

- clinical remission：200→100 mg 群 17.8%（45/253 例），400→200 mg 群 17.9%（46/257 例），プラセボ群 6.4%（16/251 例）；いずれも p<0.0001，カイ二乗検定

- mucosal healing：200→100 mg 群 42.3%（107/253 例），400→200 mg 群 45.1%（116/257 例），プラセボ群 28.7%（72/251 例）；それぞれ p=0.0014 及び p=0.0001，カイ二乗検定
- IBDQ の平均変化量（SD）：200→100 mg 群 27.0（33.72），400→200 mg 群 26.9（34.28），プラセボ群 14.8（31.25）；いずれも p<0.0001，van der Waerden 正規スコアに基づく ANOVA
- IBDQ の 21 以上の改善：200→100 mg 群 50.6%（128/253 例），400→200 mg 群 51.0%（131/257 例），プラセボ群 35.5%（89/251 例）；それぞれ p=0.0006 及び p=0.0004，カイ二乗検定

0 週の Partial Mayo スコア（中央値）は，200→100 mg 群，400→200 mg 群及びプラセボ群いずれも 6 であった。200→100 mg 群及び 400→200 mg 群は 2 週に 4 となり，200→100 mg 群では 6 週に 3 まで減少した。プラセボ群は 2 週に 5 となり，6 週まで持続した（図 2.7.3-10）。



Source: Figure 12 of T17 in Re-analysis report for C0524T17 and C0524T18 54-Week

図 2.7.3-10 Partial Mayo スコアの推移（T17 試験，Part 2 投与量選択後）

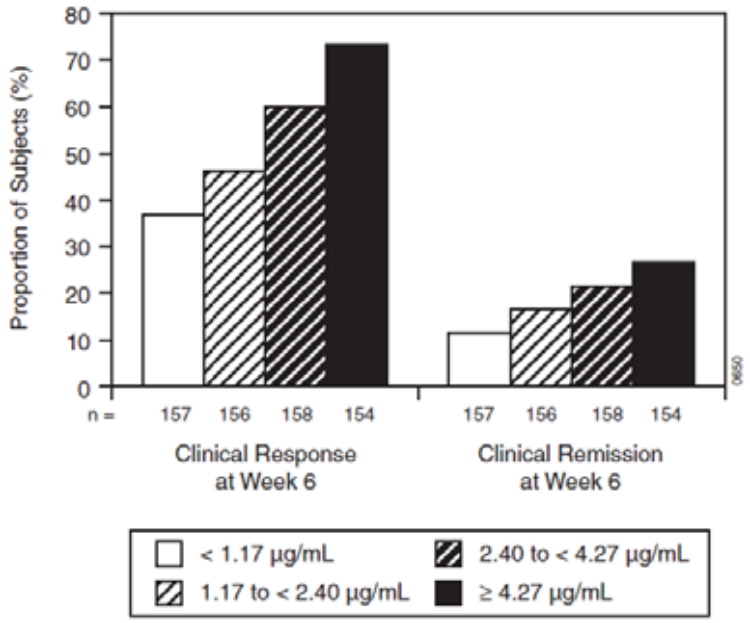
(3) 有効性及び薬物動態

6 週の血清中ゴリムマブ濃度が高値であるほど，疾患活動性の改善が認められた（6 週の Mayo スコアのベースラインからの変化量，6 週に clinical response が認められた被験者の割合，及び 6 週に clinical remission が認められた被験者の割合）。

T17 試験全体では，6 週の血清中ゴリムマブ濃度の第 4 四分位（≥ 4.27 μg/mL）で，6 週に clinical response が認められた被験者の割合が最も高かった［73.4%（113/154 例）］。第 3 四分位（≥ 2.40～ < 4.27 μg/mL）の 6 週に clinical response が認められた被験者の割合［60.1%（95/158 例）］は，第 2 四分位［≥ 1.17～ < 2.40 μg/mL，46.2%（72/156 例）］及び第 1 四分位［< 1.17 μg/mL，36.9%（58/157 例）］と比べて高かった（図 2.7.3-11）。

T17 試験 Part 2（投与量選択後）においても，6 週の血清中ゴリムマブ濃度の第 4 四分位（≥ 4.27 μg/mL）で，6 週に clinical response が認められた被験者の割合が最も高かった［75.0%（90/120 例）］。第 3 四分位（≥ 2.40～ < 4.27 μg/mL）の 6 週に clinical response が認められた被

験者の割合［58.7%（71/121 例）］は，第 2 四分位［≥ 1.17～＜2.40 μg/mL，47.3%（52/110 例）］及び第 1 四分位［＜1.17 μg/mL，34.1%（31/91 例）］と比べて高かった。6 週の血清中ゴリムマブ濃度を測定された被験者において，第 3 又は第 4 四分位に該当する被験者の割合は，200→100 mg 群［33.9%（74/218 例）］と比べて，400→200 mg 群［74.6%（167/224 例）］で高かったものの，両群の有効性は同程度であった。



Source: Figure 17 of T17 in Re-analysis report for C0524T17 and C0524T18 54-Week

図 2.7.3-11 有効性と薬物動態（T17 試験，Part 2 投与量選択後）

(4) 有効性及び免疫原性

抗ゴリムマブ抗体陽性の被験者は 3 例であった。うち 1 例（200→100 mg 群）では 6 週に clinical response が認められ，2 例（400→200 mg 群）では認められなかった。

2.7.3.2.3 T18 試験

【評価資料 5.3.5.1.3-1】【評価資料 5.3.5.1.3-2】【評価資料 5.3.5.1.4】

(1) T18 試験（54 週まで）

本試験には 1228 例が組み入れられ，うち，T16 及び T17 試験のゴリムマブ寛解導入 responder（T16 試験 89 例及び T17 試験 375 例，計 464 例）がランダムに割り付けられた（50 mg 群 154 例，100 mg 群 154 例及びプラセボ群 156 例）。残り 764 例の内訳は，プラセボ寛解導入 responder が 129 例，プラセボ寛解導入 nonresponder が 230 例，ゴリムマブ寛解導入 nonresponder が 405 例であった。本試験に組み入れられたすべての被験者に治験薬が投与された。

1) ランダム化された被験者（有効性の主要解析対象集団）

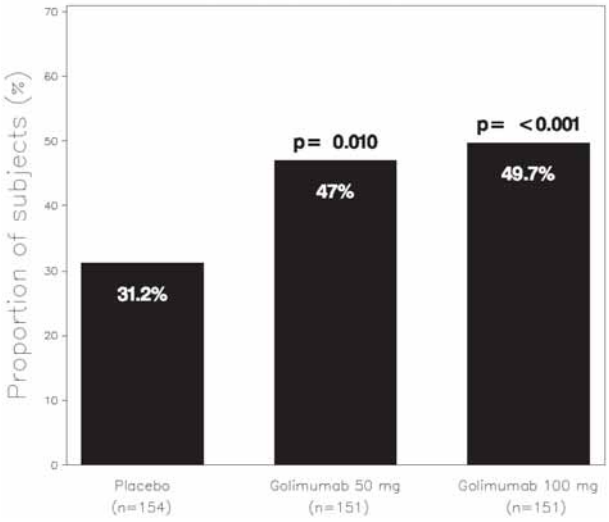
T18 試験の維持期 0 週にランダム化された被験者の T16 又は T17 試験の 0 週（導入期 0 週）の被験者背景を以下に示す。

被験者の 51.9%が男性，87.3%が白人であり，年齢の中央値（範囲）は 39.0（18～79）歳，体重の中央値（範囲）は 71.95（35.0～137.8）kg であった。UC 罹病期間の中央値（範囲）は 4.55

（0.1～41.7）年，Mayo スコアの中央値（範囲）は 8.0（6～12）点，全大腸炎型の被験者の割合は 44.2%，CRP の中央値（範囲）は 3.61（0.1～98.2）mg/L であった。人口統計学的特性及び CRP を除くベースラインの疾患特性は，群間でおおむね類似していた。

- 50 mg 群の CRP が他の群より高値：50 mg 群 4.51（0.1～74.1）mg/L，100 mg 群 3.35（0.1～98.2）mg/L 及びプラセボ群 3.20（0.1～85.8）mg/L

主要評価項目である 54 週まで clinical response が維持された被験者の割合は，50 mg 群 47.0%（71/151 例）及び 100 mg 群 49.7%（75/151 例）であり，プラセボ群 31.2%（48/154 例）と比べて，いずれも統計学的に有意な差が認められた（それぞれ，p=0.010 及び p<0.001，維持期 0 週の clinical remission の有無及び寛解導入時の投与量を層別因子とした CMH カイ二乗検定，図 2.7.3-12）。



Source: Figure 5 of T18 in Re-analysis report for C0524T17 and C0524T18 54-Week

図 2.7.3-12 54 週まで clinical response が維持された被験者の割合（T18 試験）

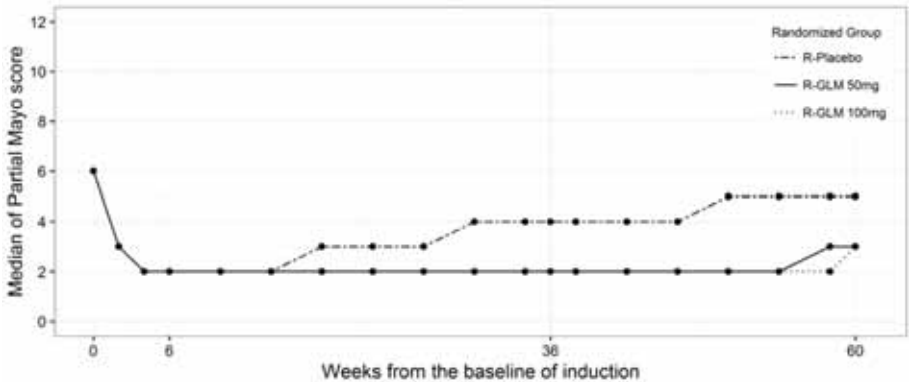
主な副次評価項目及び IBDQ の結果を以下に示す。

- 30 及び 54 週ともに clinical remission が認められた被験者の割合は，50 mg 群 23.2%（35/151 例）及び 100 mg 群 27.8%（42/151 例）であり，100 mg 群では，プラセボ群 15.6%（24/154 例）と比べて統計学的に有意な差が認められた（p=0.004，維持期 0 週の clinical remission の有無及び寛解導入時の投与量を層別因子とした CMH カイ二乗検定）。
- 30 及び 54 週ともに mucosal healing が認められた被験者の割合は，50 mg 群 41.7%（63/151 例）及び 100 mg 群 42.4%（64/151 例）であり，100 mg 群では，プラセボ群 26.6%（41/154 例）と比べて，統計学的に有意な差が認められた（p=0.002，維持期 0 週の clinical remission の有無及び寛解導入時の投与量を層別因子とした CMH カイ二乗検定）。
- 維持期 0 週に clinical remission が認められていた被験者のうち，30 及び 54 週ともに clinical remission が認められた被験者の割合は，50 mg 群 36.5%（19/52 例）及び 100 mg 群 38.9%（21/54 例）であり，プラセボ群 24.1%（13/54 例）と比べて高かった（それぞれ p=0.365 及び p=0.098，寛解導入時の投与量を層別因子とした CMH カイ二乗検定）。

・ 維持期 0 週にコルチコステロイドを併用していた被験者のうち，54 週に clinical remission が認められ，かつコルチコステロイドを併用していなかった被験者の割合は，50 mg 群 28.2%（22/78 例）及び 100 mg 群 23.2%（19/82 例）であり，50 mg 群では，プラセボ群 18.4%（16/87 例）と比べて高かった（それぞれ p=0.279 及び p=0.423，維持期 0 週の clinical remission の有無及び寛解導入時の投与量を層別因子とした CMH カイ二乗検定）。

・ 導入期 0 週と比べて，維持期 0 週に IBDQ が 21 以上改善した被験者のうち，54 週の IBDQ も 21 以上改善していた被験者の割合は，50 mg 群 44.5%（57/128 例）及び 100 mg 群 40.0%（46/115 例）であり，プラセボ群 27.8%（30/108 例）と比べて高かった（それぞれ p=0.026 及び p=0.051，維持期 0 週の clinical remission の有無及び寛解導入時の投与量を層別因子とした CMH カイ二乗検定）。

50 mg 群，100 mg 群及びプラセボ群の partial Mayo スコア（中央値）は，いずれも，T16 又は T17 試験で 6 から 2 に減少した。50 mg 群及び 100 mg 群は，それぞれ維持期 48 及び 52 週まで 2 を維持した。プラセボ群は維持期 12 週に 3 となり，維持期 44 週には 5 まで増加した（図 2.7.3-13）。



Source: FEFPMAYO01 in analysis for Japan submission dossier

図 2.7.3-13 Partial Mayo score の推移（T18 試験，ランダム化された被験者）

2) ランダム化されなかった被験者

プラセボ寛解導入 responder にはプラセボ，プラセボ寛解導入 nonresponder 及びゴリムマブ寛解導入 nonresponder には 100 mg を投与した。

・ プラセボ寛解導入 nonresponder 及びゴリムマブ寛解導入 nonresponder の 30 週及び 54 週に clinical response が認められた被験者の割合は，同程度であった［それぞれ，30 週：38.7%（86/222 例）及び 35.4%（141/398 例），54 週：36.9%（82/222 例）及び 32.2%（128/398 例）］。プラセボ寛解導入 responder の 30 週及び 54 週に clinical response が認められた被験者の割合は，それぞれ 45.5%（56/123 例）及び 36.6%（45/123 例）であった。

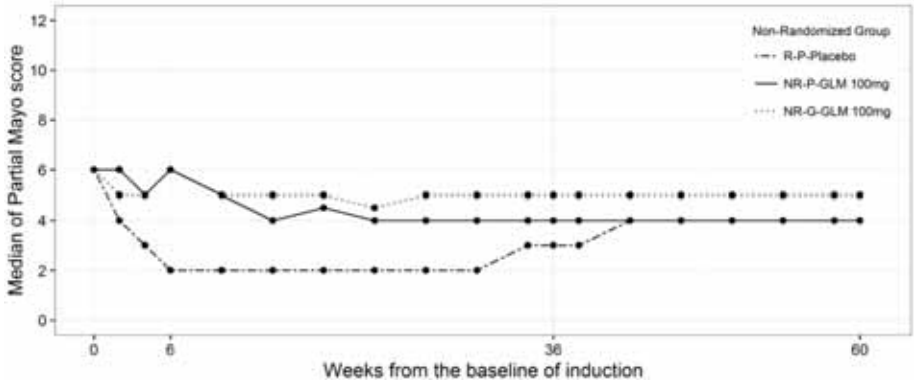
・ プラセボ寛解導入 nonresponder 及びゴリムマブ寛解導入 nonresponder の 30 週及び 54 週に clinical remission が認められた被験者の割合は，同程度であった［それぞれ，30 週：15.8%（35/222 例）及び 15.8%（63/398 例），54 週：21.6%（48/222 例）及び 16.6%（66/398

例）］。プラセボ寛解導入 responder の 30 週及び 54 週に clinical remission が認められた被験者の割合は，それぞれ 30.1%（37/123 例）及び 25.2%（31/123 例）であった。

・ プラセボ寛解導入 nonresponder 及びゴリムマブ寛解導入 nonresponder の 30 週及び 54 週に mucosal healing が認められた被験者の割合は，同程度であった［それぞれ，30 週：30.6%（68/222 例）及び 29.1%（116/398 例），54 週：31.1%（69/222 例）及び 27.1%（108/398 例）］。プラセボ寛解導入 responder の 30 週及び 54 週に mucosal healing が認められた被験者の割合は，それぞれ 46.3%（57/123 例）及び 34.1%（42/123 例）であった。

プラセボ寛解導入 nonresponder，ゴリムマブ寛解導入 nonresponder 及びプラセボ寛解導入 responder の partial Mayo スコア（中央値）の推移を図 2.7.3-14 に示す。

プラセボ寛解導入 nonresponder 及びゴリムマブ寛解導入 nonresponder の partial Mayo スコア（中央値）は，T16 又は T17 試験の 0 及び 6 週はいずれも 6 であった。維持期には，それぞれ 4 及び 4.5 まで減少したが，減少幅は小さかった。プラセボ寛解導入 responder は，T16 又は T17 試験で 6 から 2 に減少し，維持期 24 週まで 2 を維持したものの，維持期 36 週以降は 4 まで増加した。



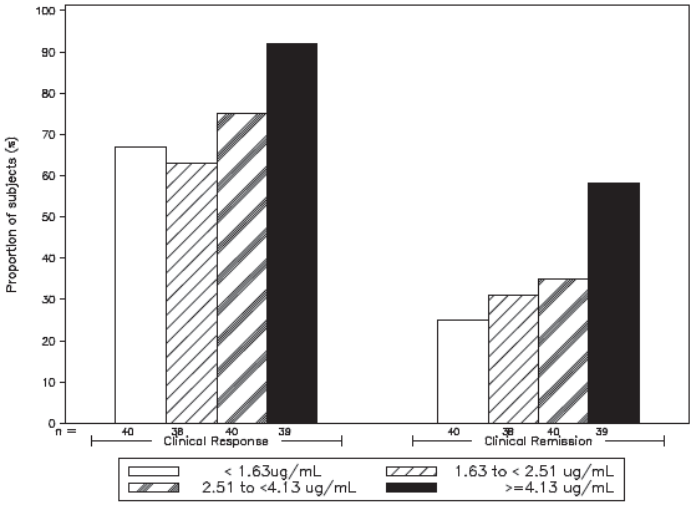
Source: FEFPMAYO02 in analysis for Japan submission dossier

図 2.7.3-14 Partial Mayo score の推移（T18 試験，ランダム化されなかった被験者）

3) 有効性及び薬物動態

血清中ゴリムマブ濃度が高値であるほど，疾患活動性の改善（clinical response，clinical remission 等）がおおむね認められた。54 週の血清中ゴリムマブ濃度の第 4 四分位（≥ 4.13 μg/mL）で，54 週まで clinical response が維持された被験者の割合が最も高かった［92.3%（36/39 例）］。第 3 四分位（≥ 2.51～ < 4.13 μg/mL）の 54 週まで clinical response が維持された被験者の割合［75.0%（30/40 例）］は，第 2 四分位［≥ 1.63～ < 2.51 μg/mL，63.2%（24/38 例）］及び第 1 四分位［< 1.63 μg/mL，67.5%（27/40 例）］と比べて高かった（図 2.7.3-15）。

第 3 又は第 4 四分位に該当する被験者の割合は，50 mg 群［24.1%（19/79 例）］と比べて，100 mg 群［76.9%（60/78 例）］で高かった。有効性と薬物動態の相関と一致して，有効性は，プラセボ群及び 50 mg 群と比べて，100 mg 群でおおむね高かった。



Source: Figure 14 of T18 in Re-analysis report for C0524T17 and C0524T18 54-Week

図 2.7.3-15 有効性と薬物動態（T18 試験，0 週にランダム化された被験者）

4) 有効性及び免疫原性

ゴリムマブ群にランダム化された被験者のうち 54 週まで clinical response が維持された被験者の割合は，抗ゴリムマブ抗体陽性の被験者では 22.2%（2/9 例），抗ゴリムマブ抗体陰性の被験者では 50.5%（144/285 例）であった（表 2.7.3-付録-10）。抗ゴリムマブ抗体陽性の被験者で 54 週まで clinical response が維持された被験者の割合が低い傾向が認められたが，抗ゴリムマブ抗体陽性の被験者は 9 例と少数であり，明確な結論は導くことはできなかった。

(2) T18 試験（継続投与：228 週まで）

本試験の維持期 0 週にランダム化された 464 例中 303 例（50 mg 群 100 例，100 mg 群 100 例及びプラセボ群 103 例）及びランダム化されなかった 764 例中 363 例（プラセボ寛解導入 responder が 78 例，プラセボ寛解導入 nonresponder が 113 例，ゴリムマブ寛解導入 nonresponder が 172 例）に 52 週と同じ投与量の治験薬を 56 週から継続投与した。56 週時の投与群の内訳を以下に示す。

- 50 mg 群 93 例（ゴリムマブ寛解導入 responder で，維持期 0 週から 52 週まで 50 mg 投与）
- 100 mg 群 477 例
  - ゴリムマブ寛解導入 responder で，維持期 0 週から 52 週まで 100 mg 投与：91 例
  - ゴリムマブ寛解導入 responder で，維持期 52 週までにプラセボ又は 50 mg から 100 mg に増量：58 例
  - ゴリムマブ寛解導入 responder で，維持期 52 週までに 100 mg から 200 mg に増量し，その後 100 mg に減量：9 例
  - プラセボ寛解導入 responder で，維持期 52 週までに 100 mg に増量：34 例
  - プラセボ寛解導入 nonresponder で，維持期 52 週まで 100 mg 投与：113 例
  - ゴリムマブ寛解導入 nonresponder で，維持期 52 週まで 100 mg 投与：172 例

・ プラセボ群 96 例

- ゴリムマブ寛解導入 responder で，維持期 52 週までプラセボ投与：52 例
- プラセボ寛解導入 responder で，維持期 52 週までプラセボ投与：44 例

T18 試験の継続投与に参加した被験者の T16 又は T17 試験の 0 週（導入期 0 週）の被験者背景を以下に示す。

被験者の 56.9%が男性，86.0%が白人であり，年齢の中央値（範囲）は 39.0（18～79）歳，体重の中央値（範囲）は 72.00（33.0～149.7）kg であった。UC 罹病期間の中央値（範囲）は 4.84（0.1～48.3）年，Mayo スコアの中央値（範囲）は 8.0（5～12）点，全大腸炎型の被験者の割合は 41.4%，CRP の中央値（範囲）は 3.87（0.1～98.9）mg/L であった。T18 試験の継続投与に参加した被験者の導入期 0 週の人口統計学的特性及び疾患特性は，維持期 0 週にランダム化された被験者とおおむね類似していた。

1) 医師による全般評価

医師による全般評価（Mayo サブスコアの 1 項目）で疾患活動性なし又は軽症の被験者の割合（表 2.7.3-3）は，維持期 0 週でランダムにゴリムマブに割り付けられた被験者（Randomized 群）では 54 週で 90.8%（177/195 例）であり，216 週までおおむね一定であった（93.3～99.3%）。

維持期 0 週にランダムに割り付けられなかった被験者を含めた全ゴリムマブ群でも同様であった［54 週で 86.2%（476/552 例），216 週まで 87.5～95.8%で推移］。

表 2.7.3-3 疾患活動性なし又は軽症の被験者（T18 試験，医師による全般評価）

	Randomized Treatment at Week 0 of maintenance	
	Placebo[a,b]	Golimumab
Randomized subjects who were treated in the study extension (excluding sites 6706, 7257 and 7407)	52	195
Patients with no disease activity		
Week 54	50.0% (26/52)	52.3% (102/195)
Week 56	58.0% (29/50)	55.7% (108/194)
Week 80	63.9% (23/36)	61.5% (115/187)
Week 104	63.6% (14/22)	66.5% (119/179)
Week 128	62.5% (10/16)	64.4% (105/163)
Week 152	55.6% (5/9)	73.6% (117/159)
Week 176	66.7% (4/6)	73.3% (110/150)
Week 200	0.0% (0/1)	75.9% (104/137)
Week 216	0.0% (0/1)	77.6% (104/134)
Patients with no or mild disease activity		
Week 54	90.4% (47/52)	90.8% (177/195)
Week 56	90.0% (45/50)	93.3% (181/194)
Week 80	100.0% (36/36)	96.8% (181/187)
Week 104	95.5% (21/22)	96.1% (172/179)
Week 128	100.0% (16/16)	96.9% (158/163)
Week 152	100.0% (9/9)	97.5% (155/159)
Week 176	100.0% (6/6)	98.7% (148/150)
Week 200	100.0% (1/1)	97.1% (133/137)
Week 216	100.0% (1/1)	99.3% (133/134)

[a] Includes data up to the time of dose increase.
[b] Excludes placebo subjects who had a dose adjustment before Week 54.

[TEFPGA01.rtf] [CNTO148\C0524T18\DBR_W228\RE_W228\TEFPGA01.sas] 24APR2015, 14:55

Source: Table 5 in T18-W228-CSR

2) CRP

CRP の中央値（範囲）は，Randomized 群では 54 週で 1.470（0.10～48.50）mg/L であり，216 週までおおむね一定であった（1.265～1.570 mg/L）。

全ゴリムマブ群でも同様であった［54 週で 1.590（0.10～74.10）mg/L，216 週まで 1.330～1.660 mg/L で推移］。

3) コルチコステロイドの併用

UC 治療としてコルチコステロイドを併用しなかった被験者の割合（表 2.7.3-4）は，Randomized 群では 56 週で 87.6%（170/194 例）であり，216 週までおおむね一定であった（88.4～93.4%）。56 週のコルチコステロイドの 1 日投与量（平均値，prednisone 換算）は 2.13 mg/day であり，216 週までおおむね一定であった（0.89～2.36 mg/day，表 2.7.3-付録-11）。

全ゴリムマブ群でも同様であった［UC 治療としてコルチコステロイドを併用しなかった被験者の割合：56 週で 81.8%（453/554 例），216 週まで 83.8～89.6%で推移；使用量（平均値，prednisone 換算）：56 週で 2.87 mg/day であり，216 週まで 1.62～2.40 mg/day で推移］。

表 2.7.3-4 UC 治療としてコルチコステロイドを併用しなかった被験者（T18 試験）

	Randomized Treatment at Week 0 of maintenance	
	Placebo[a,b]	Golimumab
Randomized subjects who were treated in the study extension (excluding sites 6706, 7257 and 7407)	52	195
Not receiving corticosteroids		
Week 56	80.0% (40/50)	87.6% (170/194)
Week 80	83.3% (30/36)	89.3% (167/187)
Week 104	86.4% (19/22)	88.9% (160/180)
Week 128	81.3% (13/16)	88.4% (145/164)
Week 152	66.7% (6/9)	91.8% (146/159)
Week 176	66.7% (4/6)	92.7% (140/151)
Week 200	100.0% (1/1)	93.4% (128/137)
Week 216	100.0% (1/1)	92.5% (124/134)

[a] Includes data up to the time of dose increase.
[b] Excludes placebo subjects who had a dose adjustment before Week 54.

[TEFCORT01.rtf] [CNTO148\C0524T18\DBR_W228\RE_W228\TEFCORT01.sas] 01MAY2015, 10:55

Source: Table 6 in T18-W228-CSR

4) IBDQ

IBDQ が 170 以上の被験者の割合（表 2.7.3-5）は，Randomized 群では 54 週で 72.5%（140/193 例）であり，216 週までおおむね一定であった（70.8～77.7%）。IBDQ の中央値（範囲）は，54 週で 191.0（79～224）であり，216 週までおおむね一定であった（192.0～198.0，表 2.7.3-付録-12）。

全ゴリムマブ群でも同様であった［IBDQ が 170 以上の被験者の割合：54 週で 68.8%（380/552 例），216 週まで 69.9～77.0%で推移；IBDQ の中央値（範囲）は，54 週で 186.5（79～224），216 週まで 188.0～195.0 で推移］。

表 2.7.3-5 IBDQ が 170 以上の被験者（T18 試験）

	Randomized Treatment at Week 0 of maintenance	
	Placebo[a,b]	Golimumab
Randomized subjects who were treated in the study extension (excluding sites 6706, 7257 and 7407)	52	195
Subjects who had an IBDQ score ≥ 170 at Week 54	78.8% (41/52)	72.5% (140/193)
Subjects who had an IBDQ score ≥ 170 at Week 80	88.9% (32/36)	70.8% (131/185)
Subjects who had an IBDQ score ≥ 170 at Week 104	90.9% (20/22)	74.4% (131/176)
Subjects who had an IBDQ score ≥ 170 at Week 128	87.5% (14/16)	72.5% (116/160)
Subjects who had an IBDQ score ≥ 170 at Week 152	87.5% (7/8)	77.7% (122/157)
Subjects who had an IBDQ score ≥ 170 at Week 176	83.3% (5/6)	74.0% (108/146)
Subjects who had an IBDQ score ≥ 170 at Week 200	100.0% (1/1)	77.4% (106/137)
Subjects who had an IBDQ score ≥ 170 at Week 216	100.0% (1/1)	76.1% (102/134)

[a] Includes data up to the time of dose increase.
[b] Excludes placebo subjects who had a dose adjustment before Week 54.

[TEFIBDQ04.rtf] [CNTO148\C0524T18\DBR_W228\RE_W228\TEFIBDQ04.sas] 24APR2015, 14:55

Source: Table 7 in T18-W228-CSR

2.7.3.2.4 UCO3001 試験

【評価資料 5.3.5.1.5】

(1) 寛解導入期

被験者の 68.1%が男性であり，年齢の中央値（範囲）は 42.0（18～73）歳，体重の中央値（範囲）は 60.75（42.2～100.4）kg であった。UC 罹病期間の中央値（範囲）は 5.08（0.1～27.4）年，Mayo スコアの中央値（範囲）は 8.0（6～12）点，全大腸炎型の被験者の割合は 38.2%，CRP の中央値（範囲）は 1.585（0.11～84.34）mg/L であった。

本試験には 144 例が組み入れられ，123 例が寛解導入期の評価を完了した。

6 週に clinical response が認められた被験者の割合は 43.8%（63/144 例），6 週に clinical remission が認められた被験者の割合は 18.8%（27/144 例），6 週に mucosal healing が認められた被験者の割合は 36.8%（53/144 例）であった。また，6 週の IBDQ スコアのベースラインからの平均変化量（SD）は 14.8（29.23），6 週の IBDQ がベースラインより 21 以上改善した被験者の割合は 40.6%（58/143 例）であった。

(2) 寛解維持期

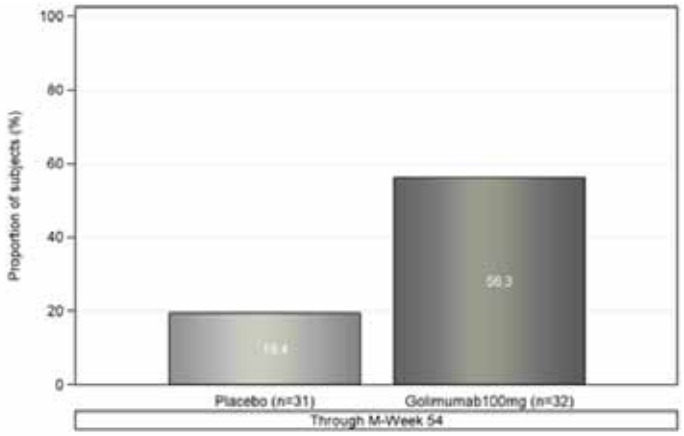
寛解導入期の評価を完了した 123 例が寛解維持期に組み入れられ，導入期 6 週に clinical response が認められた 63 例がランダムに割り付けられた（100 mg 群 32 例及びプラセボ群 31 例）。残り 60 例はゴリムマブ寛解導入 nonresponder であった。寛解維持期に組み入れられたすべての被験者に治験薬が投与された。

1) ランダム化された被験者

ランダム化された被験者の 60.3%が男性であり，年齢の中央値（範囲）は 40.0（18～73）歳，体重の中央値（範囲）は 60.70（42.3～100.4）kg であった。UC 罹病期間の中央値（範囲）は 5.66（0.3～24.7）年，Mayo スコアの中央値（範囲）は 8.0（6～12）点，全大腸炎型の被験者の割合は 38.1%，CRP の中央値（範囲）は 1.480（0.11～84.34）mg/L であった。下記項目を除いて，人口統計学的特性及び疾患特性は，群間でおおむね類似していた。

・ 100 mg 群の CRP がプラセボ群より高値：100 mg 群 1.805（0.11～84.34）mg/L 及びプラセボ群 0.930（0.14～40.77）mg/L

主要評価項目である維持期 54 週まで clinical response が維持された被験者の割合は，100 mg 群 56.3%（18/32 例）及びプラセボ群 19.4%（6/31 例）であった（図 2.7.3-16）。その差は 36.9%（95%CI：14.8;59.0）であり，T18 試験で 54 週まで clinical response が維持された被験者の割合の 100 mg 群及びプラセボ群の差 19.2%の 95%CI（8.5;29.9）の下限値 8.5%を大きく上回った。



FAS-DB=efficacy full analysis set for double-blind maintenance phase; n=number of subjects
[GEFCR01.rtf] [CNTO148CNTO148UCO3001DBR_CSRW54RE_CSRW54 gefcr01.sas] 03DEC2015, 12:06

Source: Figure 5 in UCO3001-54W-CSR

図 2.7.3-16 54 週まで clinical response が維持された被験者の割合（UCO3001 試験）

主な副次評価項目及び IBDQ の結果を以下に示す。

・ 維持期 30 及び 54 週ともに clinical remission が認められた被験者の割合は，100 mg 群 50.0%（16/32 例）であり，プラセボ群 6.5%（2/31 例）と比べて高かった。

・ 維持期 30 及び 54 週ともに mucosal healing が認められた被験者の割合は，100 mg 群 59.4%（19/32 例）であり，プラセボ群 16.1%（5/31 例）と比べて高かった。

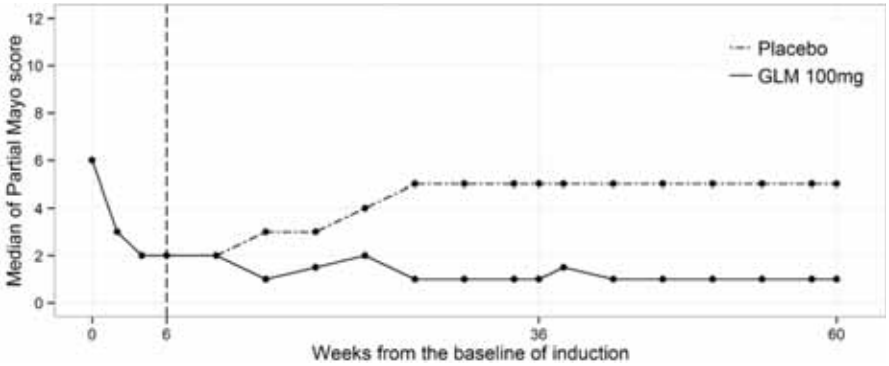
・ 維持期 0 週に clinical remission が認められていた被験者のうち，維持期 30 及び 54 週ともに clinical remission が認められた被験者の割合は，100 mg 群 64.3%（9/14 例）であり，プラセボ群 15.4%（2/13 例）と比べて高かった。

・ 維持期 0 週にコルチコステロイドを併用していた被験者のうち，維持期 54 週に clinical remission が認められ，かつコルチコステロイドを併用していなかった被験者の割合は，100 mg 群 55.6%（5/9 例）であり，プラセボ群 11.1%（1/9 例）と比べて高かった。

・ 導入期 0 週と比べて，維持期 0 週に IBDQ が 21 以上改善した被験者のうち，54 週の IBDQ も 21 以上改善していた被験者の割合は，100 mg 群 55.0%（11/20 例）であり，プラセボ群 22.2%（6/27 例）と比べて高かった。

ランダム化された被験者の partial Mayo スコア（中央値）は，導入期に 6 から 2 に減少した。100 mg 群は 14 週（維持期 8 週）に 1 となり，26 週（維持期 20 週）以降はおおむね 1 を維持した。

プラセボ群では 14 週（維持期 8 週）には 3 となり，26 週（維持期 20 週）には 5 まで増加した（図 2.7.3-17）。



Source: FEFPMAYO03 in analysis for Japan submission dossier

図 2.7.3-17 Partial Mayo score の推移（UCO3001 試験，ランダム化された被験者）

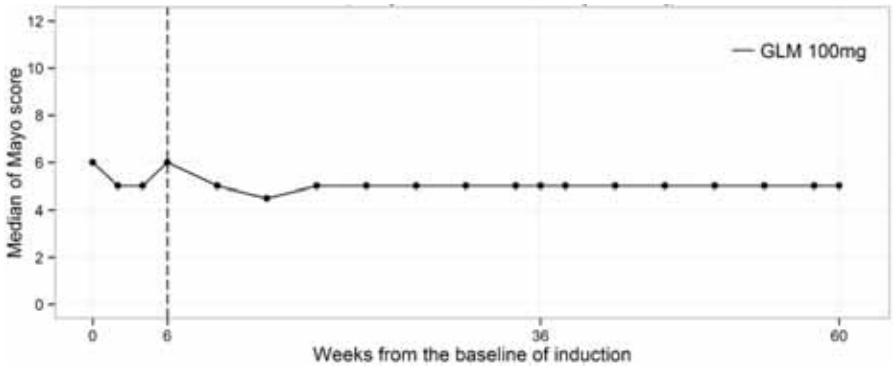
2) ランダム化されなかった被験者

ランダム化されなかった 60 例のゴリムマブ寛解導入 nonresponder には，ゴリムマブ 100 mg を維持期 52 週まで 4 週ごとに皮下投与した。なお，維持期 8 週までに疾患活動性の改善（clinical response）が認められない場合，維持期 8 週以降の治験薬投与を中止した。

- ゴリムマブ寛解導入 nonresponder の 8 週，30 週及び 54 週に clinical response が認められた被験者の割合は，それぞれ 38.3%（18/47 例），25.0%（15/60 例）及び 18.3%（11/60 例）であった。
- ゴリムマブ寛解導入 nonresponder の 8 週，30 週及び 54 週に clinical remission が認められた被験者の割合は，それぞれ 4.3%（2/47 例），6.7%（4/60 例）及び 10.0%（6/60 例）であった。
- ゴリムマブ寛解導入 nonresponder の 8 週，30 週及び 54 週に mucosal healing が認められた被験者の割合は，それぞれ 21.7%（13/60 例），15.0%（9/60 例）及び 15.0%（9/60 例）であった。

ゴリムマブ寛解導入 nonresponder の partial Mayo スコア（中央値）の推移を図 2.7.3-18 に示す。

ゴリムマブ寛解導入 nonresponder の partial Mayo スコア（中央値）は，導入期 0 及び 6 週は 6 であり，維持期でもおおむね 5 であった。

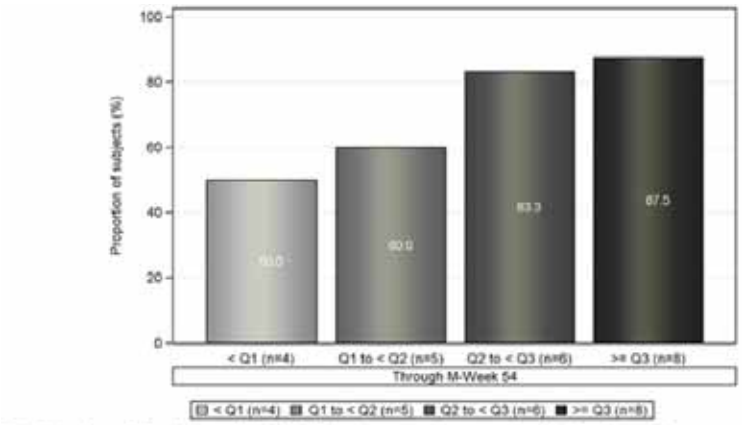


Source: FEFPMAYO04 in analysis for Japan submission dossier

図 2.7.3-18 Partial Mayo score の推移（UCO3001 試験，ランダム化されなかった被験者）

(3) 有効性及び薬物動態

血清中ゴリムマブ濃度が高値であるほど，疾患活動性の改善（clinical response，clinical remission 等）がおおむね認められた。54 週の血清中ゴリムマブ濃度の第 4 四分位（≥ 6.04 μg/mL）で，54 週まで clinical response が維持された被験者の割合が最も高かった［87.5%（7/8 例）］。第 3 四分位（≥ 4.81～ < 6.04 μg/mL）の 54 週まで clinical response が維持された被験者の割合［83.3%（5/6 例）］は，第 2 四分位［≥ 3.26～ < 4.81 μg/mL，60.0%（3/5 例）］及び第 1 四分位［< 3.26 μg/mL，50.0%（2/4 例）］と比べて高かった（図 2.7.3-19）。



FAS-DB=efficacy full analysis set for double-blind maintenance phase; n=number of subject; Q=quartile
Note: Q1: 3.26 μg/mL, Q2: 4.81 μg/mL, Q3: 6.04 μg/mL
[GPKPDBAR01.rtf] [CNTO148\CNTO148UCO3001\DBR_CSRW54\RE_CSRW54\GPKPDBAR01.sas] 20JAN2016, 14:13

Source: Figure 6 in UCO3001-54W-CSR

図 2.7.3-19 有効性（54 週まで clinical response が維持された被験者の割合）と薬物動態（UCO3001 試験，維持期 0 週にランダム化された被験者）

(4) 有効性及び免疫原性

寛解導入期では，抗ゴリムマブ抗体陽性の被験者は認められなかった。

維持期 0 週にランダム化された被験者のうち，ゴリムマブ群では抗ゴリムマブ抗体陽性の被験者は認められなかったが，プラセボ群では 12.9%（4/31 例）が抗ゴリムマブ抗体陽性であった。うち 1 例は 54 週まで clinical response を維持したが，3 例は維持できなかった（うち 1 例は投与量調節により 100 mg 投与された）。

ランダム化されなかったゴリムマブ寛解導入 nonresponder では，1.7%（1/60 例）が抗ゴリムマブ抗体陽性であった。当該 1 例では，54 週の clinical response は認められなかった。

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

T16 試験，T17 試験 Part 2（投与量選択後）及び T18 試験においてランダム化された被験者の背景（導入期 0 週の人口統計学的特性，疾患特性，併用した UC 治療薬及び UC 前治療に対する反応性）を表 2.7.3-付録-1 に，UCO3001 試験の被験者背景を表 2.7.3-付録-2，表 2.7.3-付録-3，表 2.7.3-付録-4，表 2.7.3-付録-5，表 2.7.3-付録-6，表 2.7.3-付録-7，表 2.7.3-付録-8 及び表 2.7.3-付録-9 に示す。

T16 試験及び T17 試験 Part 2（投与量選択後）の人口統計学的特性，疾患特性及び UC 治療薬併用は，おおむね一致していた［それぞれ，男性：59.8%及び 56.0%，白人：82.1%及び 82.1%，年齢（中央値）：40.0 歳及び 38.0 歳，体重（中央値）：70.0 kg 及び 72.0 kg，UC 罹病期間（中央値）：4.57 年及び 4.30 年，Mayo スコア（中央値）：8.0 及び 8.0，UC 治療薬併用：94.2%及び 92.1%］。Prednisone 換算で 20 mg/day 以上のコルチコステロイドを併用していた被験者の割合は，T17 試験（25.1%）と比べて，T16 試験（36.1%）で高かった。

T18 試験には，T16 及び T17 試験の被験者を組み入れており，T18 試験の維持期 0 週でランダム化された被験者の背景（T16 又は T17 試験のゴリムマブ寛解導入 responder の導入期 0 週の被験者背景）は，T16 及び T17 試験とおおむね一致していた。

UCO3001 試験に組み入れた被験者の背景［年齢（中央値）42.0 歳，UC 罹病期間（中央値）5.08 年，Mayo スコア（中央値）8.0，UC 治療薬併用 97.9%］は，性別（男性 68.1%），人種，体重（中央値 60.75 kg）及び prednisone 換算で 20 mg/day 以上のコルチコステロイドを併用していた被験者の割合（8.3%）を除いて，T16 及び T17 試験とおおむね一致していた。

UCO3001 試験の維持期 0 週でランダム化された被験者の背景［年齢（中央値）40.0 歳，UC 罹病期間（中央値）5.66 年，Mayo スコア（中央値）8.0，UC 治療薬併用 98.4%］は，性別（男性 60.3%），人種，体重（中央値 60.70 kg）及び prednisone 換算で 20 mg/day 以上のコルチコステロイドを併用していた被験者の割合（14.3%）を除いて，T18 試験とおおむね一致していた。

2.7.3.3.2 全有効性試験の結果の比較検討

本項では，国際共同臨床試験の T17 及び T18 試験と国内臨床試験の UCO3001 試験の結果を比較する。なお，T17 及び T18 試験のそれぞれの日本人集団と試験全体との比較は 2.7.3.3.3 に示す。

2.7.3.3.2.1 寛解導入療法（T17 試験と UCO3001 試験の比較）

T17 試験の結果は，UCO3001 試験でもおおむね再現されていた。なお，T17 試験における日本人集団と試験全体の比較の結果は，2.7.3.3.3.1(1)に示す。

(1) 6 週の clinical response

T17 試験 Part 2（投与量選択後）の 6 週に clinical response が認められた被験者の割合（主要評価項目）は，200→100 mg 群 51.0%（129/253 例）及び 400→200 mg 群 54.9%（141/257 例）であり，プラセボ群 30.3%（76/251 例）と比べて，いずれも統計学的に有意な差が認められた（表 2.7.3-6）。UCO3001 試験の寛解導入期の 6 週に clinical response が認められた被験者の割合は

43.8%（63/144 例）であった（表 2.7.3-7）。UCO3001 試験の寛解導入期のデザイン（非盲検）は T17 試験（二重盲検）と異なるものの，UCO3001 試験の寛解導入期の結果は，T17 試験の結果とおおむね同程度であった。

表 2.7.3-6 6 週に clinical response が認められた被験者（T17 試験，Part 2 投与量選択後）

		Golimumab		
	Placebo	200 mg → 100 mg	400 mg → 200 mg	Combined
Randomized subjects in Part 2 after the dose selection (excluding sites 6706, 7257 and 7407)	251	253	257	510
Week 6				
n	251	253	257	510
Subjects in clinical response[a,b]	76 (30.3%)	129 (51.0%)	141 (54.9%)	270 (52.9%)
p-value		< 0.0001	< 0.0001	< 0.0001

[a] Subjects who had a prohibited change in concomitant UC medication, an ostomy or colectomy, or discontinued study agent due to lack of therapeutic effect prior to the Week 6 visit are considered not to be in clinical response.
[b] Subjects who had all 4 Mayo subscores missing at Week 6 are considered not to be in clinical response.

RE630:fE CRES 93 B BBL 01MAY2015 11:18

Source: Attachment 3.1 of T17 in Re-analysis report for C0524T17 and C0524T18 54-Week

表 2.7.3-7 6 週に clinical response が認められた被験者（UCO3001 試験）

	Golimumab 200 mg -> 100 mg
Analysis set: FAS-I	144
Week 6	
N	144
Subjects with Clinical Response [a,b]	63 (43.8%)

[a] Subjects who had a prohibited change in concomitant UC medication, an ostomy or colectomy, or discontinued study agent due to lack of therapeutic effect prior to the Week 6 visit are considered not to be in clinical response.
[b] Subjects who had all 4 Mayo subscores missing at Week 6 are considered not to be in clinical response.

[TEFCR01IN.rtf] [CNTO148¥CNTO148UCO3001¥DBR_CSRW54¥RE_NDAJPKK¥TEFCR01IN.sas] 27JAN2016, 16:33

Source: TEFCR01IN in analysis for Japan submission dossier

(2) 6 週の clinical remission

T17 試験 Part 2（投与量選択後）において，6 週に clinical remission が認められた被験者の割合は，200→100 mg 群 17.8%（45/253 例）及び 400→200 mg 群 17.9%（46/257 例）であり，プラセボ群 6.4%（16/251 例）と比べて，いずれも統計学的に有意な差が認められた（表 2.7.3-8）。UCO3001 試験の寛解導入期において，6 週に clinical remission が認められた被験者の割合は 18.8%（27/144 例）であった（表 2.7.3-9）。UCO3001 試験の寛解導入期のデザイン（非盲検）は T17 試験（二重盲検）と異なるものの，UCO3001 試験の寛解導入期の結果は，T17 試験の結果とおおむね同程度であった。

表 2.7.3-8 6 週に clinical remission が認められた被験者（T17 試験，Part 2 投与量選択後）

	Placebo	Golimumab 200 mg → 100 mg	Golimumab 400 mg → 200 mg	Golimumab Combined
Randomized subjects in Part 2 after the dose selection (excluding sites 6706, 7257 and 7407)	251	253	257	510
Week 6				
n	251	253	257	510
Subjects in clinical remission[a,b]	16 (6.4%)	45 (17.8%)	46 (17.9%)	91 (17.8%)
p-value		< 0.0001	< 0.0001	< 0.0001

[a] Subjects who had a prohibited change in concomitant UC medication, an ostomy or colectomy, or discontinued study agent due to lack of therapeutic effect prior to the Week 6 visit are considered not to be in clinical remission.
[b] Subjects who had all 4 Mayo subscores missing at Week 6 are considered not to be in clinical remission.

RE630/IE CREM 1 B BB1 01MAY2015 11:02

Source: Attachment 3.23 of T17 in Re-analysis report for C0524T17 and C0524T18 54-Week

表 2.7.3-9 6 週に clinical remission が認められた被験者（UCO3001 試験）

	Golimumab 200 mg -> 100 mg
Analysis set: FAS-I	144
Week 6	
N	144
Subjects with Clinical Remission [a,b]	27 (18.8%)

[a] Subjects who had a prohibited change in concomitant UC medication, an ostomy or colectomy, or discontinued study agent due to lack of therapeutic effect prior to the Week 6 visit are considered not to be in clinical remission.
[b] Subjects who had all 4 Mayo subscores missing at Week 6 are considered not to be in clinical remission.

[TEFREM01IN.rtf] [CNTO148¥CNTO148UCO3001¥DBR_CSRW54¥RE_NDAJPKK¥TEFREM01IN.sas] 27JAN2016, 16:35

Source: TEFREM01IN in analysis for Japan submission dossier

(3) 6 週の mucosal healing

T17 試験 Part 2（投与量選択後）において，6 週に mucosal healing が認められた被験者の割合は，200→100 mg 群 42.3%（107/253 例）及び 400→200 mg 群 45.1%（116/257 例）であり，プラセボ群 28.7%（72/251 例）と比べて，いずれも統計学的に有意な差が認められた（表 2.7.3-10）。UCO3001 試験の寛解導入期において，6 週に mucosal healing が認められた被験者の割合は 36.8%（53/144 例）であった（表 2.7.3-11）。UCO3001 試験の寛解導入期のデザイン（非盲検）は T17 試験（二重盲検）と異なるものの，UCO3001 試験の寛解導入期の結果は，T17 試験の結果とおおむね同程度であった。

表 2.7.3-10 6 週に mucosal healing が認められた被験者（T17 試験，Part 2 投与量選択後）

	Placebo	Golimumab 200 mg → 100 mg	Golimumab 400 mg → 200 mg	Golimumab Combined
Randomized subjects in Part 2 after the dose selection (excluding sites 6706, 7257 and 7407)	251	253	257	510
Week 6				
n	251	253	257	510
Subjects with mucosal healing[a,b]	72 (28.7%)	107 (42.3%)	116 (45.1%)	223 (43.7%)
p-value		0.0014	0.0001	< 0.0001

[a] Subjects who had a prohibited change in concomitant UC medication, an ostomy or colectomy, or discontinued study agent due to lack of therapeutic effect prior to the Week 6 visit are considered not to have mucosal healing.
[b] Subjects who had a missing endoscopy subscore at Week 6 are considered not to have mucosal healing.

RE630:IE MUCO 2 B BBL 01MAY2015 12:22

Source: Attachment 3.25 of T17 in Re-analysis report for C0524T17 and C0524T18 54-Week

表 2.7.3-11 6 週に mucosal healing が認められた被験者（UCO3001 試験）

	Golimumab 200 mg -> 100 mg
Analysis set: FAS-I	144
Week 6	
N	144
Subjects with mucosal healing [a,b]	53 (36.8%)

[a] Subjects who had a prohibited change in medication, an ostomy or colectomy, or discontinued study agent due to a lack of therapeutic effect prior to Week 6 are considered not to have mucosal healing.
[b] Subjects who had a missing endoscopy subscore at Week 6 are considered not to have mucosal healing.

[TEFMH01.rtf] [CNTO148CNTO148UCO3001\DBR_CSR\W54\RE_CSR\W54\refmh01.sas] 03DEC2015, 12:07

Source: Attachment TEFMH01 in UCO3001-54W-CSR

(4) IBDQ

1) 6 週の IBDQ のベースラインからの平均変化量

T17 試験 Part 2（投与量選択後）において，6 週の IBDQ スコアのベースラインからの平均変化量（SD）は，200→100 mg 群 27.0（33.72）及び 400→200 mg 群 26.9（34.28）であり，プラセボ群 14.8（31.25）と比べて，いずれも統計学的に有意な差が認められた（表 2.7.3-12）。UCO3001 試験の寛解導入期において，6 週の IBDQ スコアのベースラインからの平均変化量（SD）は 14.8（29.23）であった（表 2.7.3-13）。

表 2.7.3-12 6 週の IBDQ のベースラインからの平均変化量（T17 試験，Part 2 投与量選択後）

	Placebo	Golimumab 200 mg → 100 mg	Golimumab 400 mg → 200 mg	Combined
Randomized subjects in Part 2 after the dose selection (excluding sites 6706, 7257 and 7407)	251	253	257	510
Baseline				
n	250	252	255	507
Mean ± SD	129.0 ± 32.61	131.7 ± 33.93	127.2 ± 33.90	129.5 ± 33.96
Median	127.5	134.0	127.0	130.0
IQ range	(104.0, 152.0)	(104.0, 157.0)	(105.0, 152.0)	(104.0, 156.0)
Range	(60, 206)	(54, 209)	(33, 201)	(33, 209)
Change from baseline				
Week 6[a,b]				
n	250	252	255	507
Mean ± SD	14.8 ± 31.25	27.0 ± 33.72	26.9 ± 34.28	26.9 ± 33.96
Median	11.0	22.5	21.0	22.0
IQ range	(-3.0, 29.0)	(0.5, 48.5)	(0.0, 50.0)	(0.0, 50.0)
Range	(-80, 115)	(-49, 131)	(-60, 187)	(-60, 187)
p-value		< 0.0001	< 0.0001	< 0.0001

[a] Subjects who had a prohibited change in concomitant UC medication, an ostomy or colectomy, or discontinued study agent due to lack of therapeutic effect prior to the Week 6 visit had their baseline value carried forward to Week 6.
[b] Subjects who had a missing IBDQ score at Week 6 had the last available value carried forward.

RE630 [E IBDQ 1 B BB], 01MAY2015 11:39

Source: Table 10 of T17 in Re-analysis report for C0524T17 and C0524T18 54-Week

表 2.7.3-13 6 週の IBDQ のベースラインからの平均変化量（UCO3001 試験）

	Golimumab 200 mg -> 100 mg
Analysis set: FAS-I	144
Week 0 of induction phase	
N	143
Mean (SD)	149.2 (29.23)
Median	152.0
IQ range	(133.0; 170.0)
Range	(54; 213)
Change from Week 0 of induction phase	
Week 6 [a,b]	
N	143
Mean (SD)	14.8 (29.23)
Median	11.0
IQ range	(-3.0; 33.0)
Range	(-68; 131)

[a] Subjects who had a prohibited change in concomitant UC medication, an ostomy or colectomy, or discontinued study agent due to lack of therapeutic effect prior to the Week 6 visit had their baseline value carried forward to Week 6.
[b] Subjects who had a missing IBDQ score at Week 6 had the last available value carried forward.

[TEFIBDQ03.rtf] [CNTO148¥CNTO148UCO3001¥DBR_CSRW54¥RE_CSRW54¥tefibdq03.sas] 03DEC2015, 12:07

Source: Attachment TEFIBDQ03 in UCO3001-54W-CSR

2) 6 週の IBDQ がベースラインより 21 以上改善した被験者の割合

T17 試験 Part 2（投与量選択後）において，6 週の IBDQ スコアがベースラインより 21 以上改善した被験者の割合は，200→100 mg 群 50.6%（128/253 例）及び 400→200 mg 群 51.0%（131/257 例）であり，プラセボ群 35.5%（89/251 例）と比べて，いずれも統計学的に有意な差が認められた（表 2.7.3-14）。UCO3001 試験の寛解導入期において，6 週の IBDQ スコアがベースラインより 21 以上改善した被験者の割合は 40.6%（58/143 例）であった（表 2.7.3-15）。

表 2.7.3-14 6 週の IBDQ がベースラインより 21 以上改善した被験者
（T17 試験，Part 2 投与量選択後）

		Golimumab		
	Placebo	200 mg → 100 mg	400 mg → 200 mg	Combined
Randomized subjects in Part 2 after the dose selection (excluding sites 6706, 7257 and 7407)	251	253	257	510
Week 6				
n	251	253	257	510
Subjects with > 20-point improvement[a,b]	89 (35.5%)	128 (50.6%)	131 (51.0%)	259 (50.8%)
p-value		0.0006	0.0004	< 0.0001

[a] Subjects who had a prohibited change in concomitant UC medication, an ostomy or colectomy, or discontinued study agent due to lack of therapeutic effect prior to the Week 6 visit are considered not to have achieved a greater than 20-point improvement.
[b] Subjects who had a missing IBDQ score at either baseline or Week 6 are considered not to have achieved a greater than 20-point improvement.

RE630:[E IBDQ 12 B BB], 06MAY2015 10:32

Source: Table 12 of T17 in Re-analysis report for C0524T17 and C0524T18 54-Week

表 2.7.3-15 6 週の IBDQ がベースラインより 21 以上改善した被験者（UCO3001 試験）

	Golimumab 200 mg -> 100 mg
Analysis set: FAS-I	144
Week 6	
N	143
Subjects with a greater than 20-point improvement from baseline in IBDQ [a,b]	58 (40.6%)

[a] Subjects who had a prohibited change in concomitant UC medication, an ostomy or colectomy, or discontinued study agent due to lack of therapeutic effect prior to the Week 6 visit had their baseline value carried forward to Week 6.
[b] Subjects who had a missing IBDQ score at Week 6 had the last available value carried forward.

[TEFIBDQIMPIN.rtf] [CNTO148¥CNTO148UCO3001¥DBR_CSRW54¥RE_NDAJPKK¥TEFIBDQIMPIN.sas] 27JAN2016, 16:34

Source: TEFIBDQIMPIN in analysis for Japan submission dossier

2.7.3.3.2.2　寛解維持療法（T18 試験と UCO3001 試験の比較）

下記の結果から，平成 [redacted] 年 [redacted] 月 [redacted] 日付けの医薬品[redacted]相談での結果（薬機審長発第[redacted]号）に基づいて，T18 試験と UCO3001 試験の有効性の結果は類似しており，日本人患者においてもゴリムマブによる寛解維持効果が期待できると判断した。

- UCO3001 試験において，維持期 54 週まで clinical response が維持された被験者の割合の 100 mg 群とプラセボ群の差は 36.9%であり，事前に設定した 8.5%を大きく上回った。
- 主要評価項目及び主な副次評価項目において，T18 試験の 100 mg 群とプラセボ群の差が> 0, かつ UCO3001 試験の 100 mg 群とプラセボ群の差が> 0 であった［「国際共同治験に関する基本的考え方について（平成 19 年 9 月 28 日薬食審査発第 0928010 号）」における「方法 2」］。
- T18 及び UCO3001 試験の 54 週まで clinical response が維持された被験者の割合，30 及び 54 週ともに clinical remission が認められた被験者の割合，並びに 30 及び 54 週ともに mucosal healing が認められた被験者の割合における各群の点推定値（95%CI）及びプラセボ群との差の点推定値（95%CI）から，T18 試験と UCO3001 試験の結果は類似していた。

以下に，T18 及び UCO3001 試験の主要評価項目及び主な副次評価項目等の結果を示す。

(1) 54 週まで clinical response が維持された被験者の割合（主要評価項目）

54 週まで clinical response が維持された被験者の割合は，T18 試験では，50 mg 群 47.0%（71/151 例）及び 100 mg 群 49.7%（75/151 例）であり，プラセボ群 31.2%（48/154 例）と比べて，いずれも統計学的に有意な差が認められた（表 2.7.3-16）。UCO3001 試験では，100 mg 群 56.3%（18/32 例）及びプラセボ群 19.4%（6/31 例）であった（表 2.7.3-17）。いずれの試験でも，100 mg 群の 54 週まで clinical response が維持された被験者の割合は，プラセボ群より高かった（プラセボ群との差：T18 試験 18.5%，UCO3001 試験 36.9%）。

表 2.7.3-16 54 週まで clinical response が維持された被験者（T18 試験）

		Golimumab		
	Placebo	50 mg	100 mg	Combined
Randomized subjects (excluding sites 6706, 7257 and 7407)	154	151	151	302
Through Week 54				
n	154	151	151	302
Subjects in clinical response[a,b]	48 (31.2%)	71 (47.0%)	75 (49.7%)	146 (48.3%)
p-value		0.010	< 0.001	< 0.001

[a] Subjects who had a prohibited change in UC medication, an ostomy or colectomy, a dose adjustment, or discontinued study agent due to lack of therapeutic effect prior to the Week 54 visit are considered not to be in clinical response.
[b] Subjects who had all 4 Mayo subscores missing at Week 30 or at Week 54 are considered not to be in clinical response.

RE631 [E CRES 93 A AA] 15MAY2015 10:36

Source: Attachment 3.1 of T18 in Re-analysis report for C0524T17 and C0524T18 54-Week

表 2.7.3-17 54 週まで clinical response が維持された被験者（UCO3001 試験）

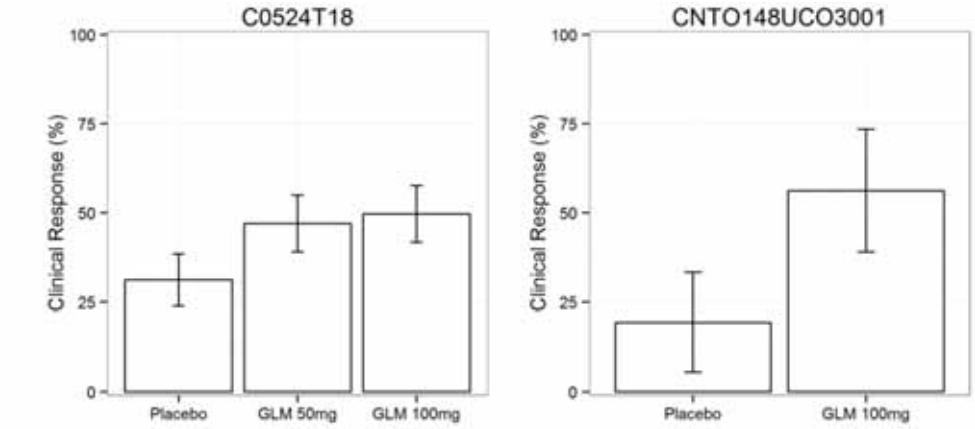
	Placebo	Golimumab 100 mg
Analysis set: FAS-DB	31	32
Through Week 54		
N	31	32
Subjects in clinical response [a,b]	6 (19.4%)	18 (56.3%)
Asymptotic 95% CI	(5.4; 33.3)	(39.1; 73.4)
CR_{100} - CR_p (%)		36.9
Asymptotic 95% CI (CR_{100} - CR_p)		(14.8; 59.0)

CI=confidence interval; CR=clinical response; FAS-DB=efficacy full analysis set for double-blind maintenance phase; N=number of subjects
[a] Subjects who had a prohibited change in UC medication, as ostomy or colectomy, a dose adjustment, or discontinued study agent due to lack of therapeutic effect prior to the Week 54 visit are considered not to be in clinical response.
[b] Subjects who had all 4 Mayo subscores missing at Week 30 or at Week 54 are considered not to be in clinical response.
[TEFCR01.rtf] [CNTO148\CNTO148UCO3001\DBR_CSRW54\RE_CSRW54\TEFCR01.sas] 03DEC2015, 11:46

Source: Table 8 in UCO3001-54W-CSR

T18 及び UCO3001 試験の 54 週まで clinical response が維持された被験者の割合における各群の点推定値（95%CI）及びプラセボ群との差の点推定値（95%CI）を図 2.7.3-20 に示す。

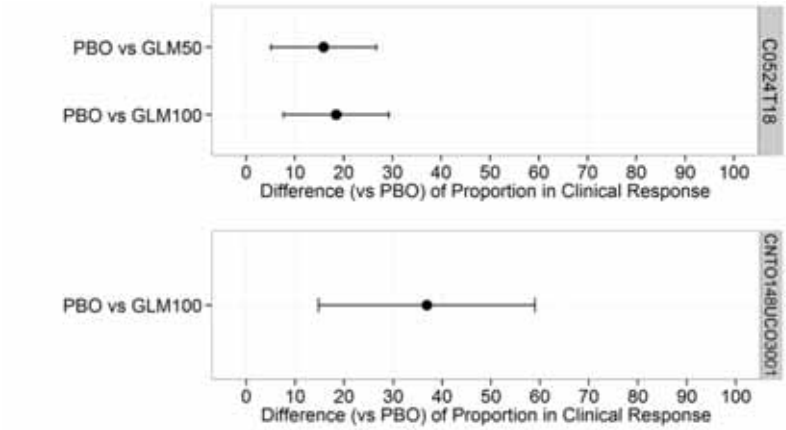
T18 試験の点推定値（95%CI）は，プラセボ群 31.2%（23.9; 38.5），50 mg 群 47.0%（39.1; 55.0）及び 100 mg 群 49.7%（41.7; 57.6），UCO3001 試験では，プラセボ群 19.4%（5.4; 33.3）及び 100 mg 群 56.3%（39.1; 73.4）であった。T18 及び UCO3001 試験の 54 週まで clinical response が維持された被験者の割合は同程度であった。



Group	Placebo	GLM 50mg	GLM 100mg	Placebo	GLM 100mg
N	154	151	151	31	32
Subjects in Response	48 (31.2%)	71 (47.0%)	75 (49.7%)	6 (19.4%)	18 (56.3%)
95%CI	(23.9, 38.5)	(39.1, 55.0)	(41.7, 57.6)	(5.4, 33.3)	(39.1, 73.4)

Reference: C0524T18 Week 54 (E_CRES_93_A_AA, excluding sites 6706, 7257 & 7407), CNTO148UCO3001 Week 54 (TEFCR01)

(A)



Study	C0524T18			CNTO148UCO3001	
Group	Placebo	GLM 50mg	GLM 100mg	Placebo	GLM 100mg
N	154	151	151	31	32
Subjects in Response	48 (31.2%)	71 (47.0%)	75 (49.7%)	6 (19.4%)	18 (56.3%)
Point estimate [95%CI] (Treatment Difference)	---	15.9 [5.0, 26.7]	18.5 [7.7, 29.3]	---	36.9 [14.8, 59.0]

Reference: C0524T18 Week 54 (E_CRES_93_A_AA, excluding sites 6706, 7257 & 7407), CNTO148UCO3001 Week 54 (TEFCR01)

(B)

(A) 点推定値及び 95%CI，(B) プラセボとの差及び 95%CI

Source: FEFCRW54-Comp and FEFCRDIFW54-Comp

図 2.7.3-20 54 週まで clinical response が維持された被験者の割合（T18 及び UCO3001 試験）

(2) 30 及び 54 週ともに clinical remission が認められた被験者の割合

30 及び 54 週ともに clinical remission が認められた被験者の割合は，T18 試験では，50 mg 群 23.2%（35/151 例）及び 100 mg 群 27.8%（42/151 例）であり，100 mg 群では，プラセボ群 15.6%（24/154 例）と比べて，統計学的に有意な差が認められた（表 2.7.3-18）。UCO3001 試験では，100 mg 群 50.0%（16/32 例）及びプラセボ群 6.5%（2/31 例）であった（表 2.7.3-19）。いずれの試験でも，100 mg 群の 30 及び 54 週ともに clinical remission が認められた被験者の割合は，プラセボ群より高かった（プラセボ群との差：T18 試験 12.2%，UCO3001 試験 43.5%）。

表 2.7.3-18 30 及び 54 週ともに clinical remission が認められた被験者（T18 試験）

	Placebo	Golimumab 50 mg	Golimumab 100 mg	Golimumab Combined
randomized subjects (excluding sites 6706, 7257 and 7407)	154	151	151	302
Both Week 30 and Week 54				
n	154	151	151	302
Subjects in clinical remission[a,b]	24 (15.6%)	35 (23.2%)	42 (27.8%)	77 (25.5%)
p-value		0.122	0.004	0.013

[a] Subjects who had a prohibited change in UC medication, an ostomy or colectomy, a dose adjustment, or discontinued study agent due to lack of therapeutic effect prior to the Week 54 visit are considered not to be in clinical remission.
[b] Subjects who had all 4 Mayo subscores missing at Week 30 or at Week 54 are considered not to be in clinical remission.

RE631 IE CREM 1 A AAl 13MAY2015 13:12

Source: Attachment 3.22 of T18 in Re-analysis report for C0524T17 and C0524T18 54-Week

表 2.7.3-19 30 及び 54 週ともに clinical remission が認められた被験者（UCO3001 試験）

	Placebo	Golimumab 100 mg
Analysis set: FAS-DB	31	32
Both Week 30 and Week 54		
N	31	32
Subjects in clinical remission [a,b]	2 (6.5%)	16 (50.0%)

FAS-DB=efficacy full analysis set for double-blind maintenance phase; N=number of subjects
[a] Subjects who had a prohibited change in UC medication, as ostomy or colectomy, a dose adjustment, or discontinued study agent due to lack of therapeutic effect prior to the Week 54 visit are considered not to be in clinical remission.
[b] Subjects who had all 4 Mayo subscores missing at Week 30 or at Week 54 are considered not to be in clinical remission.
[TEFREM01.rtf] [CNTO148\CNTO148UCO3001\DBR_CSRW54\RE_CSRW54\TEFREM01.sas] 03DEC2015, 11:46

Source: Table 9 in UCO3001-54W-CSR

また，維持期 0 週に clinical remission が認められていた被験者のうち，維持期 30 及び 54 週ともに clinical remission が認められた被験者の割合は，T18 試験では，50 mg 群 36.5%（19/52 例）及び 100 mg 群 38.9%（21/54 例）であり，プラセボ群 24.1%（13/54 例）と比べて高かった（表 2.7.3-20）。UCO3001 試験では，100 mg 群 64.3%（9/14 例）及びプラセボ群 15.4%（2/13 例）であった（表 2.7.3-21）。いずれの試験でも，100 mg 群の維持期 0 週に clinical remission が認められていた被験者のうち，維持期 30 及び 54 週ともに clinical remission が認められた被験者の割合は，プラセボ群より高かった（プラセボ群との差：T18 試験 14.8%，UCO3001 試験 48.9%）。

表 2.7.3-20 維持期 0 週に clinical remission が認められていた被験者のうち，維持期 30 及び 54 週ともに clinical remission が認められた被験者（T18 試験）

	Placebo	Golimumab 50 mg	Golimumab 100 mg	Golimumab Combined
Randomized subjects who were in clinical remission at Week 0 of this maintenance study (excluding sites 6706, 7257 and 7407)	54	52	54	106
Both Week 30 and Week 54				
n	54	52	54	106
Subjects in clinical remission[a,b]	13 (24.1%)	19 (36.5%)	21 (38.9%)	40 (37.7%)
p-value		0.365	0.098	0.116

[a] Subjects who had a prohibited change in UC medication, an ostomy or colectomy, a dose adjustment, or discontinued study agent due to lack of therapeutic effect prior to the Week 54 visit are considered not to be in clinical remission.
[b] Subjects who had all 4 Mayo subscores missing at Week 30 or at Week 54 are considered not to be in clinical remission.

RE631 [E_CREM_1_B_AA]_13MAY2015 13:19

Source: Table 5 of T18 in Re-analysis report for C0524T17 and C0524T18 54-Week

表 2.7.3-21 維持期 0 週に clinical remission が認められていた被験者のうち，維持期 30 及び 54 週ともに clinical remission が認められた被験者（UCO3001 試験）

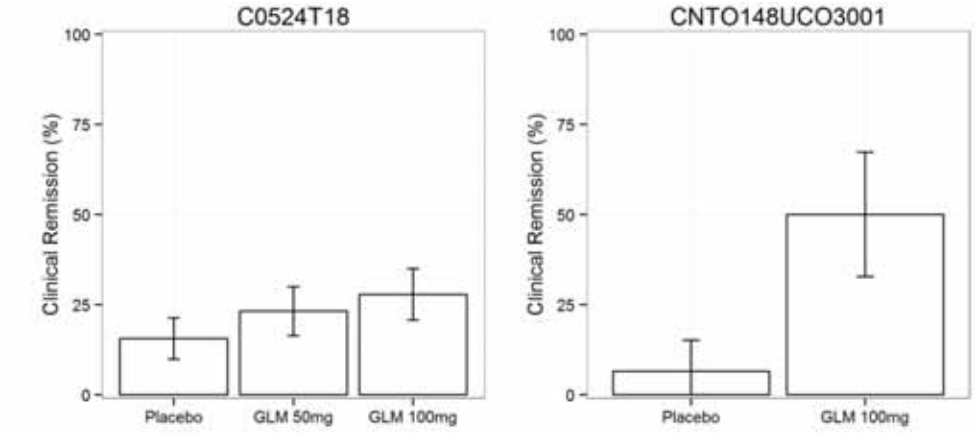
	Placebo	Golimumab 100 mg
Analysis set: FAS-DB who were in clinical remission at Week 0 of maintenance phase	13	14
Both Week 30 and Week 54		
N	13	14
Subjects in clinical remission [a,b]	2 (15.4%)	9 (64.3%)

FAS-DB=efficacy full analysis set for double-blind maintenance phase; N=number of subjects
[a] Subjects who had a prohibited change in UC medication, as ostomy or colectomy, a dose adjustment, or discontinued study agent due to lack of therapeutic effect prior to the Week 54 visit are considered not to be in clinical remission.
[b] Subjects who had all 4 Mayo subscores missing at Week 30 or at Week 54 are considered not to be in clinical remission.
[TEFREM02.rtf] [CNTO148\CNTO148UCO3001\DBR_CSRW54\RE_CSRW54\TEFREM02.sas] 03DEC2015, 11:47

Source: Table 11 in UCO3001-54W-CSR

T18 及び UCO3001 試験の 30 及び 54 週ともに clinical remission が認められた被験者の割合における各群の点推定値（95%CI）及びプラセボ群との差の点推定値（95%CI）を図 2.7.3-21 に示す。

T18 試験の点推定値（95%CI）は，プラセボ群 15.6%（9.9; 21.3），50 mg 群 23.2%（16.4; 29.9）及び 100 mg 群 27.8%（20.7; 35.0），UCO3001 試験では，プラセボ群 6.5%（0.0; 15.1）及び 100 mg 群 50.0%（32.7; 67.3）であった。T18 及び UCO3001 試験の 30 及び 54 週ともに clinical remission が認められた被験者の割合は，少なくとも同程度であった。

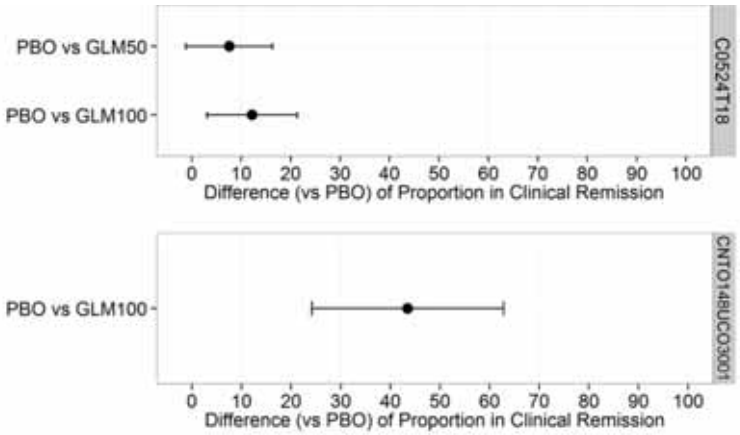


Group	Placebo	GLM 50mg	GLM 100mg	Placebo	GLM 100mg
N	154	151	151	31	32
Subjects in Clinical Remission	24 (15.6%)	35 (23.2%)	42 (27.8%)	2 (6.5%)	16 (50.0%)
95%CI	(9.9, 21.3)	(16.4, 29.9)	(20.7, 35.0)	(0.0, 15.1)[a]	(32.7, 67.3)

a) Lower limit is set to 0 because lower limit by asymptotic approximation becomes negative

Reference: C0524T18 Week 54 (E_CREM_1_A_AA, excluding sites 6706, 7257 & 7407), CNTO148UCO3001 Week 54 (TEFREM01)

(A)



Study	C0524T18			CNTO148UCO3001	
Group	Placebo	GLM 50mg	GLM 100mg	Placebo	GLM 100mg
N	154	151	151	31	32
Subjects in Clinical Remission	24 (15.6%)	35 (23.2%)	42 (27.8%)	2 (6.5%)	16 (50.0%)
Point estimate [95%CI] (Treatment Difference)	---	7.6 [-1.2, 16.4]	12.2 [3.1, 21.4]	---	43.5 [24.2, 62.9]

Reference: C0524T18 Week 54 (E_CREM_1_A_AA, excluding sites 6706, 7257 & 7407), CNTO148UCO3001 Week 54 (TEFREM01)

(B)

(A) 点推定値及び 95%CI，(B) プラセボとの差及び 95%CI

Source: FEFREMW54-Comp and FEFREMDIFW54-Comp

図 2.7.3-21 30 及び 54 週ともに clinical remission が認められた被験者の割合
（T18 及び UCO3001 試験）

(3) 30 及び 54 週ともに mucosal healing が認められた被験者の割合

30 及び 54 週ともに mucosal healing が認められた被験者の割合は，T18 試験では，50 mg 群 41.7%（63/151 例）及び 100 mg 群 42.4%（64/151 例）であり，プラセボ群 26.6%（41/154 例）と比べて，高かった（表 2.7.3-22）。UCO3001 試験では，100 mg 群 59.4%（19/32 例）及びプラセボ群 16.1%（5/31 例）であった（表 2.7.3-23）。いずれの試験でも，100 mg 群の 30 及び 54 週ともに mucosal healing が認められた被験者の割合は，プラセボ群より高かった（プラセボ群との差：T18 試験 15.8%，UCO3001 試験 43.2%）。

表 2.7.3-22 30 及び 54 週ともに mucosal healing が認められた被験者（T18 試験）

	Placebo	Golimumab 50 mg	Golimumab 100 mg	Golimumab Combined
randomized subjects (excluding sites 6706, 7257 and 7407)	154	151	151	302
Both Week 30 and Week 54				
n	154	151	151	302
Subjects with mucosal healing[a,b]	41 (26.6%)	63 (41.7%)	64 (42.4%)	127 (42.1%)
p-value		0.011	0.002	0.001

[a] Subjects who had a prohibited change in UC medication, an ostomy or colectomy, a dose adjustment, or discontinued study agent due to lack of therapeutic effect prior to the Week 54 visit are considered not to have mucosal healing.
[b] Subjects who had a missing endoscopy subscore at Week 30 or at Week 54 are considered not to have mucosal healing.

RE631 [E MUCO 2 A AA] 18MAY2015 10:12

Source: Attachment 3.24 of T18 in Re-analysis report for C0524T17 and C0524T18 54-Week

表 2.7.3-23 30 及び 54 週ともに mucosal healing が認められた被験者（UCO3001 試験）

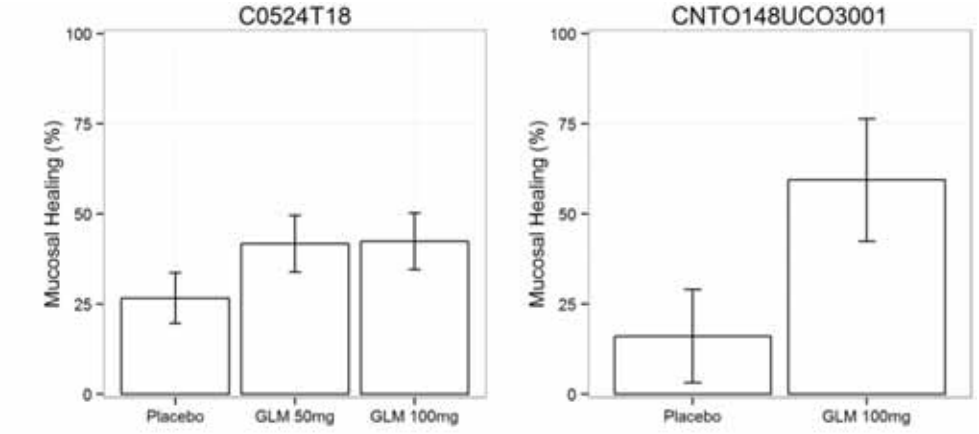
	Placebo	Golimumab 100 mg
Analysis set: FAS-DB	31	32
Both Week 30 and Week 54		
N	31	32
Subjects with mucosal healing [a,b]	5 (16.1%)	19 (59.4%)

FAS-DB=efficacy full analysis set for double-blind maintenance phase; N=number of subjects
[a] Subjects who had a prohibited change in UC medication, as ostomy or colectomy, a dose adjustment, or discontinued study agent due to lack of therapeutic effect prior to the Week 54 visit are considered not to have mucosal healing.
[b] Subjects who had a missing endoscopy subscore at Week 30 or at Week 54 are considered not to have mucosal healing.
[TEFMUCO01.rtf] [CNTO148\CNTO148UCO3001\DBR_CSRW54\RE_CSRW54\TEFMUCO01.sas] 03DEC2015, 11:46

Source: Table 10 in UCO3001-54W-CSR

T18 及び UCO3001 試験の 30 及び 54 週ともに mucosal healing が認められた被験者の割合における各群の点推定値（95%CI）及びプラセボ群との差の点推定値（95%CI）を図 2.7.3-22 に示す。

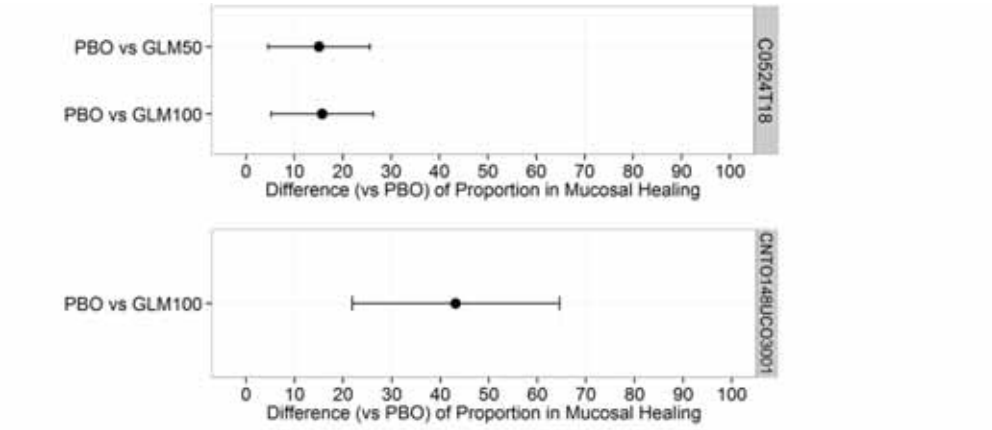
T18 試験の点推定値（95%CI）は，プラセボ群 26.6%（19.6; 33.6），50 mg 群 41.7%（33.9; 49.6）及び 100 mg 群 42.4%（34.5; 50.3），UCO3001 試験では，プラセボ群 16.1%（3.2; 29.1）及び 100 mg 群 59.4%（42.4; 76.4）であった。T18 及び UCO3001 試験の 30 及び 54 週ともに mucosal healing が認められた被験者の割合は同程度であった。



Group	Placebo	GLM 50mg	GLM 100mg	Placebo	GLM 100mg
N	154	151	151	31	32
Subjects with Mucosal Healing	41 (26.6%)	63 (41.7%)	64 (42.4%)	5 (16.1%)	19 (59.4%)
95%CI	(19.6, 33.6)	(33.9, 49.6)	(34.5, 50.3)	(3.2, 29.1)	(42.4, 76.4)

Reference: C0524T18 Week 54 (E_MUCO_2_A_AA, excluding sites 6706, 7257 & 7407), CNTO148UCO3001 Week 54 (TEFMUCO01)

(A)



Study	C0524T18			CNTO148UCO3001	
Group	Placebo	GLM 50mg	GLM 100mg	Placebo	GLM 100mg
N	154	151	151	31	32
Subjects with Mucosal Healing	41 (26.6%)	63 (41.7%)	64 (42.4%)	5 (16.1%)	19 (59.4%)
Point estimate [95%CI] (Treatment Difference)	---	15.1 [4.6, 25.6]	15.8 [5.2, 26.3]	---	43.2 [21.9, 64.6]

Reference: C0524T18 Week 54 (E_MUCO_2_A_AA, excluding sites 6706, 7257 & 7407), CNTO148UCO3001 Week 54 (TEFMUCO01)

(B)

(A) 点推定値及び 95%CI，(B) プラセボとの差及び 95%CI

Source: FEFMHW54-Comp and FEFMHDIFW54-Comp

図 2.7.3-22 30 及び 54 週ともに mucosal healing が認められた被験者の割合
（T18 及び UCO3001 試験）

(4) 54 週の IBDQ も 21 以上改善していた被験者

導入期 0 週と比べて，維持期 0 週に IBDQ が 21 以上改善した被験者のうち，54 週の IBDQ も 21 以上改善していた被験者の割合は，T18 試験では，50 mg 群 44.5%（57/128 例）及び 100 mg 群 40.0%（46/115 例）であり，プラセボ群 27.8%（30/108 例）と比べて高かった（表 2.7.3-24）。UCO3001 試験では，100 mg 群 55.0%（11/20 例）及びプラセボ群 22.2%（6/27 例）であった（表 2.7.3-25）。いずれの試験でも，100 mg 群の維持期 0 週に IBDQ が 21 以上改善した被験者のうち，54 週の IBDQ も 21 以上改善していた被験者の割合は，プラセボ群より高かった（プラセボ群との差：T18 試験 12.2%，UCO3001 試験 32.8%）。

表 2.7.3-24 54 週の IBDQ も 21 以上改善していた被験者（T18 試験）

	Placebo	Golimumab 50 mg	Golimumab 100 mg	Golimumab Combined
Randomized subjects with > 20 points improvement in IBDQ at Week 0 of this maintenance study from Week 0 of an induction study (excluding sites 6706, 7257 and 7407)	108	128	115	243
Week 54				
n	108	128	115	243
Subjects who maintained improvement in IBDQ[a,b,c]	30 (27.8%)	57 (44.5%)	46 (40.0%)	103 (42.4%)
p-value		0.026	0.051	0.017

[a] Subjects with > 20 points improvement in IBDQ at both Week 30 and Week 54 from Week 0 of an induction study.
[b] Subjects who had a prohibited change in UC medication, an ostomy or colectomy, a dose adjustment, or discontinued study agent due to lack of therapeutic effect prior to the Week 54 visit are considered not to have maintained improvement in IBDQ.
[c] Subjects who had a missing IBDQ score at either Week 30 or Week 54 of this maintenance study are considered not to have maintained improvement in IBDQ.

RE631 [E IBDQ 12 A AA] 28MAY2015 13:03

Source: Table 6 of T18 in Re-analysis report for C0524T17 and C0524T18 54-Week

表 2.7.3-25 54 週の IBDQ も 21 以上改善していた被験者（UCO3001 試験）

	Placebo	Golimumab 100mg
Analysis set: FAS-DB with > 20 points improvement in IBDQ at Week 0 of maintenance phase from Week 0 of induction phase	27	20
Week 54		
N	27	20
Subjects who maintained improvement in IBDQ [a,b,c]	6 (22.2%)	11 (55.0%)

[a] Subjects with > 20 points improvement in IBDQ through M-Week 54 in maintenance phase from Week 0 of induction phase.
[b] Subjects who had a prohibited change in UC medication, an ostomy or colectomy, a dose adjustment, or discontinued study agent due to lack of therapeutic effect prior to the Week 54 visit are considered not to have maintained improvement in IBDQ.
[c] Subjects who had a missing IBDQ score at either Week 30 or Week 54 of maintenance phase are considered not to have maintained improvement in IBDQ.

[TEFIBDQ01.rtf] [CNTO148#CNTO148UCO3001#DBR_CSRW54#RE_CSRW54#tefibdq01.sas] 03DEC2015, 12:07

Source: Attachment TEFIBDQ01 in UCO3001-54W-CSR

(5) コルチコステロイドの併用

維持期 0 週にコルチコステロイドを併用していた被験者のうち，維持期 54 週に clinical remission が認められ，かつコルチコステロイドを併用していなかった被験者の割合は，T18 試験では，50 mg 群 28.2%（22/78 例）及び 100 mg 群 23.2%（19/82 例）であり，50 mg 群では，プラセボ群 18.4%（16/87 例）と比べて高かった（表 2.7.3-26）。UCO3001 試験では，100 mg 群 55.6%（5/9 例）及びプラセボ群 11.1%（1/9 例）であった（表 2.7.3-27）。対象被験者数が少ないものの，いずれの試験でも，維持期 0 週にコルチコステロイドを併用していた被験者のうち，維持期 54 週に clinical remission が認められ，かつコルチコステロイドを併用していなかった被験者の割合は，プラセボ群より高かった（プラセボ群との差：T18 試験 4.8%，UCO3001 試験 44.4%）。

表 2.7.3-26 維持期 0 週にコルチコステロイド併用ありの被験者のうち，維持期 54 週に clinical remission が認められ，かつコルチコステロイド未併用の被験者（T18 試験）

	Placebo	Golimumab 50 mg	Golimumab 100 mg	Golimumab Combined
Randomized subjects who were receiving concomitant corticosteroids at Week 0 of this maintenance study (excluding sites 6706, 7257 and 7407)	87	78	82	160
Subjects in clinical remission at Week 54 and not receiving corticosteroids at Week 54[a,b,c]	16 (18.4%)	22 (28.2%)	19 (23.2%)	41 (25.6%)
p-value		0.279	0.423	0.294

[a] Subjects who had a prohibited change in UC medication, an ostomy or colectomy, a dose adjustment, or discontinued study agent due to lack of therapeutic effect prior to the Week 54 visit are considered not to have achieved the clinical endpoint of clinical remission and not receiving concomitant corticosteroids.
[b] Subjects who had all 4 Mayo subscores missing at Week 54 are considered not to have achieved the clinical endpoint of clinical remission and not receiving concomitant corticosteroids.
[c] Subjects who had a missing value in corticosteroid use at Week 54 had their last value carried forward.

RE631JE CREM 116 A AAJ 13MAY2015 13:26

Source: Attachment 3.25 of T18 in Re-analysis report for C0524T17 and C0524T18 54-Week

表 2.7.3-27 維持期 0 週にコルチコステロイド併用ありの被験者のうち，維持期 54 週に clinical remission が認められ，かつコルチコステロイド未併用の被験者（UCO3001 試験）

	Placebo	Golimumab 100 mg
Analysis set: FAS-DB who were receiving concomitant corticosteroids at Week 0 of maintenance phase	9	9
Subjects in clinical remission at Week 54 and not receiving corticosteroids at Week 54 [a,b,c]	1 (11.1%)	5 (55.6%)

FAS-DB=efficacy full analysis set for double-blind maintenance phase; N=number of subjects
[a] Subjects who had a prohibited change in UC medication, as ostomy or colectomy, a dose adjustment, or discontinued study agent due to lack of therapeutic effect prior to the Week 54 visit are considered not to be in clinical remission.
[b] Subjects who had all 4 Mayo subscores missing at Week 30 or at Week 54 are considered not to have achieved the clinical endpoint of clinical remission and not receiving concomitant corticosteroids.
[c] Subjects who had a missing value in corticosteroid use at Week 54 had their last value carried forward.
[TEFREM03.rtf] [CNTO148\CNTO148UCO3001\DBR_CSRW54\RE_CSRW54\TEFREM03.sas] 03DEC2015, 11:47

Source: Table 12 in UCO3001-54W-CSR

2.7.3.3.3 部分集団における結果の比較

T17 及び T18 試験について，有効性の部分集団解析の結果を以下に示す。なお，UCO3001 試験においてランダム化された被験者は少数（100 mg 群 32 例，プラセボ群 31 例）であるため，部分集団解析を実施しなかった。

2.7.3.3.3.1 T17 及び T18 試験の日本人集団

以下の結果より，T17 試験 Part 2（投与量選択後）の主要評価項目及び主な副次評価項目の日本人集団の結果は，いずれも試験全体より低かったが，試験全体の結果とおおむね一貫していたと判断した。

(1) T17 試験の日本人集団と試験全体との比較

1) 6 週の clinical response

T17 試験 Part 2（投与量選択後）の 6 週に clinical response が認められた被験者の割合について，日本人集団の結果を表 2.7.3-28 に示し，試験全体の結果（表 2.7.3-6）を再掲する。また，オッズ比を図 2.7.3-23 に示す。

T17 試験 Part 2（投与量選択後）の 6 週に clinical response が認められた日本人の割合は，プラセボ群 13.3%（4/30 例），200→100 mg 群 26.1%（6/23 例）及び 400→200 mg 群 31.6%（6/19 例）であり，試験全体では，プラセボ群 30.3%（76/251 例），200→100 mg 群 51.0%（129/253 例）及び 400→200 mg 群 54.9%（141/257 例）であった。日本人集団におけるプラセボ群に対するオッズ比は，200→100 mg 群 2.3 及び 400→200 mg 群 3.0 であり，試験全体のオッズ比（200→100 mg 群 2.4 及び 400→200 mg 群 2.8）と同様であった。

表 2.7.3-28 6 週に clinical response が認められた被験者
（T17 試験，Part 2 投与量選択後；日本人集団）

		Golimumab		
	Placebo	200 mg → 100 mg	400 mg → 200 mg	Combined
Randomized Japanese subjects in Part 2 after the dose selection in C0524T17	30	23	19	42
Week 6				
n	30	23	19	42
Subjects in clinical response[a,b]	4 (13.3%)	6 (26.1%)	6 (31.6%)	12 (28.6%)
p-value[c]		0.2395	0.1226	0.1252

[a] Subjects who had a prohibited change in concomitant UC medication, an ostomy or colectomy, or discontinued study agent due to lack of therapeutic effect prior to the Week 6 visit are considered not to be in clinical response.
[b] Subjects who had all 4 Mayo subscores missing at Week 6 are considered not to be in clinical response.
[c] Based on chi-square test.

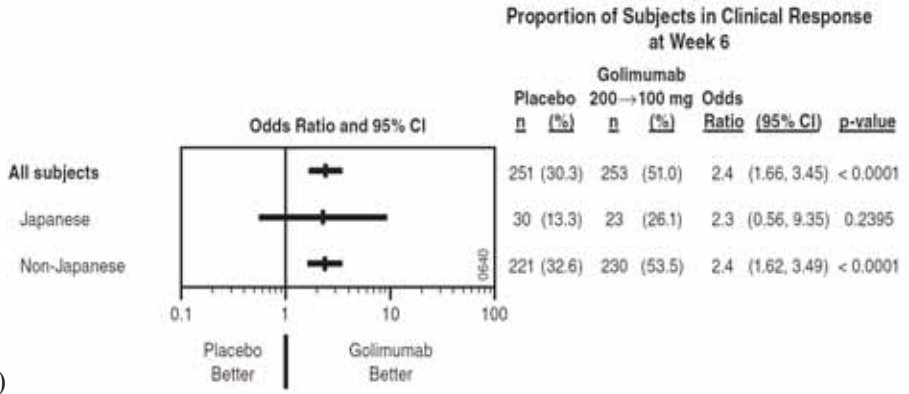
RE630:[E CRES 93 M JJ], 01MAY2015 11:28

表 2.7.3-6 6 週に clinical response が認められた被験者
（T17 試験，Part 2 投与量選択後；再掲）

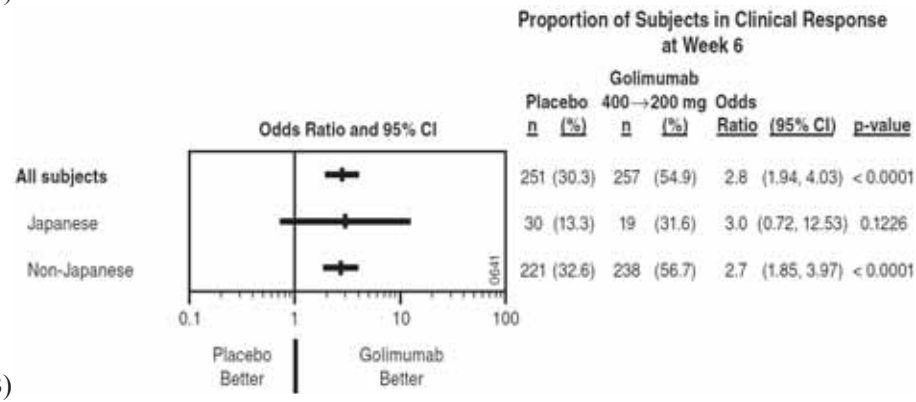
		Golimumab		
	Placebo	200 mg → 100 mg	400 mg → 200 mg	Combined
Randomized subjects in Part 2 after the dose selection (excluding sites 6706, 7257 and 7407)	251	253	257	510
Week 6				
n	251	253	257	510
Subjects in clinical response[a,b]	76 (30.3%)	129 (51.0%)	141 (54.9%)	270 (52.9%)
p-value		< 0.0001	< 0.0001	< 0.0001

[a] Subjects who had a prohibited change in concomitant UC medication, an ostomy or colectomy, or discontinued study agent due to lack of therapeutic effect prior to the Week 6 visit are considered not to be in clinical response.
[b] Subjects who had all 4 Mayo subscores missing at Week 6 are considered not to be in clinical response.

RE630:[E CRES 93 B BB], 01MAY2015 11:18



(A)



(B)

(A) 200→100 mg 群，(B) 400→200 mg 群

Source: [E_FIG_RESP_6_A-0640] and [E_FIG_RESP_6_B-0641] in analysis for J-SCE

図 2.7.3-23 6 週に clinical response が認められた被験者の割合のオッズ比
（T17 試験，Part 2 投与量選択後）

2) 6 週の clinical remission

T17 試験 Part 2（投与量選択後）における 6 週に clinical remission が認められた被験者について，日本人集団の結果を表 2.7.3-29 に示し，試験全体の結果（表 2.7.3-8）を再掲する。

T17 試験 Part 2（投与量選択後）の 6 週に clinical remission が認められた日本人の割合は，プラセボ群 0%（0/30 例），200→100 mg 群 8.7%（2/23 例）及び 400→200 mg 群 15.8%（3/19 例）であり，試験全体では，プラセボ群 6.4%（16/251 例），200→100 mg 群 17.8%（45/253 例）及び 400→200 mg 群 17.9%（46/257 例）であった。

表 2.7.3-29 6 週に clinical remission が認められた被験者
（T17 試験，Part 2 投与量選択後；日本人集団）

		Golimumab		
	Placebo	200 mg → 100 mg	400 mg → 200 mg	Combined
Randomized Japanese subjects in Part 2 after the dose selection in C0524T17	30	23	19	42
Week 6				
n	30	23	19	42
Subjects in clinical remission[a,b]	0 (0.0%)	2 (8.7%)	3 (15.8%)	5 (11.9%)
p-value[c]		0.0997	0.0247	0.0501

[a] Subjects who had a prohibited change in concomitant UC medication, an ostomy or colectomy, or discontinued study agent due to lack of therapeutic effect prior to the Week 6 visit are considered not to be in clinical remission.
[b] Subjects who had all 4 Mayo subscores missing at Week 6 are considered not to be in clinical remission.
[c] Based on chi-square test.

RE630:[E CREM 1 1 JJ], 01MAY2015 11:13

表 2.7.3-8 6 週に clinical remission が認められた被験者
（T17 試験，Part 2 投与量選択後；再掲）

		Golimumab		
	Placebo	200 mg → 100 mg	400 mg → 200 mg	Combined
Randomized subjects in Part 2 after the dose selection (excluding sites 6706, 7257 and 7407)	251	253	257	510
Week 6				
n	251	253	257	510
Subjects in clinical remission[a,b]	16 (6.4%)	45 (17.8%)	46 (17.9%)	91 (17.8%)
p-value		< 0.0001	< 0.0001	< 0.0001

[a] Subjects who had a prohibited change in concomitant UC medication, an ostomy or colectomy, or discontinued study agent due to lack of therapeutic effect prior to the Week 6 visit are considered not to be in clinical remission.
[b] Subjects who had all 4 Mayo subscores missing at Week 6 are considered not to be in clinical remission.

RE630:[E CREM 1 B BB1 01MAY2015 11:02

3) 6 週の mucosal healing

T17 試験 Part 2（投与量選択後）における 6 週に mucosal healing が認められた被験者について，日本人集団の結果を表 2.7.3-30 に示し，試験全体の結果（表 2.7.3-10）を再掲する。

T17 試験 Part 2（投与量選択後）の 6 週に mucosal healing が認められた日本人の割合は，プラセボ群 6.7%（2/30 例），200→100 mg 群 34.8%（8/23 例）及び 400→200 mg 群 26.3%（5/19 例）であり，試験全体では，プラセボ群 28.7%（72/251 例），200→100 mg 群 42.3%（107/253 例）及び 400→200 mg 群 45.1%（116/257 例）であった。

表 2.7.3-30 6 週に mucosal healing が認められた被験者
（T17 試験，Part 2 投与量選択後；日本人集団）

		Golimumab		
	Placebo	200 mg → 100 mg	400 mg → 200 mg	Combined
Randomized Japanese subjects in Part 2 after the dose selection in C0524T17	30	23	19	42
Week 6				
n	30	23	19	42
Subjects with mucosal healing[a,b]	2 (6.7%)	8 (34.8%)	5 (26.3%)	13 (31.0%)
p-value[c]		0.0095	0.0555	0.0124

[a] Subjects who had a prohibited change in concomitant UC medication, an ostomy or colectomy, or discontinued study agent due to lack of therapeutic effect prior to the Week 6 visit are considered not to have mucosal healing.
[b] Subjects who had a missing endoscopy subscore at Week 6 are considered not to have mucosal healing.
[c] Based on chi-square test.

RE630:[E MUCO 2 H JJ], 01MAY2015 12:23

表 2.7.3-10 6 週に mucosal healing が認められた被験者
（T17 試験，Part 2 投与量選択後；再掲）

		Golimumab		
	Placebo	200 mg → 100 mg	400 mg → 200 mg	Combined
Randomized subjects in Part 2 after the dose selection (excluding sites 6706, 7257 and 7407)	251	253	257	510
Week 6				
n	251	253	257	510
Subjects with mucosal healing[a,b]	72 (28.7%)	107 (42.3%)	116 (45.1%)	223 (43.7%)
p-value		0.0014	0.0001	< 0.0001

[a] Subjects who had a prohibited change in concomitant UC medication, an ostomy or colectomy, or discontinued study agent due to lack of therapeutic effect prior to the Week 6 visit are considered not to have mucosal healing.
[b] Subjects who had a missing endoscopy subscore at Week 6 are considered not to have mucosal healing.

RE630:[E MUCO 2 B BBL 01MAY2015 12:22

4) 6 週の IBDQ のベースラインからの平均変化量

T17 試験 Part 2（投与量選択後）における 6 週の IBDQ のベースラインからの平均変化量について，日本人集団の結果を表 2.7.3-31 に示し，試験全体の結果（表 2.7.3-12）を再掲する。

T17 試験 Part 2（投与量選択後）の 6 週の IBDQ のベースラインからの平均変化量（SD）は，日本人集団では，プラセボ群 10.9（19.46），200→100 mg 群 12.9（27.34）及び 400→200 mg 群 6.5（24.97）であり，試験全体では，プラセボ群 14.8（31.25），200→100 mg 群 27.0（33.72）及び 400→200 mg 群 26.9（34.28）であった。

表 2.7.3-31 6 週の IBDQ のベースラインからの平均変化量
（T17 試験，Part 2 投与量選択後；日本人集団）

		Golimumab		
	Placebo	200 mg → 100 mg	400 mg → 200 mg	Combined
Randomized Japanese subjects in Part 2 after the dose selection in C0524T17	30	23	19	42
Baseline				
n	30	23	19	42
Mean ± SD	141.3 ± 33.00	154.3 ± 32.13	147.5 ± 27.80	151.2 ± 30.09
Median	143.5	163.0	153.0	157.5
IQ range	(119.0, 169.0)	(147.0, 174.0)	(121.0, 169.0)	(137.0, 172.0)
Range	(83, 198)	(67, 189)	(99, 201)	(67, 201)
Change from baseline				
Week 6[a,b]				
n	30	23	19	42
Mean ± SD	10.9 ± 19.46	12.9 ± 27.34	6.5 ± 24.97	10.0 ± 26.18
Median	7.5	4.0	7.0	5.0
IQ range	(0.0, 19.0)	(-1.0, 23.0)	(-4.0, 30.0)	(-2.0, 25.0)
Range	(-27, 71)	(-21, 123)	(-51, 38)	(-51, 123)
p-value[c]		0.8838	0.4695	0.5970

[a] Subjects who had a prohibited change in concomitant UC medication, an ostomy or colectomy, or discontinued study agent due to lack of therapeutic effect prior to the Week 6 visit had their baseline value carried forward to Week 6.
[b] Subjects who had a missing IBDQ score at Week 6 had the last available value carried forward.
[c] Based on an analysis of variance test on the van der Waerden normal scores.

RE630.[E IBDQ 1 J J7], 01MAY2015 11:40

表 2.7.3-12 6 週の IBDQ のベースラインからの平均変化量
（T17 試験，Part 2 投与量選択後；再掲）

		Golimumab		
	Placebo	200 mg → 100 mg	400 mg → 200 mg	Combined
Randomized subjects in Part 2 after the dose selection (excluding sites 6706, 7257 and 7407)	251	253	257	510
Baseline				
n	250	252	255	507
Mean ± SD	129.0 ± 32.61	131.7 ± 33.93	127.2 ± 33.90	129.5 ± 33.96
Median	127.5	134.0	127.0	130.0
IQ range	(104.0, 152.0)	(104.0, 157.0)	(105.0, 152.0)	(104.0, 156.0)
Range	(60, 206)	(54, 209)	(33, 201)	(33, 209)
Change from baseline				
Week 6[a,b]				
n	250	252	255	507
Mean ± SD	14.8 ± 31.25	27.0 ± 33.72	26.9 ± 34.28	26.9 ± 33.96
Median	11.0	22.5	21.0	22.0
IQ range	(-3.0, 29.0)	(0.5, 48.5)	(0.0, 50.0)	(0.0, 50.0)
Range	(-80, 115)	(-49, 131)	(-60, 187)	(-60, 187)
p-value		< 0.0001	< 0.0001	< 0.0001

[a] Subjects who had a prohibited change in concomitant UC medication, an ostomy or colectomy, or discontinued study agent due to lack of therapeutic effect prior to the Week 6 visit had their baseline value carried forward to Week 6.
[b] Subjects who had a missing IBDQ score at Week 6 had the last available value carried forward.

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5) 日本人集団と試験全体の有効性

T17 試験 Part 2（投与量選択後）における日本人集団及び試験全体の有効性の結果を表 2.7.3-32 に示す。

有効性の主な評価項目のゴリムマブ併合群とプラセボ群の差についての日本人集団（D_{Japan}）と試験全体（D_{all}）の比（D_{Japan}/D_{all}）は，6 週の IBDQ のベースラインからの変化量を除いて，いずれも 0.5 を上回っていた。

表 2.7.3-32 日本人集団と試験全体の有効性（T17 試験，Part 2 投与量選択後）

	T17 Japanese			T17 Overall			
	Placebo	Combined	D_{Japan}	Placebo	Combined	D_{all}	D_{Japan}/D_{all}
Clinical response	13.3% (4/30)	28.6% (12/42)	15.2%	30.3% (76/251)	52.9% (270/510)	22.7%	0.67
Clinical remission	0.0% (0/30)	11.9% (5/42)	11.9%	6.4% (16/251)	17.8% (91/510)	11.5%	1.04
Mucosal healing	6.7% (2/30)	31.0% (13/42)	24.3%	28.7% (72/251)	43.7% (223/510)	15.0%	1.61
IBDQ[c] (Change from baseline)	10.9±19.46 7.5	10.0±26.18 5.0	-2.5	14.8±31.25 11.0	26.9±33.96 22.0	11.0	-0.23
Mayo score[d] (change from baseline)	-0.5±1.41 0.0	-1.8±2.83 -1.0	-1.2	-1.6±2.53 -1.0	-3.1±2.93 -3.0	-1.5	0.82

a) Subjects who had a prohibited change in concomitant UC medication, an ostomy or colectomy, or discontinued study agent due to lack of therapeutic effect prior to the Week 6 visit are considered not to be in clinical response.
b) Subejcts who had all 4 Mayo subscores missing at Week 6 are considered not to be in clinical response.
c) Mean and median of change from baseline. D_{Japan} and D_{all} are median difference between Combined and Placebo group.
d) Mean of change from baseline. D_{Japan} and D_{all} are mean difference between Combined and Placebo group.
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(2) T18 試験の日本人集団と試験全体との比較

T18 試験の日本人集団の 54 週まで clinical response が維持された被験者の割合を表 2.7.3-33 に示す。T18 試験に組み入れられ，維持期 0 週にランダム化された被験者は 12 例と少なく，試験全体との比較は困難であった。

表 2.7.3-33 54 週まで clinical response が維持された被験者（T18 試験，日本人集団）

		Golimumab		
	Placebo	50 mg	100 mg	Combined
Randomized Japanese subjects in C0524T18	4	3	5	8
Through Week 54				
n	4	3	5	8
Subjects in clinical response[a,b]	1 (25.0%)	0 (0.0%)	3 (60.0%)	3 (37.5%)

[a] Subjects who had a prohibited change in UC medication, an ostomy or colectomy, a dose adjustment, or discontinued study agent due to lack of therapeutic effect prior to the Week 54 visit are considered not to be in clinical response.
[b] Subjects who had all 4 Mayo subscores missing at Week 30 or at Week 54 are considered not to be in clinical response.

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2.7.3.3.3.2 T17 及び T18 試験のその他の部分集団解析

(1) T17 試験（投与量選択後）

6 週に clinical response が認められた被験者の割合に関する部分集団解析（人口統計学的特性，疾患特性，併用した UC 治療薬及び UC 前治療に対する反応性）の結果を図 2.7.3-付録-1，図 2.7.3-付録-2，図 2.7.3-付録-3 及び図 2.7.3-付録-4 に示す。これらの部分解析集団の結果は，試験全体の結果とおおむね一致していた。

(2) T18 試験

54 週まで clinical response が維持された被験者の割合に関する部分集団解析（導入期の人口統計学的特性，疾患特性，併用した UC 治療薬及び UC 前治療に対する反応性，並びに維持期 0 週の clinical remission の有無及びコルチコステロイド使用の有無，導入期の投与経路及び投与量）の結果を図 2.7.3-付録-5，図 2.7.3-付録-6，図 2.7.3-付録-7，図 2.7.3-付録-8 及び図 2.7.3-付録-9 に示す。これらの部分集団解析の結果は，試験全体の結果とおおむね一致していた。

2.7.3.4 推奨用法・用量に関する臨床情報の解析

海外では，ゴリムマブは中等症から重症の活動期 UC の効能効果も既に承認されており，その推奨用法・用量は，寛解導入療法として 0 週に 200 mg，2 週に 100 mg，寛解維持療法としてその後 4 週ごとに 100 mg の皮下投与である。本項では，海外及び国内の用法・用量について記述する。

2.7.3.4.1 寛解導入期の用法・用量の検討

(1) 海外での寛解導入期の用法・用量の検討

寛解導入期の投与量探索パートである T16 試験 Part 1 及び T17 試験 Part 1 において，ゴリムマブ群の Mayo スコアのベースラインからの変化量が，T16 試験 Part 1 と比べて，T17 試験 Part 1 でより大きかった。また，単回静脈内投与では，6 週での効果を得るために必要な血清中濃度が十分得られないと考えられた。そのため，0 週に単回静脈内投与する T16 試験 Part 2 への被験者の登録を中止し，0 週及び 2 週に皮下投与する T17 試験を継続して，寛解導入期の用法・用量を検討した。T16 試験 Part 1 及び T17 試験 Part 1 の結果を以下に示す。

- ゴリムマブ又はプラセボを 0 週に単回静脈内投与した T16 試験 Part 1 では，6 週の Mayo スコアのベースラインからの変化量（中央値）は，1 mg/kg 群：−2.0，2 mg/kg 群：−2.0，4 mg/kg 群：−1.5 及びプラセボ群：−1.0 であり，ゴリムマブ群の減少量はいずれも小さく，同程度であった。6 週の Mayo スコアのベースラインからの変化量（平均値）は，1 mg/kg 群：−2.0，2 mg/kg 群：−2.3，4 mg/kg 群：−1.8 及びプラセボ群：−1.3 であった（2.7.3.2.1(1)）。また，単回静脈内投与では，6 週での効果を得るために必要な血清中濃度が十分に得られないと考えられた（2.7.3.2.1(2)）。
- ゴリムマブ又はプラセボを 0 週及び 2 週に皮下投与した T17 試験 Part 1 では，6 週の Mayo スコアのベースラインからの変化量（中央値）は，100→50 mg 群：−3.0，200→100 mg 群：−2.0，400→200 mg 群：−3.0 及びプラセボ群：−1.0 であった。6 週の Mayo スコアのベースラインからの変化量（平均値）は，100→50 mg 群：−2.7，200→100 mg 群：−2.6，400

→200 mg 群：−3.1 及びプラセボ群：−1.8 であり，400→200 mg 群はプラセボ群と比べて統計学的に有意な差が認められた（2.7.3.2.2(1)）。

その後，200→100 mg，400→200 mg 及びプラセボを皮下投与した T17 試験 Part 2（投与量選択後）にて，以下の良好な有効性が示された（2.7.3.2.2(2)）。

- 主要評価項目である 6 週に clinical response が認められた被験者の割合は，200→100 mg 群 51.0%（129/253 例）及び 400→200 mg 群 54.9%（141/257 例）であり，プラセボ群 30.3%（76/251 例）と比べて，いずれも統計学的に有意な差が認められた。
- 6 週に clinical remission が認められた被験者の割合は，200→100 mg 群 17.8%（45/253 例），400→200 mg 群 17.9%（46/257 例）であり，プラセボ群 6.4%（16/251 例）と比べて，いずれも統計学的に有意な差が認められた。
- 6 週に mucosal healing が認められた被験者の割合は，200→100 mg 群 42.3%（107/253 例），400→200 mg 群 45.1%（116/257 例）であり，プラセボ群 28.7%（72/251 例）と比べて，いずれも統計学的に有意な差が認められた。
- 6 週の IBDQ のベースラインからの平均変化量（SD）は，200→100 mg 群 27.0（33.72），400→200 mg 群 26.9（34.28）であり，プラセボ群 14.8（31.25）と比べて，いずれも統計学的に有意な差が認められた。
- 6 週の IBDQ がベースラインより 21 以上改善した被験者の割合は，200→100 mg 群 50.6%（128/253 例），400→200 mg 群 51.0%（131/257 例）であり，プラセボ群 35.5%（89/251 例）と比べて，いずれも統計学的に有意な差が認められた。

200→100 mg 又は 400→200 mg を皮下投与したときの忍容性はおおむね良好であり，200→100 mg 群及び 400→200 mg 群の有効性は同程度であったことから，海外の寛解導入期の推奨用法・用量は，『0 週に 200 mg 及び 2 週に 100 mg を皮下投与する』と設定した。

(2) 国内での寛解導入期の用法・用量の検討

T17 試験 Part 2（投与量選択後）の日本人集団の有効性は，6 週の IBDQ のベースラインからの変化量を除いて，プラセボ群と比較してゴリムマブ群で高く，ゴリムマブ群のプラセボ群に対するオッズ比は，試験全体のオッズ比と同様であった。以下に，T17 試験 Part 2（投与量選択後）の主な有効性の結果を示す。

- 6 週に clinical response が認められた日本人の割合は，プラセボ群 13.3%（4/30 例），200→100 mg 群 26.1%（6/23 例）及び 400→200 mg 群 31.6%（6/19 例）であり，試験全体では，プラセボ群 30.3%（76/251 例），200→100 mg 群 51.0%（129/253 例）及び 400→200 mg 群 54.9%（141/257 例）であった。日本人集団におけるゴリムマブ群のプラセボ群に対するオッズ比は，200→100 mg 群 2.3 及び 400→200 mg 群 3.0 であり，試験全体のオッズ比（200→100 mg 群 2.4 及び 400→200 mg 群 2.8）と同様であった（2.7.3.3.3.1(1)1)）。
- 6 週に clinical remission が認められた日本人の割合は，プラセボ群 0%（0/30 例），200→100 mg 群 8.7%（2/23 例）及び 400→200 mg 群 15.8%（3/19 例）であり，試験全体では，プ

ラセボ群 6.4%（16/251 例），200→100 mg 群 17.8%（45/253 例）及び 400→200 mg 群 17.9%（46/257 例）であった（2.7.3.3.3.1(1)2)）。

- 6 週に mucosal healing が認められた日本人の割合は，プラセボ群 6.7%（2/30 例），200→100 mg 群 34.8%（8/23 例）及び 400→200 mg 群 26.3%（5/19 例）であり，試験全体では，プラセボ群 28.7%（72/251 例），200→100 mg 群 42.3%（107/253 例）及び 400→200 mg 群 45.1%（116/257 例）であった（2.7.3.3.3.1(1)3)）。
- 6 週の IBDQ のベースラインからの平均変化量（SD）は，日本人集団では，プラセボ群 10.9（19.46），200→100 mg 群 12.9（27.34）及び 400→200 mg 群 6.5（24.97）であり，試験全体では，プラセボ群 14.8（31.25），200→100 mg 群 27.0（33.72）及び 400→200 mg 群 26.9（34.28）であった（2.7.3.3.3.1(1)4)）。
- 有効性の主な評価項目のゴリムマブ併合群とプラセボ群の差についての日本人集団（D_{Japan}）と試験全体（D_{all}）の比（D_{Japan}/D_{all}）は，6 週の IBDQ のベースラインからの変化量を除いて，いずれも 0.5 を上回っていた（2.7.3.3.3.1(1)5)）。

200→100 mg 群と比べて 400→200 mg 群の有効性が高い指標も認められたが，投与量と有効性に一貫した傾向は認められなかった。日本人被験者は少数であり，結果に対する 1 例の寄与が比較的大きいことを考慮すると，T17 試験全体と同様に，日本人集団でも 200→100 mg 群及び 400→200 mg 群の有効性に明らかな差はないと考えられた。また，200→100 mg 又は 400→200 mg を皮下投与したときの日本人集団の忍容性はおおむね良好であった。

T17 試験において，日本人の血清中ゴリムマブ濃度の中央値は，外国人と比較して同程度か若干高値を示す傾向が認められたが，400→200 mg 群の 6 週を除き，いずれの投与量及び時点においても，日本人における血清中ゴリムマブ濃度の範囲は外国人における血清中ゴリムマブ濃度の範囲内であった【2.7.2.3.1.5 (1) 1)】。寛解導入期に 200→100 mg を非盲検下で皮下投与した UCO3001 試験での 6 週に clinical response が認められた被験者の割合は，T17 試験の結果とおおむね同様であった（2.7.3.3.2.1）。また，健康成人に 200 mg 又は 400 mg を単回皮下投与したときの日本人及び白人の血清中ゴリムマブの薬物動態は，ほぼ同程度であった【2.7.2.2.4.1】。

以上より，日本の寛解導入期の推奨用法・用量は，『初回投与時に 200 mg，初回投与 2 週後に 100 mg を皮下注射する』と設定した。

2.7.3.4.2　寛解維持期の用法・用量の検討

(1) 海外での寛解維持期の用法・用量の検討

海外では，T16 又は T17 試験の 6 週に clinical response が認められた被験者を有効性の主要解析集団とした T18 試験の結果に基づいて，寛解維持期の用法・用量を検討した。T18 試験の主な有効性の結果を以下に示す（2.7.3.2.3(1)1)）。

- 主要評価項目である 54 週まで clinical response が維持された被験者の割合は，50 mg 群 47.0%（71/151 例）及び 100 mg 群 49.7%（75/151 例）であり，プラセボ群 31.2%（48/154 例）と比べて，いずれも統計学的に有意な差が認められた。

- 30 及び 54 週ともに clinical remission が認められた被験者の割合は，50 mg 群 23.2%（35/151 例）及び 100 mg 群 27.8%（42/151 例）であり，100 mg 群では，プラセボ群 15.6%（24/154 例）と比べて統計学的に有意な差が認められた。
- 30 及び 54 週ともに mucosal healing が認められた被験者の割合は，50 mg 群 41.7%（63/151 例）及び 100 mg 群 42.4%（64/151 例）であり，100 mg 群では，プラセボ群 26.6%（41/154 例）と比べて，統計学的に有意な差が認められた。
- 維持期 0 週に clinical remission が認められていた被験者のうち，30 及び 54 週ともに clinical remission が認められた被験者の割合は，50 mg 群 36.5%（19/52 例）及び 100 mg 群 38.9%（21/54 例）であり，プラセボ群 24.1%（13/54 例）と比べて高かった。
- 維持期 0 週にコルチコステロイドを併用していた被験者のうち，54 週に clinical remission が認められ，かつコルチコステロイドを併用していなかった被験者の割合は，50 mg 群 28.2%（22/78 例）及び 100 mg 群 23.2%（19/82 例）であり，50 mg 群では，プラセボ群 18.4%（16/87 例）と比べて高かった。
- 導入期 0 週と比べて，維持期 0 週に IBDQ が 21 以上改善した被験者のうち，54 週の IBDQ も 21 以上改善していた被験者の割合は，50 mg 群 44.5%（57/128 例）及び 100 mg 群 40.0%（46/115 例）であり，プラセボ群 27.8%（30/108 例）と比べて高かった。

主要評価項目では，プラセボ群と比べて，50 mg 群及び 100 mg 群のいずれも統計学的に有意な差が認められたが，30 及び 54 週ともに clinical remission が認められた被験者の割合，並びに 30 及び 54 週ともに mucosal healing が認められた被験者の割合では，100 mg 群のみに統計学的に有意な差が認められた。また，50 mg 又は 100 mg を皮下投与したときの忍容性はおおむね良好であった。以上より，海外の寛解維持期の推奨用法・用量は，寛解導入 2 週時の投与後，『4 週ごとに 100 mg を皮下投与する』と設定した。

(2) 国内での寛解維持期の用法・用量の検討

T18 試験に組み入れられ，維持期 0 週にランダム化された日本人被験者は 12 例と少なく，試験全体との類似性について考察することはできなかった。そのため，UCO3001 試験にて寛解導入 6 週に clinical response が認められた被験者に 100 mg 又はプラセボを二重盲検下で皮下投与し，日本人における寛解維持期の用法・用量を検討した。以下に，主な有効性の結果を示す（2.7.3.2.4(2)1)）。

- 主要評価項目である維持期 54 週まで clinical response が維持された被験者の割合は，100 mg 群 56.3%（18/32 例）及びプラセボ群 19.4%（6/31 例）であった。その差は 36.9%（95%CI：14.8;59.0）であり，T18 試験で 54 週まで clinical response が維持された被験者の割合の 100 mg 群及びプラセボ群の差 19.2%の 95%CI（8.5;29.9）の下限値 8.5%を大きく上回った。
- 維持期 30 及び 54 週ともに clinical remission が認められた被験者の割合は，100 mg 群 50.0%（16/32 例）であり，プラセボ群 6.5%（2/31 例）と比べて高かった。

- 維持期 30 及び 54 週ともに mucosal healing が認められた被験者の割合は，100 mg 群 59.4%（19/32 例）であり，プラセボ群 16.1%（5/31 例）と比べて高かった。
- 維持期 0 週に clinical remission が認められていた被験者のうち，維持期 30 及び 54 週ともに clinical remission が認められた被験者の割合は，100 mg 群 64.3%（9/14 例）であり，プラセボ群 15.4%（2/13 例）と比べて高かった。
- 維持期 0 週にコルチコステロイドを併用していた被験者のうち，維持期 54 週に clinical remission が認められ，かつコルチコステロイドを併用していなかった被験者の割合は，100 mg 群 55.6%（5/9 例）であり，プラセボ群 11.1%（1/9 例）と比べて高かった。
- 導入期 0 週と比べて，維持期 0 週に IBDQ が 21 以上改善した被験者のうち，54 週の IBDQ も 21 以上改善していた被験者の割合は，100 mg 群 55.0%（11/20 例）であり，プラセボ群 22.2%（6/27 例）と比べて高かった。

なお，T18 試験において，維持期 8 週以降の日本人の血清中ゴリムマブ濃度の中央値は，外国人と比較して同程度か若干高値を示す傾向が認められたが，100 mg 群の維持期 28 週を除き，いずれの投与量及び時点においても，日本人における血清中ゴリムマブ濃度の範囲は外国人における血清中ゴリムマブ濃度の範囲内であった【2.7.2.3.1.5 (1) 1)】。また，健康成人に 50 mg 又は 100 mg を単回皮下投与したときの血清中ゴリムマブの薬物動態は，日本人と白人で類似していることも既に確認している【初回申請時資料 2.7.2.3.7 (1) 1)】。

T18 試験及び UCO3001 試験の寛解維持期の有効性の結果は類似していると考えられる（2.7.3.3.2.2）こと，日本人の活動期 UC 患者に 100 mg を皮下投与したときの忍容性はおおむね良好であった【2.5.5.5.3.2】ことから，日本の寛解維持期の推奨用法・用量は，『初回投与 6 週目以降は 100 mg を 4 週に 1 回，皮下注射する』と設定した。

2.7.3.5 効果の持続，耐薬性

T18 試験（54 週まで）及び UCO3001 試験の partial Mayo スコア（中央値）の推移，30 週及び 54 週に clinical remission が認められた被験者の割合，並びに 30 週及び 54 週に mucosal healing が認められた被験者の割合から，効果は 54 週までおおむね持続すると考えられた。また，T18 試験（維持期 54 週から 216 週まで）の医師による全般評価（疾患活動性なしの被験者の割合）から，216 週まで効果はおおむね持続すると考えられた。以下に，それぞれの結果を示す。

なお，抗ゴリムマブ抗体陽性被験者は少数であったため，有効性との関連は明らかにできなかった。

(1) 維持期 54 週まで

1) T18 試験（54 週まで）及び UCO3001 試験の partial Mayo スコア

T18 試験（54 週まで）において，50 mg 群及び 100 mg 群にランダムに割り付けられた被験者の partial Mayo スコア（中央値）は，いずれも維持期 0 週では 2 であり，それぞれ維持期 48 週及び 52 週まで 2 を維持した（図 2.7.3-13）。UCO3001 試験においても同様に，100 mg 群にランダムに割り付けられた被験者の維持期 0 週の partial Mayo スコア（中央値）は，維持期 0 週のスコアを維持期 54 週までおおむね持続した（図 2.7.3-17）。

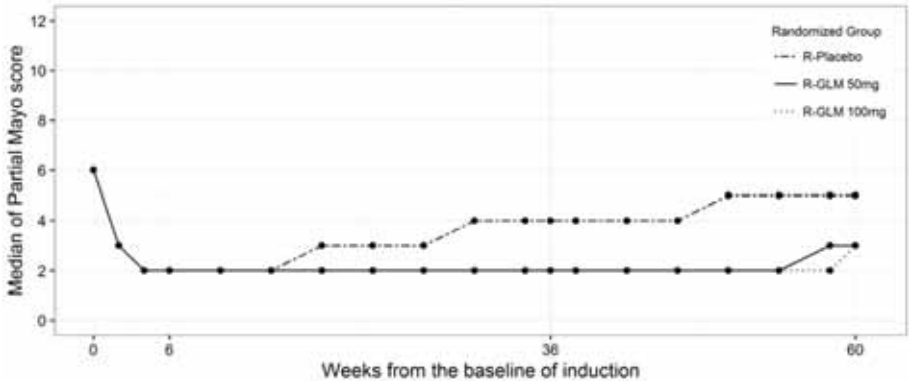


図 2.7.3-13 Partial Mayo score の推移（T18 試験，ランダム化された被験者；再掲）

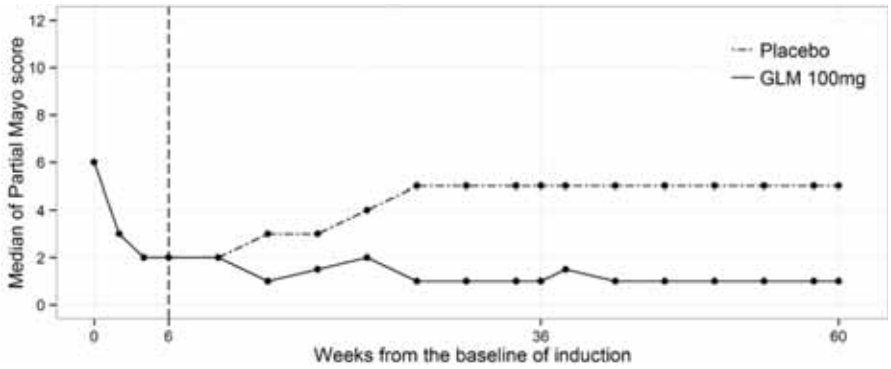


図 2.7.3-17 Partial Mayo score の推移（UCO3001 試験，ランダム化された被験者；再掲）

2) T18 試験（54 週まで）及び UCO3001 試験の 30 週及び 54 週に clinical remission が認められた被験者，並びに 30 週及び 54 週に mucosal healing が認められた被験者

T18 試験の 30 週及び 54 週に clinical remission が認められた被験者の割合は，100 mg 群でそれぞれ 39.7%（60/151 例）及び 33.8%（51/151 例），30 週及び 54 週に mucosal healing が認められた被験者の割合は，100 mg 群でそれぞれ 56.3%（85/151 例）及び 46.4%（70/151 例）であった（表 2.7.3-34 及び表 2.7.3-35）。UCO3001 試験の 30 週及び 54 週に clinical remission が認められた被験者の割合は，100 mg 群でそれぞれ 53.1%（17/32 例）及び 56.3%（18/32 例），30 週及び 54 週に mucosal healing が認められた被験者の割合は，100 mg 群でそれぞれ 59.4%（19/32 例）及び 62.5%（20/32 例）であった（表 2.7.3-36 及び表 2.7.3-37）。いずれの試験でも，維持期 30 週で得られた効果は，維持期 54 週までおおむね持続すると考えられた。

表 2.7.3-34 30 週及び 54 週に clinical remission が認められた被験者（T18 試験）

	Placebo	Golimumab 50 mg	Golimumab 100 mg	Golimumab Combined
Randomized subjects (excluding sites 6706, 7257 and 7407)	154	151	151	302
Week 30				
n	154	151	151	302
Subjects in clinical remission[a,b]	35 (22.7%)	54 (35.8%)	60 (39.7%)	114 (37.7%)
p-value		0.013	< 0.001	< 0.001
Week 54				
n	154	151	151	302
Subjects in clinical remission[a,b]	34 (22.1%)	50 (33.1%)	51 (33.8%)	101 (33.4%)
p-value		0.068	0.011	0.013

[a] Subjects who had a prohibited change in UC medication, an ostomy or colectomy, a dose adjustment, or discontinued study agent due to lack of therapeutic effect prior to the Week 30 (or Week 54) visit are considered not to be in clinical remission at Week 30 (or Week 54).
[b] Subjects who had all 4 Mayo subscores missing at Week 30 (or Week 54) are considered not to be in clinical remission at Week 30 (or Week 54).

RE631:[E CREM 89 A AA], 13MAY2015 13:51

Source: Attachment 3.35 of T18 in Re-analysis report for C0524T17 and C0524T18 54-Week

表 2.7.3-35 30 週及び 54 週に mucosal healing が認められた被験者（T18 試験）

	Placebo	Golimumab 50 mg	Golimumab 100 mg	Golimumab Combined
Randomized subjects (excluding sites 6706, 7257 and 7407)	154	151	151	302
Week 30				
n	154	151	151	302
Subjects with mucosal healing[a,b]	54 (35.1%)	79 (52.3%)	85 (56.3%)	164 (54.3%)
p-value		0.005	< 0.001	< 0.001
Week 54				
n	154	151	151	302
Subjects with mucosal healing[a]	44 (28.6%)	66 (43.7%)	70 (46.4%)	136 (45.0%)
p-value		0.012	< 0.001	< 0.001

[a] Subjects who had a prohibited change in UC medication, an ostomy or colectomy, a dose adjustment, or discontinued study agent due to lack of therapeutic effect prior to Week 30 (or Week 54) are considered not to have mucosal healing at Week 30 (or Week 54).
[b] Subjects who had a missing endoscopy subscore at Week 30 (or Week 54) are considered not to have mucosal healing at Week 30 (or Week 54).

RE631:[E MUCO 4 A AA], 18MAY2015 10:12

Source: Attachment 3.37 of T18 in Re-analysis report for C0524T17 and C0524T18 54-Week

表 2.7.3-36 30 週及び 54 週に clinical remission が認められた被験者（UCO3001 試験）

	Placebo	Golimumab 100mg
Analysis set: FAS-DB	31	32
Week 30		
N	31	32
Subjects in clinical remission [a,b]	4 (12.9%)	17 (53.1%)
Week 54		
N	31	32
Subjects in clinical remission [a,b]	5 (16.1%)	18 (56.3%)

[a] Subjects who had a prohibited change in UC medication, an ostomy or colectomy, a dose adjustment, or discontinued study agent due to lack of therapeutic effect prior to the Week 30 (or Week 54) visit are considered not to be in clinical remission at Week 30 (or Week 54).
[b] Subjects who had all 4 Mayo subscores missing at Week 30 (or Week 54) are considered not to be in clinical remission at Week 30 (or Week 54).

[TEFREMDB.rtf] [CNTO148¥CNTO148UCO3001¥DBR_CSRW54¥RE_NDAJPKK¥TEFREMDB.sas] 15FEB2016, 14:17

Source: TEFREMDB in analysis for Japan submission dossier

表 2.7.3-37 30 週及び 54 週に mucosal healing が認められた被験者（UCO3001 試験）

	Placebo	Golimumab 100mg
Analysis set: FAS-DB	31	32
Week 30		
N	31	32
Subjects with mucosal healing [a,b]	8 (25.8%)	19 (59.4%)
Week 54		
N	31	32
Subjects with mucosal healing [a,b]	5 (16.1%)	20 (62.5%)

[a] Subjects who had a prohibited change in UC medication, an ostomy or colectomy, a dose adjustment, or discontinued study agent due to lack of therapeutic effect prior to Week 30 (or Week 54) are considered not to have mucosal healing at Week 30 (or Week 54).
[b] Subjects who had a missing endoscopy subscore at Week 30 (or Week 54) are considered not to have mucosal healing at Week 30 (or Week 54).

[TEFMH02.rtf] [CNTO148CNTO148UCO3001\DBR_CSRW54\RE_CSRW54\refmh02.sas] 03DEC2015, 12:07

Source: TEFMH02 in analysis for Japan submission dossier

3) T18 試験（54 週まで）及び UCO3001 試験の維持期 54 週までの評価を完了した被験者

T18 試験（54 週まで）及び UCO3001 試験の 100 mg 群で，維持期 0 週にランダム化され，維持期 54 週までの評価を完了した被験者の割合は，それぞれ 75.3%（116/154 例）及び 84.4%（27/32 例）であった。いずれの試験でも，維持期 0 週にランダム化された被験者が 52 週までに clinical response を消失した場合，投与量を 1 回のみ調節でき，投与量調節後の初回投与から 16 週（UCO3001 試験は 12 週）までに疾患活動性の改善が認められなかった場合，治験薬投与を中止するため，維持期 54 週までの評価を完了した被験者では，効果はおおむね維持していたと考えられた。

(2) T18 試験（維持期 54 週から 216 週まで）の医師による全般評価

T18 試験の医師による全般評価において，「疾患活動性なし」の被験者数は，Randomized 群では 54 週で 102 例であり，216 週までおおむね一定であった（104～119 例，表 2.7.3-3）。T18 試験の継続投与では，治験薬を継続投与することにより効果が得られると治験担当医師が判断した被験者を対象としているため，解釈には注意が必要であるものの，ゴリムマブの 54 週の寛解維持で得られた効果は，216 週までおおむね持続すると考えられた。

表 2.7.3-3 疾患活動性なし又は軽症の被験者（T18 試験，医師による全般評価；再掲）

	Randomized Treatment at Week 0 of maintenance	
	Placebo[a,b]	Golimumab
Randomized subjects who were treated in the study extension (excluding sites 6706, 7257 and 7407)	52	195
Patients with no disease activity		
Week 54	50.0% (26/52)	52.3% (102/195)
Week 56	58.0% (29/50)	55.7% (108/194)
Week 80	63.9% (23/36)	61.5% (115/187)
Week 104	63.6% (14/22)	66.5% (119/179)
Week 128	62.5% (10/16)	64.4% (105/163)
Week 152	55.6% (5/9)	73.6% (117/159)
Week 176	66.7% (4/6)	73.3% (110/150)
Week 200	0.0% (0/1)	75.9% (104/137)
Week 216	0.0% (0/1)	77.6% (104/134)
Patients with no or mild disease activity		
Week 54	90.4% (47/52)	90.8% (177/195)
Week 56	90.0% (45/50)	93.3% (181/194)
Week 80	100.0% (36/36)	96.8% (181/187)
Week 104	95.5% (21/22)	96.1% (172/179)
Week 128	100.0% (16/16)	96.9% (158/163)
Week 152	100.0% (9/9)	97.5% (155/159)
Week 176	100.0% (6/6)	98.7% (148/150)
Week 200	100.0% (1/1)	97.1% (133/137)
Week 216	100.0% (1/1)	99.3% (133/134)

[a] Includes data up to the time of dose increase.
[b] Excludes placebo subjects who had a dose adjustment before Week 54.

[TEFPGA01.rtf] [CNTO148\C0524T18\DBR_W228\RE_W228\TEFPGA01.sas] 24APR2015, 14:55

2.7.3.6 付録

表 2.7.3-付録-1 被験者背景（T16，T17 及び T18 試験）

	Induction		Maintenance
	C0524T16	C0524T17 (after dose selection)	C0524T18[a]
Randomized subjects	291	774	464
Demographic characteristics			
Sex			
Male	59.8%	56.0%	51.9%
Female	40.2%	44.0%	48.1%
Race			
Caucasian	82.1%	82.1%	87.3%
Black	1.4%	2.5%	1.7%
Asian	15.1%	11.8%	8.2%
Other	1.4%	3.6%	2.8%
Median age (years)	40.0	38.0	39.0
Median weight (kg)	70.0	72.0	72.0
UC disease characteristics			
Median UC disease duration (years)	4.57	4.30	4.55
Median Mayo score	8.0	8.0	8.0
Extensive disease	44.7%	42.4%	44.2%
Median CRP (mg/L)	4.62	4.76	3.61
Subjects receiving concomitant UC therapies	94.2%	92.1%	93.8%
Corticosteroids (excluding budesonide)	53.3%	43.2%	51.5%
≥ 20 mg/day P.Eq	36.1%	25.1%	35.8%
Immunomodulatory drugs	31.3%	29.8%	31.7%
6-MP/AZA	30.2%	28.3%	31.0%
MTX	1.0%	1.6%	0.6%
5-ASA	81.8%	81.4%	80.2%
Subjects with inadequate response, intolerance, or dependence on conventional UC therapy	99.3%	100.0%	100.0%
Refractory to, dependent on, or intolerant of corticosteroids	79.4%	68.9%	75.4%
Refractory to or intolerant of 6-MP/AZA	52.6%	49.6%	50.4%
Refractory to or intolerant of 5-ASAs[b]	94.6%	95.7%	94.5%

5-ASA = 5-aminosalicylate; 6-MP = 6-mercaptopurine; AZA = azathioprine; MTX = methotrexate; P.Eq = prednisone equivalent;

[a]Randomized subjects who were golimumab induction responders

[b]These data were only collected for subjects recruited following implementation of Protocol Amendment 1 of the induction studies.

Source: Table 8 in SCE _EDMS-ERI-31059095: 1.0

表 2.7.3-付録-2 人口統計学的特性（UCO3001 試験，組み入れられた被験者）

	Golimumab 200 mg -> 100 mg
Analysis set: FAS-I	144
Sex	
N	144
Male	98 (68.1%)
Female	46 (31.9%)
Race	
N	144
Asian	144 (100.0%)
Age (yrs)	
N	144
Mean (SD)	42.4 (14.74)
Median	42.0
IQ range	(30.0; 54.0)
Range	(18; 73)
Category	
< 65 yrs	132 (91.7%)
>= 65 yrs	12 (8.3%)
Weight (kg)	
N	144
Mean (SD)	61.51 (11.175)
Median	60.75
IQ range	(51.90; 68.90)
Range	(42.2; 100.4)
Height (cm)	
N	144
Mean (SD)	165.63 (7.499)
Median	166.00
IQ range	(160.30; 170.55)
Range	(147.0; 183.8)
Body mass index (kg/m^2)	
N	144
Mean (SD)	22.38 (3.685)
Median	21.76
IQ range	(19.80; 24.34)
Range	(15.8; 42.7)

[TSIDEM01IN.rtf] [CNTO148\CNTO148UCO3001\DBR_CSRW54\RE_CSRW54\tsdem01in.sas] 03DEC2015, 12:02

Source: Attachment TSIDEM01IN in UCO3001-54W-CSR

表 2.7.3-付録-3 疾患特性（UCO3001 試験，組み入れられた被験者）

	Golimumab 200 mg -> 100 mg
Analysis set: FAS-I	144
UC disease duration (yrs)	
N	144
Mean (SD)	7.08 (6.654)
Median	5.08
IQ range	(2.02; 9.91)
Range	(0.1; 27.4)
Category	
<= 5 yrs	71 (49.3%)
> 5 yrs to 15 yrs	53 (36.8%)
> 15 yrs	20 (13.9%)
Extent of disease	
N	144
Limited to left side of colon	89 (61.8%)
Extensive	55 (38.2%)
Mayo score (0-12)	
N	144
Mean (SD)	8.1 (1.39)
Median	8.0
IQ range	(7.0; 9.0)
Range	(6; 12)
Category	
< 9	86 (59.7%)
>= 9	58 (40.3%)
Severity of UC disease	
N	144
Moderate	141 (97.9%)
Severe	3 (2.1%)
CRP (mg/L)	
N	144
Mean (SD)	4.896 (10.9526)
Median	1.585
IQ range	(0.580; 4.595)
Range	(0.11; 84.34)
Category	
< 8 mg/L	126 (87.5%)
>= 8 mg/L	18 (12.5%)
Extraintestinal manifestation	
N	144
Absent	126 (87.5%)
Present	18 (12.5%)

[TSIDEM02IN.rtf] [CNTO148\CNTO148UCO3001\DBR_CSRW54\RE_CSRW54\tsdem02in.sas] 03DEC2015, 12:03

Source: Attachment TSIDEM02IN in UCO3001-54W-CSR

表 2.7.3-付録-4 併用した UC 治療薬（UCO3001 試験，組み入れられた被験者）

	Golimumab 200 mg -> 100 mg
Analysis set: SF-I	144
Any UC medication	141 (97.9%)
Corticosteroid (excluding budesonide)	42 (29.2%)
>= 20 mg/day P.Eq	12 (8.3%)
< 20 mg/day P.Eq	30 (20.8%)
Budesonide	0
Immunomodulatory drugs	64 (44.4%)
6-MP/AZA	64 (44.4%)
Methotrexate	0
Aminosalicylates	128 (88.9%)

[TSICM01IN.rtf] [CNTO148\CNTO148UCO3001\DBR_CSRW54\RE_CSRW54\tsicm01in.sas] 03DEC2015, 12:04

Source: Attachment TSICM01IN in UCO3001-54W-CSR

表 2.7.3-付録-5 UC 前治療に対する反応性（UCO3001 試験，組み入れられた被験者）

	Golimumab 200 mg -> 100 mg
Analysis set: SF-I	144
Subjects with inadequate response, intolerance, or dependence	144 (100.0%)
Corticosteroids	
N	144
Subjects refractory,dependent, or intolerant	91 (63.2%)
Subjects refractory	33 (22.9%)
Subjects refractory to past treatment	32 (22.2%)
Subjects refractory to current treatment	13 (9.0%)
Subjects dependent	71 (49.3%)
Subjects intolerant	20 (13.9%)
6-MP/AZA	
N	144
Subjects refractory or intolerant	85 (59.0%)
Subjects refractory	73 (50.7%)
Subjects refractory to past treatment	71 (49.3%)
Subjects refractory to current treatment	64 (44.4%)
Subjects intolerant	30 (20.8%)
5-ASAs	
N	144
Subjects refractory or intolerant	144 (100.0%)
Subjects refractory	130 (90.3%)
Subjects refractory to past treatment	130 (90.3%)
Subjects refractory to current treatment	128 (88.9%)
Subjects intolerant	25 (17.4%)

[TSICMRT01IN.rtf] [CNTO148\CNTO148UCO3001\DBR_CSRW54\RE_CSRW54\tucmrt01in.sas] 03DEC2015, 12:04

Source: Attachment TSICMRT01IN in UCO3001-54W-CSR

表 2.7.3-付録-6 人口統計学的特性（UCO3001 試験，ランダム化された被験者）

	Placebo	Golimumab 100 mg	Total	Dose Adjustment: Placebo → Golimumab 100 mg	Dose Adjustment: Golimumab 100 mg → Golimumab 100 mg
Analysis set: FAS-DB	31	32	63	19	8
Sex					
N	31	32	63	19	8
Male	19 (61.3%)	19 (59.4%)	38 (60.3%)	12 (63.2%)	3 (37.5%)
Female	12 (38.7%)	13 (40.6%)	25 (39.7%)	7 (36.8%)	5 (62.5%)
Race					
N	31	32	63	19	8
Asian	31 (100.0%)	32 (100.0%)	63 (100.0%)	19 (100.0%)	8 (100.0%)
Age (yrs)					
N	31	32	63	19	8
Mean (SD)	42.9 (14.41)	39.3 (12.00)	41.1 (13.26)	44.6 (16.09)	41.3 (12.53)
Median	42.0	40.0	40.0	42.0	37.5
IQ range	(31.0; 56.0)	(29.5; 45.5)	(31.0; 53.0)	(31.0; 58.0)	(31.0; 51.0)
Range	(18; 73)	(19; 70)	(18; 73)	(18; 73)	(28; 63)
Category					
< 65 yrs	30 (96.8%)	31 (96.9%)	61 (96.8%)	18 (94.7%)	8 (100.0%)
>= 65 yrs	1 (3.2%)	1 (3.1%)	2 (3.2%)	1 (5.3%)	0
Weight (kg)					
N	31	32	63	19	8
Mean (SD)	59.48 (9.729)	64.59 (14.732)	62.07 (12.687)	60.85 (10.376)	56.61 (10.640)
Median	57.90	64.60	60.70	58.40	50.85
IQ range	(51.50; 66.00)	(50.80; 73.00)	(51.50; 70.30)	(53.80; 68.50)	(48.35; 67.05)
Range	(42.3; 82.7)	(44.5; 100.4)	(42.3; 100.4)	(44.0; 82.7)	(47.9; 72.5)
Height (cm)					
N	31	32	63	19	8
Mean (SD)	163.49 (6.210)	163.77 (7.049)	163.63 (6.597)	162.42 (6.175)	160.46 (4.964)
Median	163.00	162.85	163.00	162.00	160.25
IQ range	(158.40; 169.50)	(160.00; 168.15)	(159.00; 169.50)	(158.00; 166.90)	(159.50; 164.05)
Range	(149.5; 173.7)	(150.1; 183.8)	(149.5; 183.8)	(149.5; 173.7)	(150.1; 166.0)
Body mass index (kg/m^2)					
N	31	32	63	19	8
Mean (SD)	22.22 (3.239)	24.07 (5.437)	23.16 (4.553)	23.02 (3.449)	22.13 (5.035)
Median	21.95	22.70	22.02	22.67	19.80
IQ range	(20.21; 24.24)	(19.92; 26.79)	(20.20; 25.67)	(20.40; 25.10)	(18.68; 25.20)
Range	(17.2; 30.7)	(17.5; 42.7)	(17.2; 42.7)	(17.4; 30.7)	(17.5; 32.2)

FAS-DB=efficacy full analysis set for double-blind maintenance phase; IQ=interquartile; N=number of subjects; SD=standard deviation
[TSIDEM01DB.rtf] [CNTO148\CNTO148UCO3001\DBR_CSRW54\RE_CSRW54\TSIDEM01DB.sas] 03DEC2015, 11:45

Source: Table 2 in UCO3001-54W-CSR

表 2.7.3-付録-7 疾患特性（UCO3001 試験，ランダム化された被験者）

	Placebo	Golimumab 100mg	Total	Dose Adjustment	
				Placebo -> 100 mg	100 mg -> 100 mg
Analysis set: FAS-DB	31	32	63	19	8
UC disease duration (yrs)					
N	31	32	63	19	8
Mean (SD)	7.09 (6.046)	7.87 (6.776)	7.49 (6.387)	6.72 (6.228)	9.38 (4.721)
Median	5.74	5.35	5.66	5.31	8.48
IQ range	(1.58; 11.58)	(2.76; 11.96)	(2.40; 11.58)	(1.58; 11.58)	(5.22; 14.03)
Range	(0.3; 21.6)	(0.5; 24.7)	(0.3; 24.7)	(0.3; 21.6)	(3.7; 15.9)
Category					
<= 5 yrs	13 (41.9%)	14 (43.8%)	27 (42.9%)	9 (47.4%)	2 (25.0%)
> 5 yrs to 15 yrs	14 (45.2%)	13 (40.6%)	27 (42.9%)	8 (42.1%)	5 (62.5%)
> 15 yrs	4 (12.9%)	5 (15.6%)	9 (14.3%)	2 (10.5%)	1 (12.5%)
Extent of disease					
N	31	32	63	19	8
Limited to left side of colon	19 (61.3%)	20 (62.5%)	39 (61.9%)	12 (63.2%)	5 (62.5%)
Extensive	12 (38.7%)	12 (37.5%)	24 (38.1%)	7 (36.8%)	3 (37.5%)
Mayo score (0-12)					
N	31	32	63	19	8
Mean (SD)	8.2 (1.42)	7.8 (1.62)	8.0 (1.52)	7.9 (1.35)	7.3 (1.58)
Median	8.0	8.0	8.0	8.0	6.5
IQ range	(7.0; 9.0)	(6.0; 9.0)	(7.0; 9.0)	(7.0; 9.0)	(6.0; 8.5)
Range	(6; 12)	(6; 11)	(6; 12)	(6; 10)	(6; 10)
Category					
< 9	18 (58.1%)	21 (65.6%)	39 (61.9%)	11 (57.9%)	6 (75.0%)
>= 9	13 (41.9%)	11 (34.4%)	24 (38.1%)	8 (42.1%)	2 (25.0%)
Severity of UC disease					
N	31	32	63	19	8
Moderate	30 (96.8%)	31 (96.9%)	61 (96.8%)	19 (100.0%)	8 (100.0%)
Severe	1 (3.2%)	1 (3.1%)	2 (3.2%)	0	0
CRP (mg/L)					
N	31	32	63	19	8
Mean (SD)	4.059 (7.7439)	5.312 (14.7856)	4.696 (11.7780)	2.702 (3.3769)	4.521 (5.5780)
Median	0.930	1.805	1.480	0.930	2.400
IQ range	(0.360; 4.780)	(0.770; 3.605)	(0.440; 4.220)	(0.380; 4.410)	(0.895; 7.530)
Range	(0.14; 40.77)	(0.11; 84.34)	(0.11; 84.34)	(0.31; 13.09)	(0.25; 14.27)
Category					
< 8 mg/L	28 (90.3%)	29 (90.6%)	57 (90.5%)	18 (94.7%)	6 (75.0%)
>= 8 mg/L	3 (9.7%)	3 (9.4%)	6 (9.5%)	1 (5.3%)	2 (25.0%)
Extraintestinal manifestation					
N	31	32	63	19	8
Absent	28 (90.3%)	27 (84.4%)	55 (87.3%)	18 (94.7%)	7 (87.5%)
Present	3 (9.7%)	5 (15.6%)	8 (12.7%)	1 (5.3%)	1 (12.5%)

[TSIDEM02DB.rtf] [CNTO148\CNTO148UCO3001\DBR_CSRW54\RE_CSRW54\TSIDEM02DB.sas] 03DEC2015, 11:45

Source: Attachment TSIDEM02DB in UCO3001-54W-CSR

表 2.7.3-付録-8 併用した UC 治療薬（UCO3001 試験，ランダム化された被験者）

	Placebo	Golimumab 100 mg	Total	Dose Adjustment	
				Placebo → 100 mg	100 mg → 100 mg
Analysis set: SF-DB	31	32	63	19	8
Any UC medication	30 (96.8%)	32 (100.0%)	62 (98.4%)	19 (100.0%)	8 (100.0%)
Corticosteroid (excluding budesonide)	9 (29.0%)	9 (28.1%)	18 (28.6%)	7 (36.8%)	1 (12.5%)
>= 20 mg/day P.Eq	5 (16.1%)	4 (12.5%)	9 (14.3%)	3 (15.8%)	1 (12.5%)
< 20 mg/day P.Eq	4 (12.9%)	5 (15.6%)	9 (14.3%)	4 (21.1%)	0
Budesonide	0	0	0	0	0
Immunomodulatory drugs	13 (41.9%)	16 (50.0%)	29 (46.0%)	8 (42.1%)	3 (37.5%)
6-MP/AZA	13 (41.9%)	16 (50.0%)	29 (46.0%)	8 (42.1%)	3 (37.5%)
Methotrexate	0	0	0	0	0
Aminosalcylates	27 (87.1%)	29 (90.6%)	56 (88.9%)	17 (89.5%)	8 (100.0%)

6-MP=6-mercaptopurine; AZA=azathioprine; P.Eq=prednisone equivalent; SF-DB=safety analysis set for double-blind maintenance phase; UC=ulcerative colitis
[TSICM01DB.rtf] [CNTO148\CNTO148UCO3001\DBR_CSRW54\RE_CSRW54\TSICM01DB.sas] 03DEC2015, 11:46

Source: Table 3 in UCO3001-54W-CSR

表 2.7.3-付録-9 UC 前治療に対する反応性（UCO3001 試験，ランダム化された被験者）

	Placebo	Golimumab 100mg	Total	Dose Adjustment: Placebo -> 100 mg	Dose Adjustment: 100 mg -> 100 mg
Analysis set: SF-DB	31	32	63	19	8
Subjects with inadequate response, intolerance, or dependence	31 (100.0%)	32 (100.0%)	63 (100.0%)	19 (100.0%)	8 (100.0%)
Corticosteroids					
N	31	32	63	19	8
Subjects refractory,dependent, or intolerant	20 (64.5%)	21 (65.6%)	41 (65.1%)	14 (73.7%)	5 (62.5%)
Subjects refractory	9 (29.0%)	7 (21.9%)	16 (25.4%)	6 (31.6%)	3 (37.5%)
Subjects refractory to past treatment	8 (25.8%)	7 (21.9%)	15 (23.8%)	5 (26.3%)	3 (37.5%)
Subjects refractory to current treatment	5 (16.1%)	4 (12.5%)	9 (14.3%)	3 (15.8%)	1 (12.5%)
Subjects dependent	15 (48.4%)	18 (56.3%)	33 (52.4%)	11 (57.9%)	3 (37.5%)
Subjects intolerant	4 (12.9%)	2 (6.3%)	6 (9.5%)	3 (15.8%)	0
6-MP/AZA					
N	31	32	63	19	8
Subjects refractory or intolerant	19 (61.3%)	19 (59.4%)	38 (60.3%)	10 (52.6%)	6 (75.0%)
Subjects refractory	15 (48.4%)	17 (53.1%)	32 (50.8%)	9 (47.4%)	4 (50.0%)
Subjects refractory to past treatment	15 (48.4%)	17 (53.1%)	32 (50.8%)	9 (47.4%)	4 (50.0%)
Subjects refractory to current treatment	13 (41.9%)	16 (50.0%)	29 (46.0%)	8 (42.1%)	3 (37.5%)
Subjects intolerant	6 (19.4%)	6 (18.8%)	12 (19.0%)	2 (10.5%)	3 (37.5%)
5-ASAs					
N	31	32	63	19	8
Subjects refractory or intolerant	31 (100.0%)	32 (100.0%)	63 (100.0%)	19 (100.0%)	8 (100.0%)
Subjects refractory	28 (90.3%)	29 (90.6%)	57 (90.5%)	18 (94.7%)	8 (100.0%)
Subjects refractory to past treatment	28 (90.3%)	29 (90.6%)	57 (90.5%)	18 (94.7%)	8 (100.0%)
Subjects refractory to current treatment	27 (87.1%)	29 (90.6%)	56 (88.9%)	17 (89.5%)	8 (100.0%)
Subjects intolerant	5 (16.1%)	4 (12.5%)	9 (14.3%)	3 (15.8%)	0

[TSICMRT01DB.rtf] [CNTO148\CNTO148UCO3001\DBR_CSRW54\RE_CSRW54\tscmrt01db.sas] 03DEC2015, 12:05

Source: Attachment TSICMRT01DB in UCO3001-54W-CSR

表 2.7.3-付録-10 寛解維持期の抗ゴリムマブ抗体陽性・陰性別の 54 週までに clinical response が認められた被験者（T18 試験，ランダム化された被験者）

	Placebo[a,b]	Golimumab[a] 50 mg	Golimumab[a] 100 mg	Golimumab[a] Combined	Total
Treated subjects who were randomized (excluding sites 6706, 7257 and 7407)	154	151	151	302	456
Subjects with appropriate samples[c]	153	149	145	294	447
Subjects positive for antibodies to golimumab at any time[d,e]	11 (7.2%)	4 (2.7%)	5 (3.4%)	9 (3.1%)	20 (4.5%)
Clinical response through Week 54[f,g,h]	5 (45.5%)	1 (25.0%)	1 (20.0%)	2 (22.2%)	7 (35.0%)
Subjects negative for antibodies to golimumab[d,i]	142 (92.8%)	145 (97.3%)	140 (96.6%)	285 (96.9%)	427 (95.5%)
Clinical response through Week 54[g,h,j]	43 (30.3%)	70 (48.3%)	74 (52.9%)	144 (50.5%)	187 (43.8%)

[a] Treatment group at Week 0 of this maintenance study.
[b] Subjects who were in clinical response to golimumab induction dosing and were randomized to placebo on entry into this maintenance study.
[c] Subjects with appropriate samples had 1 or more samples obtained after their first study agent administration of this maintenance study.
[d] Denominator is subjects with appropriate samples.
[e] Includes all subjects who had at least 1 positive sample at any time in this maintenance study.
[f] Denominator is subjects positive for antibodies to golimumab at any time in this maintenance study.
[g] Subjects who had a prohibited change in UC medication, an ostomy or colectomy, a dose adjustment, or discontinued study agent due to lack of therapeutic effect prior to the Week 54 visit are considered not to be in clinical response.
[h] Subjects who had all 4 Mayo subscores missing at Week 30 or at Week 54 are considered not to be in clinical response.
[i] Excludes subjects who were positive at any time in this maintenance study and includes subjects whose samples may contain golimumab.
[j] Denominator is subjects negative for antibodies to golimumab.

RE631 [E_ATSA_129_A_AA], 13MAY2015 13:12

Source: Attachment 3.81 of T18 in Re-analysis report for C0524T17 and C0524T18 54-Week

表 2.7.3-付録-11 コルチコステロイドの 1 日投与量

（predonison 換算量；T18 試験継続投与，228 週まで）

	Randomized Treatment at Week 0 of maintenance	
	Placebo[a,b]	Golimumab
Randomized subjects who were treated in the study extension (excluding sites 6706, 7257 and 7407)	52	195
Week 56		
N	50	194
Mean (SD)	2.02 (5.070)	2.13 (6.453)
Median	0.00	0.00
IQ range	(0.00; 0.00)	(0.00; 0.00)
Range	(0.0; 20.0)	(0.0; 40.0)
Week 80		
N	36	187
Mean (SD)	1.63 (4.589)	1.56 (5.353)
Median	0.00	0.00
IQ range	(0.00; 0.00)	(0.00; 0.00)
Range	(0.0; 20.0)	(0.0; 40.0)
Week 104		
N	22	180
Mean (SD)	1.82 (6.463)	1.70 (6.002)
Median	0.00	0.00
IQ range	(0.00; 0.00)	(0.00; 0.00)
Range	(0.0; 30.0)	(0.0; 40.0)
Week 128		
N	16	164
Mean (SD)	1.88 (5.123)	2.36 (7.708)
Median	0.00	0.00
IQ range	(0.00; 0.00)	(0.00; 0.00)
Range	(0.0; 20.0)	(0.0; 42.5)
Week 152		
N	9	159
Mean (SD)	4.44 (9.825)	1.18 (4.919)
Median	0.00	0.00
IQ range	(0.00; 5.00)	(0.00; 0.00)
Range	(0.0; 30.0)	(0.0; 42.5)
Week 176		
N	6	151
Mean (SD)	5.83 (12.007)	1.13 (4.758)
Median	0.00	0.00
IQ range	(0.00; 5.00)	(0.00; 0.00)
Range	(0.0; 30.0)	(0.0; 40.0)
Week 200		
N	1	137
Mean (SD)	0 (-)	0.89 (3.685)
Median	0.00	0.00
IQ range	(0.00; 0.00)	(0.00; 0.00)
Range	(0.0; 0.0)	(0.0; 20.0)
Week 216		
N	1	134
Mean (SD)	0 (-)	1.21 (5.026)
Median	0.00	0.00
IQ range	(0.00; 0.00)	(0.00; 0.00)
Range	(0.0; 0.0)	(0.0; 40.0)

[a] Includes data up to the time of dose increase.
[b] Excludes placebo subjects who had a dose adjustment before Week 54.

[TEFCORT03.rtf] [CNTO148\C0524T18\DBR_W228\RE_W228\TEFCORT03.sas] 01MAY2015, 10:56

Source: Attachment TEFCORT03 of T18-228W-CSR

表 2.7.3-付録-12 IBDQ（T18 試験，継続投与：228 週まで）

	Placebo[a]	Golimumab[b]
Subjects who were treated in the study extension (excluding sites 6706, 7257 and 7407)	95	555
Week 54		
N	93	552
Mean (SD)	187.3 (26.89)	179.6 (31.88)
Median	196.0	186.5
IQ range	(175.0; 206.0)	(161.5; 204.0)
Range	(96; 223)	(79; 224)
Week 80		
N	65	522
Mean (SD)	189.3 (25.11)	180.2 (31.84)
Median	196.0	188.0
IQ range	(181.0; 207.0)	(164.0; 205.0)
Range	(110; 224)	(66; 224)
Week 104		
N	40	480
Mean (SD)	186.5 (30.90)	182.4 (31.56)
Median	200.0	190.0
IQ range	(167.0; 208.0)	(164.0; 206.0)
Range	(83; 224)	(58; 224)
Week 128		
N	24	437
Mean (SD)	187.8 (33.39)	183.5 (30.18)
Median	199.0	191.0
IQ range	(173.5; 212.0)	(167.0; 206.0)
Range	(92; 221)	(56; 224)
Week 152		
N	12	414
Mean (SD)	189.3 (22.43)	184.4 (29.38)
Median	196.5	192.5
IQ range	(172.5; 205.0)	(170.0; 207.0)
Range	(141; 215)	(79; 224)
Week 176		
N	6	383
Mean (SD)	192.0 (19.84)	185.2 (30.05)
Median	192.5	193.0
IQ range	(184.0; 211.0)	(171.0; 208.0)
Range	(159; 213)	(53; 224)
Week 200		
N	1	363
Mean (SD)	189 (-)	186.4 (28.62)
Median	189.0	194.0
IQ range	(189.0; 189.0)	(173.0; 208.0)
Range	(189; 189)	(64; 224)
Week 216		
N	1	356
Mean (SD)	195 (-)	187.5 (28.20)
Median	195.0	195.0
IQ range	(195.0; 195.0)	(173.0; 209.0)
Range	(195; 195)	(63; 224)

[a] Includes data up to the time of dose increase.
[b] Placebo subjects data from the time of the first golimumab dose are not included.

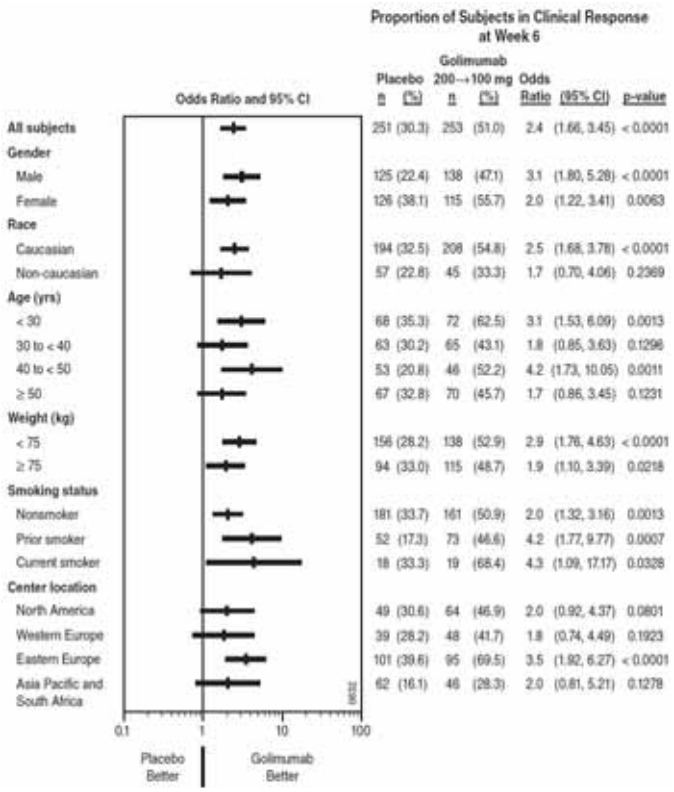
[TEFIBDQ03.rtf] [CNTO148C0524T18\DBR_W228\RE_W228\TEFIBDQ03.sas] 24APR2015, 14:55

Source: Attachment TEFIBDQ03 of T18-228W-CSR

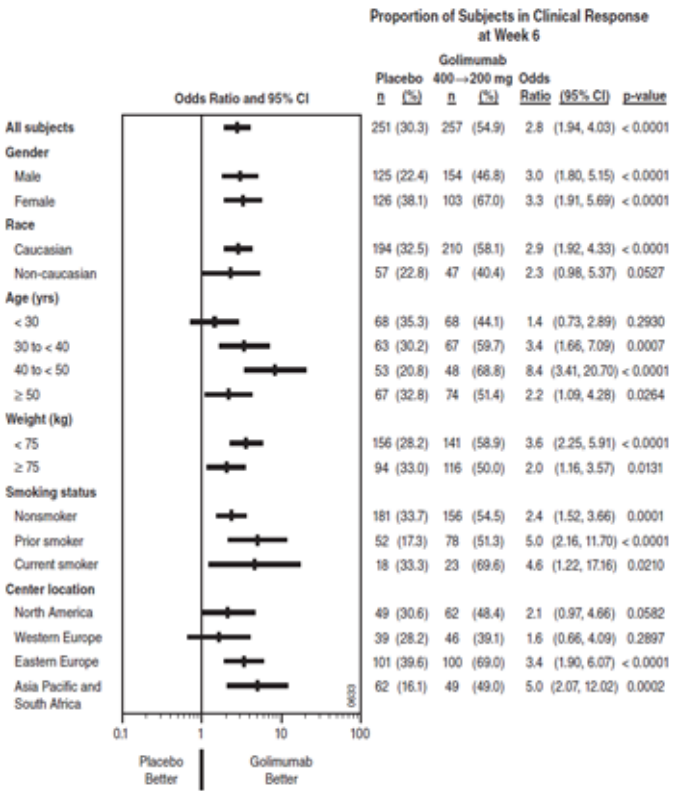
表 2.7.3-付録-13 T17 試験（Part 2 投与量選択後）における患者背景別の 6 週時点の clinical response 率

		プラセボ群（251 例）	200->100mg 群（253 例）	400->200mg 群（257 例）
全体		30.3 (76/251)	51.0 (129/253)	54.9 (141/257)
性別	男性	22.4 (28/125)	47.1 (65/138)	46.8 (72/154)
	女性	38.1 (48/126)	55.7 (64/115)	67.0 (69/103)
年齢	50 歳未満	29.3 (54/184)	53.0 (97/183)	56.3 (103/183)
	50 歳以上	32.8 (22/67)	45.7 (32/70)	51.4 (38/74)
体重	75kg 未満	28.2 (44/156)	52.9 (73/138)	58.9 (83/141)
	75kg 以上	33.0 (31/94)	48.7 (56/115)	50.0 (58/116)
罹病期間	5 年以下	32.2 (46/143)	52.4 (75/143)	51.1 (71/139)
	5 年超	27.8 (30/108)	49.1 (54/110)	59.3 (70/118)
Mayo スコア	9 未満	31.2 (44/141)	53.8 (63/117)	56.6 (73/129)
	9 以上	29.1 (32/110)	48.5 (66/136)	53.1 (68/128)
経口コルチコステロイド併用	20mg/日以上	49.2 (29/59)	66.1 (41/62)	63.9 (46/72)
	20mg/日未満	19.0 (8/42)	46.9 (23/49)	61.7 (29/47)
	ブデソニド	0.0 (0/3)	50.0 (2/4)	75.0 (6/8)
	無	26.5 (39/147)	45.7 (63/138)	46.2 (60/130)
6-MP/AZA/MTX 併用	有	23.0 (17/74)	49.3 (36/73)	50.0 (39/78)
	無	33.3 (59/177)	51.7 (93/180)	57.0 (102/179)

割合（例数）



(A)

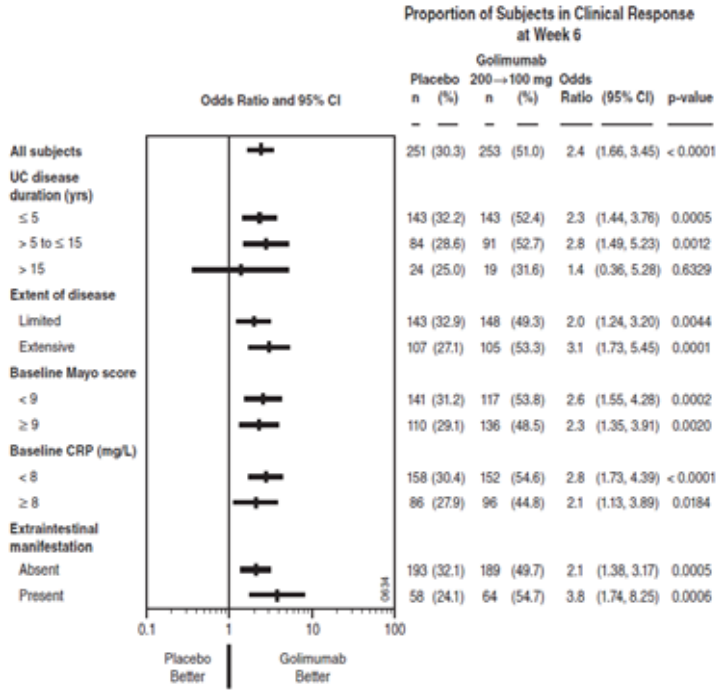


(B)

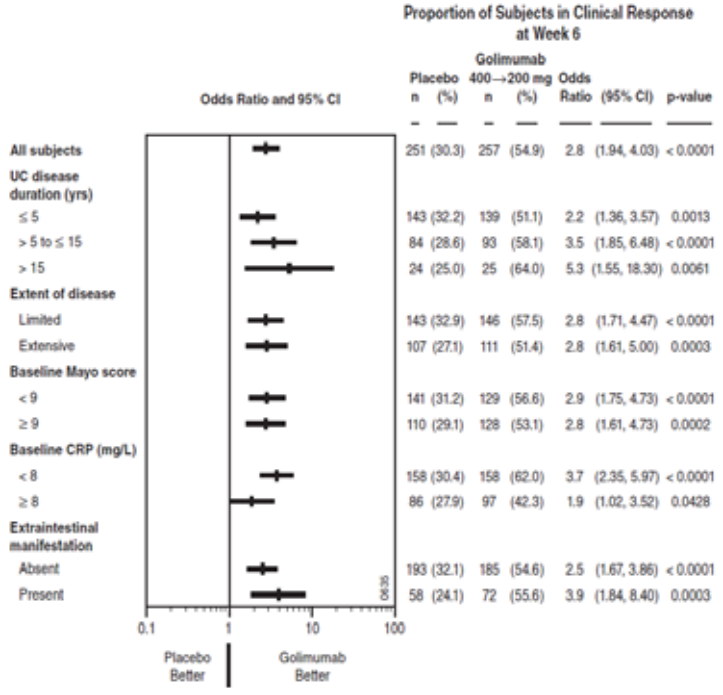
(A) 200→100 mg 群及びプラセボ群，(B) 400→200 mg 群及びプラセボ群

Source: Attachment 3.4 and 3.5 of T17 in Re-analysis report for C0524T17 and C0524T18 54-Week

図 2.7.3-付録-1 6 週に clinical response が認められた被験者の割合
（人口統計学的特性別，T17 試験，Part 2 投与量選択後）



(A)

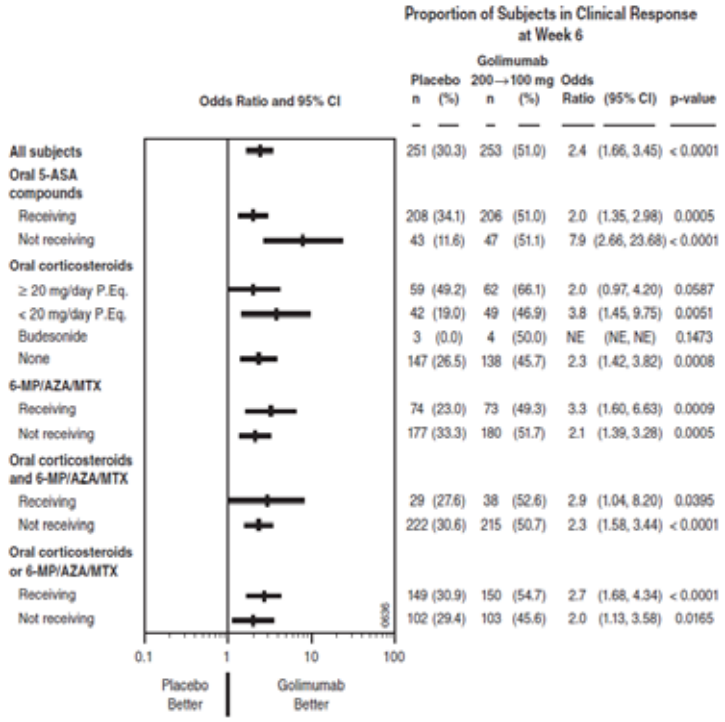


(B)

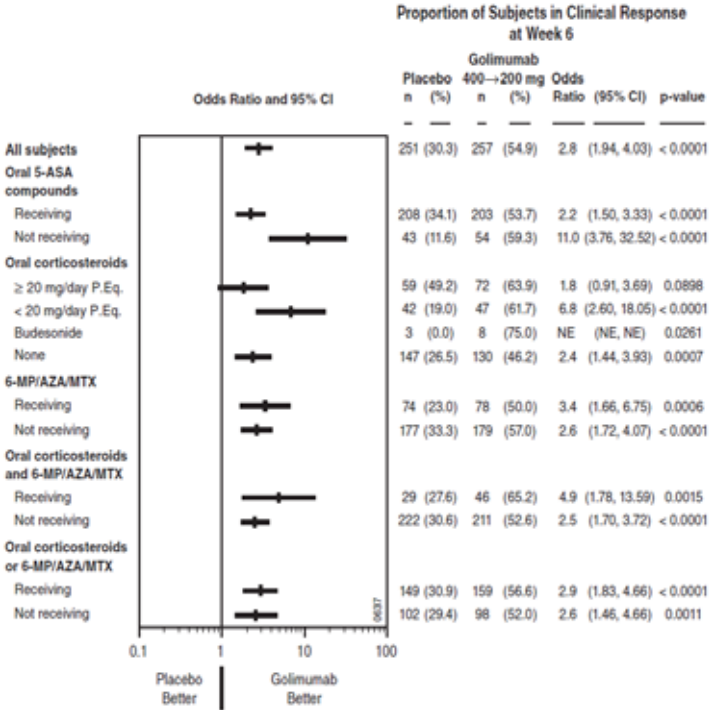
(A) 200→100 mg 群及びプラセボ群，(B) 400→200 mg 群及びプラセボ群

Source: Attachment 3.6 and 3.7 of T17 in Re-analysis report for C0524T17 and C0524T18 54-Week

図 2.7.3-付録-2 6 週に clinical response が認められた被験者の割合
（疾患特性別，T17 試験，Part 2 投与量選択後）



(A)

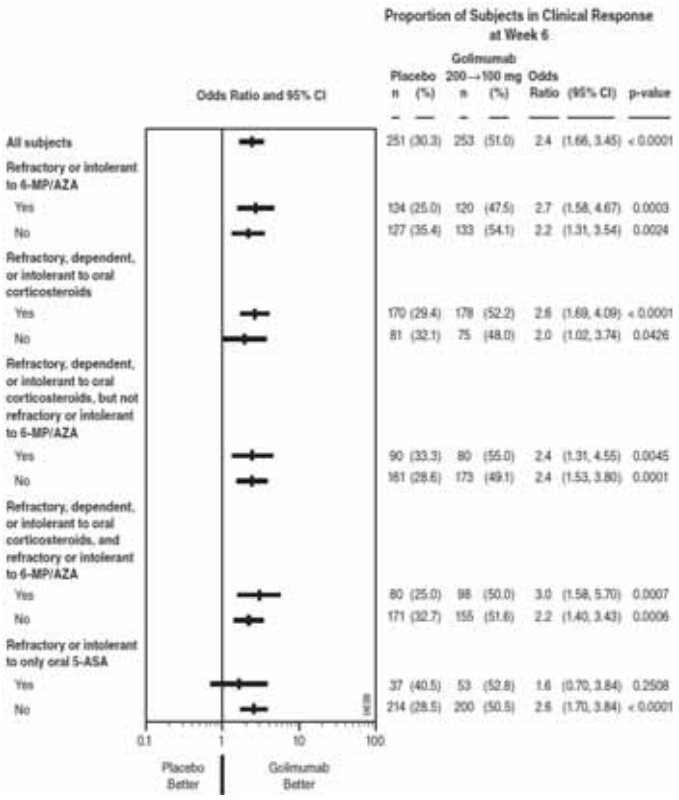


(B)

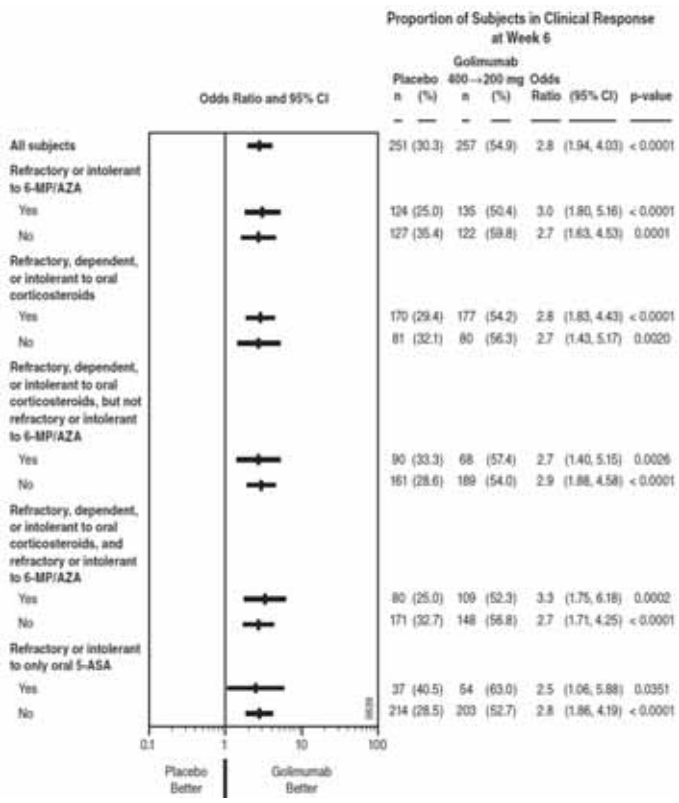
(A) 200→100 mg 群及びプラセボ群，(B) 400→200 mg 群及びプラセボ群

Source: Attachment 3.8 and 3.9 of T17 in Re-analysis report for C0524T17 and C0524T18 54-Week

図 2.7.3-付録-3 6 週に clinical response が認められた被験者の割合
（併用した UC 治療薬別，T17 試験，Part 2 投与量選択後）



(A)

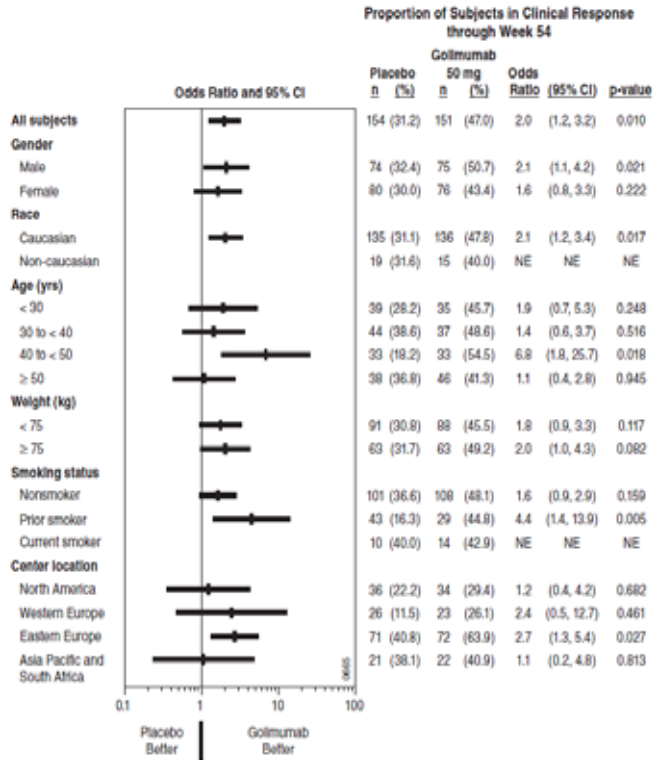


(B)

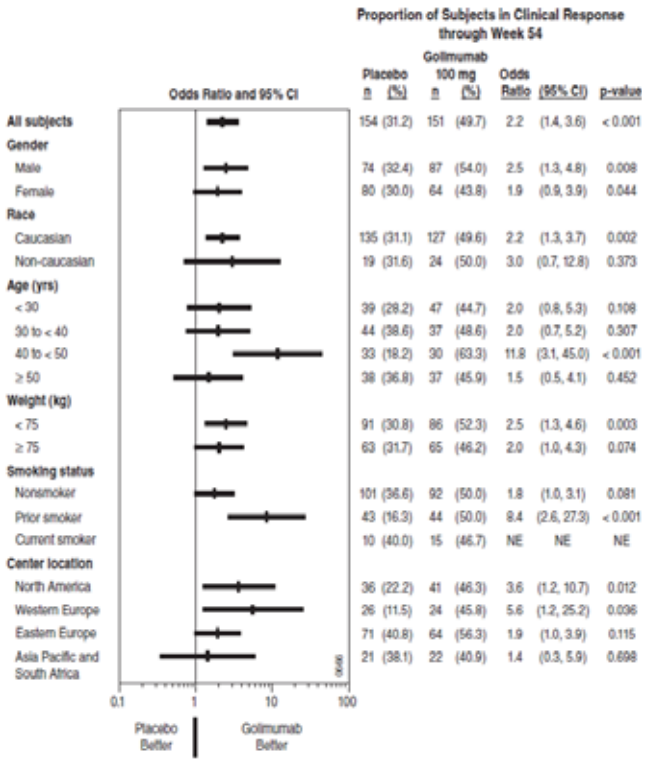
(A) 200→100 mg 群及びプラセボ群，(B) 400→200 mg 群及びプラセボ群

Source: Attachment 3.10 and 3.11 of T17 in Re-analysis report for C0524T17 and C0524T18 54-Week

図 2.7.3-付録-4 6 週に clinical response が認められた被験者の割合
（UC 前治療に対する反応性別，T17 試験，Part 2 投与量選択後）



(A)

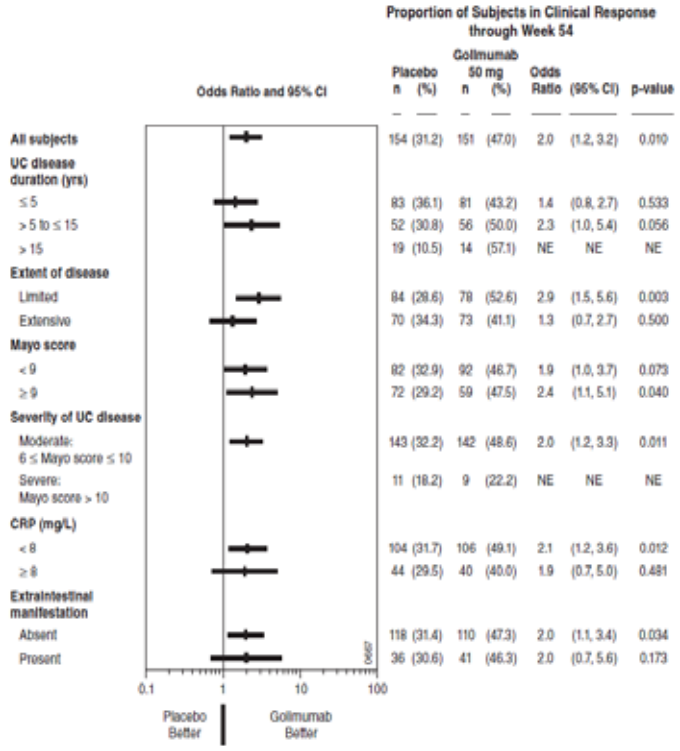


(B)

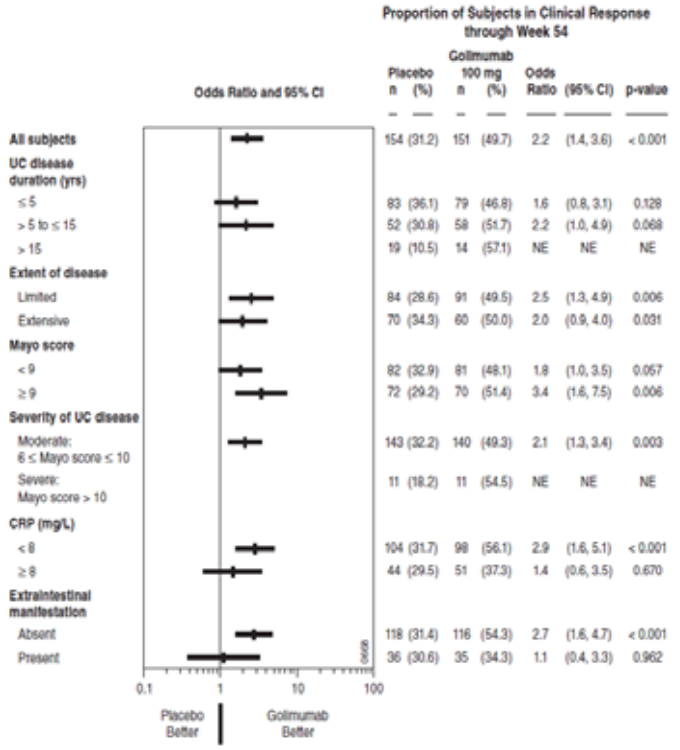
(A) 50 mg 群及びプラセボ群，(B) 100 mg 群及びプラセボ群

Source: Attachment 3.5 and 3.6 of T18 in Re-analysis report for C0524T17 and C0524T18 54-Week

図 2.7.3-付録-5 54 週までに clinical response が得られた被験者の割合
（導入期 0 週の人口統計学的特性別，T18 試験）



(A)

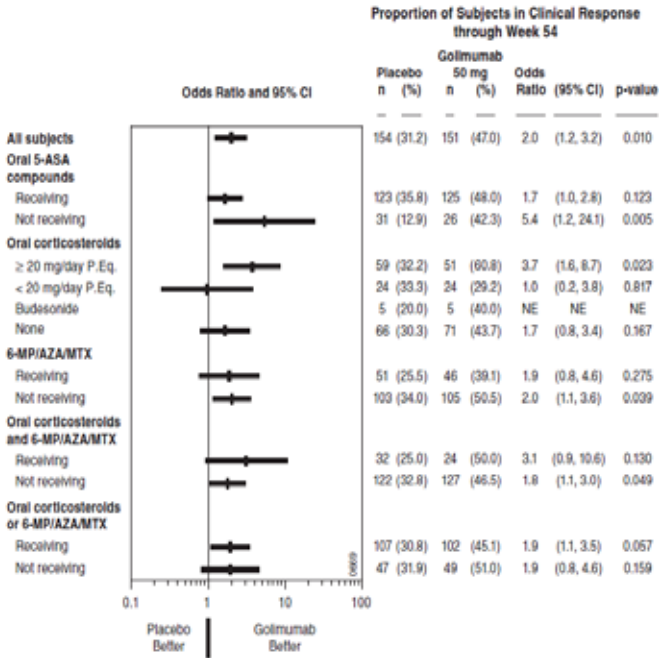


(B)

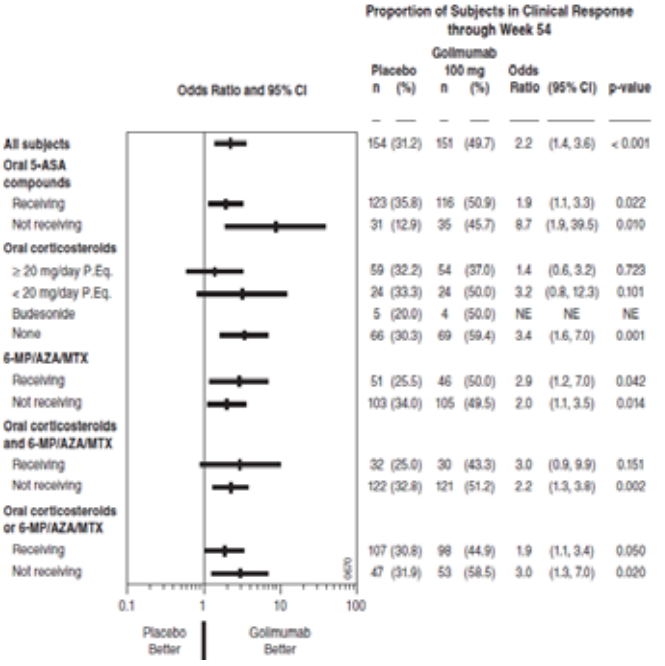
(A) 50 mg 群及びプラセボ群，(B) 100 mg 群及びプラセボ群

Source: Attachment 3.7 and 3.8 of T18 in Re-analysis report for C0524T17 and C0524T18 54-Week

図 2.7.3-付録-6 54 週までに clinical response が得られた被験者の割合
（導入期 0 週の疾患特性別，T18 試験）



(A)

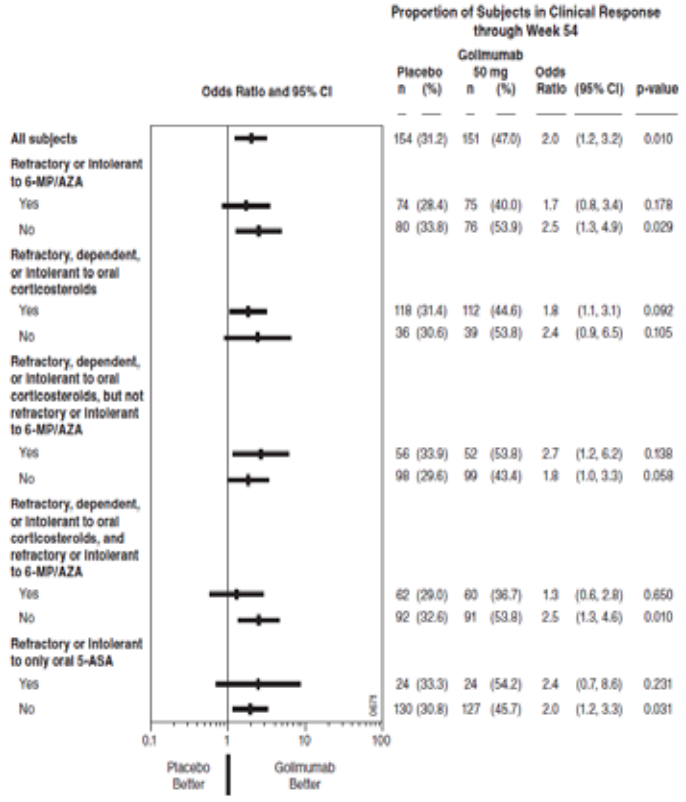


(B)

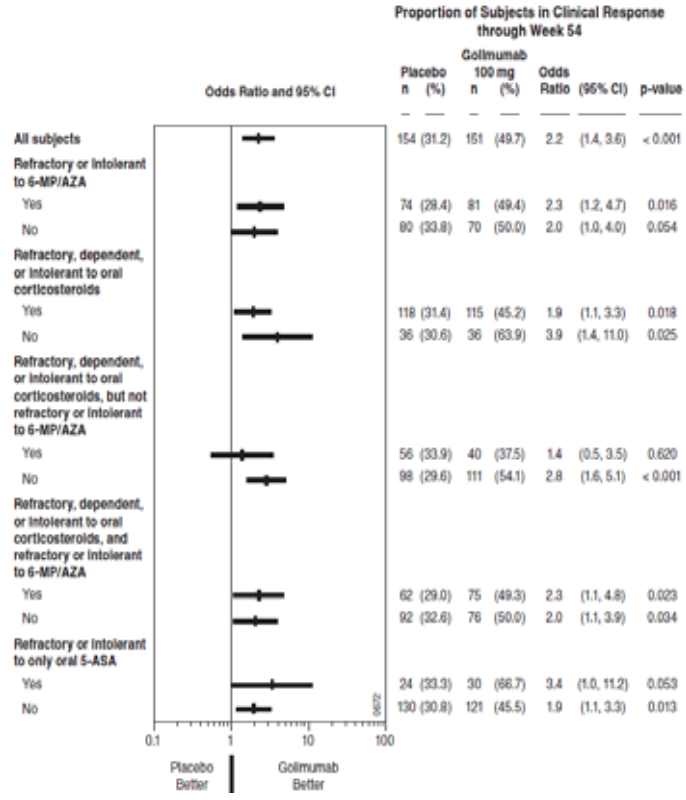
(A) 50 mg 群及びプラセボ群，(B) 100 mg 群及びプラセボ群

Source: Attachment 3.9 and 3.10 of T18 in Re-analysis report for C0524T17 and C0524T18 54-Week

図 2.7.3-付録-7 54 週までに clinical response が得られた被験者の割合
（導入期 0 週の併用した UC 治療薬別，T18 試験）



(A)

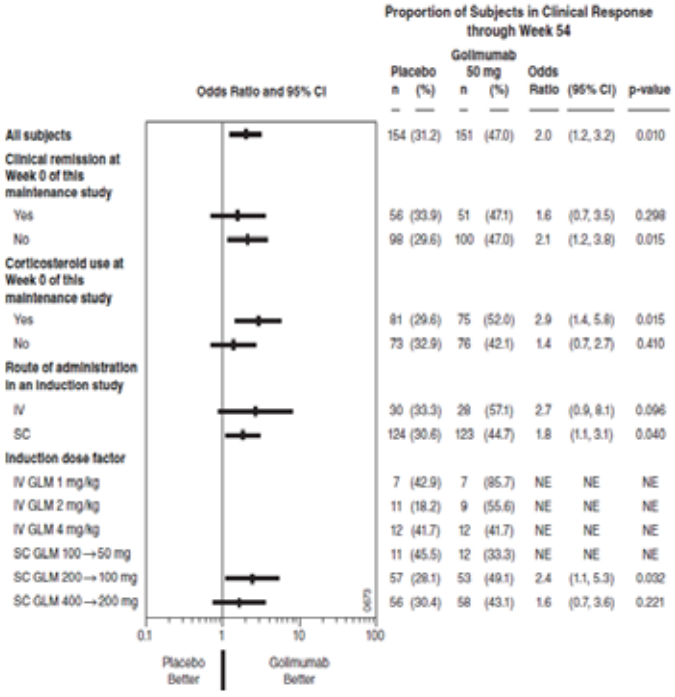


(B)

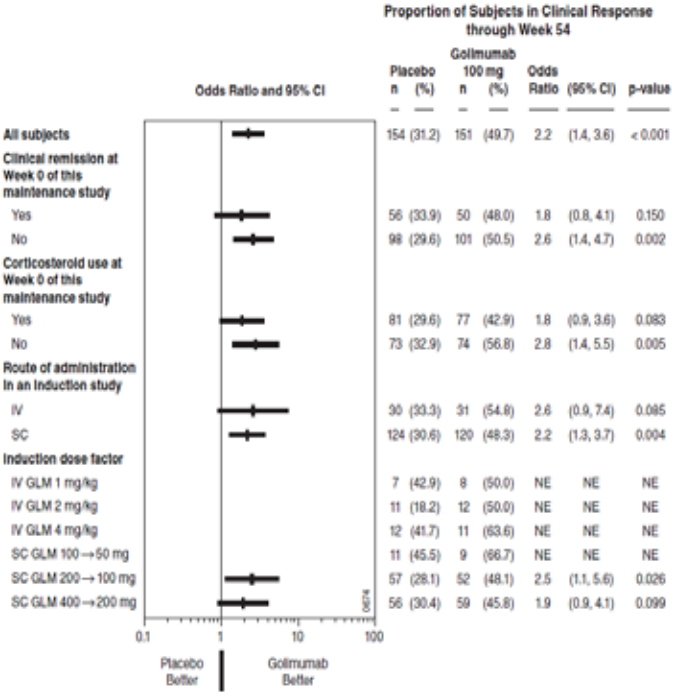
(A) 50 mg 群及びプラセボ群，(B) 100 mg 群及びプラセボ群

Source: Attachment 3.11 and 3.1.2 of T18 in Re-analysis report for C0524T17 and C0524T18 54-Week

図 2.7.3-付録-8 54 週までに clinical response が得られた被験者の割合
（導入期 0 週の UC 前治療に対する反応性別，T18 試験）



(A)



(B)

(A) 50 mg 群及びプラセボ群，(B) 100 mg 群及びプラセボ群

Source: Attachment 3.13 and 3.14 of T18 in Re-analysis report for C0524T17 and C0524T18 54-Week

図 2.7.3-付録-9 54 週までに clinical response が得られた被験者の割合

（維持期 0 週の clinical remission の有無別，コルチコステロイド併用の有無別，導入期の投与経路別，投与量別，T18 試験）

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略号一覧表

略号又は略称	名称及び内容
5-ASA	5-aminosalicylate（5-アミノサリチル酸）
6-MP	6-mercaptopurine（6-メルカプトプリン）
ANA	antinuclear antibody（抗核抗体）
AZA	azathioprine（アザチオプリン）
CSR	clinical study report（治験総括報告書）
dsDNA	double-stranded DNA（二本鎖 DNA）
PBRER/PSUR	Periodic Benefit Risk Evaluation Report/ Periodic Safety Update Report
PT	preferred term（基本語）
SEER	Surveillance, Epidemiology, and End Results （サーベイランス・疫学・転帰）
SOC	system organ class（器官別大分類）
UC	ulcerative colitis（潰瘍性大腸炎）

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 安全性評価に用いた臨床試験

ゴリムマブの潰瘍性大腸炎（UC）に対する安全性の評価に用いた臨床試験を表 2.7.4.1-1 に示す。2.7.4 には，国際共同試験 3 試験［C0524T16，C0524T17 及び C0524T18 試験（T16，T17 及び T18 試験）］並びに国内臨床試験［CNTO148UCO3001 試験（UCO3001 試験）］の結果を提示した。日本人及び白人の健康被験者を対象とした第 I 相試験［CNTO148NAP1001 試験（NAP1001 試験）］の結果の概要は【2.7.6.1】項に記載した。

表 2.7.4.1-1 安全性評価に用いた臨床試験一覧

試験番号 開発の相 評価／参考資料番号	試験デザイン	対象	投与方法 投与量・解析対象被験者数	試験期間
T16 第 II/III 相 参考資料 【5.3.5.1.1】	国際共同 ランダム化 二重盲検 プラセボ対照	外国人 UC 患者	寛解導入療法：単回静脈内投与 ・ プラセボ 77 例 ・ 1 mg/kg 63 例 ・ 2 mg/kg 74 例 ・ 4 mg/kg 76 例	6 週間 T18 試験に参加しない被験者は治験薬最終投与後 16 週まで
T17 第 II/III 相 評価資料 【5.3.5.1.2】 【5.3.5.1.4】	国際共同 ランダム化 二重盲検 プラセボ対照	外国人／ 日本人 UC 患者	寛解導入療法：0 及び 2 週に皮下投与 ・ プラセボ→プラセボ 330 例 ・ 100→50 mg 71 例 ・ 200→100 mg 331 例 ・ 400→200 mg 332 例	6 週間 T18 試験に参加しない被験者は治験薬最終投与後 16 週まで
T18 第 III 相 評価資料 【5.3.5.1.3-1】 【5.3.5.1.3-2】 【5.3.5.1.4】	国際共同 ランダム化 二重盲検 プラセボ対照	外国人／ 日本人 UC 患者	寛解維持療法：4 週に 1 回に皮下投与 ランダム化された被験者[*1]（ゴリムマブ寛解導入 responder） ・ プラセボ 156 例 ・ 50 mg 154 例 ・ 100 mg 154 例 ランダム化されなかった被験者[*2] ・ プラセボ（プラセボ寛解導入 responder）129 例 ・ 100 mg（プラセボ寛解導入 nonresponder） 230 例 ・ 100 mg（ゴリムマブ寛解導入 nonresponder） 405 例	維持期： 54 週間 継続投与期： 54 週から 228 週まで

試験番号 開発の相 評価／参考 資料番号	試験デザイン	対象	投与方法 投与量・解析対象被験者数	試験期間
UCO3001 第 III 相 評価資料 【5.3.5.1.5】	多施設共同 ランダム化 二重盲検 プラセボ対照	日本人 UC 患者	寛解導入期（非盲検）：0 及び 2 週に皮下投与 ・　200→100 mg　144 例	6 週間
			寛解維持期（二重盲検）：最長 52 週まで 4 週に 1 回皮下投与 ランダム化された被験者*3（ゴリムマブ寛解導入 responder） ・　プラセボ　31 例 ・　100 mg　32 例 ランダム化されなかった被験者*4（ゴリムマブ寛解導入 nonresponder） ・　ゴリムマブ 100 mg　60 例	68 週間
NAP 第 I 相 評価資料 【5.3.3.3.1】	単施設 ランダム化 二重盲検 プラセボ対照	白人／ 日本人 健康成人	単回皮下投与 ・　プラセボ　8 例 ・　200 mg　21 例 ・　400 mg　20 例	投与後 77 日間

*1：T16 又は T17 試験のゴリムマブ群で 6 週に clinical response が認められた被験者（ゴリムマブ寛解導入 responder）。投与量調節前の被験者数。
*2：T16 又は T17 試験のプラセボ群で 6 週に clinical response が認められた被験者（プラセボ寛解導入 responder），及びゴリムマブ群及びプラセボ群で 6 週に clinical response が認められなかった被験者（ゴリムマブ寛解導入 nonresponder 及びプラセボ寛解導入 nonresponder）。投与量調節前の被験者数。
*3：UCO3001 試験の導入期 6 週に clinical response が認められた被験者（ゴリムマブ寛解導入 responder）。投与量調節前の被験者数。
*4： UCO3001 試験の導入期 6 週に clinical response が認められなかった被験者（ゴリムマブ寛解導入 nonresponder）。投与量調節前の被験者数。

ゴリムマブの既知の安全性プロファイルと比較するため，UC 患者を対象とした試験に加え，他疾患（関節リウマチ，関節症性乾癬，軸性脊椎関節炎，non-radiographic 軸性脊椎関節炎）を対象とした海外臨床試験との統合データを適宜用いた。試験間及び投与群間の観察期間の違いを調整するため，観察期間 100 人年あたりの有害事象の発現率を比較した。

なお，重大な逸脱が認められた施設（施設番号 6706，7257 及び 7407）の被験者を除外した集団と除外しない集団との間で，安全性プロファイルに大きな違いがないことを確認している【5.3.5.1.4】。2.7.4 には，当該 3 施設の被験者を含めた結果を記述した。

2.7.4.1.2　総括的安全性評価計画及び安全性試験の記述

2.7.4.1.2.1　主な試験の概観

T16 試験，T17 試験，T18 試験及び UCO3001 試験の概観を【2.7.3.1.1】に記載した。

2.7.4.1.2.2　安全性評価計画

ゴリムマブの安全性は，有害事象，臨床検査値，抗核抗体（ANA），抗 double-stranded DNA（dsDNA）抗体，抗ゴリムマブ抗体及び注射部位反応に基づき評価した。

T18 及び UCO3001 試験の維持期 54 週までの結果は，以下のランダム化された被験者及び全投与被験者（ランダム化された被験者及びランダム化されなかった被験者）に分けて示した。

ランダム化された被験者

プラセボ群：

・ 寛解導入ゴリムマブ群で導入期 6 週に clinical response が認められた被験者（ゴリムマブ寛解導入 responder）のうち，維持期 0 週にプラセボ群に割り付けられた被験者のデータ（投与量調節によりゴリムマブを投与された場合，ゴリムマブ投与前までのデータ）

50 mg 群（T18 試験のみ）：

・ ゴリムマブ寛解導入 responder のうち，維持期 0 週にゴリムマブ 50 mg 群に割り付けられた被験者のデータ（投与量調節によりゴリムマブ 100 mg を投与された場合，投与量調節前までのデータ）

100 mg 群：

・ ゴリムマブ寛解導入 responder のうち，維持期 0 週にゴリムマブ 100 mg 群に割り付けられた被験者のデータ（投与量調節によりゴリムマブ 200 mg を投与された場合，投与量調節前までのデータ）

全投与被験者

プラセボ群：

・ ゴリムマブ寛解導入 responder のうち，維持期 0 週にプラセボ群に割り付けられた被験者のデータ（投与量調節によりゴリムマブを投与された場合，ゴリムマブ投与前までのデータ）

・ プラセボ寛解導入 responder で，維持期に引き続きプラセボを投与された被験者のデータ

50 mg 群（T18 試験のみ）：

・ ゴリムマブ寛解導入 responder のうち，維持期 0 週にゴリムマブ 50 mg 群に割り付けられた被験者のデータ（投与量調節によりゴリムマブ 100 mg を投与された場合，投与量調節前までのデータ）

100 mg 群：

・ ゴリムマブ寛解導入 responder のうち，維持期 0 週にゴリムマブ 100 mg 群に割り付けられた被験者のデータ（投与量調節によりゴリムマブ 200 mg を投与された場合，投与量調節前までのデータ）

・ 寛解導入ゴリムマブ群及び寛解導入プラセボ群で，導入期 6 週に clinical response が認められなかった被験者（ゴリムマブ寛解導入 nonresponder 及びプラセボ寛解導入 nonresponder）であり，維持期にゴリムマブ 100 mg を投与された被験者のデータ

・ ゴリムマブ寛解導入 responder であり，維持期 0 週にプラセボ又はゴリムマブ 50 mg 群に割り付けられ，投与量調節によりゴリムマブ 100 mg を投与された被験者のデータ（投与量調節前のデータは含まない）

200 mg 群（T18 試験のみ）：

・ ゴリムマブ寛解導入 responder であり，維持期 0 週にゴリムマブ 100 mg 群に割り付けられ，投与量調節によりゴリムマブ 200 mg を投与された被験者のデータ（投与量調節前のデータは含まない。200 mg から 100 mg へ減量後のデータを含む）

個々の試験結果に加え，導入期から維持期のデータを統合し，ゴリムマブの安全性を評価した。

2.7.4.1.2.3 評価方法

(1) 有害事象

有害事象の重篤度，重症度及び治験薬との関連性は治験担当医師が判断した。有害事象の重症度は，軽度，中等度，高度の 3 段階で評価した。有害事象と治験薬との関連性は，「関連なし」，「多分なし」，「可能性小」，「可能性大」，「ほぼ確実」の 5 段階で評価し，これらのうち「可能性小」，「可能性大」，「ほぼ確実」又は関連性が不明の有害事象を，治験薬と関連性のある有害事象とした。また，感染症及び注射部位反応はゴリムマブの重要な有害事象であると考えられることから，各有害事象が感染症又は注射部位反応であるか否かを治験担当医師が判断し，症例報告書に記録した。

有害事象のコーディングには MedDRA を用いた。MedDRA の version は，T16 試験は 12.0，T17 試験は 13.0，T18 試験（54 週）並びに T16，T17 及び T18 試験統合は 14.0，T18 試験（228 週）は 17.1，UCO3001 試験は 18.1 を用いた。

(2) 臨床検査値

血液学的検査及び血液生化学検査を各試験で実施し，臨床検査値の顕著な異常の有無を評価した。顕著な臨床検査値の異常の判断基準を【表 2.7.4.7-付録-1】に示す。臨床的に問題となる臨床検査値の異常は有害事象として報告した。

また，血液学的検査は以下の基準により重症度を評価した。

・ グレード 0：中央検査機関の正常範囲下限値以上とした。

・ グレード 1～4：Common Terminology Criteria for Adverse Events (CTCAE) v3.0 を用いた。

(3) その他の評価項目

血清中抗ゴリムマブ抗体を測定し，注射部位反応との関連を評価した。

2.7.4.1.2.4 解析方法

治験薬を少なくとも 1 回投与された被験者を安全性の解析対象とした。

有害事象の集計では，有害事象を発現した被験者数及び発現割合を各器官別大分類（SOC）及び基本語（PT）ごとに集計した。

器官別又は症候群別の有害事象の解析では，治験担当医師により感染症と判断された有害事象，重要な感染症（敗血症，肺炎，結核，日和見感染，蜂巣炎），注射部位反応，脱髄疾患，うっ血

性心不全，過敏症反応，血清病様反応及びアナフィラキシー反応，肝胆道系の有害事象，悪性腫瘍について評価した。

臨床検査値は，顕著な異常の判断基準を用いて，各検査項目で異常値が認められた被験者の割合を集計した。

なお，有害事象を発現した被験者数は，有害事象発現時の投与量に基づき集計したため，一人の被験者が複数の投与群に含まれる場合がある。

2.7.4.1.3 全般的な曝露状況

2.7.4.1.3.1 国際共同試験

(1) T16 試験

T16 試験では 290 例（プラセボ群 77 例，全ゴリムマブ群 213 例）に治験薬を単回静脈内投与した。本試験では Part 1 データの解析の結果，2 mg/kg 及び 4 mg/kg の投与量が選択されたため，1 mg/kg 群は他群より少なかった。全ゴリムマブ群の内訳を以下に示す。

- 1 mg/kg 群：63 例
- 2 mg/kg 群：74 例
- 4 mg/kg 群：76 例

(2) T17 試験

T17 試験では 1064 例（プラセボ群 330 例，全ゴリムマブ群 734 例）に治験薬を皮下投与した。Part 2 の投与量として 200→100 mg 及び 400→200 mg が選択されたため，100→50 mg 群は他群より少なかった。全ゴリムマブ群の内訳を以下に示す。

- 100→50 mg 群：71 例
- 200→100 mg 群：331 例
- 400→200 mg 群：332 例

(3) T18 試験

1) T18 試験（54 週まで）

T18 試験では 1228 例に治験薬を皮下投与した。このうち 0 週にランダム化された被験者は 464 例，ランダム化されなかった被験者は 764 例であった。

ランダム化された被験者の各群の被験者数，平均投与回数及び平均観察期間を以下に示す。

- プラセボ群：156 例，8.2 回，32.7 週
- 50 mg 群：154 例，11.1 回，44.3 週
- 100 mg 群：154 例，11.3 回，46.3 週

全投与被験者の各群の被験者数，平均投与回数及び平均観察期間を以下に示す。投与量調節により投与量を変更した被験者は，変更前後の投与群に集計した。

- プラセボ群：285 例，8.5 回，34.4 週
- 50 mg 群：154 例，11.1 回，44.3 週

・ 100 mg 群：946 例，9.2 回，39.7 週

・ 200 mg 群：14 例，6.9 回，27.5 週

2) T18 試験（54 週から 228 週まで，全投与被験者）

T18 試験（54 週から 228 週まで）では 666 例に治験薬を投与した。全投与被験者の各群の被験者数，平均投与回数及び平均観察期間を以下に示す。投与量調節により投与量を変更した被験者は，変更前後の投与群に集計した。

・ プラセボ群：96 例，12.4 回，57.1 週

・ 50 mg 群：94 例，30.6 回，134.1 週

・ 100 mg 群：524 例，30.3 回，134.8 週

(4) T16，T17 及び T18 試験（54 週まで，全投与被験者）

T16，T17 及び T18 試験（54 週まで）にゴリムマブを投与した被験者数は 1233 例であった。寛解導入ゴリムマブ群の，T18 試験の投与群別の被験者数，平均投与回数（T16 試験の静脈内投与を除く）及び平均観察期間を以下に示す。投与量調節により投与量を変更した被験者は，変更前後の投与群に集計した。

・ プラセボ群：157 例，9.8 回，39.0 週

・ 50 mg 群：154 例，12.7 回，50.4 週

・ 100 mg 群：660 例，10.5 回，45.1 週

2.7.4.1.3.2 日本人集団

(1) T17 試験の日本人部分集団

T17 試験にて治験薬を投与した日本人被験者数を以下に示す。

・ プラセボ群：30 例

・ 200→100 mg 群：23 例

・ 400→200 mg 群：19 例

(2) T18 試験の日本人部分集団（全投与被験者）

T18 試験（54 週まで）にて治験薬を投与した日本人被験者数，平均投与回数及び平均観察期間を以下に示す。投与量調節により投与量を変更した被験者は，変更前後の投与群に集計した。

・ プラセボ群：8 例，6.3 回，26.5 週

・ 50 mg 群：3 例，3.7 回，18.5 週

・ 100 mg 群：59 例，9.5 回，42.3 週

(3) T17 及び T18 試験（54 週まで）の日本人部分集団（全投与被験者）

T17 及び T18 試験（54 週まで）にてゴリムマブを投与した日本人被験者数は 68 例であった（平均投与回数：9.9 回）。プラセボのみを投与した被験者数は 30 例であった（平均投与回数：2.9 回）。

(4) UCO3001 試験

UCO3001 試験の寛解導入期では 144 例にゴリムマブを投与した。このうち 123 例が寛解維持期に移行した。

寛解維持期では，ランダム化された被験者は 63 例，ランダム化されなかった被験者は 60 例であった。ランダム化された被験者の各群の被験者数，平均投与回数及び平均観察期間を以下に示す。

・ プラセボ群：31 例，6.4 回，24.2 週

・ 100 mg 群：32 例，12.6 回，49.0 週

寛解維持期の全投与被験者の各群の被験者数，平均投与回数及び平均観察期間を以下に示す。投与量調節により投与量を変更した被験者は，変更前後の投与群に集計した。

・ プラセボ群：31 例，6.4 回，24.2 週

・ 100 mg 群：111 例，7.9 回，30.6 週

導入期 0 週から維持期 54 週までにゴリムマブを投与した全投与被験者数は 144 例であった（平均投与回数：10.5 回）。

2.7.4.1.4 治験対象集団の人口統計学的特性及びその他の特性

2.7.4.1.4.1 国際共同試験

(1) T16 及び T17 試験（寛解導入試験）

T16 試験と T17 試験では，ランダム化された被験者のベースライン時の主な人口統計学的特性，疾患特性及び UC 治療薬併用はおおむね一致していた（表 2.7.4.1-2）。被験者の多くは男性（約 60%），白人（約 80%）であり，年齢（中央値）は約 40 歳であった。被験者の罹病期間（中央値）は約 4 年，Mayo スコア（中央値）は 8.0 であった。被験者の 90%以上が UC 治療薬を投与されていた。いずれの試験も，人口統計学的特性，疾患特性及び UC 治療薬併用は群間でおおむね一致していた。（T16 試験：【5.3.5.1.1】Table 2，Table 3，Table 4；T17 試験：【5.3.5.1.2】Table 4，Table 5，Table 6）。

表 2.7.4.1-2 ベースライン時の主な人口統計学的特性，疾患特性及び UC 治療薬併用（T16 及び T17 試験，ランダム化された被験者）

	C0524T16	C0524T17
Randomized subjects	291	1065
Demographic characteristics		
Sex		
Male	59.8%	56.0%
Female	40.2%	44.0%
Race		
Caucasian	82.1%	82.1%
Black	1.4%	2.5%
Asian	15.1%	11.8%
Other	1.4%	3.6%
Age (years)		
Median	40.0	38.0
Weight (kg)		
Median	70.0	72.00
Subjects receiving concomitant UC therapies	94.2%	93.0%
Corticosteroids (excluding budesonide)	53.3%	42.8%
≥ 20 mg/day P.Eq	36.1%	26.4%
Immunomodulatory drugs	31.3%	32.4%
6-MP/AZA	30.2%	31.2%
MTX	1.0%	1.2%
5-ASA	81.8%	81.9%
Subjects with inadequate response, intolerance, or dependence on conventional UC therapy	99.3%	99.8%
Refractory to, dependent on, or intolerant of corticosteroids	79.4%	71.9%
Refractory to or intolerant of 6-MP/AZA	52.6%	52.0%
Refractory to or intolerant of 5-ASAs	94.6%	94.7%
UC disease duration (years)		
Median	4.57	4.22
Extent of disease		
Limited to left side of colon	55.3%	57.8%
Extensive	44.7%	42.2%

Extracted from:'RE310: [P_DEM_1_B], 29OCT2009 17:22', 'RE311: [P_DEM_1_D_DD], 08DEC2010 16:36', RE311:[P_IBD_12_D_DD], 08DEC2010 16:37; RE310:[P_IBD_12_B], 29OCT2009 17:22; RE310:[P_MEDS_5_A], 29OCT2009 17:23; RE311:[P_MEDS_5_D_DD], 08DEC2010 16:44; RE311:[P_MEDS_146_C_DD], 08DEC2010 16:46; RE599:[P_MEDS_146_A], 19APR2012 14:25

(2) T18 試験

ランダム化された被験者及び全投与被験者の，ベースライン時の主な人口統計学的特性，疾患特性及び UC 治療薬併用を表 2.7.4.1-3 に示す。本集計は T16 及び T17 試験の 0 週のデータに基づいている。ランダム化された被験者と全投与被験者で，主な人口統計学的特性，疾患特性及び UC 治療薬併用はおおむね一致していた。

表 2.7.4.1-3 ベースライン時の主な人口統計学的特性，疾患特性及び UC 治療薬併用（T18 試験，ランダム化された被験者及び全投与被験者）

	Randomized Subjects	Treated Subjects
Subjects who participated in C0524T18	464	1228
Demographic characteristics		
Sex		
Male	51.9%	57.0%
Female	48.1%	43.0%
Race		
Caucasian	87.3%	82.4%
Black	1.7%	2.0%
Asian	8.2%	12.3%
Other	2.8%	3.3%
Age (years)		
Median	39.0	39.0
Weight (kg)		
Median	71.95	72.00
Subjects receiving concomitant UC therapies	93.8%	93.4%
Corticosteroids (excluding budesonide)	51.5%	45.8%
≥ 20 mg/day P.Eq	35.8%	29.2%
Immunomodulatory drugs	31.7%	32.1%
6-MP/AZA	31.0%	30.8%
MTX	0.6%	1.3%
5-ASA	80.2%	82.2%
Subjects with inadequate response, intolerance, or dependence on conventional UC therapy	100%	99.8%
Refractory to, dependent on, or intolerant of corticosteroids	75.4%	73.5%
Refractory to or intolerant of 6-MP/AZA	50.4%	51.7%
Refractory to or intolerant of 5-ASAs	94.5%	94.8%
UC disease duration (years)		
Median	4.55	4.32
Extent of disease		
Limited to left side of colon	55.8%	57.5%
Extensive	44.2%	42.5%

Extracted from: RE309:[P_DEM_49_A_CC], 29NOV2011 17:35 RE309:[P_MEDS_146_B_CC], 28MAR2012 10:45 RE309:[P_IBD_16_A_CC], 23NOV2011 10:42 RE309:[P MEDS 176 A CC], 23NOV2011 10:45

2.7.4.1.4.2　日本人集団

(1) T16，T17 及び T18 試験の日本人部分集団（全投与被験者）

T16，T17 及び T18 試験に参加した日本人及び外国人のベースライン時の主な人口統計学的特性，疾患特性及び併用 UC 治療薬を【表 2.7.4.7-付録-2】，【表 2.7.4.7-付録-3】及び【表 2.7.4.7-付録-4】に示す。日本人は 72 例，外国人は 1284 例であった。人口統計学的特性のうち体重（中央値）は日本人 58.00 kg，外国人 72.20 kg であり，外国人に比べ日本人で低かった。その他の特性は日本人と外国人でおおむね一致していた。

(2) UCO3001 試験

UCO3001 試験に参加した被験者の寛解導入期 0 週の主な人口統計学的特性，疾患特性及び UC 治療薬併用を，それぞれ【5.3.5.1.5】Attachment TSIDEM01IN，Attachment TSIDEM02IN 及び Attachment TSICM01IN に示す。被験者の多くは男性（68.1%）で，年齢（中央値）は 42.0 歳，体重（中央値）は 60.75 kg であった。被験者の罹病期間（中央値）は 5.08 年，Mayo スコア（中央値）は 8.0 であった。被験者の 97.9%が UC 治療薬を投与されていた。

UCO3001 試験の維持期 0 週にランダム化された被験者の，寛解導入期 0 週の主な人口統計学的特性，疾患特性及び UC 治療薬併用を，それぞれ【5.3.5.1.5】Table 2，Attachment TSIDEM02DB 及び Table 3 に示す。被験者の多くは男性（60.3%）で，年齢（中央値）は 40.0 歳，体重（中央値）は 60.70 kg であった。被験者の罹病期間（中央値）は 5.66 年，Mayo スコア（中央値）は 8.0 であった。被験者の 98.4%が UC 治療薬を投与されていた。プラセボ群とゴリムマブ群で，人口統計学的特性，疾患特性及び UC 治療薬併用はおおむね一致していた。

UCO3001 試験の被験者と T17 及び T18 試験に参加した日本人で，人口統計学的特性，疾患特性及び UC 治療薬併用はおおむね一致していた。

2.7.4.2 有害事象

各試験で得られた安全性に関する結果の詳細は，それぞれの治験総括報告書に示した［T16 試験【5.3.5.1.1】，T17 試験【5.3.5.1.2】，T18 試験（54 週まで）【5.3.5.1.3-1】，T18 試験（54 週から 228 週まで）【5.3.5.1.3-2】，UCO3001 試験【5.3.5.1.5】］。重大な逸脱が認められた 3 施設（施設番号 6706，7257 及び 7407）の被験者を除いて集計した T17 及び T18 試験（54 週まで）の結果は【5.3.5.1.4】に示した。

また，各試験の安全性の概要は個々の試験のまとめに示した［T16 試験【2.7.6.2】，T17 試験【2.7.6.3】，T18 試験（54 週まで）【2.7.6.4-1】，T18 試験（54 週から 228 週まで）【2.7.6.4-2】，UCO3001 試験【2.7.6.5】］。

2.7.4.2.1 有害事象の解析

有害事象の解析では，T16 及び T17 試験は 6 週まで，T18 試験は 54 週まで及び 228 週まで，UCO3001 試験は導入期 6 週まで及び維持期 54 週までのデータを主に示した。

T17 試験は，Part 2 で選択された 200→100 mg 群及び 400→200 mg 群のデータを主に示した。T18 試験は，治験実施計画書 3 版発行以降はゴリムマブ 200 mg への増量を中止したため，50 mg 群及び 100 mg 群のデータを主に示した。

2.7.4.2.1.1 比較的よく見られる有害事象

(1) 有害事象

1) 国際共同試験

a) T16 試験

T16 試験（6 週まで）の有害事象の発現割合は，プラセボ群 31.2%（24/77 例），全ゴリムマブ群 36.6%（78/213 例）であった（【2.7.6.2】表 2.7.6.2-3，【5.3.5.1.1】Table 11）。

全ゴリムマブ群で最も発現割合が高い SOC は「胃腸障害」であった［プラセボ群 6.5%（5/77 例）及び全ゴリムマブ群 11.3%（24/213 例）］。

全ゴリムマブ群で最も発現割合が高い有害事象は，潰瘍性大腸炎［プラセボ群 2.6%（2/77 例）及び全ゴリムマブ群 3.8%（8/213 例）］，咳嗽［0.0%（0/77 例）及び 2.8%（6/213 例）］及び頭痛［1.3%（1/77 例）及び 2.8%（6/213 例）］であった。

b) T17 試験

T17 試験（6 週まで）の有害事象の発現割合は，プラセボ群 38.2%（126/330 例），200→100 mg 群 37.5%（124/331 例），400→200 mg 群 38.9%（129/332 例）であった（【2.7.6.3】表 2.7.6.3-5，【5.3.5.1.2】Table 13）。

全ゴリムマブ群で最も発現割合が高い SOC は「感染症および寄生虫症」［プラセボ群 10.9%（36/330 例），200→100 mg 群 12.1%（40/331 例）及び 400→200 mg 群 12.3%（41/332 例）］，次いで「胃腸障害」［12.4%（41/330 例），7.9%（26/331 例）及び 13.3%（44/332 例）］であった。

全ゴリムマブ群で最も発現割合が高い有害事象は，頭痛［プラセボ群 5.2%（17/330 例），200→100 mg 群 3.0%（10/331 例）及び 400→200 mg 群 4.5%（15/332 例）］，次いで鼻咽頭炎［3.3%（11/330 例），3.3%（11/331 例）及び 2.4%（8/332 例）］，発熱［2.1%（7/330 例），1.8%（6/331 例）及び 3.0%（10/332 例）］であった。

c) T18 試験

① T18 試験（54 週まで，ランダム化された被験者）

T18 試験（54 週まで）のランダム化された被験者の有害事象発現割合は，プラセボ群 66.0%（103/156 例），50 mg 群 72.7%（112/154 例）及び 100 mg 群 73.4%（113/154 例）であった（【2.7.6.4-1】表 2.7.6.4-3，【5.3.5.1.3-1】Table 7）。100 人年あたりの有害事象の発現率は，それぞれ 211.22，187.16 及び 172.68 であった（【5.3.5.1.3-1】Attachment 4.2）。

全ゴリムマブ群で最も発現割合が高い SOC は「胃腸障害」［プラセボ群 32.1%（50/156 例），50 mg 群 32.5%（50/154 例）及び 100 mg 群 37.0%（57/154 例）］，及び「感染症および寄生虫症」［25.6%（40/156 例），37.0%（57/154 例）及び 39.6%（61/154 例）］であった。

全ゴリムマブ群で最も発現割合が高い有害事象は，潰瘍性大腸炎［プラセボ群 18.6%（29/156 例），50 mg 群 17.5%（27/154 例）及び 100 mg 群 15.6%（24/154 例）］，次いで鼻咽頭炎［7.1%（11/156 例），9.1%（14/154 例）及び 13.6%（21/154 例）］，頭痛［9.0%（14/156 例），7.8%（12/154 例）及び 7.8%（12/154 例）］であった。

② T18 試験（54 週まで，全投与被験者）

T18 試験（54 週まで）の全投与被験者の有害事象発現割合は，プラセボ群 63.9%（182/285 例），50 mg 群 72.7%（112/154 例）及び 100 mg 群 73.9%（699/946 例）であった（【2.7.6.4-1】表 2.7.6.4-4，【5.3.5.1.3-1】Attachment 4.7）。

全ゴリムマブ群で最も発現割合が高い有害事象は，ランダム化された被験者と同様に，潰瘍性大腸炎，次いで鼻咽頭炎，頭痛であった。

③ T18 試験（54 週から 228 週まで，全投与被験者）

T18 試験（54 週から 228 週まで）の有害事象発現割合は，プラセボ群 54.2%（52/96 例），50 mg 群 76.6%（72/94 例）及び 100 mg 群 79.4%（416/524 例）であった（【2.7.6.4-2】表 2.7.6.4-9，【5.3.5.1.3-2】Table 9）。100 人年あたりの有害事象の発現率（95%CI）は，それぞれ 187.71

（162.47，215.76），187.68（170.83，205.74）及び 211.45（203.78，219.32）であった（【5.3.5.1.3-2】Table 8）。

全ゴリムマブ群で最も発現割合が高い SOC は「感染症および寄生虫症」［プラセボ群 29.2%（28/96 例），50 mg 群 46.8%（44/94 例）及び 100 mg 群 56.1%（294/524 例）］，次いで「胃腸障害」［32.3%（31/96 例），42.6%（40/94 例）及び 49.4%（259/524 例）］であった。

全ゴリムマブ群で最も発現割合が高い有害事象は，潰瘍性大腸炎［プラセボ群 20.8%（20/96 例），50 mg 群 19.1%（18/524 例）及び 100 mg 群 26.9%（141/524 例）］，次いで鼻咽頭炎［5.2%（5/96 例），11.7%（11/94 例）及び 16.0%（84/524 例）］であった。

d) T16，T17 及び T18 試験統合

① T16，T17 及び T18 試験（54 週まで，ランダム化された被験者）

T16，T17 及び T18 試験（54 週まで）のランダム化された被験者の有害事象発現割合は，T18 試験の投与群別に，プラセボ群 73.7%（115/156 例），50 mg 群 77.9%（120/154 例）及び 100 mg 群 79.2%（122/154 例）であった【表 2.7.4.7-付録-5】。

全ゴリムマブ群で最も発現割合が高い SOC は「感染症および寄生虫症」［プラセボ群 32.7%（51/156 例），50 mg 群 40.9%（63/154 例）及び 100 mg 群 43.5%（67/154 例）］であり，次いで「胃腸障害」［35.3%（55/156 例），35.7%（55/154 例）及び 42.2%（65/154 例）］であった。

全ゴリムマブ群で最も発現割合が高い有害事象は，潰瘍性大腸炎［プラセボ群 18.6%（29/156 例），50 mg 群 17.5%（27/154 例）及び 100 mg 群 15.6%（24/154 例）］であった。

② T16，T17 及び T18 試験（54 週まで，全投与被験者）

T16，T17 及び T18 試験（54 週まで）の全投与被験者の有害事象発現割合は，T18 試験の投与群別に，プラセボ群 73.2%（115/157 例），50 mg 群 77.9%（120/154 例）及び 100 mg 群 78.6%（519/660 例）であった【表 2.7.4.7-付録-6】。全ゴリムマブ群で発現割合 5%以上の有害事象を表 2.7.4.2-1 に示す。

全ゴリムマブ群で最も発現割合が高い SOC は「胃腸障害」［プラセボ群 35.0%（55/157 例），50 mg 群 35.7%（55/154 例）及び 100 mg 群 43.0%（284/660 例）］であり，次いで「感染症および寄生虫症」［32.5%（51/157 例），40.9%（63/154 例）及び 38.8%（256/660 例）］であった。

全ゴリムマブ群で最も発現割合が高い有害事象は，潰瘍性大腸炎［プラセボ群 18.5%（29/157 例），50 mg 群 17.5%（27/154 例）及び 100 mg 群 19.8%（131/660 例）］，次いで鼻咽頭炎［8.3%（13/157 例），10.4%（16/154 例）及び 11.8%（78/660 例）］であった。

③ T16，T17 及び T18 試験（228 週まで，全投与被験者）

T16，T17 及び T18 試験（228 週まで）の，全投与被験者の 100 人年あたりの有害事象発現率（95%CI）は，プラセボ群 362.41（334.98，391.49），50 mg 群 263.37（247.58，279.90）及び 100 mg 群 286.74（278.23，295.43）であった【表 2.7.4.7-付録-7】。

表 2.7.4.2-1 全ゴリムマブ群で発現割合 5%以上の有害事象（T16，T17 及び T18 試験 54 週まで；全投与被験者）

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
Treated subjects in C0524T16 and C0524T17	49	358	286	77	157	154	660	14	1233
Avg duration of follow-up (weeks)	12.3	19.1	39.2	11.9	39.0	50.4	45.1	27.5	45.6
Avg exposure (number of administrations)	1.6	5.0	9.2	1.6	10.0	12.9	10.7	6.9	11.0
Subjects with 1 or more adverse events	30 (61.2%)	164 (45.8%)	212 (74.1%)	50 (64.9%)	115 (73.2%)	120 (77.9%)	519 (78.6%)	9 (64.3%)	964 (78.2%)
System-organ class/preferred term									
胃腸障害	19 (38.8%)	63 (17.6%)	96 (33.6%)	29 (37.7%)	55 (35.0%)	55 (35.7%)	284 (43.0%)	4 (28.6%)	500 (40.6%)
潰瘍性大腸炎	14 (28.6%)	21 (5.9%)	47 (16.4%)	22 (28.6%)	29 (18.5%)	27 (17.5%)	131 (19.8%)	1 (7.1%)	251 (20.4%)
腹痛	2 (4.1%)	8 (2.2%)	9 (3.1%)	3 (3.9%)	5 (3.2%)	12 (7.8%)	41 (6.2%)	0 (0.0%)	69 (5.6%)
感染症および寄生虫症	11 (22.4%)	59 (16.5%)	108 (37.8%)	22 (28.6%)	51 (32.5%)	63 (40.9%)	256 (38.8%)	5 (35.7%)	490 (39.7%)
鼻咽頭炎	2 (4.1%)	15 (4.2%)	22 (7.7%)	4 (5.2%)	13 (8.3%)	16 (10.4%)	78 (11.8%)	3 (21.4%)	132 (10.7%)
上気道感染	0 (0.0%)	12 (3.4%)	20 (7.0%)	1 (1.3%)	6 (3.8%)	8 (5.2%)	44 (6.7%)	1 (7.1%)	77 (6.2%)
一般・全身障害および投与部位の状態	5 (10.2%)	32 (8.9%)	42 (14.7%)	14 (18.2%)	22 (14.0%)	26 (16.9%)	115 (17.4%)	4 (28.6%)	219 (17.8%)
発熱	3 (6.1%)	5 (1.4%)	10 (3.5%)	7 (9.1%)	9 (5.7%)	10 (6.5%)	30 (4.5%)	0 (0.0%)	65 (5.3%)
皮膚および皮下組織障害	7 (14.3%)	33 (9.2%)	41 (14.3%)	4 (5.2%)	28 (17.8%)	25 (16.2%)	113 (17.1%)	3 (21.4%)	210 (17.0%)
筋骨格系および結合組織障害	5 (10.2%)	29 (8.1%)	41 (14.3%)	2 (2.6%)	30 (19.1%)	27 (17.5%)	105 (15.9%)	3 (21.4%)	203 (16.5%)
関節痛	1 (2.0%)	14 (3.9%)	14 (4.9%)	0 (0.0%)	14 (8.9%)	12 (7.8%)	52 (7.9%)	1 (7.1%)	90 (7.3%)
神経系障害	4 (8.2%)	36 (10.1%)	34 (11.9%)	5 (6.5%)	29 (18.5%)	18 (11.7%)	93 (14.1%)	1 (7.1%)	178 (14.4%)
頭痛	2 (4.1%)	21 (5.9%)	26 (9.1%)	4 (5.2%)	17 (10.8%)	14 (9.1%)	68 (10.3%)	1 (7.1%)	128 (10.4%)

表 2.7.4.2-1 全ゴリムマブ群で発現割合 5%以上の有害事象（T16，T17 及び T18 試験 54 週まで；全投与被験者）（続き）

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
呼吸器、胸郭および縦隔障害	4 (8.2%)	23 (6.4%)	33 (11.5%)	4 (5.2%)	12 (7.6%)	22 (14.3%)	79 (12.0%)	2 (14.3%)	151 (12.2%)
咳嗽	1 (2.0%)	14 (3.9%)	14 (4.9%)	0 (0.0%)	5 (3.2%)	7 (4.5%)	38 (5.8%)	0 (0.0%)	64 (5.2%)
血液およびリンパ系障害	8 (16.3%)	14 (3.9%)	21 (7.3%)	9 (11.7%)	12 (7.6%)	14 (9.1%)	71 (10.8%)	0 (0.0%)	127 (10.3%)
貧血	6 (12.2%)	6 (1.7%)	12 (4.2%)	5 (6.5%)	2 (1.3%)	4 (2.6%)	39 (5.9%)	0 (0.0%)	62 (5.0%)
臨床検査	5 (10.2%)	22 (6.1%)	20 (7.0%)	3 (3.9%)	13 (8.3%)	20 (13.0%)	53 (8.0%)	1 (7.1%)	107 (8.7%)
傷害、中毒および処置合併症	2 (4.1%)	8 (2.2%)	12 (4.2%)	1 (1.3%)	9 (5.7%)	7 (4.5%)	43 (6.5%)	1 (7.1%)	73 (5.9%)
精神障害	0 (0.0%)	13 (3.6%)	11 (3.8%)	1 (1.3%)	6 (3.8%)	7 (4.5%)	36 (5.5%)	1 (7.1%)	62 (5.0%)

[a] Includes data up to the time of the first golimumab dose in the maintenance study.
[b] Includes data from the time of dose adjustment onward for those who increased to the indicated dose during the maintenance study.
[c] Includes data up to the time of dose adjustment for those who increased dose from the indicated dose during the maintenance study.
[d] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[e] Includes data from the time of the first golimumab dose onward.

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2) 日本人集団

a) T17 試験の日本人部分集団

T17 試験（6 週まで）の日本人の有害事象発現割合は，プラセボ群 60.0%（18/30 例）及び全ゴリムマブ群 45.2%（19/42 例）であった【表 2.7.4.7-付録-8】，【表 2.7.4.7-付録-9】。

全ゴリムマブ群で最も発現割合が高い SOC は「感染症および寄生虫症」［プラセボ群 23.3%（7/30 例），200→100 mg 群 26.1%（6/23 例）及び 400→200 mg 群 21.1%（4/19 例）］，次いで「胃腸障害」［10.0%（3/30 例），4.3%（1/23 例）及び 10.5%（2/19 例）］並びに「神経系障害」［6.7%（2/30 例），8.7%（2/23 例）及び 5.3%（1/19 例）］であった。

全ゴリムマブ群で最も発現割合が高い有害事象は，鼻咽頭炎［プラセボ群 10.0%（3/30 例），200→100 mg 群 8.7%（2/23 例）及び 400→200 mg 群 5.3%（1/19 例）］，次いで潰瘍性大腸炎［3.3%（1/30 例），0%（0/23 例）及び 5.3%（1/19 例）］並びに発熱［6.7%（2/30 例），4.3%（1/23 例）及び 5.3%（1/19 例）］であった。

b) T18 試験の日本人部分集団（全投与被験者）

T18 試験（54 週まで）の日本人の有害事象発現割合は，プラセボ群 62.5%（5/8 例）及び全ゴリムマブ群 86.7%（52/60 例）であった【表 2.7.4.7-付録-10】，【表 2.7.4.7-付録-11】。

全ゴリムマブ群で最も発現割合が高い SOC は「感染症および寄生虫症」［プラセボ群 25.0%（2/8 例）及び全ゴリムマブ群 53.3%（32/60 例）］，次いで「胃腸障害」［12.5%（1/8 例）及び 38.3%（23/60 例）］であった。

全ゴリムマブ群で最も発現割合が高い有害事象は，鼻咽頭炎［プラセボ群 12.5%（1/8 例）及び全ゴリムマブ群 33.3%（20/60 例）］，次いで発熱［0%（0/8 例）及び 11.7%（7/60 例）］であった。

T18 試験に参加した日本人被験者数は，ランダム化された被験者が 12 例，全投与被験者が 62 例と少なく，全被験者数に対する割合はそれぞれ 2.6%（12/464 例），5.0%（62/1228 例）であった。このため T18 試験（54 週から 228 週まで）では，日本人部分集団の安全性解析は行わなかった。

c) T16，T17 及び T18 試験（54 週まで）の日本人部分集団（全投与被験者）

T16，T17 及び T18 試験（54 週まで）の，日本人及び外国人の有害事象の発現割合は，日本人ではプラセボ群 66.7%（20/30 例）及び全ゴリムマブ群 88.2%（60/68 例），外国人ではプラセボ群 46.2%（174/377 例）及び全ゴリムマブ群 77.6%（904/1165 例）であり，いずれの投与群でも日本人での発現割合が高かった【表 2.7.4.7-付録-12】，【表 2.7.4.7-付録-13】。日本人又は外国人の全ゴリムマブ群で発現割合 2%以上の有害事象を表 2.7.4.2-2 に示す。

日本人の全ゴリムマブ群で最も発現割合が高い有害事象は鼻咽頭炎で 36.8%（25/68 例）であったのに対し，外国人の全ゴリムマブ群では 9.2%（107/1165 例）であった。次いで発現割合が高い有害事象は，潰瘍性大腸炎［日本人の全ゴリムマブ群 13.2%（9/68 例）及び外国人の全ゴリムマブ群 20.8%（242/1165 例）］並びに頭痛［13.2%（9/68 例）及び 10.2%（119/1165 例）］であった。外国人と比較して日本人の全ゴリムマブ群で発現割合の差が 10 ポイント以上高かった有害事象は，鼻咽頭炎のみであった。

表 2.7.4.2-2 日本人又は外国人の全ゴリムマブ群で発現割合 2%以上の有害事象（T16，T17 及び T18 試験 54 週まで；日本人 vs 外国人；全投与被験者）

	Japanese		Non-Japanese		Total	
	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]
Treated subjects in C0524T16 and C0524T17	30	68	377	1165	407	1233
Avg duration of follow-up (weeks)	11.5	43.6	18.8	45.7	18.3	45.6
Avg exposure (number of administrations)	2.9	9.9	4.7	11.0	4.6	11.0
Subjects with 1 or more adverse events	20 (66.7%)	60 (88.2%)	174 (46.2%)	904 (77.6%)	194 (47.7%)	964 (78.2%)
System-organ class/preferred term						
胃腸障害	6 (20.0%)	26 (38.2%)	76 (20.2%)	474 (40.7%)	82 (20.1%)	500 (40.6%)
潰瘍性大腸炎	2 (6.7%)	9 (13.2%)	33 (8.8%)	242 (20.8%)	35 (8.6%)	251 (20.4%)
腹痛	1 (3.3%)	2 (2.9%)	9 (2.4%)	67 (5.8%)	10 (2.5%)	69 (5.6%)
悪心	1 (3.3%)	4 (5.9%)	13 (3.4%)	51 (4.4%)	14 (3.4%)	55 (4.5%)
下痢	1 (3.3%)	1 (1.5%)	5 (1.3%)	36 (3.1%)	6 (1.5%)	37 (3.0%)
嘔吐	0 (0.0%)	0 (0.0%)	5 (1.3%)	27 (2.3%)	5 (1.2%)	27 (2.2%)
痔核	1 (3.3%)	1 (1.5%)	4 (1.1%)	24 (2.1%)	5 (1.2%)	25 (2.0%)
腹部膨満	0 (0.0%)	3 (4.4%)	1 (0.3%)	9 (0.8%)	1 (0.2%)	12 (1.0%)
胃食道逆流性疾患	0 (0.0%)	2 (2.9%)	1 (0.3%)	9 (0.8%)	1 (0.2%)	11 (0.9%)
腹部不快感	0 (0.0%)	2 (2.9%)	4 (1.1%)	6 (0.5%)	4 (1.0%)	8 (0.6%)
口内炎	0 (0.0%)	5 (7.4%)	1 (0.3%)	3 (0.3%)	1 (0.2%)	8 (0.6%)
感染症および寄生虫症	7 (23.3%)	41 (60.3%)	63 (16.7%)	449 (38.5%)	70 (17.2%)	490 (39.7%)
鼻咽頭炎	3 (10.0%)	25 (36.8%)	14 (3.7%)	107 (9.2%)	17 (4.2%)	132 (10.7%)
上気道感染	1 (3.3%)	4 (5.9%)	11 (2.9%)	73 (6.3%)	12 (2.9%)	77 (6.2%)
咽頭炎	0 (0.0%)	1 (1.5%)	0 (0.0%)	40 (3.4%)	0 (0.0%)	41 (3.3%)
副鼻腔炎	0 (0.0%)	1 (1.5%)	5 (1.3%)	36 (3.1%)	5 (1.2%)	37 (3.0%)
インフルエンザ	0 (0.0%)	4 (5.9%)	8 (2.1%)	30 (2.6%)	8 (2.0%)	34 (2.8%)
気管支炎	1 (3.3%)	0 (0.0%)	4 (1.1%)	29 (2.5%)	5 (1.2%)	29 (2.4%)
口腔ヘルペス	0 (0.0%)	2 (2.9%)	1 (0.3%)	19 (1.6%)	1 (0.2%)	21 (1.7%)
尿路感染	0 (0.0%)	2 (2.9%)	4 (1.1%)	16 (1.4%)	4 (1.0%)	18 (1.5%)

表 2.7.4.2-2 日本人又は外国人の全ゴリムマブ群で発現割合 2%以上の有害事象（T16，T17 及び T18 試験 54 週まで；日本人 vs 外国人；全投与被験者）

（続き）

	Japanese		Non-Japanese		Total	
	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]
膀胱炎	0 (0.0%)	2 (2.9%)	0 (0.0%)	7 (0.6%)	0 (0.0%)	9 (0.7%)
毛包炎	0 (0.0%)	2 (2.9%)	1 (0.3%)	7 (0.6%)	1 (0.2%)	9 (0.7%)
サイトメガロウイルス感染	0 (0.0%)	3 (4.4%)	1 (0.3%)	1 (0.1%)	1 (0.2%)	4 (0.3%)
感染性腸炎	0 (0.0%)	3 (4.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.2%)
感染性小腸結腸炎	1 (3.3%)	2 (2.9%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	2 (0.2%)
一般・全身障害および投与部位の状態	4 (13.3%)	14 (20.6%)	33 (8.8%)	205 (17.6%)	37 (9.1%)	219 (17.8%)
発熱	2 (6.7%)	8 (11.8%)	6 (1.6%)	57 (4.9%)	8 (2.0%)	65 (5.3%)
疲労	0 (0.0%)	1 (1.5%)	7 (1.9%)	38 (3.3%)	7 (1.7%)	39 (3.2%)
皮膚および皮下組織障害	5 (16.7%)	20 (29.4%)	35 (9.3%)	190 (16.3%)	40 (9.8%)	210 (17.0%)
発疹	1 (3.3%)	6 (8.8%)	6 (1.6%)	43 (3.7%)	7 (1.7%)	49 (4.0%)
そう痒症	0 (0.0%)	2 (2.9%)	5 (1.3%)	26 (2.2%)	5 (1.2%)	28 (2.3%)
脱毛症	0 (0.0%)	2 (2.9%)	2 (0.5%)	12 (1.0%)	2 (0.5%)	14 (1.1%)
湿疹	1 (3.3%)	5 (7.4%)	3 (0.8%)	7 (0.6%)	4 (1.0%)	12 (1.0%)
接触性皮膚炎	0 (0.0%)	3 (4.4%)	1 (0.3%)	4 (0.3%)	1 (0.2%)	7 (0.6%)
脂漏性皮膚炎	0 (0.0%)	2 (2.9%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	5 (0.4%)
筋骨格系および結合組織障害	2 (6.7%)	7 (10.3%)	32 (8.5%)	196 (16.8%)	34 (8.4%)	203 (16.5%)
関節痛	1 (3.3%)	2 (2.9%)	14 (3.7%)	88 (7.6%)	15 (3.7%)	90 (7.3%)
背部痛	0 (0.0%)	3 (4.4%)	7 (1.9%)	34 (2.9%)	7 (1.7%)	37 (3.0%)
筋骨格系胸痛	0 (0.0%)	2 (2.9%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	5 (0.4%)
神経系障害	3 (10.0%)	13 (19.1%)	37 (9.8%)	165 (14.2%)	40 (9.8%)	178 (14.4%)
頭痛	2 (6.7%)	9 (13.2%)	21 (5.6%)	119 (10.2%)	23 (5.7%)	128 (10.4%)
浮動性めまい	0 (0.0%)	2 (2.9%)	2 (0.5%)	22 (1.9%)	2 (0.5%)	24 (1.9%)
感覚鈍麻	0 (0.0%)	2 (2.9%)	0 (0.0%)	6 (0.5%)	0 (0.0%)	8 (0.6%)
呼吸器、胸郭および縦隔障害	4 (13.3%)	15 (22.1%)	23 (6.1%)	136 (11.7%)	27 (6.6%)	151 (12.2%)
咳嗽	1 (3.3%)	4 (5.9%)	14 (3.7%)	60 (5.2%)	15 (3.7%)	64 (5.2%)
口腔咽頭痛	2 (6.7%)	4 (5.9%)	3 (0.8%)	26 (2.2%)	5 (1.2%)	30 (2.4%)

表 2.7.4.2-2 日本人又は外国人の全ゴリムマブ群で発現割合 2%以上の有害事象（T16，T17 及び T18 試験 54 週まで；日本人 vs 外国人；全投与被験者）

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	Japanese		Non-Japanese		Total	
	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]
上気道の炎症	2 (6.7%)	3 (4.4%)	0 (0.0%)	1 (0.1%)	2 (0.5%)	4 (0.3%)
血液およびリンパ系障害	2 (6.7%)	7 (10.3%)	20 (5.3%)	120 (10.3%)	22 (5.4%)	127 (10.3%)
貧血	0 (0.0%)	2 (2.9%)	12 (3.2%)	60 (5.2%)	12 (2.9%)	62 (5.0%)
白血球減少症	1 (3.3%)	3 (4.4%)	2 (0.5%)	20 (1.7%)	3 (0.7%)	23 (1.9%)
鉄欠乏性貧血	1 (3.3%)	2 (2.9%)	0 (0.0%)	3 (0.3%)	1 (0.2%)	5 (0.4%)
臨床検査	2 (6.7%)	5 (7.4%)	25 (6.6%)	102 (8.8%)	27 (6.6%)	107 (8.7%)
白血球数減少	0 (0.0%)	2 (2.9%)	1 (0.3%)	4 (0.3%)	1 (0.2%)	6 (0.5%)
傷害、中毒および処置合併症	1 (3.3%)	8 (11.8%)	9 (2.4%)	65 (5.6%)	10 (2.5%)	73 (5.9%)
挫傷	1 (3.3%)	3 (4.4%)	4 (1.1%)	11 (0.9%)	5 (1.2%)	14 (1.1%)
精神障害	1 (3.3%)	4 (5.9%)	12 (3.2%)	58 (5.0%)	13 (3.2%)	62 (5.0%)
不眠症	1 (3.3%)	4 (5.9%)	5 (1.3%)	22 (1.9%)	6 (1.5%)	26 (2.1%)
血管障害	2 (6.7%)	2 (2.9%)	8 (2.1%)	50 (4.3%)	10 (2.5%)	52 (4.2%)
高血圧	1 (3.3%)	0 (0.0%)	3 (0.8%)	30 (2.6%)	4 (1.0%)	30 (2.4%)
代謝および栄養障害	2 (6.7%)	3 (4.4%)	11 (2.9%)	44 (3.8%)	13 (3.2%)	47 (3.8%)
眼障害	2 (6.7%)	7 (10.3%)	4 (1.1%)	36 (3.1%)	6 (1.5%)	43 (3.5%)
白内障	0 (0.0%)	2 (2.9%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	5 (0.4%)
アレルギー性結膜炎	0 (0.0%)	2 (2.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
腎および尿路障害	0 (0.0%)	1 (1.5%)	6 (1.6%)	34 (2.9%)	6 (1.5%)	35 (2.8%)
生殖系および乳房障害	0 (0.0%)	2 (2.9%)	4 (1.1%)	29 (2.5%)	4 (1.0%)	31 (2.5%)
乳房痛	0 (0.0%)	2 (2.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
耳および迷路障害	0 (0.0%)	0 (0.0%)	3 (0.8%)	25 (2.1%)	3 (0.7%)	25 (2.0%)
肝胆道系障害	0 (0.0%)	2 (2.9%)	1 (0.3%)	12 (1.0%)	1 (0.2%)	14 (1.1%)

[a] Includes data up to the time of the first golimumab dose.
[b] Includes data from the time of the first golimumab dose onward.

d) UCO3001 試験

① 寛解導入期

UCO3001 試験の寛解導入期の有害事象発現割合は 45.1%（65/144 例）であった（【5.3.5.1.5】Attachment TSFAE01IN）。

最も発現割合が高い SOC は「感染症および寄生虫症」16.0%（23/144 例），次いで「胃腸障害」11.8%（17/144 例）であった。

最も発現割合が高い有害事象は，鼻咽頭炎 11.8%（17/144 例），次いで潰瘍性大腸炎 6.3%（9/144 例）であった。

② 寛解維持期

(i) ランダム化された被験者

UCO3001 試験の寛解維持期では，ランダム化された被験者の有害事象発現割合はプラセボ群 71.0%（22/31 例）及び 100 mg 群 96.9%（31/32 例）であった（【5.3.5.1.5】Attachment TSFAE01DB）。

100 mg 群で最も発現割合が高い SOC は「感染症および寄生虫症」［プラセボ群 41.9%（13/31 例）及び 100 mg 群 62.5%（20/32 例）］，次いで「一般・全身障害および投与部位の状態」［6.5%（2/31 例）及び 25.0%（8/32 例）］であった。

100 mg 群で最も発現割合が高い有害事象は，鼻咽頭炎［プラセボ群 22.6%（7/31 例）及び 100 mg 群 53.1%（17/32 例）］，次いで注射部位紅斑［0%（0/31 例）及び 15.6%（5/32 例）］であった。

(ii) 全投与被験者

UCO3001 試験の寛解維持期では，全投与被験者の有害事象発現割合はプラセボ群 71.0%（22/31 例）及び 100 mg 群 85.6%（95/111 例）であった（【5.3.5.1.5】Attachment TSFAE01MA）。

100 mg 群で最も発現割合が高い SOC は「感染症および寄生虫症」［プラセボ群 41.9%（13/31 例）及び 100 mg 群 48.6%（54/111 例）］，次いで「胃腸障害」［16.1%（5/31 例）及び 24.3%（27/111 例）］であった。

100 mg 群で最も発現割合が高い有害事象は，鼻咽頭炎［プラセボ群 22.6%（7/31 例）及び 100 mg 群 32.4%（36/111 例）］，次いで注射部位紅斑［0%（0/31 例）及び 8.1%（9/111 例）］であった。

③ 導入期 0 週から維持期 54 週まで（全投与被験者）

UCO3001 試験の導入期 0 週から維持期 54 週まででは，全投与被験者の有害事象発現割合は 88.9%（128/144 例）であった【表 2.7.4.7-付録-14】。

最も発現割合が高い SOC は「感染症および寄生虫症」52.8%（76/144 例）であり，次いで「胃腸障害」31.3%（45/144 例）であった。

最も発現割合が高い有害事象は鼻咽頭炎 38.2%（55/144 例）であり，次いで潰瘍性大腸炎 13.2%（19/144 例）であった。

2.7.4.2.1.2 死亡

(1) 国際共同試験

1) T16 試験

T16 試験では死亡例の報告はなかった。

2) T17 試験

T17 試験では 1 例の死亡が報告された【表 2.7.4.7-付録-15】。死亡例（被験者 ID：7586-00015，男性 5[redacted]歳）は 400→200 mg 群の被験者であった。94 日目（治験薬の最後の投与から 79 日後）に死亡し，死因は坐骨直腸膿瘍であった。治験薬との関連性は「関連なし」と判断された。

3) T18 試験

a) T18 試験（54 週まで，全投与被験者）

T18 試験（54 週まで）に 3 例の死亡が報告された【表 2.7.4.7-付録-16】。T18 試験で 54 週までに報告された死亡について，以下に要約する。

- 被験者 ID：6407-00032（男性 6[redacted]歳）は，T17 試験では 400→200 mg 群に割り付けられ，T18 試験では 100 mg 群に割り付けられた。335 日目（治験薬の最後の投与から 82 日後）に死亡し，死因は心不全であった。血栓症の既往があったが，心疾患又は動脈性高血圧の既往はなかった。治験薬との関連性は「多分なし」と判断された。
- 被験者 ID：6260-00002（女性 6[redacted]歳）は，T16 試験で 2 mg/kg 群に割り付けられ，T18 試験では 100 mg が投与された。364 日目（治験薬の最後の投与から 26 日後）に死亡し，死因は栄養障害及び敗血症性ショックであった。敗血症の原因は不明であった。治験薬との関連性は「関連なし」と判断された。
- 被験者 ID：6407-00031（男性 5[redacted]歳）は，T17 試験で 200→100 mg 群に割り付けられ，T18 試験では 100 mg が投与された。206 日目（治験薬の最後の投与から 37 日後）に死亡し，死因は播種性結核であった。T17 試験参加時に QuantiFERON-TB Gold の結果が陽性であった。T18 試験中，イソニアジドによる治療を受けていた。治験薬との関連性は「ほぼ確実」と判断された。

b) T18 試験（54 週から 228 週まで，全投与被験者）

T18 試験（54 週から 228 週まで）では，9 例の死亡が報告された（【5.3.5.1.3-2】Attachment LSFAE02）。T18 試験で 54 週以降に報告された死亡について，以下に要約する。

- 被験者 ID：6402-00002（男性 3[redacted]歳）は，T16 試験で 2 mg/kg 群に割り付けられ，T18 試験では 100 mg が投与された。1159 日目に死亡し，死因は胆嚢癌であった。治験薬と死因との関連性は「多分なし」と判断された。
- 被験者 ID：7203-00002（男性 7[redacted]歳）は，T17 試験で 100→50 mg 群に割り付けられ，T18 試験では 50 mg が投与された。継続投与試験に組み入れられたが，継続投与試験期間中に治験薬を投与されることはなく，388 日目に死亡した。死因は心室機能不全であった。治験薬と死因との関連性は「関連なし」と判断された。

- 被験者 ID：6076-00002（女性 4[redacted] 歳）は，T16 試験で 2 mg/kg 群に割り付けられ，T18 試験では 100 mg が投与された。639 日目に死亡し，死因は敗血症であった。治験薬と死因との関連性は「可能性小」と判断された。
- 被験者 ID：7407-00010（男性 6[redacted] 歳）は，T17 試験及び T18 試験でプラセボが投与された。747 日目に死亡し，死因は心不全及び肺炎であった。治験薬と死因との関連性は「関連なし」と判断された。
- 被験者 ID：7205-00005（男性 4[redacted] 歳）は，T17 試験でプラセボ群に割り付けられ，T18 試験では 100 mg が投与された。1255 日目に死亡し，死因は転移性直腸癌であった。治験薬と死因との関連性は「可能性小」と判断された。
- 被験者 ID：7213-00008（男性 2[redacted] 歳）は，T17 試験で 400 mg→200mg 群に割り付けられ，T18 試験では 100 mg が投与された。1562 日目に死亡し，死因は転移性結腸腺癌であった。治験薬と死因との関連性は「関連なし」と判断された。
- 被験者 ID：7427-00003（男性 5[redacted] 歳）は，T17 試験でプラセボ群に割り付けられ，T18 試験では 100 mg が投与された。1111 日目に死亡し，死因は急性心筋梗塞であった。治験薬と死因との関連性は「多分なし」と判断された。
- 被験者 ID：7743-00013（男性 4[redacted] 歳）は，T17 試験で 200 mg→100 mg 群に割り付けられ，T18 試験ではプラセボ群に割り付けられた。その後，100 mg に投与量調節された。771 日目に死亡し，死因は亜酸化窒素の偶発的過量投与であった。治験薬と死因との関連性は「関連なし」と判断された。
- 被験者 ID：7753-00004（男性 5[redacted] 歳）は，T17 試験で 200 mg→100 mg 群に割り付けられ，T18 試験では 100 mg が投与された。1145 日目に死亡し，死因は待機的結腸切除術の合併症により生じた誤嚥であった。治験薬と死因との関連性は「関連なし」と判断された。

T18 試験（54 週から 228 週まで）の 100 人年あたりの死亡率（95%CI）は，プラセボ群 0.95（0.02，5.28）及び 100 mg 群 0.52（0.21，1.06）であり，プラセボ群と 100 mg 群でおおむね同様であった。50 mg 群で死亡例は報告されなかった（【5.3.5.1.3-2】Table 8）。

c) T18 試験（0 週から 228 週まで，全投与被験者）

T18 試験（0 週から 228 週まで）の 100 mg 群の 100 人年あたりの死亡率（95%CI）は 0.49（0.23，0.90）であり，他疾患を対象とした臨床試験との統合データ 50 mg 群 0.32（0.17，0.56）及び 100 mg 群 0.46（0.32，0.64）と大きな違いはなかった【表 2.7.4.7-付録-17】。

4) T16，T17 及び T18 試験（54 週まで，全投与被験者）

T16，T17 及び T18 試験（54 週まで）の死亡例は 4 例であり，このうち 3 例が T18 試験の 100 mg 群の被験者であった。この 100 mg 群の試験期間中のゴリムマブ総曝露量及び投与期間は，プラセボ群及び 50 mg 群に比べ，被験者間での差異が大きいため，死亡例とゴリムマブ投与量の関連を考察するのは困難であった。全ゴリムマブ群の 100 人年あたりの死亡率（95%CI）は 0.37（0.10，0.95）であった【表 2.7.4.7-付録-18】。

(2) 日本人集団

1) T17 及び T18 試験の日本人部分集団（全投与被験者）

T17 及び T18 試験に参加した日本人では死亡例の報告はなかった。

2) UCO3001 試験

UCO3001 試験では死亡例の報告はなかった。

2.7.4.2.1.3 その他の重篤な有害事象

(1) 国際共同試験

1) T16 試験

T16 試験（6 週まで）の重篤な有害事象の発現割合は，プラセボ群 2.6%（2/77 例）及び全ゴリムマブ群 3.8%（8/213 例）であり，両群で同程度であった（【表 2.7.4.7-付録-19】，【5.3.5.1.1】Table 12）。

2 例以上に発現した重篤な有害事象は潰瘍性大腸炎のみであり，ゴリムマブの投与を受けた 4 例（発現割合 1.9%）で発現し，プラセボ群では報告はなかった。

2) T17 試験

T17 試験（6 週まで）の重篤な有害事象の発現割合は，プラセボ群 6.1%（20/330 例），200→100 mg 群 2.7%（9/331 例）及び 400→200 mg 群 3.3%（11/332 例）であった（【2.7.6.3】表 2.7.6.3-8，【5.3.5.1.2】Attachment 4.11）。

各群で最も発現割合が高い重篤な有害事象は潰瘍性大腸炎であった［プラセボ群 2.4%（8/330 例），200→100 mg 群 0.9%（3/331 例）及び 400→200 mg 群 1.2%（4/332 例）］。潰瘍性大腸炎のほかにいずれかのゴリムマブ群で 2 例以上に発現した重篤な有害事象は貧血であり，各群の発現割合はプラセボ群 0.6%（2/330 例），200→100 mg 群 0.6%（2/331 例）及び 400→200 mg 群 0%（0/332 例）であった。

3) T18 試験

a) T18 試験（54 週まで，ランダム化された被験者）

T18 試験（54 週まで）では，ランダム化された被験者の重篤な有害事象の発現割合は，プラセボ群 7.7%（12/156 例），50 mg 群 8.4%（13/154 例）及び 100 mg 群 14.3%（22/154 例）であった（【2.7.6.4.1】表 2.7.6.4-7，【5.3.5.1.3-1】Attachment 4.14）。100 人年あたりの重篤な有害事象の発現率はそれぞれ 12.62，10.41 及び 17.09 であった（【5.3.5.1.3-1】Attachment 4.2）。

最も発現割合が高い重篤な有害事象は，いずれの群でも潰瘍性大腸炎であった［プラセボ群 1.9%（3/156 例），50 mg 群 1.9%（3/154 例）及び 100 mg 群 3.9%（6/154 例）］。潰瘍性大腸炎のほかに 2 例以上に発現した重篤な有害事象は，100 mg 群の虫垂炎［3 例（発現割合 1.9%）］であり，他群では報告はなかった。

b) T18 試験（54 週まで，全投与被験者）

T18 試験（54 週まで）では，全投与被験者の重篤な有害事象の発現割合は，プラセボ群 6.7%（19/285 例），50 mg 群 8.4%（13/154 例）及び 100 mg 群 14.7%（139/946 例）であり，発現傾向

はランダム化された被験者とおおむね同様であった（【表 2.7.4.7-付録-20】，【5.3.5.1.3-1】Attachment 4.17）。

最も発現割合が高い重篤な有害事象は，いずれの群でも潰瘍性大腸炎であった［プラセボ群 2.1%（6/285 例），50 mg 群 1.9%（3/154 例）及び 100 mg 群 7.9%（75/946 例）］。潰瘍性大腸炎のほかに 3 例以上に発現した重篤な有害事象は，100 mg 群で発現した虫垂炎［4 例（発現割合 0.4%）］及び不眠症［3 例（0.3%）］であり，他群では報告はなかった。

c) T18 試験（54 週から 228 週まで，全投与被験者）

T18 試験（54 週から 228 週まで）の重篤な有害事象の発現割合は，プラセボ群 8.3%（8/96 例），50 mg 群 11.7%（11/94 例）及び 100 mg 群 19.1%（100/524 例）であった（【5.3.5.1.3-2】Attachment TSFAE03）。100 人年あたりの発現率（95%CI）はそれぞれ 9.48（4.55，17.43），7.48（4.72，12.24）及び 10.23（8.60，12.08）であった（【5.3.5.1.3-2】Table 8）。

全ゴリムマブ群で最も発現割合が高い SOC は，「感染症および寄生虫症」［プラセボ群 1.0%（1/96 例），50 mg 群 4.3%（4/94 例）及び 100 mg 群 5.9%（31/524 例）］，次いで「胃腸障害」［1.0%（1/96 例），2.1%（2/94 例）及び 6.1%（32/524 例）］であった。

全ゴリムマブ群で最も発現割合が高い重篤な有害事象は，潰瘍性大腸炎［プラセボ群 1.0%（1/96 例），50 mg 群 2.1%（2/94 例）及び 100 mg 群 3.8%（20/524 例）］，次いで肺炎［1.0%（1/96 例），1.1%（1/94 例）及び 1.1%（6/524 例）］であった。

4) T16，T17 及び T18 試験統合

a) T16，T17 及び T18 試験（54 週まで，ランダム化された被験者）

T16，T17 及び T18 試験（54 週まで）では，ランダム化された被験者の重篤な有害事象の発現割合は，T18 試験の投与群別に，プラセボ群 8.3%（13/156 例），50 mg 群 8.4%（13/154 例）及び 100 mg 群 14.9%（23/154 例）であった【表 2.7.4.7-付録-21】。

最も発現割合が高い重篤な有害事象は，潰瘍性大腸炎［プラセボ群 1.9%（3/156 例），50 mg 群 1.9%（3/154 例）及び 100 mg 群 3.9%（6/154 例）］であった。

b) T16，T17 及び T18 試験（54 週まで，全投与被験者）

T16，T17 及び T18 試験（54 週まで）では，全投与被験者の重篤な有害事象の発現割合は，T18 試験の投与群別に，プラセボ群 8.3%（13/157 例），50 mg 群 8.4%（13/154 例）及び 100 mg 群 15.6%（103/660 例）であった【表 2.7.4.7-付録-22】。

全ゴリムマブ群で最も発現割合が高い SOC は，「胃腸障害」［プラセボ群 1.9%（3/157 例），50 mg 群 2.6%（4/154 例）及び 100 mg 群 10.2%（67/660 例）］，次いで「感染症および寄生虫症」［2.5%（4/157 例），3.2%（5/154 例）及び 2.6%（17/660 例）］であった。

全ゴリムマブ群で最も発現割合が高い重篤な有害事象は，潰瘍性大腸炎［プラセボ群 1.9%（3/157 例），50 mg 群 1.9%（3/154 例）及び 100 mg 群 8.6%（57/660 例）］，次いで貧血［0%（0/157 例），0%（0/154 例）及び 0.5%（3/660 例）］であった。

c) T16，T17 及び T18 試験（228 週まで，全投与被験者）

T16，T17 及び T18 試験（228 週まで）の全投与被験者の 100 人年あたりの重篤な有害事象発現率（95%CI）は，プラセボ群 15.73（10.45，22.74），50 mg 群 9.90（7.04，13.54）及び 100 mg 群 15.93（13.97，18.08）であった【表 2.7.4.7-付録-7】。

T16，T17 及び T18 試験統合で，新たな安全性シグナルは認められなかった。

(2) 日本人集団

1) T17 試験の日本人部分集団

T17 試験（6 週まで）の日本人の重篤な有害事象の発現割合は，プラセボ群 10.0%（3/30 例），200→100 mg 群 8.7%（2/23 例）及び 400→200 mg 群 5.3%（1/19 例）であった【表 2.7.4.7-付録-23】。

日本人の全ゴリムマブ群で発現した重篤な有害事象は，潰瘍性大腸炎 2 例，肺炎 1 例であった。

2) T18 試験の日本人部分集団（全投与被験者）

T18 試験（54 週まで）の日本人の重篤な有害事象の発現割合はプラセボ群 12.5%（1/8 例），全ゴリムマブ群 15.0%（9/60 例）であった【表 2.7.4.7-付録-24】。

日本人の全ゴリムマブ群で発現した重篤な有害事象は，潰瘍性大腸炎 6 例，結腸ポリープ，感染性小腸結腸炎及び直腸癌が各 1 例であった。

3) T16，T17 及び T18 試験（54 週まで）の日本人部分集団（全投与被験者）

T16，T17 及び T18 試験（54 週まで）の，日本人及び外国人被験者の重篤な有害事象の発現割合は，日本人ではプラセボ群 10.0%（3/30 例）及び全ゴリムマブ群 20.6%（14/68 例），外国人ではプラセボ群 7.2%（27/377 例）及び全ゴリムマブ群 15.6%（182/1165 例）であった【表 2.7.4.7-付録-25】。

4) UCO3001 試験

a) 寛解導入期

UCO3001 試験の寛解導入期の重篤な有害事象の発現割合は 3.5%（5/144 例）であった（【5.3.5.1.5】Attachment TSFSAE01IN）。

発現した重篤な有害事象は潰瘍性大腸炎 4 例（発現割合 2.8%）及びサイトメガロウイルス性大腸炎 1 例（0.7%，被験者 ID：812701）であった。

b) 寛解維持期

① ランダム化された被験者

UCO3001 試験の寛解維持期では，ランダム化された被験者の重篤な有害事象の発現割合は，プラセボ群 12.9%（4/31 例）及び 100 mg 群 3.1%（1/32 例）であった（【5.3.5.1.5】Table 18）。

プラセボ群で発現した重篤な有害事象は，潰瘍性大腸炎，手骨折，関節脱臼及び脳梗塞であった。100 mg 群で発現した重篤な有害事象は，高安動脈炎であった。

② 全投与被験者

UCO3001 試験の寛解維持期では，全投与被験者の重篤な有害事象の発現割合は，プラセボ群 12.9%（4/31 例）及び 100 mg 群 9.0%（10/111 例）であった（【5.3.5.1.5】Attachment TSFSAE01MA）。

100 mg 群で最も発現割合が高い重篤な有害事象は潰瘍性大腸炎［6.3%（7/111 例）］であった。

c) 導入期 0 週から維持期 54 週まで（全投与被験者）

UCO3001 試験の寛解導入期 0 週から維持期 54 週までの，全投与被験者の重篤な有害事象の発現割合は 13.2%（19/144 例）であった（【表 2.7.4.7-付録-26】，【2.7.6.5】表 2.7.6.5-9）。

最も発現割合が高い SOC は「胃腸障害」（8.3%）であり，次いで「感染症および寄生虫症」（3.5%）であった。

最も発現割合が高い重篤な有害事象は潰瘍性大腸炎 8.3%（12/144 例）であり，次いで帯状疱疹 1.4%（2/144 例）であった。

2.7.4.2.1.4 治験薬の投与中止に至った有害事象

(1) 国際共同試験

1) T16 試験

T16 試験は単回投与試験であるため，投与中止に至った有害事象は検討しなかった。

2) T17 試験

T17 試験（6 週まで）の投与中止に至った有害事象発現割合は，プラセボ群 0.9%（3/330 例），200→100 mg 群 0.3%（1/331 例）及び 400→200 mg 群 0.3%（1/332 例）であった。

いずれの群でも，治験薬の投与中止に至った有害事象のうち 2 例以上に発現した事象はなかった（【5.3.5.1.2】Attachment 4.13，Attachment 4.18）。

3) T18 試験

a) T18 試験（54 週まで，ランダム化された被験者）

T18 試験（54 週まで）のランダム化された被験者の投与中止に至った有害事象発現割合は，プラセボ群 6.4%（10/156 例），50 mg 群 5.2%（8/154 例）及び 100 mg 群 9.1%（14/154 例）であった（【5.3.5.1.3-1】Attachment 4.22）。100 人年あたりの発現率はそれぞれ 10.43，6.16 及び 10.44 であった（【5.3.5.1.3-1】Attachment 4.2）。

最も発現割合が高い投与中止に至った有害事象は，いずれの群でも潰瘍性大腸炎であった［プラセボ群 1.9%（3/156 例），50 mg 群 3.9%（6/154 例）及び 100 mg 群 4.5%（7/154 例）］。

b) T18 試験（54 週まで，全投与被験者）

T18 試験（54 週まで）の全投与被験者の投与中止に至った有害事象発現割合は，プラセボ群 5.6%（16/285 例），50 mg 群 5.2%（8/154 例）及び 100 mg 群 12.8%（121/946 例）であった（【5.3.5.1.3-1】Attachment 4.25，Attachment 4.26）。

最も発現割合が高い投与中止に至った有害事象は，いずれの群でも潰瘍性大腸炎であった［プラセボ群 1.8%（5/285 例），50 mg 群 3.9%（6/154 例）及び 100 mg 群 9.0%（85/946 例）］。

c) T18 試験（54 週から 228 週まで，全投与被験者）

T18 試験（54 週から 228 週まで）の投与中止に至った有害事象の発現割合は，プラセボ群 5.2%（5/96 例），50 mg 群 7.4%（7/94 例）及び 100 mg 群 12.0%（63/524 例）であった（【5.3.5.1.3-2】Attachment TSFAE05）。100 人年あたりの発現率（95%CI）はそれぞれ 6.64（2.67，13.67），2.89（1.16，5.95）及び 6.18（4.93，7.66）であった（【5.3.5.1.3-2】Table 8）。

最も発現割合が高い投与中止に至った有害事象は，いずれの群でも潰瘍性大腸炎で，プラセボ群 2.1%（2/96 例），50 mg 群 2.1%（2/94 例）及び 100 mg 群 2.9%（15/524 例）であった。

4) T16，T17 及び T18 試験統合

a) T16，T17 及び T18 試験（54 週まで，ランダム化された被験者）

T16 及び T17 試験で治験薬の投与を中止した被験者は T18 試験に組み入れられなかった。このため，T16，T17 及び T18 試験（54 週まで）のランダム化された被験者の投与中止に至った有害事象の発現割合は，T18 試験（54 週まで）と同じである。

b) T16，T17 及び T18 試験（54 週まで，全投与被験者）

T16，T17 及び T18 試験（54 週まで）の，全投与被験者の投与中止に至った有害事象発現割合は，T18 試験の投与群別に，プラセボ群 6.4%（10/157 例），50 mg 群 5.2%（8/154 例）及び 100 mg 群 12.3%（81/660 例）であった【表 2.7.4.7-付録-27】。

最も発現割合が高い投与中止に至った有害事象は，いずれの群でも潰瘍性大腸炎であった［プラセボ群 1.9%（3/157 例），50 mg 群 3.9%（6/154 例）及び 100 mg 群 9.2%（61/660 例）］。

c) T16，T17 及び T18 試験（228 週まで，全投与被験者）

T16，T17 及び T18 試験（228 週まで）の，全投与被験者の 100 人年あたりの投与中止に至った有害事象発現率（95%CI）は，プラセボ群 7.87（4.30，13.20），50 mg 群 4.57（2.71，7.22）及び 100 mg 群 10.66（9.08，12.45）であった【表 2.7.4.7-付録-7】。

(2) 日本人集団

1) T17 試験の日本人部分集団

T17 試験（6 週まで）に日本人の投与中止に至った有害事象の報告はなかった【表 2.7.4.7-付録-28】。

2) T18 試験の日本人部分集団（全投与被験者）

T18 試験（54 週まで）の日本人の投与中止に至った有害事象発現割合は，プラセボ群 12.5%（1/8 例）及び全ゴリムマブ群 10.0%（6/60 例）であった【表 2.7.4.7-付録-29】。

日本人の全ゴリムマブ群で最も発現割合が高い治験薬の投与中止に至った有害事象は，潰瘍性大腸炎であった［プラセボ群 0%（0/8 例），全ゴリムマブ群 6.7%（4/60 例）］。

3) UCO3001 試験

a) 寛解導入期

UCO3001 試験の寛解導入期の投与中止に至った有害事象の発現割合は 6.9%（10/144 例）であった（【5.3.5.1.5】Attachment TSFAEDS01IN）。

最も発現割合が高い投与中止に至った有害事象は，潰瘍性大腸炎 5.6%（8/144 例），次いで貧血及びサイトメガロウイルス性大腸炎が各 0.7%（1/144 例）であった。

b) 寛解維持期

① ランダム化された被験者

UCO3001 試験の寛解維持期のランダム化された被験者で発現した投与中止に至った有害事象は，プラセボ群で発現した脳梗塞 1 例のみであった（【5.3.5.1.5】Attachment TSFAEDS01DB）。

② 全投与被験者

UCO3001 試験の寛解導入期の全投与被験者で発現した投与中止に至った有害事象は，ランダム化された被験者で発現した事象のほかに，ランダム化されなかった被験者で発現した潰瘍性大腸炎 2 例であった（【5.3.5.1.5】Attachment TSFAEDS01MA）。

c) 導入期 0 週から維持期 54 週まで（全投与被験者）

UCO3001 試験の寛解導入期 0 週から維持期 54 週までの，全投与被験者の投与中止に至った有害事象の発現割合は 9.0%（13/144 例）であった【表 2.7.4.7-付録-30】。

最も発現割合が高い投与中止に至った有害事象は潰瘍性大腸炎 6.9%（10/144 例）であった。潰瘍性大腸炎のほかに発現した投与中止に至った有害事象は，貧血，サイトメガロウイルス性大腸炎及び脳梗塞が各 0.7%（1/144 例）であった。

2.7.4.2.1.5 器官別又は症候群別有害事象の解析

(1) 感染症

感染症はゴリムマブの重要な有害事象であると考えられることから，各有害事象が感染症であるか否かを治験担当医師が判断し，症例報告書に記録した。本項では，治験担当医師により感染症と判断された有害事象について検討した。

1) すべての感染症

a) 国際共同試験

① T16 試験

T16 試験（6 週まで）の感染症の発現割合は，プラセボ群 6.5%（5/77 例）及び全ゴリムマブ群 10.8%（23/213 例）であった。（【5.3.5.1.1】Attachment 4.11）

全ゴリムマブ群で最も発現割合が高い感染症は，咽頭炎［プラセボ群 0%（0/77 例）及び全ゴリムマブ群 1.9%（4/213 例）］，次いで上気道感染［1.3%（1/77 例）及び 1.4%（3/213 例）］であった。プラセボ群で 2 例以上に発現した感染症はなかった。

② T17 試験

T17 試験（6 週まで）の感染症の発現割合は，プラセボ群 12.1%（40/330 例），200→100 mg 群 11.8%（39/331 例）及び 400→200 mg 群 12.3%（41/332 例）であり，群間でおおむね同程度であった（【5.3.5.1.2】Attachment 4.20）。

全ゴリムマブ群で最も発現割合が高い感染症は，鼻咽頭炎［プラセボ群 2.4%（8/330 例），200→100 mg 群 3.0%（10/331 例）及び 400→200 mg 群 2.1%（7/332 例）］，次いで上気道感染［1.5%（5/330 例），1.5%（5/331 例）及び 1.2%（4/332 例）］，副鼻腔炎［0.6%（2/330 例），0.3%（1/331 例）及び 1.2%（4/332 例）］であった。

③ T18 試験

(i) T18 試験（54 週まで，ランダム化された被験者）

T18 試験（54 週まで）では，ランダム化された被験者の感染症の発現割合は，プラセボ群 28.2%（44/156 例），50 mg 群 39.0%（60/154 例）及び 100 mg 群 39.0%（60/154 例）であった

（【5.3.5.1.3-1】Attachment 4.27）。100 人年あたりの発現率はそれぞれ 55.09，61.06 及び 60.39 であった（【5.3.5.1.3-1】Attachment 4.2）。

全ゴリムマブ群で最も発現割合が高い感染症は，鼻咽頭炎［プラセボ群 6.4%（10/156 例），50 mg 群 9.1%（14/154 例）及び 100 mg 群 11.0%（17/154 例）］，次いで上気道感染［2.6%（4/156 例），5.2%（8/154 例）及び 5.8%（9/154 例）］であった。

(ii) T18 試験（54 週まで，全投与被験者）

T18 試験（54 週まで）では，全投与被験者の感染症の発現割合は，プラセボ群 26.7%（76/285 例），50 mg 群 39.0%（60/154 例）及び 100 mg 群 36.0%（341/946 例）であった（【5.3.5.1.3-1】Attachment 4.31）。

全ゴリムマブ群で最も発現割合が高い感染症は，鼻咽頭炎［プラセボ群 5.3%（15/285 例），50 mg 群 9.1%（14/154 例）及び 100 mg 群 8.5%（80/946 例）］，次いで上気道感染［3.5%（10/285 例），5.2%（8/154 例）及び 6.1%（58/946 例）］であった。

全投与被験者での感染症の発現傾向は，ランダム化された被験者とおおむね同様であった。

(iii) T18 試験（54 週から 228 週まで，全投与被験者）

T18 試験（54 週から 228 週まで）の感染症の発現割合は，プラセボ群 30.2%（29/96 例），50 mg 群 50.0%（47/94 例）及び 100 mg 群 55.7%（292/524 例）であった（【5.3.5.1.3-2】Attachment TSFAE09）。100 人年あたりの発現率（95%CI）はそれぞれ 38.87（27.89，52.73），51.97（43.29，61.88）及び 67.37（63.07，71.88）であった（【5.3.5.1.3-2】Table 8）。

全ゴリムマブ群で最も発現割合が高い感染症は，鼻咽頭炎［プラセボ群 5.2%（5/96 例），50 mg 群 10.6%（10/94 例）及び 100 mg 群 12.6%（66/524 例）］，次いで上気道感染［4.2%（4/96 例），6.4%（6/94 例）及び 8.8%（46/524 例）］であった。

④ T16，T17 及び T18 試験統合

(i) T16，T17 及び T18 試験（54 週まで，ランダム化された被験者）

T16，T17 及び T18 試験（54 週まで）の，ランダム化された被験者の感染症の発現割合は，T18 試験の投与群別に，プラセボ群 35.3%（55/156 例），50 mg 群 43.5%（67/154 例）及び 100 mg 群 42.9%（66/154 例）であった【表 2.7.4.7-付録-31】。

各群で最も発現割合が高い感染症は，鼻咽頭炎［プラセボ群 7.7%（12/156 例），50 mg 群 10.4%（16/154 例）及び 100 mg 群 11.7%（18/154 例）］であった。

(ii) T16，T17 及び T18 試験（54 週まで，全投与被験者）

T16，T17 及び T18 試験（54 週まで）の，全投与被験者の感染症の発現割合は，T18 試験の投与群別に，プラセボ群 35.0%（55/157 例），50 mg 群 43.5%（67/154 例）及び 100 mg 群 38.9%（257/660 例）であった【表 2.7.4.7-付録-32】。100 人年あたりの発現率（95%CI）はそれぞれ 95.21（78.39，114.56），100.41（84.98，117.82）及び 85.76（78.34，93.69）であった【表 2.7.4.7-付録-33】。

各群で最も発現割合が高い感染症は，鼻咽頭炎［プラセボ群 7.6%（12/157 例），50 mg 群 10.4%（16/154 例）及び 100 mg 群 10.2%（67/660 例）］であった。

(iii) T16，T17 及び T18 試験（228 週まで，全投与被験者）

T16，T17 及び T18 試験（228 週まで）の，全投与被験者の 100 人年あたりの感染症発現率（95%CI）は，プラセボ群 75.85（63.60，89.78），50 mg 群 70.86（62.79，79.68）及び 100 mg 群 71.65（67.43，76.07）であった（【表 2.7.4.7-付録-7】）。

b) 日本人集団

① T17 試験の日本人部分集団

T17 試験（6 週まで）の日本人の感染症の発現割合は，プラセボ群 26.7%（8/30 例），200→100 mg 群 26.1%（6/23 例）及び 400→200 mg 群 21.1%（4/19 例）であった【表 2.7.4.7-付録-34】。

全ゴリムマブ群で最も発現割合が高い感染症は，鼻咽頭炎［プラセボ群 6.7%（2/30 例），200→100 mg 群 8.7%（2/23 例）及び 400→200 mg 群 5.3%（1/19 例）］であった。

② T18 試験の日本人部分集団（全投与被験者）

T18 試験（54 週まで）の日本人の感染症の発現割合は，プラセボ群 37.5%（3/8 例）及び全ゴリムマブ群 53.3%（32/60 例）であった【表 2.7.4.7-付録-35】。

全ゴリムマブ群で最も発現割合が高い感染症は，鼻咽頭炎［プラセボ群 12.5%（1/8 例）及び全ゴリムマブ群 31.7%（19/60 例）］であった。

③ T16，T17 及び T18 試験（54 週まで）の日本人部分集団（全投与被験者）

T16，T17 及び T18 試験（54 週まで）の，日本人及び外国人の感染症の発現割合は，日本人の全ゴリムマブ群で 60.3%（41/68 例）及び外国人の全ゴリムマブ群で 39.4%（459/1165 例）であり，外国人に比べ日本人で高かった【表 2.7.4.7-付録-36】。

いずれの群でも最も発現割合が高い感染症は鼻咽頭炎であった。各群の発現割合は，日本人ではプラセボ群 10.0%（3/30 例）及び全ゴリムマブ群 35.3%（24/68 例），外国人ではプラセボ群 3.2%（12/377 例）及び全ゴリムマブ群 8.2%（96/1165 例）であり，プラセボ群及びゴリムマブ群とも，日本人と外国人で比較的大きな差がみられた。

④ UCO3001 試験

(i) 寛解導入期

UCO3001 試験の寛解導入期の感染症の発現割合は 16.0%（23/144 例）であった（【5.3.5.1.5】Attachment TSFAEINF01IN）。

最も発現割合が高い感染症は鼻咽頭炎 11.1%（16/144 例），次いで上気道感染 2.1%（3/144 例）であった。

(ii) 寛解維持期

● ランダム化された被験者

UCO3001 試験の寛解維持期の，ランダム化された被験者の感染症の発現割合は，プラセボ群 35.5%（11/31 例）及び 100 mg 群 65.6%（21/32 例）であった（【5.3.5.1.5】Attachment TSFAEINF01DB）。

100 mg 群で最も発現割合が高い感染症は鼻咽頭炎［プラセボ群 19.4%（6/31 例）及び 100 mg 群 46.9%（15/32 例）］，次いでインフルエンザ［3.2%（1/31 例）及び 12.5%（4/32 例）］であった。

● **全投与被験者**

UCO3001 試験の寛解維持期の，全投与被験者の感染症の発現割合は，プラセボ群 35.5%（11/31 例）及び 100 mg 群 49.5%（55/111 例）であった（【5.3.5.1.5】Attachment TSFAEINF01MA）。

100 mg 群で最も発現割合が高い感染症は鼻咽頭炎［プラセボ群 19.4%（6/31 例）及び 100 mg 群 29.7%（33/111 例）］，次いでインフルエンザ［3.2%（1/31 例）及び 7.2%（8/111 例）］であった。

2) 重篤な感染症

a) 国際共同試験

① T16 試験

T16 試験（6 週まで）に全ゴリムマブ群の 4 例に重篤な感染症が発現した。発現した事象は，蜂巣炎，敗血症（各 1 例），潰瘍性大腸炎（2 例）であった（【5.3.5.1.1 】Attachment 4.8，Attachment 4.9）。

② T17 試験

T17 試験（6 週まで）の重篤な感染症の発現割合は，プラセボ群 1.8%（6/330 例），200→100 mg 群 0.3%（1/331 例）及び 400→200 mg 群 0.9%（3/332 例）であり，いずれの群でも低かった。

2 例以上に発現した重篤な感染症は肺炎のみであり，プラセボ群及び 200→100 mg 群で各 1 例に報告された（【5.3.5.1.2】Attachment 4.24）。

③ T18 試験

(i) T18 試験（54 週まで，ランダム化された被験者）

T18 試験（54 週まで）のランダム化された被験者の重篤な感染症の発現割合は，プラセボ群 1.9%（3/156 例），50 mg 群 3.2%（5/154 例）及び 100 mg 群 3.2%（5/154 例）であった（【5.3.5.1.3-1】Attachment 4.33）。100 人年あたりの発現率は，それぞれ 3.08，3.88 及び 3.73 であった（【5.3.5.1.3-1】Attachment 4.2）。

2 例以上に発現した重篤な感染症は虫垂炎のみであり，100 mg 群の 3 例に報告された。

(ii) T18 試験（54 週まで，全投与被験者）

T18 試験（54 週まで）の全投与被験者の重篤な感染症の発現割合は，プラセボ群 1.1%（3/285 例），50 mg 群 3.2%（5/154 例）及び 100 mg 群 3.0%（28/946 例）であった（【5.3.5.1.3-1】Attachment 4.35）。

全投与被験者の重篤な感染症の発現傾向は，ランダム化された被験者とおおむね同様であった。

(iii) T18 試験（54 週から 228 週まで，全投与被験者）

T18 試験（54 週から 228 週まで）の重篤な感染症の発現割合は，プラセボ群 1.0%（1/96 例），50 mg 群 3.2%（3/94 例）及び 100 mg 群 6.1%（32/524 例）であった（【5.3.5.1.3-2】TSFAE11）。

最も発現割合が高い重篤な感染症は肺炎［プラセボ群 1.0%（1/96 例），50 mg 群 1.1%（1/94 例）及び 100 mg 群 1.1%（6/524 例）］であった。肺炎のほかに 2 例以上に発現した重篤な感染症は，100 mg 群で発現した肛門膿瘍及び肺結核が各 3 例（発現割合 0.6%），胃腸炎，帯状疱疹及びウイルス性髄膜炎が各 2 例（0.4%）であった。100 人年あたりの発現率（95%CI）は，プラ

セボ群 0.95（0,02，5.28），50 mg 群 1.24（0.26，3.62）及び 100 mg 群 2.65（1.86，3.67）であった（【5.3.5.1.3-2】Table 8）。

(iv) T18 試験（0 週から 228 週まで，全投与被験者）

T18 試験（0 週から 228 週まで）の 100 mg 群の 100 人年あたりの重篤な感染症の発現率（95%CI）は 3.12（2.40，3.98）であり，他疾患を対象とした臨床試験との統合データの 50 mg 群 2.51（2.03，3.07）及び 100 mg 群 4.05（3.61，4.53）と大きな違いはなかった【表 2.7.4.7-付録-37】。

④ T16，T17 及び T18 試験統合

(i) T16，T17 及び T18 試験（54 週まで，ランダム化された被験者）

T16，T17 及び T18 試験（54 週まで）の，ランダム化された被験者の重篤な感染症の発現割合は，T18 試験の投与群別に，プラセボ群 2.6%（4/156 例），50 mg 群 3.2%（5/154 例）及び 100 mg 群 3.2%（5/154 例）であり，群間でおおむね同程度であった【表 2.7.4.7-付録-38】。

最も多く発現した重篤な感染症は，虫垂炎［プラセボ群 0%（0/156 例），50 mg 群 0%（0/154 例）及び 100 mg 群 1.9%（3/154 例）］であった。虫垂炎のほかに 2 例以上に発現した重篤な感染症はなかった。

(ii) T16，T17 及び T18 試験（54 週まで，全投与被験者）

T16，T17 及び T18 試験（54 週まで）の，全投与被験者の重篤な感染症の発現割合は，T18 試験の投与群別に，プラセボ群 2.5%（4/157 例），50 mg 群 3.2%（5/154 例）及び 100 mg 群 3.3%（22/660 例）であり，群間でおおむね同程度であった【表 2.7.4.7-付録-39】。平均観察期間はそれぞれ 39.0 週間，50.4 週間及び 45.1 週間であり，100 人年あたりの発現率（95%CI）はそれぞれ 5.95（2.39，12.26），5.36（2.31，10.55）及び 3.84（2.41，5.82）であった【表 2.7.4.7-付録-40】。

全ゴリムマブ群で最も発現割合が高い重篤な感染症は，虫垂炎［プラセボ群 0%（0/157 例），50 mg 群 0%（0/154 例）及び 100 mg 群 0.5%（3/660 例）］，気管支炎［0%（0/157 例），0.6%（1/154 例）及び 0%（0/660 例）］，播種性結核［0.6%（1/157 例），0%（0/154 例）及び 0.3%（2/660 例）］，肺炎［0%（0/157 例），0%（0/154 例）及び 0.2%（1/660 例）］及び潰瘍性大腸炎［0%（0/157 例），0%（0/154 例）及び 0.3%（2/660 例）］であった。

(iii) T16，T17 及び T18 試験（228 週まで，全投与被験者）

T16，T17 及び T18 試験（228 週まで）の，全投与被験者の 100 人年あたりの重篤な感染症発現率（95%CI）は，プラセボ群 4.50（1.94，8.86），50 mg 群 2.79（1.39，5.00）及び 100 mg 群 3.20（2.36，4.24）であった（【表 2.7.4.7-付録-7】）。

b) 日本人集団

① T17 試験の日本人部分集団

T17 試験（6 週まで）の日本人で発現した重篤な感染症は，プラセボ群で発現した肛門膿瘍及び感染性小腸結腸炎が各 1 例（発現割合 3.3%）並びに 200→100 mg 群で発現した肺炎 1 例（4.3%）であった【表 2.7.4.7-付録-41】。

② T18 試験の日本人部分集団（54 週まで，全投与被験者）

T18 試験（54 週まで）に日本人で発現した重篤な感染症は，プラセボ群で発現したサイトメガロウイルス感染 1 例（発現割合 12.5%）及び 100 mg 群で発現した感染性小腸結腸炎 1 例（1.7%）であった【表 2.7.4.7-付録-42】。

③ UCO3001 試験

(i) 寛解導入期

UCO3001 試験の寛解導入期に発現した重篤な感染症はサイトメガロウイルス性大腸炎 1 例（発現割合 0.7%）のみであった（【5.3.5.1.5】Attachment TSFSAEINF01IN）。

(ii) 寛解維持期

- ランダム化された被験者

UCO3001 試験の寛解維持期にランダム化された被験者で発現した重篤な感染症は，投与量調節群（プラセボ→100 mg 群）で発現した喉頭炎 1 例のみであり，プラセボ群及び 100 mg 群での報告はなかった（【5.3.5.1.5】Attachment TSFSAEINF01DB）。

- 全投与被験者

UCO3001 試験の寛解維持期に全投与被験者で発現した重篤な感染症は，100 mg 群（投与量調節後の被験者を含む）で発現した帯状疱疹 2 例（発現割合 1.8%），喉頭炎及び咽頭炎が各 1 例（0.9%）であった。（【5.3.5.1.5】Attachment TSFSAEINF01MA）

(iii) 導入期 0 週から維持期 54 週まで（全投与被験者）

UCO3001 試験の寛解導入期 0 週から維持期 54 週までの，重篤な感染症の発現割合は 3.5%（5/144 例）であった。発現した重篤な感染症は帯状疱疹 2 例（発現割合 1.4%），サイトメガロウイルス性大腸炎，喉頭炎，咽頭炎が各 1 例（0.7%）であった【表 2.7.4.7-付録-43】。

(2) その他の重要な有害事象

1) 重要な感染症

a) 敗血症

① 国際共同試験

T16，T17 及び T18 試験（54 週まで）の全ゴリムマブ群での敗血症の発現割合は 0.5%（6/1233 例），100 人年あたりの発現率（95%CI）は 0.56（0.20，1.21）であった（【表 2.7.4.7-付録-44】，【5.3.5.3.1】Table 23）。

T18 試験（0 週から 228 週まで）の 100 mg 群の 100 人年あたりの敗血症の発現率（95%CI）は 0.34（0.14，0.70）であり，他疾患を対象とした臨床試験との統合データの 50 mg 群 0.16（0.06，0.35）及び 100 mg 群 0.34（0.22，0.50）と大きな違いはなかった【表 2.7.4.7-付録-45】。

② 日本人集団

(i) T17 及び T18 試験の日本人部分集団（全投与被験者）

T17 及び T18 試験に参加した日本人では敗血症の報告はなかった。

(ii) UCO3001 試験

UCO3001 試験では敗血症の報告はなかった。

b) 肺炎

① 国際共同試験

T16，T17 及び T18 試験（54 週まで）の全ゴリムマブ群での肺炎の発現割合は 1.4%（17/1233 例），100 人年あたりの発現率（95%CI）は 1.76（1.06，2.75）であった（【表 2.7.4.7-付録-46】，【5.3.5.3.1】Table 24）。

T18 試験（0 週から 228 週まで）の 100 mg 群の 100 人年あたりの肺炎の発現率（95%CI）は 1.46（0.99，2.09）であり，他疾患を対象とした臨床試験との統合データの 50 mg 群 1.82（1.41，2.30）及び 100 mg 群 2.28（1.95，2.64）と大きな違いはなかった【表 2.7.4.7-付録-47】。

② 日本人集団

(i) T17 及び T18 試験の日本人部分集団（全投与被験者）

T17 試験に参加した日本人 1 例（被験者 ID：7815-00001）で重篤な肺炎が報告された。この 1 例は 200→100 mg 群の被験者であった。治験薬との関連性は「可能性大」と判断された。T18 試験に参加した日本人では肺炎の報告はなかった。

(ii) UCO3001 試験

UCO3001 試験の後観察期に重篤な肺炎が 1 例（被験者 ID：811501）報告された。この 1 例は寛解維持期にランダム化されなかった被験者であった。治験薬との関連性は「可能性小」と判断された。

c) 結核

① 国際共同試験

T16，T17 及び T18 試験（54 週まで）の全ゴリムマブ群の結核の発現割合は 0.3%（4/1233 例），100 人年あたりの結核の発現率（95%CI）は 0.37（0.10，0.95）であった（【表 2.7.4.7-付録-48】，【5.3.5.3.1】Table 25）。この 4 例中 3 例（被験者 ID：6252-00020，6252-00009 及び 6407-00031）は播種性結核であった。4 例とも，コルチコステロイドを含む免疫抑制剤を投与されていた。4 例中 1 例（被験者 ID：6407-00031）は治療を受けた潜在性結核であると確認された。4 例中 1 例は T18 試験のプラセボ群，3 例は 100 mg 群で発現した。

T18 試験（54 週から 228 週まで）では，4 例の活動性結核（肺結核 3 例，肺外結核 1 例）が発現した（【5.3.5.1.3-2】Attachment LSFAE04）。いずれも発現時はゴリムマブ 100 mg を投与されていた。肺結核の 3 例は治験中に回復したが，肺外結核の 1 例は最終調査時までに回復しなかった。

T18 試験（0 週から 228 週まで）の 100 mg 群の 100 人年あたりの結核の発現率（95%CI）は 0.34（0.14，0.70）であり，他疾患を対象とした臨床試験との統合データの 50 mg 群 0.11（0.03，0.27）及び 100 mg 群 0.34（0.22，0.50）と大きな違いはなかった【表 2.7.4.7-付録-49】。

② 日本人集団

(i) T17 及び T18 試験の日本人部分集団（全投与被験者）

T17 及び T18 試験に参加した日本人では結核の報告はなかった。

(ii) UCO3001 試験

UCO3001 試験では結核の報告はなかった。

d) 日和見感染

① 国際共同試験

T16，T17 及び T18 試験（54 週まで）の，全ゴリムマブ群の日和見感染の発現割合は 0.2%（3/1233 例），100 人年あたりの発現率（95%CI）は 0.28（0.06，0.81）であった（【表 2.7.4.7-付録-50】，【5.3.5.3.1】Table 26）。この 3 例の内訳は，T17 試験の 400→200 mg 群で報告された食道カンジダ 1 例，T18 試験の 100 mg 群で報告された食道カンジダ及び多発性脳膿瘍の各 1 例であった。

T18 試験（54 週から 228 週まで）では，3 例の日和見感染（レジオネラ菌性肺炎，ウイルス性髄膜炎及び肝障害を伴うサイトメガロウイルス感染が各 1 例）が報告された（【5.3.5.1.3-2】Attachment LSFAE07)。いずれの被験者も発現時は 100 mg を投与されていた。3 例とも治験中に回復した。

T18 試験（0 週から 228 週まで）の 100 mg 群の 100 人年あたりの日和見感染の発現率（95%CI）は 0.15（0.03，0.43）であり，他疾患を対象とした臨床試験との統合データの 50 mg 群 0.08（0.02，0.23）及び 100 mg 群 0.24（0.14，0.37）と大きな違いはなかった【表 2.7.4.7-付録-51】。

② 日本人集団

(i) T17 及び T18 試験の日本人部分集団（全投与被験者）

T17 及び T18 試験に参加した日本人では日和見感染の報告はなかった。

(ii) UCO3001 試験

UCO3001 試験では日和見感染の報告はなかった。

e) 蜂巣炎

① 国際共同試験

T16，T17 及び T18 試験（54 週まで）の全ゴリムマブ群での蜂巣炎の発現割合は 0.9%（11/1233 例），100 人年あたりの発現率（95%CI）は 1.48（0.85，2.41）であった（【表 2.7.4.7-付録-52】，【5.3.5.3.1】Table 27）。

T18 試験（0 週から 228 週まで）の 100 mg 群の 100 人年あたりの蜂巣炎の発現率（95%CI）は 0.44（0.20，0.83）であり，他疾患を対象とした臨床試験との統合データの 50 mg 群 1.63（1.25，2.09）及び 100 mg 群 1.43（1.18，1.73）と大きな違いはなかった【表 2.7.4.7-付録-53】。

② 日本人集団

(i) T17 及び T18 試験の日本人部分集団（全投与被験者）

T17 試験に参加した日本人では蜂巣炎の報告はなかった。T18 試験に参加した日本人では，継続投与期に非重篤な蜂巣炎が 2 例で報告された。1 例は T17 試験 200 mg→100 mg 群，T18 試験 100 mg 群であり，1 例は T17 試験のプラセボ寛解導入 nonresponder で，T18 試験で 100 mg を投与された被験者であった。いずれも治験薬との関連性は「関連なし」と判断された。

(ii) UCO3001 試験

UCO3001 試験の寛解導入期 0 週から維持期 54 週までに，非重篤な蜂巣炎が 1 例で報告された（発現割合 0.7%）。この 1 例は寛解維持期にランダム化されなかった被験者であった。

2) 注射部位反応

注射部位反応はゴリムマブの重要な有害事象であると考えられることから，各有害事象が注射部位反応であるか否かを治験担当医師が判断し，症例報告書に記録した。本項では，治験担当医師により注射部位反応と判断された有害事象について検討した。

a) 国際共同試験

① T16 試験

T16 試験（6 週まで）に全ゴリムマブ群の 2.3%（5/213 例）に注入部位反応が発現した。プラセボ群には報告はなかった（【5.3.5.1.1】Attachment 4.13）。

② T17 試験

T17 試験（6 週まで）の注射部位反応の発現割合は，プラセボ群 1.5%（5/330 例），200→100 mg 群 3.3%（11/331 例）及び 400→200 mg 群 3.0%（10/332 例）であり，いずれの群でも低かった（【5.3.5.1.2】Attachment 4.26）。

③ T18 試験

(i) T18 試験（54 週まで，ランダム化された被験者）

T18 試験（54 週まで）では，ランダム化された被験者の注射部位反応の発現割合は，プラセボ群 1.9%（3/156 例），50 mg 群 1.9%（3/154 例）及び 100 mg 群 7.1%（11/154 例）であった（【5.3.5.1.3-1】Attachment 4.36）。重篤及び高度な注射部位反応の報告はなかった。

(ii) T18 試験（54 週まで，全投与被験者）

T18 試験（54 週まで）では，全投与被験者の注射部位反応の発現割合は，プラセボ群 2.1%（6/285 例），50 mg 群 1.9%（3/154 例）及び 100 mg 群 2.9%（27/946 例）であった（【5.3.5.1.3-1】Attachment 4.42）。重篤及び高度な注射部位反応の報告はなかった。

(iii) T18 試験（54 週から 228 週まで）

T18 試験（54 週から 228 週まで）の注射部位反応の発現割合は，50 mg 群 1.1%（1/94 例）及び 100 mg 群 2.3%（12/524 例）であった（【5.3.5.1.3-2】TSFAE13）。重篤及び高度な注射部位反応の報告はなかった。

b) 日本人集団

① T17 試験の日本人部分集団

T17 試験（6 週まで）に日本人で注射部位反応の報告はなかった【表 2.7.4.7-付録-54】。

② T18 試験の日本人部分集団（全投与被験者）

T18 試験（54 週まで）に日本人で発現した注射部位反応を【表 2.7.4.7-付録-55】に示す。注射部位反応の発現割合は，プラセボ群 0%（0/8 例）及び全ゴリムマブ群 1.7%（1/60 例）であった。

③ UCO3001 試験

(i) 寛解導入期

UCO3001 試験の寛解導入期の，注射部位反応の発現割合は 4.9%（7/144 例）であった（【5.3.5.1.5】Attachment TSFAEINJ01IN）。

(ii) 寛解維持期

● ランダム化された被験者

UCO3001 試験の寛解維持期の，ランダム化された被験者の注射部位反応の発現割合は，プラセボ群 0%（0/31 例）及び 100 mg 群 18.8%（6/32 例）であった（【5.3.5.1.5】Attachment TSFAEINJ01DB）。重篤及び高度な注射部位反応の報告はなかった。

● 全投与被験者

UCO3001 試験の寛解維持期の，全投与被験者の注射部位反応の発現割合は，プラセボ群 0%（0/31 例）及び 100 mg 群 9.9%（11/111 例）であった（【5.3.5.1.5】Attachment TSFAEINJ01MA）。重篤及び高度な注射部位反応の報告はなかった。

3) 脱髄疾患

a) 国際共同試験

T16，T17 及び T18 試験（54 週まで）では，全ゴリムマブ群の 1 例に脱髄疾患が発現した（発現割合 0.1%）（【表 2.7.4.7-付録-56】，【5.3.5.3.1】Table 28）。この 1 例は T17 試験で 400→200 mg 群，T18 試験でプラセボ群の被験者であった。全ゴリムマブ群の 100 人年あたりの発現率（95%CI）は 0.09（0.00，0.52）であった。

T18 試験（54 週から 228 週まで）では，100 mg 群で脱髄及び多発性硬化症が各 1 例（発現割合 0.2%）に発現した。いずれも重篤な脱髄疾患であり，治験薬の投与を中止した。

T18 試験（0 週から 228 週まで）の 100 mg 群の 100 人年あたりの脱髄疾患の発現率（95%CI）は 0.10（0.01，0.35）であり，他疾患を対象とした臨床試験との統合データの 50 mg 群 0.00（0.00，0.08）及び 100 mg 群 0.12（0.05，0.22）と大きな違いはなかった【表 2.7.4.7-付録-57】。

b) 日本人集団

① T17 及び T18 試験の日本人部分集団（全投与被験者）

T17 及び T18 試験に参加した日本人では脱髄疾患の報告はなかった。

② UCO3001 試験

UCO3001 試験では脱髄疾患の報告はなかった。

4) うっ血性心不全

a) 国際共同試験

T16，T17 及び T18 試験（54 週まで）では，うっ血性心不全は 1 例（発現割合 0.1%）で 2 件報告された（【表 2.7.4.7-付録-58】，【5.3.5.3.1】Table 29）。この 1 例は T17 試験の 400→200 mg 群，T18 試験の 100 mg 群の被験者であり，転帰は死亡であった。全ゴリムマブ群の 100 人年あたりの発現率（95%CI）は 0.19（0.02，0.67）であった。

T18 試験（0 週から 228 週まで）の 100 mg 群の 100 人年あたりのうっ血性心不全の発現率（95%CI）は 0.15（0.03，0.43）であり，他疾患を対象とした臨床試験との統合データの 50 mg 群 0.03（0.00，0.15）及び 100 mg 群 0.20（0.11，0.33）と大きな違いはなかった【表 2.7.4.7-付録-59】。

b) 日本人集団

① T17 及び T18 試験の日本人部分集団（全投与被験者）

T17 及び T18 試験に参加した日本人ではうっ血性心不全の報告はなかった。

② UCO3001 試験

UCO3001 試験ではうっ血性心不全の報告はなかった。

5) 過敏症反応

a) 国際共同試験

T16，T17 及び T18 試験（54 週まで）の全ゴリムマブ群の過敏症反応の発現割合は 1.8%（22/1233 例），100 人年あたりの発現率（95%CI）は 2.13（1.35，3.20）であった（【表 2.7.4.7-付録-60】，【5.3.5.3.1】Table 30）。

T18 試験（54 週から 228 週まで）に報告された過敏症反応のうち，治験薬投与中止に至った非重篤な過敏症反応が 1 件あった。

T18 試験（0 週から 228 週まで）の 100 mg 群の 100 人年あたりの過敏症反応の発現率（95%CI）は 1.56（1.07，2.20）であり，他疾患を対象とした臨床試験との統合データの 50 mg 群 1.17（0.85，1.58）及び 100 mg 群 1.51（1.25，1.82）と大きな違いはなかった【表 2.7.4.7-付録-61】。

b) 日本人集団

① T17 及び T18 試験の日本人部分集団（全投与被験者）

T17 試験に参加した日本人では過敏症反応の報告はなかった。T18 試験の 54 週までではプラセボ群 1 例，T18 試験の継続投与期では 1 例で過敏症反応が報告された。いずれも非重篤であり，治験薬投与中止に至った事象はなかった。

② UCO3001 試験

UCO3001 試験の 54 週まででは 4 例で過敏症反応が報告された。いずれも非重篤であり，治験薬投与中止に至った事象はなかった。

6) 血清病様反応及びアナフィラキシー様反応

a) 国際共同試験

T16，T17 及び T18 試験（54 週まで）では，非重篤な血清病様反応が 1 例で発現した（発現割合 0.1%）（【表 2.7.4.7-付録-62】，【5.3.5.3.1】Table 32）。全ゴリムマブ群の 100 人年あたりの発現率（95%CI）は 0.09（0.00，0.52）であった。アナフィラキシー様反応の報告はなかった。

T18 試験（54 週から 228 週まで）では，血清病様反応及びアナフィラキシー様反応の報告はなかった。

T18 試験（0 週から 228 週まで）の 100 mg 群の 100 人年あたりの血清病様反応及びアナフィラキシー様反応の発現率（95%CI）は 0.00（0.00，0.15）であり，他疾患を対象とした臨床試験との統合データの 50 mg 群 0.00（0.00，0.08）及び 100 mg 群 0.00（0.00，0.04）と大きな違いはなかった【表 2.7.4.7-付録-63】。

b) 日本人集団

① T17 及び T18 試験の日本人部分集団（全投与被験者）

T17 及び T18 試験に参加した日本人では血清病様反応及びアナフィラキシー様反応の報告はなかった。

② UCO3001 試験

UCO3001 試験では血清病様反応及びアナフィラキシー様反応の報告はなかった。

7) 肝胆道系の有害事象

a) 国際共同試験

基準値上限の 3 倍以上の ALT の上昇及び基準値上限の 2 倍以上のビリルビンの上昇の同時発現を臨床的に重要な肝胆道系の有害事象と定義した。T16，T17 及び T18 試験（54 週まで）の発現割合は，T18 試験の投与群別に，プラセボ群 0.6%（1/157 例），50 mg 群 1.3%（2/154 例）及び 100 mg 群 0%（0/660 例）であり，群間で大きな差はなかった（【表 2.7.4.7-付録-64】，【5.3.5.3.1】Table 33）。

b) 日本人集団

① T17 及び T18 試験の日本人部分集団（全投与被験者）

T17 及び T18 試験に参加した日本人では臨床的に重要な肝胆道系の有害事象の報告はなかった。

② UCO3001 試験

UCO3001 試験の 54 週までに臨床的に重要な肝胆道系の有害事象は発現しなかった。

(3) 悪性腫瘍

1) 国際共同試験

a) T16，T17 及び T18 試験（54 週まで，全投与被験者）

T16，T17 及び T18 試験（54 週まで）では，悪性腫瘍は 6 例で発現した。このうち 5 例はゴリムマブを投与された被験者であり，1 例はプラセボのみ投与された被験者であった。ゴリムマブを投与された 5 例の被験者 ID，悪性腫瘍及び投与量を以下に示す。5 例のうち，2 例（被験者 ID：7775-00001 及び 7812-00002）は寛解導入療法でプラセボを投与されている間に発現が確認され，1 例（被験者 ID：7207-00024）は治験薬投与前に採取された結腸生検により診断されたものであった（【5.3.5.3.1】Table 34）。

- 6006-00008：非黒色腫皮膚癌（扁平上皮癌），T16 試験 4 mg/kg，T18 試験 100 mg
- 7207-00024：結腸癌，T17 試験 400→200 mg，T18 試験で投与なし
- 7704-00002：肺腺癌，T17 試験 200→100 mg，T18 試験 100 mg

・ 7775-00001：甲状腺癌，T17 試験プラセボ，T18 試験 100 mg

・ 7812-00002：直腸癌，T17 試験プラセボ，T18 試験 100 mg

T16，T17 及び T18 試験（54 週まで）の全ゴリムマブ群の 100 人年あたりの悪性腫瘍の発現率（95%CI）は以下のとおりであった。【表 2.7.4.7-付録-65】

・ すべての悪性腫瘍の発現率は 0.46（0.15，1.08）であった。

・ リンパ腫は発現しなかった。

・ 非黒色腫皮膚癌の発現率は 0.09（0.00，0.52）であった。

・ その他の悪性腫瘍の発現率は 0.37（0.10， 0.95）であった。

b) T18 試験（54 週から 228 週まで，全投与被験者）

T18 試験（54 週から 228 週まで）に発現した悪性腫瘍は 13 例，14 件であった。プラセボ群では悪性腫瘍の報告はなかった。13 例の被験者 ID，投与群及び悪性腫瘍を以下に示す（【5.3.5.1.3-2】Attachment LSFAE06）。

非黒色腫皮膚癌

・ 6051-00002：100 mg 群，耳の基底細胞癌（2 件）

・ 6478-00011：100 mg 群，基底細胞癌

・ 7008-00004：100 mg 群，扁平上皮癌

・ 7743-00002：50 mg 群，基底細胞癌

リンパ腫

・ 7414-00019：100 mg 群，ホジキン病

・ 7753-00004：100 mg 群，T 細胞リンパ腫

固形腫瘍

・ 6101-00001：100 mg 群，右卵巣癌

・ 6402-00002：100 mg 群，胆嚢癌

・ 6716-00008：50 mg 群，前立腺癌

・ 6751-00018：50 mg 群，卵巣腺癌

・ 7205-00005：100 mg 群，肝転移を伴う結腸直腸癌

・ 7213-00008：100 mg 群，遠隔転移を伴う結腸腺癌

・ 7776-00005：100 mg 群，遠隔転移を伴う腎癌

T18 試験（54 週から 228 週まで）の全ゴリムマブ群の 100 人年あたりの悪性腫瘍発現率（95%CI）は 0.82（0.44，1.40）であった。プラセボ群では悪性腫瘍は報告されなかった。50 mg 群及び 100 mg 群の 100 人年あたりの悪性腫瘍の発現率（95%CI）は以下のとおりであり，用量反応性は認められなかった（【5.3.5.1.3-2】Attachment TSFAE20AAH）。

・ すべての悪性腫瘍の発現率は 50 mg 群 1.26（0.26，3.67）及び 100 mg 群 0.74（0.35，1.36）であった。

・ リンパ腫の発現率は 50 mg 群 0.00（0.00，1.24）及び 100 mg 群 0.15（0.02，0.53）であった。

・ 非黒色腫皮膚癌の発現率は 50 mg 群 0.42（0.01，2.33）及び 100 mg 群 0.22（0.05，0.65）であった。

・ その他の悪性腫瘍の発現率は 50 mg 群 0.83（0.10，2.99）及び 100 mg 群 0.37（0.12，0.86）であった。

c) T18 試験（0 週から 228 週まで，全投与被験者）

T18 試験（0 週から 228 週まで）の 100 mg 群及び他疾患を対象とした臨床試験との統合データの 50 mg 群及び 100 mg 群の，100 人年あたりの悪性腫瘍発現率（95%CI）は以下のとおりであった【表 2.7.4.7-付録-66】。

・ すべての悪性腫瘍の発現率は，T18 試験（0 週から 228 週まで）の 100 mg 群では 0.64（0.34，1.09）であり，他疾患を対象とした臨床試験との統合データの 50 mg 群では 0.86（0.59，1.21），100 mg 群では 1.01（0.80，1.26）であった。

・ リンパ腫の発現率は，T18 試験（0 週から 228 週まで）の 100 mg 群では 0.10（0.01，0.35）であり，他疾患を対象とした臨床試験との統合データの 50 mg 群では 0.03（0.00，0.15），100 mg 群では 0.13（0.06，0.24）であった。

・ 非黒色腫皮膚癌の発現率は，T18 試験（0 週から 228 週まで）の 100 mg 群では 0.15（0.03，0.43）であり，他疾患を対象とした臨床試験との統合データの 50 mg 群では 0.27（0.13，0.49），100 mg 群では 0.41（0.28，0.58）であった。

・ その他の悪性腫瘍の発現率は，T18 試験（0 週から 228 週まで）の 100 mg 群では 0.39（0.17，0.77）であり，他疾患を対象とした臨床試験との統合データの 50 mg 群では 0.56（0.35，0.86），100 mg 群では 0.45（0.31，0.63）であった。

海外臨床試験において，リンパ腫の発現は，0.09/100 人年であった（曝露期間の中央値：4.2 年，被験者数：3666 例，延べ投与：11663 人年）。この発現率は，一般集団［SEER データベース（2004）］での推定値の 3.81 倍であった。その他の悪性腫瘍の発現は，一般集団での推定値と類似していた【表 2.7.4.7-付録-67】，【表 2.7.4.7-付録-68】。

2) 日本人集団

a) T17 及び T18 試験（54 週まで）の日本人部分集団（全投与被験者）

T17 及び T18 試験に参加した日本人では，1 例（被験者 ID：7812-00002）に直腸癌が発現した。当該被験者は，T17 試験でプラセボを，T18 試験でゴリムマブ 100 mg を投与された被験者であった。治験薬との関連性は「関連なし」と判断された。

b) UCO3001 試験

UCO3001 試験では，寛解維持期 52 週の投与後の後観察期の 1 例（被験者 ID：810604）に，直腸腺癌が発現した。当該被験者は，寛解維持期に 100mg 群に割り付けられた被験者であった。治験薬との関連性は「多分なし」と判断された。

2.7.4.2.1.6 発現時期別有害事象

(1) 国際共同試験

1) T16，T17 及び T18 試験（54 週まで，全投与被験者）

T16，T17 及び T18 試験（54 週まで）の全ゴリムマブ群の 2%以上に発現した有害事象について，投与期間を 0～3 カ月，4～6 カ月，7～9 カ月，10～12 カ月及び 13 カ月以降に区分して発現割合を集計した。有害事象の発現割合は，0～3 カ月 53.4%，4～6 カ月 38.8%，7～9 カ月 33.0%及び 10～12 カ月 29.6%であった。ゴリムマブの投与期間が長くなるに従って有害事象発現割合が高くなる傾向は認められなかった【表 2.7.4.7-付録-69】。

2) T16，T17 及び T18 試験統合（228 週まで，全投与被験者）

T16，T17 及び T18 試験（54 週まで），及び，T18 試験（54 週から 228 週まで）に区分して，100 人年あたりの死亡，治験薬の投与中止に至った有害事象，有害事象，重篤な有害事象，感染症，重篤な感染症，悪性腫瘍及び投与部位反応の発現率を比較した。ゴリムマブの投与期間が長くなるに従って発現率が高くなる傾向は認められなかった（【5.3.5.1.3-2】Table10）。

(2) 日本人集団

1) T17 及び T18 試験（54 週まで）の日本人部分集団（全投与被験者）

T17 及び T18 試験（54 週まで）の日本人の全ゴリムマブ群で 2 例以上に発現した有害事象について，投与期間を 0～3 カ月，4～6 カ月，7～9 カ月，10～12 カ月及び 13 カ月以降に区分して発現割合を集計した。有害事象の発現割合は，0～3 カ月 63.2%，4～6 カ月 48.5%，7～9 カ月 40.0%及び 10～12 カ月 37.0%であった。ゴリムマブの投与期間が長くなるに従って有害事象発現割合が高くなる傾向は認められなかった【表 2.7.4.7-付録-70】。

2) UCO3001 試験

UCO3001 試験の寛解導入期 0 週から維持期 54 週までに 2 例以上に発現した有害事象について，投与期間を 0～3 カ月，4～6 カ月，7～9 カ月，10～12 カ月及び 13 カ月以降に区分して発現割合を集計した。有害事象の発現割合は，0～3 カ月 60.4%，4～6 カ月 53.2%，7～9 カ月 50.0%及び 10～12 カ月 44.9%であった。ゴリムマブの投与期間が長くなるに従って有害事象発現割合が高くなる傾向は認められなかった【表 2.7.4.7-付録-71】。

2.7.4.2.2 個別有害事象の文章による説明

死亡，その他の重篤な有害事象及びその他の重要な有害事象に関する詳細な記載は，各試験の治験総括報告書（【5.3.5.1.1】，【5.3.5.1.2】，【5.3.5.1.3-1】，【5.3.5.1.3-2】，【5.3.5.1.5】）及び個々の試験のまとめ（【2.7.6.2】，【2.7.6.3】，【2.7.6.4-1】，【2.7.6.4-2】，【2.7.6.5】）に示した。

2.7.4.3 臨床検査値の評価

2.7.4.3.1 血液学的検査

各検査項目で認められた顕著な異常について検討した。

2.7.4.3.1.1 国際共同試験

(1) T16 試験

T16 試験（6 週まで）に最も多く認められた血液学的検査値の顕著な異常は，リンパ球数減少であった［プラセボ群 21.1%（16/76 例）及び全ゴリムマブ群 18.1%（38/210 例）］（【5.3.5.1.1】Attachment 4.21）。同一被験者で 2 回以上のリンパ球数減少の発現割合は，プラセボ群 2.6%（2/76 例）及び全ゴリムマブ群 4.3%（9/210 例）であった。

T16 試験（6 週まで）に最大グレード 3 以上の血液学的検査値の異常はほとんど認められなかった（【5.3.5.1.1】Attachment 4.24）。

(2) T17 試験

T17 試験（6 週まで）に最も多く認められた血液学的検査値の顕著な異常は，リンパ球数減少であった［プラセボ群 18.3%（60/327 例）及び全ゴリムマブ群 11.6%（84/727 例）］（【5.3.5.1.2】Attachment 4.46）。同一被験者で 2 回以上のリンパ球数減少の発現割合は，プラセボ群 7.0%（23/327 例）及び全ゴリムマブ群 4.0%（29/727 例）であった。

リンパ球数減少のほかに，同一被験者で 2 回以上，かつ，2 例以上に異常が認められた項目は，ヘマトクリット減少［プラセボ群 2.1%（7/329 例）及び全ゴリムマブ群 1.6%（12/729 例）］並びに好中球絶対数減少［プラセボ群 0.3%（1/326 例）及び全ゴリムマブ群 0.7%（5/724 例）］であった。

T17 試験（6 週まで）の血液学的検査値の最大グレードは群間でおおむね同様であり，グレード 3 以上の血液学的検査値の異常はほとんど認められなかった（【5.3.5.1.2】Attachment 4.28）。

(3) T18 試験

1) T18 試験（54 週まで，ランダム化された被験者）

T18 試験（54 週まで）のランダム化された被験者で最も多く認められた血液学的検査値の顕著な異常は，リンパ球数減少であった［プラセボ群 36.1%（56/155 例），50 mg 群 25.3%（39/154 例）及び 100 mg 群 22.2%（34/153 例）］（【5.3.5.1.3-1】Attachment 4.46）。同一被験者で 2 回以上のリンパ球数減少の発現割合は，プラセボ群 21.3%（33/155 例），50 mg 群 14.9%（23/154 例）及び 100 mg 群 13.1%（20/153 例）であった。

好中球絶対数減少の発現割合は，プラセボ群 2.6%（4/155 例），50 mg 群 3.9%（6/154 例）及び 100 mg 群 6.5%（10/153 例）であった。同一被験者で 2 回以上の好中球絶対数減少の発現割合は，プラセボ群 1.3%（2/155 例），50 mg 群 1.3%（2/154 例）及び 100 mg 群 2.6%（4/153 例）であった。4 例（プラセボ群 2 例及び 100 mg 群 2 例）で好中球絶対数が $1.0\times10^3/\mu L$ 未満まで減少したが，重篤な感染症の報告はなかった。

T18 試験（54 週まで）の血液学的検査値の最大グレードは群間でおおむね同様であり，グレード 3 以上の血液学的検査値の異常は少なく，多くは一過性であった（【5.3.5.1.3-1】Attachment 4.50）。

2) T18 試験（54 週まで，全投与被験者）

T18 試験（54 週まで）の全投与被験者で認められた血液学的検査値の顕著な異常は，ランダム化された被験者とおおむね同様であった。最も発現割合が高い血液学的検査値の顕著な異常は，リンパ球数減少であった［プラセボ群 34.9%（98/281 例），50 mg 群 25.3%（39/154 例）及び 100 mg 群 23.6%（219/929 例）］（【5.3.5.1.3-1】Attachment 4.48）。同一被験者で 2 回以上のリンパ球数減少の発現割合は，プラセボ群 19.2%（54/281 例），50 mg 群 14.9%（23/154 例）及び 100 mg 群 11.1%（103/929 例）であった。

好中球絶対数減少の発現割合は，プラセボ群 3.2%（9/281 例），50 mg 群 3.9%（6/154 例）及び 100 mg 群 5.8%（54/926 例）であった。同一被験者で 2 回以上の好中球絶対数減少の発現割合は，プラセボ群 1.1%（3/281 例），50 mg 群 1.3%（2/154 例）及び 100 mg 群 1.8%（17/926 例）であった。8 例では好中球絶対数が 1.0×10^3/μL 未満まで減少したが，一過性であった。別の 2 例では 2 回，好中球絶対数が 1.0×10^3/μL 未満まで減少した。これらの被験者で重篤な感染症は報告されなかった。

T18 試験（54 週まで）の血液学的検査値の最大グレードは群間でおおむね同様であり，グレード 3 以上の血液学的検査値の異常は少なかった（【5.3.5.1.3-1】Attachment 4.51）。グレード 4 の血液学的検査値の多くは一過性であった。

3) T18 試験（54 週から 228 週まで，全投与被験者）

T18 試験（54 週から 228 週まで）に最も多く認められた血液学的検査値の顕著な異常は，リンパ球数減少であった［プラセボ群 21.9%（21/96 例），50 mg 群 26.9%（25/93 例）及び 100 mg 群 20.9%（109/522 例）］。同一被験者で 2 回以上のリンパ球数減少の発現割合は，プラセボ群 9.4%（9/96 例），50 mg 群 14.0%（13/93 例）及び 100 mg 群 11.3%（59/522 例）であった（【5.3.5.1.3-2】Attachment TSFLAB02）。

好中球絶対数減少の発現割合は，プラセボ群 1.0%（1/96 例），50 mg 群 7.5%（7/93 例）及び 100 mg 群 5.7%（30/522 例）であった。同一被験者で 2 回以上の好中球絶対数減少の発現割合は，プラセボ群 0%（0/96 例），50 mg 群 1.1%（1/93 例）及び 100 mg 群 1.5%（8/522 例）であった。全ゴリムマブ群の 3 例では，好中球絶対数が 1.0×10^3/μL 未満まで減少したが一過性であった。別の 1 例に重篤な再生不良性貧血が報告された。これらの被験者で重篤な感染症は報告されなかった（【5.3.5.1.3-2】Attachment LSFLAB03）。

T18 試験（54 週から 228 週まで）の血液学的検査値の最大グレードは群間でおおむね同様であり，グレード 3 以上の血液学的検査値の異常は少なかった（【5.3.5.1.3-2】Attachment TSFLAB05）。グレード 4 の血液学的検査値はわずかで，多くは一過性であった。

2.7.4.3.1.2 日本人集団

(1) T17 試験の日本人部分集団

T17 試験（6 週まで）の日本人で最も多く認められた血液学的検査値の顕著な異常は，リンパ球数減少であった［プラセボ群 6.7%（2/30 例）及び全ゴリムマブ群 4.8%（2/42 例）］【表 2.7.4.7-付録-72】。同一被験者で 2 回以上のリンパ球数減少の発現割合は，プラセボ群 3.3%（1/30 例）及び全ゴリムマブ群 2.4%（1/42 例）であった。

T17 試験（6 週まで）の日本人でグレード 3 以上の血液学的検査値の異常は少なく，ヘモグロビン減少［プラセボ群 6.7%（2/30 例）及び全ゴリムマブ群 4.8%（2/42 例）］並びにリンパ球数減少［プラセボ群 10.0%（3/30 例）及び全ゴリムマブ群 4.8%（2/42 例）］のみであった【表 2.7.4.7-付録-73】。

(2) T18 試験の日本人部分集団（全投与被験者）

T18 試験（54 週まで）の日本人の全ゴリムマブ群に最も多く認められた血液学的検査値の顕著な異常は，リンパ球数減少であった［プラセボ群 62.5%（5/8 例）及び全ゴリムマブ群 16.7%（10/60 例）］。同一被験者で 2 回以上のリンパ球数減少は，プラセボ群 25.0%（2/8 例），全ゴリムマブ群 5.0%（3/60 例）で認められた【表 2.7.4.7-付録-74】。

T18 試験（54 週まで）の日本人にグレード 3 以上の血液学的検査値の異常は少なく，ヘモグロビン減少［プラセボ群 0%（0/8 例）及び全ゴリムマブ群 3.4%（2/60 例）］並びにリンパ球数減少［プラセボ群 12.5%（1/8 例）及び全ゴリムマブ群 8.3%（5/60 例）］のみであった【表 2.7.4.7-付録-75】。

(3) UCO3001 試験

1) 寛解導入期

UCO3001 試験の寛解導入期に最も多く認められた血液学的検査値の顕著な異常は，リンパ球数減少［8.3%（12/144 例）］であった（【5.3.5.1.5】Attachment TSFLABABN01IN）。同一被験者で 2 回以上のリンパ球数減少はなかった。

好中球絶対数減少の発現割合は 6.9%（10/144 例）であった。同一被験者で 2 回以上の好中球絶対数減少は 1.4%（2/144 例）であった。

グレード 3 以上の血液学的検査値の異常は少なく，ヘモグロビン減少 1.4%（2/144 例），好中球絶対数減少 0.7%（1/144 例）及びリンパ球数減少 0.7%（1/144 例）のみであった（【5.3.5.1.5】Attachment TSFLABGR01IN）。

2) 寛解維持期

a) ランダム化された被験者

UCO3001 試験の寛解維持期のランダム化された被験者に最も多く認められた血液学的検査値の顕著な異常は，リンパ球数減少［プラセボ群 40.0%（12/30 例）及び 100 mg 群 12.5%（4/32 例）］であった（【5.3.5.1.5】Attachment TSFLABABN01DB）。同一被験者で 2 回以上のリンパ球数減少の発現割合は，プラセボ群 20.0%（6/30 例）及び 100 mg 群 3.1%（1/32 例）であった。

UCO3001 試験の寛解維持期のランダム化された被験者に認められたグレード 3 以上の血液学的検査値の異常は，ヘモグロビン減少［プラセボ群 3.3%（1/30 例）及び 100 mg 群 0%（0/32 例）］並びに好中球絶対数減少［プラセボ群 0%（0/30 例）及び 100 mg 群 3.1%（1/32 例）］であった（【5.3.5.1.5】Attachment TSFLABGR01DB）。

b) 全投与被験者

UCO3001 試験の寛解維持期の全投与被験者に最も多く認められた血液学的検査値の顕著な異常は，リンパ球数減少であった［プラセボ群 40.0%（12/30 例）及び 100 mg 群 22.9%（25/109

例）］（【5.3.5.1.5】Attachment TSFLABABN01MA）。同一被験者で 2 回以上のリンパ球数減少の発現割合は，プラセボ群 20.0%（6/30 例）及び 100 mg 群 9.2%（10/109 例）であった。

好中球絶対数減少の発現割合は，プラセボ群 3.3%（1/30 例）及び 100 mg 群 13.8%（15/109 例）であった。同一被験者で 2 回以上の好中球絶対数減少の発現割合は，プラセボ群 0%（0/30 例）及び 100 mg 群 4.6%（5/109 例）であった。

寛解維持期に全投与被験者で認められたグレード 3 以上の血液学的検査値の異常は，ヘモグロビン減少［プラセボ群 3.3%（1/30 例）及び 100 mg 群 1.8%（2/109 例）］，好中球絶対数減少［0%（0/30 例）及び 2.8%（3/109 例）］，並びにリンパ球数減少［0%（0/30 例）及び 1.8%（2/109 例）］であった（【5.3.5.1.5】Attachment TSFLABGR01MA）。

2.7.4.3.2 血液生化学検査

各検査項目の顕著な異常，並びに総ビリルビン，ALT 及び AST の上昇について検討した。

2.7.4.3.2.1 国際共同試験

(1) T16 試験

T16 試験（6 週まで）に認められた血液生化学検査値の顕著な異常は少なく，同一被験者で 2 回以上の ALT 又は AST の顕著な異常は認められなかった（【5.3.5.1.1】Attachment 4.38）。

全ゴリムマブ群の 1 例で，ALT 及び AST の最大値が基準値上限の 5～8 倍の値になったが，いずれも一過性であった。本被験者の総ビリルビン値に異常はなく，この ALT 及び AST の上昇は有害事象とは報告されなかった（【5.3.5.1.1】Attachment 4.42，Attachment 4.43）。

(2) T17 試験

T17 試験（6 週まで）に認められた血液生化学検査値の顕著な異常は少なく，カリウム増加［プラセボ群 0%（0/330 例）及び全ゴリムマブ群 1.1%（8/730 例）］を除き，発現割合はプラセボ群及び全ゴリムマブ群で同程度であった（【5.3.5.1.2】Attachment 4.77）。同一被験者で 2 回以上認められた血液生化学検査値の顕著な異常は，カリウム増加［200→100 mg 群及び 400→200 mg 群で各 0.3%（1/330 例）］のみであった。

ALT 及び AST の最大値が基準値上限の 3 倍を超えた被験者は少数であり，群間で大きな差はなかった（【5.3.5.1.2】Attachment 4.78，Attachment 4.79）。全ゴリムマブ群の 2 例（100 mg → 50 mg 群及び 400 mg → 200 mg 群の各 1 例）で総ビリルビンの最大値が基準値上限の 2 倍を超えたが，この 2 例のいずれでも ALT 及び AST の臨床的に意義のある変化は認められなかった（【5.3.5.1.2】Attachment 4.80）。

(3) T18 試験

1) T18 試験（54 週まで，ランダム化された被験者）

T18 試験（54 週まで）のランダム化された被験者で認められた血液生化学検査値の顕著な異常は少なく，群間に大きな差はなかった（【5.3.5.1.3-1】Attachment 4.54）。

ALT 及び AST の最大値が基準値上限の 3 倍を超えた被験者は少数であり，群間に大きな差はなかった（【5.3.5.1.3-1】Attachment 4.58，Attachment 4.59）。プラセボ群 1 例及び 50 mg 群 2 例では，ALT の最大値が基準値上限の 3 倍を超え，かつ，総ビリルビンの最大値が基準値上限の 2

倍を超えたが，いずれも一過性であり，また，治験薬投与中に消失したため，薬物性肝障害とは考えられなかった。

2) T18 試験（54 週まで，全投与被験者）

T18 試験（54 週まで）の全投与被験者で認められた血液生化学検査値の顕著な異常は少なく，2 回以上の顕著な異常を発現した被験者も少数であった（【5.3.5.1.3-1】Attachment 4.56）。

全投与被験者で認められた血液生化学検査値の顕著な異常は，ランダム化された被験者の項で示した以外にはなかった。

3) T18 試験（54 週から 228 週まで，全投与被験者）

T18 試験（54 週から 228 週まで）で認められた血液生化学検査値の顕著な異常は少なく，カリウム増加［プラセボ群 1.0%（1/96 例），50 mg 群 9.7%（9/93 例）及び 100 mg 群 5.2%（27/522 例）］を除き，群間で同程度であった（【5.3.5.1.3-2】Attachment TSFLAB01）。

T18 試験 54 週に ALT が正常範囲内だった被験者のうち，228 週までに ALT の最大値が基準値上限の 3 倍を超えた被験者はプラセボ群 1 例及び全ゴリムマブ群 9 例であった。T18 試験 54 週に AST が正常範囲内だった被験者のうち，228 週までに AST の最大値が基準値上限の 3 倍を超えた被験者数は全ゴリムマブ群 6 例であり，プラセボ群ではいなかった。このうち 100 mg 群の 1 例（被験者 ID：6078-00002）は，重篤な急性 A 型肝炎のため治験薬投与を中止した。そのほかは，いずれも一過性であり，治験薬投与中に消失した（【5.3.5.1.3-2】Attachment TSFLAB03，Attachment TSFLAB04，Attachment LSFLAB01）。

総ビリルビンの最大値が基準値上限の 2 倍を超えた被験者は，100 mg 群の 4 例のみであった。このうち 1 例は，上述の被験者（被験者 ID：6078-00002）であった（【5.3.5.1.3-2】Attachment TSFLAB06）。

2.7.4.3.2.2 日本人集団

(1) T17 試験の日本人部分集団

T17 試験（6 週まで）に日本人で認められた血液生化学検査値の顕著な異常はわずかであり，群間に大きな差は認められなかった。2 回以上の顕著な異常が認められた被験者はいなかった。【表 2.7.4.7-付録-76】

ALT 及び AST の最大値が基準値上限の 3 倍を超えた被験者及び総ビリルビンの最大値が基準値上限の 2 倍を超えた被験者はいなかった【表 2.7.4.7-付録-77】，【表 2.7.4.7-付録-78】，【表 2.7.4.7-付録-79】。

(2) T18 試験の日本人部分集団（全投与被験者）

T18 試験（54 週まで）に日本人で認められた血液生化学検査値の顕著な異常はわずかであり，群間に大きな差はなかった。【表 2.7.4.7-付録-80】。

T18 試験（54 週まで）に日本人で ALT 及び AST の最大値が基準値上限の 3 倍を超えた被験者はいなかった【表 2.7.4.7-付録-81】【表 2.7.4.7-付録-82】。総ビリルビンの最大値が基準値上限の 2 倍を超えた被験者は全ゴリムマブ群の 3 例（発現割合 5.0%）であり，プラセボ群ではいなかった【表 2.7.4.7-付録-83】。

(3) UCO3001 試験

1) 寛解導入期

UCO3001 試験の寛解導入期に認められた血液生化学検査値の顕著な異常は無機リン酸塩減少のみであり，発現割合は 1.4%（2/144 例）であった。2 回以上の顕著な異常が認められた被験者はいなかった（【5.3.5.1.5】Attachment TSFLABABN02IN）。

総ビリルビンが基準値上限の 2 倍を超えた被験者は 1 例であった。ALT 及び AST が基準値上限の 3 倍を超えた被験者はいなかった（【5.3.5.1.5】Attachments TSFLABMAX01IN, TSFLABMAX02IN，TSFLABMAX03IN）。

2) 寛解維持期

a) ランダム化された被験者

UCO3001 試験の寛解維持期に，ランダム化された被験者で認められた血液生化学検査値の顕著な異常は，投与量調節群（プラセボ→100 mg 群）の無機リン酸塩減少 1 例のみであった。2 回以上の顕著な異常が認められた被験者はいなかった（【5.3.5.1.5】Attachment TSFLABABN02DB）。

総ビリルビンの最大値が基準値上限の 2 倍を超えた被験者は，プラセボ群 1 例及び投与量調節群（プラセボ→100 mg 群）1 例のみであった。維持期 0 週に ALT 又は AST が正常範囲内だった被験者のうち，維持期 54 週までに ALT の最大値が基準値上限の 3 倍を超えた被験者及び AST の最大値が基準値上限の 3 倍を超えた被験者はいなかった（【5.3.5.1.5】Attachments TSFLABMAX01DB，Attachments TSFLABMAX02DB，Attachments TSFLABMAX03DB）。

b) 全投与被験者

UCO3001 試験の寛解維持期に，全投与被験者で認められた血液生化学検査値の顕著な異常は，100 mg 群で認められた無機リン酸塩減少［0.9%（1/109 例）］のみであった（【5.3.5.1.5】Attachment TSFLABABN02MA）。2 回以上の血液生化学検査値の顕著な異常を発現した被験者はいなかった。ランダム化された被験者の項で示した以外に血液生化学検査値の顕著な異常は認められなかった（【5.3.5.1.5】Attachments TSFLABMAX01MA，TSFLABMAX02MA, TSFLABMAX03MA）。

2.7.4.4 バイタルサイン，身体所見及び安全性に関連する他の観察項目

2.7.4.4.1 バイタルサイン及び身体所見

治験担当医師がバイタルサイン及び身体所見をモニタリングし，重要な変化は有害事象として報告した。モニタリングで得られた測定データは解析用のデータベースには含めなかった。

2.7.4.4.2 抗核抗体（ANA）及び抗 dsDNA 抗体

2.7.4.4.2.1 抗核抗体（ANA）

ANA 検査では抗体価 1:160 以上を ANA 陽性とした。

(1) 国際共同試験

1) T16 試験

T16 試験の 0 週に ANA 陰性であった被験者のうち，6 週までに ANA 陽性を示した被験者の割合は，プラセボ群 1.6%（1/63 例）及び全ゴリムマブ群 1.7%（3/180 例）であり，群間でおおむね同程度であった（【5.3.5.1.1】Attachment 4.44）。

2) T17 試験

T17 試験の 0 週に ANA 陰性であった被験者のうち，6 週までに ANA 陽性を示した被験者の割合は，プラセボ群 2.4%（7/293 例），200 mg→100 mg 群 0.7%（2/295 例）及び 400 mg→200 mg 群 0.7%（2/298 例）であった（【5.3.5.1.2】Attachment 4.98）。

3) T18 試験

a) T18 試験（54 週まで）

T18 試験のランダム化された被験者で，T18 試験の 0 週に ANA 陰性であった被験者のうち，54 週までのいずれかの時点で ANA 陽性を示した被験者の割合は，プラセボ群 1.7%（2/118 例），50 mg 群 4.3%（6/139 例）及び 100 mg 群 2.9%（4/136 例）であった（【5.3.5.1.3-1】Attachment 4.79）。全投与被験者では，それぞれ 2.7%（6/219 例），4.3%（6/139 例）及び 3.8%（31/819 例）であった（【5.3.5.1.3-1】Attachment 4.81）。

b) T18 試験（54 週から 228 週まで）

T18 試験の 54 週に ANA 陰性であった被験者のうち，54 週以降のいずれかの時点で ANA 陽性を示した被験者の割合は，プラセボ群 0.0%（0/76 例），50 mg 群 4.7%（4/86 例），100 mg 群 5.1%（24/474 例）であった（【5.3.5.1.3-2】Attachment TSFLAB07，Attachment LSFLAB05）。

(2) 日本人集団

1) UCO3001 試験

UCO3001 試験の寛解導入期では，0 週に ANA 陰性であった被験者 125 例のうち，ANA 陽性を示した被験者の割合は 2.4%（3/125 例）であった（【5.3.5.1.5】Attachments TIRANA01）。

寛解維持期では，維持期 0 週に ANA 陰性であった被験者のうち，54 週までのいずれかの時点で ANA 陽性を示した被験者は，投与量調節群（プラセボ→100 mg 群）の 1 例のみであった（【5.3.5.1.5】Attachments TIRANA02，Attachments TIRANA04）。

2.7.4.4.2.2 抗 dsDNA 抗体

(1) 国際共同試験

1) T16 試験

T16 試験では，抗 dsDNA 抗体陽性の被験者はいなかった（【5.3.5.1.1】Attachment 4.45，Attachment 4.46）。

2) T17 試験

T17 試験では，抗 dsDNA 抗体陽性の被験者はいなかった（【5.3.5.1.2】Attachment 4.100）。

3) T18 試験

a) T18 試験（54 週まで）

T18 試験の 0 週に抗 dsDNA 抗体陽性の被験者はいなかった。54 週までに抗 dsDNA 抗体陽性を示した被験者の発現割合は，ランダム化された被験者では 50 mg 群 0.7%（1/140 例）及び 100 mg 群 0.7%（1/139 例），全投与被験者では 50 mg 群 0.7%（1/140 例）及び 100 mg 群 0.4%（3/855 例）であり，プラセボ群ではいなかった（【5.3.5.1.3-1】Attachment 4.83，Attachment 4.85）。

b) T18 試験（54 週から 228 週まで）

T18 試験の 54 週に抗 dsDNA 抗体陰性であった被験者のうち，54 週以降に抗 dsDNA 抗体が陽性であった被験者の発現割合は，100 mg 群で 1.2%（6/497 例）であり，プラセボ群及び 50 mg 群ではいなかった（【5.3.5.1.3-2】Attachment TSFLAB08）。

(2) 日本人集団

1) UCO3001 試験

UCO3001 試験では，抗 dsDNA 抗体陽性の被験者はいなかった（【5.3.5.1.5】Attachments TIRDSDNA01，Attachments TIRDSDNA02 及び Attachments TIRDSDNA04）。

2.7.4.4.3 抗ゴリムマブ抗体及び注射部位反応

(1) 国際共同試験

1) T16 試験

T16 試験では，評価可能な検体が採取された被験者 206 例に，抗ゴリムマブ抗体陽性の被験者はいなかった（【5.3.5.1.1】Attachment 2.2）。

2) T17 試験

T17 試験では，評価可能な検体が採取された被験者 721 例のうち，抗ゴリムマブ抗体陽性の被験者の割合は 0.4%（3/721 例）であった（【5.3.5.1.2】Table 9）。この 3 例（200→100 mg 群 1 例，400→200 mg 群 2 例）の抗体価はいずれも低かった（【5.3.5.1.2】Attachment 2.7）。

3) T18 試験

T18 試験（54 週まで）に評価可能な検体が採取された全投与被験者 1103 例のうち，抗ゴリムマブ抗体陽性の被験者の割合は 2.9%（32/1103 例）であった（【5.3.5.1.3-1】Table 4）。

T18 試験（54 週まで）の抗ゴリムマブ抗体と注射部位反応との関連を，ランダム化された被験者及び全投与被験者で評価した（【5.3.5.1.3-1】Attachment 4.86 及び Attachment 4.88）。ゴリムマブを投与され，評価可能な検体が採取された被験者 1020 例のうち，抗ゴリムマブ抗体陽性の被験者 25 例に注射部位反応の報告はなかった。抗ゴリムマブ抗体陰性の被験者 995 例のうち 31 例（3.1%）に注射部位反応が発現したが，いずれも高度又は重篤とは判断されず，また，治験薬の投与中止には至らなかった。

(2) 日本人集団

1) T17 試験の日本人部分集団

T17 試験の日本人 72 例に，抗ゴリムマブ抗体陽性の被験者はいなかった【表 2.7.4.7-付録-84】。

2) T18 試験の日本人部分集団（全投与被験者）

T18 試験（54 週まで）の日本人で評価可能な検体が採取された被験者のうち，抗ゴリムマブ抗体陽性を示した被験者は 2 例であった。1 例は T17 試験で 400 mg→200 mg 群，T18 試験で 100 mg 群に割り付けられた被験者であり，1 例はプラセボのみ投与された被験者であった【表 2.7.4.7-付録-85】。

3) UCO3001 試験

UCO3001 試験の全投与被験者で評価可能な検体が採取された被験者のうち，導入期 0 週から維持期 54 週までのいずれかの時点で抗ゴリムマブ抗体陽性を示した被験者の割合は，維持期 0 週の投与群別に，プラセボ群 12.9%（4/31 例）及び 100 mg 群 1.1%（1/92 例）であった（【5.3.5.1.5】TIRANTI04）。

UCO3001 試験の寛解導入期に，抗ゴリムマブ抗体陽性を示した被験者はいなかった（【5.3.5.1.5】TIRANTI01）。

UCO3001 試験の寛解維持期の全投与被験者において，抗ゴリムマブ抗体と注射部位反応との関連を評価した。評価可能な検体が採取された被験者のうち，全ゴリムマブ群の抗ゴリムマブ抗体陰性の被験者 15.3%（9/59 例）に注射部位反応が発現したが，いずれも高度又は重篤とは判断されず，また，治験薬の投与中止には至らなかった。そのほかの被験者に注射部位反応の報告はなかった（【5.3.5.1.5】TSFAEINJ02MA）。

国際共同試験及び国内試験とも，抗ゴリムマブ抗体陽性例は少数であったが，抗ゴリムマブ抗体陽性の被験者に注射部位反応の発現はなく，抗ゴリムマブ抗体と注射部位反応との関連は示唆されなかった。

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

2.7.4.5.1.1 人口統計学的特性

性別，人種（白人又は白人以外），年齢カテゴリー及び体重カテゴリーに基づき部分集団を設定し，すべての有害事象，重篤な有害事象，治験薬の投与中止に至った有害事象及び感染症の発現割合を評価した。

いずれの人口統計学的特性についても，T16，T17 及び T18 試験（54 週まで）の部分集団間で，有害事象の発現割合に明確な差は認められなかった【表 2.7.4.7-付録-86】，【表 2.7.4.7-付録-87】，【表 2.7.4.7-付録-88】及び【表 2.7.4.7-付録-89】。なお，人種別の解析では白人以外の被験者が少数であり，結果の解釈には注意が必要である。

日本人被験者では部分集団での解析は行っていない。

2.7.4.5.1.2 疾患特性

ベースライン時の UC の重症度（Mayo スコア）カテゴリー，罹病期間カテゴリー及び罹患範囲に基づき部分集団を設定し，すべての有害事象，重篤な有害事象，治験薬の投与中止に至った有害事象及び感染症の発現割合を評価した。

いずれの疾患特性についても，T16，T17 及び T18 試験（54 週まで）の部分集団間で，有害事象の発現割合に明確な差は認められなかった【表 2.7.4.7-付録-90】，【表 2.7.4.7-付録-91】，【表 2.7.4.7-付録-92】，【表 2.7.4.7-付録-93】。

日本人被験者では部分集団での解析は行っていない。

2.7.4.5.2 外因性要因

UC 患者で併用薬として使用される可能性が高い免疫調節薬の影響を，ベースライン時の併用の有無別に評価した。

T16，T17 及び T18 試験（54 週まで）のランダム化された被験者及び全投与被験者の，死亡，治験薬の投与中止に至った有害事象，有害事象，重篤な有害事象，感染症，重篤な感染症，悪性新生物及び注射部位反応の発現割合において，ベースライン時の免疫調節薬の併用の有無に基づく明確な差は認められなかった【表 2.7.4.7-付録-94】，【表 2.7.4.7-付録-95】。

日本人被験者では部分集団での解析は行っていない。

2.7.4.5.3 薬物相互作用

ゴリムマブに関して薬物相互作用を検討する試験は実施されていない。

2.7.4.5.4 妊娠及び授乳時の使用

妊婦又は授乳婦を対象とした試験は実施されていない。

2.7.4.5.5 過量投与

臨床試験では 10 mg/kg までのゴリムマブ単回静脈内投与が行われ，毒性作用は認められなかった。

2.7.4.5.6 薬物乱用

ゴリムマブに起因する薬物嗜癖又は薬物乱用の可能性は示唆されていない。

2.7.4.5.7 離脱症状及び反跳現象

ゴリムマブの離脱症状及び反跳現象に関する正式な試験は実施されていない。

2.7.4.5.8 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

ゴリムマブによる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は明らかではなく，正式な試験は実施されていない。

2.7.4.6 市販後データ

2.7.4.6.1 全世界（日本を含む）

2.7.4.6.1.1 定期的安全性最新報告（PSUR）

ゴリムマブの最新の Periodic Benefit Risk Evaluation Report/Periodic Safety Update Report（PBRER/PSUR）は 2016 年 5 月に発行された（集積期間：2015 年 4 月 7 日～2016 年 4 月 6 日）。本 PBRER/PSUR によると，世界全体で，臨床試験でのゴリムマブの累積投与数は 11990 例，市販のゴリムマブの投与数は，この集積期間で 190106 例，累積で 446445 例と推計される。ゴリム

マブの安全性プロファイルは良好で，臨床試験で確立された安全性プロファイルと同様であり，過去の PBRER/PSUR 等の評価結果と一致していた【5.3.6.1】。

2.7.4.6.1.2 重篤な有害事象

国際誕生日である 2009 年 4 月 7 日以降，自発報告されたゴリムマブの有害事象情報が米国 Johnson & Johnson 社のデータベースに集積されている。2016 年 4 月 6 日までに報告された重篤な有害事象は 9749 件であった。報告件数の多い重篤な有害事象は，肺炎 284 件，下気道感染 280 件，関節リウマチ 185 件，尿路感染 143 件，死亡 99 件等であった【5.3.6.3】。

2.7.4.6.2 国内

2.7.4.6.2.1 市販後安全性調査

日本では，2011 年 7 月 1 日に「既存治療で効果不十分な関節リウマチ（関節の構造的損傷の防止を含む）」の効能・効果で承認され，2011 年 9 月から市販されている。承認後，以下の使用成績調査，特定使用成績調査及び製造販売後臨床試験を実施した。

- 使用成績調査（調査期間：2011 年 9 月 16 日～2014 年 1 月 31 日）
- 長期使用に関する特定使用成績調査（調査期間：2011 年 9 月 16 日～2014 年 2 月 28 日）
- 悪性腫瘍及び重篤な感染症に関する特定使用成績調査（調査期間：2011 年 9 月 16 日～2014 年 10 月 31 日）
- 製造販売後臨床試験（試験期間：2011 年 7 月 1 日～2011 年 9 月 16 日）

最新の安全性定期報告書の調査単位期間終了日（2016 年 4 月 6 日）までに，安全性解析対象症例 6024 例のうち，重篤な有害事象は 541 例（734 件）に認められ，発現割合は 8.98%（541/6024 例）であった。発現割合が高い重篤な有害事象は，肺炎 0.90%（54/6024 例），間質性肺疾患 0.50%（30/6024 例），肝機能異常 0.40%（24/6024 例），転倒 0.33%（20/6024 例）等であった【5.3.6.2】。

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Hematology Test	**Criteria for Markedly Abnormal Status**
Hemoglobin (g/dL)	Decrease > 2 & Value < 8.0
Hematocrit (%)	Value < 27
Platelets ($\times 10^3/\mu L$)	Percent decrease ≥ 50 & Value < 75
Total WBC ($\times 10^3/\mu L$)	Value < 2.0 OR Value > 20.0
Eosinophils, absolute ($\times 10^3/\mu L$)	Percent increase ≥ 100 & Value > 1.3
Lymphocytes, absolute ($\times 10^3/\mu L$)	Percent decrease ≥ 33 & Value < 1.5
Neutrophils, absolute ($\times 10^3/\mu L$)	Percent decrease ≥ 33 & Value < 1.5
Chemistry Test	**Criteria for Markedly Abnormal Status**
BUN/Urea (mg/dL)	Percent increase ≥ 66 & Value > 40
Creatinine (mg/dL)	Percent increase ≥ 66 & Value > 1.5
Total Bilirubin (mg/dL)	Percent increase ≥ 100 & Value > 3.0
Alkaline phosphatase (IU/L)	Percent increase ≥ 100 & Value > 250
ALT (IU/L)	Percent increase ≥ 100 & Value > 150
AST (IU/L)	Percent increase ≥ 100 & Value > 150
Sodium (mEq/L)	(Increase ≥ 10 & Value > 150) OR (Decrease ≥ 10 & Value < 120)
Potassium (mEq/L)	(Increase ≥ 0.8 & Value > 5.5) OR (Decrease ≥ 0.8 & Value < 3.0)
Chloride (mEq/L)	Value < 85 OR Value > 120
Calcium (mg/dL)	(Increase ≥ 1.5 & Value > 10.5) OR (Decrease ≥ 1.5 & Value < 7.5)
Phosphorus (mg/dL)	(Increase ≥ 2.5 & Value > 6.0) OR (Decrease ≥ 1.0 & Value < 2.0)
Albumin (g/dL)	Decrease ≥ 1.0 & Value < 3.0
Total protein (g/dL)	Value < 4.5 OR Value > 10.0

表 2.7.4.7-付録-2 ベースライン時の主な人口統計学的特性（T16 試験及び T17 試験，日本人 vs 外国人）

	Japanese			Non-Japanese			Total		
	Placebo	Golimumab	Total	Placebo	Golimumab	Total	Placebo	Golimumab	Total
Randomized subjects in C0524T16 and C0524T17	30	42	72	378	906	1284	408	948	1356
Sex									
n	30	42	72	378	906	1284	408	948	1356
Male	19 (63.3%)	25 (59.5%)	44 (61.1%)	203 (53.7%)	523 (57.7%)	726 (56.5%)	222 (54.4%)	548 (57.8%)	770 (56.8%)
Female	11 (36.7%)	17 (40.5%)	28 (38.9%)	175 (46.3%)	383 (42.3%)	558 (43.5%)	186 (45.6%)	400 (42.2%)	586 (43.2%)
Race									
n	30	42	72	378	906	1284	408	948	1356
Caucasian	0 (0.0%)	0 (0.0%)	0 (0.0%)	325 (86.0%)	788 (87.0%)	1113 (86.7%)	325 (79.7%)	788 (83.1%)	1113 (82.1%)
Black	0 (0.0%)	0 (0.0%)	0 (0.0%)	13 (3.4%)	18 (2.0%)	31 (2.4%)	13 (3.2%)	18 (1.9%)	31 (2.3%)
Asian	30 (100.0%)	42 (100.0%)	72 (100.0%)	29 (7.7%)	69 (7.6%)	98 (7.6%)	59 (14.5%)	111 (11.7%)	170 (12.5%)
Other	0 (0.0%)	0 (0.0%)	0 (0.0%)	11 (2.9%)	31 (3.4%)	42 (3.3%)	11 (2.7%)	31 (3.3%)	42 (3.1%)
Age (yrs)									
n	30	42	72	378	906	1284	408	948	1356
Mean ± SD	39.6 ± 13.78	38.0 ± 13.28	38.7 ± 13.42	39.4 ± 12.91	40.7 ± 13.66	40.3 ± 13.45	39.4 ± 12.96	40.6 ± 13.65	40.2 ± 13.45
Median	40.0	35.5	37.0	38.0	39.0	39.0	38.0	39.0	38.0
IQ range	(26.0, 51.0)	(27.0, 52.0)	(26.5, 51.0)	(29.0, 49.0)	(29.0, 50.0)	(29.0, 50.0)	(29.0, 49.0)	(29.0, 50.0)	(29.0, 50.0)
Range	(19, 68)	(18, 68)	(18, 68)	(18, 72)	(18, 79)	(18, 79)	(18, 72)	(18, 79)	(18, 79)
Weight (kg)									
n	30	42	72	377	906	1283	407	948	1355
Mean ± SD	60.56 ± 11.094	59.05 ± 11.411	59.68 ± 11.226	73.68 ± 18.223	74.15 ± 18.018	74.01 ± 18.073	72.71 ± 18.114	73.48 ± 18.043	73.25 ± 18.061
Median	59.00	57.30	58.00	72.00	72.65	72.20	70.90	72.00	71.70
IQ range	(52.00, 67.30)	(53.20, 65.00)	(52.85, 66.50)	(60.00, 84.60)	(61.00, 84.90)	(60.90, 84.90)	(59.00, 83.00)	(60.00, 84.00)	(60.00, 84.00)
Range	(43.2, 88.6)	(37.4, 87.0)	(37.4, 88.6)	(37.9, 140.0)	(33.0, 150.0)	(33.0, 150.0)	(37.9, 140.0)	(33.0, 150.0)	(33.0, 150.0)
Height (cm)									
n	30	42	72	378	905	1283	408	947	1355
Mean ± SD	166.3 ± 8.18	165.3 ± 7.95	165.7 ± 8.01	170.5 ± 10.24	171.1 ± 9.74	170.9 ± 9.89	170.2 ± 10.15	170.8 ± 9.74	170.7 ± 9.87
Median	166.5	166.5	166.5	170.0	171.0	170.0	170.0	170.0	170.0
IQ range	(164.0, 171.0)	(159.0, 172.0)	(160.0, 171.0)	(163.0, 178.0)	(164.0, 178.0)	(164.0, 178.0)	(163.0, 178.0)	(164.0, 178.0)	(164.0, 178.0)
Range	(143, 182)	(150, 180)	(143, 182)	(142, 196)	(136, 205)	(136, 205)	(142, 196)	(136, 205)	(136, 205)

表 2.7.4.7-付録-3 ベースライン時の主な疾患特性（T16 試験及び T17 試験，日本人 vs 外国人）

	Japanese			Non-Japanese			Total		
	Placebo	Golimumab	Total	Placebo	Golimumab	Total	Placebo	Golimumab	Total
Randomized subjects in C0524T16 and C0524T17	30	42	72	378	906	1284	408	948	1356
UC disease duration (yrs)									
n	30	42	72	378	906	1284	408	948	1356
Mean ± SD	7.92 ± 8.739	7.20 ± 5.592	7.50 ± 7.027	6.03 ± 6.440	6.48 ± 6.459	6.34 ± 6.454	6.16 ± 6.641	6.51 ± 6.422	6.41 ± 6.488
Median	4.51	4.78	4.75	4.03	4.39	4.26	4.12	4.43	4.31
IQ range	(2.74, 8.80)	(3.61, 9.15)	(3.12, 9.05)	(1.88, 8.05)	(2.00, 8.90)	(1.96, 8.65)	(1.97, 8.15)	(2.04, 8.93)	(2.02, 8.69)
Range	(0.1, 39.1)	(0.3, 24.4)	(0.1, 39.1)	(0.1, 48.3)	(0.1, 41.7)	(0.1, 48.3)	(0.1, 48.3)	(0.1, 41.7)	(0.1, 48.3)
Extent of disease									
n	30	42	72	377	906	1283	407	948	1355
Limited to left side of colon	15 (50.0%)	22 (52.4%)	37 (51.4%)	216 (57.3%)	523 (57.7%)	739 (57.6%)	231 (56.8%)	545 (57.5%)	776 (57.3%)
Extensive	15 (50.0%)	20 (47.6%)	35 (48.6%)	161 (42.7%)	383 (42.3%)	544 (42.4%)	176 (43.2%)	403 (42.5%)	579 (42.7%)
Mayo score (0-12)									
n	30	42	72	378	906	1284	408	948	1356
Mean ± SD	8.4 ± 1.43	8.2 ± 1.69	8.3 ± 1.58	8.3 ± 1.54	8.5 ± 1.47	8.4 ± 1.49	8.3 ± 1.53	8.5 ± 1.48	8.4 ± 1.50
Median	9.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0
IQ range	(7.0, 9.0)	(7.0, 9.0)	(7.0, 9.0)	(7.0, 9.0)	(7.0, 9.0)	(7.0, 9.0)	(7.0, 9.0)	(7.0, 9.0)	(7.0, 9.0)
Range	(6, 11)	(5, 12)	(5, 12)	(5, 12)	(5, 12)	(5, 12)	(5, 12)	(5, 12)	(5, 12)
CRP (mg/L)									
n	30	42	72	364	884	1248	394	926	1320
Mean ± SD	7.53 ± 17.066	9.89 ± 11.853	8.91 ± 14.193	10.92 ± 16.855	12.02 ± 20.877	11.70 ± 19.788	10.66 ± 16.873	11.92 ± 20.555	11.55 ± 19.531
Median	2.99	6.01	4.25	4.72	4.79	4.77	4.47	4.86	4.76
IQ range	(1.21, 6.41)	(2.51, 13.80)	(1.62, 9.68)	(1.29, 12.10)	(1.63, 13.55)	(1.57, 13.20)	(1.28, 11.70)	(1.63, 13.60)	(1.57, 13.00)
Range	(0.1, 94.6)	(0.1, 53.5)	(0.1, 94.6)	(0.1, 110.0)	(0.1, 258.0)	(0.1, 258.0)	(0.1, 110.0)	(0.1, 258.0)	(0.1, 258.0)

表 2.7.4.7-付録-4 ベースライン時の主な UC 治療薬併用（T16 試験及び T17 試験，日本人 vs 外国人）

	Japanese			Non-Japanese			Total		
	Placebo	Golimumab	Total	Placebo	Golimumab	Total	Placebo	Golimumab	Total
Randomized subjects in C0524T16 and C0524T17	30	42	72	378	906	1284	408	948	1356
Any UC medication	30 (100.0%)	40 (95.2%)	70 (97.2%)	351 (92.9%)	843 (93.0%)	1194 (93.0%)	381 (93.4%)	883 (93.1%)	1264 (93.2%)
Corticosteroids (excluding budesonide)	9 (30.0%)	18 (42.9%)	27 (37.5%)	165 (43.7%)	419 (46.2%)	584 (45.5%)	174 (42.6%)	437 (46.1%)	611 (45.1%)
≥ 20 mg/day P.Eq	1 (3.3%)	3 (7.1%)	4 (5.6%)	99 (26.2%)	283 (31.2%)	382 (29.8%)	100 (24.5%)	286 (30.2%)	386 (28.5%)
< 20 mg/day P.Eq	8 (26.7%)	15 (35.7%)	23 (31.9%)	66 (17.5%)	136 (15.0%)	202 (15.7%)	74 (18.1%)	151 (15.9%)	225 (16.6%)
Budesonide	0 (0.0%)	0 (0.0%)	0 (0.0%)	9 (2.4%)	24 (2.6%)	33 (2.6%)	9 (2.2%)	24 (2.5%)	33 (2.4%)
Immunomodulatory drugs	16 (53.3%)	20 (47.6%)	36 (50.0%)	116 (30.7%)	284 (31.3%)	400 (31.2%)	132 (32.4%)	304 (32.1%)	436 (32.2%)
6-mercaptopurine/azathioprine	16 (53.3%)	20 (47.6%)	36 (50.0%)	109 (28.8%)	275 (30.4%)	384 (29.9%)	125 (30.6%)	295 (31.1%)	420 (31.0%)
Methotrexate	0 (0.0%)	0 (0.0%)	0 (0.0%)	7 (1.9%)	9 (1.0%)	16 (1.2%)	7 (1.7%)	9 (0.9%)	16 (1.2%)
Aminosalicylates	28 (93.3%)	35 (83.3%)	63 (87.5%)	310 (82.0%)	737 (81.3%)	1047 (81.5%)	338 (82.8%)	772 (81.4%)	1110 (81.9%)

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表 2.7.4.7-付録-5 すべての有害事象（T16，T17 及び T18 試験 54 週まで；ランダム化された被験者）

	Golimumab Induction				
	Placebo Maintenance[a]	50 mg Maintenance[a]	100 mg Maintenance[a]	Combined 50 mg and 100 mg Maintenance[a]	Total Golimumab[a,b]
Treated subjects in C0524T16 and C0524T17 who were randomized in C0524T18	156	154	154	308	464
Avg duration of follow-up (weeks)	38.8	50.4	52.4	51.4	47.2
Avg exposure (number of administrations)	10.0	12.9	13.1	13.0	12.0
Subjects with 1 or more adverse events	115 (73.7%)	120 (77.9%)	122 (79.2%)	242 (78.6%)	357 (76.9%)
System-organ class/preferred term					
感染症および寄生虫症	51 (32.7%)	63 (40.9%)	67 (43.5%)	130 (42.2%)	181 (39.0%)
鼻咽頭炎	13 (8.3%)	16 (10.4%)	22 (14.3%)	38 (12.3%)	51 (11.0%)
上気道感染	6 (3.8%)	8 (5.2%)	10 (6.5%)	18 (5.8%)	24 (5.2%)
咽頭炎	7 (4.5%)	10 (6.5%)	5 (3.2%)	15 (4.9%)	22 (4.7%)
副鼻腔炎	4 (2.6%)	7 (4.5%)	8 (5.2%)	15 (4.9%)	19 (4.1%)
インフルエンザ	6 (3.8%)	7 (4.5%)	2 (1.3%)	9 (2.9%)	15 (3.2%)
気管支炎	3 (1.9%)	6 (3.9%)	2 (1.3%)	8 (2.6%)	11 (2.4%)
胃腸炎	4 (2.6%)	2 (1.3%)	5 (3.2%)	7 (2.3%)	11 (2.4%)
口腔ヘルペス	3 (1.9%)	3 (1.9%)	2 (1.3%)	5 (1.6%)	8 (1.7%)
尿路感染	4 (2.6%)	3 (1.9%)	1 (0.6%)	4 (1.3%)	8 (1.7%)
外陰腟真菌感染	1 (0.6%)	4 (2.6%)	1 (0.6%)	5 (1.6%)	6 (1.3%)
膀胱炎	1 (0.6%)	2 (1.3%)	2 (1.3%)	4 (1.3%)	5 (1.1%)
毛包炎	3 (1.9%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	5 (1.1%)
ウイルス性胃腸炎	1 (0.6%)	2 (1.3%)	2 (1.3%)	4 (1.3%)	5 (1.1%)
真菌感染	0 (0.0%)	0 (0.0%)	4 (2.6%)	4 (1.3%)	4 (0.9%)
レンサ球菌性咽頭炎	0 (0.0%)	1 (0.6%)	3 (1.9%)	4 (1.3%)	4 (0.9%)
鼻炎	2 (1.3%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	4 (0.9%)
ウイルス感染	0 (0.0%)	3 (1.9%)	1 (0.6%)	4 (1.3%)	4 (0.9%)
虫垂炎	0 (0.0%)	0 (0.0%)	3 (1.9%)	3 (1.0%)	3 (0.6%)
クロストリジウム感染	2 (1.3%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	3 (0.6%)
耳感染	2 (1.3%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	3 (0.6%)
麦粒腫	1 (0.6%)	2 (1.3%)	0 (0.0%)	2 (0.6%)	3 (0.6%)
爪真菌症	1 (0.6%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	3 (0.6%)
肺炎	2 (1.3%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	3 (0.6%)
気道感染	1 (0.6%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	3 (0.6%)
急性副鼻腔炎	1 (0.6%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	2 (0.4%)
急性扁桃炎	0 (0.0%)	2 (1.3%)	0 (0.0%)	2 (0.6%)	2 (0.4%)
せつ	0 (0.0%)	2 (1.3%)	0 (0.0%)	2 (0.6%)	2 (0.4%)
単純ヘルペス	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	2 (0.4%)
帯状疱疹	1 (0.6%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	2 (0.4%)
限局性感染	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	2 (0.4%)
下気道感染	2 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.4%)
外耳炎	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	2 (0.4%)

	Golimumab Induction				
	Placebo Maintenance[a]	50 mg Maintenance[a]	100 mg Maintenance[a]	Combined 50 mg and 100 mg Maintenance[a]	Total Golimumab[a,b]
皮膚感染	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	2 (0.4%)
ブドウ球菌感染	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	2 (0.4%)
足部白癬	1 (0.6%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	2 (0.4%)
癜風	0 (0.0%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	2 (0.4%)
気管炎	0 (0.0%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	2 (0.4%)
創傷感染	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	2 (0.4%)
腹壁膿瘍	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
膿瘍	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
肛門膿瘍	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
肛門性器疣贅	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
細菌感染	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
ボレリア感染	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
脳膿瘍	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
カンジダ症	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
蜂巣炎	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
クロストリジウム・ディフィシレ大腸炎	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
サイトメガロウイルス感染	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
感染性皮膚炎	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
播種性結核	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
感染性小腸結腸炎	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
エンテロウイルス感染	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
丹毒	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
紅色陰癬	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
外耳蜂巣炎	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
ブドウ球菌性眼感染	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
ロタウイルス胃腸炎	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
消化管感染	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
ジアルジア症	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
感染	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
喉頭炎	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
マラリア	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
爪感染	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
口腔カンジダ症	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
口腔真菌感染	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
中耳炎	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
爪囲炎	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
原発性異型肺炎	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
ウイルス性気道感染	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
皮膚細菌感染	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
皮下組織膿瘍	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
白癬感染	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
扁桃炎	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
歯膿瘍	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)

	Golimumab Induction				
	Placebo Maintenance[a]	50 mg Maintenance[a]	100 mg Maintenance[a]	Combined 50 mg and 100 mg Maintenance[a]	Total Golimumab[a,b]
歯感染	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
結核	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
尿道炎	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
ワクチン接種部位感染	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
腟感染	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
ウイルス性上気道感染	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
外陰部腟カンジダ症	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
胃腸障害	55 (35.3%)	55 (35.7%)	65 (42.2%)	120 (39.0%)	175 (37.7%)
潰瘍性大腸炎	29 (18.6%)	27 (17.5%)	24 (15.6%)	51 (16.6%)	80 (17.2%)
腹痛	5 (3.2%)	12 (7.8%)	12 (7.8%)	24 (7.8%)	29 (6.3%)
悪心	3 (1.9%)	8 (5.2%)	9 (5.8%)	17 (5.5%)	20 (4.3%)
下痢	7 (4.5%)	4 (2.6%)	5 (3.2%)	9 (2.9%)	16 (3.4%)
嘔吐	5 (3.2%)	4 (2.6%)	2 (1.3%)	6 (1.9%)	11 (2.4%)
便秘	4 (2.6%)	2 (1.3%)	3 (1.9%)	5 (1.6%)	9 (1.9%)
消化不良	2 (1.3%)	3 (1.9%)	4 (2.6%)	7 (2.3%)	9 (1.9%)
痔核	2 (1.3%)	3 (1.9%)	4 (2.6%)	7 (2.3%)	9 (1.9%)
上腹部痛	1 (0.6%)	5 (3.2%)	2 (1.3%)	7 (2.3%)	8 (1.7%)
血便排泄	2 (1.3%)	1 (0.6%)	5 (3.2%)	6 (1.9%)	8 (1.7%)
腹部膨満	2 (1.3%)	3 (1.9%)	2 (1.3%)	5 (1.6%)	7 (1.5%)
下腹部痛	1 (0.6%)	2 (1.3%)	3 (1.9%)	5 (1.6%)	6 (1.3%)
裂肛	0 (0.0%)	1 (0.6%)	3 (1.9%)	4 (1.3%)	4 (0.9%)
アフタ性口内炎	1 (0.6%)	2 (1.3%)	1 (0.6%)	3 (1.0%)	4 (0.9%)
排便回数増加	2 (1.3%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	4 (0.9%)
胃食道逆流性疾患	1 (0.6%)	1 (0.6%)	2 (1.3%)	3 (1.0%)	4 (0.9%)
直腸ポリープ	1 (0.6%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	3 (0.6%)
歯痛	1 (0.6%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	3 (0.6%)
腹部不快感	0 (0.0%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	2 (0.4%)
肛門直腸不快感	1 (0.6%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	2 (0.4%)
結腸ポリープ	0 (0.0%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	2 (0.4%)
便意切迫	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	2 (0.4%)
齲歯	1 (0.6%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	2 (0.4%)
血性下痢	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	2 (0.4%)
腹部硬直	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
口唇炎	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
大腸炎	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
結腸狭窄	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
口内乾燥	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
鼓腸	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
食中毒	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
胃炎	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
胃腸出血	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
胃腸の炎症	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
歯肉炎	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
肛門肥大乳頭	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)

	Golimumab Induction				
	Placebo Maintenance[a]	50 mg Maintenance[a]	100 mg Maintenance[a]	Combined 50 mg and 100 mg Maintenance[a]	Total Golimumab[a,b]
鼠径ヘルニア	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
粘液便	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
食道浮腫	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
口腔内痛	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
排便痛	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
膵炎	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
直腸炎	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
偽性ポリポーシス	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
直腸出血	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
歯の知覚過敏	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
口内炎	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
皮膚および皮下組織障害	28 (17.9%)	25 (16.2%)	38 (24.7%)	63 (20.5%)	91 (19.6%)
発疹	5 (3.2%)	9 (5.8%)	10 (6.5%)	19 (6.2%)	24 (5.2%)
脱毛症	3 (1.9%)	0 (0.0%)	6 (3.9%)	6 (1.9%)	9 (1.9%)
そう痒症	2 (1.3%)	3 (1.9%)	4 (2.6%)	7 (2.3%)	9 (1.9%)
アレルギー性皮膚炎	6 (3.8%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	8 (1.7%)
皮膚炎	3 (1.9%)	2 (1.3%)	1 (0.6%)	3 (1.0%)	6 (1.3%)
ざ瘡	2 (1.3%)	2 (1.3%)	1 (0.6%)	3 (1.0%)	5 (1.1%)
皮膚乾燥	0 (0.0%)	3 (1.9%)	2 (1.3%)	5 (1.6%)	5 (1.1%)
湿疹	3 (1.9%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	5 (1.1%)
紅斑	2 (1.3%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	4 (0.9%)
乾癬	1 (0.6%)	2 (1.3%)	0 (0.0%)	2 (0.6%)	3 (0.6%)
そう痒性皮疹	0 (0.0%)	1 (0.6%)	2 (1.3%)	3 (1.0%)	3 (0.6%)
蕁麻疹	1 (0.6%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	3 (0.6%)
日光性角化症	1 (0.6%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	2 (0.4%)
滴状乾癬	0 (0.0%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	2 (0.4%)
汗腺炎	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	2 (0.4%)
多汗症	1 (0.6%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	2 (0.4%)
嵌入爪	1 (0.6%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	2 (0.4%)
寝汗	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	2 (0.4%)
痒疹	1 (0.6%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	2 (0.4%)
酒さ	0 (0.0%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	2 (0.4%)
皮膚病変	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	2 (0.4%)
水疱	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
ざ瘡様皮膚炎	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
アトピー性皮膚炎	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
接触性皮膚炎	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
乾癬様皮膚炎	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
皮脂欠乏性湿疹	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
結節性紅斑	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
顔面感覚鈍麻	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
内出血発生の増加傾向	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
脂肪肥大症	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
斑	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)

	Golimumab Induction				
	Placebo Maintenance[a]	50 mg Maintenance[a]	100 mg Maintenance[a]	Combined 50 mg and 100 mg Maintenance[a]	Total Golimumab[a,b]
爪破損	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
光線性皮膚症	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
膿疱性乾癬	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
全身性皮疹	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
斑状皮疹	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
斑状丘疹状皮疹	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
瘢痕	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
瘢痕痛	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
脂漏性皮膚炎	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
ひび・あかぎれ	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
皮膚亀裂	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
皮膚色素減少	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
皮膚刺激	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
筋骨格系および結合組織障害	30 (19.2%)	27 (17.5%)	30 (19.5%)	57 (18.5%)	87 (18.8%)
関節痛	14 (9.0%)	12 (7.8%)	11 (7.1%)	23 (7.5%)	37 (8.0%)
背部痛	5 (3.2%)	3 (1.9%)	8 (5.2%)	11 (3.6%)	16 (3.4%)
筋肉痛	3 (1.9%)	4 (2.6%)	2 (1.3%)	6 (1.9%)	9 (1.9%)
四肢痛	4 (2.6%)	4 (2.6%)	1 (0.6%)	5 (1.6%)	9 (1.9%)
筋骨格痛	3 (1.9%)	2 (1.3%)	3 (1.9%)	5 (1.6%)	8 (1.7%)
変形性関節症	0 (0.0%)	3 (1.9%)	1 (0.6%)	4 (1.3%)	4 (0.9%)
関節炎	0 (0.0%)	1 (0.6%)	2 (1.3%)	3 (1.0%)	3 (0.6%)
筋痙縮	1 (0.6%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	3 (0.6%)
骨痛	0 (0.0%)	2 (1.3%)	0 (0.0%)	2 (0.6%)	2 (0.4%)
椎間板突出	0 (0.0%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	2 (0.4%)
筋骨格系胸痛	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	2 (0.4%)
重感	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	2 (0.4%)
線維筋痛	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
鼡径部痛	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
関節腫脹	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
筋力低下	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
頚部痛	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
骨粗鬆症	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
脊椎炎	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
腱痛	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
腱鞘炎	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
一般・全身障害および投与部位の状態	22 (14.1%)	26 (16.9%)	28 (18.2%)	54 (17.5%)	76 (16.4%)
発熱	9 (5.8%)	10 (6.5%)	3 (1.9%)	13 (4.2%)	22 (4.7%)
疲労	4 (2.6%)	4 (2.6%)	9 (5.8%)	13 (4.2%)	17 (3.7%)
注射部位紅斑	3 (1.9%)	1 (0.6%)	4 (2.6%)	5 (1.6%)	8 (1.7%)
末梢性浮腫	1 (0.6%)	3 (1.9%)	4 (2.6%)	7 (2.3%)	8 (1.7%)
無力症	2 (1.3%)	2 (1.3%)	2 (1.3%)	4 (1.3%)	6 (1.3%)
インフルエンザ様疾患	0 (0.0%)	3 (1.9%)	2 (1.3%)	5 (1.6%)	5 (1.1%)
胸痛	0 (0.0%)	0 (0.0%)	3 (1.9%)	3 (1.0%)	3 (0.6%)

	Golimumab Induction				
	Placebo Maintenance[a]	50 mg Maintenance[a]	100 mg Maintenance[a]	Combined 50 mg and 100 mg Maintenance[a]	Total Golimumab[a,b]
悪寒	1 (0.6%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	3 (0.6%)
注射部位血腫	0 (0.0%)	2 (1.3%)	1 (0.6%)	3 (1.0%)	3 (0.6%)
注射部位そう痒感	2 (1.3%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	3 (0.6%)
注射部位腫脹	2 (1.3%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	3 (0.6%)
疼痛	1 (0.6%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	3 (0.6%)
注射部位炎症	1 (0.6%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	2 (0.4%)
注射部位疼痛	1 (0.6%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	2 (0.4%)
注射部位発疹	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	2 (0.4%)
注射部位蕁麻疹	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	2 (0.4%)
倦怠感	1 (0.6%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	2 (0.4%)
浮腫	0 (0.0%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	2 (0.4%)
投与部位発疹	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
投与部位反応	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
顔面浮腫	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
冷感	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
酩酊感	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
体温変動感	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
高熱	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
注入部位静脈炎	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
注射部位硬結	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
注射部位反応	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
微石症	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
非心臓性胸痛	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
口渇	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
神経系障害	29 (18.6%)	18 (11.7%)	28 (18.2%)	46 (14.9%)	75 (16.2%)
頭痛	17 (10.9%)	14 (9.1%)	20 (13.0%)	34 (11.0%)	51 (11.0%)
浮動性めまい	4 (2.6%)	0 (0.0%)	7 (4.5%)	7 (2.3%)	11 (2.4%)
錯感覚	3 (1.9%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	5 (1.1%)
感覚鈍麻	2 (1.3%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	4 (0.9%)
片頭痛	1 (0.6%)	3 (1.9%)	0 (0.0%)	3 (1.0%)	4 (0.9%)
味覚異常	1 (0.6%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	2 (0.4%)
坐骨神経痛	1 (0.6%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	2 (0.4%)
手根管症候群	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
痙攣	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
肘部管症候群	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
脱髄	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
異常感覚	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
顔面不全麻痺	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
筋緊張低下	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
嗜眠	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
意識消失	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
神経圧迫	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
振戦	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
呼吸器、胸郭および縦隔障害	12 (7.7%)	22 (14.3%)	22 (14.3%)	44 (14.3%)	56 (12.1%)

	Golimumab Induction				
	Placebo Maintenance[a]	50 mg Maintenance[a]	100 mg Maintenance[a]	Combined 50 mg and 100 mg Maintenance[a]	Total Golimumab[a,b]
咳嗽	5 (3.2%)	7 (4.5%)	11 (7.1%)	18 (5.8%)	23 (5.0%)
口腔咽頭痛	2 (1.3%)	2 (1.3%)	7 (4.5%)	9 (2.9%)	11 (2.4%)
鼻漏	0 (0.0%)	3 (1.9%)	1 (0.6%)	4 (1.3%)	4 (0.9%)
呼吸困難	0 (0.0%)	2 (1.3%)	1 (0.6%)	3 (1.0%)	3 (0.6%)
気道うっ血	0 (0.0%)	2 (1.3%)	1 (0.6%)	3 (1.0%)	3 (0.6%)
鼻出血	1 (0.6%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	2 (0.4%)
アレルギー性鼻炎	0 (0.0%)	2 (1.3%)	0 (0.0%)	2 (0.6%)	2 (0.4%)
季節性鼻炎	0 (0.0%)	2 (1.3%)	0 (0.0%)	2 (0.6%)	2 (0.4%)
副鼻腔うっ血	1 (0.6%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	2 (0.4%)
上気道うっ血	1 (0.6%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	2 (0.4%)
上気道の炎症	1 (0.6%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	2 (0.4%)
アレルギー性咳嗽	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
喘息	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
息詰まり感	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
労作性呼吸困難	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
喀血	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
肺浸潤	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
鼻閉	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
呼吸時疼痛	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
呼吸障害	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
くしゃみ	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
喘鳴	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
臨床検査	13 (8.3%)	20 (13.0%)	16 (10.4%)	36 (11.7%)	49 (10.6%)
アラニン・アミノトランスフェラーゼ増加	1 (0.6%)	4 (2.6%)	5 (3.2%)	9 (2.9%)	10 (2.2%)
アスパラギン酸アミノトランスフェラーゼ増加	1 (0.6%)	5 (3.2%)	3 (1.9%)	8 (2.6%)	9 (1.9%)
肝酵素上昇	3 (1.9%)	2 (1.3%)	0 (0.0%)	2 (0.6%)	5 (1.1%)
好酸球数増加	1 (0.6%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	3 (0.6%)
血小板数増加	1 (0.6%)	2 (1.3%)	0 (0.0%)	2 (0.6%)	3 (0.6%)
体重増加	2 (1.3%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	3 (0.6%)
白血球数減少	1 (0.6%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	3 (0.6%)
ヘモグロビン減少	1 (0.6%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	2 (0.4%)
好中球数減少	0 (0.0%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	2 (0.4%)
好中球数増加	1 (0.6%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	2 (0.4%)
血小板数減少	1 (0.6%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	2 (0.4%)
トランスアミナーゼ上昇	0 (0.0%)	2 (1.3%)	0 (0.0%)	2 (0.6%)	2 (0.4%)
白血球数増加	0 (0.0%)	2 (1.3%)	0 (0.0%)	2 (0.6%)	2 (0.4%)
血中アルカリホスファターゼ増加	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
血中ビリルビン増加	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
血中カルシウム増加	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
血中クレアチニン増加	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
血中カリウム減少	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
収縮期血圧上昇	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)

	Golimumab Induction				
	Placebo Maintenance[a]	50 mg Maintenance[a]	100 mg Maintenance[a]	Combined 50 mg and 100 mg Maintenance[a]	Total Golimumab[a,b]
血中テストステロン減少	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
血中尿素増加	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
体温上昇	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
胸部X線異常	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
ヘマトクリット減少	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
肝機能検査異常	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
リンパ球数減少	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
単球数減少	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
体重減少	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
尿中白血球陽性	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
血液およびリンパ系障害	12 (7.7%)	14 (9.1%)	13 (8.4%)	27 (8.8%)	39 (8.4%)
白血球減少症	4 (2.6%)	4 (2.6%)	5 (3.2%)	9 (2.9%)	13 (2.8%)
貧血	2 (1.3%)	4 (2.6%)	6 (3.9%)	10 (3.2%)	12 (2.6%)
白血球増加症	1 (0.6%)	1 (0.6%)	2 (1.3%)	3 (1.0%)	4 (0.9%)
好酸球増加症	1 (0.6%)	2 (1.3%)	0 (0.0%)	2 (0.6%)	3 (0.6%)
リンパ球減少症	2 (1.3%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	3 (0.6%)
好中球減少症	1 (0.6%)	2 (1.3%)	0 (0.0%)	2 (0.6%)	3 (0.6%)
リンパ節症	0 (0.0%)	2 (1.3%)	0 (0.0%)	2 (0.6%)	2 (0.4%)
リンパ球増加症	1 (0.6%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	2 (0.4%)
好中球増加症	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	2 (0.4%)
血小板減少症	1 (0.6%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	2 (0.4%)
二血球減少症	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
リンパ節痛	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
単球減少症	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
血小板増加症	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
傷害、中毒および処置合併症	9 (5.8%)	7 (4.5%)	13 (8.4%)	20 (6.5%)	29 (6.3%)
挫傷	2 (1.3%)	2 (1.3%)	4 (2.6%)	6 (1.9%)	8 (1.7%)
節足動物咬傷	2 (1.3%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	3 (0.6%)
関節脱臼	0 (0.0%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	2 (0.4%)
肉離れ	1 (0.6%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	2 (0.4%)
処置後合併症	1 (0.6%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	2 (0.4%)
偶発的過量投与	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
足関節部骨折	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
節足動物刺傷	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
第２度熱傷	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
上顆炎	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
擦過傷	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
足骨折	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
手骨折	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
関節捻挫	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
裂傷	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
四肢損傷	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
口唇損傷	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
筋損傷	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)

	Golimumab Induction				
	Placebo Maintenance[a]	50 mg Maintenance[a]	100 mg Maintenance[a]	Combined 50 mg and 100 mg Maintenance[a]	Total Golimumab[a,b]
処置による疼痛	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
橈骨骨折	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
肋骨骨折	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
腱損傷	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
精神障害	6 (3.8%)	7 (4.5%)	12 (7.8%)	19 (6.2%)	25 (5.4%)
不眠症	3 (1.9%)	2 (1.3%)	3 (1.9%)	5 (1.6%)	8 (1.7%)
うつ病	1 (0.6%)	3 (1.9%)	3 (1.9%)	6 (1.9%)	7 (1.5%)
不安	1 (0.6%)	2 (1.3%)	3 (1.9%)	5 (1.6%)	6 (1.3%)
激越	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
抑うつ気分	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
神経過敏	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
落ち着きのなさ	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
睡眠障害	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
社会恐怖症	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
物質乱用	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
血管障害	10 (6.4%)	4 (2.6%)	8 (5.2%)	12 (3.9%)	22 (4.7%)
高血圧	6 (3.8%)	2 (1.3%)	2 (1.3%)	4 (1.3%)	10 (2.2%)
潮紅	0 (0.0%)	1 (0.6%)	2 (1.3%)	3 (1.0%)	3 (0.6%)
ほてり	1 (0.6%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	3 (0.6%)
血腫	1 (0.6%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	2 (0.4%)
深部静脈血栓症	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
出血	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
間欠性跛行	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
末梢冷感	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
血管炎	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
眼障害	6 (3.8%)	6 (3.9%)	7 (4.5%)	13 (4.2%)	19 (4.1%)
結膜炎	2 (1.3%)	2 (1.3%)	0 (0.0%)	2 (0.6%)	4 (0.9%)
白内障	1 (0.6%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	3 (0.6%)
眼の炎症	1 (0.6%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	2 (0.4%)
眼充血	1 (0.6%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	2 (0.4%)
加齢黄斑変性	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
複視	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
眼刺激	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
眼部腫脹	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
眼瞼障害	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
眼瞼そう痒症	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
緑内障	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
翼状片	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
視力障害	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
腎および尿路障害	5 (3.2%)	6 (3.9%)	5 (3.2%)	11 (3.6%)	16 (3.4%)
腎結石症	2 (1.3%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	4 (0.9%)
腎仙痛	0 (0.0%)	2 (1.3%)	1 (0.6%)	3 (1.0%)	3 (0.6%)
排尿困難	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	2 (0.4%)
水腎症	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)

	Golimumab Induction				
	Placebo Maintenance[a]	50 mg Maintenance[a]	100 mg Maintenance[a]	Combined 50 mg and 100 mg Maintenance[a]	Total Golimumab[a,b]
夜間頻尿	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
頻尿	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
腎嚢胞	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
腎臓痛	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
尿道痛	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
尿失禁	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
尿閉	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
生殖系および乳房障害	3 (1.9%)	7 (4.5%)	4 (2.6%)	11 (3.6%)	14 (3.0%)
精巣上体炎	0 (0.0%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	2 (0.4%)
前立腺炎	1 (0.6%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	2 (0.4%)
無月経	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
バルトリン嚢腫	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
良性前立腺肥大症	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
乳房嚢胞	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
乳房腫瘤	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
膀胱瘤	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
月経困難症	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
不正子宮出血	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
頻発月経	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
前立腺腫大	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
精巣痛	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
子宮ポリープ	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
腟分泌物	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
耳および迷路障害	2 (1.3%)	5 (3.2%)	4 (2.6%)	9 (2.9%)	11 (2.4%)
回転性めまい	2 (1.3%)	2 (1.3%)	1 (0.6%)	3 (1.0%)	5 (1.1%)
耳痛	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
耳管機能障害	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
内耳の炎症	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
乗物酔い	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
耳鳴	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
鼓膜穿孔	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
代謝および栄養障害	1 (0.6%)	5 (3.2%)	4 (2.6%)	9 (2.9%)	10 (2.2%)
脱水	1 (0.6%)	1 (0.6%)	2 (1.3%)	3 (1.0%)	4 (0.9%)
食欲減退	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	2 (0.4%)
細胞死	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
糖尿病	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
痛風	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
高カルシウム血症	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
低カリウム血症	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	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）	1 (0.6%)	4 (2.6%)	5 (3.2%)	9 (2.9%)	10 (2.2%)
子宮平滑筋腫	0 (0.0%)	1 (0.6%)	2 (1.3%)	3 (1.0%)	3 (0.6%)
皮膚乳頭腫	1 (0.6%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	2 (0.4%)

	Golimumab Induction				
	Placebo Maintenance[a]	50 mg Maintenance[a]	100 mg Maintenance[a]	Combined 50 mg and 100 mg Maintenance[a]	Total Golimumab[a,b]
乳房の良性新生物	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
唾液腺の良性新生物	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
脂肪腫	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
肺腺癌	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
前立腺腺腫	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
肝胆道系障害	1 (0.6%)	2 (1.3%)	3 (1.9%)	5 (1.6%)	6 (1.3%)
脂肪肝	1 (0.6%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	2 (0.4%)
胆管結石	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
胆石症	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
肝嚢胞	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
高ビリルビン血症	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
免疫系障害	4 (2.6%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	6 (1.3%)
季節性アレルギー	4 (2.6%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	6 (1.3%)
心臓障害	1 (0.6%)	2 (1.3%)	2 (1.3%)	4 (1.3%)	5 (1.1%)
心不全	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
心血管障害	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
動悸	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
心嚢液貯留	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
心膜炎	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
外科および内科処置	0 (0.0%)	1 (0.6%)	2 (1.3%)	3 (1.0%)	3 (0.6%)
副鼻腔手術	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	2 (0.4%)
抜歯	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
妊娠、産褥および周産期の状態	1 (0.6%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	2 (0.4%)
妊娠	1 (0.6%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	2 (0.4%)
先天性、家族性および遺伝性障害	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
遺伝性フルクトース不耐症	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
社会環境	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
パートナーの妊娠	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)

[a] Includes data up to the time of dose adjustment for those who increased dose from the indicated dose during the maintenance study.
[b] Includes data from the time of the first golimumab dose onward.

表 2.7.4.7-付録-6 すべての有害事象（T16，T17 及び T18 試験 54 週まで；全投与被験者）

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
Treated subjects in C0524T16 and C0524T17	49	358	286	77	157	154	660	14	1233
Avg duration of follow-up (weeks)	12.3	19.1	39.2	11.9	39.0	50.4	45.1	27.5	45.6
Avg exposure (number of administrations)	1.6	5.0	9.2	1.6	10.0	12.9	10.7	6.9	11.0
Subjects with 1 or more adverse events	30 (61.2%)	164 (45.8%)	212 (74.1%)	50 (64.9%)	115 (73.2%)	120 (77.9%)	519 (78.6%)	9 (64.3%)	964 (78.2%)
System-organ class/preferred term									
胃腸障害	19 (38.8%)	63 (17.6%)	96 (33.6%)	29 (37.7%)	55 (35.0%)	55 (35.7%)	284 (43.0%)	4 (28.6%)	500 (40.6%)
潰瘍性大腸炎	14 (28.6%)	21 (5.9%)	47 (16.4%)	22 (28.6%)	29 (18.5%)	27 (17.5%)	131 (19.8%)	1 (7.1%)	251 (20.4%)
腹痛	2 (4.1%)	8 (2.2%)	9 (3.1%)	3 (3.9%)	5 (3.2%)	12 (7.8%)	41 (6.2%)	0 (0.0%)	69 (5.6%)
悪心	4 (8.2%)	10 (2.8%)	4 (1.4%)	4 (5.2%)	3 (1.9%)	8 (5.2%)	35 (5.3%)	1 (7.1%)	55 (4.5%)
下痢	1 (2.0%)	5 (1.4%)	4 (1.4%)	1 (1.3%)	7 (4.5%)	4 (2.6%)	21 (3.2%)	1 (7.1%)	37 (3.0%)
嘔吐	2 (4.1%)	3 (0.8%)	1 (0.3%)	2 (2.6%)	5 (3.2%)	4 (2.6%)	15 (2.3%)	0 (0.0%)	27 (2.2%)
痔核	0 (0.0%)	5 (1.4%)	4 (1.4%)	0 (0.0%)	2 (1.3%)	3 (1.9%)	15 (2.3%)	1 (7.1%)	25 (2.0%)
便秘	1 (2.0%)	5 (1.4%)	5 (1.7%)	1 (1.3%)	4 (2.5%)	2 (1.3%)	10 (1.5%)	0 (0.0%)	22 (1.8%)
上腹部痛	0 (0.0%)	3 (0.8%)	2 (0.7%)	1 (1.3%)	1 (0.6%)	5 (3.2%)	12 (1.8%)	0 (0.0%)	21 (1.7%)
消化不良	0 (0.0%)	4 (1.1%)	5 (1.7%)	0 (0.0%)	2 (1.3%)	3 (1.9%)	10 (1.5%)	0 (0.0%)	20 (1.6%)
血便排泄	1 (2.0%)	6 (1.7%)	1 (0.3%)	0 (0.0%)	2 (1.3%)	1 (0.6%)	9 (1.4%)	0 (0.0%)	13 (1.1%)
腹部膨満	0 (0.0%)	1 (0.3%)	3 (1.0%)	0 (0.0%)	2 (1.3%)	3 (1.9%)	4 (0.6%)	0 (0.0%)	12 (1.0%)
下腹部痛	0 (0.0%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	2 (1.3%)	8 (1.2%)	0 (0.0%)	11 (0.9%)
裂肛	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (1.3%)	0 (0.0%)	1 (0.6%)	8 (1.2%)	0 (0.0%)	11 (0.9%)
胃食道逆流性疾患	0 (0.0%)	1 (0.3%)	3 (1.0%)	0 (0.0%)	1 (0.6%)	1 (0.6%)	6 (0.9%)	0 (0.0%)	11 (0.9%)
歯痛	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.6%)	1 (0.6%)	7 (1.1%)	0 (0.0%)	10 (0.8%)
腹部不快感	0 (0.0%)	4 (1.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	8 (1.2%)	0 (0.0%)	8 (0.6%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
結腸ポリープ	0 (0.0%)	0 (0.0%)	2 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (0.9%)	0 (0.0%)	8 (0.6%)
口内炎	0 (0.0%)	1 (0.3%)	4 (1.4%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	3 (0.5%)	0 (0.0%)	8 (0.6%)
排便回数増加	1 (2.0%)	1 (0.3%)	1 (0.3%)	0 (0.0%)	2 (1.3%)	0 (0.0%)	4 (0.6%)	0 (0.0%)	7 (0.6%)
アフタ性口内炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (1.3%)	1 (0.6%)	2 (1.3%)	1 (0.2%)	0 (0.0%)	6 (0.5%)
直腸ポリープ	0 (0.0%)	1 (0.3%)	2 (0.7%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	3 (0.5%)	0 (0.0%)	6 (0.5%)
齲歯	0 (0.0%)	0 (0.0%)	2 (0.7%)	0 (0.0%)	1 (0.6%)	1 (0.6%)	1 (0.2%)	0 (0.0%)	5 (0.4%)
鼓腸	0 (0.0%)	1 (0.3%)	1 (0.3%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	3 (0.5%)	0 (0.0%)	5 (0.4%)
肛門周囲痛	0 (0.0%)	0 (0.0%)	3 (1.0%)	2 (2.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (0.4%)
口唇炎	0 (0.0%)	0 (0.0%)	2 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	4 (0.3%)
口内乾燥	0 (0.0%)	0 (0.0%)	2 (0.7%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	4 (0.3%)
肛門直腸不快感	1 (2.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	3 (0.2%)
便意切迫	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	2 (0.3%)	0 (0.0%)	3 (0.2%)
血性下痢	0 (0.0%)	3 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	2 (0.3%)	0 (0.0%)	3 (0.2%)
食中毒	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	2 (0.3%)	0 (0.0%)	3 (0.2%)
胃炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.5%)	0 (0.0%)	3 (0.2%)
過敏性腸症候群	0 (0.0%)	1 (0.3%)	3 (1.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.2%)
口腔内潰瘍形成	0 (0.0%)	0 (0.0%)	3 (1.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.2%)
膵炎	0 (0.0%)	0 (0.0%)	2 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	3 (0.2%)
偽性ポリポーシス	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.2%)	0 (0.0%)	3 (0.2%)
肛門の炎症	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
腸憩室	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
腸炎	0 (0.0%)	1 (0.3%)	2 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
便失禁	0 (0.0%)	1 (0.3%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
胃腸音異常	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	2 (0.2%)
排便痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
直腸炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	2 (0.2%)
腹部ヘルニア	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.1%)	1 (0.1%)
腹部硬直	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
肛門皮膚垂	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
バレット食道	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
便通不規則	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
口唇症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
大腸炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
結腸狭窄	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
十二指腸炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
嚥下障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
小腸炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
萎縮性胃炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
胃腸出血	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
胃腸の炎症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
消化器痛	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
歯肉痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
歯肉炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
痔出血	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
胃酸過多	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
肛門肥大乳頭	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
イレウス	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
鼠径ヘルニア	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
腸管虚血	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
口唇腫脹	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
機械的イレウス	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
口腔嚢胞	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
口腔内出血	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
粘液便	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
食道浮腫	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
口腔内痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
急性膵炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
口の錯感覚	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
肛門周囲炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
直腸出血	0 (0.0%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
直腸攣縮	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
直腸しぶり	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
歯の知覚過敏	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
小腸閉塞	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
舌腫脹	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
脆弱歯	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
歯の障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
異常便	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
痔瘻	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
亜イレウス	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
舌水疱形成	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
感染症および寄生虫症	11 (22.4%)	59 (16.5%)	108 (37.8%)	22 (28.6%)	51 (32.5%)	63 (40.9%)	256 (38.8%)	5 (35.7%)	490 (39.7%)
鼻咽頭炎	2 (4.1%)	15 (4.2%)	22 (7.7%)	4 (5.2%)	13 (8.3%)	16 (10.4%)	78 (11.8%)	3 (21.4%)	132 (10.7%)
上気道感染	0 (0.0%)	12 (3.4%)	20 (7.0%)	1 (1.3%)	6 (3.8%)	8 (5.2%)	44 (6.7%)	1 (7.1%)	77 (6.2%)
咽頭炎	0 (0.0%)	0 (0.0%)	7 (2.4%)	1 (1.3%)	7 (4.5%)	10 (6.5%)	15 (2.3%)	1 (7.1%)	41 (3.3%)
副鼻腔炎	2 (4.1%)	3 (0.8%)	6 (2.1%)	0 (0.0%)	4 (2.5%)	7 (4.5%)	20 (3.0%)	0 (0.0%)	37 (3.0%)
インフルエンザ	0 (0.0%)	8 (2.2%)	7 (2.4%)	0 (0.0%)	6 (3.8%)	7 (4.5%)	14 (2.1%)	0 (0.0%)	34 (2.8%)
気管支炎	2 (4.1%)	3 (0.8%)	4 (1.4%)	2 (2.6%)	3 (1.9%)	6 (3.9%)	15 (2.3%)	0 (0.0%)	29 (2.4%)
胃腸炎	0 (0.0%)	3 (0.8%)	5 (1.7%)	1 (1.3%)	4 (2.5%)	2 (1.3%)	12 (1.8%)	0 (0.0%)	24 (1.9%)
口腔ヘルペス	1 (2.0%)	0 (0.0%)	3 (1.0%)	2 (2.6%)	3 (1.9%)	3 (1.9%)	10 (1.5%)	0 (0.0%)	21 (1.7%)
尿路感染	0 (0.0%)	4 (1.1%)	2 (0.7%)	1 (1.3%)	4 (2.5%)	3 (1.9%)	7 (1.1%)	1 (7.1%)	18 (1.5%)
ウイルス感染	1 (2.0%)	3 (0.8%)	5 (1.7%)	0 (0.0%)	0 (0.0%)	3 (1.9%)	6 (0.9%)	0 (0.0%)	14 (1.1%)
ウイルス性胃腸炎	0 (0.0%)	4 (1.1%)	3 (1.0%)	0 (0.0%)	1 (0.6%)	2 (1.3%)	7 (1.1%)	0 (0.0%)	13 (1.1%)
クロストリジウム感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (6.5%)	2 (1.3%)	0 (0.0%)	4 (0.6%)	0 (0.0%)	11 (0.9%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
肺炎	1 (2.0%)	0 (0.0%)	1 (0.3%)	1 (1.3%)	2 (1.3%)	0 (0.0%)	7 (1.1%)	0 (0.0%)	11 (0.9%)
鼻炎	0 (0.0%)	0 (0.0%)	3 (1.0%)	1 (1.3%)	2 (1.3%)	1 (0.6%)	4 (0.6%)	0 (0.0%)	11 (0.9%)
膀胱炎	0 (0.0%)	0 (0.0%)	2 (0.7%)	0 (0.0%)	1 (0.6%)	2 (1.3%)	4 (0.6%)	0 (0.0%)	9 (0.7%)
毛包炎	0 (0.0%)	1 (0.3%)	3 (1.0%)	1 (1.3%)	3 (1.9%)	1 (0.6%)	1 (0.2%)	0 (0.0%)	9 (0.7%)
帯状疱疹	0 (0.0%)	0 (0.0%)	4 (1.4%)	0 (0.0%)	1 (0.6%)	1 (0.6%)	3 (0.5%)	0 (0.0%)	9 (0.7%)
真菌感染	0 (0.0%)	0 (0.0%)	3 (1.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (0.8%)	0 (0.0%)	8 (0.6%)
気道感染	0 (0.0%)	0 (0.0%)	2 (0.7%)	1 (1.3%)	1 (0.6%)	0 (0.0%)	4 (0.6%)	0 (0.0%)	8 (0.6%)
外陰腟真菌感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	4 (2.6%)	3 (0.5%)	0 (0.0%)	8 (0.6%)
麦粒腫	0 (0.0%)	2 (0.6%)	3 (1.0%)	0 (0.0%)	1 (0.6%)	2 (1.3%)	1 (0.2%)	0 (0.0%)	7 (0.6%)
歯膿瘍	0 (0.0%)	2 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (0.9%)	0 (0.0%)	7 (0.6%)
せつ	0 (0.0%)	0 (0.0%)	3 (1.0%)	0 (0.0%)	0 (0.0%)	2 (1.3%)	1 (0.2%)	0 (0.0%)	6 (0.5%)
単純ヘルペス	1 (2.0%)	1 (0.3%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	4 (0.6%)	0 (0.0%)	6 (0.5%)
ウイルス性気道感染	0 (0.0%)	1 (0.3%)	2 (0.7%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	3 (0.5%)	0 (0.0%)	6 (0.5%)
肛門膿瘍	0 (0.0%)	0 (0.0%)	2 (0.7%)	1 (1.3%)	0 (0.0%)	1 (0.6%)	1 (0.2%)	0 (0.0%)	5 (0.4%)
耳感染	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	2 (1.3%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	5 (0.4%)
喉頭炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	4 (0.6%)	0 (0.0%)	5 (0.4%)
爪真菌症	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.3%)	0 (0.0%)	5 (0.4%)
レンサ球菌性咽頭炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	3 (0.5%)	0 (0.0%)	5 (0.4%)
扁桃炎	0 (0.0%)	1 (0.3%)	2 (0.7%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	2 (0.3%)	0 (0.0%)	5 (0.4%)
ウイルス性上気道感染	0 (0.0%)	0 (0.0%)	2 (0.7%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.2%)	1 (7.1%)	5 (0.4%)
外陰部腟カンジダ症	0 (0.0%)	1 (0.3%)	3 (1.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.2%)	0 (0.0%)	5 (0.4%)
急性扁桃炎	0 (0.0%)	1 (0.3%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	2 (1.3%)	1 (0.2%)	0 (0.0%)	4 (0.3%)
虫垂炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.5%)	0 (0.0%)	4 (0.3%)
蜂巣炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	2 (2.6%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.3%)
サイトメガロウイルス感染	1 (2.0%)	0 (0.0%)	0 (0.0%)	2 (2.6%)	1 (0.6%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	4 (0.3%)
下気道感染	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	2 (1.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	4 (0.3%)
口腔カンジダ症	1 (2.0%)	0 (0.0%)	1 (0.3%)	1 (1.3%)	0 (0.0%)	1 (0.6%)	1 (0.2%)	0 (0.0%)	4 (0.3%)
外耳炎	0 (0.0%)	0 (0.0%)	2 (0.7%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.2%)	0 (0.0%)	4 (0.3%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
歯感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	3 (0.5%)	0 (0.0%)	4 (0.3%)
気管炎	0 (0.0%)	1 (0.3%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.5%)	0 (0.0%)	4 (0.3%)
肛門性器疣贅	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	3 (0.2%)
慢性副鼻腔炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	3 (0.2%)
播種性結核	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	3 (0.2%)
憩室炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	3 (0.2%)
感染性腸炎	0 (0.0%)	0 (0.0%)	3 (1.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.2%)
エンテロウイルス感染	0 (0.0%)	1 (0.3%)	2 (0.7%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	3 (0.2%)
丹毒	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	3 (0.2%)
限局性感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	2 (0.3%)	0 (0.0%)	3 (0.2%)
爪囲炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.5%)	0 (0.0%)	3 (0.2%)
膿疱性皮疹	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.5%)	0 (0.0%)	3 (0.2%)
ブドウ球菌感染	0 (0.0%)	1 (0.3%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.2%)	0 (0.0%)	3 (0.2%)
皮下組織膿瘍	0 (0.0%)	0 (0.0%)	2 (0.7%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.2%)
足部白癬	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.6%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	3 (0.2%)
創傷感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	2 (0.3%)	0 (0.0%)	3 (0.2%)
膿瘍	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
急性副鼻腔炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
ブラストシスティス感染	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
脳膿瘍	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
カンジダ症	1 (2.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
感染性小腸結腸炎	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	2 (0.2%)
ウイルス性消化管感染	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
ヘルペスウイルス感染	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
マラリア	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
食道カンジダ症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	2 (0.2%)
敗血症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
皮膚感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
癜風	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	2 (0.2%)
ウイルス性咽頭炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	1 (7.1%)	2 (0.2%)
腹壁膿瘍	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
ダニ皮膚炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
エロモナス感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
アメーバ症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
真菌性肛門感染	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
細菌感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
細菌性敗血症	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
ボレリア感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
乳房蜂巣炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
クロストリジウム・ディフィシレ大腸炎	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
感染性皮膚炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
紅色陰癬	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
外耳蜂巣炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
眼感染	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
ブドウ球菌性眼感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
皮膚真菌感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
ロタウイルス胃腸炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
サルモネラ菌性胃腸炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
消化管感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
ジアルジア症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
鼠径部膿瘍	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
感染性表皮嚢胞	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
感染性皮膚潰瘍	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
注射部位膿瘍	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
椎間板炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
迷路炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
潜伏結核	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
ウイルス性下気道感染	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
ライム病	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
メタニューモウイルス感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
伝染性軟属腫	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
爪感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
口腔真菌感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
精巣炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
中耳炎	0 (0.0%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
寄生虫性胃腸炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
歯周感染	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
百日咳	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
毛巣嚢胞	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
原発性異型肺炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
術後膿瘍	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
偽膜性大腸炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
腎盂腎炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
直腸膿瘍	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
敗血症性ショック	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
皮膚細菌感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
軟部組織感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
ブドウ球菌性菌血症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
レンサ球菌性敗血症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
白癬感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
結核	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
腸チフス熱	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
尿道炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
泌尿生殖器真菌感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
ワクチン接種部位感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
腟感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
水痘	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
乳房膿瘍	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
気管支肺炎	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Ｈ１Ｎ１インフルエンザ	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
血腫感染	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
細菌の過剰増殖	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
直腸周囲膿瘍	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
一般・全身障害および投与部位の状態	5 (10.2%)	32 (8.9%)	42 (14.7%)	14 (18.2%)	22 (14.0%)	26 (16.9%)	115 (17.4%)	4 (28.6%)	219 (17.8%)
発熱	3 (6.1%)	5 (1.4%)	10 (3.5%)	7 (9.1%)	9 (5.7%)	10 (6.5%)	30 (4.5%)	0 (0.0%)	65 (5.3%)
疲労	0 (0.0%)	7 (2.0%)	9 (3.1%)	2 (2.6%)	4 (2.5%)	4 (2.6%)	20 (3.0%)	0 (0.0%)	39 (3.2%)
注射部位紅斑	0 (0.0%)	1 (0.3%)	3 (1.0%)	0 (0.0%)	3 (1.9%)	1 (0.6%)	17 (2.6%)	1 (7.1%)	23 (1.9%)
無力症	1 (2.0%)	3 (0.8%)	3 (1.0%)	1 (1.3%)	2 (1.3%)	2 (1.3%)	14 (2.1%)	0 (0.0%)	22 (1.8%)
インフルエンザ様疾患	0 (0.0%)	3 (0.8%)	6 (2.1%)	0 (0.0%)	0 (0.0%)	3 (1.9%)	11 (1.7%)	0 (0.0%)	20 (1.6%)
末梢性浮腫	1 (2.0%)	2 (0.6%)	4 (1.4%)	0 (0.0%)	1 (0.6%)	3 (1.9%)	11 (1.7%)	0 (0.0%)	19 (1.5%)
胸痛	0 (0.0%)	0 (0.0%)	3 (1.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.6%)	1 (7.1%)	8 (0.6%)
悪寒	0 (0.0%)	2 (0.6%)	1 (0.3%)	1 (1.3%)	1 (0.6%)	1 (0.6%)	4 (0.6%)	0 (0.0%)	8 (0.6%)
疼痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.6%)	1 (0.6%)	5 (0.8%)	0 (0.0%)	8 (0.6%)
注射部位疼痛	0 (0.0%)	2 (0.6%)	0 (0.0%)	1 (1.3%)	1 (0.6%)	0 (0.0%)	4 (0.6%)	0 (0.0%)	6 (0.5%)
注射部位血腫	0 (0.0%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.3%)	3 (0.5%)	0 (0.0%)	5 (0.4%)
高熱	0 (0.0%)	0 (0.0%)	1 (0.3%)	2 (2.6%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.3%)
注射部位そう痒感	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.3%)	1 (0.6%)	1 (0.2%)	0 (0.0%)	4 (0.3%)
注射部位発疹	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	2 (0.3%)	1 (7.1%)	4 (0.3%)
注射部位腫脹	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.3%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	4 (0.3%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
注射部位反応	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	3 (0.2%)
倦怠感	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.6%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	3 (0.2%)
胸部不快感	0 (0.0%)	2 (0.6%)	2 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
薬効欠如	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	2 (0.2%)
注射部位炎症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
注射部位蕁麻疹	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
粘膜の炎症	0 (0.0%)	0 (0.0%)	2 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
浮腫	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	2 (0.2%)
口渇	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
投与部位発疹	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
投与部位反応	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
医薬品副作用	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
適用部位紅斑	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
腋窩痛	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
嚢胞	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
薬物不耐性	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
顔面浮腫	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
冷感	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
酩酊感	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
体温変動感	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
低体温	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
注入部位炎症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
注入部位疼痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
注入部位静脈炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
注入部位そう痒感	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
注入部位反応	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
注射部位出血	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
注射部位硬結	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	1 (7.1%)	1 (0.1%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
注射部位腫瘤	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
限局性浮腫	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
医療機器合併症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
微石症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
非心臓性胸痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
偽ポリープ	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
圧迫感	0 (0.0%)	1 (0.3%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
軟部組織の炎症	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
熱感	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
びくびく感	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
治癒不良	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
腫脹	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
乾燥症	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
皮膚および皮下組織障害	7 (14.3%)	33 (9.2%)	41 (14.3%)	4 (5.2%)	28 (17.8%)	25 (16.2%)	113 (17.1%)	3 (21.4%)	210 (17.0%)
発疹	0 (0.0%)	7 (2.0%)	9 (3.1%)	0 (0.0%)	5 (3.2%)	9 (5.8%)	25 (3.8%)	1 (7.1%)	49 (4.0%)
そう痒症	1 (2.0%)	4 (1.1%)	6 (2.1%)	1 (1.3%)	2 (1.3%)	3 (1.9%)	16 (2.4%)	0 (0.0%)	28 (2.3%)
脱毛症	0 (0.0%)	2 (0.6%)	2 (0.7%)	0 (0.0%)	3 (1.9%)	0 (0.0%)	9 (1.4%)	0 (0.0%)	14 (1.1%)
皮膚乾燥	0 (0.0%)	1 (0.3%)	2 (0.7%)	0 (0.0%)	0 (0.0%)	3 (1.9%)	9 (1.4%)	0 (0.0%)	14 (1.1%)
湿疹	0 (0.0%)	4 (1.1%)	2 (0.7%)	0 (0.0%)	3 (1.9%)	1 (0.6%)	5 (0.8%)	1 (7.1%)	12 (1.0%)
ざ瘡	0 (0.0%)	3 (0.8%)	1 (0.3%)	1 (1.3%)	2 (1.3%)	2 (1.3%)	4 (0.6%)	1 (7.1%)	11 (0.9%)
アレルギー性皮膚炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	6 (3.8%)	1 (0.6%)	2 (0.3%)	1 (7.1%)	11 (0.9%)
紅斑	0 (0.0%)	1 (0.3%)	2 (0.7%)	1 (1.3%)	2 (1.3%)	0 (0.0%)	5 (0.8%)	0 (0.0%)	10 (0.8%)
寝汗	0 (0.0%)	3 (0.8%)	4 (1.4%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	5 (0.8%)	0 (0.0%)	10 (0.8%)
皮膚炎	0 (0.0%)	1 (0.3%)	1 (0.3%)	0 (0.0%)	3 (1.9%)	2 (1.3%)	4 (0.6%)	0 (0.0%)	9 (0.7%)
接触性皮膚炎	0 (0.0%)	1 (0.3%)	3 (1.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	3 (0.5%)	0 (0.0%)	7 (0.6%)
蕁麻疹	0 (0.0%)	2 (0.6%)	2 (0.7%)	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.3%)	0 (0.0%)	6 (0.5%)
多汗症	1 (2.0%)	1 (0.3%)	0 (0.0%)	1 (1.3%)	1 (0.6%)	1 (0.6%)	3 (0.5%)	0 (0.0%)	5 (0.4%)
乾癬	0 (0.0%)	1 (0.3%)	1 (0.3%)	0 (0.0%)	1 (0.6%)	2 (1.3%)	1 (0.2%)	0 (0.0%)	5 (0.4%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
脂漏性皮膚炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	3 (0.5%)	0 (0.0%)	5 (0.4%)
結節性紅斑	4 (8.2%)	1 (0.3%)	2 (0.7%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.2%)	0 (0.0%)	4 (0.3%)
全身性皮疹	0 (0.0%)	1 (0.3%)	2 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	4 (0.3%)
そう痒性皮疹	0 (0.0%)	3 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	3 (0.5%)	0 (0.0%)	4 (0.3%)
皮膚病変	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	3 (0.5%)	0 (0.0%)	4 (0.3%)
薬疹	0 (0.0%)	0 (0.0%)	2 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	3 (0.2%)
酒さ	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.5%)	0 (0.0%)	3 (0.2%)
皮膚変色	0 (0.0%)	0 (0.0%)	2 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	3 (0.2%)
日光性角化症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
水疱	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
ざ瘡様皮膚炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
アトピー性皮膚炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
皮脂欠乏性湿疹	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
貨幣状湿疹	0 (0.0%)	0 (0.0%)	2 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
滴状乾癬	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	2 (0.2%)
汗腺炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
嵌入爪	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
爪破損	0 (0.0%)	1 (0.3%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
痒疹	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
膿疱性乾癬	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	2 (0.2%)
斑状丘疹状皮疹	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
皮膚亀裂	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
皮膚嚢腫	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
乾癬様皮膚炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
発汗障害	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
皮下出血	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
顔面感覚鈍麻	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
内出血発生の増加傾向	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
苔癬様角化症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
脂肪肥大症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
斑	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
爪変色	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
点状出血	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
光線性皮膚症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
ばら色粃糠疹	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
紫斑	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
毛孔性皮疹	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
斑状皮疹	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
丘疹性皮疹	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
瘢痕	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
瘢痕痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
皮膚灼熱感	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
ひび・あかぎれ	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
皮膚剥脱	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
皮膚色素減少	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
皮膚刺激	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
皮膚線条	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
尋常性白斑	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
斑状出血	0 (0.0%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
扁平苔癬	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
全身性そう痒症	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
壊疽性膿皮症	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
皮膚色素脱失	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
顔面腫脹	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
筋骨格系および結合組織障害	5 (10.2%)	29 (8.1%)	41 (14.3%)	2 (2.6%)	30 (19.1%)	27 (17.5%)	105 (15.9%)	3 (21.4%)	203 (16.5%)
関節痛	1 (2.0%)	14 (3.9%)	14 (4.9%)	0 (0.0%)	14 (8.9%)	12 (7.8%)	52 (7.9%)	1 (7.1%)	90 (7.3%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
背部痛	0 (0.0%)	7 (2.0%)	7 (2.4%)	1 (1.3%)	5 (3.2%)	3 (1.9%)	20 (3.0%)	1 (7.1%)	37 (3.0%)
四肢痛	0 (0.0%)	1 (0.3%)	5 (1.7%)	0 (0.0%)	4 (2.5%)	4 (2.6%)	5 (0.8%)	0 (0.0%)	18 (1.5%)
筋痙縮	1 (2.0%)	2 (0.6%)	3 (1.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	10 (1.5%)	0 (0.0%)	14 (1.1%)
筋肉痛	0 (0.0%)	3 (0.8%)	2 (0.7%)	1 (1.3%)	3 (1.9%)	4 (2.6%)	4 (0.6%)	0 (0.0%)	14 (1.1%)
筋骨格痛	0 (0.0%)	2 (0.6%)	1 (0.3%)	0 (0.0%)	3 (1.9%)	2 (1.3%)	6 (0.9%)	0 (0.0%)	12 (1.0%)
頚部痛	0 (0.0%)	0 (0.0%)	4 (1.4%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	7 (0.6%)
関節炎	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	5 (0.8%)	0 (0.0%)	6 (0.5%)
筋骨格系胸痛	0 (0.0%)	0 (0.0%)	2 (0.7%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	2 (0.3%)	0 (0.0%)	5 (0.4%)
滑液包炎	0 (0.0%)	1 (0.3%)	4 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.3%)
変形性関節症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (1.9%)	1 (0.2%)	0 (0.0%)	4 (0.3%)
骨痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.3%)	1 (0.2%)	0 (0.0%)	3 (0.2%)
骨粗鬆症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	3 (0.2%)
線維筋痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	2 (0.2%)
椎間板突出	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	2 (0.2%)
関節腫脹	2 (4.1%)	1 (0.3%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
筋骨格不快感	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	2 (0.2%)
骨減少症	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
重感	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
腱痛	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
バニオン	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
軟骨疾患	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
外骨腫	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
側腹部痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
鼡径部痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
関節ロック	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
筋攣縮	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
筋力低下	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
筋骨格硬直	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
骨壊死	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
骨粗鬆症性骨折	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
骨硬化症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
関節周囲炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
多発性関節炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
仙腸骨炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
変形性脊椎症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.1%)	1 (0.1%)
脊椎炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
滑液嚢腫	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
腱性拘縮	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
腱鞘炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
狭窄性腱鞘炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
関節障害	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
椎間関節症候群	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
瘻孔	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
関節硬直	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
顎痛	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
足底筋膜炎	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
神経系障害	4 (8.2%)	36 (10.1%)	34 (11.9%)	5 (6.5%)	29 (18.5%)	18 (11.7%)	93 (14.1%)	1 (7.1%)	178 (14.4%)
頭痛	2 (4.1%)	21 (5.9%)	26 (9.1%)	4 (5.2%)	17 (10.8%)	14 (9.1%)	68 (10.3%)	1 (7.1%)	128 (10.4%)
浮動性めまい	0 (0.0%)	2 (0.6%)	4 (1.4%)	0 (0.0%)	4 (2.5%)	0 (0.0%)	16 (2.4%)	0 (0.0%)	24 (1.9%)
片頭痛	0 (0.0%)	3 (0.8%)	5 (1.7%)	0 (0.0%)	1 (0.6%)	3 (1.9%)	2 (0.3%)	0 (0.0%)	11 (0.9%)
錯感覚	0 (0.0%)	5 (1.4%)	1 (0.3%)	0 (0.0%)	3 (1.9%)	0 (0.0%)	5 (0.8%)	0 (0.0%)	9 (0.7%)
感覚鈍麻	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	2 (1.3%)	0 (0.0%)	5 (0.8%)	0 (0.0%)	8 (0.6%)
振戦	0 (0.0%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	3 (0.5%)	0 (0.0%)	4 (0.3%)
坐骨神経痛	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.6%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	3 (0.2%)
副鼻腔炎に伴う頭痛	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.5%)	0 (0.0%)	3 (0.2%)
失神	0 (0.0%)	1 (0.3%)	2 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	3 (0.2%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
痙攣	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
味覚異常	0 (0.0%)	3 (0.8%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
嗜眠	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	2 (0.2%)
神経圧迫	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
末梢性ニューロパチー	1 (2.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
手根管症候群	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
頚髄症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
肘部管症候群	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
脱髄	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
異常感覚	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
顔面不全麻痺	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
筋緊張低下	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
虚血性脳卒中	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
意識消失	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
神経根圧迫	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
神経痛	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
感覚障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
知覚過敏	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
傾眠	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
呼吸器、胸郭および縦隔障害	4 (8.2%)	23 (6.4%)	33 (11.5%)	4 (5.2%)	12 (7.6%)	22 (14.3%)	79 (12.0%)	2 (14.3%)	151 (12.2%)
咳嗽	1 (2.0%)	14 (3.9%)	14 (4.9%)	0 (0.0%)	5 (3.2%)	7 (4.5%)	38 (5.8%)	0 (0.0%)	64 (5.2%)
口腔咽頭痛	3 (6.1%)	2 (0.6%)	5 (1.7%)	0 (0.0%)	2 (1.3%)	2 (1.3%)	21 (3.2%)	0 (0.0%)	30 (2.4%)
鼻漏	0 (0.0%)	0 (0.0%)	2 (0.7%)	0 (0.0%)	0 (0.0%)	3 (1.9%)	3 (0.5%)	0 (0.0%)	8 (0.6%)
鼻閉	0 (0.0%)	1 (0.3%)	2 (0.7%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	3 (0.5%)	1 (7.1%)	7 (0.6%)
喘息	0 (0.0%)	1 (0.3%)	2 (0.7%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	3 (0.5%)	0 (0.0%)	6 (0.5%)
呼吸困難	0 (0.0%)	2 (0.6%)	2 (0.7%)	0 (0.0%)	0 (0.0%)	2 (1.3%)	2 (0.3%)	0 (0.0%)	6 (0.5%)
鼻出血	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	3 (0.5%)	0 (0.0%)	5 (0.4%)
呼吸障害	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	4 (0.6%)	0 (0.0%)	5 (0.4%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
副鼻腔うっ血	0 (0.0%)	1 (0.3%)	2 (0.7%)	0 (0.0%)	1 (0.6%)	1 (0.6%)	1 (0.2%)	0 (0.0%)	5 (0.4%)
上気道うっ血	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.6%)	1 (0.6%)	1 (0.2%)	1 (7.1%)	5 (0.4%)
湿性咳嗽	0 (0.0%)	1 (0.3%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.5%)	0 (0.0%)	4 (0.3%)
気道うっ血	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.3%)	2 (0.3%)	0 (0.0%)	4 (0.3%)
アレルギー性鼻炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.3%)	2 (0.3%)	0 (0.0%)	4 (0.3%)
上気道の炎症	1 (2.0%)	1 (0.3%)	1 (0.3%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	4 (0.3%)
喘鳴	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	4 (0.3%)
慢性閉塞性肺疾患	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (2.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
労作性呼吸困難	0 (0.0%)	1 (0.3%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
肺塞栓症	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
季節性鼻炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.3%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
アレルギー性咳嗽	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
慢性気管支炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
息詰まり感	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
咽喉乾燥	0 (0.0%)	1 (0.3%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
発声障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
喀血	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
上気道分泌増加	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
肺浸潤	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
鼻乾燥	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
鼻閉塞	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
呼吸時疼痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
胸水	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
くしゃみ	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
咽喉刺激感	0 (0.0%)	2 (0.6%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
鼻部不快感	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
胸膜炎	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
血液およびリンパ系障害	8 (16.3%)	14 (3.9%)	21 (7.3%)	9 (11.7%)	12 (7.6%)	14 (9.1%)	71 (10.8%)	0 (0.0%)	127 (10.3%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
貧血	6 (12.2%)	6 (1.7%)	12 (4.2%)	5 (6.5%)	2 (1.3%)	4 (2.6%)	39 (5.9%)	0 (0.0%)	62 (5.0%)
白血球減少症	0 (0.0%)	3 (0.8%)	0 (0.0%)	0 (0.0%)	4 (2.5%)	4 (2.6%)	15 (2.3%)	0 (0.0%)	23 (1.9%)
好中球減少症	0 (0.0%)	1 (0.3%)	3 (1.0%)	1 (1.3%)	1 (0.6%)	2 (1.3%)	8 (1.2%)	0 (0.0%)	15 (1.2%)
好酸球増加症	0 (0.0%)	1 (0.3%)	2 (0.7%)	1 (1.3%)	1 (0.6%)	2 (1.3%)	4 (0.6%)	0 (0.0%)	10 (0.8%)
リンパ球減少症	0 (0.0%)	2 (0.6%)	3 (1.0%)	0 (0.0%)	2 (1.3%)	0 (0.0%)	4 (0.6%)	0 (0.0%)	9 (0.7%)
白血球増加症	0 (0.0%)	1 (0.3%)	2 (0.7%)	1 (1.3%)	1 (0.6%)	1 (0.6%)	3 (0.5%)	0 (0.0%)	8 (0.6%)
単球減少症	0 (0.0%)	2 (0.6%)	3 (1.0%)	1 (1.3%)	0 (0.0%)	1 (0.6%)	1 (0.2%)	0 (0.0%)	6 (0.5%)
好中球増加症	0 (0.0%)	0 (0.0%)	3 (1.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	2 (0.3%)	0 (0.0%)	6 (0.5%)
血小板増加症	0 (0.0%)	1 (0.3%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	4 (0.6%)	0 (0.0%)	6 (0.5%)
鉄欠乏性貧血	1 (2.0%)	0 (0.0%)	2 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.5%)	0 (0.0%)	5 (0.4%)
リンパ節症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.3%)	3 (0.5%)	0 (0.0%)	5 (0.4%)
リンパ球増加症	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (1.3%)	1 (0.6%)	1 (0.6%)	1 (0.2%)	0 (0.0%)	5 (0.4%)
血小板減少症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	3 (0.2%)
二血球減少症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
血液障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
溶血性貧血	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
出血性貧血	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
リンパ節痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
小球性貧血	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
単球増加症	0 (0.0%)	1 (0.3%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
赤血球大小不同症	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
特発性血小板減少性紫斑病	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
多染性	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
臨床検査	5 (10.2%)	22 (6.1%)	20 (7.0%)	3 (3.9%)	13 (8.3%)	20 (13.0%)	53 (8.0%)	1 (7.1%)	107 (8.7%)
アラニン・アミノトランスフェラーゼ増加	0 (0.0%)	9 (2.5%)	6 (2.1%)	0 (0.0%)	1 (0.6%)	4 (2.6%)	13 (2.0%)	0 (0.0%)	24 (1.9%)
アスパラギン酸アミノトランスフェラーゼ増加	0 (0.0%)	6 (1.7%)	2 (0.7%)	0 (0.0%)	1 (0.6%)	5 (3.2%)	8 (1.2%)	0 (0.0%)	16 (1.3%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
ヘモグロビン減少	1 (2.0%)	2 (0.6%)	2 (0.7%)	2 (2.6%)	1 (0.6%)	1 (0.6%)	3 (0.5%)	0 (0.0%)	9 (0.7%)
肝酵素上昇	0 (0.0%)	2 (0.6%)	2 (0.7%)	0 (0.0%)	3 (1.9%)	2 (1.3%)	2 (0.3%)	0 (0.0%)	8 (0.6%)
好酸球数増加	0 (0.0%)	4 (1.1%)	2 (0.7%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	3 (0.5%)	0 (0.0%)	6 (0.5%)
白血球数減少	0 (0.0%)	1 (0.3%)	2 (0.7%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	3 (0.5%)	0 (0.0%)	6 (0.5%)
白血球数増加	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.3%)	3 (0.5%)	1 (7.1%)	6 (0.5%)
ヘマトクリット減少	1 (2.0%)	2 (0.6%)	1 (0.3%)	1 (1.3%)	0 (0.0%)	1 (0.6%)	2 (0.3%)	0 (0.0%)	5 (0.4%)
体重減少	1 (2.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (0.8%)	0 (0.0%)	5 (0.4%)
血中カリウム減少	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	1 (0.6%)	2 (0.3%)	0 (0.0%)	4 (0.3%)
好中球数減少	0 (0.0%)	0 (0.0%)	2 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	4 (0.3%)
血小板数増加	1 (2.0%)	2 (0.6%)	1 (0.3%)	0 (0.0%)	1 (0.6%)	2 (1.3%)	0 (0.0%)	0 (0.0%)	4 (0.3%)
血中アルカリホスファターゼ増加	0 (0.0%)	2 (0.6%)	2 (0.7%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	3 (0.2%)
血中ビリルビン増加	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	3 (0.2%)
血圧上昇	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	3 (0.2%)
肝機能検査異常	1 (2.0%)	0 (0.0%)	2 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	3 (0.2%)
好中球数増加	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.6%)	0 (0.0%)	1 (7.1%)	3 (0.2%)
トランスアミナーゼ上昇	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.3%)	1 (0.2%)	0 (0.0%)	3 (0.2%)
体重増加	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	3 (0.2%)
血中アルブミン減少	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
血中カルシウム減少	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	2 (0.2%)
血中カルシウム増加	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	2 (0.2%)
血中クレアチニン増加	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	2 (0.2%)
血中リン増加	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
血中尿素増加	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
体温上昇	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
リンパ球数増加	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
単球数減少	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
血小板数減少	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	2 (0.2%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
総蛋白減少	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	2 (0.2%)
尿中白血球陽性	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
杆状核好中球数増加	1 (2.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
好塩基球数増加	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
抱合ビリルビン増加	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
乳房生検	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
血中酸性ホスファターゼ増加	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
血中非抱合ビリルビン増加	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
血中ブドウ糖増加	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
血中鉄減少	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
収縮期血圧上昇	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
血中テストステロン減少	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
胸部Ｘ線異常	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
心エコー像異常	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
心拍数増加	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
心音異常	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
ＩＮＲ増加	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
リンパ球数減少	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
後骨髄球数増加	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
単球数増加	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
骨髄球数増加	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
好中球数異常	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
腎機能検査異常	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
トレポネーマ検査陽性	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
α１フェトプロテイン増加	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
血中コレステロール増加	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
グラム染色陰性	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
リンパ球数異常	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
単球数異常	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
骨髄球存在	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
血小板形態異常	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
バーセル陽性	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
傷害、中毒および処置合併症	2 (4.1%)	8 (2.2%)	12 (4.2%)	1 (1.3%)	9 (5.7%)	7 (4.5%)	43 (6.5%)	1 (7.1%)	73 (5.9%)
挫傷	0 (0.0%)	5 (1.4%)	2 (0.7%)	0 (0.0%)	2 (1.3%)	2 (1.3%)	8 (1.2%)	0 (0.0%)	14 (1.1%)
節足動物咬傷	0 (0.0%)	0 (0.0%)	2 (0.7%)	0 (0.0%)	2 (1.3%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	6 (0.5%)
肉離れ	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	5 (0.8%)	0 (0.0%)	6 (0.5%)
関節捻挫	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.6%)	0 (0.0%)	4 (0.3%)
処置後合併症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	3 (0.5%)	0 (0.0%)	4 (0.3%)
動物咬傷	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.5%)	0 (0.0%)	3 (0.2%)
手骨折	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.2%)	1 (7.1%)	3 (0.2%)
関節脱臼	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.5%)	0 (0.0%)	3 (0.2%)
裂傷	0 (0.0%)	2 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.2%)	0 (0.0%)	3 (0.2%)
処置による疼痛	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	2 (0.3%)	0 (0.0%)	3 (0.2%)
足関節部骨折	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
上顆炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
肋骨骨折	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
熱傷	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	2 (0.2%)
偶発的過量投与	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
偶発的中毒	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
節足動物刺傷	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
背部損傷	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
骨亀裂	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
第２度熱傷	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
脳振盪	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
擦過傷	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
転倒	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
足骨折	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
瘢痕ヘルニア	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
関節損傷	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
靱帯断裂	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
四肢損傷	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
口唇損傷	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
筋損傷	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
処置による頭痛	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
橈骨骨折	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
脊柱損傷	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
脊椎圧迫骨折	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
腱損傷	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
歯牙破折	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
創傷	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
手首関節骨折	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
多発性外傷	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
鋭的腹部外傷	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
創合併症	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
精神障害	0 (0.0%)	13 (3.6%)	11 (3.8%)	1 (1.3%)	6 (3.8%)	7 (4.5%)	36 (5.5%)	1 (7.1%)	62 (5.0%)
不眠症	0 (0.0%)	6 (1.7%)	6 (2.1%)	0 (0.0%)	3 (1.9%)	2 (1.3%)	15 (2.3%)	0 (0.0%)	26 (2.1%)
うつ病	0 (0.0%)	5 (1.4%)	2 (0.7%)	0 (0.0%)	1 (0.6%)	3 (1.9%)	10 (1.5%)	1 (7.1%)	17 (1.4%)
不安	0 (0.0%)	3 (0.8%)	2 (0.7%)	0 (0.0%)	1 (0.6%)	2 (1.3%)	7 (1.1%)	0 (0.0%)	12 (1.0%)
異常な夢	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
激越	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
錯乱状態	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
抑うつ気分	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
情動障害	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
幻覚	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
精神障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
神経過敏	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
落ち着きのなさ	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
睡眠障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
社会恐怖症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
物質乱用	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
リビドー減退	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
血管障害	3 (6.1%)	7 (2.0%)	7 (2.4%)	1 (1.3%)	10 (6.4%)	4 (2.6%)	30 (4.5%)	0 (0.0%)	52 (4.2%)
高血圧	1 (2.0%)	3 (0.8%)	6 (2.1%)	1 (1.3%)	6 (3.8%)	2 (1.3%)	15 (2.3%)	0 (0.0%)	30 (2.4%)
潮紅	2 (4.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	3 (0.5%)	0 (0.0%)	4 (0.3%)
深部静脈血栓症	0 (0.0%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.5%)	0 (0.0%)	3 (0.2%)
血腫	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.6%)	1 (0.2%)	0 (0.0%)	3 (0.2%)
ほてり	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.6%)	1 (0.2%)	0 (0.0%)	3 (0.2%)
低血圧	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	2 (0.2%)
大動脈瘤破裂	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
出血	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
間欠性跛行	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
末梢冷感	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
静脈炎	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
血栓性静脈炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
表在性血栓性静脈炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
静脈瘤	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
血管脆弱化	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
血管炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
代謝および栄養障害	5 (10.2%)	8 (2.2%)	12 (4.2%)	4 (5.2%)	1 (0.6%)	5 (3.2%)	25 (3.8%)	0 (0.0%)	47 (3.8%)
脱水	1 (2.0%)	1 (0.3%)	2 (0.7%)	1 (1.3%)	1 (0.6%)	1 (0.6%)	6 (0.9%)	0 (0.0%)	11 (0.9%)
食欲減退	0 (0.0%)	1 (0.3%)	2 (0.7%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	3 (0.5%)	0 (0.0%)	6 (0.5%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
糖尿病	0 (0.0%)	1 (0.3%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.6%)	0 (0.0%)	5 (0.4%)
低カリウム血症	1 (2.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	3 (0.5%)	0 (0.0%)	4 (0.3%)
痛風	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	2 (0.3%)	0 (0.0%)	3 (0.2%)
鉄欠乏	0 (0.0%)	1 (0.3%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	3 (0.2%)
栄養障害	3 (6.1%)	0 (0.0%)	0 (0.0%)	2 (2.6%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	3 (0.2%)
高カルシウム血症	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
高脂血症	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
低マグネシウム血症	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
異常体重減少	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
細胞死	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
高アルブミン血症	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
高アミラーゼ血症	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
高コレステロール血症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
高血糖	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
高蛋白血症	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
低アルブミン血症	1 (2.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
低カルシウム血症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
低ナトリウム血症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
血液量減少症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
ビタミンＢ群欠乏	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
ビタミンＤ欠乏	1 (2.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
高リン酸塩血症	0 (0.0%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
低蛋白血症	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
ラクトース不耐性	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
眼障害	0 (0.0%)	6 (1.7%)	11 (3.8%)	1 (1.3%)	6 (3.8%)	6 (3.9%)	18 (2.7%)	1 (7.1%)	43 (3.5%)
結膜炎	0 (0.0%)	0 (0.0%)	4 (1.4%)	1 (1.3%)	2 (1.3%)	2 (1.3%)	3 (0.5%)	1 (7.1%)	13 (1.1%)
白内障	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	3 (0.5%)	0 (0.0%)	5 (0.4%)
霰粒腫	0 (0.0%)	1 (0.3%)	2 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	3 (0.2%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
上強膜炎	0 (0.0%)	1 (0.3%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	3 (0.2%)
眼の炎症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	3 (0.2%)
眼瞼炎	0 (0.0%)	0 (0.0%)	2 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
アレルギー性結膜炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
眼充血	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
視力障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	2 (0.2%)
加齢黄斑変性	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
眼精疲労	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
複視	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
眼乾燥	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
眼刺激	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
眼そう痒症	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
眼部腫脹	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
眼瞼障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
眼瞼そう痒症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
緑内障	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
黄斑症	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
眼窩浮腫	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
翼状片	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
眼瞼痙攣	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
眼出血	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
眼球乾燥	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
腎および尿路障害	0 (0.0%)	6 (1.7%)	4 (1.4%)	0 (0.0%)	5 (3.2%)	6 (3.9%)	19 (2.9%)	1 (7.1%)	35 (2.8%)
腎結石症	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	2 (1.3%)	1 (0.6%)	5 (0.8%)	0 (0.0%)	8 (0.6%)
頻尿	0 (0.0%)	0 (0.0%)	2 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.5%)	1 (7.1%)	6 (0.5%)
排尿困難	0 (0.0%)	2 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	2 (0.3%)	0 (0.0%)	4 (0.3%)
腎仙痛	0 (0.0%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.3%)	2 (0.3%)	0 (0.0%)	4 (0.3%)
血尿	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	3 (0.2%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
腎嚢胞	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	3 (0.2%)
夜間頻尿	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	2 (0.2%)
糸球体腎炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
水腎症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
尿意切迫	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.1%)	1 (0.1%)
蛋白尿	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
急性腎不全	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
慢性腎不全	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
腎臓痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
尿道痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
尿失禁	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
尿閉	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
着色尿	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
腎不全	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
生殖系および乳房障害	1 (2.0%)	3 (0.8%)	6 (2.1%)	1 (1.3%)	3 (1.9%)	7 (4.5%)	14 (2.1%)	1 (7.1%)	31 (2.5%)
良性前立腺肥大症	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (1.3%)	1 (0.6%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	4 (0.3%)
精巣上体炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.6%)	0 (0.0%)	4 (0.3%)
月経過多	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	3 (0.2%)
無月経	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	2 (0.2%)
乳房痛	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
月経困難症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
前立腺炎	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
バルトリン嚢腫	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
乳房嚢胞	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
乳房腫瘤	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
子宮頚部嚢胞	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
子宮頚部出血	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.1%)	1 (0.1%)
膀胱瘤	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
子宮内膜増殖症	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
女性化乳房	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
不規則月経	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
不正子宮出血	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
頻発月経	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
前立腺腫大	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
陰部そう痒症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
精巣痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
子宮出血	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
子宮ポリープ	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
腟分泌物	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
外陰腟そう痒症	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
卵巣嚢胞	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
卵巣嚢胞破裂	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
外陰腟灼熱感	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
耳および迷路障害	0 (0.0%)	3 (0.8%)	3 (1.0%)	0 (0.0%)	2 (1.3%)	5 (3.2%)	14 (2.1%)	1 (7.1%)	25 (2.0%)
回転性めまい	0 (0.0%)	1 (0.3%)	1 (0.3%)	0 (0.0%)	2 (1.3%)	2 (1.3%)	5 (0.8%)	0 (0.0%)	10 (0.8%)
耳痛	0 (0.0%)	1 (0.3%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	2 (0.3%)	1 (7.1%)	5 (0.4%)
耳垢栓塞	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	2 (0.2%)
内耳の炎症	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
耳介軟骨膜炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
耳不快感	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
耳の障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
耳管機能障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
乗物酔い	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
耳鳴	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
鼓膜穿孔	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
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）	0 (0.0%)	1 (0.3%)	5 (1.7%)	1 (1.3%)	1 (0.6%)	4 (2.6%)	9 (1.4%)	0 (0.0%)	20 (1.6%)
子宮平滑筋腫	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	3 (0.5%)	0 (0.0%)	4 (0.3%)
大腸腺腫	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	3 (0.2%)
脂肪腫	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
皮膚乳頭腫	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
乳房の良性新生物	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
唾液腺の良性新生物	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
上皮内癌	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
結腸癌	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
線維性組織球腫	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
胃腸管腺腫	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
肺腺癌	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
骨軟骨腫	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
前立腺腺腫	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
直腸癌	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
脂漏性角化症	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
扁平上皮癌	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
甲状腺癌	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
乳癌	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
免疫系障害	0 (0.0%)	4 (1.1%)	4 (1.4%)	0 (0.0%)	4 (2.5%)	1 (0.6%)	7 (1.1%)	1 (7.1%)	16 (1.3%)
季節性アレルギー	0 (0.0%)	1 (0.3%)	1 (0.3%)	0 (0.0%)	4 (2.5%)	1 (0.6%)	7 (1.1%)	1 (7.1%)	13 (1.1%)
過敏症	0 (0.0%)	1 (0.3%)	2 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
４型過敏症	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
金属アレルギー	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
薬物過敏症	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
肝胆道系障害	1 (2.0%)	0 (0.0%)	1 (0.3%)	2 (2.6%)	1 (0.6%)	2 (1.3%)	8 (1.2%)	0 (0.0%)	14 (1.1%)
肝炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	3 (0.2%)
脂肪肝	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
高ビリルビン血症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	2 (0.2%)
胆管結石	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
胆嚢炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
胆石症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
肝嚢胞	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
肝不全	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
肝機能異常	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
肝腫大	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
心臓障害	1 (2.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.6%)	2 (1.3%)	7 (1.1%)	0 (0.0%)	11 (0.9%)
狭心症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	2 (0.2%)
不整脈	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
心房細動	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	2 (0.2%)
冠動脈疾患	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
動悸	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
急性心筋梗塞	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
徐脈	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
心不全	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
心血管障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
心嚢液貯留	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
心膜炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
妊娠、産褥および周産期の状態	0 (0.0%)	2 (0.6%)	3 (1.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	6 (0.5%)
妊娠	0 (0.0%)	2 (0.6%)	3 (1.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	6 (0.5%)
自然流産	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
社会環境	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (1.3%)	0 (0.0%)	1 (0.6%)	3 (0.5%)	0 (0.0%)	6 (0.5%)
パートナーの妊娠	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (1.3%)	0 (0.0%)	1 (0.6%)	3 (0.5%)	0 (0.0%)	6 (0.5%)
外科および内科処置	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	4 (0.6%)	0 (0.0%)	5 (0.4%)
副鼻腔手術	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
前頭洞手術	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
病変部切除	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
抜歯	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
先天性、家族性および遺伝性障害	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.5%)	0 (0.0%)	4 (0.3%)
重複尿管	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
ジルベール症候群	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
遺伝性フルクトース不耐症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
静脈奇形	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
内分泌障害	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
クッシング様	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

[a] Includes data up to the time of the first golimumab dose in the maintenance study.
[b] Includes data from the time of dose adjustment onward for those who increased to the indicated dose during the maintenance study.
[c] Includes data up to the time of dose adjustment for those who increased dose from the indicated dose during the maintenance study.
[d] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[e] Includes data from the time of the first golimumab dose onward.

表 2.7.4.7-付録-7 100 人年あたりの有害事象発現率（T16，T17 及び T18 試験 228 週まで；全投与被験者）

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	Golimumab Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
Treated subjects in C0524T16 and C0524T17	49	358	298	77	157	155	695	22	1245
Avg duration of follow-up (weeks)	12.3	26.3	108.6	11.9	58.9	132.1	112.3	115.5	115.3
Avg exposure (number of administrations)	1.6	6.5	24.5	1.6	14.2	31.3	25.7	26.7	26.4
Total subject years of follow-up	12	181	622	18	178	394	1500	49	2761
Number of specified events per hundred subject years of follow-up (95% confidence interval)[f]									
Adverse events	1024.99 (849.12, 1226.55)	414.56 (385.44, 445.30)	281.71 (268.68, 295.22)	828.56 (699.62, 974.39)	362.41 (334.98, 391.49)	263.37 (247.58, 279.90)	286.74 (278.23, 295.43)	413.45 (358.40, 474.57)	292.85 (286.50, 299.30)
Serious adverse events	223.95 (146.29, 328.13)	14.90 (9.82, 21.68)	13.50 (10.77, 16.71)	221.33 (157.39, 302.56)	15.73 (10.45, 22.74)	9.90 (7.04, 13.54)	15.93 (13.97, 18.08)	6.14 (1.27, 17.94)	15.65 (14.21, 17.20)
Infections[g]	232.56 (153.26, 338.36)	68.45 (56.93, 81.61)	84.69 (77.61, 92.24)	255.38 (186.28, 341.72)	75.85 (63.60, 89.78)	70.86 (62.79, 79.68)	71.65 (67.43, 76.07)	135.09 (104.48, 171.86)	77.04 (73.80, 80.39)
Serious infections[g]	68.91 (29.75, 135.77)	1.66 (0.34, 4.84)	2.57 (1.47, 4.18)	73.78 (39.28, 126.16)	4.50 (1.94, 8.86)	2.79 (1.39, 5.00)	3.20 (2.36, 4.24)	2.05 (0.05, 11.40)	3.51 (2.85, 4.29)
Neoplasms (malignant)	0.00 (0.00, 25.80)	0.55 (0.01, 3.08)	0.64 (0.18, 1.65)	11.35 (1.37, 41.00)	0.00 (0.00, 1.68)	0.76 (0.16, 2.23)	0.93 (0.51, 1.57)	0.00 (0.00, 6.13)	0.83 (0.53, 1.25)
Injection-site reactions	0.00 (0.00, 25.80)	9.38 (5.47, 15.02)	1.29 (0.56, 2.53)	0.00 (0.00, 17.00)	23.04 (16.53, 31.25)	10.67 (7.69, 14.42)	18.80 (16.67, 21.12)	36.84 (21.83, 58.23)	14.16 (12.79, 15.64)
Adverse events leading to discontinuation of study agent	43.07 (13.98, 100.50)	7.73 (4.23, 12.97)	11.41 (8.91, 14.39)	34.05 (12.50, 74.11)	7.87 (4.30, 13.20)	4.57 (2.71, 7.22)	10.66 (9.08, 12.45)	2.05 (0.05, 11.40)	9.78 (8.65, 11.02)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	Golimumab Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
Death	0.00	0.55	0.32	5.68	0.00	0.25	0.53	0.00	0.43
	(0.00, 25.80)	(0.01, 3.08)	(0.04, 1.16)	(0.14, 31.62)	(0.00, 1.68)	(0.01, 1.42)	(0.23, 1.05)	(0.00, 6.13)	(0.22, 0.76)

[a] Includes data up to the time of the first golimumab dose.
[b] Includes data from the time of dose adjustment onward for those who increased to the indicated dose.
[c] Includes data up to the time of dose adjustment for those who increased dose from the indicated dose.
[d] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[e] Includes data from the time of the first golimumab dose onward.
[f] Confidence intervals based on exact method.
[g] Infection as assessed by the investigator.

表 2.7.4.7-付録-8 すべての有害事象（T17 試験 6 週まで，日本人）

		Golimumab				
	Placebo	100 mg -> 50 mg	200 mg -> 100 mg	400 mg -> 200 mg	Combined	All Golimumab
Treated subjects in C0524T17	30	-	23	19	42	42
Avg duration of follow-up (weeks)	6.07	-	6.08	5.93	6.01	6.01
Avg exposure (number of administrations)	1.97	-	1.96	2.00	1.98	1.98
Subjects with 1 or more TEAEs	18 (60.0%)	-	13 (56.5%)	6 (31.6%)	19 (45.2%)	19 (45.2%)
System-organ class/preferred term						
感染症および寄生虫症	7 (23.3%)	-	6 (26.1%)	4 (21.1%)	10 (23.8%)	10 (23.8%)
膀胱炎	0	-	0	1 (5.3%)	1 (2.4%)	1 (2.4%)
帯状疱疹	0	-	0	1 (5.3%)	1 (2.4%)	1 (2.4%)
鼻咽頭炎	3 (10.0%)	-	2 (8.7%)	1 (5.3%)	3 (7.1%)	3 (7.1%)
百日咳	0	-	0	1 (5.3%)	1 (2.4%)	1 (2.4%)
気道感染	0	-	0	1 (5.3%)	1 (2.4%)	1 (2.4%)
肛門膿瘍	1 (3.3%)	-	0	0	0	0
気管支炎	1 (3.3%)	-	0	0	0	0
感染性小腸結腸炎	1 (3.3%)	-	0	0	0	0
毛包炎	0	-	1 (4.3%)	0	1 (2.4%)	1 (2.4%)
肺炎	0	-	1 (4.3%)	0	1 (2.4%)	1 (2.4%)
上気道感染	1 (3.3%)	-	1 (4.3%)	0	1 (2.4%)	1 (2.4%)
尿路感染	0	-	1 (4.3%)	0	1 (2.4%)	1 (2.4%)
胃腸障害	3 (10.0%)	-	1 (4.3%)	2 (10.5%)	3 (7.1%)	3 (7.1%)
潰瘍性大腸炎	1 (3.3%)	-	1 (4.3%)	1 (5.3%)	2 (4.8%)	2 (4.8%)
悪心	1 (3.3%)	-	0	1 (5.3%)	1 (2.4%)	1 (2.4%)
腹痛	1 (3.3%)	-	0	0	0	0
便秘	1 (3.3%)	-	0	0	0	0
下痢	1 (3.3%)	-	0	0	0	0
腸炎	1 (3.3%)	-	0	0	0	0
全身障害および投与局所様態	4 (13.3%)	-	1 (4.3%)	1 (5.3%)	2 (4.8%)	2 (4.8%)
発熱	2 (6.7%)	-	1 (4.3%)	1 (5.3%)	2 (4.8%)	2 (4.8%)
医薬品副作用	1 (3.3%)	-	0	0	0	0
熱感	1 (3.3%)	-	0	0	0	0
傷害、中毒および処置合併症	0	-	1 (4.3%)	1 (5.3%)	2 (4.8%)	2 (4.8%)
挫傷	0	-	0	1 (5.3%)	1 (2.4%)	1 (2.4%)
熱傷	0	-	1 (4.3%)	0	1 (2.4%)	1 (2.4%)
神経系障害	2 (6.7%)	-	2 (8.7%)	1 (5.3%)	3 (7.1%)	3 (7.1%)
浮動性めまい	0	-	0	1 (5.3%)	1 (2.4%)	1 (2.4%)

		Golimumab				
	Placebo	100 mg -> 50 mg	200 mg -> 100 mg	400 mg -> 200 mg	Combined	All Golimumab
異常感覚	0	-	0	1 (5.3%)	1 (2.4%)	1 (2.4%)
頭痛	2 (6.7%)	-	1 (4.3%)	0	1 (2.4%)	1 (2.4%)
感覚鈍麻	0	-	1 (4.3%)	0	1 (2.4%)	1 (2.4%)
血液およびリンパ系障害	2 (6.7%)	-	2 (8.7%)	0	2 (4.8%)	2 (4.8%)
鉄欠乏性貧血	1 (3.3%)	-	1 (4.3%)	0	1 (2.4%)	1 (2.4%)
白血球減少症	1 (3.3%)	-	1 (4.3%)	0	1 (2.4%)	1 (2.4%)
好中球減少症	0	-	1 (4.3%)	0	1 (2.4%)	1 (2.4%)
眼障害	1 (3.3%)	-	0	0	0	0
霰粒腫	1 (3.3%)	-	0	0	0	0
肝胆道系障害	0	-	1 (4.3%)	0	1 (2.4%)	1 (2.4%)
肝炎	0	-	1 (4.3%)	0	1 (2.4%)	1 (2.4%)
臨床検査	2 (6.7%)	-	1 (4.3%)	0	1 (2.4%)	1 (2.4%)
ヘモグロビン減少	1 (3.3%)	-	0	0	0	0
体重増加	1 (3.3%)	-	0	0	0	0
白血球数減少	0	-	1 (4.3%)	0	1 (2.4%)	1 (2.4%)
代謝および栄養障害	2 (6.7%)	-	0	0	0	0
高リン酸塩血症	2 (6.7%)	-	0	0	0	0
筋骨格系および結合組織障害	1 (3.3%)	-	0	0	0	0
関節痛	1 (3.3%)	-	0	0	0	0
精神障害	1 (3.3%)	-	0	0	0	0
不眠症	1 (3.3%)	-	0	0	0	0
生殖系および乳房障害	0	-	1 (4.3%)	0	1 (2.4%)	1 (2.4%)
乳房痛	0	-	1 (4.3%)	0	1 (2.4%)	1 (2.4%)
陰部そう痒症	0	-	1 (4.3%)	0	1 (2.4%)	1 (2.4%)
呼吸器、胸郭および縦隔障害	1 (3.3%)	-	1 (4.3%)	0	1 (2.4%)	1 (2.4%)
咳嗽	1 (3.3%)	-	0	0	0	0
口腔咽頭痛	0	-	1 (4.3%)	0	1 (2.4%)	1 (2.4%)
皮膚および皮下組織障害	2 (6.7%)	-	2 (8.7%)	0	2 (4.8%)	2 (4.8%)
アトピー性皮膚炎	0	-	1 (4.3%)	0	1 (2.4%)	1 (2.4%)
結節性紅斑	1 (3.3%)	-	0	0	0	0
発疹	1 (3.3%)	-	1 (4.3%)	0	1 (2.4%)	1 (2.4%)
皮膚剥脱	1 (3.3%)	-	0	0	0	0

Note: Adverse Events are coded using MedDRA 13.0

表 2.7.4.7-付録-9 すべての有害事象一覧（T17 試験 6 週まで，日本人）

Treatment Group	Study Part[a]	Subject ID	Age/ Sex	Country/ Race	Study Agent Dose Prior to AE	Study Day of Study Agent Admini-stration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relation-ship to Study Agent	Action Taken with Study Agent	Infection/ Infusion-site Reaction[c, d]
Placebo	Part 2b	7802-00001	3[redacted]/M	JAPAN/Asian	0 mg	1	熱感	GENERALIZED HOT FEELING	1	1	Resolved	No	Mild	Possible	None/not applicable	No/No
		7803-00001	2[redacted]/F	JAPAN/Asian	0 mg	1	鉄欠乏性貧血	IRONDEFICIENCY ANEMIA EXACERBATION	15	17	Resolved	No	Moderate	Unlikely	None/not applicable	No/No
					0 mg	15	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	15	55	Resolved	Yes	Severe	Unlikely	None/not applicable	No/No
					0 mg	15	頭痛	HEADACHE	28	4	Resolved	No	Mild	Not related	None/not applicable	No/No
					0 mg	15	悪心	NAUSEA	31	1	Resolved	No	Mild	Not related	None/not applicable	No/No
					0 mg	15	腹痛	ABDOMINAL PAIN	32	35	Resolved	No	Mild	Not related	None/not applicable	No/No
					0 mg	15	悪心	NAUSEA	38	1	Resolved	No	Mild	Not related	None/not applicable	No/No
					0 mg	15	便秘	CONSTIPATION	45	31	Resolved	No	Mild	Not related	None/not applicable	No/No
					0 mg	15	体重増加	INCREASE IN BODY WEIGHT	47	-	Ongoing	No	Mild	Not related	None/not applicable	No/No
		7803-00002	2[redacted]/M	JAPAN/Asian	0 mg	1	下痢	DIARRHEA	6	2	Resolved	No	Moderate	Not related	None/not applicable	No/No
					0 mg	18	霰粒腫	RIGHT CHALAZIA	39	3	Resolved	No	Mild	Not related	None/not applicable	Yes/No
		7804-00006	5[redacted]/M	JAPAN/Asian	0 mg	1	気管支炎	BRONCHITIS	9	21	Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No
		7805-00001	3[redacted]/M	JAPAN/Asian	0 mg	14	高リン酸塩血症	HYPERPHOSPHATEMIA	39	-	Ongoing	No	Mild	Not related	None/not applicable	No/No
		7805-00009	4[redacted]/M	JAPAN/Asian	0 mg	15	高リン酸塩血症	HYPERPHOSPHATEMIA	46	-	Ongoing	No	Mild	Not related	None/not applicable	No/No
		7806-00003	2[redacted]/F	JAPAN/Asian	0 mg	1	医薬品副作用	STEROID NEUROPATHY	16	16	Resolved	No	Moderate	Not related	None/not applicable	No/No
		7807-00004	2[redacted]/F	JAPAN/Asian	0 mg	12	肛門膿瘍	PERIPROCTAL ABSCESS	23	20	Resolved	No	Moderate	Possible	None/not applicable	Yes/No
					0 mg	12	肛門膿瘍	PERIPROCTAL ABSCESS	42	100	Resolved	Yes	Moderate	Possible	None/not applicable	Yes/No

Treatment Group	Study Part[a]	Subject ID	Age/ Sex	Country/ Race	Study Agent Dose Prior to AE	Study Day of Study Agent Admini-stration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relation-ship to Study Agent	Action Taken with Study Agent	Infection/ Infusion-site Reaction[c, d]
		7807-00005	4[redacted]/F	JAPAN/Asian	0 mg	1	咳嗽	COUGH	7	-	Ongoing	No	Mild	Possible	None/not applicable	Yes/No
					0 mg	1	上気道感染	UPPER RESPIRATORY INFECTION	7	8	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
					0 mg	15	発熱	FEVER UP	30	2	Resolved	No	Mild	Possible	None/not applicable	Yes/No
					0 mg	15	発熱	FEVER UP	40	1	Resolved	No	Mild	Possible	None/not applicable	Yes/No
		7807-00007	4[redacted]/M	JAPAN/Asian	0 mg	1	不眠症	SLEEPLESSNESS	2	-	Ongoing	No	Mild	Possible	None/not applicable	No/No
					0 mg	1	頭痛	HEADACHE	8	1	Resolved	No	Mild	Possible	None/not applicable	No/No
					0 mg	10	発熱	SLIGHT FEVER	12	-	Ongoing	No	Mild	Possible	None/not applicable	Yes/No
					0 mg	10	鼻咽頭炎	COLD	13	1	Resolved	No	Mild	Possible	None/not applicable	Yes/No
					0 mg	10	鼻咽頭炎	COLD	20	1	Resolved	No	Mild	Possible	None/not applicable	Yes/No
					0 mg	10	鼻咽頭炎	COLD	24	1	Resolved	No	Mild	Possible	None/not applicable	Yes/No
					0 mg	10	鼻咽頭炎	COLD	37	2	Resolved	No	Mild	Possible	None/not applicable	Yes/No
		7808-00002	3[redacted]/M	JAPAN/Asian	0 mg	1	腸炎	ACUTE ENTEROCRITIS	14	7	Resolved	No	Moderate	Possible	None/not applicable	Yes/No
		7808-00006	4[redacted]/M	JAPAN/Asian	0 mg	15	関節痛	KNEE PAIN	40	-	Ongoing	No	Mild	Not related	None/not applicable	No/No
		7811-00001	3[redacted]/M	JAPAN/Asian	0 mg	11	鼻咽頭炎	COLD	16	-	Ongoing	No	Mild	Not related	None/not applicable	Yes/No
		7812-00002	6[redacted]/F	JAPAN/Asian	0 mg	15	白血球減少症	LEUKOPENIA	40	-	Ongoing	No	Mild	Unlikely	None/not applicable	No/No
		7814-00001	1[redacted]/M	JAPAN/Asian	0 mg	1	ヘモグロビン減少	HEAMOGLOBIN DECREASED	1	15	Resolved	No	Mild	Not related	None/not applicable	No/No
		7819-00003	5[redacted]/F	JAPAN/Asian	0 mg	1	発疹	RASH	2	28	Resolved	No	Mild	Probable	None/not applicable	No/No
					0 mg	18	皮膚剥脱	EXFOLIATIVE CONDITIONS	21	7	Resolved	No	Mild	Unlikely	None/not applicable	No/No

Treatment Group	Study Part[a]	Subject ID	Age/ Sex	Country/ Race	Study Agent Dose Prior to AE	Study Day of Study Agent Admini-stration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relation-ship to Study Agent	Action Taken with Study Agent	Infection/ Infusion-site Reaction[c, d]
		7820-00001	1[redacted]/M	JAPAN/Asian	0 mg	12	感染性小腸結腸炎	INFECTIOUS COLITIS	32	6	Resolved	No	Severe	Unlikely	None/not applicable	Yes/No
					0 mg	12	感染性小腸結腸炎	INFECTIOUS COLITIS	37	8	Resolved	Yes	Severe	Unlikely	None/not applicable	Yes/No
		7821-00002	5[redacted]/F	JAPAN/Asian	0 mg	1	結節性紅斑	ERYTHEMANODOSUM	8	36	Resolved	No	Mild	Possible	None/not applicable	No/No
					0 mg	15	鼻咽頭炎	COLD	42	-	Ongoing	No	Mild	Not related	None/not applicable	No/No
200 mg -> 100 mg	Part 2b	7802-00002	2[redacted]/M	JAPAN/Asian	200 mg	1	白血球減少症	LEUKOCYTEPENIA	1	-	Ongoing	No	Mild	Possible	None/not applicable	No/No
					200 mg	1	好中球減少症	NEUTROPENIA	1	-	Ongoing	No	Mild	Possible	None/not applicable	No/No
		7804-00005	5[redacted]/M	JAPAN/Asian	200 mg	1	上気道感染	UPPER RESPIRATORY TRACT INFECTION	7	23	Resolved	No	Mild	Not related	None/not applicable	Yes/No
		7807-00003	3[redacted]/M	JAPAN/Asian	100 mg	15	陰部そう痒症	ITCHINESS OF GENITILIA	15	-	Ongoing	No	Mild	Possible	None/not applicable	No/No
					100 mg	15	熱傷	LIPS OF MOUTH BURN	17	13	Resolved	No	Mild	Not related	None/not applicable	No/No
					100 mg	15	乳房痛	BREAST PAIN	23	4	Resolved	No	Mild	Unlikely	None/not applicable	No/No
		7808-00001	5[redacted]/F	JAPAN/Asian	100 mg	15	鼻咽頭炎	COLD	28	7	Resolved	No	Mild	Possible	None/not applicable	Yes/No
		7812-00003	5[redacted]/M	JAPAN/Asian	100 mg	15	潰瘍性大腸炎	EXACERBATION OF ULCERATIVE COLITIS	36	19	Resolved	Yes	Severe	Not related	None/not applicable	No/No
		7813-00002	3[redacted]/F	JAPAN/Asian	200 mg	1	尿路感染	URINARY INFECTION	12	60	Resolved	No	Mild	Probable	None/not applicable	Yes/No
		7815-00001	5[redacted]/M	JAPAN/Asian	100 mg	15	肺炎	PNEUMONIA	17	4	Resolved	No	Moderate	Probable	None/not applicable	Yes/No
					100 mg	15	肺炎	PNEUMONIA	20	11	Resolved	Yes	Moderate	Probable	None/not applicable	Yes/No
					100 mg	15	肝炎	DRUG-INDUCED HEPATITIS	26	18	Resolved	No	Mild	Not related	None/not applicable	No/No

Treatment Group	Study Part[a]	Subject ID	Age/ Sex	Country/ Race	Study Agent Dose Prior to AE	Study Day of Study Agent Admini-stration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relation-ship to Study Agent	Action Taken with Study Agent	Infection/ Infusion-site Reaction[c, d]
		7815-00003	4[redacted]/F	JAPAN/Asian	200 mg	1	感覚鈍麻	SENSE OF NUMBNESS	8	3	Resolved	No	Mild	Unlikely	None/not applicable	No/No
					100 mg	15	鉄欠乏性貧血	HYPOFERRIC ANAEMIA	15	-	Ongoing	No	Mild	Not related	None/not applicable	No/No
		7817-00002	2[redacted]/M	JAPAN/Asian	200 mg	1	口腔咽頭痛	SORE THROAT	16	5	Resolved	No	Mild	Not related	None/not applicable	No/No
		7819-00002	2[redacted]/M	JAPAN/Asian	200 mg	1	アトピー性皮膚炎	CONDITION OF ATOPIC ECZEMA AGGRAVATED	8	-	Ongoing	No	Mild	Unlikely	None/not applicable	No/No
					100 mg	15	発熱	SLIGHT FEVER	47	1	Resolved	No	Mild	Unlikely	None/not applicable	No/No
		7819-00004	2[redacted]/F	JAPAN/Asian	200 mg	1	鼻咽頭炎	COMMON COLD	8	17	Resolved	No	Mild	Not related	None/not applicable	Yes/No
					200 mg	1	頭痛	HEADACHE	10	5	Resolved	No	Mild	Not related	None/not applicable	No/No
		7821-00003	2[redacted]/M	JAPAN/Asian	100 mg	15	発疹	RASH	22	21	Resolved	No	Mild	Not related	None/not applicable	No/No
					100 mg	15	毛包炎	FOLLICULITIS	43	-	Ongoing	No	Mild	Possible	None/not applicable	Yes/No
		7822-00003	6[redacted]/F	JAPAN/Asian	100 mg	15	白血球数減少	WBC COUNT DECREASE	45	-	Ongoing	No	Mild	Probable	None/not applicable	No/No
400 mg -> 200 mg	Part 2b	7801-00003	3[redacted]/M	JAPAN/Asian	400 mg	1	鼻咽頭炎	COMMON COLD	4	3	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
					200 mg	15	気道感染	RESPIRATORY INFECTION	29	29	Resolved	No	Mild	Possible	None/not applicable	Yes/No
		7801-00006	2[redacted]/F	JAPAN/Asian	200 mg	15	百日咳	WHOOPING COUGH	39	23	Resolved	No	Mild	Possible	None/not applicable	Yes/No
					200 mg	15	潰瘍性大腸炎	WORSEINING OF UC	43	78	Resolved	Yes	Moderate	Unlikely	None/not applicable	No/No
		7807-00006	4[redacted]/M	JAPAN/Asian	400 mg	1	発熱	FEVER UP	16	1	Resolved	No	Mild	Unlikely	None/not applicable	No/No
		7808-00004	3[redacted]/F	JAPAN/Asian	200 mg	13	悪心	NAUSEA	13	2	Resolved	No	Mild	Not related	None/not applicable	No/No
					200 mg	13	悪心	NAUSEA	13	22	Resolved	No	Mild	Probable	None/not applicable	No/No

Treatment Group	Study Part[a]	Subject ID	Age/ Sex	Country/ Race	Study Agent Dose Prior to AE	Study Day of Study Agent Admini-stration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relation-ship to Study Agent	Action Taken with Study Agent	Infection/ Infusion-site Reaction[c, d]
		7814-00002	5[redacted]/F	JAPAN/Asian	400 mg	1	異常感覚	FINGER DYSAESTHESIA	4	-	Ongoing	No	Mild	Possible	None/not applicable	No/No
					200 mg	15	膀胱炎	CYSTITIS	29	-	Ongoing	No	Mild	Possible	None/not applicable	Yes/No
					200 mg	15	浮動性めまい	DIZZINESS	29	-	Ongoing	No	Mild	Possible	None/not applicable	No/No
					200 mg	15	挫傷	BRUISING	36	-	Ongoing	No	Mild	Possible	None/not applicable	No/No
		7819-00001	3[redacted]/F	JAPAN/Asian	200 mg	15	帯状疱疹	HERPES ZOSTER	21	19	Resolved	No	Mild	Possible	None/not applicable	Yes/No

[a] Part 2a: Part 2 before the dose selection; Part 2b; Part 2 after the dose selection.
[b] Based on MedDRA version 13.0.
[c] Infection as assessed by the investigator.
[d] Injection-site reaction as assessed by the investigator.

表 2.7.4.7-付録-10 すべての有害事象（T18 試験 54 週まで，日本人）

		Golimumab				
	Placebo [a,b]	50 mg [a]	100 mg[a,c,d]	Combined 50 mg and 100 mg	200 mg[d,e]	All Golimumab[f]
Treated subjects in C0524T18	8	3	59	60	-	60
Avg duration of follow-up (weeks)	26.5	18.5	42.3	42.6	-	42.6
Avg exposure (number of administrations)	6.3	3.7	9.5	9.5	-	9.5
Subjects with 1 or more TEAE	5 (62.5%)	3 (100.0%)	51 (86.4%)	52 (86.7%)	-	52 (86.7%)
System-organ class/preferred term						
感染症および寄生虫症	2 (25.0%)	1 (33.3%)	32 (54.2%)	32 (53.3%)	-	32 (53.3%)
鼻咽頭炎	1 (12.5%)	0	20 (33.9%)	20 (33.3%)	-	20 (33.3%)
感染性腸炎	0	0	3 (5.1%)	3 (5.0%)	-	3 (5.0%)
インフルエンザ	1 (12.5%)	0	3 (5.1%)	3 (5.0%)	-	3 (5.0%)
上気道感染	0	0	3 (5.1%)	3 (5.0%)	-	3 (5.0%)
感染性小腸結腸炎	0	0	2 (3.4%)	2 (3.3%)	-	2 (3.3%)
口腔ヘルペス	0	0	2 (3.4%)	2 (3.3%)	-	2 (3.3%)
慢性副鼻腔炎	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
膀胱炎	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
サイトメガロウイルス感染	1 (12.5%)	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
毛包炎	1 (12.5%)	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
胃腸炎	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
感染性表皮嚢胞	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
咽頭炎	0	1 (33.3%)	0	1 (1.7%)	-	1 (1.7%)
鼻炎	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
副鼻腔炎	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
尿路感染	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
皮下組織膿瘍	1 (12.5%)	0	0	0	-	0
胃腸障害	1 (12.5%)	2 (66.7%)	22 (37.3%)	23 (38.3%)	-	23 (38.3%)
潰瘍性大腸炎	0	1 (33.3%)	5 (8.5%)	6 (10.0%)	-	6 (10.0%)
口内炎	0	0	5 (8.5%)	5 (8.3%)	-	5 (8.3%)
悪心	0	0	4 (6.8%)	4 (6.7%)	-	4 (6.7%)
腹部膨満	0	0	3 (5.1%)	3 (5.0%)	-	3 (5.0%)
腹部不快感	0	0	2 (3.4%)	2 (3.3%)	-	2 (3.3%)
腹痛	0	0	2 (3.4%)	2 (3.3%)	-	2 (3.3%)
胃食道逆流性疾患	0	1 (33.3%)	1 (1.7%)	2 (3.3%)	-	2 (3.3%)
裂肛	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
口唇炎	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
結腸ポリープ	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)

		Golimumab				
	Placebo [a,b]	50 mg [a]	100 mg[a,c,d]	Combined 50 mg and 100 mg	200 mg[d,e]	All Golimumab[f]
便秘	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
齲歯	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
下痢	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
腸炎	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
萎縮性胃炎	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
痔核	1 (12.5%)	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
肛門周囲痛	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
歯の知覚過敏	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
皮膚および皮下組織障害	3 (37.5%)	0	15 (25.4%)	15 (25.0%)	-	15 (25.0%)
発疹	0	0	5 (8.5%)	5 (8.3%)	-	5 (8.3%)
湿疹	2 (25.0%)	0	4 (6.8%)	4 (6.7%)	-	4 (6.7%)
脱毛症	0	0	2 (3.4%)	2 (3.3%)	-	2 (3.3%)
接触性皮膚炎	1 (12.5%)	0	2 (3.4%)	2 (3.3%)	-	2 (3.3%)
脂漏性皮膚炎	0	0	2 (3.4%)	2 (3.3%)	-	2 (3.3%)
貨幣状湿疹	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
そう痒症	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
膿疱性乾癬	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
皮脂欠乏性湿疹	1 (12.5%)	0	0	0	-	0
呼吸器、胸郭および縦隔障害	2 (25.0%)	0	13 (22.0%)	13 (21.7%)	-	13 (21.7%)
咳嗽	0	0	4 (6.8%)	4 (6.7%)	-	4 (6.7%)
口腔咽頭痛	0	0	3 (5.1%)	3 (5.0%)	-	3 (5.0%)
上気道の炎症	2 (25.0%)	0	2 (3.4%)	2 (3.3%)	-	2 (3.3%)
喘息	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
息詰まり感	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
鼻閉	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
鼻閉塞	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
鼻漏	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
一般・全身障害および投与部位の状態	0	0	12 (20.3%)	12 (20.0%)	-	12 (20.0%)
発熱	0	0	7 (11.9%)	7 (11.7%)	-	7 (11.7%)
投与部位発疹	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
投与部位反応	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
無力症	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
胸部不快感	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
疲労	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)

		Golimumab				
	Placebo [a,b]	50 mg [a]	100 mg[a,c,d]	Combined 50 mg and 100 mg	200 mg[d,e]	All Golimumab[f]
注入部位反応	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
浮腫	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
末梢性浮腫	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
神経系障害	1 (12.5%)	0	8 (13.6%)	8 (13.3%)	-	8 (13.3%)
頭痛	0	0	6 (10.2%)	6 (10.0%)	-	6 (10.0%)
浮動性めまい	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
神経痛	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
振戦	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
感覚鈍麻	1 (12.5%)	0	0	0	-	0
傷害、中毒および処置合併症	1 (12.5%)	0	7 (11.9%)	7 (11.7%)	-	7 (11.7%)
挫傷	1 (12.5%)	0	3 (5.1%)	3 (5.0%)	-	3 (5.0%)
関節捻挫	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
裂傷	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
肋骨骨折	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
脊椎圧迫骨折	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
眼障害	1 (12.5%)	0	6 (10.2%)	6 (10.0%)	-	6 (10.0%)
白内障	0	0	2 (3.4%)	2 (3.3%)	-	2 (3.3%)
アレルギー性結膜炎	0	0	2 (3.4%)	2 (3.3%)	-	2 (3.3%)
眼精疲労	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
霰粒腫	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
黄斑症	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
眼出血	1 (12.5%)	0	0	0	-	0
筋骨格系および結合組織障害	1 (12.5%)	0	5 (8.5%)	5 (8.3%)	-	5 (8.3%)
背部痛	0	0	2 (3.4%)	2 (3.3%)	-	2 (3.3%)
筋骨格系胸痛	0	0	2 (3.4%)	2 (3.3%)	-	2 (3.3%)
関節痛	1 (12.5%)	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
滑液包炎	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
筋肉痛	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
関節周囲炎	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
血液およびリンパ系障害	1 (12.5%)	0	4 (6.8%)	4 (6.7%)	-	4 (6.7%)
貧血	0	0	2 (3.4%)	2 (3.3%)	-	2 (3.3%)
鉄欠乏性貧血	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
白血球減少症	1 (12.5%)	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
精神障害	0	0	4 (6.8%)	4 (6.7%)	-	4 (6.7%)
不眠症	0	0	4 (6.8%)	4 (6.7%)	-	4 (6.7%)

		Golimumab				
	Placebo [a,b]	50 mg [a]	100 mg[a,c,d]	Combined 50 mg and 100 mg	200 mg[d,e]	All Golimumab[f]
臨床検査	1 (12.5%)	0	3 (5.1%)	3 (5.0%)	-	3 (5.0%)
収縮期血圧上昇	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
好酸球数増加	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
白血球数減少	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
アラニン・アミノトランスフェラーゼ増加	1 (12.5%)	0	0	0	-	0
アスパラギン酸アミノトランスフェラーゼ増加	1 (12.5%)	0	0	0	-	0
血小板数減少	1 (12.5%)	0	0	0	-	0
代謝および栄養障害	0	0	3 (5.1%)	3 (5.0%)	-	3 (5.0%)
食欲減退	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
高アミラーゼ血症	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
低マグネシウム血症	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
先天性、家族性および遺伝性障害	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
静脈奇形	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
肝胆道系障害	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
肝不全	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
免疫系障害	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
過敏症	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
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）	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
直腸癌	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
生殖系および乳房障害	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
乳房痛	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
子宮出血	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
血管障害	2 (25.0%)	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
潮紅	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
高血圧	1 (12.5%)	0	0	0	-	0
血管炎	1 (12.5%)	0	0	0	-	0
腎および尿路障害	1 (12.5%)	0	0	0	-	0
尿道痛	1 (12.5%)	0	0	0	-	0

	Golimumab				
Placebo [a,b]	50 mg [a]	100 mg [a,c,d]	Combined 50 mg and 100 mg	200 mg [d,e]	All Golimumab [f]

[a] Includes data up to the time of dose adjustment for those who increased dose from the indicated dose.
[b] Includes 1) subjects who were in clinical response to golimumab induction dosing and were randomized to placebo on entry into this maintenance study; and 2) subjects who were in clinical response to placebo induction dosing and received placebo on entry into this maintenance study.
[c] Includes 1) subjects who were in clinical response to golimumab induction dosing and were randomized to golimumab 100 mg on entry into this maintenance study; 2) subjects who were not in clinical response to either placebo or golimumab induction dosing and received golimumab 100 mg on entry into this maintenance study; and 3) subjects who were dose adjusted to golimumab 100 mg from placebo (randomized or nonrandomized) or from golimumab 50 mg.
[d] Includes data from the time of dose adjustment onward for those who increased to the indicated dose.
[e] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[f] Includes data from the time of the first golimumab dose onward.
Note: Adverse Events are coded using MedDRA 14.0

[TSFAE01JP.rtf] [CNTO148\C0524T18\DBR_WEEK54\RE_NDAJPKK\TSFAE01JP.sas] 29JAN2016, 17:24

表 2.7.4.7-付録-11 すべての有害事象一覧（T18 試験 54 週まで，日本人）

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/Sex	Country/Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Infusion-site Reaction[c, d]
Yes	Placebo	200 mg/100 mg SC	7801-00002	3[redacted]/M	JAPAN/Asian	100 mg	92	100 mg	92	潰瘍性大腸炎	WORSENING OF UC	101	15	Resolved	Yes	Severe	Unlikely	Permanent discontinuation of study agent	No/No
								100 mg	92	注入部位反応	INJECTION SITE PAIN(DUE TO IV OF MED GLUCOSE-ELECTOLYTE FLUID)	106	10	Resolved	No	Mild	Not related	None/not applicable	No/No
								100 mg	92	振戦	TREMOR	120	-	Ongoing	No	Mild	Not related	None/not applicable	No/No
			7802-00004	1[redacted]/M	JAPAN/Asian	-	-	0 mg	29	インフルエンザ	INFLUENZA	39	7	Resolved	No	Moderate	Possible	None/not applicable	Yes/No
								0 mg	58	接触性皮膚炎	CONTACT DERMATITIS	86	-	Ongoing	No	Mild	Possible	None/not applicable	No/No
								0 mg	337	関節痛	LT.ELBOW JOINT ACHE	337	141	Resolved	No	Mild	Unlikely	None/not applicable	No/No
								0 mg	337	皮下組織膿瘍	RT.PERIAURICALAR ABSESS	355	11	Resolved	No	Moderate	Possible	None/not applicable	Yes/No
			7821-00003	2[redacted]/M	JAPAN/Asian	-	-	0 mg	1	毛包炎	FOLLICULITIS	1	47	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								0 mg	1	毛包炎	FOLLICULITIS	1	-	Ongoing	No	Mild	Possible	None/not applicable	Yes/No
								0 mg	1	感覚鈍麻	NUMBNESS	8	-	Ongoing	No	Mild	Unlikely	None/not applicable	No/No
								0 mg	1	湿疹	ECZEMA	12	36	Resolved	No	Mild	Unlikely	None/not applicable	No/No

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Infusion-site Reaction[c, d]
								0 mg	1	上気道の炎症	UPPER RESPIRATORY INFLAMMATION	26	11	Resolved	No	Mild	Not related	None/not applicable	No/No
								0 mg	33	サイトメガロウイルス感染	CYTOMEGALO VIRUS INFEECTION	55	10	Resolved	No	Mild	Unlikely	Permanent discontinuation of study agent	Yes/No
								0 mg	33	アスパラギン酸アミノトランスフェラーゼ増加	AST HI	57	15	Resolved	No	Mild	Unlikely	None/not applicable	No/No
								0 mg	33	白血球減少症	LEUKOPENIA	57	5	Resolved	No	Mild	Unlikely	None/not applicable	No/No
								0 mg	33	血小板数減少	LOW PLATELETS	57	22	Resolved	No	Mild	Unlikely	None/not applicable	No/No
								0 mg	33	アラニン・アミノトランスフェラーゼ増加	ALT HI	61	7	Resolved	No	Mild	Unlikely	None/not applicable	No/No
								0 mg	33	サイトメガロウイルス感染	CYTOMEGALO VIRUS INFECTION	64	17	Resolved	Yes	Moderate	Unlikely	Permanent discontinuation of study agent	Yes/No
								0 mg	33	尿道痛	URETHRAL PAIN	69	22	Resolved	No	Mild	Not related	None/not applicable	No/No
								0 mg	33	血管炎	VASCULITIS(LEFT UPPER LIMB)	70	6	Resolved	No	Mild	Not related	None/not applicable	No/No

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/Sex	Country/Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Infusion-site Reaction[c, d]
								0 mg	33	鼻咽頭炎	COLD	99	8	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								0 mg	33	皮脂欠乏性湿疹	ASTEATOTIC ECZEMA	127	-	Ongoing	No	Mild	Not related	None/not applicable	No/No
			7822-00003	6[redacted]/F	JAPAN/Asian	100 mg	43	100 mg	62	下痢	DIARRHA	84	1	Resolved	No	Mild	Not related	None/not applicable	No/No
								100 mg	90	脊椎圧迫骨折	LUMBER COMPRESSION FRACTURE	103	-	Ongoing	No	Mild	Not related	None/not applicable	No/No
								100 mg	111	鼻咽頭炎	COMMON COLD	129	11	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
	Golimumab 50 mg	400 mg/200 mg SC	7804-00007	5[redacted]/M	JAPAN/Asian	100 mg	85	50 mg	29	胃食道逆流性疾患	GASTROESOPHAGEAL REFLUX DISEASE	29	-	Ongoing	No	Mild	Unlikely	None/not applicable	No/No
								100 mg	85	そう痒症	ITCHING	99	43	Resolved	No	Mild	Possible	None/not applicable	No/No
								100 mg	162	頭痛	HEADACHE	197	65	Resolved	No	Mild	Not related	None/not applicable	No/No
								100 mg	162	悪心	QUEASY	197	1	Resolved	No	Mild	Not related	None/not applicable	No/No
								100 mg	162	鼻咽頭炎	COMMON COLD	217	6	Resolved	No	Mild	Not related	None/not applicable	No/No
			7807-00006	4[redacted]/M	JAPAN/Asian	50 mg	120	50 mg	137	潰瘍性大腸炎	EXACERBATION OF ULCERATIVE COLITIS	189	14	Resolved	Yes	Moderate	Not related	None/not applicable	No/No
			7822-00002	3[redacted]/F	JAPAN/Asian	100 mg	58	50 mg	23	咽頭炎	PHARYNGITIS	56	8	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100 mg	107	鼻咽頭炎	COMMON COLD	128	12	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100 mg	251	鼻咽頭炎	COMMON COLD	280	28	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/Sex	Country/Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/Infusion-site Reaction[c, d]
	Golimumab 100 mg	200 mg/100 mg SC	7804-00003	3[redacted]/F	JAPAN/Asian	100 mg	106	100 mg	25	脱毛症	ALOPECIA	32	-	Ongoing	No	Mild	Unlikely	None/not applicable	No/No
								100 mg	25	発疹	ERUPTION	33	-	Ongoing	No	Mild	Possible	None/not applicable	No/No
								100 mg	25	鼻咽頭炎	COMMON COLD	39	23	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100 mg	106	頭痛	HEADACHE	118	-	Ongoing	No	Mild	Possible	None/not applicable	No/No
								100 mg	277	鼻咽頭炎	COMMON COLD	281	14	Resolved	No	Mild	Unlikely	None/not applicable	No/No
								100 mg	305	鼻咽頭炎	COMMON COLD	319	8	Resolved	No	Mild	Unlikely	None/not applicable	No/No
								100 mg	340	鼻咽頭炎	COMMON COLD	354	11	Resolved	No	Mild	Unlikely	None/not applicable	No/No
			7814-00003	3[redacted]/M	JAPAN/Asian	-	-	100 mg	113	咳嗽	COUGH	137	38	Resolved	No	Mild	Unlikely	None/not applicable	No/No
								100 mg	113	鼻咽頭炎	COLD	137	5	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100 mg	169	歯の知覚過敏	SENSITIVITY OF TEETH	176	106	Resolved	No	Mild	Unlikely	None/not applicable	No/No
		400 mg/200 mg SC	7803-00003	2[redacted]/F	JAPAN/Asian	100 mg	29	100 mg	29	息詰まり感	CHOKING SENSATION [EXCL PHYCHOGENIC AND DYSHAGIA]	69	1	Resolved	No	Mild	Not related	None/not applicable	No/No
								100 mg	29	潮紅	FLUSHED FACE	69	1	Resolved	No	Mild	Not related	None/not applicable	No/No

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Infusion-site Reaction[c, d]
			7806-00002	2[redacted]/F	JAPAN/Asian	-	-	100 mg	1	上気道の炎症	ACUTE UPPER RESPIRATORY INFLAMMATION	3	41	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100 mg	29	白血球数減少	WHITE BLOOD CELL COUNT DECREASED	54	32	Resolved	No	Mild	Not related	None/not applicable	No/No
								100 mg	169	白血球数減少	WHITE BLOOD CELL COUNT DECREASED	197	15	Resolved	No	Mild	Not related	None/not applicable	No/No
								100 mg	197	白血球数減少	WHITE BLOOD CELL COUNT DECREASED	226	57	Resolved	No	Mild	Not related	None/not applicable	No/No
								100 mg	369	感染性小腸結腸炎	ACUTE BACTERIAL COLITIS	370	4	Resolved	No	Moderate	Not related	None/not applicable	Yes/No
								100 mg	369	感染性小腸結腸炎	ACUTE BACTERIAL COLITIS	373	8	Resolved	Yes	Moderate	Not related	None/not applicable	Yes/No
								100 mg	369	湿疹	ECZEMA	383	-	Ongoing	No	Mild	Not related	None/not applicable	No/No

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Infusion-site Reaction[c, d]
			7814-00002	5[redacted]/F	JAPAN/Asian	-	-	100 mg	33	口腔ヘルペス	HERPES LABIALIS	54	12	Resolved	No	Mild	Probable	None/not applicable	Yes/No
								100 mg	61	脱毛症	ALOPECIA	-	-	Resolved	No	Mild	Possible	None/not applicable	No/No
								100 mg	91	挫傷	BRUISING	91	162	Resolved	No	Mild	Possible	None/not applicable	No/No
								100 mg	91	頭痛	HEAD ACHE	96	101	Resolved	No	Mild	Possible	None/not applicable	No/No
								100 mg	91	尿路感染	URINARY TRACT INFECTION	112	5	Resolved	No	Mild	Possible	None/not applicable	Yes/No
								100 mg	91	口腔ヘルペス	HERPES LABIALIS	114	10	Resolved	No	Mild	Probable	None/not applicable	Yes/No
								100 mg	147	便秘	CONSTIPATION	148	111	Resolved	No	Mild	Possible	None/not applicable	No/No
								100 mg	147	背部痛	LOW BACK PAIN	155	54	Resolved	No	Mild	Unlikely	None/not applicable	No/No
								100 mg	175	腹部不快感	STOMACH DISCOMFORT	175	50	Resolved	No	Mild	Unlikely	None/not applicable	No/No
								100 mg	175	口腔ヘルペス	HERPES LABIALIS	181	44	Resolved	No	Mild	Probable	None/not applicable	Yes/No
								100 mg	175	鼻咽頭炎	COMMON COLD	187	22	Resolved	No	Mild	Possible	None/not applicable	Yes/No
								100 mg	175	関節痛	COXALGIA RIGHT	193	207	Resolved	No	Mild	Unlikely	None/not applicable	No/No
								100 mg	196	収縮期血圧上昇	BLOOD-PRESSURE SYSTOLIC HIGH	196	113	Resolved	No	Mild	Possible	None/not applicable	No/No
								100 mg	196	筋骨格系胸痛	RIB PAIN RIGHT	208	45	Resolved	No	Mild	Unlikely	None/not applicable	No/No
								100 mg	196	筋肉痛	GENERALISED MUSCLE ACHES	208	-	Ongoing	No	Mild	Possible	None/not applicable	No/No

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Infusion-site Reaction[c, d]
								100 mg	196	浮腫	EDEMA	208	276	Resolved	No	Mild	Possible	None/not applicable	No/No
								100 mg	252	白内障	WORSENING OF CATARACT	-	-	Resolved	No	Moderate	Not related	None/not applicable	No/No
								100 mg	308	投与部位発疹	ADMINISTRATION SITE REACTION (RASH)	308	3	Resolved	No	Mild	Probable	None/not applicable	No/Yes
								100 mg	308	投与部位反応	ADMINISTRATION SITE REACTION. (ITCHING)	308	3	Resolved	No	Mild	Probable	None/not applicable	No/Yes
								100 mg	308	食欲減退	ANOREXIA	321	79	Resolved	No	Mild	Unlikely	None/not applicable	No/No
								100 mg	336	投与部位発疹	ADMINISTRATION SITE REACTION(RASH)	336	4	Resolved	No	Mild	Probable	None/not applicable	No/Yes
								100 mg	336	投与部位反応	ADMINISTRATION SITE REACTION. (ITCHING)	336	4	Resolved	No	Mild	Probable	None/not applicable	No/Yes

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/Sex	Country/Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/Infusion-site Reaction[c, d]
No	Placebo (Placebo induction responder)	Placebo SC	7805-00001	3[redacted]/M	JAPAN/Asian	100 mg	148	0 mg	110	挫傷	HEAD BRUISE	137	33	Resolved	No	Mild	Not related	None/not applicable	No/No
			7816-00002	2[redacted]/F	JAPAN/Asian	100 mg	227	100 mg	227	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	248	55	Resolved	Yes	Severe	Unlikely	Permanent discontinuation of study agent	No/No
								100 mg	227	鼻咽頭炎	COMMON COLD	254	12	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100 mg	227	萎縮性胃炎	GASTRITIS ATROPHIC	260	-	Ongoing	No	Mild	Not related	None/not applicable	No/No
								100 mg	227	不眠症	INSOMNIA	266	10	Resolved	No	Mild	Not related	None/not applicable	No/No
			7817-00001	6[redacted]/M	JAPAN/Asian	100 mg	310	0 mg	1	湿疹	ECZEMA	3	167	Resolved	No	Mild	Probable	None/not applicable	No/No
								0 mg	141	痔核	HAEMORRHOID	161	20	Resolved	No	Mild	Not related	None/not applicable	No/No
								0 mg	196	高血圧	HYPERTENSION	211	-	Ongoing	No	Mild	Not related	None/not applicable	No/No
								0 mg	196	眼出血	LEFT-HEMORRHAGE INTRAOCULAR	225	29	Resolved	No	Mild	Not related	None/not applicable	No/No
								0 mg	287	痔核	HAEMORRHOID	297	42	Resolved	No	Mild	Not related	None/not applicable	No/No
								100 mg	310	口内炎	STOMATITIS	336	9	Resolved	No	Mild	Not related	None/not applicable	No/No
								100 mg	358	発疹	ERUPTION	364	22	Resolved	No	Mild	Not related	None/not applicable	No/No
			7818-00001	4[redacted]/F	JAPAN/Asian	100 mg	141	0 mg	111	上気道の炎症	UPPER RESPIRATORY INFLAMMATION	122	74	Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Infusion-site Reaction[c, d]
	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7802-00001	3[redacted]/M	JAPAN/Asian	-	-	100 mg	193	不眠症	INSOMNIA	232	23	Resolved	No	Mild	Unlikely	None/not applicable	No/No
			7803-00002	2[redacted]/M	JAPAN/Asian	-	-	100 mg	1	腹部膨満	LOWER ABDOMINAL BLOATING	1	2	Resolved	No	Mild	Not related	None/not applicable	No/No
								100 mg	26	霰粒腫	LEFT CHALAZIA	40	6	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100 mg	26	霰粒腫	LEFT CHALAZIA	51	4	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100 mg	138	鼻咽頭炎	COMMON COLD	150	8	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100 mg	138	脂漏性皮膚炎	DERMATITIS SEBORRHEICA	161	55	Resolved	No	Mild	Not related	None/not applicable	No/No
								100 mg	313	鼻咽頭炎	COMMON COLD	340	8	Resolved	No	Mild	Not related	None/not applicable	Yes/No
			7805-00009	4[redacted]/M	JAPAN/Asian	-	-	100 mg	27	上気道の炎症	ACUTE UPPER RESPIRATORY INFLAMMATION	44	5	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100 mg	165	貨幣状湿疹	ECZEMA NUMMULAR	165	-	Ongoing	No	Mild	Unlikely	None/not applicable	No/No
								100 mg	165	鼻咽頭炎	COMMON COLD	180	1	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100 mg	279	発熱	FEVER UP	282	2	Resolved	No	Mild	Unlikely	None/not applicable	No/No
								100 mg	279	発熱	FEVER UP	294	1	Resolved	No	Mild	Unlikely	None/not applicable	No/No

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Infusion-site Reaction[c, d]
			7807-00005	4[redacted]/F	JAPAN/Asian	-	-	100 mg	112	齲歯	DENTAL CARIES	127	10	Resolved	No	Mild	Not related	None/not applicable	No/No
								100 mg	175	頭痛	HEADACHE	181	2	Resolved	No	Mild	Not related	None/not applicable	No/No
								100 mg	175	発熱	FEVER UP	181	2	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100 mg	196	咳嗽	COUGH	234	41	Resolved	No	Mild	Not related	None/not applicable	No/No
			7807-00007	4[redacted]/M	JAPAN/Asian	-	-	100 mg	1	咳嗽	COUGH	8	2	Resolved	No	Mild	Possible	None/not applicable	Yes/No
								100 mg	1	感染性腸炎	INFECTIOUSNESS ENTERITIS	10	7	Resolved	No	Mild	Possible	None/not applicable	Yes/No
			7808-00002	3[redacted]/M	JAPAN/Asian	-	-	100 mg	1	筋骨格系胸痛	RIB PAIN	15	45	Resolved	No	Mild	Not related	None/not applicable	No/No
								100 mg	197	静脈奇形	WORSENING MALFORMATION VENOUS OF LEFT PLANTAR	197	84	Resolved	No	Mild	Not related	None/not applicable	No/No
								100 mg	337	悪心	NAUSEA	352	14	Resolved	No	Mild	Not related	None/not applicable	No/No
								100 mg	337	低マグネシウム血症	HYPOMAGNESEMIA	358	2	Resolved	No	Mild	Not related	None/not applicable	No/No
			7808-00006	4[redacted]/M	JAPAN/Asian	-	-	100 mg	1	鼻漏	NASAL DISCHARGE	8	155	Resolved	No	Mild	Not related	None/not applicable	No/No
								100 mg	1	口内炎	STOMATITIS	23	13	Resolved	No	Mild	Not related	None/not applicable	No/No
								100 mg	31	感染性腸炎	ENTERITIS INFECTIOUS	37	17	Resolved	No	Mild	Possible	None/not applicable	Yes/No
								100 mg	113	鼻咽頭炎	COLD	113	8	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Infusion-site Reaction[c, d]
								100 mg	143	鼻咽頭炎	COLD	158	5	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100 mg	227	腸炎	ACUTE ENTEROCOLITIS	247	9	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100 mg	255	腸炎	ACUTE ENTEROCOLITIS	270	42	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100 mg	311	鼻咽頭炎	COLD	334	11	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100 mg	367	鼻咽頭炎	COLD	368	4	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
			7809-00002	5[redacted]/M	JAPAN/Asian	-	-	100 mg	30	発熱	FEVER UP	31	4	Resolved	No	Mild	Definite	None/not applicable	No/No
								100 mg	79	上気道感染	URI	81	4	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100 mg	79	上気道感染	URI	91	17	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100 mg	163	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	173	-	Ongoing	Yes	Severe	Not related	Permanent discontinuation of study agent	No/No
								100 mg	163	背部痛	ACUTE LUMBAR PAIN	275	-	Ongoing	No	Mild	Not related	None/not applicable	No/No
			7811-00001	3[redacted]/M	JAPAN/Asian	-	-	100 mg	27	頭痛	HEADACHE	29	2	Resolved	No	Mild	Not related	None/not applicable	No/No
								100 mg	27	挫傷	BRUISE	39	27	Resolved	No	Mild	Not related	None/not applicable	No/No
								100 mg	111	貧血	ANEMIA	111	29	Resolved	No	Mild	Not related	None/not applicable	No/No
								100 mg	111	頭痛	HEADACHE	138	1	Resolved	No	Moderate	Not related	None/not applicable	No/No
								100 mg	139	頭痛	HEADACHE	163	1	Resolved	No	Moderate	Not related	None/not applicable	No/No

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/Sex	Country/Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Infusion-site Reaction[c, d]
								100 mg	167	神経痛	NEURALGIA (RIGHT SHOULDER)	184	3	Resolved	No	Mild	Not related	None/not applicable	No/No
								100 mg	167	頭痛	HEADACHE	192	1	Resolved	No	Mild	Not related	None/not applicable	No/No
								100 mg	223	頭痛	HEADACHE	233	2	Resolved	No	Mild	Not related	None/not applicable	No/No
								100 mg	223	頭痛	HEADACHE	245	2	Resolved	No	Mild	Not related	None/not applicable	No/No
								100 mg	251	感染性腸炎	INFECTIOUS ENTERITIS	251	6	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100 mg	251	インフルエンザ	INFLUENZA	327	6	Resolved	No	Moderate	Not related	None/not applicable	Yes/No
			7812-00002	6[redacted]/F	JAPAN/Asian	-	-	100 mg	1	直腸癌	ADENOCARCINOMA OF RECTUM	15	50	Resolved	Yes	Severe	Not related	Permanent discontinuation of study agent	No/No
			7813-00001	4[redacted]/M	JAPAN/Asian	-	-	100 mg	1	湿疹	CHRONIC CZEMA AGGRAVATED	-	-	Resolved	No	Mild	Not related	None/not applicable	No/No
								100 mg	1	潰瘍性大腸炎	EXCERBATION OF UC	8	16	Resolved	No	Moderate	Not related	Permanent discontinuation of study agent	No/No
								100 mg	1	潰瘍性大腸炎	EXCERBATION OF UC	23	30	Resolved	Yes	Moderate	Not related	Permanent discontinuation of study agent	No/No
								100 mg	1	湿疹	CHRONIC ECZEMA AGGRAVATED	50	29	Resolved	No	Mild	Not related	None/not applicable	No/No

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								100 mg	1	鼻咽頭炎	COLD	77	23	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100 mg	1	高アミラーゼ血症	HYPERAMYLASAEMIA	78	43	Resolved	No	Mild	Not related	None/not applicable	No/No
			7815-00002	5[redacted]/F	JAPAN/Asian	-	-	100 mg	29	鼻閉塞	SENSE OF NASAL OBSTRUCTION	51	14	Resolved	No	Mild	Possible	None/not applicable	No/No
								100 mg	29	発疹	SKIN RASH	54	116	Resolved	No	Mild	Possible	None/not applicable	No/No
								100 mg	57	アレルギー性結膜炎	ALLERGIC CONJUNCTIVITIS	61	4	Resolved	No	Mild	Possible	None/not applicable	No/No
								100 mg	113	口腔咽頭痛	THROAT DISCOMFORT	119	18	Resolved	No	Mild	Possible	None/not applicable	No/No
								100 mg	225	毛包炎	GENITAL FOLLICULITIS	248	10	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100 mg	253	毛包炎	GENITAL FOLLICULITIS	284	9	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
			7816-00003	4[redacted]/F	JAPAN/Asian	-	-	100 mg	169	発熱	FEVER	189	9	Resolved	No	Mild	Possible	None/not applicable	No/No
			7817-00004	2[redacted]/M	JAPAN/Asian	-	-	100 mg	1	腹痛	ABDOMINAL PAIN	23	3	Resolved	No	Mild	Not related	None/not applicable	No/No
								100 mg	260	過敏症	NASAL ALLERGY	260	8	Resolved	No	Mild	Not related	None/not applicable	No/No
			7817-00005	4[redacted]/M	JAPAN/Asian	-	-	100 mg	140	鼻咽頭炎	COMMON COLD	169	4	Resolved	No	Mild	Not related	None/not applicable	Yes/No
			7819-00003	5[redacted]/F	JAPAN/Asian	-	-	100 mg	1	口内炎	STOMATITIS	23	-	Ongoing	No	Mild	Unlikely	None/not applicable	No/No
								100 mg	1	発熱	PYREXIA	24	3	Resolved	No	Mild	Unlikely	None/not applicable	No/No
								100 mg	61	発熱	PYREXIA	61	29	Resolved	No	Mild	Unlikely	None/not applicable	No/No

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								100 mg	89	鼻閉	NASAL STUFFINESS	141	68	Resolved	No	Mild	Unlikely	None/not applicable	No/No
			7820-00001	1[redacted]/M	JAPAN/Asian	-	-	100 mg	91	発熱	FEVER	107	1	Resolved	No	Mild	Possible	None/not applicable	No/No
								100 mg	253	鼻炎	CORYZA	261	6	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100 mg	337	鼻炎	CORYZA	347	14	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
			7820-00002	5[redacted]/M	JAPAN/Asian	-	-	100 mg	254	滑液包炎	RIGHT PREPATELLAR BURSITIS	279	60	Resolved	No	Mild	Unlikely	None/not applicable	No/No
								100 mg	282	接触性皮膚炎	CONTACT DERMATITIS	302	37	Resolved	No	Mild	Not related	None/not applicable	No/No
								100 mg	361	滑液包炎	LEFT PREPATELLAR BURSITIS	379	121	Resolved	No	Mild	Possible	None/not applicable	No/No
			7821-00002	5[redacted]/F	JAPAN/Asian	-	-	100 mg	1	浮動性めまい	DIZZINESS	19	12	Resolved	No	Mild	Not related	None/not applicable	No/No
								100 mg	85	口唇炎	ANGULAR CHEILITIS	92	16	Resolved	No	Mild	Unlikely	None/not applicable	No/No
								100 mg	85	腹部膨満	ABDOMINAL DISTENSION	105	680	Resolved	No	Mild	Not related	None/not applicable	No/No
								100 mg	85	肛門周囲痛	PAIN(ANUS)	105	-	Ongoing	No	Mild	Not related	None/not applicable	No/No
								100 mg	113	胸部不快感	CHEST DISCOMFORT	113	672	Resolved	No	Mild	Unlikely	None/not applicable	No/No
								100 mg	113	胃食道逆流性疾患	GASTRIC REFLUX	113	672	Resolved	No	Mild	Not related	None/not applicable	No/No
								100 mg	113	鼻咽頭炎	COLD	114	22	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100 mg	113	口唇炎	ANGULAR CHEILITIS	117	26	Resolved	No	Mild	Unlikely	None/not applicable	No/No

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								100 mg	113	黄斑症	PRERETINAL FIBROSIS(R) AGGRAVATED	132	380	Resolved	No	Moderate	Not related	None/not applicable	No/No
								100 mg	141	鼻咽頭炎	COLD	145	22	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100 mg	141	湿疹	ECZEMA (THE UPPER PART)	152	5	Resolved	No	Mild	Unlikely	None/not applicable	No/No
								100 mg	141	口内炎	STOMATITIS	152	15	Resolved	No	Mild	Unlikely	None/not applicable	No/No
								100 mg	169	慢性副鼻腔炎	CHRONIC SINUSITIS	170	575	Resolved	No	Mild	Unlikely	Temporary interruption/dose modification	Yes/No
								100 mg	169	無力症	FEELING OF WEAKNESS (RIGHT FINGER)	176	-	Ongoing	No	Mild	Unlikely	None/not applicable	No/No
								100 mg	169	湿疹	ECZEMA (NECK)	186	12	Resolved	No	Mild	Not related	None/not applicable	No/No
								100 mg	169	口内炎	STOMATITIS	186	8	Resolved	No	Mild	Unlikely	None/not applicable	No/No
								100 mg	253	湿疹	ECZEMA(FACE AND NECK)	274	29	Resolved	No	Mild	Unlikely	None/not applicable	No/No
								100 mg	253	乳房痛	BREAST PAIN	277	61	Resolved	No	Mild	Not related	None/not applicable	No/No
								100 mg	281	白内障	CATARACT(R)	293	219	Resolved	No	Moderate	Not related	None/not applicable	No/No
								100 mg	281	発疹	ERUPTION (RIGHT FOREARM)	294	64	Resolved	No	Mild	Unlikely	None/not applicable	No/No

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								100 mg	337	子宮出血	UTERINE HAEMORRHAGE	355	27	Resolved	No	Mild	Not related	None/not applicable	No/No
	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7802-00002	2[redacted]/M	JAPAN/Asian	-	-	100 mg	1	上気道感染	ACUTE UPPER RESPIRATORY INFECTION	26	11	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
			7804-00005	5[redacted]/M	JAPAN/Asian	-	-	100 mg	204	サイトメガロウイルス感染	CMV INFECTION	211	-	Ongoing	No	Mild	Possible	None/not applicable	Yes/No
			7805-00003	4[redacted]/M	JAPAN/Asian	-	-	100 mg	142	鉄欠乏性貧血	IRON DEFICIENCY ANEMIA	156	53	Resolved	No	Mild	Not related	None/not applicable	No/No
								100 mg	142	潰瘍性大腸炎	WORSENING OF UC	207	12	Resolved	Yes	Moderate	Not related	None/not applicable	No/No
			7807-00003	3[redacted]/M	JAPAN/Asian	-	-	100 mg	30	口腔咽頭痛	PHARYNGEAL PAIN	33	4	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100 mg	54	口腔ヘルペス	HERPES LABIALIS	80	7	Resolved	No	Mild	Possible	None/not applicable	Yes/No
								100 mg	54	口内炎	STOMATITIS	80	7	Resolved	No	Mild	Unlikely	None/not applicable	No/No
								100 mg	86	鼻咽頭炎	COLD	91	23	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100 mg	113	鼻咽頭炎	COLD	136	3	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100 mg	142	鼻咽頭炎	COLD	167	8	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100 mg	198	鼻咽頭炎	COLD	208	3	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100 mg	198	鼻咽頭炎	COLD	227	2	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100 mg	230	悪心	FEELING NAUSEATED	251	2	Resolved	No	Mild	Unlikely	None/not applicable	No/No

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								100 mg	286	鼻咽頭炎	COLD	349	3	Resolved	No	Mild	Not related	None/not applicable	Yes/No
			7808-00001	5[redacted]/F	JAPAN/Asian	-	-	100 mg	198	結腸ポリープ	COLONIC POLYP	210	15	Resolved	No	Moderate	Not related	None/not applicable	No/No
								100 mg	219	結腸ポリープ	COLONIC POLYP	224	3	Resolved	Yes	Moderate	Not related	None/not applicable	No/No
								100 mg	366	結腸ポリープ	COLONIC POLYP	379	41	Resolved	No	Moderate	Not related	None/not applicable	No/No
			7809-00001	2[redacted]/M	JAPAN/Asian	-	-	100 mg	340	上気道感染	URI	347	26	Resolved	No	Mild	Not related	None/not applicable	Yes/No
			7815-00003	4[redacted]/F	JAPAN/Asian	-	-	100 mg	367	膿疱性乾癬	PALMOPLANTAR PUSTULOSIS	367	-	Ongoing	No	Moderate	Probable	Permanent discontinuation of study agent	No/No
			7817-00002	2[redacted]/M	JAPAN/Asian	-	-	100 mg	197	腹痛	ABDOMINAL PAIN	222	4	Resolved	No	Moderate	Not related	None/not applicable	No/No
								100 mg	337	不眠症	WORESENING OF INSOMNIA	337	-	Ongoing	No	Mild	Not related	None/not applicable	No/No
								100 mg	337	湿疹	ECZEMA	360	91	Resolved	No	Mild	Not related	None/not applicable	No/No
			7818-00002	5[redacted]/F	JAPAN/Asian	-	-	100 mg	1	貧血	ANEMIA	35	216	Resolved	No	Moderate	Unlikely	None/not applicable	No/No
								100 mg	54	インフルエンザ	INFLUENZA	83	6	Resolved	No	Moderate	Not related	None/not applicable	Yes/No
								100 mg	194	不眠症	INSOMNIA	214	-	Ongoing	No	Mild	Not related	None/not applicable	No/No
								100 mg	194	肝不全	HEPATIC INSUFFISIENCY	278	-	Ongoing	No	Moderate	Unlikely	None/not applicable	No/No
			7819-00002	2[redacted]/M	JAPAN/Asian	-	-	100 mg	1	発熱	SLIGHT FEVER	1	1	Resolved	No	Mild	Unlikely	None/not applicable	No/No
								100 mg	63	鼻咽頭炎	COMMON COLD	81	29	Resolved	No	Mild	Not related	None/not applicable	Yes/No

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			7819-00004	2[redacted]/F	JAPAN/Asian	-	-	100 mg	78	鼻咽頭炎	COMMON COLD	105	41	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100 mg	78	白血球減少症	LEUKOPENIA	106	85	Resolved	No	Mild	Unlikely	None/not applicable	No/No
		400 mg/200 mg SC	7801-00001	3[redacted]/M	JAPAN/Asian	-	-	100 mg	85	鼻咽頭炎	COMMON COLD	141	5	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
			7801-00005	5[redacted]/M	JAPAN/Asian	-	-	100 mg	1	発疹	SKIN RASH	5	18	Resolved	No	Mild	Unlikely	None/not applicable	No/No
			7808-00004	3[redacted]/F	JAPAN/Asian	-	-	100 mg	1	悪心	NAUSEA	2	32	Resolved	No	Mild	Probable	None/not applicable	No/No
								100 mg	1	脂漏性皮膚炎	SEBORRHOEIC DERMATITIS	28	-	Ongoing	No	Mild	Unlikely	None/not applicable	No/No
								100 mg	29	接触性皮膚炎	CONTACT DERMATITIS	29	141	Resolved	No	Mild	Probable	None/not applicable	No/No
								100 mg	59	鼻咽頭炎	COLD	63	9	Resolved	No	Mild	Possible	None/not applicable	Yes/No
								100 mg	59	感染性表皮嚢胞	PYOGENIC ATHEROMA(SKIN)	80	64	Resolved	No	Moderate	Probable	None/not applicable	Yes/No
								100 mg	224	腹部不快感	STOMACH DISCOMFORT	249	9	Resolved	No	Mild	Not related	None/not applicable	No/No
								100 mg	253	関節周囲炎	PERIARTHRITIS(RIGHT SHOULDER)	275	-	Ongoing	No	Mild	Not related	None/not applicable	No/No
								100 mg	281	関節捻挫	HAND SPRAIN	288	3	Resolved	No	Mild	Not related	None/not applicable	No/No
								100 mg	309	アレルギー性結膜炎	ALLERGIC CONJUNCTIVITIS	317	-	Ongoing	No	Mild	Not related	None/not applicable	No/No

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								100 mg	309	胃腸炎	ACUTE GASTROENTERITIS	317	64	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100 mg	365	頭痛	HEADACHE	372	3	Resolved	No	Mild	Not related	None/not applicable	No/No
			7808-00007	2[redacted]/M	JAPAN/Asian	-	-	100 mg	30	鼻咽頭炎	COLD	43	3	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100 mg	58	副鼻腔炎	SINUSITIS	65	2	Resolved	No	Mild	Possible	None/not applicable	No/No
			7809-00003	3[redacted]/M	JAPAN/Asian	-	-	100 mg	79	感染性小腸結腸炎	INFECTION ENTEROCOLITIS	104	11	Resolved	No	Moderate	Not related	None/not applicable	Yes/No
								100 mg	303	喘息	COUGH VARIANT ASTHMA	305	139	Resolved	No	Mild	Not related	None/not applicable	No/No
			7813-00003	6[redacted]/M	JAPAN/Asian	-	-	100 mg	1	眼精疲労	TIRED EYES	4	126	Resolved	No	Mild	Possible	None/not applicable	No/No
								100 mg	1	口腔咽頭痛	PAIN PHARYNX	15	3	Resolved	No	Mild	Unlikely	None/not applicable	No/No
								100 mg	92	肋骨骨折	RIB FRACTURE	102	49	Resolved	No	Moderate	Not related	None/not applicable	No/No
								100 mg	197	鼻咽頭炎	COLD	279	44	Resolved	No	Mild	Not related	None/not applicable	Yes/No
			7816-00001	2[redacted]/M	JAPAN/Asian	-	-	100 mg	246	裂傷	CUT ON RIGHT MIDDLE FINGER	250	38	Resolved	No	Mild	Not related	None/not applicable	No/No
			7817-00003	5[redacted]/F	JAPAN/Asian	-	-	100 mg	25	疲労	GENERALIZED FATIGABILITY	47	12	Resolved	No	Mild	Not related	None/not applicable	No/No
								100 mg	81	挫傷	BRUISED LOW BACK	85	45	Resolved	No	Mild	Not related	None/not applicable	No/No

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/Sex	Country/Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Infusion-site Reaction[c, d]
								100 mg	112	腹部膨満	BLOATING SENSATION	137	31	Resolved	No	Mild	Not related	None/not applicable	No/No
								100 mg	137	咳嗽	COUGHING	165	17	Resolved	No	Mild	Not related	None/not applicable	No/No
								100 mg	137	疲労	GENERALIZED FATIGABILITY	165	22	Resolved	No	Mild	Not related	None/not applicable	No/No
								100 mg	195	裂肛	ANAL FISSURE	219	31	Resolved	No	Mild	Not related	None/not applicable	No/No
								100 mg	273	痔核	HEMORRHOID WORSEN	303	4	Resolved	No	Mild	Not related	None/not applicable	No/No
			7819-00001	3[redacted]/F	JAPAN/Asian	-	-	100 mg	26	末梢性浮腫	EDEMA BOTH FEET	57	89	Resolved	No	Mild	Unlikely	None/not applicable	No/No
								100 mg	61	好酸球数増加	EOSINOPHIL COUNT INCREASED	61	270	Resolved	No	Moderate	Unlikely	None/not applicable	No/No
			7820-00003	3[redacted]/F	JAPAN/Asian	-	-	100 mg	1	インフルエンザ	INFLUENZA A	12	6	Resolved	No	Moderate	Possible	None/not applicable	Yes/No
								100 mg	50	膀胱炎	CYSTITIS	75	3	Resolved	No	Moderate	Possible	None/not applicable	Yes/No

a) For subjects who were dose adjusted to golimumab 200 mg and later had their decreased to 100 mg following implemantation of Protocol Amendment 3, 'Treatment Group At Dose Adjustment' is presented as '200 mg (100 mg)', and 'Study Day of Dose adjustment' is presented in the form of xxx (yyy), where xxx is the study day of dose adjustment and yyy is the study day of dose decrease.
b) Based on MedDRA version 14.0.
c) Infection as assessed by the investigator.
d) Injection-site reaction as assessed by the investigator.

表 2.7.4.7-付録-12 安全性の概要（T16，T17 及び T18 試験 54 週まで；日本人 vs 外国人；全投与被験者）

	Japanese		Non-Japanese		Total	
	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]
Treated subjects in C0524T16 and C0524T17	30	68	377	1165	407	1233
Avg duration of follow-up (weeks)	11.5	43.6	18.8	45.7	18.3	45.6
Avg exposure (number of administrations)	2.9	9.9	4.7	11.0	4.6	11.0
Subjects who discontinued study agent because of 1 or more adverse events	0 (0.0%)	7 (10.3%)	10 (2.7%)	138 (11.8%)	10 (2.5%)	145 (11.8%)
Subjects with 1 or more of the following events						
Adverse events	20 (66.7%)	60 (88.2%)	174 (46.2%)	904 (77.6%)	194 (47.7%)	964 (78.2%)
Drug-related adverse events	8 (26.7%)	27 (39.7%)	70 (18.6%)	400 (34.3%)	78 (19.2%)	427 (34.6%)
Serious adverse events	3 (10.0%)	14 (20.6%)	27 (7.2%)	182 (15.6%)	30 (7.4%)	196 (15.9%)

[a] Includes data up to the time of the first golimumab dose.
[b] Includes data from the time of the first golimumab dose onward.

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表 2.7.4.7-付録-13 すべての有害事象（T16，T17 及び T18 試験 54 週まで；日本人 vs 外国人；全投与被験者）

	Japanese		Non-Japanese		Total	
	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]
Treated subjects in C0524T16 and C0524T17	30	68	377	1165	407	1233
Avg duration of follow-up (weeks)	11.5	43.6	18.8	45.7	18.3	45.6
Avg exposure (number of administrations)	2.9	9.9	4.7	11.0	4.6	11.0
Subjects with 1 or more adverse events	20 (66.7%)	60 (88.2%)	174 (46.2%)	904 (77.6%)	194 (47.7%)	964 (78.2%)
System-organ class/preferred term						
胃腸障害	6 (20.0%)	26 (38.2%)	76 (20.2%)	474 (40.7%)	82 (20.1%)	500 (40.6%)
潰瘍性大腸炎	2 (6.7%)	9 (13.2%)	33 (8.8%)	242 (20.8%)	35 (8.6%)	251 (20.4%)
腹痛	1 (3.3%)	2 (2.9%)	9 (2.4%)	67 (5.8%)	10 (2.5%)	69 (5.6%)
悪心	1 (3.3%)	4 (5.9%)	13 (3.4%)	51 (4.4%)	14 (3.4%)	55 (4.5%)
下痢	1 (3.3%)	1 (1.5%)	5 (1.3%)	36 (3.1%)	6 (1.5%)	37 (3.0%)
嘔吐	0 (0.0%)	0 (0.0%)	5 (1.3%)	27 (2.3%)	5 (1.2%)	27 (2.2%)
痔核	1 (3.3%)	1 (1.5%)	4 (1.1%)	24 (2.1%)	5 (1.2%)	25 (2.0%)
便秘	1 (3.3%)	1 (1.5%)	5 (1.3%)	21 (1.8%)	6 (1.5%)	22 (1.8%)
上腹部痛	0 (0.0%)	0 (0.0%)	3 (0.8%)	21 (1.8%)	3 (0.7%)	21 (1.7%)
消化不良	0 (0.0%)	0 (0.0%)	4 (1.1%)	20 (1.7%)	4 (1.0%)	20 (1.6%)
血便排泄	0 (0.0%)	0 (0.0%)	7 (1.9%)	13 (1.1%)	7 (1.7%)	13 (1.1%)
腹部膨満	0 (0.0%)	3 (4.4%)	1 (0.3%)	9 (0.8%)	1 (0.2%)	12 (1.0%)
下腹部痛	0 (0.0%)	0 (0.0%)	2 (0.5%)	11 (0.9%)	2 (0.5%)	11 (0.9%)
裂肛	0 (0.0%)	1 (1.5%)	0 (0.0%)	10 (0.9%)	0 (0.0%)	11 (0.9%)
胃食道逆流性疾患	0 (0.0%)	2 (2.9%)	1 (0.3%)	9 (0.8%)	1 (0.2%)	11 (0.9%)
歯痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	10 (0.9%)	0 (0.0%)	10 (0.8%)
腹部不快感	0 (0.0%)	2 (2.9%)	4 (1.1%)	6 (0.5%)	4 (1.0%)	8 (0.6%)
結腸ポリープ	0 (0.0%)	1 (1.5%)	0 (0.0%)	7 (0.6%)	0 (0.0%)	8 (0.6%)
口内炎	0 (0.0%)	5 (7.4%)	1 (0.3%)	3 (0.3%)	1 (0.2%)	8 (0.6%)
排便回数増加	0 (0.0%)	0 (0.0%)	2 (0.5%)	7 (0.6%)	2 (0.5%)	7 (0.6%)
アフタ性口内炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (0.5%)	0 (0.0%)	6 (0.5%)
直腸ポリープ	0 (0.0%)	0 (0.0%)	1 (0.3%)	6 (0.5%)	1 (0.2%)	6 (0.5%)
齲歯	0 (0.0%)	1 (1.5%)	0 (0.0%)	4 (0.3%)	0 (0.0%)	5 (0.4%)

	Japanese		Non-Japanese		Total	
	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]
鼓腸	0 (0.0%)	0 (0.0%)	1 (0.3%)	5 (0.4%)	1 (0.2%)	5 (0.4%)
肛門周囲痛	0 (0.0%)	1 (1.5%)	0 (0.0%)	4 (0.3%)	0 (0.0%)	5 (0.4%)
口唇炎	0 (0.0%)	1 (1.5%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	4 (0.3%)
口内乾燥	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.3%)	0 (0.0%)	4 (0.3%)
肛門直腸不快感	0 (0.0%)	0 (0.0%)	1 (0.3%)	3 (0.3%)	1 (0.2%)	3 (0.2%)
便意切迫	0 (0.0%)	0 (0.0%)	1 (0.3%)	3 (0.3%)	1 (0.2%)	3 (0.2%)
血性下痢	0 (0.0%)	0 (0.0%)	3 (0.8%)	3 (0.3%)	3 (0.7%)	3 (0.2%)
食中毒	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	3 (0.2%)
胃炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	3 (0.2%)
過敏性腸症候群	0 (0.0%)	0 (0.0%)	1 (0.3%)	3 (0.3%)	1 (0.2%)	3 (0.2%)
口腔内潰瘍形成	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	3 (0.2%)
膵炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	3 (0.2%)
偽性ポリポーシス	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	3 (0.2%)
肛門の炎症	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
腸憩室	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
腸炎	1 (3.3%)	1 (1.5%)	0 (0.0%)	1 (0.1%)	1 (0.2%)	2 (0.2%)
便失禁	0 (0.0%)	0 (0.0%)	1 (0.3%)	2 (0.2%)	1 (0.2%)	2 (0.2%)
胃腸音異常	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
排便痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
直腸炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
腹部ヘルニア	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
腹部硬直	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
肛門皮膚垂	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
バレット食道	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
便通不規則	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
口唇症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
大腸炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
結腸狭窄	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)

	Japanese		Non-Japanese		Total	
	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]
十二指腸炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
嚥下障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
小腸炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
萎縮性胃炎	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
胃腸出血	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
胃腸の炎症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
消化器痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
歯肉痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
歯肉炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
痔出血	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
胃酸過多	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
肛門肥大乳頭	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
イレウス	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.1%)	1 (0.2%)	1 (0.1%)
単径ヘルニア	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
腸管虚血	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
口唇腫脹	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
機械的イレウス	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
口腔嚢胞	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
口腔内出血	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
粘液便	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
食道浮腫	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
口腔内痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
急性膵炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
口の錯感覚	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
肛門周囲炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
直腸出血	0 (0.0%)	0 (0.0%)	2 (0.5%)	1 (0.1%)	2 (0.5%)	1 (0.1%)
直腸攣縮	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
直腸しぶり	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)

	Japanese		Non-Japanese		Total	
	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]
歯の知覚過敏	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
小腸閉塞	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
舌腫脹	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
脆弱歯	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
歯の障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
異常便	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
痔瘻	1 (3.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
亜イレウス	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
舌水疱形成	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
感染症および寄生虫症	7 (23.3%)	41 (60.3%)	63 (16.7%)	449 (38.5%)	70 (17.2%)	490 (39.7%)
鼻咽頭炎	3 (10.0%)	25 (36.8%)	14 (3.7%)	107 (9.2%)	17 (4.2%)	132 (10.7%)
上気道感染	1 (3.3%)	4 (5.9%)	11 (2.9%)	73 (6.3%)	12 (2.9%)	77 (6.2%)
咽頭炎	0 (0.0%)	1 (1.5%)	0 (0.0%)	40 (3.4%)	0 (0.0%)	41 (3.3%)
副鼻腔炎	0 (0.0%)	1 (1.5%)	5 (1.3%)	36 (3.1%)	5 (1.2%)	37 (3.0%)
インフルエンザ	0 (0.0%)	4 (5.9%)	8 (2.1%)	30 (2.6%)	8 (2.0%)	34 (2.8%)
気管支炎	1 (3.3%)	0 (0.0%)	4 (1.1%)	29 (2.5%)	5 (1.2%)	29 (2.4%)
胃腸炎	0 (0.0%)	1 (1.5%)	3 (0.8%)	23 (2.0%)	3 (0.7%)	24 (1.9%)
口腔ヘルペス	0 (0.0%)	2 (2.9%)	1 (0.3%)	19 (1.6%)	1 (0.2%)	21 (1.7%)
尿路感染	0 (0.0%)	2 (2.9%)	4 (1.1%)	16 (1.4%)	4 (1.0%)	18 (1.5%)
ウイルス感染	0 (0.0%)	0 (0.0%)	4 (1.1%)	14 (1.2%)	4 (1.0%)	14 (1.1%)
ウイルス性胃腸炎	0 (0.0%)	0 (0.0%)	4 (1.1%)	13 (1.1%)	4 (1.0%)	13 (1.1%)
クロストリジウム感染	0 (0.0%)	1 (1.5%)	0 (0.0%)	10 (0.9%)	0 (0.0%)	11 (0.9%)
肺炎	0 (0.0%)	1 (1.5%)	1 (0.3%)	10 (0.9%)	1 (0.2%)	11 (0.9%)
鼻炎	0 (0.0%)	1 (1.5%)	0 (0.0%)	10 (0.9%)	0 (0.0%)	11 (0.9%)
膀胱炎	0 (0.0%)	2 (2.9%)	0 (0.0%)	7 (0.6%)	0 (0.0%)	9 (0.7%)
毛包炎	0 (0.0%)	2 (2.9%)	1 (0.3%)	7 (0.6%)	1 (0.2%)	9 (0.7%)
帯状疱疹	0 (0.0%)	1 (1.5%)	0 (0.0%)	8 (0.7%)	0 (0.0%)	9 (0.7%)
真菌感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	8 (0.7%)	0 (0.0%)	8 (0.6%)

	Japanese		Non-Japanese		Total	
	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]
気道感染	0 (0.0%)	1 (1.5%)	0 (0.0%)	7 (0.6%)	0 (0.0%)	8 (0.6%)
外陰腟真菌感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	8 (0.7%)	0 (0.0%)	8 (0.6%)
麦粒腫	0 (0.0%)	0 (0.0%)	2 (0.5%)	7 (0.6%)	2 (0.5%)	7 (0.6%)
歯膿瘍	0 (0.0%)	0 (0.0%)	2 (0.5%)	7 (0.6%)	2 (0.5%)	7 (0.6%)
せつ	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (0.5%)	0 (0.0%)	6 (0.5%)
単純ヘルペス	0 (0.0%)	0 (0.0%)	2 (0.5%)	6 (0.5%)	2 (0.5%)	6 (0.5%)
ウイルス性気道感染	0 (0.0%)	0 (0.0%)	1 (0.3%)	6 (0.5%)	1 (0.2%)	6 (0.5%)
肛門膿瘍	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (0.4%)	0 (0.0%)	5 (0.4%)
耳感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (0.4%)	0 (0.0%)	5 (0.4%)
喉頭炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (0.4%)	0 (0.0%)	5 (0.4%)
爪真菌症	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (0.4%)	0 (0.0%)	5 (0.4%)
レンサ球菌性咽頭炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (0.4%)	0 (0.0%)	5 (0.4%)
扁桃炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	5 (0.4%)	1 (0.2%)	5 (0.4%)
ウイルス性上気道感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (0.4%)	0 (0.0%)	5 (0.4%)
外陰部腟カンジダ症	0 (0.0%)	0 (0.0%)	1 (0.3%)	5 (0.4%)	1 (0.2%)	5 (0.4%)
急性扁桃炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	4 (0.3%)	1 (0.2%)	4 (0.3%)
虫垂炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.3%)	0 (0.0%)	4 (0.3%)
蜂巣炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.3%)	0 (0.0%)	4 (0.3%)
サイトメガロウイルス感染	0 (0.0%)	3 (4.4%)	1 (0.3%)	1 (0.1%)	1 (0.2%)	4 (0.3%)
下気道感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.3%)	0 (0.0%)	4 (0.3%)
口腔カンジダ症	0 (0.0%)	0 (0.0%)	1 (0.3%)	4 (0.3%)	1 (0.2%)	4 (0.3%)
外耳炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.3%)	0 (0.0%)	4 (0.3%)
歯感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.3%)	0 (0.0%)	4 (0.3%)
気管炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	4 (0.3%)	1 (0.2%)	4 (0.3%)
肛門性器疣贅	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	3 (0.2%)
慢性副鼻腔炎	0 (0.0%)	1 (1.5%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	3 (0.2%)
播種性結核	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	3 (0.2%)
憩室炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	3 (0.2%)

	Japanese		Non-Japanese		Total	
	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]
感染性腸炎	0 (0.0%)	3 (4.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.2%)
エンテロウイルス感染	0 (0.0%)	0 (0.0%)	1 (0.3%)	3 (0.3%)	1 (0.2%)	3 (0.2%)
丹毒	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	3 (0.2%)
限局性感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	3 (0.2%)
爪囲炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	3 (0.2%)
膿疱性皮疹	0 (0.0%)	0 (0.0%)	1 (0.3%)	3 (0.3%)	1 (0.2%)	3 (0.2%)
ブドウ球菌感染	0 (0.0%)	0 (0.0%)	1 (0.3%)	3 (0.3%)	1 (0.2%)	3 (0.2%)
皮下組織膿瘍	0 (0.0%)	1 (1.5%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	3 (0.2%)
足部白癬	0 (0.0%)	1 (1.5%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	3 (0.2%)
創傷感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	3 (0.2%)
膿瘍	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
急性副鼻腔炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
ブラストシスティス感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
脳膿瘍	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
カンジダ症	0 (0.0%)	0 (0.0%)	1 (0.3%)	2 (0.2%)	1 (0.2%)	2 (0.2%)
感染性小腸結腸炎	1 (3.3%)	2 (2.9%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	2 (0.2%)
ウイルス性消化管感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
ヘルペスウイルス感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
マラリア	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
食道カンジダ症	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
敗血症	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
皮膚感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
癜風	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
ウイルス性咽頭炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
腹壁膿瘍	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
ダニ皮膚炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
エロモナス感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)

	Japanese		Non-Japanese		Total	
	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]
アメーバ症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
真菌性肛門感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
細菌感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
細菌性敗血症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
ボレリア感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
乳房蜂巣炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
クロストリジウム・ディフィシレ大腸炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.1%)	1 (0.2%)	1 (0.1%)
感染性皮膚炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
紅色陰癬	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
外耳蜂巣炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
眼感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
ブドウ球菌性眼感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
皮膚真菌感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
ロタウイルス胃腸炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
サルモネラ菌性胃腸炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
消化管感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
ジアルジア症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
鼠径部膿瘍	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
感染性表皮嚢胞	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
感染性皮膚潰瘍	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
注射部位膿瘍	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
椎間板炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
迷路炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
潜伏結核	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
ウイルス性下気道感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
ライム病	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
メタニューモウイルス感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
伝染性軟属腫	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)

	Japanese		Non-Japanese		Total	
	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]
爪感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
口腔真菌感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
精巣炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
中耳炎	0 (0.0%)	0 (0.0%)	2 (0.5%)	1 (0.1%)	2 (0.5%)	1 (0.1%)
寄生虫性胃腸炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
歯周感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
百日咳	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
毛巣嚢胞	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
原発性異型肺炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
術後膿瘍	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
偽膜性大腸炎	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
腎盂腎炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
直腸膿瘍	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
敗血症性ショック	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
皮膚細菌感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
軟部組織感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
ブドウ球菌性菌血症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
レンサ球菌性敗血症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
白癬感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
結核	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
腸チフス熱	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
尿道炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
泌尿生殖器真菌感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
ワクチン接種部位感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
腟感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
水痘	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
乳房膿瘍	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
気管支肺炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)

	Japanese		Non-Japanese		Total	
	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]
Ｈ１Ｎ１インフルエンザ	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
血腫感染	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
細菌の過剰増殖	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
直腸周囲膿瘍	1 (3.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
一般・全身障害および投与部位の状態	4 (13.3%)	14 (20.6%)	33 (8.8%)	205 (17.6%)	37 (9.1%)	219 (17.8%)
発熱	2 (6.7%)	8 (11.8%)	6 (1.6%)	57 (4.9%)	8 (2.0%)	65 (5.3%)
疲労	0 (0.0%)	1 (1.5%)	7 (1.9%)	38 (3.3%)	7 (1.7%)	39 (3.2%)
注射部位紅斑	0 (0.0%)	0 (0.0%)	1 (0.3%)	23 (2.0%)	1 (0.2%)	23 (1.9%)
無力症	0 (0.0%)	1 (1.5%)	4 (1.1%)	21 (1.8%)	4 (1.0%)	22 (1.8%)
インフルエンザ様疾患	0 (0.0%)	0 (0.0%)	3 (0.8%)	20 (1.7%)	3 (0.7%)	20 (1.6%)
末梢性浮腫	0 (0.0%)	1 (1.5%)	3 (0.8%)	18 (1.5%)	3 (0.7%)	19 (1.5%)
胸痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	8 (0.7%)	0 (0.0%)	8 (0.6%)
悪寒	0 (0.0%)	0 (0.0%)	2 (0.5%)	8 (0.7%)	2 (0.5%)	8 (0.6%)
疼痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	8 (0.7%)	0 (0.0%)	8 (0.6%)
注射部位疼痛	0 (0.0%)	1 (1.5%)	2 (0.5%)	5 (0.4%)	2 (0.5%)	6 (0.5%)
注射部位血腫	0 (0.0%)	0 (0.0%)	2 (0.5%)	5 (0.4%)	2 (0.5%)	5 (0.4%)
高熱	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.3%)	0 (0.0%)	4 (0.3%)
注射部位そう痒感	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.3%)	0 (0.0%)	4 (0.3%)
注射部位発疹	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.3%)	0 (0.0%)	4 (0.3%)
注射部位腫脹	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.3%)	0 (0.0%)	4 (0.3%)
注射部位反応	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	3 (0.2%)
倦怠感	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	3 (0.2%)
胸部不快感	0 (0.0%)	1 (1.5%)	2 (0.5%)	1 (0.1%)	2 (0.5%)	2 (0.2%)
薬効欠如	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
注射部位炎症	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
注射部位蕁麻疹	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
粘膜の炎症	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
浮腫	0 (0.0%)	1 (1.5%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	2 (0.2%)

	Japanese		Non-Japanese		Total	
	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]
口渇	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
投与部位発疹	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
投与部位反応	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
医薬品副作用	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.1%)	1 (0.2%)	1 (0.1%)
適用部位紅斑	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
腋窩痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
嚢胞	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.1%)	1 (0.2%)	1 (0.1%)
薬物不耐性	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
顔面浮腫	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
冷感	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
酩酊感	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
体温変動感	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
低体温	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
注入部位炎症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
注入部位疼痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
注入部位静脈炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
注入部位そう痒感	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
注入部位反応	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
注射部位出血	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.1%)	1 (0.2%)	1 (0.1%)
注射部位硬結	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
注射部位腫瘤	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
限局性浮腫	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.1%)	1 (0.2%)	1 (0.1%)
医療機器合併症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
微石症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
非心臓性胸痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
偽ポリープ	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
圧迫感	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.1%)	1 (0.2%)	1 (0.1%)
軟部組織の炎症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)

	Japanese		Non-Japanese		Total	
	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]
熱感	1 (3.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
びくびく感	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
治癒不良	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
腫脹	1 (3.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
乾燥症	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
皮膚および皮下組織障害	5 (16.7%)	20 (29.4%)	35 (9.3%)	190 (16.3%)	40 (9.8%)	210 (17.0%)
発疹	1 (3.3%)	6 (8.8%)	6 (1.6%)	43 (3.7%)	7 (1.7%)	49 (4.0%)
そう痒症	0 (0.0%)	2 (2.9%)	5 (1.3%)	26 (2.2%)	5 (1.2%)	28 (2.3%)
脱毛症	0 (0.0%)	2 (2.9%)	2 (0.5%)	12 (1.0%)	2 (0.5%)	14 (1.1%)
皮膚乾燥	0 (0.0%)	0 (0.0%)	1 (0.3%)	14 (1.2%)	1 (0.2%)	14 (1.1%)
湿疹	1 (3.3%)	5 (7.4%)	3 (0.8%)	7 (0.6%)	4 (1.0%)	12 (1.0%)
ざ瘡	0 (0.0%)	1 (1.5%)	3 (0.8%)	10 (0.9%)	3 (0.7%)	11 (0.9%)
アレルギー性皮膚炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	11 (0.9%)	0 (0.0%)	11 (0.9%)
紅斑	0 (0.0%)	1 (1.5%)	1 (0.3%)	9 (0.8%)	1 (0.2%)	10 (0.8%)
寝汗	0 (0.0%)	0 (0.0%)	3 (0.8%)	10 (0.9%)	3 (0.7%)	10 (0.8%)
皮膚炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	9 (0.8%)	1 (0.2%)	9 (0.7%)
接触性皮膚炎	0 (0.0%)	3 (4.4%)	1 (0.3%)	4 (0.3%)	1 (0.2%)	7 (0.6%)
蕁麻疹	0 (0.0%)	0 (0.0%)	2 (0.5%)	6 (0.5%)	2 (0.5%)	6 (0.5%)
多汗症	1 (3.3%)	0 (0.0%)	1 (0.3%)	5 (0.4%)	2 (0.5%)	5 (0.4%)
乾癬	0 (0.0%)	0 (0.0%)	1 (0.3%)	5 (0.4%)	1 (0.2%)	5 (0.4%)
脂漏性皮膚炎	0 (0.0%)	2 (2.9%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	5 (0.4%)
結節性紅斑	2 (6.7%)	0 (0.0%)	3 (0.8%)	4 (0.3%)	5 (1.2%)	4 (0.3%)
全身性皮疹	0 (0.0%)	0 (0.0%)	1 (0.3%)	4 (0.3%)	1 (0.2%)	4 (0.3%)
そう痒性皮疹	0 (0.0%)	0 (0.0%)	3 (0.8%)	4 (0.3%)	3 (0.7%)	4 (0.3%)
皮膚病変	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.3%)	0 (0.0%)	4 (0.3%)
薬疹	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	3 (0.2%)
酒さ	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	3 (0.2%)
皮膚変色	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	3 (0.2%)

	Japanese		Non-Japanese		Total	
	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]
日光性角化症	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
水疱	0 (0.0%)	0 (0.0%)	1 (0.3%)	2 (0.2%)	1 (0.2%)	2 (0.2%)
ざ瘡様皮膚炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
アトピー性皮膚炎	0 (0.0%)	1 (1.5%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	2 (0.2%)
皮脂欠乏性湿疹	0 (0.0%)	1 (1.5%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	2 (0.2%)
貨幣状湿疹	0 (0.0%)	1 (1.5%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	2 (0.2%)
滴状乾癬	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
汗腺炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
嵌入爪	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
爪破損	0 (0.0%)	0 (0.0%)	1 (0.3%)	2 (0.2%)	1 (0.2%)	2 (0.2%)
痒疹	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
膿疱性乾癬	0 (0.0%)	1 (1.5%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	2 (0.2%)
斑状丘疹状皮疹	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
皮膚亀裂	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
皮膚嚢腫	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
乾癬様皮膚炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
発汗障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
皮下出血	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
顔面感覚鈍麻	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
内出血発生の増加傾向	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
苔癬様角化症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
脂肪肥大症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
斑	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
爪変色	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
点状出血	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
光線性皮膚症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
ばら色粃糠疹	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
紫斑	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)

	Japanese		Non-Japanese		Total	
	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]
毛孔性皮疹	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.1%)	1 (0.2%)	1 (0.1%)
斑状皮疹	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.1%)	1 (0.2%)	1 (0.1%)
丘疹性皮疹	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
瘢痕	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
瘢痕痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
皮膚灼熱感	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
ひび・あかぎれ	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
皮膚剥脱	1 (3.3%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.2%)	1 (0.1%)
皮膚色素減少	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
皮膚刺激	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
皮膚線条	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
尋常性白斑	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
斑状出血	0 (0.0%)	0 (0.0%)	2 (0.5%)	0 (0.0%)	2 (0.5%)	0 (0.0%)
扁平苔癬	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
全身性そう痒症	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
壊疽性膿皮症	1 (3.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
皮膚色素脱失	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
顔面腫脹	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
筋骨格系および結合組織障害	2 (6.7%)	7 (10.3%)	32 (8.5%)	196 (16.8%)	34 (8.4%)	203 (16.5%)
関節痛	1 (3.3%)	2 (2.9%)	14 (3.7%)	88 (7.6%)	15 (3.7%)	90 (7.3%)
背部痛	0 (0.0%)	3 (4.4%)	7 (1.9%)	34 (2.9%)	7 (1.7%)	37 (3.0%)
四肢痛	0 (0.0%)	0 (0.0%)	1 (0.3%)	18 (1.5%)	1 (0.2%)	18 (1.5%)
筋痙縮	1 (3.3%)	0 (0.0%)	2 (0.5%)	14 (1.2%)	3 (0.7%)	14 (1.1%)
筋肉痛	0 (0.0%)	1 (1.5%)	3 (0.8%)	13 (1.1%)	3 (0.7%)	14 (1.1%)
筋骨格痛	0 (0.0%)	0 (0.0%)	2 (0.5%)	12 (1.0%)	2 (0.5%)	12 (1.0%)
頚部痛	0 (0.0%)	1 (1.5%)	0 (0.0%)	6 (0.5%)	0 (0.0%)	7 (0.6%)
関節炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	6 (0.5%)	1 (0.2%)	6 (0.5%)
筋骨格系胸痛	0 (0.0%)	2 (2.9%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	5 (0.4%)

	Japanese		Non-Japanese		Total	
	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]
滑液包炎	0 (0.0%)	1 (1.5%)	1 (0.3%)	3 (0.3%)	1 (0.2%)	4 (0.3%)
変形性関節症	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.3%)	0 (0.0%)	4 (0.3%)
骨痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	3 (0.2%)
骨粗鬆症	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	3 (0.2%)
線維筋痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
椎間板突出	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
関節腫脹	0 (0.0%)	0 (0.0%)	3 (0.8%)	2 (0.2%)	3 (0.7%)	2 (0.2%)
筋骨格不快感	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
骨減少症	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
重感	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
腱痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
バニオン	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
軟骨疾患	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
外骨腫	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
側腹部痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
胤径部痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
関節ロック	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
筋攣縮	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
筋力低下	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
筋骨格硬直	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
骨壊死	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
骨粗鬆症性骨折	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
骨硬化症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
関節周囲炎	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
多発性関節炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
仙腸骨炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
変形性脊椎症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
脊椎炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)

	Japanese		Non-Japanese		Total	
	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]
滑液嚢腫	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
腱性拘縮	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
腱鞘炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
狭窄性腱鞘炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
関節障害	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
椎間関節症候群	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
瘻孔	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
関節硬直	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
顎痛	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
足底筋膜炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
神経系障害	3 (10.0%)	13 (19.1%)	37 (9.8%)	165 (14.2%)	40 (9.8%)	178 (14.4%)
頭痛	2 (6.7%)	9 (13.2%)	21 (5.6%)	119 (10.2%)	23 (5.7%)	128 (10.4%)
浮動性めまい	0 (0.0%)	2 (2.9%)	2 (0.5%)	22 (1.9%)	2 (0.5%)	24 (1.9%)
片頭痛	0 (0.0%)	0 (0.0%)	3 (0.8%)	11 (0.9%)	3 (0.7%)	11 (0.9%)
錯感覚	0 (0.0%)	0 (0.0%)	5 (1.3%)	9 (0.8%)	5 (1.2%)	9 (0.7%)
感覚鈍麻	0 (0.0%)	2 (2.9%)	0 (0.0%)	6 (0.5%)	0 (0.0%)	8 (0.6%)
振戦	0 (0.0%)	1 (1.5%)	2 (0.5%)	3 (0.3%)	2 (0.5%)	4 (0.3%)
坐骨神経痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	3 (0.2%)
副鼻腔炎に伴う頭痛	0 (0.0%)	0 (0.0%)	1 (0.3%)	3 (0.3%)	1 (0.2%)	3 (0.2%)
失神	0 (0.0%)	0 (0.0%)	1 (0.3%)	3 (0.3%)	1 (0.2%)	3 (0.2%)
痙攣	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
味覚異常	0 (0.0%)	0 (0.0%)	3 (0.8%)	2 (0.2%)	3 (0.7%)	2 (0.2%)
嗜眠	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
神経圧迫	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
末梢性ニューロパチー	1 (3.3%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	1 (0.2%)	2 (0.2%)
手根管症候群	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
頚髄症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
肘部管症候群	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)

	Japanese		Non-Japanese		Total	
	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]
脱髄	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
異常感覚	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
顔面不全麻痺	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
筋緊張低下	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.1%)	1 (0.2%)	1 (0.1%)
虚血性脳卒中	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
意識消失	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
神経根圧迫	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
神経痛	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
感覚障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
知覚過敏	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
傾眠	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
呼吸器、胸郭および縦隔障害	4 (13.3%)	15 (22.1%)	23 (6.1%)	136 (11.7%)	27 (6.6%)	151 (12.2%)
咳嗽	1 (3.3%)	4 (5.9%)	14 (3.7%)	60 (5.2%)	15 (3.7%)	64 (5.2%)
口腔咽頭痛	2 (6.7%)	4 (5.9%)	3 (0.8%)	26 (2.2%)	5 (1.2%)	30 (2.4%)
鼻漏	0 (0.0%)	1 (1.5%)	0 (0.0%)	7 (0.6%)	0 (0.0%)	8 (0.6%)
鼻閉	0 (0.0%)	1 (1.5%)	1 (0.3%)	6 (0.5%)	1 (0.2%)	7 (0.6%)
喘息	0 (0.0%)	1 (1.5%)	1 (0.3%)	5 (0.4%)	1 (0.2%)	6 (0.5%)
呼吸困難	0 (0.0%)	0 (0.0%)	2 (0.5%)	6 (0.5%)	2 (0.5%)	6 (0.5%)
鼻出血	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (0.4%)	0 (0.0%)	5 (0.4%)
呼吸障害	0 (0.0%)	0 (0.0%)	1 (0.3%)	5 (0.4%)	1 (0.2%)	5 (0.4%)
副鼻腔うっ血	0 (0.0%)	0 (0.0%)	1 (0.3%)	5 (0.4%)	1 (0.2%)	5 (0.4%)
上気道うっ血	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (0.4%)	0 (0.0%)	5 (0.4%)
湿性咳嗽	0 (0.0%)	0 (0.0%)	1 (0.3%)	4 (0.3%)	1 (0.2%)	4 (0.3%)
気道うっ血	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.3%)	0 (0.0%)	4 (0.3%)
アレルギー性鼻炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.3%)	0 (0.0%)	4 (0.3%)
上気道の炎症	2 (6.7%)	3 (4.4%)	0 (0.0%)	1 (0.1%)	2 (0.5%)	4 (0.3%)
喘鳴	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.3%)	0 (0.0%)	4 (0.3%)
慢性閉塞性肺疾患	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)

	Japanese		Non-Japanese		Total	
	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]
労作性呼吸困難	0 (0.0%)	0 (0.0%)	1 (0.3%)	2 (0.2%)	1 (0.2%)	2 (0.2%)
肺塞栓症	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
季節性鼻炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
アレルギー性咳嗽	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
慢性気管支炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
息詰まり感	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
咽喉乾燥	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.1%)	1 (0.2%)	1 (0.1%)
発声障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
喀血	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
上気道分泌増加	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
肺浸潤	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
鼻乾燥	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
鼻閉塞	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
呼吸時疼痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
胸水	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
くしゃみ	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
咽喉刺激感	0 (0.0%)	0 (0.0%)	2 (0.5%)	1 (0.1%)	2 (0.5%)	1 (0.1%)
鼻部不快感	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
胸膜炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
血液およびリンパ系障害	2 (6.7%)	7 (10.3%)	20 (5.3%)	120 (10.3%)	22 (5.4%)	127 (10.3%)
貧血	0 (0.0%)	2 (2.9%)	12 (3.2%)	60 (5.2%)	12 (2.9%)	62 (5.0%)
白血球減少症	1 (3.3%)	3 (4.4%)	2 (0.5%)	20 (1.7%)	3 (0.7%)	23 (1.9%)
好中球減少症	0 (0.0%)	1 (1.5%)	1 (0.3%)	14 (1.2%)	1 (0.2%)	15 (1.2%)
好酸球増加症	0 (0.0%)	0 (0.0%)	1 (0.3%)	10 (0.9%)	1 (0.2%)	10 (0.8%)
リンパ球減少症	0 (0.0%)	0 (0.0%)	2 (0.5%)	9 (0.8%)	2 (0.5%)	9 (0.7%)
白血球増加症	0 (0.0%)	0 (0.0%)	1 (0.3%)	8 (0.7%)	1 (0.2%)	8 (0.6%)
単球減少症	0 (0.0%)	0 (0.0%)	2 (0.5%)	6 (0.5%)	2 (0.5%)	6 (0.5%)
好中球増加症	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (0.5%)	0 (0.0%)	6 (0.5%)

	Japanese		Non-Japanese		Total	
	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]
血小板増加症	0 (0.0%)	0 (0.0%)	1 (0.3%)	6 (0.5%)	1 (0.2%)	6 (0.5%)
鉄欠乏性貧血	1 (3.3%)	2 (2.9%)	0 (0.0%)	3 (0.3%)	1 (0.2%)	5 (0.4%)
リンパ節症	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (0.4%)	0 (0.0%)	5 (0.4%)
リンパ球増加症	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (0.4%)	0 (0.0%)	5 (0.4%)
血小板減少症	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	3 (0.2%)
二血球減少症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
血液障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
溶血性貧血	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
出血性貧血	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
リンパ節痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
小球性貧血	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
単球増加症	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.1%)	1 (0.2%)	1 (0.1%)
赤血球大小不同症	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
特発性血小板減少性紫斑病	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
多染性	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
臨床検査	2 (6.7%)	5 (7.4%)	25 (6.6%)	102 (8.8%)	27 (6.6%)	107 (8.7%)
アラニン・アミノトランスフェラーゼ増加	0 (0.0%)	1 (1.5%)	9 (2.4%)	23 (2.0%)	9 (2.2%)	24 (1.9%)
アスパラギン酸アミノトランスフェラーゼ増加	0 (0.0%)	1 (1.5%)	6 (1.6%)	15 (1.3%)	6 (1.5%)	16 (1.3%)
ヘモグロビン減少	1 (3.3%)	0 (0.0%)	2 (0.5%)	9 (0.8%)	3 (0.7%)	9 (0.7%)
肝酵素上昇	0 (0.0%)	0 (0.0%)	2 (0.5%)	8 (0.7%)	2 (0.5%)	8 (0.6%)
好酸球数増加	0 (0.0%)	1 (1.5%)	4 (1.1%)	5 (0.4%)	4 (1.0%)	6 (0.5%)
白血球数減少	0 (0.0%)	2 (2.9%)	1 (0.3%)	4 (0.3%)	1 (0.2%)	6 (0.5%)
白血球数増加	0 (0.0%)	0 (0.0%)	1 (0.3%)	6 (0.5%)	1 (0.2%)	6 (0.5%)
ヘマトクリット減少	0 (0.0%)	0 (0.0%)	3 (0.8%)	5 (0.4%)	3 (0.7%)	5 (0.4%)
体重減少	0 (0.0%)	0 (0.0%)	2 (0.5%)	5 (0.4%)	2 (0.5%)	5 (0.4%)
血中カリウム減少	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.3%)	0 (0.0%)	4 (0.3%)
好中球数減少	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.3%)	0 (0.0%)	4 (0.3%)

	Japanese		Non-Japanese		Total	
	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]
血小板数増加	0 (0.0%)	0 (0.0%)	3 (0.8%)	4 (0.3%)	3 (0.7%)	4 (0.3%)
血中アルカリホスファターゼ増加	0 (0.0%)	0 (0.0%)	2 (0.5%)	3 (0.3%)	2 (0.5%)	3 (0.2%)
血中ビリルビン増加	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	3 (0.2%)
血圧上昇	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	3 (0.2%)
肝機能検査異常	0 (0.0%)	0 (0.0%)	1 (0.3%)	3 (0.3%)	1 (0.2%)	3 (0.2%)
好中球数増加	0 (0.0%)	0 (0.0%)	1 (0.3%)	3 (0.3%)	1 (0.2%)	3 (0.2%)
トランスアミナーゼ上昇	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	3 (0.2%)
体重増加	1 (3.3%)	0 (0.0%)	0 (0.0%)	3 (0.3%)	1 (0.2%)	3 (0.2%)
血中アルブミン減少	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
血中カルシウム減少	0 (0.0%)	0 (0.0%)	1 (0.3%)	2 (0.2%)	1 (0.2%)	2 (0.2%)
血中カルシウム増加	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
血中クレアチニン増加	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
血中リン増加	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
血中尿素増加	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
体温上昇	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
リンパ球数増加	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
単球数減少	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
血小板数減少	0 (0.0%)	1 (1.5%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	2 (0.2%)
総蛋白減少	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
尿中白血球陽性	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
杆状核好中球数増加	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.1%)	1 (0.2%)	1 (0.1%)
好塩基球数増加	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
抱合ビリルビン増加	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
乳房生検	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
血中酸性ホスファターゼ増加	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
血中非抱合ビリルビン増加	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
血中ブドウ糖増加	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
血中鉄減少	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)

	Japanese		Non-Japanese		Total	
	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]
収縮期血圧上昇	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
血中テストステロン減少	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
胸部Ｘ線異常	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
心エコー像異常	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
心拍数増加	1 (3.3%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.2%)	1 (0.1%)
心音異常	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
ＩＮＲ増加	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
リンパ球数減少	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.1%)	1 (0.2%)	1 (0.1%)
後骨髄球数増加	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
単球数増加	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
骨髄球数増加	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
好中球数異常	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
腎機能検査異常	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
トレポネーマ検査陽性	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
α１フェトプロテイン増加	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
血中コレステロール増加	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
グラム染色陰性	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
リンパ球数異常	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
単球数異常	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
骨髄球存在	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
血小板形態異常	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
バーセル陽性	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
傷害、中毒および処置合併症	1 (3.3%)	8 (11.8%)	9 (2.4%)	65 (5.6%)	10 (2.5%)	73 (5.9%)
挫傷	1 (3.3%)	3 (4.4%)	4 (1.1%)	11 (0.9%)	5 (1.2%)	14 (1.1%)
節足動物咬傷	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (0.5%)	0 (0.0%)	6 (0.5%)
肉離れ	0 (0.0%)	0 (0.0%)	1 (0.3%)	6 (0.5%)	1 (0.2%)	6 (0.5%)
関節捻挫	0 (0.0%)	1 (1.5%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	4 (0.3%)
処置後合併症	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.3%)	0 (0.0%)	4 (0.3%)

	Japanese		Non-Japanese		Total	
	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]
動物咬傷	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	3 (0.2%)
手骨折	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	3 (0.2%)
関節脱臼	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	3 (0.2%)
裂傷	0 (0.0%)	1 (1.5%)	2 (0.5%)	2 (0.2%)	2 (0.5%)	3 (0.2%)
処置による疼痛	0 (0.0%)	0 (0.0%)	1 (0.3%)	3 (0.3%)	1 (0.2%)	3 (0.2%)
足関節部骨折	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
上顆炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
肋骨骨折	0 (0.0%)	1 (1.5%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	2 (0.2%)
熱傷	0 (0.0%)	1 (1.5%)	1 (0.3%)	1 (0.1%)	1 (0.2%)	2 (0.2%)
偶発的過量投与	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
偶発的中毒	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
節足動物刺傷	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
背部損傷	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
骨亀裂	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
第２度熱傷	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
脳振盪	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
擦過傷	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
転倒	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
足骨折	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
瘢痕ヘルニア	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
関節損傷	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
靭帯断裂	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
四肢損傷	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
口唇損傷	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
筋損傷	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
処置による頭痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
橈骨骨折	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
脊柱損傷	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)

	Japanese		Non-Japanese		Total	
	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]
脊椎圧迫骨折	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
腱損傷	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
歯牙破折	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
創傷	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
手首関節骨折	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
多発性外傷	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
鋭的腹部外傷	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
創合併症	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
精神障害	1 (3.3%)	4 (5.9%)	12 (3.2%)	58 (5.0%)	13 (3.2%)	62 (5.0%)
不眠症	1 (3.3%)	4 (5.9%)	5 (1.3%)	22 (1.9%)	6 (1.5%)	26 (2.1%)
うつ病	0 (0.0%)	0 (0.0%)	5 (1.3%)	17 (1.5%)	5 (1.2%)	17 (1.4%)
不安	0 (0.0%)	0 (0.0%)	3 (0.8%)	12 (1.0%)	3 (0.7%)	12 (1.0%)
異常な夢	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.1%)	1 (0.2%)	1 (0.1%)
激越	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
錯乱状態	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
抑うつ気分	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
情動障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
幻覚	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
精神障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
神経過敏	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
落ち着きのなさ	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
睡眠障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
社会恐怖症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
物質乱用	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
リビドー減退	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
血管障害	2 (6.7%)	2 (2.9%)	8 (2.1%)	50 (4.3%)	10 (2.5%)	52 (4.2%)
高血圧	1 (3.3%)	0 (0.0%)	3 (0.8%)	30 (2.6%)	4 (1.0%)	30 (2.4%)
潮紅	1 (3.3%)	1 (1.5%)	1 (0.3%)	3 (0.3%)	2 (0.5%)	4 (0.3%)

	Japanese		Non-Japanese		Total	
	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]
深部静脈血栓症	0 (0.0%)	0 (0.0%)	2 (0.5%)	3 (0.3%)	2 (0.5%)	3 (0.2%)
血腫	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	3 (0.2%)
ほてり	0 (0.0%)	0 (0.0%)	1 (0.3%)	3 (0.3%)	1 (0.2%)	3 (0.2%)
低血圧	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
大動脈瘤破裂	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
出血	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
間欠性跛行	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
末梢冷感	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
静脈炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.1%)	1 (0.2%)	1 (0.1%)
血栓性静脈炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
表在性血栓性静脈炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
静脈瘤	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
血管脆弱化	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
血管炎	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
代謝および栄養障害	2 (6.7%)	3 (4.4%)	11 (2.9%)	44 (3.8%)	13 (3.2%)	47 (3.8%)
脱水	0 (0.0%)	0 (0.0%)	2 (0.5%)	11 (0.9%)	2 (0.5%)	11 (0.9%)
食欲減退	0 (0.0%)	1 (1.5%)	1 (0.3%)	5 (0.4%)	1 (0.2%)	6 (0.5%)
糖尿病	0 (0.0%)	0 (0.0%)	1 (0.3%)	5 (0.4%)	1 (0.2%)	5 (0.4%)
低カリウム血症	0 (0.0%)	0 (0.0%)	1 (0.3%)	4 (0.3%)	1 (0.2%)	4 (0.3%)
痛風	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	3 (0.2%)
鉄欠乏	0 (0.0%)	0 (0.0%)	1 (0.3%)	3 (0.3%)	1 (0.2%)	3 (0.2%)
栄養障害	0 (0.0%)	0 (0.0%)	3 (0.8%)	3 (0.3%)	3 (0.7%)	3 (0.2%)
高カルシウム血症	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
高脂血症	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
低マグネシウム血症	0 (0.0%)	1 (1.5%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	2 (0.2%)
異常体重減少	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
細胞死	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
高アルブミン血症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)

	Japanese		Non-Japanese		Total	
	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]
高アミラーゼ血症	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
高コレステロール血症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
高血糖	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
高蛋白血症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
低アルブミン血症	0 (0.0%)	0 (0.0%)	2 (0.5%)	1 (0.1%)	2 (0.5%)	1 (0.1%)
低カルシウム血症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
低ナトリウム血症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
血液量減少症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
ビタミンＢ群欠乏	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
ビタミンＤ欠乏	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.1%)	1 (0.2%)	1 (0.1%)
高リン酸塩血症	2 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)	0 (0.0%)
低蛋白血症	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
ラクトース不耐性	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
眼障害	2 (6.7%)	7 (10.3%)	4 (1.1%)	36 (3.1%)	6 (1.5%)	43 (3.5%)
結膜炎	0 (0.0%)	1 (1.5%)	0 (0.0%)	12 (1.0%)	0 (0.0%)	13 (1.1%)
白内障	0 (0.0%)	2 (2.9%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	5 (0.4%)
霰粒腫	1 (3.3%)	1 (1.5%)	0 (0.0%)	2 (0.2%)	1 (0.2%)	3 (0.2%)
上強膜炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	3 (0.3%)	1 (0.2%)	3 (0.2%)
眼の炎症	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	3 (0.2%)
眼瞼炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
アレルギー性結膜炎	0 (0.0%)	2 (2.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
眼充血	0 (0.0%)	0 (0.0%)	1 (0.3%)	2 (0.2%)	1 (0.2%)	2 (0.2%)
視力障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
加齢黄斑変性	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
眼精疲労	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
複視	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
眼乾燥	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
眼刺激	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)

	Japanese		Non-Japanese		Total	
	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]
眼そう痒症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
眼部腫脹	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
眼瞼障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
眼瞼そう痒症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
緑内障	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
黄斑症	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
眼窩浮腫	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
翼状片	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
眼瞼痙攣	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
眼出血	1 (3.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
眼球乾燥	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
腎および尿路障害	0 (0.0%)	1 (1.5%)	6 (1.6%)	34 (2.9%)	6 (1.5%)	35 (2.8%)
腎結石症	0 (0.0%)	0 (0.0%)	1 (0.3%)	8 (0.7%)	1 (0.2%)	8 (0.6%)
頻尿	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (0.5%)	0 (0.0%)	6 (0.5%)
排尿困難	0 (0.0%)	0 (0.0%)	2 (0.5%)	4 (0.3%)	2 (0.5%)	4 (0.3%)
腎仙痛	0 (0.0%)	0 (0.0%)	2 (0.5%)	4 (0.3%)	2 (0.5%)	4 (0.3%)
血尿	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	3 (0.2%)
腎嚢胞	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	3 (0.2%)
夜間頻尿	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
糸球体腎炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
水腎症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
尿意切迫	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
蛋白尿	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
急性腎不全	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
慢性腎不全	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
腎臓痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
尿道痛	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
尿失禁	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)

	Japanese		Non-Japanese		Total	
	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]
尿閉	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
着色尿	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
腎不全	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
生殖系および乳房障害	0 (0.0%)	2 (2.9%)	4 (1.1%)	29 (2.5%)	4 (1.0%)	31 (2.5%)
良性前立腺肥大症	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.3%)	0 (0.0%)	4 (0.3%)
精巣上体炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.3%)	0 (0.0%)	4 (0.3%)
月経過多	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	3 (0.2%)
無月経	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
乳房痛	0 (0.0%)	2 (2.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
月経困難症	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
前立腺炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	2 (0.2%)	1 (0.2%)	2 (0.2%)
バルトリン嚢腫	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
乳房嚢胞	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
乳房腫瘤	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
子宮頚部嚢胞	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
子宮頚部出血	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
膀胱瘤	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
子宮内膜増殖症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
女性化乳房	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
不規則月経	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
不正子宮出血	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
頻発月経	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.1%)	1 (0.2%)	1 (0.1%)
前立腺腫大	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
陰部そう痒症	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
精巣痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
子宮出血	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
子宮ポリープ	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
腟分泌物	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)

	Japanese		Non-Japanese		Total	
	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]
外陰腟そう痒症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
卵巣嚢胞	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
卵巣嚢胞破裂	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
外陰腟灼熱感	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
耳および迷路障害	0 (0.0%)	0 (0.0%)	3 (0.8%)	25 (2.1%)	3 (0.7%)	25 (2.0%)
回転性めまい	0 (0.0%)	0 (0.0%)	1 (0.3%)	10 (0.9%)	1 (0.2%)	10 (0.8%)
耳痛	0 (0.0%)	0 (0.0%)	1 (0.3%)	5 (0.4%)	1 (0.2%)	5 (0.4%)
耳垢栓塞	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
内耳の炎症	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
耳介軟骨膜炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
耳不快感	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.1%)	1 (0.2%)	1 (0.1%)
耳の障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
耳管機能障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
乗物酔い	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
耳鳴	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
鼓膜穿孔	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
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）	0 (0.0%)	1 (1.5%)	1 (0.3%)	19 (1.6%)	1 (0.2%)	20 (1.6%)
子宮平滑筋腫	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.3%)	0 (0.0%)	4 (0.3%)
大腸腺腫	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	3 (0.2%)
脂肪腫	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
皮膚乳頭腫	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
乳房の良性新生物	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
唾液腺の良性新生物	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
上皮内癌	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
結腸癌	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
線維性組織球腫	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
胃腸管腺腫	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
肺腺癌	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)

	Japanese		Non-Japanese		Total	
	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]
骨軟骨腫	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
前立腺腺腫	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
直腸癌	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
脂漏性角化症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
扁平上皮癌	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
甲状腺癌	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
乳癌	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
免疫系障害	0 (0.0%)	1 (1.5%)	4 (1.1%)	15 (1.3%)	4 (1.0%)	16 (1.3%)
季節性アレルギー	0 (0.0%)	0 (0.0%)	1 (0.3%)	13 (1.1%)	1 (0.2%)	13 (1.1%)
過敏症	0 (0.0%)	1 (1.5%)	1 (0.3%)	1 (0.1%)	1 (0.2%)	2 (0.2%)
４型過敏症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
金属アレルギー	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
薬物過敏症	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
肝胆道系障害	0 (0.0%)	2 (2.9%)	1 (0.3%)	12 (1.0%)	1 (0.2%)	14 (1.1%)
肝炎	0 (0.0%)	1 (1.5%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	3 (0.2%)
脂肪肝	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
高ビリルビン血症	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
胆管結石	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
胆嚢炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
胆石症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
肝嚢胞	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.1%)	1 (0.2%)	1 (0.1%)
肝不全	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
肝機能異常	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
肝腫大	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
心臓障害	1 (3.3%)	0 (0.0%)	0 (0.0%)	11 (0.9%)	1 (0.2%)	11 (0.9%)
狭心症	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
不整脈	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
心房細動	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)

	Japanese		Non-Japanese		Total	
	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]
冠動脈疾患	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
動悸	1 (3.3%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	1 (0.2%)	2 (0.2%)
急性心筋梗塞	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
徐脈	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
心不全	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
心血管障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
心嚢液貯留	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
心膜炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
妊娠、産褥および周産期の状態	0 (0.0%)	0 (0.0%)	2 (0.5%)	6 (0.5%)	2 (0.5%)	6 (0.5%)
妊娠	0 (0.0%)	0 (0.0%)	2 (0.5%)	6 (0.5%)	2 (0.5%)	6 (0.5%)
自然流産	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
社会環境	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (0.5%)	0 (0.0%)	6 (0.5%)
パートナーの妊娠	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (0.5%)	0 (0.0%)	6 (0.5%)
外科および内科処置	0 (0.0%)	0 (0.0%)	1 (0.3%)	5 (0.4%)	1 (0.2%)	5 (0.4%)
副鼻腔手術	0 (0.0%)	0 (0.0%)	1 (0.3%)	2 (0.2%)	1 (0.2%)	2 (0.2%)
前頭洞手術	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
病変部切除	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
抜歯	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
先天性、家族性および遺伝性障害	0 (0.0%)	1 (1.5%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	4 (0.3%)
重複尿管	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
ジルベール症候群	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
遺伝性フルクトース不耐症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
静脈奇形	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
内分泌障害	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
クッシング様	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)

[a] Includes data up to the time of the first golimumab dose.
[b] Includes data from the time of the first golimumab dose onward.

表 2.7.4.7 -付録-14 すべての有害事象（導入期 0 週から維持期 54 週まで，UCO3001 試験）

	Golimumab
Analysis set: SF-I	144
Average duration of follow-up (weeks)	34.7
Average exposure (number of administrations)	10.5
Subjects with 1 or more adverse events	128 (88.9%)
System-organ class/preferred term	
感染症および寄生虫症	76 (52.8%)
鼻咽頭炎	55 (38.2%)
インフルエンザ	9 (6.3%)
口腔ヘルペス	6 (4.2%)
上気道感染	5 (3.5%)
結膜炎	4 (2.8%)
帯状疱疹	4 (2.8%)
胃腸炎	3 (2.1%)
咽頭炎	3 (2.1%)
口角口唇炎	2 (1.4%)
口腔カンジダ症	2 (1.4%)
扁桃炎	2 (1.4%)
急性副鼻腔炎	1 (0.7%)
気管支炎	1 (0.7%)
蜂巣炎	1 (0.7%)
サイトメガロウイルス性大腸炎	1 (0.7%)
毛包炎	1 (0.7%)
せつ	1 (0.7%)
単純ヘルペス	1 (0.7%)
麦粒腫	1 (0.7%)
膿痂疹	1 (0.7%)
感染	1 (0.7%)
喉頭炎	1 (0.7%)
眼部単純ヘルペス	1 (0.7%)
中耳炎	1 (0.7%)
爪囲炎	1 (0.7%)
副鼻腔炎	1 (0.7%)
レンサ球菌感染	1 (0.7%)
皮下組織膿瘍	1 (0.7%)
手白癬	1 (0.7%)
胃腸障害	45 (31.3%)
潰瘍性大腸炎	19 (13.2%)
齲歯	7 (4.9%)
上腹部痛	4 (2.8%)
痔核	4 (2.8%)
裂肛	2 (1.4%)
便秘	2 (1.4%)
大腸ポリープ	2 (1.4%)
悪心	2 (1.4%)
肛門周囲痛	2 (1.4%)
腹部不快感	1 (0.7%)
口唇炎	1 (0.7%)
慢性胃炎	1 (0.7%)
下痢	1 (0.7%)
排便障害	1 (0.7%)
小腸炎	1 (0.7%)
胃炎	1 (0.7%)
びらん性胃炎	1 (0.7%)
血栓性痔核	1 (0.7%)
裂孔ヘルニア	1 (0.7%)
急性膵炎	1 (0.7%)
口内炎	1 (0.7%)
皮膚および皮下組織障害	30 (20.8%)
湿疹	5 (3.5%)

	Golimumab
発疹	5 (3.5%)
ざ瘡	4 (2.8%)
脱毛症	2 (1.4%)
皮脂欠乏性湿疹	2 (1.4%)
紅斑	2 (1.4%)
そう痒症	2 (1.4%)
皮膚炎	1 (0.7%)
ざ瘡様皮膚炎	1 (0.7%)
アトピー性皮膚炎	1 (0.7%)
水疱性皮膚炎	1 (0.7%)
多形紅斑	1 (0.7%)
汗疹	1 (0.7%)
寝汗	1 (0.7%)
乾癬	1 (0.7%)
膿疱性乾癬	1 (0.7%)
全身性皮疹	1 (0.7%)
そう痒性皮疹	1 (0.7%)
脂漏性皮膚炎	1 (0.7%)
蕁麻疹	1 (0.7%)
一般・全身障害および投与部位の状態	29 (20.1%)
注射部位紅斑	11 (7.6%)
発熱	7 (4.9%)
倦怠感	3 (2.1%)
悪寒	2 (1.4%)
注射部位疼痛	2 (1.4%)
注射部位そう痒感	2 (1.4%)
注射部位腫脹	2 (1.4%)
医薬品副作用	1 (0.7%)
胸部不快感	1 (0.7%)
異常感	1 (0.7%)
全身性浮腫	1 (0.7%)
治癒不良	1 (0.7%)
注入部位血管外漏出	1 (0.7%)
注射部位内出血	1 (0.7%)
注射部位小水疱	1 (0.7%)
末梢性浮腫	1 (0.7%)
末梢腫脹	1 (0.7%)
筋骨格系および結合組織障害	19 (13.2%)
背部痛	6 (4.2%)
筋骨格痛	3 (2.1%)
関節痛	2 (1.4%)
四肢痛	2 (1.4%)
関節炎	1 (0.7%)
筋痙縮	1 (0.7%)
筋骨格系胸痛	1 (0.7%)
筋骨格不快感	1 (0.7%)
筋肉痛	1 (0.7%)
変形性脊椎症	1 (0.7%)
腱鞘炎	1 (0.7%)
神経系障害	17 (11.8%)
頭痛	7 (4.9%)
感覚鈍麻	3 (2.1%)
脳梗塞	1 (0.7%)
浮動性めまい	1 (0.7%)
意識消失	1 (0.7%)
片頭痛	1 (0.7%)
ヘルペス後神経痛	1 (0.7%)
失神寸前の状態	1 (0.7%)
傾眠	1 (0.7%)

	Golimumab
呼吸器、胸郭および縦隔障害	17 (11.8%)
咳嗽	6 (4.2%)
口腔咽頭痛	6 (4.2%)
上気道の炎症	5 (3.5%)
喘息	1 (0.7%)
咽頭の炎症	1 (0.7%)
湿性咳嗽	1 (0.7%)
鼻漏	1 (0.7%)
臨床検査	15 (10.4%)
白血球数減少	4 (2.8%)
血中ビリルビン増加	2 (1.4%)
肝機能検査異常	2 (1.4%)
好中球数減少	2 (1.4%)
白血球数増加	2 (1.4%)
アラニンアミノトランスフェラーゼ増加	1 (0.7%)
血中クレアチンホスホキナーゼ増加	1 (0.7%)
血中乳酸脱水素酵素増加	1 (0.7%)
血中マグネシウム減少	1 (0.7%)
体重増加	1 (0.7%)
傷害、中毒および処置合併症	14 (9.7%)
挫傷	3 (2.1%)
節足動物咬傷	2 (1.4%)
足骨折	2 (1.4%)
第３度熱傷	1 (0.7%)
手骨折	1 (0.7%)
関節脱臼	1 (0.7%)
裂傷	1 (0.7%)
靭帯捻挫	1 (0.7%)
外傷後頚部症候群	1 (0.7%)
処置による疼痛	1 (0.7%)
肋骨骨折	1 (0.7%)
創傷	1 (0.7%)
血液およびリンパ系障害	10 (6.9%)
貧血	6 (4.2%)
鉄欠乏性貧血	2 (1.4%)
骨髄機能不全	1 (0.7%)
リンパ節症	1 (0.7%)
血管障害	7 (4.9%)
高血圧	3 (2.1%)
動脈硬化症	1 (0.7%)
静脈炎	1 (0.7%)
表在性静脈炎	1 (0.7%)
高安動脈炎	1 (0.7%)
精神障害	5 (3.5%)
不眠症	4 (2.8%)
抑うつ症状	1 (0.7%)
耳および迷路障害	3 (2.1%)
回転性めまい	2 (1.4%)
耳漏	1 (0.7%)
眼障害	3 (2.1%)
眼瞼炎	3 (2.1%)
肝胆道系障害	3 (2.1%)
肝機能異常	2 (1.4%)
脂肪肝	1 (0.7%)
免疫系障害	3 (2.1%)
季節性アレルギー	3 (2.1%)
心臓障害	2 (1.4%)
動悸	2 (1.4%)
内分泌障害	2 (1.4%)
クッシング様症状	2 (1.4%)

	Golimumab
代謝および栄養障害	2 (1.4%)
糖尿病	1 (0.7%)
高血糖	1 (0.7%)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	2 (1.4%)
皮膚良性新生物	1 (0.7%)
脂漏性角化症	1 (0.7%)
生殖系および乳房障害	2 (1.4%)
乳房出血	1 (0.7%)
月経過多	1 (0.7%)
腎および尿路障害	1 (0.7%)
尿路結石	1 (0.7%)

Note: Adverse events were coded using MedDRA Version 18.1.

[TSFAE01INMA.rtf] [CNTO148\CNTO148UCO3001\DBR_CSRW54\RE_NDAJPKK\TSFAE01INMA.sas] 04FEB2016, 14:20

表 2.7.4.7-付録-15 死亡例の概要（T17 試験）

Treatment Group	Study Part[a]	Subject ID	Age/ Sex	Country/ Race	Study Agent Dose Prior to Death	Study Day of Study Agent Administration Prior to Death	Study Day of Death	Primary Cause
400 mg -> 200 mg	Part 2b	7586-00015	5[redacted]/M	UKRAINE/ Caucasian	200 mg	15	94	ENDOTOXIC SHOCK. SEPSIS. ABSCESS ISCHIORECTAL

[a] Part 2a: Part 2 before the dose selection; Part 2b: Part 2 after the dose selection.

RE311:[L S DTH 6 B JJ], 28NOV2011 16:20

表 2.7.4.7-付録-16 死亡例の概要（T18 試験 54 週まで）

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to Death	Study Day of Study Agent Administration Prior to Death	Study Day of Death	Primary Cause
Yes	Golimumab 100 mg	400 mg/200 mg SC	6407-00032	6[redacted] / M	POLAND / Caucasian			Golimumab 100 mg	253	335	HEART FAILURE
No	Golimumab 100 mg (Golimumab induction nonresponder)	2 mg/kg IV	6260-00002	5[redacted] / F	INDIA / Asian			Golimumab 100 mg	338	364	SEVERE MALNUTRITION AND SEPTIC SHOCK
		200 mg/100 mg SC	6407-00031	5[redacted] / M	POLAND / Caucasian			Golimumab 100 mg	169	206	MULTIORGAN FAILURE DUE TO MILIARY TUBERCULOSIS

[a] For subjects who were dose adjusted to golimumab 200 mg and later had their dose decreased to 100 mg following implementation of Protocol Amendment 3, "Treatment Group At Dose Adjustment" is presented as "200 mg (100 mg)", and "Study Day of Dose adjustment" is presented in the form of xxx (yyy), where xxx is the study day of dose adjustment and yyy is the study day of dose decrease.

表 2.7.4.7-付録-17 100 人年あたりの死亡率（T18 試験 0 から 228 週まで，他疾患との統合データ）

	nrAxSpA Study[a]		Phase 3 RA, PsA, AS Studies[b]			UC Studies[c]			All Studies		
	Placebo[d,j]	Golimumab 50mg[e,j]	Placebo[d,j]	Golimumab 50mg[e,j]	Golimumab 100mg[e,j,k]	Placebo[f,j]	Golimumab 50mg[g,h,j]	Golimumab 100mg[g,h,i,j,k]	Placebo[j]	Golimumab 50mg[j]	Golimumab 100mg[j,k]
Treated subjects in Phase 3 SC rheumatologic studies and UC studies	100	193	639	1251	1555	129	155	993	868	1599	2548
Number of subjects who died	0	0	1 (0.2%)	11 (0.9%)	25 (1.6%)	1 (0.8%)	1 (0.6%)	10 (1.0%)	2 (0.2%)	12 (0.8%)	35 (1.4%)
Total subject-years of follow-up	31	185	349	3185	5549	141	376	2052	521	3745	7601
Incidence per 100 subject-years	0.00	0.00	0.29	0.35	0.45	0.71	0.27	0.49	0.38	0.32	0.46
95% confidence interval[l]	(0.00, 9.59)	(0.00, 1.62)	(0.01, 1.59)	(0.17, 0.62)	(0.29, 0.67)	(0.02, 3.96)	(0.01, 1.48)	(0.23, 0.90)	(0.05, 1.39)	(0.17, 0.56)	(0.32, 0.64)

[a] P07642
[b] C0524T05, C0524T06, C0524T11, C0524T08, and C0524T09
[c] From Week 0 through Week 228 of the maintenance study (C0524T18) for subjects who were treated in the maintenance study; subjects who received golimumab during the induction studies (C0524T16 and C0524T17) and only placebo during the maintenance study (C0524T18) are not included in the analyses.
[d] Received placebo SC every 4 weeks with or without MTX
[e] Received golimumab 50 mg SC every 4 weeks in P07642; received golimumab 50 mg or 100 mg SC every 4 weeks, with or without MTX in C0524T05, C0524T06, C0524T11, C0524T08, and C0524T09.
[f] In C0524T16, subjects received placebo IV at Week 0. In C0524T17, subjects received placebo SC at Week 0 and Week 2. In C0524T18, subjects in response to placebo induction from C0524T16 or C0524T17 continued to receive placebo SC every 4 weeks.
[g] In C0524T16, subjects received placebo or golimumab 1 mg/kg, 2 mg/kg or 4 mg/kg IV at Week 0. In C0524T17, subjects received placebo or golimumab SC 100 mg/50 mg, 200 mg/100 mg, or 400 mg/200 mg at Weeks 0/2, respectively.
[h] In C0524T18, subjects received study agent every 4 weeks. Subjects who were in response to golimumab induction from C0524T16 and C052T17 received placebo or golimumab 50 mg or 100 mg SC (subjects who lost response to placebo were allowed to receive golimumab 100 mg SC and subjects who lost response to golimumab were allowed to increase their dose of golimumab). Subjects who were not in response to golimumab or placebo induction from C0524T16 or C0524T17 received golimumab 100 mg SC. Subjects in response to placebo induction remained on placebo in maintenance but were allowed to dose adjust to golimumab 100 mg SC.
[i] For subjects who received golimumab during the induction studies (C0524T16 and C0524T17) and placebo during the maintenance study (C0524T18), data is included from the time of dose adjustment for those who increased dose.
[j] Includes data up to the time of dose adjustment for those who increased dose.
[k] Includes data from the time of dose adjustment onward.
[l] Confidence intervals based on an exact method.

表 2.7.4.7-付録-18 100 人年あたりの死亡率（T16，T17 及び T18 試験 54 週まで；全投与被験者）

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
Treated subjects in C0524T16 and C0524T17	49	358	286	77	157	154	660	14	1233
Total subject-years of follow-up	12	131	216	18	118	149	573	7	1080
Number of subjects who died	0	0	0	1	0	0	3	0	4
Incidence per 100 subject-years	0.00	0.00	0.00	5.68	0.00	0.00	0.52	0.00	0.37
95% confidence interval[f]	(0.00, 25.80)	(0.00, 2.28)	(0.00, 1.39)	(0.14, 31.62)	(0.00, 2.55)	(0.00, 2.01)	(0.11, 1.53)	(0.00, 40.43)	(0.10, 0.95)

[a] Includes data up to the time of the first golimumab dose in the maintenance study.
[b] Includes data from the time of dose adjustment onward for those who increased to the indicated dose during the maintenance study.
[c] Includes data up to the time of dose adjustment for those who increased dose from the indicated dose during the maintenance study.
[d] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[e] Includes data from the time of the first golimumab dose onward.
[f] Confidence intervals based on an exact method.

表 2.7.4.7-付録-19 重篤な有害事象一覧（T16 試験）

Treatment Group	Study Part[a]	Subject ID	Age/ Sex	Country/ Race	Study Agent Dose Prior to AE	Study Day of Study Agent Adminis-tration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Dur-ation of AE (days)	Outcome	Ser-ious	Intensity	Relation-ship to Study Agent	Action Taken with Study Agent	Infection/ Infusion Reaction[c]
Placebo	Part 1	6259-00001	5[redacted]/F	INDIA/Asian	0.0 mg/kg	1	貧血	ANAEMIA	16		Ongoing	No	Moderate	Unlikely	None/not applicable	No /No
					0.0 mg/kg	1	多発性外傷	MULTIPLE INJURIES ON BOTH ARMS AND LEGS	40	17	Resolved	Yes	Moderate	Not related	None/not applicable	No /No
	Part 2a	6279-00002	6[redacted]/F	ISRAEL/Caucasian	0.0 mg/kg	1	貧血	ANEMIA	34	9	Resolved	Yes	Moderate	Not related	None/not applicable	No /No
	Part 2b	6177-00005	5[redacted]/M	FRANCE/Caucasian	0.0 mg/kg	1	潰瘍性大腸炎	WORSERING OF UC	12	25	Resolved	No	Severe	Possible	None/not applicable	No /No
					0.0 mg/kg	1	潰瘍性大腸炎	ULCERATIVE COLITIS FLARE	56		Ongoing	Yes	Severe	Unlikely	None/not applicable	No /No
					0.0 mg/kg	1	亜イレウス	SUB OCCLUSIVE SYNDROME	69	9	Resolved	Yes	Severe	Unlikely	None/not applicable	Yes/No
Golimumab 1 mg/kg	Part 2a	6112-00006	2[redacted]/F	CANADA/Caucasian	1.0 mg/kg	1	潰瘍性大腸炎	EXACERBATION OF ULCERATIVE COLITIS	17	12	Resolved	Yes	Moderate	Unlikely	None/not applicable	No /No
					1.0 mg/kg	1	クロストリジウム感染	CLOSTRIDIUM DIFFICILE INFECTION	34	30	Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No
					1.0 mg/kg	1	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	48	25	Resolved	Yes	Severe	Unlikely	None/not applicable	No /No
					1.0 mg/kg	1	栄養障害	MALNUTRITION	49	22	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
		6406-00008	3[redacted]/F	POLAND/Caucasian	1.0 mg/kg	1	発熱	FEVER	11	10	Resolved	No	Moderate	Possible	None/not applicable	Yes/No
					1.0 mg/kg	1	嘔吐	VOMITING	14	7	Resolved	No	Mild	Unlikely	None/not applicable	No /No
					1.0 mg/kg	1	腹痛	INTESTINAL COLIC	14	7	Resolved	No	Mild	Unlikely	None/not applicable	No /No
					1.0 mg/kg	1	発熱	FEVER	37	5	Resolved	No	Moderate	Possible	None/not applicable	Yes/No

Treatment Group	Study Part[a]	Subject ID	Age/ Sex	Country/ Race	Study Agent Dose Prior to AE	Study Day of Study Agent Adminis-tration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Dur-ation of AE (days)	Outcome	Ser-ious	Intensity	Relation-ship to Study Agent	Action Taken with Study Agent	Infection/ Infusion Reaction[c]
					1.0 mg/kg	1	貧血	ANAEMIA HGB < 8,5 G/DL	42	29	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
					1.0 mg/kg	1	潰瘍性大腸炎	EXACERBATION OF UC	54	2	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
					1.0 mg/kg	1	潰瘍性大腸炎	DISEASE EXACERBATION WITH SEVERE ANAEMIA	56	15	Resolved	Yes	Severe	Unlikely	None/not applicable	Yes/No
Golimumab 2 mg/kg	Part 1	6726-00005	5[redacted]/F	UNITED STATES/Caucasian	2.0 mg/kg	1	潰瘍性大腸炎	ACTIVE ULCERATIVE COLITIS	25	9	Resolved	Yes	Severe	Not related	None/not applicable	No /No
	Part 2a	6406-00007	4[redacted]/F	POLAND/Caucasian	1.9 mg/kg	1	咽頭炎	PHARYNGITIS	22	9	Resolved	No	Moderate	Possible	None/not applicable	Yes/No
					1.9 mg/kg	1	発熱	FEVER	22	9	Resolved	No	Moderate	Possible	None/not applicable	Yes/No
					1.9 mg/kg	1	潰瘍性大腸炎	DISEASE EXACERBATION WITH BLEEDING	44	35	Resolved	Yes	Severe	Possible	None/not applicable	Yes/No
		6407-00008	4[redacted]/M	POLAND/Caucasian	2.0 mg/kg	1	胃腸出血	BLEEDING FROM GASTROINTESTINAL TRACT.	7	4	Resolved	Yes	Moderate	Possible	None/not applicable	No /No
Golimumab 4 mg/kg	Part 1	6111-00002	3[redacted]/F	CANADA/Caucasian	4.1 mg/kg	1	好中球減少症	NEUTROPENIA	1	14	Resolved	No	Severe	Not related	None/not applicable	No /No
					4.1 mg/kg	1	敗血症	SEPTICEMIA	4	8	Resolved	Yes	Severe	Not related	None/not applicable	Yes/No
		6232-00001	4[redacted]/M	HUNGARY/ Caucasian	4.0 mg/kg	1	腎結石症	RENAL STONE	6	3	Resolved	Yes	Moderate	Unlikely	None/not applicable	No /No
	Part 2a	6705-00011	5[redacted]/F	UNITED STATES/Caucasian	4.0 mg/kg	1	蜂巣炎	CELLULITIS LEFT LOWER EXTREMITY	16	6	Resolved	Yes	Moderate	Possible	None/not applicable	Yes/No
					4.0 mg/kg	1	低カリウム血症	HYPOKALEMIA	16	2	Resolved	No	Mild	Not related	None/not applicable	No /No
					4.0 mg/kg	1	蜂巣炎	CELLULITIS LEFT LOWER EXTREMITY	21	65	Resolved	No	Mild	Possible	None/not applicable	Yes/No

Treatment Group	Study Part[a]	Subject ID	Age/ Sex	Country/ Race	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Infusion Reaction[c]
					4.0 mg/kg	1	アレルギー性皮膚炎	SKIN RASH-ALLERGIC REACTION TO AUGMENTIN	22	1	Resolved	No	Moderate	Not related	None/not applicable	No /No

[a] Part 2a: Part 2 before the dose selection; Part 2b: Part 2 after the dose selection.
[b] Based on MedDRA version 12.0.
[c] Infection as assessed by the investigator.

表 2.7.4.7-付録-20 重篤な有害事象一覧（T18 試験 54 週まで，全投与被験者）

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Injection-site Reaction[c, d]
Yes	Placebo	2 mg/kg IV	6407-00013	5[redacted]/F	POLAND/ Caucasian			0	57	錯感覚	TRANSISTENT ACROPARESTHESIA OF RIGHT ARM	71	43	Resolved	No	Mild	Not related	None/not applicable	No /No
								0	255	胃腸の炎症	GASTROCOLITIS	272	2	Resolved	No	Mild	Possible	None/not applicable	Yes/No
								0	337	筋骨格痛	OMALGIA OF RIGHT SHOULDER	349	6	Resolved	Yes	Mild	Not related	None/not applicable	No /No
		4 mg/kg IV	6231-00001	2[redacted]/M	HUNGARY/Caucasian			0	29	うつ病	RECCURENT DEPRESSION	35	16	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								0	141	擦過傷	DIRECT SKIN LESION (ABRASION) IN THE RIGHT LEG	155	222	Resolved	No	Moderate	Not related	None/not applicable	No /No
								0	308	うつ病	RECURRENT DEPRESSION	331	12	Resolved	Yes	Moderate	Unlikely	None/not applicable	No /No
								0	308	偶発的過量投与	ACCIDENTAL OVERDOSE	331	12	Resolved	Yes	Moderate	Unlikely	None/not applicable	No /No
								0	337	高血圧	WORSENING OF HYPERTENSION	349	2	Resolved	Yes	Moderate	Unlikely	None/not applicable	No /No
								0	337	非心臓性胸痛	NON CARDIAC CHEST PAIN	349	2	Resolved	Yes	Moderate	Unlikely	None/not applicable	No /No
			6252-00020	3[redacted]/M	INDIA/Asian			0	25	腎結石症	LT RENAL CALCULI	26		Not Resolved	Yes	Moderate	Unlikely	None/not applicable	No /No

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Injection-site Reaction[c,d]
								0	25	発熱	PYREXIA	26	51	Resolved	No	Moderate	Probable	Temporary interruption /dose modification	Yes/No
								0	25	水腎症	LT PUJ STRICTURE WITH HYDRONEPHROSIS	26		Not Resolved	Yes	Moderate	Probable	Temporary interruption /dose modification	Yes/No
								0	25	播種性結核	MILARY TUBERCLOSIS	65		Not Resolved	Yes	Mild	Probable	Permanent discontinuation of study agent	Yes/No
								0	25	発熱	RECURRENT PYREXIA	76		Not Resolved	Yes	Severe	Probable	Temporary interruption /dose modification	Yes/No
			6354-00001	3[redacted]/F	NETHERLANDS/Caucasian	100 mg	48	0	1	眼の炎症	INFLAMED EYES			Resolved	No	Mild	Unlikely	None/not applicable	No /No
						100 mg	48	0	29	乾癬	PSORIASIS			Resolved	No	Mild	Possible	None/not applicable	No /No
						100 mg	48	0	1	発疹	EXANTHEMA	1		Not Resolved	No	Mild	Possible	None/not applicable	No /No
						100 mg	48	100	48	頭痛	HEADACHE	51	4	Resolved	No	Mild	Unlikely	None/not applicable	No /No
						100 mg	48	100	48	潰瘍性大腸炎	EXACERBATION UC	98	16	Resolved	Yes	Severe	Not related	Permanent discontinuation of study agent	No /No
						100 mg	48	100	48	脱毛症	HAIRLOSS DUE TO NARCOSIS	112		Not Resolved	No	Moderate	Not related	None/not applicable	No /No

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Injection-site Reaction[c,d]
			6426-00006	3[redacted]/M	ROMANIA/Caucasian	100 mg	162	0	1	脱毛症	HAIR LOSS	2		Not Resolved	No	Mild	Probable	None/not applicable	No /No
						100 mg	162	0	1	頭痛	HEADACHE	4	57	Resolved	No	Mild	Unlikely	None/not applicable	No /No
						100 mg	162	0	85	関節痛	ARTHRALGIA	92	57	Resolved	No	Moderate	Probable	None/not applicable	No /No
						100 mg	162	0	85	筋肉痛	MIALGIA	92	57	Resolved	No	Moderate	Probable	None/not applicable	No /No
						100 mg	162	100	169	潰瘍性大腸炎	ULCERATIVE COLITIS FLARE	175	10	Resolved	Yes	Severe	Not related	Permanent discontinuation of study agent	No /No
						100 mg	162	100	169	潰瘍性大腸炎	ULCERATIVE COLITIS FLARE	239	15	Resolved	Yes	Moderate	Not related	Permanent discontinuation of study agent	No /No
		200 mg/100 mg SC	6716-00010	6[redacted]/M	UNITEDSTATES/Caucasian	100 mg	51	0	1	関節痛	WORSENING LEFT HIP PAIN	21	4	Resolved	Yes	Severe	Unlikely	None/not applicable	No /No
						100 mg	51	0	1	浮動性めまい	LIGHTHEADEDNESS	22	1	Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	51	0	1	発熱	FEVER	22	3	Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	51	0	1	ヘモグロビン減少	DECREASE HEMOGLOBIN/HEMATOCRIT	24		Not Resolved	No	Mild	Unlikely	None/not applicable	No /No
						100 mg	51	0	1	血便排泄	HEMATOCHEZIA	25		Not Resolved	No	Moderate	Unlikely	None/not applicable	No /No
						100 mg	51	0	1	脂漏性皮膚炎	SEBORRHEIC DERMITITIS	35		Not Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	51	0	1	日光性角化症	WORSENING OF ACTINIC KERATOSES	35		Not Resolved	No	Mild	Not related	None/not applicable	No /No

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Injection-site Reaction[c,d]
						100 mg	51	0	37	潰瘍性大腸炎	WORSENING OF HIS ULCERTIVE COLITIS	43	49	Resolved	No	Moderate	Possible	None/not applicable	No /No
						100 mg	51	100	91	口腔ヘルペス	COLD SORE (HERPES ZOSTER) UPPER AND LOWER LIP	100	8	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
						100 mg	51	100	111	憩室炎	DIVERTICULITIS	116	4	Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No
						100 mg	51	100	111	直腸炎	PROCTIITS	135	117	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
						100 mg	51	100	135	良性前立腺肥大症	BENIGN PROSTATIC HYPERTROPHY	169		Not Resolved	No	Moderate	Unlikely	None/not applicable	No /No
						100 mg	51	100	135	皮膚炎	DERMATITIS, ARMS	251		Not Resolved	No	Moderate	Unlikely	None/not applicable	No /No
						100 mg	51	100	135	関節痛	ARTHRALGIAS	251		Not Resolved	No	Mild	Unlikely	None/not applicable	No /No
			7001-00005	3[redacted]/M	AUSTRALIA/Other	100 mg	18	100	54	湿性咳嗽	PRODUCTIVE COUGH	75		Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	18	100	372	痔出血	WORSENING ANAEMIA DUE TO BLEEDING HAEMORRHOIDS	372	4	Resolved	Yes	Moderate	Not related	None/not applicable	No /No
			7205-00002	3[redacted]/F	GERMANY/Caucasian			0	1	肛門性器疣贅	CONDYLOMA ANAL REGION	18		Not Resolved	No	Mild	Not related	None/not applicable	Yes/No
								0	138	潰瘍性大腸炎	ACUTE WORSENING ULCERATIVE COLITIS	166	81	Resolved	No	Moderate	Possible	None/not applicable	No /No

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Injection-site Reaction[c,d]
								0	194	細菌感染	BACTERIAL INFECTION	194	21	Resolved	No	Moderate	Not related	Permanent discontinuation of study agent	Yes/No
								0	194	潰瘍性大腸炎	ACUTE WORSENING UC	246	22	Resolved	Yes	Severe	Not related	None/not applicable	No /No
								0	194	骨粗鬆症	OSTEOPOROSIS	263		Not Resolved	No	Moderate	Not related	None/not applicable	No /No
			7801-00002	3[redacted]/M	JAPAN/Asian	100 mg	92	100	92	潰瘍性大腸炎	WORSENING OF UC	101	15	Resolved	Yes	Severe	Unlikely	Permanent discontinuation of study agent	No /No
						100 mg	92	100	92	注入部位反応	INJECTION SITE PAIN(DUE TO IV OF MED GLUCOSE-ELECTOLYTE FLUID)	106	10	Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	92	100	92	振戦	TREMOR	120		Not Resolved	No	Mild	Not related	None/not applicable	No /No
			7821-00003	2[redacted]/M	JAPAN/Asian			0	1	毛包炎	FOLLICULITIS	1	47	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								0	1	毛包炎	FOLLICULITIS	1		Not Resolved	No	Mild	Possible	None/not applicable	Yes/No
								0	1	感覚鈍麻	NUMBNESS	8		Not Resolved	No	Mild	Unlikely	None/not applicable	No /No
								0	1	湿疹	ECZEMA	12	36	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								0	1	上気道の炎症	UPPER RESPIRATORY INFLAMMATION	26	11	Resolved	No	Mild	Not related	None/not applicable	No /No

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Injection-site Reaction[c,d]
								0	33	サイトメガロウイルス感染	CYTOMEGALO VIRUS INFEECTION	55	10	Resolved	No	Mild	Unlikely	Permanent discontinuation of study agent	Yes/No
								0	33	白血球減少症	LEUKOPENIA	57	5	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								0	33	アスパラギン酸アミノトランスフェラーゼ増加	AST HI	57	15	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								0	33	血小板数減少	LOW PLATELETS	57	22	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								0	33	アラニン・アミノトランスフェラーゼ増加	ALT HI	61	7	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								0	33	サイトメガロウイルス感染	CYTOMEGALO VIRUS INFECTION	64	17	Resolved	Yes	Moderate	Unlikely	Permanent discontinuation of study agent	Yes/No
								0	33	尿道痛	URETHRAL PAIN	69	22	Resolved	No	Mild	Not related	None/not applicable	No /No
								0	33	血管炎	VASCULITIS(LEFT UPPER LIMB)	70	6	Resolved	No	Mild	Not related	None/not applicable	No /No
								0	33	鼻咽頭炎	COLD	99	8	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								0	33	皮脂欠乏性湿疹	ASTEATOTIC ECZEMA	127		Not Resolved	No	Mild	Not related	None/not applicable	No /No
		400 mg/200 mg SC	6402-00008	7[redacted]/M	POLAND/ Caucasian			0	54	前立腺炎	PROSTATITIS	64	8	Resolved	No	Mild	Not related	None/not applicable	No /No

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Injection-site Reaction[c, d]
								0	77	良性前立腺肥大症	HYPERTROPHY OF PROSTATE	90		Not Resolved	No	Mild	Not related	None/not applicable	No /No
								0	133	良性前立腺肥大症	BENINGN PROSTATE HYPERTROPHY	136	5	Resolved	Yes	Severe	Not related	None/not applicable	No /No
								0	173	尿道炎	URETRITIS	197	11	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								0	201	挫傷	CONTUSION OF THE THORAX	214	1	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								0	286	膀胱炎	CYSTITIS	310	4	Resolved	No	Mild	Not related	None/not applicable	Yes/No
			6578-00008	3[redacted]/M	UKRAINE/ Other	100 mg	50	100	281	肺炎	RIGHTSIDE FOCAL PNEUMONIA. MODERATE DURATION. HYPERTHERMIC SYNDROME.	318	14	Resolved	Yes	Moderate	Not related	None/not applicable	Yes/No
			7006-00006	3[redacted]/F	AUSTRALIA/Caucasian	100 mg	134	0	29	上気道感染	UPPER RESPIRATORY TRACT INFECTION	33	20	Resolved	No	Moderate	Possible	None/not applicable	Yes/No
						100 mg	134	0	29	頭痛	HEADACHE	48	34	Resolved	No	Moderate	Possible	None/not applicable	No /No
						100 mg	134	0	53	腹痛	ABDOMINAL PAIN	74		Resolved	No	Mild	Possible	None/not applicable	No /No
						100 mg	134	0	53	湿疹	ECZEMA ON HAND	76	67	Resolved	No	Mild	Unlikely	None/not applicable	No /No
						100 mg	134	0	109	潰瘍性大腸炎	EXACERBATION OF ULCERATIVE COLITIS	125	59	Resolved	No	Mild	Unlikely	None/not applicable	No /No

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Injection-site Reaction[c,d]
						100 mg	134	100	156	上気道感染	UPPER RESPIRATORY TRACT INFECTION	161	10	Resolved	No	Mild	Possible	None/not applicable	Yes/No
						100 mg	134	100	176	潰瘍性大腸炎	EXACERBATION OF ULCERATIVE COLITIS	183	8	Resolved	Yes	Severe	Not related	Permanent discontinuation of study agent	No /No
			7008-00006	3[redacted]/M	AUSTRALIA/Caucasian	100 mg	34	100	90	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	111	8	Resolved	Yes	Severe	Unlikely	Permanent discontinuation of study agent	No /No
			7008-00020	3[redacted]/F	AUSTRALIA/Caucasian	100 mg	106	0	62	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	78	74	Resolved	Yes	Severe	Unlikely	Permanent discontinuation of study agent	No /No
						100 mg	106	100	106	潰瘍性大腸炎	SEVERE FLARE OF ULCERATIVE COLITIS IN RECTAL REMNANT	168	8	Resolved	Yes	Severe	Not related	None/not applicable	No /No
			7413-00010	2[redacted]/M	POLAND/ Caucasian	100 mg	85	0	28	潰瘍性大腸炎	UC AGRAVATION	41	36	Resolved	No	Moderate	Not related	None/not applicable	No /No
						100 mg	85	0	57	潰瘍性大腸炎	UC AGARAVATION	77	8	Resolved	Yes	Severe	Not related	None/not applicable	No /No
						100 mg	85	100	308	消化不良	DYSPEPSIA	322	1	Resolved	No	Mild	Not related	None/not applicable	No /No
			7457-00001	5[redacted]/F	RUSSIANFEDERATION/Caucasian			0	29	アレルギー性皮膚炎	TOXICO-ALLERGIC DERMATITIS	34	54	Resolved	Yes	Moderate	Possible	Permanent discontinuation of study agent	No /No
			7727-00001	4[redacted]/F	UNITEDSTATES/Caucasian			0	1	注入部位静脈炎	PHLEBITIS-LEFT HAND IV SITE	4	53	Resolved	No	Mild	Not related	None/not applicable	No /No

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Injection-site Reaction[c,d]
								0	1	粘液便	MUCOUS IN STOOL	26	41	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								0	29	足部白癬	FUNGAL INFECTION-LEFT FOOT	39	83	Resolved	No	Mild	Possible	None/not applicable	Yes/No
								0	29	爪真菌症	FUNGAL INFECTION-LEFT HAND FINGERNAIL	39	103	Resolved	No	Mild	Probable	None/not applicable	Yes/No
								0	29	腹部膨満	BLOATING	46		Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								0	29	鼓腸	GAS PAIN	46		Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								0	56	クロストリジウム感染	C DIFF INFECTION	81	7	Resolved	No	Moderate	Possible	Temporary interruption /dose modification	Yes/No
								0	56	脱水	DEHYDRATION	85	3	Resolved	Yes	Moderate	Unlikely	Temporary interruption /dose modification	No /No
								0	194	血中テストステロン減少	LOW TESTOSTERONE	202		Not Resolved	No	Mild	Unlikely	None/not applicable	No /No
								0	222	注射部位紅斑	INJECTION SITE REDNESS-LOWER RIGHT ABDOMEN	222	1	Resolved	No	Mild	Probable	None/not applicable	No /Yes
								0	222	注射部位紅斑	INJECTION SITE REDNESS-LOWER LEFT ABDOMEN	222	1	Resolved	No	Mild	Probable	None/not applicable	No /Yes

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Injection-site Reaction[c, d]
								0	222	注射部位紅斑	INJECTION SITE REDNESS-UPPER LEFT ABDOMEN	222	1	Resolved	No	Mild	Probable	None/not applicable	No /Yes
								0	222	注射部位そう痒感	ITCHING AT INJECTION SITE- RIGHT LOWER ABDOMEN	222	1	Resolved	No	Mild	Probable	None/not applicable	No /Yes
								0	222	斑	1 INCH CIRCUMFERENTIAL MACULE BLANCHING WITH PRESSURE APPLIED	222	1	Resolved	No	Mild	Probable	None/not applicable	No /Yes
								0	222	筋骨格痛	SHOULDER PAIN	236	35	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								0	251	注射部位腫脹	SWELLING RIGHT UPPER ABDOMEN INJECTION SITE	251	1	Resolved	No	Moderate	Probable	None/not applicable	No /Yes
								0	251	注射部位紅斑	REDNESS RIGHT UPPER ABDOMEN INJECTION SITE	251	1	Resolved	No	Mild	Probable	None/not applicable	No /Yes
								0	251	注射部位紅斑	REDNESS UPPER LEFT ABDOMINAL INJECTION SITE	251	1	Resolved	No	Mild	Probable	None/not applicable	No /Yes
								0	251	注射部位腫脹	SWELLING LEFT UPPER ABDOMEN INJECTION SITE	251	1	Resolved	No	Mild	Probable	None/not applicable	No /Yes

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Injection-site Reaction[c,d]
								0	251	腹痛	ABDOMINAL PAIN	256	17	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								0	251	下痢	INCREASED DIARRHEA	256	17	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								0	251	倦怠感	MALAISE	256	17	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								0	251	疲労	FATIGUE	256	17	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								0	308	インフルエンザ	INFLUENZA	322	6	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								0	308	耳感染	RIGHT EAR INFECTION	325	9	Resolved	No	Moderate	Possible	None/not applicable	Yes/No
			7743-00004	4[redacted]/M	UNITEDSTATES/Caucasian			0	1	副鼻腔炎	SINUS INFECTION			Resolved	No	Mild	Not related	None/not applicable	Yes/No
								0	54	脳膿瘍	RIGHT FACIAL WEAKNESS DUE TO BRAIN ABCESS	56	48	Resolved	Yes	Mild	Not related	Permanent discontinuation of study agent	Yes/No
								0	54	脳膿瘍	BRAIN ABCESS ON MRI	57	47	Resolved	Yes	Moderate	Possible	None/not applicable	Yes/No
								0	54	脱髄	DEMYELINATING BRAIN LESION ON MRI	160		Not Resolved	Yes	Mild	Possible	None/not applicable	No /No
								0	54	脱髄	DEMYELINATING BRAIN LESION ON MRI	160		Resolved	Yes	Mild	Not related	None/not applicable	No /No
	Golimumab 50 mg	4 mg/kg IV	6281-00005	6[redacted]/M	ISRAEL/Caucasian	100 mg	337	50	1	そう痒症	ITCHING AT PALMS	27	1	Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	337	50	28	注射部位血腫	HEMATOMA AT INJECTION SITE	31	3	Resolved	No	Mild	Not related	None/not applicable	No /Yes

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Injection-site Reaction[c,d]
						100 mg	337	100	337	潰瘍性大腸炎	ULCERATIVE COLITIS EXACERBATION	351	13	Resolved	No	Severe	Not related	Permanent discontinuation of study agent	No /No
						100 mg	337	100	337	潰瘍性大腸炎	ULCERATIVE COLITIS EXACERBATION	363	4	Resolved	Yes	Severe	Not related	None/not applicable	No /No
			6716-00008	6[redacted]/M	UNITEDSTATES/Caucasian			50	29	下痢	LOOSE STOOLS	31	519	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								50	59	咽頭炎	STREPT THROAT INFECTION	73	10	Resolved	No	Moderate	Possible	None/not applicable	Yes/No
								50	87	インフルエンザ様疾患	FLULIKE SYMPTOMS	97	22	Resolved	No	Mild	Possible	None/not applicable	No /No
								50	203	変形性関節症	WORSENING OF RIGHT KNEE OSTEOARTHRITIS	217	4	Resolved	Yes	Severe	Not related	None/not applicable	No /No
								50	203	貧血	ANEMIA	218	72	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								50	289	疲労	FATIGUE	294	46	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								50	339	悪寒	CHILLS	340	56	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								50	371	瘢痕	ANAL SCARRING	385		Not Resolved	No	Mild	Not related	None/not applicable	No /No
		100 mg/50 mg SC	7203-00002	7[redacted]/M	GERMANY/Caucasian	50 mg	282	50	113	ロタウイルス胃腸炎	ROTAVIRUS ENTERITIS	128	6	Resolved	Yes	Moderate	Unlikely	None/not applicable	Yes/No
						50 mg	282	50	141	潰瘍性大腸炎	CLINICAL FLARE OF COLITIS ULCEROSA	159	40	Resolved	No	Severe	Unlikely	None/not applicable	No /No

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Injection-site Reaction[c, d]
						50 mg	282	50	254	潰瘍性大腸炎	CLINICAL FLARE OF ULCERATIVE COLITIS	274		Resolved	No	Moderate	Unlikely	None/not applicable	No /No
			7720-00006	5[redacted]/F	UNITEDSTATES/Caucasian			50	56	不眠症	MILD INSOMNIA	56		Not Resolved	No	Mild	Unlikely	None/not applicable	No /No
								50	84	気管支炎	HOSPITALIZATION FOR CHEST PAIN (NON-CARDIAC CHEST PAIN) RELATED TO BRONCHITIS	101	3	Resolved	Yes	Mild	Unlikely	None/not applicable	Yes/No
								50	84	咳嗽	COUGH	102	39	Resolved	No	Mild	Possible	None/not applicable	No /No
								50	84	不安	INCREASE IN ANXIETY	104		Not Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								50	84	気管支炎	BRONCHITIS	104	37	Resolved	No	Mild	Possible	None/not applicable	Yes/No
								50	199	腹痛	ABDOMINAL PAIN	210	3	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								50	199	外陰腟真菌感染	VAGINAL YEAST INFECTION	210	80	Resolved	No	Moderate	Possible	None/not applicable	Yes/No
								50	317	外陰腟真菌感染	VAGINAL YEAST INFECTION	321	53	Resolved	No	Moderate	Possible	Permanent discontinuation of study agent	Yes/No
								50	317	消化不良	HEARTBURN	344		Not Resolved	No	Mild	Unlikely	None/not applicable	No /No
		200 mg/100 mg SC	6501-00014	4[redacted]/F	SLOVAKIA(SlovakRepublic)/Caucasian			50	1	咽頭炎	PHARYNGITIS	27	6	Resolved	No	Mild	Not related	None/not applicable	Yes/No

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								50	86	帯状疱疹	INTERCOSTAL HERPES ZOOSTER	104	6	Resolved	Yes	Mild	Not related	None/not applicable	Yes/No
			7002-00010	6[redacted]/F	AUSTRALIA/Caucasian	100 mg	59	100	106	歯膿瘍	LEFT TOOTH ABSCESS	146	8	Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No
						100 mg	59	100	106	潰瘍性大腸炎	WORSENING OF UC	203	1	Resolved	Yes	Severe	Not related	None/not applicable	No /No
						100 mg	59	100	106	創傷感染	PERISTOMAL WOUND INFECTION	211		Resolved	No	Moderate	Not related	None/not applicable	Yes/No
			7007-00007	5[redacted]/F	AUSTRALIA/Caucasian			50	30	腹痛	ABDOMINAL PAIN	34	8	Resolved	Yes	Severe	Unlikely	None/not applicable	No /No
								50	30	膿瘍	SIGMOID ABSCESS	37	2	Resolved	Yes	Severe	Possible	Permanent discontinuation of study agent	Yes/No
								50	30	悪心	NAUSEA	37	9	Resolved	No	Moderate	Not related	None/not applicable	No /No
								50	30	尿閉	URINARY RETENTION	38	1	Resolved	No	Moderate	Not related	None/not applicable	No /No
								50	30	便秘	CONSTIPATION	40	5	Resolved	No	Mild	Not related	None/not applicable	No /No
			7008-00009	3[redacted]/F	AUSTRALIA/Caucasian	50 mg	190	50	1	上腹部痛	EPIGASTRIC PAIN	20	62	Resolved	No	Mild	Unlikely	None/not applicable	No /No
						50 mg	190	50	82	口腔咽頭痛	SORE THROAT	88	31	Resolved	No	Mild	Possible	None/not applicable	Yes/No
						50 mg	190	50	82	鼻咽頭炎	HEAD COLD	102	17	Resolved	No	Mild	Possible	None/not applicable	Yes/No
						50 mg	190	50	139	鼻咽頭炎	HEAD COLD	155	2	Resolved	No	Mild	Possible	None/not applicable	No /No

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Injection-site Reaction[c, d]
						50 mg	190	50	174	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	184	75	Resolved	No	Mild	Unlikely	None/not applicable	No /No
						50 mg	190	50	225	脱水	DEHYDRATION	235	2	Resolved	Yes	Moderate	Not related	None/not applicable	No /No
						50 mg	190	50	307	上気道感染	UPPER RESPIRATORY TRACT INFECTION	317	48	Resolved	No	Mild	Possible	None/not applicable	Yes/No
						50 mg	190	50	370	四肢痛	PAIN IN LEFT ARM	376	1	Resolved	No	Mild	Unlikely	None/not applicable	No /No
			7078-00008	5[redacted]/M	BULGARIA/Caucasian			50	28	潰瘍性大腸炎	ULCERATIVE COLITIS IN RELAPSE	45	51	Resolved	Yes	Severe	Not related	Permanent discontinuation of study agent	No /No
								50	28	カンジダ症	CANDIDA ALBICANS INFECTION IN THE COLON.	51	15	Resolved	No	Severe	Possible	None/not applicable	Yes/No
								50	28	白血球数増加	ELEVATED WBC	79	2	Resolved	No	Moderate	Not related	None/not applicable	Yes/No
			7278-00004	5[redacted]/F	ISRAEL/Caucasian	100 mg	169	50	29	筋肉痛	WORSENING OF LEG MUSCLE PAIN	29	7	Resolved	No	Moderate	Possible	None/not applicable	No /No
						100 mg	169	50	29	骨痛	TEMPRORY MANDIBULAR PAIN	31	8	Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	169	50	29	四肢痛	LEFT ARM MUSCLE PAIN	31	8	Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	169	50	59	血性下痢	BLOODY DIARRIA	61	8	Resolved	No	Moderate	Probable	None/not applicable	No /No
						100 mg	169	50	59	四肢痛	PAIN IN LEG FINGER	75	6	Resolved	No	Moderate	Not related	None/not applicable	No /No

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						100 mg	169	50	111	血便排泄	HEMATOCHEZIA	129	5	Resolved	No	Moderate	Not related	None/not applicable	No /No
						100 mg	169	50	111	下痢	DIARRHEA	129	5	Resolved	No	Moderate	Not related	None/not applicable	No /No
						100 mg	169	50	139	腹痛	ABDOMINAL PAIN	160	3	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
						100 mg	169	50	139	血便排泄	HEMATOCHEZIA	160	3	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
						100 mg	169	100	303	発熱	FEVER	310	7	Resolved	No	Moderate	Not related	None/not applicable	No /No
						100 mg	169	100	303	頭痛	HEAD ACHE	310	7	Resolved	No	Moderate	Not related	None/not applicable	No /No
						100 mg	169	100	303	白血球減少症	LEUKOPENIA	314	3	Resolved	No	Moderate	Not related	None/not applicable	No /No
						100 mg	169	100	303	ウイルス感染	VIRAL INFECION	314	3	Resolved	Yes	Moderate	Possible	None/not applicable	Yes/No
			7281-00002	5[redacted]/F	ISRAEL/Caucasian	100 mg	28	100	54	排便回数増加	NUMBER OF STOOLS INCREASED	82	4	Resolved	Yes	Mild	Unlikely	None/not applicable	No /No
						100 mg	28	100	54	貧血	ANEMIA	82	4	Resolved	Yes	Mild	Unlikely	None/not applicable	No /No
			7376-00003	2[redacted]/M	NEWZEALAND/Caucasian	50 mg	26	50	54	上気道感染	UPPER RESPIRATORY TRACT INFECTION	80	8	Resolved	No	Mild	Not related	None/not applicable	Yes/No
						50 mg	26	50	82	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	103	8	Resolved	Yes	Severe	Unlikely	None/not applicable	No /No
						50 mg	26	50	82	血中カリウム減少	LOW POTASSIUM	109	71	Resolved	No	Mild	Not related	None/not applicable	No /No
			7457-00003	4[redacted]/F	RUSSIANFEDERATION/Caucasian			50	143	子宮ポリープ	ENDOMETRIC POLYP	163	8	Resolved	Yes	Mild	Unlikely	None/not applicable	No /No

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			7727-00007	1[redacted]/M	UNITEDSTATES/Caucasian	100 mg	141	50	1	頭痛	HEADACHE	22	16	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
						100 mg	141	100	141	発熱	FEVER	169	5	Resolved	No	Mild	Unlikely	Temporary interruption /dose modification	No /No
						100 mg	141	100	141	嘔吐	VOMITING	169	5	Resolved	No	Moderate	Unlikely	Temporary interruption /dose modification	No /No
						100 mg	141	100	141	潰瘍性大腸炎	FULMINANT ULCERATIVE COLITIS	175	7	Resolved	Yes	Severe	Unlikely	Permanent discontinuation of study agent	No /No
		400 mg/200 mg SC	7007-00003	5[redacted]/F	AUSTRALIA/Caucasian			50	252	皮膚細菌感染	NASAL SKIN INFECTION BACTERIAL			Not Resolved	No	Mild	Possible	None/not applicable	Yes/No
								50	1	膀胱瘤	RECCURRENCE OF VAGINAL CYSTOCELE			Resolved	Yes	Moderate	Not related	Temporary interruption /dose modification	No /No
								50	84	注射部位発疹	LOCALISED RASH AROUND UPPER ABDOMINAL INJECTION SITE	85	2	Resolved	No	Mild	Probable	None/not applicable	No /Yes
								50	84	気管支炎	BRONCHITIS	106	27	Resolved	No	Mild	Possible	None/not applicable	Yes/No
			7026-00014	3[redacted]/F	AUSTRIA/Caucasian			50	1	そう痒性皮疹	SKIN RASH WITH PRURITUS	15	126	Resolved	No	Mild	Possible	None/not applicable	No /No

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								50	30	心嚢液貯留	PERICARDIAL EFFUSION DUE TO POLYSEROSITIS	52	14	Resolved	Yes	Severe	Unlikely	Temporary interruption /dose modification	No /No
								50	113	悪心	NAUSEA	138		Not Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								50	141	扁桃炎	TONSILLITIS	154	11	Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No
								50	197	皮膚乾燥	DRY SKIN WITH PRURITUS	212		Not Resolved	No	Mild	Not related	None/not applicable	No /No
								50	281	鼻咽頭炎	COMMON COLD	289	5	Resolved	No	Mild	Possible	None/not applicable	Yes/No
								50	281	鼻咽頭炎	COMMON COLD	302	15	Resolved	No	Moderate	Possible	None/not applicable	Yes/No
								50	281	発疹	EXANTHEMA	308	12	Resolved	No	Moderate	Possible	None/not applicable	No /No
								50	309	光線性皮膚症	EXACERBATION OF PHOTODERNATOSIS	314	116	Resolved	No	Moderate	Possible	None/not applicable	No /No
			7206-00003	2[redacted]/F	GERMANY/Caucasian			50	33	湿疹	RETROAURICULAR AND PERIORBITAL ECZEMA	61	15	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								50	61	ブドウ球菌性眼感染	CONJUNCTIVITIS DUE TO MRSA-INFECTION	83	24	Resolved	No	Moderate	Unlikely	Temporary interruption /dose modification	Yes/No
								50	175	リンパ節症	CERVICAL LYMPHADENOPATHY	179	11	Resolved	Yes	Severe	Unlikely	None/not applicable	Yes/No
								50	175	結膜炎	ACUTE CONJUNCTIVITIS	179	11	Resolved	Yes	Severe	Unlikely	None/not applicable	Yes/No

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								50	175	外耳炎	RETROAURICULAR INFECTION	179	11	Resolved	Yes	Severe	Unlikely	None/not applicable	Yes/No
								50	175	ブドウ球菌感染	INFECTION DUE TO STAPHYLOCOCCUS AUREUS	181		Resolved	Yes	Severe	Unlikely	None/not applicable	Yes/No
			7807-00006	4[redacted]/M	JAPAN/Asian	50 mg	120	50	137	潰瘍性大腸炎	EXACERBATION OF ULCERATIVE COLITIS	189	14	Resolved	Yes	Moderate	Not related	None/not applicable	No /No
	Golimumab 100 mg	1 mg/kg IV	6737-00003	2[redacted]/M	UNITEDSTATES/Caucasian			100	57	虫垂炎	APPENDICITIS	80	2	Resolved	Yes	Severe	Not related	None/not applicable	Yes/No
								100	253	関節脱臼	DISLOCATED RIGHT KNEE	270	18	Resolved	No	Severe	Not related	None/not applicable	No /No
		4 mg/kg IV	6101-00003	4[redacted]/F	CANADA/Caucasian	200 mg	274	100	56	関節痛	WORSENING ARTHRALGIA	84		Resolved	No	Moderate	Possible	None/not applicable	No /No
						200 mg	274	100	91	上腹部痛	ACUTE EPIGASTRIC PAIN	111	2	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
						200 mg	274	100	112	胆管結石	A COMMON BILE DUCT STONE	132	5	Resolved	Yes	Severe	Unlikely	None/not applicable	No /No
						200 mg	274	100	112	膵炎	PANCREATITIS	132	8	Resolved	Yes	Severe	Unlikely	None/not applicable	No /No
						200 mg	274	100	247	痔核	THROMBOSED HEMORRHOID	271	115	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
						200 mg	274	100	247	裂肛	POSTERIOR ANAL FISSURE	274		Resolved	No	Moderate	Unlikely	None/not applicable	No /No

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						200 mg	274	200	274	上気道うっ血	UPPER RESPIRATORY CONGESTION.	285	6	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
						200 mg	274	200	366	下痢	WORSENING DIARRHEA	366		Not Resolved	No	Moderate	Unlikely	None/not applicable	No /No
		100 mg/50 mg SC	7478-00001	3[redacted]/M	SERBIA/Caucasian			100	1	注射部位紅斑	REDNESS ON INECTION SITE	1	2	Resolved	No	Mild	Definite	None/not applicable	No /Yes
								100	57	虫垂炎	ACUTE APPENDICITIS	62	8	Resolved	Yes	Severe	Possible	None/not applicable	Yes/No
								100	189	注射部位紅斑	REDNESS ON INECTION SITE, FRONT LEFT THIGH	189	2	Resolved	No	Mild	Definite	None/not applicable	No /Yes
								100	281	注射部位紅斑	REDNESS ON INECTION SITE,FRONT LEFT THIGH	281	1	Resolved	No	Mild	Definite	None/not applicable	No /Yes
			7703-00002	5[redacted]/F	UNITEDSTATES/Caucasian			100	1	疲労	FATIGUE	20	28	Resolved	No	Moderate	Possible	None/not applicable	No /No
								100	1	副鼻腔炎	SINUSITIS	20	22	Resolved	No	Moderate	Possible	None/not applicable	Yes/No
								100	34	顔面浮腫	FACIAL EDEMA	34	14	Resolved	No	Moderate	Possible	None/not applicable	No /No
								100	34	末梢性浮腫	EDEMA IN HANDS	34	14	Resolved	No	Mild	Possible	None/not applicable	No /No
								100	34	肺炎	PNEUMONIA	36	61	Resolved	No	Moderate	Probable	None/not applicable	Yes/No
								100	34	浮動性めまい	DIZZINESS	43	32	Resolved	No	Mild	Not related	None/not applicable	No /No

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								100	57	うつ病	DEPRESSION	93		Not Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	57	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	93		Resolved	Yes	Severe	Not related	Permanent discontinuation of study agent	No /No
		200 mg/100 mg SC	7026-00023	4[redacted]/M	AUSTRIA/ Caucasian	200 mg (100 mg)	33 (197)	100	1	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	19	67	Resolved	No	Moderate	Not related	None/not applicable	No /No
						200 mg (100 mg)	33 (197)	100	1	痙攣	SEIZURE	29	1	Resolved	Yes	Moderate	Unlikely	Temporary interruption /dose modification	No /No
						200 mg (100 mg)	33 (197)	200	85	鼻咽頭炎	COMMON COLD	106	12	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
						200 mg (100 mg)	33 (197)	200	113	湿疹	EKZEMA	127	136	Resolved	No	Mild	Unlikely	None/not applicable	No /No
						200 mg (100 mg)	33 (197)	200	141	季節性アレルギー	SEASONAL ALLERGY	165		Not Resolved	No	Mild	Unlikely	None/not applicable	No /No
						200 mg (100 mg)	33 (197)	100	337	腹部ヘルニア	ABDOMINAL HERNIA	358	65	Resolved	Yes	Mild	Not related	None/not applicable	No /No
						200 mg (100 mg)	33 (197)	100	365	胸痛	CHEST PAIN	373	2	Resolved	Yes	Severe	Not related	None/not applicable	No /No
			7207-00004	5[redacted]/M	GERMANY/Caucasian			100	142	顔面不全麻痺	PERIPHERAL FACIAL NERVE PARESIS	169		Resolved	Yes	Moderate	Unlikely	Permanent discontinuation of study agent	No /No
			7408-00005	3[redacted]/F	POLAND/ Caucasian	100 mg	143	100	143	気道感染	RESPIRATORY TRACT INFECTION	149	15	Resolved	No	Moderate	Possible	None/not applicable	Yes/No
						100 mg	143	100	143	爪真菌症	TINEA UNGUIUM	156	21	Resolved	No	Mild	Possible	None/not applicable	Yes/No

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						100 mg	143	100	143	消化管感染	GASTROINTESTINAL INFECTION	156	21	Resolved	No	Moderate	Possible	None/not applicable	Yes/No
						100 mg	143	100	172	潰瘍性大腸炎	UCELARIVE COLLITIS EXACERBATION	179	14	Resolved	Yes	Severe	Not related	Permanent discontinuation of study agent	No /No
			7704-00002	6[redacted]/F	UNITEDSTATES/Caucasian			100	1	手根管症候群	CARPAL TUNNEL OF LEFT WRIST/HAND	2		Not Resolved	No	Moderate	Possible	None/not applicable	No /No
								100	254	肺腺癌	ADENOCARCINOMA RIGHT UPPER LOBE/LUNG	287	13	Resolved	Yes	Severe	Possible	Permanent discontinuation of study agent	No /No
								100	254	食道浮腫	SWELLING OF ESOPHAGUS	320		Not Resolved	No	Moderate	Not related	None/not applicable	No /No
			7743-00009	4[redacted]/M	UNITEDSTATES/Caucasian			100	1	不安	ANXIETY	18	36	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	32	胃腸炎	GASTROENTERITIS	50	5	Resolved	No	Moderate	Not related	None/not applicable	Yes/No
								100	88	精巣上体炎	EPIDIDYMITIS	104	12	Resolved	No	Moderate	Not related	None/not applicable	Yes/No
								100	120	背部痛	BACK PAIN	133	380	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	141	椎間板突出	HERNIATED LUMBAR DISC	147	39	Resolved	Yes	Severe	Not related	None/not applicable	No /No
								100	207	胃腸炎	GASTROENTERITIS	211	3	Resolved	No	Moderate	Not related	None/not applicable	Yes/No
								100	254	前立腺腫大	POSSIBLE ENLARGED PROSTATE	274	23	Resolved	No	Mild	Not related	None/not applicable	No /No

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								100	282	悪心	NAUSEA	282	1	Resolved	No	Moderate	Probable	None/not applicable	No /No
								100	359	悪心	NAUSEA	359	6	Resolved	No	Moderate	Probable	None/not applicable	No /No
			7796-00002	2[redacted]/M	UNITEDSTATES/Caucasian	100 mg	358	100	1	痔核	HEMORRHOIDS	2	6	Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	358	100	60	腹痛	RIGHT-SIDED ABDOMINAL PAIN.	81	2	Resolved	No	Severe	Unlikely	None/not applicable	No /No
						100 mg	358	100	60	虫垂炎	ACUTE APPENDICITIS	82	2	Resolved	Yes	Severe	Unlikely	None/not applicable	Yes/No
						100 mg	358	100	232	血便排泄	BLOODY STOOLS AND RECTAL BLEEDING	263		Not Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	358	100	232	腹痛	GENERAL ABDOMINAL PAIN	265		Not Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	358	100	343	潰瘍性大腸炎	CLINICAL FLARE OF ULCERATIVE COLITIS	357		Not Resolved	No	Severe	Not related	Temporary interruption /dose modification	No /No
		400 mg/200 mg SC	6402-00007	4[redacted]/M	POLAND/ Caucasian			100	120	肺浸潤	INFILTRATION OF RIHT MEDIAL LUNG LOBE	129	9	Resolved	Yes	Moderate	Unlikely	None/not applicable	No /No
								100	120	呼吸困難	DYSPNEA	129	118	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	151	結核	MYCOBACTERIUM TUBERCULOSIS INFECTION LIKELY	177	206	Resolved	No	Moderate	Possible	Temporary interruption /dose modification	Yes/No

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								100	331	肺浸潤	INFILTRATION OF RIGHT MEDIAL LUNG LOBE OF UNKNOWN ORIGIN	353		Not Resolved	Yes	Severe	Unlikely	Permanent discontinuation of study agent	No /No
			6407-00032	6[redacted]/M	POLAND/ Caucasian			100	225	咽頭炎	PHARYNGITIS	230	11	Resolved	No	Mild	Probable	None/not applicable	Yes/No
								100	253	心不全	HEART FAILURE WITH PRESERVED SYSTOLIC FUNCTION.	270	5	Resolved	Yes	Mild	Unlikely	Permanent discontinuation of study agent	No /No
								100	253	心不全	HEART FAILURE	320	16	Resolved	Yes	Severe	Unlikely	None/not applicable	No /No
			7007-00004	4[redacted]/F	AUSTRALIA/Caucasian	100 mg	168	100	140	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS			Resolved	Yes	Severe	Unlikely	Permanent discontinuation of study agent	No /No
						100 mg	168	100	140	腹痛	ABDOMINAL PAIN			Resolved	No	Moderate	Unlikely	None/not applicable	No /No
						100 mg	168	100	28	全身性皮疹	GENERALISED RASH	31	54	Resolved	No	Mild	Unlikely	None/not applicable	No /No
			7008-00016	6[redacted]/F	AUSTRALIA/Caucasian	100 mg	248	100	1	口唇炎	ANGULAR STOMATITIS	5	99	Resolved	No	Mild	Unlikely	None/not applicable	No /No
						100 mg	248	100	85	皮膚病変	SKIN LESION ON RIGHT ANKLE	107	185	Resolved	No	Mild	Possible	None/not applicable	Yes/No
						100 mg	248	100	274	白内障	CATARACT RIGHT EYE (REMOVED)	286	1	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
						100 mg	248	100	274	足関節部骨折	FRACTURE LEFT MALLEOLUS	292		Resolved	Yes	Moderate	Not related	None/not applicable	No /No

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						100 mg	248	100	302	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	304	7	Resolved	Yes	Moderate	Unlikely	Permanent discontinuation of study agent	No /No
			7026-00030	2[redacted]/M	AUSTRIA/ Caucasian	100 mg	114	100	29	白血球減少症	LEUKOPENIA	29	57	Resolved	No	Mild	Unlikely	None/not applicable	No /No
						100 mg	114	100	85	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	100	98	Resolved	No	Severe	Possible	Temporary interruption /dose modification	No /No
						100 mg	114	100	85	皮膚乾燥	DRYNESS OF SKIN	110		Not Resolved	No	Mild	Probable	None/not applicable	No /No
						100 mg	114	100	141	鼻咽頭炎	COMMON COLD	161	5	Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No
						100 mg	114	100	197	心膜炎	PERIKARDITIS	203	114	Resolved	Yes	Moderate	Possible	Permanent discontinuation of study agent	Yes/No
						100 mg	114	100	197	クロストリジウム感染	C. DIFFICILE INFECTION	226	6	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
			7116-00012	2[redacted]/F	CANADA/ Caucasian			100	85	口腔ヘルペス	COLD SORE	110	4	Resolved	No	Moderate	Possible	None/not applicable	Yes/No
								100	85	そう痒症	BODY ITCH	110	29	Resolved	No	Moderate	Possible	None/not applicable	No /No
								100	85	真菌感染	YEAST INFECTION	112	2	Resolved	No	Moderate	Possible	None/not applicable	Yes/No
								100	114	高ビリルビン血症	ISOLATED HYPERBILIRUBINEMIA	124	5	Resolved	Yes	Severe	Unlikely	None/not applicable	No /No
								100	142	レンサ球菌性咽頭炎	STREP THROAT	156	11	Resolved	No	Moderate	Probable	None/not applicable	Yes/No
								100	142	真菌感染	YEAST INFECTION	166	7	Resolved	No	Moderate	Probable	None/not applicable	Yes/No

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Injection-site Reaction[c, d]
								100	198	真菌感染	YEAST INFECTION	212	31	Resolved	No	Mild	Possible	None/not applicable	Yes/No
			7126-00011	6[redacted]/F	DENMARK/Caucasian	100 mg	156	100	1	インフルエンザ	INFLUENZA	9	16	Resolved	No	Mild	Possible	None/not applicable	Yes/No
						100 mg	156	100	1	眼の炎症	EYE INFLAMMATION	9	4	Resolved	No	Mild	Possible	None/not applicable	Yes/No
						100 mg	156	100	64	中耳炎	MEDIA OTITIS/INFLAMMATION OF MIDDEL EAR	85	14	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
						100 mg	156	100	96	挫傷	THORACAL CONTUSION	115	15	Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	156	100	156	潰瘍性大腸炎	FLARE OF UC	162	6	Resolved	Yes	Severe	Not related	Permanent discontinuation of study agent	No /No
			7402-00003	4[redacted]/M	POLAND/ Caucasian			100	1	真菌感染	MYCOSIS OF HANDS AND FEET SKIN.	17	33	Resolved	No	Moderate	Possible	None/not applicable	Yes/No
								100	57	発疹	UNDEFINED RASH OF HANDS AND FEET	78	5	Resolved	Yes	Moderate	Unlikely	None/not applicable	No /No
			7504-00007	3[redacted]/M	SLOVAKIA(SlovakRepublic)/Caucasian			100	85	鼠径ヘルニア	RIGHT INGUINAL HERNIA	112	50	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	85	肝機能検査異常	LIVER TESTS ELEVATION	116	43	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	145	鼠径ヘルニア	RIGHT INGUINAL HERNIA	161	4	Resolved	Yes	Mild	Not related	None/not applicable	No /No

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			7716-00010	3[redacted]/F	UNITEDSTATES/Black			100	168	物質乱用	POLYSUBSTANCE ABUSE			Resolved	Yes	Severe	Not related	None/not applicable	No /No
								100	141	ブドウ球菌感染	MRSA IN STOOL			Not Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1	血便排泄	INCREASE BLOOD IN STOOL	2	70	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	1	下痢	INCREASE IN DIARRHEA	2	70	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	85	鼻咽頭炎	COMMON COLD	110	5	Resolved	No	Moderate	Not related	None/not applicable	Yes/No
								100	141	うつ病	DEPRESSION	159		Not Resolved	No	Mild	Not related	None/not applicable	No /No
								100	141	関節脱臼	DISLOCATED RIGHT KNEE	163	18	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	224	腹痛	INCREASED ABDOMINAL PAIN	255	23	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	224	悪心	NAUSEA	255	23	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	224	嘔吐	VOMITTING	255	23	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	224	低カリウム血症	HYPOKALEMIA	276		Not Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	224	貧血	ANEMIA	276		Not Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	224	脱水	DEHYDRATION	276	5	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	224	ジアルジア症	GIARDIASIS	276	5	Resolved	No	Moderate	Not related	None/not applicable	Yes/No
								100	224	白血球増加症	LEUKOCYTOSIS	276		Not Resolved	No	Mild	Unlikely	None/not applicable	No /No

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								100	224	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	276	6	Resolved	Yes	Severe	Not related	Permanent discontinuation of study agent	No /No
			7752-00002	3[redacted]/F	UNITEDSTATES/Caucasian			100	112	腹痛	ABDOMINAL PAIN	120	37	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	112	下痢	DIARRHEA	120	2	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	112	鼻漏	NASAL SECRETION	137	8	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	112	口腔咽頭痛	SORE THROAT	137	8	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	112	気道うっ血	CHEST CONGESTION	137	8	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	112	眼充血	REDDENED EYES	137	8	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	139	頭痛	INTERMITTENT HEADACHES	164		Not Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	195	不眠症	WORSENING INSOMNIA	200	15	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	195	副鼻腔炎	SINUS DRAINAGE	202	13	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	195	関節痛	INCREASED JOINT PAIN	202	94	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	195	発熱	INTERMITTENT FEVER	205	3	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	195	腹痛	ABDOMINAL PAIN	214	1	Resolved	No	Severe	Unlikely	None/not applicable	No /No
								100	195	腹痛	ABDOMINAL PAIN	223		Not Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	195	悪心	NAUSEA	223	2	Resolved	No	Mild	Unlikely	None/not applicable	No /No

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								100	223	末梢性浮腫	FEET SWELLING	239	6	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	223	末梢性浮腫	HAND SWELLING	239	110	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	223	関節腫脹	ANKLES SWELLING	239	110	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	223	感覚鈍麻	RIGHT HAND NUMBNESS	242	40	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	250	感覚鈍麻	LEFT HAND NUMBNESS	252	30	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	250	咳嗽	COUGH	277	20	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	250	副鼻腔手術	NASAL SINUS DRAINAGE	277	20	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	279	外耳炎	OTITIS EXTERNA INFECTIVE	281	16	Resolved	No	Moderate	Not related	None/not applicable	Yes/No
								100	279	耳管機能障害	EUSTACHIAN TUBE DYSFUNCTION	281	16	Resolved	No	Moderate	Not related	None/not applicable	Yes/No
								100	279	急性副鼻腔炎	SINUSITIS ACUTE	281	16	Resolved	No	Moderate	Not related	None/not applicable	Yes/No
								100	302	下痢	DIARRHEA	303		Not Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	302	感覚鈍麻	RIGHT HAND NUMBNES	312	37	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	302	関節痛	INCREASED JOINT PAIN	312	37	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	302	節足動物咬傷	LEFT LOWER ABDOMEN SPIDER BITE	312	11	Resolved	No	Moderate	Not related	None/not applicable	No /No

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								100	302	下腹部痛	LEFT LOWER ABDOMEN SORE	320	37	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	333	妊娠	PREGNANCY	336	226	Resolved	Yes	Mild	Not related	Permanent discontinuation of study agent	No /No
			7806-00002	2[redacted]/F	JAPAN/Asian			100	1	上気道の炎症	ACUTE UPPER RESPIRATORY INFLAMMATION	3	41	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	29	白血球数減少	WHITE BLOOD CELL COUNT DECREASE	54	32	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	169	白血球数減少	WHITE BLOOD CELL COUNT DECREASE	197	15	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	197	白血球数減少	WHITE BLOOD CELL COUNT DECREASE	226	57	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	369	感染性小腸結腸炎	ACUTE BACTERIAL COLITIS	370	4	Resolved	No	Moderate	Not related	None/not applicable	Yes/No
								100	369	感染性小腸結腸炎	ACUTE BACTERIAL COLITIS	373	8	Resolved	Yes	Moderate	Not related	None/not applicable	Yes/No
								100	369	湿疹	ECZEMA	383		Not Resolved	No	Mild	Not related	None/not applicable	No /No

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Injection-site Reaction[c,d]
No	Placebo (PBO induction Responder)	Placebo SC	6234-00010	3[redacted]/M	HUNGARY/Caucasian	100 mg	281	0	253	潰瘍性大腸炎	WORSENING OF UC	275		Not Resolved	No	Moderate	Not related	Temporary interruption /dose modification	No /No
						100 mg	281	100	281	滑液包炎	BURSITIS PREPATELLARIS	294	4	Resolved	Yes	Severe	Not related	None/not applicable	No /No
						100 mg	281	100	281	高血圧	HYPERTENSION	296		Not Resolved	No	Mild	Not related	None/not applicable	No /No
			6501-00017	5[redacted]/F	SLOVAKIA(SlovakRepublic)/Caucasian			0	1	アラニン・アミノトランスフェラーゼ増加	ELEVATION ALT AFTER NIDRAZID THERAPY OF LATENT TBC	10	48	Resolved	No	Mild	Not related	None/not applicable	No /No
								0	57	潰瘍性大腸炎	RELAPS COLITIS ULCEROSA	68	5	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								0	57	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	72	8	Resolved	Yes	Mild	Unlikely	None/not applicable	No /No
								0	85	下痢	DIARRHOEA	107	7	Resolved	No	Mild	Not related	None/not applicable	No /No
								0	198	下痢	DIARRHOEA	210	3	Resolved	No	Mild	Not related	None/not applicable	No /No
			6501-00021	3[redacted]/F	SLOVAKIA(SlovakRepublic)/Caucasian	100 mg	379	0	57	鼻咽頭炎	COLD	71	4	Resolved	No	Mild	Not related	None/not applicable	Yes/No
						100 mg	379	0	226	背部痛	BACK PAIN	239	7	Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	379	0	340	薬物過敏症	CIPHIN ALERGY	355	25	Resolved	No	Mild	Not related	None/not applicable	No /No

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						100 mg	379	0	340	潰瘍性大腸炎	WORSENING OF BASIC DISEASE (= COLITIS ULCEROSA)	355	95	Resolved	Yes	Severe	Unlikely	None/not applicable	No /No
			6747-00011	2[redacted]/F	UNITEDSTATES/Black	100 mg	45	100	57	潰瘍性大腸炎	WORSENING UC	91		Not Resolved	Yes	Moderate	Unlikely	None/not applicable	No /No
			7080-00020	3[redacted]/F	BULGARIA/Caucasian	100 mg	114	100	171	ばら色粃糠疹	PITYRIASIS ROSEA	191	21	Resolved	No	Mild	Possible	None/not applicable	No /No
						100 mg	114	100	199	貨幣状湿疹	ECZEMA NUMMULARE	221	8	Resolved	No	Moderate	Possible	None/not applicable	No /No
						100 mg	114	100	199	薬疹	DERMATITIS MEDICAMENTOUS	229	8	Resolved	Yes	Severe	Possible	None/not applicable	No /No
			7126-00006	5[redacted]/F	DENMARK/Caucasian			0	21	痔核	WORSENING OF HAEMORRHIODES	43	61	Resolved	No	Moderate	Not related	None/not applicable	No /No
								0	115	椎間関節症候群	FACET JOINT SYNDROME	140	58	Resolved	No	Mild	Not related	None/not applicable	No /No
								0	140	細菌の過剰増殖	BACTERIAL OVERGROTH IN SMALL TESTINE	151	23	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								0	197	乳癌	MALIGNANT BREAST TUMOR, LEFT	219	448	Resolved	Yes	Mild	Unlikely	None/not applicable	No /No
			7129-00009	2[redacted]/F	DENMARK/Caucasian			0	1	錯感覚	TINGLING OF HANDS AND FEET	1	9	Resolved	No	Mild	Unlikely	None/not applicable	No /No

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								0	1	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS NECESSITATING COLECTOMY	36	15	Resolved	Yes	Severe	Not related	None/not applicable	No /No
								0	1	イレウス	ILEUS	41	3	Resolved	Yes	Moderate	Not related	None/not applicable	No /No
								0	1	尿路感染	URINARY TRACT INFECTION	50	6	Resolved	No	Mild	Possible	None/not applicable	Yes/No
								0	1	瘻孔	FISTULA	53		Not Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								0	1	外陰部腟カンジダ症	VAGINAL CANDIDIASIS	106		Not Resolved	No	Mild	Possible	None/not applicable	Yes/No
			7413-00002	2[redacted]/M	POLAND/ Caucasian			0	141	裂傷	LACERATIONS	153	5	Resolved	Yes	Severe	Not related	None/not applicable	No /No
								0	141	鋭的腹部外傷	PENETRATING WOUND OF EPIGASTRII	153	5	Resolved	Yes	Severe	Not related	None/not applicable	No /No
								0	141	挫傷	BRUISE OF FOREHEAD	153	5	Resolved	Yes	Severe	Not related	None/not applicable	No /No
								0	141	裂傷	CUT WOUNDESR, LEFT THUMB,	153	5	Resolved	Yes	Severe	Not related	None/not applicable	No /No
								0	141	裂傷	CUT WOUNDES OF EFT EYELID	153	5	Resolved	No	Moderate	Not related	None/not applicable	No /No
								0	225	アラニン・アミノトランスフェラーゼ増加	ALT INCREASE	253	87	Resolved	No	Moderate	Unlikely	Permanent discontinuation of study agent	No /No

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								0	281	アスパラギン酸アミノトランスフェラーゼ増加	AST INCREASE	282	58	Resolved	No	Mild	Unlikely	Permanent discontinuation of study agent	No /No
								0	309	挫傷	CONTUSION OF LEGS	323	100	Resolved	No	Moderate	Not related	Permanent discontinuation of study agent	No /No
			7732-00005	4[redacted]/F	UNITEDSTATES/Caucasian	100 mg	185	0	1	アスパラギン酸アミノトランスフェラーゼ増加	ELEVATED AST	1		Not Resolved	No	Mild	Unlikely	None/not applicable	No /No
						100 mg	185	0	1	アラニン・アミノトランスフェラーゼ増加	ELEVATED ALT	1		Not Resolved	No	Mild	Unlikely	None/not applicable	No /No
						100 mg	185	0	83	歯膿瘍	R MANDIBULAR TOOTH ABCESS	91	18	Resolved	No	Moderate	Not related	None/not applicable	Yes/No
						100 mg	185	0	142	副鼻腔炎	SINUSITIS	149	12	Resolved	No	Mild	Possible	None/not applicable	Yes/No
						100 mg	185	0	142	副鼻腔炎に伴う頭痛	SINUS HEADACHE	149	12	Resolved	No	Mild	Possible	None/not applicable	Yes/No
						100 mg	185	0	142	湿性咳嗽	PRODUCTIVE COUGH	149	12	Resolved	No	Mild	Possible	None/not applicable	Yes/No
						100 mg	185	0	142	寝汗	INTERMITTENT POSITIVE NIGHTS SWEATS	149	12	Resolved	No	Mild	Possible	None/not applicable	Yes/No
						100 mg	185	0	142	血便排泄	INCREASE BLOOD, STOOLS	160	66	Resolved	No	Moderate	Unlikely	None/not applicable	No /No

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						100 mg	185	0	142	発熱	FEVER AT NIGHT	160	66	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
						100 mg	185	0	142	疲労	INCREASED FATIGUE	160	66	Resolved	No	Mild	Unlikely	None/not applicable	No /No
						100 mg	185	0	142	便意切迫	INCREASE STOOLS URGENCY	160	5	Resolved	No	Mild	Unlikely	None/not applicable	No /No
						100 mg	185	0	142	多汗症	SWEAT	160	66	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
						100 mg	185	0	142	悪寒	CHILLS	160	66	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
						100 mg	185	0	142	深部静脈血栓症	LEFT LOWER LEG DVT	164	298	Resolved	Yes	Severe	Not related	None/not applicable	No /No
						100 mg	185	100	198	齲歯	INCREASE DENTAL DECAY	214		Not Resolved	No	Mild	Not related	None/not applicable	No /No
			7752-00011	2[redacted]/F	UNITEDSTATES/Black			0	1	妊娠	PREGNANCY	6	49	Resolved	Yes	Moderate	Not related	Permanent discontinuation of study agent	No /No
								0	1	自然流産	SPONTANEOUS ABORTION	54	1	Resolved	Yes	Severe	Not related	None/not applicable	No /No
								0	1	潰瘍性大腸炎	ULCERATIVE COLITIS FLARE	357		Not Resolved	No	Moderate	Not related	None/not applicable	No /No
								0	1	クロストリジウム・ディフィシレ大腸炎	C-DIFF COLITIS	361	15	Resolved	No	Moderate	Not related	None/not applicable	Yes/No
			7752-00012	2[redacted]/F	UNITEDSTATES/Caucasian	100 mg	87	0	29	胸膜炎	PLEURISY	39	8	Resolved	No	Moderate	Not related	None/not applicable	No /No
						100 mg	87	0	58	うつ病	INCREASED DEPRESSION	85	8	Resolved	No	Moderate	Not related	None/not applicable	No /No

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Injection-site Reaction[c, d]
						100 mg	87	100	87	潰瘍性大腸炎	ULCERATIVE COLITIS EXACERBATION	92	7	Resolved	Yes	Severe	Unlikely	Permanent discontinuation of study agent	No /No
						100 mg	87	100	87	口腔カンジダ症	ORAL CANDIDIASIS	94	6	Resolved	No	Mild	Not related	None/not applicable	Yes/No
			7755-00003	4[redacted]/F	UNITEDSTATES/Caucasian	100 mg	129	0	57	悪心	NAUSEA	85	79	Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	129	0	85	疲労	FATIGUE	87	111	Resolved	No	Severe	Possible	None/not applicable	No /No
						100 mg	129	0	113	潰瘍性大腸炎	UC FLARE	122	34	Resolved	No	Moderate	Not related	None/not applicable	No /No
						100 mg	129	100	141	上気道感染	UPPER RESPIRATORY INFECTION	150	4	Resolved	No	Moderate	Possible	None/not applicable	Yes/No
						100 mg	129	100	141	気管支炎	ACUTE BRONCHITIS	153	7	Resolved	Yes	Moderate	Possible	None/not applicable	Yes/No
						100 mg	129	100	141	うつ病	DEPRESSION	155	43	Resolved	No	Moderate	Not related	None/not applicable	No /No
						100 mg	129	100	169	上気道感染	UPPER RESPIRATORY INFECTION	191	6	Resolved	No	Mild	Not related	None/not applicable	Yes/No
						100 mg	129	100	232	季節性アレルギー	WORSENING OF SEASONAL ALLERGIES	251	19	Resolved	No	Moderate	Not related	None/not applicable	No /No
						100 mg	129	100	310	滑液包炎	RIGHT HIP BURSITIS	336	198	Resolved	No	Moderate	Not related	None/not applicable	No /No
			7771-00003	5[redacted]/F	UNITEDSTATES/Asian	100 mg	203	0	167	潰瘍性大腸炎	FLARE OF ULCERATIVE COLITIS	197	30	Resolved	No	Mild	Not related	None/not applicable	No /No

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Injection-site Reaction[c, d]
						100 mg	203	100	203	潰瘍性大腸炎	FLARE OF ULCERATIVE COLITIS	226	6	Resolved	Yes	Severe	Not related	None/not applicable	No /No
						100 mg	203	100	203	大腸腺腫	COLON ADENOMATOUS POLYPS (REMOVED)	230	1	Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	203	100	203	潰瘍性大腸炎	FLARE OF ULCERATIVE COLITIS	231	111	Resolved	No	Mild	Not related	None/not applicable	No /No
			7816-00002	2[redacted]/F	JAPAN/Asian	100 mg	227	100	227	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	248	55	Resolved	Yes	Severe	Unlikely	Permanent discontinuation of study agent	No /No
						100 mg	227	100	227	鼻咽頭炎	COMMON COLD	254	12	Resolved	No	Mild	Not related	None/not applicable	Yes/No
						100 mg	227	100	227	萎縮性胃炎	GASTRITIS ATROPHIC	260		Not Resolved	No	Mild	Not related	None/not applicable	No /No
						100 mg	227	100	227	不眠症	INSOMNIA	266	10	Resolved	No	Mild	Not related	None/not applicable	No /No
	Golimumab 100 mg (PBO induction nonresponder)	Placebo IV	6257-00008	5[redacted]/F	INDIA/Asian			100	88	潰瘍性大腸炎	ACUTE EXCERBATION OF ULCERATIVE COLITIS	90	6	Resolved	Yes	Moderate	Unlikely	Permanent discontinuation of study agent	No /No
			6278-00002	3[redacted]/M	ISRAEL/Caucasian			100	28	扁桃炎	TONSILLITIS	40		Not Resolved	No	Moderate	Possible	None/not applicable	Yes/No
								100	28	肺塞栓症	MASSIVE BILATERAL PULMONARY EMBOLISM	93	10	Resolved	Yes	Severe	Not related	None/not applicable	No /No
			6377-00001	4[redacted]/M	NEWZEALAND/Other			100	57	胸痛	CHESTPAIN	58	2	Resolved	Yes	Mild	Unlikely	None/not applicable	No /No

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Injection-site Reaction[c,d]
								100	57	胃食道逆流性疾患	GASTRO-OESOPHAGEAL REFLUX DISEASE	58	2	Resolved	Yes	Mild	Unlikely	None/not applicable	No /No
								100	143	潰瘍性大腸炎	FAILED MEDICAL MANAGEMENT OF ULCERATIVE COLITIS	191	1	Resolved	Yes	Moderate	Not related	None/not applicable	No /No
								100	143	関節痛	ARTHRALGIA	249	12	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	143	耳痛	PAINFUL INNER L) EAR	249	12	Resolved	No	Mild	Not related	None/not applicable	No /No
			6407-00006	2[redacted]/M	POLAND/ Caucasian			100	1	咽頭炎	PHARYNGITIS	9	9	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	308	潰瘍性大腸炎	AGGRAVATION OF ULCERATIVE COLITIS	335	5	Resolved	Yes	Moderate	Unlikely	None/not applicable	No /No
		Placebo SC	6112-00009	4[redacted]/M	CANADA/ Caucasian			100	22	神経圧迫	PINCHED NERVE CERVICAL SPINE	26	366	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	197	鼻咽頭炎	COLD VIRUS	219	15	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	344	急性心筋梗塞	NON-ST ELEVATION MYOCARDIAL INFARCTION	347	7	Resolved	Yes	Mild	Unlikely	None/not applicable	No /No
								100	344	不整脈	TRANSIENT ARRHYTHMIA	347	7	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	344	冠動脈疾患	CORONARY ARTERY DISEASE	348	38	Resolved	Yes	Moderate	Unlikely	Temporary interruption /dose modification	No /No

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								100	344	高脂血症	HYPERLIPIDEMIA	348		Not Resolved	No	Moderate	Unlikely	None/not applicable	No /No
			6112-00014	2[redacted]/M	CANADA/ Caucasian			100	1	鼻咽頭炎	COLD VIRUS	18	6	Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No
								100	77	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	105	7	Resolved	Yes	Severe	Unlikely	Permanent discontinuation of study agent	No /No
								100	77	肛門膿瘍	PERIANAL ABSCESS	110	2	Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No
								100	77	小腸閉塞	SMALL BOWEL OBSTRUCTION	146	5	Resolved	Yes	Moderate	Unlikely	None/not applicable	No /No
			6207-00002	1[redacted]/M	GERMANY/Caucasian			100	113	肺炎	PNEUMONIA	120	15	Resolved	No	Severe	Possible	None/not applicable	Yes/No
								100	113	肺炎	PNEUMONIA	139	10	Resolved	Yes	Severe	Possible	Permanent discontinuation of study agent	Yes/No
			6354-00003	5[redacted]/M	NETHERLANDS/Caucasian			100	1	鼻咽頭炎	A COMMON COLD	26	10	Resolved	No	Mild	Possible	None/not applicable	Yes/No
								100	28	ウイルス性胃腸炎	VIRAL GASTRO-ENTERITIS	41	3	Resolved	No	Mild	Possible	None/not applicable	No /No
								100	196	貧血	ANAEMIA	196		Not Resolved	No	Moderate	Possible	None/not applicable	No /No
								100	196	口渇	THIRST	199	62	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	196	口内乾燥	DRY MOUTH	199	62	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	196	咽喉乾燥	DRY THROAT	199	62	Resolved	No	Mild	Not related	None/not applicable	No /No

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Injection-site Reaction[c,d]
								100	252	腹痛	ABDOMINAL PAIN	259	25	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	273	腹痛	ABDOMINAL PAIN	284	45	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	305	細菌性敗血症	BACTEREMIA/ SEPSIS	329		Not Resolved	Yes	Moderate	Possible	Permanent discontinuation of study agent	No /No
			6747-00009	3[redacted]/F	UNITEDSTATES/Caucasian			100	57	筋肉痛	ACHEY MUSCLES	64	7	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	168	妊娠	PREGNANCY	196	282	Resolved	Yes	Severe	Not related	Permanent discontinuation of study agent	No /No
								100	200	上気道感染	UPPER RESPIRATORY INFECTION	231	18	Resolved	No	Moderate	Possible	None/not applicable	Yes/No
								100	253	副鼻腔炎	SINUSITIS	262	27	Resolved	No	Moderate	Possible	None/not applicable	Yes/No
								100	316	胃食道逆流性疾患	WORSENING OF GERD	321	31	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	316	胃食道逆流性疾患	INCREASED GERD	322	30	Resolved	No	Mild	Not related	None/not applicable	No /No
			7001-00003	2[redacted]/F	AUSTRALIA/Caucasian			100	1	不規則月経	IRREGULAR MENSTRUAL CYCLE	22		Not Resolved	No	Mild	Not related	None/not applicable	No /No
								100	57	潰瘍性大腸炎	MINOR PROGRESSION OF DISEASE	85	5	Resolved	Yes	Severe	Not related	Permanent discontinuation of study agent	No /No
			7002-00009	4[redacted]/M	AUSTRALIA/Caucasian			100	30	ウイルス性下気道感染	VIRAL CHEST INFECTION	64	3	Resolved	Yes	Mild	Possible	None/not applicable	Yes/No

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								100	30	咳嗽	COUGH	64	8	Resolved	No	Moderate	Possible	None/not applicable	Yes/No
								100	30	潰瘍性大腸炎	WORSENING OF UC	90	2	Resolved	Yes	Severe	Not related	None/not applicable	No /No
			7003-00003	3[redacted]/F	AUSTRALIA/Caucasian			100	1	肝機能検査異常	ABNORMAL LIVER FUNCTION TESTS	4	26	Resolved	Yes	Moderate	Possible	None/not applicable	No /No
								100	1	頭痛	HEADACHE	23	1	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1	頭痛	HEADACHE	26	1	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	86	背部痛	BILATERAL BACK PAIN	92	15	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
			7008-00007	2[redacted]/F	AUSTRALIA/Caucasian			100	55	上気道感染	UPPER RESPIRATORY TRACT INFECTION	83	35	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	146	処置による頭痛	HEADACHE (POST IRON INFUSION)	165	3	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	173	発疹	RASH ON TOP OF FEET	184	302	Resolved	No	Mild	Possible	None/not applicable	No /No
								100	209	発疹	RASH ON HANDS	216	270	Resolved	No	Mild	Possible	None/not applicable	No /No
								100	230	皮下組織膿瘍	SUPERFICIAL SUBCUTANEOUS ABSCESS ON BACK OF NECK	241	72	Resolved	Yes	Moderate	Possible	None/not applicable	Yes/No
								100	230	発疹	RASH ON BACK OF KNEES	273	213	Resolved	No	Mild	Possible	None/not applicable	No /No
								100	230	寄生虫性胃腸炎	POSSIBLE INTESTINAL PARASITES	283	4	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Injection-site Reaction[c, d]
								100	230	咽頭炎	PHARYNIGITIS	284	5	Resolved	No	Mild	Possible	None/not applicable	Yes/No
								100	314	筋骨格硬直	STIFF NECK	333	20	Resolved	No	Mild	Possible	None/not applicable	No /No
								100	342	麦粒腫	STYE IN EYE (LEFT LOWER LID)	346	4	Resolved	No	Mild	Possible	None/not applicable	Yes/No
			7008-00025	1[redacted]/F	AUSTRALIA/Caucasian			100	1	潰瘍性大腸炎	EXACERBATION OF ULCERATIVE COLITIS	24	5	Resolved	Yes	Moderate	Unlikely	Permanent discontinuation of study agent	No /No
			7085-00002	6[redacted]/M	BULGARIA/Caucasian			100	1	浮動性めまい	SHORT EPISODES OF DIZZINESS			Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	57	挫傷	BRUISE OF RIGHT ANKLE AFTAR TRAUMA	80	41	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	87	大動脈瘤破裂	RUPTURE OF ANEURISMA OF THE ABDOMINAL AORTA	89	32	Resolved	Yes	Severe	Not related	Permanent discontinuation of study agent	No /No
			7128-00001	3[redacted]/M	DENMARK/Caucasian			100	28	疲労	FATIGUE	30		Not Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	28	気管支炎	BRONCHITIS	40		Resolved	No	Moderate	Possible	None/not applicable	Yes/No
								100	56	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	84	35	Resolved	No	Severe	Not related	Permanent discontinuation of study agent	No /No
								100	56	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	118	49	Resolved	Yes	Severe	Not related	None/not applicable	No /No

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Injection-site Reaction[c, d]
			7207-00009	2[redacted]/M	GERMANY/Caucasian			100	30	鼻咽頭炎	COMMON COLD	47	10	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	58	鼻咽頭炎	COMMON COLD	62	11	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	112	湿性咳嗽	PRODUCTIVE COUGH	119	10	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	112	潰瘍性大腸炎	ULCERATIVE COLITIS FLARE	122	7	Resolved	Yes	Severe	Unlikely	Permanent discontinuation of study agent	No /No
			7209-00008	5[redacted]/F	GERMANY/Caucasian			100	1	肛門周囲痛	ANAL PAIN	4	19	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	1	肛門直腸不快感	ANAL SWELLING	4	19	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	22	末梢性浮腫	EDEMA OF THE LEGS	22		Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	22	丹毒	ERYSIPELAS	52	6	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	57	潰瘍性大腸炎	WORSENING OF DISEASE OF UC	139	15	Resolved	Yes	Severe	Unlikely	None/not applicable	No /No
			7234-00001	2[redacted]/F	HUNGARY/Caucasian			100	1	貧血	ANAEMIA WORSENED	23	5	Resolved	Yes	Mild	Not related	None/not applicable	No /No
								100	84	好中球減少症	NEUTROPENIA	84	36	Resolved	No	Mild	Possible	None/not applicable	No /No
			7235-00001	3[redacted]/F	HUNGARY/Caucasian			100	1	発熱	FEVER	5	13	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	1	肛門の炎症	PERIRECTAL INFLAMMATION	6	12	Resolved	No	Moderate	Possible	None/not applicable	Yes/No

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Injection-site Reaction[c, d]
								100	55	肛門膿瘍	PERIANAL ABSCESS	56	3	Resolved	Yes	Moderate	Unlikely	None/not applicable	Yes/No
								100	99	潰瘍性大腸炎	WORSENING OF UC	120	14	Resolved	No	Severe	Not related	Permanent discontinuation of study agent	No /No
			7257-00004	4[redacted]/F	INDIA/Asian			100	57	失神	MITCURITION SYNCOPE	78	13	Resolved	Yes	Severe	Unlikely	Temporary interruption /dose modification	No /No
			7376-00001	3[redacted]/F	NEWZEALAND/Caucasian			100	1	潰瘍性大腸炎	WORSENING UC			Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	1	寝汗	NIGHT SWEATS	25		Not Resolved	No	Mild	Possible	None/not applicable	No /No
								100	1	舌腫脹	SWOLLEN TONGUE	27	1	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	1	頭痛	HEADACHES INTERMITTENTLY	27		Not Resolved	No	Moderate	Possible	None/not applicable	No /No
								100	29	インフルエンザ様疾患	FLU-LIKE ILLNESS	46		Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	29	脱水	DEHYDRATION	49	1	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	52	膵炎	PANCREATITIS	57	16	Resolved	Yes	Severe	Unlikely	Permanent discontinuation of study agent	No /No
			7377-00001	3[redacted]/F	NEWZEALAND/Caucasian			100	85	潰瘍性大腸炎	WORSENING OF U/C REQUIRING HOSPITAL ADMISSION	107	134	Resolved	Yes	Severe	Unlikely	Permanent discontinuation of study agent	No /No
								100	85	頭痛	HEADACHE	107	2	Resolved	No	Severe	Unlikely	None/not applicable	No /No

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			7378-00004	3[redacted]/M	NEWZEALAND/Caucasian			100	27	鼻咽頭炎	HEADCOLD	31	6	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	27	頚部痛	NECK ACHE	43	255	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	83	喘息	EXACERBATION OF ASTHMA	88	16	Resolved	No	Moderate	Not related	None/not applicable	Yes/No
								100	83	毛包炎	FOLICULITIS	89	508	Resolved	No	Mild	Possible	None/not applicable	Yes/No
								100	83	胃腸炎	GASTROENTERITIS	108	2	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	110	痔核	HAEMORRHOIDS	111	107	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	169	背部痛	EXACERBATION OF BACK PAIN	187	120	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	195	ウイルス感染	VIRAL ILLNESS	203	15	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	247	せつ	BOILS ON LOWER ABDOMEN	268	305	Resolved	No	Mild	Probable	None/not applicable	Yes/No
								100	279	便通不規則	DIFFICULTY DEFECATING	292	4	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	279	排尿困難	DIFFICULTY URINATING	292	9	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	279	感覚鈍麻	NUMBNESS IN BOTH LEGS	292	15	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	279	四肢痛	BILATERAL ARM PAIN	292	15	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	279	椎間板炎	POSSIBLE DISCITIS	295	9	Resolved	Yes	Severe	Unlikely	None/not applicable	No /No
								100	279	口内乾燥	DRY MOUTH	296	2	Resolved	No	Mild	Unlikely	None/not applicable	No /No

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Injection-site Reaction[c,d]
								100	279	筋痙縮	NECK SPASM	297	1	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	279	感覚鈍麻	NUMBNESS IN BUTTOCKS	299	8	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
			7402-00002	5[redacted]/F	POLAND/ Caucasian			100	310	腸炎	ACUTE ENTEROCOLITIS	334	13	Resolved	Yes	Severe	Unlikely	Temporary interruption /dose modification	Yes/No
			7415-00005	3[redacted]/M	POLAND/ Caucasian			100	199	裂肛	ANAL FISSURAE	219	150	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	309	貧血	ANAEMIA	337	43	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	337	咽頭炎	PHARYNGITIS	351	4	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	365	裂肛	ANAL FISSURAE	367	2	Resolved	Yes	Mild	Not related	None/not applicable	No /No
			7460-00003	2[redacted]/M	RUSSIANFEDERATION/Other			100	344	虫垂炎	APPENDICITIS	347	4	Resolved	Yes	Mild	Not related	None/not applicable	No /No
			7716-00006	3[redacted]/M	UNITEDSTATES/Caucasian			100	57	鉄欠乏性貧血	IRON DEFICIENCY ANEMIA	57	9	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	57	鉄欠乏性貧血	WORSENING OF IRON DEFICIENCY ANEMIA	65	4	Resolved	Yes	Moderate	Unlikely	None/not applicable	No /No
								100	57	悪心	NAUSEA	65	4	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	57	腹痛	ABDOMINAL PAIN	65	4	Resolved	No	Mild	Not related	None/not applicable	No /No
			7722-00004	3[redacted]/M	UNITEDSTATES/Caucasian			100	52	潰瘍性大腸炎	EXACERBATION OF ULCERATIVE COLITIS	67	8	Resolved	Yes	Moderate	Not related	Permanent discontinuation of study agent	No /No

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			7775-00001	5[redacted]/F	UNITEDSTATES/Black			100	1	甲状腺癌	HURTHLE CELL CARCINOMA	1	205	Resolved	Yes	Mild	Possible	Permanent discontinuation of study agent	No /No
								100	1	甲状腺癌	HURTHLE CELL CARCINOMA	1		Not Resolved	Yes	Mild	Possible	None/not applicable	No /No
								100	1	直腸ポリープ	RECTAL PSEUDOPOLYPS	1	1	Resolved	No	Mild	Possible	None/not applicable	No /No
								100	1	疲労	FATIGUE	17	8	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1	眼瞼炎	BLEPHARITIS IN BOTH EYES	24		Not Resolved	No	Mild	Possible	None/not applicable	Yes/No
								100	1	ブドウ球菌感染	MRSA LEASION ON ABDOMEN	24		Not Resolved	No	Moderate	Possible	None/not applicable	Yes/No
								100	91	頚部痛	PAIN IN RIGHT SIDE OF NECK	91		Not Resolved	No	Mild	Possible	None/not applicable	No /No
								100	91	関節痛	JOINT PAIN IN HANDS, WRISTS, KNEES, AND ANKLES	105		Not Resolved	No	Mild	Possible	None/not applicable	No /No
			7786-00001	2[redacted]/M	UNITEDSTATES/Asian			100	1	偶発的中毒	ACCIDENTAL POISONING OF CAMPHOR	16	2	Resolved	Yes	Moderate	Not related	None/not applicable	No /No
								100	31	咳嗽	COUGH	59	99	Resolved	No	Mild	Possible	None/not applicable	No /No
								100	31	爪変色	DISCOLORATION OF TOENAILS ON BOTH FEET	59	8	Resolved	No	Mild	Possible	None/not applicable	No /No

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Injection-site Reaction[c, d]
								100	59	回転性めまい	VERTIGO	59	1	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	59	四肢痛	PAIN IN RIGHT FOREARM	60	3	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	59	鼻閉	NASAL CONGESTION	77	208	Resolved	No	Mild	Possible	None/not applicable	No /No
								100	92	頭痛	HEADACHE	98	13	Resolved	No	Moderate	Possible	None/not applicable	No /No
								100	92	倦怠感	MALAISE	98	13	Resolved	No	Moderate	Possible	None/not applicable	No /No
								100	92	胸痛	CHEST PAIN	110	33	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	142	口腔咽頭痛	SORE THROAT	157	78	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	199	咳嗽	COUGH	234	51	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	254	皮脂欠乏性湿疹	WINTER ITCH (DRY ITCHY SKIN)	255	30	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	254	上強膜炎	EPISCLERITIS	255	30	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	254	外耳炎	OTITIS EXTERNA	255	83	Resolved	No	Moderate	Possible	None/not applicable	No /No
								100	254	眼瞼炎	EYELID DERMATITIS	255	30	Resolved	No	Moderate	Possible	None/not applicable	No /No
								100	284	上強膜炎	EPISCLERITIS	291	13	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	284	眼瞼炎	EYELID DERMATITIS	291	13	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	284	外耳炎	OTITIS EXTERNA	298	20	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	309	上強膜炎	EPISCLERITIS	335		Not Resolved	No	Moderate	Unlikely	None/not applicable	No /No

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								100	309	眼瞼炎	EYELID DERMATITIS	335	3	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
			7809-00002	5[redacted]/M	JAPAN/Asian			100	30	発熱	FEVER UP	31	4	Resolved	No	Mild	Definite	None/not applicable	No /No
								100	79	上気道感染	URI	81	4	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	79	上気道感染	URI	91	17	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	163	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	173		Not Resolved	Yes	Severe	Not related	Permanent discontinuation of study agent	No /No
								100	163	背部痛	ACUTE LUMBAR PAIN	275		Not Resolved	No	Mild	Not related	None/not applicable	No /No
			7812-00002	6[redacted]/F	JAPAN/Asian			100	1	直腸癌	ADENOCARCINOMA OF RECTUM	15	50	Resolved	Yes	Severe	Not related	Permanent discontinuation of study agent	No /No
			7813-00001	4[redacted]/M	JAPAN/Asian			100	1	湿疹	CHRONICCZEMA AGGRAVATED			Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1	潰瘍性大腸炎	EXCERBATION OF UC	8	16	Resolved	No	Moderate	Not related	Permanent discontinuation of study agent	No /No
								100	1	潰瘍性大腸炎	EXCERBATION OF UC	23	30	Resolved	Yes	Moderate	Not related	Permanent discontinuation of study agent	No /No
								100	1	湿疹	CHRONIC ECZEMA AGGRAVATED	50	29	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1	鼻咽頭炎	COLD	77	23	Resolved	No	Mild	Not related	None/not applicable	Yes/No

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Injection-site Reaction[c, d]
								100	1	高アミラーゼ血症	HYPERAMYLASAEMIA	78	43	Resolved	No	Mild	Not related	None/not applicable	No /No
	Golimumab 100 mg (Golimumab induction nonresponder)	1 mg/kg IV	6004-00001	2[redacted]/M	AUSTRALIA/Caucasian			100	1	白血球減少症	LEUKOPENIA	1	8	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	22	悪心	NAUSEA	31	7	Resolved	No	Severe	Unlikely	Permanent discontinuation of study agent	No /No
								100	22	嘔吐	VOMITING	31	14	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	22	潰瘍性大腸炎	REFRACTORY ULCERATIVE COLITIS	34	35	Resolved	Yes	Severe	Unlikely	Permanent discontinuation of study agent	No /No
			6406-00004	2[redacted]/M	POLAND/ Caucasian			100	1	発熱	FEVER OF UNKNOWN ORIGIN	12	25	Resolved	No	Severe	Unlikely	Permanent discontinuation of study agent	Yes/No
								100	1	潰瘍性大腸炎	EXACERBATION OF ULCERATIVE COLITIS	19	18	Resolved	Yes	Severe	Unlikely	Permanent discontinuation of study agent	Yes/No
		2 mg/kg IV	6260-00002	5[redacted]/F	INDIA/Asian			100	28	栄養障害	MALNUTRITION	57	199	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	231	無力症	WEAKNESS	251	9	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	231	腹痛	MILD ABDOMINAL PAIN	254	1	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	255	無力症	WEAKNESS	284	6	Resolved	No	Mild	Not related	None/not applicable	No /No

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								100	288	無力症	WEAKNESS	297		Not Resolved	No	Mild	Not related	None/not applicable	No /No
								100	288	発熱	FEVER	301	2	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	288	栄養障害	MALNUTRITION	311	52	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	338	栄養障害	MALNUTRITION	362	3	Resolved	Yes	Severe	Not related	None/not applicable	No /No
								100	338	敗血症性ショック	SEPTIC SHOCK	363	2	Resolved	Yes	Severe	Not related	None/not applicable	Yes/No
			6407-00012	2[redacted]/M	POLAND/ Caucasian			100	57	頭痛	HEADACHE	68		Not Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	139	潰瘍性大腸炎	PROGRESSION OF ULCERATIVE COLITIS	157	12	Resolved	Yes	Severe	Not related	Permanent discontinuation of study agent	No /No
			6726-00011	2[redacted]/F	UNITEDSTATES/Caucasian			100	1	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	3	8	Resolved	Yes	Severe	Not related	None/not applicable	No /No
			6747-00006	6[redacted]/M	UNITEDSTATES/Caucasian			100	89	胃食道逆流性疾患	GERD	107		Not Resolved	No	Mild	Not related	None/not applicable	No /No
								100	89	関節痛	JOINT PAIN	107		Resolved	No	Mild	Not related	None/not applicable	No /No
								100	89	狭心症	PROGRESSIVE ANGINA	107	2	Resolved	Yes	Mild	Unlikely	None/not applicable	No /No
								100	89	冠動脈疾患	CORONARY ARTERY DISEASE	107		Not Resolved	No	Mild	Not related	None/not applicable	No /No
								100	89	糖尿病	DIABETES	107		Not Resolved	No	Mild	Not related	None/not applicable	No /No
								100	89	高コレステロール血症	HYPERCHOLESTEROLEMIA	107		Not Resolved	No	Mild	Not related	None/not applicable	No /No

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		4 mg/kg IV	6006-00008	6[redacted]/F	AUSTRALIA/Caucasian			100	1	口腔ヘルペス	ORAL COLD SORE	3	11	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	29	口腔ヘルペス	ORAL COLD SORE	29	11	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	29	外陰部腟カンジダ症	VAGINAL THRUSH	38	11	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	29	静脈瘤	DILATED LOWER LIMB VARICOSE	45	12	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	29	口腔ヘルペス	ORAL COLD SORE	52	11	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	29	潰瘍性大腸炎	REFRACTORY ULCERATIVE COLITIS	52	11	Resolved	Yes	Severe	Unlikely	Permanent discontinuation of study agent	No /No
			6052-00001	2[redacted]/M	BELGIUM/Caucasian			100	1	節足動物咬傷	ALLERGIC SKIN REACTION TO MOSQUITOBITES	27	115	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	29	毛巣嚢胞	PILONIDAL CYST, INFECTED	82	2	Resolved	Yes	Moderate	Not related	None/not applicable	Yes/No
			6252-00009	2[redacted]/M	INDIA/Asian			100	255	発熱	FEVER	272	4	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	278	播種性結核	MILLIARY TUBERCULOSIS	288	292	Resolved	Yes	Moderate	Probable	Permanent discontinuation of study agent	Yes/No
			6279-00003	3[redacted]/F	ISRAEL/Caucasian			100	25	潰瘍性大腸炎	EXACERBETION OF UC	41	36	Resolved	Yes	Severe	Not related	Permanent discontinuation of study agent	No /No

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Injection-site Reaction[c, d]
			6378-00002	6[redacted]/M	NEWZEALAND/Caucasian			100	1	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	11	21	Resolved	No	Severe	Unlikely	Permanent discontinuation of study agent	No /No
								100	1	潰瘍性大腸炎	ACTIVE ULCERATIVE COLITIS	31	57	Resolved	Yes	Severe	Unlikely	None/not applicable	No /No
								100	1	潰瘍性大腸炎	HIGH STOMA OUTPUT, SECONDARY TO PANPROCTOCOLECTOMY FOR UC	90	5	Resolved	Yes	Moderate	Not related	None/not applicable	No /No
								100	1	表在性血栓性静脈炎	SUPERFICIAL VENOUS THROMBOSIS LEFT LOWER LEG	96		Not Resolved	Yes	Moderate	Not related	None/not applicable	No /No
			6407-00016	2[redacted]/M	POLAND/Caucasian			100	56	潰瘍性大腸炎	PROGRESSION OF ULCERATIVE COLITIS.	68	9	Resolved	Yes	Moderate	Unlikely	Permanent discontinuation of study agent	No /No
								100	56	潰瘍性大腸炎	PROGRESSION OF ULCERATIVE COLITIS	89	46	Resolved	Yes	Moderate	Unlikely	Permanent discontinuation of study agent	No /No
		100 mg/50 mg SC	7003-00004	3[redacted]/F	AUSTRALIA/Caucasian			100	1	不安	ANXIETY	8	24	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	65	潰瘍性大腸炎	CHRONICALLY ACTIVE ULCERATIVE COLITIS	80	8	Resolved	Yes	Severe	Not related	Permanent discontinuation of study agent	No /No
			7204-00005	5[redacted]/F	GERMANY/Caucasian			100	1	帯状疱疹	HERPES ZOSTER			Resolved	No	Moderate	Possible	None/not applicable	Yes/No

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								100	1	裂肛	ANAL FISSURE	1	24	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1	潰瘍性大腸炎	WORSENING OF UC	14	22	Resolved	Yes	Severe	Not related	Permanent discontinuation of study agent	No /No
								100	1	クロストリジウム感染	INFECTION CLOSTRIDIUM	17	12	Resolved	No	Moderate	Possible	None/not applicable	Yes/No
								100	1	瘢痕ヘルニア	ABDOMINAL INCISIONAL HERNIA	70	10	Resolved	Yes	Moderate	Not related	None/not applicable	No /No
								100	1	潰瘍性大腸炎	ACUTE FLARE OF UC	83	4	Resolved	Yes	Severe	Not related	None/not applicable	No /No
								100	1	季節性アレルギー	HAY FEVER	102		Not Resolved	No	Mild	Not related	None/not applicable	No /No
			7262-00004	3[redacted]/M	INDIA/Asian			100	1	骨壊死	AVASCULAR NECROSIS OF HIP JOINT	11	303	Resolved	Yes	Moderate	Not related	None/not applicable	No /No
								100	30	関節痛	PAIN IN SMALL JOINTS, FINGER,KNEES	55	33	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	30	筋骨格痛	MILD PAIN IN RIGHT SHOULDER	55	33	Resolved	No	Mild	Not related	None/not applicable	No /No
			7427-00004	2[redacted]/F	ROMANIA /Caucasian			100	119	低カルシウム血症	HIPOCALCEMIA	140		Not Resolved	No	Mild	Not related	None/not applicable	No /No
								100	119	腹痛	ABDOMINAL PAIN	140		Not Resolved	No	Mild	Not related	None/not applicable	No /No
								100	119	血小板増加症	THROMBOCYTOSIS	140		Not Resolved	No	Moderate	Not related	None/not applicable	No /No

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								100	119	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	141	24	Resolved	Yes	Moderate	Not related	Permanent discontinuation of study agent	No /No
		200 mg/100 mg SC	6233-00002	2[redacted]/M	HUNGARY/Caucasian			100	1	潰瘍性大腸炎	WORSENING OF UC	20	8	Resolved	Yes	Moderate	Not related	None/not applicable	No /No
			6279-00006	4[redacted]/F	ISRAEL/Caucasian			100	1	肺炎	PNEUMONIA	15	15	Resolved	No	Mild	Possible	None/not applicable	Yes/No
								100	54	腎盂腎炎	PYELONEPHRITIS	107	8	Resolved	Yes	Moderate	Possible	None/not applicable	Yes/No
			6352-00004	4[redacted]/M	NETHERLANDS/Caucasian			100	58	潰瘍性大腸炎	WORSENING OF UC	98	6	Resolved	Yes	Severe	Not related	None/not applicable	No /No
			6407-00031	5[redacted]/M	POLAND/ Caucasian			100	169	播種性結核	MILIARY TUBERCULOSIS	179	28	Resolved	Yes	Severe	Definite	Permanent discontinuation of study agent	Yes/No
			6501-00015	5[redacted]/M	SLOVAKIA(SlovakRepublic)/Caucasian			100	196	血便排泄	RISE OF AMMOUNT OF BLOOD IN STOOL	217	8	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	196	鼻咽頭炎	COMMON COLD	217	8	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	253	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	253	15	Resolved	Yes	Severe	Unlikely	Permanent discontinuation of study agent	No /No
			7005-00006	3[redacted]/F	AUSTRALIA/Caucasian			100	29	喉頭炎	LARYNGITIS	37	72	Resolved	No	Mild	Possible	None/not applicable	Yes/No
								100	58	潰瘍性大腸炎	FLARE OF ULCERATIVE COLITIS	100	4	Resolved	Yes	Mild	Not related	None/not applicable	No /No
								100	58	鼻咽頭炎	COLD	100	2	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Injection-site Reaction[c,d]
			7007-00002	6[redacted]/M	AUSTRALIA/Caucasian			100	308	側腹部痛	RIGHT FLANK PAIN			Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	336	腎仙痛	RENAL COLIC	359	324	Resolved	Yes	Moderate	Not related	None/not applicable	No /No
								100	336	便秘	CONSTIPATION	361	9	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	336	悪心	NAUSEA	362	1	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	336	不整脈	IRREGULAR HEART BEAT	362	3	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	336	心房細動	ATRIAL FIBRILATION	364	2	Resolved	No	Moderate	Not related	None/not applicable	No /No
			7008-00011	7[redacted]/F	AUSTRALIA/Caucasian			100	1	医療機器合併症	WORSENING OF DENTAL PROSTHESIS			Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	1	関節損傷	ANKLE INJURY FLARE UP (INITIAL INJURY 2YRS AGO)	1		Not Resolved	No	Mild	Not related	None/not applicable	No /No
								100	113	感染性皮膚潰瘍	INFECTION OF LEFT LOWER LEG ULCER	118	13	Resolved	No	Mild	Possible	None/not applicable	Yes/No
								100	169	感染性皮膚潰瘍	INFECTION OF LEFT LOWER LEG ULCER	172		Not Resolved	No	Mild	Possible	None/not applicable	Yes/No
								100	169	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	264	10	Resolved	Yes	Severe	Not related	Permanent discontinuation of study agent	No /No

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			7129-00005	2[redacted]/M	DENMARK/Caucasian			100	30	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS NECESSITATING COLECTOMI	70	10	Resolved	Yes	Moderate	Not related	None/not applicable	No /No
								100	30	イレウス	ILEUS	80	2	Resolved	Yes	Severe	Not related	None/not applicable	No /No
								100	30	敗血症	SEPSIS	81	7	Resolved	Yes	Severe	Possible	None/not applicable	Yes/No
								100	30	深部静脈血栓症	DEEP VENOUS TROMBOSIS IN THE TRUNCUS BRACHIO CEPHALICUS SINISTER	89	54	Resolved	Yes	Severe	Unlikely	None/not applicable	No /No
								100	30	肺塞栓症	EMBOLI OF THE LUNGS.	89	11	Resolved	Yes	Severe	Unlikely	None/not applicable	No /No
								100	30	処置後合併症	RUPTURE VULNERIS POSTOPERATIVA = RUPTURE OF THE POSTOPERATIVE SCAR AFTER COLECTOMI (REMOVAL OF THE COLON)	90	23	Resolved	Yes	Moderate	Unlikely	None/not applicable	No /No
			7238-00002	6[redacted]/F	HUNGARY/Caucasian			100	308	心房細動	ATRIAL FIBRILLATION	316	9	Resolved	Yes	Moderate	Not related	None/not applicable	No /No
								100	308	高血圧	WORSENING OF HYPERTENSION	316	9	Resolved	Yes	Moderate	Not related	None/not applicable	No /No

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Injection-site Reaction[c, d]
								100	308	狭心症	ANGINA PECTORIS	316	9	Resolved	Yes	Moderate	Not related	None/not applicable	No /No
			7407-00007	5[redacted]/M	POLAND/ Caucasian			100	1	関節痛	PAIN OF ELBOW JOINT	29	113	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	226	気道感染	INFECTIO RESPIRATORIA	252	9	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	282	潰瘍性大腸炎	EXACERBATION OF ULCERATIVE COLITIS	294	17	Resolved	Yes	Moderate	Not related	Permanent discontinuation of study agent	No /No
			7411-00002	3[redacted]/M	POLAND/ Caucasian			100	28	気管支炎	BROCHITIS	48	6	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	175	機械的イレウス	MECHANICAL ILEUS-TORSION OF THE SMALL INTESTINE	193	13	Resolved	Yes	Severe	Not related	None/not applicable	No /No
			7528-00001	6[redacted]/M	SOUTHAFRICA/Caucasian			100	1	脳膿瘍	MULTIPLE BRAIN ABSCESSES	128	59	Resolved	Yes	Severe	Not related	None/not applicable	Yes/No
			7530-00011	6[redacted]/F	SOUTHAFRICA/Other			100	1	頭痛	HEADACHES	3	41	Resolved	No	Moderate	Possible	None/not applicable	No /No
								100	85	疲労	FATIGUE	89		Not Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	144	膀胱炎	CYSTITIS	170	29	Resolved	No	Moderate	Not related	None/not applicable	Yes/No
								100	170	糸球体腎炎	GLOMERULONEPHRITIS	198	38	Resolved	No	Moderate	Not related	None/not applicable	Yes/No
								100	170	貧血	ANAEMIA	200		Not Resolved	No	Mild	Not related	None/not applicable	No /No
								100	200	血尿	HAEMATURIA	213	23	Resolved	No	Moderate	Not related	None/not applicable	Yes/No

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Injection-site Reaction[c,d]
								100	200	尿中白血球陽性	LEUCOCYTES IN URINE	225	11	Resolved	No	Moderate	Unlikely	None/not applicable	Yes/No
								100	225	胸水	PLEURAL EFFUSION LEFT	225	12	Resolved	Yes	Moderate	Not related	None/not applicable	Yes/No
								100	225	悪心	NAUSEA	236	18	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	225	嘔吐	VOMITING	236	18	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	225	肝炎	DRUG INDUCED HEPATITIS	249	29	Resolved	Yes	Severe	Not related	Permanent discontinuation of study agent	No /No
								100	225	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	251	12	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	225	便秘	CONSTIPATION	258	1	Resolved	No	Moderate	Not related	None/not applicable	No /No
			7739-00001	2[redacted]/F	UNITEDSTATES/Caucasian			100	29	悪心	WORSENING OF NAUSEA	35	2	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	29	発熱	PYREXIA	35	2	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	29	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	49	12	Resolved	Yes	Severe	Unlikely	Permanent discontinuation of study agent	No /No
								100	29	尿路感染	URINARY TRACT INFECTION	49	12	Resolved	Yes	Moderate	Possible	None/not applicable	Yes/No
								100	29	結節性紅斑	ERYTHEMA NODOSUM	50	11	Resolved	No	Severe	Possible	Permanent discontinuation of study agent	No /No

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Injection-site Reaction[c, d]
								100	29	悪心	WORSENING OF NAUSEA	51	10	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	29	発熱	PYREXIA	54	7	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	29	肛門皮膚垂	WORSENING OF ANAL TAG INFLAMATION	63	24	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
			7741-00002	5[redacted]/M	UNITEDSTATES/Caucasian			100	1	潰瘍性大腸炎	ULCERATIVE COLITIS WITH POSSIBLE FLARE	3	4	Resolved	Yes	Moderate	Not related	None/not applicable	Yes/No
								100	1	急性腎不全	ACUTE RENAL FAILURE	3	4	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	1	低ナトリウム血症	HYPONATREMIA	3	4	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	1	血液量減少症	HYPOVOLEMIA	3	4	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
			7746-00005	4[redacted]/M	UNITEDSTATES/Caucasian			100	1	急性膵炎	ACUTE PANCREATITIS	16	5	Resolved	Yes	Moderate	Unlikely	None/not applicable	Yes/No
								100	141	口腔咽頭痛	SORE THROAT	162	3	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	197	血圧上昇	ELEVATED BLOOD PRESSURE	225		Not Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	251	鼻閉	NASAL CONGESTION	261	6	Resolved	No	Mild	Not related	None/not applicable	No /No
			7746-00010	6[redacted]/M	UNITEDSTATES/Caucasian			100	113	末梢性浮腫	BILATERAL LOWER EXTREMITY EDEMA			Not Resolved	No	Moderate	Not related	None/not applicable	No /No

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Injection-site Reaction[c,d]
								100	113	下痢	INTRACTABLE DIARRHEA	177	5	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	113	レンサ球菌性敗血症	STREPTOCOCCAL PNEUMONIA SEPSIS	177	5	Resolved	Yes	Severe	Not related	None/not applicable	Yes/No
								100	113	高血糖	HYPERGLYCEMIA	177	5	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	113	振戦	BILATERAL HAND TREMORS	197		Not Resolved	No	Mild	Not related	None/not applicable	No /No
			7755-00001	4[redacted]/M	UNITEDSTATES/Caucasian			100	1	バレット食道	BARRETT'S ESOPHAGUS	45		Not Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1	毛孔性皮疹	FOLLICULAR RASH ON BACK	107	7	Resolved	No	Severe	Not related	None/not applicable	No /No
								100	1	ブドウ球菌性菌血症	METHICILLIN SENSITIVE STAPHYLOCCUS AUREUS BACTEREMIA	107	7	Resolved	Yes	Moderate	Unlikely	None/not applicable	Yes/No
								100	1	憩室炎	ACUTE DIVERTICULITIS	107	3	Resolved	No	Mild	Not related	None/not applicable	Yes/No
								100	1	低カリウム血症	HYPOKALEMIA	107	7	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	1	不眠症	INSOMNIA	111	3	Resolved	No	Moderate	Not related	None/not applicable	No /No
			7805-00003	4[redacted]/M	JAPAN/Asian			100	142	鉄欠乏性貧血	IRON DEFICIENCY ANEMIA	156	53	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	142	潰瘍性大腸炎	WORSENING OF UC	207	12	Resolved	Yes	Moderate	Not related	None/not applicable	No /No

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Injection-site Reaction[c,d]
			7808-00001	5[redacted]/F	JAPAN/Asian			100	198	結腸ポリープ	COLONIC POLYP	210	15	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	219	結腸ポリープ	COLONIC POLYP	224	3	Resolved	Yes	Moderate	Not related	None/not applicable	No /No
								100	366	結腸ポリープ	COLONIC POLYP	379	41	Resolved	No	Moderate	Not related	None/not applicable	No /No
		400 mg/200 mg SC	6112-00008	4[redacted]/M	CANADA/ Caucasian			100	78	うつ病	POSSIBLE DEPRESSION	101	34	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	134	薬効欠如	ULCERATIVE COLITIS, LACK OF EFFICACY OF STUDY DRUG	170	8	Resolved	Yes	Moderate	Unlikely	None/not applicable	No /No
			6112-00013	4[redacted]/M	CANADA/ Caucasian			100	1	嘔吐	EMESIS	32	3	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	35	脱水	ACUTE RENAL FAILURE DUE TO DEHYDRATION	35	9	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	35	脱水	DEHYDRATION	35	9	Resolved	Yes	Severe	Unlikely	None/not applicable	No /No
								100	82	錯乱状態	INTERMITTENT MENTAL CONFUSION	107		Not Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	82	薬効欠如	ULCERATIVE COLITIS, LACK OF EFFICACY OF STUDY DRUG	136	8	Resolved	Yes	Moderate	Unlikely	Permanent discontinuation of study agent	No /No
								100	82	重複尿管	DIVISION OF LEFT URETER	136	1	Resolved	No	Moderate	Unlikely	None/not applicable	No /No

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Injection-site Reaction[c,d]
			6112-00016	3[redacted]/F	CANADA/ Caucasian			100	1	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	31	10	Resolved	Yes	Severe	Unlikely	None/not applicable	No /No
								100	1	痔核	HEMORRHOIDS	31	12	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
								100	1	術後膿瘍	POST-COLECTOMY PELVIC ABSCESS	42	10	Resolved	Yes	Moderate	Not related	None/not applicable	Yes/No
			6115-00003	1[redacted]/F	CANADA/ Caucasian			100	1	潰瘍性大腸炎	LACK OF IMPROVEMENT IN ULCERATIVE COLITIS	25	51	Resolved	Yes	Severe	Not related	Permanent discontinuation of study agent	No /No
			6177-00012	5[redacted]/M	FRANCE/Caucasian			100	1	骨亀裂	MENISCAL FISSURE	6	2	Resolved	Yes	Mild	Not related	None/not applicable	No /No
								100	1	静脈炎	PHLEBITIS	112		Resolved	No	Mild	Not related	None/not applicable	No /No
			6207-00001	2[redacted]/M	GERMANY/Caucasian			100	1	排便回数増加	INCREASED FREQUENCY OF STOOLS	2	24	Resolved	No	Severe	Possible	None/not applicable	No /No
								100	1	体重減少	WEIGHT LOSS(10 KG)	2	25	Resolved	No	Moderate	Possible	None/not applicable	No /No
								100	1	発熱	INTERMITTEND FEVER(MAX. 38.5 °C)	19		Not Resolved	No	Moderate	Possible	None/not applicable	No /No
								100	1	寝汗	NIGHT SWEATING	19		Not Resolved	No	Moderate	Possible	None/not applicable	No /No
								100	1	潰瘍性大腸炎	SEVERE FLARE OF ULCERATIVE COLITIS	26	17	Resolved	Yes	Severe	Not related	Permanent discontinuation of study agent	No /No
			6281-00010	4[redacted]/M	ISRAEL/Caucasian			100	1	潰瘍性大腸炎	ULCERATIVE COLITIS EXACERBATION	10	33	Resolved	No	Moderate	Not related	Permanent discontinuation of study agent	No /No

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Injection-site Reaction[c,d]
								100	22	潰瘍性大腸炎	ULCERATIVE COLITIS EXACERBATION	42	16	Resolved	Yes	Severe	Not related	None/not applicable	No /No
			7001-00006	4[redacted]/M	AUSTRALIA/Caucasian			100	1	咳嗽	COUGH	23	5	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	29	貧血	ANAEMIA	57	151	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	57	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	88	4	Resolved	Yes	Moderate	Unlikely	None/not applicable	No /No
								100	57	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	157	16	Resolved	Yes	Severe	Unlikely	None/not applicable	No /No
								100	57	痛風	GOUT	169	34	Resolved	No	Mild	Not related	None/not applicable	No /No
			7002-00001	4[redacted]/F	AUSTRALIA/Caucasian			100	29	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	63	1	Resolved	Yes	Severe	Not related	None/not applicable	No /No
			7002-00003	4[redacted]/M	AUSTRALIA/Caucasian			100	1	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	26	13	Resolved	Yes	Severe	Not related	None/not applicable	No /No
			7002-00004	6[redacted]/M	AUSTRALIA/Caucasian			100	1	病変部切除	PIGMENTED LESION RIGHT DELTOID REMOVED			Resolved	No	Mild	Not related	None/not applicable	No /No
								100	85	潰瘍性大腸炎	WORSENING UC	135	1	Resolved	Yes	Severe	Not related	None/not applicable	No /No
			7002-00005	4[redacted]/F	AUSTRALIA/Caucasian			100	84	潰瘍性大腸炎	WORSENING OF UC	170	1	Resolved	Yes	Severe	Not related	None/not applicable	No /No

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			7005-00005	6[redacted]/M	AUSTRALIA/Caucasian			100	29	潰瘍性大腸炎	LACK OF IMPROVEMENT OF ULCERATIVE COLITIS	71	14	Resolved	Yes	Severe	Not related	None/not applicable	No /No
								100	29	肺炎	PNEUMONIA	77	4	Resolved	No	Moderate	Possible	None/not applicable	Yes/No
								100	29	低カリウム血症	HYPOKALAEMIA	78	23	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	29	低マグネシウム血症	HYPOMAGNESEMIA	80	21	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	29	関節痛	JOINT PAIN	92		Not Resolved	No	Moderate	Not related	None/not applicable	No /No
			7079-00010	3[redacted]/M	BULGARIA/Caucasian			100	1	血小板増加症	THROMBOCITOSIS	1	61	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	1	貧血	WORSENING OF ANAEMIA	33	12	Resolved	Yes	Severe	Not related	None/not applicable	No /No
								100	1	潰瘍性大腸炎	UC EXACERBATION.	33	12	Resolved	Yes	Severe	Not related	None/not applicable	No /No
								100	230	貧血	ANAEMIA	251	85	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	230	好酸球増加症	EOSINOPHILIA	251	57	Resolved	No	Mild	Not related	None/not applicable	No /No
			7116-00006	2[redacted]/F	CANADA/ Caucasian			100	1	潰瘍性大腸炎	EXACERBATION OF ULCERATIVE COLITIS LEADING TO COLECTOMY	16	11	Resolved	Yes	Severe	Not related	Permanent discontinuation of study agent	No /No
			7126-00015	2[redacted]/M	DENMARK/Caucasian			100	1	胃腸炎	GASTROENTERITIS	16	11	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Injection-site Reaction[c,d]
								100	29	潰瘍性大腸炎	EXACERBATION OF ULCERATIVE COLITIS (DISEASE PROGRESSION)	30	3	Resolved	Yes	Moderate	Unlikely	None/not applicable	No /No
								100	29	鉄欠乏	ION DIFFICIENCY	31	14	Resolved	No	Mild	Unlikely	None/not applicable	No /No
			7204-00013	3[redacted]/F	GERMANY/Caucasian			100	28	気道感染	RESPIRATORY INFECTION	40	17	Resolved	No	Moderate	Possible	None/not applicable	Yes/No
								100	84	潰瘍性大腸炎	WORSENING OF UC	99	17	Resolved	No	Moderate	Unlikely	Permanent discontinuation of study agent	No /No
								100	84	潰瘍性大腸炎	ACUTE WORSENING OF ULCERATIVE COLITIS	115	34	Resolved	Yes	Severe	Unlikely	None/not applicable	No /No
								100	84	尿路感染	INFECTION OF URINARY TRACT	144	7	Resolved	No	Moderate	Not related	None/not applicable	Yes/No
			7206-00004	2[redacted]/F	GERMANY/Caucasian			100	1	鼻咽頭炎	COMMON COLD			Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	1	頭痛	HEADACHE			Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	30	鼻咽頭炎	COMMON COLD			Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	58	潰瘍性大腸炎	EXACERBATION OF ULCERATIVE COLITIS	60	12	Resolved	Yes	Severe	Not related	Permanent discontinuation of study agent	No /No

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Injection-site Reaction[c, d]
			7207-00001	3[redacted]/M	GERMANY/Caucasian			100	1	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	3	12	Resolved	Yes	Severe	Unlikely	None/not applicable	No /No
								100	1	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	18	18	Resolved	Yes	Severe	Unlikely	Permanent discontinuation of study agent	No /No
			7207-00018	5[redacted]/M	GERMANY/Caucasian			100	1	神経根圧迫	NERVE ROOT COMPRESSION SYNDROM	14	17	Resolved	Yes	Severe	Unlikely	None/not applicable	No /No
								100	1	発熱	FEVER	23	8	Resolved	No	Moderate	Possible	None/not applicable	Yes/No
								100	1	腸管虚血	POUCH ISCHEMIA	67	1	Resolved	No	Moderate	Unlikely	None/not applicable	No /No
			7264-00002	4[redacted]/M	INDIA/Asian			100	113	注射部位発疹	RASH OVER THE SITE OF IP ADMINISTRATION	113	1	Resolved	No	Mild	Probable	None/not applicable	No /Yes
								100	225	無力症	GENERALISED WEAKNESS	225	29	Resolved	No	Mild	Unlikely	None/not applicable	No /No
								100	225	好中球減少症	NEUTROPENIA	253	31	Resolved	No	Mild	Possible	None/not applicable	No /No
								100	283	多発性関節炎	SERONEGATIVE POLYARTHRITIS	283	39	Resolved	Yes	Mild	Probable	Permanent discontinuation of study agent	No /No
								100	253	溶血性貧血	DRUG INDUCED HAEMOLYTIC ANAEMIA	283	39	Resolved	Yes	Moderate	Possible	Permanent discontinuation of study agent	No /No

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Injection-site Reaction[c,d]
								100	253	潰瘍性大腸炎	IDIOPATHIC ULCERATIVE COLITIS	283	39	Resolved	Yes	Moderate	Possible	Permanent discontinuation of study agent	No /No
								100	283	無力症	GENERALISED WEAKNESS	312	10	Resolved	No	Mild	Unlikely	Permanent discontinuation of study agent	No /No
								100	283	発熱	FEVER	317	3	Resolved	No	Mild	Not related	None/not applicable	No /No
			7354-00004	6[redacted]/M	NETHERLANDS/Caucasian			100	1	潰瘍性大腸炎	PROGRESSION OF ULCERATIVE COLITIS	15	29	Resolved	Yes	Severe	Not related	Permanent discontinuation of study agent	No /No
			7417-00001	3[redacted]/M	POLAND/ Caucasian			100	36	潰瘍性大腸炎	ANEMIA RELATED TO ULCERATIVE COLITIS	36	3	Resolved	Yes	Moderate	Not related	None/not applicable	No /No
								100	78	ウイルス感染	VIRAL INFECTION	95	3	Resolved	No	Mild	Unlikely	None/not applicable	Yes/No
								100	141	潰瘍性大腸炎	SECONDARY ANEMIA RELATED TO ULCERATIVE COLITIS	155	8	Resolved	Yes	Moderate	Unlikely	None/not applicable	No /No
								100	141	注入部位炎症	INFLAMMATION OF SOFT TISSUE AFTER INFUSION IN THE LEFT BOTTOM OF THE ELBOW.	157	13	Resolved	No	Moderate	Not related	None/not applicable	Yes/No
								100	197	ウイルス感染	VIRAL INFECTION	201	3	Resolved	No	Mild	Not related	None/not applicable	Yes/No

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Injection-site Reaction[c,d]
								100	281	潰瘍性大腸炎	SECONDARY ANEMIA RELATED TO ULCERATIVE COLITIS	289	3	Resolved	Yes	Moderate	Unlikely	None/not applicable	No /No
			7701-00002	3[redacted]/M	UNITEDSTATES/Caucasian			100	113	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	140	8	Resolved	Yes	Moderate	Not related	Permanent discontinuation of study agent	No /No
			7703-00001	3[redacted]/F	UNITEDSTATES/Caucasian			100	198	歯膿瘍	ABCESSED TOOTH	213	6	Resolved	No	Moderate	Not related	None/not applicable	Yes/No
								100	343	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	366	27	Resolved	Yes	Severe	Not related	Permanent discontinuation of study agent	No /No
			7785-00002	6[redacted]/M	UNITEDSTATES/Caucasian			100	84	上気道感染	UPPER RESPIRATORY INFECTION	86	12	Resolved	No	Moderate	Not related	None/not applicable	Yes/No
								100	84	血便排泄	WORSENING OF BLOODY STOOLS	97	232	Resolved	No	Moderate	Not related	None/not applicable	No /No
								100	196	潰瘍性大腸炎	WORSENING OF ULCERATIVE COLITIS	232		Not Resolved	No	Severe	Not related	None/not applicable	No /No
								100	246	胆嚢炎	CHOLECYSITIS	306	11	Resolved	Yes	Severe	Not related	None/not applicable	No /No
								100	246	出血性貧血	BLOOD LOSS ANEMIA	309	1	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	246	血腫	HEMATOMA	309	1	Resolved	No	Mild	Not related	None/not applicable	No /No
								100	246	徐脈	BRADYCARDIA	313	4	Resolved	No	Mild	Not related	None/not applicable	No /No

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Adjustment[a]	Study Day of Dose Adjustment[a]	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection/ Injection-site Reaction[c,d]

[a] For subjects who were dose adjusted to golimumab 200 mg and later had their dose decreased to 100 mg following implementation of Protocol Amendment 3, "Treatment Group At Dose Adjustment" is presented as "200 mg (100 mg)", and "Study Day of Dose adjustment" is presented in the form of xxx (yyy), where xxx is the study day of dose adjustment and yyy is the study day of dose decrease.
[b] Based on MedDRA version 14.0.
[c] Infection as assessed by the investigator.
[d] Injection-site reaction as assessed by the investigator.

表 2.7.4.7-付録-21 重篤な有害事象（T16，T17 及び T18 試験 54 週まで；ランダム化された被験者）

	Golimumab Induction				
	Placebo Maintenance[a]	50 mg Maintenance[a]	100 mg Maintenance[a]	Combined 50 mg and 100 mg Maintenance[a]	Total Golimumab[a,b]
Treated subjects in C0524T16 and C0524T17 who were randomized in C0524T18	156	154	154	308	464
Avg duration of follow-up (weeks)	38.8	50.4	52.4	51.4	47.2
Avg exposure (number of administrations)	10.0	12.9	13.1	13.0	12.0
Subjects with 1 or more serious adverse events	13 (8.3%)	13 (8.4%)	23 (14.9%)	36 (11.7%)	49 (10.6%)
System-organ class/preferred term					
胃腸障害	3 (1.9%)	4 (2.6%)	9 (5.8%)	13 (4.2%)	16 (3.4%)
潰瘍性大腸炎	3 (1.9%)	3 (1.9%)	6 (3.9%)	9 (2.9%)	12 (2.6%)
腹痛	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
胃腸出血	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
鼠径ヘルニア	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
膵炎	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
感染症および寄生虫症	4 (2.6%)	5 (3.2%)	4 (2.6%)	9 (2.9%)	13 (2.8%)
虫垂炎	0 (0.0%)	0 (0.0%)	3 (1.9%)	3 (1.0%)	3 (0.6%)
膿瘍	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
脳膿瘍	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
気管支炎	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
サイトメガロウイルス感染	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
播種性結核	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
感染性小腸結腸炎	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
ロタウイルス胃腸炎	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
ウイルス性胃腸炎	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
帯状疱疹	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
外耳炎	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
ブドウ球菌感染	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
筋骨格系および結合組織障害	2 (1.3%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	4 (0.9%)
関節痛	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
椎間板突出	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
筋骨格痛	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
変形性関節症	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
心臓障害	0 (0.0%)	1 (0.6%)	2 (1.3%)	3 (1.0%)	3 (0.6%)
心不全	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
心嚢液貯留	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
心膜炎	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
神経系障害	1 (0.6%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	3 (0.6%)
痙攣	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
脱髄	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
顔面不全麻痺	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)

	Golimumab Induction				
	Placebo Maintenance[a]	50 mg Maintenance[a]	100 mg Maintenance[a]	Combined 50 mg and 100 mg Maintenance[a]	Total Golimumab[a,b]
生殖系および乳房障害	1 (0.6%)	2 (1.3%)	0 (0.0%)	2 (0.6%)	3 (0.6%)
良性前立腺肥大症	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
膀胱瘤	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
子宮ポリープ	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
一般・全身障害および投与部位の状態	2 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.4%)
非心臓性胸痛	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
発熱	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
肝胆道系障害	0 (0.0%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	2 (0.4%)
胆管結石	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
高ビリルビン血症	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
傷害、中毒および処置合併症	1 (0.6%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	2 (0.4%)
偶発的過量投与	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
足関節部骨折	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
代謝および栄養障害	1 (0.6%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	2 (0.4%)
脱水	1 (0.6%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	2 (0.4%)
精神障害	1 (0.6%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	2 (0.4%)
うつ病	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
物質乱用	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
皮膚および皮下組織障害	1 (0.6%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	2 (0.4%)
アレルギー性皮膚炎	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
発疹	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
血液およびリンパ系障害	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
リンパ節症	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
眼障害	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
結膜炎	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	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）	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
肺腺癌	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
妊娠、産褥および周産期の状態	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
妊娠	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
腎および尿路障害	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
水腎症	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
腎結石症	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
呼吸器、胸郭および縦隔障害	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
肺浸潤	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
血管障害	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
高血圧	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)

[a] Includes data up to the time of dose adjustment for those who increased dose from the indicated dose during the maintenance study.
[b] Includes data from the time of the first golimumab dose onward.

表 2.7.4.7-付録-22 重篤な有害事象（T16，T17 及び T18 試験 54 週まで；全投与被験者）

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
Treated subjects in C0524T16 and C0524T17	49	358	286	77	157	154	660	14	1233
Avg duration of follow-up (weeks)	12.3	19.1	39.2	11.9	39.0	50.4	45.1	27.5	45.6
Avg exposure (number of administrations)	1.6	5.0	9.2	1.6	10.0	12.9	10.7	6.9	11.0
Subjects with 1 or more serious adverse events	16 (32.7%)	14 (3.9%)	41 (14.3%)	28 (36.4%)	13 (8.3%)	13 (8.4%)	103 (15.6%)	1 (7.1%)	196 (15.9%)
System-organ class/preferred term									
胃腸障害	9 (18.4%)	4 (1.1%)	21 (7.3%)	15 (19.5%)	3 (1.9%)	4 (2.6%)	67 (10.2%)	1 (7.1%)	110 (8.9%)
潰瘍性大腸炎	8 (16.3%)	4 (1.1%)	18 (6.3%)	14 (18.2%)	3 (1.9%)	3 (1.9%)	57 (8.6%)	0 (0.0%)	94 (7.6%)
腹痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
膵炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
腹部ヘルニア	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.1%)	1 (0.1%)
上腹部痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
裂肛	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
結腸ポリープ	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
腸炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
排便回数増加	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
胃腸出血	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
胃食道逆流性疾患	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
痔出血	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
イレウス	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
単径ヘルニア	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
機械的イレウス	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
急性膵炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
小腸閉塞	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
嘔吐	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
悪心	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
亜イレウス	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
感染症および寄生虫症	5 (10.2%)	2 (0.6%)	8 (2.8%)	10 (13.0%)	4 (2.5%)	5 (3.2%)	17 (2.6%)	0 (0.0%)	44 (3.6%)
虫垂炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.5%)	0 (0.0%)	4 (0.3%)
気管支炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (1.3%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	3 (0.2%)
播種性結核	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	3 (0.2%)
肺炎	1 (2.0%)	0 (0.0%)	1 (0.3%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	3 (0.2%)
肛門膿瘍	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
脳膿瘍	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
蜂巣炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (2.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
サイトメガロウイルス感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
敗血症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
膿瘍	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
細菌性敗血症	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
感染性小腸結腸炎	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
胃腸炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
ロタウイルス胃腸炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
ウイルス性胃腸炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
帯状疱疹	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
椎間板炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
ウイルス性下気道感染	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
メタニューモウイルス感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
外耳炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
毛巣嚢胞	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
術後膿瘍	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
腎盂腎炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
直腸膿瘍	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
敗血症性ショック	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
ブドウ球菌性菌血症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
ブドウ球菌感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
レンサ球菌性敗血症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
皮下組織膿瘍	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
尿路感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
ウイルス感染	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
乳房膿瘍	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
カンジダ症	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
血腫感染	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
単純ヘルペス	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
直腸周囲膿瘍	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
血液およびリンパ系障害	1 (2.0%)	2 (0.6%)	2 (0.7%)	4 (5.2%)	0 (0.0%)	1 (0.6%)	4 (0.6%)	0 (0.0%)	11 (0.9%)
貧血	1 (2.0%)	2 (0.6%)	1 (0.3%)	3 (3.9%)	0 (0.0%)	0 (0.0%)	3 (0.5%)	0 (0.0%)	7 (0.6%)
血液障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
溶血性貧血	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
鉄欠乏性貧血	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
リンパ節症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
一般・全身障害および投与部位の状態	0 (0.0%)	1 (0.3%)	1 (0.3%)	1 (1.3%)	2 (1.3%)	0 (0.0%)	3 (0.5%)	1 (7.1%)	8 (0.6%)
発熱	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.6%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	3 (0.2%)
胸痛	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.1%)	2 (0.2%)
薬効欠如	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	2 (0.2%)
非心臓性胸痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
医薬品副作用	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
傷害、中毒および処置合併症	1 (2.0%)	1 (0.3%)	1 (0.3%)	1 (1.3%)	1 (0.6%)	0 (0.0%)	4 (0.6%)	0 (0.0%)	7 (0.6%)
足関節部骨折	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
偶発的過量投与	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
偶発的中毒	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
骨亀裂	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
転倒	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
瘢痕ヘルニア	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
処置後合併症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
挫傷	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
裂傷	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
多発性外傷	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
鋭的腹部外傷	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
筋骨格系および結合組織障害	1 (2.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	2 (1.3%)	1 (0.6%)	3 (0.5%)	0 (0.0%)	7 (0.6%)
関節痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
滑液包炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
椎間板突出	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
筋骨格痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
変形性関節症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
骨壊死	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
多発性関節炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
関節障害	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
神経系障害	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (1.3%)	1 (0.6%)	0 (0.0%)	4 (0.6%)	0 (0.0%)	7 (0.6%)
痙攣	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
脱髄	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
浮動性めまい	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
顔面不全麻痺	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
頭痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
虚血性脳卒中	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
神経根圧迫	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
失神	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
心臓障害	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	4 (0.6%)	0 (0.0%)	6 (0.5%)
狭心症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	2 (0.2%)
急性心筋梗塞	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
心房細動	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
心不全	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
冠動脈疾患	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
心嚢液貯留	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
心膜炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
呼吸器、胸郭および縦隔障害	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	3 (0.5%)	0 (0.0%)	5 (0.4%)
肺塞栓症	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
慢性閉塞性肺疾患	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
肺浸潤	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
胸水	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
血管障害	0 (0.0%)	2 (0.6%)	1 (0.3%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	3 (0.5%)	0 (0.0%)	5 (0.4%)
高血圧	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
大動脈瘤破裂	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
深部静脈血栓症	0 (0.0%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
表在性血栓性静脈炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
肝胆道系障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.6%)	0 (0.0%)	4 (0.3%)
胆管結石	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
胆嚢炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
肝炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
高ビリルビン血症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
代謝および栄養障害	1 (2.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.3%)	0 (0.0%)	4 (0.3%)
脱水	1 (2.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.6%)	1 (0.2%)	0 (0.0%)	3 (0.2%)
栄養障害	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
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）	0 (0.0%)	1 (0.3%)	2 (0.7%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	4 (0.3%)
上皮内癌	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
結腸癌	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
肺腺癌	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
直腸癌	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
甲状腺癌	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
乳癌	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
腎および尿路障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	3 (0.2%)
腎結石症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
水腎症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
腎仙痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
生殖系および乳房障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	2 (1.3%)	0 (0.0%)	0 (0.0%)	3 (0.2%)
良性前立腺肥大症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
膀胱瘤	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
子宮ポリープ	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
皮膚および皮下組織障害	3 (6.1%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	3 (0.2%)
アレルギー性皮膚炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
薬疹	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
発疹	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
結節性紅斑	3 (6.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
斑状皮疹	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
臨床検査	0 (0.0%)	1 (0.3%)	1 (0.3%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
ヘモグロビン減少	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
肝機能検査異常	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
肝酵素上昇	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
妊娠、産褥および周産期の状態	0 (0.0%)	1 (0.3%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
妊娠	0 (0.0%)	1 (0.3%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
自然流産	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
精神障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
うつ病	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
物質乱用	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
眼障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
結膜炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)

[a] Includes data up to the time of the first golimumab dose in the maintenance study.
[b] Includes data from the time of dose adjustment onward for those who increased to the indicated dose during the maintenance study.
[c] Includes data up to the time of dose adjustment for those who increased dose from the indicated dose during the maintenance study.
[d] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[e] Includes data from the time of the first golimumab dose onward.

RE599:[S SAE 22 5 C], 19JAN2012 23:27

表 2.7.4.7-付録-23 重篤な有害事象（T17 試験 6 週まで，日本人）

		Golimumab				
	Placebo	100 mg -> 50 mg	200 mg -> 100 mg	400 mg -> 200 mg	Combined	All Golimumab
Treated subjects in C0524T17	30	-	23	19	42	42
Avg duration of follow-up (weeks)	6.07	-	6.08	5.93	6.01	6.01
Avg exposure (number of administrations)	1.97	-	1.96	2.00	1.98	1.98
Subjects with 1 or more serious adverse events	3 (10.0%)	-	2 (8.7%)	1 (5.3%)	3 (7.1%)	3 (7.1%)
System-organ class/preferred term						
胃腸障害	1 (3.3%)	-	1 (4.3%)	1 (5.3%)	2 (4.8%)	2 (4.8%)
潰瘍性大腸炎	1 (3.3%)	-	1 (4.3%)	1 (5.3%)	2 (4.8%)	2 (4.8%)
感染症および寄生虫症	2 (6.7%)	-	1 (4.3%)	0	1 (2.4%)	1 (2.4%)
肛門膿瘍	1 (3.3%)	-	0	0	0	0
感染性小腸結腸炎	1 (3.3%)	-	0	0	0	0
肺炎	0	-	1 (4.3%)	0	1 (2.4%)	1 (2.4%)

Note: Adverse Events are coded using MedDRA 13.0

[TSFAE02JP.rtf] [CNTO148\C0524T17\DBR_WEEK6\RE_NDAJPKK\TSFAE02JP.sas] 28JAN2016, 10:23

表 2.7.4.7-付録-24 重篤な有害事象（T18 試験 54 週まで，日本人）

		Golimumab				
	Placebo [a,b]	50 mg [a]	100 mg[a,c,d]	Combined 50 mg and 100 mg	200 mg[d,e]	All Golimumab[f]
Treated subjects in C0524T18	8	3	59	60	-	60
Avg duration of follow-up (weeks)	26.5	18.5	42.3	42.6	-	42.6
Avg exposure (number of administrations)	6.3	3.7	9.5	9.5	-	9.5
Subjects with 1 or more serious adverse events	1 (12.5%)	1 (33.3%)	8 (13.6%)	9 (15.0%)	-	9 (15.0%)
System-organ class/preferred term						
胃腸障害	0	1 (33.3%)	6 (10.2%)	7 (11.7%)	-	7 (11.7%)
潰瘍性大腸炎	0	1 (33.3%)	5 (8.5%)	6 (10.0%)	-	6 (10.0%)
結腸ポリープ	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
感染症および寄生虫症	1 (12.5%)	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
感染性小腸結腸炎	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
サイトメガロウイルス感染	1 (12.5%)	0	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）	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
直腸癌	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)

[a] Includes data up to the time of dose adjustment for those who increased dose from the indicated dose.
[b] Includes 1) subjects who were in clinical response to golimumab induction dosing and were randomized to placebo on entry into this maintenance study; and 2) subjects who were in clinical response to placebo induction dosing and received placebo on entry into this maintenance study.
[c] Includes 1) subjects who were in clinical response to golimumab induction dosing and were randomized to golimumab 100 mg on entry into this maintenance study; 2) subjects who were not in clinical response to either placebo or golimumab induction dosing and received golimumab 100 mg on entry into this maintenance study; and 3) subjects who were dose adjusted to golimumab 100 mg from placebo (randomized or nonrandomized) or from golimumab 50 mg.
[d] Includes data from the time of dose adjustment onward for those who increased to the indicated dose.
[e] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[f] Includes data from the time of the first golimumab dose onward.
Note: Adverse Events are coded using MedDRA 14.0

[TSFAE02JP.rtf] [CNTO148\C0524T18\DBR_WEEK54\RE_NDAJPKK\TSFAE02JP.sas] 29JAN2016, 17:24

表 2.7.4.7-付録-25 安全性の概要（T16，T17 及び T18 試験；日本人 vs 外国人；全投与被験者）

	Japanese		Non-Japanese		Total	
	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]
Treated subjects in C0524T16 and C0524T17	30	68	377	1165	407	1233
Avg duration of follow-up (weeks)	11.5	43.6	18.8	45.7	18.3	45.6
Avg exposure (number of administrations)	2.9	9.9	4.7	11.0	4.6	11.0
Subjects who discontinued study agent because of 1 or more adverse events	0 (0.0%)	7 (10.3%)	10 (2.7%)	138 (11.8%)	10 (2.5%)	145 (11.8%)
Subjects with 1 or more of the following events						
Adverse events	20 (66.7%)	60 (88.2%)	174 (46.2%)	904 (77.6%)	194 (47.7%)	964 (78.2%)
Drug-related adverse events	8 (26.7%)	27 (39.7%)	70 (18.6%)	400 (34.3%)	78 (19.2%)	427 (34.6%)
Serious adverse events	3 (10.0%)	14 (20.6%)	27 (7.2%)	182 (15.6%)	30 (7.4%)	196 (15.9%)

[a] Includes data up to the time of the first golimumab dose.
[b] Includes data from the time of the first golimumab dose onward.

RE599:[S SAE 125 A JJ], 03FEB2012 15:36

表 2.7.4.7-付録-26 重篤な有害事象（UCO3001 試験，導入期 0 週から維持期 54 週まで，全投与被験者）

	Golimumab
Analysis set: SF-I	144
Average duration of follow-up (weeks)	34.7
Average exposure (number of administrations)	10.5
Subjects with 1 or more serious adverse events	19 (13.2%)
System-organ class/preferred term	
胃腸障害	12 (8.3%)
潰瘍性大腸炎	12 (8.3%)
感染症および寄生虫症	5 (3.5%)
帯状疱疹	2 (1.4%)
サイトメガロウイルス性大腸炎	1 (0.7%)
喉頭炎	1 (0.7%)
咽頭炎	1 (0.7%)
傷害、中毒および処置合併症	2 (1.4%)
手骨折	1 (0.7%)
関節脱臼	1 (0.7%)
神経系障害	1 (0.7%)
脳梗塞	1 (0.7%)
血管障害	1 (0.7%)
高安動脈炎	1 (0.7%)

Note: Adverse events were coded using MedDRA Version 18.1.

[TSFSAE01INMA.rtf] [CNTO148\CNTO148UCO3001\DBR_CSRW54\RE_NDAJPKK\TSFSAE01INMA.sas]
04FEB2016, 14:25

表 2.7.4.7-付録-27 治験薬の投与中止に至った有害事象（T16，T17 及び T18 試験 54 週まで；全投与被験者）

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
Treated subjects in C0524T16 and C0524T17	49	358	286	77	157	154	660	14	1233
Avg duration of follow-up (weeks)	12.3	19.1	39.2	11.9	39.0	50.4	45.1	27.5	45.6
Avg exposure (number of administrations)	1.6	5.0	9.2	1.6	10.0	12.9	10.7	6.9	11.0
Subjects who discontinued study agent because of 1 or more adverse events	3 (6.1%)	7 (2.0%)	42 (14.7%)	4 (5.2%)	10 (6.4%)	8 (5.2%)	81 (12.3%)	0 (0.0%)	145 (11.8%)
System-organ class/preferred term									
胃腸障害	1 (2.0%)	2 (0.6%)	28 (9.8%)	2 (2.6%)	3 (1.9%)	6 (3.9%)	63 (9.5%)	0 (0.0%)	102 (8.3%)
潰瘍性大腸炎	1 (2.0%)	2 (0.6%)	26 (9.1%)	2 (2.6%)	3 (1.9%)	6 (3.9%)	61 (9.2%)	0 (0.0%)	98 (7.9%)
悪心	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	2 (0.2%)
上腹部痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
膵炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
肛門周囲炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
偽性ポリポーシス	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
嘔吐	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
感染症および寄生虫症	1 (2.0%)	0 (0.0%)	3 (1.0%)	1 (1.3%)	4 (2.5%)	2 (1.3%)	2 (0.3%)	0 (0.0%)	12 (1.0%)
播種性結核	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	3 (0.2%)
膿瘍	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
細菌感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
細菌性敗血症	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
脳膿瘍	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
クロストリジウム感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
サイトメガロウイルス感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
帯状疱疹	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
肺炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
外陰腟真菌感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
ウイルス感染	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
皮膚および皮下組織障害	1 (2.0%)	0 (0.0%)	2 (0.7%)	0 (0.0%)	2 (1.3%)	0 (0.0%)	4 (0.6%)	0 (0.0%)	8 (0.6%)
膿疱性乾癬	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	2 (0.2%)
皮膚炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
アレルギー性皮膚炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
薬疹	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
結節性紅斑	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
そう痒症	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
発疹	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
斑状皮疹	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
一般・全身障害および投与部位の状態	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (0.8%)	0 (0.0%)	6 (0.5%)
無力症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.5%)	0 (0.0%)	3 (0.2%)
胸部不快感	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
薬効欠如	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
疲労	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
疼痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
発熱	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
臨床検査	0 (0.0%)	2 (0.6%)	4 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	5 (0.4%)
アラニン・アミノトランスフェラーゼ増加	0 (0.0%)	1 (0.3%)	2 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
アスパラギン酸アミノトランスフェラーゼ増加	0 (0.0%)	1 (0.3%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
心エコー像異常	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
リンパ球数増加	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
トレポネーマ検査陽性	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
血中アルカリホスファターゼ増加	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
妊娠、産褥および周産期の状態	0 (0.0%)	2 (0.6%)	2 (0.7%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	5 (0.4%)
妊娠	0 (0.0%)	2 (0.6%)	2 (0.7%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	5 (0.4%)
血液およびリンパ系障害	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.6%)	0 (0.0%)	4 (0.3%)
貧血	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	2 (0.2%)
溶血性貧血	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
好中球増加症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
特発性血小板減少性紫斑病	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	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）	0 (0.0%)	0 (0.0%)	2 (0.7%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	4 (0.3%)
上皮内癌	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
結腸癌	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
肺腺癌	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
直腸癌	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
甲状腺癌	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
心臓障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	2 (0.2%)
心不全	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
心膜炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
眼障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	2 (0.2%)
眼窩浮腫	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
視力障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
筋骨格系および結合組織障害	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
関節痛	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
関節腫脹	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
多発性関節炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
呼吸器、胸郭および縦隔障害	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
呼吸困難	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
労作性呼吸困難	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
肺浸潤	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
肝胆道系障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
肝炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
免疫系障害	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
４型過敏症	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
代謝および栄養障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
食欲減退	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
神経系障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
顔面不全麻痺	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
社会環境	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
パートナーの妊娠	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
血管障害	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
大動脈瘤破裂	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
傷害、中毒および処置合併症	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
挫傷	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

[a] Includes data up to the time of the first golimumab dose in the maintenance study.
[b] Includes data from the time of dose adjustment onward for those who increased to the indicated dose during the maintenance study.
[c] Includes data up to the time of dose adjustment for those who increased dose from the indicated dose during the maintenance study.
[d] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[e] Includes data from the time of the first golimumab dose onward.

RE599:[S DCAE 8 5 C], 19JAN2012 22:07

表 2.7.4.7-付録-28 治験薬の投与中止に至った有害事象（T17 試験 6 週まで，日本人）

		Golimumab				
	Placebo	100 mg -> 50 mg	200 mg -> 100 mg	400 mg -> 200 mg	Combined	All Golimumab
Treated subjects in C0524T17	30	-	23	19	42	42
Avg duration of follow-up (weeks)	6.07	-	6.08	5.93	6.01	6.01
Avg exposure (number of administrations)	1.97	-	1.96	2.00	1.98	1.98
Subjects who discontinued study agent because of 1 or more adverse events	0	-	0	0	0	0
System-organ class/preferred term						
No data to report	-	-	-	-	-	-

Note: Adverse Events are coded using MedDRA 13.0

[TSFAE03JP.rtf] [CNTO148\C0524T17\DBR_WEEK6\RE_NDAJPKK\TSFAE03JP.sas] 28JAN2016, 10:26

表 2.7.4.7-付録-29 治験薬の投与中止に至った有害事象（T18 試験 54 週まで，日本人）

		Golimumab				
	Placebo [a,b]	50 mg [a]	100 mg[a,c,d]	Combined 50 mg and 100 mg	200 mg[d,e]	All Golimumab[f]
Treated subjects in C0524T18	8	3	59	60	-	60
Avg duration of follow-up (weeks)	26.5	18.5	42.3	42.6	-	42.6
Avg exposure (number of administrations)	6.3	3.7	9.5	9.5	-	9.5
Subjects who discontinued study agent because of 1 or more adverse events	1 (12.5%)	0	6 (10.2%)	6 (10.0%)	-	6 (10.0%)
System-organ class/preferred term						
胃腸障害	0	0	4 (6.8%)	4 (6.7%)	-	4 (6.7%)
潰瘍性大腸炎	0	0	4 (6.8%)	4 (6.7%)	-	4 (6.7%)
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）	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
直腸癌	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
皮膚および皮下組織障害	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
膿疱性乾癬	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
感染症および寄生虫症	1 (12.5%)	0	0	0	-	0
サイトメガロウイルス感染	1 (12.5%)	0	0	0	-	0

[a] Includes data up to the time of dose adjustment for those who increased dose from the indicated dose.
[b] Includes 1) subjects who were in clinical response to golimumab induction dosing and were randomized to placebo on entry into this maintenance study; and 2) subjects who were in clinical response to placebo induction dosing and received placebo on entry into this maintenance study.
[c] Includes 1) subjects who were in clinical response to golimumab induction dosing and were randomized to golimumab 100 mg on entry into this maintenance study; 2) subjects who were not in clinical response to either placebo or golimumab induction dosing and received golimumab 100 mg on entry into this maintenance study; and 3) subjects who were dose adjusted to golimumab 100 mg from placebo (randomized or nonrandomized) or from golimumab 50 mg.
[d] Includes data from the time of dose adjustment onward for those who increased to the indicated dose.
[e] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[f] Includes data from the time of the first golimumab dose onward.
Note: Adverse Events are coded using MedDRA 14.0

[TSFAE03JP.rtf] [CNTO148\C0524T18\DBR_WEEK54\RE_NDAJPKK\TSFAE03JP.sas] 29JAN2016, 17:56

表 2.7.4.7-付録-30 治験薬の投与中止に至った有害事象（UCO3001 試験，導入期 0 週から維持期 54 週まで，全投与被験者）

	Golimumab
Analysis set: SF-I	144
Average duration of follow-up (weeks)	34.7
Average exposure (number of administrations)	10.5
Subjects who discontinued study agent because of 1 or more adverse events	13 (9.0%)
System-organ class/preferred term	
胃腸障害	10 (6.9%)
潰瘍性大腸炎	10 (6.9%)
血液およびリンパ系障害	1 (0.7%)
貧血	1 (0.7%)
感染症および寄生虫症	1 (0.7%)
サイトメガロウイルス性大腸炎	1 (0.7%)
神経系障害	1 (0.7%)
脳梗塞	1 (0.7%)

Note: Adverse events were coded using MedDRA Version 18.1.

[TSFAEDS01INMA.rtf] [CNTO148\CNTO148UCO3001\DBR_CSRW54\RE_NDAJPKK\TSFAEDS01INMA.sas]
04FEB2016, 14:17

表 2.7.4.7-付録-31 すべての感染症（T16，T17 及び T18 試験 54 週まで；ランダム化された被験者）

	Golimumab Induction				
	Placebo Maintenance[a]	50 mg Maintenance[a]	100 mg Maintenance[a]	Combined 50 mg and 100 mg Maintenance[a]	Total Golimumab[a,b]
Treated subjects in C0524T16 and C0524T17 who were randomized in C0524T18	156	154	154	308	464
Avg duration of follow-up (weeks)	38.8	50.4	52.4	51.4	47.2
Avg exposure (number of administrations)	10.0	12.9	13.1	13.0	12.0
Subjects with 1 or more infections[c]	55 (35.3%)	67 (43.5%)	66 (42.9%)	133 (43.2%)	188 (40.5%)
System-organ class/preferred term					
感染症および寄生虫症	50 (32.1%)	63 (40.9%)	63 (40.9%)	126 (40.9%)	176 (37.9%)
鼻咽頭炎	12 (7.7%)	16 (10.4%)	18 (11.7%)	34 (11.0%)	46 (9.9%)
上気道感染	6 (3.8%)	8 (5.2%)	10 (6.5%)	18 (5.8%)	24 (5.2%)
咽頭炎	6 (3.8%)	10 (6.5%)	5 (3.2%)	15 (4.9%)	21 (4.5%)
副鼻腔炎	4 (2.6%)	7 (4.5%)	7 (4.5%)	14 (4.5%)	18 (3.9%)
インフルエンザ	5 (3.2%)	7 (4.5%)	2 (1.3%)	9 (2.9%)	14 (3.0%)
気管支炎	3 (1.9%)	6 (3.9%)	2 (1.3%)	8 (2.6%)	11 (2.4%)
胃腸炎	3 (1.9%)	1 (0.6%)	5 (3.2%)	6 (1.9%)	9 (1.9%)
口腔ヘルペス	3 (1.9%)	3 (1.9%)	2 (1.3%)	5 (1.6%)	8 (1.7%)
尿路感染	4 (2.6%)	3 (1.9%)	1 (0.6%)	4 (1.3%)	8 (1.7%)
外陰腟真菌感染	1 (0.6%)	4 (2.6%)	1 (0.6%)	5 (1.6%)	6 (1.3%)
膀胱炎	1 (0.6%)	2 (1.3%)	2 (1.3%)	4 (1.3%)	5 (1.1%)
毛包炎	3 (1.9%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	5 (1.1%)
真菌感染	0 (0.0%)	0 (0.0%)	4 (2.6%)	4 (1.3%)	4 (0.9%)
レンサ球菌性咽頭炎	0 (0.0%)	1 (0.6%)	3 (1.9%)	4 (1.3%)	4 (0.9%)
ウイルス感染	0 (0.0%)	3 (1.9%)	1 (0.6%)	4 (1.3%)	4 (0.9%)
虫垂炎	0 (0.0%)	0 (0.0%)	3 (1.9%)	3 (1.0%)	3 (0.6%)
クロストリジウム感染	2 (1.3%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	3 (0.6%)
耳感染	2 (1.3%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	3 (0.6%)

	Golimumab Induction				
	Placebo Maintenance[a]	50 mg Maintenance[a]	100 mg Maintenance[a]	Combined 50 mg and 100 mg Maintenance[a]	Total Golimumab[a,b]
ウイルス性胃腸炎	1 (0.6%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	3 (0.6%)
麦粒腫	1 (0.6%)	2 (1.3%)	0 (0.0%)	2 (0.6%)	3 (0.6%)
爪真菌症	1 (0.6%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	3 (0.6%)
肺炎	2 (1.3%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	3 (0.6%)
気道感染	1 (0.6%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	3 (0.6%)
急性副鼻腔炎	1 (0.6%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	2 (0.4%)
急性扁桃炎	0 (0.0%)	2 (1.3%)	0 (0.0%)	2 (0.6%)	2 (0.4%)
せつ	0 (0.0%)	2 (1.3%)	0 (0.0%)	2 (0.6%)	2 (0.4%)
単純ヘルペス	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	2 (0.4%)
帯状疱疹	1 (0.6%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	2 (0.4%)
限局性感染	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	2 (0.4%)
下気道感染	2 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.4%)
外耳炎	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	2 (0.4%)
鼻炎	1 (0.6%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	2 (0.4%)
皮膚感染	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	2 (0.4%)
足部白癬	1 (0.6%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	2 (0.4%)
癜風	0 (0.0%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	2 (0.4%)
気管炎	0 (0.0%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	2 (0.4%)
創傷感染	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	2 (0.4%)
腹壁膿瘍	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
膿瘍	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
肛門膿瘍	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
肛門性器疣贅	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
細菌感染	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
ボレリア感染	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
脳膿瘍	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
カンジダ症	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
蜂巣炎	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)

	Golimumab Induction				
	Placebo Maintenance[a]	50 mg Maintenance[a]	100 mg Maintenance[a]	Combined 50 mg and 100 mg Maintenance[a]	Total Golimumab[a,b]
クロストリジウム・ディフィシレ大腸炎	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
サイトメガロウイルス感染	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
感染性皮膚炎	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
播種性結核	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
感染性小腸結腸炎	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
エンテロウイルス感染	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
丹毒	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
紅色陰癬	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
外耳蜂巣炎	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
ブドウ球菌性眼感染	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
ロタウイルス胃腸炎	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
消化管感染	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
ジアルジア症	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
感染	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
喉頭炎	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
マラリア	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
爪感染	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
口腔カンジダ症	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
口腔真菌感染	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
中耳炎	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
爪囲炎	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
原発性異型肺炎	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
ウイルス性気道感染	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
皮膚細菌感染	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
ブドウ球菌感染	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
皮下組織膿瘍	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
白癬感染	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
扁桃炎	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)

	Golimumab Induction				
	Placebo Maintenance[a]	50 mg Maintenance[a]	100 mg Maintenance[a]	Combined 50 mg and 100 mg Maintenance[a]	Total Golimumab[a,b]
歯膿瘍	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
歯感染	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
結核	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
尿道炎	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
ワクチン接種部位感染	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
腟感染	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
ウイルス性上気道感染	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
外陰部腟カンジダ症	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
呼吸器、胸郭および縦隔障害	2 (1.3%)	5 (3.2%)	6 (3.9%)	11 (3.6%)	13 (2.8%)
口腔咽頭痛	0 (0.0%)	2 (1.3%)	3 (1.9%)	5 (1.6%)	5 (1.1%)
咳嗽	1 (0.6%)	1 (0.6%)	2 (1.3%)	3 (1.0%)	4 (0.9%)
鼻閉	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
呼吸障害	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
気道うっ血	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
鼻漏	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
上気道の炎症	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
胃腸障害	2 (1.3%)	4 (2.6%)	4 (2.6%)	8 (2.6%)	10 (2.2%)
アフタ性口内炎	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	2 (0.4%)
大腸炎	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
下痢	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
血性下痢	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
食中毒	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
排便回数増加	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
胃腸の炎症	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
歯肉炎	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
歯痛	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
嘔吐	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)

	Golimumab Induction				
	Placebo Maintenance[a]	50 mg Maintenance[a]	100 mg Maintenance[a]	Combined 50 mg and 100 mg Maintenance[a]	Total Golimumab[a,b]
一般・全身障害および投与部位の状態	4 (2.6%)	2 (1.3%)	1 (0.6%)	3 (1.0%)	7 (1.5%)
発熱	4 (2.6%)	2 (1.3%)	0 (0.0%)	2 (0.6%)	6 (1.3%)
インフルエンザ様疾患	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
眼障害	2 (1.3%)	3 (1.9%)	1 (0.6%)	4 (1.3%)	6 (1.3%)
結膜炎	2 (1.3%)	2 (1.3%)	0 (0.0%)	2 (0.6%)	4 (0.9%)
眼の炎症	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
眼部腫脹	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
皮膚および皮下組織障害	2 (1.3%)	3 (1.9%)	1 (0.6%)	4 (1.3%)	6 (1.3%)
皮膚炎	1 (0.6%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	2 (0.4%)
発疹	1 (0.6%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	2 (0.4%)
湿疹	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
嵌入爪	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
皮膚病変	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
血液およびリンパ系障害	1 (0.6%)	2 (1.3%)	0 (0.0%)	2 (0.6%)	3 (0.6%)
リンパ節症	0 (0.0%)	2 (1.3%)	0 (0.0%)	2 (0.6%)	2 (0.4%)
好酸球増加症	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
耳および迷路障害	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	2 (0.4%)
耳痛	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
耳管機能障害	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
臨床検査	0 (0.0%)	2 (1.3%)	0 (0.0%)	2 (0.6%)	2 (0.4%)
体温上昇	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
白血球数増加	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	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）	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.6%)	2 (0.4%)
脂肪腫	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
皮膚乳頭腫	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)

	Golimumab Induction				
	Placebo Maintenance[a]	50 mg Maintenance[a]	100 mg Maintenance[a]	Combined 50 mg and 100 mg Maintenance[a]	Total Golimumab[a,b]
腎および尿路障害	1 (0.6%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	2 (0.4%)
排尿困難	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
水腎症	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
生殖系および乳房障害	0 (0.0%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	2 (0.4%)
精巣上体炎	0 (0.0%)	0 (0.0%)	2 (1.3%)	2 (0.6%)	2 (0.4%)
精巣痛	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
心臓障害	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
心膜炎	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)

[a] Includes data up to the time of dose adjustment for those who increased dose from the indicated dose during the maintenance study.
[b] Includes data from the time of the first golimumab dose onward.
[c] Infection as assessed by the investigator.

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表 2.7.4.7-付録-32 すべての感染症（T16，T17 及び T18 試験 54 週まで；全投与被験者）

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
Treated subjects in C0524T16 and C0524T17	49	358	286	77	157	154	660	14	1233
Avg duration of follow-up (weeks)	12.3	19.1	39.2	11.9	39.0	50.4	45.1	27.5	45.6
Avg exposure (number of administrations)	1.6	5.0	9.2	1.6	10.0	12.9	10.7	6.9	11.0
Subjects with 1 or more infections[f]	15 (30.6%)	63 (17.6%)	108 (37.8%)	25 (32.5%)	55 (35.0%)	67 (43.5%)	257 (38.9%)	4 (28.6%)	500 (40.6%)
System-organ class/preferred term									
感染症および寄生虫症	10 (20.4%)	56 (15.6%)	101 (35.3%)	22 (28.6%)	50 (31.8%)	63 (40.9%)	236 (35.8%)	4 (28.6%)	462 (37.5%)
鼻咽頭炎	2 (4.1%)	13 (3.6%)	22 (7.7%)	4 (5.2%)	12 (7.6%)	16 (10.4%)	67 (10.2%)	3 (21.4%)	120 (9.7%)
上気道感染	0 (0.0%)	12 (3.4%)	20 (7.0%)	1 (1.3%)	6 (3.8%)	8 (5.2%)	44 (6.7%)	1 (7.1%)	77 (6.2%)
咽頭炎	0 (0.0%)	0 (0.0%)	7 (2.4%)	1 (1.3%)	6 (3.8%)	10 (6.5%)	13 (2.0%)	0 (0.0%)	37 (3.0%)
副鼻腔炎	2 (4.1%)	3 (0.8%)	6 (2.1%)	0 (0.0%)	4 (2.5%)	7 (4.5%)	17 (2.6%)	0 (0.0%)	34 (2.8%)
インフルエンザ	0 (0.0%)	7 (2.0%)	7 (2.4%)	0 (0.0%)	5 (3.2%)	7 (4.5%)	12 (1.8%)	0 (0.0%)	31 (2.5%)
気管支炎	2 (4.1%)	3 (0.8%)	4 (1.4%)	2 (2.6%)	3 (1.9%)	6 (3.9%)	14 (2.1%)	0 (0.0%)	28 (2.3%)
胃腸炎	0 (0.0%)	2 (0.6%)	4 (1.4%)	0 (0.0%)	3 (1.9%)	1 (0.6%)	12 (1.8%)	0 (0.0%)	20 (1.6%)
口腔ヘルペス	1 (2.0%)	0 (0.0%)	2 (0.7%)	2 (2.6%)	3 (1.9%)	3 (1.9%)	10 (1.5%)	0 (0.0%)	20 (1.6%)
尿路感染	0 (0.0%)	4 (1.1%)	2 (0.7%)	1 (1.3%)	4 (2.5%)	3 (1.9%)	7 (1.1%)	1 (7.1%)	18 (1.5%)
ウイルス感染	1 (2.0%)	3 (0.8%)	5 (1.7%)	0 (0.0%)	0 (0.0%)	3 (1.9%)	6 (0.9%)	0 (0.0%)	14 (1.1%)
クロストリジウム感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (6.5%)	2 (1.3%)	0 (0.0%)	4 (0.6%)	0 (0.0%)	11 (0.9%)
肺炎	1 (2.0%)	0 (0.0%)	1 (0.3%)	1 (1.3%)	2 (1.3%)	0 (0.0%)	7 (1.1%)	0 (0.0%)	11 (0.9%)
膀胱炎	0 (0.0%)	0 (0.0%)	2 (0.7%)	0 (0.0%)	1 (0.6%)	2 (1.3%)	4 (0.6%)	0 (0.0%)	9 (0.7%)
毛包炎	0 (0.0%)	1 (0.3%)	3 (1.0%)	1 (1.3%)	3 (1.9%)	1 (0.6%)	1 (0.2%)	0 (0.0%)	9 (0.7%)
帯状疱疹	0 (0.0%)	0 (0.0%)	4 (1.4%)	0 (0.0%)	1 (0.6%)	1 (0.6%)	3 (0.5%)	0 (0.0%)	9 (0.7%)
真菌感染	0 (0.0%)	0 (0.0%)	3 (1.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (0.8%)	0 (0.0%)	8 (0.6%)
ウイルス性胃腸炎	0 (0.0%)	3 (0.8%)	1 (0.3%)	0 (0.0%)	1 (0.6%)	1 (0.6%)	5 (0.8%)	0 (0.0%)	8 (0.6%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
気道感染	0 (0.0%)	0 (0.0%)	2 (0.7%)	1 (1.3%)	1 (0.6%)	0 (0.0%)	4 (0.6%)	0 (0.0%)	8 (0.6%)
外陰腟真菌感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	4 (2.6%)	3 (0.5%)	0 (0.0%)	8 (0.6%)
麦粒腫	0 (0.0%)	1 (0.3%)	3 (1.0%)	0 (0.0%)	1 (0.6%)	2 (1.3%)	1 (0.2%)	0 (0.0%)	7 (0.6%)
単純ヘルペス	1 (2.0%)	1 (0.3%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	4 (0.6%)	0 (0.0%)	6 (0.5%)
ウイルス性気道感染	0 (0.0%)	1 (0.3%)	2 (0.7%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	3 (0.5%)	0 (0.0%)	6 (0.5%)
歯膿瘍	0 (0.0%)	2 (0.6%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (0.8%)	0 (0.0%)	6 (0.5%)
肛門膿瘍	0 (0.0%)	0 (0.0%)	2 (0.7%)	1 (1.3%)	0 (0.0%)	1 (0.6%)	1 (0.2%)	0 (0.0%)	5 (0.4%)
耳感染	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	2 (1.3%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	5 (0.4%)
せつ	0 (0.0%)	0 (0.0%)	2 (0.7%)	0 (0.0%)	0 (0.0%)	2 (1.3%)	1 (0.2%)	0 (0.0%)	5 (0.4%)
喉頭炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	4 (0.6%)	0 (0.0%)	5 (0.4%)
爪真菌症	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.6%)	1 (0.6%)	2 (0.3%)	0 (0.0%)	5 (0.4%)
レンサ球菌性咽頭炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	3 (0.5%)	0 (0.0%)	5 (0.4%)
鼻炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (1.3%)	1 (0.6%)	1 (0.6%)	1 (0.2%)	0 (0.0%)	5 (0.4%)
扁桃炎	0 (0.0%)	1 (0.3%)	2 (0.7%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	2 (0.3%)	0 (0.0%)	5 (0.4%)
ウイルス性上気道感染	0 (0.0%)	0 (0.0%)	2 (0.7%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.2%)	1 (7.1%)	5 (0.4%)
外陰部腟カンジダ症	0 (0.0%)	1 (0.3%)	3 (1.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.2%)	0 (0.0%)	5 (0.4%)
蜂巣炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	2 (2.6%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.3%)
サイトメガロウイルス感染	1 (2.0%)	0 (0.0%)	0 (0.0%)	2 (2.6%)	1 (0.6%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	4 (0.3%)
下気道感染	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	2 (1.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	4 (0.3%)
口腔カンジダ症	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (1.3%)	0 (0.0%)	1 (0.6%)	1 (0.2%)	0 (0.0%)	4 (0.3%)
歯感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	3 (0.5%)	0 (0.0%)	4 (0.3%)
急性扁桃炎	0 (0.0%)	1 (0.3%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	2 (1.3%)	0 (0.0%)	0 (0.0%)	3 (0.2%)
虫垂炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.5%)	0 (0.0%)	3 (0.2%)
播種性結核	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	3 (0.2%)
憩室炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	3 (0.2%)
感染性腸炎	0 (0.0%)	0 (0.0%)	3 (1.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.2%)
エンテロウイルス感染	0 (0.0%)	1 (0.3%)	2 (0.7%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	3 (0.2%)
丹毒	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	3 (0.2%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
限局性感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	2 (0.3%)	0 (0.0%)	3 (0.2%)
外耳炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.2%)	0 (0.0%)	3 (0.2%)
爪囲炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.5%)	0 (0.0%)	3 (0.2%)
皮下組織膿瘍	0 (0.0%)	0 (0.0%)	2 (0.7%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.2%)
足部白癬	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.6%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	3 (0.2%)
気管炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.5%)	0 (0.0%)	3 (0.2%)
創傷感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	2 (0.3%)	0 (0.0%)	3 (0.2%)
膿瘍	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
急性副鼻腔炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
肛門性器疣贅	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
ブラストシスティス感染	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
脳膿瘍	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
カンジダ症	1 (2.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
慢性副鼻腔炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
感染性小腸結腸炎	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	2 (0.2%)
ウイルス性消化管感染	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
ヘルペスウイルス感染	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
マラリア	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
食道カンジダ症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	2 (0.2%)
膿疱性皮疹	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	2 (0.2%)
敗血症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
皮膚感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
ブドウ球菌感染	0 (0.0%)	1 (0.3%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
癜風	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	2 (0.2%)
ウイルス性咽頭炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	1 (7.1%)	2 (0.2%)
腹壁膿瘍	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
エロモナス感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
アメーバ症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
真菌性肛門感染	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
細菌感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
ボレリア感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
乳房蜂巣炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
クロストリジウム・ディフィシレ大腸炎	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
感染性皮膚炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
紅色陰癬	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
外耳蜂巣炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
眼感染	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
ブドウ球菌性眼感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
皮膚真菌感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
ロタウイルス胃腸炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
サルモネラ菌性胃腸炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
消化管感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
ジアルジア症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
感染性表皮嚢胞	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
感染性皮膚潰瘍	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
注射部位膿瘍	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
迷路炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
ウイルス性下気道感染	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
ライム病	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
メタニューモウイルス感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
伝染性軟属腫	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
爪感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
口腔真菌感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
中耳炎	0 (0.0%)	2 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
寄生虫性胃腸炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
歯周感染	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
百日咳	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
毛巣嚢胞	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
原発性異型肺炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
術後膿瘍	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
偽膜性大腸炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
腎盂腎炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
直腸膿瘍	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
敗血症性ショック	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
皮膚細菌感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
軟部組織感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
ブドウ球菌性菌血症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
レンサ球菌性敗血症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
白癬感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
結核	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
腸チフス熱	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
尿道炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
泌尿生殖器真菌感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
ワクチン接種部位感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
腟感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
水痘	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
乳房膿瘍	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
気管支肺炎	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
H1n1 influenza	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
血腫感染	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
細菌の過剰増殖	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
直腸周囲膿瘍	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
呼吸器、胸郭および縦隔障害	3 (6.1%)	6 (1.7%)	15 (5.2%)	0 (0.0%)	2 (1.3%)	5 (3.2%)	24 (3.6%)	1 (7.1%)	47 (3.8%)
咳嗽	1 (2.0%)	3 (0.8%)	9 (3.1%)	0 (0.0%)	1 (0.6%)	1 (0.6%)	10 (1.5%)	0 (0.0%)	21 (1.7%)
口腔咽頭痛	2 (4.1%)	1 (0.3%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	2 (1.3%)	10 (1.5%)	0 (0.0%)	13 (1.1%)
呼吸障害	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	3 (0.5%)	0 (0.0%)	4 (0.3%)
上気道の炎症	1 (2.0%)	1 (0.3%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	3 (0.2%)
喘息	0 (0.0%)	0 (0.0%)	2 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
鼻閉	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (7.1%)	2 (0.2%)
気道うっ血	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
副鼻腔うっ血	0 (0.0%)	0 (0.0%)	2 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
胸水	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
湿性咳嗽	0 (0.0%)	1 (0.3%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
鼻漏	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
上気道うっ血	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
胃腸障害	3 (6.1%)	2 (0.6%)	5 (1.7%)	2 (2.6%)	2 (1.3%)	4 (2.6%)	15 (2.3%)	0 (0.0%)	28 (2.3%)
潰瘍性大腸炎	1 (2.0%)	1 (0.3%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	3 (0.5%)	0 (0.0%)	4 (0.3%)
下痢	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	2 (0.3%)	0 (0.0%)	4 (0.3%)
食中毒	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	2 (0.3%)	0 (0.0%)	3 (0.2%)
アフタ性口内炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
腸炎	0 (0.0%)	1 (0.3%)	2 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
歯痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	2 (0.2%)
嘔吐	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	2 (0.2%)
肛門の炎症	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
大腸炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
齲歯	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
血性下痢	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
小腸炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
排便回数増加	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
胃腸の炎症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
歯肉炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
急性膵炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
肛門周囲炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
肛門周囲痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
歯の障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
悪心	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
亜イレウス	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
一般・全身障害および投与部位の状態	2 (4.1%)	4 (1.1%)	5 (1.7%)	4 (5.2%)	4 (2.5%)	2 (1.3%)	13 (2.0%)	0 (0.0%)	28 (2.3%)
発熱	2 (4.1%)	3 (0.8%)	4 (1.4%)	3 (3.9%)	4 (2.5%)	2 (1.3%)	8 (1.2%)	0 (0.0%)	21 (1.7%)
インフルエンザ様疾患	0 (0.0%)	1 (0.3%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.6%)	0 (0.0%)	5 (0.4%)
高熱	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
注入部位炎症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
粘膜の炎症	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
眼障害	0 (0.0%)	1 (0.3%)	4 (1.4%)	0 (0.0%)	2 (1.3%)	3 (1.9%)	3 (0.5%)	1 (7.1%)	13 (1.1%)
結膜炎	0 (0.0%)	0 (0.0%)	2 (0.7%)	0 (0.0%)	2 (1.3%)	2 (1.3%)	2 (0.3%)	1 (7.1%)	9 (0.7%)
霰粒腫	0 (0.0%)	1 (0.3%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
眼瞼炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
眼の炎症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
眼部腫脹	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
皮膚および皮下組織障害	0 (0.0%)	1 (0.3%)	2 (0.7%)	0 (0.0%)	2 (1.3%)	3 (1.9%)	5 (0.8%)	0 (0.0%)	12 (1.0%)
発疹	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.6%)	1 (0.6%)	1 (0.2%)	0 (0.0%)	4 (0.3%)
皮膚炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
ざ瘡	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
水疱	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
接触性皮膚炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
湿疹	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
結節性紅斑	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
嵌入爪	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
脂漏性皮膚炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
皮膚病変	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
寝汗	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
臨床検査	1 (2.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	2 (1.3%)	3 (0.5%)	0 (0.0%)	6 (0.5%)
白血球数増加	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
体温上昇	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
骨髄球数増加	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
トレポネーマ検査陽性	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
尿中白血球陽性	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
グラム染色陰性	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
血液およびリンパ系障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (2.6%)	1 (0.6%)	2 (1.3%)	0 (0.0%)	0 (0.0%)	5 (0.4%)
リンパ節症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.3%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
貧血	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
好酸球増加症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
白血球増加症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
耳および迷路障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	3 (0.5%)	0 (0.0%)	4 (0.3%)
耳痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	2 (0.3%)	0 (0.0%)	3 (0.2%)
耳管機能障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
腎および尿路障害	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.6%)	1 (0.6%)	1 (0.2%)	0 (0.0%)	4 (0.3%)
排尿困難	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
糸球体腎炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
血尿	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
水腎症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
頻尿	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
生殖系および乳房障害	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.6%)	0 (0.0%)	4 (0.3%)
精巣上体炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.6%)	0 (0.0%)	4 (0.3%)
精巣痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
前立腺炎	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
傷害、中毒および処置合併症	0 (0.0%)	0 (0.0%)	3 (1.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.2%)
節足動物咬傷	0 (0.0%)	0 (0.0%)	2 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
歯牙破折	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
筋骨格系および結合組織障害	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
関節痛	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
筋骨格痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
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）	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
脂肪腫	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
皮膚乳頭腫	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
心臓障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
心膜炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
神経系障害	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
副鼻腔炎に伴う頭痛	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
血管障害	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
静脈炎	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

[a] Includes data up to the time of the first golimumab dose in the maintenance study.
[b] Includes data from the time of dose adjustment onward for those who increased to the indicated dose during the maintenance study.
[c] Includes data up to the time of dose adjustment for those who increased dose from the indicated dose during the maintenance study.
[d] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[e] Includes data from the time of the first golimumab dose onward.
[f] Infection as assessed by the investigator.

表 2.7.4.7-付録-33 100 人年あたりの感染症発現率（T16，T17 及び T18 試験 54 週まで；全投与被験者）

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
Treated subjects in C0524T16 and C0524T17	49	358	286	77	157	154	660	14	1233
Number of subjects with infections[f]	15 (30.6%)	63 (17.6%)	108 (37.8%)	25 (32.5%)	55 (35.0%)	67 (43.5%)	257 (38.9%)	4 (28.6%)	500 (40.6%)
Total subject-years of follow-up	12	131	216	18	118	149	573	7	1080
Number of infections[f]	27	96	225	45	112	150	491	11	1034
Incidence per 100 subject-years	232.56	73.10	104.40	255.38	95.21	100.41	85.76	148.46	95.73
95% confidence interval[g]	(153.26, 338.36)	(59.21, 89.27)	(91.20, 118.97)	(186.28, 341.72)	(78.39, 114.56)	(84.98, 117.82)	(78.34, 93.69)	(74.11, 265.64)	(89.98, 101.75)

[a] Includes data up to the time of the first golimumab dose in the maintenance study.
[b] Includes data from the time of dose adjustment onward for those who increased to the indicated dose during the maintenance study.
[c] Includes data up to the time of dose adjustment for those who increased dose from the indicated dose during the maintenance study.
[d] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[e] Includes data from the time of the first golimumab dose onward.
[f] Infection as assessed by the investigator.
[g] Confidence intervals based on an exact method.

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表 2.7.4.7-付録-34 すべての感染症（T17 試験 6 週まで，日本人）

		Golimumab				
	Placebo	100 mg -> 50 mg	200 mg -> 100 mg	400 mg -> 200 mg	Combined	All Golimumab
Treated subjects in C0524T17	30	-	23	19	42	42
Avg duration of follow-up (weeks)	6.07	-	6.08	5.93	6.01	6.01
Avg exposure (number of administrations)	1.97	-	1.96	2.00	1.98	1.98
Subjects with 1 or more infections	8 (26.7%)	-	6 (26.1%)	4 (21.1%)	10 (23.8%)	10 (23.8%)
System-organ class/preferred term						
感染症および寄生虫症	6 (20.0%)	-	6 (26.1%)	4 (21.1%)	10 (23.8%)	10 (23.8%)
膀胱炎	0	-	0	1 (5.3%)	1 (2.4%)	1 (2.4%)
帯状疱疹	0	-	0	1 (5.3%)	1 (2.4%)	1 (2.4%)
鼻咽頭炎	2 (6.7%)	-	2 (8.7%)	1 (5.3%)	3 (7.1%)	3 (7.1%)
百日咳	0	-	0	1 (5.3%)	1 (2.4%)	1 (2.4%)
気道感染	0	-	0	1 (5.3%)	1 (2.4%)	1 (2.4%)
肛門膿瘍	1 (3.3%)	-	0	0	0	0
気管支炎	1 (3.3%)	-	0	0	0	0
感染性小腸結腸炎	1 (3.3%)	-	0	0	0	0
毛包炎	0	-	1 (4.3%)	0	1 (2.4%)	1 (2.4%)
肺炎	0	-	1 (4.3%)	0	1 (2.4%)	1 (2.4%)
上気道感染	1 (3.3%)	-	1 (4.3%)	0	1 (2.4%)	1 (2.4%)
尿路感染	0	-	1 (4.3%)	0	1 (2.4%)	1 (2.4%)
眼障害	1 (3.3%)	-	0	0	0	0
霰粒腫	1 (3.3%)	-	0	0	0	0
胃腸障害	1 (3.3%)	-	0	0	0	0
腸炎	1 (3.3%)	-	0	0	0	0
全身障害および投与局所様態	2 (6.7%)	-	0	0	0	0
発熱	2 (6.7%)	-	0	0	0	0
呼吸器、胸郭および縦隔障害	1 (3.3%)	-	0	0	0	0
咳嗽	1 (3.3%)	-	0	0	0	0

Note: Adverse Events are coded using MedDRA 13.0

表 2.7.4.7-付録-35 すべての感染症（T18 試験 54 週まで，日本人）

		Golimumab				
	Placebo [a,b]	50 mg [a]	100 mg[a,c,d]	Combined 50 mg and 100 mg	200 mg[d,e]	All Golimumab[f]
Treated subjects in C0524T18	8	3	59	60	-	60
Avg duration of follow-up (weeks)	26.5	18.5	42.3	42.6	-	42.6
Avg exposure (number of administrations)	6.3	3.7	9.5	9.5	-	9.5
Subjects with 1 or more infections[g]	3 (37.5%)	1 (33.3%)	32 (54.2%)	32 (53.3%)	-	32 (53.3%)
System-organ class/preferred term						
感染症および寄生虫症	2 (25.0%)	1 (33.3%)	31 (52.5%)	31 (51.7%)	-	31 (51.7%)
鼻咽頭炎	1 (12.5%)	0	19 (32.2%)	19 (31.7%)	-	19 (31.7%)
感染性腸炎	0	0	3 (5.1%)	3 (5.0%)	-	3 (5.0%)
インフルエンザ	1 (12.5%)	0	3 (5.1%)	3 (5.0%)	-	3 (5.0%)
上気道感染	0	0	3 (5.1%)	3 (5.0%)	-	3 (5.0%)
感染性小腸結腸炎	0	0	2 (3.4%)	2 (3.3%)	-	2 (3.3%)
口腔ヘルペス	0	0	2 (3.4%)	2 (3.3%)	-	2 (3.3%)
慢性副鼻腔炎	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
膀胱炎	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
サイトメガロウイルス感染	1 (12.5%)	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
毛包炎	1 (12.5%)	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
胃腸炎	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
感染性表皮嚢胞	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
咽頭炎	0	1 (33.3%)	0	1 (1.7%)	-	1 (1.7%)
鼻炎	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
尿路感染	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
皮下組織膿瘍	1 (12.5%)	0	0	0	-	0
呼吸器、胸郭および縦隔障害	1 (12.5%)	0	4 (6.8%)	4 (6.7%)	-	4 (6.7%)
上気道の炎症	1 (12.5%)	0	2 (3.4%)	2 (3.3%)	-	2 (3.3%)
咳嗽	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
口腔咽頭痛	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
眼障害	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
霰粒腫	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
胃腸障害	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
腸炎	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
一般・全身障害および投与部位の状態	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
発熱	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)

	Golimumab				
Placebo [a,b]	50 mg [a]	100 mg [a,c,d]	Combined 50 mg and 100 mg	200 mg [d,e]	All Golimumab [f]

[a] Includes data up to the time of dose adjustment for those who increased dose from the indicated dose.
[b] Includes 1) subjects who were in clinical response to golimumab induction dosing and were randomized to placebo on entry into this maintenance study; and 2) subjects who were in clinical response to placebo induction dosing and received placebo on entry into this maintenance study.
[c] Includes 1) subjects who were in clinical response to golimumab induction dosing and were randomized to golimumab 100 mg on entry into this maintenance study; 2) subjects who were not in clinical response to either placebo or golimumab induction dosing and received golimumab 100 mg on entry into this maintenance study; and 3) subjects who were dose adjusted to golimumab 100 mg from placebo (randomized or nonrandomized) or from golimumab 50 mg.
[d] Includes data from the time of dose adjustment onward for those who increased to the indicated dose.
[e] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[f] Includes data from the time of the first golimumab dose onward.
[g] Infections as assessed by the investigator.
Note: Adverse Events are coded using MedDRA 14.0

表 2.7.4.7-付録-36 すべての感染症（T16，T17 及び T18 試験 54 週まで；日本人 vs 外国人；全投与被験者）

	Japanese		Non-Japanese		Total	
	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]
Treated subjects in C0524T16 and C0524T17	30	68	377	1165	407	1233
Avg duration of follow-up (weeks)	11.5	43.6	18.8	45.7	18.3	45.6
Avg exposure (number of administrations)	2.9	9.9	4.7	11.0	4.6	11.0
Subjects with 1 or more infections[c]	11 (36.7%)	41 (60.3%)	67 (17.8%)	459 (39.4%)	78 (19.2%)	500 (40.6%)
System-organ class/preferred term						
感染症および寄生虫症	7 (23.3%)	40 (58.8%)	59 (15.6%)	422 (36.2%)	66 (16.2%)	462 (37.5%)
鼻咽頭炎	3 (10.0%)	24 (35.3%)	12 (3.2%)	96 (8.2%)	15 (3.7%)	120 (9.7%)
上気道感染	1 (3.3%)	4 (5.9%)	11 (2.9%)	73 (6.3%)	12 (2.9%)	77 (6.2%)
咽頭炎	0 (0.0%)	1 (1.5%)	0 (0.0%)	36 (3.1%)	0 (0.0%)	37 (3.0%)
副鼻腔炎	0 (0.0%)	0 (0.0%)	5 (1.3%)	34 (2.9%)	5 (1.2%)	34 (2.8%)
インフルエンザ	0 (0.0%)	4 (5.9%)	7 (1.9%)	27 (2.3%)	7 (1.7%)	31 (2.5%)
気管支炎	1 (3.3%)	0 (0.0%)	4 (1.1%)	28 (2.4%)	5 (1.2%)	28 (2.3%)
胃腸炎	0 (0.0%)	1 (1.5%)	2 (0.5%)	19 (1.6%)	2 (0.5%)	20 (1.6%)
口腔ヘルペス	0 (0.0%)	2 (2.9%)	1 (0.3%)	18 (1.5%)	1 (0.2%)	20 (1.6%)
尿路感染	0 (0.0%)	2 (2.9%)	4 (1.1%)	16 (1.4%)	4 (1.0%)	18 (1.5%)
ウイルス感染	0 (0.0%)	0 (0.0%)	4 (1.1%)	14 (1.2%)	4 (1.0%)	14 (1.1%)
クロストリジウム感染	0 (0.0%)	1 (1.5%)	0 (0.0%)	10 (0.9%)	0 (0.0%)	11 (0.9%)
肺炎	0 (0.0%)	1 (1.5%)	1 (0.3%)	10 (0.9%)	1 (0.2%)	11 (0.9%)
膀胱炎	0 (0.0%)	2 (2.9%)	0 (0.0%)	7 (0.6%)	0 (0.0%)	9 (0.7%)
毛包炎	0 (0.0%)	2 (2.9%)	1 (0.3%)	7 (0.6%)	1 (0.2%)	9 (0.7%)
帯状疱疹	0 (0.0%)	1 (1.5%)	0 (0.0%)	8 (0.7%)	0 (0.0%)	9 (0.7%)
真菌感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	8 (0.7%)	0 (0.0%)	8 (0.6%)
ウイルス性胃腸炎	0 (0.0%)	0 (0.0%)	3 (0.8%)	8 (0.7%)	3 (0.7%)	8 (0.6%)
気道感染	0 (0.0%)	1 (1.5%)	0 (0.0%)	7 (0.6%)	0 (0.0%)	8 (0.6%)
外陰腟真菌感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	8 (0.7%)	0 (0.0%)	8 (0.6%)

	Japanese		Non-Japanese		Total	
	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]
麦粒腫	0 (0.0%)	0 (0.0%)	1 (0.3%)	7 (0.6%)	1 (0.2%)	7 (0.6%)
単純ヘルペス	0 (0.0%)	0 (0.0%)	2 (0.5%)	6 (0.5%)	2 (0.5%)	6 (0.5%)
ウイルス性気道感染	0 (0.0%)	0 (0.0%)	1 (0.3%)	6 (0.5%)	1 (0.2%)	6 (0.5%)
歯膿瘍	0 (0.0%)	0 (0.0%)	2 (0.5%)	6 (0.5%)	2 (0.5%)	6 (0.5%)
肛門膿瘍	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (0.4%)	0 (0.0%)	5 (0.4%)
耳感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (0.4%)	0 (0.0%)	5 (0.4%)
せつ	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (0.4%)	0 (0.0%)	5 (0.4%)
喉頭炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (0.4%)	0 (0.0%)	5 (0.4%)
爪真菌症	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (0.4%)	0 (0.0%)	5 (0.4%)
レンサ球菌性咽頭炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (0.4%)	0 (0.0%)	5 (0.4%)
鼻炎	0 (0.0%)	1 (1.5%)	0 (0.0%)	4 (0.3%)	0 (0.0%)	5 (0.4%)
扁桃炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	5 (0.4%)	1 (0.2%)	5 (0.4%)
ウイルス性上気道感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (0.4%)	0 (0.0%)	5 (0.4%)
外陰部腟カンジダ症	0 (0.0%)	0 (0.0%)	1 (0.3%)	5 (0.4%)	1 (0.2%)	5 (0.4%)
蜂巣炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.3%)	0 (0.0%)	4 (0.3%)
サイトメガロウイルス感染	0 (0.0%)	3 (4.4%)	1 (0.3%)	1 (0.1%)	1 (0.2%)	4 (0.3%)
下気道感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.3%)	0 (0.0%)	4 (0.3%)
口腔カンジダ症	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.3%)	0 (0.0%)	4 (0.3%)
歯感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.3%)	0 (0.0%)	4 (0.3%)
急性扁桃炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	3 (0.3%)	1 (0.2%)	3 (0.2%)
虫垂炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	3 (0.2%)
播種性結核	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	3 (0.2%)
憩室炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	3 (0.2%)
感染性腸炎	0 (0.0%)	3 (4.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.2%)
エンテロウイルス感染	0 (0.0%)	0 (0.0%)	1 (0.3%)	3 (0.3%)	1 (0.2%)	3 (0.2%)
丹毒	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	3 (0.2%)
限局性感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	3 (0.2%)
外耳炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	3 (0.2%)

	Japanese		Non-Japanese		Total	
	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]
爪囲炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	3 (0.2%)
皮下組織膿瘍	0 (0.0%)	1 (1.5%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	3 (0.2%)
足部白癬	0 (0.0%)	1 (1.5%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	3 (0.2%)
気管炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	3 (0.2%)
創傷感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	3 (0.2%)
膿瘍	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
急性副鼻腔炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
肛門性器疣贅	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
ブラストシスティス感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
脳膿瘍	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
カンジダ症	0 (0.0%)	0 (0.0%)	1 (0.3%)	2 (0.2%)	1 (0.2%)	2 (0.2%)
慢性副鼻腔炎	0 (0.0%)	1 (1.5%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	2 (0.2%)
感染性小腸結腸炎	1 (3.3%)	2 (2.9%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	2 (0.2%)
ウイルス性消化管感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
ヘルペスウイルス感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
マラリア	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
食道カンジダ症	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
膿疱性皮疹	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
敗血症	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
皮膚感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
ブドウ球菌感染	0 (0.0%)	0 (0.0%)	1 (0.3%)	2 (0.2%)	1 (0.2%)	2 (0.2%)
癜風	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
ウイルス性咽頭炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
腹壁膿瘍	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
エロモナス感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
アメーバ症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
真菌性肛門感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)

	Japanese		Non-Japanese		Total	
	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]
細菌感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
ボレリア感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
乳房蜂巣炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
クロストリジウム・ディフィシレ大腸炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.1%)	1 (0.2%)	1 (0.1%)
感染性皮膚炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
紅色陰癬	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
外耳蜂巣炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
眼感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
ブドウ球菌性眼感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
皮膚真菌感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
ロタウイルス胃腸炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
サルモネラ菌性胃腸炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
消化管感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
ジアルジア症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
感染性表皮嚢胞	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
感染性皮膚潰瘍	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
注射部位膿瘍	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
迷路炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
ウイルス性下気道感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
ライム病	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
メタニューモウイルス感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
伝染性軟属腫	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
爪感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
口腔真菌感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
中耳炎	0 (0.0%)	0 (0.0%)	2 (0.5%)	1 (0.1%)	2 (0.5%)	1 (0.1%)
寄生虫性胃腸炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
歯周感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
百日咳	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)

	Japanese		Non-Japanese		Total	
	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]
毛巣嚢胞	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
原発性異型肺炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
術後膿瘍	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
偽膜性大腸炎	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
腎盂腎炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
直腸膿瘍	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
敗血症性ショック	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
皮膚細菌感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
軟部組織感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
ブドウ球菌性菌血症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
レンサ球菌性敗血症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
白癬感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
結核	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
腸チフス熱	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
尿道炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
泌尿生殖器真菌感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
ワクチン接種部位感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
腟感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
水痘	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
乳房膿瘍	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
気管支肺炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
H1n1 influenza	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
血腫感染	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
細菌の過剰増殖	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
直腸周囲膿瘍	1 (3.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
呼吸器、胸郭および縦隔障害	4 (13.3%)	4 (5.9%)	5 (1.3%)	43 (3.7%)	9 (2.2%)	47 (3.8%)
咳嗽	1 (3.3%)	1 (1.5%)	3 (0.8%)	20 (1.7%)	4 (1.0%)	21 (1.7%)
口腔咽頭痛	2 (6.7%)	1 (1.5%)	1 (0.3%)	12 (1.0%)	3 (0.7%)	13 (1.1%)
呼吸障害	0 (0.0%)	0 (0.0%)	1 (0.3%)	4 (0.3%)	1 (0.2%)	4 (0.3%)

	Japanese		Non-Japanese		Total	
	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]
上気道の炎症	2 (6.7%)	2 (2.9%)	0 (0.0%)	1 (0.1%)	2 (0.5%)	3 (0.2%)
喘息	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
鼻閉	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
気道うっ血	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
副鼻腔うっ血	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
胸水	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
湿性咳嗽	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.1%)	1 (0.2%)	1 (0.1%)
鼻漏	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
上気道うっ血	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
胃腸障害	1 (3.3%)	1 (1.5%)	4 (1.1%)	27 (2.3%)	5 (1.2%)	28 (2.3%)
潰瘍性大腸炎	0 (0.0%)	0 (0.0%)	2 (0.5%)	4 (0.3%)	2 (0.5%)	4 (0.3%)
下痢	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.3%)	0 (0.0%)	4 (0.3%)
食中毒	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	3 (0.2%)
アフタ性口内炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
腸炎	1 (3.3%)	1 (1.5%)	0 (0.0%)	1 (0.1%)	1 (0.2%)	2 (0.2%)
歯痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
嘔吐	0 (0.0%)	0 (0.0%)	1 (0.3%)	2 (0.2%)	1 (0.2%)	2 (0.2%)
肛門の炎症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
大腸炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
齲歯	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
血性下痢	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
小腸炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
排便回数増加	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
胃腸の炎症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
歯肉炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
急性膵炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
肛門周囲炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
肛門周囲痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)

	Japanese		Non-Japanese		Total	
	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]
歯の障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
悪心	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
亜イレウス	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
一般・全身障害および投与部位の状態	2 (6.7%)	1 (1.5%)	4 (1.1%)	27 (2.3%)	6 (1.5%)	28 (2.3%)
発熱	2 (6.7%)	1 (1.5%)	3 (0.8%)	20 (1.7%)	5 (1.2%)	21 (1.7%)
インフルエンザ様疾患	0 (0.0%)	0 (0.0%)	1 (0.3%)	5 (0.4%)	1 (0.2%)	5 (0.4%)
高熱	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
注入部位炎症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
粘膜の炎症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
眼障害	1 (3.3%)	1 (1.5%)	0 (0.0%)	12 (1.0%)	1 (0.2%)	13 (1.1%)
結膜炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	9 (0.8%)	0 (0.0%)	9 (0.7%)
霰粒腫	1 (3.3%)	1 (1.5%)	0 (0.0%)	1 (0.1%)	1 (0.2%)	2 (0.2%)
眼瞼炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
眼の炎症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
眼部腫脹	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
皮膚および皮下組織障害	0 (0.0%)	0 (0.0%)	1 (0.3%)	12 (1.0%)	1 (0.2%)	12 (1.0%)
発疹	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.3%)	0 (0.0%)	4 (0.3%)
皮膚炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
ざ瘡	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
水疱	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
接触性皮膚炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
湿疹	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
結節性紅斑	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
嵌入爪	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
脂漏性皮膚炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
皮膚病変	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
寝汗	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)

	Japanese		Non-Japanese		Total	
	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]
臨床検査	0 (0.0%)	0 (0.0%)	1 (0.3%)	6 (0.5%)	1 (0.2%)	6 (0.5%)
白血球数増加	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
体温上昇	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
骨髄球数増加	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
トレポネーマ検査陽性	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
尿中白血球陽性	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
グラム染色陰性	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
血液およびリンパ系障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (0.4%)	0 (0.0%)	5 (0.4%)
リンパ節症	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
貧血	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
好酸球増加症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
白血球増加症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
耳および迷路障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.3%)	0 (0.0%)	4 (0.3%)
耳痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	3 (0.2%)
耳管機能障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
腎および尿路障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.3%)	0 (0.0%)	4 (0.3%)
排尿困難	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
糸球体腎炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
血尿	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
水腎症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
頻尿	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
生殖系および乳房障害	0 (0.0%)	0 (0.0%)	1 (0.3%)	4 (0.3%)	1 (0.2%)	4 (0.3%)
精巣上体炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.3%)	0 (0.0%)	4 (0.3%)
精巣痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
前立腺炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
傷害、中毒および処置合併症	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.3%)	0 (0.0%)	3 (0.2%)
節足動物咬傷	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
歯牙破折	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)

	Japanese		Non-Japanese		Total	
	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]	Placebo[a]	Golimumab[b]
筋骨格系および結合組織障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
関節痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
筋骨格痛	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
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）	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)	0 (0.0%)	2 (0.2%)
脂肪腫	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
皮膚乳頭腫	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
心臓障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
心膜炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	1 (0.1%)
神経系障害	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
副鼻腔炎に伴う頭痛	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
血管障害	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
静脈炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)	0 (0.0%)

[a] Includes data up to the time of the first golimumab dose.
[b] Includes data from the time of the first golimumab dose onward.
[c] Infection as assessed by the investigator.

表 2.7.4.7-付録-37 100 人年あたりの重篤な感染症発現率（T18 試験 0 から 228 週まで，他疾患との統合データ）

	nrAxSpA Study[a]		Phase 3 RA, PsA, AS Studies[b]			UC Studies[c]			All Studies		
	Placebo[d,j]	Golimumab 50mg[e,j]	Placebo[d,j]	Golimumab 50mg[e,j]	Golimumab 100mg[e,j,k]	Placebo[f,j]	Golimumab 50mg[g,h,j]	Golimumab 100mg[g,h,i,j,k]	Placebo[j]	Golimumab 50mg[j]	Golimumab 100mg[j,k]
Treated subjects in Phase 3 SC rheumatologic studies and UC studies	100	193	639	1251	1555	129	155	993	868	1599	2548
Number of subjects with Serious Infections[m]	0	2 (1.0%)	17 (2.7%)	64 (5.1%)	159 (10.2%)	1 (0.8%)	8 (5.2%)	59 (5.9%)	18 (2.1%)	74 (4.6%)	218 (8.6%)
Total subject-years of follow-up	31	185	349	3185	5549	141	376	2052	521	3745	7601
Median subject-years of follow up	0.3	0.9	0.5	1.9	4.0	0.7	2.2	1.3	0.5	1.6	3.2
Number of infections	0	2	17	81	244	1	11	64	18	94	308
Incidence per 100 subject-years	0.00	1.08	4.86	2.54	4.40	0.71	2.93	3.12	3.45	2.51	4.05
95% confidence interval[l]	(0.00, 9.59)	(0.13, 3.91)	(2.83, 7.79)	(2.02, 3.16)	(3.86, 4.98)	(0.02, 3.96)	(1.46, 5.24)	(2.40, 3.98)	(2.05, 5.46)	(2.03, 3.07)	(3.61, 4.53)

	nrAxSpA Study[a]		Phase 3 RA, PsA, AS Studies[b]			UC Studies[c]			All Studies		
	Placebo[d,j]	Golimumab 50mg[e,j]	Placebo[d,j]	Golimumab 50mg[e,j]	Golimumab 100mg[e,j,k]	Placebo[f,j]	Golimumab 50mg[g,h,j]	Golimumab 100mg[g,h,i,j,k]	Placebo[j]	Golimumab 50mg[j]	Golimumab 100mg[j,k]

[a] P07642
[b] C0524T05, C0524T06, C0524T11, C0524T08, and C0524T09
[c] From Week 0 through Week 228 of the maintenance study (C0524T18) for subjects who were treated in the maintenance study; subjects who received golimumab during the induction studies (C0524T16 and C0524T17) and only placebo during the maintenance study (C0524T18) are not included in the analyses.
[d] Received placebo SC every 4 weeks with or without MTX
[e] Received golimumab 50 mg SC every 4 weeks in P07642; received golimumab 50 mg or 100 mg SC every 4 weeks, with or without MTX in C0524T05, C0524T06, C0524T11, C0524T08, and C0524T09.
[f] In C0524T16, subjects received placebo IV at Week 0. In C0524T17, subjects received placebo SC at Week 0 and Week 2. In C0524T18, subjects in response to placebo induction from C0524T16 or C0524T17 continued to receive placebo SC every 4 weeks.
[g] In C0524T16, subjects received placebo or golimumab 1 mg/kg, 2 mg/kg or 4 mg/kg IV at Week 0. In C0524T17, subjects received placebo or golimumab SC 100 mg/50 mg, 200 mg/100 mg, or 400 mg/200 mg at Weeks 0/2.
[h] In C0524T18, subjects received study agent every 4 weeks. Subjects who were in response to golimumab induction from C0524T16 and C052T17 received placebo or golimumab 50 mg or 100 mg SC (subjects who lost response to placebo were allowed to receive golimumab 100 mg SC and subjects who lost response to golimumab were allowed to increase their dose of golimumab). Subjects who were not in response to golimumab or placebo induction from C0524T16 or C0524T17 received golimumab 100 mg SC. Subjects in response to placebo induction remained on placebo in maintenance but were allowed to dose adjust to golimumab 100 mg SC.
[i] For subjects who received golimumab during the induction studies (C0524T16 and C0524T17) and placebo during the maintenance study (C0524T18), data is included from the time of dose adjustment for those who increased dose.
[j] Includes data up to the time of dose adjustment for those who increased dose.
[k] Includes data from the time of dose adjustment onward.
[l] Confidence intervals based on an exact method.
[m] Infections as assessed by the investigator; for nrAxSpA study P07642, using SOC="Infections and infestations".

[TSFS1B01.rtf] [CNTO148\Z_POOLED\DBR_AXSPA_T18_FINAL\RE_LABEL_FEB2016\tsfs1b01.sas] 03NOV2015, 10:45

表 2.7.4.7-付録-38 重篤な感染症（T16，T17 及び T18 試験 54 週まで；ランダム化された被験者）

	Golimumab Induction				
	Placebo Maintenance[a]	50 mg Maintenance[a]	100 mg Maintenance[a]	Combined 50 mg and 100 mg Maintenance[a]	Total Golimumab[a,b]
Treated subjects in C0524T16 and C0524T17 who were randomized in C0524T18	156	154	154	308	464
Avg duration of follow-up (weeks)	38.8	50.4	52.4	51.4	47.2
Avg exposure (number of administrations)	10.0	12.9	13.1	13.0	12.0
Subjects with 1 or more serious infections[c]	4 (2.6%)	5 (3.2%)	5 (3.2%)	10 (3.2%)	14 (3.0%)
System-organ class/preferred term					
感染症および寄生虫症	4 (2.6%)	5 (3.2%)	4 (2.6%)	9 (2.9%)	13 (2.8%)
虫垂炎	0 (0.0%)	0 (0.0%)	3 (1.9%)	3 (1.0%)	3 (0.6%)
膿瘍	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
脳膿瘍	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
気管支炎	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
サイトメガロウイルス感染	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
播種性結核	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
感染性小腸結腸炎	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
ロタウイルス胃腸炎	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
ウイルス性胃腸炎	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
帯状疱疹	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
外耳炎	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
ブドウ球菌感染	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
血液およびリンパ系障害	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
リンパ節症	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
心臓障害	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
心膜炎	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.3%)	1 (0.2%)
眼障害	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
結膜炎	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.3%)	1 (0.2%)

	Golimumab Induction				
	Placebo Maintenance[a]	50 mg Maintenance[a]	100 mg Maintenance[a]	Combined 50 mg and 100 mg Maintenance[a]	Total Golimumab[a,b]
一般・全身障害および投与部位の状態	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
発熱	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
腎および尿路障害	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
水腎症	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)

[a] Includes data up to the time of dose adjustment for those who increased dose from the indicated dose during the maintenance study.
[b] Includes data from the time of the first golimumab dose onward.
[c] Infection as assessed by the investigator.

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表 2.7.4.7-付録-39 重篤な感染症（T16，T17 及び T18 試験 54 週まで；全投与被験者）

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
Treated subjects in C0524T16 and C0524T17	49	358	286	77	157	154	660	14	1233
Avg duration of follow-up (weeks)	12.3	19.1	39.2	11.9	39.0	50.4	45.1	27.5	45.6
Avg exposure (number of administrations)	1.6	5.0	9.2	1.6	10.0	12.9	10.7	6.9	11.0
Subjects with 1 or more serious infections[f]	7 (14.3%)	2 (0.6%)	6 (2.1%)	12 (15.6%)	4 (2.5%)	5 (3.2%)	22 (3.3%)	0 (0.0%)	49 (4.0%)
System-organ class/preferred term									
感染症および寄生虫症	5 (10.2%)	2 (0.6%)	5 (1.7%)	9 (11.7%)	4 (2.5%)	5 (3.2%)	17 (2.6%)	0 (0.0%)	40 (3.2%)
虫垂炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.5%)	0 (0.0%)	3 (0.2%)
気管支炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (1.3%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	3 (0.2%)
播種性結核	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	3 (0.2%)
肺炎	1 (2.0%)	0 (0.0%)	1 (0.3%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	3 (0.2%)
肛門膿瘍	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
脳膿瘍	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
蜂巣炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (2.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
サイトメガロウイルス感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
敗血症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
膿瘍	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
感染性小腸結腸炎	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
ロタウイルス胃腸炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
ウイルス性胃腸炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
帯状疱疹	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
ウイルス性下気道感染	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
メタニューモウイルス感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
外耳炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
毛巣嚢胞	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
術後膿瘍	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
腎盂腎炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
直腸膿瘍	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
敗血症性ショック	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
ブドウ球菌性菌血症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
ブドウ球菌感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
レンサ球菌性敗血症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
皮下組織膿瘍	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
尿路感染	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
ウイルス感染	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
乳房膿瘍	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
カンジダ症	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
血腫感染	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
単純ヘルペス	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
直腸周囲膿瘍	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
胃腸障害	2 (4.1%)	0 (0.0%)	1 (0.3%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	3 (0.5%)	0 (0.0%)	5 (0.4%)
潰瘍性大腸炎	1 (2.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	2 (0.3%)	0 (0.0%)	3 (0.2%)
腸炎	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
急性膵炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
亜イレウス	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
血液およびリンパ系障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
貧血	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
リンパ節症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
一般・全身障害および投与部位の状態	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
発熱	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
心臓障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
心膜炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
眼障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
結膜炎	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
腎および尿路障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
水腎症	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
呼吸器、胸郭および縦隔障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
胸水	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)

[a] Includes data up to the time of the first golimumab dose in the maintenance study.
[b] Includes data from the time of dose adjustment onward for those who increased to the indicated dose during the maintenance study.
[c] Includes data up to the time of dose adjustment for those who increased dose from the indicated dose during the maintenance study.
[d] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[e] Includes data from the time of the first golimumab dose onward.
[f] Infection as assessed by the investigator.

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表 2.7.4.7-付録-40 100 人年あたりの重篤な感染症発現率（T16，T17 及び T18 試験 54 週まで；全投与被験者）

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
Treated subjects in C0524T16 and C0524T17	49	358	286	77	157	154	660	14	1233
Number of subjects with serious infections[f]	7 (14.3%)	2 (0.6%)	6 (2.1%)	12 (15.6%)	4 (2.5%)	5 (3.2%)	22 (3.3%)	0 (0.0%)	49 (4.0%)
Total subject-years of follow-up	12	131	216	18	118	149	573	7	1080
Number of serious infections[f]	8	2	6	13	7	8	22	0	56
Incidence per 100 subject-years	68.91	1.52	2.78	73.78	5.95	5.36	3.84	0.00	5.18
95% confidence interval[g]	(29.75, 135.77)	(0.18, 5.50)	(1.02, 6.06)	(39.28, 126.16)	(2.39, 12.26)	(2.31, 10.55)	(2.41, 5.82)	(0.00, 40.43)	(3.92, 6.73)

[a] Includes data up to the time of the first golimumab dose in the maintenance study.
[b] Includes data from the time of dose adjustment onward for those who increased to the indicated dose during the maintenance study.
[c] Includes data up to the time of dose adjustment for those who increased dose from the indicated dose during the maintenance study.
[d] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[e] Includes data from the time of the first golimumab dose onward.
[f] Infection as assessed by the investigator.
[g] Confidence intervals based on an exact method.

表 2.7.4.7-付録-41 重篤な感染症（17 試験 6 週まで，日本人）

		Golimumab				
	Placebo	100 mg -> 50 mg	200 mg -> 100 mg	400 mg -> 200 mg	Combined	All Golimumab
Treated subjects in C0524T17	30	-	23	19	42	42
Avg duration of follow-up (weeks)	6.07	-	6.08	5.93	6.01	6.01
Avg exposure (number of administrations)	1.97	-	1.96	2.00	1.98	1.98
Subjects with 1 or more serious infections	2 (6.7%)	-	1 (4.3%)	0	1 (2.4%)	1 (2.4%)
System-organ class/preferred term						
感染症および寄生虫症	2 (6.7%)	-	1 (4.3%)	0	1 (2.4%)	1 (2.4%)
肛門膿瘍	1 (3.3%)	-	0	0	0	0
感染性小腸結腸炎	1 (3.3%)	-	0	0	0	0
肺炎	0	-	1 (4.3%)	0	1 (2.4%)	1 (2.4%)

Note: Adverse Events are coded using MedDRA 13.0

[TSFAE05JP.rtf] [CNTO148\C0524T17\DBR_WEEK6\RE_NDAJPKK\TSFAE05JP.sas] 28JAN2016, 10:33

表 2.7.4.7-付録-42 重篤な感染症（18 試験 54 週まで，日本人）

		Golimumab				
	Placebo [a,b]	50 mg [a]	100 mg[a,c,d]	Combined 50 mg and 100 mg	200 mg[d,e]	All Golimumab[f]
Treated subjects in C0524T18	8	3	59	60	-	60
Avg duration of follow-up (weeks)	26.5	18.5	42.3	42.6	-	42.6
Avg exposure (number of administrations)	6.3	3.7	9.5	9.5	-	9.5
Subjects with 1 or more serious infections[g]	1 (12.5%)	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
System-organ class/preferred term						
感染症および寄生虫症	1 (12.5%)	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
感染性小腸結腸炎	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
サイトメガロウイルス感染	1 (12.5%)	0	0	0	-	0

[a] Includes data up to the time of dose adjustment for those who increased dose from the indicated dose.
[b] Includes 1) subjects who were in clinical response to golimumab induction dosing and were randomized to placebo on entry into this maintenance study; and 2) subjects who were in clinical response to placebo induction dosing and received placebo on entry into this maintenance study.
[c] Includes 1) subjects who were in clinical response to golimumab induction dosing and were randomized to golimumab 100 mg on entry into this maintenance study; 2) subjects who were not in clinical response to either placebo or golimumab induction dosing and received golimumab 100 mg on entry into this maintenance study; and 3) subjects who were dose adjusted to golimumab 100 mg from placebo (randomized or nonrandomized) or from golimumab 50 mg.
[d] Includes data from the time of dose adjustment onward for those who increased to the indicated dose.
[e] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[f] Includes data from the time of the first golimumab dose onward.
[g] Infections as assessed by the investigator.
Note: Adverse Events are coded using MedDRA 14.0

[TSFAE05JP.rtf] [CNTO148\C0524T18\DBR_WEEK54\RE_NDAJPKK\TSFAE05JP.sas] 29JAN2016, 17:57

表 2.7.4.7-付録-43 重篤な感染症（UCO3001 試験，導入期 0 週から維持期 54 週まで，全投与被験者）

	Golimumab
Analysis set: SF-I	144
Average duration of follow-up (weeks)	34.7
Average exposure (number of administrations)	10.5
Subjects with 1 or more serious infections	5 (3.5%)
System-organ class/preferred term	
感染症および寄生虫症	5 (3.5%)
帯状疱疹	2 (1.4%)
サイトメガロウイルス性大腸炎	1 (0.7%)
喉頭炎	1 (0.7%)
咽頭炎	1 (0.7%)

Note: Adverse events were coded using MedDRA Version 18.1.

[TSFSAEINF01INMA.rtf] [CNTO148\CNTO148UCO3001\DBR_CSRW54\RE_NDAJPKK\TSFSAEINF01INMA.sas] 04FEB2016, 14:21

表 2.7.4.7-付録-44 100 人年あたりの敗血症発現率（T16，T17 及び T18 試験 54 週まで；全投与被験者）

	Placebo Induction	Golimumab Induction					
			Maintenance				
	100 mg Maintenance[a]	No Maintenance	Placebo[b]	50 mg[b]	100 mg[a,b]	200 mg[a,c]	Any Golimumab[d]
Treated subjects in C0524T16 and C0524T17 who received at least one administration of golimumab	286	77	157	154	660	14	1233
Number of subjects with events of sepsis[e,f]	1 (0.3%)	2 (2.6%)	0 (0.0%)	0 (0.0%)	3 (0.5%)	0 (0.0%)	6 (0.5%)
Total subject-years of follow-up	216	18	118	149	573	7	1080
Number of events of sepsis[e,f]	1	2	0	0	3	0	6
Incidence per 100 subject-years	0.46	11.35	0.00	0.00	0.52	0.00	0.56
95% confidence interval[g]	(0.01, 2.59)	(1.37, 41.00)	(0.00, 2.55)	(0.00, 2.01)	(0.11, 1.53)	(0.00, 40.43)	(0.20, 1.21)

[a] Includes data from the time of dose adjustment onward for those who increased to the indicated dose during the maintenance study.
[b] Includes data up to the time of dose adjustment for those who increased dose from the indicated dose during the maintenance study
[c] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[d] Includes data from the time of the first golimumab dose onward.
[e] MedDRA terms sepsis, bacterial sepsis, urosepsis, septic shock, listeria sepsis, staphylococcal sepsis, streptococcal sepsis, sepsis syndrome.
[f] Upon review of the data by medical monitors, rectal abscess is counted as sepsis in UC study C0524T17.
[g] Confidence intervals based on an exact method.

RE599:[S INFE 47 M], 01MAY2012 15:59

表 2.7.4.7-付録-45 100 人年あたりの敗血症発現率（T18 試験 0 から 228 週まで，他疾患との統合データ）

	nrAxSpA Study[a]		Phase 3 RA, PsA, AS Studies[b]			UC Studies[c]			All Studies		
	Placebo[d,j]	Golimumab 50mg[e,j]	Placebo[d,j]	Golimumab 50mg[e,j]	Golimumab 100mg[e,j,k]	Placebo[f,j]	Golimumab 50mg[g,h,j]	Golimumab 100mg[g,h,i,j,k]	Placebo[j]	Golimumab 50mg[j]	Golimumab 100mg[j,k]
Treated subjects in Phase 3 SC rheumatologic studies and UC studies	100	193	639	1251	1555	129	155	993	868	1599	2548
Number of subjects with Sepsis[m]	0	0	1 (0.2%)	6 (0.5%)	19 (1.2%)	0	0	7 (0.7%)	1 (0.1%)	6 (0.4%)	26 (1.0%)
Total subject-years of follow-up	31	185	349	3185	5549	141	376	2052	521	3745	7601
Number of Sepsis	0	0	1	6	19	0	0	7	1	6	26
Incidence per 100 subject-years	0.00	0.00	0.29	0.19	0.34	0.00	0.00	0.34	0.19	0.16	0.34
95% confidence interval[l]	(0.00, 9.59)	(0.00, 1.62)	(0.01, 1.59)	(0.07, 0.41)	(0.21, 0.53)	(0.00, 2.13)	(0.00, 0.80)	(0.14, 0.70)	(0.00, 1.07)	(0.06, 0.35)	(0.22, 0.50)

[a] P07642
[b] C0524T05, C0524T06, C0524T11, C0524T08, and C0524T09
[c] From Week 0 through Week 228 of the maintenance study (C0524T18) for subjects who were treated in the maintenance study; subjects who received golimumab during the induction studies (C0524T16 and C0524T17) and only placebo during the maintenance study (C0524T18) are not included in the analyses.
[d] Received placebo SC every 4 weeks with or without MTX
[e] Received golimumab 50 mg SC every 4 weeks in P07642; received golimumab 50 mg or 100 mg SC every 4 weeks, with or without MTX in C0524T05, C0524T06, C0524T11, C0524T08, and C0524T09.
[f] In C0524T16, subjects received placebo IV at Week 0. In C0524T17, subjects received placebo SC at Week 0 and Week 2. In C0524T18, subjects in response to placebo induction from C0524T16 or C0524T17 continued to receive placebo SC every 4 weeks.
[g] In C0524T16, subjects received placebo or golimumab 1 mg/kg, 2 mg/kg or 4 mg/kg IV at Week 0. In C0524T17, subjects received placebo or golimumab SC 100 mg/50 mg, 200 mg/100 mg, or 400 mg/200 mg at Weeks 0/2, respectively.
[h] In C0524T18, subjects received study agent every 4 weeks. Subjects who were in response to golimumab induction from C0524T16 and C052T17 received placebo or golimumab 50 mg or 100 mg SC (subjects who lost response to placebo were allowed to receive golimumab 100 mg SC and subjects who lost response to golimumab were allowed to increase their dose of golimumab). Subjects who were not in response to golimumab or placebo induction from C0524T16 or C0524T17 received golimumab 100 mg SC. Subjects in response to placebo induction remained on placebo in maintenance but were allowed to dose adjust to golimumab 100 mg SC.
[i] For subjects who received golimumab during the induction studies (C0524T16 and C0524T17) and placebo during the maintenance study (C0524T18), data is included from the time of dose adjustment for those who increased dose.
[j] Includes data up to the time of dose adjustment for those who increased dose.
[k] Includes data from the time of dose adjustment onward.
[l] Confidence intervals based on an exact method.
[m] AE terms based on clinical review.

表 2.7.4.7-付録-46 100 人年あたりの肺炎発現率（T16，T17 及び T18 試験 54 週まで；全投与被験者）

	Placebo Induction	Golimumab Induction					
			Maintenance				
	100 mg Maintenance[a]	No Maintenance	Placebo[b]	50 mg[b]	100 mg[a,b]	200 mg[a,c]	Any Golimumab[d]
Treated subjects in C0524T16 and C0524T17 who received at least one administration of golimumab	286	77	157	154	660	14	1233
Number of subjects with events of pneumonia[e]	3 (1.0%)	1 (1.3%)	5 (3.2%)	0 (0.0%)	8 (1.2%)	0 (0.0%)	17 (1.4%)
Total subject-years of follow-up	216	18	118	149	573	7	1080
Number of events of pneumonia[e]	4	2	5	0	8	0	19
Incidence per 100 subject-years	1.86	11.35	4.25	0.00	1.40	0.00	1.76
95% confidence interval[f]	(0.51, 4.75)	(1.37, 41.00)	(1.38, 9.92)	(0.00, 2.01)	(0.60, 2.75)	(0.00, 40.43)	(1.06, 2.75)

[a] Includes data from the time of dose adjustment onward for those who increased to the indicated dose during the maintenance study.
[b] Includes data up to the time of dose adjustment for those who increased dose from the indicated dose during the maintenance study.
[c] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[d] Includes data from the time of the first golimumab dose onward.
[e] MedDRA terms bronchopneumonia, lobar pneumonia, lower respiratory tract infection, lower respiratory tract infection viral, lung infection, lung infection pseudomonal, pneumocystis jiroveci pneumonia, pneumonia, pneumonia bacterial, pneumonia legionella, pneumonia primary atypical, pulmonary tuberculosis, pneumonitis, lung abscess.
[f] Confidence intervals based on an exact method.

表 2.7.4.7-付録-47 100 人年あたりの肺炎発現率（T18 試験 0 から 228 週まで，他疾患との統合データ）

	nrAxSpA Study[a]		Phase 3 RA, PsA, AS Studies[b]			UC Studies[c]			All Studies		
	Placebo[d,j]	Golimumab 50mg[e,j]	Placebo[d,j]	Golimumab 50mg[e,j]	Golimumab 100mg[e,j,k]	Placebo[f,j]	Golimumab 50mg[g,h,j]	Golimumab 100mg[g,h,i,j,k]	Placebo[j]	Golimumab 50mg[j]	Golimumab 100mg[j,k]
Treated subjects in Phase 3 SC rheumatologic studies and UC studies	100	193	639	1251	1555	129	155	993	868	1599	2548
Number of subjects with Pneumonia[m]	0	2 (1.0%)	9 (1.4%)	52 (4.2%)	116 (7.5%)	3 (2.3%)	4 (2.6%)	28 (2.8%)	12 (1.4%)	58 (3.6%)	144 (5.7%)
Total subject-years of follow-up	31	185	349	3185	5549	141	376	2052	521	3745	7601
Number of Pneumonia	0	2	11	62	143	3	4	30	14	68	173
Incidence per 100 subject-years	0.00	1.08	3.15	1.95	2.58	2.13	1.07	1.46	2.69	1.82	2.28
95% confidence interval[l]	(0.00, 9.59)	(0.13, 3.91)	(1.57, 5.63)	(1.49, 2.50)	(2.17, 3.04)	(0.44, 6.24)	(0.29, 2.73)	(0.99, 2.09)	(1.47, 4.51)	(1.41, 2.30)	(1.95, 2.64)

[a] P07642
[b] C0524T05, C0524T06, C0524T11, C0524T08, and C0524T09
[c] From Week 0 through Week 228 of the maintenance study (C0524T18) for subjects who were treated in the maintenance study; subjects who received golimumab during the induction studies (C0524T16 and C0524T17) and only placebo during the maintenance study (C0524T18) are not included in the analyses.
[d] Received placebo SC every 4 weeks with or without MTX
[e] Received golimumab 50 mg SC every 4 weeks in P07642; received golimumab 50 mg or 100 mg SC every 4 weeks, with or without MTX in C0524T05, C0524T06, C0524T11, C0524T08, and C0524T09.
[f] In C0524T16, subjects received placebo IV at Week 0. In C0524T17, subjects received placebo SC at Week 0 and Week 2. In C0524T18, subjects in response to placebo induction from C0524T16 or C0524T17 continued to receive placebo SC every 4 weeks.
[g] In C0524T16, subjects received placebo or golimumab 1 mg/kg, 2 mg/kg or 4 mg/kg IV at Week 0. In C0524T17, subjects received placebo or golimumab SC 100 mg/50 mg, 200 mg/100 mg, or 400 mg/200 mg at Weeks 0/2, respectively.
[h] In C0524T18, subjects received study agent every 4 weeks. Subjects who were in response to golimumab induction from C0524T16 and C052T17 received placebo or golimumab 50 mg or 100 mg SC (subjects who lost response to placebo were allowed to receive golimumab 100 mg SC and subjects who lost response to golimumab were allowed to increase their dose of golimumab). Subjects who were not in response to golimumab or placebo induction from C0524T16 or C0524T17 received golimumab 100 mg SC. Subjects in response to placebo induction remained on placebo in maintenance but were allowed to dose adjust to golimumab 100 mg SC.
[i] For subjects who received golimumab during the induction studies (C0524T16 and C0524T17) and placebo during the maintenance study (C0524T18), data is included from the time of dose adjustment for those who increased dose.
[j] Includes data up to the time of dose adjustment for those who increased dose.
[k] Includes data from the time of dose adjustment onward.
[l] Confidence intervals based on an exact method.
[m] AE terms based on clinical review.

表 2.7.4.7-付録-48 100 人年あたりの結核発現率（T16，T17 及び T18 試験 54 週まで；全投与被験者）

	Placebo Induction	Golimumab Induction					
			Maintenance				
	100 mg Maintenance[a]	No Maintenance	Placebo[b]	50 mg[b]	100 mg[a,b]	200 mg[a,c]	Any Golimumab[d]
Treated subjects in C0524T16 and C0524T17 who received at least one administration of golimumab	286	77	157	154	660	14	1233
Number of subjects with events of tuberculosis[e]	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	3 (0.5%)	0 (0.0%)	4 (0.3%)
Total subject-years of follow-up	216	18	118	149	573	7	1080
Number of events of tuberculosis[e]	0	0	1	0	3	0	4
Incidence per 100 subject-years	0.00	0.00	0.85	0.00	0.52	0.00	0.37
95% confidence interval[f]	(0.00, 1.39)	(0.00, 17.00)	(0.02, 4.74)	(0.00, 2.01)	(0.11, 1.53)	(0.00, 40.43)	(0.10, 0.95)

[a] Includes data from the time of dose adjustment onward for those who increased to the indicated dose during the maintenance study.
[b] Includes data up to the time of dose adjustment for those who increased dose from the indicated dose during the maintenance study
[c] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[d] Includes data from the time of the first golimumab dose onward.
[e] MedDRA terms tuberculosis, lymph node tuberculosis, pulmonary tuberculosis, peritoneal tuberculosis, tuberculous pleurisy, disseminated tuberculosis.
[f] Confidence intervals based on an exact method.

RE599:[S INFE 47 O], 03FEB2012 17:50

表 2.7.4.7-付録-49 100 人年あたりの結核発現率（T18 試験 0 から 228 週まで，他疾患との統合データ）

	nrAxSpA Study[a]		Phase 3 RA, PsA, AS Studies[b]			UC Studies[c]			All Studies		
	Placebo[d,j]	Golimumab 50mg[e,j]	Placebo[d,j]	Golimumab 50mg[e,j]	Golimumab 100mg[e,j,k]	Placebo[f,j]	Golimumab 50mg[g,h,j]	Golimumab 100mg[g,h,i,j,k]	Placebo[j]	Golimumab 50mg[j]	Golimumab 100mg[j,k]
Treated subjects in Phase 3 SC rheumatologic studies and UC studies	100	193	639	1251	1555	129	155	993	868	1599	2548
Number of subjects with active tuberculosis[m]	0	0	0	4 (0.3%)	17 (1.1%)	0	0	6 (0.6%)	0	4 (0.3%)	23 (0.9%)
Total subject-years of follow-up	31	185	349	3185	5549	141	376	2052	521	3745	7601
Number of infections	0	0	0	4	19	0	0	7	0	4	26
Incidence per 100 subject-years	0.00	0.00	0.00	0.13	0.34	0.00	0.00	0.34	0.00	0.11	0.34
95% confidence interval[l]	(0.00, 9.59)	(0.00, 1.62)	(0.00, 0.86)	(0.03, 0.32)	(0.21, 0.53)	(0.00, 2.13)	(0.00, 0.80)	(0.14, 0.70)	(0.00, 0.57)	(0.03, 0.27)	(0.22, 0.50)

[a] P07642
[b] C0524T05, C0524T06, C0524T11, C0524T08, and C0524T09
[c] From Week 0 through Week 228 of the maintenance study (C0524T18) for subjects who were treated in the maintenance study; subjects who received golimumab during the induction studies (C0524T16 and C0524T17) and only placebo during the maintenance study (C0524T18) are not included in the analyses.
[d] Received placebo SC every 4 weeks with or without MTX
[e] Received golimumab 50 mg SC every 4 weeks in P07642; received golimumab 50 mg or 100 mg SC every 4 weeks, with or without MTX in C0524T05, C0524T06, C0524T11, C0524T08, and C0524T09.
[f] In C0524T16, subjects received placebo IV at Week 0. In C0524T17, subjects received placebo SC at Week 0 and Week 2. In C0524T18, subjects in response to placebo induction from C0524T16 or C0524T17 continued to receive placebo SC every 4 weeks.
[g] In C0524T16, subjects received placebo or golimumab 1 mg/kg, 2 mg/kg or 4 mg/kg IV at Week 0. In C0524T17, subjects received placebo or golimumab SC 100 mg/50 mg, 200 mg/100 mg, or 400 mg/200 mg at Weeks 0/2.
[h] In C0524T18, subjects received study agent every 4 weeks. Subjects who were in response to golimumab induction from C0524T16 and C052T17 received placebo or golimumab 50 mg or 100 mg SC (subjects who lost response to placebo were allowed to receive golimumab 100 mg SC and subjects who lost response to golimumab were allowed to increase their dose of golimumab). Subjects who were not in response to golimumab or placebo induction from C0524T16 or C0524T17 received golimumab 100 mg SC. Subjects in response to placebo induction remained on placebo in maintenance but were allowed to dose adjust to golimumab 100 mg SC.
[i] For subjects who received golimumab during the induction studies (C0524T16 and C0524T17) and placebo during the maintenance study (C0524T18), data is included from the time of dose adjustment for those who increased dose.
[j] Includes data up to the time of dose adjustment for those who increased dose.
[k] Includes data from the time of dose adjustment onward.
[l] Confidence intervals based on an exact method.
[m] AE terms based on clinical review.

[TSFS1B03.rtf] [CNTO148\Z_POOLED\DBR_AXSPA_T18_FINAL\RE_LABEL_FEB2016\tsfs1b03.sas] 03NOV2015, 10:45

表 2.7.4.7-付録-50 100 人年あたりの日和見感染発現率（T16，T17 及び T18 試験 54 週まで；全投与被験者）

	Placebo Induction	Golimumab Induction					
			Maintenance				
	100 mg Maintenance[a]	No Maintenance	Placebo[b]	50 mg[b]	100 mg[a,b]	200 mg[a,c]	Any Golimumab[d]
Treated subjects in C0524T16 and C0524T17 who received at least one administration of golimumab	286	77	157	154	660	14	1233
Number of subjects with events of opportunistic infections[e,f]	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.5%)	0 (0.0%)	3 (0.2%)
Total subject-years of follow-up	216	18	118	149	573	7	1080
Number of events of opportunistic infections[e,f]	0	0	0	0	3	0	3
Incidence per 100 subject-years	0.00	0.00	0.00	0.00	0.52	0.00	0.28
95% confidence interval[g]	(0.00, 1.39)	(0.00, 17.00)	(0.00, 2.55)	(0.00, 2.01)	(0.11, 1.53)	(0.00, 40.43)	(0.06, 0.81)

[a] Includes data from the time of dose adjustment onward for those who increased to the indicated dose during the maintenance study.
[b] Includes data up to the time of dose adjustment for those who increased dose from the indicated dose during the maintenance study
[c] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[d] Includes data from the time of the first golimumab dose onward.
[e] MedDRA terms coccidioidomycosis, eye infection toxoplasmal, histoplasmosis, listeria sepsis, mycobacterium kansasii infection, oesophageal candidiasis, pneumocystis jiroveci pneumonia, pneumonia legionella, aspergilloma, candidiasis with adverse event marked serious, oral candidiasis with adverse event marked serious,oropharyngeal candidiasis with adverse event marked serious.
[f] Upon review of the data by medical monitors, brain abscess is counted as OI in UC study C0524T18 for subject 7528-00001.
[g] Confidence intervals based on an exact method.

RE599:[S INFE 47 P], 01MAY2012 16:07

表 2.7.4.7-付録-51 100 人年あたりの日和見感染発現率（T18 試験 0 から 228 週まで，他疾患との統合データ）

	nrAxSpA Study[a]		Phase 3 RA, PsA, AS Studies[b]			UC Studies[c]			All Studies		
	Placebo[d,j]	Golimumab 50mg[e,j]	Placebo[d,j]	Golimumab 50mg[e,j]	Golimumab 100mg[e,j,k]	Placebo[f,j]	Golimumab 50mg[g,h,j]	Golimumab 100mg[g,h,i,j,k]	Placebo[j]	Golimumab 50mg[j]	Golimumab 100mg[j,k]
Treated subjects in Phase 3 SC rheumatologic studies and UC studies	100	193	639	1251	1555	129	155	993	868	1599	2548
Number of subjects with opportunistic infections[m]	0	0	0	3 (0.2%)	14 (0.9%)	0	0	3 (0.3%)	0	3 (0.2%)	17 (0.7%)
Total subject-years of follow-up	31	185	349	3185	5549	141	376	2052	521	3745	7601
Median subject-years of follow up	0.3	0.9	0.5	1.9	4.0	0.7	2.2	1.3	0.5	1.6	3.2
Number of infections	0	0	0	3	15	0	0	3	0	3	18
Incidence per 100 subject-years	0.00	0.00	0.00	0.09	0.27	0.00	0.00	0.15	0.00	0.08	0.24
95% confidence interval[l]	(0.00, 9.59)	(0.00, 1.62)	(0.00, 0.86)	(0.02, 0.28)	(0.15, 0.45)	(0.00, 2.13)	(0.00, 0.80)	(0.03, 0.43)	(0.00, 0.57)	(0.02, 0.23)	(0.14, 0.37)

	nrAxSpA Study[a]		Phase 3 RA, PsA, AS Studies[b]			UC Studies[c]			All Studies		
	Placebo[d,j]	Golimumab 50mg[e,j]	Placebo[d,j]	Golimumab 50mg[e,j]	Golimumab 100mg[e,j,k]	Placebo[f,j]	Golimumab 50mg[g,h,j]	Golimumab 100mg[g,h,i,j,k]	Placebo[j]	Golimumab 50mg[j]	Golimumab 100mg[j,k]

[a] P07642
[b] C0524T05, C0524T06, C0524T11, C0524T08, and C0524T09
[c] From Week 0 through Week 228 of the maintenance study (C0524T18) for subjects who were treated in the maintenance study; subjects who received golimumab during the induction studies (C0524T16 and C0524T17) and only placebo during the maintenance study (C0524T18) are not included in the analyses.
[d] Received placebo SC every 4 weeks with or without MTX
[e] Received golimumab 50 mg SC every 4 weeks in P07642; received golimumab 50 mg or 100 mg SC every 4 weeks, with or without MTX in C0524T05, C0524T06, C0524T11, C0524T08, and C0524T09.
[f] In C0524T16, subjects received placebo IV at Week 0. In C0524T17, subjects received placebo SC at Week 0 and Week 2. In C0524T18, subjects in response to placebo induction from C0524T16 or C0524T17 continued to receive placebo SC every 4 weeks.
[g] In C0524T16, subjects received placebo or golimumab 1 mg/kg, 2 mg/kg or 4 mg/kg IV at Week 0. In C0524T17, subjects received placebo or golimumab SC 100 mg/50 mg, 200 mg/100 mg, or 400 mg/200 mg at Weeks 0/2.
[h] In C0524T18, subjects received study agent every 4 weeks. Subjects who were in response to golimumab induction from C0524T16 and C052T17 received placebo or golimumab 50 mg or 100 mg SC (subjects who lost response to placebo were allowed to receive golimumab 100 mg SC and subjects who lost response to golimumab were allowed to increase their dose of golimumab). Subjects who were not in response to golimumab or placebo induction from C0524T16 or C0524T17 received golimumab 100 mg SC. Subjects in response to placebo induction remained on placebo in maintenance but were allowed to dose adjust to golimumab 100 mg SC.
[i] For subjects who received golimumab during the induction studies (C0524T16 and C0524T17) and placebo during the maintenance study (C0524T18), data is included from the time of dose adjustment for those who increased dose.
[j] Includes data up to the time of dose adjustment for those who increased dose.
[k] Includes data from the time of dose adjustment onward.
[l] Confidence intervals based on an exact method.
[m] AE terms based on the clinical review.

表 2.7.4.7-付録-52 100 人年あたりの蜂巣炎発現率（T16，T17 及び T18 試験 54 週まで；全投与被験者）

	Placebo Induction	Golimumab Induction					
			Maintenance				
	100 mg Maintenance[a]	No Maintenance	Placebo[b]	50 mg[b]	100 mg[a,b]	200 mg[a,c]	Any Golimumab[d]
Treated subjects in C0524T16 and C0524T17 who received at least one administration of golimumab	286	77	157	154	660	14	1233
Number of subjects with events of cellulitis[e]	2 (0.7%)	2 (2.6%)	2 (1.3%)	2 (1.3%)	3 (0.5%)	0 (0.0%)	11 (0.9%)
Total subject-years of follow-up	216	18	118	149	573	7	1080
Number of events of cellulitis[e]	2	3	2	3	6	0	16
Incidence per 100 subject-years	0.93	17.03	1.70	2.01	1.05	0.00	1.48
95% confidence interval[f]	(0.11, 3.35)	(3.51, 49.76)	(0.21, 6.14)	(0.41, 5.87)	(0.38, 2.28)	(0.00, 40.43)	(0.85, 2.41)

[a] Includes data from the time of dose adjustment onward for those who increased to the indicated dose during the maintenance study.
[b] Includes data up to the time of dose adjustment for those who increased dose from the indicated dose during the maintenance study
[c] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[d] Includes data from the time of the first golimumab dose onward.
[e] MedDRA terms cellulitis, breast cellulitis, cellulitis staphylococcal, cellulitis streptococcal, external ear cellulitis, periorbital cellulitis, skin bacterial infection, skin infection, staphylococcal skin infection, erysipelas.
[f] Confidence intervals based on an exact method.

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表 2.7.4.7-付録-53 100 人年あたりの蜂巣炎発現率（T18 試験 0 から 228 週まで，他疾患との統合データ）

	nrAxSpA Study[a]		Phase 3 RA, PsA, AS Studies[b]			UC Studies[c]			All Studies		
	Placebo[d,j]	Golimumab 50mg[e,j]	Placebo[d,j]	Golimumab 50mg[e,j]	Golimumab 100mg[e,j,k]	Placebo[f,j]	Golimumab 50mg[g,h,j]	Golimumab 100mg[g,h,i,j,k]	Placebo[j]	Golimumab 50mg[j]	Golimumab 100mg[j,k]
Treated subjects in Phase 3 SC rheumatologic studies and UC studies	100	193	639	1251	1555	129	155	993	868	1599	2548
Number of subjects with Cellulitis[m]	0	1 (0.5%)	9 (1.4%)	51 (4.1%)	87 (5.6%)	0	2 (1.3%)	9 (0.9%)	9 (1.0%)	54 (3.4%)	96 (3.8%)
Total subject-years of follow-up	31	185	349	3185	5549	141	376	2052	521	3745	7601
Number of Cellulitis	0	1	9	56	100	0	4	9	9	61	109
Incidence per 100 subject-years	0.00	0.54	2.58	1.76	1.80	0.00	1.07	0.44	1.73	1.63	1.43
95% confidence interval[l]	(0.00, 9.59)	(0.01, 3.02)	(1.18, 4.89)	(1.33, 2.28)	(1.47, 2.19)	(0.00, 2.13)	(0.29, 2.73)	(0.20, 0.83)	(0.79, 3.28)	(1.25, 2.09)	(1.18, 1.73)

[a] P07642
[b] C0524T05, C0524T06, C0524T11, C0524T08, and C0524T09
[c] From Week 0 through Week 228 of the maintenance study (C0524T18) for subjects who were treated in the maintenance study; subjects who received golimumab during the induction studies (C0524T16 and C0524T17) and only placebo during the maintenance study (C0524T18) are not included in the analyses.
[d] Received placebo SC every 4 weeks with or without MTX
[e] Received golimumab 50 mg SC every 4 weeks in P07642; received golimumab 50 mg or 100 mg SC every 4 weeks, with or without MTX in C0524T05, C0524T06, C0524T11, C0524T08, and C0524T09.
[f] In C0524T16, subjects received placebo IV at Week 0. In C0524T17, subjects received placebo SC at Week 0 and Week 2. In C0524T18, subjects in response to placebo induction from C0524T16 or C0524T17 continued to receive placebo SC every 4 weeks.
[g] In C0524T16, subjects received placebo or golimumab 1 mg/kg, 2 mg/kg or 4 mg/kg IV at Week 0. In C0524T17, subjects received placebo or golimumab SC 100 mg/50 mg, 200 mg/100 mg, or 400 mg/200 mg at Weeks 0/2, respectively.
[h] In C0524T18, subjects received study agent every 4 weeks. Subjects who were in response to golimumab induction from C0524T16 and C052T17 received placebo or golimumab 50 mg or 100 mg SC (subjects who lost response to placebo were allowed to receive golimumab 100 mg SC and subjects who lost response to golimumab were allowed to increase their dose of golimumab). Subjects who were not in response to golimumab or placebo induction from C0524T16 or C0524T17 received golimumab 100 mg SC. Subjects in response to placebo induction remained on placebo in maintenance but were allowed to dose adjust to golimumab 100 mg SC.
[i] For subjects who received golimumab during the induction studies (C0524T16 and C0524T17) and placebo during the maintenance study (C0524T18), data is included from the time of dose adjustment for those who increased dose.
[j] Includes data up to the time of dose adjustment for those who increased dose.
[k] Includes data from the time of dose adjustment onward.
[l] Confidence intervals based on an exact method.
[m] AE terms based on clinical review.

表 2.7.4.7-付録-54 注射部位反応（T17 試験 6 週まで，日本人）

		Golimumab				
	Placebo	100 mg -> 50 mg	200 mg -> 100 mg	400 mg -> 200 mg	Combined	All Golimumab
Treated subjects in C0524T17	30	-	23	19	42	42
Avg number of administrations	1.97	-	1.96	2.00	1.98	1.98
Total number of study agent injections	193	-	145	125	270	270
Injections with injection-site reactions	0	-	0	0	0	0
Subjects with 1 or more injection-site reactions	0	-	0	0	0	0
Preferred terms						
No data to report	-	-	-	-	-	-

Note: Adverse Events are coded using MedDRA 13.0

[TSFAE06JP.rtf] [CNTO148\C0524T17\DBR_WEEK6\RE_NDAJPKK\TSFAE06JP.sas] 28JAN2016, 19:38

表 2.7.4.7-付録-55 注射部位反応（T18 試験 54 週まで，日本人）

		Golimumab				
	Placebo [a,b]	50 mg [a]	100 mg[a,c,d]	Combined 50 mg and 100 mg	200 mg[d,e]	All Golimumab[f]
Treated subjects in C0524T18	8	3	59	60	-	60
Avg number of administrations	6.3	3.7	9.5	9.5	-	9.5
Total number of study agent injection	133	26	1375	1401	-	1401
Injections with injection-site reactions	0	0	2 (0.1%)	2 (0.1%)	-	2 (0.1%)
Subjects with 1 or more injection-site reactions	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
Preferred terms						
投与部位発疹	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
投与部位反応	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)

[a] Includes data up to the time of dose adjustment for those who increased dose from the indicated dose.
[b] Includes 1) subjects who were in clinical response to golimumab induction dosing and were randomized to placebo on entry into this maintenance study; and 2) subjects who were in clinical response to placebo induction dosing and received placebo on entry into this maintenance study.
[c] Includes 1) subjects who were in clinical response to golimumab induction dosing and were randomized to golimumab 100 mg on entry into this maintenance study; 2) subjects who were not in clinical response to either placebo or golimumab induction dosing and received golimumab 100 mg on entry into this maintenance study; and 3) subjects who were dose adjusted to golimumab 100 mg from placebo (randomized or nonrandomized) or from golimumab 50 mg.
[d] Includes data from the time of dose adjustment onward for those who increased to the indicated dose.
[e] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[f] Includes data from the time of the first golimumab dose onward.
Note: Adverse Events are coded using MedDRA 14.0

[TSFAE06JP.rtf] [CNTO148\C0524T18\DBR_WEEK54\RE_NDAJPKK\TSFAE06JP.sas] 29JAN2016, 17:57

表 2.7.4.7-付録-56 100 人年あたりの脱髄疾患発現率（T16，T17 及び T18 試験 54 週まで；全投与被験者）

	Placebo Induction	Golimumab Induction					
			Maintenance				
	100 mg Maintenance[a]	No Maintenance	Placebo[b]	50 mg[b]	100 mg[a,b]	200 mg[a,c]	Any Golimumab[d]
Treated subjects in C0524T16 and C0524T17 who received at least one administration of golimumab	286	77	157	154	660	14	1233
Number of subjects with events of demyelination[e]	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
Total subject-years of follow-up	216	18	118	149	573	7	1080
Number of events of demyelination[e]	0	0	1	0	0	0	1
Incidence per 100 subject-years	0.00	0.00	0.85	0.00	0.00	0.00	0.09
95% confidence interval[f]	(0.00, 1.39)	(0.00, 17.00)	(0.02, 4.74)	(0.00, 2.01)	(0.00, 0.52)	(0.00, 40.43)	(0.00, 0.52)

[a] Includes data from the time of dose adjustment onward for those who increased to the indicated dose during the maintenance study.
[b] Includes data up to the time of dose adjustment for those who increased dose from the indicated dose during the maintenance study
[c] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[d] Includes data from the time of the first golimumab dose onward.
[e] MedDRA terms demyelination and multiple sclerosis.
[f] Confidence intervals based on an exact method.

表 2.7.4.7-付録-57 100 人年あたりの脱髄疾患発現率（T18 試験 0 から 228 週まで，他疾患との統合データ）

	nrAxSpA Study[a]		Phase 3 RA, PsA, AS Studies[b]			UC Studies[c]			All Studies		
	Placebo[d,j]	Golimumab 50mg[e,j]	Placebo[d,j]	Golimumab 50mg[e,j]	Golimumab 100mg[e,j,k]	Placebo[f,j]	Golimumab 50mg[g,h,j]	Golimumab 100mg[g,h,i,j,k]	Placebo[j]	Golimumab 50mg[j]	Golimumab 100mg[j,k]
Treated Subjects in Phase 3 SC Rheumatologic Studies and UC Studies	100	193	639	1251	1555	129	155	993	868	1599	2548
Number of subjects with demyelination[m]	0	0	0	0	7	0	0	2	0	0	9
Total subject-years of follow up	31	185	349	3185	5545	141	376	2052	521	3745	7597
Median subject-years of follow up	0.3	0.9	0.5	1.9	4.0	0.7	2.2	1.3	0.5	1.6	3.2
Incidence per 100 subject-years	0.00	0.00	0.00	0.00	0.13	0.00	0.00	0.10	0.00	0.00	0.12
95% confidence interval[l]	(0.00, 9.59)	(0.00, 1.62)	(0.00, 0.86)	(0.00, 0.09)	(0.05, 0.26)	(0.00, 2.13)	(0.00, 0.80)	(0.01, 0.35)	(0.00, 0.57)	(0.00, 0.08)	(0.05, 0.22)

[a] P07642
[b] C0524T05, C0524T06, C0524T11, C0524T08, and C0524T09
[c] From Week 0 through Week 228 of the maintenance study (C0524T18) for subjects who were treated in the maintenance study; subjects who received golimumab during the induction studies (C0524T16 and C0524T17) and only placebo during the maintenance study (C0524T18) are not included in the analyses.
[d] Received placebo SC every 4 weeks with or without MTX
[e] Received golimumab 50 mg SC every 4 weeks in P07642; received golimumab 50 mg or 100 mg SC every 4 weeks, with or without MTX in C0524T05, C0524T06, C0524T11, C0524T08, and C0524T09.
[f] In C0524T16, subjects received placebo IV at Week 0. In C0524T17, subjects received placebo SC at Week 0 and Week 2. In C0524T18, subjects in response to placebo induction from C0524T16 or C0524T17 continued to receive placebo SC every 4 weeks.
[g] In C0524T16, subjects received placebo or golimumab 1 mg/kg, 2 mg/kg or 4 mg/kg IV at Week 0. In C0524T17, subjects received placebo or golimumab SC 100 mg/50 mg, 200 mg/100 mg, or 400 mg/200 mg at Weeks 0/2.
[h] In C0524T18, subjects received study agent every 4 weeks. Subjects who were in response to golimumab induction from C0524T16 and C052T17 received placebo or golimumab 50 mg or 100 mg SC (subjects who lost response to placebo were allowed to receive golimumab 100 mg SC and subjects who lost response to golimumab were allowed to increase their dose of golimumab). Subjects who were not in response to golimumab or placebo induction from C0524T16 or C0524T17 received golimumab 100 mg SC. Subjects in response to placebo induction remained on placebo in maintenance but were allowed to dose adjust to golimumab 100 mg SC.
[i] For subjects who received golimumab during the induction studies (C0524T16 and C0524T17) and placebo during the maintenance study (C0524T18), data is included from the time of dose adjustment for those who increased dose.
[j] Includes data up to the time of dose adjustment for those who increased dose.
[k] Includes data from the time of dose adjustment onward.
[l] Confidence intervals based on an exact method.
[m] AE terms based on clinical review.

[TSFS1B04.rtf] [CNTO148\Z_POOLED\DBR_AXSPA_T18_FINAL\RE_LABEL_FEB2016\tsfs1b04.sas] 04DEC2015, 17:41

表 2.7.4.7-付録-58 100 人年あたりのうっ血性心不全発現率（T16，T17 及び T18 試験 54 週まで；全投与被験者）

	Placebo Induction	Golimumab Induction					
			Maintenance				
	100 mg Maintenance[a]	No Maintenance	Placebo[b]	50 mg[b]	100 mg[a,b]	200 mg[a,c]	Any Golimumab[d]
Treated subjects in C0524T16 and C0524T17 who received at least one administration of golimumab	286	77	157	154	660	14	1233
Number of subjects with events of congestive heart failure[e]	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	1 (0.1%)
Total subject-years of follow-up	216	18	118	149	573	7	1080
Number of events of congestive heart failure[e]	0	0	0	0	2	0	2
Incidence per 100 subject-years	0.00	0.00	0.00	0.00	0.35	0.00	0.19
95% confidence interval[f]	(0.00, 1.39)	(0.00, 17.00)	(0.00, 2.55)	(0.00, 2.01)	(0.04, 1.26)	(0.00, 40.43)	(0.02, 0.67)

[a] Includes data from the time of dose adjustment onward for those who increased to the indicated dose during the maintenance study.
[b] Includes data up to the time of dose adjustment for those who increased dose from the indicated dose during the maintenance study
[c] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[d] Includes data from the time of the first golimumab dose onward.
[e] MedDRA terms acute left ventricular failure, acute pulmonary oedema, acute right ventricular failure, cardiac asthma, cardiac failure, cardiac failure acute, cardiac failure chronic, cardiac failure congestive, cardiac failure high output, cardiogenic shock, cardiopulmonary failure, cardiorenal syndrome, chronic left ventricular failure, chronic right ventricular failure, cor pulmonale, cor pulmonale acute, cor pulmonale chronic, ejection fraction decreased, hepatic congestion, hepatojugular reflux, left ventricular failure, low cardiac output syndrome, neonatal cardiac failure, pulmonary oedema, pulmonary oedema neonatal, right ventricular failure, ventricular failure.
[f] Confidence intervals based on an exact method.

表 2.7.4.7-付録-59 100 人年あたりのうっ血性心不全発現率（T18 試験 0 から 228 週まで，他疾患との統合データ）

	nrAxSpA Study[a]		Phase 3 RA, PsA, AS Studies[b]			UC Studies[c]			All Studies		
	Placebo[d,j]	Golimumab 50mg[e,j]	Placebo[d,j]	Golimumab 50mg[e,j]	Golimumab 100mg[e,j,k]	Placebo[f,j]	Golimumab 50mg[g,h,j]	Golimumab 100mg[g,h,i,j,k]	Placebo[j]	Golimumab 50mg[j]	Golimumab 100mg[j,k]
Treated subjects in Phase 3 SC rheumatologic studies and UC studies	100	193	639	1251	1555	129	155	993	868	1599	2548
Number of subjects with CHF[m]	0	0	1 (0.2%)	1 (0.1%)	11 (0.7%)	1 (0.8%)	0	2 (0.2%)	2 (0.2%)	1 (0.1%)	13 (0.5%)
Total subject-years of follow-up	31	185	349	3185	5549	141	376	2052	521	3745	7601
Number of CHF	0	0	2	1	12	1	0	3	3	1	15
Incidence per 100 subject-years	0.00	0.00	0.57	0.03	0.22	0.71	0.00	0.15	0.58	0.03	0.20
95% confidence interval[l]	(0.00, 9.59)	(0.00, 1.62)	(0.07, 2.07)	(0.00, 0.17)	(0.11, 0.38)	(0.02, 3.96)	(0.00, 0.80)	(0.03, 0.43)	(0.12, 1.68)	(0.00, 0.15)	(0.11, 0.33)

[a] P07642
[b] C0524T05, C0524T06, C0524T11, C0524T08, and C0524T09
[c] From Week 0 through Week 228 of the maintenance study (C0524T18) for subjects who were treated in the maintenance study; subjects who received golimumab during the induction studies (C0524T16 and C0524T17) and only placebo during the maintenance study (C0524T18) are not included in the analyses.
[d] Received placebo SC every 4 weeks with or without MTX
[e] Received golimumab 50 mg SC every 4 weeks in P07642; received golimumab 50 mg or 100 mg SC every 4 weeks, with or without MTX in C0524T05, C0524T06, C0524T11, C0524T08, and C0524T09.
[f] In C0524T16, subjects received placebo IV at Week 0. In C0524T17, subjects received placebo SC at Week 0 and Week 2. In C0524T18, subjects in response to placebo induction from C0524T16 or C0524T17 continued to receive placebo SC every 4 weeks.
[g] In C0524T16, subjects received placebo or golimumab 1 mg/kg, 2 mg/kg or 4 mg/kg IV at Week 0. In C0524T17, subjects received placebo or golimumab SC 100 mg/50 mg, 200 mg/100 mg, or 400 mg/200 mg at Weeks 0/2, respectively.
[h] In C0524T18, subjects received study agent every 4 weeks. Subjects who were in response to golimumab induction from C0524T16 and C052T17 received placebo or golimumab 50 mg or 100 mg SC (subjects who lost response to placebo were allowed to receive golimumab 100 mg SC and subjects who lost response to golimumab were allowed to increase their dose of golimumab). Subjects who were not in response to golimumab or placebo induction from C0524T16 or C0524T17 received golimumab 100 mg SC. Subjects in response to placebo induction remained on placebo in maintenance but were allowed to dose adjust to golimumab 100 mg SC.
[i] For subjects who received golimumab during the induction studies (C0524T16 and C0524T17) and placebo during the maintenance study (C0524T18), data is included from the time of dose adjustment for those who increased dose.
[j] Includes data up to the time of dose adjustment for those who increased dose.
[k] Includes data from the time of dose adjustment onward.
[l] Confidence intervals based on an exact method.
[m] AE terms based on SMQ Cardiac failure (narrow).

表 2.7.4.7-付録-60 100 人年あたりの過敏症反応発現率（T16, T17 及び T18 試験 54 週まで；全投与被験者）

	Placebo Induction	Golimumab Induction					
			Maintenance				
	100 mg Maintenance[a]	No Maintenance	Placebo[b]	50 mg[b]	100 mg[a,b]	200 mg[a,c]	Any Golimumab[d]
Treated subjects in C0524T16 and C0524T17 who received at least one administration of golimumab	286	77	157	154	660	14	1233
Number of subjects with events of hypersensitivity reactions[e]	6 (2.1%)	0 (0.0%)	5 (3.2%)	2 (1.3%)	9 (1.4%)	1 (7.1%)	22 (1.8%)
Total subject-years of follow-up	216	18	118	149	573	7	1080
Number of events of hypersensitivity reactions[e]	6	0	5	2	9	1	23
Incidence per 100 subject-years	2.78	0.00	4.25	1.34	1.57	13.50	2.13
95% confidence interval[f]	(1.02, 6.06)	(0.00, 17.00)	(1.38, 9.92)	(0.16, 4.84)	(0.72, 2.98)	(0.34, 75.20)	(1.35, 3.20)

[a] Includes data from the time of dose adjustment onward for those who increased to the indicated dose during the maintenance study.
[b] Includes data up to the time of dose adjustment for those who increased dose from the indicated dose during the maintenance study
[c] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[d] Includes data from the time of the first golimumab dose onward.
[e] MedDRA HLT allergic conditions NEC, anaphylactic responses, angioedemas, atopic disorders, urticarias, allergies to foods, food additives, drugs and other chemicals.
[f] Confidence intervals based on an exact method.

RE599:[S INFE 47 Y], 19APR2012 12:06

表 2.7.4.7-付録-61 100 人年あたりの過敏症反応発現率（T18 試験 0 から 228 週まで，他疾患との統合データ）

	nrAxSpA Study[a]		Phase 3 RA, PsA, AS Studies[b]			UC Studies[c]			All Studies		
	Placebo[d,j]	Golimumab 50mg[e,j]	Placebo[d,j]	Golimumab 50mg[e,j]	Golimumab 100mg[e,j,k]	Placebo[f,j]	Golimumab 50mg[g,h,j]	Golimumab 100mg[g,h,i,j,k]	Placebo[j]	Golimumab 50mg[j]	Golimumab 100mg[j,k]
Treated subjects in Phase 3 SC rheumatologic studies and UC studies	100	193	639	1251	1555	129	155	993	868	1599	2548
Number of subjects with Hypersensitivity Reactions	0	2 (1.0%)	10 (1.6%)	30 (2.4%)	61 (3.9%)	3 (2.3%)	7 (4.5%)	29 (2.9%)	13 (1.5%)	39 (2.4%)	90 (3.5%)
Total subject-years of follow-up	31	185	349	3185	5549	141	376	2052	521	3745	7601
Number of Hypersensitivity Reactions	0	2	12	35	83	3	7	32	15	44	115
Incidence per 100 subject-years	0.00	1.08	3.43	1.10	1.50	2.13	1.86	1.56	2.88	1.17	1.51
95% confidence interval[l]	(0.00, 9.59)	(0.13, 3.91)	(1.77, 6.00)	(0.77, 1.53)	(1.19, 1.85)	(0.44, 6.24)	(0.75, 3.84)	(1.07, 2.20)	(1.61, 4.75)	(0.85, 1.58)	(1.25, 1.82)

[a] P07642
[b] C0524T05, C0524T06, C0524T11, C0524T08, and C0524T09
[c] From Week 0 through Week 228 of the maintenance study (C0524T18) for subjects who were treated in the maintenance study; subjects who received golimumab during the induction studies (C0524T16 and C0524T17) and only placebo during the maintenance study (C0524T18) are not included in the analyses.
[d] Received placebo SC every 4 weeks with or without MTX
[e] Received golimumab 50 mg SC every 4 weeks in P07642; received golimumab 50 mg or 100 mg SC every 4 weeks, with or without MTX in C0524T05, C0524T06, C0524T11, C0524T08, and C0524T09.
[f] In C0524T16, subjects received placebo IV at Week 0. In C0524T17, subjects received placebo SC at Week 0 and Week 2. In C0524T18, subjects in response to placebo induction from C0524T16 or C0524T17 continued to receive placebo SC every 4 weeks.
[g] In C0524T16, subjects received placebo or golimumab 1 mg/kg, 2 mg/kg or 4 mg/kg IV at Week 0. In C0524T17, subjects received placebo or golimumab SC 100 mg/50 mg, 200 mg/100 mg, or 400 mg/200 mg at Weeks 0/2, respectively.
[h] In C0524T18, subjects received study agent every 4 weeks. Subjects who were in response to golimumab induction from C0524T16 and C052T17 received placebo or golimumab 50 mg or 100 mg SC (subjects who lost response to placebo were allowed to receive golimumab 100 mg SC and subjects who lost response to golimumab were allowed to increase their dose of golimumab). Subjects who were not in response to golimumab or placebo induction from C0524T16 or C0524T17 received golimumab 100 mg SC. Subjects in response to placebo induction remained on placebo in maintenance but were allowed to dose adjust to golimumab 100 mg SC.
[i] For subjects who received golimumab during the induction studies (C0524T16 and C0524T17) and placebo during the maintenance study (C0524T18), data is included from the time of dose adjustment for those who increased dose.
[j] Includes data up to the time of dose adjustment for those who increased dose.
[k] Includes data from the time of dose adjustment onward.
[l] Confidence intervals based on an exact method.

表 2.7.4.7-付録-62 100 人年あたりの血清病様反応及びアナフィラキシー様反応発現率（T16，T17 及び T18 試験 54 週まで；全投与被験者）

	Placebo Induction	Golimumab Induction					
			Maintenance				
	100 mg Maintenance[a]	No Maintenance	Placebo[b]	50 mg[b]	100 mg[a,b]	200 mg[a,c]	Any Golimumab[d]
Treated subjects in C0524T16 and C0524T17 who received at least one administration of golimumab	286	77	157	154	660	14	1233
Number of subjects with events of any anaphylactic or serum sickness-like reactions[e]	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
Total subject-years of follow-up	216	18	118	149	573	7	1080
Number of events of any anaphylactic or serum sickness-like reactions[e]	1	0	0	0	0	0	1
Incidence per 100 subject-years	0.46	0.00	0.00	0.00	0.00	0.00	0.09
95% confidence interval[f]	(0.01, 2.59)	(0.00, 17.00)	(0.00, 2.55)	(0.00, 2.01)	(0.00, 0.52)	(0.00, 40.43)	(0.00, 0.52)

[a] Includes data from the time of dose adjustment onward for those who increased to the indicated dose during the maintenance study.
[b] Includes data up to the time of dose adjustment for those who increased dose from the indicated dose during the maintenance study
[c] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[d] Includes data from the time of the first golimumab dose onward.
[e] Anaphylaxis reactions are defined by the following preferred terms: anaphylactic reaction, anaphylactic shock, anaphylactoid reaction, anaphylactoid shock, Type I hypersensitivity, Type IV hypersensitivity reaction. Serum-sickness reactions are defined by the following preferred terms: serum sickness, serum sickness-like reaction.
[f] Confidence intervals based on an exact method.

表 2.7.4.7-付録-63 100 人年あたりの血清病様反応及びアナフィラキシー様反応発現率（T18 試験 0 から 228 週まで，他疾患との統合データ）

	nrAxSpA Study[a]		Phase 3 RA, PsA, AS Studies[b]			UC Studies[c]			All Studies		
	Placebo[d,j]	Golimumab 50mg[e,j]	Placebo[d,j]	Golimumab 50mg[e,j]	Golimumab 100mg[e,j,k]	Placebo[f,j]	Golimumab 50mg[g,h,j]	Golimumab 100mg[g,h,i,j,k]	Placebo[j]	Golimumab 50mg[j]	Golimumab 100mg[j,k]
Treated subjects in Phase 3 SC rheumatologic studies and UC studies	100	193	639	1251	1555	129	155	993	868	1599	2548
Number of subjects with Serum Sickness and Anaphylactic Reactions	0	0	1 (0.2%)	0	0	0	0	0	1 (0.1%)	0	0
Total subject-years of follow-up	31	185	349	3185	5549	141	376	2052	521	3745	7601
Number of Serum Sickness and Anaphylactic Reactions	0	0	3	0	0	0	0	0	3	0	0
Incidence per 100 subject-years	0.00	0.00	0.86	0.00	0.00	0.00	0.00	0.00	0.58	0.00	0.00
95% confidence interval[l]	(0.00, 9.59)	(0.00, 1.62)	(0.18, 2.51)	(0.00, 0.09)	(0.00, 0.05)	(0.00, 2.13)	(0.00, 0.80)	(0.00, 0.15)	(0.12, 1.68)	(0.00, 0.08)	(0.00, 0.04)

[a] P07642
[b] C0524T05, C0524T06, C0524T11, C0524T08, and C0524T09
[c] From Week 0 through Week 228 of the maintenance study (C0524T18) for subjects who were treated in the maintenance study; subjects who received golimumab during the induction studies (C0524T16 and C0524T17) and only placebo during the maintenance study (C0524T18) are not included in the analyses.
[d] Received placebo SC every 4 weeks with or without MTX
[e] Received golimumab 50 mg SC every 4 weeks in P07642; received golimumab 50 mg or 100 mg SC every 4 weeks, with or without MTX in C0524T05, C0524T06, C0524T11, C0524T08, and C0524T09.
[f] In C0524T16, subjects received placebo IV at Week 0. In C0524T17, subjects received placebo SC at Week 0 and Week 2. In C0524T18, subjects in response to placebo induction from C0524T16 or C0524T17 continued to receive placebo SC every 4 weeks.
[g] In C0524T16, subjects received placebo or golimumab 1 mg/kg, 2 mg/kg or 4 mg/kg IV at Week 0. In C0524T17, subjects received placebo or golimumab SC 100 mg/50 mg, 200 mg/100 mg, or 400 mg/200 mg at Weeks 0/2, respectively.
[h] In C0524T18, subjects received study agent every 4 weeks. Subjects who were in response to golimumab induction from C0524T16 and C052T17 received placebo or golimumab 50 mg or 100 mg SC (subjects who lost response to placebo were allowed to receive golimumab 100 mg SC and subjects who lost response to golimumab were allowed to increase their dose of golimumab). Subjects who were not in response to golimumab or placebo induction from C0524T16 or C0524T17 received golimumab 100 mg SC. Subjects in response to placebo induction remained on placebo in maintenance but were allowed to dose adjust to golimumab 100 mg SC.
[i] For subjects who received golimumab during the induction studies (C0524T16 and C0524T17) and placebo during the maintenance study (C0524T18), data is included from the time of dose adjustment for those who increased dose.
[j] Includes data up to the time of dose adjustment for those who increased dose.
[k] Includes data from the time of dose adjustment onward.
[l] Confidence intervals based on an exact method.

[TSFS1B15.rtf] [CNTO148\Z_POOLED\DBR_AXSPA_T18_FINAL\RE_LABEL_FEB2016\tsfs1b15.sas] 03MAR2016, 17:15

表 2.7.4.7-付録-64 肝胆道系の有害事象（T16，T17 及び T18 試験 54 週まで；全投与被験者）

	Placebo Induction	Golimumab Induction					
			Maintenance				
	100 mg Maintenance[a]	No Maintenance	Placebo[b]	50 mg[b]	100 mg[a,b]	200 mg[a,c]	Any Golimumab[d]
Treated subjects in C0524T16 and C0524T17 who received at least one administration of golimumab	286	77	157	154	660	14	1233
Avg duration of follow-up (weeks)	39.2	11.9	39.0	50.4	45.1	27.5	45.6
Avg exposure (number of administrations)	9.2	1.6	10.0	12.9	10.7	6.9	11.0
Subjects with 1 or more hepatobiliary adverse events[e]	0 (0.0%)	0 (0.0%)	1 (0.6%)	2 (1.3%)	0 (0.0%)	0 (0.0%)	3 (0.2%)
ALT ≥ 3 × ULN and bilirubin ≥ 2 × ULN	0 (0.0%)	0 (0.0%)	1 (0.6%)	2 (1.3%)	0 (0.0%)	0 (0.0%)	3 (0.2%)
ALT ≥ 3 × ULN and serious AE in hepatobiliary system-organ class	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

[a] Includes data from the time of dose adjustment onward for those who increased to the indicated dose during the maintenance study.
[b] Includes data up to the time of dose adjustment for those who increased dose from the indicated dose during the maintenance study
[c] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[d] Includes data from the time of the first golimumab dose onward.
[e] Hepatobiliary adverse event defined as ALT ≥ 3 × ULN and either bilirubin ≥ 2 × ULN or occurrence of a serious adverse event in the hepatobiliary system-organ class.

RE599:[S CHM 126 C], 27JAN2012 17:56

表 2.7.4.7-付録-65 100 人年あたりの悪性腫瘍発現率（T16，T17 及び T18 試験 54 週まで；全投与被験者）

	Placebo Induction	Golimumab Induction					
			Maintenance				
	100 mg Maintenance[a]	No Maintenance	Placebo[b]	50 mg[b]	100 mg[a,b]	200 mg[a,c]	Any Golimumab[d]
Treated subjects in C0524T16 and C0524T17 who received at least one administration of golimumab	286	77	157	154	660	14	1233
All malignancies							
Total subject-years of follow-up	214	18	118	149	572	7	1079
Median subject-years of follow-up	0.9	0.2	0.7	1.2	1.0	0.6	1.0
Observed number of subjects with event	2	1	0	0	2	0	5
Incidence per 100 subject-years	0.93	5.68	0.00	0.00	0.35	0.00	0.46
95% confidence interval[e]	(0.11, 3.37)	(0.14, 31.64)	(0.00, 2.55)	(0.00, 2.01)	(0.04, 1.26)	(0.00, 40.43)	(0.15, 1.08)
Type of malignancy							
Lymphoma							
Total subject-years of follow-up	216	18	118	149	573	7	1080
Median subject-years of follow-up	0.9	0.2	0.7	1.2	1.0	0.6	1.0
Observed number of subjects with event	0	0	0	0	0	0	0
Incidence per 100 subject-years	0.00	0.00	0.00	0.00	0.00	0.00	0.00
95% confidence interval[e]	(0.00, 1.39)	(0.00, 17.00)	(0.00, 2.55)	(0.00, 2.01)	(0.00, 0.52)	(0.00, 40.43)	(0.00, 0.28)
Nonmelanoma skin cancers							
Total subject-years of follow-up	216	18	118	149	572	7	1080
Median subject-years of follow-up	0.9	0.2	0.7	1.2	1.0	0.6	1.0
Observed number of subjects with event	0	0	0	0	1	0	1
Incidence per 100 subject-years	0.00	0.00	0.00	0.00	0.17	0.00	0.09
95% confidence interval[e]	(0.00, 1.39)	(0.00, 17.00)	(0.00, 2.55)	(0.00, 2.01)	(0.00, 0.97)	(0.00, 40.43)	(0.00, 0.52)

	Placebo Induction	Golimumab Induction					
			Maintenance				
	100 mg Maintenance[a]	No Maintenance	Placebo[b]	50 mg[b]	100 mg[a,b]	200 mg[a,c]	Any Golimumab[d]
Other malignancies							
Total subject-years of follow-up	214	18	118	149	573	7	1079
Median subject-years of follow-up	0.9	0.2	0.7	1.2	1.0	0.6	1.0
Observed number of subjects with event	2	1	0	0	1	0	4
Incidence per 100 subject-years	0.93	5.68	0.00	0.00	0.17	0.00	0.37
95% confidence interval[e]	(0.11, 3.37)	(0.14, 31.64)	(0.00, 2.55)	(0.00, 2.01)	(0.00, 0.97)	(0.00, 40.43)	(0.10, 0.95)

[a] Includes data from the time of dose adjustment onward for those who increased to the indicated dose during the maintenance study.
[b] Includes data up to the time of dose adjustment for those who increased dose from the indicated dose during the maintenance study.
[c] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[d] Includes data from the time of the first golimumab dose onward.
[e] Confidence intervals based on an exact method.

RE599:[S MAL 60 T], 03FEB2012 17:55

表 2.7.4.7-付録-66 100 人年あたりの悪性腫瘍発現率（T18 試験 0 から 228 週まで，他疾患との統合データ）

	nrAxSpA Study[a]		Phase 3 RA, PsA, AS Studies[b]			UC Studies[c]			All Studies		
	Placebo[d,j]	Golimumab 50mg[e,j]	Placebo[d,j]	Golimumab 50mg[e,j]	Golimumab 100mg[e,j,k]	Placebo[f,j]	Golimumab 50mg[g,h,j]	Golimumab 100mg[g,h,i,j,k]	Placebo[j]	Golimumab 50mg[j]	Golimumab 100mg[j,k]
Treated subjects in Phase 3 SC rheumatologic studies and UC studies	100	193	639	1251	1555	129	155	993	868	1599	2548
Type of malignancy											
Lymphoma											
Total subject-years of follow up	31	185	349	3185	5547	141	376	2052	521	3745	7599
Median subject-years of follow up	0.3	0.9	0.5	1.9	4.0	0.7	2.2	1.3	0.5	1.6	3.2
Observed number of subjects with event	0	0	0	1	8	0	0	2	0	1	10
Incidence per 100 subject-years	0.00	0.00	0.00	0.03	0.14	0.00	0.00	0.10	0.00	0.03	0.13
95% confidence interval[l]	(0.00, 9.59)	(0.00, 1.62)	(0.00, 0.86)	(0.00, 0.17)	(0.06, 0.28)	(0.00, 2.13)	(0.00, 0.80)	(0.01, 0.35)	(0.00, 0.57)	(0.00, 0.15)	(0.06, 0.24)
Melanoma											
Total subject-years of follow up	31	185	349	3184	5549	141	376	2052	521	3745	7601
Median subject-years of follow up	0.3	0.9	0.5	1.9	4.0	0.7	2.2	1.3	0.5	1.6	3.2
Observed number of subjects with event	0	0	0	1	2	0	0	0	0	1	2
Incidence per 100 subject-years	0.00	0.00	0.00	0.03	0.04	0.00	0.00	0.00	0.00	0.03	0.03
95% confidence interval[l]	(0.00, 9.59)	(0.00, 1.62)	(0.00, 0.86)	(0.00, 0.17)	(0.00, 0.13)	(0.00, 2.13)	(0.00, 0.80)	(0.00, 0.15)	(0.00, 0.57)	(0.00, 0.15)	(0.00, 0.10)

	nrAxSpA Study[a]		Phase 3 RA, PsA, AS Studies[b]			UC Studies[c]			All Studies		
	Placebo[d,j]	Golimumab 50mg[e,j]	Placebo[d,j]	Golimumab 50mg[e,j]	Golimumab 100mg[e,j,k]	Placebo[f,j]	Golimumab 50mg[g,h,j]	Golimumab 100mg[g,h,i,j,k]	Placebo[j]	Golimumab 50mg[j]	Golimumab 100mg[j,k]
Nonmelanoma											
Total subject-years of follow up	31	185	348	3177	5494	141	373	2047	520	3735	7542
Median subject-years of follow up	0.3	0.9	0.5	1.9	4.0	0.7	2.1	1.3	0.5	1.5	3.2
Observed number of subjects with event	0	0	5	9	28	0	1	3	5	10	31
Incidence per 100 subject-years	0.00	0.00	1.44	0.28	0.51	0.00	0.27	0.15	0.96	0.27	0.41
95% confidence interval[l]	(0.00, 9.59)	(0.00, 1.62)	(0.47, 3.35)	(0.13, 0.54)	(0.34, 0.74)	(0.00, 2.13)	(0.01, 1.50)	(0.03, 0.43)	(0.31, 2.24)	(0.13, 0.49)	(0.28, 0.58)
Other malignancies[m]											
Total subject-years of follow up	31	185	348	3181	5541	141	375	2051	520	3741	7592
Median subject-years of follow up	0.3	0.9	0.5	1.9	4.0	0.7	2.2	1.3	0.5	1.6	3.2
Observed number of subjects with event	0	0	4	19	26	1	2	8	5	21	34
Incidence per 100 subject-years	0.00	0.00	1.15	0.60	0.47	0.71	0.53	0.39	0.96	0.56	0.45
95% confidence interval[l]	(0.00, 9.59)	(0.00, 1.62)	(0.31, 2.94)	(0.36, 0.93)	(0.31, 0.69)	(0.02, 3.96)	(0.06, 1.93)	(0.17, 0.77)	(0.31, 2.24)	(0.35, 0.86)	(0.31, 0.63)
All malignancies											
Total subject-years of follow up	31	185	347	3172	5484	141	372	2046	519	3729	7531
Median subject-years of follow up	0.3	0.9	0.5	1.9	4.0	0.7	2.1	1.3	0.5	1.5	3.2
Observed number of subjects with event	0	0	9	29	63	1	3	13	10	32	76
Incidence per 100 subject-years	0.00	0.00	2.60	0.91	1.15	0.71	0.81	0.64	1.93	0.86	1.01
95% confidence interval[l]	(0.00, 9.59)	(0.00, 1.62)	(1.19, 4.93)	(0.61, 1.31)	(0.88, 1.47)	(0.02, 3.96)	(0.17, 2.36)	(0.34, 1.09)	(0.92, 3.55)	(0.59, 1.21)	(0.80, 1.26)

	nrAxSpA Study[a]		Phase 3 RA, PsA, AS Studies[b]			UC Studies[c]			All Studies		
	Placebo[d,j]	Golimumab 50mg[e,j]	Placebo[d,j]	Golimumab 50mg[e,j]	Golimumab 100mg[e,j,k]	Placebo[f,j]	Golimumab 50mg[g,h,j]	Golimumab 100mg[g,h,i,j,k]	Placebo[j]	Golimumab 50mg[j]	Golimumab 100mg[j,k]

[a] P07642
[b] C0524T05, C0524T06, C0524T11, C0524T08, and C0524T09
[c] From Week 0 through Week 228 of the maintenance study (C0524T18) for subjects who were treated in the maintenance study; subjects who received golimumab during the induction studies (C0524T16 and C0524T17) and only placebo during the maintenance study (C0524T18) are not included in the analyses.
[d] Received placebo SC every 4 weeks with or without MTX
[e] Received golimumab 50 mg SC every 4 weeks in P07642; received golimumab 50 mg or 100 mg SC every 4 weeks, with or without MTX in C0524T05, C0524T06, C0524T11, C0524T08, and C0524T09.
[f] In C0524T16, subjects received placebo IV at Week 0. In C0524T17, subjects received placebo SC at Week 0 and Week 2. In C0524T18, subjects in response to placebo induction from C0524T16 or C0524T17 continued to receive placebo SC every 4 weeks.
[g] In C0524T16, subjects received placebo or golimumab 1 mg/kg, 2 mg/kg or 4 mg/kg IV at Week 0. In C0524T17, subjects received placebo or golimumab SC 100 mg/50 mg, 200 mg/100 mg, or 400 mg/200 mg at Weeks 0/2.
[h] In C0524T18, subjects received study agent every 4 weeks. Subjects who were in response to golimumab induction from C0524T16 and C052T17 received placebo or golimumab 50 mg or 100 mg SC (subjects who lost response to placebo were allowed to receive golimumab 100 mg SC and subjects who lost response to golimumab were allowed to increase their dose of golimumab). Subjects who were not in response to golimumab or placebo induction from C0524T16 or C0524T17 received golimumab 100 mg SC. Subjects in response to placebo induction remained on placebo in maintenance but were allowed to dose adjust to golimumab 100 mg SC.
[i] For subjects who received golimumab during the induction studies (C0524T16 and C0524T17) and placebo during the maintenance study (C0524T18), data is included from the time of dose adjustment for those who increased dose.
[j] Includes data up to the time of dose adjustment for those who increased dose.
[k] Includes data from the time of dose adjustment onward.
[l] Confidence intervals based on an exact method.
[m] Exclude lymphoma, nonmelanoma and melanoma.

表 2.7.4.7-付録-67 100 人年あたりの悪性腫瘍発現率（T16，T17 及び T18 試験 54 週まで；他疾患との統合データ）

	nrAxSpA Study[a]		Phase 3 RA, PsA, AS Studies[b]		UC Studies[c]		All Studies	
	Placebo[d]	Golimumab[e]	Placebo[d]	Golimumab[e]	Placebo[f]	Golimumab[g,h]	Placebo	Golimumab
Treated subjects in Phase 3 SC rheumatologic studies and Phase 2/3 UC studies	100	193	639	2228	407	1245	1146	3666
Type of malignancy								
Lymphoma								
Total subject-years of follow up	31	185	349	8718	193	2760	573	11663
Median subject-years of follow up	0.3	0.9	0.5	4.9	0.1	1.5	0.3	4.2
Observed number of subjects with event	0	0	0	9	0	2	0	11
Incidence per 100 subject-years	0.00	0.00	0.00	0.10	0.00	0.07	0.00	0.09
95% confidence interval[i]	(0.00, 9.59)	(0.00, 1.62)	(0.00, 0.86)	(0.05, 0.20)	(0.00, 1.55)	(0.01, 0.26)	(0.00, 0.52)	(0.05, 0.17)
Melanoma								
Total subject-years of follow up	31	185	349	8719	193	2760	573	11664
Median subject-years of follow up	0.3	0.9	0.5	4.9	0.1	1.5	0.3	4.2
Observed number of subjects with event	0	0	0	3	0	0	0	3
Incidence per 100 subject-years	0.00	0.00	0.00	0.03	0.00	0.00	0.00	0.03
95% confidence interval[i]	(0.00, 9.59)	(0.00, 1.62)	(0.00, 0.86)	(0.01, 0.10)	(0.00, 1.55)	(0.00, 0.11)	(0.00, 0.52)	(0.01, 0.08)

	nrAxSpA Study[a]		Phase 3 RA, PsA, AS Studies[b]		UC Studies[c]		All Studies	
	Placebo[d]	Golimumab[e]	Placebo[d]	Golimumab[e]	Placebo[f]	Golimumab[g,h]	Placebo	Golimumab
Nonmelanoma								
Total subject-years of follow up	31	185	348	8652	193	2752	572	11589
Median subject-years of follow up	0.3	0.9	0.5	4.8	0.1	1.5	0.3	4.1
Observed number of subjects with event	0	0	5	37	0	5	5	42
Incidence per 100 subject-years	0.00	0.00	1.44	0.43	0.00	0.18	0.87	0.36
95% confidence interval[i]	(0.00, 9.59)	(0.00, 1.62)	(0.47, 3.35)	(0.30, 0.59)	(0.00, 1.55)	(0.06, 0.42)	(0.28, 2.04)	(0.26, 0.49)
Other malignancies[j]								
Total subject-years of follow up	31	185	348	8708	193	2758	572	11650
Median subject-years of follow up	0.3	0.9	0.5	4.9	0.1	1.5	0.3	4.2
Observed number of subjects with event	0	0	4	45	1	11	5	56
Incidence per 100 subject-years	0.00	0.00	1.15	0.52	0.52	0.40	0.87	0.48
95% confidence interval[i]	(0.00, 9.59)	(0.00, 1.62)	(0.31, 2.94)	(0.38, 0.69)	(0.01, 2.89)	(0.20, 0.71)	(0.28, 2.04)	(0.36, 0.62)
All malignancies								
Total subject-years of follow up	31	185	347	8637	193	2749	571	11570
Median subject-years of follow up	0.3	0.9	0.5	4.8	0.1	1.5	0.3	4.1
Observed number of subjects with event	0	0	9	92	1	18	10	110
Incidence per 100 subject-years	0.00	0.00	2.60	1.07	0.52	0.65	1.75	0.95
95% confidence interval[i]	(0.00, 9.59)	(0.00, 1.62)	(1.19, 4.93)	(0.86, 1.31)	(0.01, 2.89)	(0.39, 1.03)	(0.84, 3.22)	(0.78, 1.15)

	nrAxSpA Study[a]		Phase 3 RA, PsA, AS Studies[b]		UC Studies[c]		All Studies	
	Placebo[d]	Golimumab[e]	Placebo[d]	Golimumab[e]	Placebo[f]	Golimumab[g,h]	Placebo	Golimumab

[a] P07642
[b] C0524T05, C0524T06, C0524T11, C0524T08, and C0524T09
[c] From Week 0 of the induction studies (C0524T16 and C0524T17) through Week 228 of the maintenance study (C0524T18).
[d] Received placebo SC every 4 weeks with or without MTX.
[e] Received golimumab 50 mg SC every 4 weeks in P07642; received golimumab 50 mg or 100 mg SC every 4 weeks, with or without MTX in C0524T05, C0524T06, C0524T11, C0524T08, and C0524T09.
[f] In C0524T16, subjects received placebo IV at Week 0. In C0524T17, subjects received placebo SC at Week 0 and Week 2. In C0524T18, subjects in response to placebo induction from C0524T16 or C0524T17 continued to receive placebo SC every 4 weeks.
[g] In C0524T16, subjects received placebo or golimumab 1 mg/kg, 2 mg/kg or 4 mg/kg IV at Week 0. In C0524T17, subjects received placebo or golimumab SC 100 mg/50 mg, 200 mg/100 mg, or 400 mg/200 mg at Weeks 0/2, respectively.
[h] In C0524T18, subjects received study agent every 4 weeks. Subjects who were in response to golimumab induction from C0524T16 and C052T17 received placebo or golimumab 50 mg or 100 mg SC (subjects who lost response to placebo were allowed to receive golimumab 100 mg SC and subjects who lost response to golimumab were allowed to increase their dose of golimumab). Subjects who were not in response to golimumab or placebo induction from C0524T16 or C0524T17 received golimumab 100 mg SC. Subjects in response to placebo induction remained on placebo in maintenance but were allowed to dose adjust to golimumab 100 mg SC.
[i] Confidence intervals based on an exact method.
[j] Exclude lymphoma, nonmelanoma and melanoma.

表 2.7.4.7-付録-68 悪性腫瘍発現率の SEER データベースとの比較（T16，T17 及び T18 試験 54 週まで；他疾患との統合データ）

	nrAxSpA Study[a]		Phase 3 RA, PsA, AS Studies[b]		UC Studies[c]		All Studies	
	Placebo[d]	Golimumab[e]	Placebo[d]	Golimumab[e]	Placebo[f]	Golimumab[g,h]	Placebo	Golimumab
Treated subjects in Phase 3 SC rheumatologic studies and Phase 2/3 UC studies	100	193	639	2228	407	1245	1146	3666
Type of malignancy[i]								
Lymphoma								
Total subject-years of follow up	31	185	349	8718	193	2760	573	11663
Median subject-years of follow up	0.3	0.9	0.5	4.9	0.1	1.5	0.3	4.2
Observed number of subjects with event	0	0	0	9	0	2	0	11
Expected number of subjects[j]	0.00	0.02	0.09	2.32	0.03	0.55	0.12	2.88
SIR[k]	0.00	0.00	0.00	3.88	0.00	3.66	0.00	3.81
SIR 95% confidence interval[l]	(0.00, 1003.62)	(0.00, 170.89)	(0.00, 33.25)	(1.77, 7.36)	(0.00, 94.46)	(0.44, 13.22)	(0.00, 24.01)	(1.90, 6.82)
Melanoma								
Total subject-years of follow up	31	185	349	8719	193	2760	573	11664
Median subject-years of follow up	0.3	0.9	0.5	4.9	0.1	1.5	0.3	4.2
Observed number of subjects with event	0	0	0	3	0	0	0	3
Expected number of subjects[j]	0.00	0.02	0.08	2.18	0.03	0.56	0.12	2.76
SIR[k]	0.00	0.00	0.00	1.38	0.00	0.00	0.00	1.09
SIR 95% confidence interval[l]	(0.00, 811.94)	(0.00, 147.79)	(0.00, 36.84)	(0.28, 4.03)	(0.00, 97.91)	(0.00, 5.34)	(0.00, 25.91)	(0.22, 3.18)

	nrAxSpA Study[a]		Phase 3 RA, PsA, AS Studies[b]		UC Studies[c]		All Studies	
	Placebo[d]	Golimumab[e]	Placebo[d]	Golimumab[e]	Placebo[f]	Golimumab[g,h]	Placebo	Golimumab
Other malignancies								
Total subject-years of follow up	31	185	348	8708	193	2758	572	11650
Median subject-years of follow up	0.3	0.9	0.5	4.9	0.1	1.5	0.3	4.2
Observed number of subjects with event	0	0	4	45	1	11	5	56
Expected number of subjects[j]	0.04	0.21	2.11	52.06	0.54	10.08	2.68	62.35
SIR[k]	0.00	0.00	1.90	0.86	1.86	1.09	1.86	0.90
SIR 95% confidence interval[l]	(0.00, 80.21)	(0.00, 14.12)	(0.52, 4.86)	(0.63, 1.16)	(0.05, 10.34)	(0.54, 1.95)	(0.61, 4.35)	(0.68, 1.17)
All malignancies								
Total subject-years of follow up	31	185	348	8705	193	2758	572	11647
Median subject-years of follow up	0.3	0.9	0.5	4.9	0.1	1.5	0.3	4.2
Observed number of subjects with event	0	0	4	56	1	13	5	69
Expected number of subjects[j]	0.03	0.17	2.05	51.95	0.58	10.57	2.67	62.69
SIR[k]	0.00	0.00	1.95	1.08	1.71	1.23	1.88	1.10
SIR 95% confidence interval[l]	(0.00, 95.40)	(0.00, 17.59)	(0.53, 5.00)	(0.81, 1.40)	(0.04, 9.54)	(0.65, 2.10)	(0.61, 4.38)	(0.86, 1.39)

	nrAxSpA Study[a]		Phase 3 RA, PsA, AS Studies[b]		UC Studies[c]		All Studies	
	Placebo[d]	Golimumab[e]	Placebo[d]	Golimumab[e]	Placebo[f]	Golimumab[g,h]	Placebo	Golimumab

[a] P07642
[b] C0524T05, C0524T06, C0524T11, C0524T08, and C0524T09
[c] From Week 0 of the induction studies (C0524T16 and C0524T17) through Week 228 of the maintenance study (C0524T18).
[d] Received placebo SC every 4 weeks with or without MTX.
[e] Received golimumab 50 mg SC every 4 weeks in P07642; received golimumab 50 mg or 100 mg SC every 4 weeks, with or without MTX in C0524T05, C0524T06, C0524T11, C0524T08, and C0524T09.
[f] In C0524T16, subjects received placebo IV at Week 0. In C0524T17, subjects received placebo SC at Week 0 and Week 2. In C0524T18, subjects in response to placebo induction from C0524T16 or C0524T17 continued to receive placebo SC every 4 weeks.
[g] In C0524T16, subjects received placebo or golimumab 1 mg/kg, 2 mg/kg or 4 mg/kg IV at Week 0. In C0524T17, subjects received placebo or golimumab SC 100 mg/50 mg, 200 mg/100 mg, or 400 mg/200 mg at Weeks 0/2, respectively.
[h] In C0524T18, subjects received study agent every 4 weeks. Subjects who were in response to golimumab induction from C0524T16 and C052T17 received placebo or golimumab 50 mg or 100 mg SC (subjects who lost response to placebo were allowed to receive golimumab 100 mg SC and subjects who lost response to golimumab were allowed to increase their dose of golimumab). Subjects who were not in response to golimumab or placebo induction from C0524T16 or C0524T17 received golimumab 100 mg SC. Subjects in response to placebo induction remained on placebo in maintenance but were allowed to dose adjust to golimumab 100 mg SC.
[i] Includes subjects with malignancies (excluding nonmelanoma skin cancers, which are not included in the SEER database) during the study.
[j] The expected number of subjects with malignancies is based on the SEER Database (2004), adjusted for age, gender, and race.
[k] SIR = Standardized Incidence Ratio (observed number of subjects with malignancy divided by expected number of subjects with malignancy)
[l] Confidence interval based on an exact method.

表 2.7.4.7-付録-69 発現時期別の発現割合 2%以上の有害事象（T16，T17 及び T18 試験 54 週まで；全投与被験者）

	Combined Golimumab					
	Total	Up to Month 3[a]	Month 4 to Month 6[a]	Month 7 to Month 9[a]	Month 10 to Month 12[a]	Month 13 or Later[a]
Golimumab-treated subjects in C0524T16 and C0524T17[b]	1233	1233	1151	998	844	748
Avg duration of follow up (weeks)	45.6	11.7	23.3	35.2	47.3	58.8
Subjects with 1 or more adverse events	964 (78.2%)	659 (53.4%)	447 (38.8%)	329 (33.0%)	250 (29.6%)	198 (26.5%)
MedDRA body system/preferred term						
胃腸障害	500 (40.6%)	241 (19.5%)	131 (11.4%)	96 (9.6%)	79 (9.4%)	68 (9.1%)
潰瘍性大腸炎	251 (20.4%)	91 (7.4%)	71 (6.2%)	40 (4.0%)	27 (3.2%)	22 (2.9%)
腹痛	69 (5.6%)	28 (2.3%)	14 (1.2%)	9 (0.9%)	13 (1.5%)	5 (0.7%)
悪心	55 (4.5%)	32 (2.6%)	8 (0.7%)	6 (0.6%)	5 (0.6%)	4 (0.5%)
下痢	37 (3.0%)	12 (1.0%)	6 (0.5%)	10 (1.0%)	4 (0.5%)	5 (0.7%)
嘔吐	27 (2.2%)	16 (1.3%)	4 (0.3%)	4 (0.4%)	3 (0.4%)	0
痔核	25 (2.0%)	9 (0.7%)	3 (0.3%)	3 (0.3%)	3 (0.4%)	7 (0.9%)
感染症および寄生虫症	490 (39.7%)	217 (17.6%)	154 (13.4%)	124 (12.4%)	101 (12.0%)	56 (7.5%)
鼻咽頭炎	132 (10.7%)	50 (4.1%)	29 (2.5%)	33 (3.3%)	10 (1.2%)	10 (1.3%)
上気道感染	77 (6.2%)	29 (2.4%)	16 (1.4%)	9 (0.9%)	17 (2.0%)	6 (0.8%)
咽頭炎	41 (3.3%)	13 (1.1%)	12 (1.0%)	7 (0.7%)	6 (0.7%)	3 (0.4%)
副鼻腔炎	37 (3.0%)	14 (1.1%)	8 (0.7%)	9 (0.9%)	6 (0.7%)	0
インフルエンザ	34 (2.8%)	7 (0.6%)	6 (0.5%)	5 (0.5%)	9 (1.1%)	7 (0.9%)
気管支炎	29 (2.4%)	11 (0.9%)	12 (1.0%)	2 (0.2%)	3 (0.4%)	1 (0.1%)
一般・全身障害および投与部位の状態	219 (17.8%)	132 (10.7%)	40 (3.5%)	33 (3.3%)	17 (2.0%)	19 (2.5%)
発熱	65 (5.3%)	36 (2.9%)	5 (0.4%)	13 (1.3%)	3 (0.4%)	8 (1.1%)
疲労	39 (3.2%)	21 (1.7%)	9 (0.8%)	2 (0.2%)	3 (0.4%)	4 (0.5%)
皮膚および皮下組織障害	210 (17.0%)	109 (8.8%)	60 (5.2%)	33 (3.3%)	25 (3.0%)	16 (2.1%)
発疹	49 (4.0%)	26 (2.1%)	12 (1.0%)	6 (0.6%)	1 (0.1%)	4 (0.5%)
そう痒症	28 (2.3%)	14 (1.1%)	6 (0.5%)	1 (0.1%)	4 (0.5%)	3 (0.4%)
筋骨格系および結合組織障害	203 (16.5%)	86 (7.0%)	54 (4.7%)	32 (3.2%)	25 (3.0%)	24 (3.2%)
関節痛	90 (7.3%)	34 (2.8%)	31 (2.7%)	10 (1.0%)	7 (0.8%)	8 (1.1%)
背部痛	37 (3.0%)	6 (0.5%)	11 (1.0%)	11 (1.1%)	4 (0.5%)	5 (0.7%)
神経系障害	178 (14.4%)	105 (8.5%)	33 (2.9%)	37 (3.7%)	12 (1.4%)	11 (1.5%)
頭痛	128 (10.4%)	75 (6.1%)	22 (1.9%)	17 (1.7%)	6 (0.7%)	8 (1.1%)
呼吸器、胸郭および縦隔障害	151 (12.2%)	72 (5.8%)	43 (3.7%)	25 (2.5%)	16 (1.9%)	9 (1.2%)
咳嗽	64 (5.2%)	24 (1.9%)	18 (1.6%)	10 (1.0%)	6 (0.7%)	6 (0.8%)
口腔咽頭痛	30 (2.4%)	14 (1.1%)	6 (0.5%)	8 (0.8%)	1 (0.1%)	1 (0.1%)
血液およびリンパ系障害	127 (10.3%)	58 (4.7%)	28 (2.4%)	25 (2.5%)	16 (1.9%)	15 (2.0%)
貧血	62 (5.0%)	28 (2.3%)	13 (1.1%)	8 (0.8%)	7 (0.8%)	6 (0.8%)

	Combined Golimumab					
	Total	Up to Month 3[a]	Month 4 to Month 6[a]	Month 7 to Month 9[a]	Month 10 to Month 12[a]	Month 13 or Later[a]
臨床検査	107 (8.7%)	43 (3.5%)	30 (2.6%)	22 (2.2%)	14 (1.7%)	9 (1.2%)
傷害、中毒および処置合併症	73 (5.9%)	29 (2.4%)	17 (1.5%)	10 (1.0%)	12 (1.4%)	9 (1.2%)
精神障害	62 (5.0%)	30 (2.4%)	13 (1.1%)	10 (1.0%)	5 (0.6%)	6 (0.8%)
不眠症	26 (2.1%)	12 (1.0%)	4 (0.3%)	5 (0.5%)	2 (0.2%)	3 (0.4%)
血管障害	52 (4.2%)	22 (1.8%)	16 (1.4%)	2 (0.2%)	5 (0.6%)	9 (1.2%)
高血圧	30 (2.4%)	13 (1.1%)	6 (0.5%)	2 (0.2%)	2 (0.2%)	7 (0.9%)
代謝および栄養障害	47 (3.8%)	20 (1.6%)	13 (1.1%)	5 (0.5%)	4 (0.5%)	5 (0.7%)
眼障害	43 (3.5%)	20 (1.6%)	3 (0.3%)	7 (0.7%)	8 (0.9%)	6 (0.8%)
腎および尿路障害	35 (2.8%)	17 (1.4%)	7 (0.6%)	4 (0.4%)	6 (0.7%)	2 (0.3%)
生殖系および乳房障害	31 (2.5%)	11 (0.9%)	8 (0.7%)	8 (0.8%)	4 (0.5%)	2 (0.3%)
耳および迷路障害	25 (2.0%)	9 (0.7%)	7 (0.6%)	2 (0.2%)	4 (0.5%)	3 (0.4%)

[a] The 0 week is first administrated day of any golimumab dose (for subjects who were in clinical response to golimumab induction dosing and were randomized to placebo on entry into the maintenance study, the period of placebo treatment is included for the period of golimumab treatment). 1 month = 4 weeks (= 28 days).
[b] Subjects who received at least one golimumab administration at any time.

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表 2.7.4.7-付録-70 発現時期別の 2 例以上に発現した有害事象（T17 及び T18 試験の 54 週まで，日本人の全ゴリムマブ群）

	Combined Golimumab					
	Total	Up to Month 3[a]	Month 4 to Month 6[a]	Month 7 to Month 9[a]	Month 10 to Month 12[a]	Month 13 or Later[a]
Golimumab-treated subjects in C0524T16 and C0524T17[b]	68	68	66	55	46	37
Avg duration of follow up (weeks)	43.6	12.0	22.9	35.2	46.9	56.6
Subjects with 1 or more adverse events	60 (88.2%)	43 (63.2%)	32 (48.5%)	22 (40.0%)	17 (37.0%)	11 (29.7%)
MedDRA body system/preferred term						
感染症および寄生虫症	41 (60.3%)	20 (29.4%)	14 (21.2%)	10 (18.2%)	5 (10.9%)	4 (10.8%)
鼻咽頭炎	25 (36.8%)	8 (11.8%)	8 (12.1%)	7 (12.7%)	2 (4.3%)	0
インフルエンザ	4 (5.9%)	2 (2.9%)	1 (1.5%)	0	1 (2.2%)	0
上気道感染	4 (5.9%)	3 (4.4%)	0	0	0	1 (2.7%)
サイトメガロウイルス感染	3 (4.4%)	1 (1.5%)	1 (1.5%)	0	1 (2.2%)	0
感染性腸炎	3 (4.4%)	2 (2.9%)	0	1 (1.8%)	0	0
膀胱炎	2 (2.9%)	1 (1.5%)	1 (1.5%)	0	0	0
感染性小腸結腸炎	2 (2.9%)	0	1 (1.5%)	0	0	1 (2.7%)
毛包炎	2 (2.9%)	1 (1.5%)	0	1 (1.8%)	0	0
口腔ヘルペス	2 (2.9%)	0	2 (3.0%)	0	0	0
尿路感染	2 (2.9%)	1 (1.5%)	1 (1.5%)	0	0	0
胃腸障害	26 (38.2%)	12 (17.6%)	5 (7.6%)	9 (16.4%)	4 (8.7%)	2 (5.4%)
潰瘍性大腸炎	9 (13.2%)	5 (7.4%)	1 (1.5%)	3 (5.5%)	0	0
口内炎	5 (7.4%)	3 (4.4%)	2 (3.0%)	0	0	0
悪心	4 (5.9%)	1 (1.5%)	0	1 (1.8%)	1 (2.2%)	1 (2.7%)
腹部膨満	3 (4.4%)	1 (1.5%)	1 (1.5%)	1 (1.8%)	0	0
腹部不快感	2 (2.9%)	0	0	1 (1.8%)	1 (2.2%)	0
腹痛	2 (2.9%)	1 (1.5%)	0	0	1 (2.2%)	0
胃食道逆流性疾患	2 (2.9%)	1 (1.5%)	1 (1.5%)	0	0	0
皮膚および皮下組織障害	20 (29.4%)	10 (14.7%)	6 (9.1%)	1 (1.8%)	2 (4.3%)	3 (8.1%)
発疹	6 (8.8%)	5 (7.4%)	0	0	1 (2.2%)	0
湿疹	5 (7.4%)	2 (2.9%)	1 (1.5%)	0	0	2 (5.4%)
接触性皮膚炎	3 (4.4%)	1 (1.5%)	1 (1.5%)	0	1 (2.2%)	0
脱毛症	2 (2.9%)	1 (1.5%)	1 (1.5%)	0	0	0
そう痒症	2 (2.9%)	1 (1.5%)	1 (1.5%)	0	0	0
脂漏性皮膚炎	2 (2.9%)	1 (1.5%)	1 (1.5%)	0	0	0
呼吸器、胸郭および縦隔障害	15 (22.1%)	9 (13.2%)	3 (4.5%)	3 (5.5%)	0	1 (2.7%)
咳嗽	4 (5.9%)	1 (1.5%)	0	3 (5.5%)	0	0
口腔咽頭痛	4 (5.9%)	3 (4.4%)	1 (1.5%)	0	0	0
上気道の炎症	3 (4.4%)	3 (4.4%)	0	0	0	0

	Combined Golimumab					
	Total	Up to Month 3[a]	Month 4 to Month 6[a]	Month 7 to Month 9[a]	Month 10 to Month 12[a]	Month 13 or Later[a]
一般・全身障害および投与部位の状態	14 (20.6%)	4 (5.9%)	6 (9.1%)	4 (7.3%)	1 (2.2%)	1 (2.7%)
発熱	8 (11.8%)	4 (5.9%)	1 (1.5%)	2 (3.6%)	1 (2.2%)	0
神経系障害	13 (19.1%)	7 (10.3%)	4 (6.1%)	3 (5.5%)	0	1 (2.7%)
頭痛	9 (13.2%)	3 (4.4%)	3 (4.5%)	2 (3.6%)	0	1 (2.7%)
浮動性めまい	2 (2.9%)	2 (2.9%)	0	0	0	0
感覚鈍麻	2 (2.9%)	2 (2.9%)	0	0	0	0
傷害、中毒および処置合併症	8 (11.8%)	3 (4.4%)	3 (4.5%)	0	2 (4.3%)	0
挫傷	3 (4.4%)	2 (2.9%)	1 (1.5%)	0	0	0
血液およびリンパ系障害	7 (10.3%)	3 (4.4%)	3 (4.5%)	1 (1.8%)	0	0
白血球減少症	3 (4.4%)	1 (1.5%)	2 (3.0%)	0	0	0
貧血	2 (2.9%)	1 (1.5%)	1 (1.5%)	0	0	0
鉄欠乏性貧血	2 (2.9%)	1 (1.5%)	0	1 (1.8%)	0	0
眼障害	7 (10.3%)	4 (5.9%)	1 (1.5%)	0	2 (4.3%)	1 (2.7%)
白内障	2 (2.9%)	0	0	0	2 (4.3%)	0
アレルギー性結膜炎	2 (2.9%)	1 (1.5%)	0	0	0	1 (2.7%)
筋骨格系および結合組織障害	7 (10.3%)	1 (1.5%)	1 (1.5%)	1 (1.8%)	3 (6.5%)	1 (2.7%)
背部痛	3 (4.4%)	0	1 (1.5%)	1 (1.8%)	1 (2.2%)	0
関節痛	2 (2.9%)	0	0	1 (1.8%)	0	1 (2.7%)
筋骨格系胸痛	2 (2.9%)	1 (1.5%)	0	1 (1.8%)	0	0
臨床検査	5 (7.4%)	1 (1.5%)	3 (4.5%)	1 (1.8%)	0	0
白血球数減少	2 (2.9%)	1 (1.5%)	1 (1.5%)	0	0	0
精神障害	4 (5.9%)	1 (1.5%)	0	1 (1.8%)	1 (2.2%)	1 (2.7%)
不眠症	4 (5.9%)	1 (1.5%)	0	1 (1.8%)	1 (2.2%)	1 (2.7%)
代謝および栄養障害	3 (4.4%)	1 (1.5%)	0	0	0	2 (5.4%)
肝胆道系障害	2 (2.9%)	1 (1.5%)	0	0	1 (2.2%)	0
生殖系および乳房障害	2 (2.9%)	1 (1.5%)	0	0	1 (2.2%)	1 (2.7%)
乳房痛	2 (2.9%)	1 (1.5%)	0	0	1 (2.2%)	0
血管障害	2 (2.9%)	0	2 (3.0%)	0	0	0

[a] The 0 week is first administrated day of any golimumab dose (for subjects who were in clinical response to golimumab induction dosing and were randomized to placebo on entry into the maintenance study, the period of placebo treatment is included for the period of golimumab treatment). 1 month = 4 weeks (= 28 days).
[b] Subjects who received at least one golimumab administration at any time.

表 2.7.4.7-付録-71 発現時期別の 2 例以上に発現した有害事象（UCO3001 試験 54 週まで，全投与被験者）

	Combined Golimumab					
	Total	Up to Month 3[a]	Month 4 to Month 6[a]	Month 7 to Month 9[a]	Month 10 to Month 12[a]	Month 13 or Later[a]
Golimumab-treated subjects[b]	144	144	111	74	69	64
Avg duration of follow up (weeks)	34.7	10.7	20.8	35.6	47.8	60.5
Subjects with 1 or more adverse events	128 (88.9%)	87 (60.4%)	59 (53.2%)	37 (50.0%)	31 (44.9%)	18 (28.1%)
MedDRA body system/preferred term						
感染症および寄生虫症	76 (52.8%)	35 (24.3%)	23 (20.7%)	18 (24.3%)	11 (15.9%)	12 (18.8%)
鼻咽頭炎	55 (38.2%)	24 (16.7%)	10 (9.0%)	9 (12.2%)	8 (11.6%)	4 (6.3%)
インフルエンザ	9 (6.3%)	1 (0.7%)	3 (2.7%)	2 (2.7%)	1 (1.4%)	2 (3.1%)
口腔ヘルペス	6 (4.2%)	1 (0.7%)	3 (2.7%)	1 (1.4%)	0	1 (1.6%)
上気道感染	5 (3.5%)	3 (2.1%)	1 (0.9%)	0	0	1 (1.6%)
結膜炎	4 (2.8%)	1 (0.7%)	1 (0.9%)	0	1 (1.4%)	1 (1.6%)
帯状疱疹	4 (2.8%)	2 (1.4%)	1 (0.9%)	1 (1.4%)	0	0
胃腸炎	3 (2.1%)	1 (0.7%)	0	0	1 (1.4%)	1 (1.6%)
咽頭炎	3 (2.1%)	2 (1.4%)	1 (0.9%)	0	0	0
口角口唇炎	2 (1.4%)	0	1 (0.9%)	1 (1.4%)	0	0
口腔カンジダ症	2 (1.4%)	1 (0.7%)	0	0	0	1 (1.6%)
扁桃炎	2 (1.4%)	0	1 (0.9%)	1 (1.4%)	0	0
胃腸障害	45 (31.3%)	28 (19.4%)	13 (11.7%)	5 (6.8%)	5 (7.2%)	1 (1.6%)
潰瘍性大腸炎	19 (13.2%)	15 (10.4%)	2 (1.8%)	1 (1.4%)	0	1 (1.6%)
齲歯	7 (4.9%)	2 (1.4%)	3 (2.7%)	1 (1.4%)	1 (1.4%)	0
上腹部痛	4 (2.8%)	2 (1.4%)	0	0	2 (2.9%)	0
痔核	4 (2.8%)	3 (2.1%)	1 (0.9%)	0	0	0
裂肛	2 (1.4%)	0	2 (1.8%)	0	0	0
便秘	2 (1.4%)	1 (0.7%)	1 (0.9%)	0	0	0
大腸ポリープ	2 (1.4%)	1 (0.7%)	0	0	1 (1.4%)	0
悪心	2 (1.4%)	0	1 (0.9%)	1 (1.4%)	0	0
肛門周囲痛	2 (1.4%)	1 (0.7%)	0	1 (1.4%)	0	0
皮膚および皮下組織障害	30 (20.8%)	17 (11.8%)	7 (6.3%)	4 (5.4%)	5 (7.2%)	1 (1.6%)
湿疹	5 (3.5%)	2 (1.4%)	0	1 (1.4%)	2 (2.9%)	0
発疹	5 (3.5%)	2 (1.4%)	1 (0.9%)	1 (1.4%)	1 (1.4%)	0
ざ瘡	4 (2.8%)	3 (2.1%)	1 (0.9%)	0	0	0
脱毛症	2 (1.4%)	0	1 (0.9%)	1 (1.4%)	0	0
皮脂欠乏性湿疹	2 (1.4%)	1 (0.7%)	0	1 (1.4%)	0	0
紅斑	2 (1.4%)	1 (0.7%)	1 (0.9%)	0	0	0
そう痒症	2 (1.4%)	0	1 (0.9%)	0	1 (1.4%)	0

	Combined Golimumab					
	Total	Up to Month 3[a]	Month 4 to Month 6[a]	Month 7 to Month 9[a]	Month 10 to Month 12[a]	Month 13 or Later[a]
一般・全身障害および投与部位の状態	29 (20.1%)	15 (10.4%)	9 (8.1%)	5 (6.8%)	4 (5.8%)	1 (1.6%)
注射部位紅斑	11 (7.6%)	6 (4.2%)	2 (1.8%)	2 (2.7%)	1 (1.4%)	0
発熱	7 (4.9%)	4 (2.8%)	2 (1.8%)	0	1 (1.4%)	0
倦怠感	3 (2.1%)	1 (0.7%)	1 (0.9%)	0	0	1 (1.6%)
悪寒	2 (1.4%)	2 (1.4%)	0	0	0	0
注射部位疼痛	2 (1.4%)	0	1 (0.9%)	0	1 (1.4%)	0
注射部位そう痒感	2 (1.4%)	1 (0.7%)	0	1 (1.4%)	0	0
注射部位腫脹	2 (1.4%)	0	1 (0.9%)	0	1 (1.4%)	0
筋骨格系および結合組織障害	19 (13.2%)	6 (4.2%)	5 (4.5%)	5 (6.8%)	2 (2.9%)	1 (1.6%)
背部痛	6 (4.2%)	2 (1.4%)	2 (1.8%)	1 (1.4%)	0	1 (1.6%)
筋骨格痛	3 (2.1%)	2 (1.4%)	0	1 (1.4%)	0	0
関節痛	2 (1.4%)	1 (0.7%)	0	1 (1.4%)	0	0
四肢痛	2 (1.4%)	1 (0.7%)	1 (0.9%)	0	0	0
神経系障害	17 (11.8%)	10 (6.9%)	2 (1.8%)	3 (4.1%)	2 (2.9%)	0
頭痛	7 (4.9%)	3 (2.1%)	1 (0.9%)	2 (2.7%)	1 (1.4%)	0
感覚鈍麻	3 (2.1%)	1 (0.7%)	0	1 (1.4%)	1 (1.4%)	0
呼吸器、胸郭および縦隔障害	17 (11.8%)	8 (5.6%)	5 (4.5%)	1 (1.4%)	3 (4.3%)	1 (1.6%)
咳嗽	6 (4.2%)	2 (1.4%)	3 (2.7%)	0	1 (1.4%)	0
口腔咽頭痛	6 (4.2%)	2 (1.4%)	0	1 (1.4%)	2 (2.9%)	1 (1.6%)
上気道の炎症	5 (3.5%)	4 (2.8%)	1 (0.9%)	0	0	0
臨床検査	15 (10.4%)	7 (4.9%)	3 (2.7%)	2 (2.7%)	2 (2.9%)	1 (1.6%)
白血球数減少	4 (2.8%)	1 (0.7%)	1 (0.9%)	0	1 (1.4%)	1 (1.6%)
血中ビリルビン増加	2 (1.4%)	2 (1.4%)	0	0	0	0
肝機能検査異常	2 (1.4%)	1 (0.7%)	1 (0.9%)	0	0	0
好中球数減少	2 (1.4%)	0	0	0	2 (2.9%)	0
白血球数増加	2 (1.4%)	0	1 (0.9%)	1 (1.4%)	0	0
傷害、中毒および処置合併症	14 (9.7%)	3 (2.1%)	3 (2.7%)	5 (6.8%)	3 (4.3%)	1 (1.6%)
挫傷	3 (2.1%)	2 (1.4%)	0	1 (1.4%)	0	0
節足動物咬傷	2 (1.4%)	0	0	1 (1.4%)	1 (1.4%)	0
足骨折	2 (1.4%)	0	1 (0.9%)	1 (1.4%)	0	0
血液およびリンパ系障害	10 (6.9%)	2 (1.4%)	7 (6.3%)	1 (1.4%)	0	0
貧血	6 (4.2%)	2 (1.4%)	3 (2.7%)	1 (1.4%)	0	0
鉄欠乏性貧血	2 (1.4%)	0	2 (1.8%)	0	0	0
血管障害	7 (4.9%)	2 (1.4%)	1 (0.9%)	3 (4.1%)	1 (1.4%)	0
高血圧	3 (2.1%)	0	0	2 (2.7%)	1 (1.4%)	0

	Combined Golimumab					
	Total	Up to Month 3[a]	Month 4 to Month 6[a]	Month 7 to Month 9[a]	Month 10 to Month 12[a]	Month 13 or Later[a]
精神障害	5 (3.5%)	3 (2.1%)	0	0	2 (2.9%)	0
不眠症	4 (2.8%)	3 (2.1%)	0	0	1 (1.4%)	0
耳および迷路障害	3 (2.1%)	0	0	2 (2.7%)	0	1 (1.6%)
回転性めまい	2 (1.4%)	0	0	2 (2.7%)	0	0
眼障害	3 (2.1%)	0	1 (0.9%)	0	2 (2.9%)	0
眼瞼炎	3 (2.1%)	0	1 (0.9%)	0	2 (2.9%)	0
肝胆道系障害	3 (2.1%)	2 (1.4%)	1 (0.9%)	0	0	0
肝機能異常	2 (1.4%)	1 (0.7%)	1 (0.9%)	0	0	0
免疫系障害	3 (2.1%)	0	0	2 (2.7%)	1 (1.4%)	0
季節性アレルギー	3 (2.1%)	0	0	2 (2.7%)	1 (1.4%)	0
心臓障害	2 (1.4%)	1 (0.7%)	0	0	1 (1.4%)	0
動悸	2 (1.4%)	1 (0.7%)	0	0	1 (1.4%)	0
内分泌障害	2 (1.4%)	1 (0.7%)	0	1 (1.4%)	0	0
クッシング様症状	2 (1.4%)	1 (0.7%)	0	1 (1.4%)	0	0
代謝および栄養障害	2 (1.4%)	0	2 (1.8%)	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）	2 (1.4%)	2 (1.4%)	0	0	0	0
生殖系および乳房障害	2 (1.4%)	1 (0.7%)	0	1 (1.4%)	0	0

[a] The 0 week is first administrated day of any golimumab dose (for subjects who were in clinical response to golimumab induction dosing and were randomized to placebo on entry into the maintenance study). 1 month = 4 weeks (= 28 days).
[b] Subjects who received at least one golimumab administration at any time.

[TSFAEONSET03.rtf] [CNTO148\CNTO148UCO3001\DBR_CSRW54\RE_NDAJPKK\TSFAEONSET03.sas] 04FEB2016, 10:46

表 2.7.4.7-付録-72 血液学的検査値の異常（T17 試験 6 週まで，日本人）

		Golimumab				
	Placebo	100 mg -> 50 mg	200 mg -> 100 mg	400 mg -> 200 mg	Combined	All Golimumab
Subject treated	30	-	23	19	42	42
Eosinophils, absolute (elevated)						
N	30	-	23	19	42	42
Subjects with any abnormal value	0	-	0	0	0	0
Subjects with > 1 abnormal value	0	-	0	0	0	0
Hematocrit (decreased)						
N	30	-	23	19	42	42
Subjects with any abnormal value	1 (3.3%)	-	1 (4.3%)	0	1 (2.4%)	1 (2.4%)
Subjects with > 1 abnormal value	0	-	0	0	0	0
Hemoglobin (decreased)						
N	30	-	23	19	42	42
Subjects with any abnormal value	0	-	0	0	0	0
Subjects with > 1 abnormal value	0	-	0	0	0	0
Lymphocytes, absolute (decreased)						
N	30	-	23	19	42	42
Subjects with any abnormal value	2 (6.7%)	-	2 (8.7%)	0	2 (4.8%)	2 (4.8%)
Subjects with > 1 abnormal value	1 (3.3%)	-	1 (4.3%)	0	1 (2.4%)	1 (2.4%)
Neutrophils, absolute (decreased)						
N	29	-	20	19	39	39
Subjects with any abnormal value	1 (3.4%)	-	0	0	0	0
Subjects with > 1 abnormal value	0	-	0	0	0	0
Platelets (decreased)						
N	30	-	23	19	42	42
Subjects with any abnormal value	0	-	0	0	0	0
Subjects with > 1 abnormal value	0	-	0	0	0	0
WBC (decreased)						
N	30	-	23	19	42	42
Subjects with any abnormal value	0	-	0	0	0	0
Subjects with > 1 abnormal value	0	-	0	0	0	0
WBC (elevated)						
N	30	-	23	19	42	42
Subjects with any abnormal value	0	-	0	0	0	0
Subjects with > 1 abnormal value	0	-	0	0	0	0

表 2.7.4.7-付録-73 血液学的検査値の最大グレード（T17 試験 6 週まで，日本人）

		Golimumab				
	Placebo	100 mg -> 50 mg	200 mg -> 100 mg	400 mg -> 200 mg	Combined	All Golimumab
Treated subjects in C0524T17	30	-	23	19	42	42
Avg duration of follow-up (weeks)	6.07	-	6.08	5.93	6.01	6.01
Hemoglobin[a]						
N	30	-	23	19	42	42
Grade 0 (>= 12 g/dL)	14 (46.7%)	-	12 (52.2%)	6 (31.6%)	18 (42.9%)	18 (42.9%)
Grade 1 (>= 10 g/dL and < 12 g/dL)	11 (36.7%)	-	7 (30.4%)	8 (42.1%)	15 (35.7%)	15 (35.7%)
Grade 2 (>= 8 g/dL and < 10 g/dL)	3 (10.0%)	-	3 (13.0%)	4 (21.1%)	7 (16.7%)	7 (16.7%)
Grade 3 (>= 6.5 g/dL and < 8 g/dL)	2 (6.7%)	-	1 (4.3%)	1 (5.3%)	2 (4.8%)	2 (4.8%)
Grade 4 (< 6.5 g/dL)	0	-	0	0	0	0
WBC[a]						
N	30	-	23	19	42	42
Grade 0 (>= 4.1 x 10^3/μL)	25 (83.3%)	-	18 (78.3%)	16 (84.2%)	34 (81.0%)	34 (81.0%)
Grade 1 (>= 3 and < 4.1 x 10^3/μL)	3 (10.0%)	-	2 (8.7%)	3 (15.8%)	5 (11.9%)	5 (11.9%)
Grade 2 (>= 2 and < 3 x 10^3/μL)	2 (6.7%)	-	3 (13.0%)	0	3 (7.1%)	3 (7.1%)
Grade 3 (>= 1 and < 2 x 10^3/μL)	0	-	0	0	0	0
Grade 4 (< 1 x 10^3/μL)	0	-	0	0	0	0
Absolute neutrophils[a]						
N	29	-	20	19	39	39
Grade 0 (>=2.03 x 10^3/μL)	25 (86.2%)	-	15 (75.0%)	19 (100.0%)	34 (87.2%)	34 (87.2%)
Grade 1 (>=1.5 and <2.03 x 10^3/μL)	2 (6.9%)	-	4 (20.0%)	0	4 (10.3%)	4 (10.3%)
Grade 2 (>=1 and <1.5 x 10^3/μL)	2 (6.9%)	-	1 (5.0%)	0	1 (2.6%)	1 (2.6%)
Grade 3 (>=0.5 and <1 x 10^3/μL})	0	-	0	0	0	0
Grade 4 (<0.5 x 10^3/μL)	0	-	0	0	0	0
Absolute lymphocytes[a]						
N	30	-	23	19	42	42
Grade 0 (>=1.02 x 10^3/μL)	17 (56.7%)	-	13 (56.5%)	14 (73.7%)	27 (64.3%)	27 (64.3%)
Grade 1 (>=0.8 and <1.02 x 10^3/μL)	4 (13.3%)	-	5 (21.7%)	3 (15.8%)	8 (19.0%)	8 (19.0%)
Grade 2 (>=0.5 and <0.8 x 10^3/μL)	6 (20.0%)	-	4 (17.4%)	1 (5.3%)	5 (11.9%)	5 (11.9%)
Grade 3 (>=0.2 and <0.5 x 10^3/μL)	3 (10.0%)	-	1 (4.3%)	1 (5.3%)	2 (4.8%)	2 (4.8%)
Grade 4 (<0.2 x 10^3/μL)	0	-	0	0	0	0
Platelets[a]						
N	30	-	23	19	42	42
Grade 0 (>=140 x 10^3/μL)	30 (100.0%)	-	23 (100.0%)	19 (100.0%)	42 (100.0%)	42 (100.0%)
Grade 1 (>=75 and <140 x 10^3/μL)	0	-	0	0	0	0
Grade 2 (>=50 and <75 x 10^3/μL)	0	-	0	0	0	0
Grade 3 (>=25 and <50 x 10^3/μL)	0	-	0	0	0	0
Grade 4 (<25 x 10^3/μL)	0	-	0	0	0	0

a) Grade 0 based on lower limit of normal for central lab. Grades 1-4 adapted from Cancer Therapy Evaluation Program, Common Terminology Criteria for Adverse Events v3.0 (CTCAE).

[TSFLABHEMTOX01JP.rtf] [CNTO148\C0524T17\DBR_WEEK6\RE_NDAJPKK\TSFLABHEMTOX01JP.sas] 28JAN2016, 11:50

表 2.7.4.7-付録-74 血液学的検査値の異常（T18 試験 54 週まで，日本人）

		Golimumab				
	Placebo [a,b]	50 mg [a]	100 mg [a,c,d]	Combined 50 mg and 100 mg	200 mg [d,e]	All Golimumab [f]
Treated subjects in C0524T18	8	3	59	60	-	60
Eosinophils, absolute (elevated)						
N	8	3	59	60	-	60
Subjects with any abnormal value	0	0	4 (6.8%)	4 (6.7%)	-	4 (6.7%)
Subjects with > 1 abnormal value	0	0	2 (3.4%)	2 (3.3%)	-	2 (3.3%)
Hematocrit (decreased)						
N	8	3	59	60	-	60
Subjects with any abnormal value	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
Subjects with > 1 abnormal value	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
Hemoglobin (decreased)						
N	8	3	59	60	-	60
Subjects with any abnormal value	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
Subjects with > 1 abnormal value	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
Lymphocytes, absolute (decreased)						
N	8	3	59	60	-	60
Subjects with any abnormal value	5 (62.5%)	0	10 (16.9%)	10 (16.7%)	-	10 (16.7%)
Subjects with > 1 abnormal value	2 (25.0%)	0	3 (5.1%)	3 (5.0%)	-	3 (5.0%)
Neutrophils, absolute (decreased)						
N	8	3	56	57	-	57
Subjects with any abnormal value	1 (12.5%)	0	3 (5.4%)	3 (5.3%)	-	3 (5.3%)
Subjects with > 1 abnormal value	1 (12.5%)	0	0	0	-	0
Platelets (decreased)						
N	8	3	59	60	-	60
Subjects with any abnormal value	0	0	0	0	-	0
Subjects with > 1 abnormal value	0	0	0	0	-	0
WBC (decreased)						
N	8	3	59	60	-	60
Subjects with any abnormal value	0	0	0	0	-	0
Subjects with > 1 abnormal value	0	0	0	0	-	0
WBC (elevated)						
N	8	3	59	60	-	60
Subjects with any abnormal value	0	0	0	0	-	0
Subjects with > 1 abnormal value	0	0	0	0	-	0

	Golimumab				
Placebo [a,b]	50 mg [a]	100 mg[a,c,d]	Combined 50 mg and 100 mg	200 mg[d,e]	All Golimumab[f]

[a] Includes data up to the time of dose adjustment for those who increased dose from the indicated dose.
[b] Includes 1) subjects who were in clinical response to golimumab induction dosing and were randomized to placebo on entry into this maintenance study; and 2) subjects who were in clinical response to placebo induction dosing and received placebo on entry into this maintenance study.
[c] Includes 1) subjects who were in clinical response to golimumab induction dosing and were randomized to golimumab 100 mg on entry into this maintenance study; 2) subjects who were not in clinical response to either placebo or golimumab induction dosing and received golimumab 100 mg on entry into this maintenance study; and 3) subjects who were dose adjusted to golimumab 100 mg from placebo (randomized or nonrandomized) or from golimumab 50 mg.
[d] Includes data from the time of dose adjustment onward for those who increased to the indicated dose.
[e] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[f] Includes data from the time of the first golimumab dose onward.

[TSFLABHEMABN01JP.rtf] [CNTO148\C0524T18\DBR_WEEK54\RE_NDAJPKK\TSFLABHEMABN01JP.sas] 29JAN2016, 18:31

表 2.7.4.7-付録-75 血液学的検査値の最大グレード（T18 試験 54 週まで，日本人）

		Golimumab				
	Placebo [a,b]	50 mg [a]	100 mg [a,c,d]	Combined 50 mg and 100 mg	200 mg [d,e]	All Golimumab [f]
Treated subjects in C0524T18	8	3	59	60	-	60
Avg duration of follow-up (weeks)	26.5	18.5	42.3	42.6	-	42.6
Hemoglobin[g]						
N	8	3	59	60	-	60
Grade 0 (>= 12 g/dL)	2 (25.0%)	3 (100.0%)	22 (37.3%)	23 (38.3%)	-	23 (38.3%)
Grade 1 (>= 10 g/dL and < 12 g/dL)	4 (50.0%)	0	20 (33.9%)	20 (33.3%)	-	20 (33.3%)
Grade 2 (>= 8 g/dL and < 10 g/dL)	2 (25.0%)	0	15 (25.4%)	15 (25.0%)	-	15 (25.0%)
Grade 3 (>= 6.5 g/dL and < 8 g/dL)	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
Grade 4 (< 6.5 g/dL)	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
WBC[g]						
N	8	3	59	60	-	60
Grade 0 (>= 4.1 x 10^3/μL)	5 (62.5%)	2 (66.7%)	43 (72.9%)	43 (71.7%)	-	43 (71.7%)
Grade 1 (>= 3 and < 4.1 x 10^3/μL)	2 (25.0%)	1 (33.3%)	12 (20.3%)	13 (21.7%)	-	13 (21.7%)
Grade 2 (>= 2 and < 3 x 10^3/μL)	1 (12.5%)	0	4 (6.8%)	4 (6.7%)	-	4 (6.7%)
Grade 3 (>= 1 and < 2 x 10^3/μL)	0	0	0	0	-	0
Grade 4 (< 1 x 10^3/μL)	0	0	0	0	-	0
Absolute neutrophils[g]						
N	8	3	56	57	-	57
Grade 0 (>=2.03 x 10^3/μL)	6 (75.0%)	3 (100.0%)	41 (73.2%)	42 (73.7%)	-	42 (73.7%)
Grade 1 (>=1.5 and <2.03 x 10^3/μL)	1 (12.5%)	0	11 (19.6%)	11 (19.3%)	-	11 (19.3%)
Grade 2 (>=1 and <1.5 x 10^3/μL)	1 (12.5%)	0	4 (7.1%)	4 (7.0%)	-	4 (7.0%)
Grade 3 (>=0.5 and <1 x 10^3/μL})	0	0	0	0	-	0
Grade 4 (<0.5 x 10^3/μL)	0	0	0	0	-	0
Absolute lymphocytes[g]						
N	8	3	59	60	-	60
Grade 0 (>=1.02 x 10^3/μL)	3 (37.5%)	2 (66.7%)	37 (62.7%)	37 (61.7%)	-	37 (61.7%)
Grade 1 (>=0.8 and <1.02 x 10^3/μL)	1 (12.5%)	0	6 (10.2%)	6 (10.0%)	-	6 (10.0%)
Grade 2 (>=0.5 and <0.8 x 10^3/μL)	3 (37.5%)	1 (33.3%)	11 (18.6%)	12 (20.0%)	-	12 (20.0%)
Grade 3 (>=0.2 and <0.5 x 10^3/μL)	1 (12.5%)	0	5 (8.5%)	5 (8.3%)	-	5 (8.3%)
Grade 4 (<0.2 x 10^3/μL)	0	0	0	0	-	0
Platelets[g]						
N	8	3	59	60	-	60
Grade 0 (>=140 x 10^3/μL)	8 (100.0%)	3 (100.0%)	59 (100.0%)	60 (100.0%)	-	60 (100.0%)
Grade 1 (>=75 and <140 x 10^3/μL)	0	0	0	0	-	0
Grade 2 (>=50 and <75 x 10^3/μL)	0	0	0	0	-	0
Grade 3 (>=25 and <75 x 10^3/μL)	0	0	0	0	-	0
Grade 4 (<25 x 10^3/μL)	0	0	0	0	-	0

	Golimumab				
Placebo [a,b]	50 mg [a]	100 mg[a,c,d]	Combined 50 mg and 100 mg	200 mg[d,e]	All Golimumab[f]

[a] Includes data up to the time of dose adjustment for those who increased dose from the indicated dose.
[b] Includes 1) subjects who were in clinical response to golimumab induction dosing and were randomized to placebo on entry into this maintenance study; and 2) subjects who were in clinical response to placebo induction dosing and received placebo on entry into this maintenance study
[c] Includes 1) subjects who were in clinical response to golimumab induction dosing and were randomized to golimumab 100 mg on entry into this maintenance study; 2) subjects who were not in clinical response to either placebo or golimumab induction dosing and received golimumab 100 mg on entry into this maintenance study; and 3) subjects who were dose adjusted to golimumab 100 mg from placebo (randomized or nonrandomized) or from golimumab 50 mg.
[d] Includes data from the time of dose adjustment onward for those who increased to the indicated dose.
[e] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[f] Includes data from the time of the first golimumab dose onward.
[g] Grade 0 based on lower limit of normal for central lab. Grades 1-4 adapted from Cancer Therapy Evaluation Program, Common Terminology Criteria for Adverse Events v3.0 (CTCAE).

[TSFLABHEMTOX01JP.rtf] [CNTO148\C0524T18\DBR_WEEK54\RE_NDAJPKK\TSFLABHEMTOX01JP.sas] 02FEB2016, 01:02

表 2.7.4.7-付録-76 血液生化学検査値の異常（T17 試験 6 週まで，日本人）

	Placebo	Golimumab				
		100 mg -> 50 mg	200 mg -> 100 mg	400 mg -> 200 mg	Combined	All Golimumab
Subject treated	30	-	23	19	42	42
ALT/SGPT (elevated)						
N	30	-	23	19	42	42
Subjects with any abnormal value	0	-	0	0	0	0
Subjects with > 1 abnormal value	0	-	0	0	0	0
AST/SGOT (elevated)						
N	30	-	23	19	42	42
Subjects with any abnormal value	0	-	0	0	0	0
Subjects with > 1 abnormal value	0	-	0	0	0	0
Albumin (decreased)						
N	30	-	23	19	42	42
Subjects with any abnormal value	0	-	0	0	0	0
Subjects with > 1 abnormal value	0	-	0	0	0	0
Alkaline phosphatase (elevated)						
N	30	-	23	19	42	42
Subjects with any abnormal value	0	-	1 (4.3%)	0	1 (2.4%)	1 (2.4%)
Subjects with > 1 abnormal value	0	-	0	0	0	0
BUN/urea (elevated)						
N	30	-	23	19	42	42
Subjects with any abnormal value	0	-	0	0	0	0
Subjects with > 1 abnormal value	0	-	0	0	0	0
Calcium (decreased)						
N	30	-	23	19	42	42
Subjects with any abnormal value	0	-	0	0	0	0
Subjects with > 1 abnormal value	0	-	0	0	0	0
Calcium (elevated)						
N	30	-	23	19	42	42
Subjects with any abnormal value	0	-	0	0	0	0
Subjects with > 1 abnormal value	0	-	0	0	0	0
Chloride (decreased)						
N	30	-	23	19	42	42
Subjects with any abnormal value	0	-	0	0	0	0
Subjects with > 1 abnormal value	0	-	0	0	0	0
Chloride (elevated)						
N	30	-	23	19	42	42
Subjects with any abnormal value	0	-	0	0	0	0
Subjects with > 1 abnormal value	0	-	0	0	0	0

	Placebo	Golimumab				
		100 mg -> 50 mg	200 mg -> 100 mg	400 mg -> 200 mg	Combined	All Golimumab
Creatinine (elevated)						
N	30	-	23	19	42	42
Subjects with any abnormal value	0	-	0	0	0	0
Subjects with > 1 abnormal value	0	-	0	0	0	0
Phosphate, inorganic (decreased)						
N	30	-	23	19	42	42
Subjects with any abnormal value	0	-	0	0	0	0
Subjects with > 1 abnormal value	0	-	0	0	0	0
Phosphate, inorganic (elevated)						
N	30	-	23	19	42	42
Subjects with any abnormal value	2 (6.7%)	-	0	0	0	0
Subjects with > 1 abnormal value	0	-	0	0	0	0
Potassium (decreased)						
N	30	-	23	19	42	42
Subjects with any abnormal value	0	-	0	0	0	0
Subjects with > 1 abnormal value	0	-	0	0	0	0
Potassium (elevated)						
N	30	-	23	19	42	42
Subjects with any abnormal value	0	-	1 (4.3%)	0	1 (2.4%)	1 (2.4%)
Subjects with > 1 abnormal value	0	-	0	0	0	0
Sodium (decreased)						
N	30	-	23	19	42	42
Subjects with any abnormal value	0	-	0	0	0	0
Subjects with > 1 abnormal value	0	-	0	0	0	0
Sodium (elevated)						
N	30	-	23	19	42	42
Subjects with any abnormal value	0	-	0	0	0	0
Subjects with > 1 abnormal value	0	-	0	0	0	0
Total bilirubin (elevated)						
N	30	-	23	19	42	42
Subjects with any abnormal value	0	-	0	0	0	0
Subjects with > 1 abnormal value	0	-	0	0	0	0
Total protein (decreased)						
N	30	-	23	19	42	42
Subjects with any abnormal value	0	-	0	0	0	0
Subjects with > 1 abnormal value	0	-	0	0	0	0
Total protein (elevated)						
N	30	-	23	19	42	42
Subjects with any abnormal value	0	-	0	0	0	0
Subjects with > 1 abnormal value	0	-	0	0	0	0

表 2.7.4.7-付録-77 最大 ALT 値（T17 試験 6 週まで，日本人）

	Placebo	Golimumab				
		100 mg -> 50 mg	200 mg -> 100 mg	400 mg -> 200 mg	Combined	All Golimumab
Treated subjects in C0524T17	30	-	23	19	42	42
Avg duration of follow-up (weeks)	6.07	-	6.08	5.93	6.01	6.01
Subjects with baseline ALT =< ULN[a]						
N	29	-	23	19	42	42
Subject within normal range (=< 1 x ULN ALT)	29 (100.0%)	-	22 (95.7%)	19 (100.0%)	41 (97.6%)	41 (97.6%)
Subjects with abnormalities	0	-	1 (4.3%)	0	1 (2.4%)	1 (2.4%)
> 1 and < 2 x ULN ALT	0	-	0	0	0	0
>= 2 and < 3 x ULN ALT	0	-	1 (4.3%)	0	1 (2.4%)	1 (2.4%)
>= 3 and < 5 x ULN ALT	0	-	0	0	0	0
>= 5 and < 8 x ULN ALT	0	-	0	0	0	0
>= 8 x ULN ALT	0	-	0	0	0	0
Subjects with baseline ALT > ULN[a]						
N	1	-	0	0	0	0
Subject within normal range (=< 1 x ULN ALT)	0	-	-	-	-	-
Subjects with abnormalities	1 (100.0%)	-	-	-	-	-
> 1 and < 2 x ULN ALT	1 (100.0%)	-	-	-	-	-
>= 2 and < 3 x ULN ALT	0	-	-	-	-	-
>= 3 and < 5 x ULN ALT	0	-	-	-	-	-
>= 5 and < 8 x ULN ALT	0	-	-	-	-	-
>= 8 x ULN ALT	0	-	-	-	-	-

[a] Includes only subjects with both baseline and at least one postbaseline measurement.

[TSFLABALT01JP.rtf] [CNTO148\C0524T17\DBR_WEEK6\RE_NDAJPKK\TSFLABALT01JP.sas] 28JAN2016, 11:17

表 2.7.4.7-付録-78 最大 AST 値（T17 試験 6 週まで，日本人）

	Placebo	Golimumab				
		100 mg -> 50 mg	200 mg -> 100 mg	400 mg -> 200 mg	Combined	All Golimumab
Treated subjects in C0524T17	30	-	23	19	42	42
Avg duration of follow-up (weeks)	6.07	-	6.08	5.93	6.01	6.01
Subjects with baseline AST =< ULN[a]						
N	30	-	23	19	42	42
Subject within normal range (=< 1 x ULN AST)	28 (93.3%)	-	23 (100.0%)	19 (100.0%)	42 (100.0%)	42 (100.0%)
Subjects with abnormalities	2 (6.7%)	-	0	0	0	0
> 1 and < 2 x ULN AST	2 (6.7%)	-	0	0	0	0
>= 2 and < 3 x ULN AST	0	-	0	0	0	0
>= 3 and < 5 x ULN AST	0	-	0	0	0	0
>= 5 and < 8 x ULN AST	0	-	0	0	0	0
>= 8 x ULN AST	0	-	0	0	0	0

a) Includes only subjects with both baseline and at least one postbaseline measurement.

[TSFLABAST01JP.rtf] [CNTO148\C0524T17\DBR_WEEK6\RE_NDAJPKK\TSFLABAST01JP.sas] 28JAN2016, 11:21

表 2.7.4.7-付録-79 最大総ビリルビン値（T17 試験 6 週まで，日本人）

	Placebo	Golimumab				
		100 mg -> 50 mg	200 mg -> 100 mg	400 mg -> 200 mg	Combined	All Golimumab
Treated subjects in C0524T17	30	-	23	19	42	42
Avg duration of follow-up (weeks)	6.07	-	6.08	5.93	6.01	6.01
Total bilirubin						
N	30	-	23	19	42	42
=< ULN (=< 1.2 mg/dL)[a]	29 (96.7%)	-	23 (100.0%)	19 (100.0%)	42 (100.0%)	42 (100.0%)
> ULN and =< 2 x ULN (> 1.2 and =< 2.4 mg/dL)[b]	1 (3.3%)	-	0	0	0	0
> 2 x ULN (> 2.4 mg/dL)[b]	0	-	0	0	0	0

[a] Based on upper limit of normal for central lab.
[b] Adapted from FDA Concept Paper: Premarketing Evaluation of Drug-Induced Liver Injury (January 2007).

[TSFLABBILI01JP.rtf] [CNTO148\C0524T17\DBR_WEEK6\RE_NDAJPKK\TSFLABBILI01JP.sas] 28JAN2016, 11:29

表 2.7.4.7-付録-80 血液生化学検査値の異常（T18 試験 54 週まで，日本人）

		Golimumab				
	Placebo [a,b]	50 mg [a]	100 mg[a,c,d]	Combined 50 mg and 100 mg	200 mg[d,e]	All Golimumab[f]
Treated subjects in C0524T18	8	3	59	60	-	60
ALT/SGPT (elevated)						
N	8	3	59	60	-	60
Subjects with any abnormal value	0	0	0	0	-	0
Subjects with > 1 abnormal value	0	0	0	0	-	0
AST/SGOT (elevated)						
N	8	3	59	60	-	60
Subjects with any abnormal value	0	0	0	0	-	0
Subjects with > 1 abnormal value	0	0	0	0	-	0
Albumin (decreased)						
N	8	3	59	60	-	60
Subjects with any abnormal value	0	0	2 (3.4%)	2 (3.3%)	-	2 (3.3%)
Subjects with > 1 abnormal value	0	0	0	0	-	0
Alkaline phosphatase (elevated)						
N	8	3	59	60	-	60
Subjects with any abnormal value	0	0	0	0	-	0
Subjects with > 1 abnormal value	0	0	0	0	-	0
BUN/urea (elevated)						
N	8	3	59	60	-	60
Subjects with any abnormal value	0	0	0	0	-	0
Subjects with > 1 abnormal value	0	0	0	0	-	0
Calcium (decreased)						
N	8	3	59	60	-	60
Subjects with any abnormal value	0	0	0	0	-	0
Subjects with > 1 abnormal value	0	0	0	0	-	0
Calcium (elevated)						
N	8	3	59	60	-	60
Subjects with any abnormal value	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
Subjects with > 1 abnormal value	0	0	0	0	-	0
Chloride (decreased)						
N	8	3	59	60	-	60
Subjects with any abnormal value	0	0	0	0	-	0
Subjects with > 1 abnormal value	0	0	0	0	-	0
Chloride (elevated)						
N	8	3	59	60	-	60
Subjects with any abnormal value	0	0	0	0	-	0
Subjects with > 1 abnormal value	0	0	0	0	-	0

	Placebo [a,b]	Golimumab				
		50 mg [a]	100 mg [a,c,d]	Combined 50 mg and 100 mg	200 mg [d,e]	All Golimumab [f]
Creatinine (elevated)						
N	8	3	59	60	-	60
Subjects with any abnormal value	0	0	0	0	-	0
Subjects with > 1 abnormal value	0	0	0	0	-	0
Phosphate, inorganic (decreased)						
N	8	3	59	60	-	60
Subjects with any abnormal value	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
Subjects with > 1 abnormal value	0	0	0	0	-	0
Phosphate, inorganic (elevated)						
N	8	3	59	60	-	60
Subjects with any abnormal value	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
Subjects with > 1 abnormal value	0	0	0	0	-	0
Potassium (decreased)						
N	8	3	59	60	-	60
Subjects with any abnormal value	0	0	0	0	-	0
Subjects with > 1 abnormal value	0	0	0	0	-	0
Potassium (elevated)						
N	8	3	59	60	-	60
Subjects with any abnormal value	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
Subjects with > 1 abnormal value	0	0	0	0	-	0
Sodium (decreased)						
N	8	3	59	60	-	60
Subjects with any abnormal value	0	0	0	0	-	0
Subjects with > 1 abnormal value	0	0	0	0	-	0
Sodium (elevated)						
N	8	3	59	60	-	60
Subjects with any abnormal value	0	0	0	0	-	0
Subjects with > 1 abnormal value	0	0	0	0	-	0
Total bilirubin (elevated)						
N	8	3	59	60	-	60
Subjects with any abnormal value	0	0	0	0	-	0
Subjects with > 1 abnormal value	0	0	0	0	-	0
Total protein (decreased)						
N	8	3	59	60	-	60
Subjects with any abnormal value	0	0	0	0	-	0
Subjects with > 1 abnormal value	0	0	0	0	-	0
Total protein (elevated)						
N	8	3	59	60	-	60
Subjects with any abnormal value	0	0	0	0	-	0
Subjects with > 1 abnormal value	0	0	0	0	-	0

	Golimumab				
Placebo [a,b]	50 mg [a]	100 mg[a,c,d]	Combined 50 mg and 100 mg	200 mg[d,e]	All Golimumab[f]

[a] Includes data up to the time of dose adjustment for those who increased dose from the indicated dose.
[b] Includes 1) subjects who were in clinical response to golimumab induction dosing and were randomized to placebo on entry into this maintenance study; and 2) subjects who were in clinical response to placebo induction dosing and received placebo on entry into this maintenance study.
[c] Includes 1) subjects who were in clinical response to golimumab induction dosing and were randomized to golimumab 100 mg on entry into this maintenance study; 2) subjects who were not in clinical response to either placebo or golimumab induction dosing and received golimumab 100 mg on entry into this maintenance study; and 3) subjects who were dose adjusted to golimumab 100 mg from placebo (randomized or nonrandomized) or from golimumab 50 mg.
[d] Includes data from the time of dose adjustment onward for those who increased to the indicated dose.
[e] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[f] Includes data from the time of the first golimumab dose onward.

[TSFLABCHMABN01JP.rtf] [CNTO148\C0524T18\DBR_WEEK54\RE_NDAJPKK\TSFLABCHMABN01JP.sas] 29JAN2016, 18:32

表 2.7.4.7-付録-81 最大 ALT 値（T18 試験 54 週まで，日本人）

		Golimumab				
	Placebo [a,b]	50 mg [a]	100 mg[a,c,d]	Combined 50 mg and 100 mg	200 mg[d,e]	All Golimumab[f]
Treated subjects in C0524T18	8	3	59	60	-	60
Avg duration of follow-up (weeks)	26.5	18.5	42.3	42.6	-	42.6
Subjects with ALT =< ULN at Week 0 of this maintenance study[g]						
N	8	3	59	60	-	60
Subject within normal range (=< 1 x ULN ALT)	7 (87.5%)	3 (100.0%)	57 (96.6%)	58 (96.7%)	-	58 (96.7%)
Subjects with abnormalities	1 (12.5%)	0	2 (3.4%)	2 (3.3%)	-	2 (3.3%)
> 1 and < 2 x ULN ALT	1 (12.5%)	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
>= 2 and < 3 x ULN ALT	0	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
>= 3 and < 5 x ULN ALT	0	0	0	0	-	0
>= 5 and < 8 x ULN ALT	0	0	0	0	-	0
>= 8 x ULN ALT	0	0	0	0	-	0

[a] Includes data up to the time of dose adjustment for those who increased dose from the indicated dose.
[b] Includes 1) subjects who were in clinical response to golimumab induction dosing and were randomized to placebo on entry into this maintenance study; and 2) subjects who were in clinical response to placebo induction dosing and received placebo on entry into this maintenance study.
[c] Includes 1) subjects who were in clinical response to golimumab induction dosing and were randomized to golimumab 100 mg on entry into this maintenance study; 2) subjects who were not in clinical response to either placebo or golimumab induction dosing and received golimumab 100 mg on entry into this maintenance study; and 3) subjects who were dose adjusted to golimumab 100 mg from placebo (randomized or nonrandomized) or from golimumab 50 mg.
[d] Includes data from the time of dose adjustment onward for those who increased to the indicated dose.
[e] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[f] Includes data from the time of the first golimumab dose onward.
[g] Includes only subjects with a measurement at both Week 0 of this maintenance study and at least one postbaseline visit.

[TSFLABALT01JP.rtf] [CNTO148\C0524T18\DBR_WEEK54\RE_NDAJPKK\TSFLABALT01JP.sas] 29JAN2016, 18:34

表 2.7.4.7-付録-82 最大 AST 値（T18 試験 54 週まで，日本人）

		Golimumab				
	Placebo [a,b]	50 mg [a]	100 mg[a,c,d]	Combined 50 mg and 100 mg	200 mg[d,e]	All Golimumab[f]
Treated subjects in C0524T18	8	3	59	60	-	60
Avg duration of follow-up (weeks)	26.5	18.5	42.3	42.6	-	42.6
Subjects with AST =< ULN at Week 0 of this maintenance study[g]						
N	8	3	59	60	-	60
Subject within normal range (=< 1 x ULN AST)	7 (87.5%)	3 (100.0%)	58 (98.3%)	59 (98.3%)	-	59 (98.3%)
Subjects with abnormalities	1 (12.5%)	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
> 1 and < 2 x ULN AST	1 (12.5%)	0	1 (1.7%)	1 (1.7%)	-	1 (1.7%)
>= 2 and < 3 x ULN AST	0	0	0	0	-	0
>= 3 and < 5 x ULN AST	0	0	0	0	-	0
>= 5 and < 8 x ULN AST	0	0	0	0	-	0
>= 8 x ULN AST	0	0	0	0	-	0

[a] Includes data up to the time of dose adjustment for those who increased dose from the indicated dose.
[b] Includes 1) subjects who were in clinical response to golimumab induction dosing and were randomized to placebo on entry into this maintenance study; and 2) subjects who were in clinical response to placebo induction dosing and received placebo on entry into this maintenance study.
[c] Includes 1) subjects who were in clinical response to golimumab induction dosing and were randomized to golimumab 100 mg on entry into this maintenance study; 2) subjects who were not in clinical response to either placebo or golimumab induction dosing and received golimumab 100 mg on entry into this maintenance study; and 3) subjects who were dose adjusted to golimumab 100 mg from placebo (randomized or nonrandomized) or from golimumab 50 mg.
[d] Includes data from the time of dose adjustment onward for those who increased to the indicated dose.
[e] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[f] Includes data from the time of the first golimumab dose onward.
[g] Includes only subjects with a measurement at both Week 0 of this maintenance study and at least one postbaseline visit.

[TSFLABAST01JP.rtf] [CNTO148\C0524T18\DBR_WEEK54\RE_NDAJPKK\TSFLABAST01JP.sas] 29JAN2016, 18:34

表 2.7.4.7-付録-83 最大総ビリルビン値（T18 試験 54 週まで，日本人）

		Golimumab				
	Placebo [a,b]	50 mg [a]	100 mg[a,c,d]	Combined 50 mg and 100 mg	200 mg[d,e]	All Golimumab[f]
Treated subjects in C0524T18	8	3	59	60	-	60
Avg duration of follow-up (weeks)	26.5	18.5	42.3	42.6	-	42.6
Total bilirubin						
N	8	3	59	60	-	60
=< ULN (=< 1.2 mg/dL)[g]	8 (100.0%)	3 (100.0%)	56 (94.9%)	57 (95.0%)	-	57 (95.0%)
> ULN and =< 2 x ULN (> 1.2 and =< 2.4 mg/dL)[h]	0	0	3 (5.1%)	3 (5.0%)	-	3 (5.0%)
> 2 x ULN (> 2.4 mg/dL)[h]	0	0	0	0	-	0

[a] Includes data up to the time of dose adjustment for those who increased dose from the indicated dose.
[b] Includes 1) subjects who were in clinical response to golimumab induction dosing and were randomized to placebo on entry into this maintenance study; and 2) subjects who were in clinical response to placebo induction dosing and received placebo on entry into this maintenance study.
[c] Includes 1) subjects who were in clinical response to golimumab induction dosing and were randomized to golimumab 100 mg on entry into this maintenance study; 2) subjects who were not in clinical response to either placebo or golimumab induction dosing and received golimumab 100 mg on entry into this maintenance study; and 3) subjects who were dose adjusted to golimumab 100 mg from placebo (randomized or nonrandomized) or from golimumab 50 mg.
[d] Includes data from the time of dose adjustment onward for those who increased to the indicated dose.
[e] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[f] Includes data from the time of the first golimumab dose onward.
[g] Based on upper limit of normal for central lab.
[h] Adapted from FDA Concept Paper: Premarketing Evaluation of Drug-Induced Liver Injury (January 2007).

[TSFLABBILI01JP.rtf] [CNTO148\C0524T18\DBR_WEEK54\RE_NDAJPKK\TSFLABBILI01JP.sas] 02FEB2016, 01:03

表 2.7.4.7-付録-84 被験者の抗ゴリムマブ抗体一覧（T17 試験，日本人）

Treatment Group	Study Part	Subject ID	Visit	Antibody to golimumab	Titer
Placebo	Part 2b	7802-00001	Baseline	Negative	-
Placebo	Part 2b	7802-00001	Week 6	Negative	-
Placebo	Part 2b	7803-00001	Baseline	Negative	-
Placebo	Part 2b	7803-00001	Unscheduled 1	Negative	-
Placebo	Part 2b	7803-00001	16 Weeks PLA	Negative	-
Placebo	Part 2b	7803-00002	Baseline	Negative	-
Placebo	Part 2b	7803-00002	Week 6	Negative	-
Placebo	Part 2b	7804-00006	Baseline	Negative	-
Placebo	Part 2b	7804-00006	Week 6	Negative	-
Placebo	Part 2b	7804-00006	16 Weeks PLA	Negative	-
Placebo	Part 2b	7805-00001	Baseline	Negative	-
Placebo	Part 2b	7805-00001	Week 6	Negative	-
Placebo	Part 2b	7805-00009	Baseline	Negative	-
Placebo	Part 2b	7805-00009	Week 6	Negative	-
Placebo	Part 2b	7806-00003	Baseline	Negative	-
Placebo	Part 2b	7806-00003	Week 2	Negative	-
Placebo	Part 2b	7806-00003	16 Weeks PLA	Negative	-
Placebo	Part 2b	7807-00004	Baseline	Negative	-
Placebo	Part 2b	7807-00004	Week 6	Negative	-
Placebo	Part 2b	7807-00004	16 Weeks PLA	Negative	-
Placebo	Part 2b	7807-00005	Baseline	Negative	-
Placebo	Part 2b	7807-00005	Week 6	Negative	-
Placebo	Part 2b	7807-00007	Baseline	Negative	-
Placebo	Part 2b	7807-00007	Week 6	Negative	-
Placebo	Part 2b	7808-00002	Baseline	Negative	-
Placebo	Part 2b	7808-00002	Week 6	Negative	-
Placebo	Part 2b	7808-00005	Baseline	Negative	-
Placebo	Part 2b	7808-00005	Week 6	Negative	-
Placebo	Part 2b	7808-00006	Baseline	Negative	-
Placebo	Part 2b	7808-00006	Week 6	Negative	-
Placebo	Part 2b	7809-00002	Baseline	Negative	-
Placebo	Part 2b	7809-00002	Week 6	Negative	-
Placebo	Part 2b	7811-00001	Baseline	Negative	-
Placebo	Part 2b	7811-00001	Week 6	Negative	-
Placebo	Part 2b	7812-00002	Baseline	Negative	-
Placebo	Part 2b	7812-00002	Week 6	Negative	-
Placebo	Part 2b	7813-00001	Baseline	Negative	-
Placebo	Part 2b	7813-00001	Week 6	Negative	-
Placebo	Part 2b	7814-00001	Baseline	Negative	-
Placebo	Part 2b	7814-00001	Week 6	Negative	-
Placebo	Part 2b	7815-00002	Baseline	Negative	-
Placebo	Part 2b	7815-00002	Week 6	Negative	-
Placebo	Part 2b	7816-00002	Baseline	Negative	-
Placebo	Part 2b	7816-00002	Week 6	Negative	-
Placebo	Part 2b	7816-00003	Baseline	Negative	-
Placebo	Part 2b	7816-00003	Week 6	Negative	-
Placebo	Part 2b	7817-00001	Baseline	Negative	-
Placebo	Part 2b	7817-00001	Week 6	Negative	-
Placebo	Part 2b	7817-00004	Baseline	Negative	-
Placebo	Part 2b	7817-00004	Week 6	Negative	-
Placebo	Part 2b	7817-00005	Baseline	Negative	-
Placebo	Part 2b	7817-00005	Week 6	Negative	-
Placebo	Part 2b	7818-00001	Baseline	Negative	-
Placebo	Part 2b	7818-00001	Week 6	Negative	-
Placebo	Part 2b	7818-00003	Baseline	Negative	-
Placebo	Part 2b	7818-00003	Week 6	Negative	-
Placebo	Part 2b	7819-00003	Baseline	Negative	-
Placebo	Part 2b	7819-00003	Week 6	Negative	-
Placebo	Part 2b	7820-00001	Baseline	Negative	-
Placebo	Part 2b	7820-00001	Week 6	Negative	-
Placebo	Part 2b	7820-00002	Baseline	Negative	-
Placebo	Part 2b	7820-00002	Week 6	Negative	-
Placebo	Part 2b	7821-00002	Baseline	Negative	-
Placebo	Part 2b	7821-00002	Week 6	Negative	-

Treatment Group	Study Part	Subject ID	Visit	Antibody to golimumab	Titer
200 mg -> 100 mg	Part 2b	7801-00002	Baseline	Negative	-
200 mg -> 100 mg	Part 2b	7801-00002	Week 6	Negative	-
200 mg -> 100 mg	Part 2b	7802-00002	Baseline	Negative	-
200 mg -> 100 mg	Part 2b	7802-00002	Week 6	Negative	-
200 mg -> 100 mg	Part 2b	7802-00004	Baseline	Negative	-
200 mg -> 100 mg	Part 2b	7802-00004	Week 6	Negative	-
200 mg -> 100 mg	Part 2b	7804-00003	Baseline	Negative	-
200 mg -> 100 mg	Part 2b	7804-00003	Week 6	Negative	-
200 mg -> 100 mg	Part 2b	7804-00005	Baseline	Negative	-
200 mg -> 100 mg	Part 2b	7804-00005	Week 6	Negative	-
200 mg -> 100 mg	Part 2b	7805-00003	Baseline	Negative	-
200 mg -> 100 mg	Part 2b	7805-00003	Week 6	Negative	-
200 mg -> 100 mg	Part 2b	7805-00006	Baseline	Negative	-
200 mg -> 100 mg	Part 2b	7805-00006	Week 2	Negative	-
200 mg -> 100 mg	Part 2b	7805-00006	16 Weeks PLA	Negative	-
200 mg -> 100 mg	Part 2b	7805-00007	Baseline	Negative	-
200 mg -> 100 mg	Part 2b	7805-00007	Week 6	Negative	-
200 mg -> 100 mg	Part 2b	7807-00003	Baseline	Negative	-
200 mg -> 100 mg	Part 2b	7807-00003	Week 6	Negative	-
200 mg -> 100 mg	Part 2b	7808-00001	Baseline	Negative	-
200 mg -> 100 mg	Part 2b	7808-00001	Week 6	Negative	-
200 mg -> 100 mg	Part 2b	7809-00001	Baseline	Negative	-
200 mg -> 100 mg	Part 2b	7809-00001	Week 6	Negative	-
200 mg -> 100 mg	Part 2b	7812-00003	Baseline	Negative	-
200 mg -> 100 mg	Part 2b	7812-00003	Unscheduled 1	Negative	-
200 mg -> 100 mg	Part 2b	7812-00003	16 Weeks PLA	Negative	-
200 mg -> 100 mg	Part 2b	7813-00002	Baseline	Negative	-
200 mg -> 100 mg	Part 2b	7813-00002	Week 6	Negative	-
200 mg -> 100 mg	Part 2b	7813-00002	16 Weeks PLA	Negative	-
200 mg -> 100 mg	Part 2b	7814-00003	Baseline	Negative	-
200 mg -> 100 mg	Part 2b	7814-00003	Week 6	Negative	-
200 mg -> 100 mg	Part 2b	7815-00001	Baseline	Negative	-
200 mg -> 100 mg	Part 2b	7815-00001	Week 6	Negative	-
200 mg -> 100 mg	Part 2b	7815-00001	16 Weeks PLA	Negative	-
200 mg -> 100 mg	Part 2b	7815-00003	Baseline	Negative	-
200 mg -> 100 mg	Part 2b	7815-00003	Week 6	Negative	-
200 mg -> 100 mg	Part 2b	7817-00002	Baseline	Negative	-
200 mg -> 100 mg	Part 2b	7817-00002	Week 6	Negative	-
200 mg -> 100 mg	Part 2b	7818-00002	Baseline	Negative	-
200 mg -> 100 mg	Part 2b	7818-00002	Week 6	Negative	-
200 mg -> 100 mg	Part 2b	7819-00002	Baseline	Negative	-
200 mg -> 100 mg	Part 2b	7819-00002	Week 6	Negative	-
200 mg -> 100 mg	Part 2b	7819-00004	Baseline	Negative	-
200 mg -> 100 mg	Part 2b	7819-00004	Week 6	Negative	-
200 mg -> 100 mg	Part 2b	7821-00003	Baseline	Negative	-
200 mg -> 100 mg	Part 2b	7821-00003	Week 6	Negative	-
200 mg -> 100 mg	Part 2b	7822-00001	Baseline	Negative	-
200 mg -> 100 mg	Part 2b	7822-00001	Week 6	Negative	-
200 mg -> 100 mg	Part 2b	7822-00003	Baseline	Negative	-
200 mg -> 100 mg	Part 2b	7822-00003	Week 6	Negative	-
400 mg -> 200 mg	Part 2b	7801-00001	Baseline	Negative	-
400 mg -> 200 mg	Part 2b	7801-00001	Week 6	Negative	-
400 mg -> 200 mg	Part 2b	7801-00003	Baseline	Negative	-
400 mg -> 200 mg	Part 2b	7801-00003	Week 6	Negative	-
400 mg -> 200 mg	Part 2b	7801-00003	16 Weeks PLA	Negative	-
400 mg -> 200 mg	Part 2b	7801-00005	Baseline	Negative	-
400 mg -> 200 mg	Part 2b	7801-00005	Week 6	Negative	-
400 mg -> 200 mg	Part 2b	7801-00006	Baseline	Negative	-
400 mg -> 200 mg	Part 2b	7801-00006	Week 6	Negative	-
400 mg -> 200 mg	Part 2b	7801-00006	16 Weeks PLA	Negative	-
400 mg -> 200 mg	Part 2b	7803-00003	Baseline	Negative	-
400 mg -> 200 mg	Part 2b	7803-00003	Week 6	Negative	-
400 mg -> 200 mg	Part 2b	7804-00007	Baseline	Negative	-
400 mg -> 200 mg	Part 2b	7804-00007	Week 6	Negative	-
400 mg -> 200 mg	Part 2b	7805-00008	Baseline	Negative	-
400 mg -> 200 mg	Part 2b	7805-00008	Week 6	Negative	-

Treatment Group	Study Part	Subject ID	Visit	Antibody to golimumab	Titer
400 mg -> 200 mg	Part 2b	7806-00002	Baseline	Negative	-
400 mg -> 200 mg	Part 2b	7806-00002	Week 6	Negative	-
400 mg -> 200 mg	Part 2b	7807-00006	Baseline	Negative	-
400 mg -> 200 mg	Part 2b	7807-00006	Week 6	Negative	-
400 mg -> 200 mg	Part 2b	7808-00004	Baseline	Negative	-
400 mg -> 200 mg	Part 2b	7808-00004	Week 6	Negative	-
400 mg -> 200 mg	Part 2b	7808-00007	Baseline	Negative	-
400 mg -> 200 mg	Part 2b	7808-00007	Week 6	Negative	-
400 mg -> 200 mg	Part 2b	7809-00003	Baseline	Negative	-
400 mg -> 200 mg	Part 2b	7809-00003	Week 6	Negative	-
400 mg -> 200 mg	Part 2b	7813-00003	Baseline	Negative	-
400 mg -> 200 mg	Part 2b	7813-00003	Week 6	Negative	-
400 mg -> 200 mg	Part 2b	7814-00002	Baseline	Negative	-
400 mg -> 200 mg	Part 2b	7814-00002	Week 6	Negative	-
400 mg -> 200 mg	Part 2b	7816-00001	Baseline	Negative	-
400 mg -> 200 mg	Part 2b	7816-00001	Week 6	Negative	-
400 mg -> 200 mg	Part 2b	7817-00003	Baseline	Negative	-
400 mg -> 200 mg	Part 2b	7817-00003	Week 6	Negative	-
400 mg -> 200 mg	Part 2b	7819-00001	Baseline	Negative	-
400 mg -> 200 mg	Part 2b	7819-00001	Week 6	Negative	-
400 mg -> 200 mg	Part 2b	7820-00003	Baseline	Negative	-
400 mg -> 200 mg	Part 2b	7820-00003	Week 6	Negative	-
400 mg -> 200 mg	Part 2b	7822-00002	Baseline	Negative	-
400 mg -> 200 mg	Part 2b	7822-00002	Week 6	Negative	-

[LIR02JP.rtf] [CNTO148\C0524T17\DBR_WEEK6\RE_NDAJPKK\LIR02JP.sas] 29JAN2016, 14:54

表 2.7.4.7-付録-85 被験者の抗ゴリムマブ抗体一覧（T18 試験，日本人）

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Visit	Sampling date/time	Antibody to golimumab	Titer
Yes	Placebo	200 mg/100 mg SC	7801-00002	Week 0 - INDC	2009-04-24, 9:05	Negative	-
Yes	Placebo	200 mg/100 mg SC	7801-00002	Baseline	2009-06-08, 13:20	Negative	-
Yes	Placebo	200 mg/100 mg SC	7801-00002	Week 12 - MAIN	2009-09-07, 13:55	Negative	-
Yes	Placebo	200 mg/100 mg SC	7801-00002	Unscheduled - MAIN	2009-09-16, 15:50	Negative	-
Yes	Placebo	200 mg/100 mg SC	7801-00002	Unscheduled - MAIN	2009-12-28, 14:30	Negative	-
Yes	Placebo	200 mg/100 mg SC	7802-00004	Week 0 - INDC	2009-11-05, 15:55	Negative	-
Yes	Placebo	200 mg/100 mg SC	7802-00004	Baseline	2009-12-17, 13:00	Negative	-
Yes	Placebo	200 mg/100 mg SC	7802-00004	Week 30 - MAIN	2010-07-15, 11:20	Negative	-
Yes	Placebo	200 mg/100 mg SC	7802-00004	Week 54 - MAIN	2010-12-27, 15:15	Negative	-
Yes	Golimumab 100 mg	400 mg/200 mg SC	7803-00003	Week 0 - INDC	2010-04-02, 10:00	Negative	-
Yes	Golimumab 100 mg	400 mg/200 mg SC	7803-00003	Baseline	2010-05-14, 10:00	Negative	-
Yes	Golimumab 100 mg	400 mg/200 mg SC	7803-00003	Week 4 - MAIN	2010-06-11, 9:28	Negative	-
Yes	Golimumab 100 mg	400 mg/200 mg SC	7803-00003	Unscheduled - MAIN	2010-06-25, 9:50	Negative	-
Yes	Golimumab 100 mg	400 mg/200 mg SC	7803-00003	Unscheduled - MAIN	2010-10-01, 9:55	Positive	1:10
Yes	Golimumab 100 mg	200 mg/100 mg SC	7804-00003	Week 0 - INDC	2009-11-18, 13:05	Negative	-
Yes	Golimumab 100 mg	200 mg/100 mg SC	7804-00003	Baseline	2009-12-25, 9:00	Negative	-
Yes	Golimumab 100 mg	200 mg/100 mg SC	7804-00003	Week 16 - MAIN	2010-04-09, 11:35	Negative	-
Yes	Golimumab 100 mg	200 mg/100 mg SC	7804-00003	Week 30 - MAIN	2010-07-23, 9:10	Negative	-
Yes	Golimumab 100 mg	200 mg/100 mg SC	7804-00003	Week 54 - MAIN	2011-01-07, 10:46	Negative	-
Yes	Golimumab 50 mg	400 mg/200 mg SC	7804-00007	Week 0 - INDC	2010-03-12, 9:08	Negative	-
Yes	Golimumab 50 mg	400 mg/200 mg SC	7804-00007	Baseline	2010-04-20, 11:12	Negative	-
Yes	Golimumab 50 mg	400 mg/200 mg SC	7804-00007	Week 12 - MAIN	2010-07-13, 9:15	Negative	-
Yes	Golimumab 50 mg	400 mg/200 mg SC	7804-00007	Unscheduled - MAIN	2010-11-01, 10:30	Negative	-
Yes	Golimumab 50 mg	400 mg/200 mg SC	7804-00007	Unscheduled - MAIN	2011-01-18, 10:10	Negative	-
Yes	Golimumab 100 mg	400 mg/200 mg SC	7806-00002	Week 0 - INDC	2009-07-03, 10:30	Negative	-
Yes	Golimumab 100 mg	400 mg/200 mg SC	7806-00002	Baseline	2009-08-17, 12:50	Negative	-
Yes	Golimumab 100 mg	400 mg/200 mg SC	7806-00002	Week 30 - MAIN	2010-03-15, 9:40	Negative	-
Yes	Golimumab 100 mg	400 mg/200 mg SC	7806-00002	Week 54 - MAIN	2010-09-06, 9:00	Negative	-
Yes	Golimumab 50 mg	400 mg/200 mg SC	7807-00006	Week 0 - INDC	2009-12-17, 15:05	Negative	-
Yes	Golimumab 50 mg	400 mg/200 mg SC	7807-00006	Baseline	2010-01-26, 12:55	Negative	-
Yes	Golimumab 50 mg	400 mg/200 mg SC	7807-00006	Unscheduled - MAIN	2010-05-25, 12:38	Negative	-
Yes	Golimumab 50 mg	400 mg/200 mg SC	7807-00006	Unscheduled - MAIN	2010-06-28, 9:38	Negative	-
Yes	Golimumab 50 mg	400 mg/200 mg SC	7807-00006	Unscheduled - MAIN	2010-10-01, 8:42	Negative	-
Yes	Golimumab 100 mg	400 mg/200 mg SC	7814-00002	Week 0 - INDC	2009-06-08, 15:00	Negative	-
Yes	Golimumab 100 mg	400 mg/200 mg SC	7814-00002	Baseline	2009-07-16, 14:40	Negative	-
Yes	Golimumab 100 mg	400 mg/200 mg SC	7814-00002	Week 30 - MAIN	2010-02-08, 9:45	Negative	-
Yes	Golimumab 100 mg	400 mg/200 mg SC	7814-00002	Week 52 - MAIN	2010-07-22, 14:10	Negative	-
Yes	Golimumab 100 mg	400 mg/200 mg SC	7814-00002	Week 54 - MAIN	2010-07-28, 9:30	Negative	-
Yes	Golimumab 100 mg	200 mg/100 mg SC	7814-00003	Week 0 - INDC	2009-11-09, 13:35	Negative	-
Yes	Golimumab 100 mg	200 mg/100 mg SC	7814-00003	Baseline	2009-12-21, 13:25	Negative	-
Yes	Golimumab 100 mg	200 mg/100 mg SC	7814-00003	Week 30 - MAIN	2010-07-21, 10:10	Negative	-
Yes	Golimumab 100 mg	200 mg/100 mg SC	7814-00003	Week 54 - MAIN	2010-12-27, 9:40	Negative	-
Yes	Placebo	200 mg/100 mg SC	7821-00003	Week 0 - INDC	2009-08-24, 8:56	Negative	-
Yes	Placebo	200 mg/100 mg SC	7821-00003	Baseline	2009-10-05, 8:45	Negative	-
Yes	Placebo	200 mg/100 mg SC	7821-00003	Unscheduled - MAIN	2009-12-04, 12:01	Negative	-

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Visit	Sampling date/time	Antibody to golimumab	Titer
Yes	Placebo	200 mg/100 mg SC	7821-00003	Unscheduled - MAIN	2010-03-08, 8:52	Negative	-
Yes	Golimumab 50 mg	400 mg/200 mg SC	7822-00002	Week 0 - INDC	2009-08-01, 8:50	Negative	-
Yes	Golimumab 50 mg	400 mg/200 mg SC	7822-00002	Baseline	2009-09-11, 8:30	Negative	-
Yes	Golimumab 50 mg	400 mg/200 mg SC	7822-00002	Week 8 - MAIN	2009-11-07, 10:30	Negative	-
Yes	Golimumab 50 mg	400 mg/200 mg SC	7822-00002	Week 30 - MAIN	2010-04-03, 10:30	Negative	-
Yes	Golimumab 50 mg	400 mg/200 mg SC	7822-00002	Unscheduled - MAIN	2010-07-14, 8:15	Negative	-
Yes	Placebo	200 mg/100 mg SC	7822-00003	Week 0 - INDC	2009-11-24, 11:40	Negative	-
Yes	Placebo	200 mg/100 mg SC	7822-00003	Baseline	2010-01-07, 13:20	Negative	-
Yes	Placebo	200 mg/100 mg SC	7822-00003	Unscheduled - MAIN	2010-02-18, 12:30	Negative	-
Yes	Placebo	200 mg/100 mg SC	7822-00003	Unscheduled - MAIN	2010-09-09, 12:30	Negative	-
Yes	Placebo	200 mg/100 mg SC	7822-00003	Unscheduled - MAIN	2010-09-21, 11:30	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	400 mg/200 mg SC	7801-00001	Week 0 - INDC	2009-04-20, 10:48	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	400 mg/200 mg SC	7801-00001	Baseline	2009-06-01, 10:15	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	400 mg/200 mg SC	7801-00001	Unscheduled - MAIN	2009-09-28, 10:27	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	400 mg/200 mg SC	7801-00001	Unscheduled - MAIN	2009-12-14, 9:23	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	400 mg/200 mg SC	7801-00005	Week 0 - INDC	2010-02-15, 13:22	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	400 mg/200 mg SC	7801-00005	Baseline	2010-03-29, 14:10	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	400 mg/200 mg SC	7801-00005	Unscheduled - MAIN	2010-04-19, 12:31	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	400 mg/200 mg SC	7801-00005	Unscheduled - MAIN	2010-07-05, 15:00	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7802-00001	Week 0 - INDC	2009-06-19, 10:20	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7802-00001	Baseline	2009-07-28, 10:30	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7802-00001	Unscheduled - MAIN	2010-02-18, 14:40	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7802-00001	Unscheduled - MAIN	2010-06-03, 9:20	Negative	-

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Visit	Sampling date/time	Antibody to golimumab	Titer
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7802-00002	Week 0 - INDC	2009-08-20, 9:30	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7802-00002	Baseline	2009-10-01, 13:40	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7802-00002	Unscheduled - MAIN	2010-05-06, 15:30	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7802-00002	Unscheduled - MAIN	2010-08-05, 9:00	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7803-00002	Week 0 - INDC	2009-06-17, 10:13	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7803-00002	Baseline	2009-08-01, 9:45	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7803-00002	Week 30 - MAIN	2010-03-06, 10:00	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7803-00002	Week 54 - MAIN	2010-08-18, 9:10	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7804-00005	Week 0 - INDC	2010-01-07, 9:58	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7804-00005	Baseline	2010-02-18, 14:06	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7804-00005	Unscheduled - MAIN	2010-09-16, 13:08	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7804-00005	Unscheduled - MAIN	2011-01-06, 11:20	Negative	-
No	Placebo (Placebo induction responder)	Placebo SC	7805-00001	Week 0 - INDC	2009-05-29, 12:57	Negative	-
No	Placebo (Placebo induction responder)	Placebo SC	7805-00001	Baseline	2009-07-06, 10:20	Negative	-
No	Placebo (Placebo induction responder)	Placebo SC	7805-00001	Week 30 - MAIN	2010-01-25, 10:50	Negative	-
No	Placebo (Placebo induction responder)	Placebo SC	7805-00001	Week 54 - MAIN	2010-07-23, 9:10	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7805-00003	Week 0 - INDC	2009-08-17, 11:22	Negative	-

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Visit	Sampling date/time	Antibody to golimumab	Titer
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7805-00003	Baseline	2009-09-25, 13:45	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7805-00003	Unscheduled - MAIN	2010-02-15, 12:54	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7805-00003	Unscheduled - MAIN	2010-06-03, 9:03	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7805-00007	Week 0 - INDC	2009-09-17, 10:00	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7805-00007	Baseline	2009-11-02, 9:05	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7805-00007	Unscheduled - MAIN	2009-12-01, 10:33	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7805-00007	Unscheduled - MAIN	2010-03-18, 9:55	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	400 mg/200 mg SC	7805-00008	Week 0 - INDC	2009-10-03, 10:20	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	400 mg/200 mg SC	7805-00008	Baseline	2009-11-16, 12:43	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	400 mg/200 mg SC	7805-00008	Week 30 - MAIN	2010-06-18, 12:19	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	400 mg/200 mg SC	7805-00008	Unscheduled - MAIN	2010-06-26, 12:03	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	400 mg/200 mg SC	7805-00008	Unscheduled - MAIN	2010-09-30, 10:33	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7805-00009	Week 0 - INDC	2009-10-16, 9:00	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7805-00009	Baseline	2009-11-30, 11:45	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7805-00009	Week 30 - MAIN	2010-06-25, 11:25	Negative	-

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Visit	Sampling date/time	Antibody to golimumab	Titer
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7805-00009	Week 54 - MAIN	2010-12-17, 13:00	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7807-00003	Week 0 - INDC	2009-08-12, 9:10	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7807-00003	Baseline	2009-09-24, 13:25	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7807-00003	Week 30 - MAIN	2010-04-27, 13:02	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7807-00003	Unscheduled - MAIN	2010-08-03, 9:55	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7807-00003	Unscheduled - MAIN	2010-11-02, 8:55	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7807-00005	Week 0 - INDC	2009-12-21, 10:40	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7807-00005	Baseline	2010-02-02, 13:44	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7807-00005	Week 30 - MAIN	2010-08-24, 12:50	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7807-00005	Unscheduled - MAIN	2010-09-13, 11:04	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7807-00005	Unscheduled - MAIN	2010-12-06, 13:32	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7807-00007	Week 0 - INDC	2010-02-16, 14:03	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7807-00007	Baseline	2010-03-25, 12:48	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7807-00007	Unscheduled - MAIN	2010-04-20, 12:50	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7807-00007	Unscheduled - MAIN	2010-08-02, 17:00	Negative	-

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Visit	Sampling date/time	Antibody to golimumab	Titer
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7808-00001	Week 0 - INDC	2009-04-09, 13:45	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7808-00001	Baseline	2009-05-20, 10:20	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7808-00001	Week 30 - MAIN	2009-12-15, 15:45	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7808-00001	Week 54 - MAIN	2010-06-02, 15:38	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7808-00002	Week 0 - INDC	2009-04-23, 14:25	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7808-00002	Baseline	2009-06-04, 14:35	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7808-00002	Week 30 - MAIN	2010-01-05, 15:10	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7808-00002	Unscheduled - MAIN	2010-05-20, 11:15	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	400 mg/200 mg SC	7808-00004	Week 0 - INDC	2009-05-08, 10:10	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	400 mg/200 mg SC	7808-00004	Baseline	2009-06-17, 11:45	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	400 mg/200 mg SC	7808-00004	Week 30 - MAIN	2010-01-20, 11:05	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	400 mg/200 mg SC	7808-00004	Week 54 - MAIN	2010-06-30, 13:25	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7808-00005	Week 0 - INDC	2009-05-07, 10:30	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7808-00005	Baseline	2009-06-18, 11:55	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7808-00005	Unscheduled - MAIN	2010-01-21, 16:35	Negative	-

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Visit	Sampling date/time	Antibody to golimumab	Titer
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7808-00005	Unscheduled - MAIN	2010-04-27, 12:55	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7808-00006	Week 0 - INDC	2009-08-13, 14:18	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7808-00006	Baseline	2009-09-29, 14:54	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7808-00006	Week 30 - MAIN	2010-04-28, 16:10	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7808-00006	Week 54 - MAIN	2010-10-08, 13:15	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	400 mg/200 mg SC	7808-00007	Week 0 - INDC	2010-02-22, 15:14	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	400 mg/200 mg SC	7808-00007	Baseline	2010-04-07, 15:17	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	400 mg/200 mg SC	7808-00007	Week 30 - MAIN	2010-10-27, 13:05	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	400 mg/200 mg SC	7808-00007	Week 54 - MAIN	2011-04-27, 13:05	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7809-00001	Week 0 - INDC	2009-04-25, 9:49	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7809-00001	Baseline	2009-06-10, 13:30	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7809-00001	Week 30 - MAIN	2010-01-08, 13:25	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7809-00001	Week 54 - MAIN	2010-06-18, 13:15	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7809-00002	Week 0 - INDC	2009-06-06, 8:45	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7809-00002	Baseline	2009-07-17, 13:15	Negative	-

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Visit	Sampling date/time	Antibody to golimumab	Titer
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7809-00002	Unscheduled - MAIN	2010-01-05, 14:50	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7809-00002	Unscheduled - MAIN	2010-04-17, 9:18	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	400 mg/200 mg SC	7809-00003	Week 0 - INDC	2009-06-23, 9:00	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	400 mg/200 mg SC	7809-00003	Baseline	2009-07-30, 9:30	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	400 mg/200 mg SC	7809-00003	Week 30 - MAIN	2010-02-18, 8:35	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	400 mg/200 mg SC	7809-00003	Week 54 - MAIN	2010-08-06, 9:10	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7811-00001	Week 0 - INDC	2009-08-18, 9:40	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7811-00001	Baseline	2009-10-01, 9:40	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7811-00001	Week 30 - MAIN	2010-04-22, 8:45	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7811-00001	Unscheduled - MAIN	2010-07-06, 15:20	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7811-00001	Unscheduled - MAIN	2010-10-07, 13:20	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7812-00002	Week 0 - INDC	2009-10-08, 11:58	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7812-00002	Baseline	2009-11-16, 12:57	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7812-00002	Unscheduled - MAIN	2009-12-09, 12:10	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7812-00002	Unscheduled - MAIN	2010-03-01, 9:34	Negative	-

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Visit	Sampling date/time	Antibody to golimumab	Titer
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7813-00001	Week 0 - INDC	2009-05-22, 10:34	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7813-00001	Baseline	2009-07-02, 10:28	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7813-00001	Unscheduled - MAIN	2009-10-29, 9:59	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	400 mg/200 mg SC	7813-00003	Week 0 - INDC	2009-06-17, 14:05	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	400 mg/200 mg SC	7813-00003	Baseline	2009-07-29, 10:05	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	400 mg/200 mg SC	7813-00003	Unscheduled - MAIN	2010-02-24, 9:15	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	400 mg/200 mg SC	7813-00003	Unscheduled - MAIN	2010-05-26, 9:32	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7814-00001	Week 0 - INDC	2009-06-04, 12:35	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7814-00001	Baseline	2009-07-15, 10:15	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7814-00001	Unscheduled - MAIN	2009-10-07, 10:55	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7815-00002	Week 0 - INDC	2009-12-14, 8:35	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7815-00002	Baseline	2010-01-27, 8:43	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7815-00002	Week 30 - MAIN	2010-08-25, 8:30	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7815-00002	Week 54 - MAIN	2011-02-09, 8:35	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7815-00003	Week 0 - INDC	2010-01-18, 12:35	Negative	-

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Visit	Sampling date/time	Antibody to golimumab	Titer
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7815-00003	Baseline	2010-03-01, 12:10	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7815-00003	Week 30 - MAIN	2010-09-29, 12:10	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7815-00003	Week 54 - MAIN	2011-03-16, 10:20	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	400 mg/200 mg SC	7816-00001	Week 0 - INDC	2009-08-08, 9:55	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	400 mg/200 mg SC	7816-00001	Baseline	2009-09-15, 8:40	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	400 mg/200 mg SC	7816-00001	Week 30 - MAIN	2010-04-10, 9:05	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	400 mg/200 mg SC	7816-00001	Week 54 - MAIN	2010-10-02, 9:10	Negative	-
No	Placebo (Placebo induction responder)	Placebo SC	7816-00002	Week 0 - INDC	2009-09-12, 9:35	Negative	-
No	Placebo (Placebo induction responder)	Placebo SC	7816-00002	Baseline	2009-10-24, 9:00	Negative	-
No	Placebo (Placebo induction responder)	Placebo SC	7816-00002	Week 30 - MAIN	2010-05-22, 11:15	Negative	-
No	Placebo (Placebo induction responder)	Placebo SC	7816-00002	Week 32 - MAIN	2010-06-07, 11:03	Negative	-
No	Placebo (Placebo induction responder)	Placebo SC	7816-00002	Unscheduled - MAIN	2010-07-07, 9:05	Negative	-
No	Placebo (Placebo induction responder)	Placebo SC	7816-00002	Unscheduled - MAIN	2010-10-02, 11:30	Positive	1:10
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7816-00003	Week 0 - INDC	2009-11-02, 9:30	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7816-00003	Baseline	2009-12-14, 9:40	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7816-00003	Week 30 - MAIN	2010-07-12, 9:32	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7816-00003	Week 54 - MAIN	2010-12-27, 10:22	Negative	-
No	Placebo (Placebo induction responder)	Placebo SC	7817-00001	Week 0 - INDC	2009-06-15, 14:00	Negative	-

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Visit	Sampling date/time	Antibody to golimumab	Titer
No	Placebo (Placebo induction responder)	Placebo SC	7817-00001	Baseline	2009-07-28, 9:40	Negative	-
No	Placebo (Placebo induction responder)	Placebo SC	7817-00001	Week 30 - MAIN	2010-02-23, 10:05	Negative	-
No	Placebo (Placebo induction responder)	Placebo SC	7817-00001	Week 44 - MAIN	2010-06-02, 11:10	Negative	-
No	Placebo (Placebo induction responder)	Placebo SC	7817-00001	Week 54 - MAIN	2010-08-16, 14:15	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7817-00002	Week 0 - INDC	2009-06-17, 10:35	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7817-00002	Baseline	2009-07-29, 10:50	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7817-00002	Week 30 - MAIN	2010-02-23, 10:35	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7817-00002	Week 54 - MAIN	2010-08-17, 10:42	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	400 mg/200 mg SC	7817-00003	Week 0 - INDC	2009-06-10, 11:00	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	400 mg/200 mg SC	7817-00003	Baseline	2009-07-22, 10:40	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	400 mg/200 mg SC	7817-00003	Week 30 - MAIN	2010-02-15, 11:25	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	400 mg/200 mg SC	7817-00003	Week 54 - MAIN	2010-08-03, 10:15	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7817-00004	Week 0 - INDC	2010-02-08, 11:50	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7817-00004	Baseline	2010-03-24, 10:30	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7817-00004	Week 4 - MAIN	2010-04-22, 11:35	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7817-00004	Week 30 - MAIN	2010-10-27, 14:45	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7817-00004	Week 54 - MAIN	2011-04-13, 10:00	Negative	-

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Visit	Sampling date/time	Antibody to golimumab	Titer
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7817-00005	Week 0 - INDC	2010-04-05, 15:05	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7817-00005	Baseline	2010-05-19, 14:30	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7817-00005	Week 30 - MAIN	2010-12-14, 15:30	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7817-00005	Week 54 - MAIN	2011-06-03, 10:15	Negative	-
No	Placebo (Placebo induction responder)	Placebo SC	7818-00001	Week 0 - INDC	2009-06-16, 10:00	Negative	-
No	Placebo (Placebo induction responder)	Placebo SC	7818-00001	Baseline	2009-07-24, 8:45	Negative	-
No	Placebo (Placebo induction responder)	Placebo SC	7818-00001	Week 20 - MAIN	2009-12-11, 8:55	Negative	-
No	Placebo (Placebo induction responder)	Placebo SC	7818-00001	Week 30 - MAIN	2010-02-26, 8:40	Negative	-
No	Placebo (Placebo induction responder)	Placebo SC	7818-00001	Week 54 - MAIN	2010-08-06, 9:10	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7818-00002	Week 0 - INDC	2009-07-23, 11:30	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7818-00002	Baseline	2009-09-04, 11:00	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7818-00002	Week 30 - MAIN	2010-03-30, 9:00	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7818-00002	Unscheduled - MAIN	2010-07-06, 12:55	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7818-00003	Week 0 - INDC	2009-09-03, 11:15	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7818-00003	Baseline	2009-10-20, 9:45	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7818-00003	Week 30 - MAIN	2010-05-21, 9:10	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7818-00003	Week 54 - MAIN	2010-10-29, 10:40	Negative	-

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Visit	Sampling date/time	Antibody to golimumab	Titer
No	Golimumab 100 mg (Golimumab induction nonresponder)	400 mg/200 mg SC	7819-00001	Week 0 - INDC	2009-06-05, 16:00	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	400 mg/200 mg SC	7819-00001	Baseline	2009-07-13, 16:35	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	400 mg/200 mg SC	7819-00001	Week 30 - MAIN	2010-02-08, 16:30	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	400 mg/200 mg SC	7819-00001	Week 54 - MAIN	2010-07-26, 16:40	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7819-00002	Week 0 - INDC	2009-06-08, 10:15	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7819-00002	Baseline	2009-07-24, 16:15	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7819-00002	Week 30 - MAIN	2010-02-22, 16:10	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7819-00002	Week 54 - MAIN	2010-08-02, 14:20	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7819-00003	Week 0 - INDC	2009-06-12, 8:55	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7819-00003	Baseline	2009-07-27, 16:30	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7819-00003	Unscheduled - MAIN	2009-11-13, 11:40	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7819-00003	Unscheduled - MAIN	2010-02-19, 8:45	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7819-00004	Week 0 - INDC	2010-03-19, 9:10	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7819-00004	Baseline	2010-04-26, 14:40	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7819-00004	Unscheduled - MAIN	2010-08-09, 15:35	Negative	-

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Visit	Sampling date/time	Antibody to golimumab	Titer
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7819-00004	Unscheduled - MAIN	2010-11-01, 9:20	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7820-00001	Week 0 - INDC	2009-09-07, 9:50	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7820-00001	Baseline	2009-10-16, 10:05	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7820-00001	Week 30 - MAIN	2010-05-18, 14:25	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7820-00001	Week 54 - MAIN	2010-10-27, 13:30	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7820-00002	Week 0 - INDC	2009-09-15, 10:55	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7820-00002	Baseline	2009-10-26, 13:45	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7820-00002	Week 30 - MAIN	2010-05-27, 9:50	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7820-00002	Week 54 - MAIN	2010-11-11, 10:02	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	400 mg/200 mg SC	7820-00003	Week 0 - INDC	2009-11-05, 12:05	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	400 mg/200 mg SC	7820-00003	Baseline	2009-12-17, 11:48	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	400 mg/200 mg SC	7820-00003	Unscheduled - MAIN	2010-04-15, 12:10	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	400 mg/200 mg SC	7820-00003	Unscheduled - MAIN	2010-08-03, 9:13	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7821-00002	Week 0 - INDC	2009-07-08, 8:54	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7821-00002	Baseline	2009-08-19, 8:50	Negative	-

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Visit	Sampling date/time	Antibody to golimumab	Titer
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7821-00002	Week 30 - MAIN	2010-03-17, 8:55	Negative	-
No	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7821-00002	Week 54 - MAIN	2010-09-01, 8:56	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7822-00001	Week 0 - INDC	2009-09-18, 11:30	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7822-00001	Baseline	2009-10-30, 11:40	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7822-00001	Week 30 - MAIN	2010-05-29, 10:20	Negative	-
No	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7822-00001	Week 54 - MAIN	2010-11-06, 10:30	Negative	-

表 2.7.4.7-付録-86 ベースライン時の人口統計学的特性別のすべての有害事象の発現割合（T16，T17 及び T18 試験 54 週まで；全投与被験者）

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
Treated subjects in C0524T16 and C0524T17	49	358	286	77	157	154	660	14	1233
Sex									
Male									
n	30	192	157	40	75	77	409	8	705
Avg duration of follow-up (weeks)	12.0	18.1	39.8	10.8	36.9	51.6	45.4	25.4	45.7
Avg exposure (number of administrations)	1.6	4.8	9.5	1.7	9.6	13.1	10.9	6.0	11.1
Subjects with 1 or more adverse events	16 (53.3%)	82 (42.7%)	117 (74.5%)	24 (60.0%)	51 (68.0%)	53 (68.8%)	320 (78.2%)	5 (62.5%)	541 (76.7%)
Female									
n	19	166	129	37	82	77	251	6	528
Avg duration of follow-up (weeks)	12.8	20.1	38.4	13.1	40.9	49.2	44.6	30.3	45.4
Avg exposure (number of administrations)	1.7	5.3	8.9	1.6	10.4	12.6	10.5	8.2	10.8
Subjects with 1 or more adverse events	14 (73.7%)	82 (49.4%)	95 (73.6%)	26 (70.3%)	64 (78.0%)	67 (87.0%)	199 (79.3%)	4 (66.7%)	423 (80.1%)
Race									
Caucasian									
n	38	286	227	61	138	138	541	12	1014
Avg duration of follow-up (weeks)	11.6	19.5	38.7	11.6	39.4	50.6	44.2	29.7	45.5
Avg exposure (number of administrations)	1.6	5.1	9.2	1.6	10.2	13.0	10.6	7.4	11.0
Subjects with 1 or more adverse events	22 (57.9%)	125 (43.7%)	166 (73.1%)	42 (68.9%)	105 (76.1%)	107 (77.5%)	431 (79.7%)	9 (75.0%)	804 (79.3%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
Non-Caucasian									
n	11	72	59	16	19	16	119	2	219
Avg duration of follow-up (weeks)	14.7	17.3	41.2	13.2	35.7	49.3	49.3	14.6	45.7
Avg exposure (number of administrations)	1.6	4.5	9.3	1.6	8.9	12.1	11.5	4.0	10.6
Subjects with 1 or more adverse events	8 (72.7%)	39 (54.2%)	46 (78.0%)	8 (50.0%)	10 (52.6%)	13 (81.3%)	88 (73.9%)	0 (0.0%)	160 (73.1%)
Age (yrs)									
< 30									
n	14	99	72	24	40	35	172	9	314
Avg duration of follow-up (weeks)	11.6	21.5	37.0	9.8	34.9	48.8	44.2	29.3	44.1
Avg exposure (number of administrations)	1.7	5.5	8.5	1.6	9.0	12.3	10.5	7.2	10.5
Subjects with 1 or more adverse events	7 (50.0%)	56 (56.6%)	51 (70.8%)	16 (66.7%)	24 (60.0%)	30 (85.7%)	129 (75.0%)	6 (66.7%)	236 (75.2%)
≥ 30 to < 40									
n	13	90	75	21	45	38	166	1	321
Avg duration of follow-up (weeks)	10.6	18.6	40.9	11.4	40.6	55.0	46.6	0.7	46.6
Avg exposure (number of administrations)	1.6	5.0	9.9	1.6	10.5	14.1	11.2	1.0	11.3
Subjects with 1 or more adverse events	6 (46.2%)	39 (43.3%)	52 (69.3%)	14 (66.7%)	33 (73.3%)	27 (71.1%)	133 (80.1%)	0 (0.0%)	245 (76.3%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
≥ 40 to < 50									
n	9	83	72	11	33	35	142	2	273
Avg duration of follow-up (weeks)	14.2	16.0	41.1	14.3	39.6	54.6	47.0	32.6	47.9
Avg exposure (number of administrations)	1.7	4.3	9.6	1.6	10.2	14.0	11.4	8.5	11.6
Subjects with 1 or more adverse events	7 (77.8%)	33 (39.8%)	58 (80.6%)	7 (63.6%)	28 (84.8%)	27 (77.1%)	111 (78.2%)	2 (100.0%)	221 (81.0%)
≥ 50									
n	13	86	67	21	39	46	180	2	325
Avg duration of follow-up (weeks)	13.5	19.7	37.6	13.6	40.7	44.8	43.1	28.0	43.9
Avg exposure (number of administrations)	1.5	5.1	8.8	1.7	10.4	11.5	10.1	7.0	10.4
Subjects with 1 or more adverse events	10 (76.9%)	36 (41.9%)	51 (76.1%)	13 (61.9%)	30 (76.9%)	36 (78.3%)	146 (81.1%)	1 (50.0%)	262 (80.6%)
Weight (kg)									
< 75									
n	29	206	165	54	93	89	356	10	700
Avg duration of follow-up (weeks)	13.0	19.1	40.0	12.4	39.9	50.6	45.9	30.5	45.9
Avg exposure (number of administrations)	1.7	5.0	9.4	1.6	10.2	12.8	10.8	7.5	10.9
Subjects with 1 or more adverse events	19 (65.5%)	92 (44.7%)	119 (72.1%)	36 (66.7%)	68 (73.1%)	72 (80.9%)	274 (77.0%)	7 (70.0%)	540 (77.1%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
≥ 75									
n	20	151	120	23	64	65	304	4	532
Avg duration of follow-up (weeks)	11.3	19.1	38.3	10.7	37.6	50.3	44.2	20.1	45.2
Avg exposure (number of administrations)	1.6	4.9	9.0	1.6	9.8	13.0	10.7	5.5	11.0
Subjects with 1 or more adverse events	11 (55.0%)	71 (47.0%)	92 (76.7%)	14 (60.9%)	47 (73.4%)	48 (73.8%)	245 (80.6%)	2 (50.0%)	423 (79.5%)

[a] Includes data up to the time of the first golimumab dose in the maintenance study.
[b] Includes data from the time of dose adjustment onward for those who increased to the indicated dose during the maintenance study.
[c] Includes data up to the time of dose adjustment for those who increased dose from the indicated dose during the maintenance study.
[d] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[e] Includes data from the time of the first golimumab dose onward.

表 2.7.4.7-付録-87 ベースライン時の人口統計学的特性別の重篤な有害事象の発現割合（T16，T17 及び T18 試験 54 週まで；全投与被験者）

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
Treated subjects in C0524T16 and C0524T17	49	358	286	77	157	154	660	14	1233
Sex									
Male									
n	30	192	157	40	75	77	409	8	705
Avg duration of follow-up (weeks)	12.0	18.1	39.8	10.8	36.9	51.6	45.4	25.4	45.7
Avg exposure (number of administrations)	1.6	4.8	9.5	1.7	9.6	13.1	10.9	6.0	11.1
Subjects with 1 or more serious adverse events	5 (16.7%)	2 (1.0%)	20 (12.7%)	15 (37.5%)	8 (10.7%)	5 (6.5%)	62 (15.2%)	1 (12.5%)	109 (15.5%)
Female									
n	19	166	129	37	82	77	251	6	528
Avg duration of follow-up (weeks)	12.8	20.1	38.4	13.1	40.9	49.2	44.6	30.3	45.4
Avg exposure (number of administrations)	1.7	5.3	8.9	1.6	10.4	12.6	10.5	8.2	10.8
Subjects with 1 or more serious adverse events	11 (57.9%)	12 (7.2%)	21 (16.3%)	13 (35.1%)	5 (6.1%)	8 (10.4%)	41 (16.3%)	0 (0.0%)	87 (16.5%)
Race									
Caucasian									
n	38	286	227	61	138	138	541	12	1014
Avg duration of follow-up (weeks)	11.6	19.5	38.7	11.6	39.4	50.6	44.2	29.7	45.5
Avg exposure (number of administrations)	1.6	5.1	9.2	1.6	10.2	13.0	10.6	7.4	11.0
Subjects with 1 or more serious adverse events	12 (31.6%)	12 (4.2%)	29 (12.8%)	24 (39.3%)	11 (8.0%)	12 (8.7%)	90 (16.6%)	1 (8.3%)	164 (16.2%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
Non-Caucasian									
n	11	72	59	16	19	16	119	2	219
Avg duration of follow-up (weeks)	14.7	17.3	41.2	13.2	35.7	49.3	49.3	14.6	45.7
Avg exposure (number of administrations)	1.6	4.5	9.3	1.6	8.9	12.1	11.5	4.0	10.6
Subjects with 1 or more serious adverse events	4 (36.4%)	2 (2.8%)	12 (20.3%)	4 (25.0%)	2 (10.5%)	1 (6.3%)	13 (10.9%)	0 (0.0%)	32 (14.6%)
Age (yrs)									
< 30									
n	14	99	72	24	40	35	172	9	314
Avg duration of follow-up (weeks)	11.6	21.5	37.0	9.8	34.9	48.8	44.2	29.3	44.1
Avg exposure (number of administrations)	1.7	5.5	8.5	1.6	9.0	12.3	10.5	7.2	10.5
Subjects with 1 or more serious adverse events	4 (28.6%)	5 (5.1%)	13 (18.1%)	9 (37.5%)	3 (7.5%)	2 (5.7%)	23 (13.4%)	0 (0.0%)	50 (15.9%)
≥ 30 to < 40									
n	13	90	75	21	45	38	166	1	321
Avg duration of follow-up (weeks)	10.6	18.6	40.9	11.4	40.6	55.0	46.6	0.7	46.6
Avg exposure (number of administrations)	1.6	5.0	9.9	1.6	10.5	14.1	11.2	1.0	11.3
Subjects with 1 or more serious adverse events	4 (30.8%)	3 (3.3%)	13 (17.3%)	6 (28.6%)	4 (8.9%)	2 (5.3%)	26 (15.7%)	0 (0.0%)	49 (15.3%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
≥ 40 to < 50									
n	9	83	72	11	33	35	142	2	273
Avg duration of follow-up (weeks)	14.2	16.0	41.1	14.3	39.6	54.6	47.0	32.6	47.9
Avg exposure (number of administrations)	1.7	4.3	9.6	1.6	10.2	14.0	11.4	8.5	11.6
Subjects with 1 or more serious adverse events	4 (44.4%)	1 (1.2%)	6 (8.3%)	4 (36.4%)	2 (6.1%)	3 (8.6%)	22 (15.5%)	1 (50.0%)	37 (13.6%)
≥ 50									
n	13	86	67	21	39	46	180	2	325
Avg duration of follow-up (weeks)	13.5	19.7	37.6	13.6	40.7	44.8	43.1	28.0	43.9
Avg exposure (number of administrations)	1.5	5.1	8.8	1.7	10.4	11.5	10.1	7.0	10.4
Subjects with 1 or more serious adverse events	4 (30.8%)	5 (5.8%)	9 (13.4%)	9 (42.9%)	4 (10.3%)	6 (13.0%)	32 (17.8%)	0 (0.0%)	60 (18.5%)
Weight (kg)									
< 75									
n	29	206	165	54	93	89	356	10	700
Avg duration of follow-up (weeks)	13.0	19.1	40.0	12.4	39.9	50.6	45.9	30.5	45.9
Avg exposure (number of administrations)	1.7	5.0	9.4	1.6	10.2	12.8	10.8	7.5	10.9
Subjects with 1 or more serious adverse events	11 (37.9%)	7 (3.4%)	20 (12.1%)	22 (40.7%)	9 (9.7%)	8 (9.0%)	53 (14.9%)	1 (10.0%)	112 (16.0%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
≥ 75									
n	20	151	120	23	64	65	304	4	532
Avg duration of follow-up (weeks)	11.3	19.1	38.3	10.7	37.6	50.3	44.2	20.1	45.2
Avg exposure (number of administrations)	1.6	4.9	9.0	1.6	9.8	13.0	10.7	5.5	11.0
Subjects with 1 or more serious adverse events	5 (25.0%)	7 (4.6%)	21 (17.5%)	6 (26.1%)	4 (6.3%)	5 (7.7%)	50 (16.4%)	0 (0.0%)	84 (15.8%)

[a] Includes data up to the time of the first golimumab dose in the maintenance study.
[b] Includes data from the time of dose adjustment onward for those who increased to the indicated dose during the maintenance study.
[c] Includes data up to the time of dose adjustment for those who increased dose from the indicated dose during the maintenance study.
[d] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[e] Includes data from the time of the first golimumab dose onward.

RE599:[S SAE 124 A], 01FEB2012 15:03

表 2.7.4.7-付録-88 ベースライン時の人口統計学的特性別の治験薬投与中止に至った有害事象の発現割合

（T16，T17 及び T18 試験 54 週まで；全投与被験者）

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
Treated subjects in C0524T16 and C0524T17	49	358	286	77	157	154	660	14	1233
Sex									
Male									
n	30	192	157	40	75	77	409	8	705
Avg duration of follow-up (weeks)	12.0	18.1	39.8	10.8	36.9	51.6	45.4	25.4	45.7
Avg exposure (number of administrations)	1.6	4.8	9.5	1.7	9.6	13.1	10.9	6.0	11.1
Subjects who discontinued study agent because of 1 or more treatment-emergent adverse events	1 (3.3%)	3 (1.6%)	20 (12.7%)	3 (7.5%)	4 (5.3%)	3 (3.9%)	44 (10.8%)	0 (0.0%)	74 (10.5%)
Female									
n	19	166	129	37	82	77	251	6	528
Avg duration of follow-up (weeks)	12.8	20.1	38.4	13.1	40.9	49.2	44.6	30.3	45.4
Avg exposure (number of administrations)	1.7	5.3	8.9	1.6	10.4	12.6	10.5	8.2	10.8
Subjects who discontinued study agent because of 1 or more treatment-emergent adverse events	2 (10.5%)	4 (2.4%)	22 (17.1%)	1 (2.7%)	6 (7.3%)	5 (6.5%)	37 (14.7%)	0 (0.0%)	71 (13.4%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
Race									
Caucasian									
n	38	286	227	61	138	138	541	12	1014
Avg duration of follow-up (weeks)	11.6	19.5	38.7	11.6	39.4	50.6	44.2	29.7	45.5
Avg exposure (number of administrations)	1.6	5.1	9.2	1.6	10.2	13.0	10.6	7.4	11.0
Subjects who discontinued study agent because of 1 or more treatment-emergent adverse events	3 (7.9%)	5 (1.7%)	34 (15.0%)	4 (6.6%)	8 (5.8%)	8 (5.8%)	71 (13.1%)	0 (0.0%)	125 (12.3%)
Non-Caucasian									
n	11	72	59	16	19	16	119	2	219
Avg duration of follow-up (weeks)	14.7	17.3	41.2	13.2	35.7	49.3	49.3	14.6	45.7
Avg exposure (number of administrations)	1.6	4.5	9.3	1.6	8.9	12.1	11.5	4.0	10.6
Subjects who discontinued study agent because of 1 or more treatment-emergent adverse events	0 (0.0%)	2 (2.8%)	8 (13.6%)	0 (0.0%)	2 (10.5%)	0 (0.0%)	10 (8.4%)	0 (0.0%)	20 (9.1%)
Age (yrs)									
< 30									
n	14	99	72	24	40	35	172	9	314
Avg duration of follow-up (weeks)	11.6	21.5	37.0	9.8	34.9	48.8	44.2	29.3	44.1
Avg exposure (number of administrations)	1.7	5.5	8.5	1.6	9.0	12.3	10.5	7.2	10.5
Subjects who discontinued study agent because of 1 or more treatment-emergent adverse events	0 (0.0%)	5 (5.1%)	13 (18.1%)	2 (8.3%)	1 (2.5%)	1 (2.9%)	19 (11.0%)	0 (0.0%)	36 (11.5%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
≥ 30 to < 40									
n	13	90	75	21	45	38	166	1	321
Avg duration of follow-up (weeks)	10.6	18.6	40.9	11.4	40.6	55.0	46.6	0.7	46.6
Avg exposure (number of administrations)	1.6	5.0	9.9	1.6	10.5	14.1	11.2	1.0	11.3
Subjects who discontinued study agent because of 1 or more treatment-emergent adverse events	1 (7.7%)	1 (1.1%)	9 (12.0%)	1 (4.8%)	4 (8.9%)	0 (0.0%)	27 (16.3%)	0 (0.0%)	41 (12.8%)
≥ 40 to < 50									
n	9	83	72	11	33	35	142	2	273
Avg duration of follow-up (weeks)	14.2	16.0	41.1	14.3	39.6	54.6	47.0	32.6	47.9
Avg exposure (number of administrations)	1.7	4.3	9.6	1.6	10.2	14.0	11.4	8.5	11.6
Subjects who discontinued study agent because of 1 or more treatment-emergent adverse events	1 (11.1%)	0 (0.0%)	6 (8.3%)	0 (0.0%)	2 (6.1%)	2 (5.7%)	13 (9.2%)	0 (0.0%)	23 (8.4%)
≥ 50									
n	13	86	67	21	39	46	180	2	325
Avg duration of follow-up (weeks)	13.5	19.7	37.6	13.6	40.7	44.8	43.1	28.0	43.9
Avg exposure (number of administrations)	1.5	5.1	8.8	1.7	10.4	11.5	10.1	7.0	10.4
Subjects who discontinued study agent because of 1 or more treatment-emergent adverse events	1 (7.7%)	1 (1.2%)	14 (20.9%)	1 (4.8%)	3 (7.7%)	5 (10.9%)	22 (12.2%)	0 (0.0%)	45 (13.8%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
Weight (kg)									
< 75									
n	29	206	165	54	93	89	356	10	700
Avg duration of follow-up (weeks)	13.0	19.1	40.0	12.4	39.9	50.6	45.9	30.5	45.9
Avg exposure (number of administrations)	1.7	5.0	9.4	1.6	10.2	12.8	10.8	7.5	10.9
Subjects who discontinued study agent because of 1 or more treatment-emergent adverse events	1 (3.4%)	3 (1.5%)	23 (13.9%)	2 (3.7%)	6 (6.5%)	4 (4.5%)	45 (12.6%)	0 (0.0%)	80 (11.4%)
≥ 75									
n	20	151	120	23	64	65	304	4	532
Avg duration of follow-up (weeks)	11.3	19.1	38.3	10.7	37.6	50.3	44.2	20.1	45.2
Avg exposure (number of administrations)	1.6	4.9	9.0	1.6	9.8	13.0	10.7	5.5	11.0
Subjects who discontinued study agent because of 1 or more treatment-emergent adverse events	2 (10.0%)	4 (2.6%)	18 (15.0%)	2 (8.7%)	4 (6.3%)	4 (6.2%)	36 (11.8%)	0 (0.0%)	64 (12.0%)

[a] Includes data up to the time of the first golimumab dose in the maintenance study.
[b] Includes data from the time of dose adjustment onward for those who increased to the indicated dose during the maintenance study.
[c] Includes data up to the time of dose adjustment for those who increased dose from the indicated dose during the maintenance study.
[d] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[e] Includes data from the time of the first golimumab dose onward.

表 2.7.4.7-付録-89 ベースライン時の人口統計学的特性別の感染症の発現割合（T16，T17 及び T18 試験 54 週まで；全投与被験者）

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
Treated subjects in C0524T16 and C0524T17	49	358	286	77	157	154	660	14	1233
Sex									
Male									
n	30	192	157	40	75	77	409	8	705
Avg duration of follow-up (weeks)	12.0	18.1	39.8	10.8	36.9	51.6	45.4	25.4	45.7
Avg exposure (number of administrations)	1.6	4.8	9.5	1.7	9.6	13.1	10.9	6.0	11.1
Subjects with 1 or more infections	8 (26.7%)	32 (16.7%)	60 (38.2%)	12 (30.0%)	20 (26.7%)	25 (32.5%)	158 (38.6%)	3 (37.5%)	272 (38.6%)
Female									
n	19	166	129	37	82	77	251	6	528
Avg duration of follow-up (weeks)	12.8	20.1	38.4	13.1	40.9	49.2	44.6	30.3	45.4
Avg exposure (number of administrations)	1.7	5.3	8.9	1.6	10.4	12.6	10.5	8.2	10.8
Subjects with 1 or more infections	7 (36.8%)	31 (18.7%)	48 (37.2%)	13 (35.1%)	35 (42.7%)	42 (54.5%)	99 (39.4%)	1 (16.7%)	228 (43.2%)
Race									
Caucasian									
n	38	286	227	61	138	138	541	12	1014
Avg duration of follow-up (weeks)	11.6	19.5	38.7	11.6	39.4	50.6	44.2	29.7	45.5
Avg exposure (number of administrations)	1.6	5.1	9.2	1.6	10.2	13.0	10.6	7.4	11.0
Subjects with 1 or more infections	11 (28.9%)	49 (17.1%)	84 (37.0%)	20 (32.8%)	49 (35.5%)	63 (45.7%)	211 (39.0%)	4 (33.3%)	416 (41.0%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
Non-Caucasian									
n	11	72	59	16	19	16	119	2	219
Avg duration of follow-up (weeks)	14.7	17.3	41.2	13.2	35.7	49.3	49.3	14.6	45.7
Avg exposure (number of administrations)	1.6	4.5	9.3	1.6	8.9	12.1	11.5	4.0	10.6
Subjects with 1 or more infections	4 (36.4%)	14 (19.4%)	24 (40.7%)	5 (31.3%)	6 (31.6%)	4 (25.0%)	46 (38.7%)	0 (0.0%)	84 (38.4%)
Age (yrs)									
< 30									
n	14	99	72	24	40	35	172	9	314
Avg duration of follow-up (weeks)	11.6	21.5	37.0	9.8	34.9	48.8	44.2	29.3	44.1
Avg exposure (number of administrations)	1.7	5.5	8.5	1.6	9.0	12.3	10.5	7.2	10.5
Subjects with 1 or more infections	3 (21.4%)	23 (23.2%)	32 (44.4%)	7 (29.2%)	10 (25.0%)	22 (62.9%)	66 (38.4%)	3 (33.3%)	135 (43.0%)
≥ 30 to < 40									
n	13	90	75	21	45	38	166	1	321
Avg duration of follow-up (weeks)	10.6	18.6	40.9	11.4	40.6	55.0	46.6	0.7	46.6
Avg exposure (number of administrations)	1.6	5.0	9.9	1.6	10.5	14.1	11.2	1.0	11.3
Subjects with 1 or more infections	6 (46.2%)	18 (20.0%)	23 (30.7%)	8 (38.1%)	19 (42.2%)	14 (36.8%)	78 (47.0%)	0 (0.0%)	138 (43.0%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
≥ 40 to < 50									
n	9	83	72	11	33	35	142	2	273
Avg duration of follow-up (weeks)	14.2	16.0	41.1	14.3	39.6	54.6	47.0	32.6	47.9
Avg exposure (number of administrations)	1.7	4.3	9.6	1.6	10.2	14.0	11.4	8.5	11.6
Subjects with 1 or more infections	2 (22.2%)	11 (13.3%)	29 (40.3%)	4 (36.4%)	14 (42.4%)	15 (42.9%)	49 (34.5%)	1 (50.0%)	109 (39.9%)
≥ 50									
n	13	86	67	21	39	46	180	2	325
Avg duration of follow-up (weeks)	13.5	19.7	37.6	13.6	40.7	44.8	43.1	28.0	43.9
Avg exposure (number of administrations)	1.5	5.1	8.8	1.7	10.4	11.5	10.1	7.0	10.4
Subjects with 1 or more infections	4 (30.8%)	11 (12.8%)	24 (35.8%)	6 (28.6%)	12 (30.8%)	16 (34.8%)	64 (35.6%)	0 (0.0%)	118 (36.3%)
Weight (kg)									
< 75									
n	29	206	165	54	93	89	356	10	700
Avg duration of follow-up (weeks)	13.0	19.1	40.0	12.4	39.9	50.6	45.9	30.5	45.9
Avg exposure (number of administrations)	1.7	5.0	9.4	1.6	10.2	12.8	10.8	7.5	10.9
Subjects with 1 or more infections	10 (34.5%)	36 (17.5%)	58 (35.2%)	20 (37.0%)	36 (38.7%)	41 (46.1%)	137 (38.5%)	2 (20.0%)	285 (40.7%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
≥ 75									
n	20	151	120	23	64	65	304	4	532
Avg duration of follow-up (weeks)	11.3	19.1	38.3	10.7	37.6	50.3	44.2	20.1	45.2
Avg exposure (number of administrations)	1.6	4.9	9.0	1.6	9.8	13.0	10.7	5.5	11.0
Subjects with 1 or more infections	5 (25.0%)	27 (17.9%)	49 (40.8%)	5 (21.7%)	19 (29.7%)	26 (40.0%)	120 (39.5%)	2 (50.0%)	214 (40.2%)

[a] Includes data up to the time of the first golimumab dose in the maintenance study.
[b] Includes data from the time of dose adjustment onward for those who increased to the indicated dose during the maintenance study.
[c] Includes data up to the time of dose adjustment for those who increased dose from the indicated dose during the maintenance study.
[d] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[e] Includes data from the time of the first golimumab dose onward.

表 2.7.4.7-付録-90 ベースライン時の疾患特性別のすべての有害事象の発現割合（T16，T17 及び T18 試験 54 週まで；全投与被験者）

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
Treated subjects in C0524T16 and C0524T17	49	358	286	77	157	154	660	14	1233
Severity of disease									
Moderate (Mayo score ≥ 6 to ≤ 10)									
n	39	332	266	62	146	145	587	14	1114
Avg duration of follow-up (weeks)	12.5	18.8	39.5	11.8	38.9	50.6	45.5	27.5	46.1
Avg exposure (number of administrations)	1.6	4.9	9.3	1.6	10.0	12.9	10.8	6.9	11.1
Subjects with 1 or more adverse events	22 (56.4%)	148 (44.6%)	200 (75.2%)	36 (58.1%)	108 (74.0%)	113 (77.9%)	462 (78.7%)	9 (64.3%)	870 (78.1%)
Severe (Mayo score > 10)									
n	10	25	19	12	11	9	73	0	115
Avg duration of follow-up (weeks)	11.6	23.8	33.7	11.0	39.2	48.4	42.2	NA	41.0
Avg exposure (number of administrations)	1.6	6.2	7.7	1.6	10.1	12.2	10.0	NA	9.7
Subjects with 1 or more adverse events	8 (80.0%)	15 (60.0%)	11 (57.9%)	12 (100.0%)	7 (63.6%)	7 (77.8%)	57 (78.1%)	0 (NA)	91 (79.1%)
Duration of disease (years)									
≤ 5									
n	32	202	159	42	84	82	359	9	672
Avg duration of follow-up (weeks)	12.2	19.4	36.5	11.4	38.2	48.8	45.3	27.1	44.6
Avg exposure (number of administrations)	1.6	5.1	8.6	1.7	9.8	12.4	10.7	6.7	10.7
Subjects with 1 or more adverse events	19 (59.4%)	94 (46.5%)	117 (73.6%)	25 (59.5%)	56 (66.7%)	65 (79.3%)	270 (75.2%)	5 (55.6%)	508 (75.6%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
> 5									
n	17	156	127	35	73	72	301	5	561
Avg duration of follow-up (weeks)	12.6	18.7	42.5	12.5	39.8	52.3	44.9	28.2	46.7
Avg exposure (number of administrations)	1.6	4.9	10.1	1.5	10.2	13.4	10.8	7.4	11.3
Subjects with 1 or more adverse events	11 (64.7%)	70 (44.9%)	95 (74.8%)	25 (71.4%)	59 (80.8%)	55 (76.4%)	249 (82.7%)	4 (80.0%)	456 (81.3%)
Extent of disease									
Limited to left side of colon									
n	29	202	153	40	86	80	388	9	697
Avg duration of follow-up (weeks)	11.4	21.6	39.4	12.2	40.2	52.5	46.2	26.7	46.4
Avg exposure (number of administrations)	1.6	5.7	9.3	1.6	10.2	13.5	11.1	6.7	11.2
Subjects with 1 or more adverse events	16 (55.2%)	91 (45.0%)	111 (72.5%)	22 (55.0%)	60 (69.8%)	65 (81.3%)	299 (77.1%)	6 (66.7%)	531 (76.2%)
Extensive									
n	20	155	132	37	71	74	272	5	535
Avg duration of follow-up (weeks)	13.7	15.9	38.9	11.6	37.4	48.2	43.6	29.1	44.5
Avg exposure (number of administrations)	1.7	4.1	9.1	1.6	9.8	12.2	10.3	7.4	10.7
Subjects with 1 or more adverse events	14 (70.0%)	73 (47.1%)	100 (75.8%)	28 (75.7%)	55 (77.5%)	55 (74.3%)	220 (80.9%)	3 (60.0%)	432 (80.7%)

[a] Includes data up to the time of the first golimumab dose in the maintenance study.
[b] Includes data from the time of dose adjustment onward for those who increased to the indicated dose during the maintenance study.
[c] Includes data up to the time of dose adjustment for those who increased dose from the indicated dose during the maintenance study.
[d] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[e] Includes data from the time of the first golimumab dose onward.

表 2.7.4.7-付録-91 ベースライン時の疾患特性別の重篤な有害事象の発現割合（T16，T17 及び T18 試験 54 週まで；全投与被験者）

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
Treated subjects in C0524T16 and C0524T17	49	358	286	77	157	154	660	14	1233
Severity of disease									
Moderate (Mayo score ≥ 6 to ≤ 10)									
n	39	332	266	62	146	145	587	14	1114
Avg duration of follow-up (weeks)	12.5	18.8	39.5	11.8	38.9	50.6	45.5	27.5	46.1
Avg exposure (number of administrations)	1.6	4.9	9.3	1.6	10.0	12.9	10.8	6.9	11.1
Subjects with 1 or more serious adverse events	11 (28.2%)	14 (4.2%)	39 (14.7%)	21 (33.9%)	13 (8.9%)	13 (9.0%)	86 (14.7%)	1 (7.1%)	170 (15.3%)
Severe (Mayo score > 10)									
n	10	25	19	12	11	9	73	0	115
Avg duration of follow-up (weeks)	11.6	23.8	33.7	11.0	39.2	48.4	42.2	NA	41.0
Avg exposure (number of administrations)	1.6	6.2	7.7	1.6	10.1	12.2	10.0	NA	9.7
Subjects with 1 or more serious adverse events	5 (50.0%)	0 (0.0%)	2 (10.5%)	7 (58.3%)	0 (0.0%)	0 (0.0%)	17 (23.3%)	0 (NA)	26 (22.6%)
Duration of disease (years)									
≤ 5									
n	32	202	159	42	84	82	359	9	672
Avg duration of follow-up (weeks)	12.2	19.4	36.5	11.4	38.2	48.8	45.3	27.1	44.6
Avg exposure (number of administrations)	1.6	5.1	8.6	1.7	9.8	12.4	10.7	6.7	10.7
Subjects with 1 or more serious adverse events	10 (31.3%)	7 (3.5%)	27 (17.0%)	17 (40.5%)	5 (6.0%)	7 (8.5%)	59 (16.4%)	0 (0.0%)	115 (17.1%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
> 5									
n	17	156	127	35	73	72	301	5	561
Avg duration of follow-up (weeks)	12.6	18.7	42.5	12.5	39.8	52.3	44.9	28.2	46.7
Avg exposure (number of administrations)	1.6	4.9	10.1	1.5	10.2	13.4	10.8	7.4	11.3
Subjects with 1 or more serious adverse events	6 (35.3%)	7 (4.5%)	14 (11.0%)	11 (31.4%)	8 (11.0%)	6 (8.3%)	44 (14.6%)	1 (20.0%)	81 (14.4%)
Extent of disease									
Limited to left side of colon									
n	29	202	153	40	86	80	388	9	697
Avg duration of follow-up (weeks)	11.4	21.6	39.4	12.2	40.2	52.5	46.2	26.7	46.4
Avg exposure (number of administrations)	1.6	5.7	9.3	1.6	10.2	13.5	11.1	6.7	11.2
Subjects with 1 or more serious adverse events	11 (37.9%)	8 (4.0%)	18 (11.8%)	11 (27.5%)	6 (7.0%)	6 (7.5%)	53 (13.7%)	1 (11.1%)	94 (13.5%)
Extensive									
n	20	155	132	37	71	74	272	5	535
Avg duration of follow-up (weeks)	13.7	15.9	38.9	11.6	37.4	48.2	43.6	29.1	44.5
Avg exposure (number of administrations)	1.7	4.1	9.1	1.6	9.8	12.2	10.3	7.4	10.7
Subjects with 1 or more serious adverse events	5 (25.0%)	6 (3.9%)	22 (16.7%)	17 (45.9%)	7 (9.9%)	7 (9.5%)	50 (18.4%)	0 (0.0%)	101 (18.9%)

[a] Includes data up to the time of the first golimumab dose in the maintenance study.
[b] Includes data from the time of dose adjustment onward for those who increased to the indicated dose during the maintenance study.
[c] Includes data up to the time of dose adjustment for those who increased dose from the indicated dose during the maintenance study.
[d] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[e] Includes data from the time of the first golimumab dose onward.

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表 2.7.4.7-付録-92 ベースライン時の疾患特性別の治験薬投与中止に至った有害事象の発現割合（T16，T17 及び T18 試験 54 週まで；全投与被験者）

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
Treated subjects in C0524T16 and C0524T17	49	358	286	77	157	154	660	14	1233
Severity of disease									
Moderate (Mayo score ≥ 6 to ≤ 10)									
n	39	332	266	62	146	145	587	14	1114
Avg duration of follow-up (weeks)	12.5	18.8	39.5	11.8	38.9	50.6	45.5	27.5	46.1
Avg exposure (number of administrations)	1.6	4.9	9.3	1.6	10.0	12.9	10.8	6.9	11.1
Subjects who discontinued study agent because of 1 or more treatment-emergent adverse events	2 (5.1%)	7 (2.1%)	41 (15.4%)	3 (4.8%)	9 (6.2%)	8 (5.5%)	71 (12.1%)	0 (0.0%)	132 (11.8%)
Severe (Mayo score > 10)									
n	10	25	19	12	11	9	73	0	115
Avg duration of follow-up (weeks)	11.6	23.8	33.7	11.0	39.2	48.4	42.2	NA	41.0
Avg exposure (number of administrations)	1.6	6.2	7.7	1.6	10.1	12.2	10.0	NA	9.7
Subjects who discontinued study agent because of 1 or more treatment-emergent adverse events	1 (10.0%)	0 (0.0%)	1 (5.3%)	1 (8.3%)	1 (9.1%)	0 (0.0%)	10 (13.7%)	0 (NA)	13 (11.3%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
Duration of disease (years)									
≤ 5									
n	32	202	159	42	84	82	359	9	672
Avg duration of follow-up (weeks)	12.2	19.4	36.5	11.4	38.2	48.8	45.3	27.1	44.6
Avg exposure (number of administrations)	1.6	5.1	8.6	1.7	9.8	12.4	10.7	6.7	10.7
Subjects who discontinued study agent because of 1 or more treatment-emergent adverse events	3 (9.4%)	5 (2.5%)	26 (16.4%)	3 (7.1%)	5 (6.0%)	6 (7.3%)	42 (11.7%)	0 (0.0%)	82 (12.2%)
> 5									
n	17	156	127	35	73	72	301	5	561
Avg duration of follow-up (weeks)	12.6	18.7	42.5	12.5	39.8	52.3	44.9	28.2	46.7
Avg exposure (number of administrations)	1.6	4.9	10.1	1.5	10.2	13.4	10.8	7.4	11.3
Subjects who discontinued study agent because of 1 or more treatment-emergent adverse events	0 (0.0%)	2 (1.3%)	16 (12.6%)	1 (2.9%)	5 (6.8%)	2 (2.8%)	39 (13.0%)	0 (0.0%)	63 (11.2%)
Extent of disease									
Limited to left side of colon									
n	29	202	153	40	86	80	388	9	697
Avg duration of follow-up (weeks)	11.4	21.6	39.4	12.2	40.2	52.5	46.2	26.7	46.4
Avg exposure (number of administrations)	1.6	5.7	9.3	1.6	10.2	13.5	11.1	6.7	11.2
Subjects who discontinued study agent because of 1 or more treatment-emergent adverse events	0 (0.0%)	2 (1.0%)	19 (12.4%)	1 (2.5%)	5 (5.8%)	5 (6.3%)	41 (10.6%)	0 (0.0%)	71 (10.2%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
Extensive									
n	20	155	132	37	71	74	272	5	535
Avg duration of follow-up (weeks)	13.7	15.9	38.9	11.6	37.4	48.2	43.6	29.1	44.5
Avg exposure (number of administrations)	1.7	4.1	9.1	1.6	9.8	12.2	10.3	7.4	10.7
Subjects who discontinued study agent because of 1 or more treatment-emergent adverse events	3 (15.0%)	5 (3.2%)	22 (16.7%)	3 (8.1%)	5 (7.0%)	3 (4.1%)	40 (14.7%)	0 (0.0%)	73 (13.6%)

[a] Includes data up to the time of the first golimumab dose in the maintenance study.
[b] Includes data from the time of dose adjustment onward for those who increased to the indicated dose during the maintenance study.
[c] Includes data up to the time of dose adjustment for those who increased dose from the indicated dose during the maintenance study
[d] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[e] Includes data from the time of the first golimumab dose onward.

RE599:[S DCAE 24 A], 31JAN2012 16:08

表 2.7.4.7-付録-93 ベースライン時の疾患特性別の感染症の発現割合（T16，T17 及び T18 試験 54 週まで；全投与被験者）

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
Treated subjects in C0524T16 and C0524T17	49	358	286	77	157	154	660	14	1233
Severity of disease									
Moderate (Mayo score ≥ 6 to ≤ 10)									
n	39	332	266	62	146	145	587	14	1114
Avg duration of follow-up (weeks)	12.5	18.8	39.5	11.8	38.9	50.6	45.5	27.5	46.1
Avg exposure (number of administrations)	1.6	4.9	9.3	1.6	10.0	12.9	10.8	6.9	11.1
Subjects with 1 or more infections	11 (28.2%)	60 (18.1%)	103 (38.7%)	20 (32.3%)	50 (34.2%)	62 (42.8%)	233 (39.7%)	4 (28.6%)	457 (41.0%)
Severe (Mayo score > 10)									
n	10	25	19	12	11	9	73	0	115
Avg duration of follow-up (weeks)	11.6	23.8	33.7	11.0	39.2	48.4	42.2	NA	41.0
Avg exposure (number of administrations)	1.6	6.2	7.7	1.6	10.1	12.2	10.0	NA	9.7
Subjects with 1 or more infections	4 (40.0%)	3 (12.0%)	4 (21.1%)	3 (25.0%)	5 (45.5%)	5 (55.6%)	24 (32.9%)	0 (NA)	40 (34.8%)
Duration of disease (years)									
≤ 5									
n	32	202	159	42	84	82	359	9	672
Avg duration of follow-up (weeks)	12.2	19.4	36.5	11.4	38.2	48.8	45.3	27.1	44.6
Avg exposure (number of administrations)	1.6	5.1	8.6	1.7	9.8	12.4	10.7	6.7	10.7
Subjects with 1 or more infections	8 (25.0%)	30 (14.9%)	53 (33.3%)	13 (31.0%)	23 (27.4%)	40 (48.8%)	140 (39.0%)	1 (11.1%)	264 (39.3%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
> 5									
n	17	156	127	35	73	72	301	5	561
Avg duration of follow-up (weeks)	12.6	18.7	42.5	12.5	39.8	52.3	44.9	28.2	46.7
Avg exposure (number of administrations)	1.6	4.9	10.1	1.5	10.2	13.4	10.8	7.4	11.3
Subjects with 1 or more infections	7 (41.2%)	33 (21.2%)	55 (43.3%)	12 (34.3%)	32 (43.8%)	27 (37.5%)	117 (38.9%)	3 (60.0%)	236 (42.1%)
Extent of disease									
Limited to left side of colon									
n	29	202	153	40	86	80	388	9	697
Avg duration of follow-up (weeks)	11.4	21.6	39.4	12.2	40.2	52.5	46.2	26.7	46.4
Avg exposure (number of administrations)	1.6	5.7	9.3	1.6	10.2	13.5	11.1	6.7	11.2
Subjects with 1 or more infections	10 (34.5%)	35 (17.3%)	50 (32.7%)	8 (20.0%)	30 (34.9%)	36 (45.0%)	149 (38.4%)	3 (33.3%)	265 (38.0%)
Extensive									
n	20	155	132	37	71	74	272	5	535
Avg duration of follow-up (weeks)	13.7	15.9	38.9	11.6	37.4	48.2	43.6	29.1	44.5
Avg exposure (number of administrations)	1.7	4.1	9.1	1.6	9.8	12.2	10.3	7.4	10.7
Subjects with 1 or more infections	5 (25.0%)	28 (18.1%)	57 (43.2%)	17 (45.9%)	25 (35.2%)	31 (41.9%)	108 (39.7%)	1 (20.0%)	234 (43.7%)

[a] Includes data up to the time of the first golimumab dose in the maintenance study.
[b] Includes data from the time of dose adjustment onward for those who increased to the indicated dose during the maintenance study.
[c] Includes data up to the time of dose adjustment for those who increased dose from the indicated dose during the maintenance study.
[d] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[e] Includes data from the time of the first golimumab dose onward.

表 2.7.4.7-付録-94 ベースライン時の免疫調節薬併用の有無別の安全性の概要（T16，T17 及び T18 試験 54 週まで；ランダム化された被験者）

	Golimumab Induction				
	Placebo Maintenance[a]	50 mg Maintenance[a]	100 mg Maintenance[a]	Combined 50 mg and 100 mg Maintenance[a]	Total Golimumab[a,b]
Treated subjects in C0524T16 and C0524T17 who were randomized in C0524T18	156	154	154	308	464
Subjects not on immunomodulators	104	107	106	213	317
Avg duration of follow-up (weeks)	39.6	51.4	52.2	51.8	47.8
Avg exposure (number of administrations)	10.2	13.1	13.1	13.1	12.2
Subjects who died	0 (0.0%)	0 (0.0%)	1 (0.9%)	1 (0.5%)	1 (0.3%)
Subjects who discontinued study agent because of 1 or more adverse events	2 (1.9%)	7 (6.5%)	9 (8.5%)	16 (7.5%)	18 (5.7%)
Subjects with 1 or more:					
Adverse events	75 (72.1%)	83 (77.6%)	85 (80.2%)	168 (78.9%)	243 (76.7%)
Serious adverse events	6 (5.8%)	10 (9.3%)	16 (15.1%)	26 (12.2%)	32 (10.1%)
Infections[c]	38 (36.5%)	49 (45.8%)	46 (43.4%)	95 (44.6%)	133 (42.0%)
Serious infections[c]	1 (1.0%)	5 (4.7%)	3 (2.8%)	8 (3.8%)	9 (2.8%)
Neoplasms (malignant)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Injection-site reactions	7 (6.7%)	4 (3.7%)	12 (11.3%)	16 (7.5%)	23 (7.3%)
Subjects on immunomodulators	52	47	48	95	147
Avg duration of follow-up (weeks)	37.2	48.2	52.8	50.5	45.8
Avg exposure (number of administrations)	9.5	12.3	13.1	12.7	11.6
Subjects who died	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Subjects who discontinued study agent because of 1 or more adverse events	8 (15.4%)	1 (2.1%)	5 (10.4%)	6 (6.3%)	14 (9.5%)
Subjects with 1 or more:					
Adverse events	40 (76.9%)	37 (78.7%)	37 (77.1%)	74 (77.9%)	114 (77.6%)
Serious adverse events	7 (13.5%)	3 (6.4%)	7 (14.6%)	10 (10.5%)	17 (11.6%)
Infections[c]	17 (32.7%)	18 (38.3%)	20 (41.7%)	38 (40.0%)	55 (37.4%)
Serious infections[c]	3 (5.8%)	0 (0.0%)	2 (4.2%)	2 (2.1%)	5 (3.4%)
Neoplasms (malignant)	0 (0.0%)	0 (0.0%)	1 (2.1%)	1 (1.1%)	1 (0.7%)
Injection-site reactions	1 (1.9%)	1 (2.1%)	3 (6.3%)	4 (4.2%)	5 (3.4%)

	Golimumab Induction				
	Placebo Maintenance[a]	50 mg Maintenance[a]	100 mg Maintenance[a]	Combined 50 mg and 100 mg Maintenance[a]	Total Golimumab[a,b]

[a] Includes data up to the time of dose adjustment for those who increased dose from the indicated dose during the maintenance study.
[b] Includes data from the time of the first golimumab dose onward.
[c] Infection as assessed by the investigator.

RE599:[S AE 256 B], 23FEB2012 10:43

表 2.7.4.7-付録-95 ベースライン時の免疫調節薬併用の有無別の安全性の概要（T16，T17 及び T18 試験 54 週まで；全投与被験者）

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
Treated subjects in C0524T16 and C0524T17	49	358	286	77	157	154	660	14	1233
Subjects not on immunomodulators	33	243	192	52	104	107	443	8	835
Avg duration of follow-up (weeks)	11.8	19.8	38.0	11.0	39.6	51.4	45.3	29.8	45.3
Avg exposure (number of administrations)	1.6	5.1	9.0	1.6	10.2	13.1	10.8	7.5	10.9
Subjects who died	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.9%)	0 (0.0%)	0 (0.0%)	2 (0.5%)	0 (0.0%)	3 (0.4%)
Subjects who discontinued study agent because of 1 or more adverse events	2 (6.1%)	5 (2.1%)	32 (16.7%)	3 (5.8%)	2 (1.9%)	7 (6.5%)	60 (13.5%)	0 (0.0%)	104 (12.5%)
Subjects with 1 or more:									
Adverse events	19 (57.6%)	112 (46.1%)	141 (73.4%)	33 (63.5%)	75 (72.1%)	83 (77.6%)	354 (79.9%)	6 (75.0%)	650 (77.8%)
Serious adverse events	10 (30.3%)	10 (4.1%)	29 (15.1%)	17 (32.7%)	6 (5.8%)	10 (9.3%)	68 (15.3%)	1 (12.5%)	129 (15.4%)
Infections[f]	10 (30.3%)	40 (16.5%)	64 (33.3%)	14 (26.9%)	38 (36.5%)	49 (45.8%)	171 (38.6%)	2 (25.0%)	325 (38.9%)
Serious infections[f]	5 (15.2%)	1 (0.4%)	4 (2.1%)	5 (9.6%)	1 (1.0%)	5 (4.7%)	14 (3.2%)	0 (0.0%)	29 (3.5%)
Neoplasms (malignant)	0 (0.0%)	0 (0.0%)	1 (0.5%)	1 (1.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.2%)
Injection-site reactions	0 (0.0%)	5 (2.1%)	1 (0.5%)	0 (0.0%)	7 (6.7%)	4 (3.7%)	24 (5.4%)	1 (12.5%)	37 (4.5%)
Subjects on immunomodulators	16	115	94	25	53	47	217	6	398
Avg duration of follow-up (weeks)	13.4	17.5	41.6	13.7	37.7	48.2	44.7	24.5	46.1
Avg exposure (number of administrations)	1.8	4.7	9.7	1.8	9.7	12.3	10.7	6.2	11.1
Subjects who died	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	0 (0.0%)	1 (0.3%)
Subjects who discontinued study agent because of 1 or more adverse events	1 (6.3%)	2 (1.7%)	10 (10.6%)	1 (4.0%)	8 (15.1%)	1 (2.1%)	21 (9.7%)	0 (0.0%)	41 (10.3%)

	Placebo Induction			Golimumab Induction					
					Maintenance				
	No Maintenance	Placebo[a]	100 mg Maintenance[b]	No Maintenance	Placebo[c]	50 mg[c]	100 mg[b,c]	200 mg[b,d]	Any Golimumab[e]
Subjects with 1 or more:									
Adverse events	11 (68.8%)	52 (45.2%)	71 (75.5%)	17 (68.0%)	40 (75.5%)	37 (78.7%)	165 (76.0%)	3 (50.0%)	314 (78.9%)
Serious adverse events	6 (37.5%)	4 (3.5%)	12 (12.8%)	11 (44.0%)	7 (13.2%)	3 (6.4%)	35 (16.1%)	0 (0.0%)	67 (16.8%)
Infections[f]	5 (31.3%)	23 (20.0%)	44 (46.8%)	11 (44.0%)	17 (32.1%)	18 (38.3%)	86 (39.6%)	2 (33.3%)	175 (44.0%)
Serious infections[f]	2 (12.5%)	1 (0.9%)	2 (2.1%)	7 (28.0%)	3 (5.7%)	0 (0.0%)	8 (3.7%)	0 (0.0%)	20 (5.0%)
Neoplasms (malignant)	0 (0.0%)	1 (0.9%)	1 (1.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.9%)	0 (0.0%)	3 (0.8%)
Injection-site reactions	0 (0.0%)	1 (0.9%)	3 (3.2%)	0 (0.0%)	1 (1.9%)	1 (2.1%)	11 (5.1%)	2 (33.3%)	15 (3.8%)

[a] Includes data up to the time of the first golimumab dose in the maintenance study.
[b] Includes data from the time of dose adjustment onward for those who increased to the indicated dose during the maintenance study.
[c] Includes data up to the time of dose adjustment for those who increased dose from the indicated dose during the maintenance study.
[d] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[e] Includes data from the time of the first golimumab dose onward.
[f] Infection as assessed by the investigator.

RE599:[S AE 256 A], 27JAN2012 17:58

表 2.7.4.7-付録-96 治験薬の使用と関連性のある有害事象（T17 試験 6 週まで，日本人）

		Golimumab				
	Placebo	100 mg to 50 mg	200 mg to 100 mg	400 mg to 200 mg	Combined	All Golimumab
Subjects treated in Japan subgroup	30	0	23	19	42	42
Avg duration of follow-up (weeks)	6.07	-	6.08	5.93	6.01	6.01
Avg exposure (number of administrations)	1.97	-	1.96	2.00	1.98	1.98
Subjects with 1 or more reasonably related adverse events	7 (23.3%)	0	7 (30.4%)	5 (26.3%)	12 (28.6%)	12 (28.6%)
System-organ class/preferred term						
Infections and infestations	2 (6.7%)	0	4 (17.4%)	4 (21.1%)	8 (19.0%)	8 (19.0%)
Cystitis	0	0	0	1 (5.3%)	1 (2.4%)	1 (2.4%)
Folliculitis	0	0	1 (4.3%)	0	1 (2.4%)	1 (2.4%)
Herpes zoster	0	0	0	1 (5.3%)	1 (2.4%)	1 (2.4%)
Nasopharyngitis	1 (3.3%)	0	1 (4.3%)	0	1 (2.4%)	1 (2.4%)
Pertussis	0	0	0	1 (5.3%)	1 (2.4%)	1 (2.4%)
Pneumonia	0	0	1 (4.3%)	0	1 (2.4%)	1 (2.4%)
Respiratory tract infection	0	0	0	1 (5.3%)	1 (2.4%)	1 (2.4%)
Urinary tract infection	0	0	1 (4.3%)	0	1 (2.4%)	1 (2.4%)
Anal abscess	1 (3.3%)	0	0	0	0	0
Blood and lymphatic system disorders	0	0	1 (4.3%)	0	1 (2.4%)	1 (2.4%)
Leukopenia	0	0	1 (4.3%)	0	1 (2.4%)	1 (2.4%)
Neutropenia	0	0	1 (4.3%)	0	1 (2.4%)	1 (2.4%)
Gastrointestinal disorders	1 (3.3%)	0	0	1 (5.3%)	1 (2.4%)	1 (2.4%)
Nausea	0	0	0	1 (5.3%)	1 (2.4%)	1 (2.4%)
Enterocolitis	1 (3.3%)	0	0	0	0	0
Injury, poisoning and procedural complications	0	0	0	1 (5.3%)	1 (2.4%)	1 (2.4%)
Contusion	0	0	0	1 (5.3%)	1 (2.4%)	1 (2.4%)
Investigations	0	0	1 (4.3%)	0	1 (2.4%)	1 (2.4%)
White blood cell count decreased	0	0	1 (4.3%)	0	1 (2.4%)	1 (2.4%)
Nervous system disorders	1 (3.3%)	0	0	1 (5.3%)	1 (2.4%)	1 (2.4%)
Dizziness	0	0	0	1 (5.3%)	1 (2.4%)	1 (2.4%)
Dysaesthesia	0	0	0	1 (5.3%)	1 (2.4%)	1 (2.4%)
Headache	1 (3.3%)	0	0	0	0	0
Reproductive system and breast disorders	0	0	1 (4.3%)	0	1 (2.4%)	1 (2.4%)

	Placebo	Golimumab				
		100 mg to 50 mg	200 mg to 100 mg	400 mg to 200 mg	Combined	All Golimumab
Pruritus genital	0	0	1 (4.3%)	0	1 (2.4%)	1 (2.4%)
General disorders and administration site conditions	3 (10.0%)	0	0	0	0	0
Feeling hot	1 (3.3%)	0	0	0	0	0
Pyrexia	2 (6.7%)	0	0	0	0	0
Psychiatric disorders	1 (3.3%)	0	0	0	0	0
Insomnia	1 (3.3%)	0	0	0	0	0
Respiratory, thoracic and mediastinal disorders	1 (3.3%)	0	0	0	0	0
Cough	1 (3.3%)	0	0	0	0	0
Skin and subcutaneous tissue disorders	2 (6.7%)	0	0	0	0	0
Erythema nodosum	1 (3.3%)	0	0	0	0	0
Rash	1 (3.3%)	0	0	0	0	0

表 2.7.4.7-付録-97 治験薬の使用と関連性のある重篤な有害事象（T17 試験 6 週まで，日本人）

		Golimumab				
	Placebo	100 mg to 50 mg	200 mg to 100 mg	400 mg to 200 mg	Combined	All Golimumab
Subjects treated in Japan subgroup	30	0	23	19	42	42
Avg duration of follow-up (weeks)	6.07	-	6.08	5.93	6.01	6.01
Avg exposure (number of administrations)	1.97	-	1.96	2.00	1.98	1.98
Subjects with 1 or more reasonably related serious adverse events	1 (3.3%)	0	1 (4.3%)	0	1 (2.4%)	1 (2.4%)
System-organ class/preferred term						
Infections and infestations	1 (3.3%)	0	1 (4.3%)	0	1 (2.4%)	1 (2.4%)
Pneumonia	0	0	1 (4.3%)	0	1 (2.4%)	1 (2.4%)
Anal abscess	1 (3.3%)	0	0	0	0	0

[HA03_C001_02.rtf] [JNJ-268229-AAC\ANS3001\DBR_HA\RE_HA\HA03_C001_02.sas] 26DEC2016, 10:35

表 2.7.4.7-付録-98 治験薬の使用と関連性のある重篤な有害事象一覧（T17 試験 6 週まで，日本人）

Treatment Group	Study Part [a]	Subject ID	Age/ Sex	Country/ Race	Study Agent Dose Prior to AE	Study Day of Study Agent Admini-stration Prior to AE	MedDRA Preferred Term [b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relations hip to Study Agent	Action Taken with Study Agent	Infection/ Injection-site Reaction [c, d]
Placebo	Part 2b	7807-00004	2[redacted]/F	JAPAN/Asian	0 mg	12	Anal abscess	PERIPROCTAL ABSCESS	42	100	Resolved	Yes	Moderate	Possible	None/not applicable	Yes/No
200 mg -> 100 mg	Part 2b	7815-00001	5[redacted]/M	JAPAN/Asian	100 mg	15	Pneumonia	PNEUMONIA	20	11	Resolved	Yes	Moderate	Probable	None/not applicable	Yes/No

[a] Part 2a: Part 2 before the dose selection; Part 2b; Part 2 after the dose selection.
[b] Based on MedDRA version 13.0.
[c] Infection as assessed by the investigator.
[d] Injection-site reaction as assessed by the investigator.

[HA03_C002_01.rtf] [JNJ-268229-AAC\ANS3001\DBR_HA\RE_HA\HA03_C002_01.sas] 26DEC2016, 10:36

表 2.7.4.7-付録-99 すべての有害事象（T18 試験 54 週まで，日本人，ランダム化された被験者）

		Golimumab[a]			Dose Adjustment[b]			
	Placebo[a,c]	50 mg	100 mg	Combined	Placebo -> 100 mg	50 mg ->100 mg	100 mg ->200 mg[d]	All Golimumab[e]
Treated subjects in Japan subgroup who were randomized	4	3	5	8	2	2	0	10
Avg duration of follow-up (weeks)	23.6	18.5	47.2	36.4	23.4	36.9	-	41.2
Avg exposure (number of administrations)	5.3	3.7	11.6	8.6	3.0	6.5	-	8.8
Subjects with 1 or more adverse events	2 (50.0%)	3 (100.0%)	5 (100.0%)	8 (100.0%)	2 (100.0%)	2 (100.0%)	0	10 (100.0%)
System-organ class/preferred term								
Infections and infestations	2 (50.0%)	1 (33.3%)	4 (80.0%)	5 (62.5%)	1 (50.0%)	2 (100.0%)	0	7 (70.0%)
Nasopharyngitis	1 (25.0%)	0	3 (60.0%)	3 (37.5%)	1 (50.0%)	2 (100.0%)	0	6 (60.0%)
Enterocolitis infectious	0	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
Oral herpes	0	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
Pharyngitis	0	1 (33.3%)	0	1 (12.5%)	0	0	0	1 (10.0%)
Urinary tract infection	0	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
Cytomegalovirus infection	1 (25.0%)	0	0	0	0	0	0	0
Folliculitis	1 (25.0%)	0	0	0	0	0	0	0
Influenza	1 (25.0%)	0	0	0	0	0	0	0
Subcutaneous abscess	1 (25.0%)	0	0	0	0	0	0	0
Gastrointestinal disorders	0	2 (66.7%)	2 (40.0%)	4 (50.0%)	2 (100.0%)	1 (50.0%)	0	6 (60.0%)
Colitis ulcerative	0	1 (33.3%)	0	1 (12.5%)	1 (50.0%)	0	0	2 (20.0%)
Abdominal discomfort	0	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
Constipation	0	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
Diarrhoea	0	0	0	0	1 (50.0%)	0	0	1 (10.0%)
Gastrooesophageal reflux disease	0	1 (33.3%)	0	1 (12.5%)	0	0	0	1 (10.0%)
Nausea	0	0	0	0	0	1 (50.0%)	0	1 (10.0%)
Sensitivity of teeth	0	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
Nervous system disorders	1 (25.0%)	0	2 (40.0%)	2 (25.0%)	1 (50.0%)	1 (50.0%)	0	4 (40.0%)
Headache	0	0	2 (40.0%)	2 (25.0%)	0	1 (50.0%)	0	3 (30.0%)
Tremor	0	0	0	0	1 (50.0%)	0	0	1 (10.0%)
Hypoaesthesia	1 (25.0%)	0	0	0	0	0	0	0
Skin and subcutaneous tissue disorders	2 (50.0%)	0	3 (60.0%)	3 (37.5%)	0	1 (50.0%)	0	4 (40.0%)
Alopecia	0	0	2 (40.0%)	2 (25.0%)	0	0	0	2 (20.0%)
Eczema	1 (25.0%)	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)

		Golimumab[a]			Dose Adjustment[b]			
	Placebo[a,c]	50 mg	100 mg	Combined	Placebo -> 100 mg	50 mg ->100 mg	100 mg ->200 mg[d]	All Golimumab[e]
Pruritus	0	0	0	0	0	1 (50.0%)	0	1 (10.0%)
Rash	0	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
Dermatitis contact	1 (25.0%)	0	0	0	0	0	0	0
Eczema asteatotic	1 (25.0%)	0	0	0	0	0	0	0
Respiratory, thoracic and mediastinal disorders	1 (25.0%)	0	3 (60.0%)	3 (37.5%)	0	0	0	3 (30.0%)
Choking sensation	0	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
Cough	0	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
Upper respiratory tract inflammation	1 (25.0%)	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
General disorders and administration site conditions	0	0	1 (20.0%)	1 (12.5%)	1 (50.0%)	0	0	2 (20.0%)
Administration site rash	0	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
Administration site reaction	0	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
Infusion site reaction	0	0	0	0	1 (50.0%)	0	0	1 (10.0%)
Oedema	0	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
Injury, poisoning and procedural complications	0	0	1 (20.0%)	1 (12.5%)	1 (50.0%)	0	0	2 (20.0%)
Contusion	0	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
Spinal compression fracture	0	0	0	0	1 (50.0%)	0	0	1 (10.0%)
Investigations	1 (25.0%)	0	2 (40.0%)	2 (25.0%)	0	0	0	2 (20.0%)
Blood pressure systolic increased	0	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
White blood cell count decreased	0	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
Alanine aminotransferase increased	1 (25.0%)	0	0	0	0	0	0	0
Aspartate aminotransferase increased	1 (25.0%)	0	0	0	0	0	0	0
Platelet count decreased	1 (25.0%)	0	0	0	0	0	0	0
Eye disorders	0	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
Cataract	0	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
Metabolism and nutrition disorders	0	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
Decreased appetite	0	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
Musculoskeletal and connective tissue disorders	1 (25.0%)	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
Arthralgia	1 (25.0%)	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
Back pain	0	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)

	Placebo[a,c]	Golimumab[a] 50 mg	Golimumab[a] 100 mg	Golimumab[a] Combined	Dose Adjustment[b] Placebo -> 100 mg	Dose Adjustment[b] 50 mg ->100 mg	Dose Adjustment[b] 100 mg ->200 mg[d]	All Golimumab[e]
Musculoskeletal chest pain	0	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
Myalgia	0	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
Vascular disorders	1 (25.0%)	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
Flushing	0	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
Vasculitis	1 (25.0%)	0	0	0	0	0	0	0
Blood and lymphatic system disorders	1 (25.0%)	0	0	0	0	0	0	0
Leukopenia	1 (25.0%)	0	0	0	0	0	0	0
Renal and urinary disorders	1 (25.0%)	0	0	0	0	0	0	0
Urethral pain	1 (25.0%)	0	0	0	0	0	0	0

[a] Includes data up to the time of dose adjustment for those who increased dose.
[b] Includes data from the time of dose adjustment onward.
[c] Subjects who were in clinical response to golimumab induction dosing and were randomized to placebo on entry into this maintenance study.
[d] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[e] Includes data from the time of the first golimumab dose onward.

表 2.7.4.7-付録-100 治験薬の使用と関連性のある有害事象（T18 試験 54 週まで，日本人，ランダム化された被験者）

		Golimumab[a]			Dose Adjustment[b]			
	Placebo[a,c]	50 mg	100 mg	Combined	Placebo -> 100 mg	50 mg ->100 mg	100 mg ->200 mg[d]	All Golimumab[e]
Treated subjects in Japan subgroup who were randomized	4	3	5	8	2	2	0	10
Avg duration of follow-up (weeks)	23.6	18.5	47.2	36.4	23.4	36.9	-	41.2
Avg exposure (number of administrations)	5.3	3.7	11.6	8.6	3.0	6.5	-	8.8
Subjects with 1 or more reasonably related adverse events	2 (50.0%)	0	2 (40.0%)	2 (25.0%)	0	1 (50.0%)	0	3 (30.0%)
System-organ class/preferred term								
Skin and subcutaneous tissue disorders	1 (25.0%)	0	2 (40.0%)	2 (25.0%)	0	1 (50.0%)	0	3 (30.0%)
Alopecia	0	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
Pruritus	0	0	0	0	0	1 (50.0%)	0	1 (10.0%)
Rash	0	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
Dermatitis contact	1 (25.0%)	0	0	0	0	0	0	0
Nervous system disorders	0	0	2 (40.0%)	2 (25.0%)	0	0	0	2 (20.0%)
Headache	0	0	2 (40.0%)	2 (25.0%)	0	0	0	2 (20.0%)
Gastrointestinal disorders	0	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
Constipation	0	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
General disorders and administration site conditions	0	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
Administration site rash	0	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
Administration site reaction	0	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
Oedema	0	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
Infections and infestations	2 (50.0%)	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
Nasopharyngitis	0	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
Oral herpes	0	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
Urinary tract infection	0	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
Folliculitis	1 (25.0%)	0	0	0	0	0	0	0
Influenza	1 (25.0%)	0	0	0	0	0	0	0
Subcutaneous abscess	1 (25.0%)	0	0	0	0	0	0	0
Injury, poisoning and procedural complications	0	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
Contusion	0	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
Investigations	0	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)

		Golimumab[a]			Dose Adjustment[b]			
	Placebo[a,c]	50 mg	100 mg	Combined	Placebo -> 100 mg	50 mg ->100 mg	100 mg ->200 mg[d]	All Golimumab[e]
Blood pressure systolic increased	0	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
Musculoskeletal and connective tissue disorders	0	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
Myalgia	0	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)

[a] Includes data up to the time of dose adjustment for those who increased dose.
[b] Includes data from the time of dose adjustment onward.
[c] Subjects who were in clinical response to golimumab induction dosing and were randomized to placebo on entry into this maintenance study.
[d] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[e] Includes data from the time of the first golimumab dose onward.

[HA03_C003_02.rtf] [JNJ-268229-AAC\ANS3001\DBR_HA\RE_HA\HA03_C003_02.sas] 26DEC2016, 12:37

表 2.7.4.7-付録-101 重篤な有害事象（T18 試験 54 週まで，日本人，ランダム化された被験者）

		Golimumab[a]			Dose Adjustment[b]			
	Placebo[a,c]	50 mg	100 mg	Combined	Placebo -> 100 mg	50 mg ->100 mg	100 mg ->200 mg[d]	All Golimumab[e]
Treated subjects in Japan subgroup who were randomized	4	3	5	8	2	2	0	10
Avg duration of follow-up (weeks)	23.6	18.5	47.2	36.4	23.4	36.9	-	41.2
Avg exposure (number of administrations)	5.3	3.7	11.6	8.6	3.0	6.5	-	8.8
Subjects with 1 or more serious adverse events	1 (25.0%)	1 (33.3%)	1 (20.0%)	2 (25.0%)	1 (50.0%)	0	0	3 (30.0%)
System-organ class/preferred term								
Gastrointestinal disorders	0	1 (33.3%)	0	1 (12.5%)	1 (50.0%)	0	0	2 (20.0%)
Colitis ulcerative	0	1 (33.3%)	0	1 (12.5%)	1 (50.0%)	0	0	2 (20.0%)
Infections and infestations	1 (25.0%)	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
Enterocolitis infectious	0	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
Cytomegalovirus infection	1 (25.0%)	0	0	0	0	0	0	0

[a] Includes data up to the time of dose adjustment for those who increased dose.
[b] Includes data from the time of dose adjustment onward.
[c] Subjects who were in clinical response to golimumab induction dosing and were randomized to placebo on entry into this maintenance study.
[d] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[e] Includes data from the time of the first golimumab dose onward.

[HA03_C003_03.rtf] [JNJ-268229-AAC\ANS3001\DBR_HA\RE_HA\HA03_C003_03.sas] 26DEC2016, 12:37

表 2.7.4.7-付録-102 治験薬の使用と関連性のある重篤な有害事象（T18 試験 54 週まで，日本人，ランダム化された被験者）

		Golimumab[a]			Dose Adjustment[b]			
	Placebo[a,c]	50 mg	100 mg	Combined	Placebo -> 100 mg	50 mg ->100 mg	100 mg ->200 mg[d]	All Golimumab[e]
Treated subjects in Japan subgroup who were randomized	4	3	5	8	2	2	0	10
Avg duration of follow-up (weeks)	23.6	18.5	47.2	36.4	23.4	36.9	-	41.2
Avg exposure (number of administrations)	5.3	3.7	11.6	8.6	3.0	6.5	-	8.8
Subjects with 1 or more reasonably related serious adverse events	0	0	0	0	0	0	0	0
System-organ class/preferred term								
No data to report	0	0	0	0	0	0	0	0

[a] Includes data up to the time of dose adjustment for those who increased dose.
[b] Includes data from the time of dose adjustment onward.
[c] Subjects who were in clinical response to golimumab induction dosing and were randomized to placebo on entry into this maintenance study.
[d] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[e] Includes data from the time of the first golimumab dose onward.

[HA03_C003_04.rtf] [JNJ-268229-AAC\ANS3001\DBR_HA\RE_HA\HA03_C003_04.sas] 26DEC2016, 12:37

表 2.7.4.7-付録-103 すべての感染症（T18 試験 54 週まで，日本人，ランダム化された被験者）

		Golimumab[a]			Dose Adjustment[b]			
	Placebo[a,c]	50 mg	100 mg	Combined	Placebo -> 100 mg	50 mg ->100 mg	100 mg ->200 mg[d]	All Golimumab[e]
Treated subjects in Japan subgroup who were randomized	4	3	5	8	2	2	0	10
Avg duration of follow-up (weeks)	23.6	18.5	47.2	36.4	23.4	36.9	-	41.2
Avg exposure (number of administrations)	5.3	3.7	11.6	8.6	3.0	6.5	-	8.8
Subjects with 1 or more infections[f]	2 (50.0%)	1 (33.3%)	4 (80.0%)	5 (62.5%)	1 (50.0%)	1 (50.0%)	0	6 (60.0%)
System-organ class/preferred term								
Infections and infestations	2 (50.0%)	1 (33.3%)	4 (80.0%)	5 (62.5%)	1 (50.0%)	1 (50.0%)	0	6 (60.0%)
Nasopharyngitis	1 (25.0%)	0	3 (60.0%)	3 (37.5%)	1 (50.0%)	1 (50.0%)	0	5 (50.0%)
Enterocolitis infectious	0	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
Oral herpes	0	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
Pharyngitis	0	1 (33.3%)	0	1 (12.5%)	0	0	0	1 (10.0%)
Urinary tract infection	0	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
Cytomegalovirus infection	1 (25.0%)	0	0	0	0	0	0	0
Folliculitis	1 (25.0%)	0	0	0	0	0	0	0
Influenza	1 (25.0%)	0	0	0	0	0	0	0
Subcutaneous abscess	1 (25.0%)	0	0	0	0	0	0	0
Respiratory, thoracic and mediastinal disorders	0	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
Upper respiratory tract inflammation	0	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)

[a] Includes data up to the time of dose adjustment for those who increased dose.
[b] Includes data from the time of dose adjustment onward.
[c] Subjects who were in clinical response to golimumab induction dosing and were randomized to placebo on entry into this maintenance study.
[d] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[e] Includes data from the time of the first golimumab dose onward.
[f] Infection as assessed by the investigator.

[HA03_C003_05.rtf] [JNJ-268229-AAC\ANS3001\DBR_HA\RE_HA\HA03_C003_05.sas] 26DEC2016, 12:37

表 2.7.4.7-付録-104 重篤な感染症（T18 試験 54 週まで，日本人，ランダム化された被験者）

		Golimumab[a]			Dose Adjustment[b]			
	Placebo[a,c]	50 mg	100 mg	Combined	Placebo -> 100 mg	50 mg ->100 mg	100 mg ->200 mg[d]	All Golimumab[e]
Treated subjects in Japan subgroup who were randomized	4	3	5	8	2	2	0	10
Avg duration of follow-up (weeks)	23.6	18.5	47.2	36.4	23.4	36.9	-	41.2
Avg exposure (number of administrations)	5.3	3.7	11.6	8.6	3.0	6.5	-	8.8
Subjects with 1 or more serious infections[f]	1 (25.0%)	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
System-organ class/preferred term								
Infections and infestations	1 (25.0%)	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
Enterocolitis infectious	0	0	1 (20.0%)	1 (12.5%)	0	0	0	1 (10.0%)
Cytomegalovirus infection	1 (25.0%)	0	0	0	0	0	0	0

[a] Includes data up to the time of dose adjustment for those who increased dose.
[b] Includes data from the time of dose adjustment onward.
[c] Subjects who were in clinical response to golimumab induction dosing and were randomized to placebo on entry into this maintenance study.
[d] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[e] Includes data from the time of the first golimumab dose onward.
[f] Infection as assessed by the investigator.

[HA03_C003_06.rtf] [JNJ-268229-AAC\ANS3001\DBR_HA\RE_HA\HA03_C003_06.sas] 26DEC2016, 12:37

表 2.7.4.7-付録-105 治験薬の投与中止に至った有害事象（T18 試験 54 週まで，日本人，ランダム化された被験者）

		Golimumab[a]			Dose Adjustment[b]			
	Placebo[a,c]	50 mg	100 mg	Combined	Placebo -> 100 mg	50 mg ->100 mg	100 mg ->200 mg[d]	All Golimumab[e]
Treated subjects in Japan subgroup who were randomized	4	3	5	8	2	2	0	10
Avg duration of follow-up (weeks)	23.6	18.5	47.2	36.4	23.4	36.9	-	41.2
Avg exposure (number of administrations)	5.3	3.7	11.6	8.6	3.0	6.5	-	8.8
Subjects who discontinued study agent because of 1 or more adverse events	1 (25.0%)	0	0	0	1 (50.0%)	0	0	1 (10.0%)
System-organ class/preferred term								
Gastrointestinal disorders	0	0	0	0	1 (50.0%)	0	0	1 (10.0%)
Colitis ulcerative	0	0	0	0	1 (50.0%)	0	0	1 (10.0%)
Infections and infestations	1 (25.0%)	0	0	0	0	0	0	0
Cytomegalovirus infection	1 (25.0%)	0	0	0	0	0	0	0

[a] Includes data up to the time of dose adjustment for those who increased dose.
[b] Includes data from the time of dose adjustment onward.
[c] Subjects who were in clinical response to golimumab induction dosing and were randomized to placebo on entry into this maintenance study.
[d] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[e] Includes data from the time of the first golimumab dose onward.

[HA03_C003_07.rtf] [JNJ-268229-AAC\ANS3001\DBR_HA\RE_HA\HA03_C003_07.sas] 26DEC2016, 12:37

表 2.7.4.7-付録-106 治験薬の使用と関連性のある重篤な有害事象一覧（T18 試験 54 週まで，日本人，ランダム化された被験者）

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/Sex	Country/Race	Treatment Group at Dose Adjustment [a]	Study Day of Dose Adjustment	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection [c]/ Injection-site Reaction
Not applicable																			

[a] For subjects who were dose adjusted to golimumab 200 mg and later had their dose decreased to 100 mg following implementation of Protocol Amendment 3, "Treatment Group At Dose Adjustment" is presented as "200 mg (100 mg)", and "Study Day of Dose adjustment" is presented in the form of xxx (yyy), where xxx is the study day of dose adjustment and yyy is the study day of dose decrease.
[b] Based on MedDRA version 14.0
[c] Infection as assessed by the investigator.

[HA03_C004_01.rtf] [JNJ-268229-AAC\ANS3001\DBR_HA\RE_HA\HA03_C004_01.sas] 26DEC2016, 15:01

表 2.7.4.7-付録-107 重篤な感染症一覧（T18 試験 54 週まで，日本人，ランダム化された被験者）

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/Sex	Country/Race	Treatment Group at Dose Adjustment [a]	Study Day of Dose Adjustment	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection [c]/ Injection-site Reaction
Yes	Placebo	200 mg/100 mg SC	7821-00003	2[redacted]/M	JAPAN/Asian	-	-	0 mg	33	Cytomegalovirus infection	CYTOMEGALOVIRUS INFECTION	64	17	Resolved	Yes	Moderate	Unlikely	Permanent discontinuation of study agent	Yes/No
	Golimumab 100 mg	400 mg/200 mg SC	7806-00002	2[redacted]/F	JAPAN/Asian	-	-	100 mg	369	Enterocolitis infectious	ACUTE BACTERIAL COLITIS	373	8	Resolved	Yes	Moderate	Not related	None/not applicable	Yes/No

[a] For subjects who were dose adjusted to golimumab 200 mg and later had their dose decreased to 100 mg following implementation of Protocol Amendment 3, "Treatment Group At Dose Adjustment" is presented as "200 mg (100 mg)", and "Study Day of Dose adjustment" is presented in the form of xxx (yyy), where xxx is the study day of dose adjustment and yyy is the study day of dose decrease.
[b] Based on MedDRA version 14.0
[c] Infection as assessed by the investigator.

[HA03_C004_02.rtf] [JNJ-268229-AAC\ANS3001\DBR_HA\RE_HA\HA03_C004_02.sas] 26DEC2016, 15:01

表 2.7.4.7-付録-108 治験薬の投与中止に至った有害事象一覧（T18 試験 54 週まで，日本人，ランダム化された被験者）

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/Sex	Country/Race	Treatment Group at Dose Adjustment [a]	Study Day of Dose Adjustment	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection [c]/ Injection-site Reaction
Yes	Placebo	200 mg/100 mg SC	7801-00002	3[redacted]/M	JAPAN/Asian	100 mg	92	100 mg	92	Colitis ulcerative	WORSENING OF UC	101	15	Resolved	Yes	Severe	Unlikely	Permanent discontinuation of study agent	No/No
			7821-00003	2[redacted]/M	JAPAN/Asian	-	-	0 mg	33	Cytomegalovirus infection	CYTOMEGALOVIRUS INFEECTION	55	10	Resolved	No	Mild	Unlikely	Permanent discontinuation of study agent	Yes/No
								0 mg	33	Cytomegalovirus infection	CYTOMEGALOVIRUS INFECTION	64	17	Resolved	Yes	Moderate	Unlikely	Permanent discontinuation of study agent	Yes/No

[a] For subjects who were dose adjusted to golimumab 200 mg and later had their dose decreased to 100 mg following implementation of Protocol Amendment 3, "Treatment Group At Dose Adjustment" is presented as "200 mg (100 mg)", and "Study Day of Dose adjustment" is presented in the form of xxx (yyy), where xxx is the study day of dose adjustment and yyy is the study day of dose decrease.
[b] Based on MedDRA version 14.0
[c] Infection as assessed by the investigator.

[HA03_C004_03.rtf] [JNJ-268229-AAC\ANS3001\DBR_HA\RE_HA\HA03_C004_03.sas] 26DEC2016, 15:01

表 2.7.4.7-付録-109 治験薬の使用と関連性のある有害事象（T18 試験 54 週まで，日本人，全投与被験者）

		Golimumab				
	Placebo[a,b]	50 mg[a]	100 mg[a,c,d]	Combined 50 mg and 100 mg	200 mg[d,e]	All Golimumab[f]
Subjects treated in Japan subgroup	8	3	59	60	0	60
Avg duration of follow-up (weeks)	26.5	18.5	42.3	42.6	-	42.6
Avg exposure (number of administrations)	6.3	3.7	9.5	9.5	-	9.5
Subjects with 1 or more reasonably related adverse events	3 (37.5%)	0	17 (28.8%)	17 (28.3%)	0	17 (28.3%)
System-organ class/preferred term						
Infections and infestations	2 (25.0%)	0	8 (13.6%)	8 (13.3%)	0	8 (13.3%)
Enteritis infectious	0	0	2 (3.4%)	2 (3.3%)	0	2 (3.3%)
Nasopharyngitis	0	0	2 (3.4%)	2 (3.3%)	0	2 (3.3%)
Oral herpes	0	0	2 (3.4%)	2 (3.3%)	0	2 (3.3%)
Cystitis	0	0	1 (1.7%)	1 (1.7%)	0	1 (1.7%)
Cytomegalovirus infection	0	0	1 (1.7%)	1 (1.7%)	0	1 (1.7%)
Infected epidermal cyst	0	0	1 (1.7%)	1 (1.7%)	0	1 (1.7%)
Influenza	1 (12.5%)	0	1 (1.7%)	1 (1.7%)	0	1 (1.7%)
Sinusitis	0	0	1 (1.7%)	1 (1.7%)	0	1 (1.7%)
Urinary tract infection	0	0	1 (1.7%)	1 (1.7%)	0	1 (1.7%)
Folliculitis	1 (12.5%)	0	0	0	0	0
Subcutaneous abscess	1 (12.5%)	0	0	0	0	0
Skin and subcutaneous tissue disorders	2 (25.0%)	0	6 (10.2%)	6 (10.0%)	0	6 (10.0%)
Rash	0	0	2 (3.4%)	2 (3.3%)	0	2 (3.3%)
Alopecia	0	0	1 (1.7%)	1 (1.7%)	0	1 (1.7%)
Dermatitis contact	1 (12.5%)	0	1 (1.7%)	1 (1.7%)	0	1 (1.7%)
Pruritus	0	0	1 (1.7%)	1 (1.7%)	0	1 (1.7%)
Pustular psoriasis	0	0	1 (1.7%)	1 (1.7%)	0	1 (1.7%)
Eczema	1 (12.5%)	0	0	0	0	0
General disorders and administration site conditions	0	0	4 (6.8%)	4 (6.7%)	0	4 (6.7%)
Pyrexia	0	0	3 (5.1%)	3 (5.0%)	0	3 (5.0%)
Administration site rash	0	0	1 (1.7%)	1 (1.7%)	0	1 (1.7%)
Administration site reaction	0	0	1 (1.7%)	1 (1.7%)	0	1 (1.7%)
Oedema	0	0	1 (1.7%)	1 (1.7%)	0	1 (1.7%)
Eye disorders	0	0	2 (3.4%)	2 (3.3%)	0	2 (3.3%)

		Golimumab				
	Placebo[a,b]	50 mg[a]	100 mg[a,c,d]	Combined 50 mg and 100 mg	200 mg[d,e]	All Golimumab[f]
Asthenopia	0	0	1 (1.7%)	1 (1.7%)	0	1 (1.7%)
Conjunctivitis allergic	0	0	1 (1.7%)	1 (1.7%)	0	1 (1.7%)
Gastrointestinal disorders	0	0	2 (3.4%)	2 (3.3%)	0	2 (3.3%)
Constipation	0	0	1 (1.7%)	1 (1.7%)	0	1 (1.7%)
Nausea	0	0	1 (1.7%)	1 (1.7%)	0	1 (1.7%)
Musculoskeletal and connective tissue disorders	0	0	2 (3.4%)	2 (3.3%)	0	2 (3.3%)
Bursitis	0	0	1 (1.7%)	1 (1.7%)	0	1 (1.7%)
Myalgia	0	0	1 (1.7%)	1 (1.7%)	0	1 (1.7%)
Nervous system disorders	0	0	2 (3.4%)	2 (3.3%)	0	2 (3.3%)
Headache	0	0	2 (3.4%)	2 (3.3%)	0	2 (3.3%)
Respiratory, thoracic and mediastinal disorders	0	0	2 (3.4%)	2 (3.3%)	0	2 (3.3%)
Cough	0	0	1 (1.7%)	1 (1.7%)	0	1 (1.7%)
Nasal obstruction	0	0	1 (1.7%)	1 (1.7%)	0	1 (1.7%)
Oropharyngeal pain	0	0	1 (1.7%)	1 (1.7%)	0	1 (1.7%)
Injury, poisoning and procedural complications	0	0	1 (1.7%)	1 (1.7%)	0	1 (1.7%)
Contusion	0	0	1 (1.7%)	1 (1.7%)	0	1 (1.7%)
Investigations	0	0	1 (1.7%)	1 (1.7%)	0	1 (1.7%)
Blood pressure systolic increased	0	0	1 (1.7%)	1 (1.7%)	0	1 (1.7%)

[a] Includes data up to the time of dose adjustment for those who increased dose from the indicated dose.
[b] Includes 1) subjects who were in clinical response to golimumab induction dosing and were randomized to placebo on entry into this maintenance study; and 2) subjects who were in clinical response to placebo induction dosing and received placebo on entry into this maintenance study.
[c] Includes 1) subjects who were in clinical response to golimumab induction dosing and were randomized to golimumab 100 mg on entry into this maintenance study; 2) subjects who were not in clinical response to either placebo or golimumab induction dosing and received golimumab 100 mg on entry into this maintenance study; and 3) subjects who were dose adjusted to golimumab 100 mg from placebo (randomized or nonrandomized) or from golimumab 50 mg.
[d] Includes data from the time of dose adjustment onward for those who increased to the indicated dose.
[e] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[f] Includes data from the time of the first golimumab dose onward.

表 2.7.4.7-付録-110 治験薬の使用と関連性のある重篤な有害事象（T18 試験 54 週まで，日本人，全投与被験者）

		Golimumab				
	Placebo[a,b]	50 mg[a]	100 mg[a,c,d]	Combined 50 mg and 100 mg	200 mg[d,e]	All Golimumab[f]
Subjects treated in Japan subgroup	8	3	59	60	0	60
Avg duration of follow-up (weeks)	26.5	18.5	42.3	42.6	-	42.6
Avg exposure (number of administrations)	6.3	3.7	9.5	9.5	-	9.5
Subjects with 1 or more reasonably related serious adverse events	0	0	0	0	0	0
System-organ class/preferred term						
No data to report	0	0	0	0	0	0

[a] Includes data up to the time of dose adjustment for those who increased dose from the indicated dose.
[b] Includes 1) subjects who were in clinical response to golimumab induction dosing and were randomized to placebo on entry into this maintenance study; and 2) subjects who were in clinical response to placebo induction dosing and received placebo on entry into this maintenance study.
[c] Includes 1) subjects who were in clinical response to golimumab induction dosing and were randomized to golimumab 100 mg on entry into this maintenance study; 2) subjects who were not in clinical response to either placebo or golimumab induction dosing and received golimumab 100 mg on entry into this maintenance study; and 3) subjects who were dose adjusted to golimumab 100 mg from placebo (randomized or nonrandomized) or from golimumab 50 mg.
[d] Includes data from the time of dose adjustment onward for those who increased to the indicated dose.
[e] Includes data from the time of dose decrease for subjects who were dose adjusted to golimumab 200 mg from golimumab 100 mg and later on had their dose decreased from 200 mg to 100 mg.
[f] Includes data from the time of the first golimumab dose onward.

[HA03_C005_02.rtf] [JNJ-268229-AAC\ANS3001\DBR_HA\RE_HA\HA03_C005_02.sas] 21DEC2016, 09:52

表 2.7.4.7-付録-111 治験薬の使用と関連性のある重篤な有害事象一覧（T18 試験 54 週まで，日本人，全投与被験者）

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/Sex	Country/Race	Treatment Group at Dose Adjustment [a]	Study Day of Dose Adjustment	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection [c]/ Injection-site Reaction
Not applicable																			

[a] For subjects who were dose adjusted to golimumab 200 mg and later had their dose decreased to 100 mg following implementation of Protocol Amendment 3, "Treatment Group At Dose Adjustment" is presented as "200 mg (100 mg)", and "Study Day of Dose adjustment" is presented in the form of xxx (yyy), where xxx is the study day of dose adjustment and yyy is the study day of dose decrease.
[b] Based on MedDRA version 14.0
[c] Infection as assessed by the investigator.

[HA03_C006_01.rtf] [JNJ-268229-AAC\ANS3001\DBR_HA\RE_HA\HA03_C006_01.sas] 26DEC2016, 15:01

表 2.7.4.7-付録-112 治験薬の投与中止に至った有害事象一覧（T18 試験 54 週まで，日本人，全投与被験者）

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/Sex	Country/Race	Treatment Group at Dose Adjustment [a]	Study Day of Dose Adjustment	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection [c]/ Injection-site Reaction
Yes	Placebo	200 mg/100 mg SC	7801-00002	3[redacted]/M	JAPAN/Asian	100 mg	92	100 mg	92	Colitis ulcerative	WORSENING OF UC	101	15	Resolved	Yes	Severe	Unlikely	Permanent discontinuation of study agent	No/No
			7821-00003	2[redacted]/M	JAPAN/Asian	-	-	0 mg	33	Cytomegalovirus infection	CYTOMEGALOVIRUS INFEECTION	55	10	Resolved	No	Mild	Unlikely	Permanent discontinuation of study agent	Yes/No
								0 mg	33	Cytomegalovirus infection	CYTOMEGALOVIRUS INFECTION	64	17	Resolved	Yes	Moderate	Unlikely	Permanent discontinuation of study agent	Yes/No
No	Placebo (Placebo induction responder)	Placebo SC	7816-00002	2[redacted]/F	JAPAN/Asian	100 mg	227	100 mg	227	Colitis ulcerative	WORSENING OF ULCERATIVE COLITIS	248	55	Resolved	Yes	Severe	Unlikely	Permanent discontinuation of study agent	No/No
	Golimumab 100 mg (Placebo induction nonresponder)	Placebo SC	7809-00002	5[redacted]/M	JAPAN/Asian	-	-	100 mg	163	Colitis ulcerative	WORSENING OF ULCERATIVE COLITIS	173	-	Ongoing	Yes	Severe	Not related	Permanent discontinuation of study agent	No/No
			7812-00002	6[redacted]/F	JAPAN/Asian	-	-	100 mg	1	Rectal cancer	ADENOCARCINOMA OF RECTUM	15	50	Resolved	Yes	Severe	Not related	Permanent discontinuation of study agent	No/No

Randomized at Week 0 of This Maintenance Study	Maintenance Treatment Group	Induction Treatment Group	Subject ID	Age/Sex	Country/Race	Treatment Group at Dose Adjustment [a]	Study Day of Dose Adjustment	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term[b]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection [c]/ Injection-site Reaction
			7813-00001	4[redacted]/M	JAPAN/Asian	-	-	100 mg	1	Colitis ulcerative	EXCERBATION OF UC	8	16	Resolved	No	Moderate	Not related	Permanent discontinuation of study agent	No/No
								100 mg	1	Colitis ulcerative	EXCERBATION OF UC	23	30	Resolved	Yes	Moderate	Not related	Permanent discontinuation of study agent	No/No
	Golimumab 100 mg (Golimumab induction nonresponder)	200 mg/100 mg SC	7815-00003	4[redacted]/F	JAPAN/Asian	-	-	100 mg	367	Pustular psoriasis	PALMOPLANTAR PUSTULOSIS	367	-	Ongoing	No	Moderate	Probable	Permanent discontinuation of study agent	No/No

[a] For subjects who were dose adjusted to golimumab 200 mg and later had their dose decreased to 100 mg following implementation of Protocol Amendment 3, "Treatment Group At Dose Adjustment" is presented as "200 mg (100 mg)", and "Study Day of Dose adjustment" is presented in the form of xxx (yyy), where xxx is the study day of dose adjustment and yyy is the study day of dose decrease.
[b] Based on MedDRA version 14.0
[c] Infection as assessed by the investigator.

表 2.7.4.7-付録-113 治験薬の使用と関連性のある重篤な有害事象（T18 継続投与試験）

	Placebo[a]	Golimumab 50 mg[b]	Golimumab 100 mg[c,d]	Golimumab Combined 50 mg and 100 mg
Subjects who were treated in the study extension	96	94	524	599
Avg duration of follow-up (weeks)	57.1	134.1	134.8	139.0
Avg exposure (number of administrations)	12.4	30.6	30.3	31.3
Subjects with 1 or more reasonably related serious adverse events	0	2 (2.1%)	30 (5.7%)	32 (5.3%)
System-organ class/preferred term				
Infections and infestations	0	0	17 (3.2%)	17 (2.8%)
Anal abscess	0	0	2 (0.4%)	2 (0.3%)
Herpes zoster	0	0	2 (0.4%)	2 (0.3%)
Meningitis viral	0	0	2 (0.4%)	2 (0.3%)
Pneumonia	0	0	2 (0.4%)	2 (0.3%)
Pulmonary tuberculosis	0	0	2 (0.4%)	2 (0.3%)
Cytomegalovirus infection	0	0	1 (0.2%)	1 (0.2%)
Escherichia pyelonephritis	0	0	1 (0.2%)	1 (0.2%)
Extrapulmonary tuberculosis	0	0	1 (0.2%)	1 (0.2%)
Gastroenteritis	0	0	1 (0.2%)	1 (0.2%)
Pyelonephritis	0	0	1 (0.2%)	1 (0.2%)
Sepsis	0	0	1 (0.2%)	1 (0.2%)
Subcutaneous abscess	0	0	1 (0.2%)	1 (0.2%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	1 (1.1%)	4 (0.8%)	5 (0.8%)
Basal cell carcinoma	0	0	1 (0.2%)	1 (0.2%)
Hodgkin's disease	0	0	1 (0.2%)	1 (0.2%)
Ovarian epithelial cancer	0	1 (1.1%)	0	1 (0.2%)
Rectal cancer metastatic	0	0	1 (0.2%)	1 (0.2%)
T-cell lymphoma	0	0	1 (0.2%)	1 (0.2%)
Gastrointestinal disorders	0	0	3 (0.6%)	3 (0.5%)
Colitis ulcerative	0	0	2 (0.4%)	2 (0.3%)
Colon dysplasia	0	0	1 (0.2%)	1 (0.2%)
Nervous system disorders	0	1 (1.1%)	2 (0.4%)	3 (0.5%)
Demyelination	0	0	1 (0.2%)	1 (0.2%)
Multiple sclerosis	0	0	1 (0.2%)	1 (0.2%)
Transient ischaemic attack	0	1 (1.1%)	0	1 (0.2%)

	Placebo[a]	Golimumab		
		50 mg[b]	100 mg[c,d]	Combined 50 mg and 100 mg
Respiratory, thoracic and mediastinal disorders	0	0	2 (0.4%)	2 (0.3%)
Interstitial lung disease	0	0	2 (0.4%)	2 (0.3%)
Pneumonitis	0	0	1 (0.2%)	1 (0.2%)
Pregnancy, puerperium and perinatal conditions	0	0	1 (0.2%)	1 (0.2%)
Abortion spontaneous	0	0	1 (0.2%)	1 (0.2%)
Reproductive system and breast disorders	0	0	1 (0.2%)	1 (0.2%)
Cervical dysplasia	0	0	1 (0.2%)	1 (0.2%)
Skin and subcutaneous tissue disorders	0	0	1 (0.2%)	1 (0.2%)
Rash	0	0	1 (0.2%)	1 (0.2%)

[a] Includes data up to the time of the first golimumab dose.
[b] Includes data up to the time of dose increase for those who increased dose from the indicated dose.
[c] Includes data from the time of dose increase onward for those who increased to the indicated dose.
[d] Includes data for subjects who increased dose to golimumab 200 mg.

表 2.7.4.7-付録-114 治験薬の使用と関連性のある重篤な有害事象一覧（T18 継続投与試験）

Randomized at Week 0 of Maintenance Study	Maintenance/ Extension Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Increase	Study Day of Dose Increase	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term [a]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection [b]/ Injection-site Reaction
Yes	Golimumab 50 mg/Golimumab 50 mg	1 mg/kg IV	6279-00001	3[redacted]/M	ISRAEL/Caucasian	-	-	50 mg	1100	Transient ischaemic attack	TRANSIENT CEREBRAL ISCHEMIA	1107	5	Resolved	Yes	Mild	Possible	None/not applicable	No/No
		4 mg/kg IV	6478-00003	3[redacted]/F	SERBIA/Caucasian	Golimumab 100 mg	1184	100 mg	1292	Multiple sclerosis	CLINICALY ISOLATED SYNDROMA POSSIBLE FIRST MANIFESTATION OF MULTIPLE SCLEROSIS	1299	8	Resolved	Yes	Moderate	Possible	Permanent discontinuation of study agent	No/No
		400 mg/200 mg SC	6751-00018	3[redacted]/F	UNITED STATES/ Black	-	-	50 mg	788	Ovarian epithelial cancer	OVARIAN INVASIVE MUCINOUS ADENOCARCINOMA	791	79	Resolved	Yes	Severe	Possible	Permanent discontinuation of study agent	No/No
	Golimumab 50 mg/Golimumab 100 mg	200 mg/100 mg SC	6726-00024	4[redacted]/M	UNITED STATES/ Caucasian	-	-	100 mg	864	Colon dysplasia	HIGH GRADE DISPLASIA IN THE AREA OF THE SPLENIC FLEXURE	878	39	Resolved	Yes	Severe	Possible	Permanent discontinuation of study agent	No/No
	Golimumab 100 mg/Golimumab 100 mg	1 mg/kg IV	6257-00005	2[redacted]/F	INDIA/Asian	-	-	100 mg	587	Abortion spontaneous	SPONTANEOUS ABORTION	-	-	Resolved	Yes	Mild	Possible	None/not applicable	No/No
		4 mg/kg IV	6281-00007	4[redacted]/M	ISRAEL/Caucasian	-	-	100 mg	1215	Rash	RASH OF UNKNOWN ORIGIN	1221	8	Resolved	Yes	Severe	Possible	Permanent discontinuation of study agent	No/No
		200 mg/100 mg SC	7258-00004	1[redacted]/M	INDIA/Asian	-	-	100 mg	1271	Pulmonary tuberculosis	PULMONARY TUBERCLOSIS	1303	301	Resolved	Yes	Mild	Probable	Permanent discontinuation of study agent	Yes/No

Randomized at Week 0 of Maintenance Study	Maintenance/ Extension Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Increase	Study Day of Dose Increase	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term [a]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection [b]/ Injection-site Reaction
			7743-00009	4[redacted]/M	UNITED STATES/ Caucasian	-	-	100 mg	863	Pneumonia	PNEUMONIA	882	55	Resolved	Yes	Severe	Probable	Temporary interruption/ dose modification	Yes/No
		400 mg/200 mg SC	7008-00004	5[redacted]/F	AUSTRALIA/Caucasian	Golimumab 100 mg	477	100 mg	834	Gastroenteritis	INFECTIOUS GASTROENTERITIS	841	4	Resolved	Yes	Moderate	Possible	None/not applicable	Yes/No
			7414-00019	2[redacted]/M	POLAND/ Caucasian	-	-	100 mg	1170	Colitis ulcerative	ULCERATIVE COLITIS PROGRESSION.	1227	13	Resolved	Yes	Severe	Possible	None/not applicable	No/No
								100 mg	1170	Hodgkin's disease	HODGKIN'S LYMPHOMA	1364	-	Ongoing	Yes	Severe	Possible	None/not applicable	No/No
No	Placebo (Placebo induction responder)/ Placebo	Placebo SC	6177-00009	5[redacted]/M	FRANCE/ Caucasian	Golimumab 100 mg	442	100 mg	490	Cytomegalovirus infection	PRIMARY CMV INFECTION	527	-	Resolved	Yes	Moderate	Possible	Permanent discontinuation of study agent	Yes/No
			7006-00002	3[redacted]/M	AUSTRALIA/Caucasian	Golimumab 100 mg	933	100 mg	1114	Herpes zoster	LOCALISED SHINGLES LEFT FLANK TO LEFT CHEST	1127	32	Resolved	Yes	Moderate	Possible	Temporary interruption/ dose modification	Yes/No
	Placebo (Placebo induction responder)/ Golimumab 100 mg	Placebo SC	7732-00005	4[redacted]/F	UNITED STATES/ Caucasian	-	-	100 mg	569	Pneumonia	MULTIFOCAL CAVITARY PNEUMONIA	581	389	Resolved	Yes	Moderate	Possible	Permanent discontinuation of study agent	Yes/No
	Golimumab 100 mg (Placebo induction nonresponder)/Golimumab 100 mg	Placebo SC	7003-00003	3[redacted]/F	AUSTRALIA/Caucasian	-	-	100 mg	842	Subcutaneous abscess	ABSCESS LEFT BUTTOCK	844	37	Resolved	Yes	Severe	Possible	None/not applicable	Yes/No
			7126-00014	4[redacted]/M	DENMARK/Caucasian	-	-	100 mg	820	Meningitis viral	VIRAL MENINGITIS	820	11	Resolved	Yes	Severe	Possible	Temporary interruption/ dose modification	Yes/No

Randomized at Week 0 of Maintenance Study	Maintenance/ Extension Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Increase	Study Day of Dose Increase	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term [a]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection [b]/ Injection-site Reaction
			7205-00005	4[redacted]/M	GERMANY/Caucasian	-	-	100 mg	532	Rectal cancer metastatic	ADVANCED RECTAL CANCER WITH LIVER METASTASIS	854	402	Resolved	Yes	Moderate	Possible	None/not applicable	No/No
			7378-00010	4[redacted]/F	NEW ZEALAND/Caucasian	-	-	100 mg	443	Escherichia pyelonephritis	E-COLI PYELONEPHRITIS	463	21	Resolved	Yes	Severe	Possible	Permanent discontinuation of study agent	Yes/No
	Golimumab 100 mg (Golimumab induction nonresponder)/Golimumab 100 mg	1 mg/kg IV	6051-00002	7[redacted]/M	BELGIUM/Caucasian	-	-	100 mg	1402	Interstitial lung disease	INTERSTITIAL LUNG DISEASE	1416	196	Resolved	Yes	Moderate	Possible	Permanent discontinuation of study agent	No/No
								100 mg	1402	Interstitial lung disease	ACUTE FLARE OF INTERSTITIAL LUNG DISEASE	1425	19	Resolved	Yes	Severe	Possible	None/not applicable	No/No
								100 mg	1402	Interstitial lung disease	ACUTE FLARE INTERSTITIAL LUNGDISEAE	1451	10	Resolved	Yes	Severe	Possible	None/not applicable	No/No
			6179-00003	4[redacted]/F	FRANCE/ Caucasian	-	-	100 mg	882	Demyelination	DEMYELINIISATION	884	442	Resolved	Yes	Moderate	Possible	Permanent discontinuation of study agent	No/No
			6502-00008	3[redacted]/F	SLOVAKIA (Slovak Republic)/ Caucasian	-	-	100 mg	792	Pulmonary tuberculosis	PULMONARY TUBERCULOSIS	801	66	Resolved	Yes	Moderate	Probable	Permanent discontinuation of study agent	Yes/No
		2 mg/kg IV	6076-00002	4[redacted]/F	BULGARIA/Caucasian	-	-	100 mg	589	Sepsis	SEPSIS	639	1	Resolved	Yes	Severe	Possible	None/not applicable	Yes/No

Randomized at Week 0 of Maintenance Study	Maintenance/ Extension Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Increase	Study Day of Dose Increase	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term [a]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection [b]/ Injection-site Reaction
			6478-00011	4[redacted]/F	SERBIA/Caucasian	Golimumab 100 mg	395	100 mg	841	Basal cell carcinoma	BASAL CELL CARCINOMA	848	15	Resolved	Yes	Mild	Possible	None/not applicable	No/No
		100 mg/50 mg SC	7376-00002	4[redacted]/M	NEW ZEALAND/Other	-	-	100 mg	876	Anal abscess	PERIANAL ABCESS	886	-	Ongoing	Yes	Severe	Possible	None/not applicable	Yes/No
		200 mg/100 mg SC	7116-00008	5[redacted]/M	CANADA/ Caucasian	Golimumab 100 mg	394	100 mg	813	Colitis ulcerative	EXACERBATION OF ULCERATIVE COLITIS	832	8	Resolved	Yes	Severe	Possible	None/not applicable	No/No
			7263-00007	3[redacted]/F	INDIA/Asian	-	-	100 mg	992	Extrapulmonary tuberculosis	EXTRA PULMONARY TUBERCULOSIS	1002	18	Resolved	Yes	Moderate	Possible	Permanent discontinuation of study agent	Yes/No
			7741-00005	6[redacted]/F	UNITED STATES/ Caucasian	-	-	100 mg	564	Interstitial lung disease	INTERSTITIAL LUNG DISEASE	618	43	Resolved	Yes	Moderate	Probable	Permanent discontinuation of study agent	No/No
								100 mg	564	Pneumonitis	PNEUMONITIS	618	128	Resolved	Yes	Moderate	Probable	Permanent discontinuation of study agent	No/No
			7753-00004	5[redacted]/M	UNITED STATES/ Black	Golimumab 100 mg	421	100 mg	999	T-cell lymphoma	T CELL LYMPHOMA	1028	-	Ongoing	Yes	Mild	Possible	Permanent discontinuation of study agent	No/No
			7822-00001	2[redacted]/M	JAPAN/Asian	-	-	100 mg	1178	Anal abscess	PERIANAL ABSSESS	1197	8	Resolved	Yes	Moderate	Probable	Temporary interruption/ dose modification	Yes/No
		400 mg/200 mg SC	7003-00010	5[redacted]/M	AUSTRALIA/Asian	-	-	100 mg	482	Pyelonephritis	PYELONEPHRITIS	500	3	Resolved	Yes	Moderate	Possible	None/not applicable	Yes/No
			7207-00012	2[redacted]/M	GERMANY/Caucasian	-	-	100 mg	456	Meningitis viral	VIRAL MENINGITIS	477	16	Resolved	Yes	Moderate	Possible	Permanent discontinuation of study agent	Yes/No

Randomized at Week 0 of Maintenance Study	Maintenance/ Extension Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Increase	Study Day of Dose Increase	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term [a]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection [b]/ Injection-site Reaction
			7413-00003	3[redacted]/M	POLAND/ Caucasian	-	-	100 mg	871	Herpes zoster	ZOSTER ON THE LEFT SIDE OF THE TRUNK	883	7	Resolved	Yes	Moderate	Possible	None/not applicable	Yes/No
			7819-00001	3[redacted]/F	JAPAN/Asian	-	-	100 mg	544	Cervical dysplasia	HIGH GRADE CERVICAL DYSPLASIA	575	68	Resolved	Yes	Moderate	Possible	Permanent discontinuation of study agent	No/No

[a] Based on MedDRA version 17.1
[b] Infection as assessed by the investigator.

表 2.7.4.7-付録-115 すべての有害事象（T18 継続投与試験，日本人）

		Golimumab		
	Placebo[a]	50 mg[b]	100 mg[c,d]	Combined 50 mg and 100 mg
Subjects in the Japan subgroup who were treated in the study extension	1	0	25	25
Avg duration of follow-up (weeks)	39.3	-	118.9	118.9
Avg exposure (number of administrations)	6.0	-	26.1	26.1
Subjects with 1 or more adverse events	1 (100.0%)	0	24 (96.0%)	24 (96.0%)
System-organ class/preferred term				
Infections and infestations	1 (100.0%)	0	22 (88.0%)	22 (88.0%)
Nasopharyngitis	0	0	16 (64.0%)	16 (64.0%)
Influenza	0	0	4 (16.0%)	4 (16.0%)
Pharyngitis	0	0	4 (16.0%)	4 (16.0%)
Enteritis infectious	0	0	3 (12.0%)	3 (12.0%)
Onychomycosis	0	0	3 (12.0%)	3 (12.0%)
Cellulitis	0	0	2 (8.0%)	2 (8.0%)
Folliculitis	0	0	2 (8.0%)	2 (8.0%)
Herpes zoster	0	0	2 (8.0%)	2 (8.0%)
Infected dermal cyst	0	0	2 (8.0%)	2 (8.0%)
Oral herpes	0	0	2 (8.0%)	2 (8.0%)
Acute sinusitis	0	0	1 (4.0%)	1 (4.0%)
Anal abscess	0	0	1 (4.0%)	1 (4.0%)
Bronchitis	0	0	1 (4.0%)	1 (4.0%)
Conjunctivitis	0	0	1 (4.0%)	1 (4.0%)
Cystitis	0	0	1 (4.0%)	1 (4.0%)
Ear infection fungal	0	0	1 (4.0%)	1 (4.0%)
Gastroenteritis Escherichia coli	0	0	1 (4.0%)	1 (4.0%)
Gastrointestinal infection	0	0	1 (4.0%)	1 (4.0%)
Genital herpes	0	0	1 (4.0%)	1 (4.0%)
Hordeolum	0	0	1 (4.0%)	1 (4.0%)
Otitis externa	0	0	1 (4.0%)	1 (4.0%)
Pseudomembranous colitis	0	0	1 (4.0%)	1 (4.0%)
Sinusitis	0	0	1 (4.0%)	1 (4.0%)
Tinea pedis	0	0	1 (4.0%)	1 (4.0%)
Vulvovaginal candidiasis	0	0	1 (4.0%)	1 (4.0%)
Wound infection	0	0	1 (4.0%)	1 (4.0%)
Upper respiratory tract infection	1 (100.0%)	0	0	0

	Placebo[a]	Golimumab		
		50 mg[b]	100 mg[c,d]	Combined 50 mg and 100 mg
Gastrointestinal disorders	0	0	12 (48.0%)	12 (48.0%)
Stomatitis	0	0	5 (20.0%)	5 (20.0%)
Colitis ulcerative	0	0	3 (12.0%)	3 (12.0%)
Nausea	0	0	3 (12.0%)	3 (12.0%)
Constipation	0	0	2 (8.0%)	2 (8.0%)
Large intestine polyp	0	0	2 (8.0%)	2 (8.0%)
Vomiting	0	0	2 (8.0%)	2 (8.0%)
Abdominal pain upper	0	0	1 (4.0%)	1 (4.0%)
Anal fissure	0	0	1 (4.0%)	1 (4.0%)
Cheilitis	0	0	1 (4.0%)	1 (4.0%)
Gastritis	0	0	1 (4.0%)	1 (4.0%)
Glossitis	0	0	1 (4.0%)	1 (4.0%)
Haemorrhoids	0	0	1 (4.0%)	1 (4.0%)
Proctalgia	0	0	1 (4.0%)	1 (4.0%)
Musculoskeletal and connective tissue disorders	0	0	11 (44.0%)	11 (44.0%)
Arthralgia	0	0	3 (12.0%)	3 (12.0%)
Musculoskeletal pain	0	0	3 (12.0%)	3 (12.0%)
Arthritis	0	0	2 (8.0%)	2 (8.0%)
Back pain	0	0	2 (8.0%)	2 (8.0%)
Periarthritis	0	0	2 (8.0%)	2 (8.0%)
Tenosynovitis	0	0	1 (4.0%)	1 (4.0%)
Respiratory, thoracic and mediastinal disorders	0	0	11 (44.0%)	11 (44.0%)
Oropharyngeal pain	0	0	4 (16.0%)	4 (16.0%)
Rhinitis allergic	0	0	3 (12.0%)	3 (12.0%)
Asthma	0	0	2 (8.0%)	2 (8.0%)
Cough	0	0	2 (8.0%)	2 (8.0%)
Upper respiratory tract inflammation	0	0	2 (8.0%)	2 (8.0%)
Productive cough	0	0	1 (4.0%)	1 (4.0%)
Sneezing	0	0	1 (4.0%)	1 (4.0%)
Skin and subcutaneous tissue disorders	0	0	8 (32.0%)	8 (32.0%)
Acne	0	0	4 (16.0%)	4 (16.0%)
Alopecia	0	0	1 (4.0%)	1 (4.0%)
Dermal cyst	0	0	1 (4.0%)	1 (4.0%)
Dermatitis allergic	0	0	1 (4.0%)	1 (4.0%)
Erythema	0	0	1 (4.0%)	1 (4.0%)
Melanosis	0	0	1 (4.0%)	1 (4.0%)

		Golimumab		
	Placebo[a]	50 mg[b]	100 mg[c,d]	Combined 50 mg and 100 mg
Miliaria	0	0	1 (4.0%)	1 (4.0%)
Pruritus	0	0	1 (4.0%)	1 (4.0%)
Rash	0	0	1 (4.0%)	1 (4.0%)
Seborrhoeic dermatitis	0	0	1 (4.0%)	1 (4.0%)
Skin fissures	0	0	1 (4.0%)	1 (4.0%)
Nervous system disorders	0	0	6 (24.0%)	6 (24.0%)
Headache	0	0	6 (24.0%)	6 (24.0%)
Dizziness	0	0	1 (4.0%)	1 (4.0%)
Sensory disturbance	0	0	1 (4.0%)	1 (4.0%)
Eye disorders	0	0	4 (16.0%)	4 (16.0%)
Cataract	0	0	2 (8.0%)	2 (8.0%)
Blepharospasm	0	0	1 (4.0%)	1 (4.0%)
Conjunctival deposit	0	0	1 (4.0%)	1 (4.0%)
Dry eye	0	0	1 (4.0%)	1 (4.0%)
Eyelid oedema	0	0	1 (4.0%)	1 (4.0%)
Macular fibrosis	0	0	1 (4.0%)	1 (4.0%)
Retinal degeneration	0	0	1 (4.0%)	1 (4.0%)
Retinal tear	0	0	1 (4.0%)	1 (4.0%)
Psychiatric disorders	0	0	4 (16.0%)	4 (16.0%)
Insomnia	0	0	4 (16.0%)	4 (16.0%)
Anxiety	0	0	1 (4.0%)	1 (4.0%)
General disorders and administration site conditions	0	0	3 (12.0%)	3 (12.0%)
Injection site erythema	0	0	2 (8.0%)	2 (8.0%)
Fatigue	0	0	1 (4.0%)	1 (4.0%)
Injection site induration	0	0	1 (4.0%)	1 (4.0%)
Injection site pruritus	0	0	1 (4.0%)	1 (4.0%)
Oedema peripheral	0	0	1 (4.0%)	1 (4.0%)
Reproductive system and breast disorders	0	0	3 (12.0%)	3 (12.0%)
Cervical dysplasia	0	0	1 (4.0%)	1 (4.0%)
Genital haemorrhage	0	0	1 (4.0%)	1 (4.0%)
Menopausal symptoms	0	0	1 (4.0%)	1 (4.0%)
Blood and lymphatic system disorders	1 (100.0%)	0	2 (8.0%)	2 (8.0%)
Aplastic anaemia	0	0	1 (4.0%)	1 (4.0%)
Iron deficiency anaemia	0	0	1 (4.0%)	1 (4.0%)
Neutropenia	1 (100.0%)	0	0	0
Investigations	0	0	2 (8.0%)	2 (8.0%)

	Placebo[a]	Golimumab 50 mg[b]	Golimumab 100 mg[c,d]	Golimumab Combined 50 mg and 100 mg
Blood pressure systolic increased	0	0	1 (4.0%)	1 (4.0%)
Weight increased	0	0	1 (4.0%)	1 (4.0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	0	2 (8.0%)	2 (8.0%)
Seborrhoeic keratosis	0	0	1 (4.0%)	1 (4.0%)
Uterine leiomyoma	0	0	1 (4.0%)	1 (4.0%)
Ear and labyrinth disorders	0	0	1 (4.0%)	1 (4.0%)
Vertigo	0	0	1 (4.0%)	1 (4.0%)
Immune system disorders	0	0	1 (4.0%)	1 (4.0%)
Drug hypersensitivity	0	0	1 (4.0%)	1 (4.0%)
Social circumstances	0	0	1 (4.0%)	1 (4.0%)
Pregnancy of partner	0	0	1 (4.0%)	1 (4.0%)
Vascular disorders	0	0	1 (4.0%)	1 (4.0%)
Arteriosclerosis	0	0	1 (4.0%)	1 (4.0%)

[a] Includes data up to the time of the first golimumab dose.
[b] Includes data up to the time of dose increase for those who increased dose from the indicated dose.
[c] Includes data from the time of dose increase onward for those who increased to the indicated dose.
[d] Includes data for subjects who increased dose to golimumab 200 mg.

[HA03_C010_01.rtf] [JNJ-268229-AAC\ANS3001\DBR_HA\RE_HA\HA03_C010_01.sas] 05JAN2017, 10:13

表 2.7.4.7-付録-116 治験薬の使用と関連性のある有害事象（T18 継続投与試験，日本人）

	Placebo[a]	Golimumab 50 mg[b]	Golimumab 100 mg[c,d]	Golimumab Combined 50 mg and 100 mg
Subjects in the Japan subgroup who were treated in the study extension	1	0	25	25
Avg duration of follow-up (weeks)	39.3	-	118.9	118.9
Avg exposure (number of administrations)	6.0	-	26.1	26.1
Subjects with 1 or more reasonably related adverse events	1 (100.0%)	0	10 (40.0%)	10 (40.0%)
System-organ class/preferred term				
Infections and infestations	1 (100.0%)	0	8 (32.0%)	8 (32.0%)
Nasopharyngitis	0	0	3 (12.0%)	3 (12.0%)
Enteritis infectious	0	0	2 (8.0%)	2 (8.0%)
Oral herpes	0	0	2 (8.0%)	2 (8.0%)
Anal abscess	0	0	1 (4.0%)	1 (4.0%)
Bronchitis	0	0	1 (4.0%)	1 (4.0%)
Genital herpes	0	0	1 (4.0%)	1 (4.0%)
Herpes zoster	0	0	1 (4.0%)	1 (4.0%)
Hordeolum	0	0	1 (4.0%)	1 (4.0%)
Pharyngitis	0	0	1 (4.0%)	1 (4.0%)
Sinusitis	0	0	1 (4.0%)	1 (4.0%)
Wound infection	0	0	1 (4.0%)	1 (4.0%)
Upper respiratory tract infection	1 (100.0%)	0	0	0
Skin and subcutaneous tissue disorders	0	0	3 (12.0%)	3 (12.0%)
Acne	0	0	1 (4.0%)	1 (4.0%)
Dermal cyst	0	0	1 (4.0%)	1 (4.0%)
Erythema	0	0	1 (4.0%)	1 (4.0%)
Gastrointestinal disorders	0	0	1 (4.0%)	1 (4.0%)
Large intestine polyp	0	0	1 (4.0%)	1 (4.0%)
General disorders and administration site conditions	0	0	1 (4.0%)	1 (4.0%)
Injection site erythema	0	0	1 (4.0%)	1 (4.0%)
Injection site induration	0	0	1 (4.0%)	1 (4.0%)
Injection site pruritus	0	0	1 (4.0%)	1 (4.0%)
Oedema peripheral	0	0	1 (4.0%)	1 (4.0%)
Investigations	0	0	1 (4.0%)	1 (4.0%)

	Placebo[a]	Golimumab		
		50 mg[b]	100 mg[c,d]	Combined 50 mg and 100 mg
Blood pressure systolic increased	0	0	1 (4.0%)	1 (4.0%)
Musculoskeletal and connective tissue disorders	0	0	1 (4.0%)	1 (4.0%)
Arthralgia	0	0	1 (4.0%)	1 (4.0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	0	1 (4.0%)	1 (4.0%)
Uterine leiomyoma	0	0	1 (4.0%)	1 (4.0%)
Nervous system disorders	0	0	1 (4.0%)	1 (4.0%)
Headache	0	0	1 (4.0%)	1 (4.0%)
Reproductive system and breast disorders	0	0	1 (4.0%)	1 (4.0%)
Cervical dysplasia	0	0	1 (4.0%)	1 (4.0%)
Respiratory, thoracic and mediastinal disorders	0	0	1 (4.0%)	1 (4.0%)
Asthma	0	0	1 (4.0%)	1 (4.0%)

[a] Includes data up to the time of the first golimumab dose.
[b] Includes data up to the time of dose increase for those who increased dose from the indicated dose.
[c] Includes data from the time of dose increase onward for those who increased to the indicated dose.
[d] Includes data for subjects who increased dose to golimumab 200 mg.

[HA03_C010_02.rtf] [JNJ-268229-AAC\ANS3001\DBR_HA\RE_HA\HA03_C010_02.sas] 05JAN2017, 10:13

表 2.7.4.7-付録-117 すべての感染症（T18 継続投与試験，日本人）

	Placebo[a]	Golimumab 50 mg[b]	Golimumab 100 mg[c,d]	Golimumab Combined 50 mg and 100 mg
Subjects in the Japan subgroup who were treated in the study extension	1	0	25	25
Avg duration of follow-up (weeks)	39.3	-	118.9	118.9
Avg exposure (number of administrations)	6.0	-	26.1	26.1
Subjects with 1 or more infections[e]	1 (100.0%)	0	20 (80.0%)	20 (80.0%)
System-organ class/preferred term				
Infections and infestations	1 (100.0%)	0	20 (80.0%)	20 (80.0%)
Nasopharyngitis	0	0	11 (44.0%)	11 (44.0%)
Influenza	0	0	4 (16.0%)	4 (16.0%)
Enteritis infectious	0	0	3 (12.0%)	3 (12.0%)
Onychomycosis	0	0	3 (12.0%)	3 (12.0%)
Cellulitis	0	0	2 (8.0%)	2 (8.0%)
Folliculitis	0	0	2 (8.0%)	2 (8.0%)
Herpes zoster	0	0	2 (8.0%)	2 (8.0%)
Oral herpes	0	0	2 (8.0%)	2 (8.0%)
Pharyngitis	0	0	2 (8.0%)	2 (8.0%)
Acute sinusitis	0	0	1 (4.0%)	1 (4.0%)
Anal abscess	0	0	1 (4.0%)	1 (4.0%)
Cystitis	0	0	1 (4.0%)	1 (4.0%)
Ear infection fungal	0	0	1 (4.0%)	1 (4.0%)
Gastroenteritis Escherichia coli	0	0	1 (4.0%)	1 (4.0%)
Gastrointestinal infection	0	0	1 (4.0%)	1 (4.0%)
Genital herpes	0	0	1 (4.0%)	1 (4.0%)
Hordeolum	0	0	1 (4.0%)	1 (4.0%)
Infected dermal cyst	0	0	1 (4.0%)	1 (4.0%)
Otitis externa	0	0	1 (4.0%)	1 (4.0%)
Pseudomembranous colitis	0	0	1 (4.0%)	1 (4.0%)
Sinusitis	0	0	1 (4.0%)	1 (4.0%)
Tinea pedis	0	0	1 (4.0%)	1 (4.0%)
Vulvovaginal candidiasis	0	0	1 (4.0%)	1 (4.0%)
Wound infection	0	0	1 (4.0%)	1 (4.0%)
Upper respiratory tract infection	1 (100.0%)	0	0	0
Skin and subcutaneous tissue disorders	0	0	4 (16.0%)	4 (16.0%)

	Placebo[a]	Golimumab		
		50 mg[b]	100 mg[c,d]	Combined 50 mg and 100 mg
Acne	0	0	3 (12.0%)	3 (12.0%)
Dermal cyst	0	0	1 (4.0%)	1 (4.0%)
Respiratory, thoracic and mediastinal disorders	0	0	2 (8.0%)	2 (8.0%)
Upper respiratory tract inflammation	0	0	2 (8.0%)	2 (8.0%)
Vascular disorders	0	0	1 (4.0%)	1 (4.0%)
Arteriosclerosis	0	0	1 (4.0%)	1 (4.0%)

[a] Includes data up to the time of the first golimumab dose.
[b] Includes data up to the time of dose increase for those who increased dose from the indicated dose.
[c] Includes data from the time of dose increase onward for those who increased to the indicated dose.
[d] Includes data for subjects who increased dose to golimumab 200 mg.
[e] Infection as assessed by the investigator.

表 2.7.4.7-付録-118 重篤な有害事象（T18 継続投与試験，日本人）

	Placebo[a]	Golimumab 50 mg[b]	Golimumab 100 mg[c,d]	Golimumab Combined 50 mg and 100 mg
Subjects in the Japan subgroup who were treated in the study extension	1	0	25	25
Avg duration of follow-up (weeks)	39.3	-	118.9	118.9
Avg exposure (number of administrations)	6.0	-	26.1	26.1
Subjects with 1 or more serious adverse events	0	0	9 (36.0%)	9 (36.0%)
System-organ class/preferred term				
Gastrointestinal disorders	0	0	4 (16.0%)	4 (16.0%)
Colitis ulcerative	0	0	3 (12.0%)	3 (12.0%)
Large intestine polyp	0	0	1 (4.0%)	1 (4.0%)
Eye disorders	0	0	2 (8.0%)	2 (8.0%)
Cataract	0	0	2 (8.0%)	2 (8.0%)
Macular fibrosis	0	0	1 (4.0%)	1 (4.0%)
Blood and lymphatic system disorders	0	0	1 (4.0%)	1 (4.0%)
Aplastic anaemia	0	0	1 (4.0%)	1 (4.0%)
Infections and infestations	0	0	1 (4.0%)	1 (4.0%)
Anal abscess	0	0	1 (4.0%)	1 (4.0%)
Reproductive system and breast disorders	0	0	1 (4.0%)	1 (4.0%)
Cervical dysplasia	0	0	1 (4.0%)	1 (4.0%)

[a] Includes data up to the time of the first golimumab dose.
[b] Includes data up to the time of dose increase for those who increased dose from the indicated dose.
[c] Includes data from the time of dose increase onward for those who increased to the indicated dose.
[d] Includes data for subjects who increased dose to golimumab 200 mg.

[HA03_C010_04.rtf] [JNJ-268229-AAC\ANS3001\DBR_HA\RE_HA\HA03_C010_04.sas] 05JAN2017, 10:13

表 2.7.4.7-付録-119 治験薬の使用と関連性のある重篤な有害事象（T18 継続投与試験，日本人）

		Golimumab		
	Placebo[a]	50 mg[b]	100 mg[c,d]	Combined 50 mg and 100 mg
Subjects in the Japan subgroup who were treated in the study extension	1	0	25	25
Avg duration of follow-up (weeks)	39.3	-	118.9	118.9
Avg exposure (number of administrations)	6.0	-	26.1	26.1
Subjects with 1 or more reasonably related serious adverse events	0	0	2 (8.0%)	2 (8.0%)
System-organ class/preferred term				
Infections and infestations	0	0	1 (4.0%)	1 (4.0%)
Anal abscess	0	0	1 (4.0%)	1 (4.0%)
Reproductive system and breast disorders	0	0	1 (4.0%)	1 (4.0%)
Cervical dysplasia	0	0	1 (4.0%)	1 (4.0%)

[a] Includes data up to the time of the first golimumab dose.
[b] Includes data up to the time of dose increase for those who increased dose from the indicated dose.
[c] Includes data from the time of dose increase onward for those who increased to the indicated dose.
[d] Includes data for subjects who increased dose to golimumab 200 mg.

[HA03_C010_05.rtf] [JNJ-268229-AAC\ANS3001\DBR_HA\RE_HA\HA03_C010_05.sas] 05JAN2017, 10:13

表 2.7.4.7-付録-120 重篤な感染症（T18 継続投与試験，日本人）

	Placebo[a]	Golimumab 50 mg[b]	Golimumab 100 mg[c,d]	Golimumab Combined 50 mg and 100 mg
Subjects in the Japan subgroup who were treated in the study extension	1	0	25	25
Avg duration of follow-up (weeks)	39.3	-	118.9	118.9
Avg exposure (number of administrations)	6.0	-	26.1	26.1
Subjects with 1 or more serious infections[e]	0	0	1 (4.0%)	1 (4.0%)
System-organ class/preferred term				
Infections and infestations	0	0	1 (4.0%)	1 (4.0%)
Anal abscess	0	0	1 (4.0%)	1 (4.0%)

[a] Includes data up to the time of the first golimumab dose.
[b] Includes data up to the time of dose increase for those who increased dose from the indicated dose.
[c] Includes data from the time of dose increase onward for those who increased to the indicated dose.
[d] Includes data for subjects who increased dose to golimumab 200 mg.
[e] Infection as assessed by the investigator.

[HA03_C010_06.rtf] [JNJ-268229-AAC\ANS3001\DBR_HA\RE_HA\HA03_C010_06.sas] 05JAN2017, 10:13

表 2.7.4.7-付録-121 治験薬の投与中止に至った有害事象（T18 継続投与試験，日本人）

	Placebo[a]	Golimumab 50 mg[b]	Golimumab 100 mg[c,d]	Golimumab Combined 50 mg and 100 mg
Subjects in the Japan subgroup who were treated in the study extension	1	0	25	25
Avg duration of follow-up (weeks)	39.3	-	118.9	118.9
Avg exposure (number of administrations)	6.0	-	26.1	26.1
Subjects who discontinued study agent because of 1 or more adverse events	0	0	5 (20.0%)	5 (20.0%)
System-organ class/preferred term				
Infections and infestations	0	0	3 (12.0%)	3 (12.0%)
Anal abscess	0	0	1 (4.0%)	1 (4.0%)
Genital herpes	0	0	1 (4.0%)	1 (4.0%)
Infected dermal cyst	0	0	1 (4.0%)	1 (4.0%)
Oral herpes	0	0	1 (4.0%)	1 (4.0%)
Blood and lymphatic system disorders	0	0	1 (4.0%)	1 (4.0%)
Aplastic anaemia	0	0	1 (4.0%)	1 (4.0%)
Reproductive system and breast disorders	0	0	1 (4.0%)	1 (4.0%)
Cervical dysplasia	0	0	1 (4.0%)	1 (4.0%)

[a] Includes data up to the time of the first golimumab dose.
[b] Includes data up to the time of dose increase for those who increased dose from the indicated dose.
[c] Includes data from the time of dose increase onward for those who increased to the indicated dose.
[d] Includes data for subjects who increased dose to golimumab 200 mg.

[HA03_C010_07.rtf] [JNJ-268229-AAC\ANS3001\DBR_HA\RE_HA\HA03_C010_07.sas] 05JAN2017, 10:13

表 2.7.4.7-付録-122 治験薬の使用と関連性のある重篤な有害事象一覧（T18 継続投与試験，日本人）

Randomized at Week 0 of Maintenance Study	Maintenance/ Extension Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Increase	Study Day of Dose Increase	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term [a]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection [b]/ Injection-site Reaction
No	Golimumab 100 mg (Golimumab induction nonresponder)/Golimumab 100 mg	200 mg/100 mg SC	7822-00001	2[redacted]/M	JAPAN/ Asian	-	-	100 mg	1178	Anal abscess	PERIANAL ABSSESS	1197	8	Resolved	Yes	Moderate	Probable	Temporary interruption/ dose modification	Yes/No
		400 mg/200 mg SC	7819-00001	3[redacted]/F	JAPAN/ Asian	-	-	100 mg	544	Cervical dysplasia	HIGH GRADE CERVICAL DYSPLASIA	575	68	Resolved	Yes	Moderate	Possible	Permanent discontinuation of study agent	No/No

[a] Based on MedDRA version 17.1
[b] Infection as assessed by the investigator.

[HA03_C010_08.rtf] [JNJ-268229-AAC\ANS3001\DBR_HA\RE_HA\HA03_C010_08.sas] 05JAN2017, 10:13

表 2.7.4.7-付録-123 重篤な感染症一覧（T18 継続投与試験，日本人）

Randomized at Week 0 of Maintenance Study	Maintenance/ Extension Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Increase	Study Day of Dose Increase	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term [a]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection [b]/ Injection-site Reaction
No	Golimumab 100 mg (Golimumab induction nonresponder)/Golimumab 100 mg	200 mg/100 mg SC	7822-00001	2[redacted]/M	JAPAN/ Asian	-	-	100 mg	1178	Anal abscess	PERIANAL ABSSESS	1197	8	Resolved	Yes	Moderate	Probable	Temporary interruption/ dose modification	Yes/No

[a] Based on MedDRA version 17.1
[b] Infection as assessed by the investigator.

[HA03_C010_09.rtf] [JNJ-268229-AAC\ANS3001\DBR_HA\RE_HA\HA03_C010_09.sas] 05JAN2017, 10:13

表 2.7.4.7-付録-124 治験薬の投与中止に至った有害事象一覧（T18 継続投与試験，日本人）

Randomized at Week 0 of Maintenance Study	Maintenance/ Extension Treatment Group	Induction Treatment Group	Subject ID	Age/ Sex	Country/ Race	Treatment Group at Dose Increase	Study Day of Dose Increase	Study Agent Dose Prior to AE	Study Day of Study Agent Administration Prior to AE	MedDRA Preferred Term [a]	Verbatim Term	Study Day of AE	Duration of AE (days)	Outcome	Serious	Intensity	Relationship to Study Agent	Action Taken with Study Agent	Infection [b]/ Injection-site Reaction
No	Golimumab 100 mg (Placebo induction nonresponder)/Golimumab 100 mg	Placebo SC	7815-00002	5[redacted]/F	JAPAN/ Asian	-	-	100 mg	589	Genital herpes	WORSENING OF GENITAL HERPES	615	-	Ongoing	No	Mild	Possible	Permanent discontinuation of study agent	Yes/No
			7816-00003	4[redacted]/F	JAPAN/ Asian	-	-	100 mg	596	Aplastic anaemia	APLASTIC ANAEMIA	617	-	Ongoing	Yes	Severe	Unlikely	Permanent discontinuation of study agent	No/No
	Golimumab 100 mg (Golimumab induction nonresponder)/Golimumab 100 mg	200 mg/100 mg SC	7822-00001	2[redacted]/M	JAPAN/ Asian	-	-	100 mg	1178	Anal abscess	PERIANAL ABSCESS	1188	355	Resolved	No	Moderate	Probable	Permanent discontinuation of study agent	Yes/No
		400 mg/200 mg SC	7808-00004	3[redacted]/F	JAPAN/ Asian	-	-	100 mg	1157	Infected dermal cyst	PYOGENIC ATHEROMA(SKIN)	1191	86	Resolved	No	Mild	Unlikely	Permanent discontinuation of study agent	Yes/No
								100 mg	1157	Oral herpes	HERPES LABIALIS	1191	86	Resolved	No	Mild	Unlikely	Permanent discontinuation of study agent	Yes/No
			7819-00001	3[redacted]/F	JAPAN/ Asian	-	-	100 mg	544	Cervical dysplasia	HIGH GRADE CERVICAL DYSPLASIA	575	68	Resolved	Yes	Moderate	Possible	Permanent discontinuation of study agent	No/No

[a] Based on MedDRA version 17.1
[b] Infection as assessed by the investigator.

表 2.7.4.7-付録-125 治験薬の使用と関連性のある重篤な有害事象（UCO3001 試験，維持期）

	Placebo[a]	Golimumab 100mg[b]
Analysis set: SF-M	31	111
Average duration of follow-up (weeks)	24.2	30.6
Average exposure (number of administrations)	6.4	7.9
Subjects with 1 or more reasonably related serious adverse events	1 (3.2%)	4 (3.6%)
System-organ class/preferred term		
Infections and infestations	0	3 (2.7%)
Herpes zoster	0	1 (0.9%)
Laryngitis	0	1 (0.9%)
Pharyngitis	0	1 (0.9%)
Vascular disorders	0	1 (0.9%)
Takayasu's arteritis	0	1 (0.9%)
Nervous system disorders	1 (3.2%)	0
Cerebral infarction	1 (3.2%)	0

[a] Includes data up to the time of dose adjustment for those who increased dose.
[b] Includes data from the time of dose adjustment onward.
Note: Adverse events were coded using MedDRA Version 18.1.

[HA03_C011_01.rtf] [JNJ-268229-AAC\ANS3001\DBR_HA\RE_HA\HA03_C011_01.sas] 22DEC2016, 10:54

表 2.7.4.7-付録-126 治験薬の使用と関連性のある重篤な有害事象一覧（UCO3001 試験，維持期）

Randomized	Maintenance Treatment Group	Subject ID	Age / Sex	Seq	Phase [a]	Study Agent Dose Prior to AE (mg)	Dose-Adjusted	MedDRA Preferred Term	Verbatim Term	Study Day of AE From I-Wk 0 (days)	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Related to Trial Procedure	Concomitant or Additional Treatment Given	Infection/ Injection-site Reaction
Yes	Placebo	810703	3[redacted]/M	2	MAIN	0		Cerebral infarction	CEREBRAL INFARCTION	54	12	RECOVERED/RESOLVED	Yes	MODERATE	POSSIBLE	DRUG WITHDRAWN	No	Yes	No/No
		811701	3[redacted]/F	1	MAIN	0	Yes	Laryngitis	ACUTE SUBGLOTTIC LARYNGITIS	262	5	RECOVERED/RESOLVED	Yes	MODERATE	POSSIBLE	NOT APPLICABLE	No	Yes	Yes/No
	100mg	813202	4[redacted]/F	4	MAIN	0	Yes	Takayasu's arteritis	TAKAYASU'S ARTERITIS	218	-	NOT RECOVERED/NOT RESOLVED	Yes	MODERATE	POSSIBLE	NOT APPLICABLE	No	Yes	No/No
No	100mg	810109	3[redacted]/M	5	MAIN	100		Herpes zoster	HERPES ZOSTER(RIGHT FOREHEAD, RIGHT PERIOCULAR)	142	8	RECOVERED/RESOLVED	Yes	SEVERE	POSSIBLE	DOSE NOT CHANGED	No	Yes	Yes/No
		813705	7[redacted]/M	1	MAIN	0		Pharyngitis	PHARYNGITIS	101	16	RECOVERED/RESOLVED	Yes	MODERATE	POSSIBLE	NOT APPLICABLE	No	Yes	Yes/No

SCR: screening phase, IND: induction phase, MAIN: maintenance phase, FUP: follow-up phase
Note: Adverse events were coded using MedDRA Version 18.1.

表 2.7.4.7-付録-127 すべての有害事象一覧（UCO3001 試験，フォローアップ期）

Ran-dom-ized	Maint-e-nance Treat-ment Group	Subject ID	Age / Sex	Seq	Phase [a]	Study Agent Dose Prior to AE (mg)	Dose-Adj-ust-ed	MedDRA Preferred Term	Verbatim Term	Study Day of AE From I-Wk 0 (days)	Dura-tion (days)	Outcome	Se-ri-ous	Seve-rity / Inten-sity	Relation to Study Agent	Action Taken Regarding Study Agent	Rela-ted to Trial Proce-dure	Concom-itant or Additional Treatment Given	Infection/ Injection-site Reaction
Yes	Placebo	810106	3[redacted]/F	2	FUP	0	Yes	Colitis ulcerative	EXACERBATION OF ULCERATIVE COLITIS	510	-	NOT RECOVERED/NOT RESOLVED	No	MODERATE	NOT RELATED	NOT APPLICABLE	No	No	No/No
		811403	7[redacted]/F	4	FUP	0	Yes	Colitis ulcerative	COLITIS ULCERATIVE AGGRAVATED	468	39	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
		811504	3[redacted]/M	4	FUP	0	Yes	Blood bilirubin increased	BILIRUBIN VALUE INCREASED	525	-	NOT RECOVERED/NOT RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	No	No/No
		811703	5[redacted]/M	8	FUP	0	Yes	Influenza	INFLUENZA	449	5	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	Yes/No
		811904	2[redacted]/M	4	FUP	0	Yes	Infusion site erythema	INFUSION SITE REACTION REDNESS	479	3	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	No	No/No
				5	FUP	0	Yes	Infusion site erythema	INFUSION SITE REACTION REDNESS(RIGHT THIGH)	493	2	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	No	No/No
				6	FUP	0	Yes	Infusion site erythema	INFUSION SITE REACTION REDNESS(LEFT THIGH)	507	3	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
				7	FUP	0	Yes	Infusion site erythema	INFUSION SITE REACTION REDNESS(RIGHT THIGH)	523	4	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
		812506	2[redacted]/M	4	FUP	0	Yes	Nasopharyngitis	COMMON COLD	462	8	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	No	Yes/No

Ran-dom-ized	Mainte-nance Treat-ment Group	Subject ID	Age / Sex	Seq	Phase [a]	Study Agent Dose Prior to AE (mg)	Dose-Adj-ust-ed	MedDRA Preferred Term	Verbatim Term	Study Day of AE From I-Wk 0 (days)	Dura-tion (days)	Outcome	Se-ri-ous	Seve-rity / Inten-sity	Relation to Study Agent	Action Taken Regarding Study Agent	Rela-ted to Trial Proce-dure	Concom-itant or Additional Treatment Given	Infection/ Injection-site Reaction
				5	FUP	0	Yes	Dermatitis acneiform	RASH ACNEIFORM(FACE)	476	-	NOT RECOVERED/NOT RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
		813401	3[redacted]/F	11	FUP	0		Pharyngitis	PHARYNGITIS	443	4	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	Yes/No
				12	FUP	0		Pruritus	ITCH SENSATION (CHEST)	443	9	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
		813903	4[redacted]/F	2	FUP	0		Nasopharyngitis	COMMON COLD	443	9	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	Yes/No
				3	FUP	0		Toxic skin eruption	TOXICODERMA(GENERALIZED)	446	4	RECOVERED/RESOLVED	No	MODERATE	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
				4	FUP	0		Toxic skin eruption	TOXICODERMA(GENERALIZED)	449	8	RECOVERED/RESOLVED	Yes	MODERATE	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
				6	FUP	0		Toxic skin eruption	TOXICODERMA(GENERALIZED)	456	22	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
				7	FUP	0		Eczema asteatotic	ECZEMA ASTEATOTIC(GENERALIZED)	477	-	RECOVERING/RESOLVING	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
	100mg	810105	3[redacted]/M	5	FUP	0		Nasopharyngitis	COMMON COLD	501	-	NOT RECOVERED/NOT RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	No	Yes/No
		811102	3[redacted]/F	11	FUP	0	Yes	Dermatophytosis of nail	NAIL TINEA(BOTH FEET)	429	-	RECOVERING/RESOLVING	No	MILD	POSSIBLE	NOT APPLICABLE	No	Yes	Yes/No
				12	FUP	0	Yes	Eczema	ECZEMA(BOTH FEET)	450	-	NOT RECOVERED/NOT RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
		811201	4[redacted]/F	7	FUP	0		Nasopharyngitis	COMMON COLD	444	30	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	Yes/No

Ran-dom-ized	Mainte-nance Treat-ment Group	Subject ID	Age / Sex	Seq	Phase [a]	Study Agent Dose Prior to AE (mg)	Dose-Adj-ust-ed	MedDRA Preferred Term	Verbatim Term	Study Day of AE From I-Wk 0 (days)	Dura-tion (days)	Outcome	Se-ri-ous	Seve-rity / Inten-sity	Relation to Study Agent	Action Taken Regarding Study Agent	Rela-ted to Trial Proce-dure	Concom-itant or Additional Treatment Given	Infection/ Injection-site Reaction
		811802	4[redacted]/ M	4	FUP	0		Vertigo positional	BENIGN PAROXYSMAL POSITIONAL VERTIGO	453	-	RECOVERING/RESOLVING	No	MILD	NOT RELATED	NOT APPLICABLE	No	No	No/No
		812203	2[redacted]/F	5	FUP	0		Headache	HEADACHE	456	1	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	No	No/No
		812801	3[redacted]/F	3	FUP	0		Gastritis	GASTRITIS	426	26	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
				4	FUP	0		Nasopharyngitis	COMMON COLD	462	11	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	Yes/No
				5	FUP	0		Gingivitis	GINGIVITIS	457	-	NOT RECOVERED/NOT RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	Yes/No
		812905	5[redacted]/ M	2	FUP	0		Heat stroke	HEAT STROKE	502	-	NOT RECOVERED/NOT RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	No	No/No
No	100mg	810604	5[redacted]/ M	5	FUP	0		Rectal adenocarcinoma	TUBULAR ADENOCARCINOMA,WELL DIFFERENTIATED TYPE(RECTUM)	425	41	RECOVERED/RESOLVED	Yes	MODERATE	DOUBTFUL	NOT APPLICABLE	No	Yes	No/No
				7	FUP	0		Insomnia	INSOMNIA	462	-	NOT RECOVERED/NOT RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
				8	FUP	0		Procedural pain	POSTOPERATION PAIN	465	9	RECOVERED/RESOLVED	No	MODERATE	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
		811511	6[redacted]/ M	13	FUP	0		Nasopharyngitis	COMMON COLD	497	-	NOT RECOVERED/NOT RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	Yes/No

Randomized	Maintenance Treatment Group	Subject ID	Age / Sex	Seq	Phase [a]	Study Agent Dose Prior to AE (mg)	Dose-Adjusted	MedDRA Preferred Term	Verbatim Term	Study Day of AE From I-Wk 0 (days)	Duration (days)	Outcome	Serious	Severity / Intensity	Relation to Study Agent	Action Taken Regarding Study Agent	Related to Trial Procedure	Concomitant or Additional Treatment Given	Infection/ Injection-site Reaction
		812301	3[redacted]/ M	4	FUP	0		Pruritus	ITCHING(ARM)	445	-	RECOVERING/RESOLVING	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
		812401	1[redacted]/ M	3	FUP	0		Fatigue	FATIGUE	434	3	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
				4	FUP	0		Haematuria	HAEMATURIA	455	39	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
				5	FUP	0		Hypoaesthesia	NUMBNESS (LEFT HALF OF THE BODY)	486	43	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	No/No
		812508	4[redacted]/ M	2	FUP	0		Infected dermal cyst	PYOGENETIC ATHEROMA (NECK)	517	10	RECOVERED/RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	Yes/No
		813706	2[redacted]/F	8	FUP	0		Colitis ulcerative	WORSENING OF ULCERATIVE COLITIS	520	-	NOT RECOVERED/NOT RESOLVED	No	MILD	NOT RELATED	NOT APPLICABLE	No	Yes	No/No

2.7.5 参考文献

2.7 臨床概要の参考文献の掲載先を以下に示す。

2.7.1 生物薬剤学試験及び関連する分析法：「参考文献」の項

2.7.2 臨床薬理試験：「参考文献」の項

2.7.3 臨床的有効性：「参考文献」の項

2.7.4 臨床的安全性：「参考文献」の項